https://wonder.cdc.gov/controller/datarequest/D8;jsessionid=BBC9469AA6F8BFC0D7E03C214014

Results are sorted in by-variable order

Adverse Event Description

C/O Headache

felt warm, hot and face and ears were red and flushed.

within 15 minutes progressive light-headedness leading to near-syncope and diaphoresis. After 20 minutes symptoms subsided.

Pt felt wave come over body @ 1218 starting in head and going down. Bad taste in mouth, tingling in body , legs, back , across stomach, BP 150/100 P 120@ 1219, EMS activated. BP 120/80, P 80 Pt alert and oriented, Pt declined transport and Benadryl. Symptoms come and go, pt feels better but then bad taste in mouth starts, shaking of hands, tingling starts again in stomach and back. @ 1300 pt requests Benadryl, 25 mg administered. Pt notified family by phone of circumstances and family in transit.@1324 BP 120/80, P 84, tongue tingling and pt reports smelling chemical smell. @1345 Pt complained of mouth itching, EMS activated and will transport to Medical Center. Pt oriented and transported at @13

"rPfizer-BionNTech COVID-19 Vaccine EUA 5-7 minutes after the vaccine Associate stated she did not feel right, mentioned chest pain. ""My chest feels funny. It feels like when you have really bad heartburn coming on"". ""I feel flushed like when you get contrast for a CT"". Pulse 90 BP 160/90 checked later 130/90"

Headache, body ache

Within a few minutes of receiving the COVID 19 vaccination, patient developed lightheadedness, shortness of breath, headache, and some nausea. She did get some redness to her neck and upper chest. No recent illness. Had elevated BPs ranged from 158/103 to 207/126 . HR ranged from 82-106. O2 sats always > 96%. Temp 37.1 C. Received Tylenol 1000 mg PO, Dexamethasone 10 mg IV, diphenhydramine 50 mg IV, famotidine 20 mg IV, ketorolac 30 mg IV, ondansetron 4 mg IV, and 1 L NS. Patient prescribed EpiPen and prednisone and discharged.

About 25 minutes after receiving vaccine complained of dizziness and being hot and nauseated. No difficulty breathing. No chest pain. B/P was 130/90 and was monitored. It went down to 124/80 after he started feeling better. He was wearing sweater over shirt and it was warm in building. Took sweater off. Cool wet cloth applied to back of neck. States he had only had a donut and cup of hot chocolate before receiving vaccine. Sprite and peanut butter crackers given. Became nauseated after eating peanut butter crackers Blood pressure monitored monitored. He laid on exam table for about 15 minutes. He felt better. Stood up and walked to conference room for another 15 minutes. Stated he felt much better and was ready to leave. Coworker drove him back. Received email from him letting us know he had made it

back and they had stopped and eaten pizza on the way. Received text from coworker that he was dizzy and seeing spots and that his blood pressure had been 120/80 and then spiked to 160/100. Coworkers taking him to ER at Hospital for evaluation.

At 12:55 pm 10 minutes following vaccine being given states feeling lightheaded and flush. Was sitting in the chair. Encouraged him to lay down on the floor which he did on his own. Feet elevated. BP 174/70 pulse 82. Denies any other complaints. Laid on floor for 15 minutes then sat in chair. Denies complaints. 1:15 pm was allowed to leave. BP 120/80 and states feeling fine.

Patient felt facial flushing, pounding in chest, burning and hot ears and blood pressure went up. Tingly in right arm and chest and hands. Symptoms resolved, after a few minutes but then returned. Patient sat with nurse during this reaction.

She claims she experienced tightness in the right side of throat and her tongue started tingling. Took her the Emergency Department, She decided to go and buy Benadryl

System was not populating immunization record, member denied having immunizations within last 14 days. Vaccine given, record populated and patient had anthrax on 12/10/20

Tingling of upper lip and cheeks, warmth in face, and itchy eyes Treatment: diphenhydramine 50 mg PO x1 Outcome: symptom onset within 15 minutes of vaccine administration. Symptoms resolved within 20-30 minutes of diphenhydramine administration.

I am a immunization nurse at this location. I gave 2 of the first 4 Covid vaccinations given at our location. Then I received dose # 5. It was easy. I did a couple of things and then returned to my desk. As I sat down, my arm started feeling very heavy. I was unable to send a text. I told staff that I was feeling funny and that I was going to the other room to lay down. Staff followed me and took my Pulse 100 and BP 164/ 82 (high for me!) . I felt shaky, but my hands were not shaking. Put a wet cloth on my head and laid there a few minutes, telling staff stories and laughing at my BP. When I sat up, my BP was 126/74 and pulse was 80. I stood up for a minute or two, then my legs got heavy and I sat down for a few more minutes. I went to the bathroom and came back to my desk, but was weak and tired. I ate and drank some fluids. Because it was snowing and I live 25 miles away, I accepted a ride home from a co-worker. I walked across the parking lot without problems and talked all the way home. At home, I was tired, but had a sandwich and talked on the phone. I would still describe myself as tired, but functioning.

1750- IM injection ot R Deltoid. She was sitting, and felt short of breath without wheeze or tightness in the chest or throat. She stood up, and then felt tunneling. Assisted to chair and floor. Pulse weak, skin flushed, sweating on torso. Face and Neck remained flushed and red. She refused epi at first. So we gave her benedryll 25 mg po with apple juice. She said she just had a big meal 30 min prior, but we checked her blood sugar- it was 85. 10 min after the first SOB feeling, it returned. BP was recorded as 160/100.

Pfizer-BioNTech COVID-19 Vaccine EUA Developed chills, nausea and vomiting beginning at 2 AM the night after receiving the vaccine. Potential fever as well (I don't have a thermometer to check). Symptoms have lasted over 3 hours thus far, still continuing.

Pain in deltoid muscle upon pressure at night. Hard to lay on the side of the vaccine due to pain in the arm

I received the vaccine @ 3:40 pm 12-15-20 and felt fine until around 9:00 pm 12-15-20 when I noted headache, nausea, no energy, overall not feeling well, and injection site pain. I did not have a fever. Symptoms still present @ 6:00 am 12-16-20.

Right sided facial/lip swelling. Started about 0200 on 12/16/20. Patient sometimes gets angioedema, so unsure if this is related but wanted to report

Patient received shot around 1pm later that night he started to experience chills, hot/cold, nausea, headache, extreme fatigue, low grade temp (99.1) Associate vomited several times the early the next morning. By the next day, day patient was vomiting less and was able to keep food down. Patient is feeling better the second day, experiencing some nausea.

diffuse rash at anterior and right lateral neck associated with feeling of warmth

Patient received shot and sat for 15 minutes, left and came back and reported she felt woozy. She felt dizzy. Patient stated she felt dizzy off and on while she was in clinic getting shot, patient left.

chills - 0730 body ache, headache - 1000 headache significantly worse - 1110

sore throat, headache, lightheadedness

"Pt. became lightheaded, and clammy. noted heart rate to be 51, oxygen saturation 100%. after sitting for a few minutes, she felt better, but then became dizzy and had some chest tightness and bilateral hand tingling. Pt. noted to have respiratory rate 22-26 with deep breath, but other vital signs were stable. (Blood pressures 108-138/70's to 80's) Heart rate remained stable in the 70-90's range, lungs remained clear to auscultation through out. No rash or swelling noted anywhere. No itching, no throat tightness. Pt. repeatedly stated ""I think I am having a panic attack"". Due to the continued complaint of chest tightness, pt. sent to the emergency department for evaluation."

redness around the injection spot, fever chills, Stomach Ache, Body Ache, Short of breath (walking up stairs), Headaches no appetite, Dry heating .

After patient received vaccine had localized reaction in left deltoid. Redness and firm to touch. Patient observed for additional time frame and redness lessened. Patient released home.

About 12 hours after the injection woke up and body was hurting all over, chills, body aches, felt feverish, temperature was 100.3F and really tired and hurting all over. Took Tylenol and returned to sleep. Woke up some hours later and took an Ibuprofen. rested for the rest of the day and now the only side effects is a little soreness on her injection mark. No other symptoms. Only the first 24 hours after the shot.

Immediately after the vaccine, I got severely nauseaed, got a yucky metal taste in my mouth and got super lightheaded and hadnt even gotten up. The agent helped walk me to a chair and I felt really loopy

in the head. After the 15 minutes, I got up and immediately felt the whole room was spinning causing me to have to sit back down another 15 minutes. Closing my eyes made the dizziness much worse. I was given juice, my sugar was checked at was 115. After about 30 minutes I stood and felt alot better. I went back to my assigned duties but was feeling super bad and my supervisor sent me home because they states I didnt look good. On the drive home I threw up and my PCP called in Zopran to help with the nausea.

"After patient received vaccine had complaints of being ""lightheaded and slightly dizzy"". Monitored vital signs and patient symptoms. Resolved after 20 minutes and patient was released to go home."

Left arm swelling of forearm, old L wrist tattoo because raised and lifted out of skin approx 3 mm, whole arm was itching with several red dots; reaction resolved within 8 hours without intervention body wide itching persisting now

Patient had sudden onset of nausea . Patient was laid flat on the floor and given and alcohol. Symptoms resolved and patient was released home.

Patient has a prior anaphylaxis reaction to Doxycycline. 10minutes after immunization, she developed sweaty palms and lightheadedness. No throat swelling or difficulty breathing. Placed supine, BP 160/100, HR 60-70, O2 97% RA. After a period of monitoring the symptoms improved. No intervention given.

Pain; This is a spontaneous report from a non-contactable physician. A 39-year-old male patient received BNT162B2 (Pfizer-BioNTech COVID-19 mRNA vaccine), via an unspecified route of administration on 14Dec2020 at 12:00 (at the age of 39-years-old) as a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. On an unknown date in Dec2020, the patient experienced pain. The clinical outcome of the pain was unknown. No follow-up attempts are possible; information about lot number cannot be obtained.

Bp of 85/44, nauseous, body aches, chills

I worked overnight after getting the vaccine. I felt really tired and came home and slept until 3 pm. When I woke up I had a dull headache and felt crummy. Decided to sleep the remainder of the day but no fever just was fatigued and had a headache. My arm was hurting at the injection site but the pain has sense left and the headache is gone also.

NORMAL ARM PAIN HOWEVER THE FOLLOWING WAS FELT REAL TIRED BARELY ABLE TO STAY AWAKE

I experienced a sore arm and could not lift my arm.

Swelling on arm. Placement lower than deltoid, 4 cm. treated with corticosteroids, antihistamines

Pt started to have a metallic taste in her mouth immediately after administration of the Covid-19 vaccine. She started to feel nauseous and myalgias. The patient was seated, given Zofran 4mg once and

Benadryl 25 mg once. After 10 min patient was eating juice + crackers. Reports she feels better. A co-worker verbalized he would drive her home, patient agreed.

12/15/2020 5:00 PM Nauseas(worst) 5:30 Pm Headache 6:00 Pm Stomach Pain

PAIN AND EDEMA AT SITE OF INJECTION LEFT ARM WITH DECREASED RANGE OF MOTION LEFT ARM RIB CAGE PAIN ON INSPIRATION MUSCLE PAIN RIGHT AND LEFT THIGHS, WORSENING UPON AMBULATION MUSCLE PAIN AND TINGLING RIGHT UPPER EXTREMITY AND BACK

Following first dose, patient became hypotensive, pale, and diaphoretic. Denies syncope. Patient went to nearby emergency department at Hospital. Was monitored for several hours and was discharged in stable condition.

Chills, Body Ache, Fever

The employee experienced headaches the evening after receiving the vaccine. The next morning he experienced improvements in the headaches but developed chills, fatigue, and fever, all of which have improved somewhat by the afternoon when he reported these adverse effects to our employee health service. As he is recently recovered from COVID, a repeat COVID test may not be helpful. He was advised to call our employee health service and followup with his own doctor if these symptoms do not improve or resolve after 3 days.

Headache, onset ~45 minutes after injection

I got it about 10 am I went home I attempted to work from home for about an hour and had a headache, took a 3 hour nap and felt much better after waking up, I felt like I couldn't concentrate. I felt fine this morning 12/16/2020 and I went to work just fine. I don't have a headache and don't feel like I need a nap, my arm still hurts but that is usual. I called my provider and asked if I could take Tylenol, but they were unsure so I did not take medication

"@ ~5 min felt cotton mouth. Got up to ask if he could go early. Then at 10 min post injection, felt eyes feeling weird and he felt ""high"". As in lightheaded. @ 10 min, skin surrounding the eyes are puffy. Given 25 mf benedryl. No immediate SOB or wheeze. No lip or mouth or throat swelling. Taken to ED. Given IM epi 1:1000 0.3ml. Pepcid and more benedryll PO."

Fever , chills, Body Ache all over body, Joint Pain (worse in hips) Injection site swollen The PT cannot life her arm

Burning and itching at injection site

Soreness and swelling at injection site

.5 inch bruise at injection site, slight swelling, sore muscle, ibuprofen, ice bag,

Vaccinator Nurse noted upon vaccination there was bleeding from site and immediate bruising. Extended post vaccination monitoring to 30 minutes and asked patient to not leave before being

reevaluated. Visual monitoring in post vaccination space by this RN. á Upon reassessment @ 1352 pt stated she felt the need to use her inhaler and chest tightness. Pt denies SOB and able to transfer independently to wheelchair. Pt began to cough and was immediately transferred to ED per FNP. á á Upon ED arrival, pt was transferred to back hall 9, report given to RN and assessed by physician. Vital signs 98% on RA, t- 98.2, HR 78.

Nausea, tremors, and decrease in HR. Patient taken to ED. No epinephrine injection administered.

Patient started to develop maculopapular rash and itching starting ~15 minutes after the vaccine administration. The patient did not report shortness of breath or other respiratory symptoms. The patient was given IV diphenhydramine 50 mg, famotidine 20 mg IV, and methylprednisolone 125 mg IV. The patient's symptoms resolved and was sent home with a Medrol dose pack and antihistamine.

redness, itching to face, armpit, and neck

Swelling and numbness at injection side. Increased blood pressure 199/99. Immediate headache. Workplace clinic called hospital ER, clinic administered Benadryl. Symptoms resolved.

The patient got a rash on the upper chest and neck approximately 3 hours after vaccination. The rash was self limiting and no treatment currently needed.

Pt presents to the ED for c/o L anterior chest wall pain after receiving covid19 vaccination today around 1030. Pt reports she received the first dose in the L bicep. Pt reports after she received that shot she started having L anterior chest wall pain. Pt states she doesn't have any chest tightness but does have stabbing pain to the L anterior chest wall. Pt denies any difficulty breathing or hives or any allergic reaction. Pt was hooked up to cardiac/sp02 and BP monitoring equipment. Medication: Ibuprofen Route: PO Dose:800 mg Patient tolerated medication well; no adverse reaction noted. Medication: Tylenol Route: PO Dose:975 mg Patient tolerated medication well; no adverse reaction noted.

Received Pfizer Covid Vaccine - Had fever of 102 and flu like symptoms. Took Tylenol and temp resolved to 99.

11 minutes after first dose of Covid Pfizer vaccine, patient became unresponsive, pale, diaphoretic with possible seizure activity. Patient dropped all belongings, leaned to the left side, with eyes rolling back in her head. Episode lasted about a minute. Patient could not remember what had happened. Vitals were BP 110/60, HR 64, RR 22. Patient was advised to go to ED for further evaluation but she refused. Patient was given a snack and an RN stayed with her for about 20 more minutes to monitor.

":1039: Responded to notification of potential adverse reaction after receiving COVID-19 vaccination. Pt had been escorted from observation area to emergency area with PA with c/o tightness in throat. On my arrival, pt was eupneic, p/w/d, ambulatory, NAD. á Vitals @ 1039: P72, 100% pulse ox on RA Vitals @ 1056: P72, 98% pulse ox on RA, 112/78 seated. á Administered 25mg diphenhydramine po per PA @ 1050, pt swallowed with water. á Called 911 for EMS response @ 1103 per instruction from provider. á Vitals @ 1103: 98% pulse ox on RA, P74, denies shortness of breath or pain. á Off phone with EMS @ 1108, en route. á EMS on site @ 1115, report given to medic. á Pt left with EMS en route to ED @ 1116.

á Report called to ED Charge Nurse @ 1121. Patient presented to vaccination clinic. Patient received her vaccination at approximately 1021. Patient reports symptoms onset at approximately 1038 with tightness of the throat and difficulty swolowing. She described it as a swelling of the throat sensation. She states she had a sensation moving from her head to her toes as in a ""wave "". Patient denied shortness of breath, chest pain denies nausea. Patient denies hives or rashes or pruitis. á á Patient was assessed and moved to the emergency area. á Her symptoms continued with some improvement. At this point time 25 mg of Benadryl was administered orally. Approximately 10 to 15 minutes after administration the patient developed numbness tingling around the upper lip, the right upper extremity. She denied shortness of breath or chest pain. She denied increasing severity of the throat sensations. á Pertinent past medical history: Reactions bee stings currently carries EpiPen. á She is not had any previous reactions to vaccinations. á á áAllergic reaction. á The patient symptoms seem to continue with the numbness tingling around the lips after administration of the Benadryl. Hand tingling of the right upper extremity also continued although it was decreasing. á Her symptoms of the tightness of the throat remain the same. She did not develop shortness or breath or chest tightness or pain. á At this time I feel be prudent to evacuate the patient to higher level care. á Patient was evacuated at 11:16 by ambulance service. á á á"

1-2 minutes later patient felt nausea, palpitations, and lightheaded

My symptoms started about 15 minutes after shot. Initially I felt slight dizziness begin in my head. Then I felt slight uncomfortable feeling in my lungs, throat, and tongue. They were very slight so I left the vaccine center about 25 minutes after injection. On drive home my lips started to feel numb as well as my tongue & throat. Arriving home very tired. BP 135/ 80 P70 R20 T97.6 Blood sugar 101. Slept for about 4 hours. Called in sick for 7PM shift. Too weak & tired.

""""Pfizer-BioNTech COVID-19 Vaccine EUA"": Acute onset of tongue swelling, throat tightness, and diffuse erythema approximately 5 minutes after receiving COVID-19 vaccine. Patient transferred to emergency department. Patient treated with Epinephrine 0.3 mg IM X1 dose, Dexamethasone 10 mg IV x1 dose, Diphenhydramine 25 mg IV x1 dose. Patient discharged same day with resolution of symptoms."

"When injecting the vaccine fluid, the vaccine administrator noted about 4 drops of liquid that leaked from the area of the syringe tip / needle hub connection. This particular dose was administered by a pharmacist who has experience administering vaccines. In speaking with a few other nurses who administered COVID-19 Pfizer vaccinations at the same clinic (this was the first clinic day), the consensus was that they all did not like the syringes/needles provided by Pfizer. It was a shared opinion that they felt ""cheap"" and ""flimsy"". Going forward, our site is not going to use the Pfizer supplied syringes/needles but will be using our own syringes and needles for vaccine administration."

I inserted my NuvaRing birth control on 12/14/2020. I have the Covid19 vaccine on 12/15/2020 at about 8:30am. The injection site was mildly sore and that continued into the next day. I woke up on 12/16/2020 feeling a little off and it progressed throughout the day. I felt a headache that I knew was turning into a migraine, threw up a few times (this is normal for me when I get migraines), and started

having hot flashes. My temperature never went above 98. After sleeping a few hours and taking some Excedrin migraine I was feeling much better, though still a little sickly, by 4pm. I really think this is due to my migraines (which I get roughly once a month) even though it was a day later than normal.

Patient marked that he had received the flu vaccine 7 days ago. This was missed on screening procedure and patient received the vaccine today. Contacted the CDC and instructed to enter a VAERS report.

Patient was feeling nauseated in the morning prior to coming to work and prior to receiving vaccine. He had a banana thinking he would feel better. He then received the vaccine and felt progressively worse experiencing diarrhea, weakness, and malaise.

Patient complained of feeling dizzy, anxious, shortness of breath. Did have some pain with injection. Did have mask on while waiting standard 15 minutes.

Associate received vaccine at 12:15 pm and was monitored for 15 minutes. After 15 minutes, associate went to check out table. While at check out table, associate fell to ground and was experiencing seizure like activity. Supportive treatment was administerd and associate was transferred to ED.

Dizziness that lasted for about an hour. Weakness, extreme fatigue lasted the rest of the day.

Feeling flush and wheezing when walking.

Patient was in observation area after admistration of covid vaccine. At 15 Minute mark patient stated throat felt tight and like it was closing up. Assesment of patient showed tongue PWD, vital signs as follows. 97.6, 118/72, 66 pulse and 100% pulse oxygenation. Observed patient for 15 minutes more, gave patient water and monitored for full 30 minutes. Breathing normal at this time. States feeling better. Discharged and advised to monitor throughout night and if worse go to emergency room. Patient agreed and stated understanding.

Fatigue, nausea, muscle aches

Redness at injection site

Headache, body aches, low grade fever (99.3 F)

Severe muscle aches Diarrhea Headaches Feverish Nauseous Left arm super sore Sore throat

I developed a new rash on my torso and have had three bouts of diarrhea.

Redness to injection site

myalgia, joint pain, local site pain

Within and hour and a half of receiving developed tinnitus in both ears lasting 6 hours. The night after receiving vaccine also developed orthostatic hypotension and started to pass out but caught myself with an assisted fall. Fever(102 F with temporal and oral thermometer) body aches/sweats/general malaise lasting close to 24 hours after receiving vaccine. Fever/aches treated with acetaminophen.

Immediately after injection of vaccination her left deltoid started swelling. Complains of pain at injection site. No other complaints. Applied ice. She took Tylenol and Benedryl. Stayed 30 minutes after vaccination without further complaint.

Patient received covid-19 vaccine. 20+ minutes later patient states she began feeling flushed and nauseous. Patient states she look at her injection site, and it was hot and red. Local reaction approx. 2 inches x 2 inches. Dr. ordered 25 mg oral Benadryl. Vitals stable at 1840 133/88, 66 for pulse and regular, SPO2 99% on room air, respirations 20. Patient continued having complaints of light headedness and nausea. 1850 119/79, 74, 99% RA. Dr. states patient may depart from clinic if able to sit up and walk out, patient given instructions go to ED in symptoms progress. 1857 120/82, 70, 99.4. Patient's face becomes flushed and hot on left side, patient states she is shaky, and does not feel well at all. 1905 patient transferred to ED on 2L O2 for further evaluation and workup. Narrative ER Medical decision making narrative: Accu-Chek was obtained noting a glucose to be at 80. She received IV fluids as well as Solu-Medrol Benadryl and IV Pepcid. She also received IV Tylenol as she developed a headache while in the emergency department. Headache resolved and she was able to ambulate without assistance. Requested to go home states she felt much improved near normal. Clinical Impression: Adverse reaction to drug Patient Education: Anaphylaxis (ED)

Patient feeling very anxious before and after vaccination. Described having difficulty swallowing water shortly (~15 min) post vaccination. Patient was tearful but breathing normally. Walked under her own power from the pharmacy down to the Emergency Room for anxiety over anaphylaxis. Given dose of Vistaril in ER.

Local pain and swelling of the injection site

Local Pain and swelling of the injection site

Started with onset of fatigue and disorientation shortly after receiving the vaccine. Several hours after the disorientation got worse, a headache came on and my whole body aches fatigue is bad. I feel like the flu just hit me.

"Allergic reaction with facial swelling, eye tearing, ""itchy"" throat"

Systemic rash, dry cough (causing cough); 650mg Tylenol every 6; 50mg Benadryl to start then 25 mg every 6, Pepcid 20mg every 12 hours; rash is slowly resolving; throat still very dry with dry cough

Nausea started about 8 hours after getting vaccine and progressively got worse over 12 hours

Day 0 of injection that evening , experienced fevers, chills, rigors, malaise. Day 1 morning experienced nausea

60 minutes after receiving the vaccine the patient became very dizzy and was unable to walk. After a couple of hours dizziness lessened and patient was able to ambulate.

"Patient presented with feeling of ""headrush"" dizziness, tachycardia to 130's, itching to neck, visible hives to face and neck."

Hives within 3 hours lasted 12 hours. Left Arm edema and erythema 24 hours

Extreme fatigue, felt very warm all over body for 14 - 16 hours, exceptional pruritus on head and back, all joints are exceptionally achey

Patient left the vaccine clinic after waiting 15 minutes. While driving home, she began to feel clammy with a tightness in her chest and throat. She reports that it felt harder for her to breathe. She describes the onset as 20-30 minutes after vaccine was administered. She returned to the vaccine clinic where she was given diphenhydramine 25 mg PO, and her blood pressure was ~130/100 mmHg. She reports that she is usually normotensive. Patient was observed for 30-45 minutes, and she reports feeling better.

NAUSEA, CHILLS, MUSCLE PAIN, WEAKNESS

02:45 PM walking , dizzy, rapid heart rate, mild chest pain. Directed to ER in hospital, CT Chest -- normal, EKG -- normal, Lab test-- normal. Xray Chest results -- basilar atelectasis, Hyperinflation of lungs. Blood pressure 171/109. No treatment given in ER -- f/u with PCP 12/18/20. 08:00PM nausea, headache, vomit 1x. 10:00PM fever 104.00; Tylenol extra strength dose. 12/17/20 6:00am temp 99.00, Tylenol dose extra strength; body aches, fatigue, mild headache.

caller reported Flushing, redness around face and nauseous. Advised that Number for IMT (Incident management Team)will be activated. Caller declined. Advised to return to observation room where shot was given. Caller stated she would. Called her 5 minutes and left a message to call back if symptoms also persist or worsens

Injection site swelling and pain

Stomach crump & vomiting

DIZZY, SLIGHTLY EVEVATED BLOOD PRESSURE

left arm soreness/pain tender to touch/palpation

"After receiving the injection the patient stated ""my throat feels funny, similar to how it has felt in the past when I have had a reaction."" Pt. transferred from the vaccine clinic location to ED."

Patient reports of itching immediately after vaccine, dizzy, feeling of flush. Medical directive given for itching that include OTC antihistamine (Claritin). Incident Management team activated for dizziness and feeling of flush.

Pfizer-BioNTech COVID-19 Vaccine EUA Fever, chills, severe body aches. Fever resolved with ibuprofen

0749 - tingling in body, scratchy throat for 10 minutes, flushing

Patient was given to co vid injection- developed numbness and tingling inside bicep- speech- slurred speech- tongue speech- tongue not swollen- feels like novican. Takes lisinopril, novolog jardiance, lansoprazole, and mirena.

0752- numbness and redness left arm (inj site)

throat dryness and scratchiness, numbness. hoarse coughing

Headache, Left arm and shoulder pain

Headache, fatigue, muscle aches, nausea, sweating

shortly after patient received vaccine became flushed, bottom lip went numb, vitals were in normal limits. 911 was called emergency staff came and patient went to ER to be monitored.

immediate burning upon injection, VS stable

Swelling of hands follwed by angioedema

Papular, pustular rash on back occurring approximately 6-10 hours after injection of vaccine.

"While waiting the 15 minute after vaccination the Patient noticed a ""tingling"" feeling in throat about 5 minutes after vaccine was given. Time: 0930 - Oxygen Saturation was 98% Pulse Rate 100. Patient stated that the feeling went away and then came back. Time: 0938 - Again vital signs were taken BP 156/88 Oxygen Saturation 100% Pulse Rate 83. Time: 0942 - 50 mg of Benadryl PO were given with water at this time. Patient was taken to ER for evaluation."

Dizziness, headache, chills

Pfizer-BioNTech COVID-19 Vaccine EUA. Injection site pain, headache, tiredness, muscle pain, chills and fever. Took acetaminophen, no longer have fever after 12 hrs.

Patient stated she started to feel a burning sensation in her chest about 7 minutes after receiving injection. Lasted about 5 minutes, then left.

Medication error - reached the patient no harm, additional monitoring to preclude harm. A nurse (RN) diluted new vial of vaccine at 10:41 am. In the midst of adding diluent to vaccine vial, a patient arrived at our vaccine station. After drawing up and administering the 0.3 ml vaccine the RN looked at the vial again and noted that it was almost empty. She became concerned because she had just mixed a new vial and the amount of fluid remaining was not at the expected level. We immediately stopped and reported this to an employee who contacted pharmacy. We notified the patient that there was a discrepancy and had him wait for > 30 minutes to watch for any reaction. (APRN) called him at 1:30p to check on him and apprise him of the possibility of receiving higher than recommended concentration of vaccine. He stated he felt fine and felt no unusual symptoms.

I was tired and took a two hour nap

Headache, fatigue, temperature of 100.3. Lasted about 8 hours.

fever, cough,chills,body aches, weakness, loss of smell

rash - treatment: acetaminophen and diphenhydramine

fatigue, soreness, headache occurred the night after receiving vaccine (approx. 8 hours later) lasting into the following day. I did not take any medications for this .

pt developed chills, nausea and vomiting. Reports > 10 episodes of vomiting total. Went to lunch and continued to have chills and vomiting. Also developed chest pain - described as burning and heaviness. Denies any shortness of breath. CT negative for any changes. Chest X ray normal.

SWEATY, NAUSEA, DIZZY, EYES GLAZED OVER, NOT TRACKING RIGHT, STARTED MORNING AFTER SHOT

Morning after injection: mild fatigue, arm soreness; later in the morning-headache then chills, muscle aches, joint pain and low grade fever (99) and nausea/loss of appetite. These persisted for approximately 12 hours then cleared completely.

12/15/2020 615 received vaccine 2pm belly pains, relief 'not like normal bowel movement', 'urge to go' 5 belly pain, relief self'not like normal bowel movement', 'urge to go' 8-10 pm body chills, covered with 3+ blankets 10 pm body chills subsided 12/16/2020 fatigue; not exercise; 5miles per day (only able to walk 2 miles) Flu vaccine; 'pretty sure it was 09/2020'; Unknown brand

Patient received the vaccine. During the 15 minute observation period she developed chest heaviness, arm tingling, and throat tingling. BP elevated at 169/79. The patient was sent to the ED and evaluated. Diagnosed with more anxiety type symptoms. Discharge from ED stable.

17 minutes after vaccine, suddenly had a , crushing squeezing chest pain, very severe lasted 45 seconds. after 45 seconds continue to have moderate chest pain, light headiness, diaphoretic, very hot. NO fever, elevated BP. Mild to moderate chest and light headiness for about 3-4 hours and it self solved.

She had received a shingles vaccine on 12/10/2020.

I had a headache, body aches and fatigue.

Patient complained of vision disturbance confusion dizziness, chills, clammy, no trouble breathing. Nausea, Patient stated she did not have any breakfast. gave patient diphenhydramine 25 mg and EMS arrived to take her to the hospital.

After receiving vaccine patient started complain of vision disturbance, confusion, nurses started he was slow to respond. Nurses also documented that he was acting the same way the day before due to UTI. No SOB . no signs of allergic reaction

started feeling nauseated, had her sit until feelings resolved.

Patient reported to CNA that they felt like they soiled their pants. CNA confirmed that patient did not soil themself and transferred patient to the restroom. While the patient was on the toilet attempting to have a bowel movement the CNA reported patient had 10 seconds of tonic clonic behavior and then went unresponsive and then back to tonic clonic behavior. This happened 3 times prior to getting patient put back into his bed. Patient went unconscious after last episode while on bed for a more extended period of time while a STAT page was called. Physical Therapist and Aid sternal rubbed him and he had gasp and woke up. Prior to and immediately following the episode his vitals were within normal limits. Neuro exam was unremarkable after patient came to. When he woke up he knew his name, date, and day of the week. He was only confused to where he was. Patient was agreeable to be transported out. EMS was called and transported the patient to Hospital. Patient displayed no seizure activity or neurological deficits in ER. Patient had a CT scan, which came back normal. Virals remained within normal limits and laboratory values were noncontributory. He was diagnosed with a UTI due to the presence of hematuria associated with a syncopal episode. Patient had a Foley catheter upon admission to the nursing home. Patient was administered Ceftriaxone at the hospital and discharged back to Nursing Home on Omnicef the same day. Patient is back at nursing home facility and has not displayed any additional signs of seizure. He is stable and Foley catheter has been removed. Facility spoke to wife who reported that patient did not have a seizure history.

Fatigue, migraine, muscle fatigue on site, diarrhea.

Approximately 11 minutes after receiving the vaccine, the patient complained of shortness of breath, tingling in arms and hands, numbness and tingling in legs and feet, and was observably shaking, with no complaints of swelling in throat or other signs of anaphylaxis. Patient was brought to ER in same facility via stretcher and was examined by staff there. ER report states the patient presented with shortness of breath and what appeared to be a panic attack, with fast breathing, slight flushing, and shaking. Per ER report, the patient was treated for an acute anaphylactic reaction, with clear lungs and given an EpiPen shot in the right thigh. IV was initiated and given a fluid bolus, solu medrol, famotidine, and lorazepam. Labs and a chest x-ray done and reviewed. After treatment, patient found to be stable and was discharged home at 4:42 pm with orders for famotidine, albuterol inhaler, and epinephrine pen.

The nurse was tapping the syringe to get all the air out and the needle popped out of the vaccine vial and stuck to the sticker that was on the vial. 0.3ml of the vaccine was discarded with the syringe into the sharps box.

I woke up at 6:15am had a terrible headache, low fever 100.1. I took Tylenol for the headache and fever. Throughout the day exp muscle aches and joint pain. I also exp hot/cold flashes and fatigue. Around 6:00pm on 12/16 started to l feel better and was able to return to work on 12/17.

I took tylenol for fever and headache and rested, left side lymph nodes were swollen on 12/16/20 which was the worst day, and has gotten better today 12/17/2020. Did not go to the doctor.

Caller stated at 11:30 a.m caller had right arm pain at injection site and headache. 12/17/20 headache and arm paid has subsided.

Fever (37.8 ¦C) and muscle pain.

Headache, right retroocular pain, exacerbation of rosacea Tx. acetaminophen Duration: 3 hours

12/15/2020 Around 7:30pm, I started to itch on neck and face. Progressed to scalp, stomach, back and whole body; ears, top of head to bottom of toes. Called critical care healthcare staff; 1 25mg benadryl Had nausea, fatigue, hip and joint pain 12/16/2020 Still itchy not as severe as 12/15/2020. Still joint pain and achiness. Nausea was a 8/10. 12/17/2020 feel better. About 80% . Mild itchiness. 'letting it run its course' and haven't taken any other benadryl since 12/15/2020. Joint and nausea has subsided. Flu shot 09/2020 Second dose of Pfizer shot is scheduled for 01/05/2021

~30 minutes after vaccination, patient reported lightheadedness, difficulty swallowing, SOB, feeling flushed, pallor, bilateral arm tingling, brief chest pain and tremors. Symptoms lasted approximately 30 minutes and then resolved. Benadryl given after resolution of acute symptoms. Reported a metallic taste in her mouth immediately after receiving the COVID vaccine (dose #1). Had uneventful 15 minute recovery period immediately after vaccination.

2 hours later pain in arm approximately 4-5 inches. Was not able to utilize left arm on yesterday. last night experienced muscle aches and chills. Taken Tylenol and rested. This morning experienced a really bad headache.

"Individual received vaccine on 12/17/20 at 0815. Began with feeling faint and ""spinning"" at approx. 11:00 am, reported resolution of symptoms at approx. 11:11 am on 12/17/20."

"Stayed for 15 minutes after the vaccine given and no reaction was noted and she left. States she got into her car about 20 minutes after the vaccine and started to ""itch"" all over and noted ""red bumps"" on the back of her neck. She had a flushed face by the time she arrived home but remained afebrile. Her itchiness is better but only concentrated on the back of her neck on 12/17/20 when she reported the reaction to Employee Health Services. She denied any further issues today."

I have a sore arm and I am experiencing severe back pain, nausea and a headache that comes and goes.

arm felt hot to the touch, felt arm heavy very difficult to move the arm, felt feverish, took temperature but no fever, but hot to the touch, lots of chills, nausea, body aches. Took some tylenol and at night it started getting a little better. This morning the injection site is red and is sore but I can move my arm again.

chills, headache, weakness, fatigue

stated her lips started to feel numb, like she was at the dentist. lips did not appear cyanotic.

about 1 1/2 hour after receiving it I felt a pain and numbness down left arm into pinky and ring finger. That only last about 2 minutes. Then the pain radiated to left side of neck and head and headache is still there at 1pm.

Caller had vaccine and at 12:30 at night caller had extreme paid in left arm and had to take Tylenol. Next day caller stated pain had subsided.

Employee states that there was confusion at the time of vaccine injection, and that she was possibly given a second injection right after the first. approximately 45 minutes later she experienced headache and dizziness and had an observed syncopal episode. She was taken to the ER, evaluated for MI. Was found to be stable and was discharged.

I WOKE UP WITH DIARRHEA AND A CONSTANT HEADACHE THAT HASNT LEFT

Headache at base of skull near spinal cord 3 hours after dose given

12/15/2020 I felt terrible with muscle aches, shivering, chills, fever was 102.8,I took tylenol and ibuprofen (alternated) 24 hours after initial fever I ceased meds and fever was still 101.5, this morning I was 98.6. The course of the fever was 36 hours total

Around 630pm I began to have a really bad had a bad headache, feverish and body aching. Tenderness in the injection site area which eventually turned into full body aches and was tired. No vomiting or nausea. No redness at the site or injection site issues

Muscle ache, fatigue, drowsiness, brief confusion, bilateral headache, onset 11 AM, duration 2-3 hours

Persistant cough, dyspnea, sweats, myalgias, mental staus changes and diarrhea, still resoving

"1145: Patient complained of minor left eye swelling. Vital signs 99%, 83, 141/80. 1155: Vitals rechecked 1155 100%, 79, 112/80. Patient has new complaints of itchy ears, facial ""heat"", and slight tingling in fingers. 1200: 25 mg of oral Benadryl given. 1211: per RN, patient states symptoms are resolving. 1230: Patient still feels slight eye discomfort, all other symptoms have resolved. Patient states she feels comfortable leaving vaccination clinic, her son will be taking her home."

Headache , dizziness, neck pain, left flank pain, fever 100.2 , chills,fatigue and muscle aches.

I noticed the injection site was sore, swollen and warm. As the day progressed headache, fatigue, joint, legs aching and feeling heavy tires. Also had a fever of 101.2.Around 9:30 pm on 12/16 started to feel better fever was down.

12/15/2020My arm was really sore at first, and then my arm was worse the next day on 12/16/2020 as the morning went on my temperature felt like it was going up and down I felt body aches and felt really tired I had covid in June and it wasn't as bad as when I had it in June but it was still pretty bad, I also had a headache, I took tylenol and my fever broke but after a few hours my headache was worse and I started to take tylenol and ibuprofen. 12/17/2020 Under my left arm my lymph nodes are swollen but I feel much better and will go to work today 12/17/2020

40 min after shot experienced dizziness, feeling like was going to pass out, not coherent, BP high, fast heart rate, light headed. Got chills, freezing cold, shivering, and later in the day my ears were ringing. Extremely fatigued.

Approximately 10 minutes after receiving the vaccine in the left arm, the patient began feeling lightheaded and had some chest heaviness. They became diaphoretic and at this point blood pressure and heart rate were checked. HR was elevated to 90 bpm from patient's baseline of approximately 60-65 bpm. Blood pressure was elevated at 150/100 mmHg. Pt was provided water and symptoms resolved. Patient was monitored an additional 30 minutes and did not have any recurrence of symptoms. Blood pressure and heart rate returned to baseline.

Patient felt flushed, heart racing. Had irregular rhythm. Transported to Emergency Department. Treated with epinephrine. EKG performed, having pre-ventricular contractions. Checked in to ED for further evaluation.

Fever, severe body aches, severe chills, still have symptoms this morning although less severe.

Patient came to workplace clinic 12/17 @ 1215 saying she had a reaction to the COVID vaccination. She stated she took ibuprofen in the morning for the headache, however, rash was still present. N/V on 12/16 at night. Patient reported no throat swelling or SOB. Rash on injection site (left) arm and chest. Patient received Benadryl 50 mg po x 1 dose and Tylenol 500 mg po x 1 dose. After Benadryl and Tylenol, patient felt better and was able to go back to work. recommended to go home and rest.

12/16/2020 episode of abdominal cramps I had a BM episode of loose stools and soon after that within seconds I started profusely sweating on my forehead and felt lightheaded and very weak, My wife noticed how much i was sweating my body was cool and clammy, episode lasted at least 5 mins if not more so I just laid down until I started feeling better. Once symptoms subsided I took 1000 mg of tylenol, Heavy head throughout the day.

Myalgias, headache, neck pain

Injection site soreness started about 3 hrs post-injection. By that evening I was experiencing body aches & chills. I took Advil 400mg with dinner and felt okay for about 4 hours. As soon as the Advil wore off, body aches & chills returned. I did not take anymore Advil that night. My sleep was restless with body aches, chills, & pain at the injection site. I took my temperature during the night and was afebrile. I woke feeling tired with a mild headache. I took Advil after breakfast and currently feel okay.

About 5 minutes after the vaccine developed chest tightness, increased work of breathing, palpitations and severe dizzyness. Transferred to the ED where i received oxygen, IV benadryl, IV fluids and monitoring. Released after about 4 hours and continue to take benadryl 50 mg PO q 4 hours. Also developed red facial rash (unknown time) Pain at injection site began the morning after the injection.

tachycardia, flushed,low grade fever

My left arm was very sore and very painful to move and ached.

Throat swelling, raspy voice, tachycardia, itching, anxiety, rash

patient felt jaw pain, a strange taste (unable to describe), and numbness in her right arm patient was monitered and symptoms resolved within 30 minutes of vaccine administration

Nausea, fatigue, body aches, joint pain, malaise

40 year female received Pfizer-BioNTech COVID-19 Vaccine today Patient reported prior h/o severe allergic reaction to influenza vaccine with eggs preservative. She has received flu vaccine w/o egg w/o problem. Due to her prior history of severe allergic reaction/ anaphylaxis to another vaccine, in this case flu vaccine with eggs, we should proceed with caution. She was told we could defer vaccination until more information becomes available. She opted to proceed with receiving Pfizer-BioNTech COVID-19 Vaccine and be observed for 30 minute observation period. Patient developed throat tightening approximately 20 minutes after vaccination. She received EpiPen within 1 minute of symptoms and was sent to ER immediately in wheelchair by nursing staff. Patient was evaluated in ED and was hemodynamically stable. She was given IV benadryl and was stable throughout observation

"1204 Patient became flushed and started saying she was having a difficult time ""catching her breath"". She then became tachycardic (upper 90's- low 100's). 1205 Benadryl given (25mg). Physician called down to clinic. Vital signs obtained and showed increased BP (145/90) and pulse. 1214 Patient verbalized she was feeling a little better. Monitoring continued until 1245, vital signs were improving and patient no longer had symptoms. She was released at 1252 but encouraged to seek medical attention if she developed new symptoms or had symptoms reoccur."

At 24 minutes after vaccination, pt experienced chest tightness, shortness of breath, cough, flushing, and rash on chest and neck.

woke up the next day and felt nauseated, could not stand up, my heart started racing, I had to lay down, felt cramping, extreme fatigue, felt overall sick, and the pain at the injection site. No fever. Just lasted that day. Feel better today.

during the administration of vaccine patient developed a wheal at the site on injection. Pressure and message reduced the wheal.

Today I have really bad stomach cramps and diarrhea. Yesterday I had a temp 101.2 with tylenol, chills, joint pain and really bad headache

Caller stated after injection at bout 9pm caller had severe headache with nausea and pain at injection site . Caller stated this morning she felt a bit better.

Pt showed for Covid Vasc #1, received the immunization in left deltoid. minutes later, felt numbness, in arm, the a lump in the throat. Denied SOB, or Dyspnea. Patient the stated weakness in the legs. Assisted to the restroom, x 1. no difficulty. after 30 minutes and no relief from symptoms, patient was wheelchaired over to urgent care, and treated there. Patient was able to leave urgent care on her own, with no problems Patient transferred to urgent care for evaluation. Left from urgent care on her own

Employee had tingling sensation in Right upper extremity, and heaviness in bilateral lower extremities 5 minutes after receiving vaccine. These symptoms resolved approximately 2 hours after they began

Patient states she got a headache 30 minutes after taking the vaccine. Checked on patient 4 hours later, still complaining of a headache.

Pain at the injection site and the whole arm felt sore. Felt like a pressure behind my eyes, very tired, extreme fatigue.

1215 pm on 12/16/2020: pfizer covid vac in left arm Poor nights sleep with left arm pain at injection site 500am on 12/17/2020: stood up to get ready and immediately started to dizzy. Then immediately threw up and had darker green diarrhea. Once that finished I had the sweats and felt cold with a subjective fever until around 9 am with continued nausea. Symptoms resolved 11:40 AM.

"Patient state, one hour after vaccination, ""I got the warm feeling, I got hot"" Temp taken at 2 hour, no temp. Temp taken 4 hours later, no temp."

Chills, Body Ache, Hard around the injection

12/15/2020 I was tired, body chills, pain in left arm but was all very light until 12/16/2020 headache was more severe

Immediately after the injection the tips of my finger began to go numb my hand started itching my throat started to go numb and itch and I got 25mg of Benedryl symptoms got worse so they had to give me in IV injection of benedryl which made the symptoms a litter better. I was released and when I got home I went to sleep. When I woke up my body felt like I had been run over by a big truck. I took my temp and it was 99.8. I laid back down and decided to sleep it off and woke up this morning not feeling any worse but not any better. My hands got red from the rash and is still a little red.

After receiving the injection, patient felt flushed and lightheaded. Began to feel like heart was racing and chest tightness. The patient's heart rate was checked, the patient was provided with Tylenol and water, and observed for an additional 15 minutes. Symptoms resolved during this time.

At 11:15am, patient received first dose of SARS-CoV-2 vaccine. At 12:00pm, patient began to develop a rash and had mild edema noted in the uvula. She did not have difficulty breathing/swallowing/speaking. She was given prednisone 50mg x 1 and diphenhydramine 50mg x 1 in the ED.

Headache

1450 COVID19 vaccine given. 1503 Patient verbalized a racing heartbeat. 1504 Vital signs obtained, BP & HR were elevated. 1507 Physician paged. 1509 Patient reports feeling much better. 1511 Physician arrived to evaluate. 1516 Patient no longer had symptoms. Vital signs improving. Verbalized understanding to seek medical attention if symptoms reoccur or new symptoms begin. Patient left.

Dr.; the following day 12/16/2020, I woke up feeling more fatigue then usual with a migraine. Severe with nausea and light sensitivity. AE occurred about 4 hours. Resolved with Advil and Zofran. Missed work 12/16/2020. 12/17/2020 feel back to normal

Sensation of swelling around the mouth and throat felt funny

Allergic reaction to vaccine +1 more Dx Referred by MD Reason for Visit Progress Notes PA-C (Physician Assistant) ? ? Physician Assistant Cosign Needed á Patient was seen at COVID Vaccine Clinic today for her first dose of the COVID 19 vaccination. She denied any history of previous adverse reactions to vaccines. á She was given the Pfizer-Biontech (lot: EH9899) vaccination in the left deltoid muscle. á During her 15 minute waiting period after the injection, the patient began to experience oral tingling (upper lip and then into the lower lib) It then progressed to the tongue and she reported tingling to the tip of the tongue and further back to the middle of tongue. She thought there might be some mild swelling to the tip of the tongue. She denied rash, hives, welts, difficulty breathing, difficulty swallowing, wheezing, throat tightness, hoarseness, stridor, itching, lightheadedness, dizziness, facial swelling and lip swelling. á This Staff member was notified of patient reaction and she was then assessed in the emergency bay area. á PMH: Hx hypertension but did not take her medication today. Patient had recovered from the COVID-19 virus about 2 weeks ago. á Vitals Time 1130 BP 170/90 HR 86 s/r RR 14 nl O2 97 % á Physical Exam Constitutional: She is oriented to person, place, and time. She appears well-developed and well-nourished. No distress. HENT: Head: Normocephalic and atraumatic. Right Ear: Hearing and external ear normal. Left Ear: Hearing and external ear normal. Eyes: Conjunctivae are normal. Right eye exhibits no discharge. Left eye exhibits no discharge. No scleral icterus. Neck: Normal range of motion. Cardiovascular: Normal rate, regular rhythm and normal heart sounds. Pulmonary/Chest: Effort normal and breath sounds normal. No stridor. No respiratory distress. She has no wheezes. She has no rales. Musculoskeletal: Normal range of motion. Neurological: She is alert and oriented to person, place, and time. No sensory deficit. Gait normal. Skin: Skin is warm and dry. She is not diaphoretic. Psychiatric: She has a normal mood and affect. Her behavior is normal. Judgment and thought content normal. Cognition and memory are normal. Vitals reviewed. á á Treatment included antihistamines. Patient was given 50 mg of benadryl at 1138. á Vitals Time 1147 BP 160/100 HR 90 S/R RR 14 nl O2 98% á Response to care: Patient states the upper lip resolved but the lower lip and tongue sensations remained but did not worsen. Patient was recommended to go to the hospital given her sudden response with concern of tongue swelling. Patient did agree to this. COVID staff was made aware that the patient would be leaving her SUV in the parking lot. á Patient was transfer by Response team to the hospital at 11:53 AM. á á

Pt underwent 15 minutes observation and felt fine during that time, while walking back to work on the way to work unit noticed tingling on the L side of her lower lip and a few inches back along jaw. It persisted so she returned to the vaccine clinic for evaluation. She was evaluated by a physician and had a normal cranial nerve and motor exam other than diminished sensation CN5- no change in appearance of lip. There was no other reaction at vaccination site or change in symptoms during a further 30 minute observation period. She was released back to work. Checkin after a few hours the tingling had improved.

On the night 12/15 exp body aches typically how you feel when having a virus, no fever, no gi symptoms. The following day I had fatigue and one point had chills, body aches. Then took Motrin on night of 12/16 and felt better on 12/17.

Began to feel weak, felt as though going to faint, became cool and clammy, BP 100/70 P 46, O2 Sat 100% on room air, no loss of consciousness. Taken to ED - noted patient did not eat prior to getting the vaccine

Light headed, felt faint. Vitals remained stable. Did need to lay down for approximately 30 min. then sent to ED for evaluation

I had pain at the injection site, swollen, body aches, and headache. It eventually just went away on its own. Did not take anything for it. Arm feels better after using it. Now I am just tired.

On day after vaccination: Left arm soreness, chills, headaches

sudden onset of rinorrhea 5 minutes after receiving vaccine. then itching near ears, 5 minutes later had diffuse itching a rash, was sent to ED. There was evaluated for mild shortness of breath and hives on wrists. Did NOT et epi but did get benedryl and steroids, discharge home

Two minutes after vaccination, she reported itching at the site. Upon assessment, red hives started to develop. Dr. came and assessed patient. Benadryl 50 mg. PO and 2 puffs Albuterol administered by Rapid Response Team RN. Tightness in chest, lightheaded, lungs clear throughout, itchiness in left arm. Resolved within 15 minutes.

Muscle aches , Joint aches, cold sweats, chills, Stomach Pain, Diarrhea

tingling in arm at the time of admin down into fingers which faded over 15 mins and then soreness in arm

Last night I was slightly nauseous, tired and full body aches and today I am just tired and still suffering from the full body aches.

tingling in lips no treatment

headache, red raised area at injection site, 100.6 fever, fatigue, muscle aches

Itching all over the body

12/15/2020 little bit of a headache at night and took an ibuprofen, intermittent nausea the next day, around 530 pm 12/16/2020 fatigue joint pain chills, I had a fever but I did not take my temp, nausea at 9pm I took ibuprofen and this morning 12/17/2020 I woke up fine.

Immediately after the injection, site turned red, I got hot and began sweating profusely. This lasted about 10 minutes and resolved.

Within about an hour headache and mild pain at the injection site, around 4:30/5PM all other symptoms hit: chills, fever, fatigue, runny nose and diarrhea, joint and muscle pain, very sweaty and clammy skin

Paresthesias of lateral tongue and throat, subjective swelling of tongue and throat, subjective shortness of breath

Caller stated that headaches occurred at 12 in the afternoon and fatigue set in through out the day. Caller took Tylenol and Advil with no relief. Caller stated 12/17/20 headache and fatigue went away.

Patient may have received undiluted Pfizer COVID-19 vaccine 0.3 ml= ~120 mcg

Headache , fever 100.8, chills, Fatigue, body ache . Nausea

Swollen tongue, scratchy throat, rash, tachycardia, and raspy voice

Morning after he got the shot....Wave of severe fatigue, had to lay down as he thought he would fall over. Temperature went up a 1/2 degree celius. Went back down later that day. 12/17/2020 2:34 am he woke up with rigors and chills, went away in 3-4 min. Had abdominal pain later during the day.N

2 1/2 hours after the shot, I felt pressure building in my head, my eyes felt bulging, my throat felt tight, and I started having an asthma attack

Symptoms- light headedness, dizziness while in the 30 minute observation window, EE reports she drank water and immediately felt better. EE also endorses mild HA shortly after. EE endorses symptoms completely resolved by 1:30 pm. Called vaccine support line at approximately 3:43 pm to notify us for our records.

During COVID vaccine administration being held at Medical Center, vaccine was administered by Health Department staff on 12/17/2. At 1:30 pm, during observation, patient stated he was having mild chest pain that was not there prior to vaccine. Client walked to observation room, blood pressure taken 169/89. Patient rated chest pain 1/10, described it as random sharp pain. In ER observation room, client was offered EKG which was declined. Patient was then offered to check in through ER for monitoring, patient also declined. Continued to monitor patient until 2:00 pm, at which point patient stated chest pain had subsided and he requested to go home to relax. Encouraged to return to ER if chest pain returns.

Severe dizzy spell about 5-10 following injection, helped to the floor, this lasted approximately 30-40 minutes after start of symptom. Hot flashes and visual disturbance lasting into following day.

12-16 I was nauseous, I received the vaccine and walked to my department, I ate a graham cracker and didn't subside the rest of my shift at 130pm and went home and ate lunch took Tylenol laid down, at that time my arm started to hurt at the injection site. And when I woke up later that night around 5pm and was feeling better kind of tired but good. Coworkers could tell I didn't feel good. I felt like I needed to have a Bowl movement and urinate more than usual

woke up at 3am with diarrhea and nausea . Woke at 6 am with fever of 101.7, joint pain, Headache and fatigue any myalgia

Fatigue and headaches 12/14/2020 about 12pm , Caller took Tylenol and advil with no relief and next day pain had subsided.

I had headache, muscle fatigue, nausea, stomach pain, severe joint pain in the shoulder where I received the injection. I got Covid tested yesterday afternoon to be safe and I'm waiting on the results.

Chills nausea sweats headache

Patient reported feeling fine for the first 15 minutes after the vaccination was given then reported itching of her face excluding her forehead. Patient was given 25mg IM diphenhydramine. Pulse ox was taken and read within normal limits. Within 5-10 minutes after the diphenhydramine was given patient reported itching involving her arms, facial flushing but no shortness of breath. An extra dose of 25mg IM diphenhydramine was given and an IM EpiPen.

Facial swelling, slurred speech, taste in mouth (medicine like), heart palpitations, rash to chest and face.

Joint Ache , Dizzy, tickly throat, Tiredness,

"Patient complains of ""tingling sensation down arm radiating to the hand"" Patient given 25 mg PO Benadryl."

COVID vaccine administered to patient. She began to have lightheadedness and dizziness. She disclosed she had not yet eaten for the day, except for a glass of milk. Writer brought her to an exam table and had her lay down. After 5-10 minutes, she was given a banana and two small apple juice boxes. She then laid back down. After another 5 minutes, she complained of headache and slight phlegm development in her throat. Dr. was called to evaluate- after an assessment, she asked for a BP. Writer completed the vitals and found her BP was 113/77. 5 more minutes passed. Dr. advised that since her situation was not improving and headache and phlegm appeared to be getting worse, patient should receive epi and go to the hospital. Writer administered 0.3mg/0.3mL of epi and drove patient to the Emergency Department of Hospital. She was there for about two hours before being discharged. Symptoms largely resolved by the evening.

Patient reports chest heaviness, muscle aches, loss of energy. No fever or chills noted.

Pain in right arm , Pain in shot site

Patient with tachycardia and elevated BP about 20 min following vaccination; O2 sat okay; sat down for 15 min and symptoms resolved without treatment

Patient is suspected to have received 0.3mL of undiluted vaccine (150mcg vs 30mcg). Patient reported having a dull headache 3/10 pain scale since yesterday afternoon post vaccination. Patient also reported soreness in her right arm down to her elbow. She did not experience any other symptoms.

12/16 It's hard to know because I have a fever but I work on the COVID unit and there has been an outbreak, chills, fatigue, and the thought of moving to take a shower I feel in pain

"Heart rate increase, flushed for about 20 minutes. She has an internal monitor/defibrillator. States ""it feels like when they do a dvice check."""

about 15 minutes after shot, pt had itching. After another 15 minutes the itching resolved and patient left facility

12/16/2020 Pain in the left deltoid uncomfortable to elevate and abduct my arm, it feels better today but it hurt yesterday to even elevate my arm to the steering wheel of my car

Pfizer-BioNTech COVID-19 Vaccine EUA within the first hour of dose, facial numbness on right side of face that migrated to lips. Within 2 hours of dose, nausea.

Patient experiences palpitations, dizziness, and hypertension within 10 minutes of receiving the vaccine.

Patient reports it started as a tingling, pain and burning in the elbow and travelled up the shoulder and up the chest and to the heart. Pain felt like a cardio thump . Grabbed the epi. Sitting forward. Talked Dr. Doctor stated to sit back and uncross legs. Initiated slow breathing. Pain subsided to a tolerable amount. Not short of breath but tachycardic. Still dizzy. Stayed an hour sitting position, after injection. Felt there was an irritating sensation around the heart. Left and walked back to clinic. 10 minutes after arriving to the clinic, dizziness, flushing , came back and irritation around the heart was still noticed but tolerable. 2 minutes after, voice started cracking and drank some water. Intensity of dizziness increased and overall symptoms also intensified. Returned to COVID immunization clinic 15 minutes later. Patient was moved to direct observation in a chair. Given oral benadryl. Instructed to stay and would evaluate if new interventions would be deemed necessary. Benadryl helped. Symptoms were relieved in 15 mins. Patient has been in the clinic under direct observation for about 3.5 hours.

I got the injection on left deltoid and went to sit doe town. seafood allergy started to get hot, flush nasal passage way got really dry and got headache, face and mouth tingling. The headache felt like a rubber band around my head and continued to get hot 20 mins. When I got up to walk out felt light headed. Then went to the clinic dint feel right couldn't focus, temp was 100.Also exp gi problems had loose stool. I took Tylenol and Motrin for headache/fever and also on 12/17. Had to leave work early on 12/16 and was able to return on 12/17.

Headache and, limited motion to the Injected arm

Fever 102, nausea, headaches, muscle pain, lightheaded, chills

Right ankle swollen within an hour of injection. Felt like sprain. Still swollen but pain better today. Took naproxen.

elevated heart rate 102, flushed, cold, tingly fingertips

Pharmacist was diluting doses of vaccine for vaccination clinic in hospital. After dilution of 3 vials, the compounding pharmacist passed off to the on coming pharmacist. The on coming pharmacist grabbed one of the empty vials of vaccine and added diluent to the empty vial. 6 doses were drawn up and delivered to the vaccine clinic with only diluent in the syringe. The pharmacist in the clinic noted the number of syringe doses exceeded the number possible from the amount of vials used and sequestered all vaccine doses in clinic. It is possible some of the patients in the first hour received diluent instead of vaccine but is not known for certain. The pharmacist at the clinic kept the record of all the patients in the morning clinic. Would you recommend any actions prior to the second dose for these patients? Is there any utility in antibody testing the identified patients prior to administering the second dose? Have parameters been established for titter? Please provide direction.

I work night shift so when I got home 12h after my injection and at approximately 11:00 (am) my back hurt but not terribly. When I woke after sleeping today at 4:00 (pm) I experienced joint pain in my bilateral elbows, bilateral shoulders, neck, lumbar spine & bilateral knees. It's mild pain and I will not be going in for an MD appt. It does hurt a little more if I bump into something.

"1658 Patient reports feeling lightheaded after receiving COVID vaccine. VS obtained, BP & HR are elevated. 1700 PA called 1702 PA arrived Patient remains lightheaded with some palpitations but denies any trouble breathing. 1711 VS are improving 1716 Patient states she starts feeling better but then gets a new wave of lightheadedness with ""fogginess"". Monitoring continued. 1741 Patient starting to feel ""extra lightheaded"" 1742 Benadryl given per PA 1748 Patient verbalized a headache 1818 Medic called because BP & HR have not improved after 1 hour of monitoring. 1825 Medic team transported patient to the ER"

Immediate swelling at injection site, approximately 1.5cm diameter and raised about 1 cm

PAIN AND REDNESS ON INJECTION SITE.

Patient developed hives, facial swelling, throat swelling/itching, and nausea approximately 13min after vaccination while in observation. Patient immediately taken to Emergency Department where epinephrine was given IM in the left thigh followed by 125mg IV solumedrol, 50mg IV benadryl, 1000mL NS, and 20mg IV famotidine. Hemodynamically stable throughout ED course.

I had arm pain. Yesterday I had a hot flash with throwing up and diarrhea.

Approximately 5 minutes after receiving vaccine I noted an intense flushing and burning sensation from my waist up followed by tachycardia with heart rate in 150s elevated BP 150/100. These symptoms subsided after approximately 10 minutes but were then followed by a ?cloudy? feeling in my head as well as tingling in bilateral hands that lasted the rest of the day but had resolved by the next morning. The next morning I felt very well until 2 pm when I had a short period (approximately 2 minutes) of elevated heart rate (120s) that then resolved.

End of monitoring period, when staff asked how he was feeling he said he was having palpations. Nursing checked his HR and associates HR was 100-120BPM. But denied chest pain and SOB.

Soreness to arm , Couldn't lift arm above shoulder

Fever of Tmax 100.5, chills and headache 24 hours after receiving the covid vaccine

Left arm pain. Painful enough it awoke from sleep when I would roll on it. It is tender to touch. However no limit to range of motion or use

Within 10min patient first experienced feeling hot and tightening of throat. Patient visibly sweating on forehead. Patient expressed feeling extremely flushed. No meds given per patient request. 30 min post-vaccination, patient now feeling very cold, throat feels better but still a little tight, and a little dizzy. No nausea.

After vaccination in the medical office building adjacent to the hospital, the hospital employee felt palpitations (within 30 minutes of shot). Employee went to the ED at the hospital and was evaluated by medical personnel. Employee was SOB but did not have difficulty breathing. No other untoward reactions were observed. All other ROS was unremarkable. Sinus tachycardia of 140bpm observed in the ED, repeated ECG was sinus tachycardia of 119bpm, no other abnormalities. IVF, 50mg IV diphenhydramine, 40mg IV famotidine, and 125mg IV methylprednisolone given. Symptoms of palpitations and SOB resolved. Discharged with instruction to return to the ED if any symptoms returned.

Elevated temperature, muscle pain, tiredness

TINGLING AROUND LIPS, MONITORED FOR ADDITIONAL 15 MINS. (TOTAL OF 30MINS), PATIENT STATES TINGLING RESOLVED. REPORTED HEADACHE BUT STATES SHE HAD IT ALL DAY.

Approximately 10 minutes after vaccine administration, patient reported wheezing and coughing. Patient received epinephrine IM, IV Benadryl, IV solumedrol and racemic epinephrine SVN. Patient never developed a rash, hypotension, swelling of the lips, mouth or tongue, other GI side effects . Per ER attending and admitting physician, this reaction seems to be a clear exacerbation of the patient's tracheomalacia. The patient was more responsive to racemic epi SVN as opposed to IM epi. Patient admits that psychological stress may have been a component of her symptoms. The admitting physician does not consider this to be an anaphylactic reaction to the vaccination.

I received the vaccination on 12/14 no problems 3-4 later sore arm. After went home next day on 12/15 had a sore arm went to work as normal. At work left early felt tired went to bed early around 8pm. The next day on 12/16 overslept important morning meeting reported to V-safe was feeling tired, mild headache and had severe fatigue. On 12/17 felt much better not as tired returned to normal and no headache.

Joint Pain , tiredness, Body Ache . Injection site pain, fever

5 minutes after I received the injection, I experienced a mild headache and metallic taste in my mouth, with very slight dizziness for a couple seconds. I reported the mild headache and taste disturbance to the RN in the Covid vaccine room before I left for her information. I stayed 15 minutes , then walked to

my car. I sat in my car, then began to feel cold, dizzy, and my heart began to race. I walked back to the Neurology clinic where I work as an NP, and sat in the Neurologist's office, who observed me to be pale and sweating. I continued to feel dizzy with tachycardia for about 7 minutes until this resolved. The only symptom remaining after this was a headache and metallic taste.

Around 4:15PM, employee's arm felt very hot and extremely itchy. Light pink rash on left upper arm around injection site. No respiratory symptoms. She received diphenhydramine 25mg IM; 15 minutes later she stated her symptoms and rash were improved.

1. Left arm very sore, could not abduct more than 40 degrees, hard time sleeping, lasted for about 26 hours 2. Elevated temp to 100.2 F with chills and myalgia, lasted about 8 hours on second day 3. Diarrhea and indigestion for 2 days

About 20 minutes after the injection, the arm i received the injection in became very cold, changed color like I was not perfusion to the limb. This was gone in about two hours. Woke up eye lid continually twitching.

numbness to right ear and in front of ear. Also right ear feels plugged/underwater sound, Very sore left arm injection site.

Loss of taste

After an hour I got vaccinated, I started to feel nauseated and started throwing up. Theres pain and heaviness on the injection site. I had a headache as well.

Patient reported she was pregnant at time of screening. Patient confirmed that her and her OB/GYN discussed the COVID19 vaccine and determined it was the right decision for her to receive the vaccine. Upon receipt of the vaccine, she stated she was feeling flushed, nauseated and felt she was going to pass out. The vaccine clinic team took her to the ED for evaluation and monitoring.

Palpitations, shortness of breath, lump in throat

Racing heart, itching throat. Heart racing resolved in 45 minutes, Itching throat never worsened and resolved after taking Benadryl and sleeping. Woke up 12/17 feeling fine, but also has a golf ball size knot and redness at injection site.

6 minutes after receiving the vaccine I became lightheaded. I was the worst for about 1-2 hours after the vaccine but then symptoms improved some. 11 hours later I am still mildly lightheaded.

Headache, fever, malaise, body ache

I developed moderate to severe pain in my deltoid (of injection) that lasted 48 hours. I would describe the pain as 8/10 and moderately affected my ability to use my right arm on 12/16/20. I reported the side effect to VSafe, who called me and asked me to submit a VAERS.

Soreness injection site Headache Prickly sensation of skin Weakness/fatigue Stomach pain/nausea/ loss of appetite

Noticed Arm pain at bedtime on the day of the injection. Soreness lasted approximately two days.

Warm flushing feeling within about 10-15 seconds of injection, as well as metallic taste in mouth. Repeated on an off for the next hour. Taken to ED of hospital. Noted right arm mild rash distal to injection site and on chest, mild to moderate nausea.. IV Bendadryl 50mg given, IV Solumedrol 125mg, IV Pepcid, IV Zofran. Discharged home with PO prednisone x 4 days. PO Pepcid and Benadryl PRN

10:00 am received vaccine @ medical center right side of mouth felt strange on the way home. 13:00 pm right side of mouth continued to feel strange. Looked in mirror and noticed uneven smile, right side of mouth drooping. 13:35 pm messaged my primary care MD. And called Nurse triage. 14:00 pm Nurse triage advised me to go the emergency room ASAP. 15:00 pm @ Emergency room. Stroke code called, labs, CT, MRI completed. Diagnosis Bell's palsy. Went home with steroid and anti-viral. Symptoms are improving.

tachycardia, HR up to 130s 1 hour after vaccination. Tachycardia while sitting down. Lightheadedness. Tachycardia improved but still100-118 while at rest for hours

SOB, tingling

Nausea, myalgia, injection site pain, malaise, diarrhea, chills, joint pain, headache, nasal congestion,

40 min after injection my throat and tongue started to feel weird and tight, pharmacy at my work hospital gave me 25 mg Benadryl and 650mg Tylenol. At about 1 hr 45 min after injection my throat got to the point of so swollen and itchy I couldn?t swallow. I went to nearest emergency room hospital they administered decadron orally, Pepcid P.O., and Toradol via IM.

I received 1st dose of the vaccine at 4:30pm on the 15th, felt well and at my baseline. The morning of the 16th (~1030), I woke up with my face and cheeks swollen and mildly red. I then took 50mg Benadryl and 10mg zyrtec, and iced my face (1 zyrtec in the morning, another at night). I began to see improvement in my swelling. The morning of the 17th I took another 50mg of Benadryl and my face is back to it's baseline.

Headache - centralized at front of head, from temples to forehead; no treatment taken; resolved after a nap; lasted about 4 hours

Patient reported that she started to feel unwell immediately after the vaccine with some nausea. She presented to the Emergency Department where she was treated by myself approximately 17 hours vaccine administration. She was having vomiting, diarrhea, diffuse rash, and throat discomfort. She was successfully treated for anaphylaxis and was able to discharge to home.

Fever and chills that started approximately 24 hours after injection lasting for approximately 8 hours.

hot flushing feeling, light headed, legs heavy gave patient a chair to sit and candy symptoms resolved by 11:36

Seizure approximately 24 hours after vaccination

vasovagal response - dizziness and nausea which lasted about one hour after injection - resolved with supine position and dry cereal

Immediately after administration felt a strange sensation on nostrils and mouth that dissipated after the initial 15 minutes. Then I started with mild itching in the next arm and neck. About 30 minutes after administration my eyelids became swollen. No shortness of breath or tachycardia. I received Benadryl and solumedrol at ER. Stay at the ED for about 2 hours and left home. After that I felt strange for a while and could not sleep at all. The next morning everything was fine except for mild left arm side of injection pain.

Headache. Aleeve X2 taken Thursday 12.17 at 2p. went away after several hours. Have another headache this morning

Hives at the injection site 2-2.5 hours later extremely itchy and bumpy, self limited to the upper arm, resolved 3 hours later only intervention was ice as uncertain if Benadryl or steroids would have blunted an immune response

COMPLAINS OF NUMBNESS TO TIP OF LIP WITHIN MINUTES OF ADMINISTRATION. DENIES HISTORY OF ANAPHYLAXSIS. TRANSFERRED IMMEDIATELY TO HOSPITAL ED

5-10 minutes after vaccination, vasovagal syncope: pallor, diaphoresis, dizziness, tunnel vision, nausea, weakness, tingling in arms/legs, BP 103/69

undiluted dose given

soreness in right hand...seems to go away as i start to move my arm

undiluted dose given

Event happened outside of the ER at a clinic and not witnessed by any hospital staff. Patient reported dizziness, shortness of breath, headache, chest pain, sore throat, hoarse voice and tightening in the throat and chest minutes after vaccine administration. Treated with IM epi on scene by EMS. In the ED abtou 30-45 minutes after event, given IV normal saline, solumedrol, benadryl, and famotidine. Given PO potassium after labs for mild hypokalemia. She was monitored for about 4-5 hours total in the ED with complete resolve of symptoms.

severe, acute hearing loss and tinnitus in R ear.

Right arm soreness, headache, hot flashes.

Received the vaccine at 2:30 PM. Approximately at 2:50 I started feeling paresthesia of my left leg, approximately 1 to 2 hours later a progressed to my left arm. Around 8:00 PM it progressed to my right

leg, right arm, torso and face. I subsequently took Aleve. No significant shortness of breath, or weakness noted. This morning paresthesia continues but less apparent. It feels more apparent in my left side. I can no longer feel it on my torso or face.

Fever with max of 101.9, headache, chills, heartburn, cough, fatigue.

Breastfeeding toddler developed rash to torso, back, and cheek

Metallic Taste in the mouth; lasted for a few hours.

Chest pain and tighness, generalized with stabbing pain intermittently elevated blood pressure 180/95

She became diaphoretic, her throat felt dry and as if it was beginning to close. Rapid response was called and she was transported to the ER. She was tachycardic, experienced chest tightness, and shortness of breath.

Pfizer-BioNTech COVID-19 Vaccine EUA - Sore and sensitive right arm

fever, fatigue, injection site slightly red and raised

31 hours after the vaccination I woke up at 11:00 p.m. and had two and a half hours of alternating sweats and chills that went away with 1000 mg of acetaminophen and 600 mg of ibuprofen. I did not have a fever, my temperature was 98.8, and I did not have diffuse muscle lakes. this was similar to but much shorter lived in milder than my reaction with shingrix earlier in the year.

Fever of 100.2, joint pain and fatigue

Dizzy,Hives on neck and chest, body aches

Monitored 30 minutes in clinic, woke up at 930pm itchy hands/arms, then spread. No respiratory issues, but called to ED. Spread to thighs, and back of legs rash. 10:30 ED medicated with IV Solumedrol, Pepcid and Benadryl. Sent home with Prednisone, Pepcid and taper. Dr. spoke with this am and plan to pre-medicate prior to 2nd dose, but does approve. Monitor another 30 minutes . Rash resolved minimal on forearms.

pruritis of upper extremities. Erythema of bilateral palms and dorsal wrists

Severe headache, fatigue, muscle aches

Metallic Taste in the mouth lasting for several hours post vaccination

body aches, chills, right arm pain and some swelling which is migrating to right axilla and right breast

Headache, fatigue sudden onset at 10 am, resolved after acetaminophen

hives all over body. with swelling.. Red eyes.

Patient received two Pfizer-bioNTech vaccinacation on the same day by accident. Received both doses in a time span of 5 minutes apart. (Received both doses in left arm). Patient kept in observation room for 30 minutes after time of vaccination to monitor for any adverse events. Patient will contact nursing supervisor if any severe adverse events occur within the week.

About 5-10 minutes the vaccine I began to get tingling and a itchiness in the back of my throat , notified personnel and vitals were checked and stable. The tingling and numbing sensationent away and came back and benedryl was given. The symptoms came in waves of about ever 2-3 minutes so I was transported to ER and somumedrol was given was monitor for 1-1.5 hrs and the numbness and tingling sensation continued for about an 1-2 hours and finally subsided and was released to go home

Bleeding and significant swelling (marble size) at site immediately after administration.

Swelling, redness, warmth at the injection site starting approx 15 min after injection was given. Then severe itching starting in right arm, right side of head approx 25 min after injection. Then itching progressed through the entire body including toes Claritin 10mg taken approx approx 2 hours prior to inj Allegra 1 tab Diclofenac 50mg Tylenol 1000mg Pepcid 1 tab Solumrdrol 40mg IM All given at approx 8:30am Itching continued. Inj site reaction started to improve. At approx 9:20am Benadryl 50mg taken at 10:00am Benadryl and Pepcid repeated at 6pm due to return of itching Facial flushing and temp of 100.1 orally noted at 6am the next morning

Dry, Scaly hands - Bilateral

Pt with dizziness, bilateral arm tingling and hand sweating. Hands extremely cold. Vital signs wnl

Ear pressure followed by bilateral under arm soreness. Later in the day both arms warm to touch and felt swollen. Face flushed and overall body aches and inability to stay awake. 600mg ibuprofen and rest. Felt myself in morning except as expected left arm pain at injection site and a little left arm tiredness or weakness.

Sore at the site of injection, and sore.

Urticaria, pruritis, headache

PATIENT REPORTED FEELING TINGLY ALL OVER AND NOT RIGHT, placed in supine position, HR 120's, BP 186/96, RR 24, not diaphoretic, patient was transported to ER where she was given Zofran and IV Benadryl. She reports that the Benadryl helped immediately. She took an oral dose of Benadryl after being discharged home.

Rash - noted all over body - mostly trunk, neck, upper arms bilaterally - mostly macular with slight papular component. Significant itch.

Approximately 90 minutes following first dose of vaccine, developed severe headache, chills, joint pain and full body muscle aches. Continued throughout the night and were improved by next morning, but not fully resolved by the time of this submission.

None stated.

Gradually improving.

None stated.

Hypothermia with body temp of 95.0 F. Treated with heating blanket and covers.

"5 minutes after the Pfizer Covid-19 vaccine administration, the patient developed flushing, hives, felt warm and eventually short of breath. She started to wheeze and was wheeled into ER c/o ""I can't breathe while holding throat and thrashing with facial flushness noted. PT took 2 Benadryls and had several Epi shots. She was then discharged from the ER and later on that day, started to feel short of breath again. In the ED today she was audibly gasping for air, however had no wheezing, had a normal saturation and a normal blood pressure. She had taken another dose of her EpiPen IM and diphenhydramine 50 mg by mouth prior to coming. She was then admitted to the hospital for further observation. While on the floor, she started to feel short of breath again (about 9 am on 12/18/2020), which required an RRT . Patient received another dose of diphenhydramine IV, methylprednisolone 125 mg IV and several doses of IM epinephrine. She also required oxygen. She was then transferred to an ICU for further care."

None stated.

My symptoms started with bodyaches and fatigue. Quckly followed by a fever that reached 102.4. Later that night I had congestion, cough and headache. Woke up the next mornign with moderate/sever bodyaches, chills, cough and headache. Moderate fatigue as well. Had to miss work.

Entire left side of body muscle aches and joint aches. Started about 2 hours after getting injection and worse the next day

After I received the vaccine about 1 1/2 hours later I started experiencing a metallic taste in my mouth. I am also experiencing no appetite. Throughout the night I had to force myself to eat. I'm still experiencing no appetite and this is very unusual. The metallic taste is still present, but it is getting better

Treatment dugs:

Patient with a h/o syncope to vaccines, felt light headed and laid down on floor roughly 3-5 minutes after vaccination in the observation area. Patient pale, pulse regular in mid-60's, A&O x3, conversant. Medical assistance team called, bp 94/60, lightheaded after attempt at standing for 90 seconds. Transported to ED for observation.

Initial symptoms started in less than 5 minutes were tingling in the lips and tongue. Thickness feeling to the tongue. Progressed to hoarseness to voice that worsened. Received 50mg Benadryl chewable tablets. Symptoms continued to worsen. Epi pen injection in left thigh. 5 minutes later still no improvement and another Epi pen injection in right thigh. Monitored for 5 to 10 min and no

improvement and was taken to the ER. In the ED, received IV fluids, IV Benadryl, IV Decadron and IV Pepcid. Monitored for 3 1/2 to 4 hour and discharged home with 3 days of Prednisone 60 mg and Benadryl po every 6 hours as long as allergic like symptoms persisted. 12/18 morning still with lip tingling and Asthma like symptoms. Voice is still in and out of hoarseness

Slight tingling down left arm into left fingertips

None stated.

On 12/16/2020, approximately two hours after administration of Pfizer BioNTech Covid-19 vaccine, patient developed SOB and chest pain. Patient reported to ED where she was given fluids, diphenhydramine, ipratropium/albuterol nebulizer treatment, magnesium, famotidine, and epinephrine. Of note, patient has anaphylactic reaction to corticosteroids. On 12/17/2020, around 3:00 pm the patient reports to the ED at a different facility (one closer to her home) with difficulty breathing and sensation of her airway closing. Patient again was given epinephrine, fluids, ipratropium/albuterol nebulizer, diphenhydramine, famotidine, and was also given a dose of lorazepam. The patient now has stated that she had an anaphylactic reaction to a prior flu vaccine, however this was not listed as an allergy prior to administration of the Pfizer BioNTech Covid-19 Vaccine.

Patient experienced mild alllergic reaction starting at 4:19pm. The ER staff came to tend to the patient. The patient reported dizziness and weakness. Her vitals are as follows: BP 142/80, O2-99% on room air, Pulse-98, Resp Rate-18, Temp-97.3F. The patient was taken to the ER and received Benadryl 50mg IV and an Epipen. The patient's pain was 0/10. The patient was reported stable at 4:27pm.

Patient began experiencing itching and tingling in lower back and down right leg after leaving the facility (had waited the required 15 minutes). Drove around building and parked and came back in. No rash noted. Vital signs BP 157/73, HR 69, Resp.- 16, O2Sat- 98, Temp- 97. No obvious distress, Alert and Oriented X3. Grips equal and strong, no facial weakness and ambulating without difficulty. After 20 more minutes C/O tingling of lips. Consented to call 911. Assessed by EMS. Vital signs remained stable and patient refused to go to hospital. Called wife to pick him up. Patient required no treatment and left facility at 5:30 pm.

Employee presented to the Emergency Department for dizziness. Patient received COVID-19 vaccination today. About an hour and half later he started experiencing dizziness and lightheadedness. Patient was normotensive with regular heart rate at the time. Patient reports when he would get up to go patient room he would start to feel unsteady. Patient has history of orthostatic hypotension intermittently in the past. Patient reports he had some tingling to his bilateral hands.

12/16/2020-6:00 pm Fever 101.6 body aches 12/17/2020 1:00 pm Sick stomach, light headed 12/17/2020-5:00 pm Stomach cramps, diarrhea Light headed Cold sweats 12/17/2020-7:00 pm Extreme intestinal cramps, diarrhea Loose bloody stool Lack of appetite Light headed Cold sweats 12/18/2020 - 4:00 am Extreme intestinal cramps Loose bloody stool Nautious Lack of appetite Unable to sleep Light headed Cold sweats 12/18/2020 Intestinal cramps/pain Lack of appetite Nautious Light headed

NAUSEA AND VOMITING

Approximately 10 minutes s/p vaccination, employee became sweaty, c/o tingly hands, low BP, c/o nausea. Medical assistance team called, patient transported to ED.

Fever, chills, body aches, headache, injection site pain and swelling

Nurse call line recommended ER visit. Employee opted not to, drank salt water and gradually feeling better, although aches persist.

1 hour after administration of vaccine 0.3ml the staff member began to have a systemic blotching on skin and dry, severe cough.

around 2 a.m. patient woke up noticed weird smell in her nose, and tingling in her fingers and hands on left side and has headache

Pfizer-BioNTech COVID-19 Vaccine EUA Pin and needle feeling throughout body with flushing and hives. Mouth and throat felt tight with numbness sensation in mouth. Voice became very raspy and breathing felt somewhat difficult. Tachycardiac and Hypertensive Reported to the ED, received 50 mg IV Benadryl, 125mg Solu-medrol and 40 mg Pepcid, symptoms began to suside after about 5-10 minutes. Had report throat tightness at approximately 1700 and self medicated with Benadryl 2 times throughout the evening.

Patient began experiencing itching all over body 15 minutes after IM injection. Patient was given benadryl 25mg at 09:22. Benadryl 25 mg dose given again and pepcid 20 mg at 09:53. Patient symptoms are resolving at this time. Notified patient to inform primary physician of itching reaction.

After receiving the vaccine approx. 1 hour he notice redness ant itching at the top/middle of chest. Area approx. 3 X 3. Area was red and warm not hot and not much warmer than surrounding area. Denied SOB or swelling in mouth or chest. Denied itching elsewhere in body.

Pfizer-BioNTech COVID-19 Vaccine EUA. Patient felt dizzy and had elevated blood pressure. Pulse normal.

Patient was seen at COVID Vaccine Clinic today for her first dose of the COVID 19 vaccination. She denied any history of previous adverse reactions to vaccines. She reports that she also had a shingles and pneumonia vaccination on Monday 12/14/2020. She confirmed with both her PCP and transplant specialist that okay to receive all vaccinations. á She was given the Pfizer vaccination in the right deltoid muscle. á During her 15 minute waiting period after the injection, the patient began to experience tongue tingling and swelling specific to the left side of her tongue. She denied rash, difficulty breathing, difficulty swallowing, wheezing, throat tightness, dizziness and lip swelling. She reports similar reactions after receiving other vaccinations. States that those symptoms always resolved with time and never required any treatment. á This APP was notified of patient reaction and she was then assessed in the emergency bay area. á Vitals Vitals: á 12/17/20 1545 12/17/20 1555 12/17/20 1620 BP: 128/85 116/72 126/73 BP Location: Left arm Left arm Left arm Patient Position: Sitting Sitting Sitting Pulse: (!) 109 100

99 Resp: 12 12 12 SpO2: 99% 97% 98% Physical Exam Constitutional: She is oriented to person, place, and time. She appears well-developed and well-nourished. No distress. HENT: Nose: Nose normal. Mouth/Throat: Oropharynx is clear and moist. Neck: No tracheal deviation present. Cardiovascular: Normal rate, regular rhythm and normal heart sounds. Pulmonary/Chest: Effort normal and breath sounds normal. No stridor. No respiratory distress. She has no wheezes. She has no rales. Musculoskeletal: General: No edema. Neurological: She is alert and oriented to person, place, and time. Skin: Skin is warm and dry. No rash noted. She is not diaphoretic. No erythema. Psychiatric: She has a normal mood and affect. Her behavior is normal. Thought content normal. á Patient's health history, medications and allergies were reviewed. She denied any further symptoms and the tongue numbness/swelling resolved in 30 minutes. She specifically denied any difficulty swallowing or breathing. No treatment was required. Pharmacy responded and did advise that current recommendations include no other vaccinations within two weeks of COVID. Discussed with patient. She is advised to notify staff of this reaction when receiving her 2nd dose. Patient release after 45 minutes of observation. á

Felt lightheaded about to faint @0920 which resolved @930

Itchy throat and back of tongue, received IM epi, pt complaints unchanged <5 min after epi inj, received diphenhydramine, famotidine, prednisone (1 hr later), patient comfortable, throat symptoms improving (2.5 hrs later)

Within minutes of receiving the vaccine I experienced a metallic taste in the back of my throat (while I had mint gum in my mouth), dizziness, increased heart rate, labored breathing, and a floating feeling. These symptoms lasted no more than 10 minutes except the floating feeling lasted about an hour.

itching all over the body after 7 hours of administration of the vaccine lasted for a couple of hours headache, body aches, chills, sweating after 12 hours of vaccine administration lasted for 24 hours

She received her covid vaccine around 1700. She had a reaction that we monitored in the observation room for approximately 40 minutes. She was not feeling better so we took her to the ED for monitoring. She was discharged from the ED after an hour and a half. No intervention was needed. Her symptoms were feeling flushed/ anxious/ shaky, injection arm felt hot (was cool to the touch), HR was 117, BP was 143/96, which is high for her. We are recommending she reach out to her PCP prior to scheduling her second dose.

Treatment dugs:

Pfizer-BioNTech COVID-19 Vaccine EUA. 5 minutes after vaccination patient felt warm, light headed, left arm pain, and blurred vision. Lasted about 3 minutes and gradually was gone by 5 minutes.

Patient experienced generalized itching in face area 1 hour after injection. Itching spread to neck and chest area soon after. Patient was given benadryl 25 mg at 09:25. Given another benadryl 25 mg and pepcid 20 mg at 10:00 due to start of itching again. Itching has mostly resolved as of 10:15. Patient

advised to contact primary physician to notify them of vaccination and to monitor for any more adverse events after leaving hospital.

Headache, neck pain, vomiting

Dizziness within 10 minutes that lasted 30 minutes or longer. Waves of nausea for over 24 hours

Felt unable to answer questions possibly hypoglycemic event, felt something in back of throat, symptoms resolved after providing apple juice

patient called in to work today at 7:15 a.m. with fever and body aches

local soreness, muscle pain in both thighs, fatigue, runny nose

Eye redness, pain, swollen Face swelling Bilateral arms and hands swelling Rash SOB

started to feel tingling in arm received shot.

Patient developed flushing, red warm itchy rash on arms and trunk area. Happened approximately an hour after receiving vaccine. Was given 50mg IM of benadryl and symptoms improved after about an hour after they appeared.

Pt reported a lump in her throat 10 min after the injections. Pt thought she needed a drink of water. Pt reported to feeling fine and returned to work. Pt then reported to the ER with dizziness and lump in her throat at 2:18pm. Pt was admitted to hospital for observation overnight.

12/16- received vaccine at 6:44pm, 12-17- 0400am woke up with nausea/ vomiting and fever, had to call off work 12/18- continued to have nausea/ vomiting and fever until 10 am at which time symptoms and fever resolved

PAIN AND SWELLING OF LEFT SUPRECLAVICULAR AREA, LEFT LEG PAIN.

Felt a lump in her throat 5 minutes after vaccination. BP and HR elevated slightly, no swelling in lips or tongue, denies lightheaded or dizziness, Alert/oriented x3. Vaccination site WNL. Listened to lungs and heart (WNL). Lungs clear throughout and able to move air without difficulty. Within 15 minutes slight improvements in Vital Signs, decreased feeling of lump in her throat, no swelling in lips or tongue, site WNL, alert/oriented x 3. Listened to lungs and heart (WNL). Lungs clear throughout and able to move air without difficulty. 30minutes later 50% improvement of feeling of lump in her throat, cont. improvements in VS, no swelling in lips or tongue, Listened to lungs and heart (WNL). Lungs clear throughout and able to move air without difficulty. 75 minutes post vaccination back to normal, Vital signs back to WNL, Alert/oriented x3, no swelling in lips or tongue. Listened to lungs and heart (WNL). Lungs clear throughout and able to move air without difficulty. Resolved on own without medications

Initial within 10 minutes, redness and burning pain at site. Ice was applied and this went away, then about 25 minutes, itchy throat, trouble swallowing, mild confusion. Oral benadryl 50mh and solumedrol IM. Once again this dissapated after 30 minutes. 3 hours later, trouble swallowing, felt as if something

was in my throat, redness and flushing all over.fluid bolus, epinephrine I'm, iv benadryl, pepcid oral, and claritin oral, fluid bolus. 12 hours after getting the vaccine blurry vision, ringing ears, headache, benadryl, steroid, claritin all oral

"lightheaded; ""funny feeling"" in throat; systolic BP in the 80's; given famotidine and loratadine @ 12/16 (2 hrs later); pressure and heart rate improved greatly (3.5 hrs later)"

10 minutes after the vaccine I had sudden cold hands (the kind of inside cold like Propofol gives you), with palpitations and dizziness. Self limited in a few minutes. BP was 150/90 which is high for me. Similar episode but shorter and less intense within next half an hour. There was also a sensation of chest awareness (not pain, but a bit of tension, which I have experienced before with anxiety and put it on anxiety). After a while decided to go home and while walking I noticed a clear sensation of chest warmth. I decided to stick around the hospital a bit more, pondering about going into the ER. DRank 2 bottles of orange juice and headed home. Then on the way home I had 2 presyncopal episodes. The fact that I had not eaten all day and wasn't well hydrated might have contributed. However, that was scary enough that I called 911. By the time they arrived I was fine. DEcided not to go to the ER. I ate some, drank some, and took Benadryl 25 mg. The chest tightness got better. I still continued to experience waves of chest warmth/heat/burning sensation and chest awareness/ tension, coming on in waves and going away in a couple of minutes. I was obviously anxious by this time but I do not believe the warmth was anxiety related. I have had anxiety before but never with this manifestation. I was tired, slept like a baby and this morning I feel at baseline. Some soreness at injection site but none of that chest warmth.

Numbness and heavy feeling on the tongue and lower lip

ITCHING AND REDNESS ON INJECTION SITE, NEXT DAY GENERALIZED ITCHING. DIARRHEA.

Lightheaded, flushed

At 8pm I developed extreme itching throughout my entire body, inside my ears,throat eyes. No rash or hives no sob or swelling. Headache also noted. I took tylenol 1000 mg and at 9pm I took benadryl 50 mg. I woke up 12-18-2020 with less intense itchiness but it was still present, not my throat or inside my ears. I took allegra 180 mg. At 1100 I developed a headache and took tylenol 1000 mg.

Patient was seen at COVID Vaccine Clinic today for her first dose of the COVID 19 vaccination. She denied any history of previous adverse reactions to vaccines. She does report a history of similar reaction that occurs fairly regularly after drinking beverages containing alcohol. á She was given the Pfizer vaccination in the right deltoid muscle. á During her 15 minute waiting period after the injection, the patient began to experience flushed, warm face and ears. She denied rash, difficulty breathing, difficulty swallowing, wheezing, throat tightness, lightheadedness, lip swelling and tongue swelling. á This APP was notified of patient reaction and she was then assessed in the emergency bay area. á Vitals Vitals: á 12/17/20 1450 12/17/20 1500 12/17/20 1515 BP: (!) 153/73 120/60 138/70 BP Location: Right arm Right arm Right arm Patient Position: Sitting Semi-fowlers Sitting Pulse: 84 79 78 Resp: 14 14 14 SpO2: 100% 98% 98% Physical Exam Constitutional: She is oriented to person, place, and time. She appears well-developed and well-nourished. No distress. HENT: Nose: Nose normal. Mouth/Throat:

Oropharynx is clear and moist. Neck: No tracheal deviation present. Cardiovascular: Normal rate, regular rhythm and normal heart sounds. Pulmonary/Chest: Effort normal and breath sounds normal. No stridor. No respiratory distress. She has no wheezes. She has no rales. Musculoskeletal: General: No edema. Neurological: She is alert and oriented to person, place, and time. Skin: Skin is warm and dry. No rash noted. She is not diaphoretic. No erythema. Psychiatric: She has a normal mood and affect. Her behavior is normal. Thought content normal. á Patient was observed x 35 minutes after receiving vaccination. All symptoms resolved within 20 minutes. No treatment was required. She reports some mild history of anxiety and questions if perhaps she was having a panic attack. She has medication to treat this at home if needed. She was observed x 35 minutes and then released. á

Lightheadedness, shortness of breath, chest tightness Needed to take Ventolin inhaler 2 puffs, Duoneb nebulizer, liquid benadryl Symptoms improved with medications. Felt very tired rest of day. Symtoms to relief was probably 1 to 1.5 hours

Fever, Chills, weakness, Headache. Fatigue. Onset symptoms 12/17/2020 to 12/18/2020. Highest fever 101.8.

"5-7 min after injection she felt flushed face and ""as if they were checking my pacer"" ""so my heart rate revved up a little"" She sat down and the feeling resolved within 15 min"

Dizziness, light headed, fatigue, easily winded, headache.

"Vaccine received 15:00 while at work at Medical Center; Around 19:00 started having intermittent ""hot flash"" feeling and general fatigued feeling. Got home from work (RN in ED) at 19:40. Took a shower and felt nauseous when I sat down to eat dinner. Declined to eat dinner and opted to lie down in bed instead, at 20:50. Awoke at 22:00 to urinate. Felt dizzy standing up, with cold-sweats and body aches. Checked temperature, 97.9 F. Went to the bathroom, drank some water, took 400mg ibuprofen and 325mg tylenol, and went back to bed. Awoke back up at 01:30am with abdominal cramping and nausea. 2 episodes of dry heaving, but no vomit. Awoke back up at 06:55am, GI symptoms resolved but bodyaches persist, as well as overwhelming fatigue. Checked temp at 07:25, 98.3 F. Employer notified."

Chills, body aches, headache

Had COVID-19 November

patient presented with a (L) hand numbness + coldness (ipsilated to vaccine) right after her vaccination symptoms resolved after a warm shower

Swelling locally in arm began within 12hrs. No systemic symptoms, started on dose pack (Medrol) antihistamines, Ice bag.

Right arm soreness, mild swelling, subjective fever, chills, bodyaches, headaches, loose stools x 2, 6 hours of duration, Treatment Tylenol

4:30pm pt noticed tingling & hot flash of face and neck- stiffness of jaw took 50mg of Benadryl. 530-6pm pt noticed the addition of numbness and tingling arms. Pt slept. Pt woke at 11:30pm and noticed that tingling was gone. Pt woke this morning and reports to feeling fine.

I have consistently had a positive ANA (anti-nuclear antibodies) test. Not positive for positive for lupus or rheumatoid arthrits. I wanted to let you know that. But after 15 min I started feeling some wooziness, and about 30 min later a headache, feeling like i was mildly drunk, shoulder (injection site) sore, chills, no fever, mild body aches.

Right eye fullness and blurry vision

I experienced after 40 or 50 minutes I felt funny. I felt fatigue, sleep and after that I felt a sharp pain from my neck to my upper back.

Within 10-15 min of injection, she was walking in the POD, waiting around to leave, but felt dizzy. Was instructed to sit down. People around her noticed a flushed face, she felt her HR increase (as a sensation, not measured) she rested and stay seated for about 10 min. While she was seated, her (she checked her own pulse) noticed it went from 55- 70.

FATIGUE, MUSCLE ACHES, JOINT PAIN, LOW GRADE FEVER 99.8

The patient began to feel itchy throughout the body, particularly both arms and the back. This happened 30 minutes after injecting her with the COVID-19 vaccine

Issues were similar to what I have experienced with the flu vaccine but a bit more pronounced including soreness at the injection site (moderate), tiredness (moderate), joint pain (moderate), headache (mild). The worst of the symptoms started on the first day post-vaccine and subsided about 36 hours later.

(1145) Left eyelid swelling 15 minutes after vaccination. (1155) b/l superior periorbital edema and erythema, b/l ear erythema and burning, and b/l hand tingling. (1200) Oral Benadryl 25 mg was given. (1230) symptoms improved and I was able to leave. While riding in the car on the way home started to have chills w/ goosebumps and nausea in short waves. Took an nap b/c my chills worsened and slept until 1630. Work up b/c of worsening chills, shivering, chest tightness, nausea, b/l hand numbness and tingling, right foot burning and stinging, and constant throat clearing b/c throat felt thick. Called the nurse on-call number provided in vaccine packet and was transferred to virtual care and report was given. Medical team advised me to go to the ED. (1900) Arrived at ED and temp was 101 and the chills, numbness, foot burning, and chest heaviness were worse and my eyes were burning and heavy. I was given oral Pepcid and an IV was started. After an IVP of Benadryl and Solu-Medrol I experienced severe burning starting in my head, neck, chest, and stomach. Then it felt like my veins were on fire all the way to my fingers and toes. This was followed by strong nausea w/o vomiting. I was then given IVP of Zofran and Ativan and NS drip. (1940-2020) Chills, burning around eyes, and vertigo continued other symptoms were improving .(2020) Provider returned and reported that labs were normal and I was probably having a reaction to the vaccine. (2035) Discharged from ED. Experienced chills, hand and foot numbness and tinging after discharge but was able to go to sleep.

Became hot and felt itching minutes after receiving vaccine. No swelling of lip or tongue or throat. No rash. No shortness of breath. ER doctor on site evaluated and determined this was not likely to be an allergic reaction.

sore arm at injection site, fever and chills, headache and felt stuffiness

extreme fatigue. Pt called in sick the next day for work.

"PATIENT FAINTED AT WORK THE DAY FOLLOWING HER VACCINE. BLOOD SUGAR AND VITALS WE'RE CHECKED FOLLOWING THE FAINTING SPELL AND WERE IN NORMAL RANGE. SHE WAS PASSED OUT FOR ""A FEW MINUTES"" PER WITNESSES AND WRITTEN REPORT. SHE SLEPT WELL THE NIGHT BEFORE. SHE WAS UNINJURED AS A COWORKER CAUGHT HER. AFTER HER VITALS WE'RE CHECKED SHE FELT WELL AND RETURNED TO WORK AND WORKED THE ENTIRE REST OF HER SHIFT WITHOUT INCEIDENT OR COMPLAINT."

CIRCUMORAL TINGLING

12/17/2020 patient reports an intense head ache with intermittent shooting pains that are debilitating. Patient also reports fever of 103.4 that is unchanged with use of antipyretics.

Vaccine recipient was administered the vaccine at 11:30 am and then around 1:30 pm started to feel dizzy with hives and itching to his arms. The vaccine recipient was sent to the emergency department for further evaluation. There was an erythematous macular/papular rash on bilateral arms. He was administered diphenhydramine 12.5 mg IV, famotidine 20 mg IV, and methylprednisolone 125 mg IV. After reexamining, the patient felt much better, no dizziness, no itching, and no rash. He was discharge to home at 4:57 pm same day.

chills, aching, fever, extremely cold feet

At 6pm patient's tongue was numb and the left side of their face was tingling. Patient felt like she had burnt her tongue and was trying to taste with it still. Around 11pm the numbness started to go away and she could taste things better. Today everything is pretty much normal.

The pain around the injection site progress to full body ache, head stuffed ness breathing though mouth and slight fever 100.1 took Ibuprofen. The next day sore all over, hard to walk and took Ibuprofen for 6 hrs. On 12/16 lost taste/smell, diarrhea, nausea .Then 12/17 continued aches and fever pt went to get a Covid test was results positive. This morning exp body aches and slightly gaining taste .Pt has been not able to work for 10 days since testing positive.

nausea, lightheadedness, and palpitations that occurred ~10 minute post injection with decreased blood pressures c/w vasovagal response, improved over a few minutes

Chills, low grade fever, body aches, injection site muscle spasm, burning sensation in the chest

Day 1 of shot: headache 10 hours after Day 2: headache, fatigue, joint pain Day 3: headache. Fatigue, joint pain Day 4: headache, fatigue, joint pain and low grade fever, diaphoresis Day 5: worsening headache, fatigue, joint pain Tylenol was obtained per bottle recommendation for pain on all days.

After injecting vaccine the patient began to fell heavy tongue, dizziness and nausea. Vital signs: BP:205/161 mmHg, R:21, 97% oxygen saturation

Approximately 20 minutes after vaccination patient c/o feeling lightheaded, hands tingling and feeling as if there was something in her throat.

Left arm and quad soreness, nausea, headache, light headedness, light sensitivity, dizziness, body aches. No fever nor respiratory symptoms.

Patient experienced heart palpitations. Pulse was 135 SpO2 99. Calmed patient to pulse 70. BP 132/84. Patient reported to feel better after 10 min. No other intervention needed.

weakness and body aches

After receiving injection 14-15 minutes after I started to get chest tightness. I took two puffs of inhaler and walked to triage room to be monitored for another twenty minutes. I took two more puffs of inhaler and chest tightness went away a few minutes after. No other reactions occurred and was cleared to leave after twenty minutes.

about 12 minutes after receiving the vaccine had a sudden onset of sharp headache while seated. When she stood up became lightheaded and dizzy and nauseous. She also had elevated Blood pressure p to 168/108. After 35 minutes her positional symptoms persisted with BP still elevated 159/102. No respiratory or skin symptoms. She was transported to the ED and had a head Ct which was normal, discharged with pain medications.

Additional to the symptoms previously reported I woke up with headache and thighs feeling heavy. Those are the remaining symptoms, the previous ones reported have subsided

on 12/16 i was given the vaccine at noon and finished my day as usual, I had a beer before bed and fell asleep at 9pm, at about 1am on 12/17/2020 I woke up with severe chest pain like something was crushing me, like a car being crush it felt like. I went to the ER at 3am and I was told I had a severe reaction to the vaccine. I had a weird taste in my mouth, cough, watery eyes, pain in all limbs, jaw pain and neck pain. I am going to get tested today 12/18/2020 for covid

"Pt was ambulating through hospital cafeteria at approx 13:50 when she developed sudden difficulty walking, gait ataxia witnessed by nursing staff. States, ""It felt like the floor was rolling and I couldn't stay balanced."" Pt diaphoretic, hypertensive. No other focal deficits. On arrival to ED, pt continues to have gait ataxia, but no ataxia on NIHHS assessment. Denies headache. Received COVID vaccine at approx 1 pm today."

PATIENT REPORTS BLURRED VISION LASTING 1 HOUR APPROX. 2 HOURS AFTER INJECTION. INJECTION SITE SORENESS ON 12/16/20 AND CONTINUES TO PERSIST; NO SIGNS OF CELLULITIS. GENERALIZED MALAISE STARTED 12/19/20 AT 1000.

First day right after the vaccine the left arm was extremely sore, the next day I felt like I had the flu. body aches , headache, knees aching , abdominal pain, could not eat, lots of chill, breaking out in sweats .

Diarrhea the day I got the vaccine and 1 time the day after

Metallic taste, chest pain, coughing or throat clearing, bilateral arm numbness

Metallic smell. Started about 10 minutes after vaccine administration and occurred intermittently for about 30 seconds at a time every 10 minutes for almost an hour. Adverse effect subsided after about an hour.

Injection site reaction. Mild localized redness and swelling. Reaction occurred on 12/15, the day after receiving 1st dose of Pfizer covid vaccine. Day 4 12/18 injection site is circular redness, approx 2.5 inches in diameter. Mild discomfort, not painful not itchy. Have been applying over the counter 1% hydrocortisone cream with some relief.

After the patient received Covid vaccine, she started experiencing itching. The nurse monitoring the patient noticed she was scratching. The patient continued to itch during the 15 minute observations period but no other adverse effects were noticed. The observation period was extended to 30 minutes and then the patient was released. An hour after she left the vaccination site she experienced an episode of vomiting which resolved. Her husband noticed her to be pale upon returning home. Later that night the patient was visibly shaking and had another episode of vomiting. All symptoms have since resolved.

Symptoms began 30 min after vaccinated was tired then HAd fatigue. Took Tylenol/Advil. Fatigue persists > 24 hours Sore @ vaccine site. No induration . nl appetite. Increased fluid intake. takes Allegra + Flonase regularly. Recent sinus surgery in Oct.

AT 0600 WOKE UP NAUSEA THEN DRY HEAVES THEN VOMITING, VOMITED NUMEROUS TIMES THEN HAD EXPLOSIVE DIARRHEA, TOOK 25 MG BENADRYL ABOUT 1 HOUR AFTER TO MAKE SURE I COULD HOLD IT DOWN AND NOT VOMIT

I experienced a fever of 100.7 with it getting as high as 101, I have joint pains and body aches and pain at the injection site. Kinda the same as when I had Covid. I was only sick one day.

Patient stated that within 3-4 hours of receiving the covid-19 vaccine he began to lose his sense of taste and smell. Patient presented to ER (12-17) with his arm was hurting, headache, weakness, back hurting, and blood pressure was up. B/P was 204/112; pulse 84;resp 19; temp 102.4; Covid-19 test- negative. He had no sob or cough. Meds given:Tylenol tabs 650mg x1, Toradol 30mg iv x 1; NS 0.9% 1000ml iv, Tusssionex 5ml x1; Lopressor 50mg po x1, Patient released at 10:23am

within 5 min, pt reported feeling dizzy and lightheaded. No loss of consciousness. Pt also reports having eaten M and Ms as only food today. Pt happened to have a pulse ox on self (is an RT). SaO2 96% on room air, pulse 94. Pt given some trail mix and water and began to feel better. Upon standing pt reported not feeling well again and returned to seated. Pt then began with jerky muscular movements of upper extremities and stuttered speech. Pt states that this is how her PNES presents. No loss of mentation or consciousness. EMT team called for transfer to ER. Pt alert and oriented on transfer

Cough Muscle Ache Fatigue Lethargy Run Down feeling Chills

Itchy, Chest pressure on a scale of 1-10 rated a 3 down to a 2 after 2 minutes. Nausea and lightheaded Requested EMS to evaluate so EMS was called and Allergist presented. Remained stable throughout entire event. Allergist recommended triptophase lab be drawn to ensure that this was an actual allergic reaction. This was particularly to prepare for 2nd dose. Because of this patient was transported to ED and discharge within a few hours.

I began getting a headache about 1hr after injection. I also got very fatigued for a few hours. I took Ibuprofen to help with the headache and I took a nap to help with the fatigure.

Site injection reaction: light swelling with raised bump to injection site arm, with tenderness to light touch. Hurt to move arm.

After I woke up next morning, experienced dry cough.

30 minutes after injection, pt experienced tiredness. About 5 hours after injection, patient experienced severe nausea. Woken up out of sleep at 01:30 AM with body cramps (legs, arms). Severe soreness at injection site as well. Pt also experienced headache and nausea today (12/18) after taking Zofran, with no effect.

The employee was vaccinated yesterday and today has a severe headache with vomiting

my symptoms were chills, fever, muscle pain, my skin hurt, fatigue, only treatment was tylenol and I went to bed

Immediately after injection I felt a tiny pinch in what felt like my heart. I happened 2 more times within seconds and nothing else after that. I did not report this to anyone since it happened so quick and was over within a minute. I did stay a few stay in the area where I had the injection just in case. After about 15 minutes I left because I felt fine. No other effects afterwards.

Round 5:30 P.m. I started becoming nauseas, I had a terrible headache , OTC Ibuprofen did not help, nasal congestion ,, Only slept 2 Hours Wednesday night.. the next day 7am stayed in bed all day , headaches, congestion was worse. Could not sleep. Feeling better today but I am super tired 10/02/2020 Was tested for COVID-19 . The test was confirmed positive the next day.

metal taste, left left ear

In between my shoulder blades and back feels like something is there. I've got worse exp headaches have history of migraines in the past. In August 2020 was exposed to Covid 19 headache was worse than now. In the past have seen neurologist for migraines and not exp migraine felt like this in 5 yrs. On 12/17 body pain, headache, and high grade, diarrhea(loose stool) and fever 101.7.After checking temp on 12/18 was 98.8.Pt had to miss one day of work on 12/17.

Employee waited for 15 minutes after injection in the Department, 40 minutes after the employee left she called employee health and was instructed to return to the hospital ED if she was able. Dr. and the ED physician evaluated her. She had peri-oral numbness, and some cheek numbness, no motor deficits. SBP was 200 in ED. Single dose of Catapress and then improved B/P. D/C to home. 12/17/2020 - AM mild chin numbness - everything else resolved. B/P remained stable 12/18/2020 - resolved

Caller stated that 12/15/20 had pain in the vaccination area , headache and exhaustion that lasted about 24hours

Sore muscle around site of injection, starting the day after injection

Patient reports 1 hour post vaccination symptoms: jittery, feeling lousy. 12/18/20 Am reported bodyaches, red/watery eyes, chills, and blurred vision. States she can see better in dark than in bright lights. Previously hx of COVID 19 illness November 2020. Took Tylenol and Allegra 12/18/20. Reports improvement in symptoms 12/18/20 12:40pm but continues to report mild blurred vision. Advised to seek immediate medical care if condition not improved or worsens.

Not all or limited to: anaphylactic reaction: Feeling lump in throat, tongue feeling funny with numbness, feeling of hard to swallow, throat tightness, shortness of breath, tachycardia, tachypnea, pressure, tingling, and numbness from head to toe, dizziness/lightheartedness, cough, voice changes.

metallic taste

Hx COVID in June, with resolved problems. By 4 hours after inj adm had flu like symptoms. Took Tylenol prior to vaccination & now with bed. Swollen & redness (L) arm: 76cm began within 6 hours of vaccination. Diarrhea, now resolved. Txt with steroids - antihistamines.

day 1: none day 2: woke at 0530 with chills, general malaise & body aches, took ibuprofen, went to work, continued with same signs/symptoms, afebrile at 1430 - 98.0 degrees, sent home at 1500 day 3: woke feeling better

1208- Flushed/warm, scratchy throat. lethargy, decreasing oxygen saturation, placed on 4L NC, EMS called 1211- Diphenhydramine 50mg, Solumedrol 125mg, Epi pen injector adult 1231- EMS arrived, patient transferred to ER on 4L NC, SP02 94%

headache, pain at sight of injection, body ache, upset stomach, fatigue

felt some skipped heart beats about 2 hours after shot and then my arm has started hurting at site about 4 hours after

metal taste for approx 3 min

Patient began experiencing itching on side of cheek about 10 minutes after IM injection. Itching began to spread to face, then on to neck/chest area. Patient given 50 mg of benadryl PO and famotidine 20 mg PO. Symptoms have resolved within 20 minutes and will be observed for another 30 minutes. Patient counseled to inform primary care physician of itching event and to follow up with physician if any new effects arise.

She received vaccine at 2:00 pm. Around 3 hours after injection began getting a rash on her face that spread to other parts of body. Felt some tightness in her chest. She took Pepcid and 50 mg of Benadryl. Rash and tightness in chest improved. Began to come back around 9pm. Took 1 more 50 mg of Benadryl. On 12/18 she reported to Employee Health. Rash was still visable . 1-25 mg Benadryl was taken. She reported she would take 50 mg of Benadryl at lunch.

Hives, scratchy throat but no swelling or change in phonation

Headache and increased HR followed by dizziness (room spinning), and throat tightening. Evaluation in vaccination clinic revealed tachycardia and elevated BP. Brought to ER to monitor throat tightening. Upon trip to ER (roughly one minute), experienced nausea. Experienced chest pain after being admitted to ER, roughly 20 minutes after vaccination. Chest tightness and throat swelling lasted for roughly about 30 minutes. All symptoms subsided with the exception of the headache about an hour after injection. Discharged from ER and went back to work. Headache continued into the afternoon, along with general weakness.

Pallor, Diaphoretic, dizziness

Patchy Maculopapular rash starting in bilateral upper extremities, then radiating to trunk. No itch,.

Pt. expereince immediate swelling below injection site.

Tightness in throat, throat swelling, tachycardia. Treated with epinephrine IM x 1, benadryl, famotidine, methylprednisolone,

Headache, increased heart rate (115) for approx 30 min.

Numbness 20min after vaccine & persisted rest of day then 12hrs later pain @ site. Then redness @ injection site 16hrs. 3cm erythema & swelling deltoid to deltoid.

I didn't eat after because I lost my appetite. I was nauseous with chills , sweating and vomitting and tired.

"Patient initially felt dizzy which resolved after a couple of minutes. Patient stated she felt better, just ""tired"". She went to her locker, felt dizzy and went to Nursing office at 10:57 pm via wheelchair."

"Approximately 4 minutes after administration, patient complained of ""tightness"" in her upper middle quadrant of her stomach, near the xiphoid process. At that time her HR was 140. At 1840, her HR was

96. At 1844, patient had a red, splotchy rash on her neck. Patient received 25 mg of bendadryl. Patient noted that she was sweaty and she felt slightly dizzy, particularly when moving her head side to side. At 1847, patient's HR was 80. At 1852, HR was 84 and at 1858, HR was 68. Patient stated she felt much better, dizziness seemed to resolve quickly per patient's report. She was able to ambulate and turn her head side to side with no further difficulties. Throughout the episode, patient denied nausea, shortness of breath, itching, urticaria or any other rash besides the redness on her neck. After discussion with MD, RN and PharmD who were present for the vaccine administration and reaction, it was determined this was more than likely anxiety and not an allergic/anaphylactic reaction."

Patient c/o dizziness immediately after receiving the vaccine. She walked from the vaccine station to the waiting area and alerted staff that she felt dizzy. No SOB, no rash, no throat tightness. She had a similar episode in October. Recently increased Lisinopril dose. She was laid down on a stretcher. Vitals were stable. Glucose=105. Transported to ER for further work-up. Dizziness resolved prior to transport.

lightheaded,dizzy,increased heart rate, increased blood pressure

lightheaded,dizzy,increased heart rate, increased blood pressure

After the vaccine I'm fine for 5 mins but when I reached my car I felt a weird taste it's not bitter but it tastes like the outside of an orange and I still taste it today 12/18/2020, it feels like I have sand in my throat and I keep drinking water but it is not helping, my arm is really sore and I have jaw pain,

Patient developed hives on lower back to the side and left leg. 25mg of benadryl tablet was given in ER and later a dose of 500mg tylenol was given by patient herself at home. The next day patient reported woke up with joints stiffness all over whole body . Hives has been diminished by day 2.

At about 4pm, started to get migraine, neck pain, both sides of head. Took Tylenol. I was at work, finished shift. 12/17/2020 - 12/18/2020 still have migraine, both sides; 'feels different'. History of migraines. If worsens refer to ER

"Shortly after vaccine felt dizzy; nurse gave me water and a granola bar to eat. Employee took a bite or two and then felt dizzy. Employee sat down and blood pressure taken 170/ 80 and then 10 minutes later B/P 200/90. Nurse manager came and recommended employee go to ER for assessment. Blood sugar was checked and employee states ""they were not low"""

Tired

C/O Chest heaviness approx. 7 minutes after injection. Pulse=60 B/P 172/82

"Patient is a very pleasant 62 year old gentleman with a history of HTN, hyperlipidemia who presented with left facial numbness and left UE numbness. He states that it is worse medially on his arm. Present in upper and lower face. He states it started around 730 am this morning. He also notes intermittent ""foggy"" sensation since Monday associated with some blurred vision that comes and goes. Denies focal weakness, unsteady gait, difficulty with speech and swallow. He denies f/c, cp, sob, rash, pruritis, n/v/d, edema. He did receive the Pfizer COVID vaccine yesterday"

"Patient reported ""don't do well with injections"", she was escorted to the wait area. She appeared nervous and denied symptoms. After ~10 mins she because anxious, reported feeling light headed to employees. Patient was assisted to gurney in supine position, O2 applied via nasal cannual by employee, Patient calm and appears in no distess laying supine. She was observed for additional 30 mins. She voiced no complaints and was asymptomatic. She was discharged without difficulty or incident. Patient was instructed to request laying down for second injection."

Tingling in lips and left side of face felt numb 20 minutes after vaccine. No treatment, resolved in 3 hours.

metallic taste in mouth, stomach cramps resolved after approx. 30 minutes, and chills

Body aches, nausea, headache I took ibuprofen and it helped the body aches and headache but the nausea is still lingering.

About 5 minutes after receiving the shot I had an off taste that lasted for a few hours. Around 5 in the afternoon my body started to ache and swell around my wrist. Went to bed and work up feeling not very sore. Around 1 pm I noticed I had a huge nodule on my elbow. I get them occasionally but this was the largest one has ever gotten. I could feel it through my sweater. Wrist and ankles still sore more that normal.

metallic taste, fever

Burning in neck and arms, flushed, and skin pain through arms and neck.

left arm paid, headache and fatigue that about 48 hours.

"She had seven (out of 10) occipital face ""pressure"" of her right neck face .With 30 minutes of observation, pressure improved to 3 (out of 10). She had unlabored breathing and stable vital signs."

metallic taste, tingling of tip of tongue

12/16/2020 woke up at 10 am and had severe body aches, chills and HA. Took Tylenol and Ibuprofren. The fatigue and chill came back later that day. Symptoms didn't go away till went to sleep. Felt better on 12/17/2020.

Was monitored for 15 minutes with no symptoms. On my way home around 810 my left arm felt numb with some tingling to my left hand. By the time I got home it was about 830 and my left lower face and jaw felt numb and a little off. My face was still symmetrical and it was just in the lower left area of my mouth and jaw region. I took Tylenol and when I woke up my face felt normal. Since then occasionally I still feel tingling in my left hand.

Vaccine recipient reported becoming slightly lightheaded at the end of their 15 minute observation period following vaccination. The recipient was awake, alert, and oriented. Vitals were within normal limits. The vaccine recipient was offered water. During re-examination, vaccine recipient felt better with no medical treatment and was able to be discharged from the vaccine clinic safely. Next day on

12/18/2020, the vaccine recipient was contacted for follow-up and reported they were no longer felt lightheaded and just had mild pain at the injection site that did not interfere with activity.

Localized soreness, redness and swelling to site. Ibuprofen for pain

left arm numbness and tingling, aching forearm

1225: 25 min after Covid vaccine pt started experiencing itching to her neck, waist and arms. Her left arm where the injection was given felt heavy and fingers were tingling. She also felt like her top lip was swollen. Pt was given PO famotidine and 25mg of Benadryl. Spoke with physician and he also wanted her to have 25mg IM Benadryl. 1236: IM Benadryl given 1245: Feeling better. Itching improved. Lip doesn't feel as swollen. 1250: Dr in room. Continues to get better-itching still improving. Lip no longer feels swollen. 1255: Pt able to return to work at the hospital. Advised to go to the ER immediately if she begins to feel worse.

I felt a little lightheaded about 5 min after receiving injection, but thought it was because I hadn't eaten that much earlier in the day and it was dinner time. Stayed in observation area for 20 min with no changes. 10-15 min into my drive home started to feel like the back of my throat was scratchy and slightly numb. Had the sensation that a cholresceptic spray had numbed the back of my throat. A few minutes later the numbness spread to my tongue and then lower lip. I never experienced trouble breathing or swelling or rash. I meet up with some nursing/paramedic friends. I took 50mg of benadryl and a pepcid tab both orally. My symptoms didn't worsen and seemed to have resolved when I woke up this morning around 6 am.

10 min. after vaccination, pt felt lightheaded, dizzy, and queasy. Intense fatigue & blurred vision 20 min later.

Vaccine injection went fine it did not hurt at all, but I sat down for observation and within 2 minutes I felt mildly dizzy and then brief chest pressure and a wave of nausea. The chest pressure went away quickly but I was more flush then usual, about 15 min in my eyes felt watery and itchy. Went to ER to be observed, EKG came out fine. 118/72 HR 68 . Everything was fine. No meds prescribed, just observation, stayed about 90 min in observation by the time I eft I was just mildly nauseated. By the time I arrived home, 2 hours later all symptoms were resolved.

"at 12:55 pm ""enormous hot flash"", became diaphoretic, chest tightness, immediate need to have BM, ""uneasy"" feeling. Waited 40 minutes, then went to ED. No meds given. 1 Liter IV fluids given. VS monitored and within ""normal"" range. Cardiac enzymes and other labs drawn and within normal range. Released to self after 2 hours. Returned to work next morning."

Pfizer-BioNTech COVID-19 Vaccine EUA. Itching and redness on the chest, back and side

rash on face, chest, abdomen, warm and itchy skin blurred vision Itchy throat Took 50 Benadryl orally 2 hour post injection around 9p,.

Hives on trunk, thighs, and arms. They were very sore and itchy. Took two 25mg benadryl and the hives cleared up in 2-3 hours.

Caller stated that about 4:00 in the morning 11/17/20 she had chills and fatigue lasting about 8 hours.

Fever 101, Headache, body aches, increased heart rate 140-160, chest pain.

Tachycardia to 130s Fatigue, low grade fever

metallic taste

Patient experienced some facial swelling while in the observation area. Patient didn't realize there was any swelling until he looked in the mirror. He also reported feeling a little flushed and light headed. No diaphoresis noted. EMS called to assist, asked him allergic to anything, he said no known allergies but suffers a lot from seasonal allergies. I offered, and he took one 25 mg PO Benadryl with water @ 11:32 a.m. EMS took @ 11:33 BP: 160/110, HR 70, R 16, Pulse Ox 97% he said this BP was high for him. Second reading @ 11:44 BP 144/104, HR 62, R 16 Pulse Ox 97% Third reading @ 11:48 BP 130/88, HR 64 R 16 Pulse Ox 97%, vitals back to more normal for him. Glucose 77 @ 11:42. We kept him for 30 minutes post vaccination, and he was said he was feeling fine, no additional symptoms, swelling above eyebrows decreased and no more flushing symptoms. EMS offered to take him to the hospital, he refused said he was a physician and was feeling better after given the Benadryl.

Within 5 minutes of receiving the COVID vaccine, patient experienced face numbness, flushing of face, lightheadedness, nausea, elevated heart rate, elevated blood pressure. Patient had premedicated with 25mg benadryl 25 minutes prior to receiving the vaccine due to having had previous adverse reactions to vaccinations. At 1010, 15 minutes after receiving the COVID vaccine, patient was given Benadryl 25mg PO. She was then evaluated and monitored by her primary care physician.

Shot at 8:24, at 1700 left arm , injection site pain 6/10. 20:33 sharp joint pain to right knee and left great toe. Then over the next 30 minutes start to have chills, no fever and joint pain 9/10 to bilateral knees, hips, shoulders, elbows, wrists. 22:00 extreme fatigue as well. Slight HA 3/10. had difficulty falling asleep but once I did, was able to sleep thru the night. This morning Joint pain 5/10, fatigue 6/10 and HA 1/10. No chills or fever. injection site discomfort 2/10

28 year old female complained of feeling flushed and ?foggy? at 2:06 pm. Patient was placed on stretcher in the Fowler?s position. Vital signs taken: BP 141/91, HR 71, RR 16, 02 99% on room air. PERRL. Lung sounds clear, CV- regular rate and rhythm. Was directed by MD to give patient Diphenhydramine 50 mg IM. Medication was given in the left deltoid at 2:11 am. Patient tolerated well. VS re-checked at 2:13 pm- BP 134/92, HR 72, RR 16, 02 98%. Patient stated she was feeling drowsy and dizzy after diphenhydramine injection. Patient requested water and was given water at 2:15 pm. She then complained of feeling feverish. Temperature 99.4. VS re-checked at 2:16 pm BP 134/73, HR 72, RR 16, 02 98%. Patient continued to be monitored with improvement in her symptoms, vital signs as follows: VS at 2:22 pm BP 133/91, HR 72, RR 16, 02 98% VS at 2:28 pm BP 129/96, HR 72, RR 16, 02 98% At 2:34 pm patient stated that she was having some difficulty taking deep breaths. Stated she was not

short of breath. Denied chest pain. MD was called over to assess patient as well. MD evaluated patient and patient?s symptoms improved. Was instructed to continue to monitor patient. VS at 2:35 pm BP 129/96, HR 73, RR 16, 02 98% VS at 2:58 pm BP 124/90, HR 70, RR 16, 02 98% At 3:04 patient stating she was feeling better, but was drowsy from the Benadryl. VS at 3:05 pm BP 117/80, HR 69, RR 16, 02 98% 3:10 pm Dr examined patient with ok to leave for home. Patient agreeable with plan. Educated on red flag s/sx and when to call 911. Instructed patient that provider will call her tomorrow for follow-up. Patient left clinic in stable condition with boyfriend driving her home.

I was at home night of 12/16 ex headache, chills upon checking temp 99.3. My arm was swollen and couldn't move my arm .I took Ibuprofen 400 mg and went to sleep. On 12/17 felt like flu symptoms and voice raspy sound and took 400 mg Ibuprofen. Then 12/18 today felt better and gaining voice back.

Headache that began at 8:00 pm on the night that the vaccine was given and mild pain and swelling at the injection site. Headache has not gone away (and she does not describe as a migraine).

"Within 2 minutes after injection, patient started to feel very hot and with increased heart rate. Pt states that she feels ""tingly"" and is tearful. Pt denies difficulty breathing. Patient then started to have a red blotchy rash on her neck and chest. No redness at injection site. Pt brought to Emergency room for evaluation/observation. Pt able to talk in full sentences. Pt states that she has a history of anxiety and has gone into SVT because of anxiety in the past. Pt received steroids in ER."

After the shot I felt dizzy, sweating profusely, felt throat tightness, my heart was racing. They gave me an epinephrine shot in the leg and I was sent to the ER at Hospital. By the time I got to the ER m symptoms were gone. They did monitor me, put me on oxygen and hooked me up and around 2:45 I got up to use the restroom and they did not have to hook me up anymore. I took the day off because after the Benadryl and epinephrine I just feel groggy for about 24 hrs.

metallic taste

Tingling lips and tongue. Symptoms have started to resolve on their own.

"Patient reported being nervous about getting her vaccine. Denied any current medical issues on her pre-vaccination questionnaire. During her observation period. Patient stated that she felt her ""throat was closing"". Pt assisted supine. Epinephine and Benadryl given IM. Emergency protocol implemented. Dr. present. No hives, wheezing, or swelling noted. After treatment pt stated she is getting worked up for WPW syndrome. VS stable. Pt transferred to ED for monitoring 1040."

About an hour after vaccine, felt itchy inside, watery eyes and congestion - treated with 25 mg Benadryl. No anaphylaxis

I received my vaccination in my left deltoid. 3 hours post-vaccination I developed swelling around my right eye. Vision was in fact. No other symptoms, I did not take anything to treat it. It is still present 1 day later, but seems to be improving on its own.

5 min into the vaccine my heart began to beat faster. 30-40min later I began to have heart burn (mild midsternal chest pain) that lasted 3 hrs. I also have mild body aches and pain at the insertion site.

Headache, sweats, low grade temperature (99.3), fatigue, and myalgias. These resolved within 24 hours with two separate doses of 650mg tylenol, but the fatigue persisted for 48 hours.

12.17.20 around 2:00pm, my stomach started cramping, I had diarrhea, started cramping up really bad, got home and had diarrhea episode 5-9:00pm. Body felt hot, i did not have a thermometer to check my temp. Woke up around 6 am, and had another cramp and diarrhea episode, and had one every other hour. Today, 12/18/2020 from 10am -3:30, I have not ate anything. Last episode has been at 11:00am. I am scared to eat and I am still experiencing cramps. I have the feeling of nausea that comes and goes. I had to miss work due to the events of my illness.

12/17 at 2?3 pm- Had a mild headache that progressed to severe within an hour. Became diaphoretic, felt dizzy, nauseated. Had GI distress and vomiting episode. Medicated with Tylenol and slept for 8 hours. 12/18 feel back to normal. No fevers

The patient began experiencing a fever of 102.7, body aches/back pain, fatigue, and headaches the next morning after receiving the vaccine. She denies any respiratory symptoms. She tested positive for COVID19 on 12-01-2020. She was advised to remain off duty for 3 days, which accounts for the time period that these adverse effects have been observed per CDC data. If symptoms worsen, she was instructed to please follow up with a physician and to quarantine according to CDC guidance.

injections site pain, chills, headache, nausea

Symptoms developed the night of the vaccine. Fever, 100.1, Joint pain, Muscle pain, headache, dizziness (intermittent), chills, feeling unwell, currently taking Tylenol, still has symptoms. Will send to physician

Right ear felt hot and had metallic taste. Felt shaky

I felt a little bit dizzy and tasted like saline in my mouth. I kept feeling dizzy, like I had a brain fog and felt lightheaded and nauseous, I started having tunnelling vision, my BP as high, I got confused and nauseous, had headache and was sent to ER to be observed. Had fever last night and still feel weird and still have headaches, treating it with tylenol. Took the day off from work since symptoms did not subside.

Recipient felt hot and described 'lump' in throat feeling for about 3 minutes

Pfizer BioNTech COVID Vaccine EUA -- Nurse gave undiluted 0.3ml dose of vaccine out of vial without diluting it

Pt with h/o of multiple environmental allergies plus latex. Received vaccine at 1115am and reported itching eyes and itching ears at 1129am. She was escorted via wheelchair to the ED for f/u treatment.

metallic taste

Excruciating headache upon waking up 12-18-2020 at 0800 along with vomiting . Took Tylenol and Fell back asleep for 4 hours which I never do. Feeling very tired today but functional.

Took the vaccine at 2:55 pm on Dec 17th. Went home at slept at 8:00 PM, felt fine. Woke up at 12:00 AM feeling low-grade fever, tired, mild headache. Took 15ml day quill 40 minutes before going to doctor's office at 2:30 PM on Dec 18th. Calculated temperature was 100.5 at the entrance. Heart rate was 122 inside the office. No treatments/medications given yet.

"Itching to hands, feet, ears. ""Tight"" feeling to skin of face. Given Zyrtec and solumedrol"

Patient reported feeling hot shortly after receiving her vaccine with an itchy arm. We provided and ice pack and laid her down on a stretcher. Patient became slightly erratic and we proceeded to wheel her down to ER. ER summary below. ED Course: Patient's pertinent past medical, social, family medical history were reviewed from both the nursing notes and the electronic medical record. This is a 27-year-old female with a past medical history as above presenting with a chief complaint of concern for urticarial rash in anaphylaxis following a COVID-19 vaccination. á I did speak with Occupational Health who stated that this patient is well-known to the hospital, stating specifically that she becomes very anxious with vaccinations/needles and breaks out in hives on previous injections. This information was given to his after her initial presentation. Patient had already been removed provided epinephrine given concern of possible anaphylactic reaction given her area, diaphoresis, pruritus and diffuse urticaria. á I was called into the room multiple times as patient continued to ask to be discharged. I did have multiple conversations with her in regards to need for continued monitoring given possibility of anaphylactic reaction. She feels that this was due to her anxiety and states that she is completely asymptomatic and at her baseline at this time. She once again is asking to leave. I did discuss my recommendation for continued monitoring as well as the risks of leaving without continued monitoring. The patient is able to choose, communicate and make choices clearly and understandably. The patient is able to understand risks, benefits and alternatives of therapy explained by myself. The patient can make a logical and rational decisions according to my assessment. The choice made by the patient is consistent with the patient's values and is consistent with character and decision capacity in the patient's past, according to friends and family present. There is no impending medical risk to this patient to warrant my holding the patient against their will. á Patient will be discharged in stable condition at this time with strict return precautions and instructions for close outpatient follow-up. She was provided EpiPen given possibility of anaphylactic reaction in the future.

R arm numbness, tingling sensation and rash

"Caregiver received first dose of Pfizer COVID-19 vaccine. After 10:00 minutes of observation phase, patient c/o lips tingling and ""on fire"". Lips not swollen, denies SOB, skin WNLs, denies difficulty swallowing. MERT called. Patient assessed, states tingling 8/10, no other symptoms. Patient given bottle of water and tolerating that fine. Allegra 60mg ordered and administered at 8:52am. Patient statedwas at a 2/10 10 minutes after getting the Allegra. Patient drinking water without difficulties. Patient remains without further symptoms, lips still 2/10 with tingling. Outpatient labwork ordered. Left at 1000

ambulatory to outpatient lab. Educated her to notify administrator of her symptoms prior to her second vaccine."

28 year old female returned to observation clinic at 11:18 am stated that she was feeling flushed again. She stated symptoms are similar to her symptoms she had yesterday. States symptoms started 5 minutes after returning to work and donning her PPE. States she had the COVID-19 vaccine at 9 am on 12/27/20. She states she feels like she has ?flu-like symptoms?. Patient was placed in wheelchair. Vital signs taken: BP 118/80, HR 108, RR 22, 02 98% on room air. PERRL. Lung sounds clear, CV- regular rate and rhythm. Patient was wheeled to the audiology room to be monitored with provider and MA. VS re-checked at 11:28 BP 121/88, HR 88, RR 18, 02 98%. Patient began to complain of feeling feverish and ?foggy?. VS at 11:35pm was 127/91, HR 97, RR 20, 02 97%. Patient was given Diphenhydramine 50 mg IM. Medication was given in the left deltoid at 11:36 am. Patient tolerated well. VS re-checked at 11:38 pm- BP 118/82, HR 104, RR 22, 02 98%. At 11:40 lung sounds clear, HR regular. VS re-check at 11:48 BP 132/65, HR 71, RR 16, 02 99%. Patient stated she was feeling better.. Consulted with Dr. who also evaluated patient. Ordered CBC and CMP. VS at 11:53 BP 122/90, HR 82, RR 18, 02 99%. At 11:58 lab tech came and drew CBC and CMP. Patient tolerated well. VS re-checked at 12:15 pm BP 109/75, HR 91, RR 20, 02 99%. Dr. ordered EKG at 12:22 pm. EKG NSR. Labs resulted and were unremarkable. Patient stated she was feeling much better. Was assisted to the bathroom at 12:28 pm. VS re-checked at 12:32 pm BP 108/74, HR 86, RR 20, 02 99%. Dr. reviewed EKG and labs and orders to release back home. Patient agreeable with plan. Educated on red flag s/sx and when to call 911 Patient left clinic in stable condition with co-worker driving her home.

Vomiting, lightheadedness, floating feeling, nausea, tachycardia within 15 minutes of vaccination

Vomiting, lightheadedness, floating feeling, nausea, tachycardia within 15 minutes of vaccination

12/16/2020 @7:00pm caller started feeling flush with hives and nausea. Caller took Ibuprofen and next day got relief.

Dizziness, Rapid Heart Rate

Hot, flushing, tingling, metallic taste, pounding heart rate.

aproximately 10 minutes after vaccine taken, I developed problems with my vision. I had double vision, and Kaleidoscopic vision with floaters in both eyes . Lasted about 30 minutes. Did not keep me from reading or walking. no pain.

Nausea, vomiting x 3, and hyperglycemia (BG: 350s) 30 to 60 minutes following 0.3 mL IM injection of Pfizer-BioNTech COVID-19 vaccine in the left deltoid.

fatigue, headache

Shortly after receiving the vaccine I experienced a warm sensation near my sternum. The sensation was internal and radiated from my left side to my sternum. I also felt slightly dizzy, but it eventually resolved. In the evening (7:00 pm) I felt fatigued and experienced headaches, body aches and pain in my left arm.

It was painful to move my left arm and difficult to put clothing on. It is still painful today (12/18/20), but I'm managing it with Tylenol.

metallic taste - like pennies

severe flushing and complaint of hot ears. tachycardia on monitor

Flushing, hot flashes, elevated heart rate and high BP (never have a problem with that), Evaluated at the ER and received Benadryl immediately. After coming home (discharged around 1:30), felt fatigued and started with a mild headache. Also joint pain in my hips and my knees. Woke up this morning pretty fatigued and with headache feeling better this afternoon. Still have a mild headache.

Tongue swelling, seen in ED and discharged. Works in hospital ICU and will continue to monitor during shift.

Patient felt flushed with tenderness at the vaccine site. Patient remained under observation for 1.5 hrs and then felt well enough to leave without further care.

After the vaccination I got really fatigued and nauseous but it resolved the next day

Itching on arms, face, back, eyes. Mild raised rash on upper back. Face flushed.

Dizziness started 30 min after vaccine administration last for a few hours, also started feeling palpitations and noticed pulse to be 100-110s. 6-8 hours after the vaccine I started feeling chills and myalgia and some chest tightness. The next morning woke up with chills and rigors and severe body ache that made me unable to go to work. The entire day I have felt fatigue, abdominal pain and nausea. Taking Tylenol and my Salbutamol inhaler helps me.

"Pt was being observed in hospital for reactions per Dr orders due to Pt's history. Pt reported ""itchy"" feeling at 9:50am. At 10:20am Pt reported generalized ""itching provider notified at 10:34. 11:05am Pt received Benadryl at this time Pt had itchy watery eyes and generalized itching. 11:50 Pt sleepy but ""itching better"" dr notified and Pt returned to Assisted Living."

Patient felt dizzy approx 10min after vacciantion. Patient drank some water and layed down for 15min and sx resolved.

Tongue and throat swelling about 30 minutes after receiving vaccine. Took Claritin about 15 minutes after onset of symptoms. Symptoms mostly subsided about 1 hour after taking Claritin. Slight throat swelling and difficulty swallowing until a dose of Benadryl was taken the following day.

Swollen lips Nerve pain -sciatic Body ache Fever Headache Chest tightness Back pain Rib pain Cold then hot in waves Burning eyes Swollen lymph nodes in throat Joint pain Kidney pain Short of breath Fatigue Trouble sleeping Mental focus off

Palpitatations, shaky, lightgheaded, irregular heartbeat

Tingling in left arm, hand and fingers

Approximately 15 minutes after receiving the Covid-19 vaccine, I started to feel a tingling in my throat. It prompted me to repeatedly try to clear my throat. I then felt a sensation of my throat getting tight mildly restricting my airflow. Next my throat became sore. I experienced pain when swallowing. I then became hoarse and lost my voice for about 8 hours. Currently (19 hours after receiving vaccine), I am still experiencing a sore throat, but all other adverse effects have since resolved.

At 10 minutes post vaccine developed itching. Then became flushed and dizzy, then developed diffuse hives.

Caller stated that after vaccine about 12 in the afternoon she felt nausea, fatigue and a headache. Caller took the Zofran and slept for 20 hours and felt better.

Patient received IM vaccination. Was observed for a period of 15 minutes with no symptoms and was released. Had no symptoms but started developing numbness and tingle sensation in left arm. Patient felt cold sensation in left arm. Patient is being monitored for signs and symptoms in observation room. Will council patient on reporting to primary care physician. Will continue to monitor patient until resolution of numbness. Currently, patient does not feel any coldness in left arm anymore and is starting to feel normal.

"5 Minutes after vaccine, patient said she started feeling really hot and nauseous. All vitals stable. No other symptoms at that time. 15 minutes later, she said she was feeling ""out of it"" and it was hard to re-call names, she had a metallic taste in her mouth. Attending doctor on duty came to assess patient, emergent care was not deemed necessary. Vitals remained stable. 30 minutes after vaccine, she said her joints were starting to get achy. Since we are a pediatric hospital, I told her she should be seen at a higher level of care facility, she refused. She was monitored for 2 hours, after that she was better. At 12:30, 2 hours after vaccine, she said she was felt much better and her mind was much clearer and her other symptoms were much better. At 3, she said all her symptoms were gone, she was just tired. She got into contact with her Lyme Disease Specialist and they said it sounded like an autoimmune reaction, but they would still like her to get the second dose in 21 days. I will remain in contact with patient to ensure she does not have other adverse effects."

Patient became light headed and dizzy, patient stated often reacts this way after injections. Minimal po intake prior to immunization. Patient laid flat on the floor, drank 10 ounces of water, 4 oz. Orange juice. BP went from 94/50 to 108/62 ten minutes after first measure. Prior to leaving BP was 110/64, pulse 64 and patient reported no symptoms. Patient refused transfer to ED and felt fine prior to leaving after 30 minutes of observation. She left in care of two co-worker RNs feeling asymptomatic and ambulating independently.

patient got hives on the left arm that began 5 minutes after vaccination on her right arm

Fevers, Chills, dizzy body aches, pain and swelling at the injection site

About 1.5 - 2 hours after receiving the vaccination I felt very dizzy and disoriented. This was around 11:00. Around 2:00 I was still feeling disoriented, so I went to report it to my doctor. They took my blood

pressure, temperature, and observed me for 30 minutes. My nurse had reported that my BP was high. After 30 minutes they took my vitals again and my BP was still high. Today on 12/18 I got my blood pressure done at 10:30 AM and my nurse had reported that my BP was still fairly high. 144/88. They then took my BP manually and it was 138/82.

She felt a little warm in the chest and stomach area. She felt her heart was racing. She didn't have shortness of breath or difficulty swallowing. She felt it was the same reaction as when she had her TDap vaccine

She felt a little warm in the chest and stomach area. She felt her heart was racing. She didn't have shortness of breath or difficulty swallowing. She felt it was the same reaction as when she had her TDap vaccine

Tachycardia, chills, nausea, and light headedness

diffuse itching immediately after injection

Dizziness, numbness and tingling bilateral legs and arms, developed after 5 minutes of vaccination. Vaccine at approx 1:00 PM, 1:05 dizziness, 1:07 numbness and tingling legs, spreading to arms. Denied SOB, chest pain.

Itchy all over body.

Metallic taste in mouth

Body pruritus, generalized, diarrhea Treatment: Benadryl 50mg Solumedrol 125mg Pepcid 20 mg

Swollen lymph nodes, sore throat, flank pain, aching joints, dizzy, feeling faint, fatigue, back pain, diarrhea

PT RECEIVED COVID VACCINE. WAITED THE REQUIRED 15 MIN OBSERVATION TIME. AFTER THE 15 MINUTES PT STATED SHE NOTICED SOME LIP SWELLING AND THROAT TIGHTNESS. PATIENT ALERTED STAFF. PT ASSISTED TO SITTING POSITION. PT REFUSED TO LAY DOWN. BP AT 1233 WAS 160/102 HR 99. PT VISABLLY SHAKING. PT STATED NO DIFFICULTY BREATHING. PT ADMINISTERED 25MG IM BENADRYL PER EMERGENCY ORDERS AT 1235. BP BP AT 1238 WAS 150/91 HR 80 SAT 96. CALLED TO PATIENT. NO INCREASED SYMPTOMS. PT WAS TOLD TO STAY TO BE MONITORED FOR FEW HOURS. RECHECKED PT AFTER 15 BP 151/76 HR 90 O2 100% ON RA. AT TIME OF THIS ENTRY PATIENT NO LONGER COMPLAINS OF FURTHER SYMPTOMS AND IS IMPROVING.

Throat tightening and patient started to tremble 30 minutes after vaccination. Also became tachycardic. Patient was treated with methylprednisolone 80 mg IV x 1, famotidine 20 mg IV x 1, and diphenhydramine 50 mg IV x 1.

Fever (temp 101.1) and headache for 8 hours

Flushing of face, mild headache, blotchy skin on truck (front and back), upset stomach Gave Benadryl 50mg at 11:15am Symptoms not progressing

Angioedema

nausea, headache, rash, hot all over

1020 Dizzy and lightheaded after she sat down for observation time. After 5 minutes complained of tongue tingling. No SOB , no swelling of the throat or lips. Vital signs normal. Injection site , no swelling or redness noted. Water was given to drink , no adverse reaction. 1040 Tongue tingling resolving. Vital signs normal. 1100 All symptoms resolved and she was released to return to work per Occupational Health Nurse.

5 minutes after receiving vaccine I felt like I was going to pass out. They took me to the ER. Heart rate went up to 160 at one point. Was given steroids, Benadryl, and Pepcid and that helped. This helped and then heart rate went up again. Tremors and BP was up.

diaphoresis, pallor, nausea, vomiting over 20 minute period

Metallic taste, headache

Rash and tingling lips approximately 40 minutes after Pfizer-BioNTech COVID-19 vaccine 0.3 mL injected IM into the left deltoid. Presented to ED to report symptoms. Symptoms mild enough that patient did not want to have any interventions. She just wanted to report them for tracking purposes. Instructed to return in symptoms worsen or if new symptoms develop. Patient did not return, so assuming no new or worsening symptoms.

Rash and tingling lips approximately 40 minutes after Pfizer-BioNTech COVID-19 vaccine 0.3 mL injected IM into the left deltoid. Presented to ED to report symptoms. Symptoms mild enough that patient did not want to have any interventions. She just wanted to report them for tracking purposes. Instructed to return in symptoms worsen or if new symptoms develop. Patient did not return, so assuming no new or worsening symptoms.

I initially had to sit down for about 15 min and felt my mouth dry, my tongue was kind of tingling, not swollen. I was checked for anaphylactic shock. I felt like an adrenaline shock, and felt my heart racing, my BP was high - stayed in the ER for an hour for observation. I felt the same kind of sensation when I had COVID in July. This morning, had chills early in the morning around 1AM but it is all gone now.

Hives, itching, warmth on bilateral face and neck and chest. Tachycardia. Facial swelling.

Chest tightness, sob, tachycardia Treatment: Benadryl 50mg Solumedrol 125mg

Patient reported numbness and tingling on the tongue 5 minutes after receiving the COVID-19 vaccine, she has a history of anaphylactic reaction to sulfa, epi pen administered at 13:50pm. Took by ambulance to emergency room at 14:10pm today

Shingles-like rash on torso and back with burning sensation and nerve pains. This began approximately 30 hours post vaccine administration. Patient has not yet received treatment for this rash however intends to go for treatment in the next day.

Vaccine recipient reported bilateral hand tingling (paresthesia) in fingers shortly after vaccination. Vaccine recipient was sent to the ED for further evaluation. She reported to be also feeling anxious. She was alert and oriented to person, place, time, and situation. No focal neurological deficit. After re-evaluation, her condition was improved/stable and was subsequently discharged to home the same day. Followed up with the vaccine recipient the same day. They are resting comfortably at home and reported that symptoms have resolved.

pt reports approx 4-5 hours after injection, low grade fever (Tmax 100.4), +emesis/vomiting, generalized body aches. pt reports resolved as of 3:00 pm on 12/18/20.

12/16/2020 five hours after the injection Pain at the injection site no redness or swelling, intense soreness, shortly after severe chills, shaking, without fevers, myalgia every muscle in my body was sore and heavy feeling and was difficult for me to walk or move and had to hold on to things to walk, intense fatigue I should not have tried to work and 36 hours later I felt better, I never felt hot and this morning 12/18/2020 I felt recovered 90% with mild lower extremity pain

local erythema and raised skin at site of injection measuring 5x4x1cm, non tender, mild warmth to site. No pain, loss sensation, no loss strength, no LAD axilla or chest, normal ROM, no tenderness to this site. NO constitutional symptoms and the patient was unaware of a local skin reaction.

"About 20 min after injection she reports feeling flushed, heart racing. Face, neck chest and upper arms are red and warm to touch. Initial Vs-198/106, HR 113, SpO2 100% on RA. Lungs CTA. Given 25mg Benadryl with HR decreased to 100 and BP 161/92 after 25 minutes of observation. Left after 30 minutes of observation to return to work, stating ""I feel much better""."

Individual started to feel light headed, tongue felt numb, felt hot. Skin had some light-red blotches around collar-bone.

Patient reports rash and burning sensation to face and some discomfort at neck. Claritin and ibuprofen OTC and if any worsening symptoms, instructed to report to the ED.

Pt complained of dizziness. Headache pain 7/10. flushing and fatigue. BP was 207/120. Pt sat down in treatment, She took 650 of APAP. She eventually had to lay down. Eventually she seemed fine but was recommended to got to the ER. Pt went to ER, got a ketorolac shot, and BP was down to 130/100.

Radiating pain to neck and back. Felt like a flare up myalgia. Also headache, nausea and feeling very dizzy .

Dazed look with nausea and dry heaving; staff standing near her said she looked green

Body Aches, Headache, Congestion, Fever, Right Eye Swollen

10 minutes after the administration of the vaccine, the patient complained that she felt very hot. She was visibly flushed and diaphoretic. She developed nausea. At 1532, BP 142/94, P88 and O2 sat 100%. She was given cold water to drink and monitored. At 1540 BP 144/93. Applied cool compresses to forehead and neck. Patient continued to drink cold water. Continued to monitor patient. No further nausea. At 1555 BP 135/87. Stated that she felt much better but still felt a little off. No longer flushed or hot, no longer diaphoretic. At 1604, stated feeling even better. BP 119/87. Walked around a bit with patient and she stated she felt ok. No further symptoms. At no time did she have any rash or respiratory issues.

A few minutes after vaccine was given patient notes numbness in L thumb then L arm felt heavy and slightly numb; This resolved completely within 30 min

"Patient described ""pulse like stinging"" at injection site shortly after injection and continued through the 15 minute observation time."

Patient felt light headed; tingling all over body which resolved within 30 min

Rash and itchiness

About an hour after the shot my face felt flushed and itchy. When I looked in the mirror I saw raised, bumpy rash on both cheeks, left for than right side, on both ears. I took benadryl and tylenol - for my itch and generalized malaise. Next morning rash spread to my neck and left antecubital. Rash on my arm continues to spread and is as itchy as poison ivy.

sob, nausea, malaise, vomit, chest pain, throat tightness

numbness in left jaw; seems superficial; feels like local anesthetic

Couple of hours after started feeling body aches, chills, subjected fever, never had a response like that to a previous vaccine. Took some advil, feel about 95% better now.

"Upon conclusion of the 15-minute observation period, when asked how he was doing, he said he felt fine but that he noticed a ""tingling sensation"" of his left (injection) arm and left leg. He was offered the option to stay for further observation, but repeated that he otherwise felt fine. He was contacted on 121820, and he reported resolution of symptoms without intervention."

12/16/2020 I experienced severe body aches and chills, severe headache, and I had a low grade temp about 95 instead of 96, I did have dizzyness about an hour after the shot and I developed a cough about 6 hours after shot, fatigue and wore out from the chills and body ache I alternated ibuprofen and tylenol for 24 hours. Today 12/18/2020 the cough is gone and I feel better

Resident became short of breath 7 hours after vaccine, went to hospital, was COVID+

Woke up the morning after the vaccine with light headedness, chills, body aches, headache, nausea.

"A 56 year old FEMALE who has been waiting at monitoring area after Covid 19 vaccination, provided called to evaluate patient c/o: Chief Complaint: Patient was being checked at 1039 for final 15 min wait time after Covid-19 vaccine. Patient states she is feeling light headed and nauseated Doctor was informed. Took patients vitals. 11:06 patient was put on 6 liter of O2 with face mask 11:08 patient was out on to 4 liters 11:10 patient states ""I'm feeling better, flutter in my stomach"" 11:17 Doctor instructed RN to give Solumedrol (IM) injection to patient 11:22 Patient states ""I'm having a heartburn feeling, tightness in my chest. I put patient in a sitting position. 11:31 Patient states ""I'm feeling better"" 11:35 Employee came and gave patient solumedrol injection (IM) RT Deltoid @11:36 11:41 Patient states ""I'm feeling better, heartburn is going away slowly, I can breath now"" 11:49 Patient states ""I'm feeling better"" 11:50 Doctor states ""I will be putting in an order for epi pen for patient and she can pick that up from pharmacy when she leaves"""

Racing heart rate, 101 at rest, palpitations

chills, muscle cramps, headache, and low grade fever 99.8

caller stated that she had fever, chills, vomiting, diarrhea and fatigue. Caller took Tylenol and slept for 20 hours and awoke this morning feeling rested.

extreme runny nose, occurred immediately after injection

Body Aches, Headache, Chills, Congestion, fever started on 12/18/2020 at 0300 AM Itching - right after injection given Benadryl and pepcid 15 min after the vaccination

Dizziness, nausea, dry mouth; felt hot; later developed chest tightness sour taste in mouth; rapid heart rate; tingling on same arm vaccinated (L arm) some numbness in same arm L arm; felt shaky for 15 min; Blood pressure elevated

I had a fever of 100.5 and migraine and a sore throat.

Severe headache onset, mild muscle aches, and fatigue starting 6am, the morning following vaccine, diminishes with ibuprofen and Tylenol but does not go away. Still ongoing at 4pm the day following vaccine.

tachycardia, flushing, severe hives on arm received vaccine, dizziness, palpitations

Day following vaccine, fever, sob - went to hospital, COVID+

severe body aches, rigors, fever, headache, joint pain,

metallic taste, sob, joint pain, cephalea tx: solumedrol 125mg Benadryl 50mg

Throughout the day following vaccination, I have felt extremely sleepy, fatigued, with generalized muscle soreness.

developed itching, nausea, light headedness - required transfer to the ED for observation

Head felt like she was swimming, headache, heaviness in chest, lump in throat, BP spiked then dropped, Fainted - was given benadryl by mouth and Solumedrol IM

Patient developed shortness of breath, cough, chest tightness, and tachycardia

"A 54 year old FEMALE who received Covid 19 vaccine today and c/o ""lightheadedness and puffy/itchy throat a few minutes after injection"" while was on monitoring area after vaccination. Nursing note:11:16 I was told by co worker that patient was going to need vitals, so I took vitals notes given to me: throat tingling/tightness, light headed, nausea, allergic to aspirin 11:17 staff gave orders to RN to give Solumedrol (IM) to patient. she took patient information to get medication 11:26 patient states ""I'm feeling okay"" 11:32 patient states ""I'm feeling good"" 11:37 RN gave patient solumedrol (IM) injection to patient on left deltoid @11:38 11:42 patient states ""my left arm hurts"" 11:47 Patient states ""my left arm is really hurting after that injection"" pain scale 10/10 11:50 staff states ""I will be putting an order in for epi pen and to pick up at pharmacy"""

blister at site of injection tiredness tx: tylenol

Patient received injection at 14:05 at 14:12 he reported not feeling well. Patient was diaphoretic, clammy, pale, described the inability to see, had difficulty following commands. Patient transferred to gurney with max assist and transferred to E.R. Patient symptoms resolving during transport. Left patient in E. R. care at 14:15.

pain at injection site mild, nausea and vomiting, body aches, migraines,fatigue

Headache, body aches, fatigue, malaise, chills starting about 12-18 hours after. Symptomatic relief with Tylenol 500 mg PO q6h helpful. Symptoms were self-limited by 48 hours post-vaccination.

Rash started on scalp and then trunk and arms. itching all over body

I felt kind of like daze and light headed 10-15 min after the vaccine. The remainder of the evening felt fatigue also felt pain at the injection site on left arm . On12/16 left arm was still hurting and wasn't able to participate physical activities couldn't go to the gym.

Pt received Covid 19 Vaccine on 12.18.20 at 10:46am in Right Deltoid. Pt presented to the ED at 1:50pm with suspected throat swelling. Denies itching, redness or tongue swelling. Treatment: Epinepherine 0.3mg SQ- 1:55p Benadryl 50mg/IV- 2pm Methylprednisolone 125mg IV- 2:02p Pepcid 20mg IV- 2:06p Discharged at 3:53pm with all symptoms resolved. Pt prescribed an epi-pen

Notes 12/18/2020 á á á á Subjective No chief complaint on file. Patient is a 25 y.o. female who had no chief complaint listed for this encounter. á á á History of Present Illness á Patient is at the Covid vaccination clinic Received her vaccination and approx 5 min following administration notified staff that she was feeling a little lightheaded Was also c/o feeling hot at time Patient admits that she did not have breakfast this AM and has not had anything to drink Denies throat discomfort or tingling No shortness of breath or headaches Patient brought to the bay for evaluation á á á History Review / Additional history á Review of Systems á Patient's medications, allergies, past medical, surgical, social and family histories

were reviewed and updated as appropriate. Objective á Blood pressure 126/74, pulse 88, SpO2 98 %, not currently breastfeeding. Physical Exam HENT: Head: Normocephalic. Cardiovascular: Rate and Rhythm: Normal rate. Pulmonary: Effort: Pulmonary effort is normal. Musculoskeletal: Normal range of motion. Skin: Capillary Refill: Capillary refill takes less than 2 seconds. Neurological: Mental Status: She is alert. Psychiatric: Mood and Affect: Mood normal. Behavior: Behavior normal. á á á á Assessment / Plan á VSS on arrival to evaluation bay Following laying down for 10 min, drinking water, and eating a granola bar patient reports feeling much better. Sat at the bedside for an additional 5 min with no recurrence of symptoms. Repeat VSS Instructions given to go to the ED if worsening symptoms, lightheaded, throat swelling or shortness of breath. Encouraged to eat and drink prior to next immunization. á

Red neck and face 10min after injection lasting 15-20min Short episode of self resolving tachycardia

throat swelling, heart palpitations, trouble swallowing

Moderate left arm pain throughout the whole arm, feeling cold in the arm. The patient has normal pulses, normal motor and sensory function.

My left arm has had pain and still hurts today. It's hard to use it to dress and undress. I got a fever that would not come down and the worst heachache that felt like a migraine and I never have ever had one before, body aches, joint and muscle pain, fatigue and I couldn't stay awake , nausea, upset stomach with diarrhea within 10 or 15 minutes of getting the vaccine. It felt like a really bad flu that lasted 8 hours.

Patient received COVID-19 Vaccine 12/17/2020. Upon waking 12/18/2020 around 8am noted swelling, itching, and redness in face. Denies any shortness of breath. Patient seen in clinic and given benadryl 25mg at 1230pm. Symptoms improved.

Patient came over and advised me he felt like his throat was swelling and he was having a little difficulty swallowing. He was able to drink water which he thought helped. He was given Benadryl 50 mg IM. Symptoms resolved completely.

chest pain on right side immediately after vaccine administered. nausea, headache, right side neck stiffness

Pfizer-BionTech COVID 19 Vaccine EUA. Received injection one in right upper arm. One hour later started to experience some nausea and mild headache. Within several hours later, headache throbbing, nausea worsening with vomiting. Eight hours later, right arm throbbing, pain going up and down arm. Hand and fingers throbbing. Pain in back of head, neck and down back into right hip. Nothing relieved pain or nausea. Tried ice packs, cool rags, motrin, tylenol, maxalt, zofran. 24 hours later, still have symptoms, not as violent, but pain and throbbing continue and unable to eat or drink anything.

nausea, low grade fever, weakness

Shortness of breath and throat tightness 45 minutes after injection

metallic taste, could not swallow

65-year-old female received COVID-19 vaccine at the Urgent Care Center. She waited around 15 minutes after the vaccine and had no reaction. About 10 minutes later while in her car she noted a numb feeling of her tongue and that the tongue felt swollen but was not necessarily swollen. She subsequently felt that her lips were tingling and had swollen feeling. She returned to the facility and was given an EpiPen shot at around 10:15 AM. Patient was transferred to ED via ambulance. Gradually the symptoms resolved and was discharged from the ED in stable condition

Patient experienced redness, itching at the injection site with tingling through fingertips within about 10 minutes of receiving injection.

"t 3am she woke up and noticed some facial tingling on the ride side that felt like ""pins and needles"" - she reports like ""when you get a numbing shot at the dentist"". She also had some right arm and right leg tingling. She reports the leg tingling as ""normal"" as she has a hx of sciatica. She she woke up for the day then this morning the tingling in her arm/leg had resolved. She had coffee and cinnamon roll then started to clean the hou also had inner eye lid with itchiness. She began to have mild chest tightness so she took her inhaler - Albuterol and she took Claritin."

Light headed and flushed

c/o chills, nausea, hypertensive (170/100), flushing of face, redness and blotching of chest and neck

Dizziness sense of throat swelling

body aches, very tired

Patient felt like he was going to pass out. Reports this is normal and occurs when he gets shots or labs drawn.

20 min, c/o slight burning and itching to R arm, declined vital signs. Sx resolved and requested to leave.

"Pt complaint: ""heart racing, hot flash, feeling like fainting if I stand up"" approx. 10 mins post 16:30 vaccine admin. RN & another RN checked pt's vitals & BS. 16:45- BP 130/105, HR 160, O2 100%. 16:48- BP 148/93, HR 96, O2 98%. 17:00- BP 123/86, HR 68, O2 100%. 17:20- BP 122/86, HR 97, O2 92%. BS 83 @17:15. Pt received H2O, ice pack & elevated feet on chair. Pt noted symptom resolution & MD evaluated & walked pt back to work site."

carpopedal spasm of both hands immediately following receipt of vaccine

Vasovagal response

"Patient recieved first dose of covid-19 Vaccination on 12/18/20 at 11:49 am. Went into observing area and at 11:54 felt hot flush that moved upwards from chest to top of head. Vital signs taken 98.9, p117, bp 172/95, 100% oxygenation per pulse ox. Repeated blood pressures 128/84. Patient states that she is always in 90's systolically and 60's diastolically. The whole time patient stated that she had a ""cold""

feeling throughout the chest area. Pulse fluctuated from high 80's to low 100's, Patient stated she also had a "" lump in her throat"". Decision was made to transport her to the ED via Wheelchair where she was assessed and dx of Adverse reaction to the covid vaccine. EKG, CBC, BMP, Troponin 1 with high sensitivity done as well as a chest Xray. All tests within normal range and patient discharged home with orders to follow up with primary care physician as soon as possible."

1759 BP 135/79 HR 78 Reports feeling woozy, like she just gave blood, hands shaky, lunch was eaten at noon, brownie eaten mid afternoon 1800 8oz water given and 8oz of orange juice and granola bar 1809 Associate reports feeling better- less woozy, less shaky 1818 B/P 134/57 HR 77, no rash, no swelling, no respiratory complaints; dr evaluated associate and offered ED for continued support and associate declined.

About 5 minutes after receiving the vaccine, recipient reported tightness in the arm he received the vaccine. Five minutes later reported feeling light headed and tightness in his throat. Blood pressure taken--142/80 with 102 pulse. Reports no difficulty with breathing. Respirations easy and nonlabored. SaO2 99%. After reporting to healthcare provider, instructed to give Benadryl and call 911. Vital signs @ 3:30pm 139/81 with 79 pulse, temp 97.6 SaO2 100% Paramedics arrived at 3:35pm Recipient refused transport. Agreed to be escorted to ER via shuttle. Arrived at ER @ 3:53pm

Dizziness

The patient received the vaccine and reported shortness of breath, pallor and feeling that her throat was closing. Patient was given 25mg PO Benadryl and brought to the ED. On arrival patient continued to report feeling tightness in throat but states that she is breathing well.

headache, chills, and fever at 102

Severe headache and body aches beginning 20 hours after vaccine, lasting 3 hours.

Pfizer-Biotech COVID-19 Vaccine EUA, PT DENIES ANY SIGN OR SYMPTOMS OF SIDE EFFECTS OR ADVERSE EVENTS AT THIS TIME. PT WAS ADMINED DOSAGE THE WAS RECONSTITUTED WITH 0.8ML INSTEAD OF 1.8ML.. WAS NOT UNTIL 4TH DOSE FOR 4TH PT WAS DRAWN UP WAS IT REALIZED THERE WAS NOT ENOUGH TO COMPLETE 6 INJECTIONS FROM MULTI DOSE VIAL. FOR REMAINING RECIPIENTS. ADMIINISTRATION WAS STOPPED, MED RETURNED TO VIAL PLACED IN SEPERATE BAGGIE AND RETURNED TO PHARMACY. PHARMACIST, PFISER AND HOSPITAL ADMIN WERE NOTIFIED. aLL REMAINDER DOSES FROM FOLLOWING VACCINE VIALS AND ADMINS WERE RECONSTITUTED WITH 1.8ML OF PRESERVATIVE FREE SODIUM CHLORIDE AS ORDERED, THE VACCINE THAT WAS RECONSTITUTED WITH INCORRECT CONCENTRATION WAS PLACED IN PHARMACY FOR PHARMACY TO FOLLOW UP. # DOSES WERE GIVEN TO 3 SEPERATE PTS OF HIGHER CONCENTRATION DOSAGE. there WERE A TOTAL OF 5 0.3ML INJECTIONS IUN THE BOTTLE INSTEAD OF 6.

"Patient did well the vaccine, then during the observation period almost 15 minutes patient stated, she felt like she was have a panic attack. Felt like her heart was racing and felt like she wanted to cry, Took vital signs and gave her a beverage and pudding. She called her mother. She felt better after she spoke

with her mother. Took another set of vitals and pt. stated, ""I feel better and the staff handed patient off to her mother. Time it took was maybe 25 minutes after receiving the vaccine."

Within half hour of receiving COVID vaccine, patient developed headache, then began feeling lightheaded and began pale. Attempted to lay down, upon standing felt lightheaded and noted some numbness around her lips, arms, and legs. Symptoms include faintness, near syncope, and numbness. After about 10-15 minutes of not feeling well, patient was escorted to the Emergency Room. Patient received fluids and was discharged home. Patient reports at 5pm that she continues to have slight headache and arm soreness with no further near syncopal episodes.

Itching

Pfizer-BioNTech COVID-19 Vaccine EUA: Approximately 10 minutes after receiving vaccine patient reported itching in her right arm and back and traveled to the rest of her body. Patient sat in chair with vital signs: blood pressure 133/70 mmHg, oxygen saturation 96%, temperature 97.3 degrees Fahrenheit, respiratory rate 18 breaths per minute, and heart rate of 62 beats per minute. Diphenhydramine 25mg oral liquid administered and at 6:54 am patient stated reaction started to go away. Repeat vital signs: blood pressure 128/68 mmHg, heart rate 68 beats per minute, respiratory rate 16 breaths per minute, oxygen saturation 97%. Patient left vaccine clinic independently in stable condition.

stomach ache, elevated heart rate, eye drainage. No treatment. Stomach pain is continuous.

Hives

Following her vaccination during the post-observation period of 15 minutes, she began to be dizzy, short of breath, and right-sided chest pressure. Also c/o headache. BP 156/102, pulse 76, O2 Sat 99%. She was evaluated by Dr. and determined to transfer to the ED

Pfizer-Biotech COVID-19 Vaccine EUA, PT DENIES ANY SIGN OR SYMPTOMS OF SIDE EFFECTS OR ADVERSE EVENTS AT THIS TIME. PT WAS ADMINED DOSAGE THE WAS RECONSTITUTED WITH 0.8ML INSTEAD OF 1.8ML.. WAS NOT UNTIL 4TH DOSE FOR 4TH PT WAS DRAWN UP WAS IT REALIZED THERE WAS NOT ENOUGH TO COMPLETE 6 INJECTIONS FROM MULTI DOSE VIAL. FOR REMAINING RECIPIENTS. ADMIINISTRATION WAS STOPPED, MED RETURNED TO VIAL PLACED IN SEPERATE BAGGIE AND RETURNED TO PHARMACY. PHARMACIST, PFISER AND HOSPITAL ADMIN WERE NOTIFIED. aLL REMAINDER DOSES FROM FOLLOWING VACCINE VIALS AND ADMINS WERE RECONSTITUTED WITH 1.8ML OF PRESERVATIVE FREE SODIUM CHLORIDE AS ORDERED, THE VACCINE THAT WAS RECONSTITUTED WITH INCORRECT CONCENTRATION WAS PLACED IN PHARMACY FOR PHARMACY TO FOLLOW UP. # DOSES WERE GIVEN TO 3 SEPERATE PTS OF HIGHER CONCENTRATION DOSAGE. there WERE A TOTAL OF 5 0.3ML INJECTIONS IUN THE BOTTLE INSTEAD OF 6.

Moderate swelling, redness & pain at injection site, warm to touch for just over 24 hours. Moderate muscle & joint pain continuing over 48 hours. Dull headache more than 48 hours. Moderate fatigue continuing more than 48 hours. Alternating taking Tylenol & Motrin since vaccination with little relief.

Employee states that after one hr she felt her heart pounding and took her pulse and it was 158 and no other symptoms. Denies chest pain. Staff took her R BP and it was151/113 on a machine. Recheck 10 minutes later BP 151/112, P 126. Patient was brought to the Occupational Medicine Dept. Recheck at 20 min BP 125/68 and an apical pulse of 88. HR regular, rate and rhythm. Employee states she feels fatigued currently, denies shortness of breath, chest pain, itching, swelling of oral cavity.

migraine, pain from shoulders to head, stomach pain, vomiting. For treatment, patient took Zofran, insomnia

Patient presented with hives to upper extremities approximately 2 hours after receiving the vaccine.

"Patient experienced tingling throughout body (""from tops of feet to earlobes"") approximately 10 minutes after the injection. It resolved after 30 minutes. Patient went home without further reported issues."

Pfizer-Biotech COVID-19 Vaccine EUA, PT DENIES ANY SIGN OR SYMPTOMS OF SIDE EFFECTS OR ADVERSE EVENTS AT THIS TIME. PT WAS ADMINED DOSAGE THE WAS RECONSTITUTED WITH 0.8ML INSTEAD OF 1.8ML.. WAS NOT UNTIL 4TH DOSE FOR 4TH PT WAS DRAWN UP WAS IT REALIZED THERE WAS NOT ENOUGH TO COMPLETE 6 INJECTIONS FROM MULTI DOSE VIAL. FOR REMAINING RECIPIENTS. ADMIINISTRATION WAS STOPPED, MED RETURNED TO VIAL PLACED IN SEPERATE BAGGIE AND RETURNED TO PHARMACY. PHARMACIST, PFISER AND HOSPITAL ADMIN WERE NOTIFIED. aLL REMAINDER DOSES FROM FOLLOWING VACCINE VIALS AND ADMINS WERE RECONSTITUTED WITH 1.8ML OF PRESERVATIVE FREE SODIUM CHLORIDE AS ORDERED, THE VACCINE THAT WAS RECONSTITUTED WITH INCORRECT CONCENTRATION WAS PLACED IN PHARMACY FOR PHARMACY TO FOLLOW UP. # DOSES WERE GIVEN TO 3 SEPERATE PTS OF HIGHER CONCENTRATION DOSAGE. there WERE A TOTAL OF 5 0.3ML INJECTIONS IUN THE BOTTLE INSTEAD OF 6.

Approximately 10 minutes after receiving vaccine, patient felt light headed. Patient drank juice and felt better. Approximately 20 minutes after vaccine administration, patient began to complain of tongue tingling. Patient received Benadryl 50 mg IVP. Rash developed on her chest. Patient given Solumedrol 125 mg IVP, Famotodine 20 mg IVP and NS wide open. Epi pen 0.3 mg IM was administered and patient became tachycardic. At that point, patient was transferred to the ED.

pt with n/v diaphoresis and hypertensive with SBP 180's

itching, starting with the arms and went to the legs and the trunk. Hot flushed ears. Tiny red pin point red rash to the inside of arm and legs. Gave benadryl 50mg for treatment. Partial resolution of symptoms.

Light headed, Itchy Chest, Chest tightness, Heart racing, Throat tightness, Tingling legs

Shooting pain and weakness in legs bilaterally, tingling around mouth, right knee is swollen and painful/stiff in the joint, Generalized muslce and joint pain/aching, headache, lightheadedness, nausea, vomit x 1, temp of 99.9, Low BP 88/60

diaphoresis, rigors, chest pain, slight sob.

PATIENT HAD AN UNEASINESS WITH RASH TO LEFT SIDE OF FACE AND TINGLING OF LIPS. PATIENT WATCHED FOR ADDITIONAL 15 MINS UNTIL RESOLVED

Was walking to car when she felt her throat become stratchy, sore, and a lump in it. She came back in to be evaluated. Was escorted to ED for further evaluation.

She had the vaccine at 0700 and at 0800 she developed Lightheadedness, sore throat, body aches, chills, headache, nausea. She was not having these symptoms before the vaccine.

numbness and tingling sensation to right hand 4th digit and ulnar border of right hand palm

Dizzy H/A Shakey Stable vitals pt monitored for an additional 30 min provided fluids pt brought to the ER at 816 am

Started to feel strange about 10 minutes after the vaccine. Dizziness, disoriented, foggy, high blood pressure that lasted about 11hrs. Monitored BP and then sent home to rest and checked blood pressure through out the day. Body aches, chills, fatigue, headache the next day.

Very vague, did not feel well, felt concerned enough to come to emergency department

Runny nose, body aches, fatigue, slight nausea

"A 44 year old FEMALE who c/o lightheadedness and ""general discomfort"" while in the monitoring area after getting Covid 19 vaccine. Denied hx of HTN. Provided PO hydration. vitals re-checked at short intervals. Patient BP stabilized. Discharged to work area w/o symptoms."

Hot flushed itchy throat monitored vitals provided fluids vials stable pt monitored for an additional 40 min Sx resolved pt ok to leave

Tingling in throat for the first 15-20 minutes, then it stopped. Had an EpiPen just in case. Painful arm after injection. Still having pain. Had headache after injection. after 4-5 hours headache started again. Hard to keep eyes open, having a lot of pressure in head, osteroarthritis has flared, back pain is worse, arm hurts even she's not moving, having joint pain in wrist, swollen lymph nodes, and feeling very tired. Having a lot of joint pain. Everything has been harder to do today. Still having throbbing headache with pressure. Did not take any medication yesterday. Took prescription medication today after about 16 hours after vaccination.

Slight non-itchy rash noted after vaccine administration. Rash well demarcated, nontender approx 4x4 cm, no desquamation. No other sxs, no respiratory sxs.

Fatigue,fever ,pain at the site of injection

Patient c/o throat tightness 16:02 T 98.2 BP 145/95 99% room air HR 76 16:08 BP 145/96 HR 73 99 % room air Patient was given Epinephrine 0.3 IM in left deltoid. Patient AAo x3, talking. Transported to ER for closer observation.

pt had c/itchiness at the injection site quick onset of HA Diaphoretic numbness upper and lower lips dry throat Monitored vitals vitals stable fluid provided Sx continued advised assessment at the ER pt agreed pt escorted to the ER denied SOB or chest pain

Mild pain in left deltoid, moderate headache for 10-12 hours

at 11pm started to lot of soreness, lump in armpit. Periods of feeling very hot, chills and profuse sweating. woke up at 11pm, 1am, 3am, 5am 'woke up every few hours with intervals of profuse sweating'. 12/18/2020 feels like 'never happened' other than some soreness in arm.

"A 42 year old FEMALE who received Covid 19 vaccine today, provider was called at monitoring site due to pt c/o headache after about 10 min of injection and ""throat tightness/scratchy"", headache, palpitations. Discussed with patient current symptoms and multiple food allergies. Medications ordered STAT as below. Patient started feeling better of her pharyngeal/laryngeal symptoms after Epipen inj applied. Headache had improved also. BP rechecked at discharge from monitoring area as below. TODAY'S ORDERS: EPINEPHRINE PEN INJ,SOLN INJECT ONE INTRAMUSCULARLY STAT Quantity: 1 Box Days: 1 Refills: 0 *Chronic Med: NO Dispense as Written: YES Indication: Adverse reaction to vaccine product | METHYLPREDNISOLONE SOD SUCC INJ,SOLN 125MG/VIAL INJECT 125MG INTRAMUSCULARLY NOW *MED GIVEN IN CLINIC OR ER* Quantity: 1 Vial Days: 1 Refills: 0 *Chronic Med: NO Dispense as Written: YES Indication: Edema of pharynx |"

Individual started complaining of an itch in her throat and felt some degree of lymph node swelling on the right side. Collective symptoms include: anxiety, flushing, short term paresthesia, right sided facial swelling, difficulty swallowing, right sided facial droop, medicinal taste. some slurring. Individual was taken to the ed in house, triaged, treated and released. Reporter is not privileged to details of treatment, but aware of release within hours of being seen.

Lightheadedness, numbness of bilateral lower extremities (below knee)

A 35 year old FEMALE who presents to monitoring station after getting Covid 19 vaccine, after a few minutes c/o lightheadedness, no other accompanying symptoms. Discussed with patient current symptoms, only lightheaded, no other accompanying symptoms. Initially HBP. Provided PO hydration. Patient recovered after a few minutes. Discharged to her working area w/o symptoms. Advised to return to ER if any headache, increased lightheadedness, chest pain, asthma exacerbation, abdominal pain, N/V. Employee agreed understanding instructions.

Patient complaint of rash,hives,difficulty breathing and swallowing, wheezing, throat tightness, hoarseness, itching and feeling light headed less than 10 minutes after receiving the vaccine. Patient received Benadryl 50mg IVP, Pepcid 20mg IVP, 0.3mg epi IM. EMS arrived and transported patient to ED. In ED, patient received second dose of 0.3mg epi IM. Patient monitored in ED for approximately 4 hours. Epi drip started and plan to admit patient for observation.

Patient complained of chest tightness, L hand tingling and throat tightening less than 10 minutes after receiving the vaccine. Patient received Benadryl 25 mg IM and NS IVF. EMS transport to ED. In ED,

Solumedrol 125 mg IVP and Famotodine 20 mg IVP. Patient monitored in ED for approximately 4 hours. Discharged home on Prednisone.

Fever Chills Fatigue Nausea Headache Sore injection site

5 minutes after shot administered, became very hot and flushed. Felt tingle in throat. Turned bright red. Sent to ER. Throat tingle subsided after about 30 min. No anaphylaxis. Given Zyrtec for slight itchiness

12/15/2020 Strong diarrhea 1x. 12/16/2020 felt 'not right'. temperature 99.3,99.5. took tylenol. headache. Temp went down. Felt weak. 12/17/2020 tylenol, nausea, light headache 12/18/2020 Felt the 'most weak'.

Described numbness to left side of face, inside of mouth and leg and arm. Arm and leg numbness quickly dissipated but left facial numbness continued.

Patient began feeling numbness/tingling in left hand. Began to feel nauseated, dizzy, flushed, and light headed. Symptoms would come in waves. Felt shaky. A few nurses and pharmacist on duty came to assess her. Heart rate was 110, SpO2 was 99. Assisted her into a wheelchair and brought her to a separate room so she could lay flat and elevate legs Checked blood pressure, 122/58. 10 minutes after reactioni started heart rate had lowered to 87. Once she was laying down she did not experience any additional dizziness, flushing, or nausea. After she sat up for a couple minutes, ambulated in the hall with nurse she was released at 6:20pm and a friend drove her home.

-Received COVID vaccine 2:15-2:30 pm -Felt fine during 15 minute observation -Came home (about 25 minute drive) -Put on new plastic gown to help 88 yo father sit up in his hospital bed. He was clean and dry. -As I was fiddling with the blue plastic gown, I felt mild itchiness on right forearm and started scratching. -I looked at right volar forearm (supine position) and noted about 6 raised 2-4 mm blanching bumps with central darkening (like a small scab almost) - 4 below antecubital fossa, one in the actual fossa and another one immediately proximal. Mild itching, nothing distressing. -Lesions still persisting (To Dec 18). I am not scratching/taking anything for it. Lesions are visible. -No other family members (including father) with any skin rashes, no bed bugs, spouse who also lifts/cleans elderly father has no skin rashes -Evening of Dec 17 and persisting to mid day Dec 18: mild sore throat, nasal congestion, mild myalgia, fatigue, subjective fever but when took temp- no fever. Then all of a sudden, the sore throat/nasal congestion, myalgias, tiredness abated all around 3:30 pm. Skin lesions still present. -All of these symptoms were mild. -Again, skin lesions on right volar forearm persist.

15 minutes into her event she begin to feel tingling and numbness, the left side where she received the vaccine became very colder, the associate blood elevated to 148/88. The associate normally have low blood pressure. by 18:45 the tingling and coldness went away.

Presented with periumbilical pain to emergency department (patient works at Medical Center). Admitted to hospital for small bowel obstruction. Labs were consistent with dehydration (Hct 55, Cr 1.25), as well as CRP 1.10. A CT Abd/Pelvis identified proximal dilation and fecalization of small bowel, with a transition point in the left lower quadrant. Distal to the transition point, the small bowel appears

thick, with hyperenhancement and inflammation progressing into the cecum. General Surgery was consulted and patient admitted to hospital for management of this small bowel obstruction.

Headache; treatment ibuprofen and excedrin; improved most with excedrin

Large painful rash over injection site of right shoulder. Sever upper arm pain over injection site.

About 3hrs after administration (1800) pt presenting with bright red rash covering bilateral arms, hands, face, ears, neck, stomach, legs. Reporting pruritus on rash sites, inside mouth, inside ears, inside nose. Rash red in color, raised, splotchy, and warm to touch. Patient took OTC diphenhydramine 50mg at approximately 1815. As of 1930 pt reporting no relief in symptoms. No reduction in rash sites observed. Pt at this time has not sought professional medical treatment.

Lightheadedness, nausea, dry heaves and lump in throat

rash appeared at site of injection, very painful, hot to touch, hard, with rash spreading to torso

"Patient stated she waited the full 20 minutes downstairs without any reactions, however started feeling itchy and swollen shortly after, which prompted her to come up to the caregiver health office. An RN visually assessed patient and patient was not SOB and able to speak in full sentences. Patient states she felt as if she was ""about to have a panic attack"" because of a possible reaction. The RN prompted the patient to go down to the ED if she felt she was having a reaction to the covid vaccination. Patient checked into Medical Center Emergency Department"

21 hours post injection patient feeling body aches, arm soreness at injection, headache, and short of breath with exertion

Chills, malaise, fatigue, muscle and joint aches, left shoulder pain at and around injection site, mild fever: 99.6; took Tylenol. Haven?t taken temps when feeling at worst. Second day symptoms continues, but not as bad. Temp 99.5 second day.

Severe arthralgias, myalgias, headache, nasal congestion noted within 12 hours

Itching started immediately, throat tightness SOB in about 10 minutes with hives on chest

Rash and severe itching/burning sensation on face and neck began the night after vaccine received. 2 days after vaccine primary doctor gave a Kenalog injection.

PVCs, tachycardia from 6:30pm to 12:00am. Took diphenhydramine, omeprazole, acetaminophen at 8:30pm. Went to sleep at 11:30. Heart rate normalized. PVCs continued. All symptoms resolved by 4am on 12/18/20.

At 4pm I began having chills. By 5:30 I began having body aches. I took my temperature at 6pm and it was 100.4. I rechecked my temp at 7:30 pm and it is 100.8

PATIENT HAD WEAKNESS/UNEASINESS (MALAISE) PATIENTS SYMPTOMS RESOLVED BEFORE LEAVING

Patient noted abdominal cramping and then later today vaginal bleeding. LMP two weeks ago.

Headache, not feeling well, slight nausea, dry throat No treatment at this time

Chills, severe headache, body ache, malaise. Recommend ibuprofen and tylenol. Testing for symptoms lasting longer than 24 hours

Pt started tonight with hives on the back of his neck. When talking to patient, he states he developed one on his arm that was spreading quickly. Encouraged to take benadryl and seek medical attention.

anxiety, palpitations, and HTN

Immediately after vaccination, pt had arm, neck and facial pain, which improved, but did not go away. Rash developed on her abdomen this evening. Recommended benadryl and close observation for anaphylaxis and medical attention if it continues to spead.

Severe Headache, sweating, ice and time

Physician 16 weeks pregnant; Administered at 7:45pm, went to observation area; experienced tachycardia; HR: 107; BP: 148/88 O2: 100% approximately 20 mins after injection; Appeared flush. Water offered, transferred to room for isolation; drank 2 bottles of cold water; offered additional medical care; denied need; rested for 1 hr after vaccine; HR: 80s; O2: 100%. Spouse picked up for transfer home; referred to PCP for any additional needs.

The day of vaccination, this employee did not experience symptoms. She woke up on 12/18/2020 with paresthesia to R side of face, that became progressively worse, and is now on the entire R side of her body. This employees face has a slight droop and asymmetric smile on the R side.

Within 5 minutes of receipt of vaccine, reddened ears and reddened blotches on chest appeared. No worsening after 10-15 minutes, but after 20 minutes appeared to worsen, and transport to ED via wheelchair initiated. Pt treated in ED with epinephrine, solumedrol, Benadryl, famotidine and 1 liter of 0.9% Normal Saline IV on arrival time to ED.

Patient reported feeling lightheaded after vaccination around 1111AM. Patient pale in color and sweaty. Patient instructed to lay down. Feet were elevated. MD called over to assess patient. Radial pulse weak. 911 called at 1112 AM. Blood pressure assessed to be 100/76. Patient began to feel better. Water given to patient. EMS arrived to assess patient and vital were reassessed by EMS. Patient confirmed feeling better and was released from EMS care. Patient observed until husband arrived at 1155AM. Released from facility with husband.

Clammy, fever to 101, light headed, malaise, joint pain, fatigue

I developed pain in right first MTP joint at about 8 hour. No prior h/o gout or other arthritis in that joint in past. Over the next 30 hours pain intensified and was associated with swelling, warmth, but no redness. Limited range of motion d/t pain and restricted activity as a result. No other joint issues or arthralgias, myalgias, fever, chills arm pain at injection site or any other significant symptoms. I took 3

doses of naproxen 440 mg 12 hours apart and the swelling and pain are significant ly improved at about 50-60 hours after vaccination. I researched gout as this seemed suspicious and it is reported in the literature that vaccination is a risk factor for precipitating gout attacks which I have never experienced. It never reached the point of severity that I wanted to get arthrocentesis done to prove it was gout, but since this vaccine is new I felt it was important to report my experience.

Woke up at 1 AM this morning with a throbbing headache and inability to go back to sleep. The headache went away after 30 minutes, but I was still unable to sleep. I felt fine enough to go about my day as usual (working out, going to work, etc.), albeit exhausted.

10 minutes after injection developed numbness and tingling in left arm and left foot. Stayed in observation an extra 15 minutes and the returned to work. Symptom persisted for the day

Following COVID19 vaccine employee returned to work and began to feel dizzy/lightheaded/shakey. Went to ED for further eval.

tachycardic, site edema, shortness of breath, dizzy, and felt like her throat was getting tight. She got one dose of epi and 50mg of oral benadryl

Developed a migraine and became really fatigued approximately 8 hours after receiving dose and lasting about 36 hours.

All over warm feeling Dizzy Generalized weakness/Tingling

Rash on his back with welts, mild itchiness of the lips and mouth and no SOB.

c/o tingling of hands/ feet

Associate had hand numbness and tingling in her left hand, left arm extermity was cold. Blood pressure was elevated to 149/96, which is not normal for the associate. She was monitior for a hour. After being monitor for a hour, the associate stated that there is no more numbness or coolness in her left extermity, and no resiratory issue so she was sent home @ 19:50.

Had numbness and tingling in the upper extremities ,associated w/dizziness .

Extreme cramps, diarrhea

Had numbness and tingling in hands , and pain feet. Observed for 30 minutes given OJ. Departed on her own after reporting s/s resolved.

3 episodes of diarrhea after receiving COVID-19 Vaccine Refused Evaluation in the UC or ER and reported will see her PCP if symptoms continued .

Patient experienced an itchy mouth after the administration of her COVID vaccine. She has a known allergy to melon and bleu cheese. She has never needed epi for these allergies. We gave her 50mg of Benadryl and she began to have resolution of symptoms at the 30 minute mark-10 minutes after her Benadryl was given, so not likely in er system yet. Her VS are stable, sats 99 on room air, BP 127/84, HR

84. Our pharmacist weighed in and felt she would be safe to be picked up by her husband so he could monitor her. Our MD concurred with this plan. As of writing this email, we are still monitoring and will continue to monitor for another 45 minutes to see the effects of the Benadryl. We will deliberate with the ED MD on call prior to her release.

"Symptoms of generalized purities ,and rash on skin and taken OTC Cetrizine. 11:20 Escalating symptoms of abdominal pain w/vomiting ,tachycardia ,mouth dryness and >BP was given Epi. 0.3 injection. 11:27 am Benadryl 50mg orally. 11:30 Transported to local ER via paramedic. """

I had a persistent mild headache all day as well as moderate fatigue starting around 2pm EST.

Throat closing sensation, lightheadedness

Soreness, tenderness at injection site

flushing, nausea, vomiting, diarrhea, chest tightness. Gradually improving over subsequent 30min. Treated in ED with 1 liter IV fluid, ondansetron 4mg, acetaminophen 1000mg.

Associate started having arm aches and pressure. She also had right ear pressure. The associate started having generalize aches (myalga). The associate denied to be seen in the ER. The patient left @ 19:50.

Exactly 3 minutes post vaccine administration, I was sitting in the observation area ?the right side of my face started tingling (pins & needles feel), HR went to high 120?s. The staff in that area recognized I was not feeling right, they brought me water and oral Benadryl 25mg and Pepcid 20mg . I sat for approx 30min. My throat started feeling funny?scratchy and like I had a lump in my throat. I kept feeling like I needed to clear throat . At this time at staff took me to a monitored bed in PICU. They gave me another 25mg of Benadryl. Vital signs were stable after approx an hour. I was discharged to family.

Perioral numbness and anxiousness starting 11 minutes after administration and terminating approximately 1 hour later soon after presenting to the emergency department.

The individual developed a quarter size welt immediately after receiving the vaccine. Within the first 5-10 minutes post vaccination, the individual was complaining of pain at the injection site going down her arm, red streaks were visible from the injection site, and she did develop some difficulty breathing, which may have been related to the situation and the mask she was wearing.

unexplainable taste in mouth and burning in her nose.

4hrs after receiving the vaccine. Right arm was swelling, red rash/flushing skin present on arm, neck, abd, and chest. Delayed cap refill on right hand with cold extremities, pallor and purple dusky discoloration. Treatment was 50mg prednisone PO, Benadryl 50mg PO around 1630 At 1700 checked in as a patient to ED and clocked out as staff. Severe chills and muscle ache present no fever. Received 1L NS, IV Pepcid, IV Benadryl 50mg. Unsure of time d/t feeling fatigued Observed in ED till 1920, chills and redness resolved. Left with only localized swelling and slight redness to site. Was instructed to take several more days of prednisone.

noted scratchy throat and lip tingling and feeling puffy- though no signs of edema

urticaria on all extremities, chest, abdomen and head. Took PO 50mg benadryl at 2000 and awaiting outcome at this time.

Joint pain (pelvic at first, then all joints over next 24 hours), body aches, fatigue (and sore arm)

numbness of the upper and lower lips on the right side, numbness of the right side of the tongue

Pfizer-BioNTech COVID-19 Vaccine EUA Fever, malaise, chills, headache, body aches, weakness

received 1526, returned 1708 with hives on chest, short of breath, itchy head to toe. phone consult with physician, taken to ED for care

Dizziness immediately after when I stood up. Within fifteen minutes increased heart rate and breathing, shortness of breath, and lips having a weird feeling. At 10 pm sore throat and injection site soreness.

pain at injection site. Encouraged patient to medicate and warm compress.

RECEIVED REPEAT VACCINATION DUE TO USER ERROR/MALFUNCTION OF RETRACTABLE NEEDLE UPON INJECTING VACCINE., AND MAJORITY OF VACCINE NOT BEING INJECTED. UNSURE OF AMOUNT INJECTED ON FIRST ATTEMPT, SO POSSIBLY RECEIVED GREATER THAN RECOMMENDED DOSE.

"The employee received 1st Covid Vaccine today at 1804 1834: Patient complained of a ""severe headache and suddenly not feeling well"". She told staff she hadn't eaten recently and was given crackers and 120ml of orange juice. 1845: Patient was assisted from the chair to a wheel chair and moved her to a cot in the back of the conference center. Her vital signs were stable at T-96.9F-HR-87 RR-20 BP: 145/78. She was responsive to questions, but had trouble opening her eyes. She did complain of feeling very cold and blankets were placed on the patient. 1905: Vitals remain stable. Patient was only responsive with direction. She was flushed in the face for a short duration, 3-5 minutes. She denied shortness of breath or trouble breathing. Notified patient's husband she was going to be transferred by EMT to Hospital for further evaluation. 2300-Spoke to patient and husband. Patient was discharged home in stable"

Patient received the Pfizer Covid-19 Vaccine at 1918. 1950 Patient reports numbness and tingling to left arm. Patient denied allergies to any previous vaccines, food, or medications. Patient stated no significant medical history. 2000 Patient reports numbness, tingling, and cold temperature from left shoulder to fingertips. Capillary refill <3 seconds. 2015 Patient reports nausea-crackers and water given by staff. 2030 Nausea resolved. Patient reports numbness, tingling, and cold temperature in bilateral feet. Elevated legs and feet. Warm blanket given. Capillary refill <3 seconds. 2045 Patient reports numbness and tingling to right arm. 2050 Called IMT. Patient called husband to pick her up and take her to be seen by an adult physician at an outside facility. Patient transferred to vehicle by wheelchair in stable condition. 2315 Spoke to patient and she stated symptoms resolved and home resting.

severe headaches, body chills, fever, bone pain, joint pain, abd pain, vomiting, nausea, sweating so much my bed sheets were damp . note: all symptoms were so severe I thought I was going to have to call off of work the next day. symptoms lasted about 12hrs

HIVES ON BOTH ARMS, LEGS, AND CHEST AREA. TAKING ANTIHISTAMINE TO RELIEVE THE PAIN.

"I noticed my body temperature becoming warm approximately 1 1/2 hours after receiving the vaccines. I then noticed at 2/12 hours, I had a red, blotchy rash on my chest, neck, back, arms and abdomen. It was not itchy, I was warm and red. I did feel a slight fullness in my throat, but I was not short of breath. For treatment, I was given 50 mg of oral benadryl immediately. I was admitted to the emergency department and given 10 mg of IV decadron and pepcid (I don't know the dose). The redness dissapated at 1 hour after the decadron. And I felt ""normal"" without any side effects approximately 3 hours after the decadron."

Fever, chills, body aches, runny nose, fatigue

Around 0300, I was awakened abruptly by a sharp pain in my Right TMJ region. This happened 2 times. It felt worse than a dentist shot. Around 0430, I went to the restroom and notice my right nasolabial fold is less prominent than my left nasolabial fold.

I initially had tingling of the lips that started 40 minutes after the injection. I took Benadryl and Pepcid. Now the tingling has progressed to upper and lower lip swelling, consistent with an allergic reaction.

Injection site pain. General feeling unwell. Low grade fever. Tiredness. Headache. Symptoms ongoing. Planned treatment: rest and fluid replenishment.

At 1:51 AM started to have throbbing headache, chills, and muscle aches mostly at the injection site 4:30 AM worsening headache, lightheaded and fever temperature of 38.7. Took Tylenol 1 Gram. 5:30 AM headache improved but still have fever temperature 38.6. Took a shower

palpitations with HR in 120s bpm for 1 hour after vaccine was administered

Injection site IMMEDIATELY felt hot, felt flushed from chest up to face, felt throat tightness, got tachypneic, tachycardic and lightheaded/weak. Throat tightness diminished after less than 30 seconds. I was immediately attended to. Was hypertensive 160/110's, pulse 140's, SPO2 100%. Less than five minutes later I developed uncontrollable generalized intermittent rigors. I was given IM Benadryl at that time. I was transferred to ED approximately 10min after initial reaction. Throat tightness came back again while in ED, EpiPen administered. PO Famotidine and 1L IV fluids given. Rigors diminished but lasted approximately two hours. I was observed in ED for four hours, felt well, VSS, was discharged home. Once home approximately six hrs post inoculation I developed more intense throat tightness, radiating to right jaw, no difficulty breathing. It resolved on its own in less than five minutes. Developed a mild headache the next day.

dizziness, low blood pressure, tingling in legs, light headed shaky

Metal taste under tongue starts about 30 seconds after injection. At the beginning, the metal taste was strong, but gradually disappeared in three to four hours. The tip of tongue started to feel tingling, numb within two hours, the symptoms are gradually improving. The tip of tongue also felt swollen within three to four hour, but improving. The pain on the injection site was getting worse in two to three hours, but stable for next twenty hours.

After initial 15 minutes dizzy, seeing stars, pale hypotensive, shaky

12/18/2020 Patient developed a rash on forehead, burning sensation in the back of throat, and chest heaviness. Patient stated that she had similar reaction to a previous vaccine that she received. Patient was reluctant to go to the ED and refused to ride in wheelchair, but was walked assisted by staff. ED RN reported patient was feeling better approximately 1 hour after injection. FROM ED REPORT 12/18/2020 Had a vaccine about 10 minutes later she states she felt a little warm. A little tingly. Had some blotchiness to her forehead and chest. She reports that she also had some similar symptoms after receiving vaccines. These were short-lived. She presents now for evaluation. She denies any chest pain abdominal pain. No trouble breathing. Pulse ox on arrival is 100%. No abdominal pain Patient does have some papules to the forehead. She states this is chronic. It is little red. Cheeks are little red. I see no urticaria on inspection

left side chest pain, warm feeling on the inside, dizziness, feeling that she couldn't stand up without getting lightheaded, nausea. Gave patient a bottle of water and a chocolate bar. Sent to ED FROM ED NOTE: She states about 10 minutes after the injection she felt a warm feeling. A bit of nausea. She had a little chest tightness. She describes this as similar to IV contrast studies. This is resolving. She denies trouble breathing. Did have a little chest tightness on this persist. On the monitor patient has pulse ox of 100%. Respiratory rate of 18.

Within 30 minutes - Skin flush to hands and forearms. Denied shortness of breath or problem with swallowing. Declined Epinephrine. Monitored for 45 minutes then she was escorted back to work within the building. 15-25 minutes later stated she was having trouble swallowing and was jittery. She walked herself to the Emergency room for triage.

Local injection site reaction, mild soreness

15 minutes after getting the vaccine began itching that quickly developed into rash/hives to face, neck, chest, abdomen. At 20 minutes post vaccine developed severe leg weakness with lightheadedness, chest tightness, and SOB. 22 minutes out collapsed to the floor unable to bear weight due to leg weakness and had severe cramping and tingling in legs, still unable to move them. Was rushed to the ER from employee health and arrived approximately 30 minutes post vaccine administration at that time there was significant mottling to arms and hands with polar nail beds. Vital signs were stable, no strider. Given Solumedrol, Benadryl, and Pepcid STAT. Rash/hives and SOB improved, but legs weakness/tingling, cramping did not and noted purple feet with cyanotic nail beds and mottling to hands/ arms that would come and go. Rash/hives reappeared much worse 2 horse post meds to face, neck, and upper chest. Was given another series of Solumedrol and Benadryl and admitted to the hospital. I am now 19 hours post vaccine with improved but persistent leg weakness, now able to bear my own weight

independently and walk a few steps, but still having legs cramps and intermittent tingling to feet. Color has improved with resolved mottling/cyanosis. I continue to have hives reappear with scheduled Benadryl, Solumedrol, and Pepcid.

Low grade headache for 24 hours

The day I received the vaccine, 8 hour post inhection, I began to have numbness in both hands and it went up my arm on the injection site arm. Almost 24 hours after getting vaccine, I woke up the following morning around 4am to body aches, chills, low grade fever, nausea, numbness in both hands, neck stiffness, and excruciating pain in the arm I received the vaccine in (unable to lift arm). I began taking Tylenol, every 4 hours and zofran for nausea. The symptoms proceeded to get worse. At 3pm the same day I decided to go to the urgent care. I was febrile 101.2, tachycardia, hypertensive, I was tested for the flu- results came back negative.

Chills fatigue muscle aches and severe pain in arm beginning five hours after vaccine.

lightheadedness, elevated BP, hives, wheezing, hot flashes, pressure on chest

pain at site, metallic taste 1 hour after , headache, fever 100.5, body ache

Nausea and fatigue 6 hours after vaccination. Resolved at 24 hours post Vaccination.

Patient had episode of hypotension First bp reading several minutes after vaccination was 82/46, second reading several minutes was 88/57, several minutes later was 93/62, next reading was 112/79 and resolved.

Started having strong chills that lasted an hour and was sweating although I felt cold. Felt dehydrated and heart was reaching. Woke up in the morning and felt sweaty, had temperature of 100.9F axillary. Took Tylenol. Still having body ache and headache through all this.

I awoke to severe upper abdominal pain centralized in the midline, just distal to Xiphoid process, and radiating across abdomen at 2AM (Approximately 14 hours post vaccination). Pain was an 8/10 and felt like somebody was squeezing my guts. Pain was worse when laying down or sitting and completely interfered with any type of sleep. I?m a paramedic and didn?t seek treatment. Pain subsided for about and hour and I was able to sleep a little bit until it came right back and lasted from about 07:00 AM until now at 09:18 AM. The pain finally seems to be subsiding. No Nausea, vomiting or Diarrhea.

lol swelling , shortness of breath

Right Foot Pain - sudden onset/similar to gout pain, however affecting the entire foot region and not the large toe.

the day of the vaccine I felt site swelling on injection site. A day after the vaccine I started to feel a headache and fatigued. I also felt sore from the vaccine and had what felt like itchy throat

Severe hives, from torso down to toes first day, and upper body and arms as well second day.

Pfizer-BioNTech COVID-19 Vaccine EUA About 5 minutes after receiving the vaccine my heart rate increased and sustained in the 140s-150s for about 10 minutes, it then subsided. My jaw and ears felt tight, then subsided. After about an hour, I felt normal.

tingling, heart racing

10/17/2020 after the injection on Thursday I had a sore body, sore throat ringing ears joint pain, my self esteem was very low, my boss sent me home because my voice sounded so rough, I checked my temp around 100 and 101 and I took Panolol and it went down to 99. Fri I woke up with sore throat every time I take a breath I have chest pain sore body ringing in ears, chills and I went to the ER Friday 12/18/2020 they gave me some anti inflammatory injection and I went back home that day, they gave me a medical order to take a covid test today 12/19/2020. ER Dr gave me good results on tests.I have a headache and sore my body feels heavy but other than that I'm trying to avoid contact and staying at home until the results come through

slight fever 99.7 (normal 97.4) , allover body aches 4/10

nausea, elevated blood pressure, syncopal episode x3, ?? seizure

PATIENT EXPERIENCED RED HOT SWOLLEN AT INJECTION SITE BP 1 WAS 154/93, 137/81, REMAINS RED AND SWOLLEN SATS AT 100%, RECEIVED 50 MG BENEDRYL PO GIVEN 0956 .

Patient received vaccine at 18:16. Approximately 18:50 the patient complained of numbness and tingling around her bottom lip. Lips were noted to be slightly swollen and cyanotic. Speech was observed to be slurred. Diphenhydramine suspension 50 mg PO was administered. At 19:15 patient was noted to have hives on her neck, upper chest and upper arms which continued to become more prominent. 911 was subsequently called and epinephrine administration was advised. Epinephrine 0.3 mg IM was administered at 19:34. Improved coloration and reduction in hives was observed after epinephrine administration. Patient was transported to the ED.

metallic taste

Pt. received vaccine at employee vaccination clinic at 1pm on 12/18, and received phone call from patient at 6:20pm at the vaccination clinic on 12/18. Patient reported Redness on thighs, arms, chest, throat and face, no redness below her knee or on her trunk. Reported itching all over where there was redness. She described tingling and burning down her right arm (compared to nerve pain) and cold hands. Patient was on her way to store to pick up Benadryl, advised patient to take 50 mg of Benadryl and to report to the emergency room or call 911 if symptoms did not resolve or worsened to involve any difficulty breathing. Called patient on 12/19 at 8:30am to follow up. Patient reports worsening symptoms overnight including developing leg cramps in calves, restless legs, chills without a fever, and a scratchy throat. Patient called family friend (ER Physician)- patient was instructed to take 60mg of prednisone, 1 tab of zyrtec, 2 tablets of magnesium. She currently reports fatigue, scratchy throate and headache with other symptoms resolving around 10pm on 12/18. Instructed patient to call on call physician at PCP office for a predisone taper prescription.

metallic taste

Patient reported feeling faint and nauseous. Placed on monitor, oxygen saturation was normal. Rapid Response Team called. Patient reported feeling that tongue was swollen. RRT escorted patient to Emergency Room.

metallic taste

The evening of 12/17/2020 pain started in the left deltoid. Over night the muscles in the left arm contracted and would no release, a hematoma developed, and constant pain was through the entire left arm. The morning of 12/18/2020 the muscle contractions and hematoma were still present and tachycardia and fatigue developed. Highest heart rate at that time was 147 with a blood pressure of 148/82. Was a pt. in the ED and received benadry, dexamethasone, and pepcid. Swelling and muscle contraction subsided and heart rate was stable in the 100's. Later in the evening tachycardia and fatigue started again with the highest heart rate being 210 (when resolved nearly immediately with rest). Heart rate was 110-130 until I went to bed. Heart rate waking up this AM was 110bpm. Injection sight is slightly painful.

Pfizer-BioNTech COVID-19 vaccine. Nearly immediately with numbness and decreased sensation to left pinky and ring finger.

"Arm is ""burning"" at injection site, sometimes the pain increase to a ""stabbing"" feeling. Pain is a 5 on the 1-10 pain scale Patient did not want any pain medication. She will take some when she returns home if she needs to. Denies any trouble breathing. States she feels fine, but because this is a new vaccine she wanted to report her symptom. Patient asked to wait and extra 15 minutes."

I had fever 101.5 body ache chills malaise and fatigue they were all moderate, I could not work and that lasted 24 hours post vaccine and continued to 48 hours and got better and after 48 hours I just had a headache, fever and chills improved I just had a worse headache and I did a virtual urgent care visit on 12/18/2020 and didn't prescribe anything. I refused to take any medication. 12/19/2020 right now I have a moderate headache . I don't have fever anymore and can function.

Patient experienced tachycardia and diaphoretic. His heart rate was in the 170s. He was taken to the hospital emergency room. He had an EKG - results normal. Lab work was performed - basic metabolic panel and CBC. All results normal. Symptoms resolved - he was discharged. No further treatment needed.

8:10pm tongue swelling noted. 6:00am woke up with head to toe hives and migraine.

Pfizer-BioNTech COVID-19 Vaccine EUA Beginning approximately 10 minutes after the injection I felt increased anxiety and possible light headedness. This could have been anxiety about the injection and its short development and some unknowns. I felt quite stimulated through the evening on the day of vaccination and kind of tingly all over like I had too much caffeine (which I had not). The only real scary part was waking up the night of the vaccination with high anxiety, tingling, and an elevated heart rate around 100-120 bpm if I had to guess. This lasted about 1-2 hours until I was able to fall back asleep. I

am now two days out from vaccination and still have increased anxiety over baseline and some diffuse tingling/hyperstimulation.

Chest Tightness and shortness of breath

Sore arm - Tylenol temporarily relieved this symptom - continues through 12/19/2020 - milder Fatigue - Rest relieved this symptom20

Patient had tingling sensation to her right arm and right arm heaviness and dizziness that started approximately 1-2 minutes after receiving vaccine. She was also dizzy so sent to ER. She was given juice and monitored in the ER. Sensations come and go in different areas of the right arm. The lightheadedness resolved after a couple of hours in the ER. She was told to rest, increase fluid intake, alternate Tylenol & Motrin every 4-6 hours as needed for pain control and follow up with her PCP in 1 day.

Tachycardia on 12/18 at 4:10am

Immediately throat tingling (thought it was me being nervous) by an hour later started to get slight headache. By two hours I was losing my voice and exhausted, coughing, chills, dizziness. Jaw pain, throat lymph nodes swelling and painful to swallow, my knees and neck hurt to bend and move, weak and bilateral ear pain. Left work by 2pm and by the time I got home last night I was unable to breath well and extremely chilled with no voice and extreme headache. Took Benadryl and headache medicine and went to sleep. This morning voice still gone, jaw still tender to move, headache is slightly better, congestion, chest pain and cough, still weak, lymph nodes are no longer swollen. Neck and joints still painful to move.

PFIZER-BIONTECH CIVUD-19 VACCINE EUA, I RECEIVED ON 12/18/2020 0730AM, BY 1230PM I STARTED NOT FEELING WELL, WITH A SLIGHT HEADACHE AND NAUSEA. I TOOK TYLENOL AND ZOFRAN. THE HEADACHE CONTINUED THROUGHOUT THE NIGHT, AND PRESENT NOW. JUST TAKING TYLENOL AND ZOFRAN TO COUNTERACT THE REACTION

Patient received dose one of the Pfizer vaccine at 1150am and around 1230 begun to feel tingling in the right of her face/cheek. She then noticed significant swelling of the left cheek and bottom lip. She was taken to the emergency department and received steroids, benadryl, and fluids. She was observed for a few hours and then discharged. She was feeling well the same day.

Faint metallic taste with injection

Rash in the back and buttock area/ patient was treated with Decadron 8 mg Intramuscularly

was in waiting area and about 10 min after vaccine said she got tachycardiac and checked her heart rate on the apple watch and it was 140. She felt tunnel vision also did not alert staff in waiting area as did not want to call attention to herself. Symptoms subsided after 1-2 minutes. said she would have passed out if she stood up at the time. Went back to work and told coworker. Vaccine clinic staff called her this am and she is fine- no further symptoms.

Mild tongue tingling approximately 15 minutes s/p vaccination and palpitations with chest pressure approximately 40 minutes s/p vaccination (HR 150-170 x 5 minutes and intermittent PVCs after for approximately 1 hour). No treatment needed, s/s resolved spontaneously approximately 2hrs s/p vaccincation.

Chest pain, dizziness, headache. Received fluid and pain meds via IV at Hospital ER. Not admitted.

Sore throat Headache Fatigue

I received the Covid Pfizer vaccine. By 6pm 12/18/2020 I started having arm pain and pain lifting right arm as well as nausea. By 11:30pm on 12/18/2020 I started having joint pain in the hips and knees and shortly after body aches. Upon waking up at 7am on 12/19/2020 I still had previous symptoms as well as right underarm tenderness.

itchy palm - right

ITCHING AND HIVES ONSET 2 DAYS AFTER ADMINISTRATION OF VACCINE

Adverse Event: Joint pain in knees bilaterally within the first 12 hours after receiving injection. Right knee joint pain subsided after 24hrs. Left knee joint pain has been constant for more than 48hrs. Treatment: Extra Strength Tylenol 500mg x 2 q6hr and left knee joint pain has not subsided Outcome: Still left knee joint pain after more than 48hrs

R arm felt numb and cold during vaccination; 30 min following vaccine pt had nausea and lightheadedness

Itching and erythema to left arm that lasted about 2 hours. Sweating without feeling hot or ill relieved by ibuprofen at hour 3 and returned at hour 9 post vaccine. Self resolved at hour 12 post vaccine.

Tingly sensations all over body on and off, like crawling feeling for 12 plus hours. No shortness of breathe noted or blisters/break outs.

feels elevated heart rate, sweaty, dizziness

"Patient reported dizziness and ""adrenaline-like feeling"" during administration of covid vaccine."

fever and rash at injection site

Tingling/numbness of lips, tongue and Area surrounding mouth 15 minutes after injection. Swelling of right upper lip Confirmed in car mirror at 20 minutes. Returned to employee clinic and was evaluated by MD, escorted to ER. Was giving Benadryl and 2 hours later was given prednisone 40mg. Was sent home with 3 day course of prednisone and was told to take Benadryl before bed and prn.

Burning in eyes, excessive, bloodshot eyes

Swelling, erythema, extreme pain over vaccination site. Full body myalgias. Night sweats.

Pt received COVID-19 vaccine and approximately 4 minutes later patient began to feel flushed, racing heart, and faint. On exam, pt was slightly tachycardic with flushing to the face and anterior chest. Symptoms relieved after IV Benadryl. Symptoms improved after Benadryl with a resolution of racing heartbeat and flushing. Patient was then monitored for 2 hrs without recurrent in symptoms. Pt discharged home.

Within minutes of getting the vaccine I experienced warm facial flushing followed by shortness of breath and palpitations. Symptoms lasted less than 5 minutes. No chest pain. Some mild dizziness during event. I was able to breathe through the event and I still drove myself home 30 minutes after receiving vaccine. I took 1000mg Tylenol before bed and went to work later that day. I admit I initially thought I was just having some anxiety but I have never had any history of anxiety or adverse reactions to vaccines.

Patient reported racing heart, tachy 88-100, tingly lips following covid vaccination. Administering RN assessed, provided emotional comfort, provided water/snacks. Continued monitoring. Tachycardia did not resolve after continued observation. Patient escorted to ED by w/c for further observation. Patient discharged from ED in stable condition.

After injecting needle in the patient's arm, upon injection of vaccine, the vaccine started to leak from the hub.

Approximately 8 hours after injection: sore shoulder Approximately 10 hours after injection: body aches, joint pain, chills, HA, nasal congestion; extreme fatigue These symptoms continued from Thursday Dec 17 approx 10pm to this morning Dec 19 at 8am. I also had a low grade temp on 12/18 of 99.4 at 5pm. Today, Dec 19 at 11:13 am my R deltoid, arm, armpit, and side is still sore; other symptoms have resolved. Still experiencing fatigue; however I had Covid in September and have had residual fatigue since then anyway.

Patient is a CCU nurse who received the COVID19 Pfizer vaccine on 12/17/20. The following day she reported to work and that afternoon at 3:50pm had nausea, vomited x1, pale, tachy. Fellow coworkers provided basic care and then transported patient to ED when symptoms persisted. Patient evaluated in ED and later sent home.

I got my vaccine on the 15 on the 16th when i woke up I felt really hot and had weakness, and the next day I already had nasal congestion on the day of the vaccine but it wasn't bad then two days later I wasn't able to smell or taste it was very faint and thought it was a cold . So I went and got covid tested Thursday the 17 and the 18th I got my covid results and tested positive.

Resident short of breath approximately 10 minutes post vaccination. Staff noted that his baseline upon activity and transferring is generally shortness of breath. Resident wears 2L NC, O2 saturation was 92%, increased to NC to 4 Liters O2 saturation up to 96%. 170/80, heart rate 94, regular rhythm. Sent to hospital.

Received vaccine on right arm. Tingling and numbness on left side of my body from my lip all the way down to my foot. Tingling and numbers started two hours after vaccine was administered. Tingling and numbness are still present.

A Lymophoedema on the left side of the body, with 3mm eduration in the arm left, no erythema no suppuration o edema.

About 5 minutes after vaccine, patient noticed mild itching at injection site, small area of redness around injection site and injection site is warm. Denies pain. Offered Hydrocortisone Cream for topical administration to injection site, but patient declined. Patient stated she had some at home that she would apply if needed. Patient waited a total of 30 minutes. Site did not appear to change. Patient denied any further allergic symptoms.

Patient received vaccine 07:52 am at 08:11 am he reported hand tingling, we noticed some swelling to left hand. BP 143/94 sat 99% P-81, patient initially declined going to ER, administered Benadryl 25 mg by mouth per protocol at 08:21 am, repeat BP 08:23 139/96 P-84, sat 98%, 08:42 BP 141/97, P-92, sat 99%, 0843 noticed rash left forearm (not sure if there before) noticed after removing watch, patient agreed to Emergency Room check in, while waiting for ER check in patient had increased swelling, spread to forearm, notified ER intake nurse and transferred care to Emergency Room

patient felt hot, sensation of tingling in her throat, sensation of heart racing, heart rate was 130. Rapid response called, patient received epi pen injection and IM Benadryl, sent to ED For evaluation with subsequent discharge home.

Patient experienced dizziness and felt like she may pass out. Given a sip of water and felt better. Declined to be taken to the ED for further evaluation.

Pfizer-BioNTech COVID-19 Vaccine EUA PATIENT DEVELOPED HIVES ON INCISION SCARS ON HER RIGHT FOREARM AND CHEST AT 15 MINUTES POST VACCINATION. AT 24 HOURS POST VACCINATION, PATIENT DEVELOPED PETECHIAE ON INCISION SCAR ON CHEST AND LEFT COLLAR BONE.

Patient received covid vaccination number one; about one minute post vaccination, patient became very light headed. Upon taking vitals, patient tachycardic at 145 bpm; patient's neck turned red and splotchy; after about 60 seconds, the redness and splotchiness went away; patients blood pressure went up to 170's/90's and heart rate remained in the 130's sustained. Patient was given cold rag and water with no improvement; she was transported to the ED upon request

Pt presented to the monitor with c/o of racing heart rate (HR). Monitor referred pt to myself. Pt reports after feeling like her heart was racing she checked and noted a HR of 110. Pt was provided a seat in the more private monitoring location. Coat removed and water provided. 9:40am = HR now 6. Pt continued to be seated. 9:50am = HR of 80. 9:55 am = HR of 78. Pt has drank 6 ounces of water. No other changes noted on physical assessment. Asked pt to stand and no dizziness reported. Pt counseled to follow with her MD in anything was to happen and noted the V-safe information. Pt d/c.

extreme sleepiness approximately 5 hours after administration. Sweats and lightheadness/dizziness 6 hours after vaccine.

Patient felt sensation of being hot and heart racing, heart rate was 80 and pulse ox was 99%, denies resp symptoms, patient requested to go to ED to be evaluated, was seen in ED, observed, and discharged home

Headache

diarrhea at 0200 on 12/19 (~ 12 hours after vaccine), patient doing fine now ~ 22 hours after vaccine

Pt reports dizziness, nausea and vomiting

The vaccine was administered on the following date: 12/18/20áand at approximately the following time: 1pm á She reports that she didn't feel great after vaccine but thought just normal post-vaccine symptoms. She felt itchy and wheezing that evening. She took benadryl and felt better. á She woke up the next morning and her face was flushed and she felt palpitations. Went to work and checked her vitals, tachycardic to 120s-130s. About 11am felt lightheaded and was taken down to ER. HR was 150s. Has history of bee sting allergy and this felt like that. No Epinephrine but was given 25mg IV bendaryl and IV fluids (1L NS). Took another 75mg of benadryl last night and Allegra this morning feels fine. á From ED visit note: Vitals at triage BP 106/73, HR 95, RR 18, O2 100% EKG HR 104. Vitals with HR 77-95 No labs, COVID negative á The symptoms began the following morning after administration of the vaccine.á The symptoms were: tachycardia, lightheadedness, flushing, itching, wheezing The treatment of the reaction was:áá o Antihistamines:áIV and PO benadryl á Other medications taken on day of reaction:ááTylenol

Patient reported feeling lightheaded, dizzy, and anxious with early heart palpitations with covid vaccine administration. Patient observed and provided food and water, reported full recovery.

At 1:10 pm, I felt warmth all over my body, face, my heart started racing up to 109 per minute. I felt dizzy soon after. The nurse observing checked my vital signs and found my blood pressure to be at 190/92. After 30 minutes, my face and ears felt really hot, my face was flushed, eyes were hot. My temperature was taken and it was 101.3. At around 6:30 pm, I developed mild headache and body aches. The next morning, my left arm was sore.

Moderate headache upon waking at 0630; treated with excedrin and resolved within 4 hours. Sore arm - mild to moderate, started within 4 hours of receiving vaccine

Pfizer-BioNTech COVID 19 vaccine EUA Shortly after receiving this vaccine (about ten minutes or less) I felt tingling throughout my body for no more than 10 minutes. It lasted the longest in my legs. I didn't think much of it as it resolved in about 10 minutes and another woman said she felt it too. I am reporting because I have seen an article that medical center has halted vaccine administration due to workers experiencing this.

Began experiencing numbness/tingling in right hand and arm approximately 20-25 minutes after receiving vaccine. Nurse and pharmacist went to monitor more closely. Began to feel flushed, lightheaded, sweating. SpO2 99. Dr ordered 25mg diphenhydramine po. Placed in wheel chair and taken to ER for further observation.

10 min after receiving vaccine had symptoms - Tachycardic, BP elevated, chest tightness, flushing, mouth felt weird. Tongue felt strange but doesn't think it was swollen and then developed throat tightness. Immediately given 50mg PO benadryl and symptoms improved over 20 min. 90% improved at 60 min.

Started with a stiff neck with aches at about 9;00pm 12-18-2020 and it lasted about 3 hours. I woke up about 4:00am and my armpit, on the side of injection, was very itchy. I looked in the mirror and it was swollen and red lump in my armpit. I?m guessing lymph node swelling. It resolved about noon 12-19-2020.

Tingling of lips and throat. Received treatment with dexamethasone, benadryl

Slightly swollen rash around the mouth and between the eyebrows with small pustules, accompanied by itching. Around 18 hours post-vaccine (received ~6:30 pm 12/18/2020, noticed symptoms ~12:00 pm 12/19/2020)

Left sided facial tingling, achiness, and heaviness approximately 45 minutes after vaccination.

Nausea, headache, ill feeling, rhinorrhea, chills, cough, loss taste

None stated.

Pt reported not feeling; tachycardia @ 110 approximately 20 mins after vaccine. sweaty, BP WNL 15L O2 given to pt along w/ 10 mg cetirizine and 25 mg diphenhydramine

Patient reports she received at 1330 than was working and had a sudden onset of chest pain and became diaphoretic and skin appeared red/blotchy

None stated.

None stated.

Mild tingling in the body, mild lightheadedness, mild nausea, brief heat and tingling of lips, face, and ears, mild swelling of the upper lip

Immediate after pain in jaw and nausea. 24 hours after started with headache, general joint pain, cough, low fever, chills, fatigue.

pain at injection site, right shoulder/neck pain

"Employee of hospital received Covid-19 vaccine, was moved to respite area and began to ""feel flushed"" and had (2) syncopal episodes. B/P 160/93, HR =80, Pulse Ox-100%. Employee transported to the ED via stretcher."

Pt reported scratchy throat, itchy lips, slight rash on chest approx. 10 min post vaccination. 25mg of Benadryl given PO. Transported to ER for continued observation.

I started having chills before bed 12 hours after receiving vaccine. I woke up late morning (now 24 hours later)with a terrible migraine and continued to have chills. I went to the bathroom after I woke up and felt very nauseated and sick. I then started seeing black dots and felt very dizzy. Soon after my vision went completely black for what seemed to be about 5 min. I was shaking, having difficulty breathing and fell to the ground. My fiancT called 911 and an ambulance was on its way. The EMTs showed up and took my vitals. At this point I was able to see again and was sitting down. My blood sugar was normal along with my oxygen stats. My blood pressure was low while sitting and standing. I was starting to feel better and didn?t end up going to the hospital. I continue to have chills, body aches and a headache but so far no more blackening out episodes. It was the scariest experience of my life!

"Nurse injected the vaccine as she removed needle the employee started to feel weak and short of breath. The employee repeated said ""I am weak"" and ""I can't breath."" A rapid response was called, checked her oxygen level (94%). Due to employee stating she could not breath the team gave her a dose of epinephrine and started oxygen. Her oxygen saturation increased to 98%. They took a blood pressure - 150/88. EMS arrived and took her to local hospital for observation."

Tingling and numbness in bilateral lower extremities. Symptoms began 40 minutes after receiving vaccine (which was received on 12/18/20 at 10:50) and are still present at this time (12/19/20 at 13:35). I have not received treatment for it.

"stated she felt ""hot, dizzy, tingling to face"" HR 84, BP 129/84, O2 Sat 97% RA, temp 100.4. Taken to ER for observation."

I received my vaccine at 1615 down in our hospitals clinic, I work as a floor nurse, I returned back to my unit to resume work, I walked in to talk to my charge nurse and felt completely fine within a minute or to (approximately 15 minutes since the vaccine was given) my legs felt like very weak, they became tingly and extremely heavy, my face and chest felt warm and I had to sit down to drink water. The nurses working with me that day took my vital signs, my blood pressure was 157/101, heart rate 80-90s and temp was 97.5F. I notified the pharmacist working on our floor about my symptoms and he directed me toward the infection control line, the pharmacst on the phone directed me to go to the emergency department. When I was admitted to the emergency department via wheelchair, the pharmacist met me there along with the Emergency medicine MD, a neurological exam was done and general assessment. While I was in the ER my heart was monitored, my CBC with diff, Mag and BMP was monitored all of which were normal. I was given a 1L bolus of IV LR through an IV in my left antecubital. Gradually the tingling wore off over a few hours in my legs bilaterally however they still felt very heavy. I was admitted from approximately 1645 until approximately 1900 and returned home.

Right side nostril broke out into ulcer sores & throbbing after vaccine

Lightheadedness onset at 3 minutes (approximately) after the vaccine. Felt like I would be unsteady on my feet if I stood up. So kind of a dizziness/vertigo.

Flushing, rash, dizziness, lightheadedness, slightly elevated BP and heart rate

Patient experienced swelling underneath injection site immediately after administration

initial left arm injection site pain. Then developed quick onset ~22 hours after receiving vaccine of significant facial, torso, and upper extremity flushing and redness. No fever. patient felt nausea and vomited. Also experienced tachycardia and a headache. Patient used an ice pack, pepto bismol, and ibuprofen. Resolved in about 2 hours, but headache persisted until the next day.

Numbness to Lips , Teeth, Toungue, Face

1 day after receiving vaccine both of my hands became cyanotic appearing (blue/purple). Outside of minor tingling sensation, I did not lose feeling of my fingers/hand and my capillary refill was normal. My 02 saturation remained at 100%

Tingling injection side arm and face rash

5-6 hives on right hand and forearm on 12/19 at around 1100, took 25mg of PO Benadryl and went away. Intermittent tingling to right foot/ calf and hand (more to foot and calf) started 2100 12/18. Tender right axillary lymph nodes.

On day 3 after the vaccine, I had been experiencing sinus issues and toward the end of the day I experienced body aches, chills, sweating, shortness of breath, and tachy up to 175 last night when walking. It has been better today in the low 100s but still persistent with some shortness of breath, covid test pending.

Bilateral lower extremity rash

Patient presents after a near syncopal episode. Was at work when she felt dizzy, nauseous and flushed. Felt like she was going to pass out. Patient appears pale and uncomfortable, but nontoxic. She is tachycardic but blood pressure stable. Has a faint erythematous rash on her neck. Give IV Benadryl, IV solu-Medrol and IV fluid in Emergency Department. Basic labs were obtained and are unremarkable.

Redness; Hives; elevated HR and BP

Minutes after the vaccine, developed perioral numbness, tingling, mild difficulty swallowing. Complained of SOB and had marked diaphoresis. BP dropped to 87/50. Maintained sats 100%RA, lungs were clear. Has a hx of a vagal response after blood donation

Body ache, coughing

Associate states he started to have a fever this morning. Associate had a COVID swab performed at the COVID drive thru this morning and was told to call the hotline to report event.

performed 30 min observation, left to go back to work, said he felt like his heart was racing and looked at his smart watch and HR was 168. Upon arriving back at clinic, denies dyspnea or resp concerns. Reports feeling hot, anxious, heart racing, pt was sweating. HR 152 BP 150/100, Pulse ox 99%. Patient taken to ED to be evaluated.

Fevers to 104.8, myalgias, chills, rigors, fatigue, diarrhea

Signs of passing out. Then numbness and tingling in all extremities, lasting longer in the lower extremities (roughly an hour and a half) then felt as if a hair was on my body for roughly 8 hours, woke up with night sweats yet all resolved by 9am.

reported eye vision changes, flashes of light, and a headache. Was treated in the emergency room.

"Patient began to feel lighththeaded and ""woozy"" about 20 minutes after injection. No loss of consciousness, BP 118/78, HR regular, color pink, began to complain of ""sore"" on one side of throat, began clearing her throat frequently,"

Approximately half hour after injection patient reports tingling in tongue, heavy chest, SOB, slight difficulty swallowing and flushing in face, at that time HR was 44, O2 sat 99%, and BP 138/80. 50mg of oral benadryl was given at that time. Patients symptoms continued and 911 was called and at 4:30 epinephrine was instructed to be given IM via epipen. Approximately 5 minutes later EMS arrived, evaluated the patient and no visible signs of allergic reaction were detected. Patients HR and BP were elevated from epinephrine. Myself and another pharmacist remained with patient until approximately 5:30 and at that time the patient was going home. I called her at 6pm that evening and again 11 AM the following morning and no other allergic symptoms were noted.

Lightheaded, heart racing in initial monitoring station, placed supine, transported to triage via wheelchair. Initial pulse ox 98%, HR 76 at 1250, denied SOB, tingling, no rash. Pulse ox 98%, HR 91 at 1256, no SOB, tingling improved. At 1300, c/o lightheaded, fuzzy vision, shaky, some chest tightness, some throat tightness, increased saliva. Diphenhydramine 50 mg IM administered 1304. Pulse ox 98%, HR 92 at 1318. Solid food intake 1322. Continued lightheaded, bilateral arm tingling, still shaky, but less cold at 1327. Self-reported weight 130. 1339, throat tightness not resolved, no difficulty swallowing or breathing, pulmonary auscultation no stridor., continued body tingling, c/o throat tightness, Pulse ox 99, HR 96. 1343, continuous monitoring to Pulse ox 90%, HR 110. Medical director updated 1347, decision to move to ER and transport initiated 1352.

Pfizer-BioNTech COVID-19 Vaccine EUA: Patient experienced flushing and dizziness after administration of Pfizer-BioNTech COVID-19 vaccine with blood pressure: 143/90 mmHg and pulse 80 beats per minute. Cold pack applied and patient ambulated and drank water. Five minutes later blood pressure was 137/85 mmHg and pulse was 63 beats per minute and patient continued to report waves of flushing. Patient ate a banana and another cold pack was applied. After another ten minutes patient reported

feeling better but stated felt lightheaded. After an additional 20 minutes blood pressure was 123/76 mmHg and pulse was 78 beats per minute. Patient stated felt much better and was discharged from clinic in stable condition.

7 minutes after her vaccine she complained of tongue numbness which progressed to swelling. No wheezing, no rash, no nausea no vomiting. She was transferred to the ED for further management

Headache, dizziness, nausea, chills, chest pain, fatigue, injection site pain. Started about 2 hours after injection. Took Tylenol. Symptoms resolved within 36 hours

Left arm soreness around injection site that started about 3 hours after the injection and remained constant until the next morning. Fever (subjective as I did not have a thermometer at home) and chills that began about 14 hours after injection and last about 4 hours. Fever and chills resolved with 1000mg Tylenol.

Scratchy throat, lip swelling and numbness

After receiving the vaccine, I waited in the facility for 15 minutes as instructed by my company and the staff who administered the vaccine. When I left and got a few miles down the road, I started to feel my heart increase and I became short of breath. My heart rate was fast and pounding. My mouth started tingling and then I started feeling the tingling on my chest and neck. I started sweating and then started to panic and called 911 because I didn?t think I would make it back to the vaccination site or to the hospital in time. When the ambulance got to me I was still experiencing tachycardia, mild shortness of breath and tingling. The symptoms started to subside after approximately 20-30 minutes after they started. The paramedics assessed me and my blood pressure was 170/90 and HR was in the 120?s. I declined to be sent to the hospital due to my symptoms subsiding

I woke up with shooting pains/cramping running down the sides of my body/arms to the bottoms of my feet. It felt like a cramp but worse, kind of like nerve pain. I tried to walk it off but it persisted for about five to ten minutes. I had never felt that kind of pain before.

My blood pressure was 172/95 right after I took Vaccine, since then my BP was 155/100 last night , 147/101 this morning. I never had h/o high BP

10:30 am on 12/19/2020 Fever of 100.6 F, malaise, nausea, muscle aches, increase HR to 111 at rest. Tylenol 500mg taken

approximately 25 minutes past receiving the COVID vaccine I felt numbness in my neck and clavicle area. This resolved on its own after about 2 hours of receiving the vaccine

Within 10 minutes of receiving vaccine patient reported arm feeling tingly and numb which progressed to a squeezing feeling. Slight shortness of breath.

Anaphylaxis within 15 minutes of administration

I got the vaccine at 0750 in the morning and was fine right after getting it, my arm was a little sore no big deal, then by 0900 both arms were sore and my neck, by 1100 I had aching and chills, but I powered through because those are common symptoms by 1300 I had a headache, by 1500 I had some abdominal cramping, by 1600 some dizziness and nausea, 1730 diarrhea, 1830 more diarrhea and 1850 hives all over my chest. By 1900 my tongue felt heavy and tingly So I walked down to the ER. When I got to the ER I felt like I was going to pass out. By 2040 I was admitted to the ER and given Benadryl, Prednisone, Pepcid, and Zofran. I was Held for observation until 0300.

brief lightheadedness Pt arrived at observation area at 1500. Was informed she has a history of allergies in teh past so instructed patient to wait or 30 minutes in observation area. Around 1505, pt stated she was feeling lightheaded, near syncope. Advised pt to lay on ground. Vitals taken - BP 140s/90s, with HR 118, pulse ox 100%. After 5 min, pt stated she was feeling better while laying down. At 1515, vitals retaken with BP 120s/80s HR 90s. At 1520, pt sat up from floor still feeling better. At 1525 pt sat in chair feeling better and at 1530 pt stated feeling no side effects.

Right after I got the injection I felt my right hand tingle. I assumed it was because I was squeezing it so I dismissed that. However later around 7:45 my right side of my face felt like it would if I had gotten nova Caine and was wearing off kind of tingly but my face moves fine. I then read that other hospitals stopped the injections because of something possibly like this and I did begin to worry. The sensation is not strong it is only on my right side. My face moves ok just feels like when your foot goes to sleep but very mild .

Within 30 minutes of receiving vaccine patient reported feeling light headed, hot and heart palpitations. BP increased to 158/110, Pulse 100. Patient was CRNA working in ICU environment and was monitored by other staff present. Signs and Symptoms resolved over the following hour.

Several minutes after the vaccine, I noticed my arm going numb. It progressed up the side of my neck and down to my fingertips. The numbness lasted over an hour. Extreme nausea vomiting and fatigue started 12 hours later. Which hasn?t yet dissipated. It has now been 34 hours since vaccination.

Numbness and tingling in left wrist and hand lasting approximately 1 hour after injection

Numbness and tingling in left wrist and hand lasting approximately 1 hour after injection

Employee developed rash at site on left deltoid, that spread across upper chest. No SOB, Chest Tightness or Itching. Transported to ED on-site.

GI symptoms, loss of appetite, fever, body aches Between 10am-2pm day following vaccination.

Within 30 minutes of vaccine patient's left pupil was dilated greater than right and reacted sluggishly to light with slight fuzzy vision. No other signs or symptoms. Pt to follow-up with Ophthalmologist next week.

Approximately 30 seconds after the injection (which was painless), I suddenly developed tachycardia and felt like my heart was pounding out of my chest. My entire body was extreme tingling and I could

not feel my hands or feet. I also got a sudden strong metallic taste in my mouth. I thought I was about to fall down, but right before I was going to ask for help, the symptoms stopped as suddenly as they came on. I probably should have said something then, but I felt fine so I walked back to my unit. About 20 minutes after my injection, I then developed an intense hot flash and soaked my clothes with sweat. I sat down with cool rags on my head and this subsided after about 10 minutes. I have felt fine ever since, other than a little bit of a sore arm and mild headache (expected). I?m not sure if my tingling, heart palpitations, and hot flashes with sweating are expected, but I thought I should report it just in case it would be helpful for the manufacturer to know.

About 3 min post vaccination I experienced a transient sensation of warmth in my chest followed approx in a minute by tachycardia and a slight tightening sensation at the base of my throat which was transient - may 15-30 seconds. It recurred in a few min and I began to feel little lightheaded . With a 3rd episode of tachycardia only I felt more lightheaded and was taken to the ED in a wheelchair. My extremities felt cool with each episode as well.

high fever, chills, swollen arm, fatigue, nausea

Fever , muscle aches, joint pain, tiredness, headache Took ibuprofen 400 mg when temp reached 38.9C

Rach, tachycardia, palpitations, shortness of breath shortly after receiving vaccine - given epi, solumedrol, Benadryl. persistent symptoms the following day.

Reports becoming flushed shortly after covid vaccine. Then developed dizziness and was diaphoretic. Laid sown on stretcher. VS 128/84, 99/ 97.6, and sat 96% on room air. Observed and repeated VS x three. Was able to sit up and drink water prior to leaving observation area. Remained stable

I received the vaccine at 0915, was observed until 0936 and felt fine. While driving home, around 0949, began to feel heart racing/beating fast. I then felt very shaky and proceeded to get off the highway exit as the symptoms continued to worsen My daughter called 911 at 0953 at my request. No throat swelling, respiratory issues, or mouth or lip swelling. No rashes noted. I then began to feel sweaty and then became a little dizzy and proceeded to lean my car seat back. My daughter called 911 again as they instructed her to call if any new symptoms began prior to ambulances arrival. Ambulance crew arrived, I ambulated myself to the ambulance, felt a little lightheaded while walking. The feeling of my heart racing had started to lessen but still not normal at this point. Pulse ox was 98% on RA, no respiratory distress at all. I'm not exactly sure of what my HR was as I couldn't see the monitor but I believe they said around 100, I'm normally in the 60's. Systolic BP's were 138, then 120's, then 101 prior to me leaving ambulance. Finger stick was 140. I was in the ambulance for about 15 minutes and was feeling much better the last 5 minutes or so of that. I declined need to go to ER, my daughter then drove. I then went to a store and while walking around at 1105, began to feel my heart racing again but not as intense. Had slight feeling of being shaky but nothing like previously. After that, I have felt fine for the rest of the day. I took 400mg Ibuprofen for a slight HA around 1130 but not unusual for me, especially since the events that occured. I called the hospital where I was given the vaccine when I got home and informed one of the employee health MD's who requested I report this here.

Approximately 45min after the injection, I started feeling dizziness, palpitations and racing heartbeat. Another 15min after that there was red hives that broke out on my upper chest but no where else on my body.

Woke up Friday morning around 5:30am and had significant fever and chills (100.8F). In the morning fever, during the day increased heart rate. Took tylenol about 3 times a day. Felt burning up all day. Felt like I was on fire. In the evening about 6PM very nauseous, muscle aches, laying down uncovered and I felt like I was burning up. Went to bed early. No taste in the evening. This morning I feel pretty good other than no taste and a little bit of nausea.

Within 15 minutes of vaccination, developed mild headache. Was resolving when left observation area. Employee reported at 1:45 had developed right sided face and arm tingling and numbness and lips numb and tingling. Consulted with ED provider -Dr Plan to observe by Employee Health and refer to ED triage if symptoms do not improve. . Symptoms improving. Employee observed by Employee health and symptoms had resolved by 2:15 . No admission to ED

Morbiliform rash on torso Tiredness

Fever chills nausea which went away next day however now I have no sense of taste or smell

heart rate increased feels that it is racing,

I felt fine other than a sore arm but then Friday morning I woke up coughing and i had a 100F fever and about an hour later it was 100.6F. I had chills, shivering, headache, took tylenol, fever was down to 100F. Went to the local UC and had a COVID 19 test and was negative (rapid test). Today I woke up, no fever, a headache in the morning, but now it is gone, no fever at all today.

"Patient reported feeling sensation of ""warmth"" around 5 minutes post immunization. á Patient was escorted to waiting area and sat in seat within range of nurse site line. á RN later sat with patient 5 minutes later as she continued to have feeling of ""warmth"" / flushing. Patient given water and moved closer to nurse area. á Patient then shortly after c/o light headedness and now feeling cool. Remains alert / oriented. á BP: 142/80 HR: 127 RR: 20 SPO2: 100% á ICC called. Medic and Dr arrived for patient handoff. RN escorted patient to ICC with Medic and MD following. á Patient to finish visit in ICC for final dispo."

Myalgia, malaise

Throat closing, feeling faint, fast heart rate. Was taken to er, was given epinephrine as well as steroids. Kept me on er for awhile to watch me.

Chills, body aches, at about 10:30am on 12/19/20. Improved with 1g of Tylenol

On the evening of the vaccination at approximately 11 PM experienced tightening around the rib cage that lasted the night, went away in the day and came back the next night and some pain at the injection

site. Noticed a light rash at and below the injection site on the second evening. Rash continues on the 3rd day.

tingling in tongue, sore throat and deeper voice, heaviness in chest took diphenhydramine tablet, also took prednisone she is prescribed

20 minutes after receiving vaccination, tingling tongue. 'first sign for shellfish reaction', noticed tongue swelling. took 2 benadryl @130. at 1:45 took Albuterol, got to hospital / ER at approximately 2pm. Elevated BP, HR increase, lungs tight and 'barely diminished'. Epi @ 4:25 Albuteral @ 4:35 Prednisone @454 IV pepcid @5pm Tongue was still swollen but improved, lungs stable. Discharged at 6:10. Continued Benadryl and med pack. F/up appt w/ Allergist the following week;

Chills, aches, mild nausea and fever up to 100.8 for 6-8 hours. Headache and fatigue for 20 hours.

After receiving vaccination, right arm was swollen and felt cold to the touch, kept arm elevated to try to keep the swelling down and took hydroxine at night to try to help it go down. Still could feel my radio pulse, felt like pins and needles. Not cold anymore, now feels warm/burning sensation.

1) flushing, sweats, and dizziness 2 hours after dose #1. Resolved after about 15 minutes. 2) severe fatigue next day with poor concentration and forgetfulness 3) whole body palpable rash with redness, itching, and development of patches of petechiae

Approximately 8 hours after injection- headache and soreness at the injection site, fatigue, very mild sore throat. Headache and fatigue progressively got worse. About 24 hours after the injection noticed small red rash to the abdomen, progressively spread throughout the abdomen to to the truck. Rash looks similar to the chicken pox and is itchy at times.

12 minutes after injection, I felt flushed and dizzy. They hooked me up to a vital sign monitor which showed my heart increasing to 133 bpm, SaO2 98%. A manual blood pressure check was 168/110. My heart felt like it was pounding, I was hot and sweating. After 10 minutes or so, I felt increasingly dizzy and my vision started fading. VS still showed tachycardia and hypertension. It became difficult to swallow and my tongue was feeling fat. A Rapid Response Team was alerted, they started and IV, and took me to the Emergency Department. I became very cold and shaky. My hands and feet became a little mottled. They gave me 50 mg IV benedryl, 20 mg IV pepcid, a dose of solumedrol, and IM epinephrine 0.3mg, and 1 Liter of fluid. My symptoms resolved and I was discharged home a couple hours later.

Headache, dizziness, lightheaded, nausea, tired all lasting for a half hour after vaccination

Within 5-10 minutes after vaccine given, patient started feeling tingling of the hands and fingers. Shortly after, she felt the need to clear her throat because she felt like there was a furball in her throat. She drank some water, which didn't help. She then started feeling hot and became flush. She then felt her inner ear and tongue swelling. Shortly later, she felt chest pain and felt like she couldn't breathe. She was given IV Benadryl 50mg, IV dexamethasone 4mg, and IV Pepcid 20mg without symptom resolution. Epipen was administered by vaccine clinic staff, and the patient felt a little better. Her shortness of

breath continued and her chest felt heavy as she was transported to the ED. She also complained of blurred vision, which could have been due to Epipen administration. In the ED, the patient still felt that her throat was tightening up. She was given IV Pepcid 20mg, IV Benadryl 25mg, IV SoluMedrol 125mg, racepinephrine & albuterol nebulizer. By 2150, she felt better. By 2257, she did not have any more tingling in hands or weakness and she stated she felt she was back to normal. Patient discharged home in stable condition at 2336.

Patient presented to the emergency department at 8:45pm on 12/18/20 with lower abdominal pain, nausea, vomiting, and constipation that started approximately 2 hours prior to presentation, at approximately 6:45pm. Her labs were significant for a lipase of > 6000 IU/L, and a CT scan of her abdomen/pelvis was done that demonstrated evidence of acute pancreatitis. Given the fact that she does not have a history of heavy alcohol use, with normal triglycerides and no evidence of gallstones on her current admission, and no recent gastroenterology procedures, there is no clear etiology of her pancreatitis; concern for post-vaccination pancreatitis. The patient is currently admitted to the hospital, on hospital day #1 of her current condition.

12/18 0815 receive vaccine 2100 slight cough and very tired 2200 chills and chattering teeth; no fever 98.9F 2230 feeling very cold; went to sleep 12/19 0430 wake up with fever of 102.6F and headache 0845 still exhausted; fever 101.1F Stayed in bed most of the day 1730 get out of bed; temp 99.9F; notice slight rash on face across nose and cheeks ; slight redness and pain at injection site

Lower facial numbness, cheeks, lips, chin, decreased sensation similar to dental injection numbness. Lasted about 12 hours. I took 25mg of benadryl.

Minutes after the vaccine, C/o throat feeling dry and SOB. NO Diaphoresis. Breathing does not appear to be labored. Iv was started as a precaution. Pulse oxygen was 100%. NO meds given on scene. Taken to ED to be evaluated. Believed to be anxiety related.

Employee has history of allergies and was being monitored for 30 minutes. About 10 minutes the vaccine injections she began to feel faint. She was sitting at time and slide to floor and was unresponsive. The team begin checking vital signs and gave her a dose of epinephrine. A rapid response team and EMS was called. The rapid response team checked vitals: BP 100/60, HR 90, O2 99%, Glucose level-77. An IV was started and bolus of normal saline 500 ml given along with 50 mg of benadryl. Vitals checked: HR 108, BP-106/60, O2 93%-it was reported she was cold and shivering-hands were cold. Employee was calm, alert, and oriented.

12/17/2020, 15 minutes after vaccination started to experience tingling on forehead and radiated on left side of face, nauseas, light headed, HR increased, 'funny on tongue' , 'felt like going to faint'. The BP was 149/109. The medical crew tried to calm down. BP would not come down. Placed in gurney, administered oxygen, given a 'benadryl and some sort of shot' to slow down the reaction. Given rest of the day off. 'I slept for a few hours' and after 4 hours, my chest started to tighten, radiated to back 'tightness' , felt like heartburn. I didn't sleep that whole night, had to keep sitting with the tightness in the chest. By morning I was better, I went to work, took inhaler (flovent and albuterol). Headache at work, took Tylenol. At 12, I went to each lunch and felt there was a lot of mucous in throat / acid reflux

feeling ; 'felt full in throat'. I went in a coughing spell, 'bubbly mucous'. I couldn't talk, drank water, sat in car until I had to go back to work. I couldn't breathe when I walked back into work. At approximately 2:15 they rushed me to urgent care, 25 childrens benadryl, administered oxygen and omeprezole for reflux. I stayed with the oxygen till 4:45; BP 140/98 and slowly came back down. 'At same time, co worker was experiencing same thing that just had had vaccination'. My asthma 'kicked in', white blood count was elevated to 17. Work in urgent care and where i was rushed to. flu shot 2 months prior TB skin test one month prior; negative

Erythema in cheeks, right greater than left. No hives, no itching, MILD edema on right cheek I took Benadryl 25mg PO. Symptom persisting, but less than initial response.

Difficulty breathing, elevated heart rate, dizziness

10 minutes after vaccination felt lightheaded and dizzy, pulse 64 resp 18 - given water and put feet up. 15 minutes later better but still woozy - pulse 80 resp 20. 15 minutes later walked around pulse 72 resp 18 20 minutes later - still feeling dizzy wishes to go to ER - transported via wheelchair.

Within 1min after administration: Tachycardia, mental fog, dizziness Within 5min after administration: Tachycardia resolved, mental fog worsening, dizziness, muscle weakness Within 15min after administration: Nausea, dizziness, mental fog (feeling like an out of body experience), muscle weakness (feeling like my legs wouldn't support me). Two hours post- administration: Severe nausea and mental fog Six hours post-administration: Muscle aches and joint pain. Nausea and dizziness resolved. Soreness and muscle ache in arm with injection site. 12 hours post-administration: Diarrhea, increase in nausea, and vomiting. Dull headache. Tylenol taken. 22 hours: Fever (99.1F), chills, sweating 32 hours: Fever (99.9F), chills, sweating, muscle weakness, body aches, headache. Tylenol taken. 43 hours: Tested for COVID by nasal swab d/t recent exposure at place of employment and presence of S&S. Test pending. Fever 99.0F. Tylenol taken. Dull headache.

Tingling of tongue, tickle in throat Benadryl 50 mg IM given Patient taken to ED

Patient began reporting a feeling of light-headedness 5-10 minutes after injection. Also reported nausea and feeling clammy, as well as numbness and tingling of both her arms. She laid on the ground in reverse trendelenberg position with some improvement in symptoms, but upon sitting upright, symptoms returned. Patient was transported to the ED for 1 L NS IV bolus with improvement of symptoms and discharge.

Sore arm, Headache, Body aches, Severe fatigue, Abdominal cramping, Brain fog (disconnected feeling)

Covid 19 vaccine was given in my right arm subcutaneously. Was not looking when vaccine was given, felt administer rub my arm with alcohol swab, and pinch skin. Did not feel vaccine...however when bandaid was placed knew it was injected subcutaneously instead of IM. Took pictures immediately after.

muscle aches. resolved in about 8 hours.

"About 24 hrs after vaccine I had chills with NO fever. Strong headache which I could feel going down my neck into my back between my shoulder blades. I just had this all over ""I feel awful feeling."" Took Ibuprofen 800mg about 3 hours later. Went to bed and woke up in the middle of the night feeling better. Felt just tired the next day until about 2pm and a slight headache until about 4pm."

Patient received covid vaccine at 1606. At 1616, pt reported feeling lightheaded and tingly. Was assisted to supine position, BP 128/79, HR 62. Was monitored by administering and RRT nurse. At 1630, pt reported symptoms completely resolved. Pt discharged at baseline status.

"Felt dizzy and lightheaded 10 minutes after injection. Client drank some water and reclined in cot. BP 142/71 Pulse - 80 O2 Sat 100% Client was evaluated by EMS, and felt better after resting for 15-20 more minutes. Total observation time after vaccine 45 minutes. Client reports ""feeling more like myself"""

She report had vaccine in AM 12/18 then later that night developed fatigue, muscle aches, and head ache. This has worsened overnight and this morning 12/19 had new symptom of sore throat that has persisted. Given sore throat has been advised to follow-up with employee health prior to potential return to work.

Pt received Covid vaccination and reported feeling dizziness at 13 min mark. HR 70, regular. Consumed water and a granola bar and then reported feeling back to 100% baseline. Was discharged from vaccine clinic after 30 min observation period. HR 72

Chills and fever of 101.F

Low grade fever of 99.9F, body aches, chills and diarrhea.

induration and bleeding at injection site, immediately after injection. Bleeding quickly controlled.

Patient experienced a rapid heart rate measured at 100 BPM. Recovered shortly with no issue.

After administration of covid vaccination, patient c/o feeling warm and diaphoretic. HR 78, pt appeared slightly pale. No other complaints. Ice pack applied to forehead. Patient reports feeling better at 1840, O2 98% RA, HR 74 regular, BP 140/96

Bleeding at injection site immediately after injection. Bleeding was quickly controlled.

Tingling sensation to left hand, traveled up to elbow and upper arm. Then tingling sensation traveled to right hand to upper arm. Both shoulders started to feel achy. Then tingling sensation switched to pins and needles sensation. Later on the day, left foot noted to have tingling sensation. Symptoms noted around 11am to current time 7pm, and continues to have tingling, pins and needles sensations.

Received vaccine around 1700-1730. At 0300 the next morning woke up in severe gi distress. Abdominal cramping, diarrhea. No fever. I was sweating but I believe that was pain related. Diarrhea lasted until 0600. Then abdominal distention and gas persist. It is currently 2000. I am able to eat and keep food in but the pain is pretty extreme for a vaccine. Right now it?s a 5/10. At 0300 it was 8/10.

Intermittent Cough (new onset) I did not see it on the list of common side effects. Not sure if its of concern or not. Started approx 8 hrs after vaccine. Other symptoms I have appears to be normal such as site soreness, fatigue and mild headache. Just wanted to make you aware of cough. Day #1 still. Thanks!

Induration at injection site immediately after injection.

I feel dizzy and woozy, almost like I'm drunk. S/S started 20 minutes after injection. Also nausea w/o emesis, fatigue

Vomiting every 20 to 45 minutes from 8:30 am to 2:00 pm. Resolved after 2:00 pm.

Itchy throat 10 minutes after injection. No shortness of breath, no breathing problem, no cough, no difficulty with swallowing. no facial swelling. Client was evaluated by EMT. BP177/91 Pulse 91 O2 Sat 97% Client did not take all of her blood pressure medication today. She felt her symptoms resolved after drinking water and resting. Client was observed for 30 minutes after injection.

Pain in the injection site, felt tired and felt feverish but normal temperature

Bilateral ears because hot, red, swollen, blistered, and painful approximately 1 hour and 20 minutes after vaccine was administered.

Patient complained of tongue tingling/numbness and feeling of swelling at 6:58pm. No shortness of breath or other symptoms. Vitals at 7:01pm HR 89, BP 125/85, O2 98%. At 7:11pm patient still felt tongue as numb but not worsening and not other symptoms. Provided Benadryl 25mg. Patients HR 92 and O2 98. AT 7:25pm patient stated she felt fine and HR 95, O2 99. Patient released to husband to drive home.

I received the dose approximately 7:15pm. Within about 8 minutes of receiving the Pfizer COVID-19 vaccine I experienced pins and needles sensation on the left side of my body in my left arm and strong muscle pain in my left neck. I felt nauseous intermittently. The nurse stated that my skin looked a little blotchy on my chest. Joint pain in my left knee and left arm was intermittent as well as intermittent pins and needles sensation in my left ear and burning in my left fore arm. I felt somewhat lightheaded. This lasted for about 15-30 minutes on and off. The nurse measured my BP and oxygen saturation which were in acceptable ranges. I kept moving my arm to relieve the strong and at times painful muscle cramping sensation in my neck and massaged my neck. By about 8pm the light headedness and nausea passed enough that I could drive home. On the way home the left side of my throat felt thick and somewhat swollen but not enough to prevent me from driving or breathing in any way. At home I focused on drinking a lot of water and gently moving my arm to relieve the pins and needles sensation. After eating dinner and hydrating I felt some improvement and most pins and needles sensation and neck soreness/throat thick sensation was resolved by about 11 pm. I was able to rest fairly well through the night until 7am the next morning when pain at the injection side woke me up. Soreness at the injection site, headache, fatigue, nausea, and mild chills are what I noticed today which appears to be more typically expected from the vaccine.

Warm flushed feeling, racing heart, dizziness that started about two minutes after injection. It dissipated after about 3-5 minutes.

Right arm burning sensation as injection was started. Right arm soreness at injection site immediately. About 45 minutes after vaccine, new onset of facial numbness and tingling (in cheeks and forehead). Symptoms went away after about 10 minutes. Facial numbness/tingling returned 3 hours post injection for >30 minutes. Woke up the next day and facial numbness/tingling was still present and also included both sides of face. This resolved around 1:00pm. Headache and significant right arm pain continued. Took 600mg of ibuprofen which reduced pain. Saturday (today) mild right arm soreness.

9 minutes after administration heart started racing, heart up to 154, lightheaded, dizzy, felt like I was going to pass out. Informed the medical team. Heart rate came down to 130s, started having chest itchiness, neck rash, and facial hives. 50mg IM Benadryl given. Heart rate came down to 90s and hives subsided. Started feeling normal but out of it. Discharged home. Slept for 24 hours. Injection site pain/leg muscle pain/joint pain/fatigue for 48 hours.

Elevated heart rate Warmth Shortness of breath

At approximately 9pm the day of the vaccination I developed a very aggressive and pounding headache, I went to sleep at about 11pm. The headache progressed throughout the night and I could feel that I had a fever. At 5:45 the following morning I got up and checked my temperature. It was came back as 101.2¦F. I took 2 tablets of 200mg ibuprofen and the headache and fever subsided in about an hour and my temperature was within normal range. For several hours I felt fine, however in the early afternoon my body felt extremely fatigued and the headache was returning and I had a few bouts of chills. At 4:30pm this afternoon (the day after vaccination), I took my temperature again and it was 100.4¦F. I took 2 more 200mg tablets of ibuprofen and took a nap. Approximately 90 minutes later, I rechecked my temperature and yielded a 100.1¦F fever and still had a mild headache. As of right now, at 9:30pm the day after vaccination, I no longer have a headache nor a noticable fever, just minor fatigue.

Patient felt throat was scratchy, then became flushed and slightly itchy. A rapid response was called and patient was brought immediately to ED by RN. Patient stabilized without any treatment within 10 minutes. Blood glucose found to be 44, given glucose and improved. Cetirizine 10mg was administered for itching, patient instructed to restart OTC antihistamines and see PCP the next day

Numbness on the right side of face (not severe)

Erythematous facial and neck rash

On 12/18/20, I woke up with a fever of 103.6, so I took Tylenol and applied wet wash cloths to my face and body to cool down. I initially was successful, and passed the temperature screening gates at work. But later that day at work I needed to take Tylenol every 8 hours because my fever returned, and I spent the whole day working while febrile. I am a respiratory therapist, so I knew that my fever was Covid vaccine related, and not because I was infectious. I also experienced base of the skull headache, bilateral

eye orbital pain, and tachycardia on my pulse ox about 130 HR, probably due to fever. I also had joint pain, mostly of hip girdle.

Flushing, racing pulse, rash (stomach, back), faint, dizzy, nausea, feeling unwell

Arm pain, controlled by heat and massage, no adverse event

10 minutes after injection in my left arm The right side of my face felt numb and was tingling. It felt like my right eye was swollen (which it didn?t appear to be) also the numbness extended to my jaw Lasted about 15 minutes then slowly went away

1520 patient reported numbness of bottom lip. Had this response in past--2005 or 2006 with preservative in influenza vaccination. Has not occurred since with use of preservative free influenza vaccination. 1522 numbness to tongue. No swelling of oral cavity on assessment. Face symmetric. 1526 feels slightly nauseous. BP 122/82, HR 72, RR 14. 1530 Patient states still has numb sensation to bottom lip and little on tongue. Denies SOB, denies difficulty swallowing, denies pain/tightness/tingling. Speech is clear. Mentation unchanged. BP on retake 124/80, HR 70, RR 12. Patient refusing further eval and treatment at ER. Patient verbalizes last time she took benadry and zantac and was fine. 1545 Patient left building. Sister driving patient. Instructed patient on signs/symptoms to call 911. 1630--Telephone call to patient to check on her. Patient states she took benadryl and zantac. States bottom lip and tongue are still numb. Highly encouraged patient to return to ER and get evaluated by physician. Patient said she was fine but knew what to do if needed. 1800--Telephone call to patient to check on her. Patient states she feels much better and is inquiring about second dose. Informed patient that we would follow up with her next week regarding next steps.

Chest tightness Hot flash for 1 minute Tight throat High heart rate 120s-130s

Chills, body aches, headache, nausea

Vaccination given at 12:50 12:54?started feeling lightheaded. Sitting in chair in observation waiting area. RN present in observation area. 12:55? feeling not right. Water given. Feeling nauseated. 1302?unable to hear BP via manual cuff in chair times 2 Lowered to floor and feet elevated 1305 ?88/54, 60 HR still nauseated and lightheaded. 1309?911 called 13:10?felt she was improving. Nausea better. 104/66, 68 13:12?110/68 HR 68 13:15?felling better. Sat up on floor. 98/50, 88 13:18?EMS arrived. BS 98. BP 112/72 Refused to go to ER by ambulance. Medics left. 13:25? RN and RN assisted patient to wheelchair. After talking with patient she did agree to going to ER to be seen by physician. Wheeled to ER and care assumed by ER team. Patient never lost consciousness and never had change in mentation. She always maintained conversation and orientation. She states didn?t feel sick enough to go to ER. Patient was discharged from ER to home.

Arm soreness, headache, fatigue

28 hrs after vaccine, woke up with tinnitus R ear, partial hearing loss R ear - went to Urgent care - Dr diagnosed with right sensorineural hearing loss with left side unrestricted hearing - prescribed prednisone 60mg a day x10days. Audiology test to be scheduled next week.

Puritic rash with multiple sites of itching all over patient's body. Lasted for about 30 minutes after onset of symptoms. Given 50mg Benadryl after initial onset of itching & 125mg of Solu-Medrol 10 minutes later.

Reports sharp, frontal chest pain worse with deep breathe/movement. began 25-30 minutes after recieving Pfizer's COVID-19 vaccination. 11:20am Vts: BP 109/54, P83, Sat 98%on RA. Exam: Alert, in NAD. airway no swelling, wide open. talking and sitting comfortably. No dyspnea. Hrrt RRR no murmur. CTA c/l. Left sternal border around rib 5 tender point reproduces her pain. Laughing and talking. Repeat bp at 11:30 109/63, P 79. Respirations 12 and normal.

Angioedema, hives, tachycardia, shortness of breath

Fever and myalgia. Temp 101.2 Left arm soreness to the point of unable to raise left arm

102F Fever since 12/18, chills, fatigue, body aches, vomiting, swollen neck/lymph nodes, severe headache. Self-medicated with Tylenol

Immediately (no delay) after injection, tingling in arm followed by flushing of face and subjective SOB, no wheezing noted, face and anterior chest with uniform erythema, no hives. Epinephrine administered immediately by vaccinating nurse. No further development of symptoms. Developed some palpitations and chest discomfort - normal EKG. Discharge home after 6 hour observation, no recurrence of symptoms.

Pfizer-BioNTech COVID-19 Vaccine EUA 12/17/2020- 12/18/2020 First day into overnight: temperature that ranged between 99-100.5 F. severe body aches, chills, extreme skin sensitivity, slight rash on right arm near injection site and on right breast, right arm pain significantly increased, fatigue, cough, temporary confusion, joint pain, nausea. 12/18/2020 Second day: Fatigue, slept for most of the day but still did not feel rested, nausea, arm pain, joint pain, headache 12/19/2020 Third day: Felt better but still drained and slightly short of breath. Joint pain, slight headache and side of face pain.

Pleurisy and pleuritic chest pain..sharp stabbing pain in left chest with every breath.

Fatigue, myalgia, chills, HA persistent for three days now

Menstrual spotting around 8:30pm the same day of vaccine injection. This was outside of my menstrual cycle. Occurred 1 time.

I was monitored for 15 minutes and felt completely fine and left the location. On my way home approximately 25 minutes after my vaccination I felt a tingling and numbness in the back of my throat. I decided to call the center and let them know how I was feeling. They suggested I return. During the 10 minute ride back the tingling and numbness had progressed to the back of my tongue. Once I arrived there they continued to monitor me and my symptoms remained stable with numbness in my throat and back of my tongue. I was not having any difficulty breathing and felt otherwise fine. There was a concern that the symptoms would progress and they initiated EMS. I was taken via ambulance to Hospital where they continued to monitor me and check my airway.. In route to the hospital I was

hypertensive with a BP of approx 190/100. I did not ask what my heart rate was. I was surprised my blood pressure was so high. They said it was probably because I was nervous however I was not feeling nervous because I knew since I could breathe I really was fine, and sending me to the hospital was simply out of an abundance of caution as this vaccine is new. Upon my arrival they took my blood pressure again and it was 140s/80s I believe with a heart rate of 106. My O2 sat we?re in the upper 90?s throughout the situation. My blood pressure tends to be in the 110s/70s with a heart rate in the upper 60s to mid 70s. So it was surprising to me that I was hypertensive and tachycardic despite not feeling like my heart was racing or that my blood pressure was high. I felt completely fine other than the numbness in the back of my throat and tongue. Since the symptoms remained stable and there wasn?t really anything for anybody to do they did release me. Between 6:30 and 7 PM I noticed the tongue numbness was subsiding. By 8 PM my throat felt completely back to normal.

12-18-20 at 0900 nausea and dry heaving started. 0920 felt freezing cold. 1000 feeling cold intensifies. 1000 headache begins. 1100 headache worsens. 1115 full body ache grows in strength. By 1200 body pain and fatigue increase. By 1300 headache and pain all over body maxes out at 8/10 on pain scale. For the rest of the day couldn?t warm up. Headache, body pain, and feeling cold lasted the rest of the day and throughout the night. 12-19-20 at 0730 headache extreme, body pain fading, feeling of cold not as intense. By 12-20-20 at 0600 only headache remains. feeling of cold, nausea, and body pain are gone.

Red rash on back, arms and legs. 101.2 oral temperature. Joint pain, bruising

Approximately 2-4 minutes after injection I began to get hot. Once sitting down I noted my hair under my hat was sweaty. Noted elevated HR at this time (did not check). No sweating anywhere else. Not clammy. I have a history of anxiety...was thinking that maybe I got hot due to room temperature / size and then my mind reacted. Symptoms started to settle around minute 12 - 15. Sat in my truck for a few minutes after the 15 minute holding time. Started to feel back to baseline. I have had no issues since. Again, thought it was anxiety however I did talk to my Aunt who experienced similar symptoms after her injection. Decided to report. No chest pain No SOB No angioedema No rash or hives No swelling

Dizziness, fever, nausea, pain at injection site, inguinal lymph node swelling, chills, generalized weakness Took 2 acetaminophen 500mg, but to no relief, symptoms passed on their own.

Pain in the injection site for several hours (probably 5 hours or less), with a pain scale of 3/10. Pain is manageable, can still use the affected arm, no pain medication taken.

acute, mild pancreatitis, associated with symptoms associated with Nausea and vomiting and abdominal pain. Patient's symptoms started 1 day after her vaccination.

"After 3-5 minutes after injection felt anxious, shaky, lightheaded and stated he ""felt off"". Patient in chair and notified observation staff who notified POD manager RN. Patient stated he had not eaten today, given water, peanut free snack and room temperature made cooler. At 1535, patient states all symptoms are resolved."

Coughing, chest tightness, decreased saturation, itching forehead and back, rash on upper back

Patient received vaccine at 0845 and left after the specified 15 minute waiting period. At 0940, the patient returned to the vaccine clinic stating that he was short of breath and his throat felt tighter than before. Arm examined and no hives or redness present, patient denied itching and hives. Patient denied that throat tightness was getting worse. PharmD and RN present and took vital signs and called house manager. Verified NKDA and then administered 25mg of PO diphenhydramine. Pt then transported via wheelchair for further workup.

Patient received COVID 19 vaccine at 1636 12/19/2020. Patient returned to clinic at 1733 complaint of throat closed and hard to clear. Patient had declined observation period and returned to work. Vitals 131/79, HR 90, 97.7 F, 98%, RR30. Complaint of dyspnea and palpations and occasional chest pain. Patient states history of asthma and hypertension.

Patient received vaccine 5 min prior, then left lightheaded, nausea, put head down, sat back up got worse then felt jittery and heart beating faster. Patient assisted to stretcher, cool cloth applied and vitals taken. Patient reassured and education given about vaccine and side effects.

Patient complained of tingling lips and tachycardia. BP 159/90 HR 105. RRT called. Patient transported to Emergency Department.

Within 5 minutes, started feeling very tired and dizzy, leaned head back trying to relax. Approximately 15 minutes after vaccine had seizure lasting up to 15 seconds possibly. Brought to floor carefully. Then had small second seizure (about 5 seconds in duration). Difficulty Breathing immediately. Then extreme trouble breathing/stopped breathing , given 0.3 mg EpiPen in right thigh, gasped and began breathing again. Checked pulse (80 b/pm) then waited about 3 minutes and EMTs arrived. BP was 140/90 ish. Both higher but not terribly high.

5pm: quick hot sensation with associated increased HR, hot sensation went away after a few seconds and HR returned to normal shortly after 5:15 pm: slight tingling in tongue, lasted only a few seconds and then went away no other side effect since, except for a slightly sore injection site.

Enlarged lymph nodes on axils initially walnut size then progressed to golf size edema/lump on Left breast

Stomach ache and slight achiness

Left arm pain.

I am an employee of Medical Center. I went to Hospital for my vaccine since it was only 5 minutes away from my house. At 5:00 PM I received the vaccine. 10 minutes after I noticed my throat felt tight and as if it was closing. This felt similar to the reaction I felt when I had morphine in Jan 2020 (that I am allergic to). I notified the nurses and they watched me for 10 minutes. It then stayed the same. They brought me back to their tent area and gave me 50 mg of benadryl. I immediately felt relief. However, maybe 3-5 minutes after the throat closing sensation came back. They then had to take me to the ER. I was then put on fluids, steroids, pepcid, and ativan. I was released after they watched me for a couple hours.

sore throat

The patient first started to feel really warm. The patient felt like her head was swimming. Then the patient had chills. Her vital were prefect.

Low grade fever 99.1 Severe myalgias Headache

Nasal congestion, headache, fatigue, 2-2.5 inch swollen, red, firm area @ injection site

two hours after getting the vaccine i had nausea/ vomiting and body aches. two days later i am still having body aches.

"Patient screened prior to vaccination for previous history of allergic reaction to other vaccine or injectable medication. Patient confirmed past history of ""numbness of lips and tongue"" secondary to iodinated contrast media. Patient was counseled and instructed to wait 30 minute observation period following vaccination. Following the injection, within 15 minutes the patient reported feeling flushed and heart was racing and felt that their throat was closing. Patient was triaged in the vaccine observation area with HR in 120's and BP of 182/60. Upon evaluation by the hospital's rapid response team she was administered 12.5 mg IM diphenhydramine and transferred to our ED for further evaluation. Upon evaluation by ED provider no additional treatments were administered and her symptoms abated. She was discharged home in stable condition without any further complications as those noted above."

Severe arm pain x2 days - injected in shoulder not deltoid Sudden onset of chills, severe shaking, shortness of breath, 02 sat = 89% that lasted 15 minutes (took Tylenol 1000 mg immediately). This occurred about 1.5 days after injection

SOB, fever,headache,body aches, chills,feeling unwell,tired for over 24 hours than on Saturday 2 days later developed injection site pain swollen lymph node under right armpit with severe pain

"28 minutes after PT. received vaccine she told RN on duty she felt funny""heart fluttery"", , light headed, dizzy B/P 190/110 HR 70-80,98-99% RA per facility RN. 0932 182/105, HR 60-70, 99% RA per RN 0945 Continue to monitor 180/95, HR 60-72, 99%RA blood glucose 90(PT ate breakfast) RN @ bedside chair 0954 119/91, 99% RA , 60-73 HR feels better but has headache 10:00 ambulance called10:08 208/96, 68-76 HR 99.24% 10:13 Ambulance arrives,report given 40 Medic 10:20 210/112 per EMS monitor HR80 100% RA 10:28 Loaded onto stretcher left with EMS"

40 hours after receiving the vaccine I am experiencing dizziness.

On 12/18/20 @ 2:58 PM, the patient experienced a really bad headache directly after received the vaccine. Her heart rate elevated 135 with heart palpation. Her BP was 178/92. She was very dizziness, short of breath, her had a hives all over her chest.

Approximately softball sized rash developed on LUQ and with additional around left flank area approximately 2 hours after injection. The redness/rashes went away spontaneously after another 2

hours. During that time, a little discomfort in left side of throat, but no change in lung sounds, uvula or any other respiratory concerns. Later in the day (approximately 4-6 hours), baseball sized redness presented on triceps bilaterally and splotchy redness on lumbar area (about 2-3 areas). Redness/rash is still present on both triceps the next day 22 hours after injection.

Fever of 102 F that developed within 12 hours of vaccination and resolved within 24 hours of onset.

Fever 102 Sinus congestion dry cough runny nose body aches

Patient is a pleasant 83 y.o. female pediatrician with history of Sjogren's, hypothyroidism, hyperlipidemia, hypertension who had been at Hospital to get her Covid vaccine. 30 minutes after doing so she reports being in the lobby and about to walk upstairs and feeling fine. The next thing she knows she wakes up on the stairs with her nose and face bleeding surrounded by healthcare team. She denies any precipitating symptoms such as chest pain, shortness of breath, fevers dizziness, headache. She reports feeling well otherwise in the last few days. I did a thorough bony palpation exam including spine and he only point of tenderness besides on her face was the area above her right ankle. She does not have a history of syncope or collapse

Patient had vaccine at 1330 on 12/20. At around 1815 she began experiencing heart palpitations. She presented to the ED and she was found to have a heart rate in the 130s. EKG showed junctional tachycardia. She was given 6mg of adenosine and an EKG was repeated and showed sinus tachycardia. Eventually her heart rate decreased to the 70s-90s. She was noted to have a potassium of 3.4 which was repleted. She was admitted overnight for observation. In the morning her potassium was normal and she remained in sinus rhythm. She was discharged later that afternoon.

Headache, fatigue, nausea, tachycardia, muscle pains, chills, subjective fever and subjective shortness of breath

Swelling and redness at injection site, swelling of lymph nodes in the same arm as injection site, painful

"Employee reported chills, shaking, dizziness ""like you feel after you faint, spacey""."

Patient became lightheaded. Felt palpatations. No shortness of breath.

Metallic Taste

Numbness and tingling throughout body

The patient experience tightness of her chest. She was hook up to be monitored. Her BP was 185/91. Her heart rate was 122. Her O2 level was 100. The nusre notice swelling at the area of the site with mild erythema (redness).

Most severe symptoms was injection site soreness initially, followed by overall myalgias, chills, and fatigue. Recovered in 2 days.

Nausea, initial SBP is 155/87 and heart rate 101. Repeat BP was 134/84 and heart rate 94.

Anaphylaxis type reaction, stridor, treated with 02, epi pen, moved to hospitals ED

8am EE noted fanning herself, states she feels warm but just got off nights. Ice pack given for neck. 8:03 C/O itchiness on chest, heart racing, neck and chest with mild redness. No SOB or tightness in throat. RN notified and came to assist. Left arm vaccine injection site asymptomatic. EE refused Benadryl. BP 143/105, P81 PO 100% 8:08am Continue to feel itchy on chest and neck BP 153/91 P-76 PO 100% continue to refuse Benadryl 8:10am Benadryl 25mg po given, juice and crackers 8:14am BP 151/86 P-65 PO 100% changed to reclining chair to elevate feet, no tightness in chest or throat. 8:20am EE c/o left arm tingling/numbness down to fingers, denies CP no SOB, states it is like she hit her funny bone. BP 151/86 P75 PO 100% RN notified and evaluated her. 8:35am EE feeling cool. BP 131/88 P-69 PO 100%. EE states she feels like the Benadryl is working , redness less on neck and states she feels more relaxed, continues to have left arm numbness. 9am EE states she feels better, a little itchy on neck but no redness. BP 123/87 P 73 numbness decreased and almost gone. OK to go home per RN and instructed to take Benadryl when she gets home and to call the Covid vaccine hotline if needed or 911 if any resp. distress or CP. Requested her to text or email RN when she arrives home. EE states she understands. RN states she heard from EE and she is home. RN

slightly elevated temp (99 deg), chills, body aches, headache over 18 hrs period

Immediately after the vaccination my arm got super sore. On, 12/17 at 10am while at work I developed a 99.1 fever, chills and severe body aches all over called Employee Health and management and was given a COVID test which was neg and was sent home. I took 600 mg motrin and around 8pm that night I began to feel better. I previously had symptomatic COVID in July.

12/19- nausea & headache. 12/20- bodyache, sore arm & headache

8:33am EE states she feels flushed and heart racing. BP 141/83 P-96 PO 100% Refused Benadryl. Denies SOB, chest or throat tightness, no itchiness. RN notified. 8:40am C/O warmth, no itchiness, no SOB, no tightness in chest or throat. BP 137/81 P-77 PO 100%. 8:50am 138/83 P-65 PO 98% abdomen with some light rash. 8:55am Benadryl 25mg given per RN 9:05am BP 129/87 P68 PO 100% c/o left eye feeling warm, no redness. 9:30am BP 127/84 P69 PO 100% denies heart racing, feels fine, Instructed to take Benadryl again if has reoccurrence and to call the Covid vaccine line or 911 if any resp distress. EE states she understands. RN

Patient states my lip feels like it is swelling, patient lower lip with swelling noted. Patient assisted to Emergency Dept via W/C 02 sat 99%, B/P 150/88, HR 99

12/17/2020 Woke up at about 7am, pain at injection site, swelling. At end of day, started to have extreme HA and joint pain. Tried to sleep as much as possible. But 12/18/2020 felt even worse. Was unable to report to work. Mgr recommended the rapid test for Covid on 12/18/2020. *drive up test. Didn't want to take tylenol to mask fever. Rested friday and sat. Felt better 12/19/2020. Symptoms were mild to moderate. Temp highest was 37.9 12/20/2020 'still feel warm', body aches, joint pain, headache are 'still there' but 'more tolerable'.

Recurrence of the exact symptoms I had when I had COVID in March, 2020, but less intense and for only one day. These were severe fatigue and wet cough. No fever. It was like deja vu, but only lasted 24 hours. No other new symptoms.

Started feeling confused. Stated felt like she was drunk. laid her down on the gurney progressed to abdominal pain, nausea and vomiting. Light headed confused, tingling in legs. Sent to the Emergency room

swelling at site of injection, fever 102.3F, muscle ache, chills

30 min, c/o feeling light headed, BP 129/71, 98% RA, HR 66, R 16. Sx resolved.

Increased Fatigue on day one after 1st dose. mild Left axillary lymphadenopathy. Axillary swelling, and tenderness radiating into left breast and very mild into left anterior neck. . 2/10 on pain scale. Constant Dull discomfort. Not really worse with movement. Axillary lymphadenopathy and tenderness more noticeable on day 2 after receiving 1st dose of vaccine. NO SOB, dyspnea, fever, change in heart rate.

Patient became very flushed and ee stated she was not feeling well. BP: 156/96-176-96 HR: 80-98. Patient states this was not normal bp. continued to monitor pt and noted to have reddened rash on face. Patient to ED for further evaluation.

9:50 am patient states she does not feel right, feels funny, leaning over in chair, denies SOB no CP c/o of heart racing, NKA RN and RN summoned to help. Patient laid down on floor. BP 192/103 P-112 PO 100%. Eyes noted to be pink, denies itchiness. RN called 911, advised not to give Benadryl. 9:55am BP 178/99 P-119 PO 100% patient continue to feel heart racing but no SOB, chest or throat tightness. 10am BP 177/100 P-114 PO 100% continues to be A&O x3 no resp. distress 10:03 EMS arrived and took her to the ER. Patient states her 15 min observation time was up at 10:05am. RN

Woke up out of sleep and felt very warm, and a tingling sensation which started mid thoracic region which then traveled up to base of my neck and then spread bilaterally to both arms and hands; was brief and then just dissipated

30 min, c/o L hand (btw 2nd and 3rd finger) swelling, no pain, no itching.

Nausea- started about 48 hours after injection. Began with a feeling of slight motion sickness and progressed over the next 12 hours to be severe enough to cause vomiting. Nausea only present when standing and improves when laying down.

30 min, c/o slight numbness, tingling at injection site arm (L) vitals taken WNL. Sx resolved.

Initially started as numbness of the lips, then progressed to angioedema (swelling of the lips) with face itchiness. Then progressed to throat tightening and swelling feeling, consistent with anaphylaxis.

shortly after receiving COVID vaccine, patient complained of arm hurting with shooting pains down to her elbow and fingers. Patient started shivering, HR 129, BP 131/78 o2 sat 98%. continued to monitor

employee. physician at side 800mg ibuprofen given. Patient hr down to 111 and bp 135/97. Patient refused evaluation in ED. was released and escorted by physician out of department.

Very painful to injection site that woke me up the night of 12/17 into 12/18. Became febrile at 100.5F oral Friday 12/18 with body aches, joint pain, extreme fatigue, skin hurt between 4-5pm. 600 mg ibuprofen helped, however became flushed and sweaty. Saturday 12/19 woke up feeling fine. Around 3pm, body aches started again with bilateral hip pain, extreme fatigue, sweating. Temp was 101.1F oral at 7:15pm. I took 500mg acetaminophen and 600mg ibuprofen. Today, again woke up feeling fine at 9am, felt asymptotic. On the way to work at 10am, became sweaty/fatigued/body aches again. At work, 10:45am temp was 99.6F oral. I took 500/600 of Tylenol and ibuprofen.

Experiencing decreased sensation in bottom lip. No decrease in function. No facial droop. Just decreased sensation/numbness. Started on the second morning after the vaccine. No exposure to known allergies.

Injection given 07:58 am, at 08:12 Patient described feeling dizzy, was diaphoretic V/S at 0812 178/99 Temp 97.0, 0813- 182/101 P-112, O2 Sat 98% on room air Respirations within normal limits, alert oriented, patient described feeling a little shortness of breath able to speak in full sentences, transferred to gurney and taken to Emergency Room, skin pale. While waiting for intake patient stated shortness of breath was feeling a little better, repeated BP 0827- 146/94 care transferred to Emergency Room

Within 5 minutes of receiving vaccine, Pt.t started to feel shaky and nauseous, became tachycardic, however patient stated she rushed to get here and was not sure if that was the reason. Pulse at this time was 100. She felt she was going to pass out. I got water for the patient and also gave her peppermint candy, after about 10 minutes she didn't feel she was getting worse but she didn't feel much better. She did not want RRT called. I gave 25mg of Benadryl. Within 5-10 minutes after the Benadryl she started to notice symptoms improving. After 20 minutes patient is standing and no longer feels she is going to pass out. Patient called her husband to pick her up.

Patient stated he didn't feel well after receiving vaccine. Patient stated his throat felt funny, BP 186/94, HR: 117, o2 99%. Patient went to ED for further evaluation.

at 1am after vaccination, woke up with body aches, couldn't sleep, restless till 0430. Woke up with mild congestion, cough, fatigue, lt. arm sore at site. Body aches continued throughout day. Contributed it to shot. Slept good Friday night, woke up Friday with mild cough, congestion, fatigue, runny nose, sore throat. Tested for COVID Friday morning with Binax and was positive. Symptoms have worsened since then; loss of taste and smell. Has had temp as high as 101 on Saturday, low 99's on Friday. Chills, SOB, and fatigue. on Saturday

12/18/2020 scrotal pain. Evening onset of rash 12/19/2020 Rash lower lumber, left butt cheek, scrotum and penis. Took picture and sent to Consult with infectious disease. Doctor deemed rash to be SHINGLES and prescribed Valtrex. By evening, rash had progressed all over and pain associated with shingles. 12/20/2020 Stable but rash is still prominent. Consult over tele

Pt is currently breastfeeding. Pt reported having 4 clogged milk ducts. 3 on the same side as injection and one on the other. All have resolved at this time through breastfeeding and pumping. No other symptoms.

I had aching muscles, headaches, diarrhea, nausea, pain in my arms and legs and vomitting.

12/19 1000 developed chills, 1230-body aches, nausea, and headache, fever 101.5 (self reported), 1300 fever increased to 102 (self reported), fever then increased to 106 (self reported). Pt reported dizziness. Visited ER. Fever 100.8 on arrival. Patient reports taking PO advil, tylenol, and benadryl. Used ice packs at home to decrease fever. TX in ER with IVF, tylenol, and zofran. D/c from ER. OHN f/u 12/20-patient feeling better, resting at home, denies fever.

headache and nausea around 2am...throwing up...reso;ved by 2:30am

Patient complained of tachycardia. Dr. examined the patient who stated he had a regular rhythm. After one minute of sitting, he felt better. After sitting for another 5 minutes the patient stated he was feeling tachycardia again. Denied any dizziness or lightheadedness. Dr called down to the ED. Patient escorted down to ED where they did an EKG and discharged him.

Approx 45 minutes after injection, patient reported generalized itching. Patient was given Zyrtec 10mg. Itching continued. Patient was given Diphenhydramine oral. Itching resolved.

Reactivation of HSV2 virus, outbreak on left buttock/flank and related lymphnode tenderness, flank pain, body aches, malaise.

The patient was well prior to vaccination (12/17). The day after, he felt mildly unwell and had a low grade fever. The following day, he had a fever of 102. He received 1L of fluid at Urgent Care and had a BP ion the 80s. Shortly thereafter, he felt palpitations and developed AF. He came to the hospital where he was tachycardia to 200 bpm and hypotensive to SBP70s. He received aggressive fluid resuscitation (4L), IV metoprolol and was started on empiric Abx. Within several hours, the HR lowered, BP increased, and AF spontaneously converted to sinus. He had no dysuria. Curtures so far have not shown growth at our hospital. Urinary culture from urgent care has reportedly shows 20k gram positive cocci.

Approximately 15 hours after getting vaccine, the morning after, noticed slight tongue discomfort. Feeling slight swelling of tongue, noticed scalloped appearance. Noticed for about 24 hours, seems to be mostly normal now. Did not take any medication. Was not in any distress really, just seemed to be an uncommon side effect and thought I should report. Only medication allergy in past was keflex many years ago and was described as serum sickness and treated with Prednisone.

15 minutes after injection. Tachycardia, Diaphoresis, mildly hypertensive, facial flushing, waxing and waning symptoms

Headache, injection site pain, blurry eyes, hoarseness, sore throat

Tingling in face shortly after dose for approximately. Symptoms resolved after eating a meal.

Symptoms: light headedness persisting 3 days after administration, high BP occasionally

102 temperature started around 11pm on the 17th. Fever went back to normal evening time on the 18th- treated with ibuprofen. Body aches started same time as fever and lasted until the 19th- treated with ibuprofen. Severe fatigue started the night of the 17th and has lasted until the 20th. Severe headaches started the night of the 19th.

A slight small itchy rash in left hand that stopped itching pretty quickly

Received 1st dose of Pfizer vaccine on Left Arm at 1630 on 12/18/20. Within 8 minutes of receiving vaccine, tongue experienced numbness and tingling. At 9 minutes post administration, symptoms intensified. And at 10 minutes post administration throat was scratchy was a tickle. At 12 minutes post administration notified Pharmacy and Employee Health Workers. By approximately 1650, health care professional administered Benadryl 50 mg IM to Right Arm. Observed. Symptoms decreased but then intensified to include numbness and tingling in lips. Transferred to Emergency Department for observation. Received decadron 10 mg IM to Right Arm at 1915 due to symptoms not resolving. Discharged from ED with prednisone course. Discharge diagnosis Angioedema. Symptoms decreased approximately 6 hours post administration of vaccine. On 12/19/20 at approximately 1425, experienced tightness of throat, with numbness and tingling of tongue and lips. Took over the counter Benadryl 50 mg p.o. at 1440. By 1520, symptoms intensified with hoarseness in voice with coughing spells. Returned to Emergency Department for observation. Noted to have rash on chest in ED. Received Pepcid 20 mg in ED. Discharged with instructions to take Benadryl 50 mg p.o. every 6 hours, famotidine 20 mg p.o twice daily, continue taking prednisone, and received prescription for epinephrine auto injector. Emergency room physician wrote to return to work on 12/22/2020 with follow up with Employee Health on 12/21/2020.

Petechiae - very mild on proximal area of right thigh. Noted two days after vaccine. Appears to be resolving.

Periorbital edema upon wakening that resolves throughout the day but reappears the next morning

Patient reported onset of mild headache immediately following injection of vaccine. Resolved after 30 min observation.

The patient expericence lightheadness, flushed, heart palpation, and chest tightness. Her vital are BP 119/54, 62 heart rate, O2 was 99. The patient was monitored until the symptoms went away. It all passed within 20 minutes. The patient was walked to her car by employee.

Patient reported onset of slight headache immediately following vaccine injection. Resolved at time of dc after 30 min obs.

Swollen lymph node on right side of neck the morning after receiving the vaccine. Telehealth appt with PCM who prescribed 800mg ibuprofen. Took 200mg motrin for swelling because i have not had the chance to pick up prescription. The following day, swollen lymph node continued and broke out in hives approx at 1300. Went to emergency room and was given an oral steroid (dekadone?). Prescribed

prednisone, claritin, and Benadryl. Have taken 1 claritin a day. Hives have disappeared within 5 hrs of oral steroid. Swollen lymph node persists and has enlarged. Painful and swollen past the jaw line. Will return to ER today for pain and continued swelling as directed by ER.

Burning at injection site, then elevated heart rate, flush, and light headedness. I was kept and observed for another 30 minutes at the hospital and everything returned to normal. Then, I developed severe dry mouth and congestion, post nasal drip, headache, and nausea. I drank 3 liters of water with continued dry mouth, intermittent feelings of flush and light headedness for the next 3 hours, but no fever. After that subsided, I had only chills and headache that were resolved by the next morning. Now I have only arm soreness and mild fatigue.

"Felt an initial ""cool"" feeling all over immediately following vaccine injection, this resolved immediately as well."

After the vaccine I immediately got a mild minor headache which passed pretty quickly. At around 9pm I noticed a bump at the base of my neck on the top of my right collar bone. I reached out to Employee Health Nurse and my PCPs nurse who agreeed it could possibly be a swollen lymph node. Today I am currently monitoring this bump and if it doesnt desolve I will reach out to my PCP in the morning.

Patient reported numbness in lips immediately following vaccination, resolved within 15 mins.

I have nasal congestion, loss of taste and smell and fever.

Pt reported feeling light headed following vaccination, resolved after 15 mins.

12/18/2020 morning I started to have runny nose, achy 'like coming down with a cold'. Late evening and early morning 12/19/2020 tender lymphnodes, same side of vaccination. As of 12/20/2020 barely palpable anymore. Temperature was normal. I took ibuprofren and tylenol; 12/18-12/19. Congested, nasal drip ' 48 hours of feeling worn down and achy'. Flu shot in October 2020

Patient received vaccine and became dizzy, nauseous, and hypertensive and was taken to the emergency room.

Light headed, cold clammy skin, pale, cold sweats and numbness to left arm where she received vaccine.

Mild dizziness followed by jitteriness and heart pounding. Increased blood pressure. Lasting for about 1-2 hours.

Received vaccine, waited 15 min. Walked to car. side of face went numb, dry mouth. Patient walked back to vaccinate location. Pulse 115, O2 Sat. 96.

Extreme fatigue, generally unwell, body aches, headache, abdominal pain, nausea, ear fullness. Near syncopal episode the morning after the vaccine.

Tachycardia (150?s), dizziness, shakiness, flushing beginning 5-10 min after injection. Lasted for approximately 45 min. Approx 24 hrs after injection, developed a rash on torso?bilateral arms, chest, neck and back.

Malaise on 12/19. Right (collateral) axillary lymphadenopathy about 1 inch in diameter noticed on 12/20 (today).

Red spot about 1 inch in diameter with swelling and warm to the touch. Muscle soreness around injection site. Still present two day later with no relief as of reporting.

Painful, Tender and redness next to injection site (not directly on). Red mark approximately 2 inches in height and 1 1/2 inches wide

Diarrhea (5 hours post-injection), duration 48 hours Fever (11 hours post-injection), duration 6 hours Feeling of lump in throat (24 hours post-injection), duration 24 hours

Itching; Hives; Patient declined Benedryl ; took Claritin with some relief

About 23 minutes after the vaccination I started feeling tightness in my throat, began coughing and wheezing and had SOB, was taken to a secure area and given 25mg benedryl and they waited a few minutes and gave another 25mg of benedry. I was given an EPI pen injection in the left thigh and was given an albuterol enhaler to help with the breating. The symptoms resolved after the EPI and the albuterol and I was released from their care

Felt flush and throat started to get scratchy and started to get tighter and was having difficulty swallowing about 4 minutes after vaccination. Continued to get more flush and laid down. Rapid response was called and taken to the emergency room.

I had an existing mild rash after I ate crabs on 12/18/20. I never had allergies to any food. My rash got worse 6 hours after receiving dose yesterday. Both ears are swollen and red. Rashes behind ear look like hives, welt-looking. It spread to my neck and upper back area. Took Benadryl and it slightly improved. Also applied Cortisone cream. Took Zyrtec as well. Slighty better. It's been 24 hours since injection.

Fever, chills, fatigue. Occurred at noon 12-19-2020. Sent home from work (ER RN) and had covid test.. awaiting results.

I had sneezing and a cough.

Injection arm very sore by 20:00 day of vaccine. Awakened with body aches at 03:00 and chilling. No fever. Went to work (frontline healthcare worker) at 08:00 but left work early (14:00) for worsening body aches moderate joint pain and increasing fatigue. Polyarthralgias and myalgias intensified as did chilling. By 10:30, abdominal pain had begun. And diarrhea had begun. The next 12 hours were continued intensity of abdominal pain (diffuse intense cramping), and severe myalgias and poly arthragias. I took additional naproxen (440mg w good 16 hours from am dosing at 07:00). I was unable to do any thing but try to rest between bouts of diarrhea. Nausea developed (moderate) but no

vomiting. No fever despite intense and unrelenting chills for about 24 hours. Continued fatigue into post vaccine day 2 (12/19/20) but improved pain and resolution of GI symptoms. On 12/20, only mild polyarthralgias of hands, arms, low back, knees, feet, and hips.

Patient took 50mg Benadryl prior to injection at 1300. She also took Xanax at 1000 prior to injection. Immediately following the vaccination, patient reported onset of slight headache and tingling lips. No SOB. O2 100%, HR 80.

Persistent headache which started night of vaccine, unrelieved with Tylenol, continues today (12/20). Fatigue which has gotten worse, to today where I struggled to function and had to call in for tonight?s shift at the hospital.

Headache, body aches, injection site soreness.

for 2 days continues fever upto 104 chills rigors sweating myalgia extreme fatigue . i am a physician by profession i had covid in may 2020 and had antibodies igg checked in september

Chills, throwing up, runny nose

Sensation of tightening in throat and sensation of difficulty swallowing. No rash. No dyspnea. No stridor/wheezing. Vital signs unremarkable. Suspect globus sensation. Plan observation until resolution or progression to anaphylaxis.

Slightly after injection I began to feel light headed, flushed, dry throat, and increase in heart rate. I was monitored after for about 15 minutes which the symptoms seem to have resolved on their own. No treatment was needed. I didn?t think much of it until I realized some people were getting same side effects.

Within 24 hours , headaches nausea, muscle and joint pain. Approximately 24 hours facial rash/hives , itching and puffiness. Within 48 hours rash spread to neck and chest , day 3 rash/ hives continued, headache and body aches improved, urgent care visit started on Mederol pack with dx of allergy to COVID vaccine. With steroid dosing facial rash some improvement. Occasional headache no unusual body or joint discomfort above baseline

12/17/2020; 1158 am had injection. at 2pm, noticed trunk itching around waist, abdomen, back. No visible rash. mild soreness and redness to injection site on left deltoid. 530/6pm developed SOB, rash is now visible, non raised, very itchy trunk. Took 10 mg Zyrtec. Went to ER nausea, vomiting, moderate to severe abdominal pain, flared angina and chest pain with the shortness of breath. ER; DR. CONTINUED WITH BENADRYL 50MG 4-6 HOURS, DUE TO ONGOING ITCHING. FAMOTIDINE 20 MG 2X/DAILY Had flu shot between 09-10/2020

Sudden onset of fainting sensation . Followed by dizziness moderate shortness of breath lightheaded ness panic tingling in hands feet top of head headache distress.

Thurs 12/17 : aching in left arm infection site. Later evening : ?flu-like ? symptoms Fri 12/18 : 04:30 am : vomiting , headache, Started work at 06:00 am. - continued nausea, chills/ warmth (but no fever) Around 1:00 -small pupils (but dilating) , increased weakness, & dizziness begins. No appetite. Slept all evening. All vitals normal range. Took 2 capsules (200 mg) q 6 hr. Sat Dec. 20 : weakness in am . Increased appetite.

Constriction of airways, rash/hives and o2 sat low (80?s). Used pt albuterol inhaler, no relief. Coughing and wheezing continued. Staff escorted me to ED where I was give IV Benadryl and solumedrol. Within 2 hours post-vaccination I was ok to leave.

Nausea, diarrhea lasting approx 12 hours

Patient with symptoms of severe myalgias, low back spasms, fevers, chills, headache, SOB since Saturday. Treatment included intravenous fluids, Tylenol, magnesium repletion, frequent reassessments, infectious disease consultation in the Emergency room.

Numbness in face and tongue, feeling of tongue swelling and touching the back of my throat, difficulty swallowing with need for more effort and more swallows. These symptoms started about 45 minutes after the injection and got worse. I went to the urgent care and received Benadryl, Pepcid, and an IM Solu-medrol. The PA said he did not see any edema and I had a patent airway so they monitored me and sent me home with an epi pen in case symptoms worsened. Symptoms started improved approximately 2-3 hours after receiving the medications and the epi pen was not needed.

Ventricular tachycardia. Defibrillator paced me out of rhythm. I have had my ICD for 3 years. This is the first abnormal rhythm I have had where it delivered a therapy to abort it.

Had full body numbness and tingling about 6 minutes after administration, while waiting in observation area. Felt lightheaded, dizzy. Laid down, symptoms resolved about 5 minutes after, except bilateral Upper extremity tingling. This resolved after an hour, with tingling then localized only to left arm. This also resolved within 2-3 hours from time of administration (estimate)

12/16/2020 7:20am After the injection few later I felt my chest started to hurt gradually increased the pain and started to have palpitations it lasted hour and thrity. Vital Sigh the time of the event BP 138/80, HR 78, RR 24, Sat 99%. I was sent to ER they blood samples, EKG, Chest X-ray and monitor my heart rate.; all was normal. The same day I was discharged home.

Patient reported metallic taste in mouth, slight tightness in upper chest. Observed chest tightness deceased over 20 min. Metallic taste almost gone. 30 min. almost all gone. Benadryl 50 mg. given at 25 min. condition improved. Instructions given to patient re-symptoms worsen, S.O.B, etc, husband driving patient home.

Within 10 minutes of receiving vaccine, I experienced shortness of breath, irritation in my throat, felt flushed and was dizzy. I was immediately transported to the emergency room where I received benadryl and was monitored.

3pm developed sore throat and rhinorrhea. Concerned that I was positive, left work and scheduled symptomatic test next day. Noted on home pulse ox that my heart rate was in 140s (otherwise vital signs were normal and I was afebrile). Symptoms got better and after pushing fluids I was able to get my heart rate under 100 by end of the day. 12/20 woke up heart rate 140s now down to 105 at time of reporting. Sore throat and rhinorrhea are getting better but tachycardia is concerning and I am worried I may have developed an arrhythmia as my Apple Watch consistently marks my rhythm as inconclusive

Throat closure (angioedema/anaphylaxis) requiring ambulance transport to Hospital emergency room and stay IV infusion of Benedryl, solumedrol, and Pepcid with excellent results. Observed twelve hours, then discharged.

Approx. 10 minutes after vaccine administered I became suddenly tachycardic while sitting in a chair. Heart rate up to 140. I started to feel some chest heaviness with some difficulty breathing. Felt like my heart was galloping. Was transported to ER and monitored for 2 hours. I was orthostatic with talking, and walking. Heart rate to 135 walking to the bathroom despite having had a liter of IV fluid given. I was discharged home with instructions to follow-up with my doctor. I have an underlying problem with exercise intolerance with elevated heart rates. It seems that the elevated heart rate made my symptoms worse. Otherwise I have just a mild headache and mild fatigue. No previous adverse reactions to vaccines.

patient vaccinated, waiting the 15 min, left clinic. in 30 min. Sudden onset of Headache. 38 min. Horse voice, Cough. eventually improved. Reported reaction at 1pm.

After receiving the vaccine I was fine. Wednesday afternoon I had a headache and at night I started feeling my sore throat. Thursday night the sore throat felt like it was on fire. I started having fever (100.2F) and it felt like I had step throat. Runny nose, headache, next day Friday the sore throat and fever was gone and right now I just have the runny nose. I was screened for COVID on Friday and it was negative.

"Slight rash/redness along face and neck and upper torso; hypersensitivity on scalp, face, upper torso (borderline painful tingling on head/face/arms, chest). Even clothing rubbing against the skin ""hurts"" a little."

Patient recieved first dose of Covid vaccination to left arm and was being observed in observing area. Patient noted that the lymph nodes in her neck, on the left side were very raised and swollen. She stated this happens after her flu shots but this was much more pronounced at this time. She has no medical history at this time. Patient was seen by Md in the room Dr who stated she had no issues noted. She was watched for 30 minutes and released with advise to follow up with her primary care physician.

Swollen upper lip Rash and itching on back And legs Took benadryl

20 to 30 red blotches on my upper torso and arms

Approximately 20 hours after receiving, I had normally pain at the injection site. The day after receiving the vaccine I started having a dull headache, Chills, fatigue, mild nausea and vomiting once (all mild to

moderate symptoms). It is tolerable and normal for most vaccines; mild enough to not seek treatment at this time. I?m expecting it to resolve in the next 48 hours. If it gets worse, I will seek treatment. I?m only reporting these side effects to help people in the future, due to it being fairly new. I will be getting my second dose if my symptoms resolve within a few days.

Within 45-60 seconds of receiving the vaccine, I experienced acute-onset of tachycardia of 130-140s BPM. For context, my resting heart rate is 65-80. At first, I assumed it was anxiety, however, I had no preconceived notions or negative thoughts regarding the vaccine. I took slow, deep breaths and performed a vagal maneuver which did not lower my heart rate. I took two Claritin pills, thinking this was a mild allergic reaction. 30 seconds later, I tried to vagal again and successfully slowed down my HR to approximately 100-105 BPM. The tachycardia resolved after 10-15 minutes.

Pt stated she felt dizzy/lightheaded while on her phone nearing the end of her observation period. She got up to leave stating she thought she just needed fresh air and promptly returned to the observation area with dizziness and palpitations. This was 45 minutes roughly post vaccine administration. B/P and heart rate were elevated. Pt began feeling short of breath and a rapid response was initiated.

Recieved vaccine and sat to be observed. Noted flush from chest up to head of heat and then racing heart as well as increased blood pressure. First set of vitals @ 0445 pm 97.7, bp 167/89, hr 74, r 20 . Pulse felt fast but was normal per assessment. Second set of vitals @ 0458. 97.7, p68, BP 141/93, hr 92, O2 97. Pulse higher. Md saw him and stated was ok to discharge with follow up with primary care MD. Discharged at 5:10 pm.

Metallic taste in mouth

Elevated blood pressure Dizziness and heaviness in legs Went to Er to be monitored and sleep Lasted about 6 hours

Neuropathy in arm resloved on own.

Less than 24 hours after getting the Pfizer Covid vaccine, pt experienced severe tinnitus and moderate hearing loss in R ear. Seen by me in urgent care with demonstrated hearing loss, which progressed the next day. Diagnosed with acute sensorineural hearing loss in consultation with Ear, Nose and Throat specialist, started on high-dose steroids, referred to audiology. It is unknown if this reaction is short-term or long-term, but if it persists long-term it would result in disability.

Metallic taste in mouth

Myalgias, low grade temperature, injection site pain

Headache, feeling tired, temp of 100

Developed rash that itches on trunk, bilateral arms and bilateral legs 2 days after received Pfizer Covid vaccine #1.

Relactation

Lymphedema right underarm and breast Treatment- ice, ibuprofen, acetaminophen, light massage and light exercise

Sore deltoid muscle starting 10 hrs after injection lasting 24 hrs. No treatment required. Menstrual cycle 3 days late as of today. Negative home pregnancy test. Menstrual cycle is normally very regular.

About two to three minutes after the Covid vaccine was administered in the vaccine clinic at my hospital where I work, I began to experience pre-syncopal symptoms (mostly light-headedness and nausea). I stood up to get help and walked to the back of the auditorium where they were observing us for 15 minutes post-vaccine, and due to standing and walking, I became much more dizzy and lightheaded and then sat down on the floor and was eased to a lying-down position on the floor by a nurse as I briefly lost consciousness. I regained consciousness very quickly (maybe 10-20 seconds, but I'm not sure) and was taken care of by a set of nurses who noted me to be hypotensive and pale, with I think a bit of a lower heart rate, though I'm not sure what my vitals were exactly. They had me then stand to do orthostatic vitals and I was orthostatic. I was too dizzy to remain standing and felt very nauseas so I was taken to the ED (in the hospital where I work) to be observed. I had a normal EKG, blood glucose, and urine sample there. After having some juice and lying down, I felt better but was very cold and had some chills. After a little over an hour, they released me from the ED and it seems to have all been an episode of vaso-vagal syncope. I've had vaso-vagal responses before, but not in response to a vaccine since I was about 13, so I was surprised by how quick and severe the vaso vagal response was. Later in the day, I felt better but was fatigued and had a headache. I also had a lot of pain at the injection site. The day after the vaccine I felt tired and had a headache, and for part of the day a mild sore throat. Now two days after the vaccine, I feel much better, and the arm pain is more mild.

About 5 minutes after the injection I felt lightheaded/ presyncopal lasting about 5 seconds. I had several more episodes of the same symptoms over the next hour. My vitals were checked after the first episode and my pulse was 130 with blood pressure 179/99 and oxygen sat was in the high 90?s. I was taken on a gurney to the ER. I was told my blood pressure and pulse improved a few minutes after the initial episode and I was observed for 2 hours with resolution of my symptoms.

"Patient alerted team to feeling dizzy and left neck muscles tight 5 mins after arriving in recover area. Recovery RN assisted patient to bench area to lay down. Vitals signs obtained (stable but patient states BP runs low, no rash or hives, color pink. Patient lied down for approximately 30 mins. Felt better, denies dizziness. Left neck remains ""sore"". Patient has boyfriend at home to watch her, was advised to call 911 or primary care if any reaction after leaving."

Swollen Lymph node in right neck supraclavicular area and diarrhea.

- 1121: Patient reported being light headed. Patient stated it might be because of the excitement of getting the vaccine. Patient has a history of hypertension, arthritis (remission). Patient has a history of Bell's palsy and takes medication for that. Patient stated normal B/P normally 130s/80s.

In the first 24 hours I had soreness of the injection site and from hours 18-24 I was quite fatigued. Around 36 hours post vaccination I developed local swelling and itching, hive like in appearance

surrounding a skin nevi on right upper abdomen. Redness, swelling and itching improved some with Pepcid, Claritin and topical steroid.

Pt was found lying on cement at base of steps. Recovery RNcalled outside to the back. Patient was alert & oriented. Stated that he fell and landed on the cement walkway. Complained of left food pain and said he heard a crack when he fell. 911 was called per patient's request. Was able to talk inside with assistance and Vitals obtained (stable). Noted swelling in posterior back of ankle, pain with palpitation. Ice was applied. 911 arrived and taken to hospital

Pt reported feeling light-headed after 15 minute monitoring period post vaccine. BP 146/94 Left arm. Pulse 68, regular rhythm. SpO2=99 Offered water to drink and continuing monitoring period with pt sitting in recliner. Pt has spouse able to drive her home when ready. Pt reports no known allergies. 1743: BP 144/92, pulse 77, regular rhythm. Resp rate 14, SpO2=100 1755: BP 139/87 (101), Pulse 64, regular rhythm, Resp rate = 16, SpO2=100. 1800: Pt stood without any dizziness, steady gait. Pt reports no further light-headedness and feels comfortable leaving monitoring area. Instructed pt to call EMS with any concerning symptoms once at home. Husband will drive pt home.

Day following vaccine, throbbing pain developed on opposite arm/shoulder, leading to decreased/limited range of motion.

"Immediately after the injection my right shoulder felt ""odd"" and seemed to be popping and clicking more than usual. I experienced severe pain of the shoulder joint about 4 hours after the injection. At this time I took 400 mg of ibuprofen and the pain was eased by about 50 percent after about an hour. The next day I went to work without any medication and could barely lift my arm without severe shoulder pain inside the joint. The muscle did not feel too bad. Mobility of the joint was possible but limited by pain. I mostly used my other arm to adjust the position of my right arm. After work that day I took 800 of ibuprofen and went home to bed. I felt better the next day but took another 600 mg of ibuprofen to get through the work day. Same for day 3. It is now approximately 80 hours since the injection and my shoulder joint is still fairly tender and stiff but improved. I fear possible SIRVA because the shot seems to have been delivered fairly high on my arm. I do have a history of rotator cuff issues with this shoulder but it was never as painful as it was on the day of the vaccine and the shoulder has been well for the last two years. I received the flu vaccine in the same arm a few months ago with no problems."

received COVID-19 vaccine on 12/19 at approx 1750. At 1804 pt c/o headache, racing heart, itching, and shakiness. Vaccine Commander called rapid response team (RRT). Upon arrival of RRT pt c/o increasing sx. Pt escorted via wheelchair to ED.

Approximately 10 minutes after the vaccine was administered, reported starting to feel light headed, sweaty and nauseous. Then reported throat was feeling tight and RN on site reported hearing change in breathing. RN administered EpiPen and called 911. EMS responded and transported to ED. ED record shows resolved symptoms. No rash, edema, difficulty breathing. In ED was monitored and discharged. Received no medications or additional treatment in ED.

3 minutes after injection felt flushed and a rapid heart beat which self resolved within a few minutes .

Patient developed flushing, diaphoresis, tachycardia approximately 7 minutes after injection into L deltoid, while waiting under observation. The symptoms resolved spontaneously after approximately 3-5 mintues. Patient was then observed for 45 more minutes and felt fine the entire time. Upon leaving to have her spouse pick her up, patient developed symptoms again while walking out of the building. Patient was then taken to the emergency department for further monitoring. Telemetry and further observations for 4 hours revealed no further abnormalities and the patient was discharged home with no more issues.

None stated.

Fever chills myalgia

left sided facial, ear, and neck paresthesia. Felt similar to numbness after dental procedure. Initially felt my ear become hot and then touched it and noticed it felt numb. Then feeling spread to side of cheek and jaw and down the side of my neck on same side. Same side as injection. Onset was about 12-15 minutes after injection, immediately prior to being told it was ok to leave the observation area. Seems to have resolved almost entirely 1.5 hours after injection, though ear still seems to have slightly abnormal feeling.

Within a few minutes of taking the vaccine, my lower lip began swelling. I was moved to the emergency department of Hospital and monitored and treated for four hours. Then I was released. At around 1:30 p.m. I felt my skin singling and started having difficulty breathing. Since I was no longer at my work (Hospital) I went to the closest hospital. This reaction was much worse. My husband drove. My heart rate increased. I was released at around 6:30 pm

I had no reaction following the vaccination. The next day I had very mild soreness at the injection site. The next morning (about 36 hours after the vaccination) I woke up with fatigue and a sore throat. I had breakfast and about 10 minutes later I vomited everything (projectile vomiting, no nausea or abdominal pain). An hour later I had episode of severe watery diarrhea (just one episode). Felt very weak so I decided to sit down, stumbled to a chair, and then proceeded to have a syncopal episode with about 4 minutes of seizure like activity (witnessed, I don't remember that part). Decided to go to the ER, where I had labs, EKG, CXR, head CT scan, MRI and EEG. I was admitted for 24 hour observation, all the tests were normal.

None

Soreness at site of injection

Patient was sitting in a chair approximately 20 minutes after vaccine administration when she became pale and quiet. Monitor asked if she was ok, and she said she was itchy on her face and that her feet were really hot and hives were noted on her cheeks and forehead at 1803. She was moved to a bed with help from other staff and the rapid response team was called. Her blood pressuree was noted to be 155/101, HR-115, O2 sat 99% on RA at 1807. 50 mg IM diphenhydramine administered to L arm by RN. Patient txported to ED for further evaluation.

Sharp pain left arm starting the morning of Dec 19th that worsened throughout the day, limiting active range of motion. Fever started in the late morning, and by that evening my temperature was 102.7. By the morning of the 20th my fever has resolved. L arm soreness improving but not gone, and still feeling fatigued throughout the day.

"Prior to injection, patient stated she was nervous and gets dizzy with shots and cries, but will be fine. Consent given and injection given in L arm. Second after injection, patient stated that she wants to be a pediatrician when she grows up, and then said ""Wait! I am not making sense..."", and her head dropped back slightly and the nurse held her head and asked the monitor for help. Both nurses carefully lowered patient to the ground without incident. She started jerking and then started crying. Others arrived and began taking her blood pressure and provided ice packs. The rapid response team was called, and they checked vitals which were all WNL. After approximately 20 minutes, patient felt good enough to stand on her own. Approximately 20 minutes after that patient felt good enough to leave under her own power."

Sore arm, 12-18-2020, low grade fever (99.2), cough and some chills 12-20-2020 am.

Generalized Rash all over upper torso with feeling itchy. Apparent to RN at approximately 15 minutes post vaccination. Patient (Health Care worker/employee) did not seem aware until it was brought to his attention. 15mg Benadryl administered and sent to Emergency Department for observation. No further symptoms occurred and patient dismissed.

Left sided chest pain Lasted for 10 min Awoke me from sleep

Hives, initially on wrists and arms, chest, then on face (very itchy), chest tightness

Tachycardia, dizziness, headache, vomiting, flushed, cold sweats

Left 2 finger, tenosynovitis, felt most back of hand, worse with extension/flexion second fingers has lasted >24 hours, better with motrin

Sweating profusely, dizzy, throat closure, hard to swallow

My symptoms started 30 minutes after the injection. My throat and tongue started to get very itchy and scratchy. I had to keep clearing my throat. My throat felt thick with secretions.

12/19: After injection: Minor pain at injection site (L deltoid) After 30 minutes: Mild headache and single episode of feeling lightheaded (lasting few minutes): drank juice and water After 1 hour: Additional mild lower back/R buttock pain After 4.5 hours: Moderate L deltoid pain and stiffness, moderate headache, moderate eye pressure/pain, mild body ache, fatigue, moderate dull lower back pain, severe sharp and dull R buttock/leg radiating pain: limping After 6 hours (and retuning home): Symptoms continue to progress, and noted moderate swelling around eyes 12/20: Moderate swollen lump and stiffness to L deltoid, moderate headache, mild/moderate body ache, moderate fatigue, mild swelling around eyes, moderate eye pressure/pain

I am the patient submitted this form, but also a physician. Within 3-4 minutes of receiving the vaccine, my left arm felt heavy/weak, and then began to tingle (full arm paresthesias). This was followed within probably 30-60 seconds by a sense of lightheadedness. Then acute tachycardia, heart pounding (I estimate around 130 BPM). I did deep breathing. Tachycardia was brief, lasting probably 2 minutes. Symptoms slowly got better. I was observed with vitals. All normal, except BP was high (140/90). Arm felt not entirely back to normal for about 30 minutes. Dull soreness in upper arm, left posterior neck/shoulder has persisted since vaccine.

Migraine Nausea Dehydration Low grade fever Fatigue

Had a numb left hand about an hour after vaccination that lasted about 5 minutes.

nausea, fever, chills, aches

12/18 received injection 12/19- woke up at 0700 with fever, spine pain-Lumbar region into the coccyx. Pain radiates down into hip joints and down bilateral femurs. Low grade fever most of the 19th. Nothing higher than 101. Arm soreness at the injection site, not bad, just sore. 12/20- fever broke around 11:00 am, still having this weird bone pain in my lower spine and both legs. 8:00 pm, no fever, arm soreness gone. Still have the low back and leg pain.

Experienced achy muscles, low grade fever, hot and cold flashes, and head ache. Very sore at the site of the injection.

#1. Injection site pain---3 hours after injection, starts injection site pain, progressivly worsening and last for 48 hours. difficult to raise the left arm #2. chills/low grade fever--started around 9 pm 12/18/20, received by Tylenol and ibuprofen, reoccurring after 6 hours, it lasted for about 36 hours #3. severe headache--feeling pulsating pain, starting around 9 pm and relieved by Tylenol and ibuprofen, but reoccurring after 4-5 hours, lasted about 36 hours #4. body aching, especially the lower extremities, coincidence with fever/Headache

Body aches Low grade fever Fatigue Loss of taste

Pfizer-Bio Tech COVID 19 Vaccine EUA #18 Facial flushing, facial warmth, fever 101.4 (post 650mg Tylenol) headache, dry mouth, loss of appetite

Pfizer-BioNTech COVID-19 Vaccine EUA Chest pain starting evening after vaccination and continued through 12/19/20. The chest pain is described as dull/heavy and continued to get worse so was advised to go to the ER. I went to the ER at 7pm on 12/19/20 and had 2 EKGs and blood drawn. It is 12/20/20 today and I still have constant mild chest pain with times that it feels moderate.

Developed Hives about 30 minutes after getting the COVID vaccine. Was given vaccine at 815 am, arms had a burning feeling and hives started to develop. Was also feeling very anxious and hyperventilating. I had no swelling or shortness of breath. Went back to vaccine clinic immediately and there they administered EPINEPHRINE at 846 am. Started to calm down around at 849 am. Burning feeling in arms started to go away and hives started to disappear. Was then taken to the ED department to be

monitored. Because I have had an recurrent hives after EPINEPHRINE, I was given Benedry IV, Solu-Medrol IV, and Pepcid IV. I was also sent home with a prescription for Prednisone as well as an Epi-pen. I am feeling much better now. Hives have not come back, yet. Fingers crossed they don't!

Woke the night following the vaccine with a fever of 100.4, body aches, a headache, and sharp pain at the injection site that made me unable to move my arm. I was unable to sleep or move around without fatigue. These symptoms continued throughout the following day and ibuprofen had little effect. My fever broke after a Tylenol PM and on the second day following the injection the other symptoms started to alleviate.

I had tachycardia within the first 5 minutes of receiving the vaccine. Heart rate increased to 151

Severe facial flushing (redness and burning warmth) radiating to ears and neck beginning suddenly about 48h after receipt of vaccine and has continued without relief for 10 hours. Tylenol and ASA taken after symptom started did not relieve the flushing or burning discomfort. Not accompanied by any other symptoms. No rash present. Felt fine up until the flushing onset at about 48h mark. Feels as how I?ve heard patients describe niacin flushing (I have personally not ever taken niacin).

"About 3-5 min after injection I felt tingling and warmth/flushing in my entire left arm and anterior chest, upper back and achy pain in my left upper trap- felt like a warm IV running through my arm. Associated with tongue tingling. Symptoms lasted about 10 minutes with the exception of the achy upper trap pain which lasted a couple hours - being a health care provider I associated these symptoms with anxiety/excitement about receiving the vaccine but subsequently developed other unexpected symptoms. Over the course of the next several hours noted metallic taste and transient extremity tingling (all extremities) also with some extremity and facial itching - no rash. Now >24 hours after still have the intermittent and transient extremity tingling (most notable in LE's and feet, but also in arms) and skin itchiness/prickly sensation though improved. Had one episode this afternoon (~28 hours after vaccine) of lightheaded, nausea, chills and profound sensation of extremities being ""heavy"" - felt like pre-syncope - which resolved in about 30 min with rest, hydration ."

1.5 hours post soreness at sight and left elbow fold; fatigue, left arm weakness, left neck stiff, right face numb, mouth numb more on left side similar to novacaine wearing off from dentist. Numbness and weakness lasted 30 minutes. Soreness over 24 hours. Friday evening generalized aches and chills. Saturday all day aches, chill, low grade fever. Slept late afternoon due to exhaustion for 4.5 hrs. Sunday morning sweat and slight fever. Sunday evening site slight sore only.

Began having body aches on 12/19/20. Today 12/20/20 feet and hands began to swell badly. Took Benadryl, not effective.

Within minutes of receiving vaccination i had blurred vision, rapid heart rate, extreme nausea, rapid heart rate, shivering but a warm sensation that started in my abdomen that went into my chest. I became blotchy on left arm where injection was per nurse and my eye started to roll back in head per nurse. I was rushed down to Er where i was given water zofran and Benadryl and steroids. BLood pressure was high and pulse was elevated. Was sent home a few hours later w Epi pen and steroids to

take over the course of four days. After coming home i developed at headache and fever and severe leg pain and fatigue that last until Saturday the 19th around the evening. I?m feeling better today Sunday the 20th. My main concern at this point is the arrhythmia and sometimes having shortness of breath.

A very bad headache that kept me awake all night and was making me nauseous

Bottom lip numb and lower jaw and throat tight

Dizzy, tired, weak, nausea, joint pain. I am resting and still feeling the effects. But slowly getting better.

Pfizer-BioNTech COVID-19 Vaccine EUA

Tachycardia, nausea, tingling

Rash, Headache, sore throat.

Previously diagnosed with COVID 19 11/7/2020 and had a mild residual cough that was improving and almost completely resolved. Post vaccine this cough recurred. The presentation and frequency increased and was similar to that of when I was actively infected. This cough has worsened over the days following the vaccine.

Pfizer-BioNTech COVID-19 Vaccine EUA Woke with very swollen and numb upper lip. Took Benadryl and Acetaminophen. Symptoms have greatly reduced over the course of the day.

Pfizer-BioNTech COVID-19 Vaccine EUA Pain at injection site Fatigue Felt ?feverish?

12/19/2020 in the evening Started with frequent flatus . Then stomach cramps early in the morning of Sunday 12/20/2020 at 4am following with diarrhea. Took Imodium 2 tablet after first loose stool. Then another 1 tablet with the second loose stool. Diarrhea continues intermittently. Took another anti-diarrheal medication: Pepto-Bismol Liquid form. Since then diarrhea slowed down.

Metallic taste

shakiness, tachycardia, breathing feels tight - went to emergency dept

syncope following vaccine

Pfizer-BioNTech COVID 19

rash across chest. numbness tingling across arm (injected arm). Bendadryl & solumedrol given, returned to ed the next day with tightness in throat & trouble swallowing - Benadryl & solumedrol given - improvement

Night sweats and fatigue on 12/19/20-Current

Severe right ankle monoarticular arthritis that woke from sleep. (did experience flu-like symptoms ~36 hrs after inoculation but these were short-lived). Unable to weight-bear despite high dose NSAIDS. While have hx of mild enthesitis, have never had these symptoms before.

left arm itchiness, observed patient itchiness did not worsen patient went home

I started having chills at 3pm At 10pm that night, I developed a fever, continued chills, body aches, fatigue, and nausea

Experienced angioedema approximately 24 hours post inoculation. Administered 50mg oral Benadryl with no response. No respiratory distress.

Morning after injection patient reported bilateral rash with some itch from elbow down

felt hot, lightheaded, nausea

Headache for 1 day Severe nausea lasting more than 3 days

Patient stated that 45 minutes after receiving the vaccine he became dizzy and foggy, requiring the individual to sit down for a period of time as they felt unsteady on their feet. No treatment was given, patient decided to have spouse pick them up and go home.

Headache, sore throath

"Approximately 14 minutes post vaccination -- developed numbness and tingling in L arm and ""swelling"" in throat. Denies antecedent illness, allergies, medication use. Member was observed for 1 hr and 45 minutes. No dyspnea, wheezing or chest pain. BP 142/100, P 98, SpO2 98% on RA. Released to home after symptoms largely resolved."

Left axillary enlarged lymph node. The lymph node has increased in tenderness and size

Hives and Throat Swelling - treated with epinephrine and steroid

STRONG PERSISTENT HEADACHE GENERALIZED MYALGIA BACK PAIN UNQUANTIFIED FEVER WEAKNESS

"Within 15 minutes, patient experienced itchy, tight throat ""felt like a tickle in throat"". Airway remained patent. No rash/hives."

Approximately 29 hours after my first dose of the Pfizer COVID 19 vaccine I started experiencing right axillary pain that was accompanied by swelling. Lymph node enlargement was not felt. Symptoms are still present at the time of filling this survey out.

Chills, sweats at night time Body aches Headache

Patient report itching and rash of the neck, upper arm and upper back on Saturday 12/19/20 . 50 mg of Benadryl taken on 12/19/20 and symptoms resolved on 12/19/20.

12/18/2020 ALMOST IMMEDIATLY FELT CHEST TIGHTNESS, RIGHT SIDE OF FACE ITCHY, BACK OF THROAT AND TONGUE WERE ITCHY, LIPS WERE TINGLY; 'FELT LIKE SOMETHING WERE WRONG'. CONTACTED CLINIC AND SPOKE TO PHARMACIST; RECOMMENDED BENADRYL. DID HELP RELIEVE

SYMPTOMS. 4-5 HOURS SYMPTOMS CAME BACK, TOOK MORE BENADRYL. AS OF 12/21 SYMPTOMS HAVE NOT COME BACK. FLU SHOT 10/29/2020

Left arn deltois with swelling hardness and redness at site ~ circumference 3 inches painful non-puritic

Left arn deltois with swelling hardness and redness at site ~ circumference 3 inches painful non-puritic

Left eye puffiness, left eye paresthesia Tx benadryl, solumedrol, head ct scan

Started feeling hot and flush pretty immediately felt dizzy very shortly felt throat closing, like I had a golf ball my throat and my heart started heart racing. Staff provided medical treatment immediately put me on a pulse ox and my heart race was up, kept monitoring me. Pretty quickly I started feeling better in about 10 min. No tests were done or meds administered. After about 10 min all was better I just feel tired and a little bit dizzy. They monitored me about 30 min - I received gatorade and was observed for about 30 min and they let me go since I just felt tired.

1. Severe chills on first night 2. Body pain and ffatigue 2nd snd 3rd day 3. Severe Radiating pain in arm of injection from day 4th and 5th continue

Employee woke up the next day with conjunctive hemorrhage of the left eye

Started with a rash to left hand and rest that spread to bilateral upper arms with scalp itching

Day 1: palpitations, dizziness Day 2: headache, redness, swelling, itching on vaccination site; GI disturbance Day 3: vaccination arm had paresthesia, heaviness, almost stroke-like symptoms; the symptoms started suddenly ** treated in the ER; IV steroids- for possible allergic reaction; tpa- for the stroke-like signs; halfway through the tpa, I felt an improvement with the arm

+ fever (Tmax 100.4), last documented fever at 10:00 pm on Saturday (12.19.20), generalized body aches, swollen L axillary lymph node, + ?knot? in L arm at injection site, endorses redness and warm to touch at injection site

Ear pressure and swelling on same side as injection

Patient refers that about 45 minutes after vaccination felt with frequents palpitations . This episodes repeat during the course of the day. Note: I was notified by patient after he was vaccinated, that he had plans to travel by airplane on Dec 18,2020.When patient call me notifying his symptoms I advised him to report to nearest emergency room for evaluation .

At 9PM I started having rigorous chills,body heat/aches. I took two Extrastrength Tylenol, went to bed. One hour later the chills stopped but the heat/aches continued for several hours. At 8:00 AM I took two more Tylenol and had no more problems.

headache unrelieved by Tylenol or ibuprofen

Within 10 minutes after the injection my left shoulder began to itch was super red and hot. I notified them and per policy I was transported to the ER and was given IM 50mg benegryl, 40mg oral

predinosone and I was monitored for another 1.5hr. 1/2 after the benedryl I still had the redness and flush in the neck and chin area the chest area redness had cleared up. I was released with a prescription of benedryl for 4 days to take every 8hrs for the symptoms. I continued with the benedryl for the next day and the symptoms subsided a little so I stopped taking the benedryl and I continued to take the prednisone.

12/18/20 10pm nausea with vomiting lasting one hour 9 pm headache, persistent and continues today at 12/1/20 at 8:30 am 8pm diarrhea lasting 2 hours

So I got up from the chair to go to the other room to be on the 15 min observation. I started feeling a little weird within a minute. A sharp shooting numbness in my jaw and my head felt a little dizzy, and a burst of heat in my spine. I felt off and sat down and took my BP and my BP was 185/80. Within a couple of minutes I was at the walk in clinic where they monitored me for a couple of hours. The jaw experience went away but I still felt a little shaky. I also had a numbness/tingling in the face and jaw. They gave me a Benadryl injection and it did not resolve. They gave me prednisone it felt a little better (about 30min) afterwards. They checked my airways and it was ok. I had elevated BP but within a couple of hours it was ok . They discharged me since I felt ok and a friend drove me home. Symptoms were better next day but in the afternoon I felt the numbness again on my lips. They decided to prescribe me medro and I started taking it since Friday evening. I still feel a little head ache and like I am a little sick. The headache is still lingering. Left side of my face since yesterday I have a stiff neck. It is like a pain in my face.

Patient stated that she started with cough, runny nose and no fever, she has a hx of alleriges and normally takes Claritin

0845 received injection 0900 started to have palpitations and feeling of ?jittery? BP 132/88, HR 98, RR 14 0912 states feeling better. BP 126/82, HR 88, RR 12 0915 palpitations resolves, states feeling ?normal?. Patient left clinic. Instructed S/S to report or seek medical attention.

Fever 102.4, Headache, Joints, Muscle aches, lymph node swelling, generalized soreness at site anticipated symptoms but more severe lasting more than 48 hours. Taking Tylenol around the clock. Tylenol did not help at first but feeling somewhat better now. However, lymph nodes still swollen and hurting.

on 12-20-2020 complained of arm soreness, muscle aches, low grade fever and cough for 24 hours.

No soreness of injection site until next date, 12-19-20. Slight soreness at injection site but woke up with body aches/pain, very stiff neck and head on left side of body, migraine type headache. Extremely fatigued. Symptoms were throughout entire day. Was flushed in the face that early evening, took temperature, normal, 97.9. Took 3 Alleve every 3 - 4 hours throughout day. Felt best for that date about 8pm. Woke up on 12-20-20 with headache still but overall felt much better though did have some upset stomach with diarrhea. 12-21-20 feel fairly well. Went to work. Left arm still slightly sore. Slight stiffness in head and neck with slight headache still remain.

Patient refers that on December 18,2020 developed headache (left side) and pulsatile pain in left eye, also generalized body ache associated with hot flashes . She took Iboprufen , Relafen and Acetaminophen with improvement for about one hour and pain later returned. If condition worsen she was advised to go to the nearest Emergency Room.

Symptoms started at midnight 12/16/20 and ended approximately 5:00pm 12/16/20, body aches, extreme fatigue , sore throat, sinus congestion, headache , pain and redness at injection site.

Approx. 5 minutes after receiving the shot in my right upper arm, my right hand and fingers felt like they were asleep - numbness & tingling. I had use of the hand but it felt like something was blocking the sense of touch and fine motor skills - touching fingertips to fingertips, were impaired. Situation lasted for about 24 hours before appearing to resolve. Sense of touch in fingertips still a little odd but hand is fully functional at this time. Thank you.

Pfizer-BioNTech COVID-19 Vaccine EUA 2 hours after injection: body aches and chills (duration approx. 8hrs) 9 hours after injection: nausea and vomiting 18 hours after injection: severe heartburn, nausea, and vomiting 24 hrs after injection: nausea and all over body soreness 48 hrs after injection: mild nausea and arm pain at injection site 72 hrs after injection: no symptoms present

on 12-20-2020 arm soreness, muscles aches, low grade fever and cough for 24 hours.

HEADACHE INFRAORBITAL PAIN GENERALIZED PRURITUS

9:11 am received injection 9:15 cool feeling from left arm injection site radiating to abdomen 98% on room air pulse 111 bp 141/89 9:21 cool sensation dissipating in arm. Cool sensation in stomach. Benadryl 25mg IM administered. Localized rash at left injection site. Pulse 111 100% on room air 9:27 still an intermittent cool feeling in stomach

Became unable to swallow and mouth got dry. Was given Epinephrine, Benadryl and Famotodine. The symptoms subsided within 2.5 hours.

light headedness, claminess, parasthesias of the hands and feet, worked night shift and day shift. no treatment

12-28-2020 body aches especially back pain, dizziness, headache and fatigue for 24 hours

Headache, fatigue, vomiting

"Patient described Hive, approximately 3 inches in diameter on her left thigh, Intermittent fever and ""Bone Aches"". Patient reported taking OTC analgesic and antihistamine. Otherwise did not seek Medical Attention."

Within 15 minutes of receiving the vaccine, patient began complaining of rapid heart rate. RN came over to monitor, and found HR @130 BPM. Rapid response/medical emergency was called. Refused further medical treatment. Stayed 5-10 mins longer than the 15 minutes recommended observation period, and felt better before leaving.

rash on neck and chest, felt flushed

symptoms started 8:00 pm 12/16/20 as of 3:00 pm on 12/17/20 she still had symptoms, headache, body aches, chills shortness of breath and fatigue. 12/21/20 RN called patient the symptoms have all resolved at this timel.

12-28-2020 body aches, back pain, dizziness, fatigue and headache for 24 hours

Began complaining of dizziness shortly after getting hte vaccine. She did not eat anything since the day before. Gave juice and a granola bar. Shortly after finishing food, began complaining of her heart feeling fluttery, a medical emergency was called. She was evaluated and found to be tachycardic. Refused further medical treatment, then ate lunch, and returned to work. She was observed on site for an additional 30 minutes beyond the 15 minute observation period.

About 8min after the vaccine I got a severe headache on the top of my head and was at a 10/10 and dropped to a 7/10 after a few moments and finally went away on its on. I was very flushed and hot. I was laid down and given ice pack. Started feeling a littler better but experienced riggers and was transported to the ER where I was given benedryl, fluids and was monitored for a few hours. I was released but for the next 2 days after I was super tired and laid around and slept for 2 days. Today I am at work but I feel very tired and fatigued

Chills, Muscle pain, headache, joint pain, tiredness

Rash shortness of breath

Pfizer-BioNTech COVID-19 EUA After receiving the vaccine, during observation period (about 10 minutes after the dose administered), patient became tachycardic and nauseous. Patient was brought over the the ER at 7:05 am with non-intractable viomiting with nausea. Ondansetron inj 4mg IVP x1 given at 7:40am, at 7:45am P 135/95; P 105 ; R 20; WBC 16.2 Patient felt better, tolerating PO, asymptomatic and discharged home at 8:34am

Patient began to complain of feeling dizzy. Was found to be anxious, flushed and tachycardia. Was asked to lay down. Medical emergency was called to respond. Patient refused further medical treatment. Continued monitoring for an additional 45 minutes after receiving the vaccine, and left in good condition.

"""Pfizer-Biontech Covid-19 Vomiting since Saturday."

difficulty breathing, paresthesia, dizziness. 1.5 hours after vaccine worsening dyspnea, tingling in fingers and toes, felt like a ball was in her throat, previous anaphylactic reaction. Pepcid, benadryl, solumedrol with continued worsening epinephrine IM give. O2 sat 81% room air, O2 provided with increase sat to 100%, second dose of epinephrine 0.3 IM. Weaned of O2 and discharged with prednisone.

Employee calling to report a reaction after receiving a COVID-19 vaccine. Vaccine Name - Pfizer Vaccine Lot # - EJ 1685 Vaccine Date and time - ? 12/18/2020 @ 9:40am Is this your first or second dose? First

Date and time of symptom onset - ? 12/19/2020 @ 12am Symptoms - ? Headache, nausea, fatigue, runny nose, no fever, cough, rash on left eye, itching Last day of work and shift - ? Friday 12/18/2020 Home remedies? - Claritin 5 mg 12/20/2020 @ 8:30pm, Warm steamy shower this morning 12/21/2020 Any improvement? - Patient noted symptoms are better and gone except for on & off headache. Recommendation? To continue to monitor symptoms & take ibuprofen or Tylenol when headache comes back. Call back if experienced any other symptoms. She's not back to work til 12/23/2020. advice to call work if she's unable to work and notify employee health for missed work. If 4 or more days, to send doctor's note for back to work clearance. Employee voiced understanding Employee of information ? yes Employee voiced any concerns ? no Employee?s questions answered to employee?s satisfaction - yes

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Needle retracted during vaccine administration and some spillage occurred. It is estimated that this person received about half the prescribed dose.

Complained of nausea, and feeling light headed. Turned very pale then got extremely flushed after. Complained of feeling warm and hot. Vision turned a little blotchy. Stayed for longer observation. Felt better when left vaccine clinic.

FELT DIZZY ABOUT 20-25 MINUTES AFTER SHOT, GIVEN GATOR AIDE AND REMOVED MASK IN AREA WITH NO OTHERS ...FELT LIL BETTER ITS BEEN ABOUT AN HOUR AND HALF STILL FEELING LIL DIZZY OR OUT OF IT BUT OTHERWISE OK.

Approximately 12 hours later, I started experiencing shortness of breath and felt my airway was closing off. I immediately took 25mg of Benadryl and monitored signs and symptoms.

Approximately 12 hours later, I started experiencing shortness of breath and felt my airway was closing off. I immediately took 25mg of Benadryl and monitored signs and symptoms.

"Staff member stated that she had an allergic reaction ""after the vaccine""...unsure of time frame and was still at work. She has a rash, hives and swelling around eyes....no immediate anaphylaxis. She verbally described her incident. Was treating with Benadryl (even though there was a stated allergy

from 2013), then followed up with her family doctor, for steriod therapy on 12/18. She has not communicated with me further or have any absences from work at this time."

Felt Flush, Elevated Blood Pressure, Nausea, Tight Throat

"I was ok for first 15-20 mins post vaccine and was sitting in chair and calling family and friends When I stood up I felt 'funny""- kind of hard to describe I walked around and mostly felt ok but not hundred % but didn't feel dizzy but didn't feel 100% myself either I checked my radial pulse and it felt normal and there was no BP machine there to have a check done I left hoping to feel 100% soon I walked to my car in the parking lot and started driving home Around 200 yards from the hospital I felt weird warm rush like feeling through my whole body Knowing that anaphylaxis can occur at this stage I panicked and turned car around and went directly to ER to be checked out My BP was not low and I was observed for short duration and discharged home then- vitals were taken almost half an hour post vaccine Further records can be sought from ER as they should have reported this as well I also had arm pain/malaise and low grade temp of 100.5 at home for 24 hrs that resolved subsequently The initial symptoms within first half an hour made me file this report"

Felt dizzy

Pt states she felt short of breath, had a hard time catching her breath, and fatigued.

Pt states she felt short of breath, had a hard time catching her breath, and fatigued.

Right side of lower face and lip began feeling numb. No drooping or issues with movement. Numbness continued from about 830p on 12/20 and is still present at the time of this report.

States after receiving vaccine, reported tingling/electrical felling in legs & arms. 4 hours after, rhinorrhea. At 48 hours after vaccine started having nasal and head congestion. States body aches X 12 hors but improved at 48 hours. States is feeling better with body aches now, is also having HA x 24 hours. Is having them moderately, also noticing fatigue at 12 hours after injection,

Low grade fever T-max 99.6F lasted about 12 hrs. broke with Tylenol. L arm soreness - improving but still ongoing (today day 4) after injection. Additionally have injection site reaction - red tender firm lump at left arm approx 2-3cm - slowly improving but still present. Now being more itchy. No drainage.

Lymphedema, Right Axillary and Right Neck.

Fever and chills 100 F for 2 days, Body ache injection site pain for 2 days Injection site itching 2 days

dizziness 5 minutes after vaccination. no other symptoms released after 35 minutes. completely resolved

12/15/2020 30 minutes after vaccination, started to taste a metallic taste; lasted 24 hours ;'like chewing on tin foil'. Pain at injection site 48 hours. 12 hours after vaccination, joints hurt, left hip is 'excruciating' . 72 hours later, joint paint dissolved. But the left hip, the pain is awful. Taking motrin, muscle relaxers, physically walking with a limp, cannot bend over, have assistance with sit or stand. Had COVID19 in

05/2020. Same hip pain when had COVID. Went away after 3 months. 'Hip pain now is 5x's worse than when had COVID'; debilitating; constant pain. appt with PCP 12/30/202; xrays, mri, etc. May go to the ER if worsens but Chief Officer Urgent care for COVID19 and cannot take the time away.

nausea right after vaccine Sore arm at the injection site. I could not lift my arm, chills, could not sleep, body aches, headaches,

Patient/Employee became dizzy 15 min after covid vaccine

Rash on chest with a burning sensation, bruise on lower leg, applied hydrocortisone on rash. Leg still showing some bruising, Rash is mostly gone now, but burning sensation is still there.

Friday night same night of vaccine. Arm started aching and hurting. After my shower, my whole arm was in pain. Pain then moved all the way to my back. I took two tylenol, and it calmed it down. At 3 am, it started hurting really bad, I had to take a lortab - a stronger pain med at 5am that morning. Around 10am, my whole back started hurting, and that evening, it still was hurting. I ended up taking 3 lortab that day. The pain went to my neck. On Sunday, I ended up taking two lortab . All together, I took 5 lortab to ease pain from this vaccine. I was scared that I was getting another blood clot from the feeling of the pain. I am still just sore. NOTE: I am on blood thinner

palpatations increased heart rate, slightly hypertensive 20 minutes after vaccination resolved on own

I felt extremely hot, headache and dizziness - pressure on left temple and top pf head - next day had diarrhea.

Throat and chest tightness following vaccination- went to ER and received epinephrine, solu-medrol, benadryl, famotidine, and EKG due to tachycardia.

Fever, body aches, migraine, swelling/redness/warm/hard lump at injection site, nausea. Symptoms started approximately 6:00pm 12/18/20

injection site pain, tiredness, severe headache, muscle pain, chills, injection site swelling, nausea, not feeling myself, difficulty breathing, fast heartbeat, dizziness and weakness in lower extremity and excruciating lower back pain. Immediately after vaccine was given, I got the side affects. Felt a little better for 2-3 hours and then it hit me hard again and lasted till the next day. Currently my arm is swollen.

Headache

12/16/20- body aches, chills. congestion, stuffy, runny nose, occasional cough from drainage, fatigue
12/17/20- congestion, stuffy, runny nose, some cough and drainage.

Developed hives/welts on her torso, chest, arms and legs. The hives hitch. Taking Benadryl and topical antihistamine lotion.

intense arm pain, migraine, nausea & vomiting

Pfizer-BioNTech COVID-19 vaccine EUA On Friday December 18th at 2:45 p.m. I received my first dose of the vaccine. After the injection while waiting in the observation area, I noticed my arm felt cold and felt weaker. I was able to move my hand and did not have tingling. I was cleared to leave after 15 minutes. While driving home approximately 35 minutes after the injection I had a quick onset hot flash (felt like it came from my left arm which is where I received the injection). Then my heart started pounding. I noticed my heart rate was climbing. It topped out at 170. I was having difficulty in breathing but that was related to my heart rate. I pulled over and called 911. I felt as if I was going to pass out. After 2 minutes or so my heart slowed and stayed at a rate between 120-130. I never lost consciousness. I canceled the ambulance and felt as if I could drive home. 30 minutes later the episode happened again. All the same symptoms as the first. The pounding felt harder and it was slightly harder to breath until the rate came down again. Again, I felt as if I was going to lose consciousness but never did. Each episode lasted about 2 minutes from hot flash to slower heart rate. This time the ambulance came. No rash. No hives. No swelling. BP-160/90 HR-120-130 Sinus Tachycardia on a 3 lead EKG I did not need transport to the hospital. I started feeling much better around 5:00 p.m. The coldness I felt in my arm was gone. My arm no longer felt weak. The hot flash, rapid heart rate and faint feeling did not return. I am a Paramedic with the Fire Department. Provided the Vaccine to EMS workers. I received my vaccine at the: Fire Department December 18, 2020 Injection time 2:45 p.m.

Have swollen lymph node on right side arm pit. Got vaccine on right side of arm

Facial flushing, bright red and itchy splotches over the face, arms and chest. Had diarrhea for 24 hours. She took a Benadryl and got relief of symptoms.

The patient reported the following symptoms approximately ~24 hours after receipt of the Pfizer BioN-Tech COVID19 vaccine: tachycardia, dry mouth, and itching between the toes and behind the ears. The patient stated she took oral diphenhyramine with relief of symptoms.

Headache, Fever, Chills, Loss of Smell, diminished taste, Nausea & Vomiting, Diarrhea

Itching began approximately 30 minutes after vaccine was administered. Itching started on the right arm and then the left arm and then the legs. Redness on the arms was noticed. Redness on the chest, but no itching on the chest.

Patient complained of light headedness, stated right arm cool, and bad taste in mouth. BP 123/80 initially. Pt stood up and became light headed BP 154/90 HR 76 SPO2 98%. RRT called. Pt transported to Emergency Department.

Pain at injection site. 24hrs after injection site, my left arm started hurting and painful to the touch. At 48 hours, the injection site is very raised and red. It's approximately 3inches long by 2inches wide. It's very sensitive to the touch and very hot. I went back to the medical clinic and was told to draw a circle around the site, and watch for further spreading, apply an ice pack, and submit this reaction to Vaers.

Patient reported feeling lightheaded, dizzy, tingling, itching, hot feet bilaterally, racing heart, and feeling flushed. Increased BP and heart rate were noted. This reaction lasted approx. 15 minutes.

Employee began experiencing tingling in roof of her mouth, watery eyes and itchy throat. She was taken to ED for further evaluation and treatment.

Runny nose, congestion, loss of smell for 36 hours

*Pain at injection site; 10 hours after injection; lasted 48 hours *Myalgia, primarily in shoulders; 12 hours after injection: lasted 24 hours; Ibuprofen 400 mg *Chills; 14 hours after injection; lasted lasted 15 minutes *Joint pain (hip, knee): 12 hours after injection; lasted 24 hours *Diarrhea; 72 hours after injection; lasted 6 hours; unsure if related

within 12 hours: sleepiness (very), pain at injection site & around to muscles in right shoulder; slight pain in moving injected arm above 45 degrees, slight generalized muscle aches.

12/16/20 awakened to an unusual headache and feeling more sluggish. Checked temp and it was 100.4. Supervisor notified and advised to get COVID testing. Throughout the day 12/16/20 temp stayed 100 and I developed body aches, arm was very tender at injection site. 12/17/20 afebrile and HA nearly resolved.

1505 right eye heaviness, BP: 114/61, 02 saturation: 100%, HR:74, pt sent to ED

One hour after receiving vaccine, my entire body became bright red and hot, the thick black lines on my tattoos on my right arm became so hot they felt like a burn and became raised, and the lymph nodes in my neck became swollen. My skin was hot to touch for the next 20 hours. The next 4 days I felt very lethargic. On Sunday (day 4), I developed a rash to the front of my abdomen that was in clear lines not extending to my abdomen. The rash also spread to my anterior neck. My hands also became bright red within an hour of the rash developing. This all disappeared with in 2 hours. My arm was extremely sore until I woke up yesterday morning (almost like I never received the vaccine). On Sunday as well, I had diarrhea and extremely painful gas. This stopped by 1600 Sunday night. Today, Monday, I feel generally back to normal other than mild lethargy.

Employee reported itching to roof of her mouth and numbness to right side of her throat. She also had elevated HR of 113. She was taken to ED for further evaluation and treatment.

Felt Flush and hot around 3 min after vaccine given. Had a slight taste change that lasted for a second. Heart rate, normal 60s, increased into the 80s.

Aches, fever, large swelling in left armpit

Headache, dizziness, muscle aches (head, neck, shoulders). Onset 5 minutes after vaccination. Symptoms resolved within 30 minutes.

"Pt received the COVID Pfizer vaccine at 1324 and at 1335 pt c/o feeling anxious and flushed. Pt VS: 143/94 91 18 99% AA. Pt admitted she had not eaten before coming in for vaccine. Pt put in recliner chair and taking water and rice crispy treat without difficulty and symptoms resolved. Pt kept for continued monitoring. 1350 pt c/o of ""not feeling right"" and that she was going to pass out. Pt layed

back in lab chair; 02 at 2L per NC applied. B/p 140/100 HR 127 02 sat 100% pt pale, cool and shivering; pt c/o she didn't feel right. Benadryl 50mg IM given at 1351 and 911 called. Pt had no hives, No itching lungs clear, HR 103 and 02 sat remained at 100%. Continued to monitor pt: VS 1400 140/90 103 18 100% on 2L/NC. Pt reports no NKA, Meds: Esterace VAg Supp started 4 days ago Levothyroid 75mcg po daily Pt has never had reaction to medication or vaccines in past. Pt still c/o feeling week but better--held off on Epi since EMS had arrived 1400. Pt transferred to ER in stable condition. 1405: ER called and report given."

left sided non positional chest pain. seen in ER . Was treated with Toradol and resolved. Negative work up in emergency room. for cardiogenic or pulmonary causes.

pain and itchying over L cheekbone, HTN Solu-Medrol 125mg IVP, Benadryl 50mg IVP slowly, Lisinopril/HCTZ 10/12.5mg PO symptoms resolved in 2 hours of observation and management

Reported tongue tingling and increased heart rate from low 90s to 130. No airway compromise resulted and tongue tingling resolved after 1 hour.

runny nose, chills, diarrhea, shortness of breath, HA tiredness and chest pain

Symptoms started early morning hours following the shot, chills, extreme body aches, extreme headaches, fatigue to the point that it was difficult to get out of bed. The skin on certain areas of my body are very sensitive and have a tingling sensation.

Employee reports 20 minutes after receiving vaccine she began to have pain across neck and shoulders, stiffness, nausea diarrhea, headache, body ache

Itching. Was given Benadryl PO by Walk-in clinic. Observed for 4 hours. Sent home with family member.

Sudden onset of intense rush of heat through body, intense increase in heart rate and inability to swallow, trembling and shaking. Employee was in car, returned to hospital ER. ER administered fluids, and diphenhydramine.

12/17/2020 VERY ORGANIZED. AFTERNOON/EVENING SORE ARM. 12/18/2020 WORKING IN ER WEARING M95 MASK AND MASK OVER PER EMPLOYER, TO WEAR WHOLE SHIFT. 9:30 NOTICED A 'FLOATER' IN RIGHT EYE, SHAPE OF A CLOUD., 10-12 WAS QUITE LARGE. 11AM NOTICED BLIND AREA IN EYE, DECIDED TO NOTIFY OPTOMETRY. EXAMINED BY DR. HEMORRAGE IN RIGHT EYE, COTTON WOOL SPOTS IN BOTH EYES. F/UP IN 1 MONTH WITH OPTOMETRY. FLU SHOT 10/2020

anaphylaxis

COVID like symptoms including fatigue, body aches, runny nose and HA.

Chills around 3am night of vaccine, moderate myalgia, specifically in neck and lower legs day after vaccine. Resolved completely 2nd day. No fever noted.

metallic taste in mouth, nausea

throat and face swelling, headache rate 10/10, nausea, vomiting and diaphoretic-Was seen in the emergency room and was given Toradol, Benedryl, Pepcid

Fever

1712 tongue tingling, 02: 100% 1725 complain lip tingling, transferred to ED

PAIN , REDNESS AND IDURATION ON VACCINATION SITE

Employee calling to report a reaction after receiving a COVID-19 vaccine. Vaccine Name - Pfizer Vaccine Lot # - EJ1685 Vaccine Date and time - ? 12/19/2020 @ 2pm Is this your first or second dose? First Date and time of symptom onset - ? 12/19/2020 @ 9pm Symptoms - ? Fever, body ache, headache Last day of work and shift - ? 12/19/2020 Home remedies? - Tylenol Any improvement? - Resolved. No more symptoms Recommendation? Continue to monitor and call us back if symptoms comes back. She off work today, scheduled to go back to work tomorrow. Employee voiced understanding Employee of information ? yes Employee voiced any concerns ? no Employee?s questions answered to employee?s satisfaction - yes

Employee reported purple discoloration to Right Arm and Right fingers. She stated her cap refill was sluggish, she had chills and a redness across her chest and stomach. Employee was evaluated and treated in emergency department.

Pt sitting in observation area. c/o L arm whole arm aches and pinky finger feels numb on outside. does have feeling, can move fingers equally, blood flow to finger with blanch test slightly slower. no redness/swelling noted on arm. no bleeding under bandaid. not improving. no s/sx distress. (dizzy, SOB,) directed to ED (where pt works) for assessment at 0810. Pt will complete workers comp form.

fever and chills for approximately 3 hours on 12/16/20

Received Pfizer COVID-19 Vaccine in right arm. 1 hr later noted left sided facial tingling lasting 48 hrs.

Fatigue, night sweats, chills, body aches

None stated.

Palpitations - patient stated he may have anxiety attacks when getting shots. Patient sent to ER for evaluation

Itching

Clammy, flush, dizziness, syncope, tachycardia

1845: hand numbness HR: 102, shaky, reports last meal was 3 hour previous 1904: HR:72, feeling better and requests to go home, decline further care

The day of the vaccine I had a sore arm. The next day I woke up extremely tired, weak, like I was in a mental twilight zone, no sneezing no coughing, notice on the right lower lip a little herpes, very little

about 2mm wide 3-4 mm long,, never had it in that location before, the blister is gone. Mild nausea, headache and joint pain (intermittently) for about 24 hours.

sx: itching treatment: Benadryl, pepcid & solumedrol.

tiredness, body ache, nausea

12/18/2020, 11pm, swollen itchy hands duration 7 hours, 12/19/2020, 6am swollen itchy hands and feet duration 5 hours, 12/19/20, 12pm body rash/arms, legs, abdomen duration 2 hours, 12/19/20, 3pm B/L UE lymphadenopathy duration 3 hours, 12/19/20, 8pm, injection site/L arm/shoulder/L clavicle swollen duration 3 hours.

Received vaccine around 7pm on December 18, 2020 and worked the midnight shift. Went to lay down during the day of December 19 and stated joints and body were severely achy way beyond normal. Did take a narcotic for pain control with no relief. December 20th symptoms had resolved.

Ten minutes after receiving the vaccine she experienced throat tightness and numbness and tingling of her extremities. She was seen in the ED and given oral pepcid and benadryl with relief of symptoms within an hour.

severe body aches, chills, left arm pain, red, warm and swollen lump at injection site

12/21@11:50-Caller stated that he had vaccine at 9am and had a seizure about 4am the next morning. Patient also had slight head. Caller stated that he is feeling better no medications were given .Caller had Cat scan and EEG. Caller has follow up 12/22.

"COVID vaccine was administered by local health department in hospital setting. Approximately 10 minutes after receiving the vaccine, the patient reports feeling ""weird,"" short of breath, heart racing, dry mouth, & anxious."

Patient reported tingling in tongue for ~30 minutes following vaccination. Monitored for 40 minutes and left clinic without symptoms.

Patient reported twitching to right eye and a warm sensation 5 mins after injection. Resolved by 10:41am.

Pfizer-BioNTech COVID-19 Vaccine EUA I received the first dose of the vaccine at the end of a vaccination clinic during which I had been administering the above vaccine. I completed screening, received the injection and waited under medical observation for about 20 minutes post-vaccination. Approximately 10 minutes after leaving the clinic (30 minutes after receiving the injection), I experienced a sensation of facial flushing, palpitations, a sense of anxiety, mild chest tightness, and lip numbness that spread into my face. I did not have any shortness of breath, tightness of the throat or any apparent swelling of the lips, tongue or face. The above symptoms lasted about 10 minutes and gradually dissipated over the next hour.

Do no suspect that vaccine caused patient condition and resulting inpatient admission. Suspect patient had COVID-19 at time of vaccination, but had not developed symptoms yet. Here is timeline: Patient went to ED on 12-18-2020 at 22:51 with complaint for fever and shortness of breath. Patient ended up testing positive for COVID-19, 12-19-2020 00:09, but was not symptomatic at time of vaccine. As of 12/21/2020 12:04 pm, patient is still inpatient and on comfort care/hospice.

Arm soreness. Small bump at injection site.

About 15 minutes after the injection employee reports her throat began feeling tight and she was having some trouble swallowing.

5 minutes after (4:28 pm) receiving the vaccine I experienced dizziness and nausea with stiffening of my neck on the left side. After laying down for a while I felt better. When I got home I wasn?t feeling right so I took it easy (6 pm). Last night I couldn?t fall asleep because I was very achy and weak with a sharp pain in my chest. This morning (5 am) I woke up feeling dizzy, with cold sweats and general malaise.

Patient endorses hx of vasovagal reactions with vaccines, patient reports slight lightheadedness 1-2 mins after injection, patient denies syncopal episode and reports feeling better during the ?observation? window. 12/19: upon awakening, noticed redness and swelling to injection site. 12/20: Patient reports improvement of redness and swelling at injection site. 12/21: Patient endorses at time of wakening red rash (blancheable per patient), mildy pruritic to L side of chest wall. When patient called (at approx. 10:35 am), reports rash has now become ?generalized.? Patient denies changes in hygiene products.

Light head, oral & generalized itching feeling flushed 25mg Benadryl PO - Resolved Sx

Hives Pharyngeal Irritation Improve with IM Epinephrine

"08:15 am - Pt reports ""feeling flushed and my heart is beating fast"". HR 96 08:23 am - Pt states ""I really don't feel very good. I feel very dizzy"". Assisted to supine position on cot. HR 100 08:26 am - No longer feeling dizzy, but still feeling flush. HR88 BP 156/93 (L) arm 08:30 am - HR 92 BP 161/101 (L) arm. Symptoms unchanged. 08:33 am - HR 97 BP 173/100 (L) arm. Symptoms unchanged. 0841 - HR 94 BP 170/98 (L) Pt reports ""No longer feeling flush, but still shaky and still feeling my heart beating fast with palpitations. 0842 - HR reg 90 BP 164/95 (R) arm 0845 - HR reg 84 BP 163/93 (R) arm 0848 - Pt reports that she is still feeling like she has a rapid heart rate. 0850 - Pt sitting up on side of cot. HR reg 83. BP 163/95 (R) arm."

Pfizer-BioNTech COVID-19 Vaccine EUA: Vaccine recipient has a history of losing consciousness after administration of injections and drawing blood for laboratory work. He stated that he did not have issues after his recent seasonal flu vaccine. After administration of the COVID-19 vaccine, the vaccine recipient drank some orange juice. The APN who was monitoring him after vaccination watched him become unresponsive shortly after. The APN raised his legs in an attempt to stimulate him and check his pulse. A CODE-10 (Medical emergency for outpatient, visitors, and employees) was called. Vaccine recipient regain consciousness and refused to go to the emergency room for follow-up. The vaccine recipient felt better, checked out of the vaccine clinic, and walked out on their own.

During the 10 minute observation period, patient developed tightness in chest as if she was having an asthma attack. Assisted to stretcher where she used her albuterol inhaler. Her SaO2 was 99% RA. After 10-15 minutes, she began to feel better.

pain at injection site malaise muscle aches fatigue

"patient felt ""very hot at 10:05 became flushed, skin was reddened all over. waited 10-15 minutes improved went home and developed red blotches all over. took benadryl po at 1100 am at home and symptoms resolved. tc to client today 12/21/2020. he is fine at this point."

severe joint pain, starting day 3 after and worsening since then

On 12/18/20 the next day at ~0830 he experienced SOB, heart palpitations, and fever. He was taken to the local hospital via ambulance. He was tested for Covid-10 at hospital. Unknown result. Discharged from hospital around 1545.

Pfizer-BioNtech COVID-19 Vaccine EUA: Pt brought up after rapid response to COVID vaccine. Pt c/o throat itching, back itching, hot, and flushed. Denies diff swallowing at this time. Upon arrival to ED, AOx4. NAD. Flushed/WD. GCS 15. Ambulates independently with steady gait upon arrival. Pt. has documented allergies to Latex, ciprofloxacin and Amoxicillin-pot Calvulanate.

Shortness of breath and cough started about 24 post vaccine. Symptoms continued and slightly worsened over next 48 hours.

Patient associate stated later that evening she felt her heart was racing, she felt dizzy and had chills. This patient stated the evening she received the shot she developed a headache. Patient took advil and felt better

39-year-old female with history of ADHD, anxiety, melanoma presents with palpitations. Patient received a Covid vaccine today and started having palpitations, lightheadedness, shortness of breath and feeling flushed a few minutes afterwards. Rapid response called and patient taken to ED for assessment. Patient denies facial or oral swelling, rash. patient denies any recent fever, nausea, vomiting, cough, diarrhea. Denies chest pain, abdominal pain. Last menstrual period end of November. Has allergies to Bactrim and clarithromycin. Presentation concerning for possible vaccine reaction, no anaphylaxis. EKG and labs within normal limits. Patient was rehydrated in the ED. Patient was discharged home on same day (12/20/2020). Pt alert and oriented x 4. Pt ambulated out of ED with a steady gait in no apparent distress.

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home on same day (12/20/2020). Pt alert and oriented x 4. Pt ambulated out of ED with a steady gait in no apparent distress.

Headache, nausea, tiredness, feeling unwell and injection site pain. Warm to touch injection site, raised lump on left arm.

Numbness un lower lip. Soar throat Headaches, patient allegedly took Maxal 10 mg at 9:00am. Erythema in the neck area.

Caller stated @ 10:15 am and about 5pm that afternoon nausea, itching and welts on the face and burning the ears. Caller took 50mg Benadryl. Once at hospital she received Decadron injection 4mg. Caller slept for two hours and symptoms had dissipated.

"Approximately 12 hours after receiving my Covid vaccination, I experienced onset of severe pharyngitis and BL earache along with severe swelling of the glands in my neck and jaw. I developed a severe headache, photophobia and BL eye pain. I developed lesions and ulcerations on the skin surrounding my mouth. My lips cracked and developed blisters and ulcerations. I developed intra-oral and buccal lesions and ulcerations. I developed nausea and severe diarrhea. Severe myalgia, skin sensitivity and fatigue. Later in the day on 12/19/2020, I developed changes in my sense of taste and smell. Everything had a metallic or ""coppery"" taste, and my sense of smell was diminished. The next day, 12/20/2020, the disturbances in taste and smell worsened. The symptoms were severe on Saturday 12/19/2020 and Sunday 12/20/2020, and have begun to improve today--Monday 12/21/2020. No further skin or oral lesions, blisters or ulcerations, and the existing lesions are now healing. Continued diarrhea and GI upset. Other symptoms are improving."

Muscular pain, general malaise Treatment: Famotidine, Acetaminophen

Fingers started tingling , progressing to numbness ascending up the left upper arm. Symptoms started approximately 10 minutes after receiving the vaccine in the same arm.

Pt left triage vm, said she received the Covid vaccine Thursday, on Sunday began having frequent stomach cramps that have not eased up. She is at work today, but is nauseas, still having frequent stomach cramps

Complaints of tingly in left leg, warm feeling all over body. This happened one hour after vaccination. Tingly resolved, but leg is still sore.

Patient reported metallic taste in the mouth immediately following vaccine, dissipated after five mins.

Severe soreness at injection site, uncontrollable shaking and chills, severe joint pain, muscle aches, heaviness of limbs, migraine like headache, abdomen bloating and weakness all within 12 hours of vaccination. Continued off and on over next 48-72 hours although symptoms were more mild within 48-72 hours.

Patient states that she is experiencing a headache, low grade fever 99-99.7, neck and shoulder soreness and is 12 weeks pregnant.

Muscle soreness at sight of injection

severe abdominal pain experience 2 days post vaccination of dose 1 of 2. Diagnoses with early acute appendicitis on Friday December 18th and had a laproscopic appendectomy on Saturday December 19th.

Had dose #1 at 1620 and started feeling itchy on her head and face about 1700. Face red. No difficulty breathing. Given 25 mg benadrly po. Observed and improved. Returned to clinical unit as a patient care tech about 1745. At about 2200 she started having swelling in her face and lower lip and tingling in tongue and left upper and lower lip. Taken to ED in our Facility. Given benadrly 25 mg, famotidine 20mg, and prednisone 60 mg all PO x 1. No difficulty breathing, or swallowing, no wheezings or angioedema of mouth or throat. Sxs improved . diagnosed with allergic reaction. given instructions when to return. Given instructions for Benadryl and famotidine otc use. given script for prednisone 40mg x 5 doses. DC at 12/19 /20 at 0144 to home. 12/21/20 1000 this rn called patient at home. She is doing much better with redness in her face and itching in her back and face. No swelling or rash. Last had benadryl last night. has been taking multiple times a day for the itching. had famotidine x 1 on 12/19. She has not filled the script for prednisone. I told her if she could tolerate itchiness tomorrow w/o use of benadryl she could work her 1600-2400 shift. I will discuss her taking covid vaccine #2 with Medical Director for Employee Health, Dr.

Approximately 10-15 minutes after receiving COVID-19 vaccine, patient reported itching, tingly feeling, face appeared more flushed. Seemed anxious due to history of allergic reactions and reported slight shortness of breath. Treated with diphenhydramine 50 mg po and epinephrine 0.5 mg IM and transported to Emergency Department. Observed in that area and released a few hours later as symptoms resolved.

Employee calling to report a reaction after receiving a COVID-19 vaccine. Vaccine Name - Pfizer Vaccine Lot # - EJ1685 Vaccine Date and time - ? 12/19/2020 @ 2:40pm Is this your first or second dose? First Date and time of symptom onset - ? 12/19/2020 @ 10pm Symptoms - ? congestion, dry cough, harsh voice Last day of work and shift - ? 12/20/2020 11:30am-8pm Home remedies? - none Any improvement? - no Recommendation? Referred to Employee Health command center for Covid-19 testing Employee voiced understanding Employee of information ? yes Employee voiced any concerns ? yes Employee?s questions answered to employee?s satisfaction - yes

Vertigo. No treatment required. Resolved spontaneously.

Joint inflammation with pain, developed knot at injection site with severe pain for 3 days

One hour after vaccination had warm feeling all over face, not flush and did not have fever. Lasted all night long and patient was also nauseous. She then stated she had numbness along left jaw, this

happened hours after vaccination. The next day she felt better, nurse told her if it happens again or doesn't resolve follow up with PCP. The following day, associate felt better.

GENERAL MALAISE, CHILLS, LEFT ARM PAIN, INFRAORBITAL PAIN, NAUSEA. SYMPTOMS LASTED 1 DAY.

Patient complained of fluctuating tachycardia between 110-150BPM after waiting about 10 minutes after receiving vaccine. Patient skin was hot and moist to the touch. Facility RN escorted patient to ER where she was seen. More information is not available at this time.

2 day post vaccine right arm is red, swollen, hot and itching. Site was initially painful on day 1. Also night of vaccine had generalized itching which was relieved with benadyrl.

Lip swelling within 24 hrs

Shortness of breath, tachycardia

1830 began experiencing numbness and tingling to R arm, the nurse there evaluated associate and noted equal movement/strenght to both arms. 1840: reported feeling better and requested to leave.

Patient had sudden onset of tachycardia - heart rate 120s - 140s. Felt lightheaded.

The patient pre-medicated with oral diphenhydramine because she had an allergic reaction to another vaccine in the past. The patient developed some upper body redness and slight eyelid swelling, and she continued to treat with oral diphenhydramine until symptoms resolved.

Patient received Pfizer COVID 19 vaccine last Thursday 12/17. Admitted today (12/21) with bleeding and low platelet count - working up for ITP, TTP. Given recency of vaccination and no known contributory allergy or medical history, physician thought potentially associated with vaccination.

Dizzy, headache, blurry vision, fatigue

Pfizer-BioNTech COVID-19 Vaccine EUA Fevers Muscle Aches Joint Pain Sweats Headaches

"Patient experienced tingling in left fingers and hand that progressed to ascending numbness up the left arm and up the left shoulder and left neck area up to under the left ear. Patient feels like there is a ""lump"" in the throat that she has experienced during dental work when mouth is numb. This occurred within 10 minutes of vaccination. Symptoms progressed to feeling of having fluid in the ear approximately 50 minutes after vaccination."

one hour post vaccination, patient had tingling on left face. Near ear to jaw line radiating to neck. Lasted one hour then resolved.

On 12/20 at 9am started having left sided facial numbness, tingling, flushing. Near syncope episode (tachycardia, diaphoretic, blurred vision) around 1130am. Took Benadryl seemed to help. On 12/21- around 7a near syncope episode, tachycardia, diaphoretic, facial flushing, itching. Took Benadryl- improvement in facial itching, decreased heart rate.

REDNESS ON THE UPPER LIP, SCALE AND ITCHING IN THE AREA.

Rash on chest pounding headache fever of 104 left side rib pain elevated heart rate 106

The shot site was swollen for two days after the injection. I had nausea, dizziness, and tiredness. Three days after the injection (today), I had shakiness, extreme fatigue and felt like I was going to pass out.

started to develop injection site soreness on the night of vaccine then by 10am the next day was having all over body aches, nausea, headache which continued to get worse and by 3pm that day had nausea, vomiting , severe body aches and cramping all over, fever, headache, and a hard warm lump at the injection site. was applying heat to cramps and taking Tylenol which was not helping much for body aches, did not want to take ibuprofen due to nausea. by noon on the 3rd day most of it was resolved

Patient described feeling numbness under the right eye. The numbness radiated down the right side of the face. Patient reported that the numbness subsided after 2 minutes

"Right arm with 2.5-3"" long 1.5-2"" wide reddened, warm to touch, developed the day after vaccine. Seen by OHS rec. Ice, Benadryl, Antihistamine. Today she returned with decreased swelling & redness."

Started 15 minutes after vaccination and it lasted for 30 minutes. Tingling arms and fingers and heaviness in shoulder. Resolved.

Employee reported redness and swelling to Right Wrist. She also noted itching to left neck/back area. Employee was taken to ED for further evaluation and treatment.

Approximately 30 minutes after COVID vaccine administered, patient reported tongue swelling/itching sensation to tongue and roof of mouth. This lasted about 15 minutes and resolved on its own without treatment.

Patient experienced nausea and fatigue a couple of days after getting the vaccine

Significant Cervical/thoracic joint pain and stiffness which referred to R shoulder girdle region, limited cervical ROM to the R. Dull, achey pain in area even without movement. Took acetaminophen and tumeric for anti inflammatory, use of heating pad and then biofreeze cream for analgesic purposes. By next morning pain and stiffness centralized back to spinal region and R shoulder girdle was pain free with normal ROM. Same treatments used again.

Mild Edema Left Side of Face

injection site pain, slight fever, tiredness, headache

Patient received Pfizer vaccine dose 1 IM in L deltoid per portcol. During 15 min post vaccine monitoring, patient developed a cough, SOB, diff swallowing and hive like rash within 10 minutes of vaccine administration

chills, body aches, skin hurt, nausea, lack of appetite and diarrhea (along with sore arm)

24 hours after injection developed muscle aches and fatigue. Approximately 36 hours developed severe vertigo with nausea. Headache present. Continued 12/19 to present. Taking Dramamine for symptoms which on 12/21/2020 is helping with vertigo and nausea. Fatigue, headache and muscle aches continue 12/21/2020.

at 1805; associate c/o lightheaded and noted to be diaphoretic. BP was 138/92 with HR 85 and room air sat 98%. at 1830; reported feeling better. BP 127/83. HR 76. room air sat 100%. at 1845: felt better 143/101 1905: discharged to home. BP 136/92

Soreness in arm

Rash on arms and legs . resolved after taking a dose of Benadryl

fatigue

The reaction to the shot was that she had alcohol taste, nausea, wretching, and a rapid response team was called and she was taken to the ED.

"Pfizer-BioNTech COVID 19 Vaccine 42 y.o. female had just received her vaccine when she became very lightheaded, was placed on a stretcher and brought to ED further evaluation. Patient has hx of rheumatoid arthritis.á Stated that she has not eaten since earlier this morning, did have some nausea vomiting earlier that is now resolved, feels that it was related to ""an adrenaline rush just prior to her vaccination.ááUpon arrival to EDáshe is denying any headache, fever, sweats, chills, cough, shortness of breath, angioedema, chest pain, palpitations, vomiting, edema, claudication, urticarial.á Diagnosed with near syncope."

"Approximately 10 to 15 minutes after vaccination, patient reported feeling dizzy with slight headache. Also reported tingling starting on the left fingers and hand that progressed to tingling (not numbness) up both arms and both sides of the upper body. Body felt ""weird"". Headache progressed to a ""pounding headache"" with pain in the eyes because the headache is ""so bad"". Patient reports feeling tired and ""drained"". Patient being frequently monitored by nursing staff."

fatigue, weakness

The night of vaccination patient had a metal taste in mouth and lost all sense of taste. 12/19/2020 she developed a fever, body aches, and chills. 12/20/20 Continued to be febrile, then was told to follow up with PCP.

fatigue, muscle soreness and weakness, headache, nausea

I had heart palpitations and extreme fatigue for 48 hours.

Fatigue, mild fever, joint ache, muscle ache, headache, eye pain (had underwent LASIK recently, date of vaccination was LASIK POD#18, but that eye pain had entirely resolved at least a week ago, now recurring), mild chills. (Instructed by employer to include this in Item 18: Pfizer-BioNTech COVID-19 Vaccine EUA)

5 in red spot underneath the injection site

Approximately 15 minutes after injection, patient reported nausea/vomiting, difficulty breathing, being clammy and having numbness/tingling in the L side of face and L arm. Cold packs were applied, BP 165/104 obtained at that time, O2 sats 99% on RA. O2 via facemask applied. Sats continued in upper 90's throughout event. Rapid response called at onset of symptoms. They connected to monitor upon arrival. HR maintained 70's-80's throughout event. At 2304 BP 165/102, HR 85, patient reported feeling better. At 1108, BP was 159/100. Patient reported feeling well enough to go home at that time and did so.

"Pfizer/BioNTech COVID 19 vaccine EUA C/O ""heart coming out of chest"", itching, and hot feeling approximately 10-15 minutes after injection. She took 25mg Benadryl PO one hour before vaccine. Was given 25 mg oral Benadryl at 1410. HR and blood pressure returned to normal and pt was released within 20 minutes of reaction."

Hypertension (220/110) and shortness of breath after Pfizer-BioNTech COVID-19 0.3 IM injection in the right deltoid. Presented to ED within 6 minutes of injection for evaluation. Symptoms resolved within 10 minutes in the ED except BP remained in 160s/90s. Blood glucose, CMP, and ECG normal. No medications given. Patient asked to leave following resolution of symptoms.

general malaise and abdominal discomfort after vaccine, three days later started with facial rash and fever Treatment: Famotidine, Benadryl

The night patient got vaccination she had abdominal pain, muscle aches and sinus congestions. She was also exposed to a positive covid 19 case and is going for testing 12/21/2020.

"I have had symptoms of a low grade fever on and off and a cough has developed that sounds like ""whooping cough"" . This is the 4th day. Is this normal or does it get better . do you need to see a dr??"

Felt achy, headache, neck sore, possible low grade fever, tired, chills occasionally. Treated with motrin and rest.

Approximately 10 minutes after the vaccine, patient became tachycardia hr 110, diaphoretic, and pale. Felt back to normal around 12:30 pm. Patient did not develop any additional symptoms until Saturday evening around 5pm when similar symptoms developed but milder.

"Approximately 30 minutes after receiving the vaccination, patient reports itching started on left arm, then the head, then both arms and then lower back. No redness, erythema, or hives. Itching progressed to the ears and throat started to feel ""sticky/funny"" within 1 hour of receiving the vaccine. Diphenhydramine 50 mg and Famotidine 20 mg administered. Itchiness resolved 15 to 30 minutes after receiving diphenhydramine and famotidine. However, lips and tongue feel ""tingly""."

Slight difficulty with exhalation. Denies difficulty with inhalation, swelling of face or throat, palpitations, rash, or dizziness and weakness. Advised to continue to monitor. Strict UC/ER precautions advised.

1813: reported feeling nauseated and was noted to diaphoretic. HR 110. BP 142/82. Room Air sat 100%. 1830: reports feeling better HR 89. BP 141/75. Room air Sat 100% 1840: symptoms resolved. associate sent home per request. HR 86 no interventions done.

Fever, chills, body aches 24 hours. Continues 72 hours later to have swollen axillary lymph right arm. Pain at injection site.

Hello to all. Patient reported feeling dizzy right after sitting down for the 15 minute wait period. I asked her if she would like to lay down. I took her in the side room to lay on the hospital bed. Her bp was 177/115. She is a physician and so is her husband. He was with her. He suggested we had a bad cuff , and he wanted a manual one. Staff went to the ER to retrieve it. Her husband took her BP and BP was elevated with the manual cuff as well. I provided juice and water for the patient and got her rags. Her blood pressure stayed elevated for the whole 30 minutes she was there. Her husband wanted to know what I had to give her. He wanted lisinopril 5mg. I explained that we only had benadryl and epipens for allergic reactions. He decided to take her home. He stated he would give her one of his blood pressure pills and that she would be fine. She was able to get up and walk out without assistance

Approximately 30hrs. post vaccine I experienced hearing loss in my right ear. I could hear very little and it became worse within the next few hours. 12hrs after this began, my hearing came back and I then acquired a ringing in my right ear. This progressively lessened, and about 24 hrs after the initial hearing loss started, all the symptoms dissapated.

flushing, felt dizzy. given Benadryl 50mg and resolved in 15 minutes

During the 15-minute observation period the patient became flushed and began complaining of a headache. She then went unconscious and had tonic-like activity for approximately 2 minutes. The patient subsequently stopped the seizure-like activity and woke up but was confused and was acting in a postictal fashion. She was evaluated emergently upon arrival in the ED and noted to have an altered mental status. Physician noted that this does not appear to be an allergic or anaphylactic reaction. There was no evidence of rash and lung sounds were clear with no wheezing. Subsequent CT showed a diffuse subarachnoid hemorrhage and patient was transferred to the Medical Center for further treatment.

Approximately 2 hrs 30 min post administration I experienced mild parasthesia in my left ring finger and pinky finger and mild left arm muscle weakness and mild lady hand grasp weakness. This episode lasted about 40-45 min, self resolved completely with no intervention.

Woke up middle of night, severe muscle aches/cramps, chills/fever, debilitating headache.

Patient reported feeling dizzy shortly after the vaccine. Symptoms resolved after she laid down and we got her a drink.

Pt experienced temp of 103.8 at 3am on 12/18/20. Temp decreased to 100 on 12/19-12/20. As of 9am on 12/21 temp was 99.3. On 12/19 pt began experiencing diarrhea, cough and stomach pain. Cough and stomach pain continued to report of 12/21. Pt had COVID + test on 10/11/2020. She stated that it was as if the symptoms she had in October were back.

Patient presents to the emergency department less than 20 minutes after getting her first COVID-19 vaccine, feels like there is a tickle in her throat, patient has some blotchy erythema on the front of her neck and chest. Patient very hypertensive on arrival here to the ED. Patient was given IM epi 300 mcg, was also given Solu-Medrol 125 mg IV, Pepcid 20 mg IV, and Benadryl 50 mg IV. Patient reexamined at 9:45 AM, states that symptoms are better. Blood pressure actually has improved down to 172/91. She no longer has the erythema edema on the front of her neck and chest, feels as though symptoms are improving. We will continue to observe patient here for the next 2 hours after epi. Pt. asymptomatic by 1230. Discharged to home and advised to not get the second COVID-19 vaccine shot in three weeks.

tingling in throat, rapid heart rate, flushing

Fatigue and shakiness in diabetic patient. Fingerstick blood sugar showed low blood sugar of 49 three to four hours after vaccine. Patient reports no other changes in diet or routine that morning. Issue resolved on its own with eating.

Patient endorses feelings of ?tired? approx. 30 minutes after vaccine. Patient reports he went home after his work day and reported feeling more and more tired. Patient reports he ordered dinner with his girlfriend and at approx. 20:00/21:00 reported bilateral swelling to lymph nodes in neck, and feelings of his ?throat closing up.? Patient endorses, ?I felt like I was having a panic attack.? At approx. 22:00 patient took 3 tabs of Benadryl and 2 tabs of acetaminophen and noticed improvement and then went to bed. Patient reports improvements in symptoms but persistent bilateral lymph node swelling in neck throughout the weekend. Today (12/21): Patient endorses increased lethargy, persistent bilateral lymph node swelling in neck and + sore throat. Patient denies fever. Patient took 2 tabs of Benadryl at 10:00 today while at work. Patient called PCP today while at work describing symptoms and advised to leave work and to get COVID tested. During call with RN, patient is awake/alert and in NAD acute respiratory distress. Pt endorses able to move air freely, no SOB, and difficulty breathing. Patient reports scheduled telemedicine appointment tmw am. Patient denies recent travel of self or girlfriend, and denies known covid exposure in community or workplace.

Rash in pectoral, shoulder and back area.

GI : nausea, dyspepsia. Headache, Myalgia

I developed vertigo and it is bad when I lie down. The room is spinning It started the night after the vaccine and it has not gone away. I feel the motion sensation all day. It feels like I am drunk all the time.

General malaise, nausea, chills, headache

Patient was in observation. She stated she saw the room take a shift. She then got a headache in the back and on the top of her head. Her heart was also racing and she was dizzy. We got the patient some juice and her lay down. Symptoms resolved other than headache. She reported it was still 5/10 when she left.

Pain at injection site after 6 hours followed by malaise, fatigue, upper body muscle soreness, chills, feeling hot which started 12 bourse after the shot and lasted till 3 days after shot. Partially improved symptoms with ibuprofen 600mg but short lasting.

Tingling on right side of lip and right of face. Felt like numbness from local anesthesia at dental office. Felt like throat was a little numb. Numbness has mostly resolved approximately 1.5 hrs after vaccination. Some lingering tingling on lips at 1 hr 45 mins post-vaccination.

48hrs after vaccination I developed axillary lymphadenopathy in my R axilla (same side vaccine was given.) Injection site is well appearing- glands remain swollen and painful.

Started having bad headache the day after shot. Also very bad fatigue. Now on 12/21/20 I?ve had a very severe migraine with visual aura.

Flu like symptoms: Headache, Muscle Ache/Soreness and Fever. Pt is currently taking Tylenol/Ibuprofen at home to treat. Will continue to monitor pt closely. If symptoms don't resolve soon, will have patient to come to hospital for further evaluation.

Pt expressed feeling tachycardic, jittery, shaky, site edema, shortness of breath and dizziness. Pt received epipen 0.3 mg IM injection x1 dose and benadryl PO, responded favorably and transported to ED for follow up care.

I had a fever of 101, body aches, fatigue, nausea, dizziness. Did not see a doctor. I am feeling better now.

Tingling, numbness down Left arm. Hot flushing across chest and left side.

Pfizer-BioNTech COVID-19 Vaccine EUA: Allergic reaction after receiving a COVID shot. Pt reports a rush of dizziness, diaphoretic, nausea, and near syncope. Pt appears pale but alert and oriented upon arrival. Patient was given IM epi, IV Solu-Medrol, Benadryl, and Pepcid, placed on a cardiac monitor. He was given 1 L of normal saline. Patient observed here in the ED for almost 8 hours. He has been persistently tachycardic; Admitted as inpt. for observation. Discharged from inpt status on 12.18.2020 @ 2152.

11started with intense itching in scalp and neck54:received COVID vaccine, within 3 min she felt flushed, dizzy and heart rate increased. 1205:she felt less lightheaded and heart rate was slowing 1208: she felt intense itching in scalp and neck 1215:itiching increasing, given Benadryl 50 mg IM 1245: itching not as intense, but itching had moved to arms, trunk and legs

Tongue felt thick, tingling in extremities, shortness of breath. Given 50mg Benadryl, 20 mg famotidine

Shingle like symptoms on left side of scalp/ face/ neck/ left arm and left torso.Extreme sensitivity to touch/cold/heat on affected side.Left neck muscles sore and aching.

Right when the patient sat down at observation she stated she was flushed and got hot in her head. She said her chest felt funny and her tongue was tingly. Her blood pressure was 169/95 and heart rate was

100. She stated she was nervous. We kept her in observation for 30 minutes. All symptoms resolved by the time she left.

Symptoms began 12/18/2020 at 9pm with severe fatigue and chills. Woke up at 0030 12/19/2020 with severe shaking chills, headache, body aches, dry cough and nausea, temperature spiked to 103.2 @ 0230, took 600mg Motrin and 500mg Tylenol but fever stayed at 103 until 0600 and slowly came down to 98 by 0900 12/19/2020; symptoms were resolved except for fatigue until approx 5pm 12/19/2020 when fatigue increased and chills came back with headache and body aches, fever spiked to 102.3 and lasted until approx 9pm after taking 600mg Motrin and 500mg Tylenol, I was able to sleep well Saturday night. Woke up Sunday 12/20/2020 at 0730 feeling well but within an hour I developed a dry cough and shortness of breath with exertion and noted elevated heart rate (90-120bpm). This lasted all day. At 3pm 12/20 I began to get fatigued again. I felt very clammy and flushed and checked my temperature and it was back up to 101.6. Fever came down to 100 by 7pm and stayed there until approx 930pm. I woke up this morning feeling slightly better. I still have a cough and shortness of breath

The day after at 1 am exp chills, low grade fever, nausea, headache and fatigue. After Tylenol after 24 hrs the symptoms was better. I was able to to return to work.

The vaccine was administered at 1130 without immediate complication. At approx 1800 the pt began to develop symptoms of general malaise. At approx 2200 the pt developed a fever and chills. Initial oral temperature was 101.3 The pt has continued to have a fever and general malaise since the injection, now for almost 5 days.

Tightness in back of throat. Received 50 mg Benadryl.

Employee complained of feeling lightheaded. She reported blotchy spots on neck and chest; tingling to back of throat. Employee was taken to ED for further evaluation and treatment.

Patient began experiencing bilateral leg weakness, chills, shortness of breath, and headache

Edema in left side of face, hand, knee, and shoulder.

Pt reported roof of mouth itchy, body itching, ears ringing and felt fullness/clogged, headache. Benadryl 50 mg PO provided with additional monitoring and resolved.

Patient states that evening of vaccination she started to have pain and swelling radiating from injection site to shoulder, up neck to under eye area and then across left clavicle. Patient states that jaw was sore. Following morning, the patient experienced joint and muscle pain and a headache (similar to when she had COVID in Oct 2020). Patient also had a cold sore occur 24 to 48 hours post vaccine. Patient called pharmacy on 12/21/20 to report ADR and pharmacist recommended contacting PCP as well.

injection site sore, sluggish, stomach pain

Nausea and tingling in hand

Several running nose that wont stop, Headache, and red watery eyes .

Arm soreness, I had dinner and maybe it was the food I ate, my stomach really hurted and lots of pain. I laid down and rested and next morning my stomach pains were gone. My arm was still hurting a lot the next day, not anymore.

After 15 minutes of monitoring post injection, I developed itching to left shoulder with diffue hives to shoulder and chest

dull headache in beginning became intense with nausea and diarrhea for 3 days, pain at the injection site.

12/17/2020 12:30 PM -- Nausea, severe; fever 101.00, fatigue, pain at injection site for 3 days ending 12/20/2020. Nausea and fatigue still persist. Employee Health at vaccine Facility site provided prescription order for Sofran to patient pharmacy of choice; patient has has no relief with prescription.

12/16 - 11AM VACCINE RECEIVED 12/17- 6AM HANDS SWELLING SEEN 12/18 - 6AM EYELIDS AND CHEEKS SWELLING SEEN

"Chest and back pain, and then ""limbs went numb"". Couldn't lift glass of water. All limbs were weak and shaky."

Rash on arm morning after injection at injection site

Developed fever to 100.5, body aches, swelling at the injection site.

Patient felt a sudden rush of tingly feeling from chest down to arms. Did resolve, lasted a few minutes.

Patient emailed 12/21 and described on set of annoying, cool tingling sensation of lower extremities that began last evening. Writer called patient to obtain more information about symptoms. States is experiencing an annoying, cool, tingling sensation in lower extremities that is hard to describe. Reports it feels almost like it's asleep, but cool. The symptoms began in the lower extremities and is now into the hips. Says has had difficulty sleeping due to the symptoms. States is able to walk, and not experiencing any shortness of breath. Instructed to notify her provider right away or report to the Emergency Department for evaluation and treatment.

39 yo male employee with history of Covid 3/2020, and SVT s/p ablation x 2 (2002, 2008) who came to hospital S/P Covid vaccination for recurrence of SVT. Given 50 mg IV benadryl prior to arrival to hospital. Prior to discharge had recurrence of SVT to HR 170. Placed in Obs overnight for telemetry monitoring. No events overnight. No dyspnea, fever, body aches, or hives. Discharge patient home with follow up with MD for possible holter monitor.

Body aches; chills; fatigue; sore arm lasting 48 hours post vaccination. Resolved with Acetaminophen

Noted headache just over an hour after receiving vaccine. No fever and subsided after about an hour. Awakened 12/19 with a headache that was relieved by Advil.

2 hours after injection patient experience hives on upper torso, and mid and low back. Hives started spreading on the neck. Patient had NO shortness of breath. Itching on left knee. Patient given oral benadryl and then 30 minutes later received 20mg of pepcid. Patient cleared of hives by that night but reoccurred Saturday afternoon with a mild case of hives on the neck. Patient took dose of benadryl. Patient does have a few small areas of redness noted on right arm.

Sinus tachycardic with rate in 130s, dizziness, hypertension 138/92. Symptoms began 20 minutes following vaccination and resolved after 30 minutes.

12/18/20 4 hrs after injection redness& swelling at site started. 12/19/20 severe fatigue, muscle/ joint aches, severe migraine with nausea, dizziness, started at around 11am at 1pm chills started& lasting through 12/21/20 1450. Headache at a pain level 8

Fever of 100.6, chills, nausea, fatigue, pain at injection site. Started 24 hours after injection, lasted about 12 hours.

Started with slight headache and sore arm, felt tired and diarrhea about 5 hours past vaccination - 3 bowel movements within 1 hour. That night around 1:30AM (next morning) I felt a little itchy all over with a throat irritation and I took some Benadryl. Just itchiness and sore throat, no fever. Had pretty bad fatigue on the 17th and had nasal congestion, cough, chills, sneezing. I worked on the 17th but felt terrible throughout the day. Got home and I could not eat anything , could not hold anything on my stomach. On the 18th at night woke up with sweats, no fever, dry cough, nausea. Chest discomfort (minor chest pain - was sure was not cardiac, could be acid reflux). Woke up with nausea and irritation and intermittently felt fatigued and would feel better, throughout the day. Also felt back pains on the 18. That same evening I felt a little better and then on the 19th I had some shortness of breath. I then decided to go to the UC on Saturday the 19th and got a COVID test. Sore throat was gone but still feel back pain and nausea. Around 11PM on the 19th I got itchy again in my arms and chest. Also got chest pains and took a Pepcid and Benadryl. On the 20th I am feeling a little better, still have a cough and some stomach upset and headache (in the AM). About 1:30PM diarrhea came back again. Had it 2X and low back pain and abdominal pain and also chills. There was a time I could not take care of my kids I just had to stay in bed (19 and 20th - I spent in bed most of the day). My heart rate has been good. The evening of the 20th I felt a little bit better and able to eat a little bit easier. This morning felling a little better. Had diarrhea this morning and a headache that I can't get rid of. Took Tylenol but it has not helped. Also low back pain.

sore arm lasting 72 hours post injection.

Patient had warm to touch injection site and experienced headache. Gave water. Patient felt better but still symptomatic.

Swollen tongue, racing heart, lightheaded

The patient was sitting in a chair and began feeling flushed, scratchy throat, and tingling in bilateral arms. Treatment included 25mg Benadryl by mouth at 1851, repeat dose at 1902.

Developed chills, body aches, swelling at vaccine site. Improved after 2 days. She did have COVID in April 2020.

Leg pain, back pain, chills, fever, headache. Unable to walk or stand still for more than a minute. Unable to sit upright back pain travels to mid back.

Left knee pain when standing up

Pfizer-BioNTech COVID-19 Vaccine EUA. Symptoms: shaking, chills, sore arm, fever: 101 beginning at 11:30pm. Took Tylenol Extra Strength prior to bed at 2am. Woke up with headache and fever of 99.4 approximately 6 hours later and took more Tylenol Extra Strength. Felt tired during the day. Rechecked temperature at 8:00pm (12/19) and fever remained at 99.4 , but did not take Tylenol.

Patient experienced Temperature increase to 99.3 oral; increased blood pressure 136/94 with dizziness about 30 minutes after injection. Blood pressure remained elevated for about 2 hours; normal blood pressure 112/64 for this young man. Vitals were taken every 30 minutes. BP and temp 134/84, 99.5 140/92, 99.1 128/92, 99.1 112/76, 97.8 vitals prior to patient leaving. Dizziness improved and patient taken home by friend. Dizziness continued. Patient taken home and told to report to ER if symptoms return

Dry Cough, Fatigue, Arthralgia, Low Grade Fever.

15 Mins after I started noticing tightness in chest, tongue swelling , heart rate 130 , 25 mg of Benadryl,, irregular heart

I developed a temp as high as 101 degrees. Terrible headache that lasted for 5 days Muscle aches Fatigue, Weak (I did have covid on March 27- was ill for 3 weeks. Had antibodies still present when tested in August) Chills alternating with sweating

12/18/2020 10:30PM body aches, chill, left arm pain. 3:00 AM pain in arm 800mg Tylenol. AM next day, arm still sore . 12/20/20 midday discomfort in l armpit. 11:30 12/20 swelling in l armpit. 9:00 Ice swelling of l armpit -- Tylenol. Some swelling persists at area of l armpit.

"0650-Within 5 min of vaccination: Lightheadedness, dizziness, ""floaty"" feeling, cleared after sitting 15 more minutes. 0900-Returned to clinic, after vaccination : recurrence of lightheadedness, sudden onset of HA 6/10 (no migraine aura), nausea and 2 episodes of watery stool, diaphoresis. No rash, no Shortness of breath, no difficulty swallowing, no throat swelling. 1000- taken to ED for continued monitoring: given Zofran 4mg SL, Benadryl 25 mg PO, Pepcid 10 mg PO, Tylenol 975 mg PO , ibuprofen 600 mg PO. DC'd from ED at 1335 with Zofran for continued nausea. Other symptoms resolved."

I developed a rash on both arms right away.

c/o of tingling and burning to right side of face and lips Covid Vaccine injection was administered. Pt. She also states develop a small blister inside her lower lip. She denies any SOB or swelling to face and throat she states has allergies to red dyes and has a hx. of DM, HTN, Anemia and breast CA. VS were taken BP

154/90 , 02 sat 100 %, HR 56. Pt. had some water and walked to the restroom, she stated was feeling much better, and said her husband was driving her home. BP recheck again 139/89 pulse 62, sats 100. She left via walking without any difficulty.

Patient said that she felt sick while in observation. She ended up dizzy, shaky, and a fast heart rate. We got her to get a drink and lay down for a bit. Her initial bp was 143/107 with a heart rate of 108. After resting for some time, she felt back to normal.

c/o problems swallowing despite drinking water. Sat pt in chair, VS taken and monitored. Epinephrine IM given when pt c/o problems swallowing worsening. 9-1-1 called and responded but pt declined escort to ED because he stated he was feeling better after Epi so instead I and patient transport escorted pt to ED via wheelchair.

Dizziness occurring approximately 4 hours after receiving vaccine. Patient presented back to vaccine clinic. Blood pressure lower than patient's reported normal blood pressure. Close monitoring by nurse. Blood pressure increased during monitoring period.

Vaccine recipient reported experiencing numbness, tingling of the arm after receiving the COVID-19 vaccine. Vaccine recipient thinks that the vaccinator most likely hit a nerve when administering the vaccine. The vaccine recipient went to the emergency department for further evaluation. The vaccine recipient was monitored, felt better, and was discharged to home subsequently the same day. On Monday, I called the vaccine recipient to follow-up and they report that they no longer have the numbness or tingling.

Developed fever , cough, congestion 1 day after vaccination.

12/16/2020 I had a fever at night I woke up with fever and chills and body aches and I also had a pretty bad headache, it lasted throughout the next day 12/17 I took tylenol and just felt tired, my headache was also off and on it just depended when I took tylenol

Patient felt some dizziness 15min post vaccination, itchiness behind both ears, some nausea, tingling feeling all over body. Pt denies worsening of symptoms 10 minutes later, reports itchiness behind ears feeling slightly better. Does report an area on abdomen feeling itchy as well as random spots on both legs. Pt agreed to 50mg of Diphenhydramine, tabs, PO 20 minutes after first sx developed. Lot# 205355, exp. 05/2023, NDC 0904-5306-61. Patient was monitored for an extra 15 minutes post medication, was feeling better and had her husband outside waiting for her to drive her home. Advised to continue to monitor sx and call PCP with new sx or for emergent sx, go to ED. Patient denied trouble breathing, chest pain/tightening, trouble swallowing throughout whole event.

39 yo male with history of Covid 3/2020, and SVT s/p ablation x 2 (2002, 2008) who came to urgent care S/P Covid vaccination for recurrence of SVT. Given 50 mg IV benadryl prior to arrival to urgent care. Prior to discharge had recurrence of SVT to HR 170. Placed in Obs overnight for telemetry monitoring. No events overnight. No dyspnea, fever, body aches, or hives. Discharge patient home with follow up with EP MD for possible holter monitor.

Flushing and lightheadedness

Patient became dizzy, vital signs -10:32 am 162/101, P-96, sat 98% on room air, hot clammy, blurry vision, heart palpitations, repeat vitals 1036- 171/102 P-85 sat 98% on room air, transferred to Emergency Room 10:43 am

Thursday night at around 11pm I lost control of my right arm. Friday I spent the day in Urgent Care doing CT scans and MRI scans of my brain and body and also did some blood work. All test came back negative. It is now Monday the 21st and the mobility in my right arm is extremely limited and I am slowly regaining the use of my right arm.

Weakness; fatigue lasting about 1 hour.

"""felt like throat scratching"""

One hour post vaccination my top lip felt tight. On inspection my buccal mucosa of my top and bottom lips were swollen greater on the top lip. My soft palate felt numb as well as my tongue from the tip to middle. My nose was also slightly swollen. 24 hours later the I have a slight swelling of areas mentioned with the exception of my nose. I was instructed to take Benadryl on the day of the event 25mg x 2 doses. the day after 12/21 I was given Claritin 10mg x 1 dose and Famatodine 20mg x 1 dose by mouth.

10 minutes after injection started to feel hot, developed a headache and nausea. had blood pressure taken and it was elevated along with heart rate in the 120's. Started feeling itchy and short of breath, along with red and blotchy on the arms and face. Was transferred to the ED and given IV fluids with Solu-Medrol, Benadryl, and Famotidine and released 1 hour and 30 minutes later with a prednisone prescription.

The evening of 12/16 my headache begin at the next day fever of 103 stayed for 7 hrs took administered Tylenol exp chills, body aches, and rash on face around the eye spread to right side of nose, side went to hand area lasted from 12/17 to 12/21.The headache started effecting my neck contacted my PCP on 12/19. I went to ER on 12/19 ran tests CT scan check for clots negative, lumbar puncture and chest X-ray was fine and dint exp respiratory problems. I missed 3 days of from work 12/9 to 12/21.

Day after the vaccine I had body aches, fatigue , headache and temp of 101.5

Patient had swelling of tongue 45-60 minutes after vaccination. Received PO benadryl. Had eyelid and facial swelling requiring IV Solu-medrol. Monitored for short period of time in emergency department and released. No further symptoms.

Sore arm, could not sleep on it about 8-10 hour post vaccination.

Spontaneous hives on face, Associate does have a hx of spontaneous hives and has been seen by allergist. Had an episode in January, February, May and October of spontaneous hives. Hives noted 5.5 after vaccine and about 1.5 hours after taking Advil

She was sore at injection site later on day of injection (12/20) that developed into whole body muscle aches the next day (12/21). She also reported a cough started on 12/20 and this has persisted and slight Shortness of breath started 12/20 that has become worse today 12/21 where if she is moving around she needs to stop and take a few breaths. She denied any feeling of life threatening shortness or breath or need to go to ER. She has been instructed to contact employee health prior to coming back to work given cough/SOB not typically a reaction to vaccine.

"felt lightheaded and a ""little off"" after doing errands at lunch about 2 hours after taking vaccine. BP was 190/110 while at work and was sent to the ER. BP there was 209/125. Was given Nifedipine CR 30 mg at 17:49. Discharged from ER with primary care follow up on 12/21. BP 4 months prior to vaccination was recorded at 168/110 at office visit."

6 min post injection felt cold, lightheaded, HR increased to 155, and became flushed.

"c/o ""I can't breathe, feels like my throat is closing"" VS taken. Pt crying, breathing rapidly possibly hyperventilating. Epi IM given, VS taken. Hospital emergency activated. Rapid team arrived assessing pt. Rapid team escorted pt via gurney for further observation."

Vasovagal reaction ashen color bradycardia for approx 1-2 minutes decreased B/P 90/60 with full recovery with ingestion of orange juice and recumbency

I had a rash that covered my neck, face and chest. A slight fever of 99.5 , soreness in the shoulder and joint area, mild headache the day I got the vaccine. Next day, rash still on face, joint pain and mild headache. Next day, joint pain. Today, a mild headache. Did a telephone call from Dr. and nurse from Health Dept. I was told to take Benadryl and go to ER if symptoms got worse. I took Benadryl one and one-half days.

She experienced nausea.

patient became dizzy, nauseated, received vaccine 10:00, at 10:09 patient became dizzy, lightheaded, nauseated, bp 125/85 p-85, sat 100%, 10:14 134/91 99% sat on room air, P- 98, 1020- BP 155/92, 1025 - 142/87, 1029- 98% on room air P-98, 1030- 129/91, 1047- sat 99% on room air, P- 89, 134/92, patient still feeling nauseated and dizzy transferred to Urgent Care

After receiving dose of COVID 19 vaccine patient reports the following: rash to both arms, right neck. Heart rate increased to 102. Reports slight shortness of breath. ER visit- administered Benadryl/Solumedrol IM

hot flushed, temporary weakness, temporary itching throat and back. lips tingling, lump in throat. 10 mins after injection symptoms started. all resolved except tingling in lips which persisted to the next day. area around mouth is itchy/burning but no other symptoms.

12/16/2020 WENT TO SLEEP AT 10PM 12/17/2020 - WOKE UP ABOUT 1:00 AM; 101 TEMP, SHAKING, CHILLS, BODY ACHES, RIGHT ARM VERY SORE, TRIED TO GO BACK TO SLEEP 12/18/2020 - FATIGUE, BODY ACHES, TEMP SUBSIDED; EVENING FELT SHAKY; 'CALLED OUT OF WORK' (NIGHTSHIFT NURSE)

12/19/2020 - ALL SYMPTOMS SUBSIDED 09/2020-10/2020 HAD FLU SHOT 'CANT REMEMBER EXACT DATE'

Patient pre-medicated with diphenhydramine due to infusion-type reactions in past. Patient with hoarse voice, itchiness to upper back, arms, and face, hives on bilateral arms. Per health system protocol (patient is health system employee) Patient administered diphenhydramine, famotidine, methylprednisolone succinate, epinephrine. All symptoms resolved by 1440.

18 minutes post vaccine dose 1, Pfizer COVID vaccine, development of globus sensation without airway compromise or stridor. Frequent throat clearing and swallowing. Followed by diaphoresis, loss of vision, extreme neuropathic tingling over entire head non painful. Bradycardic event to heart rate 35 recorded by Apple watch. Loss of consciousness with pupil dilation. Weak pulses but no loss of pulse. Heart rate recovered quickly. Blood pressure after initiation of iv fluids was normal in upright position once loss of consciousness subsided. Continued globus sensation. 30 minutes after initial event, again developed clammy hands, head tingling and worsening globus sensation but again no stridor or airway compromise. Given PO Benadryl 25 mg which did resolve globus sensation in next 30 minutes. Monitored for one hour post event with no subsequent symptoms other than fatigue.

"Tingling in right arm where vaccine was given. Hot at the site in her ""R"" hand. Still tingling 45 minutes after. Following up with Telemedicine."

Next day between 3 -6 AM - swelling of left eyelid followed by swelling and paresthesias of lips, followed by severe paresthesias of the left side of the face mostly lower half associated with a heavy sensation. Emergency treatment with 150 mg solumedrol and 50 mg benadryl. Symptoms persisted on and off for 3 days requiring benadryl 50 mg and claritin round the clock. On the second day post-vaccine headache, mouth blister (1), and diarrhea. Today (4 days post) very tired and fatigued.

Left arm erythema at injection site, lethargy, fever

Pt received Covid vaccine and afterward developed hives on chest and arms

Employee experienced headache and dry heaving

Patient complaint of itchiness, shortness of breath,tongue swelling, hyperventilating. Epipen was administered at 3:20pm

Body aches; cold symptoms; fatigue x 24 hours. ibuprofen

Widespread Pain; diarrhea; fever; vomiting; This is a spontaneous report from a non-contactable other healthcare professional. An 85-year-old female (non-pregnant) patient received first dose bnt162b2, intramuscularly on right arm on 14Dec2020 at 14:00 at single dose for immunization. Medical history included High cholesterol (no cholesterol lowering medication) edema, dementia, and no known allergies. Prior to vaccination, the patient was not diagnosed with COVID-19. Concomitant medication included influenza vaccine (INFLUENZA) on 30Nov2020 for immunization within 4 weeks prior to the COVID vaccine, other medications the patient received within 2 weeks of vaccination included daily

vitamin, diuretic, dementia medication, anti inflammatory. On 14Dec2020, the patient experienced widespread pain, diarrhea, fever, vomiting. The adverse event result in doctor or other healthcare professional office/clinic visit. No treatment was received for the events. Since the vaccination, the patient hadn't been tested for COVID-19. The outcome of the events was not resolved. No follow-up attempts are possible. Information about Lot/Batch could not be obtained. No further information is expected.

Headache, fever, chest congestion, cough, malaise, fatigue

Fast heart rate; Leg numbness; Hand numbness; This is a spontaneous report from a contactable consumer (patient). This 21-year-old male patient received the first dose of bnt162b2 (BNT162B2) (Lot # EH9899), via an unspecified route of administration at single dose in the left arm on 15Dec2020 12:00 PM at hospital for immunisation. The patient medical history and concomitant medications were not reported. On 16Dec2020 04:00 AM, the patient experienced fast heart rate, leg numbness, hand numbness. No treatment required. The outcome of the events was unknown. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, the patient has not been tested for COVID-19.

Yesterday my head felt heavy. I took swab. Started coughing 2 days after vaccine. Second day experienced swelling in arm. Runny nose. Waiting on test results. Messaged PCP and they advised her to be tested. Coughing on and off.

Headache; muscle and joint aches; muscle and joint aches; This is a spontaneous report from a contactable physician reporting for herself. A 44-years-old female patient received the first dose of bnt162b2 (BNT162B2, Pfizer product), intramuscular in the right arm on 15Dec2020 12:45 at hospital at single dose for immunisation. Medical history included was none. Concomitant medication included bupropion (unknown manufacturer). The patient experienced headache, muscle and joint aches on 15Dec2020 with outcome of not recovered. No treatment was performed. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, the patient has not been tested for COVID-19. Information on the lot/batch number has been requested.

Gradual onset of very mild rash and symptoms gradual improved with IM administration of diphenhydramine 50 mg and oral famotidine 20 mg. The physician was questioning if the mild rash was from where the patient was scratching secondary to anxiety vs allergic reaction. Patient was monitored for improvements.

She is feeling dizzy, a little wonky; Feeling bad like when she is about to get the flu; Her feet feeling like gelatin; Little nausea; Headaches; This is a spontaneous report from a contactable consumer (patient). This female patient of an unspecified age received BNT162B2 (Lot number EK5730) via an unspecified route of administration on 16Dec2020 at single dose for immunisation. Relevant medical history and concomitant medications were not reported. On 16Dec2020, the patient was feeling dizzy, a little wonky, feeling bad like when she was about to get the flu, with her feet feeling like gelatin, with a little nausea and headaches. The patient reported that when she got home after the administration, she reviewed the information provided after the vaccine and she found this information in the sheet,

realizing that she was feeling that way. At the time of the report, the outcome of the events was unknown.

Felt hot, chest felt different, BP elevated

Diarrhea; right arm pain; fatigue; This is a spontaneous report from a contactable nurse. A 27-year-old female patient received BNT162B2 (Pfizer-BioNTech COVID-19 mRNA vaccine, lot number: EK5730), intramuscular at right arm on 16Dec2020 at 08:15 at single dose for immunization. The patient medical history was not reported. Concomitant medication included paracetamol (TYLENOL) for headache. On 16Dec2020 at 09:00, the patient experienced diarrhea, right arm pain and fatigue. The patient outcome of the events was recovering.

Starting 5 minutes from vaccination left sided arm numbness and tingling down the arm into the fingers. Felt the entire day. 12/21/20, symptoms improved but again returned today.

Headache; Dizzy; Front of her calves and into her feet felt a little like jello; Lightheadedness; Nausea; This is a spontaneous report from a contactable consumer reporting for herself. This 45-year-old female patient received on 16Dec2020 around 7:30am first dose of BNT162B2 (Pfizer-BioNTech COVID-19 mRNA vaccine, lot number: EK5730) intramuscular in the right arm for vaccination. Medical history was none. Concomitant medications were not provided. She sat there for the 15 minutes following administration of the vaccine.After that initial 15 minutes passed she had onset of side effects. On 16Dec2020, while walking to her car, she experienced what she described as dizzy, but it was more like feeling a little wonky like when you are coming down with the flu, where she did not feel right. She was ok to drive herself home, she took a shower. She worked the following night. She noted that mostly the front of her calves and into her feet felt a little like jello. She has brief moments of lightheadedness, a little bit of nausea and a tiny bit of headache starting. The room is not spinning, she is walking fine, bending over and does not seem to be struggling at all. Outcome she initially reported as having subsided, but then reported ongoing, further details unknown. Final outcome was unknown.

I had a fever and that's all

After sitting and waiting the 15 minutes, I left and as I was walking, I had the strongest taste of metal in my mouth. It lasted for about a minute, then slowly went away.; This is a spontaneous report from a contactable consumer. A 54-year-old female patient received first dose of bnt162b2 (BNT162B2; lot EK5730), via an unspecified route of administration on 16Dec2020, at 11:00 AM at single dose (right arm) for immunization. Medical history included asthma, hypertension (HTN), and allergies penicillin (PCN), medications, food or other products, many seasonal items, grass, trees, molds, dust mites, carrots, apples, celery, and walnuts. The patient did not received any other vaccines within four weeks prior to Covid vaccine. Concomitant medications were not reported. Patient reported that she had other medications received within 2 weeks of vaccination. On 16Dec2020, at 11:15 AM, after sitting and waiting the 15 minutes, the patient left and as she was walking, she had the strongest taste of metal in her mouth. It lasted for about a minute, then slowly went away. There was no treatment for the event. The patient did not have Covid prior the vaccination and was not Covid tested post vaccination. Outcome of event was recovered on 16Dec2020.

Anxious, tachycardiac and hypertensive.

felt very warm, overheated; clammy; started feeling slightly light headed; Thought I would pass out; This is a spontaneous report from a contactable consumer (patient). A 41-year-old female patient received the first dose of bnt162b2 (BNT162B2; lot:eh9899) via an unspecified route of administration in the left arm on 16Dec2020 10:00 at a single dose for immunization. Medical history was reported as none. Concomitant medication included paracetamol (TYLENOL) for an unspecified indication. On 16Dec2020 11:30, the patient started feeling slightly light headed and thought she was going to pass out. On 16Dec2020 11:50, she felt very warm, overheated and clammy. The patient sat down, attempted to eat her lunch and the events slowly subsided. The patient's blood pressure and pulse were checked on 16Dec2020 and they were relatively normal. The events were reported as non-serious and the patient did not receive treatment for the reported events. Outcome of the events was recovering.

Sore arm lasting about 24 hours post injection. Ibuprofen

received the vaccine on 12/18, 12/19 woke up with a headache and fatigue: lasted until the end of the day.

mild fever; chest pressure; dizziness; This is a spontaneous report from a contactable consumer. A 29-year-old female patient received dose number 1 of BNT162B2 (solution for injection, lot number Eh9899/expiration date unknown) via an unspecified route of administration on her right arm on 16Dec2020 at a single dose for immunisation. Medical history included penicillin allergy and allergies to gluten. Concomitant medications were not reported. The patient experienced chest pressure and dizziness that later turned into a mild fever on 16Dec2020; all of which prompted visit to the emergency room/department or urgent care. The patient received Tylenol for the events. The patient did not receive any other vaccines within 4 weeks prior to the COVID-19 vaccine. She was not diagnosed with COVID-19 prior vaccination and was not tested for COVID-19 since vaccination. The outcome of the event was recovering.

Circum-oral numbness; This is a spontaneous report from a contactable consumer reporting for himself (patient). This 59-year-old male patient received the first dose of BNT162B2 via an unspecified route of administration in the left arm on 15Dec2020 at 18:00 at single dose for immunisation. Relevant medical history included penicillin allergy. Concomitant medications were not reported. On 15Dec2020 at 18:30, the patient experienced circum-oral numbness. The patient did not receive corrective treatments for the reported event. The facility where the vaccine was administered was hospital. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient was not diagnosed with COVID-19 prior to vaccination and since the vaccination he had not been tested for COVID-19. The outcome of the event was unknown. The information on the lot/batch number has been requested.

tachycardia, flushing

a fever of 99.5; body chills/chills; Not feeling well; Body itch; Pain; This is a spontaneous report from a Pfizer-sponsored program, received from a contactable healthcare professional (patient). A 36-year-old male patient received BNT162B2 (lot number: not provided) solution for injection, via an unspecified

route of administration on 15Dec2020 at a single dose for an unspecified indication. Patient has no medical history. There were no concomitant medications. The patient reported having a fever of 99.5 and body chills/chills after getting the Covid vaccine yesterday (15Dec2020). This was the first dose. The patient reported he was not feeling well, he had body itch, and pain on 15Dec2020. Patient stated he was just trying to think, he actually was feeling like drinking a lot of water and probably have some Tylenol. He asked if he should have the Tylenol or not really. The reason he was calling was because he was trying to figure out what was going on with his system before he do whole 8 to 10 minutes thing. He asked if this was required to find out if he could just drink some water and just take the Tylenol. He just wants the answer before he goes any further. Patient reported he was taking Tylenol for fever and chills. He reported he was in pain and he just needed to see if everything was alright. Outcome of the events was unknown. Information on the lot/batch number has been requested.

Patient states that after receiving the vaccine she felt lightheaded and dizzy. In the days following the vaccine she has experienced periods of vertigo and photosensitivity.

Site soreness - no treatment required.

swollen eyelids; cotton mouth; This is a spontaneous report from a contactable Nurse. A 43-year-old male patient received first dose of BNT162B2 (lot number EK5730), intramuscular on 16Dec2020 09:30 at a single dose in left arm for immunization. Medical history included smoker, overweight and known allergies with PCN. The patient's concomitant medications were not reported. The patient experienced swollen eyelids and cotton mouth on 16Dec2020 with outcome of recovered on an unknown date in Dec2020. The patient was given Benadryl and was under observation. The event was assessed as no-serious and did not caused hospitalization.

Mild sore arm at injection site; This is a spontaneous report from a contactable pharmacist. A 29-year-old male patient received bnt162b2 (BNT162B2), intramuscular (Arm Left) on 16Dec2020 11:00 at single for an unspecified indication. There were no relevant medical history and concomitant medications. The patient experienced Mild Sore arm at injection site on 16Dec2020 15:00. The outcome of the event was recovering. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

developed soreness at injection site 3-4 hours after the injection; This is a spontaneous report from a contactable consumer. A 50-year-old female patient received the 1st dose of bnt162b2 (BNT162B2) at single dose on 15Dec2020 for immunisation. The patient medical history and concomitant medications were not reported. The patient experienced soreness at injection site 3-4 hours after the injection on 15Dec2020. The outcome of the event was unknown. Information about Lot/Batch no has been requested.

The night after receiving the vaccine, I developed fever, severe muscle aches, nausea, headache, and a red area on my arm. These symptoms progressively got worse through the next day. Fever got up to 102. On 12/20/2020, I felt some better with temp 100.2 headache and body aches. Today is better with temp just 99.4. Still have minor headache and some chills. There is still a pinkish/red area about 2 inches

long and 1 inch wide on my arm where the vaccine was given. I did have a covid exposure at work last week and the employee health is going to test me before I go back to work.

Rash starting behind ears, moving to neck and trunk. Patient took a 2nd generation antihistamine (unsure which one) and this has helped with the itching. Rash is still present.

Moderate abdominal cramping; diarrhea; This is a spontaneous report from a non-contactable consumer (patient). A 37-years-old male patient receive the first dose of bnt162b2 (Pfizer-BioNTech COVID-19 mRNA vaccine batch/lot number: Eks730), via an unspecified route of administration on the arm left on 16Dec2020 16:15 at a single dose for immuninzation at the hospital. Medical history was reported as none. The patient had no allergies to medications, food, or other products. There were no concomitant medications. Prior to vaccination, the patient not diagnosed with COVID-19 and the patient has not been tested for COVID-19 since the vaccination. On 16Dec2020 17:30, the patient experienced moderate abdominal and diarrhea. The patient did not receive any treatments for the events. The patient was recovering from the events. No follow-up attempts are possible. No further information is expected.

my Doctor had a broken blood vessel that was like really bad, like a little hemorrhage; my Doctor had a broken blood vessel that was like really bad, like a little hemorrhage; This is a spontaneous report from a non-contactable consumer. A patient of unspecified age and gender receive dbnt162b2 (BNT162B2) at single dose on an unspecified date for immunization. The patient medical history and concomitant medications were not reported. The patient stated that the doctor had a broken blood vessel that was like really bad, like a little hemorrhage on an unspecified date. The outcome of events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

patient reports rapid heart rate 110-120

"burning in her throat; This is a spontaneous report from a contactable nurse. A 37-year-old female patient received bnt162b2, intramuscular from 16Dec2020 at 11:45 to at 0.3 mL, single for immunization ()COVID-19 vaccine). Medical history reported as ""none"". There were no concomitant medications. On 16Dec2020 11:48, three minutes after receiving the vaccine, the patient experienced burning in her throat . It was further described as it felt like constant reflux in the bottom of her throat. The patient was monitored for about an hour and forty five minutes. The burning was not more or not less. She was swallowing fine. She was breathing fine. Her vital signs and ""sats"" (saturation) were stable. Outcome of event was unknown."

"mild abdominal cramp; an episode of loose stools; profuse sweating; lightheadedness; headache; severe weakness; entire body felt cool and clammy; entire body felt cool and clammy; This is a spontaneous report from a contactable physician (patient himself). A 34-year-old male patient received the first dose of bnt162b2 (BNT162B2, Solution for injection; batch/lot number: ek5730), intramuscularly on the left arm on 15Dec2020 at 19:30 at a single dose for immunization at the hospital facility. Relevant medical history included childhood asthma and attention deficit hyperactivity disorder (ADD). Concomitant medication included lisdexamfetamine mesilate (VYVANSE) from an unspecified date in Dec2020. The patient had no allergies to medications, food, or other products. The patient did

not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. Roughly 13 hours after the vaccine administration, on 16Dec2020 at 08:00, the patient had mild abdominal cramp. He went to have a bowel movement and had an episode of loose stools. Within seconds after that, he started experiencing profuse sweating, lightheadedness, headache, severe weakness and his entire body felt cool and clammy. He managed to drink some water and laid down on the floor for the next few minutes. The episode lasted for a few minutes. All the events occurred on 16Dec2020 at 08:00 AM. The patient was not hospitalized for the events. Therapeutic measures were taken as a result of mild abdominal cramp, an episode of loose stools, profuse sweating, lightheadedness, headache, severe weakness, and entire body felt cool and clammy, which included acetaminophen (TYLENOL) 1000 mg. The patient recovered from the events ""mild abdominal cramp, an episode of loose stools, profuse sweating, lightheadedness, headache, severe weakness, and entire body felt cool and clammy on an unspecified date in Dec2020."

"Arm soreness at site of injection; This is a spontaneous report from a contactable consumer. A patient of unspecified age and gender received bnt162b2 (BNT162B2, also reported as ""COVID vaccine,"" Solution for injection; lot/batch number and expiration date were not provided), via an unspecified route of administration on an unspecified date at a single dose for immunization. The patient's medical history and concomitant medications were not reported. On an unspecified date after use of the product, the patient experienced arm soreness at site of injection. The outcome of the event was unknown. Information on the lot/batch number has been requested."

minor soreness; This is a spontaneous report from a non-contactable consumer. A male patient of an unspecified age received BNT162B2 (lot number was not reported) solution for injection, via an unspecified route of administration on an unspecified date at a single dose for an unspecified indication. The patient's medical history and concomitant medications were not reported. The patient experienced minor soreness after his injection on an unspecified date. Outcome of the event was unknown. No follow-up attempts are possible. Information about lot/batch number cannot be obtained. No further information is expected.

"hives on my neck and above my ear/few sparse hives; This is a spontaneous report from a contactable nurse (patient). A 49-year-old female patient received bnt162b2 (BNT162B2) lot number and expiration date were not reported, via an unspecified route of administration on 16Dec2020 at 07:15, 0.3 ml single dose for immunization. Medical history included seasonal allergy and seasonal asthma. The patient's concomitant medications were not reported. The patient stated that she received the product this morning (16Dec2020) at 0715. She mentioned that she took a shower this evening, 13 hours later, and observed hives on her neck and above her ear. She confirmed that she was not having an anaphylaxis and there are no other symptoms. She also denied any soreness at the injection site or pain. She stated that she has no other symptoms and no pain, no soreness. She added that she received vaccine on 16Dec2020 and wondered if there was a side effect of some hives, she meant that she was not having an allergic reaction and she got the vaccine at 7:15 this morning and she have been fine, but she just have like a few sparse hives at 20:30. When asked about causality, the nurse stated ""Yes I do. I have never had hives before."" She did not think that she needed treatment but she was wondering if it was

common or she wasnot having any anaphylactic reaction and they were sparse. She doesn't have it on her trunk, she just have some on her neck and there was like one above her ear. She put BENADRYL cream on them, they are fine, and they don't itch. She was just like preemptively treating them because of her high risk for work. Therapeutic measures were taken as a result of hives on my neck and above my ear (urticaria). The outcome of the event was unknown. Information on the lot/batch number has been requested."

Nausea 10 minutes after injection; This is a spontaneous report from a contactable consumer. A 25-year-old female patient received first dose of bnt162b2 (Pfizer-BioNTech COVID-19 mRNA vaccine), via an unspecified route of administration on 16Dec2020 18:15 at single dose (right arm) for immunization. Medical history included polycystic ovarian syndrome. The patient had no allergies to medications, food, or other products. Concomitant medication included ethinylestradiol, norethisterone (DASETTA 7/7/7) as Birth control. On 16Dec2020 18:15, the patient experienced nausea 10 minutes after injection. The Covid-19 vaccine was administered at the workplace clinic. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient did not received treatment for the event. The patient was not diagnosed with COVID-19 prior to vaccination and since the vaccination, the patient had not been tested for COVID-19. Outcome of event was recovered in Dec2020. Information on the lot/batch number has been requested.

muscle pain in thigh area; felt like muscle pain, cramp; This is a spontaneous report from a contactable consumer. A 52-year-old female patient received BNT162B2 (solution for injection, lot number EH9899/expiration date unknown), via an unspecified route of administration on 14Dec2020 at a single dose for vaccine. Medical history included blood pressure (abnormal). Concomitant medications included unspecified blood pressure pills. The patient experienced muscle pain in thigh area in Dec2020. She further reported that she was asleep and when she woke up somewhere around it went wave like 1-2 minute. It felt like muscle pain, cramp. The outcome of the event was unknown.

woke up today had a headache just on the right side of her head and injection site is sore and a little knot at the site; woke up today had a headache just on the right side of her head and injection site is sore and a little knot at the site; woke up today had a headache just on the right side of her head and injection site is sore and a little knot at the site; This is a spontaneous report from a contactable nurse. A 60-year-old female patient started to receive bnt162b2 (BNT162B2), via an unspecified route of administration on 16Dec2020 12:45 at SINGLE for immunization. The patient's medical history and concomitant medications were not reported. On 17Dec2020, it was reported that the patient woke had a headache just on the right side of her head and injection site is sore and a little knot at the site. Headache woke her up, no discoloration at injection site. The outcome of the events was unknown. Information about Lot/Batch has been requested.

"her arm is sore, to move or to lift; This is a spontaneous report from a contactable nurse via a Pfizer-sponsored program. A female patient of an unspecified age received bnt162b2 (BNT162B2), via an unspecified route of administration on 16Dec2020 at a single dose for COVID-19 immunisation. Medical history and concomitant medications were not reported. The nurse that received the COVID-19 vaccine on 161Dec2020 and described ""her arm is sore, to move or to lift"". She asked if Pfizer could tell her to

take Tylenol or Advil for her arm soreness. Clinical outcome of the event was unknown. Information on the lot/batch number has been requeste"

tingling; warmth and coolness in ears, head and face radiates to arms, legs and back; painful teeth; nausea; extremely flushed; goosebumps; This is a spontaneous report from a contactable consumer (patient) and healthcare professional. A 35-year-old female patient received the first dose of bnt162b2 (BNT162B2; lot number: EH9899), via an unspecified route of administration on the left arm on 16Dec2020 18:30 at single dose for immunization. Medical history included eczema. Concomitant medication included vitamin D3, zinc, ascorbic acid (VITAMIN C). The patient previously took trimethoprim / sulfamethoxazole (BACTRIM) and cefaclor (CELOR) and experienced allergies. The patient experienced tingling, warmth and coolness in ears, head and face radiates to arms, legs and back, painful teeth, nausea and extremely flushed with goosebumps on 16Dec2020 18:45. Outcome of the event was not recovered. It was reported that patient had no prior COVID vaccination and did not test positive for COVID. Reporter considered that events non-serious. It was unknown if treatment was received for the adverse events.

"both her hands were feeling pressure in her knuckles; redness in her hands; Itching; feeling headachy; feeling fluish; This is a spontaneous report from a contactable nurse. A 61-year-old female patient received the first dose of bnt162b2 (BNT162B2; lot number EK5730), intramuscularly in the right upper arm on 16Dec2020 at 15:40 at 61-years-old at a single dose for COVID-19 immunization. The vaccination facility was a hospital. There were no additional vaccines administered on the same date of the Pfizer suspect or prior vaccinations within 4 weeks. Medical history included ongoing asthma (asthma began sometime in her 50s and was ongoing) from an unspecified date. The patient had no other adverse events to any other vaccines in the past and there was no relevant family medical history. There were no concomitant medications. On 16Dec2020, the patient experienced: both her hands were feeling pressure in her knuckles, redness in her hands, itching. On an unspecified date in Dec2020, the patient experienced feeling headachy, feeling fluish. There was no visit to an emergency room or physician office. The clinical course was reported as follows: The patient was a nurse and she had a Pfizer lot number EK5730. The patient said she got the shot on 16Dec2020 at about 15:40 and when she got home both her hands were feeling pressure in her knuckles and they were red. Since then she had not stopped inching. The patient took cetirizine hydrochloride (ZYRTEC) and that made it stop enough; however, she could sleep but she still felt like she was itching all over. The patient clarified the pressure in her hands was primarily in her knuckles and then once that resolved she went to itching and feeling headachy. The patient clarified the redness was on her hands when she was having the pressure, her hands kind of got red. The patient reported the pressure in her knuckles had resolved completely and the redness in her hands and knuckles had resolved as well. The patient reported the itching began about an hour and a half after the injection and was ongoing, but it was not as bad since taking cetirizine hydrochloride twice. The patient reported the itching had improved. The patient did not have the NDC or expiration date. The patient did not know what dose was given. The card was all she had, and it just had the lot number and was to remind her to return for the next shot. The patient was calling Pfizer primarily about the itching and how she was feeling kind of ""fluish"", which she assumed was normal. The patient wanted to know, should she get the second shot, would she have a worse reaction to the second one.

The patient needed to know because she was ""miserable itching so bad and she thought the second one could be worse than the first."" There was no relevant testing Therapeutic measures were taken as a result of both her hands were feeling pressure in her knuckles, redness in her hands, and itching The clinical outcome of the events: both her hands were feeling pressure in her knuckles, redness in her hands, was recovered on an unspecified date. The clinical outcome of the event, itching, was recovering. The clinical outcome of the event, feeling headachy and feeling fluish, was unknown."

Palpitations and lightheadedness after vaccination.

scratchy throat; fever of 100.0 [units unspecified]; Headache; Nausea; body aches; Diarrhea; This is a spontaneous report from a non-contactable consumer. A 35-year-old female patient started to receive bnt162b2 (BNT162B2; unknown lot number and expiration date), via an unspecified route of administration on 16Dec2020 to 16Dec2020 single dose for an unspecified indication. The patient medical history was not reported. The patient has no allergies to medications, food, or other products. Concomitant medication included levothyroxine. The patient reported that she had scratchy throat several minutes (reported as 02:30 AM) after receiving the vaccine (16Dec2020). It did subside but then 14 hours after receiving the vaccine, she had different symptoms, She had a fever of 100.0 [units unspecified], headache, nausea, body aches and diarrhea. The events did not cause hospitalization/ prolonged hospitalization. The patient has not received other vaccines in the last four weeks. The facility where the most recent COVID-19 vaccine was administered in a hospital. There was no treatment received for the adverse events. It was unknown if the patient was diagnosed with COVID-19 prior to vaccination and the patient has not been tested for COVID-19 since the vaccination. The outcome of the events was recovering. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

Headache about 3-4 hours post vaccine gone 45 minutes post acetaminophen; sore arm later that day. Acetaminophen.

Right hand felt cold at first but that sensation has subsided; Within less than 10 minutes I had a warm tingling feeling; heaviness in my legs which still continues over an hour later; Dry mouth; This is a spontaneous report from a contactable consumer reporting for herself. This 44-year-old female patient received on 17dec2020 10:00 first dose of BNT162B2 (Pfizer-BioNTech COVID-19 mRNA vaccine, lot EK5730) at single dose in the right arm for immunization. Medical history included reflux. No allergies to medications, food, or other products. Concomitant medications included omeprazole (PRILOSEC). On 17Dec2020, within less than 10 minutes, the patient had a warm tingling feeling, heaviness in her legs which still continued over an hour later. Right hand felt cold at first, but that sensation has subsided. Also had a dry mouth about 15-20 minutes after the vaccine. All symptoms subsided after 2 1/2 hours. Patient went to emergency room. Final outcome was recovered on 17Dec2020.

Employee calling to report a reaction after receiving a COVID-19 vaccine. Vaccine Name - Pfizer Vaccine Lot # - EK5730 Vaccine Date and time - ? 12/18/2020 @ 4:30pm Is this your first or second dose? First Date and time of symptom onset - ? 12/19/2020 @ 11am Symptoms - ? Fever of 104.6, headache, BLE pain Last day of work and shift - ?Friday 12/18/2020 @ work today 2:30pm-11pm Home remedies? -

Tylenol Any improvement? - Denies any headache and fever. Both leg pain are still present. Recommendation? Continue to monitor, take OTC Tylenol for pain and follow directions on the label and call PCP if concern arises. Employee voiced understanding Employee of information ? yes Employee voiced any concerns ? yes. She asked if it's a symptoms of covid-19. Mentioned that leg pain is not signs or symptoms of covid-19 Employee?s questions answered to employee?s satisfaction - yes

He woke up this morning and had a temperature of 100.8 degrees Fahrenheit; This is a spontaneous report from a contactable consumer reported for himself. A 27-year-old male patient received BNT162B2 (Pfizer-BioNTech COVID-19 mRNA vaccine, lot EH9899) via unknow route at the right upper arm at single dose for COVID-19 Vaccination on 16Dec2020 11:45. The patient had no medical history. Concomitant medications included zinc and Vitamin D. On 17Dec2020 08:30 the patient woke up and had a temperature of 100.8 degrees Fahrenheit. He was supposed to get the second dose on 06Jan2021. He was planning on taking Tylenol for the fever if that was ok. The patient had no history of previous immunization with Pfizer vaccine and he did not receive other vaccine on the same date. The event did not require a visit to Physician the patient felt ok. The outcome of the event was unknown.

No chief complaint on file. Patient is a 25 y.o. female who had no chief complaint listed for this encounter. á á á History of Present Illness á Patient is at the Covid vaccination clinic Received her vaccination and approx 5 min following administration notified staff that she was feeling a little lightheaded Was also c/o feeling hot at time Patient admits that she did not have breakfast this AM and has not had anything to drink Denies throat discomfort or tingling No shortness of breath or headaches Patient brought to the bay for evaluation á á á History Review / Additional history á Review of Systems á Patient's medications, allergies, past medical, surgical, social and family histories were reviewed and updated as appropriate. Objective á Blood pressure 126/74, pulse 88, SpO2 98 %, not currently breastfeeding. Physical Exam HENT: Head: Normocephalic. Cardiovascular: Rate and Rhythm: Normal rate. Pulmonary: Effort: Pulmonary effort is normal. Musculoskeletal: Normal range of motion. Skin: Capillary Refill: Capillary refill takes less than 2 seconds. Neurological: Mental Status: She is alert. Psychiatric: Mood and Affect: Mood normal. Behavior: Behavior normal. á á á á Assessment / Plan á VSS on arrival to evaluation bay Following laying down for 10 min, drinking water, and eating a granola bar patient reports feeling much better. Sat at the bedside for an additional 5 min with no recurrence of symptoms. Repeat VSS Instructions given to go to the ED if worsening symptoms, lightheaded, throat swelling or shortness of breath. Encouraged to eat and drink prior to next immunization. á Per Attending APRN Electronic Signature 12/18/2020 10:10 AM á á

Injection site pain; This is a spontaneous report from a contactable consumer (the patient). A 27-year-old male patient received BNT162B2 (Pfizer-BioNTech COVID-19 mRNA vaccine), via an unspecified route of administration on 16Dec2020 14:15 at single dose for immunisation. The patient medical history and patient's concomitant medications were not reported. The patient experienced injection site pain on 17Dec2020 07:00. The vaccine was administered at Hospital Facility. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient was not diagnosed with COVID-19 prior to vaccination. The patient had not been tested for COVID-19 since the vaccination. The event was non-serious with outcome of recovering. No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.

Immediately after receiving the dose of vaccine, rash, tickle in throat taken to ED treated with Benadryl on 12/20 developed swollen lips taken to ED treated with epinephrine, steroids, Pepcid discharged from ED 12/21/20 symptoms resolved

Complained of scratchy throat and feeling like throat was swelling.

painful chills; fever (101.7 f); body aches; headache; some tenderness at injection site; This is a spontaneous report from a non-contactable nurse. A 45-year-old female patient received BNT162B2 vaccine (Lot number EK5730) intramuscular in the left arm on 16Dec2020 at 18:30 at single dose for immunisation. Relevant medical history included high blood pressure and seasonal allergy. Concomitant medications included lisinopril and over the counter allergy pill. On 17Dec2020 at 10:00, the patient experienced painful chills, fever (101.7 F), body aches, headache and some tenderness at injection site. Corrective treatments taken as a result of the events included paracetamol (TYLENOL). The patient was not pregnant. Facility type vaccine: Hospital. The patient did not receive other vaccines in four weeks. The patient did not have COVID-19 prior to vaccination, and she was not tested post vaccination. At the time of the report, the patient had not recovered from the events.

15 minutes after vaccination start experiencing nausea and vomiting

Arrived to drive through as passenger in car. á He did let RN know before vaccine he has felt faint and has had syncopal episodes after injections or blood draws. Immediately after injection he had a loss of conciseness. Lasting approximately 1 min. Partner states this was a normal reaction. He then had a second episode lasting longer than first. Partner states this was not a normal reaction for him. He was not responding to voice or touch . After approx 1-2 mins he was alert and responsesive to person, place and situation. RN stayed with Patient as he remained in car. á á 911 called to evaluate RN gave report and hand of to EMS. EMS evaluated and found pt stable.

Significant arm soreness at injection site; body aches; chills; mild headache; restless night's sleep; This is a spontaneous report from a contactable nurse. A 46-year-old female patient received BNT162B2 vaccine (Lot number EH9899) intramuscular in the left arm on 16Dec2020 at 08:45 at single dose for immunisation. Relevant medical history included recent Urinary Tract Infection (UTI), treated and recovered. Concomitant medications included sulfamethoxazole/trimethoprim (BACTRIM), famotidine (PEPCID) and melatonin. Past drug reaction included allergy to doxycycline. On 16Dec2020 at 14:00, the patient experienced significant arm soreness at injection site, body aches, chills, mild headache and restless night's sleep. Corrective treatments taken as a result of the events included ibuprofen (ADVIL). The patient was not pregnant. Facility type vaccine: Hospital. The patient did not receive other vaccines in four weeks. The patient did not have COVID-19 prior to vaccination, and she was not tested after vaccination. At the time of the report, the patient was recovering from the events.

Patient got dizzy immediately and wanted to sit down, he also stated he was short of breath. His blood pressure was 160/111 and pulse 107. Rechecked shortly after that blood pressure check and it went to 176/115 and pulse 138. Patient stated he was feeling well and requested to go to ED, staff called 911.

he most painful vaccine he's ever gotten - arm hurts a lot; felt heavy; tired; This is a spontaneous report from a contactable consumer (patient's wife) A 64 year-old male patient received bnt162b2 (BNT162B2) , via an unspecified route of administration on 16Dec2020 at single dose for immunisation . The patient medical history and concomitant medications were not reported. The patient felt heavy on 16Dec2020 with outcome of unknown , tired on 16Dec2020 with outcome of unknown , arm hurts a lot on 17Dec2020 with outcome of unknown. The patient stated this was the most painful vaccine he has ever gotten. Information on the lot/batch number has been requested.

chills, body ache, sore throat, sever cough with chest pain

Approximately 10 minutes after receiving vaccine, patient experienced itching of lips, tongue and throat. Itching also on neck and left arm. Some erythema around neck and upper chest. Lips swelling. Symptoms resolved within about 30 minutes of administration of oral diphenhydramine 50 mg and famotidine 20 mg.

FATIGUE , HEADACHE, I WOKE UP WITH A MIGRAINE . Mild headache for two days

Repetitive intense sneezing night of vaccination which ended with overnight sleep. Arm pain the next day followed by swelling of lymph nodes with intense aching pain. Swelling lasted 24 hours, pain in lymph nodes has now lasted 36 hours.

Asymptomatic patient who had an immediate temperature of 100.8 degrees F, which they felt was too fast; This is a spontaneous report from a contactable physician. A male patient of an unspecified age started to receive bnt162b2 (BNT162B2) , via an unspecified route of administration on 17Dec2020 at single dose for immunisation . The patient medical history and concomitant medications were not reported. The patient experienced had an immediate temperature of 100.8 ¦F, which they felt was too fast . The patient resulted positive to Covid 19 virus immediately after receiving the vaccine when the temperatura was 100.8¦F. Five minutes later the body temperature was 99.8 ¦F, the patient returned negative the Covid 19. Information about lot/batch number has been requested.

At one and a half hours after receiving her vaccine, developed tongue and throat swelling, went immediately to the ER. She was treated in the ER and was discharged to home with EPI pen. She still has the following symptoms headache, dizziness, lightheaded, fever 99.2. Difficulty concentration and talking. She is following up with her primary care physician on 12/21/2020

approx. 5 minutes after injection, palms were itchy and lips felt tingly. After 30 min observation, pt returned home and noticed her lip felt tight. When she looked in the mirror, she saw one side was swollen.

This is a CCU nurse who received vaccine on 12/18/20 and later that day while at work developed nausea, vomited x1, became tachy and pale. Coworkers provided basic care. Patient went to ED at approx. 4p that day and was later discharged.

Severe fatigue; Myalgia; Head aches; Weakness; This is a spontaneous report from a contactable other hcp reporting for himself. This 33-year-old male patient received the first dose of bnt162b2 (BNT162B2),

intramuscular at single dose in the left arm on 16Dec2020 12:00 at hospital for immunisation. Medical history included atypical cluster headaches. Concomitant medication included docusate sodium (COLACE), verapamil and vitamin D3. On 16Dec2020 18:00, the patient experienced severe fatigue, myalgia, head aches, weakness. No treatment required. The outcome of the events was recovering. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, the patient has not been tested for COVID-19. Information on the lot/batch number has been requested.

15 minutes after vaccination Employee began to experience light headiness, and rapid dehydration

approx. 10 min after injection felt light headed, flushed, and pre syncope. BP and HR were taken by staff and ER physician,, BP was hypertensive for me 145/90, 145/104, 137/89, 138/86, 132/91. I am normally 116/74. HR was 100. Oxygen was 100%, At 12;33 was given 50mg IM x 1 Benadryl. 12:40 felt loopy and shakey. 12:54 moved to room in PACU and monitored by nurse. BP remained in the 130-140's until appox 1430 BP returned to normal 118/80 and Benedryl had worn off. My co-worker took me home.

Left facial nerve tingling; discomfort especially around orbital area and cheek; discomfort especially around orbital area and cheek; Left posterior neck and head discomfort; Left posterior neck and head discomfort; This is a spontaneous report from a contactable Nurse reporting for herself. A 54-years-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK5730), intramuscular in left deltoid at hospital on 16Dec2020 08:45 at single dose for COVID-19 immunization. The patient was not pregnant at the time of vaccination. Medical history included colitis ulcerative as a child, colectomy total 27 years before. The patient previously experienced allergy to IV contrast as hives. Concomitant medication included loperamide hydrochloride (LOMOTIL) and bifidobacterium breve, bifidobacterium infantis, bifidobacterium longum, lactobacillus acidophilus, lactobacillus bulgaricus, lactobacillus paracasei, lactobacillus plantarum, streptococcus thermophilus (VSL#3). The patient experienced left facial nerve tingling, discomfort especially around orbital area and cheek; left posterior neck and head discomfort lasting 60-90 minutes on 16Dec2020 18:00 with outcome of recovered on 16Dec2020. The events resolved on own, no medications taken. Prior to vaccination the patient was not diagnosed with COVID-19 and has not been tested for COVID-19.

hives on hands that appeared next morning and still remain 3 days post vaccination

hives on hands that appeared next morning and still remain 3 days post vaccination

Sore arm; This is a spontaneous report from a contactable consumer reporting for herself. A 63-years-old female patient received the first dose on BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration in the right arm on 15Dec2020 at 16:30 at single dose for COVID-19 immunization. Medical history included chronic angioedema and hops allergy. Concomitant medication included simvastatin (SIMVASTATIN), losartan (LOSARTAN). The patient experienced sore arm on an unspecified date with outcome of recovered. The patient was not treated for the event. Prior to vaccination the patient was not diagnosed with COVID-19. The patient underwent sars-cov-1 test (nasal swab) with unknown results on unspecified date and negative on 16Dec2020. Information on lot/batch number has been requested.

"stomach upset and then felt ""hot and cold"" and Temp was 99.3. Relieved with Tylenol and sleep. Next morning felt ""blah"" and slept and symptoms resolved"

Itching all over

Nurse reports that patient had no problems after receiving vaccination. Patient went home and EMS was called early the next morning and team administered vaccination was contacted physician that the associate works for stating the patient had a heart attack.

Nausea, lightheaded, some throat swelling, difficult to swallow. Transported to ED. No respiratory distress. Stable

Nausea; vomiting; diarrhea; This is a spontaneous report from a contactable consumer. A 42-year-old male patient received first dose of BNT162B2 (Pfizer-BioNTech COVID-19 mRNA vaccine, lot number: EH9899), via an unspecified route of administration at arm left on 16Dec2020 at 12:30 at single dose for immunization. Medical history included hyperlipidemia from an unknown date and unknown if ongoing. Concomitant medication included rosuvastatin calcium (CRESTOR) and finasteride. On 16Dec2020 at 22:30, the patient experienced nausea, vomiting and diarrhea. The patient outcome of the events was recovering. No follow-up attempts are possible. No further information is expected.

On 12/20/2020 I received the Pfizer covid vaccine at 3pm and 10 minutes after vaccine, felt tingling and a heavy sensation on my right eye. Was seen in ER at same facility. Per MD, no facial asymmetry noted and was sent home. On 12/21/2020, I woke up with mild right facial numbness and sensation of heaviness and very subtle right labial dropping. When closing my eyes tight felt the muscles of my right eye were mildly weaker but I was able to close my eye. I presented to the ER. Blood work normal and per MD, did not feel the need for steroids and told to monitor at home. Since then, the sensation on my right cheek is slightly better, my eye still bothering me slightly and the numbness still present but a bit less.

random metallic smell; This is a spontaneous report from a contactable physician (patient herself). A female patient of an unspecified age received bnt162b2 (lot number: EK5730; Expiration date: 31Mar2021), via an unspecified route of administration on 17Dec2020 at single dose for immunisation. The patient's medical history and concomitant medications were not reported. About a half hour later, the patient experienced random metallic smell on 17Dec2020. The outcome of event was unknown.

Body/joint pain Headache Joint Stiffness Injection site pain and soreness of the arm malaise Symptoms begin approx. seven hours after the injection and continues

Runny nose, sore throat

headache; dizziness; nausea; This is a spontaneous report from a contactable other health professional. A 56-year-old female patient received bnt162b2 (BNT162B2), via an unspecified route of administration on an unspecified date at single dose for immunization. The patient medical history was not reported. The patient's concomitant medications were not reported. The patient experienced headache, dizziness and nausea on an unspecified date with outcome of not recovered. The patient received the vaccine in

the emergency department. The reporter stated that the symptoms began immediately after getting the vaccine and are persisting. Information about batch/lot number has been requested.

Migraine (similar to the one I experienced when I had COVID in July/August) began a few minutes after the shot was adminstered. It started mild but continued to get worse. It started to get better the following night (12/16/2020) and was gone by the time I went to bed. The day after I got the shot I felt extremely nauseous when I woke up. It was bad enough that I missed two days of work. This lasted for several days and only just went away completely today (12/21/2020. I took ondansetron to treat the nausea. I felt lightheaded and fatigued around the same timeframe as the nausea, but did not use anything treat either. I am not a regular caffeine drinker but tried it every day to help combat the fatigue. It did nothing to help and made me anxious. I still do not feel great but I am well enough to work.

Fever (100 degrees Fahrenheit); Violent chills; she was shaking/Her hands shake terrible; she slept the entire night, which she never does; This is a spontaneous report from a contactable consumer reporting for herself. A 72-years-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), intramuscular in the left deltoid on 16Dec2020 08:05 at single dose for COVID-19 immunization. Medical history was none. There were no concomitant medications. The patient experienced fever on 17Dec2020 with outcome of not recovered, violent chills on 16Dec2020 19:00 with outcome of recovering. The reporter described the events as pretty bad violent chills where she was shaking, and she could not get warm. Her hands shake terrible. She did not realize she had a fever until she slept the entire night through 16Dec2020-17Dec2020 which she never does. She took her temperature after she woke on 17Dec2020 09:50am and her temperature was 100 degrees Fahrenheit which is her ongoing temperature at time of the call. She asked if there are any recommendations regarding treatment or management of fever following administration of the vaccine; like if it is ok to take Tylenol or something. Information about lot/batch number has been requested.

Nausea, headache, epigastric pain, feeling flushed, metallic taste

5 days after vaccination on 12/20, patient developed a mild, erythematous rash on left hand (dorsal) and forearm. The character of symptoms is redness, no pain, no itching, and no swelling. Radiating symptom(s): spreading proximally. The degree of symptoms is minimal.

Initial arm pain, then nausea and dizziness while at work 2 hours after administration. Presented to the emergency department at the same facility where he works as instructed per occupational health. Symptoms were almost fully resolved 3 hours after receiving the vaccine, after a dose of ondansetron. Patient discharged and instructed to follow up with primary MD.

tiredness; This is a spontaneous report from contactable pharmacist via Pfizer sales representative. A 50-year-old patient of an unspecified gender received the first dose of bnt162b2 (BNT162B2; lot and expiry date was not reported) via an unspecified route of administration on an unspecified date at a single dose for immunization. Medical history was reported as none. The patient's concomitant medications were not reported. The patient experienced tiredness on an unspecified date following

administration of bnt162b2 vaccine. Outcome of the event recovered on an unspecified date No follow-up attempts are possible; information about lot/batch number cannot be obtained.

Felt like I had covid. Headache, nausea,light headed, hot and could not cool down. Overall tried. This was the next day after receiving vaccine.

Sore arm after injection; This is a spontaneous report from a non-contactable pharmacist received via a Pfizer sales representative. A 32-year-old female patient received BNT162B2 (solution for injection, lot number/expiration date unknown) via an unspecified route of administration on her arm in Dec2020 at a single dose for immunisation. Medical history and concomitant medications were not reported. The patient experienced sore arm after injection in Dec2020. The outcome of the event was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

10 minutes post-vaccine - tingling in both arms, all the way down arms. Right arm subsided after 20 minutes, but left arm continued to be warm and tingly. Left leg and foot tingly. 2 hours post-vaccine - Left side of face warm and tingly. Left back muscles heavy and fatigued, 24 hours later subsided. 12/21/20 - Left forearm to pinky tingling, palm numb. Left side of face pink and heavy.

Swollen, painful right armpit. It was present Sunday 12/20/2020 when I woke up. It has not reduced or improved over 24 hours.

Nausea was first noted followed by a sudden tachycardia with pulse in the upper 130's. With this my tongue and mouth began to tingle and it felt like I had something stuck in my throat. The facility gave me liquid benadryl immediately (50mg). Symptoms began to improve over the hour and a half that I was monitored and had fully resolved 3 hours post injection.

"feel lightheaded; I have a bright red, itchy, raised and warm welt at the injection site as well; Pain and itching at the injections site immediately; Pain and itching at the injections site immediately; Throat tightness across the front; Tongue began to tingle, felt a little ""fat"" and then went numb for approximately 3-5 minutes; Swallowing feels like a ""lump"" in my throat, but does feel obstructed; I have a bright red, itchy, raised and warm welt at the injection site as well; This is a spontaneous report from a contactable Nurse who reported for herself. A 51-years-old female patient received the first dose of bnt162b2 (BNT162B2, lot number EK5730), intramuscular in the left arm at hospital on 17Dec2020 09:45 at single dose for immunisation. The patient medical history and concomitant medications were not reported. The patient previously took bacitracin zinc, neomycin sulfate, polymyxin b sulfate (NEOSPORIN) and experienced rash. The patient experienced pain and itching at the injections site on 17Dec2020 at 09:45 (reported as immediately), lasted approximately 3 hours (as reported), the final outcome was recovering (as reported). Throat tightness across the front, but not ""inside."" Tongue began to tingle, felt a little ""fat"" and then went numb for approximately 3-5 minutes. Swallowing felt like a ""lump"" in her throat, but did feel obstructed. Ate lunch without difficulty. Drinking without difficulty. The front of her throat, distal from jawline, to top of breast-line felt like she had a very light weight resting on it, even 8 hours post injection. Approximately 30 minutes after injection, the patient began to feel lightheaded. Lightheadedness became more intermittent for the next 4 hours and resolved. She had a bright red, itchy, raised and warm welt at the injection site as well, 8 hours later, on

17Dec2020. The patient did not receive any treatment for the events. The outcome for the event lightheaded was recovered, for the other events was recovering. Prior to vaccination the patient was not diagnosed with COVID-19 and has not been tested for COVID-19.; Sender's Comments: The reported information is limited. Based on the close temporal relationship and the description of the events, there is a reasonable possibility that the events are related to BNT162 vaccine. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate."

Sudden consent of right sided facial numbness paralysis

About 4 hours after the vaccine during dinner felt tired. Around 11, midnight I felt achy, body hurts, I had chills, and developed cough and shortness of breath. By Thursday I felt horrible and now I can not even taste or smell anything. My body aches are gone I feel somewhat better. No shortness of breathe and no cough, still fatigued. Took Ibuprofen and Tylenol on Thursday Friday and Saturday. Was tested for COVID on 12/18 - tested positive.

Uncontrollable chills; Fever; Headache; Arm is sore a bit; This is a spontaneous report from a contactable consumer (patient). A patient of unspecified age and gender received BNT162B2 (Pfizer-BioNTech COVID-19 vaccine), via an unspecified route of administration at on an unspecified date at single dose for COVID-19 immunization. Medical history included Covid. The patient's concomitant medications were not reported. On 16Dec2020, Last night, about 12 o' clock, patient woke up with the same side effects that patient had Covid. Patient had uncontrollable chills and a fever. Those were better. Patient still had a headache. Of course, his/her arm was sore a bit, that was expected. Outcome of uncontrollable chills and fever were recovering, outcome of other events was unknown. Information on the lot/batch number has been requested.

Swelling and redness in my left eye. Severe pressure on the left side of head.

I am breastfeeding my 20 month old and she developed a rash on trunk. Maculopapular.

Right Ear red and purple and warm.

Migraine; Migraine; fatigue; nausea; diarrhea; This is a spontaneous report from a contactable consumer reported for herself. A 36-year-old female patient received the first dose of BNT162B2 (Pfizer product, lot number EH9899) , via an unspecified route of administration on 15Dec2020 13:30 at single dose on left arm for immunisation. Medical history included migraine. There were no concomitant medications. No allergies to medications, food, or other products. No other vaccines in four weeks and no other medications in two weeks. The patient experienced migraine, fatigue, nausea, diarrhea starting the following day around 10 am (16Dec2020 10:00). The patient was not pregnant. No Covid prior vaccination, and no Covid tested post vaccination. No treatment was received for the events. The outcome of the events was resolved on an unspecified date in Dec2020. The report was assessed as non-serious.

"Date: 12/21/2020 á Subjective Patient is a 33 y.o. female who was seen at COVID Vaccine Clinic today for her first dose of the COVID 19 vaccination. á She denied any history of previous adverse reactions to vaccines. á She was given the Pfizer vaccination in the left deltoid muscle. á During her 15 minute waiting period after the injection, the patient began to experience feelings of hypoglycemia. She checked her blood glucose with her own monitor and had 77 at 1104. She chewed 1 glucose tab that she had in her purse. She noted some difficulty with swallowing it and notified clinic staff. Associated dizziness and was escorted by clinic staff to the emergency bay. á This provider was notified of patient reaction and she was then assessed in the emergency bay area. She denied difficulty breathing and chest pain, history of adverse reactions with prior vaccinations or allergies to medications with the exception of spironolactone. á Pateint had already been given a bottle of water by clinic staff and reported that the glucose tablet went down easier following the water. She took a second glucose tab sometime before 1113. She rechecked her sugar and had slight increase of 79. She did eat breakfast this morning about 0800 and had a protein bar right before her arrival today. á Monitored patient for severe reaction symptoms, including rapid progression of symptoms, respiratory distress with dyspnea and increased work of breathing, vomiting, abdominal pain, hypotension and chest pain. á Review of Systems HENT: Positive for trouble swallowing. Negative for facial swelling, hearing loss, rhinorrhea and voice change. Eyes: Negative for redness. Respiratory: Negative for cough, chest tightness and shortness of breath. Cardiovascular: Negative for chest pain. Skin: Negative for color change, pallor and rash. Neurological: Positive for dizziness. Negative for syncope and speech difficulty. Psychiatric/Behavioral: Negative for agitation and confusion. The patient is not nervous/anxious. á Objective Vitals There were no vitals filed for this visit. á á Physical Exam Constitutional: General: She is not in acute distress. HENT: Head: Normocephalic and atraumatic. Nose: No rhinorrhea. Cardiovascular: Rate and Rhythm: Normal rate and regular rhythm. Pulmonary: Effort: Pulmonary effort is normal. No respiratory distress. Skin: General: Skin is warm and dry. Coloration: Skin is not pale. Findings: No rash. Neurological: Motor: No weakness. Psychiatric: Mood and Affect: Mood normal. Behavior: Behavior normal. á á á Assessment/Plan Patient is a 33-year-old female who has a 15-year history of type 2 diabetes, and experienced a hypoglycemic event without complaint of chest pain or shortness of breath. á Vital signs obtained at 1105 with blood pressure within normal limits at 132/88, heart rate 83 and 98% O2 saturation on room air. Patient continued to compensate appropriately and reported feeling slightly better. Glucose checks repeated by patient at 1117 was 84, vital signs were blood pressure 116/80, heart rate 89, O2 saturation of 98% on room air. She continues to deny chest pain, shortness of breath or difficulty swallowing at this time. á At 1117 a 10 mg cetirizine was administered by mouth. Patient was able to swallow this with a small sip of water without any difficulty. á 1121, patient continues to deny chest pain or shortness of breath. She continues to be compensating appropriately and sitting at the edge of the bed. She states that she is feeling better. á Vital signs obtained at 1123 with blood glucose per the patient's own meter, continuing to elevate at 103, blood pressure within normal limits at 116/91, heart rate at 85 and 100% O2 saturation on room air. á At 1126, the patient continues to feel better. She is provided a granola bar to eat. She does note feeling sleepy though attributes this to this being the first day she has had off after working 4 days last week. She notes that she has been sleepy even prior to her arrival at the vaccine clinic today. She is able to eat the granola bar and continues conversing appropriately without difficulty. She continues taking small sips of water without issues. Continues to deny chest pain or shortness of breath. Blood sugar is rechecked at 1138 and continues to

elevate to 116. She reports that her meter says her sugar is ""stable."" á Final set of vital signs obtained at 1138 revealed blood glucose within normal limits at 116, blood pressure of 119/84, heart rate 83 and 100% O2 sats on room air. Patient denied complaints of chest pain, shortness of air, nausea, dizziness or blurred vision at this time. She felt much improved and we discussed her leaving the clinic and heading home to have lunch. She had no further complaints. She was able to rise to standing on her own without any further issues and ambulated out of the clinic without difficulty. á She was advised with strict return precautions should she develop chest pain or shortness of breath to present to the ED or call 911. She expressed understanding of this. á LPN, RN, PharmD present through this encounter and assisted as asked of the, by this provider. á Follow up response to treatment:excellent. á Patient discharge: Stable to go home and follow up with PCP. á Orders Placed This Encounter Procedures ? COVID-19 MRNA LNP-S PF á PA-C Electronically Signed 12/21/2020 11:17 AM á á"

Burning at injection site followed by tachycardia and lightheadedness within 2 minutes. Lasted over half an hour

sore arm; This is a spontaneous report from a contactable pharmacist (patient). A 35-year-old female patient (who happened to be a pharmacist) received BNT162B2 (Pfizer-BioNTech COVID-19 vaccine), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced a sore arm following administration of Covid 19 vaccine on an unspecified date with outcome of unknown. No follow-up attempts are needed. Information about lot/batch number cannot be obtained.

Patient has known anxiety and diabetes. Blood glucose 220 - patient admitted that they had not taken DM medications. Patient did not required any medication.

EE stated that she started feeling itchy within 30 minutes of receiving her vaccine but she didn?t tell anyone because it was not bad, the next day she noticed a rash on her chest (left side), it then spread down the left side of torso to the left leg, EE has a history of eczema and took her prescribed steroid, she also started using hydrocortisone cream on her rash, no reported fever, EE stated that she was fatigued with body aches and joint pain, EE does not have a history of Covid positive testing, she has not been around anyone with Covid, she has not traveled or live with anyone who has traveled, She stated that she went to see her PCP today, 12/21/2020 and was instructed to continue the hydrocortisone cream and do not get the 2nd dose of the Covid Vaccine.

36 hours after injection lymph node pain in back of neck, this flared my trigeminal neuralgia. Took 800 Ibuprofen 1 hour later that pain stopped and massive headache. Headache was followed by drunken type vertigo. I took 20mg steroid, Benadryl, Afrin, Albuterol. Two hours later better but still had vertigo. By 4am symptoms light enough to do light work out, legs felt fatigued. Today no symptoms.

Injection site pain; myalgia; arthralgia; congestion; neck pain; fatigue; This is a spontaneous report from a contactable consumer (patient). A 62-year-old male patient received first dose of bnt162b2 (lot number EK5730), via an unspecified route of administration in arm left on 16Dec2020 07:15 at single dose for immunization. Medical history included hypertension and CAD (coronary artery disease). Patient had no allergy history to medications, food, or other products. Concomitant medication included

ticagrelor (BRILINTA), lisinopril, acetylsalicylic acid (ASA), ergocalciferol (VIT D) and magnesium (MAGNESIUM). Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. The patient experienced injection site pain, myalgia, arthralgia, congestion, neck pain, fatigue all on 16Dec2020 20:00. Treatment paracetamol (TYLENOL) were taken as a result of reported events. The outcome of the events was recovering.

Left arm feels swollen - resolved on own.

Developed numbness and tingling to face, forehead and lips about 45 minutes after administration. Everything but nose resolved in 5-10 minutes but nose remained feeling numb - had some sensation but not normal. 2 1/2 hrs later felt like it was continuing to improve, but not normal yet.

Patient developed hives 30 minutes after receiving injection. Received Benadryl and seen in ER for evaluation. No further issues reported.

About 5-7 minutes after the injection, I was sitting in the waiting area for my 15 minutes observation period. After about 5-7 minutes I noticed that it was hard for me to swallow and I became really flushed and hot and tachycardia. I was not anxious or upset about getting the shot. I am actually an ER physician and have had lots of shots in my life without any adverse reaction. The flushing and tachycardia resolved after about 20 minutes but the sensation of difficulty swallowing did not subside completely until I took dose of Benadryl 50mg orally. Symptoms resolved after about 1 hour post Benadryl. I also had a recurrence of symptoms the next day at around 24 hours where I felt again like I couldn't swallow, so I took Benadryl 50mg again, but this time I also had some numbness of the left side of my tongue and the left side of my face. The abnormal sensation in the left side of my face subsided over about an hour or so.

lots of pain on the site radiating from shoulder to hands; lots of pain on the site radiating from shoulder to hands; lots of pain on the site radiating from shoulder to hands; swelling; This is a spontaneous report from a contactable consumer. A male patient of an unspecified age received bnt162b2, via an unspecified route of administration on an unspecified date at single dose for immunisation. The patient's medical history and concomitant medications were not reported. The patient experienced lots of pain on the site radiating from shoulder to hands and swelling on an unspecified date. The outcome of event was unknown. Information on the Lot/Batch number has been requested.

headache; dizzy; ringing in her ears for hours -high pitched ring; sore arm where injection was administered; This is a spontaneous report from a contactable nurse (patient). A 28-year-old female patient (not pregnant) received first dose of bnt162b2 via intramuscular in arm right on 17Dec2020 11:30 at single dose for immunization. The patient medical history was not reported. The patient had no medications, food, or other products allergy history. The patient's concomitant medications were not reported. The patient reported 8 hours after administration of vaccine, on 17Dec2020 8:00 pm, the patient started to get a headache then dizzy then ringing in her ears for hours -high pitched ring, and sore arm where injection was administered. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. No treatment was

received in response for reported events. The outcome of the events was recovering. Information on the lot/Batch number has been requested.

"complained of ""chest tightness"" after receiving the vaccine; being nervous; This is a spontaneous report from contactable Pharmacist. A patient of unspecified age and gender received bnt162b2 (Pfizer-BioNTech COVID-19 Vaccine), via an unspecified route of administration in 2020 at single dose for immunization. The patient's medical history and concomitant medications were not reported. The patient (healthcare worker) received the Pfizer-BioNTech COVID-19 vaccine in 2020 and complained of chest tightness after receiving the vaccine. Chest tightness resolved quickly and the patient attributed it to being nervous. No medical interventions were received and the patient left the observation area without issue. The outcome of the events was resolved in 2020. Information about lot/batch number has been requested."

feeling tired; achy; This is a spontaneous report from a contactable consumer. This consumer reported similar events for two patients. This is 1st of two reports. A patient of unspecified age and gender received bnt162b2 (Covid-19 vaccine) , via an unspecified route of administration on 16Dec2020 at single dose for immunization. The patient's medical history and concomitant medications were not reported. The consumer had two friends who are health care professionals who received the Covid-19 vaccine on 16Dec2020. They just reported feeling tired and achy in Dec2020 to the consumer. The outcome of the events was unknown. Information on the Batch/Lot number has been requested.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2020501305 same reporter/drug/event, different patient

feeling tired; achy; This is a spontaneous report from a contactable consumer. This consumer reported similar events for two patients. This is 2nd of two reports. A patient of unspecified age and gender received bnt162b2 (Covid-19 vaccine) , via an unspecified route of administration on 16Dec2020 at single dose for immunization. The patient's medical history and concomitant medications were not reported. The consumer had two friends who are health care professionals who received the Covid-19 vaccine on 16Dec2020. They just reported feeling tired and achy in Dec2020 to the consumer. The outcome of the events was unknown. Information on the Batch/Lot number has been requested.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2020501278 same reporter/drug/event, different patient

Left arm swelling; rash throughout body; left leg going numb; loss of balance; This is a spontaneous report from a contactable Other healthcare professional reported for herself. A 22-year-old non-pregnant female patient received first dose of bnt162b2 (pfizer-biontech covid 19 vaccine), intramuscularly on left arm on 17Dec2020 at 08:30 at single dose for immunization at workplace clinic. Medical history included known allergies to watermelon, cantaloupe, honey dew, kiwi. There were no concomitant medications in two weeks nor other vaccine in four weeks. There is no prior covid vaccination nor covid tested post vaccination. The patient experienced left arm swelling, rash throughout body, left leg going numb, loss of balance on 17Dec2020 at 09:15 with outcome of unknown. No treatment was received for the events. Information on the lot/batch number has been requested.

Physician receiving Pfizer BioNTech COViD 19 vaccine experienced sore arm; This is a spontaneous report from a contactable physician (patient) via Pfizer sales representative. A patient of unspecified age and gender received BNT162B2, via an unspecified route of administration in 2020 at single dose for immunization. The patient's medical history and concomitant medications were not reported. The physician receiving pfizer biontech covid 19 vaccine experienced sore arm within 24 hours of receiving vaccination dose in 2020 with outcome of unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

Pain in injection site; slight nasal congestion; This is a spontaneous report from contactable Nurse (patient) via Pfizer Sales Representative. A 27-year-old female patient received BNT162B2 (Pfizer-BioNTech COVID-19 vaccine), via an unspecified route of administration on an unspecified date at single dose for immunization. The patient's medical history and concomitant medications were not reported. The patient experienced pain in injection site, and slight nasal congestion on an unspecified date with outcome of unknown. Events took place after use of product. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

Has pain around injection site of COVID vaccine; This is a spontaneous report from a non-contactable Physician. A patient of unspecified age and gender received BNT162B2 (Pfizer-BioNTech COVID-19 vaccine), via an unspecified route of administration on an unspecified date at single dose for COVID vaccine. The patient's medical history and concomitant medications were not reported. The patient had pain around injection site of COVID vaccine on an unspecified date with outcome of unknown. No follow-up attempts are possible. Information about lot/batch number cannot be obtained.

sent to the emergency room for body rashes and hives.; sent to the emergency room for body rashes and hives.; This is a spontaneous report from a contactable pharmacist. This pharmacist reported similar events for 4 patients. This is a third of four reports. A patient of an unspecified age and gender received BNT162B2(Solution for injection) via an unspecified route of administration on an unspecified date at single dose for immunization. The medical history included allergies to bee stings. The patient's concomitant medications were not reported. The patient sent to the emergency room for body rashes and hives. The outcome of the events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2020502532 same reporter, drug, event different patient

Mild throat swelling, not enough to obscure airway, went home and took Benadryl and went to sleep. Symptoms gone post nap (also had fatigue and mailase both gone after nap)

flushed face, shortness of breath, feeling like I was going to pass out, tightness in my throat but could still swallow, had heart palpitations and feeling like my heart was going to come out of my chest. Those symptoms lasted for about 5-10 minuets and slowly the flushed feeling went away and heart stopped racing after about 10 min. I was very shaky and still had a bit of tightness in my throat. I left the area out 40min but was still very jittery. Currently its 1510 and I still have some localized flush feeling in my cheeks and continued jitteriness but am breathing fine.

Fatigue Headache Pain at injection site

Approx 5 hours after receiving vaccine, developed an aching sharp pain between my shoulder blades worsening with inspiration, intermittent mild chills, and fatigue. Pain between my shoulder blades lasted 4 hours, until i took tylenol and went to bed.. i woke up 5 hours later and the pain was now a dull ache.

Fatigue: 18 hours after injection to current time. Dizziness: 24 hours to current time, Vertigo: 36 hours to current time, subsiding with use of Dramamine Nausea: coincides with the dizziness/vertigo Spoke with PCP office 3 times who referred me back to hospital, the provider of the vaccination. Hospital COVID-19 Incident Command pulled me from employment until I get a back to work note from my PCP. PCP states this is a Hospital issue, they pulled you, they need to reinstate you. Hospital Occupational Health agrees in principal and is working on an outcome.

Chest pain and diffuse, severe myalgias, as well as persistent tachycardia to 110's and hypertension resulting in ER evaluation. No abnormalities found on basic labs and studies. Symptoms started one hour after injection and worsened over the next 24 hours.

The evening of the shot, patient reported he had headache and nausea. Next day nausea and Headache continued and also included Body aches, chills, achy joints which lasted for 3 days.

Flushing Hives Nausea Heartburn Throat itching and swelling Hot flash Blood pressure and pulse spiked All of this happened within 5 minutes of administration. Patient was given benedryl and Pepcid and sent to the Emergency Room.

-Sore injection arm (left) starting at 4pm on day of injection (12/16/20) and resolved on 12/20/20. -Chills starting at 5pm on second day (12/17/20) and resolved on 12/18/20.

"PATIENT REPORTS RECEIVING VACCINATION AT APPROXIMATELY 830AM. SHE WAS BUSY THROUGHOUT THE DAY BUT ONCE SHE RETURNED TO HER OFFICE AROUND 120 PM, SHE STARTED TO NOTICE HER ARM IN WHICH SHE RECEIVED HER VACCINE WAS PAINFUL AND SHE WAS UNABLE TO ""LIFT IT UP"". SHE ALSO NOTICED HER TONGUE BEGAN TO FEEL ""WIERD AND TINGLY"". SHE THEN REALIZED HER TONGUE WAS PUSHED UP AGAINST HER TEETH AND COULD SEE A VISIBLE TOOTH MARK ON HER TONGUE. SHE ALSO REPORTS THAT HER BRAIN FELT ""FOGGY"" DURING THIS TIME"". ADDITIONALLY, SHE REPORTS THAT ONSENT OF ALL HER SYMPTOMS PRESENTED PROGRESSIVELY. SHE RECIEVED IM BENADRYL ONSITE PRIOR TO TRANSFER TO THE EMERGENCY ROOM FOR EVALUATION. AT THE EMERGENCY ROOM SHE WAS GIVEN THREE MEDICATIONS, SHE RECALLS ONE WAS A STERIOD AND BELIEVES ATLEAST ONE WAS AN ANTIHISTAMINE. HOWEVER, SHE IS NOT COMPELTELY CERTAIN WHAT THE OTHER MEDICATIONS WERE. SHE REPORTED IMPROVEMENT OF SYMPTOMS WITH MEDICATION. SHE WAS PRESCRIBED BENADRYL AND A MEDROL DOSE PAK AT TIME OF DISCHARGE. SHE WAS NOT ADMITTED TO THE HOSPITAL."

headache, dizziness, hypertension, subjective mild shortness of breath, BP 160/100 Taken to the ER for evaluation

"Received COVID-19 vaccine the afternoon on 12-18-2020 on 12-19-2020 developed chest pain and ""heart racing"" intermittently. Lasted approximately 1 hour . Patient did take Nitroglycerin 2 times ."

"Per documentation of other RNs invloved, at 1009, patient began reporting sensation of numbness in right arm and ""feeling funny"", she also presented with visible flushing and reported itching and feeling anxious. We monitored the patient's vital signs q5min and administered 25mg Benadryl IM. Over the course of aproximately 1.5 hours, the patient's flushing had visibly diminished, she reported significant improvement in her anxiety and stated that the itching was ""nearly resolved."" Her vital signs also improved and were WNL, including pulse, O2 saturation, temperature and blood pressure. The patient stated that she felt well enough to return to work and verbalized understanding that if any symptoms develped or worsened she was to report immediatley to the ED."

Injection site pain, malaise, fatigue decreased appetite, chills, joint pain

transient dizziness, history of dizziness with piercings and shots

Staff reported numbness, tingling and heat all the way down her left arm. She was sent to ER for further evaluation and monitoring.

Staff reported numbness, tingling and heat all the way down her left arm. She was sent to ER for further evaluation and monitoring.

Fever, headache, body aches, arm pain for two days at site of injection. Approaching 72 hours with fever.

"Patient woke up 3 am next morning and felt like she couldn't move limbs hardly at all and ""felt like a boulder sitting on my chest"". She also felt nauseous, dizzy and a headache. By 5 am the ""heaviness"" of her limbs and her chest and throat felt so heavy patient was scared and was transported to ED by her husband. ED physician didn't think it was an anaphylactic reaction, but just thought it was an extreme adverse reaction. EKG, labs including Cardiac enzymes, and chest xray were all normal. Given IV benadryl, IV zofran, Aspirin, tylenol and norflex. during ED visit. Discharged from ED 10:30 am. Took Benadryl and Solumedrol dose pack once home. by Saturday patient felt 95% better, but as of this report, still says arms still feel heavy and she is fatigued. Went back to work today."

Injection site pain

Vaccine on Wednesday. Sneezing (allergies) around the time of injection. Sore arm for a day. Felt fine on Thursday and Friday. A little off on Saturday. Myalgia, headache w temp of 99 on Sunday. Took Tylenol at 2000 and went to bed. Did not sleep well. Temp at 0400 was 100. Took additional Tylenol. Achfnese returned at 1100 on Monday. No fever. Shaking chills but no fever from 1400-1500. Resolved but temp of 101.2. This is where I am now.

12/18/20 @1400 - light headache 12/18/20 @2100 - extreme soreness at injection site (right arm). Difficulty sleeping on right arm during night. 12/19/20 @1030 - extreme fatigue. Took a 1.5 hour nap and awoke with chills. 12/19/20 @ 1230 - extreme fatigue and chills. Took a hot shower to help relieve chills. After about 15 minutes in shower, began to sweat profusely and my face was flush. *I did not take my temperature, therefore it is unknown whether or not I had fever, but I would assume so* Finished shower and slept until 1830, but only because my daughter awoke me. I was still tired when I awoke.

12/19/20 @ 2200 - Fell asleep and slept through the night. Awoke at 0930 the following morning and felt better, feeling almost normal by 1200.

Began to feel slight pain at injection site Friday, 12/18/2020, evening and was experiencing significant pain when trying to raise left arm above shoulder height. This sensation subsided by Sunday, 12/20/2020, morning Began to have a numbing sensation in both cheeks, nose, and throat on Saturday, 12/19/2020, early evening. The sensation was similar to that feeling of getting Novocaine at the dentist. There was no facial swelling, no difficulty breathing, no facial drooping, or slurred speech. Began to feel dizzy on Saturday, 12/19/2020, evening and this lasted until Sunday, 12/20/2020, morning. No sensation of nausea or vomiting. I contacted my Director and Occ Health dept as instructed. Occ Health felt that these symptoms may be an inflammatory response to the vaccine, I was advised to take Motrin to see if any relief could be obtained. Minimal numbness noted in mouth and nose on Monday, 12/21/2020.

Injection site pain. No redness or swelling. Fatigue, dizziness, lightheadedness, night sweats, body aches.

Shingles right arm 2 days after COVID 19 vaccination. Evaluated 12/21 and prescribed topical acyclovir and oral vatrex 1g TID x 7 days. Labs obtained and pending (CMP, CMP, ESR, CRP, Zoster IgG,M, viral swab)

Within two minutes of receiving the vaccine I experienced tachycardia and dizziness that were severe for approximately five minutes and improved over the subsequent ten minutes. Beginning approximately twenty minutes after receiving the vaccine I experienced another bout of dizziness accompanied by chest tightness. This resolved within approximately ten minutes.

I had nausea starting about 2 hours post vaccine and 7 hours later I was vomiting, I had Zophran I was taking and was still unable to keep anything down tuesday in the AM. I had a Teledoc appointment and was prescribed 2mg of sinofren, I was still vomiting with both meds until saturday morning and since then I've had nausuea that have been getting lighter everyday since. I am back to being able to eat solid food with light use of the Zophran

Patient is a 72 y.o. female who was seen at COVID Vaccine Clinic today for her first dose of the COVID 19 vaccination. á She denied any history of previous adverse reactions to vaccines. á She was given the Pfizer vaccination in the right deltoid muscle. á During her 15 minute waiting period after the injection, the patient began to experience lightheadedness and tingling to right upper and lower arm. Also c/o pain to mid forearm. She denied hives, difficulty breathing, difficulty swallowing, wheezing, throat tightness, itching and tongue swelling. When walking to the emergency bay reports some lightheadedness and generalized weakness Denies facial drooping or weakness. No loss of strength and normal ROM to hand and arms á This provider was notified of patient reaction and she was then assessed in the emergency bay area. á á Monitored patient for severe reaction symptoms, including: rapid progression of symptoms, respiratory distress with dyspnea and increased work of breathing, hypotension and chest pain á Review of Systems á á Objective á Vitals Vitals: á 12/18/20 1023 12/18/20 1025 BP: (!) 175/93 (!) 182/85 BP Location: Left arm Left arm Pulse: (!) 115 (!) 112 á á Physical Exam Constitutional: General: She is not in acute distress. Appearance: She is not ill-appearing. HENT: Head: Normocephalic. Mouth/Throat: Mouth: Mucous membranes are moist. Pharynx: Oropharynx is clear.

Cardiovascular: Rate and Rhythm: Normal rate. Pulses: Normal pulses. Pulmonary: Effort: Pulmonary effort is normal. Comments: Initially with slight shortness of breath After 3-4 min was able to return to normal rate of breathing SpO2 remained 99-100% for duration of observation Musculoskeletal: Right shoulder: She exhibits tenderness (where identified). She exhibits normal range of motion, no swelling, no effusion, no deformity and normal strength. Arms: Comments: C/o generalized tingling and mild weakness to right arm. Point tenderness where identified. Grip strength equal bilaterally Full ROM Injection site to right deltoid covered with bandaid Skin: General: Skin is warm. Capillary Refill: Capillary refill takes less than 2 seconds. Neurological: Mental Status: She is alert. á á Assessment/Plan á Treatment included antihistamines. Zyrtec given po at 1025 Follow up response to treatment:no change Patient discharge: Transported by ambulance á Report provided for Medical Record Patient reports some improvement in arm tingling, but pain to forearm and weakness remains á APRN Electronically Signed 12/18/2020 11:31 AM á á

Flu like systems, chills, headache , fatigue . Next morning I had a headache for the rest of the day .

Tingling in the back of throat with possible decreased ability to breathe and swallow. She was given oral Benadryl, 2 doses of IM Epi. Reaction improved. She was sent to the ER to be evaluated. Received IV Decadron. Clinically improved. Discharged home on Decadron, Zyrtec and Pepcid as well as an Epi pen. Discussed to follow up with primary care physician.

4 hours after injection, got right medial subconjunctival hemorrhage, 14 hours after injection, experienced chills, headaches x 2 days

On 12/19/20 Woke up at 4:30 , 3 hours after going to bed (9.5 hrs after receiving vaccination) with left arm throbbing. Was nauseated, whole body violently shaking, feverish (never took temperature). States he could not control shaking. Lasted about 30 minutes, could barely walk. Afterwards felt achy and very weak. Felt better on awakening, but whole body aching and weakness returned around 600PM and again at 1000PM. Took Tylenol/Ibuprofen for relief. On 12/20 at 600PM also experienced whole body aching and felt generally poorly. 12/21/2020 Doing well today.

She c/o of numbness and tingling on left side of entire body. 98.8, 92,142/84, o2 sat 99, rr 16. denied other compliant. emerenccy response team called. taken to ED

Minor pain and swelling at injection site, mild fever responsive to tylenol, fatigue. Fully recovered from all side effects at 48 hrs. Reporting only due to the fact that this is a new vaccine for tracking purposes.

Metallic taste in her mouth Itchiness to site, then progressed to whole body and back pain Arm pain

10 minutes after vaccine, leg itching, checked for redness. Between 2200-2330 swelling of tongue, and lips swelling, administered epipen and prednisone. No 911 or did not notify her PCP. Today she feels fine but still has fine pink rash over body.

Following vaccine, pt became nauseated and lightheaded. Offered water. Refused need to lie down

Patient reports redness and swelling around the injection site the size of an egg in terms of shape. She also reported red fingerlike projections that wrap partially around the arm. Offered patient acetaminophen and patient declined. She would prefer to ice injection site. She is to follow up with provider if issue persists or worsens

Right arm weakness; heavy chest. Given Orange juice due to low blood sugar, transported to ED.

Hives, rash, and tingling to lips 14 minutes post injection

Injection site / l arm soreness - 2-3days Headache - 2 days, treated with Tylenol

12/17/2020 deep sharp pain in my arm and not just at the injection site it was the entire upper arm where I couldn't pick up my daughter. I took tylenol 12/18/2020 and within an hour later I had no pain in my arm and I was fine

palpitations, shortness of breath, warmth in throat

Rash with itch to the extremities (upper and lower) as well as itch/ irritation to the vaccination site (right upper arm/ deltoid

45 minutes after receiving injection I got generalized large hives all over my body, my chest started to feel tight, and under my chin up to my bottom lip felt numb and tingly. Took 50mg Benadryl, Zyrtec, and Pepcid, symptoms subsided. Went to ER for follow up and they prescribed me 18 days of tapering prednisone and an epi pen, advised me to not get 2nd dose.

12/18/2020 ABOUT 5 MINUTES AFTER VACCINATION, STARTED TO FEEL DIZZINESS. 'IT WAS VERY WEIRD. LIKE I WAS MOVING. I MADE IT TO THE OTHER CHAIR'. I FELT MY LEGS GO NUMB, TINGLING IN ARMS AND LEGS. STAFF CALLED NURSE OVER. TOLD ME TO LIE DOWN ON THE FLOOR, STARTED TO CRY, 'DONT LIKE HOW MY FEET FEEL NUMB'. TOOK ME TO THE ER. TOLD MIGHT BE A 'NASAL VASOVAGAL REACTION'. DIDN'T LOSE CONSCIOUSNESS. BUT THE TINGLING IS STILL GOING ON .

Patient returned back to clinic after her observation time stating she had some heart palpitations and slight chest tightness. Declines medical attention at this time.

About 10 minutes after the injection I started feeling dizzy and hot. Then the headache started with pain moving up my head. Throat became dry. Started feeling nauseous. RN's started to check my vitals. Temperature was at 99.4. O2 was at 99%. Blood pressure was 135-92. Symptoms were not getting better and I started feeling worse. RN (House Supervisor) encouraged going to the ER. Was checked into ER where they gave me Benadryl, Tylenol, Zofran & steroids. Symptoms stayed about the same. Received second dose of Benadryl. Started to feel a little better about 30 minutes after. Spent about 3 hours total in ER. We home to sleep for about 7.5 hours. Woke up the next morning feeling very fatigued with a terrible headache. Continued to dose with Benadryl and Tylenol as needed.

All day Saturday the right side of my face felt tingly and when pressed hurt. Was able to smile, talk and move my face. Tongue tingled a little, and lips (right edge of mouth) off and on until it finally stopped

Sunday morning. Haven?t had any issues with it since then. Never had that happen before, so was a bit concerning.

Extreme dizziness

Paresthesia of part of tongue starting about 5 min. after injection; no swelling or airway problem. No other signs of allergic reaction. Observed x 30 min. w/o worsening. Given 25 mg diphenhydramine as precaution.

"Employee complained of metallic taste in mouth. Then complained of scratchy throat and a feeling of ""throat swollen on the inside"""

"Pt c/o diffuse itching ""all over"" approximately 2 hours after the vaccine was administered. no rash or other sx reported. treated with claritin, water. followed up at end of shift around 4:30 Pm and reports improvement, but still feeling ""itchy"". instructed to take PO benadryl once got home if didn't subside."

Hypersensitivity to touch all over body and joint pain, headache fatigue the day after vaccine administered. No medical intervention warranted

felt nausea, lightheaded and dizzy. developed itching and redness on chest. 25mg benedryl IM administered. Called emergency response. Patient taken to ED. Reports in ED not remembering the events.

Dizziness, Hot flash. Laid supine for 30 minutes, while repeatedly checking blood pressure.

Patient observed for over an hour due to symptom development including complaints of pressure in head, diaphoretic, swelling and increase muscle tone/rigidity in her left arm, tongue feeling thick. Brought to ED for care after an hour of observation. In the ED, left arm rigidity/spasm worsened. Here is the physician note: Patient's headache is improved. She has no neurological deficits or subjective complaints or objective exam consistent with a recurrent CVA. She has no evidence of significant anaphylaxis related to the immunization. May be a recurrence of her underlying medical problems that she has been seen by neurology for something similar. Possible unmasking of this is related to the Covid vaccine is difficult to determine. We will have her work individually with our pharmacy, infectious disease team to determine whether she is a candidate for a second vaccination. She would like to return home right now her CT labs are otherwise unremarkable I think this is reasonable. Return precautions for more significant etiologies were discussed at length. Received lorazepam 0.5 mg IV x1, diphenhydramine 25 mg IV x1, and methylprednisolone 60 mg IV x1.

approximately 30 minutes after the vaccine the patient began to experience itching and swelling of the throat and tongue.

Patient felt dizzy and tired after receiving the vaccine, additional monitoring, no further treatment.

I had diarrhea, aches, nasuea and fatigue

Patient was sitting in observation area after vaccine. Approximately 5 minutes (1050) after administration the patient reports feeling a 'head rush', like he was going to pass out, and nausea. Patient taken to exam room via W/C. Skin pale, cool, moist. BP taken with feet elevated. Denies SOB, itching. 1115 patient reports nausea has resolved. Denies dizzy, lightheaded, SOB, nausea, itching. Patient not as pale. Transitioned to sitting with feet down. 1125 patient denies dizzy, lightheaded, SOB, itching, nausea. Color natural. Blood pressure WDL. Patient standing and walking in exam room with no symptoms. Patient dismissed to home. 12/21/20 no symptoms reported.

Dizziness, Vertigo, Tachycardia, nausea, numbness and tingling of both arms

felt itchy on back, and then throat became scratchy.

Dizziness, chest tightness. Laid supine for 30 minutes while repeatedly check blood pressure.

Lacerations and blisters in mouth.

1645- Patient gave vague reports strange taste in her mouth and shortly after that began, strange sensation of tongue and heaviness in chest. VS 118/64, pulse74, SaO1 97, Resp 16. 1655- no change in symptoms. Ambulated around clinic with no change in symptoms. 1710- Patient reported some numbness and itching of her face and arms along with the heaviness in the chest. Denies lightheaded/dizzy. Benedryl given per allergic reaction protocol. 1730- patient report itching of face and arms continues. 1735- patient ambulating in clinic with steady gait. 1745- patient reports slight improvement of itching and chest heaviness resolved. Dismissed to home. 12/21/2020 Asymptomatic.

Dizzy first 20 minutes lasted all day. Very tired. 1:30 very tired. Went home slept the entire next day. Headache took motrin. Had palpitations on Sunday.

Left face/lips with decreased sensation. Intermittent left hand and foot tingling.

"Admin vx at 1530. Developed itching on lips at 1535. Pt reports this as a reaction to the surgical mask she was wearing. Exchanged surgical mask for cloth mask. 1555-Pt reports increased itching. BP 120/84, P 82, O2 96%. OHN offered Benadryl per S.O.; pt declined. 1600 BP 122/83. 1605-BP 133/84 P 84 O2-96%. Pt continues to report increased itching. Reports ""internal itching"" and itching of feet. No obvious rash visible. Offered Benadryl, pt declined. Offered to set up appt with Med Group to be seen now; patient declined. OHN again encouraged pt to f/u with OH doc. Pt seen in clinic at approx 1645. Dr. reports admin of depomedrol and phenergan."

"felt lightheaded, flushed about 10 minutes after vaccine administration while still within the observation period. The patient was laid on a gurney, given water to drink and vitals were taken. Patient was hypertensive, blood sugar was normal. She was examined by an emergency room MD in the vaccine room and it was determined unlikely to be an anaphylactic reaction. There was scattered blotchiness on the neck region, but no raised areas, swelling or other appearance on the face, trunk or at the site of the injection. The patient recovered well and was observed an additional 15 minutes. She did have a brief recurrence of the same symptoms approximately 10 minutes later but attributed it to a ""hot flash""."

"within 5-10 mins of receiving vaccine she started to feel light headed and jittery and ""floaty"" - she says she feels like, ""I am not here, right now"" - there are no hives - no swollen lips or tongue - pt denies SOB. pt was sent to ED at 8:18 AM for further evaluation. no significant findings and patient was discharged at 10:22 AM"

10 minutes after receiving the vaccine the patient began to vomit, stated her throat felt scratchy, face became flushed. patient taken to the ER

tingling in arm & chest directly after vaccine given. Tightness in throat and a little feeling of short of breath. Went to emergency dept and received bendaryl & solumedrol - symptoms resolved except arm tingling.

Pt arrived for her COVID vaccination. Dose received and during monitoring period she reported throat tightness and difficulty swallowing. VS WNL with BP 130/88, HR 90, O2 sats 98% on room air. Pt ambulatory and escorted by staff to ED for further monitoring.

Within 35-40 minutes after vaccination; lips became a little swollen and tingly. Benadryl taken within 10-15 min and s/s subsided.

Vaccine #1 12/19/2020. No immediate reaction. 12/20/2020 started to get burning around Left eye. 12/21/2020 started to get swelling and puffiness around both eyes, also started with cough and back pain. Feels like symptoms improving. Taking Benadryl.

One and a half hours after receiving injection redness, rash and itching to right arm from palm up to forearm. Given 25 mg PO Benadryl with resolution of symptoms in 30-45 minutes.

FEVER, FATIGUE, BODY ACHES, NAUSEA, HEADACHE

My arm was very swollen from the injection site to my fingers, pretty sore and I had a bit of a rash on my right arm. Nauseous, felt like I was going to pass out. Fatigued.

My lips and throat were swelling and I felt like my airway was being compromised. I was also experiencing neck pain and general malaise. I did not have a fever but have experienced adverse reactions in the past and knew that with the increased secretions and feeling like my throat was closing that I needed to administer my epinephrine pen injection. I administered my epinephrine pen at 11:18 am and within 1 minute my airway was clear and the secretions subsided. My upper lip/periorbital area are still somewhat numb and feel swollen but I no longer feel as if I cannot breathe.

Received the vaccine Wednesday evening, after work. Waited the recommended 15 minutes, then went home and went to bed. Woke up Thursday feeling fatigued and had injection site pain, no other side effects or fever. Thursday evening, I developed body aches and a low-grade fever. I took Tylenol and went to bed. Friday, when I woke up around 1pm, I noticed a small rash behind my left knee. I took Benadryl and ended up falling back asleep. When I woke up Friday evening, I had the rash, and hives, and red/white splotches all over my legs. I took Benadryl and consulted my doctor. The rash continued to spread to my arms, and stomach. The rash itched and burned. I went to the ER Friday night for it.

Before they gave me medication, I started coughing, couldn't breathe for a minute, and got lightheaded. They gave a steroid, Pepcid, Benadryl, and fluids. They observed me for several hours. I felt better then was discharged. They told to continue to take Benadryl or Zyrtec for a couple days. 5 days later, the rash/hives are still red, itchy and present, especially when Benadryl wears off.

9:00 pm. heart palpitations and pressure in midline. Heart felt like it was beating out of my chest. A little light headed. Took antacids. Lasted about 60 minutes. Woke up around midnight with a painful muscle cramp down back of left leg. lasted about 5 minutes. woke the next morning and have felt fine since.

Change in sense of taste; had a perpetual salty taste since the day after vaccination. Has lasted so far 5 days post-vaccination

Arm felt sore at the injection site (very sore) and it went away within a day. Mostly headache and fatigue, that was the worse of it. Almost like flu symptoms, but mild, like scratchy throat, a little bit of body aches, I noticed it at night, not so much during day time

Experienced a vasovagal response about 30 minutes after receiving the vaccine. I felt it coming on and knew I needed to elevate my legs above my heart but could not at the time, so I sat down and put my head down. I had intense cold sweats and loss of vision for about 2 minutes until my blood flow returned to my head. I was then able to get to a recliner to elevate my legs with assistance. The entire episode lasted approximately 30 minutes. I was able to stand and walk after this time without dizziness. I contacted my doctor today 12/21/20 and he advised I report this episode.

Fever 101.3F, fatigue, body aches 12/20 2245 Chills overnight & cough, fatigue remain 12/21(time of this report).

Itchy Throat 30 minutes after, throat swelling reported and hour later, SOB.

"PT WITH KNOWN H/O SEVERE ALLERGIC REACTION - APPROXIMATELY 15 MINUTES AFTER INJECTION, BEGAN TO COUGH AND EXPERIENCE ITCHY THROAT. SHE REPORTED THAT THIS IS WHAT HAS HAPPENED WITH OTHER ALLERGIC REACTIONS. SHE REQUESTED ORAL DIPHENHYDRAMINE HOWEVER SYMPTOMS WORSENED QUICKLY - DETERMINATION WAS MADE TO ADMINISTER EPINEPHRINE. SHE WAS GIVEN A DOSE OF 0.3 MG EPINEPHINE IM AT 1402. PT QUICKLY BEGAN TO FEEL BETTER. SHE WAS GIVEN ORAL BENADRYL 100 MG (PER HER REQUEST - SHE SAYS THIS IS HOW MUCH SHE TAKES EVERY TIME SHE HAS AN ALLERGIC REACTION). DOSE GIVEN AT 1410. SHE DID HAVE COMPLETE RESOLUTION OF HER SYMPTOMS. SHE WAS KEPT IN THE CLINIC FOR OBSERVATION. AT 1430, PT AGAIN BEGAN EXPERIENCING SYMPTOMS AGAIN, SHE WAS COUGHING AND HAD ITCHY THROAT. SHE WAS IMMEDIATELY TAKEN TO THE ED. SHE HAD COUGH, RUNNY NOSE, RASH ON FORARMS ONLY - NOT PRESENT ON CHEST OR BACK OR FACE. AN IV WAS PLACED BY ULTRASOUND IN HER LEFT AC. AT 1438, EPI 0.3 MG IM GIVEN 1440 - FAMOTIDINE 20 MG IV GIVEN 1441 - METHYLPREDNISOLONE 125 MG IV GIVEN 1442 - FAMOTIDINE 20 MG IV GIVEN 1443 - DIPHENHYDRAMINE 50 MG IV 1444 - VITALS - 136/94, HR - 92, OXYGEN SAT - 96% ON RA 1445 - PT C/O HEADACHE, STILL COUGHING, RASH PERSISTS 1450 - IPRATROPIUM / ALBUTEROL + RACEMIC EPI GIVEN 1453 - STILL CONTINUOUS DRY COUGH, RASH BETTER 1455 - BREATHING TREATMENT COMPLETE - COUGH MUCH BETTER 1457 - HEIGHT - 63""

WEIGHT - 87.7 KG, 97.4 TEMP, HR - 77, OXYGEN SAT 96% 1504 - PT REPORTS FEELING MUCH BETTER, NO COUGH, NO RASH, LUNGS CTA BIL, NSR - HR - 75, 127/89, 96% ON RA 1610 - PT DOING WELL - PLANNING TO BE DISCHARGED - WITH RX FOR EPI PEN AND PREDNISONE 50 MG DAILY X 3 1616 - SYMPTOMS RETURNED, CONTINUOUS COUGH RETURNED, RASH PRESENT ON ARM, OXYGEN SAT 93%, 146/102, HR - 91, RUNNY NOSE 1619 - IPRATROPIUM / ALBUTEROL + RACEMIC EPI GIVEN - LUNGS DIMINISHED IN BASES WTIH STRIDOR HIGHER UP NEW IV PLACED IN LEFT HAND 1620 - 151/91, OXYGEN SAT 99% ON RA, HR - 86"

None stated.

Treatment dugs:

12/17 6:30 pm- started to have general malaise to the point I couldn't cut carrots in the kitchen, then 645pm- 9pm general chills, sweating, muscle ache and pains, severe headache (unresponsive to ibuprofen 600 mg x1 and APAP 1 g x1), 10pm fever of 100.4 F, at 11 pm, symptoms started to decrease, by 12 pm 12/18, all symptoms suddenly stopped 12/19 woke up with sore throat, and overall consistent general malaise 12/20 sore throat continues, mild headaches 12/21 sore throat continues and muscle pain/chills returned note all other activities remained the same, and no new introduction of OTC/prescription medications, or change in daily activities

monitor vs 70 MIN, feels hot, NO HX OF PREVIOUS REACTIONS REPORTED, left at 1620

Approximately 30 minutes after vaccination developed intense pins and needles sensation to the left side of my face. I then developed a heavy, aching, tingling sensation to the left side of my face. I returned to the facility and was evaluated post vaccination. Symptoms persisted still 2 days later so I was evaluated by my PCP today and diagnosed with Bells Palsy. I was prescribed high dose steroids today.

8 minutes after injection I began to get dizzy. The nurse right away put ice packs on my neck. She checked my blood pressure and it had spiked. She had me drink a full bottle of cold water. She monitored me. Then after 25 minutes I was transported in a wheelchair to a observation area. About 1 hour later the dizziness went away. I also broke out in a rash on my neck for 3 days

12/16-headache/abdominal pain 12/16 3am nausea/headache/dizziness 12/17 headache/dizziness 12/18 dizzy/diaphoretic 12/19 headache/dizziness/night sweats 12/20 headache that worsened at night, dizziness, night sweats 12/21 headache/dizzy-went to doctor -pulse thready EKG was performed (normal). Dr felt I was dehydrated and suggested drinking plenty of water and following up with him.

Burning pain in site, starting to get numb down my arm, pain on side of breast going down to rib, chest pain in the middle ..

monitor for 45 min, vaccine at 1845, felt flush, NO HX OF PREVIOUS REACTIONS REPORTED, LEFT AT 1930

Within 3 minutes of receiving vaccine, had extreme nausea, dizziness, diaphoresis, and motion sickness. Had vomiting 30 minutes after vaccine. Within 3 hours injection site had swelling the size of a baseball with purple/blue discoloration and tenderness around the site.

Pt states that ~ 20 minutes after receiving the COVID-19 vaccine on her right deltoid, the R side of her face felt numbness and tingling on the R-side of her face. States her muscles felt weaker. Improved after waiting another 10-15 minutes. Advised to monitor and record her symptoms, speak with her doctor if necessary, and enroll in the V-safe reporting app.

After having the vaccine, felt out of breath, decided to take a shower, heart rate 155 bpm. Yesterday it was 133 bpm. Took it now it is 134 bpm. Feeling very anxious. Having some soreness in the arm.

About 20 minutes after vaccination patient vomited several times and experienced increased blood pressure and heart rate. Physician assistant consulted and recommended to continue to monitor for patient improvement. Patient blood pressure and heart rate began to decrease.

Received the vaccine approximately 1pm on Saturday 12/19/20 while working at the hospital. Slight pain at injections site but no other problems that day. Did not sleep well that night due to achy muscles especially in my neck. Next morning went to work and felt chills and I could not seem to warm myself up. Also felt very sore with all my muscles aching as though I has been exercising every muscle in my body. This continued during the day but was helped by Ibuprofen 800mg. Also very tired and exhausted during the work day. (10hrs) Went home and went to bed and slept well. Monday am I felt fine again.

Sustained HR 130's for 20 minutes, no chest pain, no SOB, taken to ED for evaluation.

stated she felt like she has cotton balls in her throat, and that was the same feeling she had when she had her allergic reaction to Gain detergent.

approximately 30 minutes after receiving the vaccine, patient reported development of symptoms including increased HR, chest tightness and mild shortness of breath. She presented to the ED and was evaluated. She was given diphenhydramine 25 mg IV x 1 1629, famotidine 40 mg iv x 1 @ 1630, methylprednisolone 125 mg iv x 1 at 1629. patient was observed for 90 minutes. She was without further symptoms, VSS and she was discharge to home in stable condition at 1800

After administration, employee stated feeling dizzy; place head btw knees; continued feeling dizzy; place employee lying on floor on side and attempted to give OJ - blood sugar 80; no LOC; called rapid response; vitals and EKG WNL; transported to ED via gurney; seen by ED MD; D/C home.

Patient received Pfizer COVID-19 vaccine on 12/21/20 at 15:24. Approximately 10-12 minutes later she reported having chest tightness, became pale, diaphoretic, short of breath, and looked unwell. She also had a feeling that the her throat was closing. She was given EpiPen 0.3 mg Inj. She had a reaction to Benadryl IV in the past, so we refrained from giving her an IM injection of benadryl. She did not feel like she could swallow so we did not give her benadryl. After Epipen Injection, she immediatley looked better and was taken to the ER for further workup and observation. Of note, she mentioned an

unspecified allergic reaction in the past. In the ED she was given pepcid IV,, solumedrol IV, and a bolus of saline.

Bilateral upper extremity myalagia. Headache. Fever to 100.5. Overall fatigue

COVID Vaccine administered 12/21/20 @ 15:16 and about 15 minutes later, pt reported feeling tachycardic. She felt short of breath and had a tingling sensation on her tongue. 25 mg of benadryl PO was given to her at 15:30. She continued to feel SOB and her voice sounded much more compromised so an additional 25 mg of benadryl PO was given and she was taken to the ED for observation. In the ed she was given prednisone and pepcid.

Shortly after receiving vaccine she began to have a scratchy throat with some mild increase work of breathing. No distress. Transported to ED for further evaluation and discharged to home approx. 2 hrs later.

Shoulder joint pain. Both sides but more on my right side. Had same pain sensation my back, right side. A few seconds. Right elbow pain sensation. Left calf pain sensation. few seconds. Wave of dizziness and feeling weakness. Experienced it 3x. Had a sensation of little itchiness similar to my radish allergic reaction. Drop and spike of blood pressure Some swelling of eyelids. Lasted for 30 min. Pain in between left knuckles Left shoulder back pain lasts few seconds Left upper shoulder warm sensation a 2-3 minutes, Consistent warm slight burning pulsing pain sensation Right forearm warm burning sensation no pain. Pain in right hip, lasted few seconds. Sudden fatigue feeling suddenly extremely drained

Left sided weakness of face, arm and left leg, onset 15 minutes after receiving vaccination Brought immediately to ED, subjective feeling of closing of throat. Given IM epinephrine 0.3mg x 1. Upon evaluation in the ED by tele-neurology consult, she received 88.5mg of alteplase on 12/20/20 at 1721 She was admitted to the Intensive Care Unit on 12/20/20 at 2208 Seen by neurology on 12/21/20 at 1227. Evaluation showed weakness on the left side but is noted that it could be effort-related. Neurologist noted that patient was treated with alteplase; CT angiogram showed no significant blockage or stenosis. Noted that this is could be related to a vasovagal effect, psychogenic or an acute ischemic stroke. As of 12/21/20 at 1615, attending provider noted left-sided paresthesia, left-sided tics and possible transient ischemic attack

About an hour after, I felt slightly lightheaded. About 4-6 hours after, I felt slightly achy, slight headache, slight nausea, and general mild unwellness. All symptoms were resolved by the following morning. I also had a very sore injection site the day of and day afterwards.

About 10 minutes after the injection, I experienced sudden onset of dizziness and shortness of breath, followed quickly by rapid heart rate. The shortness of breath and dizziness resolved in less than a minute. The rapid heart rate a few minutes later.

I?m having real bad muscle aches. I can barely walk and I?m in a lot of pain when I do walk.

Fast heart rate, palpitations, whole body flushed feeling

tiredness nausea- baking soda in water, with some relief last night. 30cc of mineral water today, with short term relief

Tingling and numbness in the face. Some itching

Reports dizziness, light headeded, heaviness on top of head 10 minutes after injection. No sob, chest discomfort, palpitation or weakness. AAOx3. VVS. States that she worked last night and did not eat breakfast yet, also ran two miles prior to getting vaccine.she was given fluids and was closely monitored. Symptoms mildly improved after about 30 Minutes but continues to keep the heaviness. States that she is likely very sleepy and tired. No acute distress. Instructed to contact clinic/ED/PCP if symptoms worsen or persist.

Injection site got swollen, big bump, red, hot to touch, painful to touch, headache, lower back pain, muscle aches, face warm to touch no fever at time temp 99 oral.

flushed face, facial swelling, lips and tongue swelling, elevated HR, elevated BP , light headedness, after vaccine I waited for 20 min with no symptoms, once I left the facility I immediately felt symptoms of face flushing and swelling and elevated heart rate . I immediately turned around and went to the ER,

headache, slight dizziness, injection site pain. symptoms started about 8 hours after vaccination.

Severe swelling, hard lump, hot to touch, severe itching

Pt. felt palpitations about 5 minutes after vaccination while seated. Pulse check revealed rapid regular rhythm at about 130 bpm

10 min post dose, I experienced a lump in my throat and tingling in my face as if I was about to break out in hives. I took an antihistamine (Zyrtec) when I got home about 20 min post dose.

Approximately 45 minutes after the injection, I felt a gradual tightening of my chest. I took about 6 puffs of my Albuterol inhaler over the next 45 minutes and still got no relief. The pharmacist took me back down to the clinic where I was told to then go to the ER. My blood pressure was 204/133 and my pulse was 136. The doctor determined that I was having a severe allergic reaction to the vaccine. I was given an epinephrine injection, 10mg of Decadron and 50mg of Benedryl. I was monitored for between 3 and 4 hours in the ER before I was discharged. The doctor told me that I should not receive the second dose of the vaccine.

severe pain at injection site radiating to elbow. Duration was 72 hours. Lightheadedness started 6 hours after injection and last 36 hours

Began with pinkish neck and chest approximately 15 minutes post vaccine administration. Within 10 minutes of further observation, more reddened splotches noted on chest, and c/o tightness in chest. Taken to ED via wheelchair immediately. Treated with Benadryl, solumedrol and famotidine. Pt discharged to home within 2 hours.

"The patient was in her normal state of good health prior to the vaccination. Almost immediately after receiving the vaccination, she began having a headache, then got an urticarial rash. She then felt a ""lump in [her] throat."" She was coughing uncontrollably. She was brought immediately to the Emergency Department where I assessed her with my resident. She had signs of a Type I Hypersensitivity Reaction including a hoarse voice, globus feeling and diffuse urticaria. She was treated at the vaccination site in the hospital with Benadryl 50 mg PO prior to ED evaluation and she self-administered Ibuprofen 400 mg. She did not have stridor or airway swelling. She was able to speak in full sentences. She was NOT treated with epinephrine, as she was in stable respiratory condition and improved with Benadryl (as previously administered at the vaccination clinic, Pepcid IV and Solumedrol IV. My concern over this reaction is that the patient has NO PRIOR HISTORY OF ANY ALLERGIES AT ALL. I have read and seen in the media reports of anaphylaxis with a history of allergies, however, this is the first case I have heard of regarding an anaphylactoid reaction in a patient with no prior history."

Generalized hives with onset not until the day after vaccination. Still an ongoing issue.

c/o lips numb. Observation 60 minutes after the reaction and gave OJ. Patient stated it was resolving and departed on her own.

~1 h 15 min after receiving experienced flushing, dizziness, near-fainting, arrhythmia, progressed rapidly to a rapid heart rate, elevated BP, hives, cool extremities, diaphoretic treatment: NS 1 liter, Benadryl 50 mg IV, Solumedrol 125 mg/ml discharged after 6 h with Rx for Epi Pen experienced dizziness/near-fainting episodes off/on for 3 days, slight headache, chest tightness, green/bloody nasal discharge for 2 days

Left armpit lymph nodes swollen and painful. Started as tender to touch on the morning of 12/20/20 and became increasing painful throughout the day and by end of day throbbing. On 12/21/20 throbbing has stopped but still painful to arm movement. Occassional tingling down the left arm.

Patient received dose #1 COVID-19 vaccine administration on 12/17/20. A day later on 12/18/20, patient experienced cold sweats, cough, body aches, fatigue, H/A, vomiting x2, chills, shaking, fatigue, and diarrhea.

Employed as a nurse at this hospital. Around 8 PM she received her COVID-19 vaccine. She waited the 15 minutes she was required to wait and then walked to her car. She reports that as she walked to her car she had a pain in her left shoulder which was short-lived but followed by numbness and tingling of her left arm and the left side of her face going up the back of her head. Symptoms started around 8:20pm. She reported back to the clinic to report the symptoms--she lives along and wanted to be assessed before going home. In the clinic, she was assessed by myself. Employee noted that she had not eaten. She ate in the clinic and had something to drink. While in the clinic over the next 10-15 minutes, she noted that she had some numbness and tingling in her feet and calves bilaterally. No leg pain or swelling. Around 9pm, the clinic was closing and she could no longer be monitored under observation. She opted to go to the ER for observation. Per ER note-- She denies any headache. She denies any left-sided weakness. Patient is right-handed. She also reports some mild chest heaviness that lasted for about 20 minutes and then resolved. No shortness of breath. No dizziness, syncope or presyncope. No

nausea or vomiting. No rash. No visual or speech changes. No ataxia. Patient continues to have the left-sided numbness and tingling but states that it is less intense than it was. She denies any other complaints. Follow up this AM-- Pt is only fatigued and has some muscle soreness where she had the vaccination. All of her symptoms have resolved and she is not having any further sxs of chest tightness or numbness

pt was given the vaccination for COVID on friday the 18th (2 days ago) had moderate aches and diarrhea yesterday and began to have rash on Saturday . Pt is a nurse where there has been a large number of children with gastroenteritis. Pt with h/o immune reaction (? Stills disease) where she breaks out in a urticarial rash ,previously only with illnesses in the past Now pt has a rash. However Pt states this rash feels different to her normal one and she has never had a reaction like this to vaccine befores. The rash began similarly to how it usually starts on upper ext and then spreads to trunk now she has swelling around eyes and rash is getting worse. benadryl ineffective pt also has swelling around her eyes and overall with irritation which she has not experienced before. pt was sent to the Emergency department for full evaluation concern for sjs type reaction with

Right after the injection I became acutely lightheaded. I tried to wait it out and it improved somewhat but not all the way. I then started to drive home after the 15 min. observation period. About 5 min into my drive home, I developed trouble swallowing/throat tighness and worsened lightheadedness. I called 911 who stayed on the phone with me as I drove back to the hospital. It started to imrpove rather soon and was resolved within 30 min later.

2 min post injection developed tingling around site, and then urticaria on left upper arm. Then diffuse flushing diffusely and headache. HR=130's, normal BP. Difficulty swallowing during EMS transport. Received EPI sc, Pepcid IV, and Benadryl 50mg IV PTA. HR+140 on arrival post Epi 6 hour obs. NS 1L D/c home with precautions, epilepsy pen rx, and allergist follow-up

Sore deltoid

Associate tested positive for COVID 12/21. Now reports symptoms of cough starting 12/18 not revealed at time of vaccine

Vaccine recipient became nauseas and light headed approximately 30 minutes after vaccine. Recipient also had started menses which was very heavy, also she said she saw the needle and she shouldn't have looked.

Within 3 minutes of receiving the vaccine, I felt a fluid like sensation trickle down my right bicep. I think proceeded to feel tachycardia, dizziness, lightheaded, and was hypertensive. My chest appearance was red and blotchy as well as my face. I was monitored in the ED for 2 hours. My vitals stabilized and the redness dissipated. I continued to feel a bit anxious and a headache. I was told to go home, take Benadryl as needed, and to follow up with an allergist.

About 10 minutes after the injection I felt something in my throat like when I have a sore throat. I was checked by the nurse and she said my pulse is beating a little faster. My breathing was fine. I was

brought to Er and my blood pressure was elevated than usual. About almost an hour after the vaccine my forehead started itching and but I was given benandryl so my hives didn?t continue to develop..

While sitting in chair in observation area after vaccine was talking on phone to friends and suddenly felt very weak with tachycardia to the 120s, SOB, pre-syncopal, very lightheaded. Weakness. No chest pain or tightness. Waved to the staff,. wanted to lay flat. They raised my legs and as there was no stretcher available. Felt heart racing and a sense of doom. HR settled down after about 3-5 mins. Tried to stand so staff could get orthostatic BP but could not support my weight. Remained under observation by the staff for about 45 min. symptoms improved. Was directed to go to ED for evaluation. My husband picked me up.

Full vial of 0.3ml concentrated vaccine administered undiluted with normal saline.

Very soon after receiving vaccine experienced some tingling in the left arm, left leg, left side of face - especially left arm in approximately C8 distribution - down into ring and pinky fingers. Left arm tingling has been intermittent since then. Today noticed a rash in both arms, but worse on the left side in the same distribution. There is numbness, tingling, slight burning along with the rash in that area.

Developed headache, chills, body aches and sore left arm

Jittery and involuntary muscle movements. Chills. Dizziness when I would try to lay down. Nausea followed by abdominal pain. Dry heaving. Later in the day I developed a headache. Resolved at 11pm that night.

around 1730 Patient was given vaccine and d/t allergy history was brought in the 15 minute observation. Patient stated that she was feeling dizzy and throat feeling funny also the same way when gets the flu shot. Patient was kept in observation while being monitored and Code Blue Team arrived d/t the possibility of an anaphylactic reaction.

Around 0800 the patient got her vaccination. During the registration process, she was seen by An Employee (Pharmacy) and associate stated that she never had any allergic reactions in the past and filled in both forms that she does not have any allergic reactions to either the vaccine components, food, and medication. She was then escorted to the Observation room for 15 minutes where she felt dizzy at first. The observation nurse and pharmacy was also present at site. After a few minutes, associate complained of more dizziness, some tightening of the jaw but was still able to speak and swallow. Associate was then given Benadryl around 0804 and connected to the vitals machine for continuous monitoring. Around 0806 patient was feeling worst and Observation RN took her vitals and her HR went down to the 30?s associate was given epinephrine and hence the CODE BLUE was called on 0807. During the CODE BLUE, ED was notified, and a gurney was sent to the Observation Room. Patient was then transported to ED for further evaluation and observation.

35yo female urgent care physician in normal State of Heath when while seeing patients I got lightheaded. Sat down, drank water, ate sugar cookie for about 10/15 minutes but symptoms persisted.

Tried to keep working, but found myself just thinking about how I am going to pass out. No LOC. Evaluates by colleague. Received 2L of IVs (Cr wnl) with transient improvement in symptoms.

Rapid heart rate of 203 bpm

Around 0320 on 12/20/20, approximately 12 hours after my vaccination, I experienced uncontrollable chills for an hour and had an onset of a headache, nausea and weakness that lasted until about 1500 on 12/20/20. Side effects have since resolved.

Woke up 2 days later with pain and swelling under my eyes and in my chin. These are places that I have had dermal filler. I started steroids immediately, swelling went down after 2 days.

Pt noted tightness/swelling around eyes along with itching/burning sensation at same. Then developed itchy erythematous rash starting right shoulder (near where injection was done) and spreading to back. Benadryl 50mg IM given. Was sent to ER for continued monitoring; she did well without further treatment (other than 500mL of saline IV) and was released in good condition. She did not have lightheadedness, lip/tongue/throat swelling, SOB, GI symptoms, or hypotension.

Numbness and tingiling on fingers (both hands and feet). Unable to extend without feeling severe pain on ring and pinky fingers on right hand.

Employee, 1st Pfizer COVID19 vaccine today. ~6min s/p shot, he felt a little itchy just @injection site, then got anxious & felt woozy, sweaty. Wearing big mask and a face shield, seemed anxious. Walked independently to go lay down. No syncope. BP up to 140/90, HR 90, RR 20, breathing fine, no itchy throat/swelling/hives. Improved w laying down. To ER out of an abundance of caution-- vitals nL, nL exam, still itchy at shot site. Got 1L NS IV, 25mg PO Benadryl for itchiness- likely anxiety > severe allergy

Migraine greater than 24 hours, included headache, photosensitivity, noise sensitivity and nausea/vomiting.

Day 2 December 20 woke up with dizziness and nausea, and soreness to left arm Day 3 December 21 having continued constant dizziness and waves of nausea thus far Spoke with Dr per phone she suggested to take Dramamine, which eased dizziness but feeling odd. Unable to register for v-safe not going thru from your end?

30 minutes after receiving the vaccine, I (the patient) felt tingling in my lips, nose, and feet. I then developed a non-itchy, macular rash on my chest and back, associated with flushing. No fevers, chest pain, shortness of breath, nausea, vomiting, or diarrhea, I was taken to the emergency department, where I had normal vital signs. I was given Benadryl 25 mg PO with complete resolution of rash and tingling sensation within one hour.

Urticaria to arms started on the eve of December 20, 2020, took benadryl and applied triamcinolone ointment to rash, woke up and found more rash all over the body took benadryl again, after an hour of taking the benadryl, my face started to itch, that;s when I went to the ED where they gave me, a steroid IV , Benadryl IV and Pepcid IV.

Numbness and tingling in face from ear to ear and forehead to jawline, especially lips

Pfizer-BioNTech COVID-19 Vaccine EUA Currently having fever up to 101.8¦F, malaise, headache, and fatigue.

L ring and pinky finger tingling/numbness

Pfizer-BioNTech COVID-19 Vaccine EUA Erythema and pain noticed at injection site at 22:00 Pain worsened over night The next morning around 0700, noticed worsening Erythema, inflammation, tenderness, warmth No fever 12/21 borders of Erythema have expanded

"Patient notes that she received the COVID vaccine around 1800 today. After receiving the vaccine she notes she had developed a headache. She was otherwise doing fine until around 2000-2100 when she noticed her left arm become numb with paresthesias from her left bicep to her hand with whole arm localization. She felt her hands and wrists were puffy at this time and somewhat swollen. She reports feeling ""floaty""/Dizzy at this time, and at least once had to sit down due to this. She started feeling her heart race and some associated SOB, this has since resolved. She notes that she had two loose stools around this time as well. This progressed to develop into right numbness/paresthesias from her mid right forearm down to her hands. As the evening progressed she developed itchiness of her bilateral arms and torso. She notes that she has had a waxing/waning reddish rash on her arms that has been pruritic. She has since developed intermittent nausea, and still endorses feeling some ""skipped beats."" While in the ED from Triage to repeat evaluations her lips began having progressive swelling. She had been given Benadryl 50mg, Zofran 4mg, 1L IVF. Given ongoing tachycardia and lip swelling she was given Prednisone 40mg and Epinephrine for allergic reaction and concern for anaphylaxis."

Fever, Nausea, Vomiting, body aches, Diarhea taking po fluids trying to stay hydrated with po fluids. rest

7 hours post vaccine, I had very runny nose, thick clear mucus kept coming out of my nose. I felt feverish although my temperature is within normal limits. I had a mild headache and very sore arm on the vaccine site, body aches and malaise which I know are part of the list of side effects I would experience post vaccine, but then about midnight, I developed a huge rash or hive near my left armpit. Then, on Sunday, 12/20/2020, more big hives appeared on my body and my left hand is very itchy and the palm looked red and more swollen than my right hand. I took some antihistamine and notified my doctor via an e-mail. He told me to take diphenhydramine 50 mg every 6 hours. The hives are still present and much bigger and appear in more areas of my body.

Around 1230pm I started to itch, then got nausea, then felt palpitations, checked my own heart rate using and I watch and heart rate was on svt with a rate of 160. I held my breath and heart rate came down after 5 min to a rate of 80 Sinus rhythm.

Rapid heart beat, difficulty breathing, itching, rash, clamminess, cold sweats, nausea

About 1 1/2 hour after injection, one hive appeared on face. Face and arm, head itchy. No rash.

Fever of 101.2F. Cold chills. sweats. Muscle aches. Headache. Lasted for 14 hours and treated with OTC tylenol and advil.

Patient reported felling light headed and dizzy after vaccination. Immunizer questioned patient as to last known meal. Patient had not eaten breakfast. Given orange juice and a light snack. Side effects subsided within 20 minutes and patient was able to return to work. Immunization given under emergency protocol. Patient is a healthcare worker in a long term care facility. Was able to resume normal duties after being monitored by immunizing staff.

redness, swelling and pain at injection site

Fever 102' Chills Body Aches Fatigue

redness, swelling and itching at injection site

"Pfizer-BioNTech COVID-19 Vaccine EUA: Shortly after receiving Pfizer-BioNTech COVID-19 vaccine patient experienced dizziness and ""shakiness"" in extremities. No hives, no swelling, no shortness of breath, no chest pain, no loss of consciousness, no numbness, and no tingling noted at any time. Initial vital signs: blood pressure 140/78 mmHg, temperature 98.7 degrees Fahrenheit, pulse 106 beats per minute, respiratory rate 20 breaths per minute, oxygen saturation 98% on room air. Repeat vitals 14 minutes later: blood pressure 125/88 mmHg, temperature 98.6 degrees Fahrenheit, pulse 110 beats per minute, repiratory rate 18 breaths per minute, oxygen saturation 98% on room air. Thirty minutes after repeat vitals assessed patient stated they felt much better and able to leave clinic ambulatory with a steady gait. Patient was awake alert and oriented the entire time."

Woke up this morning around 5:30 with chills, could not get warm, took temperature around 6:30- 100.4, right side of the throat is slightly scratchy, took temperature again at 7:15am- 99.7, feel very flushed and warm, starting drinking water and took Tylenol

About 1-2 hours after receiving the vaccine, I began to have tongue Hb and throat swelling?mild to moderate. About 3-4 hours later, I had one episode of diarrhea, followed by chills and palpitations. I took Benadryl and Zantac around 8P. When I woke up in the morning, I still had tongue and throat swelling (no trouble breathing), so went to the ER and was treated for an allergic reaction with IV Benadryl, Solumedrol, and Pepcid.

Employee had tingling and numbness in arm a few minutes after injection. This improved within 30 she left the clinic at 40 minutes post vaccine injection. While driving home employee reports having a sudden onset of headache, palpitations and thick speech. Her sister with whom she was taking on the phones told her that her speech sounded strange. Employee had pulled over and called 911. EMS spent time with her and her symptoms subsided so they released her to her own care. She went home and noted nausea, chills then had the onset of a migraine. She took po Benadryl thinking this would help if she was having an allergic reaction. Employee reports feeling achy and chilled so missed work on Saturday. Sunday she was well enough to report to work. Monday upon checking in with this employee she reports mild soreness at injection site, otherwise no residual symptoms

"Patient developed sudden onset of headache with hypertension (BP 205/112), tachycardia (HR 137), redness and hives around 10 minutes after receiving the Pfizer covid vaccine (time 1600). She described ""feeling a wave of heat climbing from her feet up to her face"". 911 called and patient was transported to ER at around 1630. Upon arrival her BP trended down to 129/89 with HR of 78. She did not report difficulty breathing, and she did not receive additional medications while in ER. She was monitored for around 2 hours and discharged at 1847."

Pfizer-BioNTech COVID-19 Vaccine EUA Woke up 12/21 feeling feverish, fatigued, and myalgia, as well as injection site soreness, got worse in the afternoon, peaked around 6pm but started to improve in the evening. Completely gone the following morning 12/22. No treatment taken

Within 1-2 minutes of vaccination, pt felt flushing. He sat down in waiting room. He started to sweat and felt dizzy. Pt requested help. He was brought back to medical room. Pt laid down for 5 minutes and felt better. He ate a snack and drank some water. BP was 162/102 initially. BP was 144/96 after 13 minutes. Pt states he has had similar reactions after giving blood.

Started to have more and more soreness at injection site after administration. Then soreness turned into muscle and joint pain. After about 6-7 hrs from injection time started to feel really bad. I took an Advil before trying to lay down. Was unable to sleep, started getting chills and headache. I took my temperature and it was 102.4. I then took some Tylenol and put some wet clothes on. Temp stayed at 102.4 for a few hours and then finally broke. My temperature went down to 101.4 and stayed there for awhile and now is 99.2. Feeling better than I was, still have severe headache and soreness in body.

Woke up with fever, chills, muscle aches, joint pain, headache, fatigue. Nausea, loss of appetite. treated with Tylenol which controlled fever. Slept a lot.

light headedness; shortness of breath; headache; some nausea; get some redness to her neck and upper chest; Had elevated BPs; This is a spontaneous report from a contactable pharmacist. A 41-year-old female patient (non-pregnant) received first dose of bnt162b2 (Pfizer-BioNTech COVID-19 Vaccine, Batch/lot number: EH9899), intramuscularly on right arm on 15Dec2020 at 13:30 at single dose for immunization. The COVID-19 vaccine was administered in hospital. Medical history included arrhythmia - right bundle branch block, GERD (Gastrooesophageal reflux disease), spinal headache, allergy to gabapentin, adhesive, duloxetine hydrochloride (CYMBALTA). The patient wears contact lenses. Prior to vaccination, the patient was not diagnosed with COVID-19. Concomitant medication within 2 weeks of vaccination included hydrocodone bitartrate, paracetamol (HYDROCODONE/ACETAMINOPHEN, 5-325 mg), omeprazole, meloxicam, docusate sodium, sennoside a+b (SENNA AND DOCUSATE SODIUM). The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Within a few minutes of receiving the shot on 15Dec2020, the patient developed lightheadedness, shortness of breath, headache, and some nausea and was taken to the ED (emergency department). She did get some redness to her neck and upper chest, had elevated blood pressure. O2 saturation was fine. The patient received treatment for the events which included acetaminophen (TYLENOL), dexamethasone, diphenhydramine, famotidine, ketorolac, ondansetron, and 1 L normal saline in ED. The patient was prescribed adrenalin autoinjector (EPIPEN) and prednisone and discharged home. Since the vaccination,

the patient hadn't been tested for COVID-19. Outcome of reactions was resolved in Dec2020.; Sender's Comments: Based on the close temporal relationship and the description of the events lightheadedness, shortness of breath, headache, nausea, erythema and high blood pressure, there is a reasonable possibility that the events are related to BNT162b2 vaccine. The case will be reassessed upon receipt of follow up information.

the patient received five times the recommended dosage; the patient received the unreconstituted dosage; body aches; headaches; This is a spontaneous report from a contactable Other Health Professional (pharmacy student) reported on behalf of a pharmacist. A 37-year-old female patient received first dose of BNT162B2 (Pfizer product, batch/lot #: EH9899, NDC number: 59267100001, Expiry Date: 31Mar2021), intramuscularly on 15Dec2020 at single dose (five times the recommended dosage) to prevent the development of COVID 19. There were no medical history and no concomitant medications and no investigation assessment. They did not reconstitute the vial. The patient received five times the recommended dosage and the dosage was unreconstituted on 15Dec2020. The patient experienced body aches and headaches on 15Dec2020 with outcome of not recovered. Reporter seriousness for the patient received five times the recommended dosage was: Medically significant. Seriousness of body aches and headaches was: Too soon to tell. The seriousness of receiving it unreconstituted was: unknown.; Sender's Comments: The reported information is limited. Based on the close temporal relationship and the description of the events body aches and headaches , there is a reasonable possibility that the events are related to BNT162 vaccine received unreconstituted and five times the recommended dosage. The case will be reassessed upon receipt of follow up information.

patient started feeling weak, dizzy and even blacked out a couple times; patient started feeling weak, dizzy and even blacked out a couple times; patient started feeling weak, dizzy and even blacked out a couple times; This is a spontaneous report from a contactable consumer. A female patient of an unspecified age received BNT162B2, via an unspecified route of administration, on 16Dec2020 at 12:00 PM at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. On 17Dec2020, at around 1:00 in the morning, the patient started feeling weak, dizzy and even blacked out a couple times. The outcome of the events was unknown. The batch/lot number for the vaccine, BNT162B2, was not provided and will be requested during follow-up.; Sender's Comments: The reported information is limited. Based on the close temporal relationship and the description of the events feeling weak, dizzy and blacked out, there is a reasonable possibility that the events are related to BNT162 vaccine. The case will be reassessed upon receipt of follow up information.

Severe fatigue until 48 hours; severe headache still present; fever; chills; nausea; This is a spontaneous report from a contactable physician. A 30-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), intramuscularly in the left arm, on 15Dec2020 at 15:15 (at the age of 30-years-old) at a single dose for COVID-19 immunization. The patient had no medical history or concomitant medications; there were no other medications the patient received within 2 weeks of the vaccination. The patient was not pregnant at the time of vaccination. Prior to the vaccination, the patient was not diagnosed with COVID-19. The patient had no known allergies to medications, food, or other products. The patient did not receive any other vaccines within four weeks

prior to the vaccination. The patient experienced severe fatigue until 48 hours, severe headache still present, fever, chills, and nausea on 16Dec2020 at 03:00. The events were reported as non-serious. No therapeutic measures were taken as a result of the events. The clinical outcome of severe fatigue until 48 hours, severe headache still present, fever, chills, and nausea was not recovered. It was also reported that since the vaccination, the patient had not been tested for COVID-19. The batch/lot number for the vaccine, BNT162B2, was not provided and was requested during follow up.

Hives; This is a spontaneous report from a contactable consumer. A 43-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot number: GH9899), via an unspecified route of administration in the left arm, on 17Dec2020 at 09:00 (at the age of 43-years-old) at a single dose for COVID-19 immunization. Medical history included allergic to unknown food. The patient's concomitant medications were not reported. Prior to the vaccination, the patient was not diagnosed with COVID-19. The patient did not receive any other vaccines within four weeks prior to the vaccination. The patient experienced hives on 17Dec2020 at 16:00. The event was reported as non-serious and did not cause/prolong hospitalization. Therapeutic measures were taken as a result of the event, which included treatment with diphenhydramine hydrochloride (BENADRYL). The clinical outcome of hives was recovering. It was also reported that since the vaccination, the patient had not been tested for COVID-19. The batch/lot number for the vaccine, BNT162B2, was not provided and has been requested during follow up.

waves of flushing through out her body; severe dry mouth; nausea; elevated heart rate into 120s; panic attack; This is a spontaneous report from a contactable consumer. A female patient of an unspecified age received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration in 2020 (at 0810 her time) at single dose for immunization. The patient's medical history and concomitant medications were not reported. The reporter is a Certified Nursing Assistant (CNA) who received the Covid 19 vaccine at 0810 her time. Five minutes after receiving the vaccine (2020) she reported having three episodes of the following symptoms: waves of flushing through out her body, severe dry mouth, nausea and elevated heart rate into 120s. She denied any shortness of breath, swelling or anaphylaxis. She was treated in the Emergency Room (ER) with fluids and lorazepam (ATIVAN) and sent home. She contacted her doctor who advised she was probably having a panic attack and was told her to take lorazepam. She reported sleeping when she got home but experienced the elevated heart rate and flushing again after waking. She spoke to her doctor a second time and was told to return to the ER to be treated for the elevated heart rate. She did not go to the ER because she took more lorazepam and the HR declined into the 90's. She stated her doctor was prescribing a beta blocker for her but advised to go to the ER if her heart rate goes over 100 again. She would like to report and Adverse Event. The outcome of the events was unknown. Information regarding lot/batch has been requested.; Sender's Comments: Based on the information available as reported at this point, a possible contributory role of the suspect products cannot be excluded for the reported event flushing, dry mouth, heart rate increased, nausea and panic attack due to temporal association.

Hearing loss; Severe tinnitus; This is a spontaneous report from a contactable pharmacist. A male patient of an unspecified age received first dose of BNT162B2 (solution for injection, lot number: EK5730, Expiry Date: 31Mar2021, NDC number: 59267-1000-01), intramuscularly on 16Dec2020 at 0.3

mg, single in deltoid for prevention of COVID viral infection. The patient's medical history and concomitant medications were not reported. The patient's wife is COVID positive, but he has not been tested and has no other symptoms. On 17Dec2020, the patient experienced hearing loss, and severe tinnitus. There is no additional vaccines administered on same date of the Pfizer suspect. The outcome of both events was not resolved.; Sender's Comments: The reported information is limited. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

Feeling of going to pass out; PVC's; PVC's; Shaking feeling internally from neck down to ankles; Sweating; palpitations; This is a spontaneous report from a contactable consumer (patient herself). A 60-year-old female patient received bnt162b2 (lot number: FK5730), via an unspecified route of administration at site of right arm at 10:15 on 17Dec2020 at single dose for immunisation. Medical history included Chronic migraine. Occasional PAC/PVC's. Concomitant medication included clonidine (strength: 0.02 mg). Within about 5 minutes of receiving the vaccine, the patient experienced shaking feeling internally from neck down to ankles, sweating, feeling of going to pass out. Some palpitations and PVC's. Shaking Symptoms lasted approx 4 hours. The patient visited emergency due to events. No treatment received for events. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. The outcome of events was recovered on 17Dec2020.

severe hypersensitivity; swelling of tongue; dyspnea; skin rash; This is a spontaneous report from a non-contactable consumer. A 35-year-old male patient received BNT162B2 (Pfizer-BioNTech COVID-19 vaccine), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient administered vaccine and developed swelling of tongue, dyspnea, skin rash on an unspecified date. There is a report of severe hypersensitivity for his awareness. The patient was treated with dexamethasone, Benadryl, IM epinephrine in ER. Outcome of events were unknown. No follow-up attempts are possible; information about batch/lot number cannot be obtained.

Bilateral itchy rash, mostly with small areas of erythema especially around arm pits, but also on abdomen, back, neck, arms, forearms, thighs, legs; Bilateral itchy rash, mostly with small areas of erythema especially around arm pits, but also on abdomen, back, neck, arms, forearms, thighs, legs; some less erythematous areas of swelling with well-marked borders at most 1cm in diameter; This is a spontaneous report from a contactable physician. A 28-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), intramuscularly, on 15Dec2020 at 02:45 (at the age of 28-years-old) at a single dose for COVID-19 immunization. Medical history included hypertension (HTN). Prior to the vaccination, the patient was not diagnosed with COVID-19. Concomitant medications, taken within two weeks of vaccination, included lisinopril (MANUFACTURER UNKNOWN), melatonin (MANUFACTURER UNKNOWN), and vitamin D (MANUFACTURER UNKNOWN) taken for supplement. The patient had no known allergies to medications, food, or other products. The patient did not receive any other vaccines within four weeks prior to the vaccination. The patient experienced bilateral itchy rash, mostly with small areas of erythema especially around arm pits, but

also on abdomen, back, neck, arms, forearms, thighs, legs and some less erythematous areas of swelling with well-marked borders at most 1cm in diameter on 16Dec2020 at 08:00. The events did not cause or prolong hospitalization. Therapeutic measures were taken as a result of the events, which included treatment with diphenhydramine hydrochloride (BENADRYL) and loratadine (CLARITIN). The events improved with loratadine but started to reoccur 18 hours after loratadine use. The clinical outcome of bilateral itchy rash, mostly with small areas of erythema especially around arm pits, but also on abdomen, back, neck, arms, forearms, thighs, legs and some less erythematous areas of swelling with well-marked borders at most 1cm in diameter was not recovered. It was also reported that since the vaccination, the patient had not been tested for COVID-19. The batch/lot number for the vaccine, BNT162B2, was not provided and has been requested during follow up.

extreme pain in her arms feeling like they are dead and heavy; extreme pain in her arms feeling like they are dead and heavy; She was unable to continue working; This is a spontaneous report from a non-contactable other health professional via Pfizer Sales Representative. This other health professional reported for a 50-year-old female patient (nurse) received BNT162B2 (Pfizer-BioNTech COVID-19 vaccine), via an unspecified route of administration at on 15Dec2020 at single dose for COVID Vaccine. The patient's medical history and concomitant medications were not reported. Nurse was administered the Pfizer COVID Vaccine on 15Dec2020. On 17Dec2020, at work she complained about extreme pain in her arms feeling like they are dead and heavy. She was unable to continue working and went home. Event took place after use of product. Outcome of events were unknown. No follow-up attempts are possible; Information about batch/lot number cannot be obtained. No further information is expected.; Sender's Comments: The reported information is limited. Based on the close temporal relationship and the description of the events, extreme pain in her arms, feeling like they are dead and heavy and unable to continue working, there is a reasonable possibility that the events are related to BNT162 vaccine. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

Headache; Dizziness; Nausea; This is a spontaneous report from a contactable other health professional. A 56-year-old female patient received bnt162b2 (BNT162B2) via intramuscular in right arm on 17Dec2020 at single dose for vaccination. There were no medical history or concomitant medications. The patient experienced headache, dizziness, nausea all on 17Dec2020. The reporter described that immediately after patient was administered the COVID-19 vaccine injection she was handed the paperwork, stood up and had sudden onset headache, dizziness and nausea. As of time of the report the headache had subsided slightly but came and went in waves. The dizziness and nausea remain persistent. She reported the seriousness criteria as probably medically significant or somewhere between not serious and medically significant. Patient was currently under observation in the ED (emergency department), but had not been admitted to the hospital. The patient had been in the ED for over 30 minutes at time of report, so patient did not believe that these events are vagal. The reporter called to report these events and to ask for recommendations on how to respond to these events relative to this product. The reporter verified that there had been no relevant testing, imaging, lab work

or investigations done at this time. The outcome of the event headache was recovering while for all other events was not recovered. Information on the Lot/Batch Number has been requested.; Sender's Comments: The reported information is limited. Based on the close temporal relationship and the description of the events, headache, dizziness and nausea, there is a reasonable possibility that the events are related to BNT162 vaccine. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

waves of heat feeling; tachycardia; chest tightness; This is a spontaneous report from contactable physician via Pfizer Sales Representative. A 50-year-old female patient received bnt162b2, via an unspecified route of administration in 2020 at single dose for immunization. The patient's medical history and concomitant medications were not reported. The patient experienced waves of heat feeling, tachycardia, chest tightness 15 min after receiving the vaccine in 2020. Patient received several doses of steroid and was kept overnight in hospital and recovered. The outcome of events was recovered in 2020. Information on the Lot/Batch number has been requested.; Sender's Comments: The reported information is limited. Based on the close temporal relationship and the description of the events, waves of heat feeling, tachycardia, chest tightness, there is a reasonable possibility that the events are related to BNT162 vaccine.The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this reviewas well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

Some mild nausea; This is a spontaneous report from a contactable consumer. A male patient of an unspecified age received BNT162B2, via an unspecified route of administration on 16Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced some mild nausea on 16Dec2020. The reporter indicated that the patient had some mild nausea that lasted for an hour or two but that it had completely passed. The outcome of some mild nausea was recovered in Dec2020. No follow-up attempts are possible; information about batch/lot number cannot be obtained.

At 18:45 patient reported development of numbness in back of throat. Pt. reported no difficulty swallowing. Patient ate her evening meal without difficulty and symptoms begin to resolve. Patient took 25 mg of diphenhydramine PO before going to bed. Patient reported no symptoms the next morning.

Patient was nauseas but did not vomit. Had the patient lay down and took the patients blood pressure first reading was BP 98/65, second reading was 94/62 with pulse rates of 80 and 67 respectively. Patient started to feel better after 30 minutes

Patient began having tingling around her mouth on 12/20/20, stated that cold sore has gotten larger and is worse than previous sores. Patient is cautious to not spread fluid from sores but they are spreading. Patient was advised to contact PCP.

Headache, nausea, subjective fever and injection site arm pain.

Patient was nauseas and lightheaded. She was instructed to lay down in which she felt better.

Shortly after receiving injection, I began feeling some lightheadedness.

Itchiness and rash on skin.

"Employee reported ""tongue thickness"" and dry mouth. Employee was taken to ED for evaluation and treatment."

generalized hives

Nausea and Vomiting

Fever, chills, body pain

fever of 101, fatigue, lethargy

Body aches, chills, dry cough

Nausea and vomiting, dry cough, sore throat

Headache, Tiredness, arm soreness

Patient became slightly tachycardic (HR 145, BP 140/75) and light-headed. Described as anxiety attack. Patient laid down and feet were elevated and heart rate and blood pressure returned to normal. Patient was observed for another 30 minutes and released

Caller stated on 12/18/20 and on 12/19/20 she had some arm pain and nasal drainage. Caller stated that she went to doctor on 12/21/20 and was diagnosis with Cellulitis and was prescribed steroids and cefalexin for 7days x three times daily. Caller stated that physician does not recommend second injection. Vaers report completed over the phone.

Headache, injection site soreness

Headache, injection site soreness

Stomach pain, nausea, vomiting, diarrhea

Nausea

Employee reported headache, flushing, and a sweaty feeling. He was taken to ED for evaluation and treatment.

12/21/2020 3:00PM Abdominal l quad pain, nausea sore arm, headache, fever 101.9 with chills -- tylenol, ibuprofen some relief. 12/22/20 tylenol in AM-- low grade fever persists with headache, some nausea.

Histamine reaction 2 hours after injection and still present at 15 hours from injection: itchy runny nose, post-nasal drip, mild itchiness around body (torso, arms, ears, head), Left ear pain on side of injection . Took 50mg benadryl at bedtime and this morning took 10mg claritin and 10mg syngulair.

Evening following receiving vaccine: Severe Dizziness, Chills, Body Ache, Increased Heart Rate (racing sensation). Following day: Minor/Noticeable Joint Pain throughout body (knees, shoulders, spine). Continuing symptoms: Minor Redness/Itchiness around injection site.

Na

Palpitations, BP 113/78, HR 115 - treated with prone position, resolved at BP 122/91, HR 111

worsening peripheral neuropathy feet/legs/hands/arms

Employee stated after 15 mins observation, that he experienced heart palpations for 2mins. This nurse then obtained employees vitals. BP - 126/80, P-80, O2-97. Employee was then observed by this nurse for 40 more mins. Employee stated @ 0902 he felt fine. Denies any prior anxiety/cardiac issuses when asked. Employee left observation @ 0905.

10 minutes after initial vaccine was given patient experienced numbness and tingling to tongue, lips, and fingers. No shortness of breath or respiratory distress noted

Immediately after vaccination developed tingling in soft palate. Pale. sat for 15 minutes and symptoms remained and was given 25mg benedryl.

fever/chill, extreme fatigue, body aches, headache, near syncope, nausea

Headache, diarrhea

Pain at injection site

Severe chills, fatigue, arm pain, dysuria

12/18/2020 5 MINUTES AFTER INJECTION, FELT HOT. TEMP KEPT GOING UP. TEMP WOULD NOT GO DOWN. STAFF PUT COLD PACKS ON ME. ITCHING STARTED BUT NO RASH VISIBLE ON ARMS AND BACK. DR. STATED TIME TO TX TO ER. THE HEAD HAD INCREASED EVEN MORE. COULDN'T BREATHE DEEPLY, 'AIR STOPPED', COULDN'T SPEAK PROPERLY. PREDNISONE, ANXIETY AND BENADRYL ADMINISTERED. MONITORED O2 STATES, MONITOR HEART. AT HOME BODY STARTED TO ACHE, NOT MEDICINE TYPE PERSON. HELD OFF TILL 1AM, TOOK 2 TYLENOL 500MG. BY 3 AM ABLE TO SLEEP. HEAT SENSATION WAS STILL THERE. BY 12/20/2020, INJECTION SITE SORE, LUMP. I WAS TIRED. BY 12/21/2020 THE SITE WAS SORE, I RUBBED WITH ALCOHOL. PROBLEMS WITH SWALLOWING, EATING GINGER CANDY TO HELP WITH DRYNESS. THROAT BOTHERS AFTER TALKING, TIGHTENING. DR. STATED AT 2ND INJECTION WILL

PROVIDE THE BENADRYL, PREDNISODE, AND ANXIETY MEDS 30-60 MINUTES BEFORE ADMINISTERED. 'I DO BELIEVE I NEED OTHER SHOT TO BE COVERED'. 'CLOSE TO ER FOR SECOND SHOT'. I DO HAVE PROBLEM WITH VACCINATIONS; I GET INTO TROUBLE. MY BODY HAS REACTIONS, TROUBLE BREATHING. 'SOLE PROVIDER FOR WHOLE FAMILY; I HAD TO TAKE THE SHOT' 'FEELING ABOUT 100%'

2hrs after vaccination, begun feeling right arm pain (on vaccine site), headache mild but continued until 4 pm same day, dizziness, felt cold though heavily dressed, right cheek tingling. Visited ED was evaluated however found to be hypertensive 170/95 (no prior history) later improved some mild headache, pain right arm improved e discharged when pain became g pain and dizziness mild , no more sensation of being cold, and assured by ED doc symptoms will improve x24 hrs. If worsen contact primary care physician

Immediately after receiving the vaccine, I felt tingling sensation in my extremities. I felt flushed, my chest became red, and I felt like my heart was racing. It generally lasted about a minute. Now, two hours later i am still feeling some tingling in my left arm.

Fast Heart Rate and light headed 10 minutes after receiving the injection and lasted around 5 minutes.

12/19/2020 Received vaccine 12/20/2020 around 2am woke up with strong body aches, pain at injection site, chills, and fever 100.9. Continued with extreme fatigue, headache, body aches and high fever through out the day. 12/21/2020 fever gone,arm still sore and headache returned mid day.

Left arm numbness/heaviness 15 minutes post injection, mostly resolved with minimal parasthesia at departure. Patient advised to go to ED for any additional symptoms.

pain at injection site, fatigue, headache, malaise, body aches, irritability

On 12/18/2020 when I woke up at 10am. The site area of the vaccine was sore, then my neck started hurting. When I went to the bathroom to view it, my right lymph node is swollen, and sore to touch. My lymph node is swollen on the same side I received the vaccine. It's still swollen today 12/22/20 and still sore to the touch. It was stated that reactions were to last 24-48hours, but this has lasted past then. No fever, no dizziness, and no nausea, just swelling in my neck.

phone call

Muscle and joint pain started 12/19/2020 and ongoing

PVCs developed about 20 minutes after administration of vaccine. Placed on Zoll cardiac monitor. Vitals to include BP, heart rate, respiratory, pulse ox several times during additional monitoring period. No respiratory distress or other issues during this monitoring period. Monitored until 1510, patient contacted primary care provider via patient portal.

12/17/20 10-mintues post injection headache, l numbness in face (15 mins, then resolved), injection site l arm and pain in r upper arm (has not resolved), nausea, loose bowel movements. 12/18/20 severe

body muscle pain has not resolved not as severe today 12/22/20, 12/19/20 joint pain in fingers more severe to l hand than the r hand, unable bend from pain today 12/22/20

Hour after vaccination: muscle and joint pain bilateral arms (still ongoing next morning but feels better after ibuprofen), right side face felt weird (numb/weakness) spouse said it looked a little swollen (face felt better next morning after benadryl)

Approximately one hour after receiving the vaccine her arm was very sore by 8pm, 12 hours later, she was very fatigued and had an upset stomach. She slept from 8pm to 5am with a very sore arm, upset stomach, pounding headache and bad body aches. She continued to sleep the remainder of the day after the vaccine.

"Employee reports onset of slight headache after vaccination on 12/17. It was relieved by motrin. On 12/18 she had ""a little dizziness"" with shifting positions. She hasn't taken any medication. The symptom has become much better. She also had mild nausea which has improved. She feels like she is not well enough to be at work today. She is going home."

Fatigue and redness around injection site about 5 hours post vaccination. Symptoms resolved by next morning.

Pt reported mild tachycardia within 15 minutes of receiving the injection with tingling in her legs. She returned to work and did not note the tingling again until the next evening. At that time, she noted tingling and a sense of weakness in her legs, though no manifestation of weakness (i.e. no falling down or legs giving out). Symptoms persisted through the 18th and 19th but were noted to resolve on the 19th.

Arm pain, shoulder pain, neck pain, back pain, fatigue, headache, chills, body ache, slight dizziness. Tylenol and Motrin taken, ice pack applied to arm

redness, hot and slight swelling in left arm and itchy all over

gout attack

TIGHTENING OF THROAT, VERTIGO - 50MG IV BENADRYL

"Initially she felt flushed and ""foggy-headed"". Then developed a metallic taste in mouth and elevated blood pressure, required extended monitoring period with continued elevation in blood pressure. Heart rate and respiratory rate stable, no respiratory distress noted. Highest BP 195/93 ranging 180s/90s, however denied need to be seen in emergency department. Final BP 155/93, less foggy, no dizziness or lightheadedness; feeling flushed remains however, declines emergency treatment. Total monitoring time: 83 minutes, without significant distress."

Fever, chills, rashes, CP, fatigue, diarrhea, congestion, pain at injection site and numbness to left arm

Head ache- started around 1pm on 12/18/20. Small joint pain started around 7pm on 12/18/20 and continues to present

About 10 hours after receiving the vaccination I became acutely lightheaded and dizzy. I walked to my bed and laid down. After 4 hours I was no longer dizzy.

Moderate soreness to injection site, mild fever, chills, body ache and head ache all started the day after the vaccine, and lasted for 2 days.

Pfizer-BioNTech COVID-19 Vaccine EAU I started with bilateral leg aches about 6-7 hours after receiving my COVID-19 vaccine. It slowly progressed through the evening. Upon awakening this morning at 4:45 am, I feel like every muscle and joint in my body is aching and hurting so bad! I am nauseated, have chills, sore throat, and fatigue.

12/21/20 fever 101.9, body aches, lower back pain, congestion and cough -- tylenol . 12/22/2020 mortin for fever AM 101.9 some relief, symptoms less today.

Headache, Angina & sore throat ALTEPLASE 2 MG ONCE left upper arm@ 12/17/20@1522

Body chills then a fever Body aches Diarrhea Headache Feeling very unwell

patient has a history of minor allergic reactions. She developed some difficulty swallowing and tightness in throat. She was not in distress and requested oral benadryl as this has worked for her in the past. Vitals monitored, benadry given 50MG PO. Patient improved over 45 minutes. Returned to work with instructions to report to ER if symptoms return.

Headache

19 y/o fully immunized female with history of anxiety presents for dizziness and nausea x 2 hours. Received COVID vaccine at 14:30. At 16:30 went from sitting to standing, felt dizzy and nauseous. No syncope. No palpitations. Similar reaction to influenza vaccine. No intervention required to previous vaccination. No history of anaphylaxis. BP 125/88, pulse 88, RR 18, 02 95%, temp 37.3.

After about 10 min, she noted numbness and tingling in the 4th and 5th digits of the hand on the side where the injection was given. She felt SOB and like she might pass out though admits this may be from anxiety. She remained in the vaccine waiting area for 45 minutes, she notified staff and was provided something to drink. She was eventually dismissed and returned to work where she completed her scheduled shift on Med Surg. On Friday, she felt numbness and tingling in both hands, both feet, and her face intermittently that persisted into Saturday. On Sunday she noted swelling in both hands to the point that she could not put her rings on. The numbness and tingling was improved in hands and face but persisted in her feet. Monday she reported that swelling is improved but still present, and there is still slight tingling in her hands. She also notes that she has been fatigued since receiving the vaccine. She had injection site pain and some generalized muscle achiness for about 36 hours after receiving the vaccine, but that has resolved. Today (Tuesday) she reports continued sensation of mild swelling in hands, reporting that they feel tight. Otherwise symptoms appear to be resolving.

A little bit of arm and neck pain still. Today I am feeling great.

Pt. received part one covid vaccine on 12/15 at 4:30 pm. The next morning at 10:30 when she woke up, she had moderate facial swelling and redness. (No rash, no GI discomfort, no difficulty breathing) Pt. took Benadryl, Zyrtec, and iced face. The following day it resolved after another dose of Benadryl.

Seen in ED - mild symptoms of feeling like his throat is swelling and he has shortness of breath. Physical exam was normal. Vital signs normal. EKG with sinus tachycardia at 106. Given PO benadryl and prednisone. Observed in the ED for a couple hours without further worsening of his symptoms. Impression/plan: possible reaction to Covid vaccination. Improved. D/C home

Vaccine was given in the ED because the employee had a history of allergic reaction to shellfish. She reported feeling like her throat was closing up and she was having shortness of breath soon after receiving the Covid vaccination. By the time the physician evaluated her she reported her symptoms had resolved. She was observed in the ED for an hour with no return of any symptoms. No medication or other treatment was required.

12/19 - onset of abdominal pain which is like her usual chronic necrotizing pancreatitis which she has had off and on for 10 years. This was accompanied by nausea. The pain & nausea last for about 3 hours. 12/20 - nausea and diarrhea. Today 12/21 she reports that she has recurrence of the abdominal pain, nausea, and feels hot. She is at work today. Advised to contact her physician for assessment and treatment as needed. Will follow-up with her

"Chills, body ache, fatigue 100.9 fever-lasted 24 hrs Injection site very sore + approximately 48hrs after injection soreness mored toward armpit. Arm is warm, red, itches slightly almost entire upper arm (5"" long x 2"" wide) + still tender to touch on 12-21-20"

Had vaccine shot on Saturday 12/19/20. Slight tingling/numbness in cheek and upper jaw for 45 minutes on Sunday 12/20/20.

Given the vaccine at 712 pm on 12/20/20. At approximately 715 pm, she began to clear her throat and then became unable to speak, followed by audible wheezes and short, shallow breaths. At 1923, Epinephrine was administered. At 1928, she was able to speak again and was transported to the ED. The patient reports after arrival to the ER, the symptoms returned. She was given PO Benadryl, followed by IV Benadryl, and then a 2nd dose of Epinephrine. She was admitted to the ICU for observation.

DEVELOPED LEFT LOWER EXTREMITY WEAKENSS for 72 hours post vaccination. Loss of sensation in left foot continues.

12/16 vaccine date 12/16 - fatigue, H/A, low grade fever 12/17 - fatigue, body aches, moderate headache 12/18 - resolution of all symptoms

At work patient had ALOC x10 minutes. Rapid response called. Transf to Hospital (12/18-12/20). D/C Dx ACUTE CORONARY SYNDROME (NON-STEMI)

"12/18 - developed headache and nausea. 12/19 - developed fever and fatigue and cough. 12/20 - temp to 100.7 with cough and some body aches. 12/21 - feels the same as 12/21 but with bad headache and

fatigue. She is taking TYLENOL and ibuprofen for the symptoms. She feels she's the same today as she was yesterday. She stayed home from work 12/21. Because of her prolonged symptoms and fever with cough - a COVID-19 PCR nasopharyngeal swab test was performed. This case back as ""DETECTED"" on 12/21."

Feels unwell. Temperature is at 100.3F.

None stated.

fever, body aches, light headness/dizzy, vomiting

chills, fever 102, fatigue, headache, sore throat, cough, SOB with exertion

Mild rash to neck and upper back- not itchy, just red starting at 9:30 pm on the night of the injection. The following morning- Body aches, headache, sore throat- moderate in severity.

Within the first 15 mins I felt flushed , the left side of face hot and red , headache , ears started to ring, hour later I felt nauseated, light headed .Left side of face felt numb , really tired . The next morning I was fine , left arm was sore couldn't lift my arm . Since the Vaccine I've been having headaches daily

Within 20 minutes of receiving the vaccine, experienced tingling on both sides of mouth and sensation of numbness in lower lip. Symptoms lasted for 15 minutes or so and resolved. No other symptoms noted.

Fatigue. Joint pains. Muscle pains. Numbness and tingling of hand/feet. Fever 101.2 . Headache

Fever, chills, sweats and a few hours later headache and myalgias

I woke up the next morning with a little puffiness in my face, my eyes and my cheeks

Very bad HA, almost migraine, 21 hrs post injection. Then added nausea. Some neck soreness. Slept/rested for 8 hours. Took excedrine and advil intermittently.

Ten minutes after received the vaccine, patient felt lightheaded, weak, diaphoretic, dizzy, nauseous, and experiencing palpitations. At that time BP 112/78 mmHg, pulse Ox 99%, HR 102. Patient was transferred to the Emergency Department for monitoring. Patient was discharged without any further sequalae.

First night local pain (1/10) only. At 45 hours post vaccine, few palpitations. At 49 hours, a few more. At 53 hours, multiple continuing palpitations without letup so went to ER Friday night 12/18. Many PVCs, some bigemminy. This is also now only 5 hours after my BID dosing of carvedilol 25mg. Cardiac and metabolic workup negative -- all normal. Went home after 4 hours. Mild chills at times but never fever. Amount of ectopy and annoying symptoms declined during following day. My internist placed me on additional propanolol beta-blockade to add to carvedilol. Still required some extra propanolol day 5 post-vaccine but otherwise felt basically normal.

hives on neck and chest 20mins after the injection. The hives burned no itching

Felt fine after vaccine. Approximately 9 pm, I went to bed and began experiencing paresthesia in right arm, then noticed the paresthesia in both hands, both feed and also in right leg. The following morning, was primarily in my hands. I went to work, and as the day progressed, noticed in my feet, and right leg again, but hands not right arm. On Sunday & Monday, the paresthesia was more intermittent with timing lengthening between bouts. Monday, I went out in my car, and noticed that the paresthesia was worse in my right foot, Mid plantar to toes, Couldn't feel the gas pedal with right right foot. No paresthesia in left foot, left hand. Also noticed besides not feeling well, that I felt like was in mental fog, unable to articulate some things. That was intermittent, also (have had poor appetite for @ least a week prior to vaccine). This morning (Tuesday) I have paresthesia from my right shoulder down to fingers, and continue with right foot from mid plantar to toes. Mentally feel a little bit better, not as foggy.

Fever, chills, body aches muscle and joints, headache, ringing ears, eye pain

Patient stated burning sensation upon administration of Pfizer-BioNTech COVID-19 Vaccine.

Hives at day 2 treated with OTC medication like benadry. Day 4 reported shortness of breath and patient being seen in the ED.

Felt pain after vaccine. I had some diarrhea. Then this morning, I had more diarrhea with my throat soreness, and congestion, and still diarrhea.

dizziness, light headedness, severe nausea, rash/hives over chest and back and forearms, severe chills/shivering

Right jaw numbness, resolved with 1 hour, did not seek medical attention.

20 minutes after receiving the vaccine this employee experienced nausea

At 35min post vaccine patient noted with redness to the chest, neck and going up to face and bilateral ears. Ears were swollen. Patient transferred to the Emergency Department where she was noticed to have swollen lips

Bodyaches, headache and chills that started the next morning after the vaccine.

nausea that night, Vomited that night and the next morning , Fatigue, headache

57-year-old female history of hypertension, hyperlipidemia, type 2 diabetes, COPD, subsegmental PE is not on anticoagulation, multiple cardiac stents presenting with greater than 12 hrs of worsening left-sided chest pressure, headache and shortness of breath. Patient takes a daily aspirin and had no improvement of symptoms with her at-home nitroglycerin. Here afebrile, HTN, remaining vitals wnl. Non-toxic, in moderate distress 2/2 to pain. EKG with minimal ST depressions in leads II and III. Will plan for CXR and labs. Pt given zofran and morphine for pain control. Will give additional aspirin for total 324 mg in last 24 hrs. On re-evaluation, pt with mild improvement in pain. Troponin elevated at 0.18, remaining labs wnl. At this time concerned for NSTEMI, pt treated with 1 mg/kg of lovenox and MOD consulted for admission. MOD evaluated pt and cardiology was consulted. Given concerning PMHx and

current hx of chest pain with findings consistent with NSTEMI, cardiology at recommended likely transfer for cardiac cath. Will pend repeat troponin and EKG for dispo decision.

Employee described being fatigued, dehydrated, and low grade fever

Woke up in the middle of the night on 12/20 and noticed that the left side of tongue felt like he had bit it. He woke up again on 12/21 at 1:10 AM with a swollen tongue. He also had left sided unilateral edema. NKDA or significant past medical history. No past allergic reactions. Went to the ED and was treated with benadryl and a methylprednisone. Sent home with additional medications in case condition worsened again.

Employee reports itching and tingling to right arm that traveled to elbow, employee reported sensation was 'easing up' 5 minutes after it started. She also reported itching to flank area, no rash was noted. Employee was taken to ED for evaluation and treatment.

Increased heart rate, increased blood pressure, cold/clammy feeling, urticaria (neck), swelling in neck and chest. At vaccine clinic area, Benadryl 50mg IM given. Rapid response called via overhead page. Patient taken to ER from vaccine clinic. In ED, given famotidine 20mg IV, methylprednisolone 125mg IV.

Tongue tingling, throat tightness @0520 Chest heaviness, lips numb @0525 Voice hoarseness @ 0530 IV Benadryl given approx 0550 PO prednisone given approx 1000 Left side of face still numb after 24 hours

Employee experienced nausea and headache

ain at injection site 8 hrs after injection, fever, chills, joint and muscle pain, tiredness 16 hrs after infection. temp reached 101.0.about 20 hrs after injection. temp down to 99.6 after 36 hrs, just still running some low grade temp. soreness, joint pain better.

12/17/2020 INJECTION. 12 HOURS LATER, NAUSEA W/ TACCYCARDIA, PROXIMAL. HEARTRATE 150. WENT TO ER. HAD TESTS DONE. NO HISTORY OF ANXIETY; HAD PRETTY ANXIETY. LASTED ABOUT 45 MINUTES. ATIVAN PRESCRIBED BY ER DOCTOR. DIAPHORETIC. I AM WORKING BUT STILL DIAPHORETIC AND STILL FEEL A LITTLE FATIGUED. DON'T KNOW IF RELATED TO VACCINE.

Exhausted, dizzy, nauseated, rapid heartbeat, pain in joints all over body, fatigue

1 episode of vomiting and diarrhea 12 hours after administration. Afebrile. No other events of nausea/vomiting yet during pregnancy. 4 weeks, 4 days pregnant. EDD 8/27/21.

Began developing tightness/soreness in his throat, some DOB, and increased blood glucose. NKDA or history of adverse reaction to vaccines. Benadryl 50 mg given IM at clinic site. Noted to improve after 15 minutes. Was sent home with instructions to return to the ED with worsening of symptoms.

Approximately 65 hours post-vaccination patient felt profound fatigue, no appetite, and had increase in baseline chronic cough, and anosmia. Patient was admitted to the hospital on 12/21 due to worsening respiratory symptoms that required supplemental oxygen-initially 2L via nasal cannula. Patient was

upgraded to ICU-level of care at 6:30PM 12/21 to receive high-flow nasal cannula, and has had one episode of fever (100.6) 12/22 at 7:00 AM.

Post-dose 1 of COVID-19 Pfizer vaccine, pt started feeling lethargic and lightheaded. Lightheadedness start 12/18(post-dose Day1) and it became more significant 12/19-12/20.

fever, chills, headache, dizziness, lightheadedness, body aches

I have a sore throat, runny nose. Also, I am having chest discomfort as my chest feels heavy, the mask did not effect my breathing, but now since I received the shot it is hard for me to breath while wearing a face mask. I am taking deep breaths to try and catch my breath. My hands are swelling with fluid and going numb. I feel warm/hot but no temperature

12/18/20 approximately 10:00am 1st COVID injection administered. within 30 minutes I had a mild headache (was not throbbing but nerve shooting in nature). later that evening i noticed heart palpitations and rapid heart rate max 130 reps. the heart rate quickly normalized but heart palpitations remained intermittently that night. Saturday morning I woke with stuffy sinuses, chest little tight but chest tightness clear with coffee intake. sinus remained irritated and then as day progressed i began feeling aches/fatigued/temp 99.0F/mild headache with shoots ear pain bilateral/mild chills/loss of appetite. woke Sunday feeling fine with the exception of loss of appetite. As Sunday progressed i attempted to eat lunch approximately 2:00pm (first meal of day). could not eat much, felt heavy on stomach, began to feel aches/chills/no Temp/loss of appetite with stomach pain and nausea after eating solid food/fatigued again. since then these symptoms have remained. reported to necessary provider and Employee Health.

swelling to uvula seen in Emergency department observed for 4 hours in Tele unit sent home on 12/21/2020

Slight tingling in injection arm

None stated.

employee self-administered epipen prior to going to ED (community)

Employee received vaccine in hospital. Waited through 15 minutes observation period and went back to his shift. There he felt some throat irritation and lip tingling. Manager took him to the ER where they evaluated him - vital signs stable, no shortness of breath, no rash - and gave him benadryl and prednisone and he was able to return to his shift and complete his entire shift.

None stated.

None stated.

Was taken to Emergency Department within the same hospital facility where vaccine was administered. No other side effects other than those mentioned above: scalp itchiness and erythema to right knuckle.

Immunized at 9:15 AM- no symptoms, 2-3 episodes of palpitations throughout the day, resolved spontaneously; 9:00 PM chills and palpitations lasting approximately 1 hour- resolved spontaneously with no further symptoms outside of a sore (expected) injection site.

Left arm pain radiating down extremity, mostly resolved immediately

About 4-6 hours after I had the vaccine, I experienced severe tenderness at the injection site. I had a low grade fever of 99.6 for a short period of time. Dizziness, headache, and body aches have continued over the past 9 hours (~2AM - 11:30AM).

All started 2 days after injection Severe Headache, Diarrhea , Chills, congestion nose

Patient provided immunizations, after injection and retraction of needle, member has some fluid seepage from injection site. Concern not entire 0.3ml were absorbed. No pain or redness at site. Member scheduled for follow up 2nd dose in 21 days.

States she had headaches lasting several days, back and hip pain, shoulder and upper back soreness, chills. Took Ibuprofen, did not alleviate symptoms. Slept and rested until symptoms subsided. Symptoms lasted for about 3-4 days.

Pfizer-BioNTech COVID-19 Vaccine EUA On 12/21/2020 13:17 the patient received the first dose of COVID-19 vaccine. During monitoring, the patient experience itching skin. Hives and welts were not located. The injection site was read and hot. No wheezing occurred, no tachycardia observed. The patient report a history of anaphylactic reactions to food (Sesame), but has never had an anaphylactic reaction to vaccines in the past. Patient also reports anaphylaxis to lidocaine. The patient was treated with ice pack on injection site, 50 mg diphenhydramine, 10 mg cetirizine, and 20 mg famotidine. Patient was observed for a full hour. Advised to pre-medicate at 2nd dose and to alert vaccinator of this reaction.

My arm was not that sore or anything but Friday morning when I woke up my throat was really really sore and I felt congested. My nasal mucus was green and I was also coughing up some green phlegm. I went to the walk in clinic because I had to go to work and wanted to make sure I was well enough.

12/19/20 AM tender arm-- PM arm/ hand tingling numb, itching hands and lips. 12/20/20 Nurse triage line advise to take medication for Loratadine 10mg, Symptoms have not resolved; not as intense today 12/22/2020.

headache and extreme pain in left arm

Dizziness, muscle aches, sore throat

Itching at medial surface of left upper arm (injection site on lateral L UE). Also reported numbness down ventral surface of L forearm into hand. No weakness. She received Benadryl 50mg po at 10:00am. Itching began to improve during this documentation. No airway compromise. Clear mental status. She is recovering from the itching, but the numbness in the hand is still present.

12/16/2020 around 2300 body aches, followed by chills progressed to rigors, developed a migraine 6 to 8 hours after fatigue, insomnia, temp was 100.4. Those symptoms progressed and stayed stable for 24 hours until the next night and didn't resolve until the 18th and late that night I developed lymphadenopathy in left axilla, al nodes very swollen and large. That subsided since then. I took Tylenol and 10mg Rizatriptan for migraines and that resolved. **I was in a double blinded study for the AstraZeneca trial and am still unsure whether or not I received the placebo or the actual shot. Nov 30th

within 10 mins of receiving the vaccine I had a burning sensation across my chest, arms and face, developed hypertension, tachycardia and had perfuse sweating. Blotchiness was noted on my face. I felt like the inside of my body was on fire, only in my torso area. I was given an ice pack, vitals were monitored and the symptoms resolved after 10 mins. Then within 5 mins, the symptoms returned. They again last for about 10 mins and resolved enough for me to leave the vaccination observation area. I was monitored closely for over an 1hr post injection. I did have itchiness in the roof of my mouth, so I took Benadryl 50 mg when I got home and the next morning had major fatigue and mild soreness in the injection site.

I would just say not sure if it's from vaccine exp severe headache 12-18 hrs after vaccination. No other symptoms was unable to return to work.

Headache, Chills, sore throat, muscle weakness, fatigue

Symptoms occurred approximately 30 minutes after vaccine administration

Chest tightness and shortness of breath since 12/19/20

"Patient noted that approximately 18 hours post vaccination, began to experience ""COVID"" symptoms, including aches, chills, dizziness, shortness of breath, fatigue, difficulty focusing, some lower limb weakness. Patient did conform past COVID infection and symptoms are consistent, yet milder than when actively infected."

Had chills at 3 am, took Tylenol 750 mg PO. Skipped work that day due to unexpected chills. Had a fever of 100.3 F, neck pain, headache and muscle aches around noon the same day. Took another Tylenol 750 mg. At 9:00 PM and next morning at 6:00 AM took Tylenol 750 PO. No more symptoms observed.

Itchiness in throat and edema at the mouth.

Sore arm, chills but no fever, body malaise

Pfizer-BioNTech COVID-19 Vaccine EAU

12/18/2020: Pain/heat at injection site, dizziness, muscle aches, nausea, increased mucus production, fever, chills. 12/19/2020: Fatigue, tiredness, headache, nose congestion, muscle aches, injection site was very painful/muscle stiffness left deltoid/applied heat didn't even help, left arm wasn't red, swollen, or hot to the touch. 12/20/2020: Fatigue, tiredness, increased mucus production, cough,. ADHD medication was not taken this day to specifically rest the majority of the day because I thought that would help

alleviate the symptoms. 12/21/2020: Cough, headache, nasal congestion and drainage. I did take a short jog (2mile) this day because I was felling overall better. 12/22/2020: Cough (no chest congestion), increased mucus production, headache (sinus), tiredness, slight confusion/unable to focus well, nausea, diarrhea.

Pt noticed discoloration/mottled appearance of skin near joints on lower extremities. Adverse event lasted less than 36 hours and resolved without treatment.

1st day- started to have left arm pain, sore, heavy at around 6PM 2nd day - started at 5 am noted my left arm was swollen, still sore & painful, having chills, headache muscle aches and later on having fever 99.8F-100.2F. Took Tylenol x 3. 3rd day - still having muscle aches and left arm pain & soreness. 4th day - still having mild left arm pain.

Left UE injection site soreness 4 hours post. Severe vertigo approximately 10 hours after, lasting about 4 hours.

Dry mouth and dry throat. Symptom began 15 minutes after injection and lasted about 3 hours.

Employee calling to report a reaction after receiving a COVID-19 vaccine. Vaccine Name - Pfizer Vaccine Lot # - EK5730 Vaccine Date and time - ?12/18/2020 @ 5:30pm Is this your first or second dose? First Date and time of symptom onset - ?12/22/2020 @ 9:00am Symptoms - ? mild dizziness, feeling hot but no fever, very mild sore throat, intermittent cough, fatigue Last day of work and shift - ? 12/22/2020 7a-3p Home remedies? none Any improvement? - n/a Recommendation? Employee asked her manager to go home early because of her symptoms. She wanted to be tested cause her family from out of states are coming over for the holiday. Advised to continue monitoring at home & call us back if symptoms worsen. Employee voiced understanding Employee of information ? yes Employee voiced any concerns ? no Employee?s questions answered to employee?s satisfaction - yes

Shortness of breath, chest tightness. Treated with epipen, benadryl, pepcid, solumedrol in ED. Symptoms resolved.

Hives

Employee reported diminished sense of smell and taste and 12/18 the day following vaccine. A nasopharyngeal swab was performed for PCR testing for COVID-19 on the day (12/18) and was negative for COVID-19 (Not Detected).

Notes APRN (Nurse Practitioner) ? ? Pediatrics Cosigned by: MD at 12/20/2020 11:30 AM Expand All Collapse All á COVID VACCINE CLINIC 12/18/2020 á Patient: Date: 12/18/2020 Subjective Patient is a 36 y.o. female who was seen at Vaccine Clinic today for her first dose of the COVID 19 vaccination. á She denied any history of previous adverse reactions to vaccines. á She was given the Pfizer vaccination in the right deltoid muscle. á During her 15 minute waiting period after the injection, the patient began to experience throat tightness. She denied rash, hives, difficulty breathing, hoarseness, lightheadedness, dizziness, facial swelling, lip swelling and tongue swelling. á This provider was notified of patient reaction and she was then assessed in the emergency bay area. á Monitored patient for severe reaction

symptoms, including rapid progression of symptoms. á Patient has PMH of mild anxiety á Review of Systems Constitutional: Negative for activity change, appetite change and fever. HENT: Negative for congestion, facial swelling, rhinorrhea and trouble swallowing. Initially with some throat tightness. Resolved within 10 min Respiratory: Negative for cough and shortness of breath. Neurological: Negative for dizziness, weakness, light-headedness and headaches. á á á Objective á Vitals Vitals: á 12/18/20 1251 BP: 130/82 BP Location: Left arm Pulse: 98 SpO2: 100% á á Physical Exam Constitutional: General: She is not in acute distress. Appearance: She is not ill-appearing. HENT: Head: Normocephalic. Mouth/Throat: Mouth: Mucous membranes are moist. Pharynx: No posterior oropharyngeal erythema. Cardiovascular: Rate and Rhythm: Normal rate. Pulmonary: Effort: Pulmonary effort is normal. Musculoskeletal: Normal range of motion. Skin: General: Skin is warm. Capillary Refill: Capillary refill takes less than 2 seconds. Neurological: Mental Status: She is alert. á á Assessment/Plan á Treatment included no therapy. Follow up response to treatment:excellent. Patient discharge: Stable to go home and follow up with PCP. á Monitored patient for 15 min in the emergency bay Within 10 min of arrival the throat tightness resolved Patient felt comfortable to be discharged home - feels that she was anxious about the vaccination. Strict orders to go to the ED if shortness of breath, throat tightness, or other allergic symptoms develop or worsen. Patient verbalized understanding. á Orders Placed This Encounter Procedures ? COVID-19 á á APRN Electronically Signed 12/18/2020 2:17

None stated.

chest pain, across bottom of rib cage, pain with deep breathing, Motrin did not help

Sore arm, shortness of breath, swollen lymph nodes, anxiousness, and tiredness.

First 10 minutes felt cold, headache and numbness in both legs. Tingling in legs and headache remained for 30 minutes. But then indicated felt much better after 30 minutes. Patient also stated that he felt he needed to urinate right away. Patient stated he is blood pressure medications and did not take his medications the morning of the vaccine administration. Pre administration BP 143/76 and Pulse 92 Post administration BP 235/135

Employee experiences nausea and injection site pain

Hives on left leg above the knee (ventrolateral surface)

Self-limiting Pain at injection site (lasted 3 days) Self limiting Tingling in left arm (pins and needles feeling) starting morning after the vaccine and lasting for 3 days and mild hand tingling (lasting 4 days).

immediately after the injection was administered, pt experienced a vagal response; experienced instant lightheadedness, dizziness, and diaphoresis. after elevating feet and sipping cool water, all symptoms resolved after about 15 minutes and pt was able to leave the clinic on her own. pt also reported high level of anxiety prior to receiving injection.

Pt called to report rash on arms and legs on day 3 after receiving the vaccine.

Entire left arm pain that radiated up left side of neck, fever, chills, body aches, joint/muscle pain, teeth hurt, hair hurt, sweats, nausea

Developed body aches and fatigue the day of the vaccine. Developed fever of 100 and high bp and p 12/22 (day after vaccine). BP 151/108, p 116. Referred to clinic for f/u.

Developed body aches and fatigue the day of the vaccine. Developed fever of 100 and high bp and p 12/22 (day after vaccine). BP 151/108, p 116. Referred to clinic for f/u.

PT states he began feeling tired the afternoon of the vaccination, approx 1500. He rested and woke during the night at 2am with temp of 103.0 and headache, muscle aches. Temp at 3 am was 100.7 and headache/muscle aches. Temp 0900 was 100.0 with headache/muscle aches. Pt denies nausea, vomiting, sore throat. will continue to monitor

"12/21/2020 4:30PM itching throat, clearing of throat, lump in throat, coughing, very dry throat, coughing sensation to remove ""something"" in throat, fat tongue/throat feeling, throat feeling as if closing, coughing fit --- pt transferred to ER. Panic attack, unable to breath feeling --medications via IV -- Benadryl (flushed), Pepcid and steroid for inflammation) administered. Heart monitored while receiving treatment. Discharged at 08:00 PM with prescription for Benadryl and steroid Prednisone."

Headache Fever- temp as high as 102.7

Patient self reported day after vaccine having an adverse reaction and taking benadryl. He reported to work today.

Developed numbness in legs and back of neck. Swelling on left side of face. Given Benadryl 50 mg PO and sent to emergency room.

Employee began to experience light headiness right after receiving the vaccine

Headache ,whole body ache , back pain ,low grade temperature 99.2 since yesterday

Dizziness, headache, body aches. Temp 99.4-99.6. Supportive measures.

Itchy rash on face and neck, slight body aches, fatigue

Shortly after receiving the vaccine I developed a headache followed by muscle aches, fever, chills, nausea, joint pain, brain fog, fatigue, dry cough.

20 mins after receiving vaccination experienced lightheadedness, palpitations, and faintness; was assessed (BP, HR, RR) which were elevated; rested, water, and started to feel better; 20 mins later had another wave of lightheadedness and my vitals increase again which was more intense then the first time; put me on O2 and sent me down to the ER where they monitored me on telemetry, general blood work, EKG, and assess me for swelling, rash and further reaction; BP got to 134/100 but other then that no outstanding numbers; 15 mins after arriving at ER they gave me benedryl and a steriod per IV and IV fluids; right after they gave me that had another wave of lightheadedness which didn't last a long as the

others; symptoms seem to subside and then the let me go home; had no further issues that night other then insomnia; Next day had shortness of breath on exertion but was able to go about my day and just ease up is I was tired; at 6pm that night I started having redness, hottness from the injection sight and the redness (like flushing, not rash) spread from my left arm across my chest to my right arm, and up to my face; felt over heated like I was having a hot flash and my left ear (side I received the vaccine) start to ring; took a dose of benedryl per the bottle instructions and it seemed to calm down; today (day 2) I woke up feeling somewhat ok but as the day is progressing my head feels floating and having trouble concentrating, my upper body from my chest up feels tingly, heavy and weak like I just worked out my muscles and my had are really cold esp on my right hand; my vaccine site is still very warm;

"Patient states that she received the vaccination at 10:24 AM. Patient states approximately 2 minutes after that she felt pain and swelling and erythema in her left arm at the injection site. Patient states she felt like she had a somewhat of a ""apple in her throat"". Patient states that her left arm was tingly. Patient states that she has a headache in the bitemporal area. She states that she has a history of headaches. Patient states that she has no visual changes. Patient states that it started after the immunization. Patient states 5 minutes before I came into the room she vomited and now feels tremendously better. She is talking in a complete sentences. Patient is somewhat tachycardic on initial Patient states that she received the vaccination at 10:24 AM. Patient states approximately 2 minutes after that she felt pain and swelling and erythema in her left arm at the injection site. Patient states she felt like she had a somewhat of a ""apple in her throat"". Patient states that her left arm was tingly. Patient states that she has a headache in the bitemporal area. She states that she has a history of headaches. Patient states that she has no visual changes. Patient states that it started after the immunization. Patient states 5 minutes before I came into the room she vomited and now feels tremendously better. She is talking in a complete sentences. Patient is somewhat tachycardic on initial presentation. Patient presents via BR RT for evaluation. Patient has a host of allergies.Patient is anxious upon presentation. Patient does have a history of anxiety. No other travel or trauma. Patient states that her pain is severe. States that she has some pressure in the bitemporal portion of her head and her left arm injection site. Otherwise nonradiating. No other known aggravating, triggering or alleviating factors. Patient dates its concurrent with the injection time. Otherwise nonradiating. BP 180/100 at 1045, O2 sat 98%, ECG sinus tachycardia Repeat Vital Signs BP 133/82 | Pulse 82 | Temp 36.9 ¦C (98.4 ¦F) (Oral) | Resp 16 | Ht 1.702 m (5' 7"") | Wt 197 lb 1.5 oz (89.4 kg) | SpO2 98% | BMI 30.87 kg/m¦ Constitutional: Well developed; well nourished; in no apparent distress; non-toxic appearance HEAD: Atraumatic. Normocephalic. Eyes: PERRL; EOM intact; conjunctiva and sclera normal to inspection. HENT: TM's normal; no rhinorrhea; normal pharynx with no erythema or exudates. Mucous membranes are moist. Uvula is midline. No hemotympanum or foreign body. NECK: Supple; non-tender; no cervical lymphadenopathy. Respiratory: No respiratory distress; normal breath sounds; breathing non-labored Cardiovascular: Normal rate; good peripheral perfusion. No murmurs or rubs CHEST: Nontender. There are no retractions. GI: Normal bowel sounds; non-distended; non-tender to palpation; no palpable organomegaly GU: Musculoskeletal: Extremities non-tender; normal range of motion; no edema; Normal distal pulses Back -Normal tone; no tenderness Integument: Well hydrated; no lesions; no significant rash or palpable nodes. Neurologic: Alert, appropriate; oriented to person; place and time. No focal deficits. Motor 5/5. Sensation intact in all 4 extremities. Psych: Mood and affect are anxious.

Mental status appears normal at time of exam. Patient upon presentation is anxious. Patient did vomit x1. Patient was talking in complete sentences upon my evaluation. Patient feels that she has some discomfort to her injection site with a headache. They feel no warmth or erythema. Patient was given Tylenol for the headache which did improve. Also received ondansetron, diphenhydramine, famotidine, methylprednisolone, NS 1000mL. Patient was monitored for an extended period of time and has had no return of symptoms. I am uncertain whether this is a true allergic reaction since the symptoms started approximately 2 minutes from the time of the injection. Patient does have a history of anxiety and this may have played a role within the symptomatology. At this time patient feels much better. Patient be dismissed we will send the patient home with a prednisone taper. She can take oral Benadryl and Pepcid. Follow-up with her family doctor next couple days not feeling better. Patient is dismissed. Patient returned to ED on 10/22/20 0100. Presents to ED complaining of numbness and tingling all the way from her head to her left toe on the left side. Has taken Benadryl 3 times today. She states that she woke up this evening with her heart racing. She still has a little bit of a headache. No fevers. He was nauseous. Again she says the whole left side of her body is tingling. All other systems negative/without deficit. HR 124, BP 168/107. Repeat Vital Signs: BP 129/77 | Pulse 99 | Temp 37.2 ¦C (98.9 ¦F) (Temporal) | Resp 20 | Wt 206 lb 2.1 oz (93.5 kg) | SpO2 100% | BMI 32.28 kg/m¦ EKG showed a sinus rhythm without acute ST changes. She is anemic but she has a history of that and her hemoglobin is not significantly lower than usual. Sed rate is little bit elevated but her C-reactive protein is normal. Her glucose slightly elevated at 173 but the rest of her labs are normal. CT and CTA of her head and neck were normal. I do not know at this time if this is a reaction we will have her continue the prednisone taper she was started on earlier as well as Benadryl and have her follow-up with her primary care physician."

Left arm soreness and pain. Began overnight. No skin changes. Painful to touch. Painful with abduction and lifting. Empty Can Test positive.

Around 1-2am I developed a fever and chills associated with moderate diffuse myalgia, arthralgia in my left elbow strangely enough (injection was in right deltoid), and fatigue. My symptoms were constant until around 1pm when I took 500mg Tylenol. Of note, I had COVID in March 2020.

Lightheaded, dizzy, nauseous, and heart palpitations about 5 minutes after getting vaccine. Laid supine for 30 minutes with blood pressure continuously taken. BP 188/93

Developed numbness and burning to left arm. Had tingling on left side of face. Given Benadryl 25 mg PO and sent to emergency room.

30 minutes post vaccination, pt started feeling flushed and itchy (mostly in the anterior neck, Rside of face and R ear). Positive pruitis and flushing, vital signs taken, within normal limits for pt

Employee Experienced hotflashes

Weakness, low fever, chills, sensitivity to touch/light/sound, headaches, muscle aches, shakey

Contracted associate received vaccine on 12/18/2020 at 1000. Within 1/2 hour began to feel very hot and extremely tired. She left and had to rest in the lobby before she could drive home. She finally drove home and all weekend was short of breath, hot (not sure if she had a fever), fatigued. She went to the ED this morning (12/21/20) had a Rapid COVID test that was neg and is now waiting for PCR test results. She has been instructed to quarantine for 20 days. She has lupus and a history of kidney transplant in 2004.

Shoulder pain, arm pit pain, deep scapula pain with inability to move arm without significant pain starting on 12/20.

Felt dizzy with blurred vision for a few seconds. Began to have chills for a few minutes, with concurrent shaking.

Temperature of 99.6 and fatigue

Numbness to left arm with shoulder blade pain and neck pain. Resolved on own.

Severe fatigue, Brain fog

Employee Experienced high blood pressure, headache, and light headiness

7 hours after vaccination onset of fever, lethargy, headache, dizziness. 1 Liter Normal Saline

"Patient reports headache 7/10 not relieved by motrin. Onset of the headache was upon awakening at 0500 on 12/17. She denies visual changes, nausea, and vomiting. She also reports that her back is sore. She has a history of migraine headaches and has not taken her migraine medication for this headache. She says she gets headaches ""all the time"" and this headache is different for her in that she didn't experience the visual aura she usually gets with her migraines."

following vaccine administration, patient verbalized dizziness and became pallor. rapid response team notified for further disposition. patient denies chest pain, SOB, N/V. patient remain AAOX3 with no LOC. treatment resolved with no ED escalation. Patient exited vaccination area ambulatory with no concerns.

Patient started new blood pressure medication this morning. Vitals at beginning of ADR: BP 91/56, HR 66 therefore, rapid response called, vitals were BP 105/67, HR 73.

phone call visit

phone visit

Arm soreness, swelling achy, cold, headache

Pfizer-BioNTech COVID-19 Vaccine EUA given to RD on 12/16 @ 12pm. Loss of feeling in right arm started @ 4pm & lasted until end of day on 12/17, along with muscle weakness & migraine. All symptoms resolved by 12/20 & she felt great.

Ee stated she started to feel dizzy. V/S as followed B/P: 96/60 P: 63 O2: 99. Ee stated she was feeling clammy and she usually gets this way when given vaccines. Adverse reaction started appro 7:38 pm. Ee felt better approx. 7:46.

phone call

Right after given the covid vaccine. When I stood up to go to another desk, I sat down and my throat started to feel funny, and my tougue started to swell and I had a hard time swallowing. I informed the nurses that I have a problem. I was taken to the emergency room right away. I was treated with an epi injection and it did not relieve my reaction. They then gave me another injection, then later my throat started to swell again, and I was given another dose of an epi injection. I was release at 7pm after observation. Last night, I had another delayed reaction, I took a benadryl, and a zertec, and prednisone and the symptoms went away. This morning, I am fine. Today, it feels a little tight, but it's not bad.

"PATIENT STATES ""I FEEL LIKE MY HEART IS RUNNING"" HEART TAKEN AT 9:30- 90 IRREGULAR TAKEN AGAIN AT 9:49- 72 IRREGULAR PATIENT STATES THAT SHE IS FEELING BETTER PATIENT OBSERVED ADDITIONAL 15 MINUTES AND RELEASED"

Tingling all over the body, nausea, pale-looking, hot/cold, clammy, duration approx. 2 hours but not as severe.

had fever, chills, body aches?..a rough night. Still have body aches beyond just the arm

Headache, myalgias, fever, chills for 24 hours, starting 18 hours after vaccination

Severe headache for four days after vaccine, trouble keeping temperature below 100, extreme fatigue, shortness of breath, chills, nausea, loss of appetite, body aches, chest pain.

About 10 hours after I received the vaccine I developed chills and a slight fever (99.4). About 18 hours after I received it I developed shaking chills, fever of 100.6, and severe body aches. The fever responded to ibuprofen. It is now approx 28 hours after I was vaccinated and my fever and chills have returned along with the body aches. It is hard to tell if this is from the vaccine or if it from an unresolved pneumonia, as these are symptoms I had with the pneumonia and strep infection.

After I got home from work, around 7 pm I started to feel side effects such as the following: fatigue, muscle aches, feverish, malaise, injection site soreness/pain. This lasted for about 48 hours.

Temp spike at approximately 32 hours post vaccination. Mild flu-like symptoms that resolved 72-80 hours post vaccination

Racing & pounding heart, dizziness, tingling feeling prior to dizziness, then shaking hands. After shaking, heart rate returned to normal. No blood pressure change was noted. Whole event lasted no more than 5-10 minutes.

Arm/injection site pain within first 12 hours, then chills, followed by fever and severe headache, muscle aches and fatigue. Symptoms continued into 48hrs post injection.

I was awoken around 1 in the morning to severe calf muscle cramps - right and left leg, fever, body aches all over for about 15 hours. Tylenol, rest and water.

Notes APRN (Nurse Practitioner) ? ? Pediatrics Cosigned by: MD at 12/20/2020 11:30 AM Expand All Collapse All á COVID VACCINE CLINIC 12/18/2020 á Patient: DOB: Date: 12/18/2020 MRN: 10148412 á Subjective Patient is a 48 y.o. female who was seen at Vaccine Clinic today for her first dose of the COVID 19 vaccination. á She denied any history of previous adverse reactions to vaccines. á She was given the Pfizer vaccination in the right deltoid muscle. á During her 15 minute waiting period after the injection, the patient began to experience tingling in hands and feet. She denied rash, hives, difficulty breathing, difficulty swallowing, wheezing, throat tightness, hoarseness, lightheadedness, dizziness and tongue swelling. á This provider was notified of patient reaction and she was then assessed in the emergency bay area. á Patient with PMH of fibromyalgia and rheumatoid arthritis No history of vaccine or medication reaction previously á Review of Systems Constitutional: Negative for chills and fatigue. HENT: Negative for congestion, facial swelling, rhinorrhea, sinus pain, sneezing, sore throat and trouble swallowing. Respiratory: Negative for cough and shortness of breath. Musculoskeletal: Negative for back pain, myalgias and neck stiffness. Skin: Negative for rash. Neurological: Tingling in hands and feet bilaterally á á á Objective á Vitals Vitals: á 12/18/20 1255 12/18/20 1318 12/18/20 1345 BP: (!) 143/86 (!) 129/91 131/83 BP Location: Left arm Left arm Left arm Pulse: 79 72 69 SpO2: 100% 100% 100% á á Physical Exam Constitutional: General: She is not in acute distress. Appearance: She is not ill-appearing or diaphoretic. HENT: Head: Normocephalic. Nose: Nose normal. Mouth/Throat: Mouth: Mucous membranes are moist. Pharynx: Oropharynx is clear. Cardiovascular: Rate and Rhythm: Normal rate. Pulmonary: Effort: Pulmonary effort is normal. Musculoskeletal: Normal range of motion. Comments: C/o tinglinig to feet and hands bilaterally Normal ROM Grip strength equal bilaterally No lightheadedness or weakness Skin: General: Skin is warm. Capillary Refill: Capillary refill takes less than 2 seconds. Coloration: Skin is not pale. Findings: No erythema or rash. Neurological: General: No focal deficit present. Mental Status: She is alert and oriented to person, place, and time. Psychiatric: Mood and Affect: Mood normal. á á á Assessment/Plan á Treatment included antihistamines. Follow up response to treatment:good Patient discharge: Stable to go home and follow up with PCP á Benadryl given at 1314 At 1330 reports significant reduction to tingling in hands and resolved in feet 1340 - tingling has resolved 1350 - Escorted by pharmacist out of building. VSS á Patient provided with paperwork about immunization Strict instruction to go to the ED if shortness of breath, cough, difficulty swallowing, tingling/weakness, or other allergic symptoms occur. Patient verbalized understanding APRN Electronically Signed 12/18/2020 2:00 PM á á Division of Health 3 of 3 á

Rash to neck with itching

Day 1: Initially left arm soreness around the site About 4 hours later I developed generalized body aches/felt foggy Day 2: Left arm soreness

Pfizer-BioNTech COVID-19 Vaccine EUA Diarrhea, shortness of breath, tachycardia, elevated blood pressure, 101F fever, dizziness, weakness, fatigue, flushing, chills

SOB/swelling of face, hands, feet, tongue lasting from 12/21/20 0200h to approx 1000h (resolved with diphenhydramine 50mg PO) Flu-like symptoms/malaise/chills lasting from 12/21/20 0200h to approx 12/21/20 1800h Headache from 12/21/20 0200h; continuing as of 12/22/2020 1130h

Hx of chills and not feeling well with flu shot but generally feels better the next day 12/18/2020 at 9pm: chills, diarrhea, itchy bumps on lower legs, rapid HR, no fever 12/19/2020 at 2pm: itchy bumps on lower legs, gets worse with scratching, chills, nausea, diarrhea, left arm soreness 12/20/2020: painful swollen lymph nodes left axillary, felt like 2 golf balls, reached out to a friend who is a doctor and was told to take Tylenol 12/21/2020: left arm soreness, chills, rapid HR, diarrhea Currently: still has the bumps on both legs and are itchy ? left leg is worse, Cortisone and Benadryl not really working, the rapid HR, chills and diarrhea come at random times January 2020, patient had the Flu

Mild soreness to upper left arm which was still present the following morning.

Pfizer-BioNTech COVID-19 Vaccine EUA Injection site pain that started 7 hours after injection and has continued to now. Pain is lessening as time goes on. Tylenol has helped. Headache, Nausea and ear ache all started this morning (7am). Headache is continuous; nausea and ear ache are intermittent

20 hours after vaccine, I had uncontrollable shaking, fever 99-101, headache, and I am still experiencing on the left side of my neck - clavicle, and in my axilla under my arm, clusters of lymph nodes that wont go away. Fever, chills, head ache and body ache all went away and lasted only for 2 days. The lymph nodes are still pretty big and are still here .

0843 vaccine administered. 0855 patient reported a rapid heart rate (112 beats per minute) and tremors. No airway complications.

High fever, upto 101.5, severe myalagias, nausea, similar intensity as of my actual infection. Took Acetaminophen with no effect. Responded to Ibuprofen. Better on day 3 12/22/20

Approximately 10 minutes after vaccination c/o feeling shaky, she then stated her neck itched and she exhibited generalized urticaria. Was given .5ml Epinephrine IM at 1000. Stated she was having thickened feeling in her throat, had high blood pressure on 191/126 and was nauseated. Was given 1ml of Benadryl IM. Ambulance called at 0958 and transported to hospital at 1008.

Flushing Sweats Chills Heart rate was ranging between 45-190 according to watch Nausea Vomiting

Next day developed approx. 2.5 x2.5 inch, round, reddened area around vaccine site, told to ice site & contact if any worse. 12/22/2020 improved site reaction

Yesterday had no energy, real tired, heart beat rapid. Not normal for him. Slept yesterday a few hours. and then again at night. Called facility and they stated that he should go to ER if needed and to call VAERS to report AE. Patient is a DOD Firefighter.

Petechiae developed on 12/19 on legs and torso and back Took Benadryl although not pruritic.

ITCHY, HARD TO BREATH,HEADACH I WAS GIVEN EPIPEN RUCHED TO ED FOR FUTHER TREATMENT

Received vaccine Saturday 12/19/20 around 0700AM. ON 12/21/20 patient began developing rash and redness around injection site. Took diphenydramine and recovered.

Nausea, headache

11 minutes into the vaccination, patient noted to have tongue and mouth tingling and heart racing. No noted tongue/lip/throat swelling, dyspnea, n/v, abdominal pain, rash, near-syncope. Started to improve after 30 seconds.. H/o tachycardia secondary to salmon, no prior anaphylaxis or use of epinephrine in the past. Sent to ED for evaulation

Developed tachycardia, tremors, hypertension, rash. Given diphenhydramine and fluid bolus in ED and discharged home.

within one hour facial prickling sensation and mild dizziness -- by 6pm same day, moderate aching all over and moderate headache also. Next day continued symptoms but milder and intermittent facial prickling

Fatigue, headache, body aches, chills, nausea, diarrhea, fever, joint pain, cough, sore throat, nasal drainage. All started 2 hours after vaccine, although she states she had a headache at time of vaccine, but stated this is not abnormal for her. She also reports that she had an exposure at lunch to co worker on the 10th, that then became symptomatic on the 15th and tested positive. Also states she had sore arm at injection site for 4 days.

5-10 minutes after the vaccination, I experienced tingling and numbness in my tongue. Very similar to the feeling when you go to the dentist and he uses the numbing agent before procedures. Comparing to the dentist, my adverse reaction is not as severe, 10 being a whole injection of numbing agent to prevent sensation in the mouth, this is likely a 4/10 tingling/numbness feeling. It has persisted for 3 hours now, the intensity of the feeling has slowly decreased overtime, but I still notice it after 3 hrs. My right arm where I get the injection is also a little sore, but that is expected and very similar to all the other vaccines I get.

Left side vaccine administration, site reaction, slightly reddened. Iced

Patient woken by sore arm in the middle of the night following vaccine. Over the next 3 days had intermittent headaches, some nausea, and fatigue.

Patient experienced tingling on lips and back of the tongue as well as coughing. Then benadryl was administered which led to resolution.

Saturday 12/19 early am, sore shoulder when rolled onto in sleep. HA through out day Sunday 12/20 quarter size red area surrounding shot Monday 12/21 knot at site of injection that others could feel through my shirt-painful. Swollen left arm pit but no distinct lymph nodes felt. Arm pit tender when palpated. Tuesday 12/22 arm pit swelling remains as well as knot at site and pain when either or both palpated.

Vaccinated at 9:00am through employee health. Within 5 minutes of vaccine administration, developed palpitations and flushing. These persisted and worsened and I was transported to the ED. During transport I developed chest tightness and throat tightness. On arrival to ED, HR 125, BP 150/97. Observed for 2 hours, given normal saline but no medications. Over time, palpitations and flushing subsided first. Then chest tightness persisted for about 2 hours. Was discharged from ED within 2 hours. Throat tightness persisted for approximately 8 hours total and gradually resolved.

PATIENT IS EXPERIENCING ELEVATED BLOOD PRESSURE OF 170/101

Burning in throat, flushed face and neck. Developed stridor. Benadryl 25 mg PO given, Epinephrine 0.5mg given IM, albuterol inhaler 4 puffs. Transferred to the Emergency department and admitted to the hospital.

"Nurse who had worked the shift and had drank an "" energy drink"" prior to vaccine. she felt palpitations and and elevation of blood pressure. No itching hives or angioedema. No dyspnea. Pt observed and discharged home without any therapy"

fever of 101.4 reduced with Tylenol administration

Next morning, patient had a rash and swelling on forehead and back of hands. She took a benadryl and went to the emergency room.

0755 Pt notified other Nurse that he is feeling nausea; slight dizziness. He reported to Nurse that he did eat light breakfast this AM prior to COVID #1 Injection. Pt resting with eyes closed. Nurse spoke with pt, DOB, pt works in, Nurse offered pt Water, Crackers, snack. Pt offered to be taken to ER or to call Rapid Response so vitals can be taken and closer monitored. Pt refused ED and Rapid Response. Pt stated he will just sit longer and complete his Observation time. Nurse provided Continuous Monitoring; checked on Pt symptoms every 5-8 minutes. Pt stated he is fine and symptoms are subsiding. After 15-20 minutes of Observation; Pt was ready to leave. Pt stated he is well, symptoms have resolved, he is fine; per pt. Pt left Observation at 0808; steady gait, denies chest pain, SOB, any further Dizziness, or any further Nausea.

Patient became Lightheaded, dizzy @ 11:24 am BP 155/92, Sat 100% on room air, P-100, repeat BP 11:25 141/94 Sat 99% P-98, 11:28 154/91 sat 100%, P-99, patient described having palpitations, transferred to ER via gurney for increased BP, light headed, dizzy palpitations

Patient received the first dose of the Pfizer covid vaccine on 12/16 and on 12/17 in the afternoon she developed a rash on her chest. She reports the rash was little raised bumps and was itchy and red. The rash extended to her abdomen, back, neck, arms and legs on 12/18-12/19. The rash began to fade on 12/20 and is almost completely gone now 12/22. Patient not treat with rash with any topicals or oral medications.

Fatigue- On going body aches Muscle pain-Torso Headache- On going - Head aches when moving around chills- 3 hours

Patient was administered the Covid19 vaccine. She was advised to wait 30 minutes post vaccination. While the patient was waiting, she reported having an itchy throat, throat tightness, then a hoarse voice and a cough developed. This happened at about 20 minutes after she received the vaccine. The patient was assessed by the nursing and provider staff. She received an adult epi pen injection and EMS was called. Patient was taken to the ER by EMS. She reports she received two more epi injections, benadryl, and Solu Medrol. She was stabilized. Patient was discharged from the ED after several hours. She then reports a second episode of throat tightening and worsening cough at 12:30 am and was taken by ambulance to the ICU and admitted. She is still in the hospital at this time 12/22/2020.

17 minutes after vaccination, had itching all over body, inside mouth; noted itching palate and tongue, hot flashes and given famotidine and diphenhydramine and sent to ED for evaluation. in ED: given diphenhydramine 25mg PO one time felt abdominal discomfort and radiating up to the chest and given GI cocktail with temporary improvement. also mild nausea given ondansetron x2; also NS IVF given for 2L Discharged with ondansetron and prednisone 40mg PO daily for 5 days.

After receiving the shot and getting up to walk across the room to sit down for the waiting period, I started to experience extreme dizziness and weakness. My heart rate jumped and I felt extremely hot. I thought I was going to faint. Within about 10 minutes I got an extreme headache that felt like someone was squeezing my head. I was given a heavy dose of benadryl as I was not experiencing difficulty breathing and we did not feel like I needed an epipen. After the benadryl kicked in my symptoms became less intense and I just had periodic bouts of sweating and chills. I am now on my third round of benadryl but have been able to lessen the dose, I do not anticipate having to take a fourth dose.

Explosive diarrhea that started nearly 24 hours after vaccination

When I got the vaccination I was 32weeks pregnant and on Saturday I had spontaeous rupture of the amnotic fluids and went immediately to the hospital and was immediately given steroid, magnesium for the baby. And on Sunday around 3:45PM I got a second round of the steroids and was transferred for observation. On Monday, at 8:06am I went into early labor I delivered my baby at 33weeks gestation and she weighed 3lb 11oz. Expected Date of Delivery-2/8/2021. I was a high risk patient d/t Fibroids but have experienced no issues the entire pregnancy and my last ultrasound was 12/17 and baby was healthy with no complications at that time.

Initially employee experienced flushing, palpatations, nausea. ER- developed hives on arms TX:Prednison 60mg po given at 11:53am Benadryl 50mg po given at 11:52am Observed for 2 hours with symptom resolution. Discharged with oral steroids.

seizure, resident sent to er and in CCU

Chills, fever over 100, body aches, tiredness, fatigue, injection site pain, feeling unwell, nausea

Received COVID19 vaccine at 730am, developed erythematous patchy rash on anterior neck and chest around 1130am. Initially began on neck, spread, then resolved over about 1 hour. No itchiness, no irritation, no fever, asymptomatic. No PMH, allergies, medications.

She went to the Emergency department 12/20 and received a high dose of Benadryl. She reported tachycardia all day yesterday in the 130?s and was itchy all over. Subsequently she developed a rash.

Pain in the site of injection

5 minutes post vaccine, while sitting in the socially distanced observation area the patient felt dizzy. While getting a gurney to the area, she had a syncopal episode. We moved her to the gurney and elevated her legs. She regained consciousness promptly. She told us she was diabetic and her glucose was 101 that morning. We gave her juice and observed her for 30 minutes more. She had no focal symptoms and felt well at discharge. No previous history of vagal episodes, hadn't eaten before the vaccine. The patient is an RN.

From patient interview: The patient stated feeling dizzy with lightheadedness and seeing spots. She felt like she was going to pass out. She was transported to our emergency department for examination. When I spoke with her she was resting and felt she had returned to baseline. From medical record:Patient Stated Complaint SYNCOPE, Narrative of Presenting Problem Patient is a 35-year-old female with history of vasovagal episodes during her prior pregnancy was in the hospital getting a Covid vaccination and became weak dizzy and sweaty and had a syncopal episode while in a chair. Patient did not hit her head. Upon evaluation patient is awake alert lying supine with no complaints. Patient states she has been suffering with Covid related anxiety and depression.

Conjunctivitis in both eyes. Uveitis in the right eye.

pain in right shoulder immediately after injection. then shortly after felt nausea and thinking I might puke. did not feel like myself. this lasted about 2 hours. (8am-11am) I also felt muscle pain, laterally in my neck on both sides.12:00pm I did not feel nauseated or neck pain anymore but felt general malaise still. and this came and went all day. today, the following day I have no symptoms.

Hypertensive to 190/80; shaking; chills; after 30 minutes, BP reduced 159/80; sent to ER; monitored; sent home; resolved, per follow-up call following day.

Patient started to experience some periorbital edema. No respiratory distress

Fever Headache Left arm discomfort Malaise; Fever Headache Left arm discomfort Malaise; Fever Headache Left arm discomfort Malaise; Fever Headache Left arm discomfort Malaise; This is a spontaneous report from a contactable physician. A 33-year-old non-pregnant female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), intramuscular in the left arm on 16Dec2020 at 10:45 (at the age of 33-years-old) as a single dose for COVID-19 immunization. Medical history included generalized anxiety disorder, gastrooesophageal reflux disease, vague gallbladder, and lactose allergy. Prior to the vaccination, the patient was not diagnosed with COVID-19. Concomitant medications included escitalopram oxalate (LEXAPRO) for an unknown indication from an unknown date and unknown if ongoing. The patient did not receive any other vaccines within four weeks prior to the vaccination. On 16Dec2020 at 21:00, the patient experienced fever, headache, left arm discomfort, and malaise. Therapeutic measures were taken as a result of fever, headache, left arm discomfort, and

malaise and included treatment with paracetamol (ACETAMINOPHEN). The clinical outcomes of the fever, headache, left arm discomfort, and malaise were recovered on an unknown date in Dec2020. It was also reported that since the vaccination, the patient had not been tested for COVID-19. The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up.

patient received vaccine at 10:31, at 10:43 am reported left arm tingling, BP unable to read, sat 98% on room air, switched vital macine, 10:46 am sitting BP 188/102 sat 100%, P-71, 10:58 repeat 179/106 sat 100% P-69, tingling remains, no shortness of breath, took patient to Urgent Care for evaluation

Upon initial injection (0940)pt reported some lightheadedness, pt sat for aprox 20 min and then stated feeling better. She returned to her clinic to work and at 1030, reported return of s/s with increased severity. She was brought back to vaccination area an evaluated by MD, given 50mg of po liquid Benadryl and then taken to ED via WC. VS: 155/77, 105, 18, 96% on room air.

headache; Body aches; induration at the vaccine area; This is a spontaneous report from a non-contactable consumer (patient). A 34-year-old female patient received bnt162b2 (BNT162B2), via an unspecified route of administration on the left arm on 16Dec2020 11:00 at a single dose for immunisation. Medical history included sever dermatitis. The patient's concomitant medications were not reported. The patient previously took influenza vaccine and experienced drug hypersensitivity. The patient experienced body aches, headache, induration at the vaccine area on 16Dec2020 11:00. Ibuprofen was given as treatment for the adverse event. Outcome of the events was recovering. The events were considered non-serious. The patient was not diagnosed with COVID-19 prior to vaccination and has not been tested since the vaccination. No follow-up attempts are possible. Information about Lot/Batch could not be obtained. No further information is expected.

12/16/2020 2:30 AFTER VACCINATION, STARTED TO FEEL INCREASE HR. STARTED TO FEEL WOOZY, UNABLE TO FOCUS. CHECKED VITALS IN ICU; HR 116. WENT TO ER, TRIAGE BP WAS 163/101; HR 115. GIVEN LITER SALINE, DREW LABS. BP AND HR CAME DOWN. TOLD TO REST COUPLE DAYS. WAS CONCERNED AS HX OF STROKE. F/UP WITH CARDIOLOGIST 'DOESN'T THINK THE SECOND VACCINE WOULD BE HARMFUL' BUT 'I JUST DON'T KNOW'. FAMILY HAS HX OF HEART DISEASE. I KNOW ANXIETY BUT NEVER HAD HR DO 'WHAT IT DID'. DON'T FEEL LIKE IT WAS ANXIETY. I KNOW MY BODY. I HAD TAKEN CARE OF COVID PATIENTS THE WEEK BEFORE. I DON'T KNOW WHAT TO THINK. TRYING TO LOOK AT ALL FACTORS. 12/17/2020 HEADACHE; FOLLOWING DAY I WAS FINE

Have nausea, malaise, headache, chills.

The vaccine recipient received the vaccine on 12/16/2020. On 12/17 they reported pain at the injection site. On 12/18 and 12/19 they reported that they became with the following symptoms: swollen glands, body aches, fatigue, and sore throat. During a follow-up phone call they reported that the symptoms have resolved 12/20.

After receiving the vaccine earlier, patient had difficulty swallowing for 3 minutes and also dizziness-- > went to ED for evaluation. Symptoms resolved after rooming in ED. ED physician DX with possible

allergic reaction and he was given diphenhydramine 50mg PO x1 and prednisone 40mg PO x1 in ED-- > discharged home with PRN diphenhydramine, cetirizine 10mg daily and epi pen PRN.

Developed headache, tachycardia and urticaria 12 minutes post immunization. Transfer to ER for care. Had NS 100 ml. bolus, Benadryl 25 mg IV, Solumedrol 125 mg IV, Pepcid 20 mg IV, Tylenol 1 Gm PO. Symptoms resolved. Discharged home from ER same day with Rx for Benadryl and Pepcid.

Headache ,muscle pain , join pain , chills , runny nose.

itchy, dizzy right after injection

Rash on arms

Palpitations and elevated heart rate from Friday 0600 until wake up on Sunday. Felt tired and aching on Thursday night however, no fever

Within 30 minutes I began to feel somewhat jittery and felt very hot . Then I began sweating profusely. I was not tachycardic but my pulse felt very strong. The sweating lasted about 20 minutes. The jittery nervous feeling about two hours.

Dizziness, headache, abdominal pain. Supportive measures.

Headache Low grade fever 99.7 Back ache Body ache Chills Cold hands Nausea These started Dec 20, the night of my vaccination. My symptoms continued on Monday the 21. On Tuesday Dec 22 I still have a slight headache and body aches. I just feel run down. I took regular strength Tylenol I-II PRN

Diaphoretic and tachycardic within 5 minutes of receiving vaccine. Rate up to 151 with BP 146/82. Rate would go down after 5 minutes sitting quietly and then return to 150. Back down and then 15 min later, up. gave 25 mg of po benadryl at 11:30 am. This continued and 911 called. Paramedics assessed. Patient brought to ed for additional monitoring and assessment in private car. D/C'd at 2:30pm with no other interventions.

Severe headache and limb numbness ~ 30 minutes after vaccination Sent to emergency department - no treatment needed

headache - pt reports she will take Tylenol , reports head is ongoing tingling between shoulders - resolved

After I ate lunch I had watery stool, Next day I had hot flashes , body aches, eyes watering, chills,

Redness and ache at injection site since noted 12/21/2020, left arm itchy since 12/20/20

"Reported ""Heart going fast, it might be anxiety"". 1400: O2 Sat 99% 65HR 12RR 154/101 1405: 02 99% 68HR 12RR 139/95 1417: O2 99% 66HR 1430: O2 100% 69HR 12RR 129/89 Symptoms began resolving between 1405 and 1430. Afterwards was escorted to work station."

Employee was being monitored post Covid19 vaccine, approximaetely 10 minutes after recieving vaccine she complained of feeling dizzy and light headed and then became unresponsive. 911 was called and employee was taken to ER

Subconjunctival hemorrhage (R eye)

Pt received vaccine around 1302. Pt experienced some minimal injection site bleeding, which was stopped gauze and a non-latex bandage was placed. While patient was at the vaccine table she reported itching around the injection site. Bandage was removed and patient was monitored further. Patient then reported that itching was worse at 1320, spreading to her thigh, head and back. 25mg PO diphenhydramine was administered and the patient was monitored for worsening symptoms. No further symptoms were reported and itching relieved by PO benadryl.

Patient developed tingling in back of throat and back of tongue. No swelling, vomiting, trouble breathing, hives. Symptoms lasted about 1 hour, did not get progressively worse and seemed to resolve within 1-2 hours. No medication, treatment or intervention was needed.

Reported received the vaccination at approx. 10am on 12/18. Developed headache during her 12 hour shift at the hospital. At 830pm after getting home from work, she developed elevated heart rate 130s, heart palpitations, body aches, severe nausea, muscle pain, and fatigue.

Abdominal pain, upset stomach, and nausea

After receiving the vaccine, within 10 min I developed a headache that lasted no more than 20 min. The day after, I developed a sore throat (don't think it's related to vaccine) in the morning and gradually got worse in the day.

12/18, 0905: metallic taste in mouth lasting all day 12/19: fatigue all day, 2200-nausea and low grade fever 12/20: fatigue lasting all day 12/21: woke up at 0400 with congestion and sore throat. Swollen lymph nodes and swollen glands over right clavicle. 12/22: congestion, drainage, sore throat, swollen glands/lymph nodes as described yesterday and fatigue

Day after vaccine patient started feeling fatigue, body aches, headache. By 1700 that evening she was running a 102 fever and her back was hurting. She took Famotidine and Benadryl and Tylenol and Ibuprofen. She went home and rested, pushed fluids. Felt completely better by the afternoon on 12/19/20

Patient's wide noticed a hive on upper chest below clavicle on L side. No resp. distress. 1435: VS: 126/80, 75 HR, 16RR, 97% O2 Sat Patient reported skin on neck blotchy. Benadryl 25mg 1448. 1453: 151/88, 97%, 76 HR, 16RR, 1512: 120/82, 97%, 75 HR, 16RR, Seen by RN Supervisor. Hive diminishing at 1528. 129/84, 97%, 75HR, Discharged w/wie at 1545.

Upper left arm/shoulder pain. Also reported 36 hours of low grade fever and body aches after injection Left arm at deltoid felt somewhat warm to touch, very mild erythema, tender to palpation. Pt sent to Urgent care for evaluation

Chest tightness; Tiredness; Headaches; Joint pain; Low grade fever; Nausea; Swollen lymph nodes in neck; Chills; Muscle pain; This is a spontaneous report from a contactable healthcare professional (patient). A 33-year-old female patient received the first dose of BNT162B2 (Pfizer-BioNTech COVID-19 mRNA vaccine; Lot Number: EH9899), intramuscular in right arm on 15Dec2020 07:45 at a single dose for an COVID-19 immunization. The vaccine was administered in a hospital. Medical history included celiac disease, allergy, and diagnosed with COVID-19 prior to vaccination. Concomitant medication included fexofenadine hydrochloride for allergy. The patient experienced tiredness, headaches, muscle pain, joint pain, chills, low grade fever, nausea, swollen lymph nodes in neck, and chest tightness on 15Dec2020, 03:00 PM. No treatment was received for the events. The outcome of the events was not recovered. The events were reported as non-serious.

"15 minutes after vaccination, started to have SOB, numbness on legs and extremities-- > sent to ED for evaluation. She c/o funny feeling in her mouth and tingling in her arms and legs after vaccination. She felt short of breath initially, but not at ED. No rash. No swelling that she is aware of. She just doesn't feel right. States she feels ""jittery"" and shaky. Received 2 L NS and epi 0.3mg IM x1 and diphenhydramine 25mg IV x-- > symptoms improved. Observed for 4 more hrs in ED. Discharged home on Epi pen."

Dizziness; hypertensive to 109/80; nauea, sweating, sent to ED for monitoring; follow up call next day: symptoms resolved.

Employee was being monitored post Covid19 vaccination. Approximately 10 minutes after vaccination employee had an allergic reaction and developed Hives all over her body and became itchy with hot flashes. Employee was given 50MG of Benadryl which was effective.

Pain at injection site; This is a spontaneous report from a contactable other healthcare professional (patient). A 54-year-old male patient received the first dose of bnt162b2 (lot number: EH9899), intramuscular on the left arm on 15Dec2020 09:00 at a single dose for immunization. There were no medical history and concomitant medications. The patient have no known allergies. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient was not diagnosed with COVID-19 and had not been tested for COVID-19 since the vaccination. On 15Dec2020 18:00, the patient experienced pain at injection site. No treatment was received for the adverse event. Outcome of the event was recovering.

Headache, tachycardia, body aches, malaise, lethargy,

Injection site tenderness for 48 hours Myalgias for 72 hours Morning nausea for 4 days post-injection Chills for 48 hours Headache for 72 hours

Arm pain at site; This is a spontaneous report from a contactable nurse. A 59-year-old female patient received bnt162b2 (lot number: EH9899), intramuscular on right arm from 16Dec2020 15:45, at an unspecified dose, single, for immunization. Medical history included hypertension. The patient's concomitant medications were not reported. Patient had other medications the patient received within 2 weeks of vaccination. On 16Dec2020 at 19:45, the patient experienced arm pain at site. Outcome of

event was unknown. Event occurred in a country different from that of the reporter. This may be a duplicate if the reporter also submitted directly to his/her local agency.

Patient states 20 minutes after receiving the injection she began having a scratchy throat and began having shortness of breath. She also developed some itching to the site. She presented to the Emergency Department and noted to have hoarseness but no severe dyspnea. Patient was given steroids and Benadryl. Her symptoms did not worsen and she was discharged home.

Patient waited her 15 minute time of observation. She said she felt her throat closing . Moved her into the observation area. Dr. was present and ordered for 25mg of Benadryl to be administered po. This was given at 16:00. Dr. observed patient for approximately 45 minutes until all symptoms resolved. Patient was allowed to leave at 16:45. Patient was provided with the instructions to please go to the ED if she should have any new symptoms tonight.

Body aches, joint pain, chills, headache, injection site pain; Body aches, joint pain, chills, headache, injection site pain; Body aches, joint pain, chills, headache, injection site pain; Body aches, joint pain, chills, headache, injection site pain; Body aches, joint pain, chills, headache, injection site pain; This is a spontaneous report from a contactable nurse (patient). A 29-year-old female patient received bnt162b2 (BNT162B2) lot number and expiration date were not reported, intramuscular (arm right) first dose on 16Dec2020 13:45 at a single dose for immunization. Medical history included migraine with aura, ovarian cyst and paragard IUD. Concomitant medication included fluconazole (DIFLUCAN), probiotics and famotidine. The patient previously took codeine and experienced drug hypersensitivity. The patient reported adverse events of body aches, joint pain, chills, headache, and injection site pain on 09Dec2020 at 03:45 PM (pending clarification). The patient had not taken any other vaccine in 4 weeks. The events were considered non-serious. The patient recovered from the events body aches, joint pain, chills, headache, and injection site pain on an unspecified date. There was no treatment given due to the events. The patient was not diagnosed with COVID-19 prior to vaccine nor was she tested positive for COVID-19 since vaccination. No follow-up attempts are possible; Information about batch/lot number cannot be obtained. No further information is expected.

"Severe Headache (""Felt like someone hit me with a bat in the head""; water/tylenol given; sent to ED - given Toradol; later: chills; resolved per follow-up call prior day."

Pfizer-BioNTech COVID-19 Vaccine EUA Headache, body aches and extreme fatigue started on 12/20/2020. I had a doctor appointment on 12/22/20 for a routine visit and I told my doctor about these symptoms that had occurred and he stated that I needed to be tested for COVID since these were symptoms. He also ordered blood work and I had blood drawn. I had informed him at the beginning of the visit of my recent COVID vaccine last week.

Phizer-BioNtech COVID-19 Vaccine EUA pain at site of infection. Fatigue, maliaise, dizziness, nausea, low grade fevers

Pt reports joint pain, nausea, headache, fatigued.

"25 mins after the vaccination his right arm became tingly ranging from the lower part of the arm to his pinky. fell asleep. He was touching it and could not feel it, like it was ""asleep"" . Felt himself get hotter and sweaty. Patient was advised to go to the ER, but refused. Called patient one hour after the event, and they reported that arm started to feel less tingly."

pain at the injection site; felt some numbness; slight headache; This is a spontaneous report from a contactable consumer. A 49-year-old female patient (not pregnant) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, batch/lot number: unknown), intramuscular on arm left on 16Dec2020 (10:00 AM) at single dose for COVID-19 immunization. The patient's medical history included rheumatoid arthritis and COVID-19. Concomitant medication included secukinumab (COSENTYX) (received within 2 weeks of vaccination). It was reported that prior vaccination, patient diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. No known allergies. The patient reported that after a few hours of initial injection she felt pain at the injection site. In addition, she mentioned that she also felt some numbness and had a slight headache on 16Dec2020 (08:00 PM). There was no treatment received for the reported adverse events. The outcome of event was recovered on an unspecified date. Information about lot/batch number cannot be obtained.

dizzy; funny feeling on the throat; vasovagal reaction; This is a spontaneous report from a contactable physician. This physician reported similar events for two patients. This is the second of two reports. Only the first case is serious. This case is non-serious. A female patient of an unspecified age (reported as 59, unit unknown) received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 17Dec2020 22:00 at a single dose for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient stated that she felt dizzy, funny feeling on the throat and ED (emergency department) assessed vasovagal reaction as normal; no rash or major allergic reaction was noted. Outcome of the events was unknown. Follow-up attempts are completed. The following information on the batch number has been requested.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2020500236 Same reporter, product, and event, different patient

tingling sensation around the mouth; tingling sensation around the mouth and in her arm; This is a spontaneous report from a contactable physician. A 59-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE lot/batch # not provided), via an unspecified route of administration on 17Dec2020 22:00 at SINGLE DOSE as COVID-19 immunization. The patient's medical history and concomitant medications were not reported. In Dec2020, the patient felt tingling sensation around the mouth and in her arm. Outcome of the events was unknown. Information regarding batch number has been requested.

Intermittent tachycardia; headache; left shoulder pain, increases when lifting elbow above pectoral; This is a spontaneous report from a contactable nurse, the patient. A 30-year-old non-pregnant female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot Number: EK5730), intramuscular in the left arm on 16Dec2020 at 16:45 (at the age of 30-years-old) as a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. Prior to the vaccination, the patient was not diagnosed with COVID-19. The patient did not receive any other vaccines within four weeks prior to the vaccination. The patient previously took

amoxicillin (MANUFACTURER UNKNOWN) from an unknown date to an unknown date for an unknown indication and experienced drug allergy. On 16Dec2020 at 21:45, the patient experienced intermittent tachycardia, headache, and left shoulder pain (which increased when lifting elbow above pectoral). Therapeutic measures were taken as a result of the intermittent tachycardia, headache, and left shoulder pain and included treatment (self-medicated) with acetaminophen (TYLENOL) and diphenhydramine hydrochloride (BENADRYL). The clinical outcomes of intermittent tachycardia, headache, and left shoulder pain were unknown. It was also reported that since the vaccination, the patient had not been tested for COVID-19.

Patient felt lightheaded & dizzy 10 minutes after receiving vaccine. Layed down flat with feet elevated for 10-15 minutes.

tingling to the tip of the tongue and further back to the middle of tongue, oral tingling (upper lip and then into the lower lip); mild swelling to the tip of the tongue; This is a spontaneous report from a contactable nurse. A 51-year-old non-pregnant female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot number: EH9899), intramuscularly in the left deltoid on 17Dec2020 11:15 at a single dose for COVID-19 immunization. Medical history included palpitations multiple premature ventricular contractions (PVC)s from 11Jan2020 to an unknown date. The patient's concomitant medications were not reported. Patient denied any history of previous adverse reactions to vaccines. The patient previously took dexamethasone (DECADRON) and experienced tingling of lips and tongue and sulfamethoxazole trimethoprim (BACTRIM) and experienced allergies and acute kidney injury. The patient experienced tingling to the tip of the tongue and further back to the middle of tongue, oral tingling (upper lip and then into the lower lip) and mild swelling to the tip of the tongue on 17Dec2020 11:15. During the 15-minute waiting period after the injection, the patient began to experience oral tingling (upper lip and then into the lower lib). It then progressed to the tongue and she reported tingling to the tip of the tongue and further back to the middle of tongue. She thought there might be some mild swelling to the tip of the tongue. She denied rash, hives, welts, difficulty breathing, difficulty swallowing, wheezing, throat tightness, hoarseness, stridor, itching, lightheadedness, dizziness, facial swelling and lip swelling. The patient went to the emergency room/department or urgent care. The patient received diphenhydramine hydrochloride (BENADRYL) as treatment for the events. The outcome of the events was recovered in Dec2020.

"feeling ""Sort of dizzy""; arm is sore; just doesn't feel well; This is a spontaneous report from a contactable consumer (patient). A 61-year-old female patient started to receive bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK5730), via an unspecified route of administration on her left upper arm on 17Dec2020 13:25 at a single dose for covid-19 prevention. The patient's medical history included blood pressure abnormal. Concomitant medications included blood pressure medicine at night. The patient went to the hospital today where she works, to have a vaccine for COVID, and then she drove herself home. After she got home, she decided to rest a bit before her shift at work tonight, she laid down for a little while, and she started feeling sort of dizzy and her arm was sore. She just doesn't feel well. She does not feel like she needs to go to the hospital or anything, but she may need rest. Patient was wondering if these are known side effects of the product. She started feeling the side effects maybe 20 or 25 minutes after getting the vaccine and after she had left the hospital. She was just

thinking at the time that it was okay and maybe she just needed rest. She takes blood pressure medicine at night, but she does not think that has anything to do with how she is feeling. Outcome of the events was unknown."

Within just over half an hour of receiving it my lungs and throat started burning. Shortly after that my upper lip started to swell. Over night my lip swelled more and my face became itchy.

She noticed that she got breakthrough bleeding, when she just got her menstruation last week; This is a spontaneous report from a contactable healthcare professional, the patient. A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), via an unspecified route of administration on 16Dec2020 at 17:00 as a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. On an unknown date in Dec2020, the patient noticed that she had breakthrough bleeding and she just had her period last week. The stated that she was very regular when it came to her period. The clinical outcome of the breakthrough bleeding was unknown. The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up.

developing a cold sore (herpes simplex type 1) the following morning/She usually develop a cold sore with an illness; developing a cold sore (herpes simplex type 1) the following morning/She usually develop a cold sore with an illness; This is a spontaneous report from a contactable consumer (patient). A 52-year-old female patient received the first dose of bnt162b2 (lot number and expiration date were not reported), via an unspecified route of administration on the right arm on 16Dec2020 16:15 at a single dose for immunization. The patient's medical history included cold sore and celiac disease. The patient was not pregnant. Concomitant medication included cetirizine hydrochloride (ZYRTEC). The patient reported that it was not necessarily an adverse event but she noticed that she was developing a cold sore (herpes simplex type 1) the following morning on 17Dec2020 10:00. She usually develop a cold sore with an illness. She also typically take valacyclovir to treat but opted not to take it (did not want to interfere with the vaccine and body developing antibodies). No treatment was received for the events. The patient was not diagnosed with COVID-19 prior to vaccination neither had been tested for COVID-19 post vaccination. Outcome of the events was recovering. The events was considered non-serious. Information on lot/batch number has been requested.; Sender's Comments: Based on the information currently provided, cold sore (herpes simplex type 1) onset more likely represents the recurrence of the underlying herpes viral infection. Currently no biological plausibility indicated the event is attributed to the vaccine use.

Red raised rash 48 hours after Extreme nausea and dizziness; Red raised rash 48 hours after Extreme nausea and dizziness; Red raised rash 48 hours after Extreme nausea and dizziness; This is a spontaneous report from a contactable healthcare professional. A non-pregnant 45-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), intramuscularly on 15Dec2020 15:45 at a single dose for COVID-19 immunization. Medical history included ulcerative colitis, hypothyroidism, allergies: sulfites. sulfa. Concomitant medication included amfetamine aspartate, amfetamine sulfate, dexamfetamine saccharate, dexamfetamine sulfate (ADDERALL), dhea (MANUFACTURER UNKNOWN), levothyroxine, liothyronine (NP THYROID),

progesterone (MANUFACTURER UNKNOWN), fluoxetine hydrochloride (PROZAC), levothyroxine sodium (SYNTHROID), bupropion hydrochloride (WELLBUTRIN). On 15Dec2020, the patient experienced red raised rash 48 hours after extreme nausea and dizziness. No treatment was received from the events. The outcome of the events was not recovered. The batch/lot number for the vaccine, BNT162B2, was not provided and will be requested during follow-up.

Client started to feel faint about 10 minutes after she had the vaccine administered. She informed the nurse. Her blood pressure was 100/62 hr 58. She sat for a few minutes and then vomited. She had bcome very diaphoretic. Her bp was 146/100 and hr was 96. She was responsive and she refused a shot of Benadryl. We called for an ambulance. We continued to monitor her bp and hr. Her husband arrived. She left with her husband. Her last bp was 136/100 hr was 70 ab she was not longer diapheretic. He husband took her to the ER. I spoke to patient today at (9:10 am. The ER doctor told her she had a vasovagal incident. He told her she can get the second dose if she is in a supine position with monitoring.

Pain at the injection site for 2 days.; This is a spontaneous report from a contactable consumer. A 23-year-old non- pregnant female patient received the first dose of the bnt162b2 (BNT162B2; also reported as COVID 19, brand=Pfizer-BioNTech; Lot Number: EH9899), via an unspecified route of administration in the left arm on 15Dec2020 at 08:30 at 23-years-old at a single dose for COVID-19 immunization. The vaccination facility was a hospital. It was also reported that there were no other vaccinations in four weeks, and there were no other medications in two weeks prior to the vaccination. The patient's medical history was reported as none. The patient did not have COVID-19 prior to the vaccination and was not tested for COVID-19 post vaccination. The patient has no known allergies (allergies to medications, food, or other products: no). Concomitant medications were not reported. On 15Dec2020 at 21:30, the patient experienced: pain at the injection site for 2 days. There was no treatment for the adverse event; nor did the event require hospitalization. The clinical outcome of the event, pain at the injection site for 2 days, was recovered on an unspecified date in Dec2020.

patient experience slight congestion; This is a spontaneous report from a contactable physician (patient) via Pfizer Sales Representative. A patient of unspecified age and gender received bnt162b2 via an unspecified route of administration on an unspecified date at single dose for administration of Covid-19 vaccine. The patient medical history was not reported. The patient's concomitant medications were not reported. The patient experienced slight congestion on an unspecified date with outcome of unknown. Event took place after use of product. Information on the lot/batch number has been requested.

episodes of facial and head numbness and heaviness, lasting 15-30 min or so; isolated to the side of injection site; episodes of facial and head numbness and heaviness, lasting 15-30 min or so; isolated to the side of injection site; This is a spontaneous report from a contactable physician. A 41-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot number: 0E51685), intramuscularly in the left arm, on 17Dec2020 at 09:00 (at the age of 41-years-old) at a single dose for COVID-19 immunization. The patient had no medical history. Concomitant medications, taken within two weeks of vaccination, included zinc (MANUFACTURER UNKNOWN), quercetin (MANUFACTURER UNKNOWN), and multivitamins (MANUFACTURER UNKNOWN). The patient

was not pregnant at the time of vaccination. Prior to the vaccination, the patient was not diagnosed with COVID-19. The patient had no known allergies to medications, food, or other products. The patient did not receive any other vaccines within four weeks prior to the vaccination. The patient experienced episodes of facial and head numbness and heaviness, lasting 15-30 minutes or so; isolated to the side of injection site on 17Dec2020 at 22:15. No therapeutic measures were taken as a result of the events. The clinical outcome of episodes of facial and head numbness and heaviness, lasting 15-30 minutes or so; isolated to the side of injection site was not recovered. It was also reported that since the vaccination, the patient had not been tested for COVID-19. No follow-up attempts are needed. No further information expected.

non-anaphylactic allergy reactions to the Pfizer BioNTech COVID-19 vaccine; Rash; Mild swelling of the throat; This is a spontaneous report from a non-contactable pharmacist. This pharmacist reported same events for 2 patients. This report is for 1st of 2 patient. A patient of unspecified age and gender received BNT162B2 via an unspecified route of administration on an unspecified date at a single dose for COVID-19 immunization, propylene glycol via an unspecified route of administration from an unspecified date at unknown dose for an unspecified indication. The patient's medical history and concomitant medications were not reported. On 17Dec2020 at 2:50 pm, PharmD, Clinical Pharmacy Manager, shared with the reporter that two employees had non-anaphylactic allergy reactions to the Pfizer BioNTech COVID-19 vaccine, this patient is one of them. She reported rash and mild swelling of the throat. They suspect it was a reaction to propylene glycol and will be doing skin testing. The action taken in response to the event for propylene glycol was unknown. The outcome of events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2020501257 same reporter/drug/event, different patient

Rash; mild swelling of the throat; non-anaphylactic allergy reactions; This is a spontaneous report from a non-contactable pharmacist. This pharmacist reported same events for two patients. This is 2nd of two reports. A patient of unspecified age and gender received BNT162B2 via an unspecified route of administration on an unspecified date at a single dose for COVID-19 immunization, propylene glycol via an unspecified route of administration from an unspecified date at unknown dose for an unspecified indication. The patient's medical history and concomitant medications were not reported. On 17Dec2020 at 2:50 pm, PharmD, Clinical Pharmacy Manager, shared with the reporter that two employees had non-anaphylactic allergy reactions to the Pfizer BioNTech COVID-19 vaccine, this patient is one of them. She reported rash and mild swelling of the throat. They suspect it was a reaction to propylene glycol and will be doing skin testing. The action taken in response to the event for propylene glycol was unknown. The outcome of events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2020501256 same reporter/drug/event, different patient

Little pain at the injection site; Felt flush afterwards; This is a spontaneous report from a non-contactable nurse. This nurse reported similar events for two patients. This is the first of two reports. A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot number: EK5730), via an unspecified route of administration on 16Dec2020 at a single dose for

COVID-19 immunization. The patient's medical history and concomitant medications were not reported. In Dec2020, the patient experienced little pain at the injection site and felt flush afterwards. The outcome of the events was unknown. No follow-up attempts are possible. No further information is expected.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2020501389 same reporter/drug/event, different patient.

Little pain at the injection site; Felt flush afterwards; This is a spontaneous report from a non-contactable nurse. This nurse reported similar events for two patients. This is the second of two reports. A patient of unspecified age and gender received the BNT162B2 (BNT162B2; also reported as PFIZER COVID-19 VACCINE; Lot number: EK5730), via an unspecified route of administration on 16Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. On an unspecified date in Dec2020, the patient experienced little pain at the injection site and felt flush afterwards. The outcome of the events was unknown. No follow-up attempts are possible. No further information is expected. ; Sender's Comments: Linked Report(s) : US-PFIZER INC-2020501372 same reporter/drug/event, different patient

Throat numbness; Lymph node swelling; Felt flush; This is a spontaneous report from a non-contactable consumer. A 28-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot number: EK5730), via an unspecified route of administration in the right arm, on 17Dec2020 at 15:15 (at the age of 28-years-old) at a single dose for COVID-19 immunization. The patient had no medical history or concomitant medications. The patient was not pregnant at the time of vaccination. Prior to the vaccination, the patient was not diagnosed with COVID-19. The patient had no known allergies to medications, food, or other products. The patient did not receive any other vaccines within four weeks prior to the vaccination. The patient experienced throat numbness, lymph node swelling, and felt flush on 17Dec2020 at 15:15. The events were reported as non-serious. Therapeutic measures were taken as a result of the events, which included treatment with diphenhydramine hydrochloride (BENADRYL). The clinical outcome of throat numbness, lymph node swelling, and felt flush was recovering. It was also reported that since the vaccination, the patient had not been tested for COVID-19. No follow-up attempts are possible. No further information expected.

Sore injection site; This is a spontaneous report from a non-contactable healthcare professional. A 29-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot number EH9899), intramuscular into the left arm on 17Dec2020 at 06:15 as single dose for COVID-19 immunization. There was no medical history. The patient's concomitant medications were not reported. The patient experienced sore injection site on 17Dec2020, at 14:00. The event was reported as non-serious. The outcome of sore injection site was recovered in Dec2020.

Fatigue; nausea; stomach ache; malaise; post-nasal drip; This is a spontaneous report from a contactable healthcare professional. A 30-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), intramuscularly in the left arm on 17Dec2020 15:00 at a single dose for COVID-19 immunization. Medical history included COVID-19 (prior to vaccination). Concomitant medication included sulfamethoxazole, trimethoprim (BACTRIM) and escitalopram (MANUFACTURER UNKNOWN). The patient had no known allergies or other medical history. The patient did not receive

any other vaccines within 4 weeks prior to the COVID vaccine. On 18Dec2020 03:00, the patient experienced fatigue, nausea, stomach ache, malaise and post-nasal drip. No treatment was received for the events. The outcome of the events was recovering. The batch/lot number for the vaccine, BNT162B2, was not provided and will be requested during follow-up.

Strong medicine taste in the back of my mouth within 5 mins of injection. Over the next hour after the injection, the taste got stronger; Over the next hour after the injection, the taste got stronger and lead to a tingling sensation in the back of my throat and tongue; This is a spontaneous report from a contactable consumer (patient). A 47-year-old female patient received bnt162b2 (BNT162B2) Lot number: FH9899, via an unspecified route of administration on the right arm, first dose on 17Dec2020 08:15 at a single dose for immunization. Medical history included glucose-6-phosphate dehydrogenase deficiency (G6PD), gastrooesophageal reflux disease (GERD) and allergies to Sulfa which is contraindicated for G6PD. Concomitant medication included famotidine and cetirizine. The patient previously took methylcobalamin and quinine (which is contraindicated for G6PD), and experienced drug hypersensitivity on both. On 17Dec2020 at 08:30 AM, the patient experienced strong medicine taste in the back of her mouth within 5 mins of injection. Over the next hour after the injection, the taste got stronger and lead to a tingling sensation in the back of her throat and tongue. These 2 symptoms are still present 22 hrs after receiving the vaccination. The medicine taste and tingling has decreased from strong to mild over the 22 hours. She mentioned that she did not have Covid prior vaccination nor did she tested positive post vaccination. She did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The events were reported as non-serious. No treatment received and the patient was recovering from the 'Strong medicine taste' and 'Strong medicine taste'.

Patient c/o lightheadedness, dizziness & nausea about 4 hour after receiving vaccine.

having aches and a fever of 100.2 so far; having aches and a fever of 100.2 so far; This is a spontaneous report from a contactable consumer (patient's wife). A male patient of an unspecified age received the bnt162b2 (BNT162B2; Lot Number, Expiration Date, NDC and UPC: unknown), via an unspecified route of administration on 17Dec2020 at 11:30 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. On 17Dec2020, the patient experienced: having aches and a fever of 100.2 so far. The patient underwent lab tests and procedures which included body temperature: 100.2 on 17Dec2020. The clinical outcome of the events was unknown. The batch/lot numbers for the vaccine, BNT162B2, were not provided and will be requested during follow up.

Fevers throughout the night of the date received, up to 101.5; This is a spontaneous report from a contactable healthcare professional. A 43-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), intramuscularly in the left arm, on 17Dec2020 at 20:00 (at the age of 43-years-old) at a single dose for COVID-19 immunization. Medical history included hypothyroidism and COVID-19. The patient was not pregnant at the time of vaccination. Concomitant medications, taken within two weeks of vaccination, included levothyroxine (MANUFACTURER UNKNOWN). The patient had no known allergies to medications, food, or other products. The patient did not receive any other vaccines within four weeks prior to the vaccination. The patient experienced

fevers throughout the night of the date received, up to 101.5 on 17Dec2020. The event was reported as non-serious. The patient underwent lab tests and procedures, which included body temperature: 101.5 on 17Dec2020. No therapeutic measures were taken as a result of the event. The clinical outcome of fevers throughout the night of the date received, up to 101.5 was recovering. It was also reported that since the vaccination, the patient had not been tested for COVID-19. The batch/lot number for the vaccine, BNT162B2, was not provided and has been requested during follow up.

About 20 minutes post vaccine, right sided chest pain, intercostal. Injection was in right arm; This is a spontaneous report from a contactable nurse and a non contactable physician. A 37-year-old female patient received bnt162b2 (reported as COVID-19 Vaccine, Pfizer, Solution for injection, lot no. and expiry date was unknown), via an unspecified route of administration (right arm) on 17Dec2020 13:30 at a single dose for COVID 19 immunization. The patient medical history was not reported. No allergies to medications, food, or other products. Prior to vaccination, patient was not diagnosed with COVID-19. Since the vaccination, patient has not been tested for COVID-19. Not pregnant at the time of vaccination. The hospital was where the most recent COVID-19 vaccine was administered. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Concomitant medication included sertraline, fish oil, colecalciferol (VITAMIN D), lactobacillus acidophilus (PROBIOTIC), and unspecified vitamin. About 20 minutes post vaccine, the patient experienced right sided chest pain, intercostal. The injection was in right arm on 17Dec2020 13:45 with outcome of recovered. There was no treatment received for the event. The event was considered as non-serious (did not result in death, was not life threatening, did not cause/prolong hospitalization, not disabling/incapacitating, congenital anomaly/birth defect. Information on the lot/batch number has been requested.

mild headache; This is a spontaneous report from a non-contactable nurse. A 25-year-old male patient received bnt162b2 (BNT162B2, Lot number: EH9899), via an unspecified route of administration on 18Dec2020 at single dose for immunization. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient's medical history and concomitant medications were not reported. The patient previously took amoxicillin and experienced allergies. The patient experienced sudden onset of mild headache approximately 10 minutes after receiving vaccine on 18Dec2020. The most recent COVID-19 vaccine was administered in the hospital. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. There was no treatment for the event. The outcome of the event was unknown.

Injection site reaction and vertigo.; Injection site reaction and vertigo.; This is a spontaneous report from a contactable pharmacist. A 63-year-old patient of an unspecified gender received first dose of bnt162b2 (Pfizer-BioNTech COVID-19 vaccine; lot EH9899), intramuscular on 17Dec2020 10:30 at single dose (left arm) for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient had no allergies to medications, food, or other products. On 17Dec2020, at 10:30, the patient experienced injection site reaction and vertigo. The patient was administered at the hospital. It was reported that the patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. There was no treatment received for the events. It was unknown if the patient was diagnosed with Covid-10 prior to vaccination and it was unknown if the patient had been tested for Covid-19 since the vaccination. Outcome of events was recovered on an unspecified date.

bleeding gums; This is a spontaneous report from a contactable nurse (patient). A 56-year-old non-pregnant female patient received first dose of BNT162B2 (Pfizer-BioNTech COVID-19 mRNA vaccine), via an unspecified route of administration at left arm on 16Dec2020 at 02:00 at a single dose for COVID-19 immunization. The patient did not have covid prior vaccination, and no covid test done post vaccination. The patient has no known allergies to medications, food, or other products. The patient has no other medical history. The patient did not receive any other vaccine in four weeks. Concomitant medication included marijuana (MARIJUANA CANDY). The patient noted bleeding gums 2 days later on 18Dec2020 at 06:30. It was not usual for her. It was just blood streaked spit with brushing teeth. The patient did not receive treatment for the reported event. The outcome of the event was unknown. The event was not considered serious. No follow-up attempts are possible; information about lot/batch number has been requested. No further information is expected.

Pain, redness, swelling and hives at the site of injection (left arm). Pain spread out from the injection site to the left shoulder blade, side of arm, left ribcage, left side of neck, and left collar; Pain spread out from the injection site to the left shoulder blade, side of arm, left ribcage, left side of neck, and left collarbone; Pain spread out from the injection site to the left shoulder blade, side of arm, left ribcage, left side of neck, and left collarbone; Pain spread out from the injection site to the left shoulder blade, side of arm, left ribcage, left side of neck, and left collarbone; Pain spread out from the injection site to the left shoulder blade, side of arm, left ribcage, left side of neck, and left collarbone; Pain spread out from the injection site to the left shoulder blade, side of arm, left ribcage, left side of neck, and left collarbone; Pain, redness, swelling and hives at the site of injection (left arm); Pain, redness, swelling and hives at the site of injection (left arm); Pain, redness, swelling and hives at the site of injection (left arm); heart palpitations; weakness; dizziness; This is a spontaneous report from a contactable other healthcare professional. A 66-year-old female patient received her first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot:EH9899) intramuscularly at the left arm on 16Dec2020 12:45 at a single dose for covid-19 immunisation. Medical history included migraine from an unknown date. The patient's concomitant medications were not reported. On 16Dec2020 15:45, the patient experienced Pain, redness, swelling and hives at the site of injection (left arm). It was further reported that the pain spread out from the injection site to the left shoulder blade, side of arm, left ribcage, left side of neck and left collarbone. The patient also experienced weakness, dizziness and heart palpitations on 16Dec2020 15:45. The events were reported as non-serious. The patient did not receive treatment for the reported events. Outcome of events was not recovered.

injection site pain 8 hours post injection. Fever 100.1 overnight with body aches and chills, headache; injection site pain 8 hours post injection. Fever 100.1 overnight with body aches and chills, headache; injection site pain 8 hours post injection. Fever 100.1 overnight with body aches and chills, headache; injection site pain 8 hours post injection. Fever 100.1 overnight with body aches and chills, headache; injection site pain 8 hours post injection. Fever 100.1 overnight with body aches and chills, headache; This is a spontaneous report from a contactable consumer. A 52-year-old female patient received the first dose of bnt162b2 (BNT162B2, lot number: EJ1685), via an unspecified route of administration in right arm on 17Dec2020 11:00 at a single dose for immunization, administered in the hospital. Medical history included allergies to Penicillin, crustaceans. Prior to vaccination, the patient was diagnosed with

COVID-19. Concomitant medication included herbal remedies: Guanyin Pearls, Shu Gan Tang. The patient experienced injection site pain 8 hours post injection, fever of 100.1 overnight with body aches, chills and headache on 17Dec2020 07:00. The outcome of the events was recovering. The events did not caused hospitalization. Since the vaccination, the patient has not been tested for COVID-19.

Left arm pain for 24 hours; This is a spontaneous report received from a non-contactable physician. A 39-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK5730), intramuscular in left arm, on 17Dec2020 09:00, at single dose, for COVID-19 immunization. The patient has no medical history and has no known allergy. Concomitant medication included lansoprazole. The patient experienced left arm pain for 24 hours on 17Dec2020 12:00. The patient was not diagnosed with COVID-19 prior to vaccination. The patient had not been tested for COVID-19 since the vaccination. The event was reported as non-serious. The outcome of the event was recovered on 18Dec2020 12:00. No follow-up attempts are possible. No further information is expected.

waxing and waning redness and intense itching of both palms; waxing and waning redness and intense itching of both palms; This is a spontaneous report from a non-contactable consumer. A 63-year-old female patient received first dose of bnt162b2 (BNT162B2, lot number EH9899), via an unspecified route of administration in left arm on 15Dec2020 17:30 at a single dose for immunization, administered in the hospital. Medical history included seasonal allergies (dust, mold, juniper pollen), allergies to erythromycin, coconut, blueberries, banana, cocoamidopropyl betaine in anything (shampoo, toothpaste, soap). The patient was not diagnosed of COVID 19 prior to vaccination. Concomitant medication included multivitamins, ergocalciferol (VIT D), ascorbic acid (VIT C), and zn [zinc] (ZN [ZINC]). On 16Dec2020 11:30, about 18 hours after injection, developed waxing and waning redness and intense itching of both palms. This lasted for about 6 hours. The patient reported that she never had this before following a vaccine. Never had this before related to any food or seasonal allergy reaction. The patient was concerned about getting the second injection of the series. The patient's BMI was 30. The patient was not tested for covid 19 after the vaccination. The outcome of the events was recovered on 16Dec2020. The events was considered non-serious. There was no treatment for the reported events. No follow-up attempts are possible. No further information is expected.

Nausea; Vomiting; Fever; This is a spontaneous report from a contactable consumer. A 25-year-old female patient received bnt162b2 (BNT162B2), via an unspecified route of administration arm left on 16Dec2020 18:44, single for immunization. Medical history included Delta granule storage pool deficiency. Concomitant medication included fluoxetine. On 16Dec2020, received vaccine at 6:44pm; On 17Dec2020- woke up with nausea/ vomiting and a fever, had to call off work; 18Dec- continued to have nausea/vomiting and low grade fever, symptoms and fever resolved by 10 am. The outcome of the events was recovered. Information on the Batch/Lot number has been requested.

Sore throat; nausea; This is a spontaneous report from a contactable nurse. A 52-year-old female patient received bnt162b2 (BNT162B2, lot number: EK5730), intramuscular on the right arm on 15Dec2020 17:30 at a single dose for COVID-19 immunisation. Medical history and concomitant medications were none. On 15Dec2020 19:30, the patient experienced sore throat and nausea. No

therapeutic measure was taken as a result of the events. Clinical outcome of the events was recovered on an unspecified date.

right eye fullness; blurred vision; This is a spontaneous report from a contactable consumer. A 42-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), lot number: EK5730, via an unspecified route of administration in the right arm on 17Dec2020 11:30 at single dose for immunization. Medical history was reported as none. The patient's concomitant medications include multivitamins within two weeks of vaccination. The patient experienced right eye fullness and blurred vision on 17Dec2020. The patient was vaccinated in the hospital and no other vaccine in four weeks was given. No treatment given for the events. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. Patient had no known allergies. The events was considered non serious. The outcome of the events was unknown.

Tingling mouth; This is a spontaneous report from a contactable physician. A patient of unspecified age and gender received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration in Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced tingling mouth in Dec2020. The event happened during the observation period after the vaccine was administered. The reporter thinks that the patient just panicked and overreacted and doesn't think they had a reaction. The patient did go the emergency room (ER) and was discharged the same day. The outcome of tingling mouth was unknown. The batch/lot number for the vaccine, BNT162B2, was not provided and will be requested during follow-up.

chills; low-grade temperature; dizziness; This is a spontaneous report from a contactable consumer. A 25-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration in the left arm, on 17Dec2020 at 07:45 (at the age of 25-years-old) at a single dose for COVID-19 immunization. The patient had no medical history. It was unknown if prior to the vaccination, the patient was not diagnosed with COVID-19. The patient was not pregnant at the time of vaccination. Concomitant medications, taken within two weeks of vaccination, included cetirizine hydrochloride (ZYRTEC) and progesterone;estrogens (MANUFACTURER UNKNOWN) oral contraceptives. The patient had no known allergies to medications, food, or other products. The patient did not receive any other vaccines within four weeks prior to the vaccination. The patient experienced chills, low-grade temperature, and dizziness on 17Dec2020 at 08:45. The events were reported as non-serious. The events were reported to have occurred within 90 minutes of vaccination. The patient underwent lab tests and procedures, which included temperature: low-grade on 17Dec2020. No therapeutic measures were taken as a result of the events. The clinical outcome of chills, low-grade temperature, and dizziness was recovered in Dec2020. It was also reported that since the vaccination, the patient had not been tested for COVID-19. The batch/lot number for the vaccine, BNT162B2, was not provided and has been requested during follow up.

Fever; Headache; Chills; This is a spontaneous report from a contactable other healthcare professional (patient). A 53-year-old female patient (not pregnant) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, batch/lot number: unknown), intramuscular on right arm on 16Dec2020

(08:45 PM) at single dose for COVID-19 immunization. The patient's medical history included diabetes mellitus, hypertension, and COVID-19. Concomitant medications were not reported. It was reported that prior vaccination, patient diagnosed with COVID-19. No known allergies. Since the vaccination, the patient has not been tested for COVID-19. The patient experienced chills, fever, and headache on 17Dec2020 (09:00 AM). There was no treatment received for the reported adverse events. The outcome of events was recovering. This case is reported as non-serious. Information on the lot/batch number has been requested.

Tongue numbness and sensitive; Tongue numbness and sensitive; This is a spontaneous report from a contactable nurse (patient) and a physician. A 31-year-old female received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot EK5730) intramuscular on17Dec2020 13:30 at a single dose on right arm as COVID-19 vaccine. Medical history was not reported. The patient had no known allergies to medications, food, or other products. Concomitant medications were not reported. On 17Dec2020, she received the vaccine and an hour after getting it, her tongue went numb and became sensitive (tongue numbness and sensitive on 17Dec2020 14:00). Today, it was not as numb feeling but was still sensitive. The events were assessed as non-serious, did not result in death, not life threatening, did not cause/prolonged hospitalization, not disabling/incapacitating, did not cause congenital anomaly/birth defect. Treatment was not received for the adverse events. The patient was not pregnant at the time of vaccination. The facility where the most recent COVID-19 vaccine was administered was noted as other. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. There was no expiry date for the vaccine. The card she has, only has the received date: 17Dec2020 and when to return for the second dose: 07Jan2021. She had submitted a claim about the side effects experienced but it wasn't clear what would happen next. The patient inquired if someone would reach out to her and would there be a follow-up. She wanted to know what the process would be regarding reporting. The outcome of the event 'numbness of tongue' was recovering while 'sensitive tongue' was not recovered.

fever; Malaise; chills; muscle and joint aches; muscle and joint aches; extreme fatigue; nausea; headache; both arms started itching on lower arm, not at site/the face and scalp started itching; This is a spontaneous report from a contactable healthcare professional. A 36-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, lot number EH9899, expiration date unknown), dose number 1, intramuscularly on 16Dec2020 10:00 at a single dose for COVID-19 immunisation. Medical history included Hashimotos Thyroiditis, MDD (major depressive disorder), and acne. Concomitant medications included zinc, ergocalciferol (VIT D), venlafaxine, levothyroxine sodium (SYNTHROID), and spironolactone. The patient had vaccine at 10 AM. At 11 AM, both arms started itching on lower arm, not at site; injection arm was worse than non injection arm. At 11:45, the face and scalp started itching. By noon, all symptoms had resolved. The patient did not medicate. Two days post vaccine, on 18Dec2020, the patient had all symptoms on warning sheet: fever, malaise, chills, muscle and joint aches, extreme fatigue, nausea and headache. The outcome of the event was recovered for itching and not recovered for the other events.

Soon after the shot I had a big headache, almost like a migraine headache; I am having tough time right now; Soon after the shot I had a big headache, almost like a migraine headache; I am having tough time right now; I have slight fever 99.6; Muscle ache; This is a spontaneous report from a contactable healthcare professional, the patient. A 58-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot Number: EK55730), via an unspecified route of administration on 17Dec2020 at 13:00 (at the age of 58-years-old) as a single dose for COVID-19 immunization. Medical history included high blood pressure, lupus, stroke, and diabetes. Concomitant medications included lisinopril (MANUFACTURER UNKNOWN). On 17Dec2020, soon after receiving the vaccine, the patient experienced a big headache, almost like a migraine headache; slight fever of 99.6 (no units provided), and muscle ache. The clinical outcomes of slight fever of 99.6 and muscle ache were unknown; while that of the big headache, like a migraine was not recovered.

HCP caller is complaining of a fever after vaccine got wed; Chills; felt tired; This is a spontaneous report from a contactable nurse (patient). A 64-year-old female patient started to received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899, expiry date: 31Mar2021), via an unspecified route of administration on 16Dec2020 at a single dose for Covid-19 immunisation. Medical history was reported as none. There were no concomitant medications. The patient called to report on the COVID vaccine, and explains that she received the vaccine on Wednesday, 16Dec2020 around 2:30pm. She received the vaccine at work. It was administered in the left upper arm. The following morning (17Dec2020) around 2am she woke up with chills and a fever that lasted all day yesterday, so she didn't go to work. She was running a fever of about 99.7-100.0 on 17Dec2020 and that was with alternating Advil and Tylenol. She felt tired and so she rested the whole day. The patient explained that she thought it would go away after a day but today she woke up at 5am with chills. She didn't take her temperature at that time but took some medication. Then on 18Dec2020 at 9am, she woke up with chills again and she still was at 100.8. She called to see how long does the fever last after the vaccine. Outcome of the events fever and chills was not recovered and for fatigue was unknown.

Patient developed a delayed onset rash 12 hours after getting vaccine and has no resolved in 3 days; This is a spontaneous report from a contactable pharmacist. A female patient in their 40's received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration at single dose on an unspecified date for immunisation. The patient medical history and concomitant medications were not reported. On an unspecified date, the patient developed a delayed onset rash 12 hours after getting vaccine and has no resolved in 3 days. The outcome of the events was not recovered. Information on the Batch/Lot number has been requested.

At first it was just muscle ache in the left arm; then I started having body aches; headache; I'm feeling very nauseous; This is a spontaneous report from a contactable consumer or other non hcp. A 24-year-old female patient received bnt162b2 (BNT162B2; lot number: EH9899, expiry date: unknown), via an unspecified route of administration arm left on 17Dec2020 08:15 at, single (Dose Number: 1) for immunization. Medical history included asthma. Concomitant medication included colecalciferol (VITAMIN D [COLECALCIFEROL]). Allergies to medications, food, or other products: Tylenol and Midol. On 17Dec2020 23:00, At first it was just muscle ache in the left arm and then I started having body aches and a headache and now I'm feeling very nauseous. The outcome of the events was unknown.

"lips/mouth swelling; lips/mouth swelling; tingling sensation in throat and on tongue; tingling sensation in throat and on tongue; This is a spontaneous report from a contactable other healthcare professional (HCP, also the patient). A 28-year-old female patient started to receive BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), intramuscular at right arm on 17Dec2020 10:45 at single dose for COVID-19 immunization. The patient's medical history included asthma, hashimoto's thyroiditis, depression, anxiety, seasonal allergies, known allergies: latex, banana. Concomitant medication included levothyroxine, amfetamine aspartate, amfetamine sulfate, dexamfetamine saccharate, dexamfetamine sulfate (ADDERALL XR), bupropion hydrochloride (WELLBUTRIN XL), escitalopram oxalate (LEXAPRO), trazodone, alprazolam (XANAX), fexofenadine hydrochloride (ALLEGRA), salbutamol (ALBUTEROL) (as needed), cyanocobalamin (VITAMIN B12), colecalciferol (VITAMIN D), zinc, all reported as other medications in two weeks. No other vaccine in four weeks. The patient previously took codeine and experienced drug alergy (known allergies). The facility type of vaccine was hospital. No COVID prior vaccination and no COVID tested post vacccination. The patient was not pregnant at the time of vaccination. On 17Dec2020 11:00, the patient experienced ""lips/mouth swelling tingling sensation in throat and on tongue"". Therapeutic measures were taken as a result of ""lips/mouth swelling tingling sensation in throat and on tongue"" included over the counter (OTC) Benadryl. The outcome of the event ""lips/mouth swelling tingling sensation in throat and on tongue"" was recovered (assumed in Dec2020). Information about lot/batch number has been requested."

"Itching and redness on chest, back, and side; Itching and redness on chest, back, and side; This is a spontaneous report from a contactable pharmacist. A 46-year-old female patient (no pregnant) received her first dose of bnt162b2 (reported as ""COVID 19 vaccine"", lot number: EJ1685), via intramuscular on 18Dec2020 on her right arm at single dose for COVID-19 immunization. Medical history included fibromyalgia, anxiety, gastrooesophageal reflux disease (GERD), post-traumatic stress disorder (PTSD) and depression, all from an unknown date and unknown if ongoing. Concomitant medications that the patient received with 2 weeks of vaccination included cyanocobalamin (B12), citalopram, pregabalin, celecoxib (CELEBREX), omeprazole, tizanidine, trazodone, vitamin D3. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. The patient experienced itching and redness on chest, back, and side on 18Dec2020. No treatment was received for the adverse event. The outcome of the events was recovering."

pretty strong chest pain; heart pain; some kind of back pain, behind her heart; This is a spontaneous report from contactable consumer (reporting for her daughter). A 29-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration on 17Dec2020 at 10:00 AM at a single dose for COVID-19 immunization. The patient's medical history were not reported. Concomitant medications included unspecified bipolar medications. The patient experienced pretty strong chest pain on 18Dec2020 at 07:00 and heart pain and some kind of back pain, behind her heart in Dec2020. The pretty strong chest pain lasted about 10 minutes and then went away. The outcome of pretty strong chest pain was recovered on 18Dec2020 and of some kind of back pain, behind her heart and heart pain was unknown. The batch/lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up.

headache; achy; weak; This is a spontaneous report from a contactable other healthcare professional (HCP) (patient). A 45-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) intramuscular on 17Dec2020 14:00 at single dose on the left arm as COVID-19 vaccine. Medical history included allergies to penicillin; allergies, ITP. Concomitant medication was noted as other vaccine in four weeks reported as allergy shots on 08Dec2020 (advance ENT). The patient also had other medications in two weeks such as zinc 50mg, 5000 Vit D, venlafaxine 225, levothyroxine sodium (SYNTHROID) 100, spironolactone 100. The patient experienced headache, achy, and weak, all on 17Dec2020 21:00. Treatment was not received for the adverse events. The patient was not pregnant at the time of vaccination. The most recent COVID-19 vaccine was administered in the hospital. The patient received other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. The events were assessed as non-serious, did not result in death, not life threatening, did not cause/prolonged hospitalization, not disabling/incapacitating, did not cause congenital anomaly/birth defect. The outcome of the events was recovering. Information about lot/batch number has been requested.

Pain at injection site; This is a spontaneous report from a contactable nurse (patient). A 51-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot EH9899) intramuscular from 16Dec2020 22:00 at a single dose on the left arm as COVID-19 vaccine. Medical history included ulcerative colitis. The patient had no known allergies to medications, food, or other products. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine and did not receive other medications within 2 weeks of vaccination (no other vaccine in four weeks and no other medications in two weeks). The patient experienced pain at injection site on 16Dec2020 23:00. Treatment was not received for the adverse event. The patient had no Covid prior vaccination and did not have Covid tested post vaccination. The event was assessed as non-serious, did not result in death, not life threatening, did not cause/prolonged hospitalization, not disabling/incapacitating, did not cause congenital anomaly/birth defect. The patient was not pregnant at the time of vaccination. The most recent COVID-19 vaccine was administered at the hospital. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. The outcome of the event was recovering.

Bifrontal headache; This is a spontaneous report from a contactable consumer and contactable physician. A 56-year-old female received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: unknown), via an unspecified route of administration at left arm on 17Dec2020 at 15:15 at single dose for COVID-19 immunization. The patient medical history and concomitant medications were not reported. The patient previously took cephalexine and experienced allergies. On 18Dec2020 at 06:00, the patient experienced bifrontal headache. The patient outcome of the event was recovered. Therapeutic measures were taken as a result of bifrontal headache and included treatment with MIDRIN.

feeling a little lightheaded; feeling hot at time; This is a spontaneous report from a contactable nurse. A 25-year-old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: HE9899), intramuscular on the right arm on 18Dec2020 10:00 at a single dose for COVID-19

immunization. The patient's medical history and concomitant medications were not reported. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. On 18Dec2020 10:05, the patient was feeling a little lightheaded. She was also feeling hot at the time. She admitted that she did not have breakfast in the morning and had not had anything to drink. She denied throat discomfort or tingling. No shortness of breath or headaches. Outcome of the events was unknown. The events were considered non-serious.

Scratchy Throat; tongue swelling; This is a spontaneous report from a contactable consumer (patient himself). A 36-year-old male patient received bnt162b2 (BNT162B2, lot no. and expiry date were not reported), via an unspecified route of administration on 18Dec2020 05:30 at single dose for Covid-19 immunisation. The patient had no known allergies. There were no medical history and concomitant medications. No other medications the patient received within 2 weeks of vaccination. The patient experienced scratchy throat and tongue swelling on 18Dec2020 (06:00 PM). The most recent COVID-19 vaccine was administered in the hospital. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. Therapeutic measures were taken as a result of the events which included Benadryl. The outcome of the events was not recovered. Information about Lot/batch no has been requested.

Swelling at injection site; headache; slight nausea; pain at injection site; This is a spontaneous report from a contactable consumer. A 43-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), lot number: EH9899, first dose via an unspecified route of administration on 17Dec2020 13:00, in left arm at single dose for immunization. The patient's medical history was not reported. Concomitant medication included emtricitabine, tenofovir disoproxil fumarate (TRUVADA). The patient was vaccinated in the hospital. No other vaccine was receive in four weeks. The patient experienced swelling at injection site, headache, slight nausea and pain at injection site on 17Dec2020 18:00. No treatment was given to the patient for the events. The patient had no COVID prior to vaccination and no COVID test post vaccination. The events was reported as non serious. The patient has no known allergies. The outcome of the events was recovering.

diaphoresis; rigors; chest pain; This is a spontaneous report from a contactable nurse. A 38-year-old female patient received first dose of BNT162B2 (Pfizer-BioNTech COVID-19 mRNA vaccine, lot number: elo140), via an unspecified route of administration at right arm on 18Dec2020 09:45 AM at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient has known allergies to flu vaccine. On 18Dec2020 at 10:15 AM, the patient experienced adverse events of diaphoresis, rigors, and slight chest pain. The adverse events resulted in emergency room/department or urgent care. It was unknown if treatment was received due to adverse events. The outcome of the events was unknown. The events were considered non-serious.

Slight headache; sore throat; This is a spontaneous report from a contactable consumer. A 61-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number EK5730/expiration date unknown) dose number 1 via an unspecified route of administration on the left arm on 18Dec2020 11:15 for COVID-19 immunization. Medical history included polycythemia

vera, high BP, and GERD (gastrooesophageal reflux disease). Concomitant medications included omeprazole, aspirin [acetylsalicylic acid], hydroxyurea, tapentadol hydrochloride (NUCYNTA), and amlodipine besilate (NORVASC). The patient experienced slight headache and sore throat on 18Dec2020 12:15. The outcome of the events was not recovered.

Arm swelling; sore; swollen; This is a spontaneous report from a contactable other healthcare professional (patient herself). A 55-year-old female patient (no pregnancy) received first dose of bnt162b2, intramuscularly at site of left arm at 11:15 on 18Dec2020 at single dose for COVID-19 immunization. Medical history included atrophied kidney, high BP, high cholesterol and allergies to medications, food, or other products. Concomitant medication included atorvastatin calcium (LIPITOR) and benazepril hydrochloride (LOTENSIN). The patient experienced arm swelling, sore, and swollen at 18:00 on 18Dec2020. No treatment received for events. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. The outcome of events was not recovered. Information on the Batch/Lot number has been requested.

Foggy feeling; headache; body aches; low grade fever; This is a spontaneous report from a contactable consumer (patient herself). A 44-year-old female patient (no pregnancy) received bnt162b2, via an unspecified route of administration at site of right arm at 15:45 on 14Dec2020 at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced foggy feeling, headache, body aches and low grade fever at 12:00 on 18Dec2020. No treatment received for events. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. The outcome of events was unknown. Information on the lot/batch number has been requested.

Soreness at injection site; mild diffuse myalgias; fatigue the following day; This is a spontaneous report from a contactable physician. This 30-year-old male physician (patient) reported that he received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot# EJ1685), via intramuscular on 16Dec2020 15:30 in arm left at single dose for covid-19 immunization. Medical history included exercise-induced asthma and allergies: certain types of deodorant. The patient's concomitant medications were not reported. The patient had no covid prior vaccination and was not covid tested post vaccination. The patient experienced soreness at injection site, mild diffuse myalgias and fatigue the following day on 17Dec2020 07:00. All events were reported as non-serious. Outcome of events were recovered in Dec2020. The patient received the treatment-ibuprofen for events.

Flushed red skin upper torso and face; Flushed red skin upper torso and face; This is a spontaneous report from a contactable nurse (patient herself). A 55-year-old female patient (non-pregnant) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via intramuscular on 18Dec2020 08:00 am in left arm at single dose for covid-19 immunization. Medical history included chronic migraines and allergies: shellfish. Concomitant medication included famotidine, memantine and ascorbic acid, ergocalciferol, nicotinamide, retinol, riboflavin, thiamine hydrochloride (VITAMINS). The patent previously took pethidine hydrochloride (DEMEROL) and experienced allergies. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. Patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The

patient experienced flushed red skin upper torso and face on 18Dec2020 13:00 with outcome of recovering. No treatment was received for flushed red skin upper torso and face. Information on the lot/batch number has been requested.

Fever; body aches; nausea; vomiting; severe fatigue; headache; abdominal pain; site pain; This is a spontaneous report from a contactable consumer (patient herself). A 61-year-old female patient (non-pregnant) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot# Ek5730), via an unspecified route of administration on 16Dec2020 16:15 in right arm at single dose for covid-19 immunization. Medical history included asthma, hypothyroidism, hyperlipidemia, allergies: codeine and sulfa. Prior to vaccination, the patient diagnosed with COVID-19. Concomitant medication included levothyroxine within 2 weeks of vaccination. Since the vaccination, the patient has not been tested for COVID-19. The patient experienced fever, body aches, nausea, vomiting, severe fatigue, headache, abdominal pain and site pain on 17Dec2020 04:00 with outcome of recovering. All events were reported as non-serious. The patient received the treatment ondansetron (ZOFRAN) for events.

sensation in throat/a menthol cough drop stuck in the throat; flushed; diaphoretic; burning into my chest; some random hives; This is a spontaneous report from a contactable consumer (patient herself). A 38-year-old female patient received first dose of bnt162b2 (lot number: EL0140), via an unspecified route of administration at site of left arm at 11:30 on 19Dec2020 at single dose for COVID-19 immunization. Medical history included Oral Allergy Syndrome, ADHD (attention deficit hyperactivity disorder), multiple food allergies, and allergies: PCN, Ceclor and Lovenox multiple. Concomitant medication included cetirizine hydrochloride (ZYRTEC), montelukast sodium (SINGULAIR), diphenhydramine hydrochloride (BENADRYL) and amfetamine aspartate, amfetamine sulfate, dexamfetamine saccharate, dexamfetamine sulfate (ADDERALL). Within minutes after vaccination, the patient became flushed and diaphoretic followed by a sensation in her throat, it felt that she had a menthol cough drop stuck in the throat and the burning into her chest. Once the medics administered IV Benadryl, the sensation in her throat went away. She was in the emergency room for about 3 hours and had some random hives throughout the rest of the evening. She had anaphylaxis previously to avocado and to an allergy shot. This was definitely nothing close to anaphylaxis. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. The outcome of events was recovered in Dec2020.

muscles aches; really tired; This is a spontaneous report from a contactable consumer (patient himself). A 37-year-old male patient received bnt162b2, via an unspecified route of administration at site of right arm on 16Dec2020 at single dose for COVID-19 immunization. Medical history included lung surgery from 2019. There were no concomitant medications. The patient experienced muscles aches, really tired on 17Dec2020. The outcome of events was unknown. Information on the lot/batch number has been requested.

top of her left arm was swollen; she had pain all down the left side of her body, the whole left side; This is a spontaneous report from a contactable consumer (Patient). A 37-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration in left arm on 17Dec2020 at single dose for COVID-19 immunization. The patient medical history was not reported.

The patient's concomitant medications were not reported. The patient got the shot in her left arm and the top of her left arm was swollen, she had pain all down the left side of her body, the whole left side in Dec2020. The patient only took paracetamol (TYLENOL) for treatment. The outcome of the events was unknown. Information on the lot/batch number has been requested.

"Felt like arm was going to ""fall off"" for 18 hours after receiving COVID vaccine; Felt like arm was going to ""fall off"" for 18 hours after receiving COVID vaccine; This is a spontaneous report from a contactable consumer (patient). A 33-year-old patient of an unspecified gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date in 2020 at single dose for COVID-19 immunization. The patient medical history and concomitant medications were not reported. The patient felt like arm was going to ""fall off"" for 18 hours after receiving COVID vaccine in 200. Event took place after use of product. The outcome of events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained."

little discomfort felt in the deltoid from the shot; This is a spontaneous report from a non-contactable consumer (patient, Pfizer employee). A female patient of an unspecified age received BNT162B2, via an unspecified route of administration on an unspecified date in 2020 at a single dose in deltoid for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced little discomfort felt in the deltoid from the shot on an unspecified date. The outcome of event was unknown. No follow-up attempts are possible, information about lot/batch cannot be obtained. No further information is expected.

After first dose, experienced sore arm, feeling foggy, headaches but better the next day.; After first dose, experienced sore arm, feeling foggy, headaches but better the next day.; After first dose, experienced sore arm, feeling foggy, headaches but better the next day.; This is a spontaneous report from a non-contactable consumer. A patient of unspecified age and gender received the first dose of bnt162b2 (BNT162B2) vaccine , via an unspecified route of administration on an unspecified date at single dose for covid-19 immunisation . The patient medical history and medications were not reported. The patient experienced sore arm, feeling foggy, headaches but better the next day on an unspecified date with outcome of recovering. No follow-up attempts are possible ; information about lot/Batch number cannot be obtained.

Severe dizziness; This is a spontaneous report from a contactable Physician reporting for herself. A 61-years-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EH9899), via an unspecified route of administration on 18Dec2020 at single dose for covid-19 immunisation. Medical history was none. There were no concomitant medications. The patient experienced severe dizziness on 18Dec2020 with outcome of recovering. No treatment was performed. The patient underwent CMP test on 07Dec2020 and it was normal.

felt dehydrated; pain in the arm; but it was still hard; arm swelling where she got the injection; Dizziness; This is a spontaneous report from a contactable consumer reporting for herself. A 26-year-old female patient received first dose BNT162B2 (Pfizer product, lot number EH9899), via an unspecified

route of administration on 17Dec2020 06:00 at single dose on left arm for COVID-19 immunization. There were no medical history and concomitant medications. No prior vaccinations (within 4 weeks); no adverse events following prior vaccinations. The patient reported that she was the unit secretary in the hospital. She got the first dose COVID vaccine yesterday (17Dec2020 06:00). Vaccination facility type was hospital; vaccine was not administered at military facility. She was reading the paper they gave her at work. She had arm swelling where she got the injection, it had gone down a little, but it was still hard. She also felt dizziness and dehydrated. The dizziness started about an hour ago (on 18Dec2020). Since laying down it had improved a little. She has felt dehydrated since around 11am (18Dec2020 11:00). She was sipping on Gatorade, but still felt dehydrated. She took a Tylenol today (18Dec2020) for the pain in the arm and swelling. She had gone to the website and it didn't say what to do about the side effects besides call #. She didn't think she needs to call # for a swollen arm. Therapeutic measures were taken as a result of arm swelling where she got the injection, pain in the arm and felt dehydrated. The adverse events did not require a visit to emergency room or physician office. The outcome for events arm swelling where she got the injection and Dizziness was resolving while for other events was unknown.

ringing in his ear on the left; This is a spontaneous report from a contactable Physician(patient). The 37-year-old male patient received first dose of vaccine BNT162B2(Batch/lot number: EK7530, Expiration date: unknown), via an unspecified route of administration on 18Dec2020 at single dose for prevention of Covid. Medical history included gastrooesophageal reflux disease(GERD). Concomitant medication included omeprazole for GERD. The patient stated in the hospital, he had the Covid vaccine 2 hours ago and he just want to report a possible side effects, about hour after the vaccine he had ringing in his ear on the left on 18Dec2020. No treatment was received. It was not that bad. It was improving. Outcome of event was recovering.

soreness at injection site at hour 3; low grade fever at hour 8; This is a spontaneous report from a contactable physician reporting for him/herself via Pfizer sales representative. This patient of unknown age and gender received on an unknown date a single dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) for COVID-19 immunization. Medical history and concomitant medications were not reported. On an unknown date, the patient noted soreness at injection site at hour 3, and low grade fever at hour 8. Outcome was unknown. No follow-up attempts are possible, information about batch number cannot be obtained.

numbness in my 'ear'/numbness in my hands; Numbness in the beginning and right now numbness and pain; right now numbness and pain; This is a spontaneous report from a contactable consumer (patient). A 48-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot/batch number and expiration date unknown), via an unspecified route of administration on 18Dec2020 at 15:00 at single dose for COVID-19 immunization (just got the vaccine). The patient's medical history and concomitant medications were not reported. The patient reported that she just got the vaccine today (18Dec2020) and she took it in her hospital, she felt numbness in her 'ear', her hands and right now going through the pain. Patient reported that numbness in the beginning and right now numbness and pain. She got the vaccine exactly at 3O'clock (15:00) and after20-25 minutes later, she started feeling numbness and pain. She did have pain right now. She had not taken anything as

treatment. The outcome of the events was unknown. Information on the Lot/Batch number has been requested.

Recently feeling chilly; I just feel very nauseous and weaken like my body some parts are hot and some parts are cold; I just feel very nauseous and weaken like my body some parts are hot and some parts are cold; weaken like my body some parts are hot and some parts are cold; This is a spontaneous report from a contactable consumer (patient). A patient of unspecified age and gender received BNT162B2 (reported as COVID Vaccine, lot number and expiration date not reported), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient received the COVID Vaccine and had been recently feeling chilly and also just really weak and nauseous and patient guessed just never felt this way before. The patient know that they were side effects but just felt very nauseous and weaken like the patient's body some parts were hot and some parts were cold. The outcome of events was unknown. Information regarding lot/batch has been requested.

light headed; tingling all over body; This is a spontaneous report from two contactable consumers. A 49-year-old female patient started to receive first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899), intramuscular at left arm on 17Dec2020 at 14:00, single dose for COVID-19 immunization. Medical history included asthma and allergy to sulfa, both from an unknown date and unknown if ongoing. Concomitant medication included salbutamol (PROVENTIL), omeprazole and cetirizine hydrochloride (ZYRTEC). The patient previously took morphine and tramadol and for both experienced allergies on an unspecified date. On 17Dec2020 at 14:10, the patient experienced light headed and tingling all over the body. The patient outcome of the light headed was not recovered, the patient outcome of tingling all over the body was recovered within 30 minutes.

allergic reaction; This is a spontaneous report from a contactable physician. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration in Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced allergic reaction in Dec2020. No further details were provided. The outcome of allergic reaction was unknown. The batch/lot number for the vaccine, BNT162B2, was not provided and will be requested during follow-up.; Sender's Comments: Based on the information available, a possible contributory role of the suspect products cannot be excluded for the reported event allergic reaction due to temporal association. However patient past medical history regarding allergy would have been helpful for a meaningful causality assessment. Case will be reevaluated upon further information

Swelling of Right arm below the elbow not at the injection site. Soreness and tightness of the right hand. After 72 hours these symptoms resolved however on 12/19/2020 developed burning and itchy hives over abdomen, back and trunk. On 12/21/2020 the hives developed on the scalp.

Low-grade temperature ranging from 99.8-100.3; chills; body aches; fatigue; This is a spontaneous report from a non-contactable nurse (patient). An adult female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date were not reported),

intramuscular on the right arm on 16Dec2020 18:00 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient was not pregnant. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. On 17Dec2020 05:00, the patient experienced low-grade temperature ranging from 99.8-100.3, chills, body aches, and fatigue. No treatment was received for the adverse events. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, the patient had not been tested for COVID-19. Outcome of the events was recovering. The events were considered non-serious. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

"bronchitis or pneumonia; pain down arm into fingers; injection site tingling; Chest felt heavy and difficulty breathing; Chest felt heavy and difficulty breathing; bronchitis or pneumonia; rash on both arms with bright purple skin; rash on both arms with bright purple skin; felt like everything was numb and like she was on drugs; felt like everything was numb and like she was on drugs; Severe headache; This is a spontaneous report from a contactable consumer (nurse) via a Pfizer sales representative. A female patient of an unspecified age received the first dose of the bnt162b2 (BNT162B2; also reported as COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. On an unspecified date, the patient experienced: bronchitis or pneumonia (medically significant), pain down arm into fingers, injection site tingling, chest felt heavy and difficulty breathing, rash on both arms with bright purple skin, felt like everything was numb and like she was on drugs, and severe headache; all of which required hospitalization. The clinical course was reported as follows: The female patient (nurse) took the first dose of the vaccine and experienced pain down arm into fingers, injection site tingling. The patient's chest felt heavy and difficulty breathing; however, the ""tongue never swelled."" Rapid response was called, and the patient was taken to the hospital. The patient was given a ""cocktail"" to treat the reaction. The patient ""felt like everything was numb and like she was on drugs"" The patient also felt like she had bronchitis or pneumonia. The patient also experienced a ""rash on both arms with bright purple skin""; along with a severe headache. Therapeutic measures were taken as a result of pain down arm into fingers, injection site tingling, and chest felt heavy and difficulty breathing. The clinical outcome of the events was unknown. No follow-up attempt possible; information about batch/lot number cannot be obtained."

Chills, severe headache, joint pain, muscle aches; Chills, severe headache, joint pain, muscle aches; Chills, severe headache, joint pain, muscle aches; Chills, severe headache, joint pain, muscle aches; This is a spontaneous report from a contactable consumer. A 48-year-old female patient received bnt162b2 (BNT162B2, lot number: EH9899), via an unspecified route of administration on the left arm on 17Dec2020 10:45 at a single dose for COVID-19 immunisation. Medical history included asthma and COVID-19 (patient was diagnosed with COVID-19 prior to vaccination). Concomitant medications included ascorbic acid, biotin, calcium carbonate, calcium pantothenate, calcium phosphate dibasic, chromium picolinate, colecalciferol, copper sulfate, cyanocobalamin, ferrous fumarate, folic acid, magnesium borate, magnesium oxide, manganese sulfate, nickel sulfate, nicotinamide, panax ginseng root, phytomenadione, potassium chloride, potassium iodide, pyridoxine hydrochloride, retinol acetate, riboflavin, sodium metavanadate, sodium molybdate, sodium selenate, stannous chloride, thiamine

mononitrate, tocopheryl acetate, zinc oxide (CENTRUM ENERGY), and pantoprazole sodium sesquihydrate (PROTONIX [PANTOPRAZOLE SODIUM SESQUIHYDRATE]). On 17Dec2020 13:00, the patient experienced chills, severe headache, joint pain, muscle aches. Therapeutic measure was not given as a result of the events. Clinical outcome of the events was not recovered.

Injection site pain; Fatigue; This is a spontaneous report from a contactable healthcare professional. A 50-year-old female patient received bnt162b2 (BNT162B2, lot number: EK5730), intramuscular on the left arm on 17Dec2020 09:00 at a single dose for COVID-19 immunisation. Medical history and concomitant medications were not reported. On 18Dec2020, the patient experienced injection site pain and fatigue. Therapeutic measure was not given as a result of the events. Clinical outcome of the events was recovering.

Arm soreness; fatigue; This is a spontaneous report from a contactable consumer. A 23-year-old female patient received the 1st dose of bnt162b2 (BNT162B2) at single dose at right arm on 18Dec2020 08:00 for immunization, administered at hospital. The patient medical history was not reported. No known allergies. Concomitant medication included MultiVitamins and colecalciferol (VITAMIN D [COLECALCIFEROL]). The patient has not received any other vaccines within 4 weeks prior to the COVID vaccine. The patient experienced arm soreness and fatigue on 18Dec2020 11:00. The patient has received not treatment for the events. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. The action taken in response to the events for bnt162b2 was not applicable. The outcome of events was recovering. Information on the lot/batch number has been requested.

mild dry mouth; felt a little foggy; This is a spontaneous report from contactable consumer via a Pfizer Sales Representative. A 52-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration, on 18Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced mild dry mouth and felt a little foggy on 18Dec2020. The clinical outcome of mild dry mouth and felt a little foggy was recovered on 18Dec2020. No follow-up attempts are possible; information about batch/lot number cannot be obtained.

100.5 fever/chills, body aches. Treated with ibuprofen. Resolved within 24hrs of vaccine.

One day after vaccination, patient returned to the injection clinic and reported noticed shoulder and arm swelling with a patchy rash to her R shoulder. Symptoms resolved. She was advised to call the call center and f/u with PCP.

Urticaria, tachycardia at 10 minutes post injection in left arm and neck Treated with oral cetirizine and montelukast. Resolved within 15 minutes of treatment. Discharged in good condition with PO diphenhydramine as needed.

Headache, explosive diarrhea, nausea & vomiting, fever, slept for 18 hours, body aches

Patient recieved dose one of the Pfizer Covid 19 Vaccine. Within ten minutes scratchy throat started. Patient was monitored for 30 minutes and throat irritation became worse. Transferred to urgent care for follow up. Received a dose of diphenhyramine, symptoms lessened, and was able to leave urgent care for home.

Patient developed dizziness shortly after receiving Pfizer Covid-19 vaccine on 12/21/2020. Patient was brought to the Emergency Department. SBP initially in 70's, rapidly improved to 90's without intervention. Patient denied SOB. No e/o angioedema on exam. SBP improved to 110's after 500cc of NS.

Body aches, and fatigue started 6 hours after vaccine administered. The next day I had a moderate headache that I took ibuprofen, and Tylenol for. Body aches, and fatigue continued the next day. It was difficult for me to participate in ADL's. Headache, nausea, and fatigue continued to two days post vaccine.

Myalgia, Fever, Chills, swollen joints

Pfizer-BioNTech COVID-19 Vaccine EUA metallic taste immediately following 1st IM dose

While driving home after receiving the vaccine I was very close to losing consciousness. After laying down in my car for 20 minutes I was able to drive home. I developed a headache that did not subside fully until three days later. On Friday December 18th, I woke up with a very sore arm, from my shoulder to my wrist, I still had a headache, developed; fever, chills, body aches, and nausea.

Dizziness, headache, nausea started 12/19/20. Vomited on 12/20/20. Came in on 12/21/20 to be seen by provider.

Vaccine recipient received vaccine on 12/19/2020.On 12/20 experienced symptoms of headache, fatigue, chills, fever 101.8 F, lower back pain, and nausea. The vaccine recipient took acetaminophen and managed symptoms at home. Reported to have slept for most of the day. On 12/22, during a follow-up phone call reported that most of the symptoms have subsided and only nausea remained.

Approx 5 minutes after receipt of vaccine, patient reported experiencing palpitations. Vitals signs were checked and HR elevated to the 130s (regular rhythm) and systolic BP elevated to the 160-170s mmHg; pulse ox within normal limits. Some mild tremors noted in left > right hand. Patient placed in supine position and given 12.5mg IV benadryl and 4mg x2 doses =8mg total IV dexamethasone with symptomatic improvement and normalization of HR / BP. No hypotension or hypoxia throughout the event. No angioedema or urticaria.

Employee reported a bloody nose and blood in urine this morning (slight tinge) Has not exhibited any other side effects at the time of this report. Noted in afternoon on 12/18/2020 urinated and no blood present.

1. Day 1- (same day) didn't feel anything until later that night, I felt a lump at site with a quarter size area around the direct shot red and sore. 2. Day 2- Sore arm, felt a bit restricted to move arm around,

minor weakness, still red quarter size and lump at site. 3. Day 3- Arm same as day 2, but by the evening I was extremely tired. Joint pains, body aches, and random chills all severe. 4. Day 4- Arm issues gone but continued with the body aches, weakness, extremely tired, and chills. A bit cloudy, and a bit forgetful. 5. Day 5- Same as day 4, but worse. Completely unable to accomplish daily activities, had to call in to work, weakness at one point as bad as struggling to lift and open a water bottle. 6. Day 6- I am here, slightly better than the day before. Still severe joint pains, body aches, and body chills.

Pfizer-BioNTech COVID-19 Vaccine EUA immediately after 1st IM dose pt experienced itching at injection site, itching resolved with 10 minutes

anaphylaxis

"Employee stated she felt her heart racing and felt ""off."" Appeared to RN to be diaphoretic and pale but remained alert, oriented, speaking full sentences no shortness of breath, scratchy throat or rash. 50mg Benadryl PO at 06:25am. Highly encouraged patient to stay for additional 15 minutes. Patient refused to stay stating she didn't have childcare beyond 7am. Instructions given to patient re: symptoms to monitor for and to seek medical assistance if symptoms worsened or persisted. Additionallyasked patient to contact employee health."

injection site soreness and slight swelling. chills, fever 99 F

Extreme swelling of lymph nodes on left side of body (specifically armpit) Fever Muscle Pain Swelling Headache Nausea Vomiting

After the injection I stayed on a recliner for 15 min before returning to work, nothing happened, I felt good. After I arrived home, about 3 hours later when I was home I felt a mild headache. The next day I felt muscle pains/body aches, specially on the right side of my body, my right shoulder was hurting really bad. after 48 hours the symptoms went away.

12/21/2020- 1 called with increased BP 12 hours after vaccination. Was seen by MD and went to ER. Med for BP increased and modified until stable.

"Patient describes flushing, upon examination: ""heart was pounding in my head"". Patient felt like she was going to ""pass out"". and ""throat fullness"" Medical team reported patient was tachycardic . Administered 25mg (oral) benadryl X1 Alerted covering physician (per protocol)"

Approximately 20 minutes following COVID-19 vaccination the patient suddenly developed hives, itching - Hives around face and upper chest. Throat was red and slightly swollen. Was brought to the Emergency Department within out hospital for assessment and medical care. Acute treatment included methylprednisolone 125 mg IV x 1 dose, diphenhydramine 50 mg IV x 1 dose, epinephrine 0.3 mg IM x 1 dose, and famotidine 20 mg IV x 1 dose. The patient felt better following this treatment Upon reassessment oropharyngeal swelling had improved, the patient no longer had hives and the throat appeared clear. The patient stated he no longer feels itchy but does feel a little short of breath. Lungs were clear with pulse oximetry 97%.

"Felt lightheaded upon standing and stated "" my body felt whooshy ""; HR-52-- baseline and remained alert and oriented x3; Benadryl 25 mg given --observed patient for 30 minutes; ambulated patient and she stated she felt fine--funny feeling gone"

Fever, Fatigue, Weakness, Body Aches, Chills, Muscle Pains lasting until Monday 12/21/2020

Patient expereinced pain at vaccination site 2 hours after administration. in 20 hours it had become red and swollen. Swelling and redness have steadily decreased to time of individual reporting today at 13:00 (Jan 22, 2020 reported)

Ten minutes after vaccine was injected pt started having elevated heart rate and mild flushing.. She was sent to the emergency department for clinical evaluation and further observation. She refused medication while at the vaccination site.

Migraine headaches chills diarrhea

About 12 hours afterward the initial injection (0330) I began feeling very cold, started shivering violently to the point where I seemed to feel like I was a Parkinson's patient and nearly froze my jaw with severe muscle aches. Was able to calm the symptoms after standing by a hot oven. Only reason I'm fairly certain this was some kind of reaction as I had a similar event happen when when I last got a tetanus shot 14 years ago where I was in the ER overnight, staff at the vaccine clinic even held me for a longer period (30 minutes) then other due to that issue and were given full disclosure of prior events before receiving the injection . I was diagnosed with Covid 19 on 12/10/20 (They discussed giving the injection with a health dept worker before giving it to me and declared it ok) and troughout the entirety of my quarantine I have never experienced something like that.

Patient developed mild lightheadedness and tingling of the lips. No SOB, CP, swelling of the throat or lips, or rash. Patient was observed for one hour from vaccine administration. She was given water and crackers. Symptoms improved at 60 minute reevaluation. Vital signs stable. Discharged to home.

Employee reported continuous chills off and on for over 12-24 hours, and major-severe headache.

Chills and headache

Vaccine recipient reported symptoms of tingling in the tips of index and middle finger on left hand at the time of COVID-19 administration. Symptoms resolved 15 mins later and vaccine recipient continued on with their day with no further issues.

She was given the Pfizer vaccination in the left deltoid muscle. á During her 15 minute waiting period after the injection, the patient began to experience localized tingling at the injection site that radiated into her 4th and 5th digits and proximally along the sternomastoid muscle. She denied rash, hives, difficulty breathing, difficulty swallowing, wheezing, throat tightness, hoarseness, stridor, itching, dizziness, facial swelling, lip swelling and tongue swelling. á This provider was notified of patient reaction and she was then assessed in the emergency bay area. Monitored patient for severe reaction symptoms, including rapid progression of symptoms, vomiting, hypotension and chest pain. Patient was

observed for approximately 30 minutes post injection with no evolution of sx. Injection site tingling that extended along the ulnar nerve distribution was improving at the time of discharge.

Day 1-4 large raised bright red injection site warm to touch Day 3 Bright red raised rash all over face and scalp, going down neck

Mild shortness of breath, heartburn

Small raised bumps on bilateral posterior hands. Roughly 1/8 cm width and 1/8 cm high. Dispersed evenly in random patches. Not red. Flesh-toned color.

Patient received the covid vaccine on Sunday12/2020. He found out that his roommate tested positive for covid on 12/20/2020 when he got home. He started to have dry cough on 12/20 evening. Had HAs but resolved 12/22. Still coughing. No fever/chills/bodyaches.

Headache, muscle aches, joint aches, photophobia, pain at site (arm pain), and fatigue

Scratchy, irritated throat with metallic taste in mouth.

I have a swollen lymph node in arm pit, and elbow and injection site is swollen and hard. -

Severe abdominal cramping, diarrhea, rectal bleeding. Went to ED.

After I got the shot I could feel it going into my system (histamine). I had myalgia on my right shoulder and up into my neck, those I felt first. I felt like a histamine release. It is like I felt a drug being released in my body, a strange feel. Made me feel woozy. Not a major reaction, no airway constrictions, just felt uneasy. As I was walking to my vehicle to leave the hospital my arms started feeling tingly so I decided to walk to the ER and get checked. Vitals were taken and a shot of Benadryl - 50mg, sat around until it kicked in about 30/40 min and it made the symptoms subside. Next morning I felt fine , arm was sore from the injection but that was all.

Patient states that he went home was slightly fatigued. By 4am patient woke up and was severly fatigued. Patient states this moring it was difficult to wake up because how fatigued he was.

body aches, headache starting 24h after injection; lasting ~12 hours

Injection site pain, muscle aches , Headache , body ache , Muscle ached lasted through the rest of the week

Chills at 5-10 min after vaccination, with voice change and SOB 15-20 min after vaccination concerning for anaphylaxis. Epi given im x1. given immediately at voice change and immediately taken to ED.and currently receiving care

Patient reports 5 minutes after getting covid vaccine she became flushed, heart was pounding and felt dizzy. Patient denies hx of allergic reactions.

For first 5 minutes after injection i had taste in mouth of iodine and warm feeling in my chest - it felt almost like ct contrast does - went away after 5 minutes - felt fine after that - nurse wanted me to report side effect just in case

Hypotension and syncope without tachycardia, 15 minutes after injection. Patient was repositioned supine, which caused her to regain consciousness. Give 1 liter NS over 2 hours and discharged in good condition.

"From the patient (a employee) ""So, I think I am having a reaction to the vaccine. I did call my PCP to check in and they also said to notify you. I felt fine until last night about 8 PM. Then I got body aches, headache, nausea, tachycardia, no fever. During the night I had to use my nebulizer 3 times to keep sat > 86. As I did some research through the night, some Covid patients were found to have positive Epstein Barr. That is what I had in September (EBV) that put me down for 3 months. So I am wondering if it caused a relapse of that. Hope not."

Received COVID-19 vaccine on 12/18/2020 around 1225pm, ten minutes later while being monitored I started to feel hot flash, got dizzy like about to pass out, I asked to let me lay down, I felt the medication bitter taste in the back of my throat, I was clammy pale, I lay on a stretcher and put my feet up elevated, rapid response was called and BP was checked and Spo2, my hands were getting cold and tingling I was talking to RN, another RN, after laying down for ten minutes I sit up I was getting my BP back to normal, I sat down in the chair again for another 10 minutes, I was offered to go to the ER but I decline, I said I was getting better, after 15 minutes I left monitored by my supervisor I felt the medication in my stomach, after the tingling my fingers were numbed for the next days until present.

Following morning after getting vaccine woke up with chills headache and a fever of 100.8. I spoke with my PCP and she advised that I take some ibuprofen.

Increased heart rate and blood pressure. Rash on anterior right side of neck. She laid down and was given water. Blood pressure and heart rate monitored. She was also reassured by friends that she was okay. The patient said she was anxious and that's why she had a reaction.

Throat and chest tightening, as was all warm and flushed feeling in throat and chest

12/21: woke up with full body aches, pressure in ears bilaterally. Took 200mg motrin, body aches resolved by early evening. 12/22: Right tonsil inflamed/irritated, painful to swallow. Ear pain bilaterally. Went to clinic, temp 99.1, some fluid in ears; strep and influenza tests came back negative. Given zyrtec, flonase, and tylenol for symptom management and advised to get a covid test when possible.

Arm Soreness Started diarrhea on the 19 of Dec, went away on the 20th. Woke up on the 22nd around 1am with really bad abdominal pain and diarrhea.

Metallic taste in mouth. Progressed to numbness of throat and tongue. No swelling. No rash. No shortness of breath. Remained alert and oriented and speaking full sentences throughout. Benadryl 25mg PO. EMS in to assess. 186/98, HR 94, SpO2 100% Remained onsite for extra 30 minutes. Patient refused transport to BMC for monitoring. Patient refused to be driven home. Throat/tongue numbness

improved. BP before leaving 156/90, HR 82, SpO2 99%. Patient stated when she received Flu shot in early October this year, 2020, she had scratchy throat which resolved independently.

Pt states that she received her vaccination at 10:00am and felt chest tightness immediately. This resolved within minutes and pt left testing site. Pt states that around 11:00am she felt numbness and tingling in her bilateral forearms and fingers. By 11:45 when we spoke, the numbness and tingling had improved but was still present.

I had joint stiffness, my body ache, abdominal pain, diarrhea and headache.

Patient is describing feeling as if he took Niacin, he is flushed, red in the face but cool to the touch and itchy skin

rash and dizziness

Within 15 min. of vaccine,I had some brief mild shortness of breath,a stab of pain in the center of my left chest,I felt strange, had 3 stabs of pain in my right ear and 3 pressure type pains in my left ear.

HEADACHE, NAUSEA, BODY ACHES, INJECTION SITE PAIN, MALAISE

Chills, body aches, mild cough, headache

"Approximately 10 minutes after receiving the vaccination the patient began complaining of dizziness and ""not feeling right"". Vital signs indicated the patient to be hypertensive, vital signs otherwise within normal limits. Patient denies rash, itching, shortness of breath, chest. Patient transported to the ER for evaluation within 15 minutes."

Swelling and numbness of right side of the face.

"Patient was done receiving vaccine at 0921, approximately 5-10 minutes later reported feeling flush, metallic taste in mouth (first symptom), heart racing. VS taken: 152/93, HR 120. Pt seated, calm, given water to drink, speaking full sentences, NAD and no difficulty breathing or swallowing. At 0948 VS: 132/91, HR 96, SpO2 98% room air. At 0955, patient continued to feel waves of heart racing, HR on monitor 90-108, SpO2 98%. At 1002, notified ED charge nurse that patient will be escorted for further monitoring, work up if necessary. Still no respiratory or swallowing symptoms. At 1002, patient escorted to ED by RN, ambulated without difficulty. Upon ED arrival, patient reported feeling ""fine"" without symptoms."

Started having shortness of breath a couple hours after vaccine, then some fatigue and headache. Woke up next morning with sore arm, worsening headache and fatigue. Those side effects dissipated as the day went on, next day arm still a little sore, but by afternoon, felt back to normal.

Moderate pain and mild swelling at injection site occurring about 16 hours after injection. Swelling and pain resolved within 2 days after onset. No other adverse events or side effects to report to Pfizer COVID-19 vaccine. No flu like symptoms, no fatigue, no fever, no chills, no headache.

Headache , Fever , Diarrhea , Muscle Aches .

12/18/2020 in PM dry cough, body aches. Symptoms resolved on 12/19/2020

Dizziness, Flushed, Light headed, Near Syncopal Episode.

It started with a tingling in my tongue, my BP went super high and my face was all red and a headache afterwards. My BP went down about 25 min later. I was just monitored at the vaccination site, did not go to the ER.

Low grade fever 100.6, took Tylenol, fever decreased 99.3, took 2 more Tylenol at 3am 12/22/2020 and hasn?t had a fever since, was tested for Covid in the past with negative results, has not been around anyone with Covid that she is aware of, she has not traveled, however her son has traveled home from college but tested for Covid twice with negative results. Patient states that she is not experiencing any other symptoms.

12/19 - hour after the vaccine had diarrhea that lasted until about 11pm that night 12/20- 2pm started to have general malice. Took a nap and woke up at 6:10 pm with a fever of 99.5 orally. 12/21- Woke up to R armpit pain. Upon examination, R armpit was visibly swollen compared to left. No redness, tenderness, pain at the injection site. Could not feel swollen lymph nodes. Fever gone in AM.

Approximately , 11am started getting chills all over, temperature 101.6 around 1pm with headache. I would take Motrin/ Tylenol when I felt my fever go up . The fever, headache and chills lasted Friday ,Sat , Sunday. On 12/21/20 had no more fever, no headache or chills. I have a great appetite, have no other symptoms.

Woke up with elevated temperature of 102.0, Chills, elevated glucose level of 499, body aches, headache, Nausea

During 15 min observation, employee reported tingling in her lips. She is allergic to grass and has experienced this feeling when she is having an allergic reaction. Employee taken to gurny, VS taken. No hives noted. Reported her throat feels a little tight. 50 mg of Benadryl given. See attachment for VS record. 1:1 observation by RN. No further s/s. Employee states points to her flowers and says it could be the flowers my mom sent me for vaccination day. Monitored employee until 1950 when she was taken home by a co-worker. Employee states she has improved s/s and is now just drowsy. Informed to discuss reaction with PCP and/or EH. Instructed to call EMS or go to ED if symptoms come back.

HEADACHE, UPSET STOMACH, INJECTION SITE PAIN, GENERAL BODY ACHES, MALAISE

Injection was given low on upper arm, below deltoid. Became red, swollen, and painful in 12 hours, worsening over 3 days, resolved in 5 days.

I received the Covid 19 vaccination at 3:00 pm on 12/18 no trouble went home. Upon going to sleep the left arm was numb thought and got up to use the bathroom had diarrhea. While in the restroom hit face

had a Syncope episode regain conscience went to ER had 4 stitches in chin. Since 12/20 felt fine and was able to return to work.

12/17/20 Received Pfizer COVID vaccine 12/18/20 Sore arm, no other side effects 12/20 Headaches refractory to ibuprofen, and vertigo 12/21 Worsening HA and vertigo 12/22 Feels lightheaded. She has multiple sclerosis and has had vertigo as a part of her MS in the past. HA onset was about 72h after COVID vaccine. Currently been having HA, vertigo for about 2 days, seems to have peaked.

"Hard lump and redness at injection site on right deltoid almost immediately after injection. Patient describes a ""fireball"" in her throat. Denies swelling. No difficulty swallowing, maintaining airway independently. Headache. In E.D., patient received NS 1000 ml at 2000 ml/hr at 19:34, Diphenhydramine 25 mg IV x1 at 19:36, Methylprednisolone 125 mg IV at 19:38, Ketorolac 30 mg IV at 19:41, Famotidine 20 mg IV at 19:42. Forty minutes post injection, all symptoms gone. Discharged from E.D. at 20:52 with prescription for prednisone 50 mg po daily x4 days, diphenhydramine 25 mg po q6h prn, and famotidine 20 mg po nightly prn."

Progress Notes PA-C (Physician Assistant) ? ? General Surgery/Trauma Cosign Needed Expand All Collapse All á COVID VACCINE CLINIC 12/22/2020 á Patient: DOB: Date: 12/22/2020 MRN: 5380787 á Subjective Patient is a 23 y.o. male who was seen at COVID Vaccine Clinic today for his first dose of the COVID 19 vaccination. á He denied any history of previous adverse reactions to vaccines. He does report recent hx of GI symptoms that he is currently being worked up for. He reports onset of similar sx around time of vaccine injection. á He was given the Pfizer vaccination in the deltoid muscle. á During his 15 minute waiting period after the injection, the patient began to experience dizziness, throat dryness, and nausea. He denied rash, hives, difficulty breathing, difficulty swallowing, throat tightness, hoarseness, stridor, itching, facial swelling, lip swelling and tongue swelling. á This provider was notified of patient reaction and he was then assessed in the emergency bay area. á Monitored patient for severe reaction symptoms, including rapid progression of symptoms, respiratory distress with stridor, vomiting, abdominal pain and hypotension. á á á Review of Systems Otherwise negative, except for above á Objective á Vitals Vitals: á 12/22/20 1131 BP: 118/66 Pulse: 88 SpO2: 96% á á Physical Exam Constitutional: Appearance: Normal appearance. HENT: Head: Normocephalic. Nose: Nose normal. Mouth/Throat: Mouth: Mucous membranes are moist. Pharynx: Oropharynx is clear. Neck: Musculoskeletal: Normal range of motion and neck supple. Cardiovascular: Rate and Rhythm: Normal rate and regular rhythm. Pulses: Normal pulses. Heart sounds: Normal heart sounds. Pulmonary: Effort: Pulmonary effort is normal. Breath sounds: Normal breath sounds. Abdominal: General: Abdomen is flat. Palpations: Abdomen is soft. Neurological: Mental Status: He is alert. á á Assessment/Plan á Treatment included no therapy. Follow up response to treatment:no side effects. Patient discharge: Stable to go home and follow up with PCP. á Patient was monitored in the emergency bay without worsening or evolving sx. Orthostatic vitals signs were negative for hypotension or tachycardia. He was able to ambulate well without assistance and reported improvement of sx prior to discharge. Signs and symptoms of systemic hypersensitivity were reviewed and discussed with instructions to call 911 or report to the ED if SOB, throat/lip/tongue swelling, chest tightness, n/v, abdominal pain, or pruritic rash develop. á á PA-C Electronically Signed 12/22/2020 12:08 PM á á

45 minutes after vaccination felt faint, palpitations, nausea and tremor in hands followed by syncope, after awoke had ongoing muscle spasm/tremor in legs. Taken to ED and labs, IVF, CXR. Observed x 90 minutes and discharged- returned to work as scrub tech in OR. Left early, no further issues that day. Next am on arising had <30 seconds of postural imbalance which resolved spontaneously and no other symptoms since.

COMPLAINT OF REDNESS TO FACE

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Dry mouth, lightheaded, dizziness, increased Hear Rate (89), normally in the 50s. Initial symptoms resolved within 90 minutes. Increased heart rate lasted longer than other symptoms. Reports additional metallic taste in mouth the following day.

Dry mouth, lightheaded, dizziness, increased Hear Rate (89), normally in the 50s. Initial symptoms resolved within 90 minutes. Increased heart rate lasted longer than other symptoms. Reports additional metallic taste in mouth the following day.

About 3 hours after vaccination, she began having hives and itching all over body. No difficulty breathinc etc. She went to ER that noted reaction to vaccine. She was Administered Benadryl 50mg PO X1 and Prednisone 60mg . She also received one dose of Pepcid 20mg PO. No signs of distress noted in ER.

Employee received vaccine and had no signs of adverse reaction after vaccination. Employee went to eat something and fainted. Shortly after employee had an emesis as well. Felt fine afterward and vitals were within normal limits.

bilateral rash/itching on ear lobes, rash/itching/swelling suborbital region, diffuse rash on forehead. bump on right side cervical region.

Nausea, deep harsh dry cough, HA, burning and tightness across shoulder blades. Arm very sore the next morning

Woke up at 12:30 am with severe body aches/feeling light-headed, had near-syncopal episode with large amount vomiting and diarrhea. Also had chills, unsure if febrile. Symptoms lasted for about 1 hour. Felt better the next morning but still with body aches

Diarrhea, hot flashes, chills all over body and in isolated areas, numbness/tingling in face/cheeks towards ears and neck.

Gave me shot did not feel anything. Probably 2-3 minutes later, it started to feel flush and chest tightening, and heart started racing. I did sit down, because they were monitoring us. Had my Apple watch on and heart was going up and down. They kept me monitored for about 30-45 minutes before I was hooked up to BP pressure machine. First reading was 180/110. At that point, they asked if I wanted to go to ER. I went to ER and they did an EKG which was normal. Heart rate came down with Benadryl. I was still feeling little tight in chest. Blood pressure 167/97 upon discharge. Sent home instructed to take

Benadryl. At home was relaxing, few hours later, heart rated spiked again and stayed for 15-20 minutes. Took Benadryl and heart rate came down. Did not take BP at home. Next day one other time where heart rate spiked again.

Severe muscle aches. Using local treatment to injection site and anti-inflammatories.

Patient had onset of a rash not abated with oral Benadryl. Sent to ED after 30 minutes of observation. In ED received IV Benadryl and symptoms resolved after appx 2 hours.(urticarial rash) resolved.

Pfizer-BioNTech COVID -19 Vaccine EAU increase muscle and joint ache.

Patient was pale and nauseous with abdomen pain. patient stated this may have been from her mensural but cycle. Patient put to lye down and left with her guardian to go home and seek medical attention.

Shortness of breath, heavy chest, heart racing, flushed, nausea

At the 10 minute mark patient reported not feeling well. She was noted to be pale. Then she reported having slight breathing problems along with her heart racing. Call for ER staff to report to vaccinating area. Patient's breathing concern resolved on its own by the time ER response team arrived within 2 minutes. Patient slowly gained her color back. Heart palpitations lessening but still reported by patient. Blood pressure / O2 Saturations / Respiratory rate monitored. No oxygen or treatment required at this time. Patient taken upstairs to be monitored by ER staff.

General malaise; body aches; chills; severe headache; low grade temperature (100.0F).

Dizziness for 48+ hours. Feeling of hypersensitive skin to touch

Tingling and numbing on the L arm where injected.

I developed a morbilliform, pustular rash 48 hours after the first injection of the Pfizer COVID-19 vaccine. The rash consists of pustules on an erythematous base on the ventral surface of both arms. It is mildly pruritic. It is not painful. I have no other associated symptoms and feel otherwise fine. I took ibuprofen 600 mg 24 hours ago. I have never had a vaccine reaction before. A dermatologist has seen pictures of the rash and thinks it is likely acute generalized Exanthemata's Pustulosis. Employee health has been notified.

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Heart racing , 15 minutes after vaccine was administered, lasting for about 10-15 min. Itching and rash on chest and upper back about an hour after vaccination.

About 5 minutes after receiving vaccination patient noticed her left arm was very cold and then it went numb from the base of her left ear to her hand. Tested strength in both hands and it was equal. After 20 minutes the patient stated that the numbness was going away but the coldness was still present in the left arm.

mild arm tenderness at injection site, upon waking at 10-11AM the next morning I experienced body aches, chills, and intermittent dizziness.

5mins after vaccine, pt c/o flushing, dizziness and fatigue. Pt monitored for 45mins. No treatment given. Flushing and dizziness resolved. Pt still fatigued. Pt vommitted four times within an hour after leaving vaccine clinic. Pt unable to work the day of vaccination.

Progress Notes; Nurse Practitioner Cosign Needed Expand All Collapse All COVID VACCINE CLINIC 12/22/2020 á Date: 12/22/2020 á Subjective Patient is a 60 y.o. female who was seen at COVID Vaccine Clinic today for her first dose of the COVID 19 vaccination. á She denied any history of previous adverse reactions to vaccines. á She was given the Pfizer vaccination in the left deltoid muscle. á During her 15 minute waiting period after the injection, the patient began to experience Headache over the front of the head. She denied rash, hives, welts, difficulty breathing, difficulty swallowing, wheezing, throat tightness, hoarseness, stridor, itching, lightheadedness, dizziness, facial swelling, lip swelling and tongue swelling. á This provider was notified of patient reaction and she was then assessed in the emergency bay area. á Monitored patient for severe reaction symptoms, including respiratory distress with stridor, wheezing, dyspnea, increased work of breathing, persistent cough and cyanosis. á Finger stick BS 101 12:15 pm granola bar and water given á Review of Systems Neurological: Positive for headaches. All other systems reviewed and are negative. á á á Objective á Vitals Vitals: á 12/22/20 1203 12/22/20 1226 BP: (!) 158/81 (!) 153/75 BP Location: Left arm Left arm Patient Position: Sitting Sitting Pulse: 76 72 SpO2: 98% 98% á á Physical Exam Vitals signs and nursing note reviewed. HENT: Head: Normocephalic. Nose: Nose normal. Mouth/Throat: Mouth: Mucous membranes are moist. Eyes: Pupils: Pupils are equal, round, and reactive to light. Neck: Musculoskeletal: Normal range of motion. Cardiovascular: Rate and Rhythm: Normal rate and regular rhythm. Pulmonary: Effort: Pulmonary effort is normal. Breath sounds: Normal breath sounds. Musculoskeletal: Normal range of motion. Skin: General: Skin is warm. Capillary Refill: Capillary refill takes less than 2 seconds. Neurological: General: No focal deficit present. Mental Status: She is alert and oriented to person, place, and time. Psychiatric: Mood and Affect: Mood normal. Behavior: Behavior normal. á á á Assessment/Plan Treatment included: no therapy. Follow up response to treatment: no side effects. Patient discharge: Stable to go home and follow up with PCP. á Pt reports headache went away after she ate. No new symptoms manifested. Pt released at 12:30 pm á á á Electronically Signed 12/22/2020 12:29 PM á á á

5mins after vaccine, pt c/o flushing, dizziness and fatigue. Pt monitored for 45mins. No treatment given. Flushing and dizziness resolved. Pt still fatigued. Pt vommitted four times within an hour after leaving vaccine clinic. Pt unable to work the day of vaccination.

Temp 100.8 next day, took Motrin and all issues resolved Outcome: Resolved and fine

"Employee complained of feeling hot, heart racing, stating ""I feel like I am going to pass out."" Vital signs taken, BP and HR WNL. Employee states she has not eaten since 0200, water and snack provided. Vitals retaken in 15 minutes WNL and employee states she is back to baseline following 30 minutes of monitoring. Dr. present at this time and assessed employee, occupational health to follow-up."

Started with Rash/Hives on Neck and upper chest and shoulder. Inside of nose rash and mouth itchiness. Progressed to arms and palms of hands. Started to get stomach upset. mouth got warm and throat warm. Breathing was OK but started to get tougher. Went to the ED Given Benadryl Pepcid and solumedrol Gave you prednisone 50mg for home 3 tablets once a day and OTC pepcid

Employee received COVID-19 vaccine on 1:45pm

Fever started at 8pm around 99.5F and then around 1:30am fever went to 101.5F, took 2 advils and fever went down in the 99s. Fever didnt break until after 4 pm next day after 2 advils were taken. Feeling tired/weak since had the shot.

Pt reported being dizzy and a headache

I was unsure whether to report this, and I will preface this by stating that as a child I got nosebleeds frequently. However, I had not gotten a nosebleed in 15+ years and on the day I received the first dose of the COVID-19 vaccine I got a nosebleed that lasted about 10-15 minutes.

Rash on neck, back, and chest

Metallic taste started several hours after injection and lasted several minutes

2 hours after vaccine started with itching face and body, eye swollen like my allergy symptoms 12 hours after vaccine got light headache, body aches, chill , throat hurt

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Pfizer-BioNTech COVID-19 Vaccine EUA: Systemic: Anaphylaxis, Fainting

On the first day shortly mild pain in left arm around 08:00pm exp brief pain in chest that occurred twice and went to bed. I woke up on 12/16 after resting on right side and tried to rollover upon waking up was in excruciating pain. arm around 5am woke up for work couldn't move my arm, barely could dress to put my shirt on on a scale 1-10 rate 7. As a result it was hard to due my daily activities or hygiene. The following day 12/17 pain felt mild and on 12/18 felt no more pain.

0835 the patient was given the vaccine in the right deltoid IM, at approximately 0838 the patient started feeling tingling and tightness in her upper chest and neck. She stated her throat was feeling funny and the back of her tongue felt like it was getting bigger and swelling. The patient did not have any difficulty breathing. At 0845 Benedryl 25mg IM was administered. Patient vital signs BP 156/88, HR 86, R 22, O2 Sat 98%. Respirations were even and unlabored. Patient was observed and within a few minutes stated that she felt better and was no longer feeling the tingling, tightness or tongue swelling. We continued to

observe the patient for 45 minutes after her initial reaction. 0855 Dr. assessed the patient and determined her to be stable. 0945 At time of dismissal, VS BP 125/82, 74, 18, 99%. Patient had no complaints other than drowsiness and respirations were even and unlabored. Patient left by ambulation in stable condition.

Body aches, fatigue and chills day after vaccine and following day, symptoms then resolved

Body aches, fatigue and chills day after vaccine and following day, symptoms then resolved

Pain local site, tenderness at local site, restriction of moving left arm, body ached, headache , Feeling feverish

Joint pain this morning- than itching in different places... some numbness all over my arm.. than at 1pm sudden onset of tachycardia, lip numbness and tongue numbness with nausea. I immediately took 10mg Benadryl. - but bc my tongue was feeling different I had to call 911. Upon arriving in the ER - they checked vitals and found tachycardia. They administered Benadryl 25mg.

Nausea and headache started approximately 21:00. Body aches and chills continued through until 12/22/2020 . On 12/22 I vomited at 7:00 and have continued to have low fever of 99.5-100.0 , chills, fatigue, body aches and headache all over.

Pt received vaccine on 12/17/20 and started experiencing side effects such a dizziness, body aches, nausea and vomiting, and body weakness shortly after. The symptoms got progressively worse as the days went by and pt came to the ED on Tuesday, 12/22/20, since symptoms were not improving and acetaminophen and ibuprofen did not help.

Chest pain, shortness of breath, tongue numbness and tingling

28 HOURS AFTER INJECTION, DEVELOPED BODY ACHES AND PAINS, 99.5 FEVER, CHILLS, SIGNIFICANT FATIGUE REQUIRING ME TO GO TO BED - SLEPT 12 HOURS

Woke up next morning around 6:30 AM the 18th with a few drops of blood on pillow. Nose was dripping blood. Was able to plug nose and stop bleeding within 15 minutes. No further issues that day, however did wake up with dried blood in nose on the 19th. No further issues after that.

"Patient received COVID-19 vaccine at 330pm. Approximately 15-20 minutes later the patient felt well, was released. At around 4:00pm patient then developed ""tongue fullness"" and felt flushed. She returned to vaccine clinic. No reported rash, voice changes, wheezing, shortness of breath at the time she presented back to the vaccine clinic. 153-173 sbp, HR 60; Doctor on call advised to give Benadryl 50mg IM and send to the ER for evaluation and monitoring for 4 hours. Benadryl was given to patient at around 4:15pm. Patient was taken to ED around 4:30pm. Patient requested early discharge from ED as she stated she "" Feels normal now. Requesting DC as she is a nurse and feels better and wants to be with her family."" Per ED note: patient discharged with antihistamines and epipen."

Employee complained of runny nose following receiving vaccination. Dr aware. Follow-up with employee done in the afternoon and employee advised symptom has resolved with no other issues.

significant headaches, nausea, fatigue and local redness/swelling/hard lump/itching.Outcome: Resolved and fine

Few hours post-vax developed headache. Took Tylenol. Went to bed, no symptoms. Woke up with cough and experienced headache and fatigue throughout the day. Seen by NP at Employee Health, below tests performed. Symptoms persisted through 12/18. By 12/19 symptoms resolved.

HPI: 56 y.o. male with no pmhx c/o generalized bruising for 2 days, noticed small blood tinged spots generalized. Gradual onset, severe on severity, no alleviating or aggravating factors. Patient denies fevers, chills, N/V/D, abdominal pain. In ER: Platelet <1. Platelet transfusion in ER. Admitted for Thrombocytopenia/ITP

Fever (102.5), Elevated Blood Pressure, Pulse resting 130 bpm, Red/swollen left arm, General body aches all lasting about 24 hours then all side effect subsided.

About 5 min after I got the vaccine I was on observation and I started getting a rapid, pounding, heartbeat, they waited about 5 min and it started getting faster and stronger, so they called paramedics to take me to the ER. It seemed it could be a severe reaction, I had fast rate for several hours and also broke up in hives while I was at the ER. They did a cardiac workup and noticed I had change on my heartrate according to the EKG they had previously done.

Local pain, heaviness in the arm, soreness for about an hour. Took 500 mg Tylenol. It kind of helped. Took Benadryl before she went to bed. Early this morning, everything felt heavy, felt nausea, mild palpitations, and dizziness. Took Famotidine this morning. Took Motrin and Benadryl this morning also. Having chills. Afterwards a couple hours was able to sleep a little bit. Pain in lymph nodes on the left side under arm by left breast area. Advil helped with the local pain. Having pain at the injection site.

Pfizer-BioNTech COVID-19 Vaccine EUA: Systemic: Rash (other than injection site), Nausea, Vomiting. Rash developed on the rash, per dr doctor, gave one dose of EPIPEN on the left upper leg. rash subsided.

Pt. (employee) reported prior to receiving vaccine that she had an allergic reaction to a measles vaccine as a child - classified as severe. Reaction thought to be related to egg. Vaccine ingredients reviewed with pt. & pt. indicated she did not recognize any ingredient with known intolerance & requested to proceed with vaccination. 20 minutes after vaccination pt. reported feeling like her throat was swelling, Vitals checked, WNL - no difficulty breathing. Continued monitoring for 15 minutes, continued feeling of swelling. 50 mg Benadryl PO given. Monitored for 20 minutes more with resolution of symptoms.

"Employee complained of a ""very mild headache,"" that she attributed to being a little dehydrated. Water given to employee. Symptoms resolved with no other issues."

1. Lip tingling started 20 minutes after injection, lasted about 30 minutes. 2. Mild chest tightness started 14 hours after injection and lasted about 30 mintues.

"Vaccinated 12/21 at 6:00 am. symptoms began roughly midnight. ""horrible headache"". notes that her left hurt badly and difficult to move. Reports she has taken advil and Tylenol and notes that these have been effective. reports still feeling fatigued, but isn't sure if that's related to lack of sleep from the headache or part of a reaction. Arm is still sore, but is not really painful the way it was last night. Still has a slight headache."

After the vaccine, patient said he felt hot. Later that day,he was starting to have muscle aches and then he noticed testicular and prostate swelling. He followed with his PCP and the PCP prescibed an antibiotic; however, patient did not recall the name of it. He is still being treated. He noticed an improvement. He started the antibiotic on 12/21/2020.

facial numbness to the left side with neck and shoulder pain. symptoms only started after 24 hrs

"At 10:30 pm felt sudden loss of feeling in right hand- unable to use right arm. ""Felt numbness on top of forearm-feels like muscles are no longer working."" Went to urgent care on 12/18/2020 (another clinic)- arrived at 0845."

After 24 hours felt tired, achy, arm hurt my head hurt for 48 hrs little longer. Upon waking up on Sat felt same symptoms. Due to patient exposure I contacted Covid hotline for that hospital employees. Then I was informed to go get tested ER for Covid results negative. I had to miss work on 12/21 due to taking Acetaminophen being a hospital criteria couldn't work while taking that medication.

Patient with a reported history of anaphylaxis to several things and carries her own EpiPen. She was brought to monitoring room at 1835 With complaints of cough and at that time had taken two puffs of albuterol inhaler. Patient also reports some medicating with 50 mg of Benadryl two hours prior to vaccine. O2 sats were 99% heart rate 69 and lungs CTA. At 1845 patient self dosed another 2puffs ofalbuterol. At 1845 HR 130 and sats 98%. At 1850, BP 173/139 HR 127. Patient continued to develop a progressive cough and SOB. Consulted Dr. by phone. We dosed with Zyrtec 10 mg po and assisted pt with administration of her own epi-pen. Followed up with ED next day. Pt had been escorted there from vaccine clinic after epi-pen administration and progressive SOB. ED reported pt remained hemodynamically stable and A&O x 4. Treatment consisted of Benadryl 50 mg IV, Pepcid 20mg,IV, solumedrol 125 mg IV, fluids 1L, and racemic epi. Discharged home after 3 hours.

15 mins after the vaccine I had a bad headache and very dizzy blood pressure 168/109 very hypertensive Possibly stoke after vaccine (No stoke) Took ibuprofen Had Tylenol before the vaccine 12/22/2020 slight high blood pressure still

funny taste in mouth, then 5 minutes later throat tingly. was given Benadryl x2 @ 14:35, at 15:04 patient reports no change. At 15:25 top of throat taste only, fullness in throat gone, at 15:35 patient normal and returned to work

Pt experienced headache and dizziness immediately after injection. Approximately 30 mins later the patient began experiencing chest tightness. The patient received 50mg Benadryl and was transferred to the emergency department within about 20 mins.

Fever of 100.2-101.1 (axillary), heart rate > 100 all day, palpitations, PVCs, ventricular bigeminy for 20-25 min (verified with ECG app on apple watch). Symptoms started at 4am (almost 12 hours after receiving vaccine) and lasted until I went to bed at 9pm. I took advil throughout the day and when I woke up at 5am Tuesday (36 hours later) I felt completely normal.

Patient presented for SARS-CoV2 Vaccination, about 15-20 minutes after vaccination patient complained of feeling a little altered but there was no swelling, rash, or any other indication of a reaction, about 5 minutes later the patient had a weird taste in her mouth and was observed to have a wheal forming on her R forehead. She was phonating ok with questionable swelling to her tongue, but airway intact with non-labored or constricted breathing. She was administered 50mg of Benadryl per pharmacist recommendation. She was monitored for an additional 15 minutes (total of 45-50 minutes after vaccination) with resolution of the wheal and no further symptoms. Patient was advised return/ED precautions and she checked in with vaccine clinic staff an hour later (via text) with no further symptoms.

12-18 vACCINATIJON 12-20 0100 LEFT EYE BEGAN TO SWELL, ALSO NOTICE 2 SMALL RAISED BUMPS, NOT FLUID FILLED. RINSED EYE WITH COOL WATER, THEN APPLIED WARM COMPRESS. 12-20 IN MORNING WHEN SHE GOT OUT OF BED BOTH EYES WERE SWOLLEN W/ DARK CIRCLE BELOW. 12-20 LATE MORNING, EDEMA SUBSIDED, EYES NORMAL. 12-20 LATER IN DAY, TOOK BENEDRYL FOR SEASONAL ALLERGIES. 12-21 NO ISSUES 12-22 1300 BOTH EYES BEGINNING TO SWELL AGAIN, L MORE THAN RIGHT.

"staff member/ pt. had vaccine at 1500, no prior allergies. after 15 min observation, staff felt ""weird"" but returned to work in building. approximately 5 minutes later felt lightheaded, dizzy & became flushed & diaphoretic. returned to vaccine clinic for observation. was found to have BP of 143/103 on a normally normotensive person.HR 70. Provided recliner, rest & monitoring. BP decreased to 128/85 after 1 hr. of monitoring. pt continued to monitor BP and self medicated at home with Benadryl & Ativan (unknown dose). Continued to feel disoriented and unwell X 48 hrs."

Speech difficulty and bilateral lower extremity tingling and numbness after COVID-19 vaccine administration. Symptoms improved at ED with IV Hydration

12/20/2020 Fatigued, brain fog, 12/21/2020 extreme fatigue and was sleeping more than normal, diarrhea, low grade fever 99.2, 12/22/2020 around 3am woke from sleep with a really bad headache, patient stated taking Tylenol to help with symptoms, never tested for Covid however she lives with her brother who had Covid in May, no travel history

"7min after vaccination ee developed ""dryness , heaviness and need to clear her throat""-- Just on the right side of throat"" 25 mg ofBenedryl given-- symptoms resolved."

Started feeling chills night of receiving vaccine, then dizzy 4 days later, with severe nausea. Still not feeling well, queasy, dizzy.

Reports within 15 min of covid vaccine she had facial pressure, throat tightening, headache, light headed, increase in BP-179/123

15 minutes after injection: headache, 10.minutes after injection: flushed skin, rapid heart rate - taken to the ER where she developed SOB, Chest heaviness, nausea, tingling in the hand- Treated with Benadryl, Pepcid, Solumedrol, Zofran, Elevated heartrate, BP stable, no O2,normal EKG 1445 client released from ER

tongue was tingly, woozy and nauseous 10 minutes after receiving injection. Drank Apple Juice and symptoms subsided about 10 minutes later. I also took Benadryl when I got home 20 minutes later. Also, left arm is sore.

flushed, tingling in face

"fatigue, light headedness, low grade fever of 99.0, nausea, ""foggy"" headed, dizzy"

Employee reports nausea, fatigue, muscle pain and feeling hot denies fever

Severe headache chills, body aches, arm pain, Nausea, fainted on standing, dizziness

Pfizer-BioNTech COVID-19 Vaccine EUA Within 5-10 minutes of vaccine, burning and tingling sensation started in chest, moving into throat, tongue, mouth, nose, and ears. Flushing sensation and red ears. Increased heart rate, resolved after a few minutes. Was treated in the ER and released from hospital. EKG and vitals were checked, no labs drawn. Occasional burning and tingling sensation but resolves within a few minutes, mainly in chest and tongue. Occasional symptoms ceased in about 3 hours.

nausea, colic, diarrhea

Reports after covid vaccination while she was driving home she experienced swelling of the tongue, dry mouth, legs twitching, and diarrhea. Went to ER for treatment.

Patient started with tingling in hands/lip approximately 10 minutes after administration. Tingling in hands/lips worsened and pt started to c/o tongue swelling. Epi and IM benadryl were administered and a rapid response was initiated.

Had symptoms after shot of: electrical shooting pain down legs, chills, dizziness, fatigue, profuse sweating.

Really bad headache. She was fine when she was sleeping but when she was awake it was bad. Still has a small headache but not as bad as the first day.

Patient describes feeling hot, clammy and lightheaded about 5 minutes after vaccine administration. BP:109/69 P:72 O2Sa:100% Patient states that injection site feels ok. Got patient a juice and had her sit for another 15 minutes. BP: 118/63 P:74 O2Sa: 99% Patient has normal hand and arm strength bi -lat. After patient had cold juice and was able to breath without her mask on she felt much better. Patient

was able to stand and walk without dizziness. Patient stated the she did not feel she needed further treatment.

Patient felt lightheaded and dizzy. She was seen to by a nurse on staff and by Dr. After laying down for a while, patient felt better and wished to return to work. When contacted to following day, she said that she was feeling better, but felt a bit foggy the day before.

Tachycardia and poor taste in the mouth

Approximately 15-30 minutes after receiving the vaccine the patient reported numbness on the left side of her face. Also reported intermittent tingling in fingertips of both hands and feet. Prescribed a medrol dose pack that evening and had taken one dose. By 0630 today (12/22) reported that the numbness was 95% improved.

"A 36 year old FEMALE who received Covid 19 vaccine today at 1009, started c/o mild lightheaded and ""tingling throat"" at 1026 am, nurse notified this provider. NOTE: This is a late entry due to documented reaction was on paper and not available for documentation at the time of adverse reaction complaint. Oral hydration, patient stable, symptoms subsided at 1037. Employee discharged to work station."

Employee reported to the employee health clinic 3 days after receiving the Pfizer COVID vaccine and had complaints of a 30mm indurated area on her right arm. She states she vomited once that night and had a headache. Took Tylenol and seemed to help. Encouraged employee to apply cold compress to arm and notify if symptoms of arm swelling get worse or any new symptoms of a reaction arise.

complaints of general itching of arms - resolved in 5 minutes. HR 80 and regular, No rash. Treatment of clolse observation for further symptoms x 10 minutes. No medication treatment required.

Pt developed throat tightening, shortness of breath, hives on the anterior chest after receiving COVID-19 Pfizer vaccine. She received vaccine around 9:15 AM and symptoms began at 9:28 AM. Received epi pen by vaccination station staff. Reported to ED. Observed for 3 hours with no further adverse effects. Treated with steroids, Pepcid, Benadryl. Discharged home with epi pen, medrol dosepak, and allergy/immunology follow up.

Pain and numbness in the left arm From the shoulder to the fingers. Cannot raise arm, nor leave it down. Relief with a sling. Also, to manage pain, she is taking Tylenol every four hours. By medical order she started diclofenac potassium 50 mg tablet.

fatigue,fever 99.5F and cold sore

Metallic taste onset within 10 minutes of injection

About 5 minutes after the vaccine was given patient describes numbness and tingling from injection site to pinky and that lasted about 5 minutes. Patient started feeling a flush/warm feeling across chest about 15 minutes after vaccine. No dizziness or lightheadedness. Flushed feeling lasted about 30 seconds.

Patient feels much better after 25 minutes of waiting time. She states she does not require any further treatment.

Hot Flashes and headache, patient reports that she feels weird and not herself. No spike in actual temperature reported.

Received Covid Vaccine on 12/18/2020, 72 hours later on 12/21/2020 had left sided tongue numbness.

Chills, fatigue, left arm soreness, joint pain, temp 99.1

My throat was swollen and sore, a rash on face and neck, runny nose, lost voice, SOB

12-18-2020 SLEEPY FELL ASLEEP 3 HOURS POST VACCINE ADMINSTRATION, THAT EVENING HE WOKE UP WITH HEAD HURTING. SLEEP A LOT ALL WEEKEND . DEVELOPED COUGH 12-22-2020. RECIPIENT STATES HE HAD MIGRAINE TWO DAYS PRIOR TO VACCINE ADMINISTRATION. RECIPIENT REPORTS HE TAKES PERCOSET FOR BACK PAIN AND IT HELPS MIGRAINES. COUGH CONTINUES AT THIS TIME 12-22-2020.

0850 Client came in to receive COVID-19 Vaccine sent to observation for 30 minutes due to allergic to latex. At 0855 client started itching and breaking out in hives, complaining of shortness of breath and scratchy throat. Nurse escorted client to ER, where client received IV fluids, Benadryl, Solumedrol, Pepcid.

anaphylactic--started with mild itching, progressed to throat tightness--patient was given IV Benadryl, Pepcid, Solu-Cortef, Epi-pen x 2, oxygen

I was at the observation area and all of a sudden I started rapidly coughing and my throat felt itchy. I notified the nurse and she started observed me. The back of my tongue started feeling weird. She then hit me with an epi-pen as a precaution. Because of that I was moved to the ER for observation for 2 hours to make sure everything was ok. After the epi-pen all symptoms went away. Before I left they drew labs to check if I was having an allergic reaction. And the results came next day and it was 0.

pt had reaction of mouth and BIL cheek numbness, SOB, chest pain, sore throat irritated throat , chest pain approx 20 mins after vaccine was given. Pt was monitored and EMS called, pt was stable after 45 mins EMS directed her to return home.

Left facial numbness and tingling.

PT WAS OBSRVED IN HOLDING AREA LEANING FORWARD IN HER CHAIR ABOUT 7 MINUTES AFTER RECIEVING THE VACINE. RN ASSESSED AND NOTED: AUDIBLE WHEEZE, RESP 40/MIN, LIP SWELLING AND PT COMPLAINED OF NAUSEA. PT WAS ESCORTED TO ER IN WHEELCHAIR ACCOMPANIED BY 2 RN'S (2 MINUTE WALK) ONE HOUR LATER - AS REPORTED BY DR (ER) WORKING DIAGNOSIS - ANAPHYLAXIS / STATUS ASTHMATICUS MEDS RECIEVED: SOLUMEDROL 125, DIPHENHYDRAMINE 50MG, FAMOTIDINE 20MG --ALL IV EPINEPHERINE 0.3MG IM X1 FOLLOWED BY 0.3MG IV X 1 FOLLOWED BY 0.1MG IV X1 PT IS RECIEVING O2 - AND PROGRESSING TO BIPAP

soreness in L arm-2 days, back pain 1/2 day, chills 1/4 day

Lymph nodes are swollen on the left side It sore and tender on the left side

Patient reported becoming dizzy 12 minutes after receiving injection. Patient felt like she was going to faint. Patient was placed on floor with legs elevated and given a snack and a sugary drink. Felt better left facility and called in reporting when she got down to go inside her home she had a repeat episode of vertigo.

Fever to 100.2 with chills lasting all day very sore arm, fatigue

Complaints of dizziness with chest tightness.

Chills, body aches, diarrhea about 24 hours after vaccine. Cough, severe headache, temp of 100.0 started about 36 hours after vaccine and are still present

Patient refers to itching and rash. Refused treatment. The event occurred approximately 35 minutes after administration of vaccine.

Left arm NumbNess going from the forearm to the side of his Neck. Chills and slight HA. No fever Noted.

Per report from LPN monitoring patient--complaining of chest tightness and anxiety. 02 sat 99, Pulse 67, BP 114/83 and repeated at 126/94. Monitored for 30 minutes, patient continued to report symptoms. Monitored for additional 15 minutes. Patient left clinic with improvement in symptoms.

Vaccine administration site was above the deltoid.

mild swelling and tingeling sensation of the lips. No significant swelling.

Sore Arm

left leg feels heavy, headache, body ache, upper back pain.

Headache Sore arm

Day 5 started having hives on arms and inner thighs

pt after receiving vaccine, felt tight chest, difficulty breathing. 25mg Benadryl po. pt hypertensive 160/100. pt remained hypertensive and with chest tightness and CP. EMS called. EKG done. EMS found no need to go to ER at this time. Pt remained in observation then d/c home with friend.

I got very sweaty and hot feeling, nauseated and light headed, my BP and O2 were stable but got a little tachycardia, it passed after I laid down for a couple of minutes but once I stood up again the symptoms returned. That is why they sent me to the ER. Also had tingling in both hands. I recovered in about 2 hours (I had covid in early november)

@ apprx 1315 patient started feeling heartbeat beating fast, then racing. States she felt hot, dizzy, ears were ringing-the ringing resolved upon being seated. Patient was given 25 mg liquid diphenhydramine

(and seated with legs elevated- back of exam table elevated to an approx. 60 degree angle). HR 109, BP 144/87, afebrile, o2 sat 100% on room air.

A dry metal taste in mouth, Sore throat, Tired, Sore arm

Developed itching to lips and left arm 10 mins after injection. Benadryl 25mg oral given. Symptoms progressed to tongue and mouth itchiness. Pt transferred to ED for further eval and care. IV NS famotidine and methylprednisolone given. Discharged home.

1406, Monitored pt 1:1. She reported feeling fine for the first 15 minutes then reported itching involving her face but not forehead. Gave 25 mg IM diphenhydramine. pulse ox Reading was wnl. Within 5-10 min after diphenhydramine pt reported itching involving her arms, facial flushing but no shortness of breath. extra 25mg diphenhydramine IM given and Epinephrine IM administered. medical director notified. Dr. came and assessed and monitored patient. Symptoms resolved while on site. Pt escorted by medical colleagues to workplace ER where she agreed to stay for further monitoring. Dr followed up with pt later in the evening and she was doing. Patient updated progress December 20, 2020. I have had continued symptoms since Thursday though initially I felt that they were just typical post-reaction type symptoms. Thursday night I just had some itching and occasional hives. Friday I woke with a terrible headache and could not lift my left arm above by head due to pain but figured that these were vaccine effects. I had intermittent hives and itching that I was able to suppress by taking Allegra, Zyrtec and Claritin (each once) throughout the day. I was also taking Pepcid at night. Saturday, I tried to decrease my antihistamines to just Allegra BID, Pepcid once and Benadryl just last night. I woke with hives and worse itching again. I also appeared to have what looked like eczema on my hands that was new. So I took Pepcid and Allegra prior to going into my shift this morning. I took Zyrtec around 9 am as I had not yet had any improvement in my hives or itching. My co-attending noted that I was progressively becoming more flushed and around 11 am I started to experience an odd sensation in my throat with a persistent cough. My vitals were normal (HR 75, sat 98%, BP 113/78), so I talked the other attending out of more epinephrine and she prescribed me dexamethasone 16mg. I took the dex plus a Claritin at noon today and by 2 pm, had resolution of all of these symptoms. I also noted that my chest felt significantly less tight and retrospectively think I have been experiencing chest tightness and pressure since Friday but hadn't realized it because it occurred gradually. As of December 21, 2020, patient was to start prednisone 40 mg daily x 5 days.

Pain in arm of injection site including numbness and pins and needle tingling in the lower arm and hand, loss of feeling in hand and loss of sensation and strength; difficulty holding onto objects. Dizziness and weakness, severe joint pain. Throbbing Headache.

Felt sleepy, Took a nap woke up around 8:30 pm. Felt nausea. Drink 7-up Laid back down. Woke up still felt nausea. Drink another 7-up, felt sick to your stomach. No appetite. Felt really nausea. Still felling nausea.

Visible hives twice, and stinging eyes.

"Patient complained of ""racing heart beat, dizziness"" BP noted 141/92 P104 oxygen 99 repeat temp 97.6 BP 145/89 P96 repeat BP 145/95 Pulse 104 taken to ER for further evaluation and treatment. Temperature rose to 101 while in ER. Patient reports symptoms resolved approximately 1 1/2 hours after injection ""feels fine"" now Discharged home steady gait."

Dizziness

"Pt returned to her work area. At 1314 - Team member was taken to the ED. She reported feeling like her tongue was swelling, she attempted to each chips and felt like her throat was sore and needed to be cleared. Pt had a syncopal episode and c/o chest pressure, and difficulty swallowing (able to control secretions). Hives were noted to her face, neck & chest upon arrival to teh ED. At that time - pt reported feeling like her tongue started swelling 15 minutes after the vacciation. Pt was confused and ""extremely"" anxious. VS: 209/102, HR 125, RR 30 SaO2 96% r/a 1321 -diphenhydramine 25mg IV, pepcid 40mg IV and IV NS started VS: 159/105, HR 118, RR 31, SaO2 100% r/a 1322 - epinephrine 0.3mg SQ, Solumedrol 125mg IV 1332 - Zofran 4mg IV 1351 - Ativan 1mg IV 1359 - 128/91, HR 100, RR 22, SaO2 99% 1411 - pt calm- redness improved. still c/o of feeling something in her throat. 1441 - Calm, asking for a drink - tolerated well. BP 110/72, HR 82, RR 18, SaO2 98% 1635 - d/c orders written."

Dizziness and headache , Sore Arm

I had a headache, body ache, chills, fever, sore throat, cough, fatigue.

Anaphylaxis/Angioedema Patient was given EpiPen 0.3 mg IM; Methylprednisolone 125 mg once; Diphenhydramine 25 mg IV push once; Famotidine 20 mg IV push once; Dexamethasone 10 mg IV push once Patient was intubated and put on propofol and midazolam drips for sedation

PT REPORTS A FULL FEELING IN HER THROAT - PT IS AN MD AND DESCRIBES IT AS GLOBUS

Approximately 48 hours after the vaccination was received I developed moderate headache, body aches,chills, dizziness and nausea and was completely bed ridden.I was unable to complete any activities or work. On day two, the dizziness and nausea worsened and I began vomiting. On day 3 of symptoms, I was able eat, sit up and walk around, but still have moderate headache. I also developed diarrhea on day 3.

at about 3am (15 hours after vaccinated), I had the chill, I was freezing from the shoulder down. I had to put on 2 coats and 3 blankets because I was shaking/tremoring. also, headache and body ache. I whole body is hot and my back felt weak. the chill was more apparent toward the night.

High temperature up to 103.2F. Hypertensive episode 165/105 with temporary blurry vision. Three days of high fevers otherwise 101-102 despite alternating Tylenol and Ibuprofen every 3-4 hours and hydrating. Also had an additional episode of hypertension with blurry vision when I wasn't febrile.

continous nose bleed - unable to stop it.

Can't taste or smell is off

States had generalized itching and ask for benedryl. 50mg Benedryl Tablet given PO after 10 minutes ask for Pepcid. After 15 minutes states he feels better and issues resolved

PARASTHESIA IN LEFT ARM - ARM THAT INJECTION WAS ADMINISTERED IN - LASTING LESS THAN 1 MINUTE WITH SPONTANIOUS RESOLUTION - PT IS AN MD

Patient had a temperature of 100.2.

Sore arm last evening (no more than a flu shot), this morning I got tired around 11:30 after a full night of sleep and ended up taking a nap during lunch. I woke up feeling foggy and went back to sleep after finishing my work for the day and slept for over 3 hours, woke up and continue to feel very foggy

Shakes(chills)/ Tachycardia/altered mental status/sent to the hospital for evaluation

After injection had L arm pain, the following day (12/17) pain continued . 12/18 onset of fever max temp 38, chills, fatigue, muscle pain and nausea. Treated with Tylenol for symptom relief. Symptoms continue and worsened 12/19 and 12/20. 12/20 underwent video clinician visit for symptoms and inability to return to work for continued symptoms 4 days after vaccination, last day of fever. 12/21 covid and flu swab negative symptoms all continued fatigue very evident going to and from swab exam. 12/22 morning near syncope while getting ready for day, tachycardia, underwent ED eval was given fluids and labs drawn and discharged home with improvement in tachycardia and lightheaded/dizziness with fluids, another covid swab was negative along with negative RVP. Continued to have fatigue 12/22 evening.

Patient had a fever of 99.1.

Fever 100.6 24 hours after vaccination , Headache chills and body aches, muscle ache .

12-19 Received Vaccine @ 0930 12-20 Did not sleep well, woke up and was dizzy, nauseaous; this has been constant.

Received vaccine around 10:40 am, by 10:50 started to feel dizzy, eyes felt full, dry, tingly, swollen, voice became raspy and throat itched. Received 25 mg Benadryl PO at around 10:55. Face, arms, chest and abdomen developed a fine red itchy rash, tongue swollen and itchy, lips tingling, wheezing, blood pressure elevated, pulse thready given 25 mg PO Benadryl, taken to the Emergency Room, symptoms persisted, stomach hurt became nauseated, received IV solumedrol, Pepcid, IV fluids, nebulized albuterol. Sent home once stable after 3 hours, with instruction to take Benadryl every 4-6 hours fir the next 2 days, albuterol as needed, and prednisone for the next 5 days.

Swelling left deltoid and left neck followed by feeling of throat closing. began 14 min after administration; Code Assist called and taken downstairs to ED; received epinephrine, Solumedrol, Benedryl. Prescribed prednisone and Pepcid 40 mg bid .

Pfizer-BioNTech COVID-19 Vaccine EUA within 5-30 minutes: dizziness, weakness, palpitations, chest tightness, injection site pain, left arm numbness and weakness, headache, nape pain, drop in BP, high

BP, left shoulder and elbow joint feeling like to be detached. Sent to Hospital ER, was given Zofran and Ativan

During 15 observation period I developed tachycardia rate in the 140?s. Hypertension 180/100. Rapid response was called and sent to ER. I also became flushed, chest rash, chills low grade temp 99.4. I was given a 500cc bolus of Normal saline. Benadryl 25mg IVP and my morning dose of carvidelol 6.25mg. On discharge Bp was 102/ 74, Hr 76.

Pt hx of DM Type I, HTN, reported pruritic uritcarial rash 5AM 12/21/2020 inner wrists, anterior distal LE bil. Resolved aprox 30 mins later. Urticaria recurred mid day 12/21/2020, pt treated with Benadryl 25mg PO, resolved. Urticaria returned evening of 12/21/2020 wrists, axilla, nape of neck. Pt treated with Benadryl 25mg PO, resolved. Urticaria returned 5AM AM 12/22/2020 similar distribution as evening of 12/21/2020. No air way or facial involvement. Pt treated with Benadryl 25mg PO, urticaria resolved. Sought medical eval 12/22/2020 around 10AM: no sx nor urticaria present. 1:30PM 12/22/2020 after eating lunch pt called to report recurrence of urticaria now involving face, lips tingling, itchy back. Administered 50mg Benadrly IM, observed, urticaria/pruritis resolved x 45 mins. Urticarial sx and lip tingling returned in 2 hours, pt transferred to ED for treatment with epinephrine, steriods, observation.

Headache, stomach problems and body aches.

Chest pressure and headache followed by generalized itchiness and hives. Progressed to facial swelling and airway swelling. Treated with EpiPen x1 IM, 50 mg diphenhydramine PO, 20 mg famotidine, and 10 mg dexamethasone. Immediate reaction improved. Itchiness and intermittent hives continued. The headache continued along with other common/expected side effects of vaccine.

On 12/16 about 10pm I began having arm pains and took tylenol. 12/17 woke up feeling exhaused with severe body aches, headache and a 101 temp. I went to work but had to leave because I just wasnt feeling good. On 12/18 I went back to work but could not perform so I had to leave again and was still experiencing the severe body aches and headaches but no fever. I was suppose to work on both 12/19 and 12/20 but had to call in. On 12/19 still same symptoms with no fever but around 5pm I began to have palpations and heart racing which caused me to go to the ER. I was given fluid and labs was done and monitored for a few hours and was released after the fluid was given. On 12/20 felt pretty good still tired and exhaused feeling and on 12/21 I felt good but later that evening I noticed my forearms began to feel stiff, tingly and heavy. My hands began to feel stiff and is very sore. Continue to feel very tired with body aches and continued to take tylenol. This morning I felt ok but after fixing breakfast the symptoms came back and they feel like the same symptoms I had when I had the vasculitis in 2009-2010 and that concerned me so I discussed it with a Neurologist and Immunologist who I will reach out to after the holidays to schedule an appointment. I have an appointment scheduled with my PCP for additional labs on tomorrow 12/23 and I have not been able to work since getting the vaccine. My hands feels clumsy and I am constantly dropping things since yesterday

"Pt with dizziness and chest pain that started about 10 minutes after getting the Moderna Covid19 vacccine. No shortness of breath, no rash, no fever, no swelling, no weakness. Feels pain in center of chest and on L side. Pt also has been having stress with work. Pain started in the R side of the chest and

migrated to the L side. It improved with Nitro and Aspirin but pt states he still feels, ""fussy."" He has no symptoms of allergic reaction or anaphylaxis. Pt has no known hx of cardiac dz, nonmoker, nondrinker. His Mom has a cardiac murmur but no other known history of heart disease."

I have face numbness, a nose bleed

headache, injection site sorenesss, nausea (moderate), fatigue (moderate), body aches/chills (moderate), temp 99.4 deg, notified employee health, had a Covid test (came out Negative), sent home for the day.

30 mins later I became completely dizzy, flush and had hard time focusing. I was placed on a gurney and blood pressure was taken. 158/103. Usually runs 110/60. Was told to go to ER but I declined. They monitored BP for about 45minutes. I then went home and did same thing. BP stayed high for two days. With headache. I stayed on the couch for those days. Monday I went to work because blood pressure was down. But now my HR is up. Highest in 130?s I felt a little dizzy. I had stomach upset and nauseous with mild headache. Left arm pain Today Tuesday as soon as I exert myself my heart rate goes up. I have mild headache

Red hives under chin, on neck, and on chest beginning 30 minutes after dose and lasting approximately 1 hour.

This nurse was notified that the worker was having tachycardia post vaccination. The worker had a baseline HR of 75 while at rest, per wrist band monitor belonging to worker. Worker's HR steadily increased as high as 94 BPM. The worker was shaking and the worker complained of throat not feeling right and dizziness. Worker described their throat as feeling tight. This nurse brought the worker to the back area of the clinic, asked the observer to initiate a MET, and this nurse went to med room and took an EpiPen from the box. This nurse administered the EpiPen into the right thigh at 1600. by 1604 the MET team had arrived. The MET team spent 20 to 25 minutes with worker. The MET team included two PICU physicians, one being a fellow. This nurse was advised that the worker was asked if wanted to go to the ED (by the worker) and worker declined. This nurse agreed to observe the worker until the close of clinic at 1730. Vitals take at 1720 were as follows: 89 HR, 94% O2 sat, 124/66 BP (RUE), 16RR. Worker was no longer feeling dizzy, no throat symptoms, and refused ED observation and went home. Nothing further reported.

itchiness in throat, mild tongue swelling. Administered Benadryl 50 mg. sx resolved 5-6 minutes after medication administered

Tingling in head, headache, mouth, itching

1015 c/o chest heaviness, scratchy throat, heart racing states injection site feels warm. taken to cot to monitor VS 173/86 P 126 RA100 States worked last night, drank Monster drink, tired and little anxious. 1020 states sx are decreasing VS 143/85 94 100 RA sitting up drinking juice and eating granola no distress noted 1035 states throat is little scratchy still given Bendadryl 25 mg PO per VO Dr. no distress noted, very calm states some chest heaviness 1/10 pain scale denies any other sx at this time sitting on

edge of bed 1048 BP130/73 87 100RA pain 1/10 chest discomfort decreased, denies HA, SOB, states throat still little scratchy but not bad at this time denies any pain at site. Site is warm to touch denies any pain at site no redness noted at this time 1100 BP 125/79 82 100 RA denies pain 0-1/10 sitting up states feeling much better denies pain in chest, minor scratchy throat but relieve 1115 Monitored for 60 minutes released to girlfriend given instruction to go to ER if any other sx.

Fever of 102 degrees F, chills, body aches, extreme fatigue, headache, weakness. Started at 10pm 12/18/20 and ended at 10am on 12/20/20.

6 weeks pregnant HCW, states she received COVID vaccine on 12/19/2020 around 1400 and at around 2200 last night started to have migraine headache and neurological symptoms , claimed that she couldn't find words to complete sentences and having numbness on the R hand- patient went to ED- per patient symptoms resolved after less than an hour. Now she is concerned if she should take the second dose,

Headache Dizziness Muscle pain (not injection site) Mild shortness of breath

Itching, shortness of breath, throat hurting

Syncopal episode

Lips tingling and burning, top and bottom. no visual effect. no redness or swelling

Swelling, Tenderness, Redness at Injection Site

warm all over, headache, feels like something in her throat

12 minutes after injection, patient started experiencing jaw discomfort on the left side with sharp intermittent pain in the left ear

On second day developed marked headache and nausea, very mild disorientation I went to office to try and sleep it off. Headache got worse so went home to bed. 5 hours later I am feeling much better

1046 states feels nauseated brought to cot to monitor VS 130/74 HR 86 99 RA site cool to touch denies pain at site just states very nausea. States she had breakfast and had fluids this am. given OJ and crackers per her request. denies any pain or other issues at this time 1056 129/75 81 100RA states feels better just needed the crackers denies any more nausea does state has a small headache starting but not bad 2/10 1110 125/68 78 100 RA denies any more nausea and headache is subsiding . She will go to ER if any more sx released at this time. 1836 called to check on pt states she was a little tired the rest of the day denies any more nausea or HA . Instructed to go to Er if any other sx occur.

Patient was dizzy at vaccine clinic and was taken to ER as a precaution. She left the emergency dept before being seen, stating she felt fine.

EMS called after patient displayed a heart rate of 160, a little over an hour after vaccine administration. Patient was taken to the hospital and diagnosed with an episode of RVR Afib; she was admitted to the hospital.

Patient experienced bronchospasm with coughing and tongue itching approximately 10 minutes after the injection.

1126 states felt funny VS 86/63 HR 79 100 RA taken to cot to monitor/evaluate denies any pain or discomfort only just weak and funny, requested drink of water and leaned back on bed 90 degree angle noticed she was not focusing 1130 VS 78/45 58 100 RA taken to ER via WC due to Hypotension. 1830 LM for her to call me on her cell for follow up

Urticaria on bilateral extremities, chest, torso, and neck No shortness of breath, closed airway, or any other signs of a severe allergic reaction

After 5 minutes of the vaccine, I felt lightheaded, pulse got week, tongue tingly and slightly swelling. The ER doctor at the vaccination site administered an epi-pen and I got sent to the ER via rapid response, received 15 liters of oxygen for 1 hours, rapid shallow breaths respiration in the 30'. 2 hours later received decadron orally then observed for 1 more hour. Symptoms resolved and went home. The following day, I woke up with a massive headache and lightheadedness.

"Per patient, she had received the COVID vaccine at her workplace and developed 30-40 minutes later symptoms of throat tightness, chest tightness and difficulty swallowing and was given at her workplace in the ED oral Benadryl, oral Decadron and IM epi. About an hour and a half later she developed symptoms of recurrent throat tightness and was given another dose of IM Epi and was then transferred to this hospital for further evaluation as per the patient ""all of her symptoms are pretty much ""unchanged""""". She was observed for many hours in the ED without evidence of recurrent symptoms and was later discharged with a 3 day prescription of prednisone and prn diphenhydramine for itching."

"1600 Patient c/o itchiness to neck and face felt on coming rash 1625 notified me of reaction, advised to take Benadryl 50mg 1630 notified Pharmacist of reaction 1645 follow up with patient ""doing okay"" 1700 follow up call feeling the same not worse, leaving work for home, aware to go to ED if symptoms worsens"

Warmth tingling on tongue and Lip 15 mins after vaccine Accelerate heart rate 120-130 7 hours after vaccine accelerated heartrate 120 10 pm 5am 12/19/2020 Heartrate of 100 12 Noon 12/19/2020 Heartrate of 100 12/202020 10 am Accelerate heart rate of 100 12/20/2020 5 pm Accelerate of heartrate of 100 oral Benadryl 25mg in the ER

"Patient was vaccinated on 12/20/2020. Four hours later, she felt dizzy at work. Her BP was 92/68 (normal BP 110s), also c/o""hot flashes"" (LMP 12/16/2020), and headaches. As the day went, she started to have sore throat, runny nose, dry cough, body aches, and neck pain. Her temp was 98.6. Denies SOB, swelling of the neck. No problem with wallowing. Still has dry cough, HAs, bodyaches, neck

pain, and off and on dizzniess. This is not normal for her. She is scheduled off from work on 12/21/20 and 12/22/20. Not well to return to work."

"began to have a ""foggy head"" feeling and then started to feel chest pressure - was NOT short of breath"

Patient felt heart racing immediately after getting vaccine. Vital signs taken: BP163/84 P:150 O2Sa:100% Patient felt hot flush all over face. Got patient ice water and had patient call for a ride home. Friend is coming to get her. Vitals taken 1802: BP: 147/116 P122 SaO2: 100% Patient sitting resting. Vitals taken: 1809: BP 156/90 P:113 Sao2:100% Patient started having chills - warm blankets given. Vitals taken 1820: BP: 138/94 P: 109 SaO2:100% T:98*F Patient resting in chair. Friend arrived to provide ride home. Vitals taken 1830: 142/84 P:94 SaO2: 100% Vitals taken 1850: BP:127/87 P:102 SaO2: 99% Patient did state that she has been under extreme stress with the death of her husband in November. And today was her first day back to work. Had patient stand and walk around a little, no dizziness noted. Gave her some pretzels to snack on and after 5 minutes she stated she was feeling almost back to normal. Patient's friend is an RN and was going to have patient spend the night at her home. Patient stated she did not feel she needed to see a provider and felt that she would be ok in her friends care.

Swelling and redness around the injection site immediately after injection at 10:50 AM, 12/22/20. Site was slightly raised with erythema, about size of a quarter (coin). Symptoms lasted >5 hours after vaccination; still ongoing at time of writing (3:18 PM). No other symptoms noted. Patient monitored for 30 minutes post-administration and line drawn around area with swelling to monitor for growth/worsening.

1000 came back to the clinic from her department states just feels fuzzy/dizzy taken to cot VS 109/77 72 100RA denies any other issues witnessed far away gaze when talking with her . She states got back to department and just didn't feel right and had a bit to eat and drink and told coworker and they brought her back down to the clinic. She was monitored as denied any pain 0/10 or any other symptoms. 1010 112/60 70 100 RA denies any pain A&O times three able to focus no more distant feeling 10/20 114/78 72 100 RA denies any pain A& O times three denies any pain, nausea SOB, chest discomfort at this time 1030 116/76 75 100 RA denies any pain states she is not fuzzy or disoriented at this tiem feels much better but just feels tired. instructed to monitor herself and if any issues to go to ER. states she will comply. 1833 spoke with pt states went home slept and is feeling much better just felt fuzzy and disoriented for that hour after the vaccination.

Flushing 3 minutes post injection. Did not report at center because I attributed it to it being very hot in the injecting center. 30 minutes post vaccine I began to have body flushing starting in my chest spreading to my face through my torso, down arms, and legs. , dizziness, clammy hands, nausea 1 hr post vaccine with facial tingling, jaw constriction, and palpitations. Pulse was not elevated, but never had difficulty breathing, wheezing, swelling, or rash. Flushing continued, Benadryl taken 1.5 hours after vaccine with relief of symptoms. Symptoms returned around 7pm which was approximately 9 hours post vaccination. Benadryl taken again.

began to have a burning sensation inside body & felt light headed

Fever to 101F, which resolved with acetaminophen 625mg PO and did not recur. Flare of existing hidradenitis lesion in left armpit, resulting in 24 hours of pain and drainage. Within 24 hours returned to baseline condition.

At the time of the injection, I felt dizzy about 5 minutes afterward but I went away rather quickly. I also started coughing, but as I have asthma and I was rather anxious, I used my inhaler. I did mention I had felt a little dizzy at the appointment but it was going away. Then, around little that same night /the next morning (12/20), I got a little short of breath and chest tighteness, but nothing major. Around 2pm that day, the tightness got worse and my inhaler stopped helping as much and I got a cough. Then, around 3 am today (12/22), I woke up with chills but no fever and nausea and threw up several times and then it went away. Around 6pm tonight, I was taking a nap and woke up with what I think was sleep apnea. I felt like I wasn't breathing quite right, and like it almost hurt to breathe because my chest was so tight. I checked my oxygen levels while sitting quietly, but not laying down like I was before and they were 95-97%. Chest tightness remains and is worse than before, breathing is ok. I have a lot of muscle pains and body aches, some cough, and very mild phlegm. No fever. I did not go to see a doctor because I don't have health insurance right now and I don't want to pay for the bill.

Vaccine received 12/18/20. Experienced fatigue, chills, body aches, fever on 12/19/20 ~3pm. Temperature ranged 101.3-102.6 deg F. Reduced with Tylonel. Temperature 12/20/20 ranged 100.5 deg F down to 99.5 deg F by end of day with no antipyretic medication taken on 12/20/20.

BEGAN TO HAVE ITCHING ON TOP OF HEAD APROX 20 MIN AFTER INJECTION - TOOK BENADRYL 25MG PO

Tachycardia 124- 132 started 10 minutes after vaccine. Resolved spontaneously about 2 minutes later

Joint ache Chills

Patient received Moderna COVID vaccine at 1926. She completed standard 15 min observation time and was dismissed from clinic. Patient returned to clinic at 2000 with redness at injection site, itching, chills. BP 126/90 and pulse 86, patient able to speak comfortably. Diphenhydramine 25 mg given orally. Patient observed for 36 minutes. All symptoms resolved and observed redness to left deltoid completeely resolved. No complaints of shortness of breath or difficulty breathing. Patient discharged from clinic to another facility with appropriate follow up instructions. Patient texted ahead to her preceptor that she is en route.

Severe pain at injection site Left upper molar tooth broke off

patient felt slightly nauseated at 10 minutes after injection, then developed slight sweating; BP 160/81; 83 at 5:45 and then 158/87 with HR 82 at 5: 52 pm. Her lungs were clear, she was speaking in full sentences and was denying any chest pressure, her usual sense of asthma exacerbation. At 6:05 it was 164/83 with HR 79 and patient developed a dry cough; we decided to have her wait just a bit longer, then cough worsened, so at 6:25, decision was made to have patient seen in ER for further assessment, and en route in wheelchair to ER the dry cough became persistent, spasmodic and patient was unable to

speak. Epi-Pen was injected in right mid thigh, and patient transported to ED urgent eval. She noted immediate palpitations, and slight improvement of breahting, was able to speak in four word sentences. On arrival to the ED, patient was administered Duonebs, Albuterol neb, IV Benedryl, IV Solumedrol; CXR was obtained, with results pending. Patient was sent to observation for ongoing monitoring and assessment of breathing. at 6:30 PM in the ER, she

Noticed a full trunk , neck and back red raised rash Tuesday night

Developed a cellulitis in the abdomen around umbilical area that has pain,itching,redness around it , seek dr.attention and put on doxycycline

Dizziness/wooziness, shortness of breath, muscle aches, high BP and heart rate

Itchy rashy hives all over. Swollen itch burning eyes. Throat inner ears tingly itchy

itching and rash - no tongue swelling, sob or throat closing stable vitals treated with benadryl 25, solumedrol 125 and pecid 20 mg IV She had gradual improvement and resolution

approximately at 3;32pm felt heart racing, then 2-3 minutes later tongue tingling, few minutes later felt a lump on throat. 25mg benadryl taken, hoarse voice and anxious, then another 25mg benadryl taken. I was then taken to ER for observation. I was given pepcid and prednisone in ER. Continued to feel lump in throat but no shortness of breath or difficulty breathing. Felt calmer and normal heart rate. Discharged approximately at 5:30 pm

Right side facial swelling and right eye twitching sensation. Given Benadryl 50mg.

numbness lower chin,

Patient felt lightheaded and dizzy. B/P 74/34 HR 92 RR 20 Water provide Legs elevated. B/P after 5 min 138/86 Feeling better

patient had immediate onset of metallic taste in her mouth and felt a slight tingling in mouth and slight need to focus on swallowing without any difficulty with breathing; no sense of doom, no lightheadedness, no palpitations, no problems breathing. blood pressure was 196/112 with HR of 110 at 4:20 pm, then was 204/112 at 4:28 with pulse of 90; her heart and lung exams were normal without any wheezing; speaking in full sentences; she sat and rested for the 30 minutes and her blood pressure returned to 142/97 with pulse of 68. injection site looked fine and patient was comfortable to go home.

Tachycardia, hypertension, flushing and tingling around mouth within minutes after injection. Lasted about an hour

c/o pain and erythema at the base of posterior scalp. no tenderness with palpation. full rom of neck, recommend ibuprofen

Dizzy, heart palpitations. Was taken to the ED for evaluation

1 cm area of induration following vaccine, no erythema, no pain

"dry mouth, feels ""different"", no dizziness, no headache"

I received an IM injection at 4:40 pm at my place of work. I sat down as per our protocol after the injection. Within 5 minutes, I felt a flushing effect start from my head and travel down my body to my toes. I became light-headed and felt like I was floating in my chair. My legs, from my knees to my toes, felt very warm, numb and tingling. After the 15 minute period of monitoring ended, I walked back to my unit. While walking, I felt light on my feet and as if I were walking on a bunch of thick blankets. There was a numbness sensation to the soles of my feet. I informed the doctors and nurses that I work alongside with once in my unit. The light-headedness dissipated within approximately 30 minutes. The numbness, tingling and warm feeling from my knees to my toes lasted approximately for 2 hours (until 6:30 pm). I had no issues after that point.

40 minutes after vaccination, developed hives, chest tightness, lip/cheek/tongue numbness/tingling, nausea Took Benadryl 50 mg and Pepcid 40 mg at 7:15pm. Continued with Zofran every 8 hours

acute onset parasthesias in left arm and bilateral lower extremity weakness within 15min of injection. Unable to stand without assist. no radicular symptoms

13:40 dizziness/vertigo feeling. 14:25 nausea, headache, dizziness. Went to Emergency room in our hospital to get checked out. My blood pressure was severely elevated, felt unwell, headache increased in intensity, nausea worsened & dizziness.

noted immediate development of swelling right at the site of the injection on right deltoid - slightly warm, 3 cm in diameter, non fluctulant, no streaking; no respiratoyr distress, no hives, no systemic symptoms. drew a line around the redness and asked patient to put cool compresses on it, monitor for worsening or genrealization, other skin findings. no change after 30 minutes.

Within minutes of admin of Pfizer vaccine, developed dry mouth, peculiar sensation through extremities/trunk/abdomen (akin to being injected with contrast), elevated BP, tachycardia, flushing, lowerabdominal cramping. Symptoms lasted app 30 minutes. Eval by RNs at the vaccine site. Eval by MD at facility. Discharged after improvement in symptoms.

"patient was very anxious and nervous prior to the vaccine, and felt fine at the time of the shot, but became slightly nauseated and felt ""nerves"" and ""like I was a nervous wreck"" - she felt overheated and was speaking calmly, in full sentences. her HR and BP were normal at 76 bpm and 129/70. her lungs were clear, heart was regular (known heart murmur), no skin changes, not sweating. she rested and upon further evaluation was feeling fine."

Arm soreness at site of injection., sore throat, tactile fever (did not measure temp), mild malaise. Not severe enough to impact daily activity meaningfully.

Headache, nausea, dizziness, lightheadedness, lack of concentration and memory issues

On the initial day about 5 minutes getting the shot I had right eye cramping lasted 25 minutes 12/18 neck stiffness worst on 12/19 On 12/19 I had extreme fatigue and headaches also on 12/20, and 12/21. Felt very dehydrated as well.

About 10-15 minutes after receiving vaccine patient reported that her heart began to race and throat began to swell.

The patient experienced a headache, nausea, metallic taste and BP was 140 and it is usaully 120. Pulse and O2 was within normal limits. Patient received water and cold compress and she felt safe to drive home.

6:45 pm asthma attack requiring albuterol inhaler. Attack was not triggered by any particular event. I was at rest when it started.

Redness, swelling and tenderness at the injection site Rash appeared at the injection site after 8 hours of administration. Chills and low grade fever

Shooting pain down my left arm about 3-5minutes after the shot was given.

headache, soreness on injection site, hives on the day of injection until current day.

About 30 minutes after vaccination while driving home, tingling was noted in injection arm, traveling up the left arm into the left neck and around the lips. Tingling resolved but the next day tingling was noted to be diffuse, light and scattered through arms, hands, fingers, and legs equally and bilaterally. No dermatomal or distinct nerve distribution. Tingling worsened by sitting on legs, became dense tingling in the anterior shins upon standing, but then resolved a few minutes later to the more diffuse light tingling. No notable difference in strength (able to hike and cook). No notable numbness. No rashes, no shortness of breath, no changes in heart rate.

(I'm a physician who received the vaccine at my medical clinic). 5 minutes after receiving the vaccine, I felt very dizzy and faint. We checked my BP (which is usually 120/70; I do not have hypertension), and it was 190/120, HR 120-130 bpm. We rechecked it several times and it stayed there. After 5 minutes, I suddenly felt better and my BP had dropped to 140/70, HR 70. I felt exhausted. No other problems. They watched me for 30 minutes and I felt fine. I had my husband drive me home. As we were driving home (now one hour after the vaccine), I realized that my throat was closing up. I was breathing fine but I realized I was having an anaphylactic reaction from the vaccine. I have never had any allergic reactions before to vaccines, etc. He drove me back to the emergency room of my hospital, where they diagnosed me with an allergic reaction/anaphylaxis to the vaccine. They gave me emergently IV solumedrol (steroids), pepcid, and benadryl, which fortunately worked immediately. They observed me for several hours and I was fine. They sent me home. The next morning, I felt exhausted and my throat was hoarse and sore, but that went away several hours later. It was a terrifying, terrible experience. I thought I was going to die. I had to pay $1000 out of pocket for the ER deductible.

Pfizer-BioNTech COVID-19 Vaccine EUA Hives/Rash on the right side of the body, Itching, Arm Pain (1 day after vaccine) Benadryl was taken and reduced the hives and itching

HIVES starting 32 Horus vaccines, unclear if related, took Benadryl,

Fever 100.4¦ F , headache; body aches , trouble focusing

Vaccine at 10 am 12/18/2020 That same day: Feet numbness at 10:45 am - resolved at 4 pm L hand numbness around 11 am - quickly resolved lower face numbness around 11 am - intermittent throughout the day all symptoms resolved by evening/overnight 12/19/2020 mild facial numbness about 4-5 hours during the day fully resolved by 12/19/2020 evening, without any further symptom recurrence at any site

48hr following dose 1: mild nausea, dizziness, foggy brain.

Numbness and tingling on left hand and left arm. Lasted a few hours. Started in fingers of left hand, progressing up to left arm.

Anaphylaxis reaction with hives, stridor/airway edema, wheezing

Congenital anomaly or birth defect; This is a spontaneous report from a contactable consumer (patient). A 57-year-old female non-pregnant patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for covid-19 immunization. Medical history included high blood pressure and hypertension and more epileptic seizures. Concomitant medication included unspecified pneumococcal vaccine on 12Dec2020 for immunization. The patient previously received flu shot (Influenza virus vaccine) and pneumonia shot (Pneumonia vaccine) both on 20Oct2020 for immunization. The patient experienced congenital anomaly or birth defect (as reported) on an unspecified date with outcome of unknown. Information on the lot/batch number has been requested.; Sender's Comments: The reported information is unclear. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

Pfizer-BioNTech Covid-19 Vaccine EUA Nausea, vomiting, body aches, fever 100.6

developed swelling of tongue; dyspnea; skin rash; This is a spontaneous report from a non-contactable consumer. A 35-year-old male patient received BNT162B2, via an unspecified route of administration on an unspecified date in 2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. This is a call from CDC this morning regarding a new case, the patient was administered vaccine and developed swelling of tongue, dyspnea, skin rash on an unspecified date in 2020, then treated with dexamethasone, diphenhydramine hydrochloride (BENADRYL), via intramuscular (IM) epinephrine in emergency room (ER). The outcome of events was unknown. She will alert him each time there is a report of severe hypersensitivity for his awareness. Further, the CDC is in the process of appointing a contact who will be able to meet with us regularly on this topic. Their conversation was amicable and demonstrated a willingness to work closely with us as we navigate the issue of hypersensitivity. No follow-up attempts are possible; Information about

lot/batch number cannot be obtained.; Sender's Comments: The reported information is limited. Based on the temporal relationship and the description of the events, swelling of tongue, dyspnea, skin rash, there is a reasonable possibility that the events are related to BNT162 vaccine. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

extreme arm soreness, fever of 101.4, chills, body ache

erythematous papular rash scattered throughout abdomen, torso, neck with areas Onset of symptoms noticed 6hrs from vaccine, rash has continued to spread 4 days from time of vaccination sparing most of the extremities.

itchy throat; itchy throat/back of the tongue reaction; This is a spontaneous report from a contactable physician. This physician reported similar events for two patients. This is the first report. A female patient of an unspecified age (reported as 50, unit unknown) received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiry date were not provided), via an unspecified route of administration on 17Dec2020 22:00 at a single dose for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient experienced itchy throat/back of the tongue reaction. No rash, then they gave her epi 10, ED (emergency department) doctor assessed for 2 hours. No evidence of tongue swelling, hemodynamics was normal. Outcome of the events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Based on the close temporal relationship and the description of the events, itchy throat/ tongue reaction there is a reasonable possibility that the events are related to BNT162 vaccine. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.,Linked Report(s) : US-PFIZER INC-2020500303 Same reporter, product, and event, different patient

Extreme arm pain alternating with numbness and tingling, joint pain in shoulder, elbow, and wrist, chills, low grade fever (100.5), fatigue

Patient developed bilateral lower extremity numbness and tingling, as well as weakness that resolved after several hours of observation in the Emergency Department. It is highly likely that the response may have been in part related to anxiety. After several hours of observation the patient had return of motor strength and was able to discharge. She continued to have paresthesia that was improving at time of discharge.

Pfizer-BoiTech COVID-19 Vaccine Immediate burning at injection site following dose. (Similar to the sensation of receiving contrast for a CT scan) which I found odd. Injection site pain continued over night, swelling and site redness to follow and A 1.5 inch welt appeared approx 24hrs after receiving vaccine.

Pain is localized to the injection site only . Treatment includes rest and Tylenol with little effect. Continuing to monitor for any further developments or additional side effects.

Swollen hands; dizzy; This is a spontaneous report from a contactable nurse. A 38-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot number: EK5730), intramuscularly in the left arm, on 17Dec2020 at 14:00 (at the age of 38-years-old) at a single dose for COVID-19 immunization. Medical history included non-ongoing COVID-19 (previous well recovered from COVID-19 months earlier) from 2020 to an unspecified date. The patient was not pregnant at the time of vaccination. The patient's concomitant medications were not reported. It was unknown whether the patient received other vaccines within four weeks prior to vaccination or other medications within two weeks of vaccination. The patient experienced swollen hands and dizzy on 17Dec2020 at 15:00. The events resulted in emergency room/department or urgent care visit. Therapeutic measures were taken as a result of the events, which included cetirizine hydrochloride (MANUFACTURER UNKNOWN) and monitoring. The clinical outcome of swollen hands and dizzy was recovering. It was also reported that since the vaccination, the patient had not been tested for COVID-19. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

40 minutes later, I became flushed, hot, sweaty and clammy and tachycardic along with a syncope episode. Nausea came after, and only treatment was fluids. This episode happened after discharge around 9:45pm and then returned to the hospital for the same course of action.

Slight intermittent headache, neck and shoulder soreness, left arm soreness. Right hip and thigh pain when getting up from the chair about 3 times over the course of a few hours. Stabbing left heel pain x1 in the middle of the night. The next morning (12/22/2020) my right thigh was just slightly sore. Later in the day I had slight right hip discomfort again but it went away quickly. About 30 hours after the injection I had right knee discomfort lasting a few hours.

Possible allergic reaction - paresthesias of L tongue and throat; Possible allergic reaction - paresthesias of L tongue and throat; Possible allergic reaction - paresthesias of L tongue and throat; Sensation of tongue and throat swelling; Sensation of tongue and throat swelling; This is a spontaneous report from a contactable Health Care Professional. A 48 years old non-pregnant female patient received BNT162B2 (Pfizer-Biontech covid-19 vaccine) on 17Dec2020 at 15:15, at single dose, for COVID-19 immunisation. The vaccine was administered at hospital. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Relevant medical history included food and drug allergy. The patient received concomitant medications (unspecified, received within 2 weeks of vaccination). Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, the patient has not been tested for COVID-19. On 17Dec2020 at 15:15, the patient experienced possible allergic reaction - paresthesias of L tongue and throat, with sensation of tongue and throat swelling. No anaphylaxis. No abnormal physical exam findings. Emergency Room Visit required and the patient received the following treatment: diphenhydramine hydrochloride (BENADRYL), prednisone, and loratadine (CLARITIN). Clinical outcome of the adverse events was unknown at time of this report. The case was assessed as non-serious. Information on the lot/batch number has been requested.

Next day after vaccine was given, I had whole body aches and low grade temp of 100.8. Off and on chills. It felt like I had covid all over again (I tested positive end of October). Very sore L arm.

"not getting any Covid nothing, always negative; "" I got 2 shot I feel like I have Covid ""; This is a spontaneous report from a contactable nurse (patient). A patient of unspecified age and gender received BNT162B2, via an unspecified route of administration in Dec2020 as single dose for COVID -19 immunization. The patient had already received two doses. The patient's medical history and concomitant medications were not reported. The patient reported not getting any COVID nothing, always negative; "" I got 2 shot I feel like I have COVID "" on an unspecified date. The patient underwent lab tests and procedures which included negative COVID; the patient indicated that it was always negative. The outcome of not getting any COVID nothing, always negative; "" I got 2 shot I feel like I have COVID "" was unknown. The batch/lot number for the vaccine, BNT162B2, was not provided and will be requested during follow-up."

Pfizer-BioNTech COVID-19 Vaccine Swollen & inflamed (right) eye, right (axilla) tenderness, & fatigue.

Tachycardia, body aches, chills, headache.

Limited ROM; Cannot move arm; Severe arm pain; sharp pain while at rest; This is a spontaneous report from a non-contactable consumer. A 26-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration, in the left arm, on 17Dec2020 at 11:00 (at the age of 26-years-old) at a single dose for COVID-19 immunization. The patient's medical history was not reported. Prior to the vaccination, the patient was not diagnosed with COVID-19. Concomitant medications included unspecified birth control. The patient had no known allergies to medications, food, or other products. The patient did not receive any other vaccines within four weeks prior to the vaccination. The patient experienced limited range of motion (ROM), cannot move arm, severe arm pain, and sharp pain while at rest on 17Dec2020 at 11:45. No therapeutic measures were taken as a result of the events. The clinical outcome of limited ROM, cannot move arm, severe arm pain, and sharp pain while at rest was not recovered. It was also reported that since the vaccination, the patient had not been tested for COVID-19. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

AT 12:30AM MIDNIGHT I BEGAN WITH A LIGHT HEADACHE AND STARTED MY BODY FEELING ACHY. I TRIED TO GO TO SLEEP, BUT I COULD'NT, IN FACT IT TOOK ME A LONG TIME TO BE ABLE TO FALL ASLEEP. I DID NOT HAVR TACHYCARDIA, BUT I DID FEEL ANXIOUS-LIKE. I WOKE UP AT AROUNF 5 AM WITH A FEVER OF 101.1 F, CHILLS, LIGHT BODY ACHES AND MY INJECTION SITE FELT AS IF I HAD BEEN PUNCHED OR HIT REALLY BADLY. I THEN TOOK TWO TYLENOL, EACH 250MG, AND I BEGAN FEELING NORMAL AGAIN.

Moderna COVID-19 Vaccine- Fever, Chills, Muscle and joint aches, headache, fatigue. Self limiting, went to bed and woke feeling better. Only fatigue now.

Fever, body aches, chills, headache

My period bleeding more than usual

my eyes were painful; my eyes were itchy; Eyes swelling; my face were swelling; A little short of breath; Hands are still swollen, my arms are slightly swollen and so is my eyes; Dry rash on hand almost looks like dry eczema rash or psoriasis like it looks like it's a dry patchy rash; Severe headache almost like a migraine; I started to feel little bit, a little off; This is a spontaneous report from a contactable nurse, the patient. A 49-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot Number: EJ1685), intramuscular in the left arm on 16Dec2020 (at the age of 49-years-old) as a single dose for COVID-19 immunization. Medical history included hypertension and hot flashes. Concomitant medications included clonidine (MANUFACTURER UNKNOWN) taken for hot flashes, fish oil (MANUFACTURER UNKNOWN) for an unknown indication, omeprazole (MANUFACTURER UNKNOWN) for an unknown indication, spironolactone (MANUFACTURER UNKNOWN) as a diuretic, and multivitamin (MANUFACTURER UNKNOWN) for an unknown indication; all from unknown dates and unknown if ongoing. On 16Dec2020, the patient experienced eyes were painful and itchy, eyes and face were swelling, a little short of breath, hands swollen, arms slightly swollen, dry rash on hand almost looks like dry eczema rash or psoriasis like it was a dry patchy rash, severe headache almost like a migraine, and felt a little bit off. The clinical course was as follows: the patient received the vaccine on 16Dec2020 and waited 15 minutes and did not have any reaction. She went back to work. As she proceeded to work her shift, she started to feel little bit, a little off. She couldn't really describe it but thought it may have been psychological because she was just really watching heavily for any type of symptoms. She had worked an hour over her shift and it usually took her about 40 minutes to get home. When she got home around 21:00, her eyes were painful and itchy and when she looked in the mirror her eyes and face were swelling. Then, she became a little short of breath not to a point where she thought she needed oxygen, just a little short of breath. She called the hospital where she worked and talked to the manager and then they advised her to go the emergency room. At the emergency room, she received intravenous fluid, diphenhydramine hydrochloride (BENADRYL), famotidine (PEPCID), and dexamethasone (DECADRON) for treatment. She also took cetirizine (ZYRTEC), prednisone (MANUFACTURER UNKNOWN) and triamcinolone cream for the dry patchy rash. The patient stated that she had lab work done earlier in Dec2020 (before the vaccination) and everything was normal. The clinical outcomes of the itchy eyes, eye swelling, hands swelling, and arms slightly swollen were not recovered and ongoing; while that of the little short of breath, dry patchy rash, headache, and feeling a little off, were unknown. The outcome of the eye pain was recovered on an unknown date in Dec2020; while that of the face swelling was recovering.; Sender's Comments: Based on the close temporal relationship and the description of the events, there is a reasonable possibility that the events are related to BNT162 vaccine. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate

Extreme Fatigue (started 3 days after vaccine), 'skipped heart beats' at least 4 times during the date of report (6 days post injection), daily morning headaches (started 2 days after vaccine) with runny nose and sneezing (started 4 days after vaccine) and myalgias with chills intermittently,

tiredness/body ache/fever/respiratory distress

arm pain at the injection site; This is a spontaneous report from a contactable consumer. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot number unknown), via an unspecified route of administration on 17Dec2020 as single dose for COVID-19 immunization. The patient's medical history and/ concomitant medications were not reported. The patient experienced arm pain at the injection site in Dec2020, reported as non-serious. Therapeutic measures were taken as a result of the event; patient took ibuprofen (ADVIL) 200 mg. The outcome of arm pain at the injection site was unknown. The batch/lot number for the vaccine, BNT162B2, was not provided and will be requested during follow-up .

felt dizzy; elevated blood pressure; This is a spontaneous report from a contactable pharmacist. A 51-year-old female non-pregnant patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number EJ1685, expiry date unknown) intramuscular on 18Dec2020 at single dose for COVID-19 immunization with her right arm. The pharmacist informed that COVID-19 vaccine was administered in a hospital facility. The patient's medical history and concomitant medications were not reported. The patient previously took doxycycline and experienced allergies. The pharmacist informed that the patient did not receive any other vaccines within 4 weeks prior to the COVID-19 vaccine. On 18Dec2020, the patient felt dizzy and has elevated blood pressure, the patient's pulse was normal. The pharmacist informed that the patient was not diagnosed with COVID-19 prior to vaccination and has not been tested with COVID-19 since vaccination. The pharmacist informed that no treatment was received due to the events. The outcome of the events felt dizzy and elevated blood pressure was recovering. The pharmacist considered the events non-serious and did not result in death, not life threatening, did not cause/prolonged hospitalization, not disabling/incapacitating, and not a congenital anomaly/birth defect.

Starting at 9am, had jaw pain, that subsided, nausea at dinner, severe chills when I went to bed, generalized fatigue and body aches throughout the day and night and continue to still have both

"Tingling throat; This is a spontaneous report from a contactable physician. This physician reported the same event for two patients. This is the first of two reports. A patient of unspecified age and gender received the first dose of the bnt162b2 (BNT162B2; also reported as COVID-19 vaccine; unknown lot number, NDC number and expiration date), via an unspecified route of administration on an unspecified date at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. It was also reported that it was unknown if other products were received or if an investigation assessment was performed. On 16Dec2020, the patient experienced: tingling throat (non-serious). The physician called regarding the COVID-19 vaccine since they had two events that happened on 16Dec2020; however, the physician stated she needed to ask a question before speaking with Pfizer's Drug Safety Unit (DSU) and reporting the events. The physician stated that two patients reported tingling in their throats during the observation period after the vaccine was administered. The physician thought ""they just panicked and overreacted "" and she did not think they had a reaction. The patients did go the ER (emergency room) and were discharged the same day. The physician wanted to be able to give the second dose. The physician wanted to ask about the side effects

of the vaccine. The outcome of the event was unknown. The batch/lot numbers for the vaccine, BNT162B2, were not provided and will be requested during follow up. ; Sender's Comments: Linked Report(s) : US-PFIZER INC-2020504906 same reporter/drug/event, different patient"

Fevers, headache, fatigue, myalgia about 12 hours after vaccine.

fever/mild side effect of fever; This is a spontaneous report from a contactable other healthcare professional (HCP, patient himself) via Medical information team. A 24-year-old male patient received the first dose of BNT162B2 (Pfizer-BioNTech COVID-19 mRNA vaccine; NDC/batch/lot number and expiration date were unknown), via an unspecified route of administration on the left shoulder on 17Dec2020 at 13:30 at a single dose for COVID-19 immunization. The patient had no medical history. There were no concomitant medications. The patient previously received a flu shot [influenza vaccine (INFLUENZA)] for immunization when he was a kid (a long time ago) and experienced the same reaction, fever. The patient was having a fever/mild side effect of fever on 18Dec2020. He said he just called the number on the packet they gave him at the site, where he got the vaccine and he was wondering if it was okay to take ibuprofen. He did not think they provided him with an NDC, lot, and expiration as it was not on the packet he got; he said they might have put the information on the little card they gave him, but he did not have it with him at the time of the report. He did not know the dose that he was administered. This was the first injection with this COVID 19 vaccine. He further stated that fever started on 18Dec2020; when he woke up, it was like that, but he woke up at 9AM. The event did not require a visit to an emergency room or physician office. The patient had no prior vaccinations (within 4 weeks). The patient had no investigation assessment. Therapeutic measures were taken as a result of fever/mild side effect of fever. The patient was not recovered from the event. No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.

headache, fatigue, fever

Symptoms include light headedness that was immediate; 30 minutes later had a headache and neck pain; 30 minutes later had a headache and neck pain; Diarrhea started 2 hours after the shot and now symptoms are improving.; This is a spontaneous report from a contactable nurse. A patient of unspecified age and gender received bnt162b2 (BNT162B2), via an unspecified route of administration on an unspecified date at a single dose for COVID-19 immunisation. Medical history and concomitant medications were not reported. On an unspecified date, the patient had symptoms that include light headedness that was immediate, 30 minutes later patient had a headache and neck pain, and then diarrhea started 2 hours after the shot and now symptoms were improving. Clinical outcome of headache was not recovered while for the other events was recovering. Information on the lot/batch number has been requested.

Fatigue and severe headache x 2 days. Moderate arm pain x 4 days. Slept for 2 days straight

Mild headache; injection site soreness; This is a spontaneous report from a contactable consumer. A 48-year-old female patient received the 1st dose of bnt162b2 (BNT162B2, Lot # EH9899) at single dose at left arm on 17Dec2020 for an immunization, at Doctor's office/urgent care. The patient medical history and concomitant medications were not reported. No known allergies. Prior to vaccination, the patient

was not diagnosed with COVID-19. The patient had not received other vaccines within 4 weeks prior to the COVID vaccine. The patient experienced mild headache and injection site soreness on 17Dec2020. The patient received no treatment. Since the vaccination, the patient has not been tested for COVID-19. The outcome of events was recovered in Dec2020. The events were assessed as non-serious.

Low grade temperature of 100.6 Friday at 1:30am; This is a spontaneous report from a contactable nurse reporting for herself. This 28-year-old female patient received on 16Dec2020 08:00 first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) at single dose in the left arm for COVID-19 immunization. Medical history and concomitant medications were not reported. On 18Dec2020 01:30 am, the patient had low grade temperature of 100.6 F. The patient recovered in Dec2020 without treatment. Information on the lot/batch number has been requested.

Nauseated; This is a spontaneous report from a contactable nurse (patient). A 54-year-old female patient received bnt162b2 (BNT162B2, Batch/lot # EK5730, Exp date Mar2021) at single dose at right deltoid on 17Dec2020 08:15 for immunization, administered at hospital. Medical history was none. There were no concomitant medications. No additional vaccines administered on same date of BNT162B2. The patient had not received any other vaccines within 4 weeks prior to the COVID vaccine. No adverse events followed prior vaccinations. The patient was really nauseated last night on 17Dec2020 from 21:00 and has been slightly nauseated 18Dec2020. The outcome of event was recovering. The event was assessed as non-serious.

Hives in her face; This is a spontaneous report from a contactable consumer (patient). A female patient of an unspecified age received BNT162B2 (Pfizer-Biontech covid-19 vaccine, Lot. PAA156051-EK5730) on 18Dec2020 at 10:15, at single dose, for COVID-19 immunisation. The vaccine was administered at hospital. Relevant medical history was none. Concomitant medications were unknown. On 18Dec2020, the patient experienced hives in her face. The patient was treated with diphenhydramine hydrochloride (BENADRYL). Clinical outcome of the adverse event was unknown at time of this report.

Mildly sore arm where injection; This is a spontaneous report from a contactable physician (patient) through a Pfizer sales representative. A patient of an unspecified age and gender received BNT162B2 (Pfizer-Biontech covid-19 vaccine) on an unspecified date, at single dose, for COVID-19 immunisation. Relevant medical history and concomitant medications were unknown. On an unspecified date, one day after the vaccination, the patient experienced mildly sore arm where injection of vaccine was given. Clinical outcome of the event was unknown at time of this report. Information on the lot/batch number has been requested.

Mild headache; This is a spontaneous report from a contactable consumer (patient) through a Pfizer sales representative. A 32-year-old female patient received the first dose of BNT162B2 (Pfizer-Biontech covid-19 vaccine) on an unspecified date, at single dose, for COVID-19 immunisation. Relevant medical history and concomitant medications were unknown. On an unspecified date, the patient experienced mild headache within 45 minutes of first Covid vaccine. Clinical outcome of the event was unknown at time of this report. Information on the Lot/Batch number has been requested.

sore arm; This is a spontaneous report from a contactable pharmacist. A male patient (physician) of an unspecified age received the bnt162b2 (BNT162B2; also reported as Pfizer-BioNTech COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. On an unspecified date, the patient experienced sore arm (non-serious). The clinical outcome of the event was unknown. No follow-up attempts are possible; information about batch/lot number cannot be obtained.

headache and feeling overheated; headache and feeling overheated; fatigue; GI symptoms; loose stool; gas; mild tightness but not so much like a cramp; This is a spontaneous report from non-contactable physician via a Pfizer Sales Representative. A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration, in Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced headache and feeling overheated, fatigue, gastrointestinal (GI) symptoms, loose stool, gas, mild tightness but not so much like a cramp in Dec2020. The clinical course was reported as follows: The patient was symptom free for the first 20 hours after vaccination, had mild symptoms from the 20-28 hour mark, and felt fine since then. The patient woke up at 3:30 in the morning one day (day of reporting) with a headache and feeling overheated. The temperature was checked several times on an unspecified date, with no fever. For the next 3-4 hours, there were a wave of symptoms; mostly a headache, fatigue, and GI symptoms. The symptoms responded pretty well to increasing water intake, taking an electrolyte supplement (MANUFACTURER UNKNOWN), and breakfast. The patient also had gas, loose stool, and mild tightness but not so much like a cramp. Therapeutic measures were taken as a result of the events as aforementioned. The clinical outcome of headache and feeling overheated, fatigue, GI symptoms, loose stool, gas, mild tightness but not so much like a cramp was unknown. No follow-up attempts are possible; information about batch/lot number cannot be obtained.

Intractable nausea and vomiting with excruciating stomach pain for 4 hours - only relieved by Zofran.

patient complained of burning when vaccine was being injected. no swelling or redness noted.

Woke up from a dead sleep in extreme joint pain at 1:20 am. (Almost went to the er as I have never had pain like this) Finally went back to sleep woke up at 7:30 am. No pain.

"""Patient was given their first COVID-19 vaccine dose. Patient was given VIS sheet and informed of all potential side effects and when to seek emergent care. Patient was given a follow-up plan and scheduled for administration of second dose. Patient tolerated procedure well. At 15 minutes post vaccine 1147 patient reports that she had just experienced chest pain sharp on left side of chest followed by nausea and slight sensation of tightness in her throat. She reports this lasted about 30 seconds and then subsided and went away. Vitals taken BP 118/76 HR 66 R 16 pulse ox 100% on room air. Patient denies any cardiac history and no history of allergic reaction in past to any medications or injections. Vaccine was given in right deltoid. She was monitored an additional 15 minutes with during which time she was asymptomatic. I consulted with ARNP provider across the hall in care clinic prior to letting patient leave clinic and she was agreeable with plan of care. Patient was advised is symptoms

chest pain, tightness in chest, any shortness of breath she needs to seek emergent care by calling 911. She communicated understanding. Patient discharged to home."""

Injection site pain; tiredness; headache; muscle pain; chills; joint pain; nausea;

Patient complained of burning on injection. No redness or swelling noted.

"Employee received covid19 vaccine without issue. At discharge became diaphoretic and tachycardia. Medical proceed out called and ED team arrived. On arrival vital signs patient was hypertensive, A&O x3, able to answer questions. ED offered to transport employee to ED for observation. Employee chose to stay at the Administration Clinic to be monitored. After 30"", vital signs were within normal range, employee stated he felt fine, no tachycardia, no diaphoresis. Ambulated out of department with out issue."

I didnt notice but evidently my eyes changed because the CNO looked at me and asked if I was ok. Im not sure of what they looked like to make her cue in on I wasnt feeling well but she came over and began to monitor me at that time. I felt light and fluffy and when I got up to get juice I felt like I was disassociated from my body, my movements were awkward, I was severely weak and was not steady on my feel. I felt as if my mind was moving but my body couldnt keep up. I was very laggy and felt as if I was intoxicated. The head of the ER made me drink alot of cold water about 24oz of water and 4 oz of juice which then caused me to get super cold and shivery. Vitals were stable the whole time but my BP shot up to 170/90 a few moments after the water. I was transferred to a monitoring room where I was covered with alot of blankets and allowed to lay down until I warmed up until my BP lowered and I was released. My arm didnt begin to hurt until about 6-8 hours after and I have a red mark and the top layer of skin just do not want to heal. I am still today having to put bandages on the spot because its red and the skin on top keeps coming off. I had joint pain and aches into the next day after causing me to take an Aleve gelcap for the pain. Nausea here and there also.

Sore/Itchy throat - 25mg Benadryl IM. Relief 8 minutes post Benadryl

"Patient received Pfizer -BioNTech COVID-19 vaccine in the clinic. At check out, patient reported 'heart racing, dizziness, and feeling flushed"" ED Proceed Out called. Patient evaluated by ED team. Patient transported to ED for further monitoring. In ED, patient complained of mild throat tightness which was resolved by Benadryl. patient was monitored for 4 hours and was discharged home on benadryl"

12/22/2020 08:00 AM Nausea, chills, slight headache, sore arm; 12/23/2020 symptoms have slightly relieved

patient complained of burning while vaccine was being injected

Notified by girlfriend. Patient woke up this morning with arm soreness. States temperature 102.3 this am. Instructed to call primary care. Instructed patient could have COVID or flu not related to shot. Waited 30 minutes post vaccination, without complication.

panic attack sunday night around 1030-11pm. Had to seek treatment from my family physician to get some antianxiety pills. As of 12/23/20 I still wake up with severe anxiousness. If COVID weren't around I would have went to the ER. I have never experienced anything like that in all my life.

Vomiting, Cheeks feel tingling, Slight difficulty swallowing. Rest and will take oral Benadryl when gets home. Will take Phenergan for nausea when gets home as well. Starting to feel better after 2 hours.

recipient became flush and began itching all over

Recieved the vaccine 12/21 and on the evening of 12/22 my arm became very sore, more than usual for other shots such as the flu shot I received in October this year. It kept me awake it hurts at the injection site down to my middle finger and up my neck. No redness or swelling that I could see. No fever that I can tell.

Approx 10 min after receiving vaccine- patient developed rash and hives on neck and chest with complaints of itchiness on R arm at vaccine site. Also developed redness to right ear. no respiratory difficulties noted. Patient transported to ED for further evaluation and treatment

After administration of COVID vaccine - pfizer, patient noted that he didn't feel that it went into the deltoid, that the injection site had been too low. Questioned if he should be administered another dose. No symptoms. consulted with other clinic staff, ID oversite and will follow-up to determine if patient develops appropriate response to vaccine or if will require additional vaccination

*Describe the adverse event(s), treatment, and outcome(s), if any: (symptoms, signs, time course, etc.) S: 35 yo F who received Pfizer vaccine at 16:47 w/acute onset of left sided facial swelling and difficulty swallowing. Within five minutes of being administered vaccination, pt reported pain at the injection site radiating up to her jaw followed by left sided facial swelling. She started reported palpitations and subsequently reported a ball in her throat O: Pulse was in the 60's, BP of 128/72, pulse of 88-97 satting at 99% on RA. General: young female, anxious. HEENT: NC, AT, mild left sided cheek swelling, OP clear, MMM. Neck: Supple, left sided tender cervical LN. Lungs: CTAB. CV: tachycardic rate, regular rhythm. Extremities: Hands are clenched and cold. Neuro: Alert & oriented. A/P: Anaphylaxis -Given left facial swelling, 25 mg Benadryl PO administered. pt tolerated well. -17:22-Throat swelling reported. EPI #1 administered right thigh. -17:32-EPI #2 administered. Throat felt better at 17:35. 17:36-FD EMS arrived. BP 194/126. -17:38-EPI #3 administered right thigh. HR 135, BP 154/105. -17:43-EPI #4 administered left thigh. -17:46 pt transported to ER via EMS.

Warm feeling to face and ears. Tingling or burning feeling to face. Started 25 minutes after injection. still with mild tingling. No breathing issues.

Severe itching, irritation, took oral Benadryl, proceeded to nearest Emergency Room

Headache, nausea, chills, runny nose, cough

"employee initially complained of itching on arms, noted slight redness bilaterally upper arms. itching progressed to neck slight redness noted around neck area. complained of feeling ""hot"",Denied

difficulty swallowing. Placed in room and Rapid Response called. Given Epi injection in right upper thigh, INT inserted. and Bendryl 50mg IV, solumedrol 125 mg IV, and Pepid 20 mg IV given IVP. placed on EKG and B\P monitor. RR nurse and Covid Nurse at Bedside. employee transported to ER for continued observation. Client remains alert, talking via transfer to ER. continues to complain of some ""itching"""

Mild rash on bilateral upper extremities, non-pruritic rash. No associated symptoms or shortness of breath.

1300 Recipient had transiet HR of 136 sustained for 5 min. Tachycardia started during 15 min. observation period. HR stabilized to baseline 80's by 8PM.

Patient called Employee Health department c/o diarrhea, cough + headache one day after receiving vaccine.

Flush, throat itchiness, red Tx Benadryl IV, EpiPen 1mg IM, Solu-medrol

Patient with hx of SVT stood up after receiving COVID-19 vaccine and did not feel well - sat back down. put pulse ox on and HR was 180. Pt vagaled twice, HR sitting in the 90s - brought to ED for evaluation.

Fever body aches chills fatigue starting 16 hrs after vaccine. Symptoms continued for 4 days after vaccine before reducing in severity. All symptoms still present today, 5th day after vaccine . Max temp recorded 100.7

After receiving the vaccine, the patient developed a hard quarter sized bump above the injection site. Ice applied to site. No bruising, bleeding, pain, or redness noticed.

Patient received vaccine during the day and overnight pateint developed chills, rigors, headache and body aches. Tylenol has helped a little but did not completely resolve symptoms

About 30-40 minutes after patient received COVID-19 vaccine, she felt that she was having difficulty swallowing. Denied respiratory distress. Some swelling felt in middle of throat. No fever, chills, pain, shortness of breath or wheezing.

facial swelling, numbness in face, red patches on neck and face.

Headache with Pressure on eyes, body aches

Woke up with severe bodyaches worse on injection site with fever of 100.6 degrees farenheit.

Next day after vaccination redness and swelling to injection site. Later that day and still today redness, swelling and now itching.

On the date of the vaccine that night my blood pressure went up to 143/130 which is higher than it has ever been. My blood pressure the bottom number would not go under 100. The entire night my head felt like I was in a tunnel and my heart and chest felt tight. I was unable to work the following day due to not getting any sleep out of fear of something tragic happening to me. In addition last night or early this morning at 3 AM I woke up and my body was itching all over. The palms of my hands were itching my

gums were itching I had red marks on my body and had Not done anything out of the ordinary or eight anything out of the ordinary. I took two Benadryl?s and was able to fall back to sleep for a little while and now the itching has stopped but my eyes are swollen.

dizziness, chest tightness, light headedness, SOB

Lightheaded, dizziness, flushed face, sweating

Patient experienced severe symptoms such as severe headache, severe myalgias, brain fog, and dizziness. Upon waking up currently he is currently fine, but symptoms yesterday were very severe

Past 24hours after being vaccinated, I got home from work and realized I had a rash over my stomach and both arm. Felt achy and had a sore throat. The rash was tiny red spots all over. I still have rash on me today, and same symptoms. It has not gotten any worse.

12/22/2020 07:00PM Rash on back

RASH ON FACE, NECK, CHEST AND ARMS. MILD NAUSEAS AND ELEVATED BLOOD PRESSURE. TREATED WITH BENADRYL 50MG IV. RASH LASTED 15 MINUTES AFTER IV TREATEMENT.

About 5 min after receiving the vaccine, I got dizzy, 15 min after I stumbled after I tried to stand up. I have not had breakfast so they thought could be low blood sugar, and gave me some trail mix with m&ms and water. About 40 min after that I stated jerking and then they called the MERT team (emergency) and was transferred to the ER. My speech was delayed. They gave me clonapin and it stopped maybe between 20-30 min later. I believe it was all caused my my PNES. Somehow the vax triggered it, it has been in control for over 2 years. After that I was just fatigued for 24 hrs later. Now I am fine

12/23@9:35am EST- Caller stated on12/22/20 at midnight he felt fever 103.0, chills, muscle soreness and aching, nausea and extreme fatigue. Caller called Primary and was told to take Tylenol 1gr. Benadryl and naproxen for headache and body aches. Rash covered arms , neck and thighs and patika on elbow and armpit. This morning rash is still prominent, eyes are swollen and urine is bright red. Caller is awaiting primary to call back.

Itching started on left arm and then around the temples of the head and on right shoulder.

Sore arm, fever (Max 100.5), body aches, chills, headache, fatigue, general malaise

Itching started on left arm and then around the temples of the head and on right shoulder.

Patient descrived a metallic taste in her mouth 10 minutes after getting the COVID19 Vaccine. Soon after, she described the posterior left side of her tongue was feeling numb. No itching of throat, no swelling of lip or tongue. No respiratory or GI symtpoms. No urticaria or pruritis. She was treated with loratadine 10 mg and famotidine 20 mg orally. She was observed for 2 hours with no progression or additional symptoms. She was discharged to home.

Pfizer-BioNTech COVID - 19 Vaccine EUA Had injection at about 1230 on 12/22/20, woke up at 6am on 12/23/20 with chills, fever of 100.1, headache, dizziness, body aches, sore arm. I had COVID 3 months ago and some of these side effects are worse now then when I had COVID.

12-22-2020 1am- arm soreness at sight 12-22-2020 7 am -arm, armpit, and chest muscle soreness 12-22-2020 1 pm chills, muscle pinches , shooting muscle pain (legs, body upper body) 12-22-2020 4 pm additional pain in right toes along with same symptoms above, facial muscle pain, irritable, tiredness 12-22-2020 10 pm headache

Patient feels metalic taste on the right side of her tongue, along with pain behind the right eye.

approximately 12 hours after receiving the Covid 19 vaccine on 12/18 that I had nausea and vomiting. The vomiting lasted about 2 hours from approx 5:30 AM to 7:30 AM on 12/19. Also, I was extremely fatigued for the rest of 12/19. I slept the entire day only being awake for approx 4 hours. The next day I was slightly nauseated but able to go about my day as normal.

Shingles, left T4 dermatome. Treated with valacyclovir. Adequate response to treatment.

urticarial rash to bilateral upper extremities

swollen and painful testicle

12/21/2020 2:20PM Facial spasms, left side of face-- eye, nose, lip (prominent) - occurring for minutes at time, symptoms have not resolved

First day I was in PPE I started to get really hot , trouble breathing , feeling flu like symptoms Second day . was extremely hot, trouble breathing again , Tiredness , chills, headaches ,

tiredness, muscle ache for approximately 12 to 14 hours

Patient was given covid vaccine, and within 3 minutes, began to develop tachycardia. Patient was placed in chair to be assessed, vital signs done. HR was 160 to begin, dropping to 140, and 117 when being transported to ED for evaluation. Patient stated that she felt like her chest was on fire, and heart was going to beat out of chest. Rapid Response Team called, and team responded, bringing patient to ED for closer evaluation. From the ER MD: 39 year old female patient who was a rapid response after receiving her Covid vaccination. She began to have palpitations and was tachycardic. She appeared to be very tremulous and anxious. She has no known history of allergic reactions. She denies recent illnesses including fevers and chills. Patient felt short of breath. She had an O2 sat of 100% on room air. Lorazepam 1mg po x1 dose ordered and was administered.

Patient felt like back of tongue swelling and itchy ~ 15 min after administration Patient received 12.5 mg Benadryl, 125 mg soul-Medrol in ED Sent home with an epi pen and steroids x 4 days

Reported fever of 100.8, nausea, headache, chills, arm pain- which is common reported side effects of vaccine. Patient reported walking up in the middle of the nights gasping for air- short of breath. Only lasted 3 times during the night, no interventions were done. Went away on it's own.

c/o (L) cheek NUmbness 3/10 scale at 9:50 AM BP 118/52, 100, 20, 98% RA. Rechecked VS at 9:57 BP 127/77, 91, 18, 98% RA. (L) cheek numbness 2/10 scale. Rechecked VS at 10:11 AM BP 137/83, 91, 18, 99% RA (L) cheek numbness 2/10 scale.

2-3 MINS after vacciNE Administered SHE BEGAN TO EXPERIENCE SHORTNESS OF BREATH FEELING OF A FUZZY TONGUE & DIFFICULTY SWalloWING. SHE WAS SEEN IN ED WHERE SHE gOT Benadryl & DECADRON

Patient c/o feeling dizzy + lightheaded 10 minutes after receiving vaccine. Treated in ER

Employee presented to COVID Clinic for Moderna COVID 19 vaccination 1st dose. Given to right arm. Left clinic after waiting 15 minute observation time. She returned to work and returned about 45 minutes reporting she was having difficulty taking deep breaths, numbness to bilateral extremities, abdominal discomfort and lightheaded, NO rash or hives noted. VSS stable A&O, Within a few minutes employee started vomiting, shaking, and C/O of severe abdominal discomfort, Epinephrine injection 0.5mg given to left arm. Employee transported to ED.

Employee presented to COVID Clinic for Moderna COVID 19 vaccination 1st dose. Given to left arm. Left clinic prior to completing 15 minute observation time and told an MA in waiting area that she felt ill ot her stomach and having trouble taking deep breaths. Employee found in nearby Bathroom sitting on the floor, she had vomited, reported she was lightheaded, couldn't breath, shaking, abdominal discomfort sweating, attempted to move employee to wheelchair, did respond well to transfer to Wheelchair, She reported symptoms worsening: HA, abdominal pain and developed blotchy skin, hyperventilating, and dizzy. CODE Blue called, patient given Epinephrine injection 0.5mg patient sent to ER

Employee presented for COVID 19 vaccination: Survey reviewed, no history of Anaphylaxis reaction Moderna 1st dose given today to Left arm. She immediately developed Numbness to her body, chest tightness, and abdominal discomfort. Remained Alert and oriented, voiced concerned she felt like she was going to pass out. She developed blotchy skin to chest and neck area within minutes of injection. Patient sat in a wheelchair. Vital taken: BP 140/98 Pulse 123, given water to drink, tolerated well. She quickly reported she continued with above stated ymptoms, and continued with nausea, blotchy skin, heart racing and weakness. She was given 0.3mg of Epinephrine IM to right arm and taken to the ED

Patient reporting pressure behind both of her eyes and some mild eye pain with extraocular movements. Patient also had generalized myalgias, arm soreness where vaccine was administered along with some chills.

tingling in throat, swelling of tongue Became very anxious upper lip swelling

Seen in urgent care approx. 30 minutes after vaccination for diffuse muscle aches, nausea and dizziness, her BP was elevated. Treatment dugs:

The day after vaccination development of abdominal cramping, urgency, repeated episodes of diarrhea. Some nausea, no vomiting. Abdominal cramping still episodic 3 days later. No fever.

Patient began feeling lip numbness shortly after receiving the vaccine. Patient reported feeling tightness in throat that felt like muscle tightening, not airway compromise. Refused IM epinephrine. Patient awake, alert, mild symptoms. Patient given water and is resting. 0704 HR 70, oxygen saturation per pulse oximetry 95%, BP 130/70. 0712 BP110/80, pulse 80, 0732 BP 116/74 and 25 mg Benadryl given. At 0830 lip tingling and throat symptoms have resolved. Patient report lips feel cool, but all other symptoms have resolved.

Woke up the morning after receiving vaccine with some queasiness, and stomach gurgling. Still having the queasiness and gurgling. No diarrhea or vomiting.

Development of flushing, hives, throat and tongue swelling, difficulty breathing, all developed within 30 min of administration, and resolved after admin of epinephrine and IM Benadryl.

Employee had tongue tingling after injection denies swelling, SOB, chest pain. She waited 30 minutes and declined ED evaluation there were no further symptoms after observation.

3hrs after had normal arm pain. 1030 am following day woke up with shivers, soo cold my bones of my spine and arms were hurting. Headache, dizziness and heart rate over 130 (normally low 60s)

she has a cough and itchy throat.

Client received Pfizer COVID vaccine at approximately 8:42am and reported that he immediately felt tingling in upper left leg/ hip area. The tingling continued and moved down his leg to his foot. First Aid and EMS assessed client. V/S WNL. Client given aspirin and leg massage. Client declined transport to ED for further evaluation. The tingling remained only in foot at time client left.

rash on chest and neck progressing to numbness & tingling of face & tongue. Went to ED, treated with Benadryl, solumedrol, famotidine. some improvement after med administration & observation. Pt sent home with steroid rx & Benadryl.

Woke up this morning with dizziness, weakness, headache, aches. Unable to come to work.

Muscle and joint pain, headache, vomiting (could be from the headache), fatigue, shortness of breath.

Sore throat, swollen lymph nodes in the neck

muscle and shoulder pain, with warmth and redness, congestion, headache, R leg soreness, with redness and warmth

This morning 12/23/20, the site is very tender and very sore.

2 Hours after vaccinated I felt hot from my neck to my head, with slight headache. went away after 3H. Had chills, slight fever and Body aches that night. Took Advil 400mg, felt better. The following day the site of injection was sore, felt warm, temperature was 99.9 degrees F, had chills and sneezing, like my seasonal allergies, with body aches. Took Advil 400mg and Zyrtec. Felt better. Today I had body aches and soreness @ the site of injection. Took Advil 400mg, now I am feeling better.

lightheadedness & dizziness soon after receiving vaccine - went to ED for evaluation

"Approximately 1-2 minutes after vaccination she felt a ""fullness"" in her throat, Felt ""woozy"" and ""altered"". given 25mg Benedryl with lessening of symptoms."

Patient was vaccinated and within just a few minutes of vaccine administration began to feel throat tightening, difficulty getting air, tachycardia, and dry mouth. Admitted to a past history of anaphylaxis with shell fish and endorses similar symptoms. Employee was treated with an epi pen and taken to the emergency room for additional monitoring and treatment as needed Treatment dugs:

Sore arm Fever 99.9 took Tylenol and it went away.

Vaccine at 1245pm on 12/16/2020, severe migraine 12/16/2020 at 6pm vomiting 8pm 12/16/2020 both continued all night and the next day 12/17/2020 I couldn?t eat or drink I would vomit it back up even water, went to Urgent care at 11:30am 12/17/2020 where they covid tested me with a Rapid swab and a PCR swab, gave me zofran for the nausea and a shot of Troradol for the migraine, called me in a prescription for Zofran and Ibprophen 800mg. Couldn?t work that night due to still feeling ill tired and weak, and dealing with the headache. 12/18/2020 no more vomiting or headache just feeling extremely tired and drained, slept most of the day and started having stomach cramps became constipated so I had to take Miralax and use a suppository and stool softener, 12/19/2020 finally went to the restroom and after that had diarrhea for the rest of the day. All symptoms subsided by 12/21/2020.

""" injection site red hot swollen and itching getting worse. having symptoms of nausea, vomiting, tired and a headache that feels like a migraine."""

Developed fever 4 days after vaccination. This patient also had a tonsillectomy done on 12/17/20 and it is unclear if fever was due to post-operative infection. No other symptoms.

The healthcare worker felt a systemic sensation of warmth and tingling throughout the entire body immediately following injection. The sensation of warmth remained with onset of weakness and dizziness requiring rest period. Noticeable rubor- flushed skin on the chest and torso area. Weakness followed by episode of tachycardia and pulse rate of 120 bpm. Episode lasted 30 minutes and fully resolved with no residual effects. No emergency or follow up medical treatment needed.

Immediate reactions were slight fuzziness of vision lasting approximately 30 minutes and body fatigue throughout the day (12/22/2020). At 2:30am I suffered from diarrhea and nausea lasting approximately 2 hours. I woke up at 9:00 am (12/23/2020) with a lowgrade fever of 99.0F.

day after vaccine started to have sweats, body ache, headache, fever. Self resolved after 24 hours. Did not report until 12/23/20 at 10:40. vaccine recipient completing RL

Right eye became heavy within 2 minutes of receiving vaccine and resolved 20 minutes following injection. No visible deficit. Bilateral eye blurring R>L that has lasted for 2+ hours following injection.

Soreness on injection site Chills Body aches Fever101

Stuffy nose-resolved. States that's the first symptom she has with any reaction body aches, injection site pain

15 mins after arm pain , neck pain, headache, cough and shortness of breath Lungs expanded Chest felt weird , took a decongested Breathing was uncomfortable took Tylenol right after for pain . Third day after lung wasn't feeling better Pain finally went away in neck and shoulder on 12/21/2020 Breathing is still not better , scheduled to see a doctor

Pfizer-BioNTech COVID-19 Vaccine EUA Injection site pain 12/22/2020 05:30 to 12/23/2020 05:30 Tiredness/Headache/Muscle pain/Chills/Fever/Feeling unwell 12/22/2020 approximately 11:15am to 12/23/2020 06:30; Took Ibuprofen on 12/22/2020 at approximately 06:15pm Minor headache 12/23/2020 06:30am; took Tylenol

Arm soreness and mild fatigue

Fever blisters appears the next day

I woke up at 2AM with a funny sensation in my esophagus, it felt tight and hot, the trouble breathing woke me up, I had chills, shaking, but no fever, extreme muscle weakness, I could barely walk steps. My main issue was the trouble breathing. Went to the ER and pulse/ox was 96/97 so it was good my oxy saturation was really good. They just observed me for some hours and by 5AM and I discharged and on Saturday I woke up ok but felt weak. I still feel some muscle weakness.

"Patient's reaction(s) noted during COVID vaccine observation period: Pt states that after 17 minutes of receiving the Covid vaccine she developed feeling of lips tingling and tongue ""prickly"". She denies SOB or dysnpea. á 1533: 180/74, HR 59, O2 98% 1544: 144/67, HR 60, O2 99%; states that her lips and tongue have stopped tingling and feel back to baseline. áActions Taken: Pt states that she is fine to drive home. áDisposition: Patient declined ED visit"

Employee had onset of chills nausea on 12/17/20, headache, body aches, fatigue, dizziness on 12/18/20 symptoms relieved by Tylenol. Treatment dugs:

12 minutes after injection developed acute onset tachycardia with HR increase from 64 to 160s (monitored on apple watch), dizziness, flushing, tachypnea. No rash, no wheezing. BP 140s-150s/90s (baseline 110s/70s). HR improved to 100s-120s in ~30 minutes and remained elevated with symptomatic orthostatics for several hours. Monitored on telemetry for ~2 hours. EKG sinus tachycardia. Given 1L NS bolus, no further treatment required. HR 80s-90s upon discharge from ER ~4.5 hours after injection

Patient had a fever of 101.0.

I was dx with possible bell palsy mainly effecting my right eye. I was prescribed prednisone and famciclovir.

diarrhea Nausea pain in upper abdomen extreme fatigue chills adverse event was over in 48 hrs

Vaccine administered at 0800. 5-10 minutes later, patient reported tightness in throat and shortness of breath. Patient became dizzy, nauseous, diaphoretic, reclined back and elevated feet. Patient was taken to emergency department for further treatment.

Patient began to experience numbness and tingling of her mouth and lips 40 mins after administration. Denies SOB, wheezing, airway compromise or oral swelling. Symptoms lasted 48-72 hours. She was prescribed a Medrol dose pack and antihistamines by her PCP.

Chest tightness and arm heaviness starting from the left arm to the right arm, with a burning sensation in the chest. Brought to the ER.

Received vaccine aprox 0745 am 12/22/2020, aprox 09:00pm 12/22/2020 while at work onset tachycardia at rest 140's-150s, , chills, flushing, and light headiness. Employee continued to work through her 12 hr shift, she advised tachycardia persisted throughout the night 140s. She reported taking Tylenol at 3am, and chills resolved. She reported to Employee Health at 0730am 12/23/2020, vitals HR 142, BP 103/72 (she advised that was her normal BP), resp 14, Temp 97.2. She denies chest pain, shortness of breath, weakness, headache, cold symptoms, n/v/d. Advised the chills, flushing and light headiness had resolved, but the tachycardia continues. Employee denies any medical history, takes no daily meds, reports recovered from COVID early November. Discussed with Employee the need to seek higher level of care, she was escorted to the ED.

Patient had a fever of 99.0.

Rash, redness, hot to the touch(fever feeling), swelling, and severe headache

Employee calling to report a reaction after receiving a COVID-19 vaccine. Vaccine Name - Pfizer Vaccine Lot # - EJ1685 Vaccine Date and time - ? 12/18/2020 @ 8:30am Is this your first or second dose? First Date and time of symptom onset - ?12/21/2020 @ 06:30am Symptoms - ? Fatigue, body ache, shortness of breath but resolved after taking albuterol breathing treatment (hx of COPD) Last day of work and shift - ? today, never missed work Home remedies? - Tylenol & Ibuprofen Any improvement? - yes Recommendation? Continue to monitor symptoms and take Tylenol as needed Employee voiced understanding Employee of information ? yes Employee voiced any concerns ? no, her manager told her to report her symptoms to vaccine support line Employee?s questions answered to employee?s satisfaction - yes

Initial c/o Lightheadedness within 15 min. of vaccine. Episodes of tachycardia 70's - 140's B/P 126/90 Patient monitored & revitaled 1620 B/P 120/72 HR IRREgular 1635 BP 120/72 HR Regular 1645 MD ON SCENE to ASSESS 1655 exited w/husbanD

EMPLOYEE STILL SYMPTOMATIC AT THE TIME OF VISIT; Treatment dugs:

nausea, headache, fever, chills

Acute change in systolic BP < 90 mmHg or > 200 mmHg and numbness

Takes promethazine for nausea and took Excedrin Migraine for her headache, has history of migraines. Low grade fever ranging from 100.1F to 100.5F

64y/o FEMALE presents to the ED for evaluation of facial itching after COVD vaccine in left arm. The patient states shortly after the vaccine (about 10 minutes) her nose and mouth started itching. She was given PO Pepcid and IM Benadryl PTA in ED. She denies any associated SOB, nausea vomiting wheezes or near syncope. Denies fever/chills, n/v/d or other complaints at this time. IMPRESSION/PROBLEM LIST:----------1. Adverse Reaction to Vaccine for COVID

37y/o FEMALE doctor was brought to the ER via gurney from the vaccination area after getting Covid 19 vaccination, patient felt SOB, buffy eye and become pale, she took immediately Claritin and Pepcid, patient was brought to the ER. she denied light headedness. Swelling of lips or the tongue. IMPRESSION ----------Adverse reaction to the Covid 19 Vaccination-Resolved

Employee was observed in emergency room for one hour Treatment dugs:

12/16/2020 - woke up at 2 in the afternoon with a sore left arm at the site of injection. (She works nights.) She also had a headache and her stomach felt bloated. She developed a temperature of 101.4 on 12/18 and it went down on Sat to 99.6. H/A, body aches and low grade temperature lingered through 12/20. She woke up feeling normal on 12/21.

Patient reported significant arm pain with the injection that within about 24 hours progresses to COVID like symptoms inclusive of vision issues (blurry, loss of peripheral vision, felt like falling), fatigue and endurance issues, resulting in lost work time second to symptoms. Patient is approximately three months post COVID infections and endorses that symptoms were similar.

44 y/o MALE doctor with no hx of allergic reaction with previous vaccination was brought to the ER from the vaccination area, patient stated he become tachycardic, dizzy and nauseated 10 min after the vaccination shot was given. Patient denied rash, SOB, wheezing or Swelling of the face and the tongue. Benadryl & Zofran given 1.Adverse Reaction to Vaccination-resolved

Nausea, headache, more SOB fatigue

Bumps on tongue

Patient's reaction(s) noted during COVID vaccine observation period: diaphoretic, pale, clammy, nausea occurred 10 minutes after vaccine administration. Pt states that she has not eaten since breakfast. á1422: 97/67, 66 BPM, O2 94% 1432: 146/93, 91 bpm, O2 96% (states she is feeling better, color in cheeks, not diaphoretic; eating cracker and drinking Sprite) 1445: 130/77, 84 BPM, 96% She states that she does not want to be further evaluated in ED. She is stable and states she is okay to drive home. Actions Taken: vitals, comfort, water, graham cracker áDisposition: Patient declined ED visit

Received the injection at 17:20 on 12/22/20 and had no immediate symptoms. At 23:00 hives and itching on chest, arms, back, and legs. Arm soreness at injection site. Soreness improved with oral

tylenol. Hives did not resolve. Asymptomatic after taking oral benadryl at approximately 7:00 on 12/23/20

Patient called vaccine clinic on 12/22/20 to report loss of bowel function. He reported that it happened on 12/21/20 on the way to work. The patient could not make it to the bathroom in time and soiled his pants. On 12/22/20 in the morning it happened again on the way to work and the patient soiled his pants. At this point the patient called the vaccine clinic with this information. The nurse at the clinic did inform the patient that there are some GI side effects that have been reported with the vaccine. She also recommended the patient get tested for Covid since GI side effects are also reported with Covid and the vaccine has not had enough time to offer immunity yet.

Pt started to complain of dizziness and feeling flushed. Pt states she has a history of SVT. Pt states the incident feels like her SVT symptoms. Pt's symptoms went away after 5 minutes. EMS was called and pt refused transport to the hospital.

"Medical History: severe anaphylactic shock requiring intubation related to rattlesnake bite August 2019. On September 2019, I went to the dentist and received septacaine, mouth and face swelled up immediately. Toxicologist said this was due to me still being in a ""cytokine storm."" 12/22/2020- I received my COVID-19 vaccine by Moderna. Within 5 minutes of me receiving the vaccine I first experienced tachycardia, felt my heart pounding, dizziness, and tunnel vision. Three hives, dime sized, appeared on my chest within 10 minutes of the vaccine. I felt difficulty swallowing (may have been anxiety related). The dizziness was intermittent for the next hour. I took 25 mg of Benadryl 15 minutes after the shot. My blood pressure was elevated for an hour, 170s/100 s, Osat maintained above 94%, and heart rate 80s-90s. My resting HR and BP are 100s/60 and HR 61. I also started to feel bloated and burping. An hour and a half after the shot, the symptoms resolved and I drove home"

Arm pain.

Irregular, skipping heartbeat, improved. Diarrhea, resolved.

hypertension, hyperglycemia, mild rash

Pfizer-BioNTech COVID-19 Vaccine EUA. This last night I experienced chills and a low grade fever, along with weakness. It doesn?t feel like I have a fever currently but weakness is still apparent.

extreme fatigue, sore throat, cough, facial swelling, extreme arm pain

Dizziness, Flush, Shortness of Breath

Onset of symptoms began approximately 1.5 hours after vaccination. Patient became weak c/o tongue swelling, nausea, difficulty breathing, numbness especially in lower extremities. Felt she couldn't breath, numbness continued to get worse and affected her upper extremities as well, weak speech.

Injection site aching, chills, body aches, fatigue, tiredness, nasal congestion. 12/23/2020 in AM All symptoms starting to resolve - feeling better; Nasal congestion, Fever 102.1, Tylenol and Ibuprofen some relief; fever at time of reporting 100.5.

The patient was doing great. After 30 min later, the pt started to have numbness on the face. Felt like the face was completely numb. Came back to clinic and numbness started to go away. It would wax and wane. It started to improve. Now the patient is doing great. Other vitals fine. NO SOB, No intervention done. Pt released home.

48 y.o female with history of atrial tachycardia who presents to the ED via EMS for a possible adverse reaction to Covid vaccine. Patient received her Covid vaccine around 1600 today, and soon became diaphoretic, shaky, and lightheaded. She had presented to the emergency department. Currently she denies any chest pain, difficulty breathing, throat swelling, tongue swelling, or any other symptoms currently except for palpitations. áAllergic Reaction The primary symptoms are shortness of breath. The primary symptoms do not include cough, abdominal pain, vomiting, dizziness or rash. The current episode started 1 to 2 hours ago. The problem has not changed since onset. The onset of the reaction was associated with a new medication. Significant symptoms also include flushing. 48-year-old female with a history of atrial septal defect, status post atrial septal defect repair in 1980. She works as a nurse at Hospital and has been experiencing increasing rapid palpitations associated with chest pain, and hypertension. With her episodes, she experiences marked lightheadedness, dyspnea, and feeling marked anxiety, as well as chest tightness. She received the COVID-19 vaccine today and while waiting in the observation room,she started feeling unwell, with rapid palpitations, associated with lightheadedness and dyspnea. She last had a sustained episode 2 - 3 weeks ago and had presented to ER and Hospital. No syncope. No orthopnea, PND or increased lower extremity swelling. Active Hospital Problems á Diagnosis ? Atrial paroxysmal tachycardia ? History of repair of atrial septal defect á á á 1. Paroxysmal atrial tachycardia in setting of prior atrial septal defect repair - she is having breakthrough episodes through flecainide/digoxin - it is likely her atrial tachycardia is related to her ASD patch. Will hold flecainide/digoxin for now, and try to schedule an ablation during her hospital admission due to highly symptomatic episodes resulting in multiple ER visits. á 2. Acute renal insufficiency - most likely pre-renal - iv fluids started. á 3. Possible COVID-19 vaccine reaction - she probably had an incidental atrial tachycardia episode post vaccine administration, rather than an actual adverse reaction. Continue to monitor.

COVID vaccine admin 1645 around 1715 sudden onset heart palpitations feels like heart racing, employee heart rate was noted to be 170s, employee was escorted to the ED. 12/23/2020 1030 spoke with Employee she advised d/c from ED last pm, this am resting heart rate 90s, but 140's-150's with ambulation. Denies chest pain, shortness of breath, palpitations, cold symptoms, n/v/d. Has reported moderate fatigue this am.

Loose stool on 12/20/20, post nasal drip 12/21/20, nasal and chest congestion, fever of 100.7 on 12/22/20.

injection site soreness, mild headache, fatigue, muscle aches with hear palpitations x 2 days then it started to improve and resolved on day 3. I am also breastfeeding an infant. There were mild heart palpitations the day prior to getting vaccine as well, which are not uncommon to patient during times of stress.

At 0030 (about 12 hours after receiving shot), awoke to sudden development of severe epigastric pain, severe headache, fever (temp 101 F, maximum later at 102 F), and rigors. Rigors quickly abated, while abdominal pain, fever and headache maintained for next 12 to 14 hours. Abdominal pain was unrelenting, could not sit up, work, sleep, or interact. Mild nausea, no vomiting or diarrhea. Pulse ox 99%, pulse in the high 90s (baseline 50s). Took 325 mg acetaminophen at about 1100 (11 hours after symptom onset) with mild relief. Experienced more relief by about 1500. Was able to eat a small meal about 1700. Mild post-flu-like symptoms the next day, and no symptoms after that.

Tachycardia, rate 135

Patient reports having horrible symptoms such as sweats, chills, bad HA, nausea and vomiting, arm pain, extreme fatigue and tachycardia. She states she feels much better now and is taking Motrin for the HA.

I received the first Pfizer Covid 19 vaccine on 12/22/2020 at Hospital. I woke up on 12/23/2020 with a fever of 102 degrees, body aches and headache. I was advised by Employee Health that if my symptoms are still bad that I should follow established protocol and take the next day off of work. December 23rd is my normal day off of work. I am scheduled to work on December 24th. I was also advised that if I felt I could work with a fever that I should go into work tomorrow. I filled out a form and a Covid 19 questionnaire. Someone is supposed to call me within 24-48 hours. I suppose I should take Tylenol for the fever/headache. Employee Health had no advise for me as to what I should do for the symptoms.

Caller stated that 30 minutes after vaccine she developed tingling sensation in lips and feet. Rash over the chest and back. Caller took Benadryl 25mg . Caller stated that symptoms lasted about 1hr and half. Symptoms have subsided. Vaers report successfully completed over phone

Staff member complained of a stiff arm. Was seen by Dr. and advised to see personal physician if problem persists. Stuff arm went away.

Patient began with hives and itching all over. Patient given 50mg IM Benadryl Patient watched for 40 minutes. All sx improved.

Dizziness, nausea, vomiting. Elevated BP. Shortness of breath. Headache. Went to ER, improved with solumedrol.

Patient reported experiencing fever, night sweats and nausea. Patient called out from work next day due to symptoms.

I received the vaccine and the sat to wait the 15 minutes of observation. Within 5 minutes of receiving the vaccine I started to feel flushed and felt my heart rate increasing . They took my vitals and my heart rate increased to 175. I was taken to the Emergency room. Given IV fluids, IV benadryl, and monitored.

My heart rate came down but continues to stat at 90-100s at rest. Almost 24 hours in now and I am very weak with no energy. I still get dizzy intermittently and my heart rate increases easily.

fatigue ,headache ,myalgia ,arthralgia ,diarrhea , stomach ache ,bloating & blood pressure dropped down . still have stomach ache , bloating & low blood pressure

Headache started a couple of hours after the vaccine . Tried 600 mg of Motrin that evening. The next morning still had headache tried excedrin. 6 hours later tried zomig. Still have the headache.

Patient had metal taste in mouth upon administration of vaccine that lasted the duration of patient's observation period of 15 minutes.

Tongue tingling and throat swelling

Diarrhea and stomach issues. They were resolved by 8pm. I took an Covid Test and it was negative

12pm started feeling fatigue and sickness throughout body. 3pm nausea. 6pm body aches and chills. Slept horribly like I was getting the flu. Up at 4:30am to go to work. Still fatigue, nausea, chills and some little bit of upper back pain, between shoulder blades. Went home early today from work.

Pt stated experiencing the onset of itching in her left arm and face after receiving the Covid vaccine in her left arm. Pt also stated experiencing a mild episode of feeling light headed after the administration of Covid vaccine. No Redness, Swelling, or Rash at injection site or on face. 25mg Benedryl administered p.o. at 9:21am.

Migraines, body aches, severely sore Lt arm, extremely fatigued, nausea, and congestion

Migraines, body aches, severely sore Lt arm, extremely fatigued, nausea, and congestion

Fever 27 hours after injection. Started with chills prior to me checking my temperature.

3 hrs after shot: chills, fever 100.7, joint pain, muscle aches, headache pain in upper left arm

injection site pain, L arm pain resolved in 24 hours

c/o dizziness, HA, nausea, went to ED on 12/18 for tx, will f/u with rheumatologist on 12/21

Soreness had spread to neck at 6:45 when patient woke up

The day after I received the vaccine I noticed some redness and swelling at the injection site. Over the next 2 day the swelling increased to about 2-2.5 inches in diameter and became itchy. At the time this form was filled out, the swelling had decreased to about 1.5 inches in diameter but the redness had not decreased and there was still mild itching at times.

Moderna COVID-19 Vaccine EUA Left arm pain started 15 min post vaccination and has not subsided. General fatigue started 2 hours post vaccination and has not subsided. Nausea started 5 hours post vaccination and subsided by 4:45AM the following day. Tinnitus usually sits at 2 on a scale of 1 to 10

with 10 being obnoxiously loud and distracting causing lack of concentration. Tinnitus started to increase 2 hours post vaccination and topped out at about 8 at around 6 hours post vaccination. Could not sleep well and maybe got 2 hours of sleep due to tinnitus and increasing left arm pain.

Some burning, discomfort in the injection site within the first 15 minutes, which dissipated after about an hour later. Some itching/irritation in the back of the throat, about 30 minutes after injection, that turned into a inflamed/sore tonsil on the right side around 8:00pm in the evening. Waking this morning the day after, around 7:00am, the soreness and irritation in the throat is on both sides, but has dissipated after a few hours, and drinking dome water. My arm has increased soreness the next day, described as a dull ache at rest, and painful with movement. I also have a residual headache that has not dissipated since waking up, but is barely noticeable, and will treat most of these side effects with Ibuprofen.

Patient noticed mild tingling and itching after vaccine was given. Patient denies the need for any medications or creams to treat her reaction.

Systemic: Rash (other than injection site)-Mild, Systemic: Headache-Mild, Systemic: EpiPen was given by nurse. Her vitals were fine 140/82, Oxy 98%. 2 benadryls were also given. Pt will be pretreated before second dose

Staff member felt a buzzing sensation was concerned that she may be having an anaphylactic reaction. She took a Benadryl and called 911. EMTs evaluated her and determined that she was fine. No further follow-up was needed.

None. Resident was given Shingrix vaccine (2nd dose in series) on 12/14/2020

fever, malaise, light headedness-- taking Tylenol

Patient felt chilled and very tired. She started falling asleep while sitting upright. She also became acutely confused and could not identify what year it is, what her phone code was, etc. 911 was notified, but pt felt better about an hour later and did not go to the emergency department for evaluation.

Sensation of palpitations. Then, she felt warm and flushed.

12 hours after dose - headache and bodyaches 18 horus after 1st dose - rigors, chills, hot flashes (flushing). Severe sore arm (could barely move arm that received dose, could not touch it) 24 hours after 1st dose - fatigue, bodyaches, headache, persistent flushing without fever (max temp 99.1 F) 36 hours after 1st dose - headache, flushing. Arm soreness significantly improved 48 hours after 1st dose - mild flushing, rest of symptoms resolved

Redness, pain, swelling hardness injection site Ice/Cold compress, Ibuprofen

Associate complained of headache and that she didnt feel well. Associate noted to have a swollen tongue and rapid response was called. Associate was taken to ED. HR 80. BP 100/70

c/o throat tightness, neck hot and tight about 8 minutes after injection. Gave Epipen at 17:10 and taken by wheelchair to our ER. Employee states she was monitored and given 1 liter of IV fluids and benadryl. States she was discharged home about 3 hours later. Felt exhausted 12/22/20. Today feeling better. Planning to see primary MD 12/24/20 for follow up.

Seizure (Grand mal)

Mild headache the day of injection. Moderate nausea and overall malaise on day 1 after injection. Mild nausea, overall malaise, mild fatigue on day 2 after injection.

Patient reported that she developed tingling in her face on the same date of her vaccine. Was evaluated by provider on 12/22/2020 and Kenalog 40mg IM given as one time dose. Patient was contacted that same evening and reported that her symptoms had resolved.

Became flush and clammy 2-3 times. Recovered after 30 minutes of observation

symptoms started afternoon following day (Saturday)around 3 pm as chills denied fever, muscle aches and pains, soreness all over, Tx Motrin as needed. The following day (Sunday) had 2x loose bowel movement last episode 6 hours before showing up for work. Denied any more symptoms.

phone call

Anaphylactic with throat swelling , tachycardia and high BP. Pt was given steroids, epi pen, Benadryl and observed in ICU overnight.

headache, injection site arm pain

Initially; confusion/difficultly focusing. Secondary: imbalance. Then developed, dizziness (room spinning sensation).

The morning after receiving the vaccine I woke up with a headache. I drank lots of fluids and tested, but the headache seemed to get worse. It was throbbing with associated light-headedness and general fatigue. Maximum temperature after vaccine so far has been 98.8

Right arm weakness

Left axillary lymph nodes swelling and pain; Left arm pain Headaches Cough Dyspnea with exertion Body aches

Vaccine recipient received COVID-19 Vaccine on 12/22/20 and 3 minutes after felt that they were going to pass out and developed dizziness and headache. Vaccine recipient was administered ketorolac 15 mg IV, acetaminophen 650 mg, IV fluids in the emergency department. Patient felt better and was subsequently discharged to home. During a follow-up phone call on 12/23, vaccine recipient reported that their symptoms have resolved and they were able to return to work.

cough, sob, sweating, belly pain for 48 hours after vaccination, body soreness, advised to contact PCP.

Patient summoned nurse over while waiting 10 minutes post-vaccination. Stated felt heart racing and like she was alternating getting hot/cold however skin was warm, pink and dry on palpation. Radial pulse 140 bpm. SpO2 100%. Stated she had a history of anxiety; nurse reassured and distracted her which helped symptoms initially but then symptom of heart racing returned accompanied by dry mouth and numbness of upper lip. Was transported in wheelchair to ED by RN. Discharged from ED after 2 hour observation diagnosed as suspected anxiety attack; was instructed to follow-up with PCP and Employee Health regarding receipt of 2nd dose.

"Individual developed rash 5-7 minutes after vaccination. Denies other symptoms including difficulty breathing or itchy/scratchy throat. Says ""I'm fine"". Individual self administered benadryl. went back to department and later called Employee Health. Employee Health instructed individual to go home and self monitor"

Muscle aches and temperature of 100.3 began 1 day post injection, headache additional symptom on day 2 post injection.

Soreness at injection site and surrounding area, deltoid muscle soreness

Vaccine administered around 10:45(am) on 12/21/2020. Around 23:00(pm) (12/21/2020) I was feeling chilly, put my jacket while at work (night shift) on but continued to feel tired, eyes hurt a little, slight headache, general muscle soreness, and increasing pain in my left arm where I got the shot. I took 600mg Advil, felt fine most the night but still really tired. End of shift (07:30(am)) I was very tired with symptoms returning. Got home (08:00 on 12/22/2020), went right to sleep but at that point had chills, felt cold, headache, body aches, pain in left arm worse / really hurting - tender to touch but not swollen or red, neck glands ?felt swollen? but I don't think they actually were swollen. I woke up 4 hours later (12:00 - 12/22/2020) around noon exactly sweating, with all the same symptoms. No GI discomfort. I took 975mg Tylenol. Checked my temp, 99.9F. I couldn't fall back asleep for several hours and my body temperature felt like it was all over the place (sweating and hot, then cold, repeat). Finally fell asleep again from 16:00 to 21:30. Symptoms were all still present. Took Tylenol 1,000mg and stayed up until 05:00 (12/23/2020) with good relief from the Tylenol throughout the night and then went back to sleep from 05:00 to 10:00 (12/23/2020). Woke up symptom free and have remained symptom free.

Patient presents palpitations

Employee complained of lightheadedness/dizziness after vaccination which was at 9:15am

Date and time of symptom onset: 12/17/20 at 4:15 PM Symptoms: 12/17 during 30 minute observation window, patient reports the following symptoms: felt dizzy, heart palpitations, shortness of breath and difficulty breathing. Patient reports, ?I didn?t tell anyone because I didn?t know who the monitors were. I tried to get eye contact with someone, but I wasn?t able to. I didn?t want to stand up because I was afraid I would pass out and would be really embarrassed for causing a scene.? Patient was tearful on phone when describing account. Patient verbalized concerns with being unable to determine who was assigned to be monitoring employees after vaccination administration. Patient reports she did not notify anyone of her symptoms/what she experienced and remained at designated ?monitoring? location for

40 minutes before she drove home. Patient endorses, ?I probably shouldn?t have driven, but I did anyway.? Patient reports she struggles with anxiety and wondered if what she was feeling was a result of hx of anxiety. Patient reports resolution of SOB approx. 1 hour she got home. Patient endorses hx of ADHD, depression, thyroid issues and hypoglycemia. Patient reports compliance of prescribed medications. Patient reports the following timeline for symptoms listed: Dizziness: Patient reports continued intermittent dizziness (denied at time of call) and feelings of ?cloudiness/spaciness?, currently experiencing today Headache: began with severe headache on night of 12/17 and continued with headaches, pt denies headaches today (12/23). Patient with hx of migraines Heart palpitations: continued with heart palpitations through evening of 12/17, intermittent palpitations on 12/18 and 12/19, denies palpitations today. Fever: low-grade fever on 12/17 (pm) and 12/21 (am), denies fever since 12/21 and has not taken antipyretics since 12/21 at approx. 9:30 pm. At time of call: Patient endorses continued ?cloudiness and feeling spacy.? Patient reports feelings of fatigue. Last day of work and shift: 12/23, working from home Home remedies: Rotated Tylenol and motrin, last dose of motrin at 9:30 PM on 12/21 Patient scheduled PTO on 12/18 and 12/21 due to concerns of not feeling well after vaccine.

coughing, itching IM soul-medrole given seen entry detail

phone visit

Rash, generalized weakness

"Patient pre-medicated with diphenhydramine, albuterol, Claritin, and singulair. After roughly 10 minutes after administration the patient reported tingling in her lips and ""felt like she needed to use her inhaler"". Our administration station is in our front lobby, when the patient reported her side effect she was taken to the Emergency department for observation. The patient was hooked up to the monitor and a set of vitals were taken. On arrvial she was tachy in the 100's wtih a BP of 140-90. On the repeat vitals in 15 minutes she was within normal limits. The patient was treated with Diphenhydramine 12.5 mg PO and Albuterol 2 puffs via spacer. The patient was observed for ~3 hours, the patient had mild angioedema and a numb tongue/lips. After resolution symptoms the patient was discharged from ED."

Diarrhea, Fatigue, headache, injection site pain, injection site swelling, malaise, new or worsened join pain and new or worsened muscle pain. more than 23 hours of severe all over pain, horrible pounding headache and nausea

Injection at 12:46, Experienced Tingling on tip of tongue at 1303 took oral Benadryl 25 mg, reported symptoms at 1309- 161/93 sat 100% on room air, P-84, Repeat 1310 135/94 sat 98% P-81, 13:13 152/101 sat 99% P-87, 13:17 145/87 sat 99% P-86, 1330- 141/82 sat 99% P-89, reports tingling decreasing, 13:38 149/83 Sat 98% P-84 13:45 still having tingling transferred to Urgent Care

Pt developed a rash on her entire upper trunk and face. Started behind her ear on day one and by the next day had spread all over with extreme itching and discomfort.

Fever 102

Chills, Headache, Body Aches, Runny nose, congestion, dizzy , nausea

Nexk to my head feel really hot, nauseous, dizziness, high blood pressure, shaking feel Hot and cold

extreme fatigue, itching at site, some redness on deltoid.

Reports had joint pain & shoulder pain, shortness of breath, pale-instructed to go to ED for medical treatment.

patient covid +,on day 13 since identified. received covid 19 vaccine 19 hours prior to fever presentation. patient to receive full medical work up to rule out other medical contributions for fever. Confusion, Fever, HYPERtension & FEVER 101.5 fahrenheit, weakness

Per Vaccine recipient approximately 4-4 1/2 hours after receiving vaccine she noticed facial swelling in and around nose, to neck area, to R elbow and a petechial rash near R elbow. She immediately took Benadryl and Pepcid and then went to ER for further evaluation, where she was given a dose of Zyrtec and 5 day course of Prednisone. She left ER with no further complication.

Headache Arm soreness Swollen Uvula

History to allergic to IVP dye, after the covid vaccine and said felt itchy in face. Patient given dexamethasone 10 mg diphenhydramine 50mg ,epinephrine 0.5 mg and lactated ringers. Patient issue resolved and will be discharged home.

"Pfizer-BioNTech COVID-19 Vaccine EUA Patient stated that 2 1/2 to 3 hours after receiving vaccine she had 2 ""red dots"" on the arm she received the vaccine in. States one dot was where vaccine was administered and second dot was next to area where she received vaccine. The next day patient stated ""the two dots became red, raised, and sore to touch"". States they were not warm or hot to touch. 2 days following vaccination, the 2 ""dot areas"" were still present. Patient stated ""running through the dot I got the shot in, I developed a red line that ran through the place I got the shot and was about 2 inches long down my arm. "" Patient described red line as ""It looks like a cat scratch"". 3 days following vaccination, states ""Bumps are still there but faint"" also states ""red line is still there"". States line is not raised, tender, or hot to touch. States no other reactions. States no fever or fatigue."

Headache Sore injection site

vasovagal syncopal reaction. I experienced sudden onset of feeling flushed and warmth body wide, sudden metallic taste in mouth, muffled hearing, dizziness, lightheaded, began to lose vision and consciousness, pallor noted by nurse caring for me, blood pressure recorded was 90/60. I have never experienced this type of reaction before to any vaccine or blood donation but know it can occur occasionally.

BODY ACHES, MIGRAINE

Itching started on left wrist approximately 20 minutes after receiving vaccine and progressed to other arm, back, and legs. Patient has no other complaints. Initial blood pressure elevated 180-210 / 120-130.

Patient reports no history of hypertension. Patient reports having taken Zyrtec approximately 30 minutes prior to receiving vaccine. Benadryl offered, but declined by patient at this time.

Staff member experienced a fever of 101.7 and chills through the evening. Symptoms then resolved.

On 12/23/2020 woke up with Fever 100.6 F, significant muscle aches, headache, diarrhea, and dizziness.

Developed SOB, chills, fever 102.0, cough and posterior back pain with symptoms improving on 12/20/2020 in the PM. He did not seek care or report issue until now. States he feels fine now.

Cellulitic response to injection site.

Stated fever 99.5, body wide aches, fatigue

Took NSAID (ibuprofen) to relieve pain and reduce fever. Applied local analgesic to injection site (Methyl/M-salicylate, camphor, menthol ointment).

rash to lower back & itching some pain @ site of injection No swelling, HA, fatigue, fever. Txt with antihistamines

Employee developed fever of 101 initially. Was 102 by 12/22/2020 @ 3AM. Alternating Tylenol/Ibuprofen and reports improvement in symptoms.

IM given 12/18/2020 at 2:40 pm , evening time 9pm claimed fever(no temperature was taken) ;; chills, myalgia, headache on and off tolerable on and off; nauseated (common symptom even in situations employee does not feel well); Took Motrin alternating with Acetaminophen at least 2 tabs a day of each. Medications alleviate symptoms but recurs again until after 48 hours Showed at work but decided to leave work to return to residence. Advised to contact primary care provider to inform provider of the signs and symptoms. Employee was advised to get Covid TEST (PCR)

12 hours after vaccination -->generalized muscle aches and arthralgia (of major joints symmetrically painful (both knees, lateral movement of neck stiff) no joint swelling; felt chills no fever. No URI symptoms; and both thigh pain aggravated by change of position (standing from sitting to rising from chair)and even going down flight of stairs. Generalized malaise, felt sick and tired. NO diarrhea no loss of taste. The following day (Sunday) all complaints resolved. No meds taken throughout post vaccination

Has allergy with prior reaction to sulfa drugs that she had the same symptoms of warmth and then developed hives. Her left upper extremity was warm to the touch when compared to her right, which was where she received her injection 20 minutes prior. Treated with motrin and benadryl 50mg po and symptoms resolved.

patient had left arm numbness and tingling, lips numbs, and headache at 15 minutes. Symptoms continued to increased headache, SOB, nasal congestion, nausea and vomiting, all extremities numb. face pale.

Employee was called 5 hours after medication administration, referring improved but still having Shortness of breath. Referred will go to the ER if symptoms continue

Soreness, stiffness, fatigue, headache nausea

Developed diarrhea x 10 episodes on 12/17/2020 through 7:00PM on 12/18/2020. Treated with Zofran, Pepcid, and Lactaid.

Developed headache and body aches by 11:00PM following injection. Fever of 100.6 on 12/19/2020.

Phone call- already 80% improved

Developed a 101 fever along with body/joint aches on 12/19/2020

One hour after injection I was at the store felt disoriented like I was on a strong pain pill. I felt impaired and used caution driving home from the store. That feeling lasted for 3 hours. I still feel a little foggy headed today at work.

developed itching within a few hours of vaccine administration. developed a rash all over body on 12/20/2020. Took Benadryl and symptoms now resolved.

Headache, lightheadedness, fatigue 5 to 10 min post vaccination

NauseaVomiting

NauseaVomiting

phone call

12/23 patient transferred out to acute care hospital for treatment/evaluation of gi bleed. patient does have h/o PPI use that was d/c 5/2020 and no recent gerd symptoms requiring intervention >60 days. NauseaVomiting, GastricBleeding & heartburn

12 hours after receiving the vaccine on saturday afternoon experienced severe headache sunday morning. was able to work through it. subsequently developed vertigo on monday night and missed work on tuesday. very unusual for this employee. now on tuesday evening symptoms are wearing off. did not seek medical attention.

Approximately one hour after receiving the vaccine, as the patient was driving home he began experiencing throat tightness and tongue swelling. Once home, they call 911 and administered 0.3 epi (had previous severe allergy to lidocaine). EMS then administered iv benadryl and an albuterol treatment. The patient was reported to go unresponsive en route and received bag and mask ventilation very briefly as well as additional 125g solumedrol and another IM epi injection. On arrival he was reported to be stable, talking, tolerating secretions, without significant complaints. He was observed in the ER for several hours without any symptoms nor objective findings to support anaphylaxis (tongue and airway normal, no wheeze, no rash). He was anxious in the ER and the treating physician wrote that he felt it may likely have been anxiety and not anaphylaxis based on their evaluation.

96hrs later still feel disoriented

About 12 hours after the vaccine I started to get a fever that got up to 101.2 degrees, headache, body aches and flank pain. I took Tylenol, which helped break the fever and body aches but still have a low grade fever and headache. I believe I have COVID antibodies from a previous infection back in September so think that having the antibodies already could have caused this.

Yesterday afternoon, she developed a loss of taste and smell. This morning around 0400, she awoke to a splitting headache. She took some Advil and tried to go back to sleep, hoping she could maybe come in to work today a little later. Around 1030 this morning, she began to have significant swelling to her face and eyes along with her skin becoming flushed. She has taken some Benadryl and been instructed to follow up with her PCP

I received the vaccine at 1:40 PM in my left arm. They had me wait 15 minutes for observation. 15 minutes later, I left feeling fine. I went back to work. Around 2:15 I started getting chills. I ignored it thinking that I was psyching myself into it thinking about the shot. But then the nausea began. I was at work and started feeling horrible. I started cramping in my stomach. I was alone at work, and then I started throwing up. It started at 3:40. I left work at 4:30 with the most body wracking chills and went to the emergency room. I was violently heaving at this point and they rushed me into a room where I received an IV drip of fluids and anti nausea medication. It wasn't until after the medication was administered that I felt better. I would say this was around 5 pm. They sent me home with an anti nausea medication. I was released to go home around 730-8 PM. I felt so much better after the medication was administered.

"Patient reported a metallic taste on vaccine administration, after ~ 10 mins reported a tongue tingling. The patient was escorted to the emergency department for observation. Patient was slightly hypertensive 140's/90's which is not normal for her. Some of this could be attributed from the ""white coat effect"". The patient had no visible angioedema, just a mild rash on her trunk/upper torso/chest. The patient was treated with 50mg PO diphenhydramine and 40mg of Famotidine. The patient's symptoms resolved within 30 minutes of medications administered. Patient was discharged after ~ 2 hours in the ED."

Patient experienced immediate and severe nausea and then tachycardia ~140 bpm within 30 minutes of dose monitored by nursing home physician assistant and sent home from work.

2 hours after the vaccine felt like she was hit by a bus. Had facial droopiness. Has Migraines with the same facial droopiness. Left eye blurred vision. Stroke like symptoms. Fatigue, weakness.

Acute onset nausea and abnormal throat sensation shortly after receiving COVID vaccine. Hemodynamically stable in ED, saturating well on RA, did receive Epi .3 mg IM for concern of throat sensation, tolerated well.

Patient received Covid vaccine while sitting without issue. Within minutes of receipt of the vaccine he had a vagal reaction (fell off his chair). Initial eval was notable for supine position, pale face, HR in 30's,

clammy skin, small lac to L forehead (not actively bleeding). Pt was alert and oriented initially then was noted to slow his speech/had decreased responsiveness <1 minute. He was then alert and able to answer all questions. Denies any past medical history, not on any meds, NKDA, no hx of reaction to vaccines. He denies any itching, rash, swelling, difficulty breathing/SOB/Wheezing, or GI sx. Exam remained unchanged with no objective signs of allergic reaction. His color improved as well and he reported feeling better, was able to sit up. He reports eating minimal breakfast this morning. Has a history vasaovagal reactions with blood draws. Decision made to call EMS for transfer for additional observation. EMS arrived at 1115 and transported patient to ER for observation.

Minutes after being vaccinated; patient felt flushed and arms and back and chest developed hives/rash. Hyperventilation with throat tightness. Healthcare worker was immediately transported to the Emergency Department and was treated with Benadryl, Epinephrine, Solu-medrol, Pepcid and Ativan.

Left arm swelling, redness, heated/ burning, bruise, rash, low grade fever 99.4, hardened area somewhat similar to a knot on site Took Benedryl

Right arm pain

Employee calling to report a reaction after receiving a COVID-19 vaccine. Vaccine Name - Pfizer Vaccine Lot # - EK5730 Vaccine Date and time - ?12/16/2020 @ 06:15am Is this your first or second dose? First Date and time of symptom onset - ? 12/20/2020 @ 09:00 am Symptoms - ? Dry Eyes Last day of work and shift - Yesterday 7a-7p? Home remedies? - eye drops, Zyrtec, flonase Any improvement? - no Recommendation? Manage per illness in the workplace policy. Told her that dry eyes is not an adverse reaction of the vaccine received. Recommend to consult her PCP about it. Employee voiced understanding Employee of information ? yes Employee voiced any concerns ? yes Employee?s questions answered to employee?s satisfaction - yes

Pfizer-BioNTech COVID-19 Vaccine EUA Patient had eaten before the vaccination, but had walked to the location of the vaccine administration, administration facility heat was on/very high, approximately 8 minutes after receiving the vaccine the patient stated that she felt hot, prickly, lightheaded and weak. She laid on the floor, remained conscious but used an ice pack on her forehead. She was able to walk to another chair located away from the heater and was observed for 30 additional minutes at which time she had a snack, drank water and was cleared to leave. Patient states that she feels okay today.

Head aches; Nausea; Fever; Metal flavor on mouth; This is spontaneous report from a contactable consumer. A 38-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), unknown route (site of vaccination left arm), on 16Dec2020 05:00 PM at single dose for COVID-19 immunisation. Medical history was none. Concomitant drugs were unknown. The patient experienced headache, nausea, fever, metal flavor on mouth, all at 07:30 PM on 17Dec2020. Patient was treated with acethaminophen. The action taken in response to the events for BNT162B2 was not applicable. The outcome of the events was recovered Information about lot/batch number has been requested.

Nausea, severe headache, very dizzy, started 22 hours after Very flushed, fever 100.6 at 28 hours after

Hand feels tingley for 15 minutes

mild pain at injection site 24 hours after receiving vaccine dose; This is a spontaneous report from a contactable via a Pfizer sales representative. A 40-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration in Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced mild pain at injection site 24 hours after receiving vaccine dose in Dec2020. Patient is healthy and within weight parameters. The outcome of the event was recovered in Dec2020. No follow-up attempts are possible; information about batch/lot number cannot be obtained.

Sore arm, body aches, headache, and fatigue.

Fever 101.7F Rigors Nausea Vomiting

"Hoarseness; Nausea; Loss of appetite; Weakness; Headache; whole body ached; pain in the area the shot was applied; some swelling at the injection site; This is a spontaneous report from a contactable nurse. A 49-year-old female patient received the first dose of the bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot Number: EH9899), via an unspecified route of administration in the left arm on 15Dec2020 at 15:30 at 49-years-old at a single dose for COVID-19 immunization. The vaccination facility type was a hospital. History of all previous immunization with the Pfizer vaccine considered as suspect (or patient age at first and subsequent immunizations if dates of birth or immunizations are not available): none. There were no additional vaccines administered on the same date of the Pfizer Suspect. The patient's medical history was reported as none. The patient was not a smoker. Family Medical History Relevant to adverse events: none. Concomitant medications included routine medications. On 15Dec2020, the patient experienced: pain in the area the shot was applied (non-serious). On 16Dec2020, the patient experienced: weakness (non-serious), headache (non-serious), whole body ached (non-serious). On 17Dec2020, the patient experienced: loss of appetite (non-serious). On 18Dec2020, the patient experienced: hoarseness (non-serious), nausea (non-serious). On an unspecified date in Dec2020, the patient experienced: some swelling at the injection site (non-serious). The events did not require a visit to an emergency room or physician office; there was no prior vaccinations (within 4 weeks), there was no adverse events following prior vaccinations. The clinical course was reported as follows: The patient (nurse) had the vaccine administered on 15Dec2020 at about 15:30; and was told to notify if she had any side effects. On the same day, the patient had a lot of pain in the area the shot was applied. The patient received the shot in the left arm and after that, she was feeling weakness, headache, her whole body ached, she had difficultly speaking, and nausea. The patient was advised to call and report anything she experienced after the vaccine. The patient first started with strong pain in the area where the vaccine was administered. It was very painful, and she had some swelling at the injection site. Next, she had a headache and loss of appetite. The patient had weakness in her body. On 18Dec2020, the headache started with some nausea. There was a very strong pain in her whole body and hoarseness (like she had no voice). The patient clarified later in the call she had a headache prior to 18Dec2020. The patient reported that the "" pain in the area the shot was applied"" was better. The patient reported ""it is not too annoying like it was yesterday."" The patient took acetaminophen for pain and applied ice packs. The patient reported that the weakness was better

on 18Dec2020. The headache was better because she took medication. The whole-body aches: were about the same, a strong pain in her back, in her arms, everywhere. The hoarseness which was clarified by the patient as what was meant when reporting difficultly speaking: The patient clarified she had no voice. On 18Dec2020, in the morning, she felt a hoarseness. The patient never presented this symptom until 18Dec2020. Loss of appetite: This started on 17Dec2020 and it was about the same since starting since she really had not eaten anything. Nausea: Started on 18Dec2020 in the morning when she woke; she had not done anything because she had lost her appetite. The patient had only fruit juice. The nausea was about the same since starting. "" When asked a seriousness criterion for the events: She would describe it has had a cold."" The patient reported that there was no difficulty breathing and so she felt it was not so urgent that there was a need for her to go to the emergency room. The patient received a call from the place where the vaccine was given; and was told if her symptoms were to get worse, she would have to go to the emergency department. The patient will get the card after her second dose; The patient was given a piece of paper. There was no expiry date or NDC provided on the paper. The patient reported that she takes nothing other than routine medications. The patient had no other vaccines on the day she received the COVID vaccine. The patient reported she had no important medical history and has had no reactions to any other vaccines previously. There was no relevant family medical history. The patient had been able to manage the symptoms herself at this point and did not require any additional trips to the hospital or doctor's office. Therapeutic measures were taken as a result of pain in the area the shot was applied, and headache. The clinical outcome of the events: pain in the area the shot was applied, weakness, headache, was recovering. The clinical outcome of the event, whole body ached, loss of appetite, hoarseness, nausea was not recovered. The clinical outcome of the event, some swelling at the injection site, was unknown."

light nausea and headache, dizziness, and vertigo, chills, overall unwell, prior to vaccine, patient states she was fine.

light nausea and headache, dizziness, and vertigo, chills, overall unwell, prior to vaccine, patient states she was fine.

MILD RASH, TINGLING IN THRAOT

Nausea, dizziness, states body feels like jelly, shaky. No vision changes or shortness of breath. Given oral Benadryl and oral Pepcid and discharged in stable condition after 2 hours.

Rash on face and neck, redness, itching, rash

The patient received the vaccine at about 1500, did wait 15 minutes for observation, and left around 1515 with no reported complaints. At around 1535 while driving home patient started having difficulty swallowing and contacted hospital advice nurse who referred the patient to the emergency department.

Elevated blood pressure Elevated pulse Heart palpitations Light headedness All started within 3 hours of receiving injection

12-22 HPI 53-year-old female with a history of Addison's disease, anaphylactic reaction who presents to the ED complaining of hives and shortness of breath. Patient reports that 3 days ago she received the COVID-19 pfizer vaccine. She reports that since that time she has developed progressively worsening hives on her legs and arms. Approximately 1 hour ago she began to develop shortness of breath and so she presented to the ER. Patient reports a previous history of anaphylactic reactions multiple times. Denies any other acute complaints at this time. MDM Patient came in with shortness of breath and hives. Suspect allergic reaction to the COVID-19 vaccine. Patient had already taken 50 mg of Benadryl. She was given Solu-Medrol and EpiPen. She reported feeling better with improvement in the pruritus. She reports that she has had rebound reaction requiring EpiPen at 24 hours. Given the distance that she lives from adequate medical care and the possibility for recurrent severe reactions, the patient will be hospitalized for further observation. 12-23 Female with history of asthma and addison's had anaphylaxis to covid vaccine. Admitted over night to ensure that she did not rebound. Received IV Dex and this am has had no reoccurrence of hives or shortness of breath. Will discharge home on epipen, hydrocortisone prn, prednisone bid for 5 days. Return to ER or go to PCP for worsening symptoms.

Patient reported that 2 days after the injections she had bilateral arm swelling (left more than right, injection was in the right arm) and hand swelling. She had some facial edema around her eyes. No difficulty with breathing, swallowing or tongue swelling. This all occurred at home.

Prior to receiving the vaccine I was feeling well, history of asthma, seasonal and environmental allergies, and no history of significant symptoms after previous vaccinations. Shortly after administration of the COVID-19 vaccine I began to feel nauseous which lasted in duration for approximately 3 days. On the vaccine administration day, several hours after administration I developed retrobulbar pain, bilateral eyelid edema, erythema of the right eyelid, this was one of the most significant symptoms that persisted for several days. In addition, on 12/20 I experienced a several hour episode of tinnitus and diminished auditory acuity in my right ear, this has also resolved. From day 2 until current I have experienced decreasing myalgias and arthralgias, the most significant has been lower back midline pain which has been improving. I developed a temperature of 99.7 Fahrenheit, with administration of acetaminophen. Although the symptoms have improved this is certainly the most significant constellation of symptoms I have experienced after any vaccination.

Dry mouth and itching on the back 20 minutes after receipt of vaccine. Throat feeling blocked. Headache. Diphenhydramine 50 mg PO x1 given. Symptoms started to subside approximately 20 to 30 minutes after administration of diphenhydramine. Blood pressure initially elevated at 178/84 but decreased to 142/82 approximately 15 minutes following administration of diphenhydramine. Patient a little drowsy from the diphenhydramine. Ears ringing and itching began 1 hour 15 minutes following administration of vaccine (and approximately 45 minutes following administration of diphenhydramine). Famotidine 20 mg PO x1 administered.

Weird taste in mouth.

After patient received the vaccine at 3:20pm, he was cleared to return home at 3:48pm. At approx. 8:20pm, patient became faint while laying down, experineced hot and cold flashes and observed

darkness closing in on his vision. He then expereinced auditory disrutpitions and became highly disoriented. He was ice cold to the touch on his forehead, expericning cramping and sweating profusely on his back. Thereafter, he had diarrhea and continues to be symptomatic. He currently has no fever, but continues to remain confused and feels like he needs to lay down from this experience. He also has a metallic taste that has developed.

Chills, fever, fatigue, muscle pain

Patient reports she also had severe flushing, burning pain in her chest dizziness. tachycardia, nausea and throat tightness.

Onset about 1 hour after injection with mild left deltoid pain. Then over course of 3 hours developed left arm pain, frontal headache, and posterior neck pain. No rash.

Progress Notes APRN (Nurse Practitioner) ? ? Nurse Practitioner Cosign Needed Expand All Collapse All COVID VACCINE CLINIC 12/22/2020 á Date: 12/22/2020 á Subjective Patient is a 23 y.o. female who was seen at COVID Vaccine Clinic today for her first dose of the COVID 19 vaccination. á She denied any history of previous adverse reactions to vaccines. á She was given the Pfizer vaccination in the left deltoid muscle. á During her 15 minute waiting period after the injection, the patient began to experience Headache and felling warm. She denied rash, hives, welts, difficulty breathing, difficulty swallowing, wheezing, throat tightness, hoarseness, stridor, itching, lightheadedness, dizziness, facial swelling, lip swelling and tongue swelling. á This provider was notified of patient reaction and she was then assessed in the emergency bay area. á Monitored patient for severe reaction symptoms, including respiratory distress with stridor, wheezing, dyspnea, increased work of breathing, persistent cough and cyanosis. á á á Review of Systems Neurological: Positive for headaches. All other systems reviewed and are negative. á á á Objective á Vitals Vitals: á 12/22/20 1554 12/22/20 1623 BP: 132/73 121/73 BP Location: Right arm Right arm Patient Position: Sitting Sitting Pulse: 94 85 Temp: (!) 96.7 ¦F (35.9 ¦C) á SpO2: 99% 99% á Physical Exam Vitals signs reviewed. HENT: Head: Normocephalic. Nose: Nose normal. Mouth/Throat: Mouth: Mucous membranes are moist. Eyes: Pupils: Pupils are equal, round, and reactive to light. Neck: Musculoskeletal: Normal range of motion. Cardiovascular: Rate and Rhythm: Normal rate. Pulses: Normal pulses. Pulmonary: Effort: Pulmonary effort is normal. Musculoskeletal: Normal range of motion. Skin: General: Skin is warm. Capillary Refill: Capillary refill takes less than 2 seconds. Neurological: General: No focal deficit present. Mental Status: She is alert and oriented to person, place, and time. Psychiatric: Mood and Affect: Mood normal. á á á Assessment/Plan Treatment included: no therapy. Follow up response to treatment: no side effects. Patient discharge: Stable to go home and follow up with PCP. á á Pt was told to take Tylenol for HA. Continue to monitor symptoms. á á APRN Electronically Signed 12/22/2020 4:27 PM á

About 1 hr after started to have muscle pain/soreness. Still sore ~40 hrs out.

Employee received vaccine, stayed 15 minutes and left ?. came back within 5-10 minutes c/o throat tightness and difficulty breathing

Warmth and tingling that started in the injection site (right deltoid) that ran down the arm and to the hand a couple minutes after injection. Warmth and tingling in moderate intensity lasted about 20 minutes and decreased with increased arm movement but lasted the first 24 hours with mild aches in the same arm. An enlarged and painful lymph node occurred in the armpit of the same arm two days later and lasted (although decreasingly) for at least the next 5 days.

Warmth and tingling that started in the injection site (right deltoid) that ran down the arm and to the hand a couple minutes after injection. Warmth and tingling in moderate intensity lasted about 20 minutes and decreased with increased arm movement but lasted the first 24 hours with mild aches in the same arm. An enlarged and painful lymph node occurred in the armpit of the same arm two days later and lasted (although decreasingly) for at least the next 5 days.

Injection site soreness

sore throat, lower back pain, fatigue, 101.8 fever, stuffy nose, joint pain, difficulty breathing

Fatigue upon waking up at 07:00 until 7 pm (12 hours)

Fatigue, Headache, Muscle Aches and Joint Pain.

Patient received covid 19 vaccine. She began to experience itching throat and swollen tongue. She was sent to the Emergency Department. She received IV Benadryl 50 mg, IV famotidine 20 mg and 125 mg IV solu-medrol. Around 930, patient stated that symptoms had resolved, except for tongue being slightly swollen. Patient was admitted to the observation unit of the hospital.

Patient complained of anxiety, palpitations, and tachypnea. Patient was laid supine, VS monitored, reassurance, fluids, and snack. Went home after feeling better. Stated some mild nausea the day after.

Employee received vaccine, within 10minutes, c/o of weakness, dizziness, shaking.... no complaints of Shortness of breath or tightness... refused to receive any additional treatment. Continued monitoring for another 2 hours, no additional symptoms, then developed numbness and tingling around mouth and trouble swallowing.... sent to ER.

Pfizer-BioNTech COVID-19 Vaccine EUA numbness in left arm and hand post injection

HEADACHE, EXCESSIVE CHILLS, EXCESSIVE SWEATING, FEVER, BODYACHES, STOMACHACHE

Blotchy skin from chest; full rash on torso and back from hips up to chest/slight rash on thighs/rash on back of knees and legs/Looks like a drug rash; Noticed being a bit itchy that evening; This is a spontaneous report from a non-contactable consumer (patient). A 41-year-old female patient received her first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot: EH9899) via an unspecified route of administration at the left arm on 15Dec2020 16:00 at a single dose for covid-19 immunisation. Medical history included Iga nephropathy from an unknown date. Concomitant medication included lisinopril. On 15Dec2020, the patient noticed being a bit itchy before going to bed. On 16Dec2020 18:00, the patient noticed blotchy skin from chest up, full rash on torso and back from hips up to chest. The

patient also noticed slight rash on thighs and more rash on back of knees and legs by 18Dec2020; looked like drug rash. The patient had no shortness of breath, fever, swelling, etc. The events were reported as non-serious and no treatment was given. Outcome of the events was recovering. No follow-up attempts are possible. No further information is expected.

sent to the emergency room for body rashes and hives.; sent to the emergency room for body rashes and hives.; This is a spontaneous report from a contactable pharmacist. This pharmacist reported similar events for 4 patients. This is the 1st of four reports. A patient with unspecified age and gender received BNT162B2 via unspecified route of administration on unspecified date at single dose for COVID-19 immunization. Medical history included allergies to bee stings. Concomitant medications were not reported. On unspecified date, the patient was sent to the emergency room for body rashes and hives, and they were recommending that those with a bee sting allergy hold off until they know more. The outcome of events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2020502533 same reporter/ drug/ events, different patient;US-PFIZER INC-2020502534 same reporter/ drug/ events, different patient;US-PFIZER INC-2020502535 same reporter/ drug/ events, different patient

4 different individuals sent to the emergency room for body rashes and hives.; 4 different individuals sent to the emergency room for body rashes and hives.; This is a spontaneous report from a contactable pharmacist. This pharmacist reported similar events for 4 patients. This is a second of four reports. A patient of unspecified age and gender received BNT162B2 (lot/batch number and expiration date not provided), via an unspecified route of administration on an unspecified date at single dose for immunization. Medical history included allergies to bee stings from an unknown date. The patient's concomitant medications were not reported. The patient was sent to the emergency room for body rashes and hives. They are recommending that those with a bee sting allergy hold off until they know more. The outcome of the events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2020502532 same reporter, event and drug but different patient

sent to the emergency room for body rashes and hives.; sent to the emergency room for body rashes and hives.; This is a spontaneous report from a contactable pharmacist. This pharmacist reported same events for 4 patients. This is the 4th of four reports. A patient of unspecified age and gender received BNT162B2 via an unspecified route of administration, on an unspecified date at single dose for immunization. Medical history included allergies to bee stings. It was reported that the patient sent to the emergency room post vaccine for body rashes and hives. There seemed to be a commonality of allergies to bee stings for the 4 different individuals. The pharmacist wondered if there are other reports of this. They are recommending that those with a bee sting allergy hold off until knowing more and wondered if any guidance from Pfizer. Event took place after use of product. Outcome of the events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2020502532 same reporter, drug, event but different patient

"more than likely anxiety; red, splotchy rash on her neck; sweaty; felt slightly dizzy, particularly when moving her head side to side; ""tightness"" in the upper middle quadrant of her stomach, near the

xiphoid process; ""tightness"" in the upper middle quadrant of her stomach, near the xiphoid process; HR was 140; This is a spontaneous report from a contactable pharmacist. A 41-year-old female patient received the first dose of BNT162B2 (Pfizer-BioNTech COVID-19 mRNA vaccine; lot number: EK5730), intramuscular (IM) on the left arm on 17Dec2020 at 18:30 at a single dose for COVID-19 immunization at the hospital. The patient's medical history and concomitant medications were not reported. The patient had no other vaccine in four weeks. Approximately 4 minutes after administration, on 17Dec2020 at 18:34, the patient complained of ""tightness"" in her upper middle quadrant of her stomach, near the xiphoid process. At that time (18:34), her heart rate (HR) was 140. At 18:40, her HR was 96. At 18:44, the patient had a red, splotchy rash on her neck. The patient received 25 mg of diphenhydramine (BENADRYL) orally. The patient noted that she was sweaty and she felt slightly dizzy, particularly when moving her head side to side. At 18:47, the patient's HR was 80. At 18:52, HR was 84 and at 18:58, HR was 68. The patient stated she felt much better, dizziness seemed to resolve quickly per patient's report. She was able to ambulate and turn her head side to side with no further difficulties. Throughout the episode, the patient denied nausea, shortness of breath, itching, urticaria or any other rash besides the redness on her neck. After discussion with the physician (MD), nurse (RN), and doctor of pharmacy (PharmD), who were present for the vaccine administration and reaction, it was determined that this was more than likely anxiety (17Dec2020 at 18:45) and not an allergic/anaphylactic reaction. The patient had no Covid prior vaccination and not Covid tested post vaccination. The events were assessed as non-serious. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. Therapeutic measures were taken as a result of ""more than likely anxiety; ""tightness"" in the upper middle quadrant of her stomach, near the xiphoid process; HR was 140; red, splotchy rash on her neck; sweaty; and felt slightly dizzy, particularly when moving her head side to side."" The patient recovered from all the events on an unspecified date."

last night legs began burning like she had rubbed icy hot on them, extending down feet/the feeling was all over her body; This is a spontaneous report from a contactable nurse. A 56-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), intramuscular from 17Dec2020 09:30 at single dose for immunization (reported as COVID-19 vaccine). Medical history included vertigo and small whole in heart. Concomitant medication included acetylsalicylic acid (BABY ASPIRIN), ergocalciferol (VIT D), magnesium taurate, selenium and zinc. The patient previously took Kepra, Oxtellar and Sulfa which she had allergies. The patient experienced that last night (17Dec2020) her legs began burning like she had rubbed icy hot on them, extending down to her feet. Then woke at 2am and the feeling was all over her body. Awoke again at 6am and feeling was still there. She went to work, feeling wass not confined to ankles and feet...icy hot although warm to touch. The patient underwent lab tests and procedures which included sars-cov-2 test: negative on 13Nov2020 and sars-cov-2 test: unknown results on Dec2020. Outcome of event was not recovered.

lost sense of taste; Headache; arm was hurting; fatigue; sinus congestion; sneezing; nose hurting because it was dry; nose hurting because it was dry; flu like symptoms; increase in urination; erythema; at the site of injection; swelling at the site of injection; malaise; pain and achiness; This is a spontaneous report from a contactable other healthcare professional (nurse practitioner) reported for himself. A 29-

year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number EH9899, expiry date unknown) via an unspecified route of administration on 17Dec2020 06:30 at single dose for COVID-19 immunization with his left deltoid. The reporter informed that the vaccination facility was a hospital and not administered at military facility. The patient's medical history included autoimmune stuff going on and the patient understand that the vaccine could intensify it. The patient informed that his autoimmune condition was psoriasis; lichen planus, irritable bowel syndrome (IBS), everything hypertension and other generic condition, migraine without aura. There were no concomitant medications. The reporter informed that no additional vaccines was administered on same date and within 4 weeks prior. The patient previously took thimerosal and was allergic. The patient had flu shot/flu vaccine (influenza vaccine) when very young and experienced allergic reaction. The patient experienced almost immediately had a headache (17Dec2020 06:35). He had the pain and achiness (Dec2020) like generic symptoms, something else was lost sense of taste that was 12 hours (17Dec2020 18:30) after taking the vaccine. His first dose was yesterday 17Dec2020 at 6:30 am. He clarified further that the headache started within 5 minutes of receiving the vaccine, arm was hurting within an hour, had the fatigue after 2 hours, and about 12 hours after noticed a loss for sense of taste. He also experienced sinus congestion and sneezing that started around 1 or 2 o clock on the same day (17Dec2020) and it was 8 hours after. The patient's headache was very mild now, fatigue was hard to say because the patient just woke up after sleeping 9 hours straight, sinus congestion greatly oscillates back and forth between being congested and not able to clear his nose at all and then it change in the matter 3 minute to suddenly his nose hurting because it was dry (Dec2020). The congestion could last half hour. The patient clarified that yesterday it was completely congested and today it was going back and forth. The patient informed that his side effects were flu like symptoms (Dec2020). The patient experienced increase in urination, erythema and swelling at the site of injection (Dec2020). The patient informed that he was tested maybe 2 months ago and at that time it was negative, but he didn't have a recent one. The events did not require a visit to emergency room and physician office. The patient took Advil for the achiness malaise (Dec2020). The outcome of the events headache was recovering, lost sense of taste, sinus congestion, sneezing was not recovered, while pain and achiness, arm was hurting, fatigue, nose hurting because it was dry, flu like symptoms, increase in urination, erythema and swelling at the site of injection, malaise was unknown. The patient's second dose was unknown, he was given a separate card for the second date and was having issues finding it. The patient has misplaced the card but knows it was his calendar, he will go in the office today and find out, he knew it was scheduled on a Friday.

Chills; fatigue; malaise; joint and muscle aches all over body as well as at and around injection site; joint and muscle aches all over body as well as at and around injection site; joint and muscle aches all over body as well as at and around injection site; mild fever: 99.6 oral Fahrenheit; This is a spontaneous report from a contactable consumer (patient). A 39-year-old male patient received bnt162b2 (BNT162B2) lot number: Ek5730, expiration date: not reported, via an unspecified route of administration in the left arm, first dose on 17Dec2020 09:45 at a single dose for immunization. Medical history included allergies to cephalosporins. The patient's concomitant medications were not reported. The patient did not receive any other vaccines within 4 weeks prior to the covid vaccine. On 17Dec2020 at 04:00 pm, the patient experienced chills, fatigue, malaise, joint and muscle aches all over body as well

as at and around injection site, mild fever of 99.6 oral Fahrenheit, lasting two days with lessening severity so far.The events were reported non-serious with no treatment received. The patient had no covid prior vaccination nor had he tested post vaccination. The outcome of chills, fatigue, malaise, joint and muscle aches all over body as well as at and around injection site, mild fever: 99.6 oral Fahrenheit was recovering.

anxiety was kicking in really bad/anxiety episode/triggered her anxiety; metallic taste; arm pain at the injection site; This is a spontaneous report from a contactable consumer (patient). A 34-year-old female patient received the first dose of BNT162B2 (Pfizer product, lot EK5730, expiry date Mar2021) via an unspecified route of administration on 18Dec2020 (reported as today at 11:45, unknown if AM or PM) at a single dose on the arm as Covid 19 Vaccine. Medical history included cervical cancer since 2010, both mother and father have had cancer; post-traumatic stress disorder (PTSD); anxiety; had been on therapy counselling. Concomitant medications included hydroxyzine, sometimes uses medical marijuana, sometimes taking prenatal vitamins just because of the whole virus and stuff thing going around; the patient might not be pregnant but become pregnant (consumer was unsure- PENDING CLARIFICATION). She's in the middle of a divorce but she just takes the prenatal vitamins because of the higher doses to help run her immune system because of the virus. The patient received the vaccine today (18Dec2020) and she was not sure what these ingredients were. She's a single mother and an EKG and EEG tech working around Covid positive patients. She inquired if any of the ingredients or the vaccine itself do cause cancer. She really had a bad anxiety and PTSD and she didn't know but her anxiety was kicking in really bad right now. She's currently having anxiety episode now. The more she got home, the more she's thinking and that's kind of triggered her anxiety. She already has anxiety taking the vaccine/have anxiety about this Covid19 vaccine. She inquired if the lady knew like what triggered the anxiety if there's like any ingredient that could potentially cause cancer, do they spike protein, do those cause cells to mutate which causes cancer, so many answers and questions the patient had and there were no answers to her questions, nobody knew because it's still being studied and that's also where her anxiety was getting triggered and all about this was just unknown. She was just trying to figure out if there's a chemical ingredient made to be administered in the vaccine because being a mother she was trying to find answers and nobody seemed to have any answers and all she heard was she did not have. It was also stated that after she got the vaccine, she had really metallic taste for about an hour and a half and it finally went away. She also had a regular arm pain at the injection site, it's normal like how one get flu shot and stuff. The patient had no investigation assessment. Treatment for the events was reported as no. The outcome of the event metallic taste was recovered on 18Dec2020 while the rest of the event was unknown.

About 5 minutes after the injection, got a flushed feeling for a couple of minutes.; This is a spontaneous report from a contactable Other Health Professional. A 43-year-old female patient received bnt162b2 (BNT162B2) lot number: EK5730, intramuscular (left arm), first dose on 16Dec2020 19:00 at a single dose for immunization. Medical history included high blood pressure and known allergies to penicillin and sulfa. Concomitant medication included escitalopram oxalate (LEXAPRO), lisinopril and omeprazole (PRILOSEC [OMEPRAZOLE]). It was reported that about 5 minutes after the injection on 16Dec2020 at 07:15 PM (as reported), the patient got a flushed feeling for a couple of minutes. The patient recovered

from flushed feeling for a couple of minutes (16Dec2020). The event was reported as non-serious with no treatment received. The patient had no covid prior vaccination. She had covid tested post vaccination on 18Dec2020 through nasal swab with negative result.

soreness at the site of injection.; This is a spontaneous report from a contactable consumer, the patient. A 54 year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), lot number EK5730 via an unspecified route of administration on 18Dec2020 at 10:45 (at the age of 54-years-old) as a single dose in the left arm for COVID-19 immunization. The patient had no relevant medical history. The patient had no known allergies to medications, food, or other products. Prior to the vaccination, the patient was not diagnosed with COVID-19. Concomitant medications included loratadine (CLARITIN) from an unknown date and unknown if ongoing, or an unknown indication. The patient did not receive any other vaccines within four weeks prior to the vaccination. On 18Dec2020 at 12:00, the patient experienced soreness at the site of injection. The patient did not receive any treatment for the event. The clinical outcome of the soreness at the site of injection was recovering. It was also reported that since the vaccination, the patient had not been tested for COVID-19.

Fatigue; Nausea; This is a spontaneous report from a contactable consumer (patient) and contactable Other healthcare professional. A 41-year-old female patient received the first dose of bnt162b2 (BNT162B2, lot number: EH9899), via an unspecified route of administration (left arm) on 18Dec2020 08:45 at single dose for immunization. Medical history included endometriosis and allergies to lavender and stevia. Concomitant medication included levonorgestrel for birth control. The patient previously took metoclopramide hydrochloride (REGLAN) experienced allergies. On 18Dec2020 03:00 PM, the patient experienced fatigue and nausea. The most recent COVID-19 vaccine was administered in the hospital. She did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. No treatment was received for the events. The events recovered on unspecified date in Dec2020.

Tiredness; Muscle pain; Chills; Fever; Joint pain; Vomiting; Nausea; Feeling unwell; This is a spontaneous report from a contactable nurse, the patient. A 54-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot number: EH9899), intramuscular in the right arm on 16Dec2020 at 09:30 AM (at the age of 54-year-old) as a single dose for COVID-19 immunization. Medical history included hypertension, sleep apnoea syndrome, glucose tolerance impaired, breast cancer (5 years ago), and anxiety. The patient was not pregnant at the time of vaccination. Prior to the vaccination, the patient was not diagnosed with COVID-19. Concomitant medication taken within two weeks of vaccination included HCTZ, losartan, anastrozole (ARIMIDEX), escitalopram oxalate (LEXAPRO), calcium, ergocalciferol (VITAMIN D), and fish oil; all for unknown indications from unknown dates and unknown if ongoing. The patient did not receive any other vaccines within four weeks prior to the vaccination. The patient previously took Bactrim and experienced drug hypersensitivity. On 17Dec2020, at 10:00 AM, the patient experienced tiredness, muscle pain, chills, fever, joint pain, vomiting, nausea, feeling unwell. The events were reported as non-serious. The patient did not receive any treatment for the tiredness, muscle pain, chills, fever, joint pain, vomiting, nausea,

and feeling unwell. The clinical outcome of the events tiredness, muscle pain, chills, fever, joint pain, vomiting, nausea, feeling unwell was unknown. It was also reported that since the vaccination, the patient had not been tested for COVID-19.

Very painful injection site 5 hours after injection; Headache; Nausea; Myalgia; Arthralgias; Severe fatigue; Mild confusion; Chills but no sweats or fevers; This is a spontaneous report from a contactable physician. A 59-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; lot number: EH9899), intramuscular on the right arm on 15Dec2020 06:30 at a single dose for immunization. Medical history included treated hypertension; he had no known allergies. Concomitant medication included chlorthalidone and nifedipine (PROCARDIA). The patient did not receive any other vaccines within four weeks prior to the COVID vaccine. On 15Dec2020 10:30, the patient experienced very painful injection site 5 hours after injection; 8-10 hours after: headache, nausea, myalgia, arthralgias, severe fatigue, mild confusion, chills but no sweats or fevers; had to take 2 days off work due to severity of symptoms; symptoms decreased but some continue on day 5. The events were reported as non-serious. No treatment was received for the events. The patient was not diagnosed with COVID prior to vaccination and has not been tested post-vaccination. Outcome of the events was recovering.

Headache; Metallic taste; This is a spontaneous report from a contactable nurse (patient). A 25-year-old female patient received bnt162b2 (BNT162B2; reported as Pfizer-BioNTech COVID vaccine; lot number: EL0140; expiration date: unknown), intramuscular left arm on 19Dec2020 06:45 AM at single dose for immunization. The patient's medical history and concomitant medications were not reported. It was reported that the patient received the COVID vaccine in a hospital. The patient did not have other vaccine in the last four weeks. The patient reported that she had headache and metallic taste on 19Dec2020. The events were non-serious and did not result in hospitalization or prolonged hospitalization. The patient received naproxen (ALEVE) as treatment. The patient was not diagnosed with COVID-19 prior vaccination and the patient has not been tested for COVID-19 since the vaccination. The outcome of the events was recovered on Dec2020. The following information on the batch/lot number has been requested

Tingling; Tachycardia; This is a spontaneous report from a contactable nurse. A 38-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number: EJ1685; Expiration date was not reported), intramuscularly on the left arm on 17Dec2020 at 1 DF, single for Covid-19 vaccination at the hospital. The patient's medical history and concomitant medications were not reported. The patient was not pregnant at the time of vaccination; and reportedly did not have Covid-19 prior to receiving BNT162B2 vaccination. On 17Dec2020 (03:00), the patient had tingling and tachycardia. The patient did not receive any treatment for the adverse event. The outcome of the events, tingling and tachycardia, was recovered in Dec2020. The patient was tested for Covid-19 post-vaccination. No follow-up attempts are possible. No further information is expected.

pain at the injection site; I had discomfort in my arm; sore throat; cough/Bit of a cough; This is a spontaneous report from a contactable nurse (patient). A female patient of an unspecified age received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE lot# not provided), via an unspecified

route of administration in Dec2020 at SINGLE DOSE for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. On Thursday (in Dec2020), the patient received her first dose of COVID vaccine that Pfizer makes. By Thursday night and yesterday (Friday), the patient had pain at the injection site. The patient also had discomfort in her arm. It was also mentioned that by Friday afternoon until night, she developed a sore throat and a bit of a cough (she doesn't know if the coughing was because her throat was sore or it's other way around). She also mentioned that she doesn't have a fever and still have her sense of taste and smell. Outcome of the events were unknown. Information on the Lot/Batch has been requested.

"left lower leg paresthesia in the left lateral sural nerve dermatome / felt like a tingling sensation localized to dermatome lateral to shin; felt like a burning sensation localized to dermatome lateral to shin; This is a spontaneous report from a contactable consumer, the patient. A 33-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot number: E51685), via an unspecified route of administration on 17Dec2020 05:45 (at the age of 33-years old) as a single dose in the left arm for COVID-19 immunization. Medical history included penicillin allergy from an unknown date and unknown if ongoing. Prior to the vaccination, the patient was not diagnosed with COVID-19. The patient's concomitant medications included an unspecified multivitamin received within 2 weeks of vaccination. The patient did not receive any other vaccines within 4 weeks prior to the vaccination. The patient experienced left lower leg paresthesia in the left lateral sural nerve dermatome which felt like a tingling/burning sensation localized to dermatome lateral to shin on 18Dec2020 08:00 (reported as about 12 hours after injection). There was no loss of sensory, ""temp"" or pain detected, as reported. The patient did not receive any treatment for the events. Since the vaccination, the patient had not been tested for COVID-19. The clinical outcomes of the lower leg paresthesia in the left lateral sural nerve dermatome which felt like a tingling/burning sensation localized to dermatome lateral to shin was not resolved."

sore and tenderness on left arm; soreness on left arm; slight HA (headache) in the morning; This is a spontaneous report from a contactable consumer (patient). A 49-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; lot number: EH9899), via an unspecified route of administration on the left arm on 15Dec2020 09:45 at a single dose for immunization. Medical history included iron deficiency and was diagnosed with COVID-19 on an unspecified date; no known allergies. Concomitant medications included ascorbic acid (VIT C), tocopherol (VIT. E), cetirizine hydrochloride (ALERCET). The patient did not have other vaccinations within four weeks prior to the COVID vaccine. The patient experienced slight HA (headache) in the morning of day 0 (15Dec2020), occasional HA and increased soreness on left arm on day 1 (16Dec2020), still sore and experienced tenderness on left arm on days 2 to 4 but was mild at the time of report. The events were reported as non-serious. The patient took Tylenol and applied heating pad on her left arm. She was diagnosed with COVID prior to the vaccination and has not been tested for COVID post-vaccination. Outcome of the events was recovering.

Mild grade fever (99.8); Unable to leave bed for 24 hrs due to extreme fatigue and muscle soreness; Unable to leave bed for 24 hrs due to extreme fatigue and muscle soreness; Unable to leave bed for 24 hrs due to extreme fatigue and muscle soreness; This is a spontaneous report from a non-contactable healthcare professional. A 32-year-old female patient received the first dose of BNT162B2 (Pfizer-

BioNTech COVID-19 mRNA vaccine; Lot Number: EH 9899), intramuscularly in the right arm on an unspecified date (at the age of 32-years-old) as a single dose for COVID-19 vaccination. The patient did not receive any other vaccines within 4 weeks prior to the vaccination. Medical history was reported as none. The patient was not pregnant at the time of vaccination. Prior to the vaccination, the patient was not diagnosed with COVID-19. Concomitant medication included ethinylestradiol, etonogestrel (NUVARING) for an unknown indication from an unknown date and unknown if ongoing. The patient did not have any allergies to medications, food, or other products. On 04Dec2020 at 09:00 (as reported), the patient experienced a mild grade fever (99.8), was unable to leave the bed for 24 hours due to extreme fatigue and muscle soreness. The patient was not treated for the mild grade fever (99.8), was unable to leave the bed for 24 hours due to extreme fatigue and muscle soreness. Since the vaccination, the patient had not been tested for COVID-19. The clinical outcome of the mild grade fever (99.8), was unable to leave the bed for 24 hours due to extreme fatigue and muscle soreness was resolved on 06Dec2020 at 9:00 (reported as resolved in 48 hours). No follow-up attempts are possible. No further information is expected.

Numbness and pain in left jaw line; Numbness and pain in left jaw line; This is a spontaneous report from a contactable consumer (patient). A 41-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number: EH9899), via an unspecified route of administration at the left arm on 18Dec2020 at 11:15 AM at single dose for COVID-19 immunization. The patient was not pregnant at the time of vaccination. The patient was not diagnosed with COVID-19 prior to vaccination, and the patient has not been tested for COVID-19 since the vaccination. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient had no medical history and no known allergies (no allergies to medications, food, or other products). Concomitant medication (other medications in two weeks) included cephalexin (CEPHALEXIN) stopped 1 week prior, and fish oil. The patient experienced numbness and pain in left jaw line on 18Dec2020 at 11:45 AM. The patient did not receive treatment for these events. The clinical outcome of the events was not recovered. The report was reported as non-serious.

Fever of 101 for hours; chills; shakes; severe joint pain; body aches; dizziness; This is a spontaneous report from a non-contactable consumer (patient). A 45-year-old female patient received the first dose of BNT162B2 (also reported as Pfizer-BioNTech COVID-19 mRNA vaccine, lot no: ELO140, expiry date not reported), via an unspecified route of administration on the right arm on 18Dec2020 at 10:45 at a single dose in the hospital for immunization. Medical history included having had COVID-19 prior to vaccination on an unspecified date. The patient had no known allergies. Concomitant medication included bifidobacterium lactis, lactobacillus acidophilus (PRO-IMMUNE) powder (as reported). The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient experienced fever of 101 for hours, chills and shakes, severe joint pain, body aches, dizziness all on 18Dec2020 at 22:45. Treatment was not received for the reported events. The outcome of the events was recovering. Since the vaccination the patient has not been tested for COVID-19.

Headache; neck and back ache; neck and back ache; injection arm very tender; Nausea; fatigue; This is a spontaneous report from a contactable consumer. A 49-year-old female patient started to receive BNT162B2 (Solution for injection, lot number and expiry date was unknown), via an unspecified route of

administration on 18Dec2020 10:00 at single dose in the left arm for immunization. Medical history included migraines and COVID-19 from an unknown date. Concomitant medication included acetylsalicylic acid (ASPRIN), potassium, curcuma longa (TURMERIC [CURCUMA LONGA]), ospemifene (OSPHENA) and black cohosh [cimicifuga racemosa] (BLACK COHOSH [CIMICIFUGA RACEMOSA]). The patient previously took penicillin and experienced allergies. On 18Dec2020 19:00, the patient experienced headache, neck and back ache, injection arm very tender, nausea and fatigue. No treatment received all the events. Since the vaccination, the patient has not been tested for COVID-19. The outcome of the events was recovering. The following information on the batch number has been requested.

had a high level of anxiety with a heart rate of approximately 100-120 bpm for about 1-2 hours; had a tingling feeling all over during this time; This is a spontaneous report from a contactable consumer. A 31-year-old male patient started to receive bnt162b2 (BNT162B2), via an unspecified route of administration from 17Dec2020 08:15 to 17Dec2020 08:15 at a single dose for COVID-19 vaccine. Medical history included intermittent anxiety. There were no concomitant medications. It was reported by the patient that the night of vaccination he woke up from sleep around 0200 and had a high level of anxiety with a heart rate of approximately 100-120 bpm for about 1-2 hours. He also had a tingling feeling all over during this time. The outcome of the events was recovering. Information about Lot/batch no has been requested.

transient (1-2 minutes) flushing; chest tightness (on the same side as vaccine); lightheadedness; This is a spontaneous report from a contactable consumer (the patient). A 33-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, lot number EK5730), via an unspecified route of administration in the left arm on 18Dec2020 at 08:45 (at the age of 33-years-old) as a single dose for COVID-19 immunization. Medical history included Hodgkin's lymphoma from Nov2019 (treated for cure Nov2019 through Feb2020). The patient did not have any allergies to medications, food, or other products. The patient was not pregnant at the time of vaccination. Prior to the vaccination, the patient was not diagnosed with COVID-19. The patient had received unspecified concomitant medications within 2 weeks of the vaccination. The patient did not receive any other vaccine within 4 weeks prior to the vaccine. On 18Dec2020 at 08:45 (as reported), the patient stated that 5-10 minutes after vaccine administration, she experienced transient (1-2 minutes) flushing, chest tightness (on the same side as vaccine), and lightheadedness. The patient was treated for flushing, chest tightness, and lightheadedness with BP measurements (as reported) and oral hydration. The clinical outcome of flushing was recovered on 18Dec2020, while chest tightness and lightheadedness were recovered in Dec2020. It was also reported that since the vaccination, the patient had not been tested for COVID-19.

Chills; shakes; headache; nausea; This is a spontaneous report from a contactable consumer (patient). A 37-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), via an unspecified route of administration on left arm on 18Dec2020 at 11:45 (dose number: 1) as a single dose for COVID-19 immunization. The patient medical history included anxiety. Concomitant medication were not reported. The patient was not pregnant at the time of vaccination and the facility where the most recent COVID-19 vaccine was administered was a hospital. The patient

did not receive any other vaccines within four weeks prior to the vaccination. Prior to the vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. The patient previously took clindamycin and had allergies. On 19Dec2020 01:30, the patient experienced chills, shakes, headache and nausea for 2 hours, 13 hours after administration (as reported). The patient did not receive any treatment for the events. The events were assessed as non-serious. The reported outcome of the events was recovering. Information on lot/batch number has been requested.

Fatigue 24 hrs after vaccination; Swelling and redness at injection site 36 hrs after vaccination; Swelling and redness at injection site 36 hrs after vaccination; This is a spontaneous report from a contactable consumer (patient). A 27-year-old female patient started to receive started to receive BNT162B2 (Solution for injection, lot number: Eh9899 and expiry date was unknown), via an unspecified route of administration on 17Dec2020 15:00 at single dose in the left arm for COVID-19 immunization. The patient was not pregnant at the time of vaccination. Medical history included allergies to sulfa drugs and diagnosed with COVID-19 prior to vaccination. The patient's concomitant medications were not reported. On 18Dec2020 18:30, the patient experienced fatigue 24 hrs after vaccination and swelling and redness at injection site 36 hrs after vaccination. No treatment received for all the events. The outcome of the events was unknown. The following information on the batch number has been requested.

shaking chills for at least 4 hours; nausea; fatigue; This is a spontaneous report from a non-contactable nurse. A 68-year-old female patient started to receive bnt162b2 (BNT162B2), via an unspecified route of administration from an unspecified date at a single dose unspecified dose for an unspecified indication. Medical history included covid-19 (Prior to vaccination). The patient's concomitant medications were not reported. It was reported that 24 hours after the first vaccine, the patient had shaking chills for at least 4 hours. She was wrapped in 2 heavy blankets and a heating pad. She also had nausea and fatigue. Symptoms gone the next day. The outcome of the events was recovered on an unspecified date. No follow-up attempts are possible. Information about lot/batch number cannot be obtained. No further information is expected.

Sore throat; This is a spontaneous report from a contactable Nurse (patient). A 21-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection) via an unspecified route of administration on 17Dec2020 06:00 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. No other vaccines received in four weeks prior to Covid-19 vaccine. No Covid-19 prior vaccination. It was unknown if patient was tested for Covid-19 post vaccination. The patient was not pregnant at the time of vaccination. The patient experienced sore throat on 18Dec2020 05:00. No treatment was received for the adverse event. The event was non-serious. The outcome of the event was recovered on unspecified date in Dec2020. Information on Lot/Batch number has been requested.

"Light headed; hypertension lasting approximately an hour/hour and a half; ""Mental fuzziness"" lasted until the headache took place.; ""Mental fuzziness"" lasted until the headache took place.; photo sensitivity; This is a spontaneous report from a contactable consumer. A 27-year-old female patient

started to receive BNT162B2 (Solution for injection, lot number and expiry date was unknown), via an unspecified route of administration on 18Dec2020 14:30 at single dose in the left arm for COVID-19 immunization. The patient was not diagnosed with COVID-19 prior to vaccination and since the vaccination, the patient has not been tested for COVID-19. The patient was not pregnant at the time of vaccination. There were no medical history. The patient has no known allergies. The patient's concomitant medications were not reported. On 18Dec2020 14:30, the patient experienced light headed, hypertension lasting approximately an hour/hour and a half, ''Mental fuzziness'' lasted until the headache took place and normal side effects accompanied such as a headache and photo sensitivity. No treatment received for all the events. The outcome of the events was recovered in Dec2020. The following information on the batch number has been requested."

"headache; This is a spontaneous report from a contactable nurse (patient) via Medical Information Team. A 31-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; lot number: EJ1685, expiry date: Mar2021), via an unspecified route of administration on 18Dec2020 at a single dose for immunization. The patient's medical history and concomitant medications were not reported. The patient reported that she was experiencing a ""really super bad headache"" on the day of report (19Dec2020) after receiving the covid vaccine the day before (18Dec2020). She took Tylenol and wanted to know if she can take Advil. She was suffering from a terrible headache and did not know if she can take Advil and there was nobody that can tell her whether it was okay with the vaccine. Outcome of the event was unknown."

have had a metallic taste since then, it has dissipated slightly; This is a spontaneous report from a contactable health care professional (patient). A 37-year-old female patient received the first dose of BNT162B2 (also reported as Pfizer-BioNTech COVID-19 mRNA vaccine, lot no: EK5730, expiry date: 01Mar2021), intramuscular on the on the left deltoid on 17Dec2020 (reported as 'at about 12:40 PM') at 0.3 mL at a single dose for COVID-19 immunization and ipratropium bromide (manufacturer unknown, specified as non-Pfizer, lot no: 348501, expiry date: May2022), nasal from an unspecified date to an unspecified date, 2 sprays, in each nostril as needed for rhinitis. Medical history included seasonal allergy for which the patient receives allergy injections regularly but have not received one recently or within the last 14 days and ongoing rhinitis. Concomitant medication included fexofenadine hydrochloride (ALLEGRA) and fluticasone propionate (FLONASE [FLUTICASONE PROPIONATE]). The patient stated that she was a healthcare worker and received the vaccine at her workplace. She called as she had a question about a very benign symptom that she was wondering if it's related to the vaccine or if it's something separate. She developed a metallic taste in her mouth about 2 hours after getting the vaccine, it's slowly dissipating but it's still there. She said no one else said that they did have it and actually one other person who she works with said that they also had a slight thing (upon further clarification it was unspecified) but it's not in the list of expected symptoms so she just wanted to call and check. The patient did not receive any treatment for the event. She stated that she also used a nasal spray, Ipratropium Bromide Nasal Solution because she has rhinitis and she did use that and she never had a symptom or side effect with that because she uses it chronically but she did use that right before and noticed the taste develop so she doesn't know if there is a possible interaction between that and the vaccine. That morning she did 2 sprays in each nostril about 6 o'clock in the morning and then she

did 2 sprays in each nostril about 2:15 PM and got her vaccine at about 12:40 PM that day. The patient got blood test for serology antibodies on 04Dec2020 with unknown results. The outcome of the event was recovering.

sore arm; patient received BNT162B2/ breastfeeding a 14 month old; patient received BNT162B2/ breastfeeding a 14 month old; This is a spontaneous report from a contactable consumer (patient). This consumer reported information about mother and baby. This is the mother case. A 36-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), via an unspecified route of administration on left arm on 17Dec2020 07:30 (dose number: 1) as a single dose for COVID-19 immunization. The patient's medical history included uncomplicated vaginal delivery (14 month old has no diagnosis. Was born 41 +5. Mother and baby have no issues postpartum). The patient had no known drug allergies. Concomitant medication were not reported. The patient was not pregnant at the time of vaccination and the facility where the most recent COVID-19 vaccine was administered was a hospital. Prior to the vaccination, the patient was not diagnosed with COVID-19. The patient did not receive any other vaccines within four weeks prior to the vaccination. Since the vaccination, the patient had not been tested for COVID-19. The patient was breastfeeding a 14 month old. The patient was not having symptoms except for a sore arm on 19Dec2020 (12:00AM). The patient did not receive any treatment for the events. The event was assessed as non-serious. The outcome of the event was not recovered. Information on the Batch/Lot number has been requested.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2020504610 baby case

Lightheadedness; This is a spontaneous report from a contactable pharmacist. A 52-year-old male patient started to receive bnt162b2 (BNT162B2, lot number EJ1685), intramuscular from 19Dec2020 10:45 to 19Dec2020 10:45 at a single dose for an unspecified indication. Medical history included hypertension. The patient's concomitant medications were not reported. The patient experienced lightheadedness on 19Dec2020 11:00 and took ondansetron. The outcome of the event was recovered on 19Dec2020.

having soreness to her arm at the injection site of the vaccine; This is a spontaneous report from a contactable healthcare professional (patient). A 26-year-old female patient received first dose of bnt162b2 (BNT162B2 lot number and expiry date were not reported), intramuscular on the left arm from an unspecified date at a single dose for immunization. The patient's medical history and concomitant medications were not reported. The patient experienced having soreness to her arm at the injection site of the vaccine on an unspecified date. Outcome of the event was unknown. Information on the lot/batch number has been requested.

puffiness and itchiness around her upper eye/last night she had a puffing, her eyes were puffed; it was itchy and she experienced itchiness everywhere/itchiness around her upper eye; This is a spontaneous report from a contactable consumer (patient herself). A 33-year-old female patient received first dose of bnt162b2 (BNT162B2, lot number: EK5730), intramuscular on Dec2020 at single dose for COVID-19 immunization. The patient has no medical history and stated that she had no other medical conditions, stated that she was generally healthy. Concomitant medication included ibuprofen and paracetamol (TYLENOL). The patient received the bnt162b2 and she had a puffing, her eyes were puffed, the upper

eye and it was itchy and she experienced itchiness everywhere on an unspecified date in Dec2020. Patient mentioned that there was no rash or hives. She said she took Benadryl and it helped with the puffiness around the eyes, it did help with itchiness but she was still having some itchiness so she wanted to go just ahead and report that to our safety department. Patient clarified that Benadryl helped with the puffiness around her eyes but the itching part was still there, it (Benadryl) helped but not that much. Patient reported that she had a CBC recently and she got her antibodies checked few days before she got the vaccine. Patient reported that there were some mild generalized itchiness. It was just mild right now. Outcome of eyes were puffed was recovering while outcome of itchiness was not recovered.

fatigue; fever; body ache; chills; headache; injection site soreness and swelling; injection site soreness and swelling; This is a spontaneous report from a contactable consumer (the patient). A 22-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, lot number EJ1685), via an unspecified route of administration in the left arm on 18Dec2020 10:15 (at the age of 22-years-old) as a single dose for COVID-19 immunization. The patient had no medical history. The patient did not have any allergies to medications, food, or other products. The patient was not pregnant at the time of vaccination. Prior to the vaccination, the patient was not diagnosed with COVID-19. The patient's concomitant medications were not reported. The patient did not receive any other vaccine within 4 weeks prior to the vaccine. On 18Dec2020 at 20:30, the patient experienced fatigue, fever, body ache, chills, headache, injection site soreness and swelling. The patient did not receive any treatment for the events. The clinical outcome of fatigue, fever, body ache, chills, headache, injection site soreness and swelling, was recovering. It was also reported that since the vaccination, the patient had not been tested for COVID-19.

body ache; fever; headache; This is a spontaneous report from a contactable consumer reporting for herself. A 52-year-old female patient received bnt162b2 (BNT162B2, lot number and expiration date were not reported), via an unspecified route of administration on 18Dec2020 at a single dose for immunization. Medical history and concomitant medications were not reported. The patient stated that she took the covid vaccine the day before (18Dec2020) and was experiencing body ache, fever and headache on an unspecified date in Dec2020. The outcome of the events was unknown. Information on batch number has been requested.

Swelling of throat; lightheaded; right arm injection site arm pain; This is a spontaneous report from a contactable consumer. A 27-year-old female patient received the first dose of bnt162b2 (BNT162B2, lot number: EK5730 expiry date: unknown), via an unspecified route of administration on the right arm on 19Dec2020 09:30 at single dose for immunization. Medical history included cervical spine disc herniations. Concomitant medications included sulfamethoxazole and bisacodyl (DULCOLAX [BISACODYL]). The patient had no known allergies. The patient was not diagnosed with COVID-19 prior to vaccination. The patient has not been tested for COVID-19 since the vaccination. The patient did not receive any other vaccine within 4 weeks prior to the COVID vaccine. On 19Dec2020 10:00, the patient experienced Swelling of throat, needing to keep clearing my throat, lightheaded, right arm injection site arm pain. The event was considered as non-serious. The patient received BENADRYL as treatment for the events swelling of throat, lightheaded, right arm injection site arm pain. Outcome of the events swelling of throat, lightheaded, right arm injection site arm pain was not recovered.

Left jaw pain slightly radiating into ear. Pain level 4/10; Left jaw pain slightly radiating into ear. Pain level 4/10; This is a spontaneous report from a contactable consumer. A 57-year-old female patient received the first dose of bnt162b2 (BNT162B2, lot number: EK5730, expiration date was not reported), via an unspecified route of administration on the left arm on 18Dec2020 09:30 at single dose for immunisation. Medical history included controlled hypertension (HTN) and allergies to milk products. Concomitant medication included meloxicam (MOBIC), escitalopram oxalate (LEXAPRO) and irbesartan. The patient was not diagnosed with COVID-19 prior to vaccination. The patient did not receive any other vaccine within 4 weeks prior to the COVID vaccine. On 19Dec2020 at 07:00, the patient experienced left jaw pain slightly radiating into ear. Pain level 4/10. No treatment was given for the events. The patient has not been tested for COVID-19 since the vaccination. The patient has not recovered from the events.

swollen lymph node on left side reddened and painful throat (left part)

today she has redness around the site; This is a spontaneous report from a contactable consumer (patient). A female patient of an unspecified age received bnt162b2 (BNT162B2, lot number and expiration date not provided), via an unspecified route of administration on 18Dec2020 at a single dose for immunization. The patient's medical history and concomitant medications were not reported. The patient took the Covid shot the day before (18Dec2020) and said it was ok, but on the day of the report, 19Dec2020, she has redness around the site. The patient wanted to know if she can put the ice pack around it, and also stated she should have not taken the shot. The outcome of the event was unknown. Information on the batch/lot number has been requested.

Heart rate 110; This is a spontaneous report from a contactable nurse. A 39-year-old female patient received bnt162b2 (BNT162B2 lot number and expiration date were not reported) intramuscular at the right arm first dose on 19Dec2020 09:00 at a single dose for immunization. The patient had no relevant medical history. The patient's concomitant medications were not reported. On 19Dec2020 11:00, the patient experienced heart rate 110. No treatment was received for the adverse event. The most recent COVID-19 vaccine was administered in a hospital. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. No other medication was received within 2 weeks of vaccination. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, has the patient has not been tested for COVID-19. No Allergies to medications, food, or other products. Outcome of the event was unknown.

Tattoo raised out of ski hours 6-14, forearm hot and red 24-36h; Tattoo raised out of ski hours 6-14, forearm hot and red 24-36h; bodywide itching 6-48h; This is a spontaneous report from a contactable physician reporting for herself. A 33-year-old female patient received first dose of bnt162b2 (BNT162B2, lot number: EK5730), intramuscular in the left arm (also reported as left deltoid) on 15Dec2020 15:15 at single dose for COVID-19 immunization. Medical history included asthma, environmental allergies, anxiety, and history of C. diff. The patient had known metal allergy (contact dermatitis). Concomitant medication included vortioxetine hydrobromide (TRINTELLIX), amfetamine aspartate, amfetamine sulfate, dexamfetamine saccharate, dexamfetamine sulfate (ADDERALL), ethinylestradiol, norethisterone (ALYACEN), all given on an unspecified date in 2020. On 15Dec2020 at 18:00, the patient reported that her tattoo raised out of ski hours 6-14, forearm hot and red 24-36h, bodywide itching 6-

48h. The events were reported as non-serious. The patient has COVID prior to vaccination and no COVID test post vaccination. The patient recovered from the events without treatment.

Aches; mild nausea; chills; fever up to 100.8 for 6-8 hours; Headache; fatigue; This is spontaneous report from a contactable consumer. A 63-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via intramuscular (left arm), on 16Dec2020 at single dose for COVID-19 immunisation. Medical history included type 1 diabetes mellitus, hypothyroidism, Raynaud's phenomenon, drug hypersensitivity (to sulfadiazine, erythromycin). The patient experienced aches on 16Dec2020 18:00, mild nausea on 16Dec2020 18:00, chills on 16Dec2020 18:00, fever up to 100.8 for 6-8 hours on 16Dec2020 18:00, headache on 16Dec2020 18:00, fatigue on 16Dec2020 18:00. The action taken in response to the events for BNT162B2 was not applicable. The outcome of the events was recovered in Dec2020 Information about lot/batch number has been requested.

nausea; This is a spontaneous report from a contactable consumer (patient). A 41-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date in Dec2020 at SINGLE DOSE for covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient received almost exactly the covid 19 vaccine 48 hours before 19Dec2020 and now experiencing nausea in Dec2020. The patient wanted to know the time to onset of the side effects. The action taken in response to the event for BNT162B2 was not applicable. The outcome of the event was unknown. Information on the lot/batch number has been requested.

Headache all day; This is a spontaneous report from a non-contactable physician. A 38-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) intramuscularly in right arm on 19Dec2020 07:30 at single dose for COVID-19 immunization. Medical history was none. There was no other vaccine received in four weeks prior to the COVID vaccine, no other medications received in two weeks. The patient experienced headache all day on 19Dec2020 08:30 AM. No treatment received. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. Facility type vaccine was hospital. The outcome of event was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

extreme diaphoresis; Diarrhea; shaking chills; shaking chills; visual disturbances; This is a spontaneous report from a contactable nurse, the patient. A 47-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE) solution for injection via an unspecified route of administration in the left arm on 10Dec2020 at 23:30 (at the age of 47-years-old) as a single dose for COVID-19 vaccination. The patient was not pregnant at the time of vaccination. Medical history and concomitant medications were not reported. The patient did not receive any other vaccine within 4 weeks prior to the vaccine. Prior to the vaccination, the patient was not diagnosed with COVID-19. On 11Dec2020 at 00:15, the patient experienced extreme diaphoresis, diarrhea, shaking chills and visual disturbances. No treatment was provided for the events extreme diaphoresis, diarrhea, shaking chills and visual disturbances. The outcome of the events extreme diaphoresis, diarrhea, shaking chills and visual disturbances was recovered in Dec2020. Since the vaccination, the patient had a Nasal Swab, Covid test

name post vaccination on 11Dec2020 was negative. The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up.

received vaccine @ 725am noted itchy ears back & (R) wrist @744 am denied SOB, difficulty swallowing, nausea rash, hives given Loratadine 10mg @ 7:50 VS BP 110/70 HR 72 O2 sat 98% RA 7:59 reported symptoms resolved

"almost unmanageable amount of jaw pain/hurting/terrible pain/jaw is sore/the worst pain ever; almost unmanageable amount of jaw pain/hurting/terrible pain/jaw is sore/the worst pain ever; Jaw is sore and swollen; This is a spontaneous report from two contactable other healthcare professionals (HCP, one of them is also the patient). A 37-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: PF12N EJ1685), intramuscular on 18Dec2020 13:00 at single dose for COVID-19 immunization at a hospital. The patient's medical history included root canal done on 07Dec2020, which was healing nicely with some jaw pain managed effectively with ibuprofen. Sore, easily manageable. Resolving nicely. No known drug allergy. No COVID prior vaccination, the patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. No COVID tested post this vacccination. The patient's concomitant medications within 2 weeks of vaccination included ibuprofen for jaw pain/Sore. No other vaccines in four weeks. It was reported that the patient had an almost unmanageable amount of jaw pain in the ""12ish"" hours after getting the first dose of vaccine. The patient received the vaccine around 1300 on 18Dec and within an hour (at 1400) it started hurting terribly. So much that he wanted to pull the tooth out with pliars. Terrible, terrible pain all through the night that would not abate at all with ibuprofen and ""tylenol number 3"". By morning, the patient started feeling better. Jaw was sore and swollen. Ibuprofen started working again. It seemed to be resolving. The patient saw the dentist urgently that morning and the dentist didn't see anything amiss in the gum line, and had the thought that some systemic response/inflammation in response to the vaccine contributed to this. The patient commented it to be literally among the worst pain he had ever experienced in his life. The outcome of the events was recovered in Dec2020."

chill; temp at 1200 was 100.4 and at 1830 101.7; shortness of breath; body aches; headache; This is a spontaneous report from a contactable consumer, the patient. A 59-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE) solution for injection via an unspecified route of administration in the right arm on 18Dec2020 at 16:30 (at the age of 59-years-old) as a single dose for COVID-19 vaccination. The patient was not pregnant at the time of vaccination. Medical history and concomitant medications were not reported. The patient previously took cefadroxil (DURICEF) and experienced allergies. The patient did not receive any other vaccine within 4 weeks prior to the vaccine. Prior to the vaccination, the patient was diagnosed with COVID-19 in Apr2020. On 19Dec2020, the patient experienced chill, temp at 1200 was 100.4 and at 1830 101.7, shortness of breath, body aches and headache. No treatment was provided for the events chill, temp at 1200 was 100.4 and at 1830 101.7, shortness of breath, body aches and headache. The outcome of the events chill, temp at 1200 was 100.4 and at 1830 101.7, shortness of breath, body aches and headache was not recovered. Since the vaccination, the patient has not been tested for COVID-19. The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up.

heart began to pound; a warm tingling through my abdomen and chest with flushing to my face; a warm tingling through my abdomen and chest with flushing to my face; a warm tingling through my abdomen and chest with flushing to my face; a metallic sort of taste in my mouth; This is a spontaneous report from a contactable consumer (patient). A 32-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EJ1685), via an unspecified route of administration on left arm on 18Dec2020 at 10:00 AM at single dose for COVID-19 immunisation at hospital. Medical history included history of svt (supraventricular tachycardia), patient had no allergies to medications, food, or any other products. Concomitant medication included escitalopram oxalate (LEXAPRO), colecalciferol (VITAMIN D) and levocetirizine dihydrochloride (XYZAL). About five minutes after vaccination on 18Dec2020, the patient experienced a warm tingling through her abdomen and chest with flushing to her face, a metallic sort of taste in her mouth and her heart began to pound. The tingling subsided after a couple minutes and heart rate returned to normal over the next 10 minutes. The patient was monitored by the clinic nurses for another 30 minutes before released. The patient felt warm for the rest of the day but no further effects. Prior to vaccination, the patient was not diagnosed with COVID-19; Since the vaccination, the patient hadn't been tested for COVID-19. The patient did not receive any treatment for events. The outcome of events was recovered on 18Dec2020.

I got a strong metallic taste; About 30 seconds later my entire body started to tingle and I couldn't feel my hands or feet; My heart started to pound out of my chest; headache; I got an extreme hot flash and all my coworkers said I looked bright red and glassy eyed; became drenched in sweat and had to sit down for about 15 minutes with cold packs; she looked bright red and glassy eyed; This is a spontaneous report from a contactable consumer (patient). A 36-year-old female patient received her first dose of bnt162b2 (PFIZER COVID-19 VACCINE, Lot Number: EK5730), via an unspecified route of administration on 18Dec2020 at 14:15 on her left arm at single dose for COVID-19 immunization. Medical history included hypothyroid- well controlled with levothyroxine and known allergies: Penicillin, sulfa, cephalosporin. Concomitant medications in two weeks included levothyroxine, multivitamin, ascorbic acid (VIT C), colecalciferol (VIT D3). It was reported that on 18Dec2020 at 14:15, the injection was painless and she felt great. About 30 seconds later she entire body started to tingle and she couldn't feel her hands or feet. Her heart started to pound out of her chest. She got a strong metallic taste. This subsided after 1-2 minutes. She went back to feeling good. Then about 15 minutes later, on 18Dec2020, the patient got an extreme hot flash and all her coworkers said she looked bright red and glassy eyed. She became drenched in sweat and had to sit down for about 15 minutes with cold packs. Then it subsided again. She had a few more hot flashes and headache the remainder of the evening, but felt generally pretty good ever since. No treatment was received for the adverse event, prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, the patient had not been tested for COVID-19. The outcome of the events was recovered in Dec2020.

erythema and swelling on injection arm below the actual injection site; erythema and swelling on injection arm below the actual injection site; Face and neck rash; This is a spontaneous report from a contactable physician. This physician reported for herself. A 42-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK5730), via an unspecified route of administration on 16Dec2020 18:00 at single dose for covid-19 immunization. It was the first dose. The

COVID-19 vaccine was administered at Hospital. The patient's vaccine location was left arm. Medical history included hypertension (HTN), and mild asthma, the patient's known allergies included Black pepper, hydroxychloroquine sulfate (PLAQUENIL), hydrochlorothiazide (HCTZ), almond extract. Concomitant medications included Losartan, spironolactone, progesterone, metformin. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient experienced face and neck rash, erythema and swelling on injection arm below the actual injection site, adverse event start date was provided as 16Dec2020 06:00 PM. The patient Took fexofenadine 360mg for facial rash. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, the patient was not tested for COVID-19. The outcome of the events was Recovering.

"Numbness at the tip of her tongue; This is a spontaneous report from a contactable nurse (patient). A 39-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 19Dec2020 at time of 15:40 at single dose for COVID-19 immunization. Medical history included Irregular heart beat. Concomitant medication included potassium, magnesium; both for irregular heart beat. The patient just had a baby 9 weeks ago, and was breastfeeding. She also mentioned that her daughter just had her 1st round of her vaccines (other vaccines: rota, mmr vaccines, etc.) last week. She wanted to know if it's still okay to nurse her daughter considering that she just had her Covid 19 vaccine this afternoon on 19Dec2020. The patient also wanted to know what was the risk or potential complication of passing her milk, which contained the Covid 19 vaccine, to her daughter. The patient also wanted to know why it was contraindicated to take the Covid 19 vaccine if she has taken other vaccines within the 2 weeks timeframe before getting the Covid 19 vaccine. The patient experienced numbness at the tip of her tongue. Her tongue was numb, just the tip. The patient stated, ""I have two things I got my vaccine today at 15:40 for now it is just passing 18:00 anyway. That's all my tongue is numb, no other symptom, nor I am feel tiring. I don't have numbness in my hand or feet anything but there is my tongue is numb."" Nurse stated, ""Just a tip (of tongue)"". The patient stated, ""I do have another questions. I had a baby 9 weeks ago so one of the question is asked is that I had not any vaccine over the past two weeks and I have not well my daughter has, she just got her a week ago. So am I okay to breastfeeding?"" The outcome of event was unknown. Information on the lot/batch number has been requested."

scratchy throat, stiff neck ,

Headache, dizziness, fatigue; Headache, dizziness, fatigue; Headache, dizziness, fatigue; This is a spontaneous report from a contactable physician. A 50-years-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE): EJ1685, via an unspecified route of administration, in left arm on 18Dec2020 at 1845 (at the age of 50-years-old) as a single dose for COVID-19 immunization. Medical history included asthma and an allergy to penicillin. Concomitant medications were not reported. The patient was not pregnant at the time of vaccination. The patient did not receive any other vaccines within four weeks prior to the vaccination. The patient experienced headache, dizziness, fatigue on 19Dec2020 at 19:00. The patient was not treated for the events. The outcome of the events was recovering. It was also reported that since the vaccination, the patient had not been tested for COVID-19.

Within 2 minutes of injection, I became tachycardic; shaky; a bit dizzy; This is a spontaneous report from a contactable consumer (patient). A 49-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL0140), via an unspecified route of administration on 18Dec2020 07:15 AM at right arm, at SINGLE DOSE for covid-19 immunization. Medical history included anxiety and depression, allergies to IV dye, Bee stings. Concomitant medication included famotidine (PEPCID), diphenhydramine hydrochloride (BENADRYL), ergocalciferol (VIT D), acetylsalicylic acid (BABY ASPIRIN). The patient previously took levofloxacin (LEVAQUIN) and experienced allergy, ceftriaxone sodium (ROCEPHIN) and experienced allergy. The patient was not pregnant at the time of vaccination. Within 2 minutes of injection, the patient became tachycardic, shaky and a bit dizzy from 18Dec2020 07:15AM. These events resulted in Emergency room/department. No treatment was received for these events. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The action taken in response to the events for bnt162b2 was not applicable. The outcome of the events was recovered in Dec2020. No seriousness criteria: no Results in death, no Life threatening, no Caused/prolonged hospitalization, no Disabling/Incapacitating, no Congenital anomaly/birth defect.

flushed 15 min post inj. tickle in throat then tongue tingling and raspy voice 20 min post inj.

Approx 36 hours after receiving the vaccine I woke up feeling tired and nauseous; Approx 36 hours after receiving the vaccine I woke up feeling tired and nauseous; Over the next 6 hours I had chills and vomited profusely twice.; Over the next 6 hours I had chills and vomited profusely twice.; This is a spontaneous report from a contactable consumer (Patient). A 58-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 17Dec2020 17:15 at single dose for covid-19 immunization. The COVID-19 vaccine was administered at Hospital. Medical history included sleep apnoea syndrome (OSA), High blood pressure (BP), depression, anxiety, chronic fatigue syndrome (CFS). Concomitant medication included methylphenidate hydrochloride (CONCERTA), bupropion hydrochloride (WELLBUTRIN), chlorthalidone, magnesium. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Approximate 36 hours after receiving the vaccine she woke up feeling tired and nauseous. Over the next 6 hours she had chills and vomited profusely twice. Adverse event start date provided as 19Dec2020 08:00 AM. No treatment received for the events. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, the patient was not been tested for COVID-19. The outcome of the events was recovering. Information on the lot/batch number has been requested.

employee received vaccine at 1525 1535 noted lightheadedness & shaky feeling. Hx of vasovagal responses to injections & blood draws. Denies SOB, difficulty swallowing, nausea (+) hand/fingers tingling - VS- tachycardia to 120, O2 sat 97% became syncopal to ED

Headache; the patient was pregnant at the time of vaccination, gestational period was 23 weeks; This is a spontaneous report from a contactable consumer (patient). A 30-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration at left arm on 18Dec2020 19:45 at single dose for COVID-19 immunization at a hospital.

For the patient's medical history, no allergies to medications, food, or other products. For concomitant drugs, no other medications was received within 2 weeks of vaccination. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient was not diagnosed with COVID-19 prior to vaccination, and since the vaccination, the patient been had not tested for COVID-19. It was reported that the patient was pregnant at the time of vaccination, gestational period was 23 weeks. The last menstrual date was reported as 08Jul2020. The patient was due to deliver on 14Apr2021. On 19Dec2020 19:00, the patient experienced headache. No treatment was received for the event headache. The outcome of the event headache was recovering. Information on the lot/batch number has been requested.

About 30 minutes after injection felt brain fog and had a hard time finding words; About 30 minutes after injection felt brain fog and had a hard time finding words; It's like we were having to concentrate more than usual to do routine stuff; This is a spontaneous report from a contactable consumer (patient himself). A 44-year-old male received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number Ej1685), intramuscular on the left arm, as first single dose on 20Dec2020 (at 06:30) for COVID-19 immunisation. The patient did not have a relevant medical history. No relevant concomitant medications were provided. About 30 minutes after injection felt brain fog and had a hard time finding words. Another nurse that got vaccinated at the same time felt the same way. It's like we were having to concentrate more than usual to do routine stuff. The patient was not treated for the events. The patient did not perform COVID test before vaccination but after vaccination Nasal Swab, Rapid PCR, was Negative. He was recovering from the events.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2020504556 same drug, same event and different patient

chills; fatigue; headache; arm soreness; nausea; Tingling in lips/mouth; itching; low grade fever; vomiting; This is a spontaneous report from a non-contactable consumer (patient). A 31-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number=14-202012170004), via an unspecified route of administration on right arm on 17Dec2020 at single dose for COVID-19 immunization. Medical history reported as none. Concomitant medication included sertraline hydrochloride (ZOLOFT) and minerals nos, vitamins nos (PRENATAL VITAMIN). The patient experienced tingling in lips/mouth, itching, nausea, vomiting, chills, headache, low grade fever, fatigue, arm soreness on 17Dec2020, all events reported as non-serious. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient hadn't been tested for COVID-19. The patient did not receive any treatment for all events. The outcome of events was recovered in Dec2020. No follow-up attempts are possible; Information about lot/batch number cannot be obtained.

Dizziness, Headache, dry mouth, arm swelling; Dizziness, Headache, dry mouth, arm swelling; Dizziness, Headache, dry mouth, arm swelling; Dizziness, Headache, dry mouth, arm swelling; other vaccine same date vaccine date on 20Dec2020; This is a spontaneous report from a contactable other health professional (patient). A 33-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot umber: Ej1685), intramuscularly on 20Dec2020 08:00 AM at left arm, at SINGLE DOSE for covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient received other vaccine same date on 20Dec2020 (lot number: Ej1686),

and experienced dizziness, headache, dry mouth, arm swelling all on 20Dec2020 08:30 AM. No treatment was received for these events dizziness, headache, dry mouth, arm swelling. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The action taken in response to the events for bnt162b2 was not applicable. The outcome of the events dizziness, headache, dry mouth, arm swelling was not recovered. No seriousness criteria: no Results in death, no Life threatening, no Caused/prolonged hospitalization, no Disabling/Incapacitating, no Congenital anomaly/birth defect. No follow-up attempts are possible. No further information is expected.

chills; myalgias; fatigue; increased cough; This is a spontaneous report from a contactable physician(patient). A 58-year-old male patient received first dose of BNT162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EJ1685), intramuscular on 11Dec2020 18:00 at left arm at single dose for COVID-19 immunization. Medical history included COVID-19 diagnosed prior to vaccination and cough. No other medical history. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine but received other medications within 2 weeks of vaccination. The patient previously took ilosone and experienced allergies. The patient experienced chills, myalgias, fatigue and increased cough on 12Dec2020 14:00. No treatment received for the events. Since the vaccination, the patient has not been tested for COVID-19. The outcome of the events was recovering.

Chills; muscle aches; fever; Not able to work; Extreme tiredness; This is a spontaneous report from a contactable consumer (patient). A 53-years-old male patient received the first dose of BNT162B2 (Lot number: eH9899), via an unspecified route of administration, in arm left, on 18Dec2020 17:00 at single dose for COVID-19 immunization. Facility where the most recent COVID-19 vaccine was administered was hospital. Medical history included heart valve replacement. Prior to vaccination, the patient was diagnosed with COVID-19. Since the vaccination, patient was not tested for COVID-19. No allergies to medications, food, or other products. No other vaccines were received within 4 weeks prior to the COVID vaccine. The other medication that the patient received within 2 weeks of vaccination was atenolol. The patient experienced chills, muscle aches, fever, not able to work and extreme tiredness on 19Dec2020 06:00 AM. The events were reported as non-serious. No treatment was received for the events. The outcome of the events was recovered in Dec2020.

sore arm (right arm where injection was administered); Headache; This is a spontaneous report from a non-contactable consumer (patient). A 25-year-old female patient received the first dose of BNT162B2 (lot number: EK5730), via intramuscular in right arm, on 18Dec2020 09:00 at single dose for COVID-19 immunization. Facility where the most recent COVID-19 vaccine was administered was hospital. The patient was not pregnant at the time of vaccination. The patient was not diagnosed with COVID-19 prior to vaccination. Since the vaccination, the patient was not tested for COVID-19. No allergies to medications, food, or other products. Relevant medical history included Ulcerative Colitis. No other vaccines were received within 4 weeks prior to the COVID vaccine. The medications received within 2 weeks of vaccination included Mercaptopurine, Remicade, Mesalamine and Junel Fe. The patient experienced headache and sore arm (right arm where injection was administered) on 19Dec2020 12:00

PM. No treatment was received for the events. The outcome of the events was recovering. No follow-up attempts are possible. No further information is expected.

Fever of 101; myalgias; injection site swelling and pain; injection site swelling and pain; This is a spontaneous report from a contactable physician. This physician reported for himself. A 34-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899), intramuscular on18Dec2020 09:00 AM at single for covid-19 immunization. The COVID-19 vaccine was administered at Hospital. Vaccine location was Left arm and it was the first dose. The patient's medical history and concomitant medications were not reported. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient experienced fever of 101, generalized myalgias, injection site swelling and pain on 18Dec2020 21:00. Acetaminophen 500 mg q6h (Every 6 hours) for 2 days was received as treatment received for the adverse events. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, the patient was not been tested for COVID-19. The outcome of the events was recovered on an unknown date in Dec2020.

lethargic; Right arm pain; body aches; tingling both arms and face; flu like symptoms; This is a spontaneous report from a contactable healthcare professional (HCP) reporting for himself. A 34-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot#EL0140) via intramuscular in right arm on 17Dec2020 16:00 at single dose for COVID-19 immunisation. The patient received the vaccine in hospital. The patient had no known allergies or other medical history. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient did not receive any medications within 2 weeks of vaccination. Prior to vaccination, the patient was not diagnosed with COVID-19. The patient experienced right arm pain, body aches, tingling both arms and face, lethargic, flu like symptoms on 17Dec2020 23:00. Since the vaccination, the patient had not been tested for COVID-19. No treatment was received for the events. The outcome of events was recovered in Dec2020.

Chills; injection site pain/tenderness; body aches; headache; fatigue; This is a spontaneous report from a non-contactable consumer (patient). A patient of unspecified age and gender received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: Ett9899), via an unspecified route of administration on 19Dec2020 09:00 on left arm at single dose for COVID-19 immunisation. The patient medical history and concomitant medications were not reported. The patient had no known allergies. The patient experienced chills, body aches, headache, fatigue, injection site pain/tenderness on 20Dec2020 at 12:00 PM. The treatment of the events included Tylenol. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, the patient had not been tested for COVID-19. The outcome of the events was not recovered. No follow-up attempts are possible. No further information is expected.

Immediate bitter/metallic taste. Lasted 1 hour post vaccination.; This is a spontaneous report from a non-contactable consumer (patient). A 42-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration at left arm on 20Dec2020 09:15 at single dose for COVID-19 immunization at a hospital. The patient's medical history

was not reported. Concomitant medication included sertraline hydrochloride (ZOLOFT), ergocalciferol (VIT D). The patient previously took butorphanol tartrate (STADOL) and experienced drug allergy (known allergies). No other vaccine in four weeks. No COVID prior vaccination and no COVID tested post vaccination. The patient was not pregnant at the time of vaccination. It was reported that the patient experienced immediate bitter/metallic taste, which lasted 1 hour post vaccination. No treatment was received for the event. The outcome of the event was recovered on recovered on 20Dec2020 10:15. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

Slight headache and aches; Slight headache and aches; This is a spontaneous report from a contactable consumer (patient). This 65-year-old-female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration in the left arm on 19Dec2020 at 14:30 at single dose for COVID-19 immunisation. Vaccination facility type was workplace clinic. The patient did not receive other vaccines in four weeks. Relevant medical history included allergy to latex. Concomitant medication included levothyroxine sodium (SYNTHROID). On an unspecified date, the patient experienced slight headache and aches. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, she had not been tested for COVID-19. The outcome of the events was unknown. The information on the lot/batch number has been requested.

Headache; muscle aches /pain; lethargy; dizziness,lightheaded; joint pain; nausea; GI upset; other vaccine same date vaccine date=19Dec2020; This is a spontaneous report from a contactable consumer (patient). This 50-Year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) Lot number Unknown, at single dose on 19Dec2020 08:30 AM on left arm at Hospital for COVID-19 immunisation. There was no medical history. The patient had no COVID prior vaccination. The patient did not have COVID tested post vaccination. The patient had no known allergies. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Concomitant medication included clonazepam (KLONOPIN) which was received within 2 weeks of vaccination. Other vaccine was received on the same date on 19Dec2020. The patient experienced headache, muscle aches /pain, lethargy, dizziness, lightheaded, joint pain, nausea, GI (Gastrointestinal) upset on 20Dec2020 06:00. No treatment was received for all events. The outcome of the events was not recovered. Information on the lot/batch number has been requested.

muscle fatigue; pain; skin feels tight over the injection site; she could not lift her arm without severe pain; This is a spontaneous report from a contactable Consumer reported for herself. A 33-year-olfd female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) at single dose for COVID-19 immunization on unknown date. Relevant medical history and concomitant medications were not reported. On unknown date the patient stated the shot felt like a flu shot at first then at bedtime the muscle fatigue increased and her pain was a 7 out of 10. After taking Tylenol, her pain was a 5-6 out of 10. No rash or redness but the skin feels tight over the injection site. Caller complains of severe soreness. When she woke up, she could not lift her arm without severe pain. The outcome of the events was reported as unknown. Lot/Batch number has been requested.

mild chest pressure/tightness; chills; slight cough; Within 5 min after shot I had mild dizziness/30min later I experienced moderate to severe dizziness/feeling faint; left hand tingling which subsided/tingling

of hands and feet; This is a spontaneous report from a contactable consumer (patient). A 34-years-old female patient received her first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration in arm left on 19Dec2020 19:30 at single dose for COVID-19 immunization. Medical history included eczema. There were no allergies to medications, food, or other products. Concomitant medication included patch birth control within 2 weeks of vaccination. Within 5 min (19Dec2020 19:35) after shot the patient had mild dizziness with left hand tingling which subsided. Then 30min later (19Dec2020 20:00) the patient experienced moderate to severe dizziness, feeling faint, tingling of hands and feet, mild chest pressure/tightness, chills, and slight cough. The feeling lasted about 1 hr. Chest tightness resolved after taking Benadryl. No treatment received for other events. The patient was no pregnant at the time of vaccination. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. The events were reported as non-serious. The outcome of the events was recovered in Dec2020. Information on the lot/batch number has been requested.

moderate pain at injection site; congested nose; This is a spontaneous report from a non-contactable consumer (patient's husband). A female patient (frontline health care professional) received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration on Dec2020 as a single dose for COVID-19 vaccination. The patient medical history and concomitant medications were not reported. On Dec2020, the patient experienced moderate pain at injection site and congested nose. In Dec2020, the pain was mild around the injection site and her congested nose was now clear. The clinical outcome of the moderate pain at injection was recovering and the outcome of the event congested nose was recovered Dec2020. No follow-up attempts are possible; information about lot number cannot be obtained.

Temp 99.6 and congestion.; Temp 99.6 and congestion.; This is a spontaneous report from a non-contactable nurse. A 24-year-old female patient received first dose of BNT162B2, intramuscularly on 18Dec2020 08:00 at a single dose for COVID 19 immunization. The patient medical history was not reported. The patient is not a pregnant at the time of vaccination. Concomitant medication included sertraline hydrochloride (ZOLOFT), ethinylestradiol, ferrous fumarate, norethisterone acetate (TAYTULLA). The patient experienced temp 99.6 and congestion, both on 18Dec2020. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. No treatment was received for the adverse event. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. This is a non-serious report. The outcome of events was not recovered. No follow-up attempts are possible, information about lot/batch number cannot be obtained.

Muscle pain; Joint pain; Sore throat; Feeling unwell; stated she feels very weak; stated she had initially had a fever of 102 degrees Fahrenheit, and now has a fever of 100 degrees Fahrenheit; Chills; injection site soreness; Headache; This is a spontaneous report from a contactable consumer. A 60-year-old female patient received the first dose of bnt162b2 (BNT162B2, lot number: EK5730), via an unspecified route of administration on 17Dec2020 09:30 on the right upper shoulder at single dose for immunization. Medical history included stomach cancer over 20 years ago, clarifying she no longer has

stomach cancer. The patient's concomitant medications were not reported. On 17Dec2020, the patient experienced injection site soreness, headache, chills, she initially had a fever of 102 degrees Fahrenheit and now has a fever of 100 degrees Fahrenheit. Yesterday evening (17Dec2020) she developed a fever with chills, saying she couldn't get warm, so she went to bed. She said when she got up this morning (18Dec2020), she had the other side effects: muscle pain, chills, joint pain, sore throat, feeling unwell, and she feels very weak. Reported she couldn't function when she woke up this morning. For the treatment of headache, the patient took 1 Ibuprofen 600mg tablet. She said she still has a headache, but her headache has improved. She said she took an over-the-counter Tylenol 500mg tablet. She received the COVID-19 shot at the hospital she is employed. The reported events did not require a visit to Emergency Room and Physician Office. The events headache, muscle pain, chills, joint pain, fever, sore throat was recovering, and the outcome of the remaining events was not recovered.

tenosynovitis L 2 finger, felt most on back of hand, worse with flexion, extension; This is a spontaneous report from a contactable physician. A 64-year-old male patient received first dose of bnt162b2, intramuscularly at site of left arm at 09:15 on 19Dec2020 at single dose for COVID-19 immunization. Medical history included allergies: bananas, kiwi, avocado, latex. Concomitant medication included atorvastatin in Dec2020. The patient experienced tenosynovitis l 2 finger, felt most on back of hand, worse with flexion, extension at 13:00 on 19Dec2020. The patient took advil 600 TID as treatment received for event. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. The outcome of event was recovering. Information on the Lot/Batch number has been requested.

Swollen Lymph Nodes; This is a spontaneous report from a contactable nurse (patient himself). A 39-year-old male patient received first dose of bnt162b2, intramuscularly at site of left arm at 12:00 on 17Dec2020 at single dose for COVID-19 immunization. Medical history included COVID-19. There were no concomitant medications. The patient experienced swollen lymph nodes at 09:00 on 19Dec2020. No treatment received for the adverse event. Prior to vaccination, patient diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. The outcome of event was recovering. Information on the lot/batch number has been requested.

Fever; Chills; muscle aches; Fatigue; Joint pain; nausea; vomiting; This is a spontaneous report from a contactable nurse (patient herself). A 33-year-old female patient (no pregnancy) received first dose of bnt162b2, intramuscularly at site of left arm at 10:00 on 18Dec2020 at single dose for COVID-19 immunization. Medical history reported none. Concomitant medication included iron, cyanocobalamin, pyridoxine hydrochloride, thiamine hydrochloride (VITAMIN B 1-6-12) (reported as vitamin B supplement) and birth control pills. The patient experienced fever, chills, muscle aches, fatigue, joint pain, nausea and vomiting at 21:00 on 18Dec2020. The outcome of events was recovering. Information on Lot/Batch number has been requested.

Patient experienced sore arm following COVID vaccine; This is a spontaneous report from a contactable consumer (patient). A patient of unspecified age and gender received bnt162b2, via an unspecified route of administration in 2020 at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced sore arm following COVID

vaccine in 2020. The outcome of event was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

fever; body aches; headache; sharp pain in my left arm; limited in mobility to bed; This is a spontaneous report from a contactable consumer reporting for herself. A 21-years-old non-pregnant female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE Lot Number: EH9899), via an unspecified route of administration in the left arm on 18Dec2020 13:45 at single dose for covid-19 immunisation. Medical history included asthma, factor v deficiency, covid-19 and allergy to bee venom. The patient was tested positive for COVID on 10Nov2020 and was asymptomatic. Concomitant medication included benzathine benzylpenicillin (DEPO PEN). On 18Dec2020 at 23:00 (the night following the vaccine) the patient woke with a fever, body aches, headache, and a sharp pain in her left arm. She was limited in mobility to bed. these symptoms continued throughout the next day. The patient took ibuprofen but that had no effect. Diphenhydramine hydrochloride; paracetamol (TYLENOL PM) was able to reduce her fever on the second night so that she was able to sleep. Most of her symptoms started to clear up by 20Dec2020. The outcome of the events was recovering.

fever/Her body is very hot (99.8F); This is a spontaneous report from a contactable consumer. A female patient (mother of the reporter) of an unspecified age receive BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 18Dec2020 at single dose for covid-19 immunisation. The patient medical history and concomitant medications were not reported. The patient woke up with fever on 19Dec2020 with outcome of unknown. Her body was very hot. The temperature was 99.8F. Information about lot/batch number has been requested.

injection site pain; Feeling more tired than usual the day off and after; headache; This is a spontaneous report from a contactable consumer. A patient of an unspecified age and gender (reported as the front-line physician) received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, batch/lot number: unknown), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. It was reported that the patient got COVID-19 vaccine and reported some injection site pain, feeling more tired than usual the day off and after. The patient also mentioned having a headache on an unspecified date. The outcome of events was unknown. No follow-up attempts are possible. No further information is expected.

Itching hands, feet, to arms, legs, scalp, inside ears, Benadryl 25 mg Qhs

"1245: Patient vitals taken, BP 169/122, HR107, 02 SAT 98%, Temp 98.4. Patient advised he no longer has the headache but still feels flushed . 1257: vitals taken again BP 167/122, HR 101, O2 SAT 98%. Patient also advised he was having GI upset (diarrhea). Dr. monitoring patient with this RN, aware of patient vitals, Allegra 80mg PO given at 1300 by CNO per protocol. 1315: BP 172/116, HR 108, O2SAT 98%. Dr. has advised patient to log BP's at home and that he may have underlying hypertension. Dr. has advised patient that he will be called for a follow-up appointment tomorrow with a physician. 1326: BP 174/104, HR 103, O2 sat 99%. Patient states he is now felling back to normal, denied headache and flushing at this time. Dr. had given the patient clearance to return to work at this time. Advised patient

that if he starts to have any s/s again to go to Urgent Care or ER. RN will follow-up with Caregiver. 1537: Spoke to patient states he currently had a mild headache and is fatigued. States he left work an hour early and is going to go home and rest. 1547: Spoke with Dr., MD advised for Caregiver to be seen at Urgent Care today for follow-up. Patient states he feels ok to drive and will make his way to Urgent Care now. 1653: Patient called RN back, states he is feeling better and declines going to urgent care at this time. He advised his headache and fatigue is resolved, stating ""I only have mild soreness at injection site."" Patient states he will go to Urgent Care tomorrow for a follow-up. RN will follow-up with Caregiver tomorrow."

Immediate pain in right arm with administration of vaccine. 30 mins after administration noticed shooting pain in to elbow. Shooting pain has continued through today. Also reports palm sized hardness at injection site.

Approximately 35 minutes after patient received the vaccine, she noted redness around her chest and neck, goin up to her face and both ears. Ears were swollen. She was transferred to the ED for evaluation, where it was noted that she had redness of her throat and chest with slight swelling of her lips. In the ED, she was given prednisone 40mg PO and famotidine 40mg PO. She was observed and discharged after ~90 minutes.

Mild headache, mild fatigue, dry non productive cough, soreness in injection site, and 100.6 ¦F temperature.

chills; pain at the injection site; This is a spontaneous report from a contactable consumer, the patient. A female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration on 17Dec2020 in the as a single dose for COVID-19 vaccination. The patient medical history and concomitant medications were not reported. On Dec2020 the patient experienced chills and pain at the injection site. The clinical outcome of the chills and pain at injection site was unknown. Information regarding lot number has been requested.

12 hours after receiving vaccine patient experienced pain in right arm, headache, fever (did not have working thermometer to check her temperature), chills and hallucinations. Symptoms persisted for 36 hours. She did not report symptoms until they had resolved.

Tingling in lips and throat, sensation of swelling in lips, not visible, that started 25 min. after the vaccination and lasted about 2 min.

feeling similar to a slight hangover; This is a spontaneous report from a contactable consumer and a non-contactable consumer. These two consumers reported for a female patient of an unspecified age who received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration on 17Dec2020 as a single dose for COVID-19 vaccination. The patient's medical history and concomitant medications were not reported. The patient experienced feeling similar to a slight hangover on 18Dec2020. The clinical outcome of feeling similar to a slight hangover was unknown. The lot number for the vaccine, VACCINE BNT162B2, was not provided and will be requested during follow up.

Lightheadedness, blurry vision, dizziness, chest tightness, nausea, red splotchy rash Pt was treated with benadryl and pepcid by mouth and Solumedrol IM. Pt's symptoms lasted 90 minutes.

Sore arm; Mild fever; Flushing; This is a spontaneous report from a non-contactable Other-HCP via Pfizer sales representative. A patient of unspecified age and gender received BNT162B2 (Pfizer-BioNTech COVID-19 vaccine) via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. It was unknown whether the patient received any other vaccine within 4 weeks prior to the vaccine. On an unspecified date, the patient experienced sore arm, mild fever and flushing after use of the product. Clinical outcome of the sore arm, mild fever and flushing was unknown. No follow-up attempts are possible. Information about batch number cannot be obtained.

Patient started experiencing dizziness, flushing and rash. Vital signs obtained at 10:19, patient was feeling better and less dizzy, slight HA, swallowing fine. BP 166/57; HR 79; Temp 99.4. At 10:20 temp was 99.7. 650 mg of APAP given po at 10:22. At 10:30, patient c/o tension across shoulders, no c/o pain or pressure. At 10:32 dizziness improving with BP 167/63; O2 sats at 100%; HR 70, Temp 99.3. Benadryl 25 mg po given at 10:25. 10:47 O2 sats 100%; HR 72; BP 152/64.

EYE AND THROAT SWELLING

flushing of face; chest arms with slight red rash slight itch; chest arms with slight red rash slight itch; This is a spontaneous report from a contactable consumer (patient) via Pfizer Sales Representative. A female patient of unspecified age (age:33, units: unknown) received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 18Dec2020 19:30 at single dose for COVID-19 immunization. The relevant medical history included idiopathic urticaria. Concomitant medications were not reported. After administration of vaccine, the patient experienced flushing of face, chest arms with slight red rash, slight itch in Dec2020. Events took place after use of product. She was given Benadryl and held in Emerge-department for 90 minutes until symptoms were better. The outcome of the events was recovering. Information about Lot/Batch number has been requested.

aches; This is a spontaneous report from contactable nurse via Pfizer Sales Representative. A 53-year-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), the first dose via an unspecified route of administration on an unspecified date at single dose for immunization. The patient's medical history and concomitant medications were not reported. One day after receiving the first dose of the COVID vaccine the patient experienced aches. Outcome of event was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

Severe dizziness and nausea 3 days after vaccine with fatigue for approximately 24 hours

Pfizer-BioNTech COVID-19 Vaccine EUA metallic taste in mouth, tingling in hand

Reported arm soreness and headache after being administered the COVID 19 vaccine; Reported arm soreness and headache after being administered the COVID 19 vaccine; This is a spontaneous report from a non-contactable Physician via Pfizer sales representative. A patient of unspecified age and

gender received BNT162B2 (Pfizer-BioNTech COVID-19 vaccine) via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. It was unknown whether the patient received any other vaccine within 4 weeks prior to the vaccine. On an unspecified date, the patient experienced arm soreness and headache after being administered the vaccine. Clinical outcome of the arm soreness and headache was unknown. No follow-up attempts are possible. Information about batch number cannot be obtained.

I was tachycardic and hypertensive.

Metallic taste in mouth, started shortly after vaccine administration (during 15 min waiting time after administration). Persisted for approx 24 hours.

Progress Notes APRN (Nurse Practitioner) ? ? Nurse Practitioner Cosign Needed Expand All Collapse All COVID VACCINE CLINIC 12/22/2020 á Patient: Date: 12/22/2020 á Subjective Patient is a 34 y.o. female who was seen at COVID Vaccine Clinic today for her first dose of the COVID 19 vaccination. á She denied any history of previous adverse reactions to vaccines. á She was given the Pfizer vaccination in the left deltoid muscle. á During her 15 minute waiting period after the injection, the patient began to experience dizziness. She denied rash, hives, welts, difficulty breathing, difficulty swallowing, wheezing, throat tightness, hoarseness, stridor, itching, facial swelling, lip swelling and tongue swelling. á This provider was notified of patient reaction and she was then assessed in the emergency bay area. á Pt has history of anxiety and takes Hydralazine prn. She presents with rapid breathing and anxiety. á Monitored patient for severe reaction symptoms, including respiratory distress with stridor, wheezing, dyspnea, increased work of breathing, persistent cough and cyanosis. á á á Review of Systems Neurological: Positive for dizziness and light-headedness. All other systems reviewed and are negative. á á á Objective á Vitals Vitals: á 12/22/20 1425 12/22/20 1428 12/22/20 1434 BP: (!) 141/119 122/84 121/73 BP Location: Right arm Right arm Right arm Patient Position: Sitting Sitting Sitting Pulse: (!) 134 (!) 109 92 SpO2: 97% 98% 98% á Physical Exam Vitals signs reviewed. HENT: Head: Normocephalic. Nose: Nose normal. Mouth/Throat: Mouth: Mucous membranes are moist. Eyes: Pupils: Pupils are equal, round, and reactive to light. Neck: Musculoskeletal: Normal range of motion. Cardiovascular: Rate and Rhythm: Normal rate and regular rhythm. Pulses: Normal pulses. Musculoskeletal: Normal range of motion. Skin: Capillary Refill: Capillary refill takes less than 2 seconds. Neurological: General: No focal deficit present. Mental Status: She is alert and oriented to person, place, and time. Psychiatric: Mood and Affect: Mood normal. Behavior: Behavior normal. á á á Assessment/Plan Treatment included: no therapy. Follow up response to treatment: no side effects. Patient discharge: Stable to go home and follow up with PCP. á Pt's breathing slowed and felt less anxious by the time she left. á á á APRN Electronically Signed 12/22/2020 2:36 PM á á á

metallic taste; This is a spontaneous report from a contactable nurse. This nurse reported similar events for two patients. This is the first of two reports. A patient of unspecified age and gender received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration, in Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced metallic taste in Dec2020.

The clinical outcome of metallic taste was unknown. The batch/lot number for the vaccine, BNT162B2, was not provided and will be requested during follow-up.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2020504716 same reporter/drug/event, different patient

Severe headache and fever up to 100.4 no treatment, resolved on own in a few hours

at 7 minutes after vaccine administered, reported feeling shaky and lips tingly, anxiety. Did not immediately notify monitoring staff thinking she was anxious, by 10 minutes after started to experience some coughs and felt voice changed, Epinephrine administered via EpiPen at 13 minutes post vaccination with immediate relief. No visible hives or swelling.

metallic taste; This is a spontaneous report from a contactable nurse. This nurse reported similar events for two patients. This is the second of two reports. A patient of unspecified age and gender received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration, in Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced metallic taste in Dec2020. The clinical outcome of metallic taste was unknown. The batch/lot number for the vaccine, BNT162B2, was not provided and will be requested during follow-up.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2020504715 same reporter/drug/event, different patient

MODERATE TO SEVERE PAIN ON INJECTION SITE WITH REDNESS AND MODERATE SWELLING. PAIN INCREASED WITH ELEVATION OF EXTREMITY. COUGH STARTED ON 12/22/2020. MILD DYSPEPSIA.

chills, and cold , pain to injection site

increased left upper arm soreness; mild injection site pain; This is a spontaneous report from a non-contactable consumer. A 51-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 18Dec2020 15:30 at single dose for COVID-19 immunization. The patient medical history was not reported. The patient's concomitant medications were not reported. The patient developed mild injection site pain that evening on 18Dec2020 and reported as increased left upper arm soreness on morning no limitation in movement on 19Dec2020. No other local/systemic events. Event took place after use of product. The outcome of the events was unknown. No follow-up attempts are possible. No further information is expected.

Starting the evening of the 5th day after receiving the vaccine I noticed a sore, irritated throat. By the 7th day it was a more severe sore throat, runny nose, violent sneezes and the beginning of a deep painful cough. No fevers have been noted to date, with the highest oral temperature of 98.6F on the 7th day. I called the employee hotline, had a virtual visit with a Dr and took the drive up COVID test around 11:00 am on 12/23/20. I am in self quarantine currently awaiting results of the COVID test.

vomiting a lot; This is a spontaneous report from a Pfizer sponsored program . A non-contactable consumer (patient's partner) reported that a male patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration in Dec2020 at single dose for covid-19 immunisation. The patient's medical history and concomitant medications were not

reported. Caller's partner received the vaccine yesterday morning and drank a lot of alcohol in the evening. In Dec2020, her partner (patient) was vomiting a lot. She was worried if this was due to the vaccine and wanted to know what else could happen. Outcome of event was unknown. No follow-up attempts are needed. Information about lot/batch number cannot be obtained.

Slight tingling/numbness in cheek and upper jaw, lasted for 45 minutes. No medication taken.

Moderna COVID-19 Vaccine EUA pain in injection site, fatigue, sneezing, runny nose

Nausea; have really bad runny nose; have really bad stuffy nose; I had a fever; I got flush rash, itchy rash kind of all over my body; I got flush rash, itchy rash kind of all over my body; Headache; This is a spontaneous report from a contactable Nurse (patient). A 32-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 18Dec2020 at single dose for COVID-19 immunization. The relevant medical history and concomitant medications were not reported. The patient stated that she got the first round of COVID vaccine the day prior the report and she was told to report her symptoms. She had a fever and got flush rash, itchy rash kind of all over her body and a headache on 18Dec2020. She took Tylenol Benadryl, it had helped with symptoms. At the time of the report morning she woke up with headache and she had really bad runny nose and stuffy nose and nausea on 19Dec2020. The outcome of the events was unknown. Information on lot/batch number has been requested.

After 15 min patient had tingling in her left arm all the way down to her hand, then started to travel to left side of face. 5 min later tingling started to travel to her left leg. Pulse ox- 96% HR 57. 1251- ED lead RN was then contacted to evaluate patient in the ED.

Nauseous; This is a spontaneous report from a contactable consumer (patient). A patient of unknown age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), at an unspecified dose via an unspecified route of administration, on 19Dec2020 at single dose for COVID-19 immunisation. Medical history and concomitant medications were unknown. The patient reported she got the vaccine yesterday (19Dec2020) and she is really nauseous right now (Dec2020). It was unknown if a treatment was received. Outcome was unknown. Information for Lot/Batch number has been requested.

In the evening, the day I got the vaccine, I started feeling body aches all over. The arm that got the vaccine hurt the most, as to be expected, and there is a knot in the muscle where I got the injection. I have felt pain all over since then. It has not been touched by naproxen sodium. A cold shower gave temporary relief.

Patient complained of a rush of feeling very hot. Patient was offered an ice pack for the back of her neck and was monitored until she felt better. Returned home following observation period.

My upper lip swell up, it is swollen, it is all swollen; This is a spontaneous report from a contactable consumer (patient). A 38-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899) first dose on 16Dec2020 around 3 o'clock in the afternoon intramuscularly in left arm at single dose for COVID-19 immunization. Co-suspect product included

mepyramine maleate, pamabrom, paracetamol (PAMPRIN) with unspecified date and dose for cramp. Medical history was none. Concomitant medication included sertraline. Patient took it on Wednesday (16Dec2020) around 3 O clock in the afternoon and then last night (18Dec2020) her upper lip of mouth swell up, it is swollen, it is all swollen. Patient worked in a hospital and they started the vaccination program for the employees and of course she wanted to take the shot and then she went in and took the shot. It was the first dose. Consumer stated she was completely healthy. Consumer further added last night she did take something for cramp it's called Pamprin, it's for, like when you have your period and you have like cramping, headache, back ache all of that, it's over the counter. For treatment for lip swell, Consumer stated No, just put ice on it. The action taken for mepyramine maleate, pamabrom, paracetamol was unknown. The outcome of the event was unknown.

Severe neck and spine pain. No neurological symptoms noted but severe pain. Feels muscle related.

Body pain and headache, second day.

Fever; Chills; My arm was killing me; Not feeling well; This is a spontaneous report from a contactable consumer (patient). A 35-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (lot number: EH9899) at single dose via unknown route of administration on 18Dec2020 for COVID-19 immunization. Medical history and concomitant medications were reported none. Consumer stated, she got the COVID vaccine yesterday (18Dec2020). And she woke up and she had fever and chills, and like her arm was killing her and it was just like she was not feeling well. So she was just wondering how long this was supposed to last. Due date for next shot was 08Jan2021. About the Indication, Consumer stated, Juts to get it she guessed. Because they worked at the hospital, they were providing it to all of them. Consumer stated, the adverse events probably started like around 4 O' clock this morning (19Dec2020). Consumer stated, she took some Ibuprofen as treatment. The outcome of the events was unknown.

Patient waited the mandatory 15 minutes and felt fine. Left for a few minutes and then came back in to the vaccine clinic with symptoms of lips tingling and possible her tongue swelling. She was given 50mg of PO Benadryl (Diphenhydramine) and was taken to the emergency department. Patient was monitored for 4 hours in the emergency department with no additional symptoms noted. Spoke with patient this morning, was still having some tingling of the lips but was being controlled with Benadryl. No problems breathing or swallowing

Headache; This is a spontaneous report from a contactable consumer (Patient). A 49-years-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EH9899, reported as BioNTech SARS-CoV-2) on right arm at single dose for covid-19 immunization. Medical history and concomitant drug were not reported. Patient stated a side effect to the vaccine (BioNTech SARS-CoV-2), she was just having the headache that won't go away. Treatment: consumer stated just took some over the counter Aspirin. Outcome of the event was not recovered. Follow-up attempts have been completed and no further information is expected

Body aches, mild headache sore throat,mild cough. Started 12/20/20

ache all over, back pain, burning in thigh, numbness in foot

Upper body hives, Low grade fever 99.6, dizziness, weakness, tiredness, upper body muscle pain, nausea. All lasting 24 hours+.

"""Equilibrium off"", nausea, headache, and nasal drainage"

"woke up with the chills and fever; woke up with the chills and fever; I don't feel good; This is a spontaneous report from a contactable consumer (patient). A patient of unspecified age and gender received BNT162B2 (Pfizer product) via an unspecified route of administration on 18Dec2020 at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient received the COVID Vaccine yesterday (18Dec2020). The patient was a health care worker (Further clarification was unknown, hence captured as consumer or Other non HCP) and stated that, ""they have gave us a paper that has a bar code to scan to report the side effects and I don't have that with me because I left work and that was regarding. I have it at the work but I cannot go to the work because I woke up with the chills and fever (Dec2020), so I just need to talk to someone regarding the side effects besides with Tylenol (incomplete sentence). Is there anyone I can talk to? I need to report this and see is there anything I need to do besides take Tylenol (Intent: Treatment) and rest."" In response to further probing, consumer stated, ""I am so sorry, I don't feel good. I don't want to talk on the phone right now."" Therapeutic measures were taken as a result of woke up with the chills and fever. The outcome of the events was unknown. Information on the lot/batch number has been requested."

"Staff was advised that patient had a brief episode of palpitaions ""30 seconds"" after receiving the COVID19 vaccine on 12/22/20 that resolved. Per report on back of patient consent, vitals done at 1513: BP 145/102, HR 84, O2 SAT 99%, RR 18, TEMP 97.6. Re-take at 15:21, BP 124/86, HR 86, O2SAT 100%, RR 18, TEMP 97.8. Patient was monitored for 30 minutes, Dr. was present at time of event."

Patient received vaccine and entered waiting queue. Within 1 0 minutes, pt requested help from pharmacy vaccination team because she felt severely dizzy. Patient ended up passing out in seated position. Systolic blood pressure dropped to ~80. Patient normalized 5-10 minutes after syncope. Blood pressure normalized. Patient escorted out in stretcher.

Patient complained of anxiety, feeling cold and clammy, and being lightheaded. Patient was laid supine, Vital signs monitored, reassurance, fluids, and snack. Patient left for home following an extended period of observation.

developed a lump in my throat within a half hour after receiving vaccine. I took Benadryl at 7pm without any improvement. Feeling of lump improved by Monday and today feels irritated in that affected area. No other treatment.

fever of 99.9 all night; Body ache; Pain in my arm from the vaccine; This is a spontaneous report from a contactable consumer. This consumer reported similar events for two patients (herself and her husband). This is a first of two reports. A female patient of unspecified age received bnt162b2

(BNT162B2, lot number: EH9899, expiration date was not reported), via an unspecified route of administration on arm on 18Dec2020 (morning) at a single dose for immunization. Medical history and concomitant medications were not reported. The patient reported that she received the Pfizer vaccine (COVID Vaccine) yesterday morning (18Dec2020) and last night (18Dec2020) she had fever of 99.9 (unspecified unit) all night. And then at this morning (19Dec2020), she came to work at the hospital. And she has been with 99.2 all day. She also experienced body ache and pain in her arm from the vaccine on 18Dec2020. She added that her husband was experiencing the same way who also got the shot yesterday (18Dec2020). The outcome of the event fever was recovered on 19Dec2020, while outcome other events was unknown. Information on batch number has been requested.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2020506517 Same reporter/ drug/ event for different patients.

A few minutes after vaccination, sitting in chair started to feel dizzy, tachycardic, almost an anxious feeling- lasted about a minute or so, then subsided. I did not report it that day because I thought it may have been anxiety

Tingling around the mouth and throat, sensation of swollen lips, but not visible. Started around 25min after vaccination, did not last more than 1 min.

The day after had chills with no fever, fatigue, and palpitations. The second day had palpitations on and off. On the third day had palpitations that did not go away with a heart rate sitting in the 140s.

lost taste and smell; lost taste and smell; This is a spontaneous report from a contactable other HCP (patient). A 21-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL0140, Expiry Date: Mar2021) (reported as COVID Vaccine), intramuscular in right deltoid on 18Dec2020 at single dose for covid-19 immunization. Medical history included had a fever on Monday and took Tylenol Cold and Flu (lot number: SHA101, Expiry Date: Jun2024) as the treatment; had an intra uterine device. There were no concomitant medications. Patient was a frontline health worker (a CNA, Certified Nursing Assistant) and received a vaccine yesterday (as of 19Dec2020) and since then she lost taste and smell, patient was not sure if this is due to the vaccination or if its due she had a fever on Monday and broke and was unknown if it's okay to get the vaccine, patient was not sure if it's like a bacterial infection or related to the vaccine. She still doesn't have taste and smell but its really congestion. The outcome of events was not recovered.

Fever 101.0 f dry cough nasal congestion

12/23/2020 10:00 am swollen , tender glands in my throat, left side, slight headache.

"site was red, it was painful, it hurt across her shoulder and up her neck; site was red, it was painful, it hurt across her shoulder and up her neck; Headache; Diarrhea; it hurt across her shoulder and up her neck; it hurt across her shoulder and up her neck; This is a spontaneous report from a contactable Nurse(patient). A 65-year-old female patient received BNT162B2(lot number EH9899) via an unspecified route of administration at arm on 17Dec2020 at single dose for the vaccine for COVID. The patient medical history included Blood pressure high and Low thyroid. The concomitant products included losartan for Blood pressure high, levothyroxine sodium(SYNTHROID) for Low thyroid. The patient got the

BNT162B2yesterday afternoon on 17Dec2020 and her site was red and she had got a headache and stuff and she was supposed to report the adverse reactions on 18Dec2020. Her site was red, it was painful, it hurt across her shoulder and up her neck and she had got a headache and diarrhea on 18Dec2020. The patient stated she didn't have it before. The patient got it for work, she didn't have a doctor prescribed it. The patient took some Advil yesterday it helped a little bit but she haven't taken anything today. For the vaccine for COVID because the patient work in ICU. The patient was given the product in her arm. The reporter consider the events ""site was red, it was painful, it hurt across her shoulder and up her neck , headache and diarrhea"" were related to BNT162B2. The outcome of the events was not recovered."

Vaccine recipient developed mild nausea, acid reflux, and stomach pain 10 minutes after vaccine administration. Vaccine recipient then developed nasal congestion and cough at 19 minutes, and then shortness of breath at 21 minutes. The vaccine recipient was then sent to the emergency department. While in the emergency department it was determined that the vaccine recipient had an allergic reaction. When vaccine recipient had shortness of breath the oxygen saturation went to 89-90%. The vaccine recipient received albuterol, diphenhydramine, famotidine, methylprednisolone, and fluids. During re-examination, the vaccine recipient?s condition improved and stable. Vitals were within normal limits. 89-90. They were discharged to home. At follow-up phone call on 12/23/2020, the vaccine recipient reported that they felt much better but was still experiencing voice hoarseness.

15 minutes after getting the vaccine, she developed a pruritic rash over her neck, chest, and precordium. Also became tachycardic up to 130-140 (may be attributed to anxiety of having a rapid response called). She reported feeling a lump in her throat but no facial swelling or angioedema, no lymphadenopathy. Was treated with diphenhydramine 50 mg IV, famotidine 20 mg IV, and methylprednisolone 125 mg IV. After 1 hour of observation and ongoing feeling of lump in her throat with new mouth tingling, was also given 0.15 mg epi IM. Was observed with resolution over 8 hours, and discharged to home with instructions to contue treatment with oral prednisone, famotidine, and cetirizine over the subsequent few days.

Arm is kind of sore; Pretty tired; This is a spontaneous report from a contactable consumer (parent). A 21-year-old female patient received bnt162b2 (BNT162B2, lot no. and expiry date was unknown), via an unspecified route of administration on 17Dec2020 at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient had the Pfizer vaccine, the new Covid vaccine yesterday (17Dec2020). The consumer reported that her daughter's arm is kind of sore and she is pretty tired on unspecified date in Dec2020. The patient was given the vaccine because she interacts with Covid patients, she works in the Intensive Care Unit, so they provided the vaccine to her. The patient gets a Covid test every three days and she has been always negative on Covid test. The outcome of the events was unknown. Information on the lot/batch number has been requested.

First night following after vaccine I woke up with chest pain (i though pleuritic) which went away. I had mild body aches and fatigue, chills. next day I experienced chest(again I thought pleuritic) discomfort especially when taking a deep breath. i felt better then had mild fatigue and body aches again. day 3

post vaccine I woke up with discomfort when taking a deep breath with continued discomfort. i felt tired through the day. Then that evening i developed SOB, severe palpitations and chest pain and went to ER. Diagnosis New onset rapid A fib. I was hospitalized and once my work up was finished and I had normal sinus rhythm I was discharged home the next evening.

Patient presented for COVID-19 vaccine (Pfizer-Sars-COV2-vac), pt received the vaccine and then 15 minutes later started feeling some lumpiness in her throat, watery eyes, and ear fullness. Pt denied feeling any itchiness, difficulty breathing, lip swelling, or throat swelling. Pt received two doses of oral diphenhydramine 25 mg each without improvement in symptoms. Patient was observed for 1 hour and 20 minutes. After consulting with Dr., it was recommended to have the patient go to the emergency room for more observation. The patient was then escorted to the ER by one of the volunteering staff. In ED, reported throat tightness without SOB or difficulty swallowing. Also reports feeling sense of ingestion/gas bubble in chest. Had COVID, dx'd 12/1/20, recovered fully. States that sensation in chest was also felt during her COVID illness and seemed to be brought back by vaccine this afternoon approximately 90min pta, Observation for additional 90min in ED. with possible mild improvement, no progression/worsening. Discharged home

itchy, red, hives and pain at injection site and generalized muscle soreness, especially left arm

I woke up I really tired, tired/I got tired and fatigue; headache; when I came to have my breakfast I felt that food doesn't tastes nor regularly as it was before; This is a spontaneous report from a contactable physician (patient). A 75-year-old male patient received bnt162b2 (lot/batch number and expiration date not provided), via an unspecified route of administration, on 18Dec2020 (reported as yesterday of 19Dec2020), at single dose, for COVID. The patient medical history included COVID and changing his taste, both in Apr2020 and not ongoing. The patient's concomitant medications were not reported. It was reported that the patient got COVID himself what it started changing his taste in April and he was sick and come to better at the bottom month and he was fine. He started to work full time. Then he got a vaccine yesterday morning and today (19Dec2020) he woke up he really tired, tired. He know these the side effects of vaccine fatigue, muscle pain and headache but these are not he was concerned. The concern is he is losing his taste that he had when originally diagnosed with COVID in April of 2020. When this morning he got up, he got tired and fatigue and headache then when he came to have his breakfast he felt that food doesn't tastes nor regularly as it was before. The same thing he had before when he diagnosed with COVID in April. His question is, probably this is not connected, question is could that be side effects of vaccine or by the he checked his antibody week ago, he had antibody, could that he got another COVID or it is the side effects of COVID Vaccine? It was also reported that the patient deal with COVID patient every day. The outcome of the events was unknown. Information on the lot/batch number has been requested.

NONE

Two days after vaccination, I felt a little bit headache after I woke up. It was getting worse at noon. Then I took one pill of advil and felt better after that.

Itchy blotchy spots, left arm, left ear, back

Got the itches today; Got the runs; Maybe from the runs that's making me tired; Got the runs; Maybe from the runs that's making me tired; This is a spontaneous report from a contactable consumer, the patient. A 61-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot Number: KN5730), via an unspecified route of administration on 17Dec2020 (at the age of 61-years-old) as a single dose for COVID-19 immunization. The patient had no known medical history. There were no concomitant medications. On 18Dec2020, the patient had the itches and runs, and was tired. The clinical outcomes of the itches, runs, and tired were unknown.

Several minutes after the injection, my right little finger was tingling. ~0815 I was driving home and lost function in my right little finger. The left side of my jaw felt tight, the left side of my tongue felt thick, and my vision was blurry in both eyes. I also noticed that my heart was out of rhythm and beating rapidly. I had a near syncopal episode. I began having mid-sternal chest pressure. I drove to my home - took 50mg of liquid Benadryl and had someone drive me to the ER. Symptoms started to resolve within 20 minutes of taking Benadryl. I was seen at Medical Center.

Progress Notes APRN (Nurse Practitioner) ? ? Nurse Practitioner Cosign Needed Expand All Collapse All COVID VACCINE CLINIC 12/22/2020 á Patient: Date: 12/22/2020 á Subjective Patient is a 55 y.o. female who was seen at COVID Vaccine Clinic today for her first dose of the COVID 19 vaccination. á She denied any history of previous adverse reactions to vaccines. á She was given the Pfizer vaccination in the right deltoid muscle. á During her 15 minute waiting period after the injection, the patient began to experience Racing heart rate. She denied rash, hives, welts, difficulty breathing, difficulty swallowing, wheezing, throat tightness, hoarseness, stridor, itching, lightheadedness, dizziness, facial swelling, lip swelling and tongue swelling. á This provider was notified of patient reaction and she was then assessed in the emergency bay area. á Pt presented with Rapid heart rate and palpitations. Had episode of chest pain 6 weeks ago and was seen in ER. D-dimer was positive and CT negative. No FU since. á Monitored patient for severe reaction symptoms, including respiratory distress with stridor, wheezing, dyspnea, increased work of breathing, persistent cough and cyanosis. á á á Review of Systems Cardiovascular: Positive for palpitations. All other systems reviewed and are negative. á á á Objective á Vitals Vitals: á 12/22/20 1453 12/22/20 1505 12/22/20 1526 BP: 133/87 133/85 123/81 BP Location: Right arm Right arm Right arm Patient Position: Sitting Sitting Sitting Pulse: 95 96 96 SpO2: 100% 99% 95% á Physical Exam Vitals signs reviewed. HENT: Head: Normocephalic. Nose: Nose normal. Mouth/Throat: Mouth: Mucous membranes are moist. Eyes: Pupils: Pupils are equal, round, and reactive to light. Neck: Musculoskeletal: Normal range of motion. Cardiovascular: Rate and Rhythm: Regular rhythm. Tachycardia present. Pulses: Normal pulses. Heart sounds: Normal heart sounds. Pulmonary: Effort: Pulmonary effort is normal. Breath sounds: Normal breath sounds. Musculoskeletal: Normal range of motion. Skin: General: Skin is warm and dry. Capillary Refill: Capillary refill takes less than 2 seconds. Neurological: General: No focal deficit present. Mental Status: She is alert and oriented to person, place, and time. Psychiatric: Mood and Affect: Mood normal. Behavior: Behavior normal. á á á Assessment/Plan Treatment included: no therapy. Follow up response to treatment: no side effects. Patient discharge: Stable to go home and follow up with PCP. á Pt released to go home at 3:25 pm. No symptoms at that time. á á á 12/22/2020 3:30 PM á

I had a cough , hives and a fever of 101

My lips, my cheeks inside and out, my jaws and the back of tongue all went numb; My lips, my cheeks inside and out, my jaws and the back of tongue all went numb; This is a spontaneous report from a contactable consumer (patient). A 58-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date in 2020 at single dose for COVID-19 immunization. Medical history included gastroparesis. Concomitant medication included lisinopril. In 2020, the patient reported she had an odd reaction to the COVID vaccination, her lips, my cheeks inside and out, her jaws and the back of tongue all went numb. There was no investigation assessment. No treatment was received for the events. The outcome of the events was resolved by itself in 2020. Information on the lot/batch number has been requested.

Within 15 minutes after the vaccine patient started to have tachycardia, dizziness, and light headedness with syncope episode. She was taken to the ER where she improved . No further syncope episodes and released.

LOW GRADE FEVER- 99.3, BODY ACHES, CHILLS, HEADACHE, MALAISE, FATIGUE, LEFT ARM SORENESS

Swelling and induration at site

Headache; Fatigue; This is a spontaneous report from a contactable physician (patient-pending clarification). A 34-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, batch/lot number: unknown), via an unspecified route of administration on 18Dec2020 at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced headache and fatigue on 19Dec2020. The outcome of events was unknown. Information on the lot/batch number has been requested.

Fever 102. - 101, Chills for about 12 hours, bed rest for 24 hrs took Tylenol every four hours and fluids. The Vaccine site is red, swollen and hot size of an orange. After 12 hours fever broke, exhausted for additional 12 hrs. No symptoms 12/22 or 12/23/2020

"Got this biggest heat flash to my face; Nervous; Everything's swollen; face numb; Everything's swollen; face numb; This is a spontaneous report from a contactable consumer (patient herself). A 49-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number EK5730), as first single dose on 19Dec2020 for COVID-19 immunisation. No relevant medical history and concomitant medications were provided. The patient is an X-ray tech, mammography tech. She stated ''I had the COVID-19 Vaccine yesterday and I had there like they told me for 50 minutes. I went home and I started driving home and, on my way, home yesterday I got this biggest heat flash to my face and then I think became numb for about 2 hours."" The patient also stated 'I came home and my husband watched me and I was like I am nervous. I was like I may try get swell because everything's swollen, I would have called but it was just my face numb."" The outcome of the events was unknown."

Employee reports right sided eye and facial droop 2 hours after receiving vaccine but did not report the incident until 12/23/20. BP-140/89, light headache. Did not seek any treatment since , BP checked today 12/23/20 was 90/60. slightly facial asymmetry still noted, no other associated s/s. Neuro check intact as of this date. Employee referred to f/u with PCP.

Itching, Tingling to scalp, trapezius area of the back and arms. Experienced this 1 week after the vaccine. Patient took Allegra and symptoms resolved after 1 hour. Patient continues to have no symptoms 24 hours after taking the Allegra.

Body ache; pain in arm from the vaccine; fever; This is a spontaneous report from a contactable consumer (patient's wife). This consumer reported same events for two patients. This is 2nd of two reports. A male patient started to receive BNT162B2 on 18Dec2020 (reported as yesterday, as of 19Dec2020) at single dose for covid-19 immunisation. Medical history, concomitant medications or past drug history were not provided. He experienced body ache, pain in arm from the vaccine and fever in Dec2020. Outcome of the events was unknown. Information about lot/batch number has been requested. ; Sender's Comments: Linked Report(s) : US-PFIZER INC-2020506072 Same reporter/ drug/ event for different patients.

awoke with chills fever nausea diarhea as well as tinitus and dizziness

"Woke up in middle of night with sore arm to include down arm to pinkie and ring finger. Next morning did not look in the mirror unknown if woke with hives. Around 11am 03/18/2020, noticed ""hives on neck, face and eyelids"". States purple dot rash ""reminded me of a hickey all over my neck."" Did not take any medications, call doctor or notify anyone until she saw her supervisor Monday. Started to Clear up almost gone away. States resolved now."

Incredible pain at the injection site that radiate down her arm, lasting through the night; Felt very fatigued after the vaccine; She didn't sleep well due to pain; This is a spontaneous report from a non-contactable consumer. A 33-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via intramuscular, on 18Dec2020 at first single dose on the arm for COVID-19 immunisation. No relevant medical history and concomitant medications were provided. The patient reported incredible pain at the injection site that radiate down her arm, lasting through the night. Also felt very fatigued after the vaccine. She didn't sleep well due to pain, fatigue may also be caused in part by this. The outcome of the events was unknown. No follow-up attempts are possible. No further information is expected.

"Woke up on 12/18 with chills, fever of 102, and achy. Also, noticed red rash on back (from shoulders to waist), under both upper arms, and belly on 12/19 (but said it could've been there on 12/18). On 12/19, spread to around neck. Pruritic (""couldn't stand it"") and used hydrocortisone."

Had a fever about a 102; This is a spontaneous report from a contactable consumer (patient's wife). A 54-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number EH9899), via an unknown route, at single dose on 18Dec2020 for COVID-19 immunisation. The patient did not have a relevant medical history and concomitant medications. On 19Dec2020, the patient had a fever about a 102. The outcome of the event was unknown.

the day she got the shot she had arm pain. The next day she had chills, fever and body aches. As of the 23rd she still has body aches.

Felt some palpitations, racing heart, scratchy throat, dizziness, a little shortness of breath. Alerted the professionals observing and was monitored. Starting feeling a little better, then got a second wave of above symptoms again. I felt tingly all over and my lips felt tingly. They ended up taking me to ER. I started to also feel nauseous. They ended up giving me 1L of fluid, 25mg of diphenhydramine, 125mg of solumedrol, and 20mg of Pepcid. Monitored me for a few hours and then discharged me home. I was instructed to take another 50mg of diphenhydramine before bed, which I did. I ended up missing work the rest of my shift since I was in ER, then missed work the next day.

Fever; Mild headache; Fatigue; This is a spontaneous report from the Pfizer-Sponsored program received by a contactable consumer. A 55-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number EH9899 with Expiration Date Mar2021), via intramuscular, on 17Dec2020 at single dose for COVID-19 immunisation. The patient did not have a relevant medical history and concomitant medications.. On 19Dec2020, the patient developed mild headache and fatigue. On 20Dec2020, the patient experienced fever. She stated ''I will take some paracetamol (TYLENOL) whatever for next couple days, if it is not then I need to get COVID Test''. The outcome of the events was unknown.

About 15 minutes I started to get hives, skin reaction and felt chest pressure, I let Dr. know I wasn't feeling well, administered Epinephrine with own EpiPen, noticeable hives and redness across neck and upper chest. Transported to the ED. 2nd dose of Epinephrine at 1:20pm for throat swelling and bronchospasm.

Patient misunderstood when to return for second Covid vaccine dose. Patient returned for dose #2 four days after dose #1. Screening process did not catch timing discrepancy. Patient received dose#2 four days after receiving dose#1. Patient did not experience any adverse effects from either injection.

Headache; This is a spontaneous report from the Pfizer-Sponsored program received by a contactable consumer (patient herself). A female patient of unknown age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via intramuscular, in Dec2020 (three days ago, as reported) at single dose for COVID-19 immunisation. No relevant medical history and concomitant medications were provided. The patient stated she took the COVID-19 shot three days ago and she started having headache. The outcome of the event was unknown. Information on the Lot/batch number has been requested.

No immediate A/E. At the one hour post-vaccine reported mild nausea, hot flashes on/off for another hour, and bumps on the forehead. Bumps we not visible, mildly palpable, not itchy, and possibly contact dermatitis from face shield - this vaccine is a nurse that returned to duty after the 15 minute observation time. No treatment, self monitor only .

Pfizer-BioNTech COVID-19 Vaccine- Chills, low grade fever 99.8, body aches/ joint pain, fatigue, start 12/19/20 and continued symptoms to present 12/23/20

She is not feeling well; Chills; Sweating; Fever; This is a spontaneous report from a Pfizer sponsored program from a contactable consumer reported for her daughter. A female patient of an unspecified age received her dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of

administration on an unspecified date at single dose for COVID-19 immunization. The patient medical history and concomitant medications were not reported. The reporter She mentioned that the patient got her vaccine this morning and unfortunately the patient was experiencing some side effects or symptoms. The patient who was a nurse who just received the vaccine, the Pfizer vaccine yesterday from the hospital where she worked. And today she was not feeling well, she got chills and she was sweating, and just not well. It sounded like she was having some side effects 30 percent (Further clarification was unknown), to get the Chills and fever, 15 percent of (incomplete sentence). The reporter asked how long they had to wait if someone was feeling unwell from the shot. The patient got to start her 12 hours shift and should she be going back to work and doing 12 hours shift, if she was not feeling well with fever, she had got chills. The reporter asked how long it anticipated her feeling like this. The outcome of the events was unknown. Information about Lot/batch number has been requested.

Pt received the Pfizer-Biontech COVID19 Vaccine, Lot #EH9899 around 1830 today (12/22). A few minutes after the vaccine was administered in the left arm, the patient started having itching on her left shoulder that spread up to her neck. This was followed up by a warm feeling and mild blotching on the neck and face, more so on the left side of her body/face. When the patient brought this to staff attention, we began very close monitoring and started taking vitals regularly. Blood pressure ranging from 141/91 to 139/86, HR ranging from 120-86 bpm. . Around 1905 the patient was given Benadryl 25 mg tabs- 2 tablets by mouth one time only. Around 1908 the patient said her L ear started to itch also. We took vitals multiple times and the blood pressure and heart rate had decreased. Around 1935 the patient said she was feeling better, the mild blotching on the L side of her face and neck had almost completely resolved. The patient stated she felt much better and felt that she can could drive home safely. The patient spent a total time of one hour being monitored. á Of note: the patient admitted that she has white coat hypertension and today it was probably even worse. She said she had a lot of caffeine today and that could have also led to her being tachycardiac.

Employee had itchiness and rash on both arms almost 30 minutes after receiving vaccine. She denied shortness if breath, tachycardia, lightheadedness, and difficulty breathing. She denies a similar reaction from any other vaccines.

Little sinus pressure; may be a little bit of soreness of the throat; Little bit a soreness in throat, scratching of little bit but not too sore; or just allergies; Heart rate low/60 beats per minute; Ache in right side of my ribs; This is a spontaneous report from a contactable consumer (patient). A 53-years-old male patient received BNT162B2 (lot number: EJ1685) via an unspecified route of administration on 18Dec2020 at single dose for COVID-19 immunization. The patient medical history was not reported. Concomitant medication included fluticasone propionate. The patient was given vaccine shot (later clarified as Covid 19 vaccine) yesterday and just got a side effects of little sinus pressure, may be a little bit of soreness of the throat. About treatment, the patient took some Advil and he took some sinus pills, congestion pills a little bit earlier. It was clarified as nasal Decongestant, nasal congestion, 30mg, take 2 in 24 hours but he had taken two of them earlier along with 3 Advil pills. He deals with sinuses too but this one is like came on pretty much kind of overnight. He was wondering if doing the shot or something, he was not sure what's the matter or just allergies. It was just the sinus pressure yet. He didn't have the fever, not fever. Little bit a soreness in throat, scratching of little bit but not too sore. His

heart rate is 60 per minute so it is low, 60 beats per minute, very low. He had just low heart rate though. About lab work the patient stated that went in for side pain, side ache in right side of his ribs. They did ear analysis, CBC. They all came back normal. He just wanted a report in and see he guessed just find it out if the symptoms go away or maybe he is having sinus infection going on or this sinus be going on so. Events outcome was unknown.

lightheaded, dizzy, nausea, vomiting, tingling in the hands and face, diaphoretic, tachycardia

"I got the injection Friday Morning I had a little soreness and tiredness and when I drove home at 7pm I was having bad arm pain , Saturday morning the arm pain was really bad I couldn't lift my arm, I called my Dr I assumed it was the same and my palanziq. Dr said the pfizer and palanziq both made my immune system hyperactive and was prescribed acetaminophen and 6 days steroid pack that starts with ""M"", after I took the steroid my mobility was better by Monday the arm pain was gone. one ear temp was 99.4 and the other ear was 98.6 I never spiked a fever"

Fever, fatigue, injection sight pain, join pain, rapid pulse, headache, feel unwell

pain at the injection site; headache; joint pain; fatigue; chills; This is a spontaneous report from a contactable Pharmacist. A female patient of an unspecified age received BNT162B2 via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient medical history was not reported. The patient's concomitant medications were not reported. The patient shared information about her experience after receiving the Pfizer BioNTech COVID-19 vaccine. The patient reported pain at the injection site, headache that she treated with Naproxen, joint pain, fatigue, and chills that lasted for 72 hours. Events outcome was unknown. Information on the Batch/Lot number has been requested.

Progress Notes MD (Physician) ? ? Endocrinology Date: 12/22/2020 á Subjective Patient is a 21 y.o. male who was seen at COVID Vaccine Clinic today for his first dose of the COVID 19 vaccination. á He denied any history of previous adverse reactions to vaccines. á He was given the Pfizer vaccination in the right deltoid muscle. Vitals: á 12/22/20 1838 12/22/20 1839 BP: á 129/81 Pulse: á 90 Temp: 97.4 ¦F (36.3 ¦C) 97.4 ¦F (36.3 ¦C) á Vitals are normal á Checked his blood sugars- normal at 96 98% o2 sat á á During his 15 minute waiting period after the injection, the patient began to experience dizziness. He denied rash, hives, welts, difficulty breathing, difficulty swallowing, wheezing, throat tightness, hoarseness, stridor, itching, facial swelling, lip swelling and tongue swelling. á This provider was notified of patient reaction and he was then assessed in the emergency bay area. á Monitored patient for severe reaction symptoms, including rapid progression of symptoms, respiratory distress with stridor, wheezing, dyspnea, increased work of breathing, persistent cough and cyanosis, vomiting, abdominal pain, hypotension, dysrhythmia, chest pain and collapse. á á á á Objective á á Physical Exam Constitutional: Appearance: Normal appearance. He is normal weight. HENT: Head: Normocephalic and atraumatic. Nose: Nose normal. Mouth/Throat: Mouth: Mucous membranes are dry. Pharynx: Oropharynx is clear. Eyes: Extraocular Movements: Extraocular movements intact. Conjunctiva/sclera: Conjunctivae normal. Pupils: Pupils are equal, round, and reactive to light. Neck: Musculoskeletal: Normal range of motion and neck supple. Cardiovascular: Rate and Rhythm: Normal rate and regular rhythm. Pulses: Normal pulses.

Heart sounds: Normal heart sounds. Pulmonary: Effort: Pulmonary effort is normal. Breath sounds: Normal breath sounds. Abdominal: General: Abdomen is flat. Bowel sounds are normal. Palpations: Abdomen is soft. Musculoskeletal: Normal range of motion. Skin: General: Skin is warm and dry. Neurological: General: No focal deficit present. Mental Status: He is alert and oriented to person, place, and time. Psychiatric: Mood and Affect: Mood normal. Behavior: Behavior normal. Thought Content: Thought content normal. Judgment: Judgment normal. á á á Assessment/Plan Treatment included: water, rest. Follow up response to treatment: excellent. Patient discharge: Stable to go home and follow up with PCP. á á á á MD Electronically Signed 12/22/2020 6:39 PM

After an hour the left foot was numb. Arm is sore at the injection site. Then it went away. Today having body aches, back pain. Temp is 99.7. Had COVID in April.

Just a tiny red mark; This is a spontaneous report from a Pfizer-sponsored program Corporate (Pfizer) Social Media Platforms. A contactable consumer (patient) of unspecified age and gender received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for Covid-19 immunisation. The medical history and concomitant medications were not reported. The patient did not have pain, swelling or anything. Just a tiny red mark. The outcome of the event was unknown. No follow-up attempts are possible. Information about batch number cannot be obtained.

Waited 30 minutes for observation. Driving back home. Left side of face got tingling and on left arm. Just going away. Tingling is going away. Walking up the stairs, and got long winded and feeling fast heart rates. Tried to get up feeling fatigue. Notified manager. Informed of Vsafe to register there as well Scheduled to work on Monday 12/28 on site. Last onsite worked day was 12/22/2020 Covid testing last August and was negative Per the algorithm, her recommendations were to monitor and call PCP and 911 if symptoms persists or worsens

Started with a very sore arm with redness and warmth to the arm around 11PM and by 2AM started with chills but no elevated temp and then nausea. She reports she slept 12 hours and was then doing well.

Tachycardia, light headed,very dry mouth, numbing of tongue

Sore left arm; This is a spontaneous report from a Pfizer sponsored program Corporate (Pfizer) Social Media Platforms from a non-contactable Other HCP reported for self. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) at single dose on an unspecified date for COVID-19 immunization. Medical history and concomitant medication were not reported. Other than a sore left arm, patient felt great. The outcome of event was unknown. No follow-up attempts are possible. information about lot/batch number cannot be obtained.

Chest pressure, dizziness, increased troponin lab value.

"Fine? I've never felt fine after antiviral inoculations.; This is a spontaneous report from a Pfizer-sponsored program Corporate (Pfizer) Social Media Platforms via a non-contactable consumer. A patient

of unspecified age and gender started to receive BNT162B2, via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. Medical history and concomitant medications were not reported. Patient reported ""fine? I've never felt fine after antiviral inoculations"". Outcome of the event was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained."

Scratchy, sore throat, cough, SOB, asthma like symptoms (closing/tightness of esophagus/throat. Lungs hurt with deep breath.

Feverish; Body is aching/I am in too much pain; This is a spontaneous report from a contactable consumer (patient herself). A patient (demographics unknown) received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unknown route, at single dose on 18Dec2020 (at 14:00) for COVID-19 immunisation. No relevant medical history and concomitant medications were provided. On 19Dec2020, the patient had feverish and body is aching/I am in too much pain. The outcome of the events was unknown.

feeling off, shaky, swollen hand and arm on injection side. slight slurred speech

At 1103 reporting feeling itching on chest and arms

1. Significant Tinnitus, no treatment. Severity decreased the following day, but persists until present (12/23/2020). 2. Numbness of front upper teeth. Resolved by 12/22/2020.

Abdominal cramps overnight with back pain, then awoke with fever, chills, headache, significant body aches including continued back pain and fatigue. Symptoms improved the morning of 12/23

12/18/2020 02:45 AM WOKE UP BECAUSE UPPER RIGHT SIDE OF BACK, WAS HURTING, THROBBING, WOKE ME UP. STOOD UP, KEPT HURTING AND GETTING MORE INTENSE. BROKE OUT IN SWEAT, UNCOMFORTABLE, PAIN, DRY HEAVES DUE TO INTENSITY OF PAIN; 10/10 PAIN LEVEL 'SOLID'; LASTED 45 MINUTES. FELL BACK ASLEEP, WENT TO WORK 12/18/2020 THAT DAY. FELT LIKE IT WAS BRUISED 'KIDNEY AREA' ON UPPER R BACK. I BELIEVE IT WAS EVENING, I URINATE AND FELT 'SLIGHT BURNING' SENSATION; THIS HAPPENED THE REST OF THE EVENING. 12/19/2020 WENT TO CLINIC. DR. STATED URINED SAMPLE WAS NEGATIVE; UNDISCLOSED DIAGNOSIS OF URTHRITIS. GIVEN SHOT OF ANTIBIOTIC, AND PRESCRIBED ANTIBIOTIC FOR 7 DAYS. 12/20/2020-12/23/2020 FELT FATIGUED AND MALAISE. FELT LIKE JOINTS WERE 'TIRED' AND 'ACHY'; 'SLIGHTLY OFF'. 2 HOURS AFTER VACCINATION ON 12/18/2020 - 'TICKLE IN MY THROAT', STAYED AND IRRITATED, BROUGHT ON COUGHING. STAYED UNTIL 12/19/2020 WHICH TURNED INTO A RASPY WITH EXCESSIVE THROAT CLEARING. I DO DRINK A LOT OF WATER, STAYING HYDRATED. FLU VACCINE IN POSSIBLY OCT 2020

Received the vaccine on Thursday December 17th. On Saturday December 19th at about 48 hours, started to have an intense nerve type itch on the right arm and the right leg. No rash visible. Treated with Benadryl oral. Itch keeps coming back and is now at Day 4 without resolution. Also has felt very tired for about 4 days.

patient complained off flushed face; waited 15 extra minutes until feeling better

Shortly after receiving the Moderna COVID-19 Vaccine (Within minutes) she complained of the injection site and that arm of feeling warm. Upon further inspection, her arm was warm to the touch and was red. Patient could feel warmth from inside and we could also feel the warmth with touch. She stayed 15 minutes and we monitored the site. There was no further reaction. The patient had been offered Benadryl and declined. This will be notated for her second dose and will pre-treat with benadryl if needed.

No side effects until 1PM on the 18th, hot flashes with dizziness and nausea, then I started feeling like I was going to pass out and then felt like the blood was rushing through my head. Also head headache. I received a shot of Zofran 4mg. 30 min later I was able to sit up up and 10 min later I was able to stand without being dizzy. Still having waves of nausea. Body aches and flu like symptoms on Saturday. Right now only the nausea. Monday I was fine, but today it started the nausea and dizziness. No intervention needed today.

Patient received COVID vaccine at approximately 9AM this morning. Stayed 15 minutes after injection for monitoring, felt fine and returned to department. Employee returned at approximately 11:45AM with possible symptoms of reaction. Admitted to a headache that started approximately an hour after injection. Symptoms now include heaviness of arm, chest, feeling emotional, light headed. Vitals taken at 11:48 BP 150/86, P 79, R16 Pox 97. Oral Benadryl 25mg administered PO 11:50AM. EKG run. Patients symptoms progressed to include difficulty breathing and swallowing. Epi pen adult 0.3mg administered IM Left thigh at 12:13PM. Vitals checked at 12:13PM BP 188/90, pulse 97, pulse ox97. Called for emergency response for transport to ER. Pt remained stable until transport by EMS to ER. Employee health informed of patient transport. ER informed of patient transport.

After leaving Clinic symptoms started within 10 minutes. Started with scratchy throat. Then tingling in my lips. Bottom lip slightly swollen.

"History Present Illness: 26 year old female presents to walk in clinic with c/o feeling dizzy, flushed and heart racing after receiving COVID-19 vaccine earlier today. She took a benadryl about 30 min before receiving the vaccination. She is 11 weeks post partum. She is still breastfeeding her baby and reports she has ""not drank very much today."" At time of visit, she reports she ""feels much better."" She denies PMH of heart issues or any prior anaphylactic reactions. She denies shortness of breath or trouble breathing. She does not appear to be in acute distress at this time. Her vital signs are WNL."

THERE WAS NO ADVERSE EVENT. We realized after administration that we had inadvertently given the vaccine to a 15 year old girl. She is not having any symptoms or problems. We have been monitoring her and encouraged her to speak with us if she has any issues at all.

general warmth and dry throat

Stayed for 25 minutes for observation and told to call in 24 hours. Sore arm

12/18/2020 Day after injection chestpain that was progessive day before visit to ER on 12/19/2020.Described pain as pressure in middle of chest, radiated to upper left chest under armpit,

with associated nausea, feelings of Heart Palpitations, EKG shows 98bpm, normal intervals, t wave inversion lead III, normal sinus rhythm. BP 151/83, sats 100% temp 98.4 HR 99. labs cardiac enzymes negative, Ddimer elevated,CT chest negative for pulm embolism and chest xray no acute process. scheduled to see her PCP on 12/22. diagnosed with lymphadenopathy and chest pain, the lymph nodes noted after injection of covid #1 vaccine. 12/22/2020 was given a steroid shot in the PCP office,

Patient complained of a rush of feeling hot, symptoms progressed to feeling light-headed and dizzy. Skin was warm and dry. Experienced hypertension which got worse when told her blood pressure was high. Patient was transferred to the ED for further observation.

10 minutes after receiving the injection I was experiencing dizziness and lightheadedness. As I was moved to a new location I was still experiencing aforementioned symptoms in addition to feeling hot and nauseous and I vomitted. I was moved to the ER for further evaluation. I was given a COVID test, an EKG and my vitals were monitored. I was discharged home.

Nausea and dizziness within 5 minutes of administration, continued for 2 hours, transferred by private to ED for continued monitoring.

dizziness, vertigo nausea diarrhea chills weakness headache

Employee received vaccine on afternoon of 12/22/2020 at clinic She states she did have COVID previously in November. She called in this morning with vomiting and now has fever of 101.9, headache, body aches,fever, productive cough, loss of appetite, She has contacted her PCP for suggesntions.

Pt C/O blurry vision, palpitations and sweating for 3 seconds. this occurred 10 minutes after receiving vaccine.

Developed redness and warmth and some swelling at injection site that began about 7 hours after injection and grew in size to about 3 inches the next day. It did itch but otherwise some discomfort pain to area. By day 5 the area had almost healed entirely.

Metallic taste in mouth immediately Headache that lasted days

"About 12 minutes after receiving covid vaccine, pt felt like she had a lump in her throat. No difficulty breathing or swallowing. No facial swellling. Pt was evaluated by PA from urgent care. Pt was transferred to urgent care for antihistamine administration. Vitals remained stable. 12/23/20 @ 1212: Note copied from UC Visit: Diagnosis Allergic reaction (ICD10-CM T78.40XA, Working, Medical). Summary: 0916 ""Lump is still there but much smaller"" Still no sign of intraoral swelling 0925 Patient reports symptoms have almost resolved completely, comfortable going home. Instructed to take Zyrtec tonight before work and for the next couple of days and to go to hospital for SOB, worsening sensation of lump in throat. Patient verbalized understanding and is in agreement with treatment plan. Opportunity for questions was given, all questions answered.. Pharmacy: diphenhydrAMINE (Benadryl) AMB (Order): 25 mg, IM, InOffice."

About 4 hours later I began have tightness in my abdomen and cramping, followed by gastrointestinal upset and diarreha and pain in my upper abdomen. I will wait and see if it resolves by tomorrow before going to the hospital for care.

Pt stated she had a reaction to the Covid-19 vaccine. Pt states she cannot raise her arm, where she got the injection is very hot to the touch, and she has pain all the way up to her neck. A slight knot at injection site.

mild transient rash with some welts, but mostly redness and itching located on right foot and ankle. Took diphenhydramine 50 mg po x 1 dose and used hydrocortisone cream x 1 application. Rash resolved in that location, but came up on both thighs just above the knee cap on both legs on Sunday. Repeated diphenhydramine 50 mg po x 1 and used hydrocortisone 1% cream x 1 application. Both events resolved within 2 hours, with no further issues. This could be unrelated since it was 4 days out, but I wanted to report it for consideration.

On 12/18 feeling congestion and stuffy nose was able to go work that night as well 12/19. Then on 12/21 realized lost taste/smell went to get test for Covid results positive. As of 12/23 still haven't gain taste/smell. I had to miss 10 days of work.

tachycardia, dizzy, dry mouth

Progress Notes MD (Physician) ? ? Endocrinology COVID VACCINE CLINIC 12/22/2020 á Patient: Date: 12/22/2020 á Subjective Patient is a 42 y.o. female who was seen at COVID Vaccine Clinic today for her first dose of the COVID 19 vaccination. á Afebrile 98.6 á She denied any history of previous adverse reactions to vaccines. á She was given the Pfizer vaccination in the right deltoid muscle. á During her 15 minute waiting period after the injection, the patient began to experience dizziness. She denied rash, hives, welts, difficulty breathing, difficulty swallowing, wheezing, throat tightness, hoarseness, stridor, itching, facial swelling, lip swelling and tongue swelling. á This provider was notified of patient reaction and she was then assessed in the emergency bay area. á Monitored patient for severe reaction symptoms, including rapid progression of symptoms, respiratory distress with wheezing and dyspnea, vomiting, abdominal pain, hypotension, dysrhythmia, chest pain and collapse. á Vitals were normal Checked her blood sugars-normal at 108 Offered her snack/water-she declined. á Repeat BP normal at 112/72 á Vitals: á 12/22/20 1737 BP: 126/82 Pulse: 87 SpO2: 100% á á á á Objective á á Physical Exam Vitals signs reviewed. Constitutional: Appearance: Normal appearance. She is normal weight. HENT: Head: Normocephalic and atraumatic. Nose: Nose normal. Mouth/Throat: Mouth: Mucous membranes are moist. Pharynx: Oropharynx is clear. Eyes: Extraocular Movements: Extraocular movements intact. Conjunctiva/sclera: Conjunctivae normal. Pupils: Pupils are equal, round, and reactive to light. Neck: Musculoskeletal: Normal range of motion and neck supple. Cardiovascular: Rate and Rhythm: Normal rate and regular rhythm. Pulses: Normal pulses. Heart sounds: Normal heart sounds. Pulmonary: Effort: Pulmonary effort is normal. Breath sounds: Normal breath sounds. Abdominal: General: Abdomen is flat. Bowel sounds are normal. Palpations: Abdomen is soft. Musculoskeletal: Normal range of motion. Skin: General: Skin is warm and dry. Neurological: General: No focal deficit present. Mental Status: She is alert and oriented to person, place, and time. Psychiatric: Mood and Affect: Mood normal. Behavior:

Behavior normal. Thought Content: Thought content normal. Judgment: Judgment normal. á á á Assessment/Plan Treatment included: no therapy. Follow up response to treatment: excellent. Patient discharge: Stable to go home and follow up with PCP. á á á á MD Electronically Signed 12/22/2020 5:38 PM á á á

Patient reports after she received the vaccine she reported to the observation area for the 30 minute monitoring period and reported feeling her heart racing. Patient with hx of histamine intolerance and angioedema, so carries epi pen with her. Patient notified monitors of her symptoms and her medical hx and that she had her epi pen with her. Patient reports ?heart racing? and recorded 130 BPM on activity tracker. Pt endorses history of anxiety and panic attacks. Patient reports resolution of symptoms at approximately 8:15 am, resting HR at that time 97-98 BPM. Patient denies any other symptoms.

Rash, Flush, felt hot, itchiness, headache, dizziness

Patient called and reported diarrhea, vomiting and nausea ~ 36 hours after vaccine was administered. Resolved in ~ 18 hours. Felt great the next day.

Right sided jaw pain started 12/22/20 in the AM progressed through the evening. When I woke I had numbness and weakness on the right side of my tongue which I quickly realized included the lower portion of my right face. An ER trip and a CT scan confirmed it was Bells Palsy. The upper portion of my face has is now included in the weakness and paralysis.

Temperature of 100.1 about 5 hours after administration with mild frontal headache. Today - about 24 hours after adminstration - herpetic rash developed along the left mandibular branch of the trigeminal nerve.

Patient given covid-19 vaccine at 1218, Symptoms started at 12:25 (dry cough, dry mouth). Benadryl 25mg by mouth given at 1238. No previous history of vaccination reaction. Of note: recent history of Clinically diagnosed bronchitis and treated with OTC medication (mucolytic) by pcp, no ATB given. No NKDA, no recent fever or illness in 24hours. Initial VS: BP: 142/84, HR: 111, RR: 24 Spo2% 99/RA, . End VS: BP: 118/94, HR: 82, RR: 16,, SpO2: 100%/RA. Patient denies shortness of breath or difficulty breathing, Lung sounds are clear. Patient states she feel better and is conscious alert and oriented X4. She was placed in he monitoring room within the vaccination clinic for intermittent monitoring of VS and reaction response at 1317.

on 12/16/2020 my arm was red from the injection like everyone else but my symptoms began the next day on 12/17/2020 I was in the shower in the morning it was noticeably sore and the following day the 18th it was quite a bit bigger and red, I could still move my arm. I was overly tired and very sluggish I went to the Dr on the 18th and they gave me a prescription for keflex and prednisode

Patient with past medical history significant for thyroid cancer was given Pfizer COVID-19 vaccine at approximately 1430 at our facility. After receiving vaccine patient felt flushed, face hot, felt something squeezing neck (similar to tight collar). 25 mg PO diphenhydramine given X 1. Patient having shivering on and off. Felt swelling progress up into back of throat. Had to clear throat and swallow harder. At 1511

patient was checked into the emergency department at our hospital. At 1527 famotidine 20 mg IV once given. BP was found to be 232/100. Amlodipine 5 mg IV once given at 1909. Labetalol 10 mg IV once given at 1812, labetalol 20 mg IV once given at 2034, clonidine 0.1 mg PO once given at 2127. Patient sent home at approximately midnight. Diagnosed with possible anaphylaxis and hypertensive urgency (no history of HTN).

Ten minutes after receiving Pfizer Covid vaccine shot in right shoulder, experienced partial numbing of the hands which persisted all day. Next day no numbing of left hand, but right hand still partially numb.

Patient complained of a rush of feeling hot. Patient was laid supine, VS monitored. Patient was transferred to the ED.

Right after patient was given vaccine injection he started to feel lightheaded and woozy. He had just worked the night shift and hadn't eaten anything. No prior illness reported. Patient brought to emergency department to be evaluated. Received 500ml of fluids and symptoms resolved and he went home. Diagnosis of near syncope.

Hives, administered Diphenhydramine 12.5mg po

Muscle aches, chills arm discomfort

Patient c/o numbness of arm and feeling like she is floating - resolved after 2-3 seconds

Diffuse hives started ~ 12 hours post vaccine, progressively worsened to involve entire body, and required solumedrol & antihistamines at an Urgent Care visit

"On the night of 10/22/20 patient sat up suddenly and had what she reports as, ""75% dimming of the right eye,"" that lasted for about 5 minutes. Vitals at that time were BP 122/82, p 72, o2 sat 97% on RA, and temp 97.8. (Patient is a CRNA) After confirming no other neurological deficits, patient laid down and experienced blurring of her left eye with left eye pain. No treatment given. Today she has no vision deficit or pain."

Frequent palpitations - never experienced before EKG on 12/23 revealed frequent PAC's, sometimes with runs of PAC's

Patient reports shortness of breath and persistent cough.

facial numbness and tingling, disappear in 24 hours

45-60 minutes post vaccination, patient experienced right eye twitching continuous for a few hours, then intermittent x 24 hrs; now resolved 12 hours post vaccination, patient experienced right ear/jaw numbness that lasted up to 36hrs 36 hrs post vaccination, the numbness is spreading to the right cheek no affect in muscle function, just numb pt seen at urgent care facility 12/23 @~0830 and prednisone initiated

Tingling down right arm into right hand, spread to left arm and hand. Stiffness in neck. After an hour progressed into muscle weakness in both forearms, more noticeable in the right arm. Best described as lactic acid buildup feel in forearm-had trouble lifting/pulling door handles. Has subsided over a day, no general soreness in both arms/ neck. Injection site has developed noticeable pain/soreness, somewhat like a tetanus shot . There was a fair amount of blood at the injection site (not typical for me), and the administration of the shot was a touch high in the arm.

Lightheadedness, tingling extremities and dizziness

Fatigue, sweaty, and dizziness

Staff member started to feel fatigue and chills the evening he received the vaccine. Symptoms continued the following day and a half. Fever was as high as 101.4. He had COVID nine months ago. Symptoms have resolved.

Nausea, fatigue, headache, flushing

PATIENT STATES HANDS TINGLING BUT WENT AWAY PATIENT HAD NOT INTERVENTIONS OR PROLONGED OBSERVATION

Lip and tongue tingling

TINGLING LIPS REPORTED

Soreness at injection site, Fever at 99.8 degrees F. Body Aches, headache

12/21/2020: fatigue, muscle ache 12/22/2020: fatigue, muscle ache, headache, fever, loss of appetite, nausea, and sore throat.

Patient became flushed, chest tightness and felt winded. BP was 130/70 and 02 saturation was 100%. Patient had not tongue swelling, previous reaction to a vaccine, medication or food and no shortness of breath. Patient was placed on gurney for 30 minutes and had no further symptoms after this time.

Fatigue, diarrhea, whole body aches, fever

Bad headache and sore on injection site

Injection site raised, firm area (size of quarter); redness but no streaking; extreme tiredness, chills, headache, neck pain. Patient went to walk in clinic and provider believed her to be having a localized allergic reaction to the COVID vaccine. She was given a steroid injection, and started on oral steroids.

1 hr post administration patient developed urticaria, pruritus

"Progress Notes PA-C (Physician Assistant) ? ? Orthopedics Cosigned by: MD at 12/22/2020 á9:48 AM á á Patient: Date: 12/21/2020 á Subjective Patient is a 34 y.o. female who was seen at COVID Vaccine Clinic today for her first dose of the COVID 19 vaccination. á á She was given the Pfizer vaccination in the right deltoid muscle. á During her 15 minute waiting period after the injection, the patient began to

experience generalized feelings of ""not feeling quite right"" as well as anxiety/nervousness, nausea and chills. She denied difficulty breathing, throat tightness, dizziness, chest pain, or other GI complaints. á This provider noticed her raising her hand from across the waiting area and tended to her where she noted the above complaints. she was then assessed in the emergency bay area. She was monitored for severe reaction symptoms, including rapid progression of symptoms, vomiting, hypotension, chest pain, collapse and Respiratory distress. á Past medical history includes anxiety for which she takes Effexor on a daily basis as well as type 2 diabetes, diagnosed approximately seven or 8 years ago during a pregnancy. She is on oral medication during the day and insulin at nighttime. She did take her oral medication today and last ate a pasta lunch right before arriving to the vaccine clinic. Last A1c was 6.5. Patient states that she generally runs a postprandial blood glucose following a heavy meal of about 180. á She reported a previous history of anxiety and nervousness following vaccinations in the past. Most recently, she experienced a 30-minute period of anxiety and nervousness following her flu vaccine this past October. These feelings passed without further incidents. á Review of Systems Constitutional: Positive for chills. HENT: Negative for drooling, facial swelling, hearing loss, rhinorrhea, sneezing and trouble swallowing. Eyes: Negative for redness and visual disturbance. Respiratory: Negative for cough, chest tightness and shortness of breath. Cardiovascular: Negative for chest pain. Gastrointestinal: Positive for nausea. Negative for vomiting. Skin: Negative for color change, pallor and rash. Neurological: Negative for dizziness, speech difficulty and light-headedness. Psychiatric/Behavioral: Negative for agitation and confusion. The patient is nervous/anxious. á á á Objective á She ambulates into the emergency treatment bay under her own power and without difficulty. She is seated on the gurney, and continues to answer questions appropriately. á Physical Exam Constitutional: General: She is not in acute distress. Appearance: Normal appearance. She is not toxic-appearing or diaphoretic. HENT: Head: Normocephalic and atraumatic. Nose: No rhinorrhea. Cardiovascular: Rate and Rhythm: Regular rhythm. Tachycardia present. Pulmonary: Effort: Pulmonary effort is normal. No respiratory distress. Skin: General: Skin is warm and dry. Coloration: Skin is not pale. Findings: No rash. Neurological: Mental Status: She is alert. Gait: Gait normal. Psychiatric: Mood and Affect: Mood normal. Behavior: Behavior normal. á á á Assessment/Plan Stress reaction secondary to vaccine administration and history of anxiety and nervousness following vaccinations. á Vital signs obtained at 1352 with blood pressure at 154/95, mild tachycardia at 109 and 97% O2 saturation on room air. Patient denies any chest pain, shortness of breath time. á She is given a bottle of water and assisted to lie down with the head of the bed slightly elevated. She continues conversating appropriately without any acute distress. Vitals reassessed at 1359 with blood pressure of 133/76, heart rate 97% on room air. Dr. at the bedside now. Suggested obtaining a blood glucose. Blood glucose obtained at 1405, elevated at 234. She continues to deny any chest pain, shortness of breath, chest tightness, swelling in the throat, nausea/vomiting or other GI complaints. á Vital signs checked again at 1406 with blood pressure 133/77, heart rate 107 and 97% on room air. á Vital signs last checked at 1415 to reveal a blood glucose of 219, blood pressure 127/82, heart rate 100 and O2 saturation of 97% on room air. Patient has no additional complaints at this time and reports feeling well. Her mother has driven her to the clinic today. She felt that she was able to safely walk out with any issues. She was assisted by nursing staff and ambulated out of the treatment bay independently. á Treatment included routine surveillance of vital signs at about a 5-minute intervals following notification of her feeling poorly. Vital signs continued to normalize and remained stable through the duration of her 30 minutes following her vaccination. á Follow up response

to treatment: excellent. á Patient discharge: Stable to go home and follow up with PCP. Recommend to patient that she present to the ED or call 911 should she develop any symptoms up to and including but not limited to chest pain, shortness of breath, chest tightness, signs or symptoms of angioedema, or syncope. She expresses understanding the above and has no further questions today. á Orders Placed This Encounter Procedures COVID-19 MRNAá PA-C Electronically Signed 12/21/2020 1:51 PM á á"

injection site soreness; myalgias; chills; fatigue; nausea; loss of appetite; enanthem (2 oral ulcers); enanthem (2 oral ulcers); This is a spontaneous report from a non-contactable consumer (patient). A 39-year-old female patient started to receive BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) Solution for injection (lot number: EH9899 and expiry date unknown) via an unspecified route of administration at the left arm on 18Dec2020 12:30PM at a single dose for COVID-19 immunization and monascus purpureus (RED YEAST RICE), via an unspecified route of administration from an unspecified date to an unspecified date at an unknown dose and frequency as supplementation therapy. The patient's medical history included elevated LDL cholesterol and supplementation therapy, both from an unknown date and unknown if ongoing. The patient had no known allergies to medications, food, or other products. Concomitant medications were not reported. The patient did not receive any other vaccines within 4 weeks prior to BNT162B2. The patient only received red yeast rice supplements within 2 weeks of vaccination. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. It was reported that on 19Dec2020, the patient experienced injection site soreness, myalgias, chills, fatigue, nausea, loss of appetite, and enanthem (2 oral ulcers). No therapeutic measures were done in response to the events. Outcome of the events was recovering. The events were assessed as Non-serious. No follow-up attempts are possible. No further information is expected.

fever; chills; malaise; This is a spontaneous report from a contactable physician (Patient) via Pfizer-sponsored program. A 27 year-old-male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 18Dec2020 at single dose for COVID-19 immunization. The patient medical history and concomitant medications were not reported. The patient experienced fever and chills on 18Dec2020 (in the night); the patient also experienced malaise throughout the weekend (in Dec2020). Patient had vaccine on 18Dec2020 and was still having symptoms 3 days later. As of 20Dec2020, patient stated he was feeling better but wanted to know if he should get tested or did the vaccine cause these symptoms. Final outcome of the events was reported as unknown. Information on the lot/batch number has been requested.

"Experiencing burning while urinating; This is a spontaneous report from a contactable consumer (patient who is Nursing assistant). This 56-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot # EK5730), via an unspecified route of administration, on 19Dec2020 approximately at 10:00 AM (age at vaccination 56-years-old) at single dose for COVID-19 immunisation. Medical history included blood pressure. Concomitant medications included losartan for blood pressure and colecalciferol (VITAMIN D). The patient experienced burning while urinating on 19Dec2020 afternoon after she came home and on 20Dec2020 morning too. About treatment consumer stated: ""Not really, long time ago I had that but yesterday I did like oh"". The patient had complete

blood count (CBC) and C-reactive protein (CRP) test, results are unknown. Outcome was not recovered. Next shot is due on 09Jan2021."

Increased heart rate up to the 115-120s for 3 hours - self reported

Sore arm at injection site night of vaccine and next day. Then resolved (without taking any acetaminophen).

I had the covid 19 virus in March 2020. Actually, I still have loss of taste and smell. When I received the vaccine on 12/21/2020, I immediately felt a burning sensation at the injection site and in my chest. A headache developed 5 minutes after the vaccine. I began to experience fatigue, nausea, muscle aches and joint pain. I have been treating myself with Tylenol and Ondansetron. I am still experiencing these side effects today (12/23/2020)

Migraine headache with nausea and aura, treated with Toradol 60 MG IM 12/23/20 at 13:35.

pt became lightheaded and nauseated. Elevated feet and given ice pack for neck. Pulse 70, resp 16. rested for 30 minutes, feeling much better - able to ambulate without difficulty. States she just feels a little off. Husband came to take her home.

"After she waited for 30 minutes after receiving vaccine she stated that she had generalized itching and 2 small hives on her right arm. She said it started about 3 mins after receiving the vaccine. She was given 25mg of Benadryl syrup po. She stayed at facility another 30 minutes before being cleared to leave after she said the itching was better and no further hives formed. 12/23/20 -9:56am She was contacted by phone. She said she woke in the night and felt like ""asthma"" and had a rash at the site. She took another 25mg of Benadryl. She took another dose of Benadryl at 06:00am. As of this time, 9:56am, she states, no shortness of breath, no more rash at site, and the itching has subsided. She will follow up as needed."

I was itchy only to find out it was Shingles

1049: CG called OH and advised she received the COVID19 vaccine yesterday and woke up this morning at 0630 with a rash to her right chest and right hand, and complains of fatigue. CG denies any SOB or any other symptoms at this time. CG advised she has a history of COPD, Asthma, and granuloma disease. Advised she spoke with her Oncologist about receibving the vaccine who did not have any concerns but also voiced that she did not speak to her PCP. Occ. Health advised CG that she be seen by urgent care or PCP for current symptoms and to go to the ER if symptoms worsen or she becomes SOB. 1106: Called CG to see if she was able to touch base with PCP, advised that she has a call out to her and messaged her PCP. CG states that the rash has remained the same since this morning and that it does not itch anymore. Again advised CG if worsens to go to Urgent care or ER. CG verbalizes understanding. Will follow-up with CG later today. 1448: Called CG states the hives are mostly gone, she took some benadryl and feels back to her normal self, just has some scabs from where she scratched herself. CG states her PCP responded back to you that if she felt necessary should go to the urgent care or do a virtual

appointment. Cargiver declined and states she is feeling a lot better. Advised CG to call OH with any changes and to go to the ER or Urgent care for any emergency symptoms. CG verbalized understanding.

30 minutes after vaccination pain occured on my left upper gums, left upper lip and into my left chee with swelling in the same locations, that have not resolved

EXTREME BILATERAL ITCHING ON BOTH ARMS THROUGHOUT

The day after receiving the vaccine, the arm that I got the vaccine in was in severe pain. I would say 7/10 pain. Anything even slightly brushing against it was very painful. It was a little red and hot to the touch. I woke up multiple times through the night because of the pain. I did NOT take anything for it. By the following morning it was just sore, like how you normally would feel after a vaccine.

11am on the 20th I noticed pain on my back torso and it came around to the left of my abdomen and was told it was textbook shingles rash and was prescribed valacyclovir 1gram 3x daily for one week, the pain is now mild and I can treat it with tylenol and I've only had to take it once, the rash is still there but it's not spreading I started the medication at 3pm after seeing the dr

25-30 min post injection patient reported feeling itchy and became flushed. Reported mouth tingling and difficulty swallowing. No difficulty breathing. Monitored the patient, sats were wnl BP was elevated. Cool pack placed on forehead, and patient took oral benedryl. After about 20 minutes color and BP had normalized, itching and tingling resolved. Patient ate and drank and felt well enough to leave on her own. No further issues.

after vaccination client had a weird taste in back of throat during 15 minute wait time. Had client wait additional 15 minutes and still had a weird taste in mouth.

First 30 min post-vaccine: flushing and lightheaded, self limiting. 1.5 hours post-vaccine: vertigo x10 minutes, palpitations, chest tightness. Palpitations were brief and at rest. BP 172/110, HR 95, O2 Sat 99% on RA. 2.5 hours post-vaccine: chest tightness has remained constant with mild restrictive sensation on full inhale, vertigo returned but briefer in duration, BP 173/100, HR 85, Temperature 98.5F, O2 Sat 97% with decrease during conversation. 3 hours post-vaccine: lightheaded with constant chest tightness, BP 168/110, HR 88, O2 Sat 98% on RA, 6 hours post-vaccine: symptoms resolved, BP 148/100, injection site burns and sore to touch.

Progress Notes 12/22/2020 á á Subjective Patient is a 46 y.o. female who was seen at COVID Vaccine Clinic today for her first dose of the COVID 19 vaccination. á She denied any history of previous adverse reactions to vaccines. á Pt has h/o hypothyroidism on LT4- last lab a few months ago Started feeling lightheaded and warm Doing a temp check á 135/94- repeat BP check Pulse between 72-90s on rechecked á á Blood sugar was just checked and normal at 76--repeat also normal at 86 á She is eating a snack and having some water. á She was given the Pfizer vaccination in the right deltoid muscle. á She said she has a h/o vasovagal episodes with shots, mammograms, etc. á During her 15 minute waiting period after the injection, the patient began to experience dizziness. She denied rash, hives, welts, difficulty breathing, difficulty swallowing, wheezing, throat tightness, hoarseness, stridor, itching, facial

swelling, lip swelling and tongue swelling. á This provider was notified of patient reaction and she was then assessed in the emergency bay area. á Monitored patient for severe reaction symptoms, including rapid progression of symptoms, vomiting, abdominal pain, hypotension, dysrhythmia, chest pain and collapse. á á á Objective á á Physical Exam Constitutional: Appearance: Normal appearance. HENT: Head: Normocephalic and atraumatic. Nose: Nose normal. Mouth/Throat: Mouth: Mucous membranes are dry. Pharynx: Oropharynx is clear. Eyes: Extraocular Movements: Extraocular movements intact. Conjunctiva/sclera: Conjunctivae normal. Pupils: Pupils are equal, round, and reactive to light. Neck: Musculoskeletal: Normal range of motion and neck supple. Cardiovascular: Rate and Rhythm: Normal rate and regular rhythm. Pulses: Normal pulses. Heart sounds: Normal heart sounds. Pulmonary: Effort: Pulmonary effort is normal. Breath sounds: Normal breath sounds. Abdominal: General: Abdomen is flat. Bowel sounds are normal. Palpations: Abdomen is soft. Musculoskeletal: Normal range of motion. Skin: General: Skin is warm and dry. Neurological: General: No focal deficit present. Mental Status: She is alert and oriented to person, place, and time. Mental status is at baseline. Psychiatric: Mood and Affect: Mood normal. Behavior: Behavior normal. Thought Content: Thought content normal. Judgment: Judgment normal. á á á Assessment/Plan Treatment included: rest, snack. Follow up response to treatment: excellent. Patient discharge: Stable to go home and follow up with PCP. á Discharge time 5:51pm á á á 12/22/2020 5:19 PM á á

visual disturbances and severe headache started about an hour after vaccine. This improved over night, then 24 hours after vaccine severe headache which lasted another 2 days, aches

Increased HR and BP 4 minutes after injection. Rest and VS monitored. Return to baseline at the 29 minute mark. Released after 30 minutes.

mild left upper arm swelling, quarter to half dollar sized lump under skin; sore tight muscle that interferes with daily activity; area is warm to the touch Symptoms started within 3 hours of dose and have continued to progress for 20 hours.

5 minutes after receiving the vaccine patient felt light headed and her heart rate was elevated.

So about 12 hours after receiving the shot I started experiencing COVID symptoms. I called employee health and they told me to come in and get tested for COVID and tested positive. Body aches, headache and a fever last night at 102.8. I took some Tylenol. Woke up and I was drenched from sweat. I also have a nagging cough and sore throat.

Severe vertigo, nausea and vomiting, and weakness presented to emergency department after 8 episodes of vomiting over 12 hours with no relief

Patient monitored x 15 min per guidelines. Returned within 10 mins c/o itching hands. 25 mg diphenhydramine given IM per order. Post adm VS stable. Symptoms resolved within 15 min.

About 22.5 hours after shot, she experienced extreme dizziness. She was shopping with husband and he had to drive home due to this dizziness. She got home and went to bed and slept 4 hours and woke up without any further issues. When she was dizzy she did experience some nausea.

DIZZINES WITH STANDING

Felt sick , sedated , as if she was going to pass out.

Immunization 12/22/2020 COVID Vaccine Clinic Need for vaccination Dx Referred by MD Reason for Visit Progress Notes MD (Physician) ? ? Endocrinology COVID VACCINE CLINIC 12/22/2020 á Patient: Date: 12/22/2020 á Subjective Patient is a 63 y.o. female who was seen at COVID Vaccine Clinic today for her first dose of the COVID 19 vaccination. á Arrived at 5:50pm á She denied any history of previous adverse reactions to vaccines. á She was given the Pfizer vaccination in the left deltoid muscle. á During her 15 minute waiting period after the injection, the patient began to experience dizziness. She denied rash, hives, welts, difficulty breathing, difficulty swallowing, wheezing, throat tightness, hoarseness, stridor, itching, facial swelling, lip swelling and tongue swelling. á This provider was notified of patient reaction and she was then assessed in the emergency bay area. á Monitored patient for severe reaction symptoms, including rapid progression of symptoms, respiratory distress with stridor, wheezing, dyspnea, increased work of breathing, persistent cough and cyanosis, vomiting, abdominal pain, hypotension, dysrhythmia, chest pain and collapse. á Vitals were normal Glucose was 100 á Felt better right away Normal BP is 110s per pt á Objective á Vitals: á 12/22/20 1759 BP: (!) 164/83 Pulse: 82 Temp: 98 ¦F (36.7 ¦C) SpO2: 95% á á Physical Exam Vitals signs reviewed. Constitutional: Appearance: Normal appearance. She is normal weight. HENT: Head: Normocephalic and atraumatic. Nose: Nose normal. Mouth/Throat: Mouth: Mucous membranes are moist. Pharynx: Oropharynx is clear. Eyes: Extraocular Movements: Extraocular movements intact. Conjunctiva/sclera: Conjunctivae normal. Pupils: Pupils are equal, round, and reactive to light. Neck: Musculoskeletal: Normal range of motion and neck supple. Cardiovascular: Rate and Rhythm: Normal rate and regular rhythm. Pulses: Normal pulses. Heart sounds: Normal heart sounds. Pulmonary: Effort: Pulmonary effort is normal. Breath sounds: Normal breath sounds. Abdominal: General: Abdomen is flat. Bowel sounds are normal. Palpations: Abdomen is soft. Musculoskeletal: Normal range of motion. Skin: General: Skin is warm and dry. Neurological: General: No focal deficit present. Mental Status: She is alert and oriented to person, place, and time. Mental status is at baseline. Psychiatric: Mood and Affect: Mood normal. Behavior: Behavior normal. Thought Content: Thought content normal. Judgment: Judgment normal. á á á Assessment/Plan Treatment included: no therapy. Follow up response to treatment: excellent. Patient discharge: Stable to go home and follow up with PCP. á á MD Electronically Signed 12/22/2020 6:01 PM

10 minutes after receiving the vaccine, I became tachycardic. Heart rate was in the 150s. I believe the rest of my vital signs were normally initially, but about 10 minutes after the tachycardia started, my BP was 170/110. I remained tachycardic so was sent to the ER. I continued to have waxing and waning tachycardia during my ED stay. Per MD, EKG, BMP, CBC were all normal. I did not receive any medications. After about 3 hours of monitoring, my heart rate was under 100 at rest so was discharged home. For the next 24 hours, with minimal exertion (talking, walking on flat surface) my heart rate would elevated into the 110-120s. 48 hours after vaccine, my heart rate returned to normal. I will be following up with cardiology 12/28/2020

Patient stated she was feeling sluggish, little to no appetite over last couple of days. Today her saturations dropped to 84% while at work.

LIGHTED HEADED

Shortly following vaccination, developed redness, skin rash, itchiness, dizziness and anxiety. Was given diphenhydramine 25mg with no relief and began worsening - walked over the Emergency Department in same building and treated there with the following: Solu-Medrol 125 mg IV Push, Diphenhydramine 50mg IV Push, and Prednisone 40 mg by mouth. Symptoms began to improve within about an hour and was given a prescription for Prednisone 20 mg Po X 3 days.

ANAPHLACTIC REACTION, SOB, CHEST PRESSURE, TIGHTNESS IN THROAT, TACHYCARDIA

swollen lymph node extends from injection site toward breast, shooting pain down side

High fever with chills approximately 12 hours after vaccination. Severe headache, mild nausea, loss of appetite, joint pain. Arm pain significant with almost no range of motion without pain. Swelling around armpit. Ibuprofen taken with minimal relief. Arm pain, headache, intermittent fever is ongoing at this point in time.

12/19/2020 MORNING WOKE UP AT 4PM FOR WORK, HAD HIVES ALL OVER EXTREMITIES AND TRUNK. WENT TO URGENT CARE; PRESCRIBED MENTHOPREDNISONE. TAKING THE PREDNISONE AND ZYRTEC SINCE THAT DATE. *HX 5-6 MONTHS OF HIVES. CONSULTING WITH ALLERGIST. SEEN 12/21/2020.

Resident noted to be experiencing a full body tonic/clonic seizure approximately one hour and forty-five minutes post receiving the vaccine. Supplemental oxygen via nasal cannula provided, vital sign monitoring, solu-medrol IM provided, epinephrine IM provided, clonidine tablet provided PO, stat labs ordered: CBC, BMP, depakene level, UA. Resident exhibited positive reaction to interventions. Seizure lasted approximately 5 minutes, afterwards resident presented at baseline: alert and oriented x3 and communicative. Oral intake tolerated approximately an hour and a half post seizure. Enhanced monitoring in place.

,headache, tiredness, chills, light headed, feeling unwell

Felt fine for first 30 minutes. Then face started to burn and tingle. 10-15 minutes later felt heart racing, slightly short of breath. Felt like I was going to faint. This only lasted 20 seconds or so. Base of the tongue felt strange. Took Benadryl 50 mg and prednisone 20 mg. Paramedics came. Hr was 68, O2 sat 99, bp176/126. Lungs clear. No trouble breathing. I felt better and they left. All symptoms improved except my face is still burning and tingling at 2 pm on same day (today). Face is mildly red but no hives. Bp is now normal 126/76, hr 50.

GI upset

Got the vaccine at 11AM. around 3PM very tired, headache wok me up around 3AM next morning I was fatigued, felt hot and cold (couldn't decide if I needed a jacket or not while at work), very tired, the next day still fatigued, chills, hot and cold, went to work and decided to leave after talking to one of the doctors. I was clammy, very sluggish, had a very mild headache, did not feel well overall. That was the worst day for me (Friday). My ears felt plugged. Slept almost entire day going through cold/hot chills,

even wore 4 layers of blankets. Back and forth with hot and cold chills. Next day ear pain and fatigue. Very mild hot and cold flasher.

A few minutes after vaccine administration, while sitting down for post-vaccine monitoring, she became dizzy and diaphoretic. Ice packs were given and the dizziness improved over about 5-10 minutes. Vital signs were taken and were normal: BP 125/80, Pulse 86, O2 Sat 100%. After symptoms resolved she went back to work.

Slight Fever of 100.4 degrees Fahrenheit

Vaccine was administered 11:45 am. Post vaccine (~30 mins) slightly nauseous and diaphoretic but resolved. Around 9:30 pm had 3 consecutive syncopal episodes. 911 was called and EMS arrived. Finger stick and BP were unremarkable; however, BP was slightly elevated for my usual (136/72 at time of reading where I am usually 110/80)

I have been experiencing intermittent, involuntary twitching of my my left thumb that started around 12;00 noon. There is no numbness or tingling (normal injection site ache, however) or recognizable pattern of when the twitching occurs, and the twitching does not seem to last longer than 10 seconds at the most before stopping. 1-3 minutes will pass before my thumb starts twitching again. Other digits do not seem to be affected. I did not experience this prior to the COVID-19 vaccine administration and not have any neurological conditions that this would be a symptom of.

Fatigue, headache, fever, muscle pain, chills

After shot arm was sore. Woke up felt not herself, tired achy. Took Tylenol went to sleep. The next day she couldn't move. Was in bed in a ball. Today she can walk a little bit. Went to pharmacy to get more Tylenol. Cannot concentrate. Chills and fever. Bolt of electricity down spine. Very tired.

visual changes- resolved within minutes; MD examined, no intervention required

Received the COVID vaccine, after the 30 min observation time she left the area and returned about an hour after her administration with complains of Shortness of breath, tightness in chest, elevated BP, Flushing and rash on upper extremities and neck.

Received the COVID vaccine, after the 30 min observation time she left the area and returned about an hour after her administration with complains of Shortness of breath, tightness in chest, elevated BP, Flushing and rash on upper extremities and neck.

Patient tested positive for Covid morning after vaccination with symptoms. Fever of 100.2, headache, eyes burning, head is heavy, chills, very fatigued

An 1 h and 20 mins after vaccine was given, driving home and felt some difficulty swallowing. Was able to drink water no difficulty but unable to do swallow without the aid of water. No SOB, some tachycardia. Went to closest ED.

I woke up and have been experiencing severe body aches, a dull headache, and it feels like I might have a low grade temperature but when I check my temperature it is normal.

hives, pruritus within 30 minutes

Increased heart rate and blood pressure, dizziness, chest tightness, tingling left arm , leg and foot, left should heavyness.

I had dyspnea and palpitations started about 5 minutes after vaccination, lasted about 2 minutes. I had similar another episode after about 9-10 minutes after vaccination which is less severe compare to first one. I was sent to ER after second episode for close monitoring. No event on tele monitor in ER.

At exactly the 10 minute mark, I started feeling very flushed and hot. 1-2 minutes later, I was very lightheaded and dizzy. Felt like my heart was going to beat out of my chest and that I might faint. Walked down to tell the RN and she could tell I didn?t feel well as I approached. She said she could see my pulse bounding in my neck. Asked me to sit down arm she checked my pulse. Said I was tachycardic, over 100bpm. She asked me to sit there another 15 min for observation and gave me some water. I started to feel less flushed but then a second round of flushing came. The bounding/tachycardic episode never stopped. They suggested I go to the ER for observation. I text the Dr I was working with and she came down and spoke with the vaccine nurses saying she was comfortable monitoring me for the next several hours. I continued to feel this way for 3-4 hours. Also very pale and shaky. The above symptoms finally lessened around lunch time. For the remainder of the day, I felt very exhausted and had a lingering headache. The next day (today) I feel better. Other than soreness in the injection arm and some general body aches.

Patient presented to ED 1 day after administration of COVID-19 vaccine. She had rigors and chills the day before and day of ED presentation. Denies having a fever prior to ED presentation but did note general body aches and nausea. Patient also had 1 episode of vomiting on 12/22. Patient's vital signs were BP 145/109, HR 75, RR 20, O2 sat 96, temp 98.7F. Receive IV bolus of NaCL 0.9% 1,000 mL in ED in addition to ketorolac 15 mg, and ondansetron 4 mg. Patient was discharged home from the ED.

Nausea

Calling in to report itching and rash after Pfizer COVID vaccination. she received a vaccination on December 18th and started having symptoms that same day. She contacted the emergency room where she received the vaccine and they told her to take Benadryl. Since that time the itching and rash has progressed and now she is having some difficulty swallowing. No difficulty breathing or speaking.

Itching followed by multiple Erythematous urticarial areas on face, chest and arm. Swelling of upper eyelid

JOINT PAIN, RIGHT HAND SWOLLEN, CAN'T BEND MIDDLE FINGER, PAIN RADIATES TO WRIST, FINGERS START TO TINGLE IF USES RIGHT HAND FOR EXTENDED PERIOD OF TIME.

fever, confusion, blurred vision, nausea

mild chest tightness, cough, feeling anxious and lightheaded minutes after receiving the shot pt received: Benadryl 25 mg iv push Solumedrol125mg iv push Normal saline 1000ml IVpb

"PT WAS ADMINISTERED MODERNA VACCINE AT HD ON 12/23 AROUND 1540. PT HAS EXTENSIVE HISTORY OF ALLERGIC REACTIONS (HEP A VACCINE AND TREE NUTS). PT ALSO COVID + ON 12/8/20 . HX REVIEWED WITH HD RN PRIOR TO ADMINISTERING. PT WAS ADVISED TO WAIT 30 MIN IN WAITING ROOM. EMS STAFF ON SITE FOR CLINIC. PT STARTED COMPLAINING OF ""ITCHY MOUTH"" AROUND 1620 AT WHICH POINT EMS ATTEMPTED TO ESCORT PT TO PERSONAL VEHICLE TO DRIVE HER TO LOCAL ED. PT MADE IT TO THE THE VEHICLE BUT DEVELOPED INCREASED RESPIRATORY DISTRESS AND AIRWAY RESTRICTION. AMBULANCE WAS CALLED. EMS ADMISNTERED .3ML EPI AT 1631 AND APPLIED 8L O2 VIA MASK. ABUMBULACE ARRIVED AT 1636. PT TAKEN TO LOCAL ED VIA AMBULANCE"

Redness and tingling of the hands, arms and then body about 5 minutes after vaccine administration. Was also hypertensive to 142/87. Did not have progression of symptoms and BP and redness improved after about 30 minutes of resting and monitoring. Did not require any medications.

After waiting 15 minutes after receiving the vaccine she complained of having generalized itching. No other adverse reactions. She was working in the Intensive Care Unit. It wad discussed with her and decision was made to let her return to work for the evening without taking any medications for the itching. She was to go to Emergency department if she had any other adverse reactions develop. She was followed up with this morning and she reported that she did not have to seek treatment. The itching had subsided, no other adverse reactions developed, she just had some soreness at injection site.

localized raised red rash at injection site - given diphenhydramine 25 mg PO x1 - increased monitoring for 30 minutes. Patient still had rash but it was improved. Was able to leave clinic to home

Patient complained that 3 hours post vaccination began to have sweats and feeling like he was running a fever. He checked his temp on 3 different occasions during a 3 hour period and it did go up to 99.2 from 97.6. The patient denies any other symtoms. He received his vaccine around 4pm 12-22. He reported his concerns at 9am on 12-23. There was soreness at the injection site. No redness. And he felt fine today. And indicated by the time he went to bed last night was feeling fine again. Advised patient to contact me if any further concerns on work cell #.

After the vaccine I was fatigued, had diarrhea, a 102 fever and headache which lasted exactly 24hrs I took tylenol and zofran and the symptoms resolved . At the time of the vaccination i was 23 weeks gestation, EDD-04/12/2021.

Lymphadenopathy in left arm pit sore arm Slight fever of 100.1 headache fatigue muscle and joint aches

"The evening after she received the vaccine, she had a HA and stomach distress. She reports waking up frequently due to sweating. On 12/22/20, her symptoms continued and got a bit worse - including soreness at the injection site with continued stomach distress and HA. She took ibuprofen 400 mg PO TID. Was unable to eat food, only drank Sprite. During the early morning hours of 12/23, was unable to

sleep due to severe pain in right upper arm. She felt a ""pulling sensation"" and felt an enlarged lymph node under her arm. It was very ""tight"" - she was able to come to work - sent to the ED for evaluation - found to have BP slightly above her normal range, mild tachycardia. Was released and told to continue symptomatic treatment and to call or come in if symptoms worsened."

Approximately three hours after receiving the vaccine I was violently puking and nauseous. I never had a fever, but I had uncontrollable shaking and chills.

Approximately four minutes after receiving the vaccine, I felt dizzy while I was seated. The feeling subsided and returned a couple more times within 15 minutes. After approx 10 min, I felt a burning sensation on the top of my right hand and it spread to both hands and arms. My skin looked a little blotchy and red. The girl next to me said my face looked flushed. I also noticed I was sweating. The Rn brought me a bottle of cold water to drink. I drank half the bottle and that seemed to help cool off my skin. Thereafter, I had the chills. Then I noticed a tingling sensation in my feet. My shoes started to feel uncomfortably tight , so, I loosened my shoe laces. That subsided after a while. After sitting for a few more minutes, I believed I was feeling better. I stood up to prepare to leave and I felt a little bit dizzy. I sat down again, notified the RN and waited some more. I tried to stand up again and I felt slightly dizzy again . I remained standing and I was talking with two RNs. At that moment, I became dizzy again. I remained seated for another period of time before being escorted by the RN back to my department where I sat down and ate my lunch. Thereafter I was fatigued with the occasional chills and hot spells . I went home and rested on my couch.

After receiving the vaccine I initially had some arm soreness that later progressed to a headache and just an overall run down feeling with some slight body aches.á I woke up for work this morning with worsened body aches and had felt like I had a fever throughout the night. I took my temperature just to be safe and it was 100.5 (take twice). I called into work and was told I was not allowed to come in today to contact employee health. I went back to sleep and now my temperature is 98.6. I still have some slight body aches but it seems improved.á I am sending this email at your request to state that I no longer have a fever as result of my COVID vaccine obtained 12/21. My temperature has returned to a range of 98.2-98.6.á Sx resolved

A little over 12hrs after vaccination experienced significant fever, chills, and body aches. Able to manage with acetaminophen PO.

Whitehead Zit over injection site Dry lips throat and mouth initial day Headache at 36 hours in Some low grade fevers

10 minutes after vaccination received, pt complained of fullness feeling in throat and itchy ears and head. Epi given, pt transferred to ED, rec'd another epi and IV fluids. Discharged after a few hours.

Patient flushed red and felt nauseated within 60 seconds of administration. Complained of difficulty breathing, became blotchy and began crying. Called 911. Paramedic on site for his own vaccine assisted. Airway sounded restricted. Administered 0.3 mg Epinephrine (Epi Pen). Color improved. Blotchy patches

improved. EMS arrived. Breathing became more labored. They took her to we assume was regional hospital

Age: 43 years 12/23/2020 12:21 Chief Complaint: ALLERGIC REACTION History of Presenting Illness: This 43 yo female presents from specialty clinic for an allergic reaction. Patient has just received the Moderna Sars-Cov2 vaccine. She has had covid in the past, and her Igg tested outpatient was positive at 5.2 (per patient). She had received the vaccine at 11, and says that she usually has a reaction to vaccinations and drugs. She began having some rash around the neck and felt like her throat was closing. She was brought to the emergency room.

tightness in chest, felt like when i get stung by a bee and my asthma is acting up. started about 7 minutes after receiving the vaccine, did not go away after about 1 1/2 hours felt increased tightness/shortness of breath/wheezing. used my albuterol mdi and felt better. lasted about 2 1/2 hours and then began to feel the tightness start again and felt need for albuterol inhaler, took albuterol again and a pepcid po. continuing to monitor and will inform primary MD also.

2am chills,achiness,shakes, temp 100 3am temp 100.7 no change 4am no change took advil no change all day 12/23 shooting pains level 8 ,chills body aches. no fever. no change all day will see employee health in AM

I got the shot on a Tuesday , woke in the middle of the night at 3 am with a fever of 101, body aches, and swollen lymph nodes on the sidt that I get the shot. Took tylenol and still had body aches until 3PM. My skin was sore afterwards.

Pt was vaccinated at Conference room COVID19, with PfizerBionTech vaccine, Lot# EK 9231, at 1258 hours, while waiting in monitoring area, complained of rash and facial flush at 1305 hrs, initially given PO Benadryl by APP's at 50 mg for the rash and seen by me at 1306 hrs and got vitals. BP 160/110, HR 120 -130, SpO2 was 100% on room air, not complaining of shortness of breath, no stridor noted, tachycardia noted with regular rate and full bounding pulse, no wheezing noted bilateral lung fields, initiated early response call for eICU staff, also initiated potential call for inhouse and 911 call as back. At 1315 hours she had mild chest discomfort, tightness and felt dryness of throat. Rash not significantly visible on chest, facial flush present, decided to go ahead and gave epinephrine 0.3 mg IM to right deltoid as she was a unitard Stat suit. She was put on continuous monitoring, had response from eICU (Tele-ICU) team and Dr., SBP still noted to be elevated to 160's and DBP 110, Pulse still around 130, additionally IV access was secured, given IV Solumedrol 125 mg and IV Pepcid 20 mg. She felt somewhat better, still felt very anxious, with chest tightness, EMS on site by 1340 hrs and moved to ED by 1400 hrs, was with patient all through and transitioned to ED care To Dr. When last discussed her condition, was still stable noted at 1745 hrs in discussion with ED RN, with still persistently elevated BP and heart rate. No clear cut evidence for typical anaphylactic reaction. Treatment and observation still ongoing in ED.

chest tightness, throat closing in, sent to Emergency room

developed dizziness, palpitations, shaky, headache

Within an hour developed a headache that got worse every hour. Within 24 hours from vaccination, felt extreme myalgia that I have not been able to find relief for. 48 hours after still feeling myalgia. Headache has gotten better but still have one.

hand shaking, chills, rash, nausea, lightheadedness ? reports hard to take a deep breath, given diphenhydramine 50 mg PO x 1 @ 10:15 in clinic and an additional 25 mg PO x 1 @ 10:30 in the clinic. Symptoms persisted - pt anxious - taken to ED for evaluation. After 10-15 minutes in ED, her symptoms subsided ? she only had mild tingling in the left hand along with two red spots on the back of her neck. Given prednisone 50 mg PO x 1 in ED. observed in ED for 2 hours ? pt feels much better ? pt felt comfortable going home ? told to continue to take Benadryl and prednisone for next 3 days. Instructions given to return to ED for any worsening of symptoms. Rx with Prednisone 50 mg daily x 3

5 minutes after administration of vaccine, patient states he does not feel well. He was sitting and passed out.

On the first day I had pain on injection site. The second day I had muscle aches, fever and chills.

approx 12 hours after administration of vaccination, teeth chattering chills for 1 hour followed by a fever with temperature increase of 2 degrees, extreme muscle and body pain, nausea, headache, runny nose, sore throat, cough, soreness at injection site and inability to lift right arm (injection site). Fever and chills resolved at 7 am on 12/22/2020. At that time I took Alka Seltzer cold and flu and finally slept and woke up with fatigue, muscle aches and headache. All symptoms, aside from bilateral shoulder pain, pretty much resolved by morning of 12/23/2020.

Fever 101, chills, aches, chest pain

site soreness and residual headache at base of skull x3 days On 12/18 at 12 noon, I found myself passed out in my office at work laying over my keyboard. My assistant had me on-hold at that time and estimated I was out for 1 minute. Was loopy the entire next day. Just hydrated and rested. Felt great by Monday

Patient developed diarrhea, chills and a measured fever 100.4 24 hours after receiving the vaccine.

Pruritus - Benadryl given at COVID vaccine area. Relieved. Symptoms advanced after the caregiver went back to work. Called vaccine provider. Went to ED. Received Solu-medrol and Epinephrine. Released in stable condition

PALPTATAIONS, ANXIOUS, MONITORED NO TREATMENT

Fever 100.9

I got the Pfizer COVID19 vaccine at a drive through site on 12/21/20 through Department of Health Services. This morning I woke up in the middle of the night with lower spinal discomfort which has increased as the day has continued. There is nothing visible on my spine externally that I noticed except a very faint pink line.

Extreme fatigue, head ache, chills, severe generalized body aches, (temp 95.5 F). Started the day after vaccine, 12/20/20, and lasted until 12/21/20. Tylenol was taken for immediately after vaccine and continued until 12/21/20.

Benadryl given at COVID vaccine area. To ED received Ativan, Decadron, Pepcid, Benadryl, and 2L NS.

I received the first dose of the Pfizer COVID vaccine on 12/19 at 3:30pm. The next day I began to feel fatigue, body aches, joint pain, headache, and a fever of up to 100.9 that began around 2:00pm. It was fully resolved by the next morning.

Malaise, brain fog, fatigue, fever (100.8), cough, runny nose, sore throat over the last 24 hr.

Injection site pain within 6 hour of administration. Mild fatigue after 8 hours. Upon waking up the next morning, fatigue, myalgias, slight headache resolved with 1000mg acetaminophen taken 3 hours afterwards. 5 hours after acetaminophen, chills, myalgias, generalized weakness are experienced. No fever. Another 500mg acetaminophen was taken.

Pruritic, erythematous, patches in forehead ans R side of face

Fever, chills, nausea, sore throat, headache, extreme body aches and cough. Fever elevated longer than 3 hours at 100.4. Had rapid heartbeat which happened about three times. Slight difficulty breathing. Had Covid 19 about a month ago and felt like she was having it again.

Developed painful lump/ knot left WRIST

Left arm injection site soreness started about 4 hours after administration. Left full arm tingling lasted about 12 hours then resolved. Left arm soreness lasted for about 36-48 hours with some mild nasal congestion and shortness of breath.

WAS HAVING MYALGIAS AND MILD FEVER STARTING ABOUT 12 HOURS AFTER VACCINE, BUT AT 2 AM, I WOKE UP TO URINATE, FELT SOME DIZZINESS. AT THE END OF VOIDING I COULD TELL I COULDN'T THINK RIGHT AND HAD TROUBLE FLUSHING. TRIED TO WALK BACK TO BED AND HAD A SYNCOPE AS I GRABBED THE DOOR HANDLE. STUMBLED DOWN SLOWLY AND LOSS CONSCIOUSNESS FOR A SHORT WHILE, SECONDS. LAYED IN THE FLOOR FOR A BIT AND WHEN I STOOD UP AGAIN AND WALKED TO MY ROOM HAD ANOTHER SYNCOPE. WOKE UP AFTER SEVERAL SECONDS AND WAS NOT CONFUSED AND DIDN'T REMEMBER THE SECOND TIME I FELL BUT COULD UNDERSTAND I HAD PASSED OUT. MY WIFE SAYS I HAD MY EYES OPEN AND WAS STIFF BUT NO TONIC CLONIC MOVEMENTS. AFTER THE EVENTS I WAS ABLE TO GET BACK IN BED AND AFTER A LITTLE WHILE TESTED FOR ORTHOSTASIS. WHEN I STOOD UP I STARTED FEELING THE LIGHT HEADEDNESS AGAIN AND PRODROME TO FAINTING AND LAYED BACK DOWN. HR 60, MY BASELINE IS 50-60. HAD A FEVER OF 100.7. I TOOK 650 MG OF TYLENOL AND WENT BACK TO BED. I DIDN'T SLEEP WELL BUT NOW (THE FOLLOWING MORNING) I AM FEELING BACK TO NORMAL MINUS SOME MILD SOARNESS. I HAD A RAPID COVID PCR TODAY THAT IS NEGATIVE. NO OTHER LABS. I HAD NEVER FAINTED BEFORE THIS EPISODE. I DID NOT HAVE ANY TRAUMA FROM SYNCOPE.

Right side of body (leg foot hand arm cheek neck torso ear, etc.) experienced tingling sensations, numbness, some burning sensations, mostly cold feeling, weakness (like moving through water) sensations have lessened in two days, but minor sensations and weakness persist. monday (12/21/2020) visited the E.R. for exam and testing. E.R. doctor reported current testing normal. 12/23/2020 visited normal MD to go over results from previous testing and get checkup.

Diagnosed with UTI Sat 12/19/2020 at Urgent Care Monday 12/21/2020 returned to urgent care for fever, flank pain, no relief from urinary symptoms, later went to Hospital for treatment Today 12/23/2020 have severe body pain, extreme fatigue, still having urinary symptoms; unable to do daily activities such as grooming and dressing without assistance

Dizziness and elevated BP

Patient stated that he had blurred vision. He was taken to the Emergency Dept at the Hospital where his vital signs were monitored to include blood pressure, pulse and oxygen. After 1 to 1.5 hours of observation, patient stated that he was no longer experiencing any symptoms.

Nausea Vomiting Fatigue

Vision changes, blurry and distorted vision lasted for about one and a half to two hours after vaccination. Vision return to normal.

Quarter sized raised red area at injection site that is warm to touch. It has gradually grown over the day.

Beginning at approx 16 hours after receiving the vaccine and continuing until approx 36 hours after the injection, I experienced fever of 100-101 that was relieved with ibuprofen and acetaminophen (alternating). Significant headache and fatigue also present during most of this time. Now appears resolved.

Patient presented to the ED vaccination clinic on 12/20. She received her first dose of the vaccine, and then went into the breakroom to finish the rest of her lunch break. Approximately 10 minutes after she received her vaccine, she noticed she was feeling very warm, like a hot flash. She asked her coworker if it was hot in the breakroom, who responded no. She then noticed that she was developing reds spots on her chest, back and neck. We moved her into a private area to monitor her, and allow her to undress and cool off. She developed redness to her chest, back, neck, and redness around the injection site. This mostly resolved within 45 minutes. At about 45 minutes, I was able to secure PO Benadryl and provided her 50 mg of Benadryl, which she took. The employee returned to work the rest of her shift with no other complications noted. The employee denied swelling or itching to the throat, denied SOB, and her vital signs were normal the entire time. The employee does want to get her 2nd dose of the vaccine, so we will plan on administering it in the ED, and may pre-medicate with Benadryl.

Difficulty breathing, no oral swelling, stridor, altered mental status. Bag valve mask ventilate. IM epi. Initial care by MD and nurse. 911 ACLS called, transported to ER.

Arm was sore and swollen, muscle pain, body aches, headaches, tireness and fever.

I had a headache, nausea, muscle soreness and stiff joints on the first day and the second day fatigue.

swelling of tongue, lips, throat

Pt was lighted and dizzy about 10 mins after vaccine. Vitals were all normal and after we changed him from N95 to surgical mask, laid him down and gave him water he recovered fully.

Vertigo. Nausea. Dizziness. Headache. On and off for 3 days. Still having symptoms .

Lightheadedness, chest tightness, body ache, fatigue, weakness,flu-like symptoms but without fever

After about 7 minutes after the vaccine she started having palpitations and generalized feeling unwell. Felt as though she had low blood sugar but did not feel lightheaded or faint. She had this reaction similar prior when she had anxiety surrounding getting TB testing. Felt anxious and did have elevated BP to 144/86. No shortness of breath, rash, nausea, chest pain, dizziness. Resolved with observation, deep breathing, crackers and water.

24 hours post vaccine developed itchy legs. Over the course of 5 days both thighs developed red hot blotchy rash that burns and itches, radiating heat. Not helped by benedryl, Zyrtec, hydrocortisone.

Fever 101.8, vomiting, mental status change

"itching, facial swelling, throat swelling ""lump in throat"", hoarse voice"

Patient became diaphoretic and nauseated about 10 minutes post vaccination with Moderna Covid-19 vaccine. Patient was assisted to stretcher who he had dry heaves and stated he felt nauseated. HR was low around 38 and we were unable to determine a B/P but patient had a very weak radial pulse which at times was unable to be felt at all (due to low B/P). Decision made to transport patient to the ED for further evaluation. Patient eventually discharged from emergency department.

On the fourth day after receiving the vaccine, I developed a rash in the anterior and posterior thoracic region consisting of dispersed 1mm - 3mm size dots ranging from the clavicle to the pelvic region. These dots appeared in a diagonal, going from superior and lateral to inferior and medial. On the second day of noticing the rash the bumps appeared as if they were blistering. No medication was used at this time.

30 mins after vaccination Felt rapid heart rate, tingling in lips, initial BP 100/60

Patient felt warm and had some tightness in her chest which subsided and changed to intermittent sharp pain at sternum. Physician's who had just received vaccine asked for her to be sent to the ER.

Severe whole body myalagia and weakness with inability to stand or walk without significant pain and weakness. Unable to work or do ADL . Doctors not sure what to do . Have seen pcp and ER with still severe pain and weakness over three days

Redness and swelling around injection site on day two (day one being day of injection). Redness and swelling on day three decreased to just small red dot. No other complaints.

Fever 102.3 , chills, body aches, headache, tachypnea,. All symptoms started 19 hours after injection. Besides that, soreness & swelling at injection site.

Incomplete administration by MD that lead to seeping of vaccine. Second dose was administered.

"About 10 min after receiving the vaccination, the patient described feeling of throat closing, coughing. Patient given IM epi with initial improvement in symptoms. No rash. On arrival to ED, no stridor, no oropharyngeal swelling, speaking normally in full sentences, clear lungs. Subsequently, patient complained of nausea, but resolved after Benadryl. Patient had recurrent ""funny feeling"" in throat about 3 hours into observation and had difficulty swallowing liquids, but had normal speaking voice normal oropharynx. Currently pending ENT evaluation."

Diarrhea/upset stomach

Employee reported reaction of hives approx 2 hours and 12 minutes after getting the covid vaccine. She was administered epipen and was sent to the ED. The ED observed her and then discharged her.

pt complained of dizziness that progressed to headache. BP taken at 1315 was 184/106, hr 106. At 1430 bp 183/104 hr 87. o2 97%. Patient stated that they forgot to take bp meds

Pain at injection site around 12 PM, Fatigue around 4 PM.

Day of injection, developed pruritus of back. Worsened the day after and started seeing a papular rash over multiple areas of back.

Received vaccine at 1259, remained for 15 minutes without symptoms and returned to work. At approximately 1600, felt itchy and discovered hives covering body. Went home and took Benadryl. When spoke with at 1900 stated that her hives were still there but improved.

Felt lightheaded since the vaccine

30 minutes after receiving her 1st dose of the COVID vaccine, she started feeling a burning sensation in her nose and in her chest when she took a deep breath. Symptoms persisted overnight, today reports to have had chills and a sore throat. She was seen by her PCP today, 12/23 for further instruction. PCP told her to take benadryl and to follow up with an allergist prior to second dose for clearance. Patient reports she was COVID positive July 2020.

Staff member felt brief lightheadedness. Blood pressure was 147/72 (normal for her). Staff member then felt fine.

The first night I had a headache, chills, soreness and bruising at the injection site.

hot all over her face, followed by itchiness on her face, tongue and throat. denies any shortness of breath or chest pain. She denies any difficulty speaking or swallowing

Staff member felt some dizziness. Then felt alright.

fatigue/fever for 48 hours of 101.5/ nausea/severe headache/ blotchy rash all over body 3 days after vaccine. Hot to touch to inchy. 4 days later still large ichy rash.

rash, vomiting, nausea, hives, migraines, tremors, facial swelling

Staff member started to feel dizzy and lightheaded a few minutes after the injection, with brief episodes of palpitation. Blood pressure taken by physician, measured 180/90. Staff member was given Amlodipine 2.5 mg at 3 pm. Another Amlodipine 2.5 mg given at 4 pm. At 4:30 pm blood pressure was 160/100. Patient symptomatically felt better. At 5:04 pm blood pressure was 150/90. Staff member was observed until 5:15 pm, the discharged home in the care and supervision of her husband. Staff member will follow-up with personal physician.

"Pfizer-BioNTech COVID 19 VACCINE EUA- within 2 minutes felt tingling on the tongue and then tingling around the mouth. Within five minutes, itching of the face that spread to scalp and neck. Continued to increase itching during the 15 minute observation time. Sensation of heart in my ""throat"" upper chest. Slightly light headed. Nausea 15- 20 minutes after receiving injection. Headache. Given 50 mg Benadryl IM that resolved symptoms of itching within 5-10 mins. Observed in ER x 1 additional hour. BP 149/90 approx. HR 88, estimated from .memory."

Generalized itching

After 5-10 min following vaccination pt began to exhibit itching of the neck and slight SOB

Pain and numbness in left side of face and lips; advil taken and improving but no resolved

Moderate body aches and headache beginning about 20 hrs after the vaccine, then progressed to severe headache, nausea, photophobia, phonophobia at about 27 hours after the vaccine and lasting about 4-5 hours, then reducing to moderate headache and fatigue until about 40 hrs after the vaccine, then gradually resolved over the following 6 hours.

"She exhibited no symptoms immediately after the shot and began driving home at approximately 6:30 pm. As she was driving home, she gradually developed perioral numbness with the sensation of a ""gummy"" throat and bilateral eye ""warmth and numbness"","

Initially started with nausea around min 5, shortly after then itching on arms. Around min 15 ?lump? sensation in throat. Around min 20 swelling of tongue, worsening feeling in throat, wheezing, itching around mouth. Sent to ER, received IM Epi, IV: Steroids, Benadryl, Zofran, Pepcid, Albuterol inhaler.

Within 20 minutes after I had the vaccine I developed a sudden feeling of warmth in my upper body, most intense over my face and especially my neck and back. I was sweating too and I also developed palpitations and chest pressure.

About 45 minutes after inject upper lip and chin tingle and itches. about 45 minutes after injection was have tickling sensation in throat which followed into voice lost, chest tightness, decrease in expiration

efforts, occasional coughing , increase breathing and heart rate. Use albuterol inhaler and called for the on call doctor. took zyzal, zertex, benadryl, Prednisone, and use nebulizer

10 min after inj. started with tingling at inj site, progresses down arm then to other arm and across chest, started to feel tingling in throat. Initial BP was high at 152/86 P94. Pt asked to defer Benadryl as was driving and symptoms were already lessening. No flush no chest pain denied other symptoms. Next BP 115/78 P85. Then 10 min later 113/81 P80. After watching, pt discharged to home with instructions.

Muscle soreness

sat 12/19/20 , approx 2000 , started to feel hot, burning, and itchy. went to emergency room 12/20/20 at 1200pm , was taking Benadryl since onset of symptoms, given peptid, loratadine, and have continued these medication as directed , called PMD , given hydroxyzine 12/21/20 due to severe itching and burning feeling, and currently taking at directed,

Woke up with just a sore arm the following day. As time progressed my arm got more sore; the site was hot, with a red circle and lump under the skin. Headache, muscle and joint aches, fatigue. Treated with some Nyquil, Excedrin, and sleep. Onset was about 16 hours after the original dose. almost 2 days later I'm still very fatigued, although the rest of the pain has largely gone away.

Injection was made into tricep and not deltoid. Tingling started town right arm into right pinky. Tricep pain when lifting arm above head. Symptoms started within 1 hour of injection.

Had chills and body aches one day after vaccine. Symptoms resolved the day after.

Approx 5 min after vac. inj started with flush and tachycardia Initial BP 137/80 P129. Given 50 mg po Benadryl Repeat BP123/76 p91 @1135 No further sx BP 124/74 P91 DC stable

Dizzy, pinching feeling in left shoulder, tingling down left leg, pins and needles. Gave patient banana and water, checked pulse and observed. Patient started to resolve in 10-15 minutes, at 8 PM, resolved, pulse back to normal. Called Chief Medical Officer to consult, patient detained for 30 minutes before release, at patient request and CMO approval.

Nausea, vomiting, headache, back ache, dizziness.

About one week after the vaccine, body aches, chills and shortness of breath began to occur. Overall fatigue and general malaise also persistent.

Left arm soreness at the injection site on 12/23 at 7:45 am

Started w cough ~15 min after inj. Cough was progressing, unable to complete sentence w/o cough even after water. Agreed to take Benadryl as stated had had 2 anaphylactic responses when she lived in (-unable to determine that cause). Initail BP 153/91 P71 Recheck BP 145/93 P 69. Coughing decreased after Benadryl 50 mg po. No other sx. Dicussed letting PCP know and possibly premedicate before booster.

12/23/2020 sore injection site, Nausea, fatigue

Headache, redness below injection site, mild swelling

headache post immunization

Patient reported numbness on left side of tongue, being lightheaded, rash under chin and excessive secretions in the throat within 15 minutes of covid-19 vaccine administration. Vital signs were stable, O2 was 98% and BG was 225. Patient reported not taking his DM and BP medication prior to vaccination.

fatigue started day after vaccine given and continued through today (two days post vaccination).

10/10 left lateral hip cutaneous burning sensation that radiated to the inguinal region in a dermatomal distribution.

More than 24 hours after getting the vaccine I noticed warm spots on my arms and legs and noticed red raised blotchy spots where it was warm. At the injection site there is a very warm raised hard lump. I took Benadryl and it helped me sleep. It got more painful and warm and I was very uncomfortable. Its not as bad 16 hours later, however the swelling is still pretty bad at the injection site

Fever of 39. Chills shakiness severe fatigue Arm soreness

soreness at injection site

Pt. c/o moderate anxiety during vaccine. Around 15 mons after the vaccine , she c/o mild headache and stated she has history of HTN. She was hypertensive and her pulse was WNL. She was rechecked in 15 mins and her BP decreased and HR stable with continued headache. The patient denied any other symptoms and declined going to the ED. She left without further complaints 45 mins after her vaccine.

Chills, headache, extreme fatigue,joint and muscle aches

My jaw felt numb. I was lightheaded, and a felt nauseated

Pt c/o tachycardia and maybe anxiety. Pt is an MD. Tachycardia at 15 mins post vaccine- radial pulse 132 and BP 150/90. Denied other symptoms. Rechecked in 15 mins and HR 84-91 and BP 154/95. Continued to deny any other symptoms to include CP or SOB. No change in mental status. Declined treatment in ED. Kept and monitored for 15 more mins. and left 45 mins post vaccine. Continued to state maybe he was anxious

Silver dollar size whelp at injection site, rash, abdominal pain, fatigue, chest discomfort requiring use of inhaler

"Pt states night of vaccine on 12/22 she felt dizziness and ""incoherent"". This resolved by 12/23 and today is experiencing headache ""10"" on 0-10 pain scale, fatigue. Advised Urgent Care or ER and pt has declined."

Headache and significant fatigue

About 20-25 minutes after injection as I was walking out I felt slightly dizzy, hot and nauseous. Lasted about 5 minutes and I felt OK to go home, but I would not have felt safe to drive after that (I had a friend drive me). This after and evening any exertion, causes the same symptoms now with a mild headache. I feel fine sitting down, but even mild activity brings back the nausea and dizziness in particular.

9:22 am tingling/itching of throat, followed by dizziness/generalized weakness and lightheadedness. Rapid HR and elevated BP .

Local injection site pain Generalized myalgias/ache diffusely

Difficulty breathing, numbness of the lips, redness of the face

Pfizer dose 1 received 12/18/20 via left deltoid. 12/19/20 the injection site had a half dollar size of redness and edema and was warm to touch. 12/20/20 the edema decreased by half and became itchy like a mosquito bite. 12/22/20 redness barely noticeable at left deltoid. Still warm to touch and indurated.

Headache Extreme fatigue Generalized body aches

Numbness to the tip of the tongue, no loss of taste 2pm the day after vaccination 12/22/2020, resolved after 1 hour, but person took one dose each of prednisone 40mg/benadryl 25mg/pepcid 20mg. Numbness recurred on the tip of tongue again at 11:50 pm the same day 12/22/2020. same one dose of 3 meds as above taken, and the numbness subsided after 30 min. no loss of taste. no reports of recurrence on 12/23/2020 as of now (6:41 pm)

severe headache

Mild to moderate headache, muscle aches, fatigue, nausea, tender armpit

Body aches, fatigue, mild headache, scratchy throat, ?foggy? feeling, sore arm

Patient experienced severe nausea and vomiting within 10 to 15 minutes after vaccination was given by the pharmacist at the clinic at the on 12/21/20 in the morning. In the afternoon patient was back to her normal service as well as the following day.

Patient experienced an anaphylactoid reaction within 20 mins of receiving the vaccine. Patient is a physician and attempted to self treat with diphenhydramine. After a short time of seemingly no resolution patient presented to the Emergency Department. Patient was examined. Elevated BP was noted (192/100), flushing, difficulty swallowing, and strange sensation of mouth and tongue were also present. An ECG was preformed and sinus tachycardia was observed at 105bpm. Patient received IM epinephrine and PO dexamethasone. Symptoms resolved. Patient was observed for 3-4 more hours.

Injection site pain, low grade fever and chills, fatigue

Migraine headaches, nausea, dizziness

Edit: about an hour after my vaccine I began itching on my neck and got a scratchy throat. Then felt blisters in my mouth and felt a tingly feeling on my face. I had swelling in my eyes, jaw, lips, nose and tongue. And hives on my neck and chest. I went to my local ER and was given IV PEPCID, benedryl and a steriod. Swelling came down significantly and I was discharged home after about 2 hours with a steroid dose pack, Claritin and Pepcid. I now have a strong migraine.

RASH, ITCHING

Patient reports allergy to potassium as itching with a history of hives. Patient was aware of the risk vs benefit and potential of ADE due to allergies prior to receiving the vaccine. Patient was observed for 30 minutes. Patient experienced itching about 25 minutes post vaccine. Diphenhydramine 25mg was given to patient.

After the vaccine on 12/21/2020 , I experienced mild muscle aches and fatigue. 12/22/2]20,I felt fine. 12/23/2020 at work I experienced an acute onset of nausea and explosive diarrhea.

Shortness of breath, fatigue, headache, muscle pain, joint pain, chills, nausea, fever

Headache, sore injection site, tiredness, some nausea, feeling unwell,

I experienced dizziness onset 5 minutes after the vaccine, mild. lasting about an hour. That night I experienced intense vivid nightmares, chills and temp 96.0. Friday night, dec 18th, awoke form intense vivid nightmares at 2 am. chills. arm 7/10 pain at injection site, all day, no erythema. On saturday chills but no fever all day. At about 10pm abrupt onset of severe abdominal pain and prolonged projectile vomiting that awoke me from sleep after eating normal dinner that I shared w family none of whom were having similar symptoms. This lasted for about 90 minutes accompanied by severe abdominal pain. afebrile, 97.Dry cough started , lasting thru Sunday morning. spontaneously resolved. Sunday dec 20th, chills, nightmares, Monday chills, sweats, 96, 97 temps. Dec 22 Tuesday 3:30 am, awoke from sleep with sudden excruciating abdominal pain and dry heaves . Family shared Monday night meal, no other symptomatic people. <30 min started itchy palms, tingling lips, tongue, and face felt prickly. Eyes swollen, and sclera puffy bubbly. I took two 25 mg Benadryl w water, had trouble swallowing - immediately proceeded to Hospital ER - admitted - steroids IV, Pepcid, IV and in 4 hours when nausea and abdominal pain began again IV Zofran. 2 liters total of NS. discharge home around 12:30pm . stable to home to rest.

Hives, joint pain, elevated B/P, elevated HR, flushed upper body and tingling

Warm and dizzy with hypotension; feet up and juice given; transported to ED; improved with rest

Throat felt tight and sticky, difficulty swallowing, anxious, tingling from waist up

Day of shot Left arm was sore after few hours Suddenly felt chills Around 930 pm and muscle ache then joint pain by 1030 pm Feverish but no fever Felt so weak by 11 pm Next day Woke up with joint pain and muscle pain slowly went away after advil came back around 7 pm then took advil by 8 pm all pain disappeared

Chills started at 1730, day of vaccine. Fever of 100.2 at 2100. Tylenol taken. Fever Returned at 0315 on 12/21/2020. Tylenol taken once more. Woke up with fatigue and mild fever at 0845 on 12/21/2020 of 99.9. Tylenol taken once more. Chills and fatigue through out the entire day of 12/21/2020.

The patient is a 57 year old female who presents to the ED with an allergic reaction. Patient received her COVID vaccine this morning at a vaccine POD at 0708, 5 minutes after receiving the injection she began to feel short of breath, with dry cough and felt tightness in her throat. Patient used her inhaler at that time and then her symptoms improved. Of note patient also took a Benadryl prior to receiving the vaccine because she has a history of allergies (reports allergy to codeine). She was evaluated by people at Covid vaccine site and cleared. She went to work at the clinic where she works as a tech but continued to have tightness in her throat, so a doctor at the facility told her to take another Benadryl. Patient states that an hour after taking the second dose of Benadryl she began to feel drowsy and nauseous. She had a sip of coffee and try to eat something but then became tremulous and vomited. She was given epinephrine at work and transferred here for further work-up and management. On arrival patient reports that she feels back to baseline. She denies at any time having any rash, pruritus, or angioedema.

Heart palpitations

Vaccination to right deltoid; 7 days later developed diminished grip strength in right hand, right thoracolumbar muscle spasm with tingling radiculopathy to right hand and leg

Hot; Cold sweats/having night sweats, like she was hot and cold; Cold sweats/having night sweats, like she was hot and cold; Chills; Shakes; intense nausea/ nauseous; just feels nauseous and depleted; it feels like she has the flu; she didn't know if maybe her body was low on oxygen, she didn't feel out of breath, but she just didn't feel well overall; This is a spontaneous report from a contactable other healthcare professional. A 27-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number: EH9899, expiry: Mar2021), via intramuscular route of administration (left deltoid) on 17Dec2020 17:40 at a single dose for COVID-19 immunisation. The patient's medical history included sulfa drug allergies. There were no concomitant medications used. The patient was having some intense nausea, and throughout the night, she had night sweats. It was further stated that she woke up a 12AM, today (18Dec2020), and she just felt like she had the flu. She was nauseous, and she was having night sweats, like she was hot and cold, and she tried to go back to sleep, but then she had an episode of chills and the shakes, and every time she was about to fall asleep, it was like her body would wake her up. Patient stated that in her mind, she didn't know if maybe her body was low on oxygen, she didn't feel out of breath, but she just didn't feel well overall. All these persisted until about 3AM, and then she went back to sleep. She woke up for the day around 530AM, and she feels a little better now, like she doesn't have the hot and cold fever feeling anymore, she just feels nauseous and depleted. She stated that she sees on her information sheet that these are possible side effects to getting the vaccine, but it feels like she has the flu. Outcome of the events was unknown. Follow-up attempts are completed. The following information on the batch number has been requested.

Anaphylaxis; This is a spontaneous report from a contactable pharmacist. A 55-year-old female patient received the bnt162b2 (BNT162B2; also reported as: PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 17Dec2020 at a single dose for COVID-19 immunization. The patient's medical history included eosinophil process allergic reaction, fish, iodine and shellfish allergy; all from an unknown date and unknown if ongoing. Concomitant medications were not reported. The patient previously took rabies vaccine for immunization and experienced anaphylactic reaction on an unspecified date. On 17Dec2020, the patient experienced anaphylaxis; which required hospitalization, and was assessed as medically significant. The patient was hospitalized for anaphylaxis from 18Dec2020 to an unknown date. The clinical course was reported as follows: The pharmacist called about a patient who received the COVID-19 vaccine on 17Dec2020 and started having a reaction approximately 30 minutes later. The patient used epinephrine (EPIPEN) and 50 mg of diphenhydramine hydrochloride (BENADRYL) and returned to the hospital on 18Dec2020. The patient was currently in the intensive care unit (ICU) receiving an epinephrine drip. The patient had a previous history of an anaphylactic reaction to the rabies vaccine, eosinophil process allergic reaction, fish, iodine and shellfish allergy. The patient was stabilized but continued to have reactions (not specified). The pharmacist had not seen the patient and was reaching out to Pfizer on behalf of the physicians. The pharmacist believed this had been reported by the hospital. The pharmacist had no patient information. Therapeutic measures were taken as a result of anaphylaxis. The clinical outcome of the event, anaphylaxis, was unknown. The batch/lot numbers for the vaccine, BNT162B2, were not provided and will be requested during follow up.; Sender's Comments: Based on the information available, a possible contributory role of the suspect products cannot be excluded for the reported event anaphylaxis due to temporal association. However patient previous history of allergic reaction cannot be excluded to have played a contributory role

"started to feel a warmth in her chest and abdomen; She felt like her heart was racing; Developed chest pain; This is a spontaneous report from a contactable other HCP (healthcare professional). A 45-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot #: EJ1685), intramuscularly in the left arm on 18Dec2020 at 15:30 (at the age of 45-years-old) as a single dose for COVID-19 vaccination. Medical history included known allergies to apple, cantaloupe, peach, avocado and IV contrast dye; all from unspecified dates. The patient was not pregnant at the time of vaccination. Prior to the vaccination, the patient was not diagnosed with COVID-19. Concomitant medications included ongoing famotidine and salbutamol (ALBUTEROL HFA) as needed (PRN); both for unknown indications from unknown dates. The patient did not receive any other vaccines within four weeks prior to the vaccination. The patient previously received hydromorphone (DILAUDID) and triamcinolone acetonide (KENALOG); both from unknown dates to unknown dates for unknown indications and experienced allergy. The patient also previously received diphtheria vaccine toxoid/pertussis vaccine acellular/tetanus vaccine toxoid (TdaP) vaccine on an unknown date for immunization and experienced allergy. On 18Dec2020 at 15:45, the patient started to feel a warmth in her chest and abdomen, she felt like her heart was racing, and developed chest pain. It was reported that ""patient started to feel a warmth in her chest and abdomen. She felt like her heart was racing. Developed chest pain. No shortness of breath or difficulty swallowing"". It was unknown whether the patient received any treatment for the events. It was reported that the adverse events resulted in emergency room/department or urgent care visit. It was also reported that the events were non-serious

and did not cause or prolong hospitalization. The clinical outcomes of the events started to feel a warmth in her chest and abdomen, she felt like her heart was racing and developed chest pain were all unknown. It was unknown whether the patient had been tested for COVID-19 since the vaccination."

dry cough; low grade fever/he had a low grade temperature of 99.0 Fahrenheit last night and 101.0 Fahrenheit this morning; body pain; body weakness; This is a spontaneous report from a contactable Nurse A 50-years-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration in the left arm on 16Dec2020 10:30 at single dose for covid-19 immunisation. Medical history was none (no relevant patient or family medical history). The patient's concomitant medications were not reported. On 17Dec2020 the patient experienced low grade fever, temperature of 99.0 F on 17Dec2020 and 101.0 F on 18Dec2020, body pain and weakness with outcome of not recovered. On unknown date the patient experienced also cough with unknown outcome. The event fever was considered serious as medically significant and was reported as worsened. The reporter wanted to know what to do. The caller read somewhere not to take Tylenol, though he did take one this morning. He was to increase fluid intake but what other treatment was recommended. Information on Lot/Batch has been requested.; Sender's Comments: The reported information is limited. Based on the close temporal relationship and the description of the events, fever, body pain, cough and weakness there is a reasonable possibility that the events are related to BNT162 vaccine. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

Nausea; Vomiting; Chills; Migraine like headache; This is a spontaneous report from a contactable consumer (patient). A 32-year-old female patient (not pregnant) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, batch/lot number: unknown), via an unspecified route of administration (left arm) from 18Dec2020 (01:15 PM) to 18Dec2020 13:15 at single dose for COVID-19 immunization. The patient's medical history included PDA (Patent ductus arteriosus) ligation, fatty liver disease, and anxiety. Concomitant medications included melatonin, escitalopram oxalate (LEXAPRO), balsalazide sodium (BALZIDE), multivitamin, and prebiotic. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. No known allergies. The patient was not diagnosed with COVID-19 prior to vaccination. The patient has not been tested for COVID-19 since the vaccination. The patient experienced nausea, vomiting, chills, and migraine like headache the night after she received the vaccine (18Dec2020 07:00 PM). There was no treatment received for the reported adverse events. The outcome of events was recovering. This case is reported as non-serious. Information on the lot/batch number has been requested.

body ache; muscle and joint pain; muscle and joint pain; fever; injection site pain; chills; headache; This is a spontaneous report from a contactable consumer. A non-pregnant 20-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot number: EJ1685), via an unspecified route of administration in the right arm on 18Dec2020 10:15 at single dose for COVID-19 immunization. Medical history included COVID-19 (prior to vaccination). Concomitant medication included ethinylestradiol, norgestimate (SPRINTEC). No other vaccinations were given within four weeks

and the patient had no known allergies. On 18Dec2020 23:30, the patient experienced body ache, muscle and joint pain, fever, injection site pain, chills and headache. No treatment was received for the events. The clinical outcome of body ache, muscle and joint pain, fever, injection site pain, chills and headache was recovering.

Fever; Shortness of breath; Headache; Muscle ache; This is a spontaneous report from a contactable consumer (patient). A 24-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) lot number: EH9899, expiration date unknown, 1st dose via an unspecified route of administration on 18Dec2020 14:00 at a single dose at right arm for COVID-19 immunization. Medical history included penicillin allergy. There were no concomitant medications. The patient experienced fever, shortness of breath, headache and muscle ache on 19Dec2020 01:00 am. There was no treatment received for the events. The patient underwent lab tests and procedures on 19Dec2020 which included COVID test post vaccination (Nasal Swab): unknown result (pending). The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine and no other medications received within 2 weeks of vaccination. Prior to vaccination, the patient was diagnosed with COVID-19 and since the vaccination, the patient has been tested for COVID-19. The action taken in response to the events was not applicable. The outcome of the events was recovering.

it felt as if pulsing was radiating was coming from the upper middle of my spine; feeling really achy in shoulders both arms and neck; left arm hurt with any motion; feeling really achy in shoulders both arms and neck; feeling really achy in shoulders both arms and neck; This is a spontaneous report from a contactable healthcare professional. A 28-year-old non-pregnant female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot number: EH9899), intramuscularly in the left arm on 16Dec2020 12:00 at a single dose for COVID-19 immunization. Medical history was none. The patient's concomitant medications were not reported. There was no known allergies. On 16Dec2020 at 16:00, the patient experienced feeling really achy in shoulders both arms and neck and left arm hurt with any motion. On 17Dec2020, it felt as if pulsing was radiating, coming from the upper middle of spine. No treatment was received for the events. The outcome of the events was recovered with sequel on an unspecified date.

fine rash noted Saturday evening on arms and chest w /slight itchiness; occasional itchiness on Friday w/ no rash noted/fine rash noted Saturday evening on arms and chest w /slight itchiness; face felt prickly and itchy; face felt prickly and itchy; This is a spontaneous report from a contactable nurse (the patient). A 54-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), lot EH9899, via Intramuscular route of administration in right arm, on 17Dec2020 at 16:30, at single dose for COVID-19 immunization. The vaccine was administered at Hospital Facility. The patient did not receive other vaccine in four weeks. The patient medical history included sinus infections and past history of mono. The patient had allergy to kindest care hand sanitizer, alcare and eucerine hand cleanser. The patient's concomitant medications included ascorbic acid, zinc oxide (IMMUNE BOOST OTC). The patient on 17Dec2020 at 17:15, felt face prickly and itchy. No airway distress. Benadryl was administered at 22:30 that night. Physician was made aware. Occasional itchiness was observed on 18Dec2020. No rash noted. Fine rash was noted on 19Dec2020 evening on arms and chest with slight

itchiness. No Covid-19 was diagnosed prior vaccination. Covid-19 was not tested. The outcome of the events was resolving.

Body aches; Muscle pain; Chills; Headache; Fatigue; This is a spontaneous report from a contactable consumer reporting for herself. A 28-year-old female patient received the 1st dose of bnt162b2 (BNT162B2, Manufacturer Pfizer-BionTech), via an unspecified route of administration, on 18Dec2020 at 12:00 PM, at single dose, for Covid-19 immunisation. Medical history was none. Concomitant included an unspecified birth control medication within 2 weeks of vaccination. The patient experienced body aches, muscle pain, chills, headache and fatigue all on 19Dec2020 at 07:00 AM with outcome of recovering. No therapeutic measures were taken as a result of the events. The events were considered non serious. The information on the lot/batch number has been requested.

arm pain at injection site; redness from injection site up over shoulder; Tired; chills; body aches; This is a spontaneous report from a contactable consumer (patient). A 42-year-old female patient (not pregnant) received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot/batch number and expiration date not provided), via an unspecified route of administration on 17Dec2020 at 12:45 on arm at single dose for COVID-19 immunization. The patient medical history included SVT (Supraventricular tachycardia) with ablation, silicone sensitivity. Prior to vaccination, patient was not diagnosed with COVID-19. The patient's concomitant medications were not reported. Patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. There was no any other medications patient received within 2 weeks of vaccination. The patient experienced tired, chills, body aches, arm pain at injection site, redness from injection site up over shoulder, all on 17Dec2020. All gone within 48 hours of injection. Since the vaccination, patient had not been tested for COVID-19. No treatment was received for the events. The outcome of the events was recovered in Dec2020 within 48 hours of injection. The report was reported as non-serious. Information on the lot/batch number has been requested.

Redness in cheeks, greater on (opposite side from injection) right cheek; Mild swelling on right cheek; This is a spontaneous report from a contactable nurse reporting for herself. A 37-year-old female patient received the 1st dose of bnt162b2 (BNT162B2) (Manufacturer Pfizer-BionTech, lot# EJ1685), intramuscular in arm left, on 19Dec2020 at 12:00 PM, at single dose, for COVID-19 immunisation. Medical history included type 1 diabetes mellitus and hypothyroidism both from an unknown date and unknown if ongoing. The patient had no known allergies. The patient was not pregnant. Concomitant medications included insulin lispro (HUMALOG), levothyroxine (unknown manufacturer), ascorbic acid (VIT C), folic acid (unknown manufacturer), minerals nos, vitamins nos (PRENATAL VITAMINS) dexamethasone (DECADRON), metoclopramide (REGLAN), ondansetron (ZOFRAN), propofol (unknown manufacturer), midazolam hydrochloride (VERSED) fentanyl (unknown manufacturer). The patient experienced redness in cheeks, greater on (opposite side from injection) right cheek on 19Dec2020 at 12:30 PM with outcome of recovering and mild swelling on right cheek on 19Dec2020 at 12:30 PM with outcome of recovering. Therapeutic measures were taken as a result of the events which included Benadryl 25 mg oral. The events were considered non serious.

After 2 hours of receiving the Vaccine I got joint pain, tiredness, and severe headache. It's been more than 24 hours and I'm still having the same symptoms.; After 2 hours of receiving the Vaccine I got joint

pain, tiredness, and severe headache. It's been more than 24 hours and I'm still having the same symptoms.; After 2 hours of receiving the Vaccine I got joint pain, tiredness, and severe headache. It's been more than 24 hours and I'm still having the same symptoms.; This is a spontaneous report from a contactable consumer and contactable other-Health Care Professional (HCP). A 33-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration in the left arm on 18Dec2020 07:45 PM (at the age of 33 years-old) as a single dose for COVID-19 vaccination. Medical history was unknown. The patient was not pregnant at the time of vaccination. Prior to the vaccination, the patient was not diagnosed with COVID-19. The patient's concomitant medications were not reported; however, there were no other medications the patient received within 2 weeks of the vaccination. The patient did not receive any other vaccine within 4 weeks prior to the vaccine. On 18Dec2020 at 09:30 PM, the patient experienced joint pain, tiredness, and severe headache. The report was reported as non-serious. Treatment was not received for joint pain, tiredness, and severe headache. The clinical outcome of joint pain, tiredness, and severe headache was not recovered. It was also reported that since the vaccination, the patient had not been tested for COVID-19. The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up.

flush; fast heartbeat (120bpm); rash; nausea; dizzy, lightheaded; feeling unwell; This is a spontaneous report from a contactable consumer (patient). A 25-year-old female patient (pregnant: no) received first dose of BNT162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiry date unknown) via an unspecified route of administration at arm left on 19Dec2020 11:45 at single dose for covid-19 immunization. The patient medical history was not reported. Concomitant medication included celecoxib (CELEXA), ethinylestradiol and etonogestrel (NUVARING) received within 2 weeks of vaccination. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient previously took cefalexin(KEFLEX) and cefdinir(OMNICEF) and experienced allergies. The patient experienced flush, fast heartbeat (120bpm), rash, nausea, dizzy, lightheaded, feeling unwell on 19Dec2020 12:00 PM, the events resulted in emergency room/department or urgent care. Treatment of Benadryl received for the events. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. The outcome of the events was recovered in Dec2020. Information on the lot/Batch number has been requested.

I got increasing pain at my injection site, it was very sore. The soreness spread through my muscles; I got increasing pain at my injection site, it was very sore. The soreness spread through my muscles; headache; general fatigue; This is a spontaneous report from a contactable consumer (patient herself). A 23-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number EJ1685), via intramuscular in the left arm, as first single dose on 04Dec2020 (at 17:30) for COVID-19 immunisation. Relevant medical history included allergy to Latex. Relevant concomitant medications included loratadine (CLARITIN), birth control and multivitamin. The patient stated 'I got the vaccine on Friday and today (Saturday) half way through my shift at around 3:00 pm I got increasing pain at my injection site, it was very sore. The soreness spread through my muscles and I got a headache and general fatigue''. The patient did not perform a Covid test prior vaccination but after vaccination Nasal

Swab, COVID test, Rapid PCR was Negative. The patient was not treated for the events. She was recovering from the events. Information on lot/batch number has been requested

Injection site pain 14 hours after with body aches; 28 hours after fevers 102 sever body aches rigors; Injection site pain 14 hours after with body aches; 28 hours after fevers 102 sever body aches rigors; This is a spontaneous report from a contactable physician (patient himself). A 27-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via intramuscular on the left arm, as first single dose on 18Dec2020 (at 12:45) for COVID-19 immunisation. Relevant medical history included acid reflux and allergy to cats. Relevant concomitant medications included omeprazole (PROTONIX). 14 hours after vaccination, the patient had injection site pain with body aches. 28 hours after vaccination, he had fevers 102, sever body aches and rigors. However, it was reported that onset of the events was on 19Dec2020 at 17:00. The patient did not have loss of smell, SOB, dyspnea, loss of taste or diarrhea. The patient did not perform COVID test prior or after vaccination. No treatments were given for the events. The patient was recovering from the events. Information on the lot/batch number has been requested.

Feel flushed and had a fast heart rate; Feel flushed and had a fast heart rate; This is a spontaneous report from a contactable other HCP. This other HCP reported for a 35-year-old male patient that: Reporter type: Healthcare Professional reporting for a patient Age group: Adult (18-64 Years) Current age: 25 Current age unit: Years Medical qualification reporter: Other Health Professional Covid vaccine details: [{Product=COVID 19, Administration date=18Dec2020, Administrator route=Intramuscular, Dose number=1}] If other vaccine in four weeks: Unknown Adverse event: Caregiver received his first COVID-19 vaccine, was observed without issues for 15 minutes; left ambulatory. States he got up to the top of the stairs and started to feel flushed and had a fast heart rate. Came back to observation area. Set timer for additional 15 minutes of observation. Patient appeared to be in NAD, skin color WNLs, no c/o SOB or difficulty swallowing. Given a bottle of water. No issues during additional 15 minute observation. Left ambulatory; stated feeling much better. Informed him to mention this before his 2nd vaccine dose so that he can be observed longer. If treatment AE: No If covid prior vaccination: Unknown If covid tested post vaccination: Unknown Serious: No Seriousness criteria-Results in death: No Seriousness criteria-Life threatening: No Seriousness criteria-Caused/prolonged hospitalization: No Seriousness criteria-Disabling/Incapacitating: No Seriousness criteria-Congenital anomaly/birth defect: No Reaction(s)/Event(s): Reaction/event as reported by primary source: Caregiver received his first COVID-19 vaccine, was observed without issues for 15 minutes; left ambulatory. States he got up to the top of the stairs and started to feel flushed and had a fast heart r Reaction/event in MedDRA terminology (LLT): Caregiver received his first COVID-19 vaccine, was observed without issues for 15 minutes; left ambulatory. States he got up to the top of the stairs and started to feel flushed and had a fast heart rate. Came back to observation area. Set timer for Drug(s) Information: Characterization of drug role: Suspect Route of administration: Intramuscular Date of start of drug: 18Dec2020 Dose number: 1 Active drug substance information: Active drug substances name: COVID 19 Narrative case summary and further information: Case narrative Age at vaccination: 25 Years Did the patient receive any other vaccines within 4 weeks prior to the COVID vaccine: Unknown Reported Event: Caregiver received his first COVID-19 vaccine, was observed without issues for 15 minutes; left ambulatory. States he got up to the top of the stairs and started to feel flushed and had a fast heart rate. Came back to observation

area. Set timer for additional 15 minutes of observation. Patient appeared to be in NAD, skin color WNLs, no c/o SOB or difficulty swallowing. Given a bottle of water. No issues during additional 15 minute observation. Left ambulatory; stated feeling much better. Informed him to mention this before his 2nd vaccine dose so that he can be observed longer. Was treatment received for the adverse event?: No Prior to vaccination, was the patient diagnosed with COVID-19?:Unknown Since the vaccination, has the patient been tested for COVID-19?:Unknown No follow up attempts are possible. Information about Lot and batch number could not be obtained. No further information is expected.

"Felt lightheaded and dizzy.; Felt lightheaded and dizzy.; skin pale; very fatigued; she was currently breastfeeding; she was currently breastfeeding; This is a spontaneous report from a contactable health care professional. A 34-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), intramuscularly on 18Dec2020 (at the age of 34-years-old) as a single dose for COVID-19 immunization. The patient medical history and concomitant medications were not reported. It was unknown if the patient received any other vaccines within 4 weeks prior to the vaccination. It was unknown if the patient was pregnant at the time of vaccination. Prior to vaccination, it was unknown if the patient was diagnosed with COVID-19. On 18Dec2020, the patient felt lightheaded and dizzy and was brought to the observation area, ambulatory. She denied shortness of breath, itching or difficulty swallowing. No rash was noted, but the skin was pale. Water was provided to the patient. It was reported that the patient was currently breastfeeding, was very fatigued, probably dehydrated and had not eaten breakfast. She stayed in the observation area until 10:37, drank a total of 3 bottles of water and was up to the restroom ambulating on her own. Her blood pressure was 131/83, heart rate was 83 and ""100% on RA"" as reported. She left ambulatory to drive home and was informed to notify the appropriate person of this episode prior to a second dose of vaccine. It was unknown if treatment was received for the events ""felt lightheaded and dizzy"", ""skin pale"", and ""very fatigued"". Since the vaccination, it was unknown if the patient had been tested for COVID-19. The patient recovered from the events ""felt lightheaded and dizzy"", ""skin pale"", and ""very fatigued"" on an unspecified date in 2020, while the clinical outcome of ""she was currently breastfeeding"" was unknown. No follow-up attempts are possible; information on lot/batch cannot be obtained.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2020504266 mother/baby case, same reporter /drug , different patient"

"Right wrist swollen and painful; Right wrist swollen and painful; Immediate itchy rash on lower left arm between wrist and elbow; This is a spontaneous report from a contactable consumer (the patient). A 55-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, lot number BH9899), via an unspecified route of administration in the left arm on 17Dec2020 at 10:00 (at the age of 55-years-old) as a single dose for COVID-19 immunization. Medical history included rheumatoid arthritis (RA), penicillin allergy, and contact dermatitis to multiple agents. The patient was not pregnant at the time of vaccination. Prior to the vaccination, the patient was not diagnosed with COVID-19. The patient's concomitant medications included: prednisone, leflunomide (ARAVA), hydroxychloroquine sulfate (PLAQUENIL), meloxicam, ""and more"" (as reported, unspecified), all for unknown indications from unknown dates and unknown if ongoing. The patient did not receive any other vaccine within 4 weeks prior to the vaccine. On 17Dec2020 at 10:30, the patient experienced immediate itchy rash on lower left arm between wrist and elbow. On day 2 post vaccine (19Dec2020),

her right wrist was swollen and painful. The patient did not receive any treatment for the events. The clinical outcome of immediate itchy rash on lower left arm between wrist and elbow and right wrist swollen and painful was not recovered. It was also reported that since the vaccination, the patient had not been tested for COVID-19."

Developed pain and swelling in right index finger late evening after injection of vaccine, same side as vaccine injection; Developed pain and swelling in right index finger late evening after injection of vaccine, same side as vaccine injection; This is a spontaneous report from a contactable physician (the patient). A 68-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, lot number EH9899), intramuscularly in the left arm on 18Dec2020 at 17:15 (at the age of 68-years-old) as a single dose for COVID-19 immunization. Medical history included hypertension and history of prostate cancer. The patient did not have any allergies to medications, food, or other products. Prior to the vaccination, the patient was not diagnosed with COVID-19. The patient's concomitant medications were not reported. The patient did not receive any other vaccine within 4 weeks prior to the vaccine. On 18Dec2020 at 23:00, the patient developed pain and swelling in his right index finger late evening after injection of the vaccine, on the same side as vaccine injection (as reported). The patient was treated for pain and swelling in his right index finger with ibuprofen 600 mg (MANUFACTURER UNKNOWN). The clinical outcome of pain and swelling in his right index finger was recovering. It was also reported that since the vaccination, the patient had not been tested for COVID-19.

Soreness at injection site; This is a spontaneous report from a contactable consumer (patient) and healthcare professional (HCP). A 52-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE) solution for injection via an unspecified route of administration on 18Dec2020 at 10:30 (at the age of 52-years-old) as a single dose for COVID-19 vaccination. The patient was not pregnant at the time of vaccination. Medical history included HTN (hypertension) and known allergies sulfa. Concomitant medications included pneumococcal vaccine polysaccharide 23valent (PNEUMOVAX 23) on 14Dec2020 in right deltoid and varicella zoster vaccine RGE (CHO) (SHINGRIX) on 14Dec2020 in left deltoid. The patient did receive other vaccines (PNEUMOVAX 23 and SHINGRIX) within 4 weeks prior to the vaccine. Prior to the vaccination, the patient was not diagnosed with COVID-19. On 18Dec2020, the patient experienced soreness at injection site. No treatment was provided for the event soreness at injection site. The outcome of the event soreness at injection site was recovered in Dec2020. Since the vaccination, the patient has not been tested for COVID-19. The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up.

Arm felt tingly after; This is a spontaneous report from a non-contactable nurse. A 30-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, Lot EK5730) solution for injection intramuscular in the left arm on 20Dec2020 at 12:30 (at the age of 30-years-old) as a single dose for COVID-19 vaccination. The patient was not pregnant at the time of vaccination. There was no medical history. There were no concomitant medications. The patient had no known allergies to medications, food, or other products. The patient did not receive any other vaccine within 4 weeks prior to the vaccine. Prior to the vaccination, the patient was not diagnosed with COVID-19. On 20Dec2020 at 12:30, the patient experienced arm felt tingly after. No treatment was provided for the event arm felt

tingly after. The outcome of the event arm felt tingly after was recovered in Dec2020. Since the vaccination, the patient has not been tested for COVID-19. No follow-up attempts are possible. No further information is expected.

"patient's several members of family tested positive for COVID 19 virus and was potentially exposed; it was like she got the flu/whole flu like symptoms; Sore throat; Joint ache; Body ache; Low grade fever; Running nose; Terrible headache; Laryngitis; Muscle ache; Loss of smell; Chest discomfort; Joint discomfort; This is a spontaneous report from a contactable nurse. A 53-year-old female patient started to receive bnt162b2 (reported as Pfizer-BioNtech vaccine; lot number: EH9899), intramuscular on left arm on 18Dec2020 at single dose for COVID-19 immunization. Medical history included migraine, arthritis, gastritis, and esophageal spasms all from unknown dates and unknown if ongoing. Concomitant medications included dicyclomine, biotin, tocopherol (VITAMIN E [TOCOPHEROL]), and ergocalciferol (VIT D). Patient reported getting the vaccine and is now having a reaction. Patient stated that she got the COVID vaccine on 18Dec2020 at 7 in the morning and she started to get sick 5 in the morning the next day. Patient stated she worked night shift the next day and got sick and it was like she got the flu from the shot. When the above concern was paraphrased, the patient stated, ""Yes I had all of my joint ache, body ache, I had low grade fever, running nose, terrible headache, just whole flu like symptoms"". The patient was informed the role of the Pfizer Drug Safety and permission to probe was asked from the patient. Patient also stated, ""Yes, I always get my flu shot every year for many years, two other times I have been sick from the flu shot (Further clarification was Unknown) and it was like this it was like the flu and I believe this because of the shot but you know I mean I still think it would have been, I think it is better than having received COVID itself"". Patient mentioned taking turmeric. Patient mentioned that she had a COVID test done on Thursday at the clinic that she works at and that must have been negative because nobody contacted her and it was just they do random testing because of the patients she works with. Patient further stated ""I got my vaccine between 7-8 am mornings Friday morning and then around 5 am on Saturday morning, I started feeling really bad and then when I woke up at 4 in the afternoon I was done. It is probably, yes 18Dec, 7 or 8 in the morning I got the shot and then 19Dec at 5 am is when I started getting sick, by the evening I was full grown sick and I had to call I am sick because I couldn't pull another 12 hour shift"". The patient also reported that she was much better today (unspecified date), had a sore throat and headaches but her joint pains were better, and she has no fever not even low grade fever. It was further stated that the patient received first dose of Pfizer-BioNtech vaccine on Friday 18Dec2020. Developed symptoms on Sat 19Dec2020 which included ""sore throat, laryngitis, muscle ache, loss of smell, chest discomfort, low grade fever, joint discomfort"". Patient mentioned that she took Theraflu and NyQuil. Patient also stated, ""And the only other question is because when I called up to work to tell them to give me COVID a day for COVID pay because it was COVID related and they said they were not sure if they could. This is COVID related they should pay me for a day of COVID pay, correct. Who would know that?"". It was also found out ""recently"" that patient's several members of family tested positive for COVID 19 virus and was potentially exposed. It was asked that if patient gets tested for COVID virus, will she be positive because of receiving the Pfizer-BioNtech vaccine and can patient test positive for COVID 19 virus after receiving the Pfizer-BioNtech vaccine. Outcome of the event 'Low grade fever' was recovered, unknown for event

'patient's several members of family tested positive for COVID 19 virus and was potentially exposed', while recovering for the remaining events."

had 1 episode of shortness of breath; tachycardia; dizziness / light headedness; This is a spontaneous report from a contactable consumer reporting for herself. This 29-year-old female patient (non-pregnant) received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 19Dec2020 at 15:30, at single dose, for COVID-19 immunization. No other vaccine was given within 4 weeks prior to the COVID vaccine. Medical history was not reported. The patient was not diagnosed with COVID before vaccination. Concomitant medications included vitamin C and sambucus nigra fruit (ELDERBERRY) and unspecified multivitamin and immune support. On 19Dec2020 at 23:30 the patient experienced one episode of shortness of breath, tachycardia, dizziness. Lasted for about 20 minutes and totally resolved within 1.5 hours. Continuing to have light headedness 24 hours after. Emergency room/department or urgent care required. No treatment was given. COVID was tested post vaccination on 20Dec2020 via nasal swab (rapid test), with negative result. The events were resolving. Information on the lot/batch number has been requested.

Near syncopal episode the morning after; Extreme fatigue; generally unwell; body aches; nausea; chills; ear fullness; abdominal pain; This is a spontaneous report from a contactable consumer (patient). This 26-year-old female consumer received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) Lot number EJ1686, at single dose on 17Dec2020 08:00 on left arm for COVID-19 immunisation. Medical history included Environmental allergies, childhood asthma. The patient had no covid prior vaccination. The patient did not have covid tested post vaccination. The patient had no known allergies. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Concomitant medication included cetirizine hydrochloride (ZYRTEC), birth control, multivitamin. The patient experienced Extreme fatigue, generally unwell, body aches, abdominal pain, nausea, chills, ear fullness. Near syncopal episode the morning after on 18Dec2020. No treatment was received for all events. The outcome of the events was resolving.

"blister on her index finger; injection site is ""typical bruise looking and is tender; injection site is ""typical bruise looking and is tender; This is a spontaneous report from a contactable physician (who is also the patient). This female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 19Dec2020 at single dose for COVID-19 immunisation. Relevant medical history and concomitant medications were not reported. On an unspecified date, the patient noticed a blister on her index finger and said it was a round, red, raised, red spot on the index finger of the same side of her vaccination. She also stated that the injection site was typical bruise looking and was tender but did not look red or raised. The outcome of the events was unknown. The information on Lot /Batch Number has been requested."

Disequilibrium; This is a spontaneous report from a contactable nurse (patient). This 38-years-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), intramuscular, on 18Dec2020 at 04:00 PM at single dose for COVID-19 immunisation. Vaccine location was right arm. The patient was vaccinated at hospital, age at vaccination was 38-years-old. No other vaccine was received in four weeks. Medical history was none. Concomitant medications were unknown. On 20Dec2020, the

patient experienced disequilibrium. The event was reported as non-serious. The patient was tested for Covid post vaccination through a nasal swab on 20Dec2020, results are unknown. Outcome was recovering. No treatment was received for the event. Information on the lot/batch number has been requested.

Chills; sweating; Fever (99.1F) started at 22 hours and peaked at 99.9 (approximately 32 hours after vaccine administration); Diarrhea at 18 hours after administration; Injection site pain; Muscle aches; fatigue; severe nausea (no vomiting); mental fog (last about 4-6hrs); Within one minute: tachycardia (lasted about 3mins); dizziness (lasted 4-6hrs); weakness (lasted 12hours); This is a spontaneous report from a contactable consumer reported for herself. A 27-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) at single dose for COVID-19 immunization on 17Dec2020 at 19:30 via unspecified route of administration at the right arm in the hospital. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient haven't known allergies. About 7 years ago the patient had received HPV vaccine on unknown date and she experienced reaction to excipient. Within one minute the patient experienced tachycardia (lasted about 3mins), mental fog (last about 4-6hrs), dizziness (lasted 4-6hrs), and weakness (lasted 12hours). Starting 15mins after vaccine, severe nausea (no vomiting) that last two hours. Muscle aches and fatigue started at two hours after vaccine administration. Injection site pain started 6hrs after administration. On 18Dec2020 chills and sweating. Fever (99.1F) started at 22 hours and peaked at 99.9 (approximately 32 hours after vaccine administration). Due to fever, other symptoms, and recent exposure to COVID at place of employment, COVID nasal swab was done on 19Dec2020 at 1300 to rule out possible active diagnose. Test pending at this time. Tylenol administered to reduce fever and symptoms. Outcome of events at the time of last observation was reported as recovering. Information about lot/batch number has been requested.

Left arm start swelling at the injection site and down to the elbow around 5:30pm; This is a spontaneous report from a contactable consumer reporting for herself. A 47-years-old female patient received bnt162b2 (BNT162B2; Lot #Eh9899) vaccine, via an unspecified route of administration in the left arm on 20Dec2020 10:00 at single dose for covid-19 immunisation . Medical history included hypertension from an unknown date , migraine from an unknown date , partial seizures from an unknown date , intracranial aneurysm from an unknown date. Concomitant medication included spironolactone (SPIRONOLACTONE), hydrochlorothiazide, triamterene (TRIAMTERENE & HCTZ), estradiol (ESTRADIOL). The patient was allergic to lisinopril , amlodipine , gentamicin sulfate; methylmethacrylate;polymethylmethacrylate;zirconium dioxide , zonisamide . The patient left arm start swelling at the injection site and down to the elbow around 5:30pm with outcome of recovering.

Generalised rash; Injection 15 mins later developed generalized rash, palpitations and rash to face. I had to go home and take medication.; Injection 15 mins later developed generalized rash, palpitations and rash to face. I had to go home and take medication.; This is a spontaneous report from a contactable Nurse for herself. A 29-years-old female patient received bnt162b2 (BNT162B2; Lot # FJ1685) vaccine , intramuscular in the right arm on 19Dec2020 08:00 at single dose for covid-19 immunisation . Medical history included drug hypersensitivity from an unknown date , food allergy from an unknown date , allergy to metals from an unknown date. The patient 15 mins after the injection developed generalized

rash, palpitations and rash to face. and had to go home and take medication. The outcome of the event was recovered.

I feel a little Tachycardia; This is a spontaneous report from a contactable nurse reporting for him/herself. A patient of unspecified age and gender received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for covid-19 immunisation. The patient medical history and concomitant medications were not reported. The patient experienced felt a little tachycardia on an unspecified date with outcome of unknown. The heart beat was 101 and body temperature was 97.7 F. The patient asked if she should go see her doctor or the emergency room or should she wait. Information about lot/batch number has been requested.

His blood pressure keeps going up right now it is like 191/111, which is really high; Has been experiencing like severe headache for the past two days; This is a spontaneous report from a contactable consumer. A 54-years-old male patient (reporter boyfriend, anesthesiologist) received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration in Dec2020 at single dose for covid-19 immunisation. The patient medical history and concomitant medications were not reported. The patient experienced severe headache for the past two days and his blood pressure keeps going up on Dec2020 with outcome of not recovered. On unspecified date the blood pressure was like 191/111, which was really high. As treatment the patient took some type of analgesic, ibuprofen (MOTRIN) or something, and he also took Propranolol to try to get his blood pressure down but it kept going up. The patient underwent COVID test on unspecified date with unknown results. Information on lot/batch number are requested.

I began intense itching & redness that began in hands & feet, then head, arms back of neck then torso turned red and itchy; I began intense itching & redness that began in hands & feet, then head, arms back of neck then torso turned red and itchy; This is a spontaneous report from a contactable consumer, the patient. A 52-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration on 20Dec2020 at 14:30 (at the age of 52 years old) as a single dose in the left arm for COVID-19 vaccination. Medical history included asthma from an unknown date. The patient was not pregnant at the time of vaccination. Prior to the vaccination, the patient was not diagnosed with COVID-19. No known allergies. Concomitant medication included progesterone (PROGESTERONE), estriol (ESTRIOL), diazepam (VALIUM) all for unknown indications from unknown dates and unknown if ongoing. The patient did not receive any other vaccines within four weeks prior to the vaccination. The vaccine was given at a hospital. On 20Dec2020 at 19:00, the patient experienced she began intense itching & redness that began in hands & feet, then head, arms back of neck then torso turned red and itchy. The event resulted in a doctor or other healthcare professional office/clinic visit. The patient received treatment for the events which included steroids and benadryl. The clinical outcome of began intense itching & redness that began in hands & feet, then head, arms back of neck then torso turned red and itchy was recovering. It was also reported that since the vaccination, the patient had not been tested for COVID-19. The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up.

tachycardia (HR 150s); hypertension (BP 180/110s); This is a spontaneous report from the contactable nurse. A 45-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date were not reported), via an unspecified route of administration on 17Dec2020 at a single dose for COVID-19 immunization. The patient's medical history included COVID-19 from Sep2020. Concomitant medications were not reported. On 17Dec2020, approximately 5 min after receiving the vaccine, the patient experienced tachycardia (HR 150s) and hypertension (BP 180/110s). Therapeutic measures were taken as a result of the events and included treatment with labetolol. Outcome of the events was unknown. Information about lot/batch number are requested.; Sender's Comments: The reported information is limited. Based on the close temporal relationship and the description of the events, tachycardia and hypertension, there is a reasonable possibility that the events are related to BNT162 vaccine. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

Headache and injection site pain; Headache and injection site pain; This is a spontaneous report from a contactable consumer. An approximately 40 year old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration on 17Dec2020 (at the age of 40 years-old) as a single dose for COVID-19 vaccination. Medical history was unknown. The patient's concomitant medications were not reported. On an unknown date, the patient experienced injection site pain and headache. The clinical outcome of injection site pain and headache was unknown. No follow up attempts are possible; information about lot/batch number cannot be obtained.

little fatigue on first two days; This is spontaneous report from a contactable consumer. A patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), unknown route, on 15Dec2020 at single dose for COVID-19 immunisation. Medical history and concomitant drugs were unknown. The patient reported so far there are no side effects except little fatigue on first two days from 15Dec2020. The action taken in response to the events for BNT162B2 was not applicable. The outcome of the events was recovered on 17Dec2020 Information about lot/batch number has been requested.

"left ankle is very swelling, redness, it's very painful; left ankle is very swelling, redness, it's very painful; left ankle is very swelling, redness, it's very painful; This is a spontaneous report from a contactable physician (patient). A 66-years-old male patient started to receive BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), Batch/lot number unknown, intramuscularly from an unspecified date (at the age of 66-years old) as a single dose (reported as I think it was 0.5 ml they gave me some card, normally it is 0.5 ml I believe, I don't know) for covid-19 immunization. Medical history included mild hypertension for which he was on blood pressure very low dose like 50 mg from an unknown date and unknown if ongoing. The patient is very active, four days of gym. He is not obese, not a smoker and doesn't drink. Concomitant medication included losartan. The physician reported he worked for the hospital so was exposed to COVID-19 patients. The hospital offered the COVID-19 vaccination and he got it on Friday like 1 O clock on unspecified date and since this morning like 3am (03:00) on unspecified date, his left ankle

is very swelling, redness, it's very painful. He read about the side effect its says joint swelling. ""I never had problem like gout or any degenerative joint disease"". He was healthy. He doesn't know if this is related with this. He was going to call the hospital. The physician further he never have swelling like this, he doesn't know what exactly happened. He cannot say 100 percent but nothing happened, he did not take any new medicine. He doesn't have any injury. He never had gout. He never have any degenerative joint disease. ""I cannot say 100 percent but there is a possibility."" For treatment the physician stated, ""no, it happened 3 am in the night since morning I am doing hot, I have put heater in front of my feet."" The patient did not have lab work performed. He was thinking to go ask hospital to rule out any gout, any arthritic pain, ""I am going for arthritic"". Outcome of the events left ankle is very swelling, redness, it's very painful was unknown. The lot number/batch for the vaccine, BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, was not provided and will be requested during follow up"

Headache; Last night was throwing up; Dizziness/light headed; nausea; just like overall unwell; This is a spontaneous report from a contactable consumer (patient). This 25-year-old female patient reported that she received BNT162B2 (COVID-19 VACCINE), via an unspecified route of administration on 18Dec2020 at single dose for COVID-19 immunization. Medical history included anxiety. Concomitant medications included bupropion for anxiety. Consumer stated she thought that she was having adverse side effects. Last night (18Dec2020), she was throwing up. She got COVID-19 vaccine yesterday (18Dec2020) around 5' O clock and last night around mid-night she was throwing up and had like dizziness, she was just getting a headache now (19Dec2020), she was light headed last night, just like overall unwell. Regarding treatment, she took like calcium carbonate (TUMS) (antacids) for like nausea and ibuprofen (ADVIL). Outcome of events was unknown. Information on the lot/batch number has been requested.

sore arm; lightheaded; This is a spontaneous report from a non-contactable consumer. A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot number: EK5730), via an unspecified route of administration on 19Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced sore arm and lightheaded on 19Dec2020. The outcome of sore arm and lightheaded was recovered in Dec2020. No follow-up attempts are possible. No further information is expected.

Chills; Experienced mild flu like symptoms; Fever; This is a spontaneous report from a non-contactable physician (patient). A 31 year old female patient (physician) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration on19Dec2020 as a single dose for COVID-19 vaccination. Medical History was reported as none. There were no concomitant medications. On Dec2020, the patient experienced chills, mild flu like symptoms and fever. In Dec2020, she was now fully recovered. The clinical outcome of chills, mild flu like symptoms and fever was recovered Dec2020 No follow-up attempts are possible; information about lot number cannot be obtained.

feeling arm soreness; This is a spontaneous report from a non-contactable physician. A male patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration in Dec2020 at a single dose for COVID-19 immunization. The patient's medical

history and concomitant medications were not reported. The patient experienced feeling arm soreness in Dec2020. No other symptoms were reported. The outcome of feeling arm soreness was recovered in Dec2020. No follow-up attempts are possible. information about lot/batch number cannot be obtained.

Headache; This is a spontaneous report from a Pfizer Sponsored Program A non-contactable consumer reported that a patient of unspecified age and gender received bnt162b2 (BNT162B2 lot number and expiration date were not reported) via an unspecified route of administration on an unspecified date at a single dose for immunization. The patient's medical history and concomitant medications were not reported. On an unspecified date, the patient had a slight headache the day after getting the vaccine. Patient had no arm soreness. Patient stated that this vaccine was the best bet at getting an excellent IgG titer level without actually getting sick with Covid. Outcome of the event was unknown. No follow-up attempts are possible. No further information is expected.

Started out as a sore arm about 4 hours after getting the shot. Then progressed to severe body aches and a headache about 8 hours after getting the shot. Then after about 10 hours post-vaccine it progressed into chills and a 100.0 degree fever. I took 2 Tylenol Extra Strength pills at 12 hours post-vaccine and the symptoms decreased significantly within an hour. Still experiencing mild symptoms of all of the above.

Severely delusional, elevated high BP, vertigo, chills, moderate fatigue, swollen ankles,

Headache, night sweats

Metallic taste

Nausea (dry heave), Light-headedness, slight hand tremors, increased respirations, pain and warmth at injection site, tiredness, slight facial skin tightening, tingling of hands and feet

"PT RECEIVED Pfizer-BioNTech COVID-19 Vaccine. During observation period, pt felt as though her tongue was ""thick"" and her lips were tingling. Pt took a Claritin Ready Melt 10 mg tablet and sat under observation for addition 30 minutes. Symptoms subsided and pt left pharmacy area. She will carry her Epi-Pen with her for the next couple days."

Leg muscle pain in quadriceps in both legs, headache, nausea, one instance of vomiting

No symptoms during the mandatory 15 minute post-vaccine period in clinic waiting area. Experienced mild fatigue/general tiredness approximately 6-7 hours after receiving vaccine (given 12:35 pm). Full body chills/muscle spasms then occurred around 9:30 pm and lasted about 40 minutes.

5 minutes post-injection onset of nausea. 10 minutes post-injection retching. 1 hour post injection intense abdominal pain. 2 hours post injection onset of full body itching with no rash or hives. Itching responded to 50 mg Benadryl po and 20 mg po pepcid. Next day light itching; no other symptoms

Tired since about 10:00 AM, lethargic, pain at injection site, muscle aches, brain fog, slight headache.

Seizure witness by wife who is a physician. Bit tongue. No history of seizure or other neurologic disease.

Had vaccine yesterday. Last night had body ache and fever 98. Today only had body ache. But when she check the temperature it was the same as yesterday.

Soreness at site, tiredness, headache, sleepiness, soreness at hand joints, lymph nodes inflammation.

I started to feel a little dizzy at work within hours of vaccine, had not slept well the night before but dizziness continued on and off remainder of the day, felt a little ?off?.

Received Covid 19 vaccine on left deltoid via IM. I felt warm in my left deltoid immediately after the injection. While I was sitting in the recovery area I started feeling palpitations and Shortness of breath. I actually felt I was going into cardiac arrest. Personnel started assessing me and upon checking my vital signs my SBP was in 150?s-160?s and DBP was in 100?s range. Normally my BP ranges in 110?s. I also started feeling numbness on my left arm. My bilateral lower extremities were also numb, tingling, burning and very weak. I was not able to stand up and bear weight. I then was taken to the ED where blood work was done and ATIVAN Po was given. I was then discharged at 2325. The next morning, I felt my legs are still heavy and sore. They are still very heavy and sore while I am writing this and I feel like they will buckle when I walk.

lip swelling, eye lid swelling began approximately 36 hours after vaccination. Patient presented to ED and was treated with benadryl, protonix and prednisone. Plan to discharge home with the same

Staff having running nose, cough, fatigue, arm/body ache. States its post nasal drip. Same symptoms she had after her last flu shot. Took sudafed and is feeling better.

Injection site pain from hour 6 of the day the vaccine was given (12/19/20) until day 3 (12/21/20).

Had vaccine on L arm on Mon. Mon afternoon stiff L arm and hurt. Tue evening felt a lot of pain to lymph note under left arm pain.

right sided tingling at corner of lip up towards top of eye approx 10 min post shot

Patient developed arm muscle twitching the day after injection.

three hours after vaccine, felt tired, dry throat, HA, loss of taste, chill, no fever, nausea

On day of vaccine, had migraines, took Excedrin yesterday for HA, Nausea started yesterday afternoon. Today feeling tired, chest tight, SOB.

c/o facial redness, sweating, and hives at 1015

Started on Monday: tired, body aches, chills, called out from work. neg test results yesterday . Today symptoms are getting better today.

1 hour after felt dizzy/nausea. Staff has back pain, pain in bone, knee and feeling cold last night. No fever. He is taking Comudin, blood thinner. Staff states feeling better.

Had body aches started last night, but is feeling better today.

Approx 54 hours after vaccination, the lymph node in my left armpit swelled up to the point it was painful and relatively uncomfortable. My arm was no longer sore at the injection site, but I was unable to lie on that side while sleeping in bed. I took 600mg of Ibuprofen every 6 hours to help with the pain and swelling. It has subsided some, but is still swollen.

Quite a bit of pain and swelling in the left arm around the injection site, chills,headache,abdominal cramping all presented within 12 hours.

Pt. developed chest tightness which she described as her usual feeling when needing her rescue inhaler for asthma about 5 minutes post vaccination, had felt very anxious prior to vaccine due to needle phobia. She denied any associated symptoms either cardiac or respiratory system related and no localized arm pain at the injection site. She was also fatigued having worked since 5AM as a medical screener at a nearby clinic and had not eaten in more than 8 hours

-Swelling, sore throat: lasted about 8 hours, exacerbated by continuous use of n95 mask. -Injection site swelling: so far, started upon injection, has stayed swollen for 3 days. Measures ~6cm wide, still itching and tender. Redness comes and goes. -Myalgia: Lasted about 4 days, exacerbated by physical nature of job.

Body aches for 24h, starting about 12 hours after vaccination. Fatigue for 24hours.

warm, raised, hard, painful to touch at injection site

Pt. developed a typical (for her) migraine headache about 5-10 minutes after vaccination. She also described significant flushing and feeling hot, quickly removing her head covering and scarf. She took her regular dose of aspirin which she carries with her and we applied cold compresses to her neck which relieved the flushing and hot flash. We turned the lights low above the cot, she rested and symptoms all resolved over about 20 minutes and she left feeling relieved her headache did not progress.

Fractured right shoulder/ dislocation while doing a work out lifting low weight

Moderna COVID 19 vaccine eua, lip swelling approximately 12 hours after injection, chills, fatigue and hardness at injection site approximately 10 hrs after injection

Approximately 2 hours after Vaccination developed body aches, feverish feeling, injection site pain Next morning woke up with severe body aches, fever 101degrees F

Generalized body aches, chills, fever

Severe nausea, headache, chills, temp 100 4 - 101 8, body aches, swollen lymph nodes under left arm, lethargy. Started at 1130 on 12/22/20. All symptoms except headache resolved by 3 am 12/24/20

patient received vaccine and walked to chair and immediately started to c/o headache 2 -advil were given, patient was allowed to lie down on stretcher, close here eyes and ice pack to forehead was given

Following Pfizer BioNTech COVID-19 Vaccine dose 1, patient complained of dizziness, nausea, and chills for about 20 minutes. Patient was placed supine and offered fluids and crackers. Symptoms improved. Vital signs taken and were stable. Patient raised to sitting position and ambulated without difficulty. She was observed in the clinic for 45 minutes after her vaccine was given and she was able to leave the clinic independently. She was advised to call her primary care provider for any return of symptoms, and to report immediately to the emergency department if symptoms become severe.

Patient broke out in hives across left chest and across her back following the vaccination. The patient did not notice this until approximately 25 minutes after her vaccination and had left the clinic area. She returned with these symptoms, and was taken to the emergency department for further evaluation. She denied any shortness of breath or difficulty breathing.

Approx 20 min after the injection a wave of dizziness came over me as I parked my car at home, I sat in the car it lasted 1 to 2 minutes. Approx 60 min after the injection the 2nd wave of dizziness came over me lasting less than a minute. I read the paperwork provided and noticed this was a reaction, not a side effect. I told myself if it happened again I would go to the emergency room. Luckily it did not happen again. I will make them aware of this when I go for my booster vaccine on Jan 8th, 2021 Happy New Year and thank you for all of your hard work on this project to help people all over the world.

Chills, Fever, Nausea and Vomiting, General feeling of malaise (not feel well)

5 minute bout of vomiting 11 hours after vaccine given. Resolved completely, did not recur.

Low grade fever, headache, muscle ahes

patient felt lightheaded for 20-30 minutes

Patient complained of a headache initially, and then several minutes later, began to experience chest pressure following the first dose of the Pfizer BioNTech COVID-19 Vaccine. She was taken to the emergency department for further evaluation.

Diffuse splotchy erythematous, mildly pruritic rash on arms, neck, trunk, and legs. More prominent on flexor surfaces of limbs.

The patient had a fever of 101.8 with increasing body aches. She was advised to go to the emergency room and her fever was 104 at the time of arrival. The patient received IV fluids and was discharged after being monitored.

Employee felt like headed pretty soon after vaccine and had never experienced that feeling before. He has had no reactions like this in the past. He was evaluated by EMS and was tachycardic and hypertensive at first. Blood pressure and tachycardia normalized. He reports his baseline heart rate is on the higher end. He was monitored for a total of about 30 minutes and felt back to baseline after he was evaluated.

about 30 min after vaccination, pt reports numbness in mouth that lasted about 1 minute then resolved. After that, he had nausea, which resolved quickly as well.

"The patient reported a numb feeling in his face for a ""short time"""

headache pain score 7 out of 10 and chills over 1.5 hours after receiving vaccine.

extremely Stiff muscles and joints. Fatigue. stuffy nose. Mild headache.

Moderna COVID 19 Vaccine EUA Next day 12/23 after 5pm Chills, Temp 100.9. 12/24 Temp Current 99

fever 101.1F mild headache body aches flu like symptoms

diarrhea, nausea, muscle aches, cough,

Chills over 1 hour after receiving vaccine. resolved in 10 minutes

Nausea the following day (12/22)--@ 11AM. Vaccination at 550PM the night before 12/21. no medications needed. mild arm soreness at injection site on 12/22. All have since resolved.

None stated.

Nausea, Lightheaded, sweating, dizziness, increased blood pressure, left ear pain and left tonsils felt swollen, felt ?off?

patient c/o nickel sized red round & hard around injection site, placed heat pack over site with good relief.

STARTED SOB AND DRY COUGH AND RASH WITHIN 15 MINUTES OF VACCINE

Vaccine administered at 0730. Pt went home and went to bed. Woke up at 0930 with shaking, chills and feeling like she was going to pass out. Evaluated in ER and noted to have sinus tachycardia in 140-160's. Given 5mg IV Lopressor which took heart rate down to 110's. Admitted to hospital 12/23/2020.

On December 22nd I became tachycardic with heart rate ranging from 105 to 130. I then went to the Ed thinking I may develop a pulmonary embolism. Fortunately, cta of chest was negative. On 12/23/20 at around 10:30 I develop diffuse erythema rash essentially from face to groin, arm. I went to the hospital?s employee health to report my adverse effects. I took prednisone 80 mg and benAdryl 50 mg and symptoms subside. However, I woke up this morning and the rash is more pronounced with slightly tachycardic.

Approximately 15+ minutes after receiving the vaccine, the patient stood up from the chair and felt dizzy and faint. She was escorted to a bed to lay down. Ice packs were placed on her neck. Patient said she felt tachycardic. Pulse was 86. She denied SOB, had appropriate mentation. No rash was visualized on face, neck, abdomen, or legs. She drank apple juice. At 4:26, patient tried to sit but again felt dizzy and faint. She was transferred to the ED via wheelchair.

Full body shakes and chills that woke me up out of a deep sleep. Felt like my body was convulsing, resolved about 4 hours Nausea and Vomiting for about, resolved after 2 hours Woke up and feel weak, and have a headache. Current as of 12-24-2020 at 8:30 AM No treatment was taken

Nearing the end of 15 minute observation period, patient began to experience palpitations, sweating and felt faint. We moved patient to a private area and RN checked BP, (144/98) and reviewed issues with patient. Patient then shared that she felt tingling in hands and arms. She then recalled that she may have experienced this before but continued to feel unwell. Two RN's continued monitoring of patient until EMS arrival in <3 minutes and they proceeded to check BP again, (slightly higher) and blood sugar which was normal. They were on site for approximately 10 minutes evaluating and both EMS and patient confirmed that she was able to leave and did not need to visit hospital.

Employee developed face/neck flushing, pruritis, and shortness of breath following receipt of COVID-19 vaccine.á There was no swelling of the lips, tongue, or throat.á She was moved to the ED for additional monitoring (not registered).á She was monitored for an additional hour in the ED.á Her flushing decreased and SOB improved.á She was released from the ED with no intervention needed.á The patient had a history of allergic reactions to multiple injectable meds and vaccines in the past.

None stated.

Shingles outbreak emerged about 72 hours after vaccine. Prescribed Acyclovir 800mg on 12/22/2020 Also had a co-worker develop shingles within 24 hours of the vaccine this week.

Right now starting to get some chills and body aches. Is any type of confusion normal?

Some Nausea, Headache, facial itching

Approx. 45 -- 60 minutes following the vaccine, pat c/o lightheadedness, blurry vision, tingling in Left cheek, x 1hour, skin turned bright red heart rate 147 BP 147/80. Iced back of neck/forehead, sat for a few minutes. Heart rate down to 104, went back to work, but continued to feel flushed. Upon examination, her skin was normal in color but she stated that she still feels flushed & hot.

Lightheaded, Dizziness, Tachypnea, Tachycardia, Diaphoresis

Scratchy throat, mild fever (100 degrees), vomiting, nausea, headache, diahrrea

None stated.

Headaches, dizziness, nausea started around 5pm. By 10pm did manual BP, was 84/48. Chills and mild sweats overnight and BP in AM was 90/50s despite 2L water intake overnight. Fatigue and generalized aches by 0500 on 12/24/20. No symptoms prior to vaccine. Of note I work as Hospitalist with ER and inpatient wards- always using ventilator mask.

Adverse events initially began with chills the night of injection. There is significant bodyaches malaise and severe headache as well as our palpitations. And aura was associated with the headache specifically difficulty visualizing through the right eye the following day for several hours. Symptoms continue

through the following day and night. There was also nausea and loss of appetite. Symptoms started to prove two days after injection at the time of this report

Patient felt flushed and hot and felt a sudden headache start. Escorted to a bed to lay down. Ice packs applied to forehead and neck. BP 137/87, pulse 92, RR 20, temp 98.2. Rapid Response team called. Patient drank apple juice. When asked about a hx of reactions, patient stated she had a hx of reactions to T-dap, Hepatitis, A, and flu. She stated her reactions usually occur 2 hours after the vaccines and has a high fever of 103.0F with chills. She stated she had pre-medicated with 1 gram of Tylenol prior to coming to the COVID vaccination clinic. Repeat vital signs BP 138/89, pulse 94, RR 22. No improvement on how she felt and was transported to the ED via wheelchair.

I woke up with my heart pounding in my chest at 0038. I put on my daughter's pulse oximeter (she has asthma) and my heart rate ranged from the 110s up to the 130s. I got back into bed and tried to relax, then took a Restoril, fell asleep, but woke up again around 0300 with the same symptoms.

Moderate chills, body aches, slight nausea and headache which developed approximately 48 hours after receiving the vaccine and lasted for approximately 4-6 hours during the middle of the night and then completely resolved.

fever, headache

None stated.

Patient received the vaccine @ 0830am in her Left deltoid, @ 10pm that night she developed chills, temp of 101.2, felt awful, mild/moderate headache. took motrin alternated with Tylenol, called out of work for one day, now present s with no temp. States she feels completely exhausted.

Pt reports heart rate in 130s x 45 minutes-1 hour. She reported shortness of breath and O2 sat 95%,. Symptoms resolved simultaneously after 45 minutes- 1 hour. She also reports weakness and fatigues that lasted x 1 day.

Had headache fatigue and sinus pressure

Patient said she felt burning hot inside and her throat had a tickle. Shortly after that, she said she felt nauseous. She was taken to the emergency department for further evaluation.

swollen glands, headache, fever 99.4, slight cough

Ringing of both ears, dizziness, headaches, body aches, temp 99.1, injection site soreness, nausea , fatigue.

I premedicated prior to injection with benadryl 50mg po and otc pepcid. Approx 25 minutes post injection felt some very mild chest pressure that slowly developed to moderate pain scale 4 over a period of approx 2 hours then returned to a mild pressure once again, all left sided and no radiation of pain noted. At approx 430pm the pressure began to increase again and became painful at approx a 5 on the pain scale, it was then I developed diaphoresis,dizziness and severe nausea/vomitting., Bright green

bile appearing vomitus. Went to ED where I was given IV,Zofran 4mg x 2 doses,Reglan 10mg IV and contiued go vomit violently. Recd prescriptions for antiemetic and dc home to ride out the vomitting.

None stated.

Developed rash about 90 minutes after receiving vaccine

Within 10 minutes of receiving the vaccine in her Left deltoid, pt. c/o tingling of the tongue & in the back of her throat & being diaphoretic. She sat down for a bit and returned to working. The next day (Saturday) she c/o mild headache & diarrhea all day. Called out of work on Sunday with continued headache & diarrhea. Denied fever & no reaction at immunization site. Back to work on Monday.

Shot received at 7:15 am. That night at 2 am I awoke after developing rigors that lasted for 1 hour then resolved. I took 600mg Motrin at 2 am and 1g of Tylenol at 2:15 am. I was able to go back to sleep around 3 am. I woke up for work at 7am feeling sweaty but temperature was normal at 97.3. Overnight temperature at time of rigors was also normal. It is now 9:15 am and I feel better with mild residual symptoms.

None stated.

MILD RIGHT NIPPLE SWELLING AND SORENESS

Right sided facial swelling involving right cheek and lower jaw. No eye involvement. No breathing or swallowing difficulty. Symptoms were noted around 21 hours after the injection

36 hours following vaccine patient c/o injection site left deltoid, being reddened, tender & swollen approx. 2.5-3 inch circle around site. Encouraged to ice, take Benadryl &/or antihistamine.

Approximately one hour after injection I noticed a feeling of slight numbness on the left side of my neck extending up the left side of my face to the top of my ear. Feeling of numbness extends to middle of my cheek on left. No neurological deficit. Sensation to touch of area intact. Sensation continues through current time with no changes.

None stated.

"vaccine administered 0900 with report of ""warmness"" around and in mouth area 0904. 25mg Benadryl given PO."

red, hard lump in arm at injection site

On the next day after vaccine, I woke up with chills. I ached all over, I had a headache and fever later. Then nausea and dizziness along with weakness. On the next day it was the same, until about 12:30pm, the symptoms started lessening and was not as severe. Today, on 12/24/20, I still have nausea and I am really tired , and injection site is bright red and really sore (about the size of a dime). Feels like I have fever around it. Swelling on both hands.

Awoke at 5am with fever of 101.5; fatigue; tachycardia (HR103-105) at rest, tenderness at injection site. Took 2000mg acetaminophen to break fever, Fever broke on Saturday evening. Slept all day Saturday.

red, swollen, hard lump at injection site

Received vaccine on 12/21, c/o injection site being very painful 7/10 24 hours later, site appears slightly pink & very tender to touch. Instructed to ice & take Tylenol & or antihistamine.

Left arm leg and face numbness bilateral legweakness Vaccine given at 915 am Symptoms started at 11 am Called Pfizer to report at 1151 am Saw primary doctor at 2 pm Return to primary md again 12/22/20 Referral to neurosurgeon 11/22/20 Hospitalized 11/22/20 to 11/24/20 lepto Meningeal inflammation hospital

None stated.

Body aches, slight dizziness, fever with chills, lack of energy/fatigue

Dizziness, nausea after the dose. Vitals; BP 135/70, pulse 91, O2 100%. After 10 minutes, both symptoms subsided

Pt described mild numbness on and around her lips and face that started within 15 minutes of vaccination and lasted several minutes.

left under arm along side of breast pain and swelling. swollen lymph node on left side of neck.

None stated.

patient felt tremulous and lightheaded after receiving the vaccine. patient had worked the overnight shift immediately prior to receiving the vaccine.

She reported having PAC via her fitness watch. She said this was a new event for her last a few hours.

Chills, fever, body aches and head ache that lasted 24 hours. Small rash near injection site and a slight arm pit pain. Patients took Ibuprofen 200mg x 4 tablets

Tender, red raised wheal, 4 cm in diameter. Began next morning, and is beginning to resolve after 48 hours. No rash, fever, pruritis. Was 26 pregnant at time of injection. No known pregnancy complications.

Moderna COVID-19 Vaccine EUA. Fever, pain at the injection site, generalized malaise, headache

Began with facial pain in my cheeks where my cosmetic filler is. Then I woke up on 23rd of December with facial swelling and a nodules in cheeks. Talked with one of the providers in the office and they said it has been happening to some with fillers. It literally happened over night. Still ongoing only day two.

None stated.

Patient received the COVID-19 vaccine. Patient described feeling dizzy and light headed. Patient placed on floor. Syncopal event / vaso-vagal. No signs of anaphylaxis or allergy, but epipen 0.3mg was

administered. anticubital IV line placed for access if needed. Patient taken to ED for observation. Returned to duties within 1 hour of the event.

Slight numbness in L cheek and inner L lip, symptoms worsened on the way home, seen in the ED (6:23PM), MRI completed, diagnosed with Bell's Palsy, discharged home (10PM)

fever with tmax 105, chills, tachycardia to 150, moderate headache, cough, lightheaded, dizzy, somnolence

Severe fatigue lasting approx 12 hours. If I sat down I felt like falling asleep. I left work early and rested

Caller stated after vaccine about 45minutes she began having pain in the neck down into her right arm with hives. Next day she had fever, shortness of breathe and extreme pain in injection site. Caller is not getting second vaccine due to bad reaction. Vaers report was completed successfully online.

Lingering fatigue. Recovered the next day.

None stated.

I was very tired at 18:30 after receiving the vaccine at 14:29. I went to bed at 18:30 that night awoke at 3 am for work and was still very tired and body aches. I was driving to work and notice that I was having a delayed reaction to such things as I was looking at Christmas lights and had to remind myself I was driving. The drive to work otherwise I do not remember. I felt as if I was just not processing things around me correctly. At work the symptoms were intermittent. The thought process or lack of continued. I began to have stomach pain felt like diarrhea coming on however I never had it. Then nauseated and thought I was going to throw up and felt like I was going to pass out. The passing out feeling continued until I had my coworker call a rapid because I knew my blood pressure was dropping and my hear rate became slow and I was passing out. I was then taken to the emergency room to where I continued to experience orthostatic blood pressure changes and bradycardia and hypotension. I was given fluids and potassium IV and was feeling slightly better. I went home and slept for the next 18 hours. When I did briefly awaken through the evening I had an elevated temperature 102, chills and an extreme headache and body aches. Today I awoke at 6 am and still sluggish with a slight headache and absolutely no appetite.

Approximately 1.5 hours after injection the patient reported right sided facial tingling, mostly around her lip.

dizziness, nausea, heart racing

Swelling, soreness, and redness at injection site on left arm. My shot was given pretty far back in my arm, and not in the deltoid muscle.

Systemic: facial and tongue swelling and tingling-Medium

After vaccine, 1 day later, I had body ache and fever, then the next day I had joint pain in elbows. On the 21st, of December, I started feeling very tired and fatigue. On the 22nd, Tuesday, I had the stuffy nose,

congestion and sore throat. Today is day three of me being sick. I was told to go get tested for the virus and report. Yesterday my husband woke up with a fever of 101 as well.

None stated.

Fever, Chills, swollen upper lip and eyes, rash on upper lip, tongue prickly and taste is some what lost

Left Jaw pain at temporomandibular joint, (Trigeminal neuralgia?). No numbness or paralysis. Jaw aches. Best description is after the anesthetic from dental work wears off and jaw aches from injections and dental procedure. Injection given at 1pm left arm. Painless injection. Injection site pain increased to moderate throughout day. Jaw pain began at 10:45pm. Next morning jaw pain still present. Took two naproxen 200mg tablets at 05:30 am.

1. Tingling and numbness to the teeth ? immediately after the vaccine (the feeling went away) 2. Tingling and numbness to the teeth, tongue, and lower jaw about 30 minutes after the vaccine (lasted for about 1 hour) 3. Experiencing residual (very mild) numbness to the lower jaw/teeth 17 hours after the vaccine

Felt fine when sitting (in monitoring room) but felt dizzy when she got up and started walking

Received vaccine Tuesday at 10:30. Woke up at midnight that evening (Wednesday morning) with fever of 101.5, heart rate in the 140s, body aches, injection site pain,and nausea. Still experiencing these symptoms today, Thursday, at 10 am.

"After employee took a hot shower 5 hours after receiving the vaccine, she experienced sensation of lump in throat and facial flushing. She also felt her tongue ""had a heartbeat"" but not swollen. She drove herself to our ED. Also after arrival to ED felt nauseous, but no vomiting."

None stated.

Received vaccine around 0700 this morning. Started itching around 1300, rash appeared on both hands around 1500. Arms also itch but no current sign of rash. Has taken benadryl. Talked to employee health and was directed to go to ED if rash spreads.

Within about 20 minutes of receiving the vaccine my lips began to tingle, throat became scratchy, and began to feel light headed. At that time, I returned the the vaccination room and took two - 25mg Benadryl capsules and just asked to have an eye kept on me incase it continued to progress. Denied epipen at that time because did not have shortness of breath and throat did not seem to be closing. Symptoms were mostly relieved within 30 minutes. Continued to have a metallic taste and itchy tongue throughout the day. Following day, no symptoms. Given underlying anxiety disorder, panic attack is not out of the realm of possibility though those have been well controlled for years.

Patient indicated feeling of nausea, arm became numb, head felt tight and a dull headache

Headache and nausea

Received the Pfizer COVID-19 vaccine on Wednesday 12/16/2020 at approx. 1700 and developed a mildly itchy, maculopapular rash under my jawline on bilateral sides of my neck, not extending onto my face or chest by Friday 12/18/20. The vaccine site is clean and without skin changes, and I have no respiratory symptoms or compromise related to the rash or otherwise. I have no changes in detergent, lotions, clothing etc to blame at this time that aware of. By Wednesday 12/23/2020 the rash has lessened and appears to be improving and has not spread.

None stated.

None stated.

None stated.

None stated.

None stated.

None stated.

None stated.

None stated.

None stated.

None stated.

12/19 - onset of abdominal pain which is like her usual chronic necrotizing pancreatitis which she has had off and on for 10 years. This was accompanied by nausea. The pain & nausea last for about 3 hours. 12/20 - nausea and diarrhea. Today 12/21 she reports that she has recurrence of the abdominal pain, nausea, and feels hot. She is at work today. Advised to contact her physician for assessment and treatment as needed. Will follow-up with her

Lymphadenopathy left axilla

None

Red blotchy skin reaction at injection site and up arm

Jaw tightness, itchy lips, throat tightness

Jaw tightness, itchy lips, throat tightness

Fatigue and tachycardia (heart rate ranging from 70-140) within 2 hours after receiving vaccine. Cardiac workup done 12/21/2020- No treatment at this time, observation of symptoms.

Woke up with lump at injection site. Very painful, red, and hot to the touch.

Chills, headache, body ache, tiredness

Visual aura, predominately in right eye, 1.5 hours after receiving vaccine. Resolved in 10 minutes, with no lasting effects. I did have a headache for 2 hours prior to receiving vaccine, but never in my life experienced an aura.

Patient tested + for COVID back in April 2020, recovered. Developed localized erythema and a circular swelling and induration that is 2-3 cm in diameter, with some pruritus at the center. Denies fever, chills, headaches, or myalgias. Advised that localized reactions to COVID vaccine are not uncommon, and to seek additional if she developed systemic symptoms, worsening pain or redness, blistering or suppuration of the localized skin rash.

Unknown / Lost due to computer system

Chills, shivers, fever (t-max 103.4), body aches, neck pain, headache, injection site soreness

2225 lower lip numbness, spread to top left. aching pain left cheek, then left sided head pain. Pressure in head especially forehead, tingling in feet. 2228 trouble swallowing. taken to ED: 2256 prednisone 20 mg x 1 Pepcid 20 mg iv x 1 Benadryl 25 mg x 1, NS 1000 ml bolus. 0123 felt like new woman, took nap feels better.

headache, tiredness, joint pain all over, muscle pain nausea, not feeling well at all

Body aches and headache

Chills and sweats, hydrated and rest. Symptoms subsided around 1530 12-21-20.

chill. nausia, headaches body aches pain in left arm

10 minutes after injection, patient began to have redness/flushing of her face/neck. Symptoms partially resolved. She flushed approximately 3 times. Reported tingling in fingers bilaterally. Kept rubbing her fingers together and shaking hands. Pulse 107, BP 154/101. Patient states normal BP for her is 120/60. Hives and itching also reported. Patient states often flushes/gets hives when stressed/upset. No issues prior to injection. Patient take to hospital ED for observation. Symptoms had resolved when she spoke to the ED doc but are lingering today 12/24 as of 1030 am.

Extreme arm soreness and stiffness starting evening of vaccination and continuing. No treatment at this time

"Patient experienced ""pounding headache"" during the 15 minute post-injection observation period. Patient was taken to the Emergency Room, treated, and released. She complained of continued symptoms the following day, noting improvement in severity."

Lightheadedness, dizziness, nausea starting 30 minutes after vaccination, bradycardia.

Sore muscle at injection site for 2 days.

Patient developed severe headache about 10 minutes post vaccination. Patient took Ibuprofen 800mg. Headache resolved approximately 1 hour later

Felt weak and congested. Called PCP, he ordered a COVID test. I tested positive 12/22. Husband tested positive for COVID 12/19. I don't think this is an adverse event, just a coincidence.

Felt weak and congested. Called PCP, he ordered a COVID test. I tested positive 12/22. Husband tested positive for COVID 12/19. I don't think this is an adverse event, just a coincidence.

Injection site soreness.

Itchy inner ears and throat 20 mins after injection

with severe muscle ache , low grade fever, eyes lids and eyes were heavy

Patient started with watery red eyes and face was flushed. initial vital signs after notice of reaction was Bp 120/88 then noticed mild hives on neck and behind ears. Decided to give patient Benedryl 50 mg IM in Right Deltoid at 1:12pm and retook vitals at 1:20 Bp 118/74 pulse 86 and SAO2 99% on room air. Vitals at 1:36 pm were BP 116/84 pulse 90 and SAO2 97% on room air. Redness and eye watering and itching improved. Spoke with patient again today she says she still has a slight itchiness between fingers and will consult physician prior to second dose.

Headache for 7 days intermittent requiring tylenol, ibuprofen 4 out of 7 days Dizziness transient on day 5 corrected with oral hydration Dizziness, presyncopal event, Sinus tachycardia, chills, nausea, headache at 930 AM on 12-22-2020. Sinus tachycardia lasted 12 hours and now improved. EKG twice, Holter and echocardiogram confirmed sinus tachycardia. Thyroid profile normal Normal comprehensive metabolic panel, CRP, ProBNP, ferritin levels are normal.

About 30 minutes after vaccine I felt heart palpitations. 1 and 1/2 hours later I felt slight chest pressure, throat swelling (still able to breath), and an adrenaline type rush causing anxiety, shakiness, and energy burst. I did not seek medical attention. Instead I managed it at home with 50mg Benadryl. I slept through the night without any distress. When I woke up my throat still had mild swelling (felt like when you have a sore throat and a lump in your throat). This continued the whole next day along with intermittent chills, mild body aches, slight shortness of breath on exertion. No fever. I did not take any medicine on this day. The next day, day 3 my throat swelling was gone. I did not seek medical attention during these symptoms because the were tolerable and able to be managed at home.

Hypersensitivity reaction. Redness, flushing, runny nose, watery eyes. Gave Diphenhydramine 25mg PO. Symptoms subsided after about 20 minutes. Patient stayed in the clinic for observation for approximately 1 hour. Advised to call 911 and seek emergency medical care if any symptoms started again after leaving the clinic. Patient expressed understanding.

"Sensation of lump in the throat and metallic taste in mouth approx. 10 minutes post vaccination while still in Vaccine Observation area. VS normal and stable. O2Sat 100%. Evaluated by on site physician. Received diphenhydramine 25mg PO at clinic. Remained stable and D/C'd home. F/U telephone call

12/24/2020. States additional 25mg diphenhydramine at home in ""evening"" for ""Scratchy"" throat. No problems overnight and all sxs resolved in AM of 12/24 2020."

Fever 101.2, chills, body aches

About 30 minutes after receiving vaccination, patient started to have tingling and mild swelling in her lips as well as tachycardia. Vital signs taken. Heart rate was 102 bpm, respiratory rate 18, blood pressure 144/80, O2 Sat 98%. Received cetirizine 10 mg PO. Symptoms resolved within one hour of receiving cetirizine.

102 fever, vomitting, headache, body ache, fatigue

Headache after 30 minutes Joint pain after 5 minutes Nausea after 30 minutes Hand/arm numbness after 3 hours Chills after 4 hours Injection site pain after a day

bp spike since Saturday, no fever head ache and nausea , Shortness of breath and big discomfort in the chest and last 2 days whole hands swelled up during night and goes during the day time

received vaccine at 1500 on 12/22. woke up at 0200 with mild headache and moderate vertigo. went back to sleep. woke up at 0730 with ongoing vertigo. vertigo resolved after 2 hours without any intervention

scratchy throat, hoarse voice, itchy ears inside. 1 1/2 hrs after vaccine. 12/23/20

12 hrs post vaccine- runny nose, severe headache, arm tenderness, and generalized body aches 24 hrs post vaccine- sluggish and achy; headache has lessened, but still there; dizziness < 1min, 1 time; Tylenol Extra strength taken 12/23 830pm, 12/24 230am, and 12/24 8am

Caller stated that he experience left side tingling and numbness that was continuous. Caller went to employee health under went neurology test. Positive for numbness on the left side of his face. Caller will be getting second vaccine 1/8/21. Vaers report was completed successfully online.

"6 hours after vaccination, chills and chest ""tightness"". Felt like reactive airways. Tight x 3 days with slow development of cough, continues to progress, feels like pneumonia. Unrelenting cough, frequent use of rescue inhaler. On day 6 full exam in ER. Chest x ray clear, covid negative, ekg normal. Day 9 back in ER. Unable to sleep. Constant cough so violent I am wrenching."

Patient was driving back to work. Became tachycardic during the drive and pulled over to a local pharmacy. She self administered 50mg of diphenhydramine and took her blood pressure at the pharmacy. The BP was found to be elevated. EMS picked the patient up and transported her to ED.

Fatigue and achiness about 6 hours after receiving injection. Developed chills, muscle aches and fever, 99.3-100.4, 8-9 hours after injection. Fever was gone by 7:30AM the next morning (11 hours after injection), however continued to have muscle soreness and increased fatigue for the remainder of the day

Pfizer-Biotech Covid-19 Vaccine. Adverse Effects: Fever (101.1¦F), Chills, Body Aches lasting 24 hours

Headache, arm pain, sleepy and very tired also I had a really bad sore throat very read and painful.

As employee entered observation area noted slight headache then complained of SOB VS BP 150/90 states took medication in am O2 Sat 99-100% HR-74 RR-24 lung sounds clear reported lightheadedness, confusion sent to ED via wheelchair

Employee received vaccine on 12/17/20 on 12/18/20 employee noted red rash to abdominal area. Raised no drainage

received vaccine at 9:30 am noted frontal headache @ 9:40am VS 124/76 HR 75 O2 Sat 95% Denied SOB, difficulty swallowing, numbness tingling given acetaminophen 650 mg 9:50 am given ibuprofen 600mg @ 10:22am VS BP 137/90 HR 71, O2 Sat 97%, feeling dizziness nausea, transported to ED

received vaccine @ 4:25pm within few mins noted red flush across face, neck extending to collar bones. No SOB, difficulty swallowing, hives, rash nausea BP 142/80 HR 64 O2 Sat 97% 15mg of liquid Benadryl @ 4:35pm resolved in 1 hr

None stated.

None stated.

15 minutes after vaccines became dizzy when she stood up. B/P elevated 158/85. Was extremely fatigued and localized site redness, swelling and pain.

Muscle aches, headache and congestion

Nausea/Headache

Rash from neck to pubic bone started 12/23 at 5am. Called and spoke with patient this am, 12/24 at 11am. rash is subsiding and she feels fine.

itchy nose and chin. Lasted about 5 minutes

At 1800 developed headache, 2000 developed chills, temperature of 99.6 (normal daily T on this thermometer 96.8-97.5), slight nausea, dizziness with standing. Excederin at 0000, sweating at 0100, T 98.2 at 0400.

"""Scratchy"" throat, dizzy, shortness of breath, and flushed approx. 10 minutes post vaccination. Evaluated onsite at vaccine clinic by physician. Received diphenhydramine 25MG PO. VS normal and stable. O2 Sat at 100%. Monitored and observed for 60 minutes and D/C'd in stable condition. Contacted by phone in AM of 12/24/2020 and states all sxs resolved yesterday evening. Will receive 2nd dose of vaccine in hospital Allergy Clinic."

At around 3 am. I woke due to excessive sweating and coughing. I also experienced a stuffy nose as well as feeling as though my saliva was thick. I drank water in an attempt to aid the coughing and the water also seemed 'thick'. I sweat throughout the remainder of the night; in addition to severe left arm pain.

The COVID vaccine was given at 2046. At approx. 2050 patient complained of tingling to her left leg and a headache. Her vitals were obtained at 2050. They are as follows; B/P 146/86, HR 111, Spo2 98 on RA. She denied any SOB, chest pain or discomfort, no difficulty swallowing. She was able to ambulate to the wheelchair without any issues. I called house supervisor at 2049. He came up to asses her and she was transported to the ED by 2 MA's and a nurse. She was transported via wheelchair on the monitor. She did not require supplemental O2

Had a low fever (99.5) last night. Minor aches. This morning I woke up and the lymph nodes under my left arm are swollen

12-18 0730- received vaccine at work. I am a registered nurse. 12-19 11am feeling extremely fatigued, chills, mild aches, and temp 100.1 12-19 2pm temp 101.8 and more severe arthalgia, myalgia, and shivering.... cant get warm 12-19 6pm temp 102.1 and rigors.... shaking head to toe and severe aches/ pains 12-19 11pm temp 104.1 12-20 temp 102.5 12-21 SOB, bradycardia to 41, dizziness, temp 100.5 12-22 SOB, vomiting, cough, temp 99.6 12-23 SOB, cough, diagnosed with Covid pneumonia

started to experience scratchy throat, lasted about 30 minutes and resolved on its own.

Developed severe epigastric pain and had a syncopal episode while at lunch. Individual lost consciousness for a few seconds and returned to baseline with in a minute. No further care was needed or given.

Headache beginning from time of wake-up about 0730. Pain slightly diminished but not relieved with migraine medication 4 hours later.

diarrhea, shortness of breath, chest pain, headache

blotchy rash flanks, not itchy. 'Flushed' head to toe. Dry Mouth

Fever starting at 5am on day after vaccination. Highest measured temperature was 102F. Also had associated fatigue and headache. Headache was helped by acetaminophen and ibuprofen. Fever was intermittent and lasted until about 6pm of the same day. Fatigue and headache also lasted until about 6pm on day after vaccine.

Headache: 2/10, global/ diffuse, responds to excedrin & getting, worse in the morning. +R Foot went numb and the resolved. No tingling, weakness, or numbness, dysphagia, slurred speech, seizures, blurry vision. Thirst: Very thirsty. ALtered Mentation: Slower in responding, Having to really think before she speaks Muscle Spasms +hot flashes no fever, chills, chest pain, or sob. hyper-emotional (Sponteneous crying).

Started 12/23/2020: Body Aches, Sore Arm, Fatigue, Cold Chills, Elevated Temp from normal.

Tasted the medication, felt flushed, heart racing, BP 166/118 P 125 PO2 100% Repeat BP 150/106 P90's Rapid response RN here BP 159/89 P 89

Received the COVID vaccine on 12/22/2020 - approximately 4 hours later started with body aches, took NSAID and went to bed, woke up with loss of taste and smell and other COVID symptoms

Achiness in neck

Patient was in the 15 minute post-observation window and was scheduling his appt for second dose. Patient noted that he has a fear of needles and mentioned that he was feeling light-headed and experiencing tunnel vision.. He subsequently became diaphoretic and syncopal. He spontaneously recovered and was helped back into the chair. Did not fall to ground or hit his head. A SWAT was called. During SWAT evaluation, patient was given cool compress for neck and mentioned that this has happened before with injections. Subsequently had another syncopal episode and witnessed clonic seizure of roughly 25 seconds in duration. Patient again spontaneously recovered and was brought to the ED. the patient was unable to recall the events and has no history of seizure activity. Patient was given crackers and juice in ED and monitored for approximately 3 hours. Patient was discharged to home.

My arm from 7pm-7am exp pain, tingling and purple in color. On 12/21 went to employee health nurse told to take Ibuprofen went home. As of today still purple and yellow in 3 to 4 inches in bruise. I dint miss any days of work.

I WOKE UP IN THE MIDDLE OF THE NIGHT WITH PAIN, SWELLING, HARDNESS AND REDNESS ON THE INJECTION SITE OF UPPER LEFT ARM.

Dizzy

sore in arm

Woke up in the night with c/o headache, malaise and soreness in the arm COVID vaccine administered.

I had a headache about an hour after the vaccine. Started feeling extremely tired around 8pm. Around bedtime I was really cold, my hands were like ice and I just kept trying to get warm. I woke up feeling fine this morning. The only pain I feel is that my left arm feels sore and aches when I move the muscle around.

12/22/2020 at 3:00pm Moderna Vaccine administered. 12/23/2020 at 2:00pm Strong shaking chills. Temperature started at 99.8. 12/23/2020 at 4pm Chills continue. Temp 101.4 Body aches. 12/23/2020 4:30pm Advil 3 tabs taken. 12/23/2020 6pm Temp 102 chills body aches. 12/24/2020 8am Temp 100.4 12/24/20 11:30 am Temp 99.5improving, body aches but no chills.

The day after receiving the vaccine, I developed rhinorrhea, ST, and dry cough. It worsened the next day, so I got a rapid COVID test that was positive. (This was confirmed with a positive PCR 2 days later). Two days after the vaccine (the day of the positive test), I developed fever to 103, chills, body aches, fatigue,

headache and worsening cough/congestion. Fever and chills resolved after 24 hrs, but mild congestion and cough has persisted until today.

within minutes after receiving vaccination employee felt lightheadedness,, clammy, nauseated and vomited x 1. slowly resolved, went back to work and totally did not resolve so sent employee to ED to be evaluated.

Immediately after I received the injection, my upper lip started tingly. My lip started getting bigger, I took Valtrex as a blister came upon my lip. About 6pm , I started getting a mild headache. I woke up this morning and my headache is getting worse, I have body aches, and fatigue. My arm is sore as well.

No adverse event reported. Found in paperwork that this person was only 16 years of age and should not have received Moderna Vaccine.

Pt received vaccination and immediately afterwards syncoped. Pt recalls receiving the inoculation and becoming acutely lightheaded before losing consciousness. No preceding SOB or palpitations noted.

Progress Notes PA-C (Physician Assistant) ? ? Orthopedics Cosigned by: MD at 12/22/2020 á9:46 AM Expand All Collapse All á 12/21/2020 á Patient: Date: 12/21/2020 á Subjective Patient is a 58 y.o. female who was seen at COVID Vaccine Clinic today for her first dose of the COVID 19 vaccination. á She denied any history of previous adverse reactions to vaccines. á She was given the Pfizer vaccination in the left deltoid muscle. á During her 15 minute waiting period after the injection, the patient began to experience dizziness/shakiness. This provider was notified of patient reaction and she was then transferred to the emergency bay via wheelchair where she was assessed. Monitored patient for severe reaction symptoms, including rapid progression of symptoms, respiratory distress with dyspnea, increased work of breathing, persistent cough and cyanosis, vomiting, hypotension, dysrhythmia, chest pain and collapse. á She denied difficulty breathing, throat tightness and tongue swelling, nausea. á She reports a history of atrial fibrillation and states that she had a procedure in the past and the anesthesia provider questioned her about this diagnosis. She reports taking metoprolol and methimazole on a daily basis. She took all of her am medications today, including an 81 mg aspirin. Reports history of watery eyes and blurred vision, takes Zyrtec daily. Denies any worsening of these symptoms outside of her baseline. Denies use of anticoagulant use or diabetes. Last ate and drank about 1130 or noon. á Review of Systems Constitutional: Negative for diaphoresis. HENT: Negative for congestion, drooling, facial swelling, rhinorrhea, sneezing and trouble swallowing. Eyes: Positive for discharge. Negative for redness. Respiratory: Negative for chest tightness and shortness of breath. Cardiovascular: Negative for chest pain and palpitations. Gastrointestinal: Negative for nausea and vomiting. Skin: Negative for color change, pallor and rash. Neurological: Positive for dizziness and headaches. Negative for syncope. Psychiatric/Behavioral: Negative for agitation and confusion. The patient is not nervous/anxious. á á á Objective Vitals There were no vitals filed for this visit. á á Physical Exam Constitutional: General: She is not in acute distress. Appearance: Normal appearance. She is obese. She is not toxic-appearing or diaphoretic. HENT: Head: Normocephalic and atraumatic. Nose: No rhinorrhea. Eyes: Comments: Watering of both eyes Cardiovascular: Rate and Rhythm: Normal rate and regular rhythm. Comments: At right radial pulse Pulmonary: Effort: Pulmonary effort is normal. No respiratory distress. Skin: General:

Skin is warm and dry. Coloration: Skin is not pale. Findings: No rash. Neurological: Mental Status: She is alert and oriented to person, place, and time. á á Assessment/Plan Stress reaction following vaccine administration. á Patient was transported to the emergency bay via wheelchair. á Treatment included no therapy, but did continue with vital checks at approximately 5 minute intervals. á 1603-blood pressure using the large adult cuff was 154/60 with large adult cuff, heart rate 69 with regular rate and rhythm at right radial pulse, 96% O2 sat on room air. Patient continues to feel slightly dizzy and shaky though denies any chest pain, shortness of breath, swelling of the lips or tongue. á 1611 vital signs reassessed with blood pressure of 150/63, heart rate 64, 97 percent on room air, continues to feel slightly dizzy/shaky, though, reports not nearly as bad. Patient continues to answer questions appropriately and is talking without any signs of further decompensation. á 1618-reports feeling better. Vital signs rechecked with BP of 121/55, 59 hearty rate and 96% RA. No new complaints. á 1624- patient reports a slight headache, but denies chest pain, shortness of breath, chest tightness, lip or tongue swelling. á Discharge vitals obtained at 1626-with blood pressure of 135/55, heart rate of 58, 95% on RA. No new complaints, except feeling a bit cold. Patient reports feeling better and feels that she can safely discharge. Discussed need for urgent evaluation at the emergency department or to call 911 if symptoms of chest pain, shortness of breath, angioedema present. Patient expresses understanding and all questions were answered to her satisfaction today. á Follow up response to treatment:excellent. á Patient discharge: Stable to go home and follow up with PCP. á Orders Placed This Encounter Procedures ? COVID-19 MRNA á á PA-C Electronically Signed 12/21/2020 4:05 PM á á

Appoximately 12:15pm patient Reporting itching all over her body, throat feeling scratchy, bumps forming on chest, ear itching. Vital signs taken Benedryl 12.5 mg given IM x2. pepcid given orally, continued to monitor x 60 min. Itching was Reduced over body, bumps on skin Resolved. Temperature Rose from 97.2F to 99.4F.

line of numbness from injection site down arm

Urticaria, allergic reaction to COVID-19 vaccine, treatment with famotidine and benadryl, along with prednisone for 5 days.

15 min post injection c/o heart racing, rate 160 on watch Skin flush Confirmed heart rate 160 RRT called , pt never LOC Pt stayed 1 hour for observation, heart rate 106.

Patient began experiencing hot flashes and chills a few hours after receiving the vaccine. The next day she experienced chills, fatigue, left arm pain (same arm as vaccine administration). Advised to obtain COVID19 testing, and seek immediate medical attention if symptoms worsen or severe symptoms appear.

"About 5 minutes after receiving the vaccine, the individual reported feeling light headed and stated that her ""vision wasn't matching up."" She was assisted to a laying position and symptoms did not resolve. She was given 50 mg of benadryl IM in her right arm. 15 minutes later, her symptoms resolved and she was able to go home."

flush on legs and arms, transient throat tingles that resolved. Arms heavy

A rash started under both armpits in the middle of the night. The armpits were swollen and welped . The rash continued to spread across my chest and back and down both arms . Went to doctor and got medrol dosepack and triamcinolone cream.

Fever, headache, chills, muscle pain all over, joint pain, general malaise

Feels like lump in back of throat, given Epi at clinic without resolution. No shortness of breath or pain

I THREW UP 4-5 TIMES AND HAD DIARRHEA AROUND 9PM, AND SLIGHT DIZZINESS PRIOR TO THAT

About 24 hours after the vaccine, arm became red and swollen at the injection site. Eyes became red and swollen. Experienced coughing if laying flat, had to sleep upright. Symptoms resolved around 12 hours later.

Progress Notes APRN (Nurse Practitioner) ? ? Nurse Practitioner Cosign Needed Expand All Collapse All COVID VACCINE CLINIC 12/22/2020 á Date: 12/22/2020 á Subjective Patient is a 34 y.o. female who was seen at COVID Vaccine Clinic today for her first dose of the COVID 19 vaccination. She denied any history of previous adverse reactions to vaccines. á She was given the Pfizer vaccination in the left deltoid muscle. á During her 15 minute waiting period after the injection, the patient began to experience lightheadedness and confussion. She denied rash, hives, welts, difficulty breathing, difficulty swallowing, wheezing, throat tightness, hoarseness, stridor, itching, facial swelling, lip swelling and tongue swelling. á This provider was notified of patient reaction and she was then assessed in the emergency bay area. á Monitored patient for severe reaction symptoms, including respiratory distress with stridor, wheezing, dyspnea, increased work of breathing, persistent cough and cyanosis. á Pt Presents with lightlessness and confusion. Blood sugar on presenting was 74. She has a history of fibromyalgia and Migraines. She had a gastric bypass in 2010. She was given a protein bar to eat. Fingerstick BS done 20 minutes later was 96. Pt was feeling better after eating. á Review of Systems Neurological: Positive for light-headedness. Psychiatric/Behavioral: Positive for confusion. All other systems reviewed and are negative. á á á Objective á Vitals Vitals: á 12/22/20 1612 12/22/20 1628 12/22/20 1639 BP: (!) 135/92 127/79 128/84 BP Location: Right arm Right arm á Patient Position: Sitting Sitting á Pulse: 98 74 88 SpO2: 98% 98% 98% á Physical Exam Vitals signs and nursing note reviewed. Constitutional: Appearance: Normal appearance. HENT: Head: Normocephalic. Right Ear: External ear normal. Left Ear: External ear normal. Nose: Nose normal. Mouth/Throat: Mouth: Mucous membranes are moist. Eyes: Pupils: Pupils are equal, round, and reactive to light. Neck: Musculoskeletal: Normal range of motion. Cardiovascular: Rate and Rhythm: Normal rate and regular rhythm. Pulses: Normal pulses. Heart sounds: Normal heart sounds. Pulmonary: Effort: Pulmonary effort is normal. Breath sounds: Normal breath sounds. Abdominal: General: Abdomen is flat. Musculoskeletal: Normal range of motion. Skin: General: Skin is warm and dry. Capillary Refill: Capillary refill takes less than 2 seconds. Neurological: Mental Status: She is alert. Psychiatric: Mood and Affect: Mood normal. Behavior: Behavior normal. Thought Content: Thought content normal. á á á Assessment/Plan Treatment included: no therapy. Follow up response to treatment: no side effects. Patient discharge: Stable to go home and follow up with PCP. á Pt was released at 4:39 with no symptoms at that time. á á á APRN Electronically Signed 12/22/2020 4:40 PM á á á Division of Health 3 of 3

Hives on arms face and chest

Pt. states an hour after, she started a 2-3/10 headache, after 2hrs, she had 7-8/10 headache. Tylenol 1000mg PO taken. After 5 hours, she was very fatigued, headache 5/10. Fell asleep. Fever started during the night, when she woke up today 12/23/20 @ 6AM, it was 101.3 - she had a cold shower and had a headache of 5/10. She took tylenol 1000mg PO at 6:30AM. at 8:30AM, temp. is 99 degrees and headache gone.

Fever, Chills, Muscle aches, joint pain, headache

Migraine at 0420 12/24/2020; Body Aches; Joint stiffness; Skin feels hypersensitive especially at injection site. Took Tylenol and symptoms are better.

Pt(I) report swelling, redness, and warmth at the injection site was first noticed in the morning at 6:30 am on 12/24/2020 currently 2.5 inches by 1 5/8 inches. Pt has history of hives. Hive type rash noted on inside of right arm. Hive do not itch.

feel flushed, warm all over, itchy, and an urticarial rash appeared on her upper chest and arms.. given diphenhydramine 50mg IM x1, methylprednisolone 125mg, famotidine 20mg. felt better and all symptoms improved except for pruritis by 1715 on 12/23. discharged home from emergency room

Eye dryness progressing to neuropathic type pain localized to the face (left upper face with clear demarcation, same side as injection). At the worst, felt neuropathic pain plus ear pain. Not improved with 1g tylenol and advil. 3 hours later with no improvement, took 10mg prednisone finally offering relief.

Patient states that she started experiencing mild arm soreness shortly after receiving the vaccine. Later that evening, she stated feeling slightly fatigued. Patient states that she was Covid positive in July. She has not been around anyone with Covid recently and she has no travel history.

Nausea Vomiting Shaking Chills Arm soreness

I received the injection at 08:15 arm after hung around upon me getting ready to go elevated heart rate and pulse started to race. Then I stayed there lips started to tingle after 10 mins heart rate came down. I went back to work 1 1/2 hrs tongue was till numb and tingling. I went back to facility where I first received my vaccine. I was told to go to the ED checked blood pressure and I was offered Benadryl I declined. I dint miss any days of work.

About 10 minutes after receiving vaccine, patient reported feeling hot and not well. Patient had not eatten breakfast prior to appointment. Patient's oxygen sat was 100% but heart rate initially 42 (normal range 55-65) and blood pressure 90/60 (normal for him). Patient was diaphoretic and was given crackers and juice. Patient's symptoms continue to progress with heart rate down as low as 34. Due to progression of symptoms, patient was taken to the ER.

"Returned to Vaccine Clinic approx. 60 minutes post vaccination with generalized itching, hive-like rash on chest, arms, and legs and ""mild"" lip swelling. VS normal and stable during clinic observation. O2 Sat at 100%. Evaluated by onsite physician. Received total of 5omg diphenhydramine during observation. D/C'd in 2 hrs with less itching and resolving rash. Accompanied and driven home by friend. Spoke with EH nurse on 12/24/2020 and stated additional 50 mg diphenhydramine at home 12/23/2020. Mild, fading rash today. PLAN: will be evaluated by Allergy Clinic and if cleared, will receive 2nd dose of vaccine in Allergy Clinic."

Had headache, Temperature of 100.3 degrees F took Tylenol 650mg Temp down to 99.7 degrees F. Also experienced Nausea, No vomiting. 12/19 in the evening Temperature was 99.6F. Called Primary MD and advised to rest.

- Swollen face - headache - area of injection raised and iches and sore Txt - steroid, antihistamine

Pt reports feeling dizzy and lightheaded & flush about 30-45 mins after vaccination. Pt reports that flush feeling resolved after 30 min however the dizziness & lightheadedness persisted. Pt ate lunch and did not feel any better and reported s/s to staff v/s were taken and were stable. Pt was given water and brought to lay down for continued observation

Pt was seated and suddenly became flushed and reported a strange taste in her mouth. Vitals taken. BP 116/65, pulse 87, O2 99%. Pt given water and continued to observe. Pt reported feeling better.

Within minutes I had lower chest pain and wired sensation in my lungs. My throat was swelling. I was very hot and red. I the gurney my right arm was tingling. Opposite arm from vaccine.

Achy, fatigue, headache, sniffles, nausea and diarrhea

Patient states she was receiving her COVID vaccination today, 12/23/20, in the left arm. About 5 minutes after the vaccine was administered, patient felt left arm pain that radiated into the left shoulder. About 10 minutes after the arm/shoulder pain began, she had left anterior chest tightness. She had her blood pressure taken, which was 109/104. She states the 104 diastolic is high for her.

Lightheadedness, dizziness, patient lowered to the floor and elevated feet. Moved to a gurney, symptoms improved with pursed lipi breathing

Chills, myalgia, fever, syncope and vomiting

severe arm pain

Severe asthma attack, duration a good 5 minutes. No history of asthma. Was given inhaler.

I had severe abdominal pain that changed at a day and a half to mild abdominal pain.

Pain and stiffness in neck and shoulders, some relief with Ibuprofen Pain in right thumb , new onset, worse pain in left thumb and wrist join

Body Aches - mainly on Left side - arm and leg - muscle and joint. Arm Sore at injection site. Took Tylenol, symptoms subsided

"Pt received vaccine at 1210. At 1220 said her throat was feeling a little scratchy. She stated that it just felt like she ""needed to clear her throat"". NP was called to assist, evaluated and epinephrine 0.3ml IM was given. Benadryl 50mg and Zantac 40 mg was also given po. Pt was monitored, 9-1-1 was called and arrived in 10 minutes. Pt was sitting up, stating that it just ""feels like my throat is thick"". After EMS arrived and assessed pt, she began to ease her anxiety and stated she was feeling less tightness and felt better. Pt was observed, VSS. She denied going to the hospital stating she was feeling better so called for a ride home. EMS left and within 10 minutes she began to feel a tightening sensation in her upper chest, not in her throat this time. She said she felt the tightness again and the back of her throat was scratchy. NP evaluated, Epi 0.3ml IM was given again and 9-1-1 was called again. Upon arrival her vitals were stable, although tachycardic running 100-120 after the epi, but her breathing was not labored or difficult. EMS loaded pt and took to hospital for evaluation where she was monitored, received IV steroids for edema in the back of throat and uvula."

Pfizer-BioNTech COVID-19 Vaccine EUA Increased site redness, swelling and pain, site is warm to the touch, also rapid heartbeat.

during our covid vaccine clinic, we ended up giving 62 doses out of 60 vials. this was not realized until the end of the day when we had 2 doses left after we filled the 60 patient slots. there is apparently a small amount of overfill in the vials where 2 extra dose were able to be retrieved out of the 6 vials used. the patients did not receive a 'short dose' they received the full 0.5ml. our state told us to report the overfill via VAERS. i will inform the nurses to only draw up 10 doses per vial at our next vaccine clinic.

Fever, chills, headache, myalgias, fatigue - 5 days

Pt felt tingling sensation throughout body and was feeling SOB. Patient given IM benadryl and symptoms subsided

Symptoms started with feeling slightly faint with legs feeling weak from knees down, followed by 3 minutes of tachycardia at 130-140 BPM. Resolved without intervention; At (12/23/2020 app 23:40PM) developed periods of hot and cold, muscle aches and restlessness

20 hours after receiving developed extreme fatigue and headache. 6 hours after that developed chills, bone pain all over and nausea. That lasted about 8 hours. When chills stopped temp was 100.2. Temp relieved by aleve.

Received 2 doses of vaccine one day apart; no adverse events

throat swelling, SVT

Patient became hot, nauseous, and blotchy five minutes after vaccine administered (09430). Clinic nurses and a physician in the clinic area responded immediately: history, comfort, pulse, BP, comfortable/safe position in chair. Approximately 8-9 minutes later (0938-9), patient asked that her

personally-owned Epinephrine Auto-Injector (EpiPen) be administered, as she was unable to do so. Her symptoms were worsening and she had developed a lump in her throat. At 0940 a clinic nurse (RN) administered the EpiPen in the patient's right anterolateral thigh. Symptoms improved. 911 was called. Paramedics arrived quickly, and transported patient to Hospital Emergency Department, less than one minute away.

Received 2 doses of the vaccine one day apart; no adverse events

vomiting, fever 101

dizziness and warm feeling in chest immediately upon receiving shot

"Intense headache started around 3 p.m (vaccinated close to 11:00 a.m.). Nausea followed. Took acetaminophen before bed because of the headache. Woke up in the middle of the night with shakes and chills. Headache worse. Was hot and sweaty. Took temp, was 99. Likely low due to high acetaminophen dose. Shakes lasted for about 2-3 hours. Slept until 12:00 p.m. today. Still having some ""hot flashes"" but feel much better."

Had a weried sensation in her head during the injection. 10 min after receiving the COVID vaccine she reported not feeling well ranf had a burning sensation throughour her body. Has burining sensation on face, rash on chest , face amd arms, started to sweat, hair and uniform became wet, she was them taken to the ED. B/p 166/100 became elevated, pule rate over 100. Was prescribed benadryl, epipen, prednisone. Next day felt better, had some itching rach under her breast and have light headaches. Taking prescribed medicine including Benadryl

Extreme body aches high fever chills nausea Extreme weakness. Felt like I was dying. Probably the sickest I've ever felt.

woke up with low grade fever 99.4, nausea, headache, injection site pain (continuously since injection), chills, tierdness

Experienced syncope after receiving vaccine injection. Clinical Assessment Team called but declined going to emergency department.

Approximately 5 minutes after vaccination, patient became diaphoretic and warm/flushed. Complained of nausea and had one episode of emesis. Patient given 50mg of diphenhydramine orally.

Fever and chills noted day after administration. Fever of 101.2 on 12/23 at 14:25 and returned to baseline at 12/23 19:03.

5:30 Chills, fever to 102, Tx with Tylenol. GI Upset, diarrhea. 11PM Difficulty sleeping; GI upset, LOC x2. Pallor. Transport to ER via ambulance. Treated with IVs, Zofran, toradol

Developed tremor, dizziness, and chills almost immediately after vaccine. She developed hives to her chest approximately 30 mins after the vaccine was given. She did get IM benadryl in the office which

resolved the hives. She was transported to the hospital via ambulance as the dizziness and tremor worsened over the time she was in the clinic. She was discharged from ER the same day.

My heart was racing, I was light headed and dizzy with 6 episodes for about an hour.

Employee received 1rt dose of COVID-19 vaccine on dec,16, 2020, two days later she developed rash at the chest, arms, swelling at Rt eye, and skin lessions on posterior aspect of thigh, legs.

Hives on wrists, under arms, groin and penis

Vomiting 5 minutes after inject.

Patient awoke at 2 am and felt like she could not breathe. felt hot, tight, and severely weak. Had chills and shaking. No fever. Patient was transported by ambulance, observed in the Emergency department until 5 am and discharged home. Patient received oral acetaminophen in the ED.

Unable to move left arm in any direction for 24 hours.

Mild itching began around injection site within 5 minutes of receiving vaccine then resolved. After another 20 minutes, mild itching noted on hand, forearms, stomach, leg (not all at the same time). Itching resolves after scratching then starts up in a new location minutes later. Itching still ongoing 24 hours after vaccination.

Developed redness, induration, warmth to touch at injection site

Fatigue, weakness in legs and arms, fever of 102.2 , tiredness, stuffy nose, headache, chills, and hot flashes with burning sensation of lips.

15-20 minutes after injection felt sore in neck and lower back; few hours later body aches, lightheaded and fatigue. Symptoms remain the same today 12/ 24/2020

INITIAL SITE PAIN FOLLOWED BY LOCALIZED ITCHING AND HIVES (30 MINUTES AFTER VACCINE). HIVES AND ITCHING SPREAD TO BILATERAL ARMS , TRUNK, NECK, AND FACE (60 MINUTES AFTER VACCINE) AND CONTINUED TO GET WORSE (90+ MINUTES AFTER VACCINE). ORAL LORATADINE TAKEN AT INITIAL ONSET OF SYMPTOMS. IV SOLUMEDEROL, BENADRYL, AND PEPCID GIVEN APROX 2 HOURS AFTER ONSET OF SYMPTOMS. SYMPTOMS HAD MOSTLY RESOLVED APROX 60 MINUTES AFTER IV MEDICATIONS. HIVES AND ITCHING RETURNED WITH FEVER/CHILLS APROX 0300, 50MG ORAL BENADRYL TAKEN AND RESOLVED SYMPTOMS.

Left-arm pain, axillary pain, and inflammation shooting down to left hand left side neck swelling, pain, shooting to the left side of the head.

Fever 100.2, taking Tylenol and GI upset post COVID vaccine 12/16/2020, resolution of symptoms in 3 days

First felt nauseous at 1103. Was moved to area where patient was able to lay down. At 1119 blood pressure was 139/78, pox 99 and HR 84. At 1124 sat up and was given diphenhydramine 25mg solution.

At 1144 was able to stand without any change in symptoms. Blood pressure, pulse ox and heart rate were monitored throughout and remained normal.

Patient had hives on right side of neck to the nape of neck, bilateral elbow creases, bottoms of bilateral feet. Redness and swelling of mouth. Patient was prescribed 80mg Depo-Medrol IM, 50 mg Benedryl IM, and sent out with 6 day Medrol Dose pack with OTC benedryl and pepcid.

Nausea, vomiting and light headed

Right after injection on 12/16, the employee developed rash, hot flush on the chest. Was sent to the ER for monitoring. Took Benadryl 50mg at home at 1500. Another rash appeared on her face at 2200, took another Benadryl 25mg. On 12/18 at 0430, she developed chills, fever of 101.7, and body aches. Took Motrin and Tylenol, continued to have low grade temperature on Saturday. No more symptoms on Sunday.

after receiving the covid vaccine 12/22/2020 in the observation area began to feel flushed in the face and head rushing, given PO Benadryl 25 mg by OBS nurse and monitored.

I received the vaccine at 11:15 am and felt fine all day, began coming down with chills, fever, body aches and headache and slightly stuffy nose about 9-10 pm that night. It is still lasting throughout today, the next day and I called off of work. Currently have a fever of 99.6, highest fever was 100.6. F.

Employee received vaccine at 1100. At 1400, rash developed on the chest and tongue and lips were swollen. Took Benadryl 25mg and symptoms resolved.

Pfizer-BioNTech COVID-19 Vaccine EUA initial IM caused intense pain at site, then through evening into night pain radiated to shoulder and neck, experienced sweats/chills during night, site swollen but not red, recovered next day but exhausted.

Day #1- Minimal Localized Right Deltoid Soreness Day #2 12-24 hours post-vaccination- Myalgias, Affected Arm Lymphalgia in axilla, Fatigue, Elevated Temperature to 100.1 despite Acetaminophen and Ibuprophen. Night sweats, worsening myalgia throughout night. Would not have been able to go to work and perform duties (fortunately did not have to work this day or the next) Day #3- Symptoms improving-still myalgias, fatigue, mild-moderate right axillary lymphalgia.

Vomiting X 3 12/24/2020

Headaches from 12/22/20-12/24/20 Nausea from 12/22/20- currently

45 mins post vaccination patient experienced severe dizziness, nausea, extreme vomiting, headache behind eyes, tachycardia (bpm 120), elevated BP (190/120), PVCs. Patient was an on-duty EMT and received Zofran and Benadryl in the ambulance. Patient presented to Emergency Room and received fluid bolus, acetaminophen, and metoclopramide. Symptoms resolved within an hour but some residual nausea existed 24 hours later.

Pfizer-BioNTech COVID-19 Vaccine Tingling from injection site to mid forearm

Tachycardia, muscle aches, fever.

"Pt states had some dizziness about 1/2 hr after Immunization Then started to have like a lump in throat- ""Frog in throat"" Provider ordered IV and NS with 25mg Benadryl PO Pt had no other complaints was transferred to ER per Emergency provider consult"

Arm started to be sore early afternoon after receiving the vaccine that morning. By that night, redness around the injection site started. This was about quarter size. The area was sore to touch., The next day I experienced generalized malaise and muscle aches. It is now 6 days post injection and I still have redness quarter size/half dollar size around injection site, but the redness has faded some.

c/o lip tingling, neck pain, & LLE heaviness x 30 mins

1915: associate had left facility, associate started feeling generalized itchiness. Associate took a dose of Zyrtec. Associate states she woke up feeling body aches that Saturday and Sunday. Itchiness had resolved. As of Monday morning, all symptoms had resolved.

Itchy arms, back, legs Noticed rash on bilateral arms, legs, and lower back

The employee received the vaccine on 12/17 at 0922. On 12/18 at 0200, he developed severe headache. At 0800, he started vomiting and had nausea until the evening. After the nausea/vomiting stopped, he took medications for headache. All symptoms were gone by 12/20 at 0200.

at 8:40 am patient felt dizzy and flushed, she asked for extra attention and indicated she felt embarrassed, but denied difficulty breathing, no trouble speaking in full sentences, no rash, no change of vision; BP was 158/108 with pulse of 95 and then patient was brought to a more quiet area and seated in a wheelchair. She was able to ambulate, a nd speak normally, but she said she felt very strange and shaky. she was visibly tremulous. She was seated, and vitals reassessed and her shakiness increased and she felt panicky. She was taken by stretcher to the Emergency room for further observation . in the emergency room, her symptoms gradually subsided. She was able to return to work after an hour of observation.

Palpitations with HR of 120 within 5 minutes after receiving the vaccine. Wheeled to the ER for further evaluation. Dizziness and high BP. Was given Benadryl, Pepcid and Solu-Medrol and a liter of NS. Discharged after 2 hours with Benadryl and Prednisone prescribed for home meds.

Moderna COVID-19 Vaccine Developed some blotchy bruising on the bottom half of both legs within 12 hours of receiving the vaccine

About 6 hours after injection, injection site pain worsened. This continued to worsen until about 48H post-injection. About 30 hours from injection, experienced aches and feverish feeling without elevated temperature. Aches primarily in joints of hands, feet, knees, back pain, neck stiffness.

Pfizer-BioNTech COVID-19 Vaccine Dizziness, headache, generalized tingling. No reactions to vaccines in the past. Rapid response called, BP 187/104, O2 sat 100% on Room Air. nauseous, vomited 2-3 times. admitted to ER, discharged 3 hrs later, BP normal 122/73

Started with sore arm and progressed to fever up to 103.0, chills, vomiting, body and joint aches.

Eyelids are itchy, neck itchy.

I had a fair amount of pain at the injection site, by night time I had crackling in my lungs and weezing and a low grade temparture.

Injection site sensitivity, unable to have anything on my arm without significant pain. Movement of any kind of my left arm, even wiggling a finger, cause significant pain radiating throughout my entire left arm

Received the vaccine on 12/18 and 1820. She developed lip swelling for 24 hours. Took Benadryl and the swelling resolved after 24 hours. No other side effects.

Pfizer-BioNTech COVID-19 Vaccine EUA metallic taste

- Received Vaccine 1045 AM 12/19 - Sore arm at injection site started later that day and persisted - On morning of 12/21 I had a mild headache, and by mid day had some muscle aches - Night of 12/21 could not get rid of fever, sweats, chills, muscle aches, headache - Symptoms persisted, and decided this may be something else as well - Tested positive for covid on 12/23 (got results today 12/24)

At 8:55am individual reported a tingling sensation down the right side of face radiating down to upper deltoid/arm area. Individual described the sensation as a feeling of pins & needles. At 9:10 individual reported the symptom was gone. At 9:12am Blood Pressure 120/76, Pulse 90 and Respirations 20. Blood Pressure and Pulse taken using an automatic machine using the left arm.

Pfizer-BioNTech COVID-19 EUA metallic taste in back of mouth

On 12/22:First noticed roof of mouth started to itch, back of throat itching, difficult to swallow, noticed hives on chest/torso, difficult breathing, wanted to vomit, close to fainting. Hives around injection site. Placed on gurney and sent to ER. In ER given epi-pen injection, benadryl injection, albuterol, pepcid, toradol, solu-medrol and observed for 4 to 5 hours. On 12/23: Hives still present, injection site has two large bruises on arm; arm in swollen down to elbow. Broke out in hives on chest and face. Re-evaluated in ER.

EE c/o pruritic rash on trunk and peeling of skin on hands

Patient developed face and periorbital swelling 3 days after receiving covid vaccine. Swelling continued next day, responding to antihistamine treatment

30 min after dose felt like my tongue was getting thicker, neck and throat felt tight, tingling around upper gum line near front teeth. Slight numbness in skin around upper mouth. Difficulty swallowing for

five hrs post dose and I took 50mg of Benadryl at 730pm when I got to my car. Swelling in throat and back of mouth remained same from 530-730, gradually noticed improvement at 1015 pm

Within an hour and half I started to experience Dry Mouth and Nausea, later that day my Lymph nodes in my neck/jaw were Swollen and I had a Runny nose and Cough. By the evening I was experiencing Body Aches, Chills, Headache, and Fatigue.

"REQUESTED BY THIS WRITER PRIOR TO INJECTION FOR HEALTH TO RECORD PROCEDURE ON PERSONAL CELLPHONE. INJECTION GIVEN TO RIGHT DELTOID. LESS THAN 1 HOUR APPROXIMATELY 3:50PM TINGLING, PINCHING FEELING TO RIGHT HAND BEGAN THEN NUMBNESS STARTED TO RIGHT ARM FOLLOWED BY SAME SENSATION ON RIGHT LOWER EXTREMITY. MEDICINE CUP STARTED TO FEEL HEAVY AND I WASNT ABLE TO WALK CORRECTLY (LIMPING). HEALTH VERBALIZED ""TO CONTINUE MONITORING YOURSELF WHILE WORKING"". APPROXIMATELY 4:35PM NUMBNESS IS FELT TO RIGHT SIDE OF FACE, FACIAL DROOPING VISUALLY SEEN ON RIGHT SIDE OF FACE. ADVISED HEALTH TO GO TO ER. HEALTH DROVE THIS WRITER TO THE ER"

Swelling and hard lump around injection site, I noticed it about 24 hours after the injection and it remains approx. 45 hours after the injection. The arm of the injection site has hurt since about an hour after the shot. I noticed some slight dizziness about 20 minutes after the shot but that was gone within about 10 minutes. I woke up with some congestion the morning after the shot.

Pain and swelling at injection site and radiating into shoulder, extreme fatigue and tiredness, headaches, dizziness and nausea. Overall feeling of maliase

Approximately 48 hours after receiving injection she began developing papular, erythematous rash to left arm spread throughout the day. Following day same rash description occurred to right arm. Papules clustered to left posterior leg, faint to anterior legs, anterior superior chest.

12/22 7 pm, severe leg cramps; 12/23 7 am: diarrhea, abdominal pain. noon: nausea requiring medication; 5 pm, shaking chills, normal temperature. 9 pm: bloody diarrhea, and what looked more like sloughing nonpigmented tissue rather than stool, continued abdominal pain. Woke with diarrhea and pain 1 am. This morning, frequent stool and moderate abdominal pain. No chills. Recovered from diverticulitis around 12/3, scheduled for colonoscopy 1/6/21 and probably colectomy 1/8/2021.

When I filled out visage I put the wrong brand of vaccine and need to change it.

Pain and slight swelling in left arm at injection site with pain upon movement and touching site, muscle aches all over body, severe pounding headache/migraine, fever up to 101¦ 12/24/2020 at 11:00 am, first fever at 100.3¦ at 3:14 am 12/24/2020, tachycardia at 164 bpm at 3:30 am 12/24/2020, tachycardia into high 120s with walking 12/24/2020 around 10 am 12/24/2020, chills, light sensitivity, weakness when fever spikes, and overall malaise.

Itchy rash on the torso

On 12/22/20 I began to feel fatigued and sore arm at 1900. By 2330 on 12/22/20 my left arm was hurting down to my fingertips and extremely painful. I took 2 325 mg Tylenol and went to sleep. I tried sleeping but felt like my heart was coming out of my chest. I checked my Heartrate and it was between 100-120. I could not sleep all night. My left arm was so painful that I could not sleep on it or lift it above the level of my heart. On 12/23/20 I was very fatigued. I went about my day but was not feeling well. By 1900 on 12/23/20 I was running a low grade fever 99.9 and felt terrible. I took 2 325mg Tylenol and 2 200mg ibuprofen to help with the pain. I went to sleep and woke feeling better.

Physician called to report an adverse reaction to the COVID-19 vaccine. Patient had a 6.5 cm x 6.5 cm reaction at her injection site. This included erythema, warmth, and swelling. The patient also reported chills. Patient's O2 saturation measured at 80% a few hours after the vaccination. Patient received a liter of oxygen on Saturday and Sunday. Patient was tested for COVID-19 and had a negative result. On Monday and Tuesday, patient was given 25mg of oral diphenhydramine as the injection site had not improved. Patient has a mild history of asthma, but is not currently taking any medications for that condition.

ARM EXTREMELY SWOLLEN; SHE SPIKED A HIGH FEVER OVERNIGHT; LOT OF REDNESS AT INJECTION SITE NO TREATMENT SOUGHT

I developed fever and chills and headach for 2 nights now my fever was a 102.3 lasted at least 6-8 hours had Pfizer-bioNTech COVID-19vaccine

Pfizer-BioNTech COVID-19 Vaccine EUA reported headache that she did not have prior to injection

Pfizer-BioNTech COVID-19 Vaccine reported headache that she did not have prior to injection

Severe total body muscle ache, fatigue,chills lasting about 40 hours after vaccine. Inabilty to lift left arm more than 45 degrees due to severity of arm pain. Improving

bumps on wrists with loss of hair, itchiness

Pfizer-BioNTech COVID-19 Vaccine EUA metallic taste, relieved after drinking water

Woke up with onset of left sided facial weakness, paralysis, and numbness around 0600. Was evaluated in the ER and diagnosed with Bell?s Palsy.

initial fatigue, chills. After 24 hours, extreme fatigue, lips tingled, went to bed. In am, about40 hours after vaccination developed swollen upper lip and swollen armpit on side where she was vaccinated.

None stated.

None stated.

None stated.

None stated.

None stated.

None stated.

None stated.

None stated.

None stated.

Treatment dugs:

Treatment dugs:

Treatment dugs:

Treatment dugs:

Treatment dugs:

None stated.

None stated.

None stated.

None stated.

None stated.

None stated.

None stated.

None stated.

None stated.

Resolved. Treatment dugs:

Phone call

phone call Treatment drugs:

Headache started AM of 12/23/20; Body aches started 1100 12/23/20; lymph node discomfort, same arm as vaccine, early AM 12/24/20; Alternating Tylenol, naproxyn and rest helps. Once meds wear off, symptoms return.

body aches, fever 100.5 oral, cough, upset stomach

Complaints of warm sensation on her throat @ 10:15 am. VS bp 165/77, Pulse 136, O2 sat 99%. 10:30 BP 133/96, Pulse 121 O2 sat 100% Had sips of water and tolerated well 10:40 complaining of warm sensation to the left side of body. Send to ED for further evaluation accompanied by an RN

Fever malaise headache tired slightly dizzy

None stated.

3-5 minutes following administration of vaccine patient experienced itching and swelling of upper lip, swelling of mouth, rash bilateral arms. Benadryl 50mg intramuscular was administered and additional 30 minutes of observation conducted. ER referral was offered to the patient, she declined. B/P 135/82 and HR 85 at time of check out.

nose bleed after injection

Headache,muscle ache,injection site pain, tiredness, chills,joint pain, feeling unwell.

I start to have allergic rashes on random places on my body. I need to take benedryl to stop the itchiness for the past 2 days and ongoing. It appears off and on.

Patient reported a headache and some itching.

Lightheadedness and palpitation

Swollen lymph node

Once I received the vaccine 2 secs immediately started feeling flushed , blood rush going up to face, heart beat more rapid, and exp difficulty breathing. I spoke with staff was taken for a observation area and had a EKG. While being observed after 5 mins felt as if I couldn't breathe. Around the 5 of 10 mins mark started feeling better and at 10 mins felt totally fine.

Headache Fatigue

I?m having sore muscles, joints pain, headache, reduced tasting, fatigue, nose congestion, sore throat, heavy chest, and facial swelling. It?s been like this since I got my shot.

"Pfizer-BioNTech Covid 19 Vaccine: Patient reports ""indescribable"" muscle pain beginning almost exactly 4 hours after vaccination which has persisted until time of this report (day 7). She notes minimal pain at injection site. Has had no fever, no nausea/vomiting/diarrhea. She states that her entire body hurts, including hair, teeth, toenails, and fingernails - she describes as throbbing pain. She also reports pain in back and thoracic muscles to the extent that she cannot bend down to put on shoes. She notes that the back pain was not initially present but started around day 5 (12/22/20). She describes this as muscle pain and does not have visceral pain. She reports some relief with acetaminophen and ibuprofen. She also describes alternating episodes of feeling ""freezing cold"" with shaking chills followed by profuse diaphoresis (describes sweat as pooling and dripping). Acetaminophen and ibuprofen have not relieved or lessened the episodes of chills and sweats."

Pt felt rush of warmth throughout body immediately after vaccine administered. About 30 minutes later, he felt itchiness at the back of his throat. Pt was accompanied to ER , where he received solumederol 125 mg, pepcid 20 mg and benadryl 50 mg IV. Pt symptoms resolved post medication.

Very mild, but unexpected nose bloody nose from left nostril. Only noted when blowing nose. With 1 clot.

Had sore throat, itchy throat, cough, running nose and shortness of breath started yesterday. But shortness of breath has gone away this morning. Anything she need to do?

Headache, Body aches, nausea

Pfizer-BioNTech COVID-19 Vaccine EUA ~30 minutes post injection developed bilateral visual disturbance best described as an aura (shiny waves) in my inferior visual fields. No associated migraine/HA, photophobia, N/V, etc. This lasted for ~ 2 hours, did NOT hinder my day-to-day activities that day.

Pfizer-BioNTech COVID-19 Vaccine 4 minutes after the injection, my heart felt like it skipped a beat and my heart rate raised to 110. I thought this was related to anxiety of getting the vaccine. My heart rate went back down to 84 within a minute. Then I felt fine, just tired so I did not report this feeling to anyone at the time. 25 minutes after receiving the vaccine, my Heart rate raised to 139-145, felt dizzy, numbness of nose and upper lip. Was in transit when this occurred. Pulled into a parking lot and rested. Heart rate decreased to 96. I called family to come pick me up. On the way hame I continued to feel tired and dizzy but my heart rate decreased to 96. By 11:45, I felt better just continued to be tired. Been working overtime so I was already feeling tired before receiving the vaccine.

patient was vaccinated at approximately 12:40 and began having an itchy face and itch throat at 1:30. Patient is breastfeeding and decided she was going to pump and toss her milk due to getting vaccine. When pumping she noticed that her milk was blue in color. Today patient is feeling achy, joint and legs week. States she feels like when she had COVID in July.

Nausea and tingling sensation in both legs

About 6am morning of 12/24 Dizziness , vertigo, extreme fatigue, nausea and vomiting (3 times) injection site pain May go to ER if condition gets worst or unable to keep anything down. Took zofran twice but has since thrown it up

Developed chills, fever 100.6, achy, nausea, hurt to move several days, sleepiness, fatigue, achy joints. Fever broke 12/19/20. 1/20/20 fever 99.3. 12/24/20 Working but still fatigued.

day after the vaccine, her arm started to hurt, the pain is radiating to the back. Fatigue Headache congestion cough weakness

Left sided facial numbness (ear, oracle, earlobe, cheek, jaw).Timeframe going on 25 hours and not yet resolved.

On administering Pfizer-BioNTech COVID-19 Vaccine 12/15/20 at 9:15 PM to recipient staff member, vaccinator did not dilute vial and administered undiluted vaccine, resulting in an estimated 5 -fold increase over the intended dose and at an increased concentration. The error was nearly immediately recognized and disclosed to the recipient staff member. They were observed for adverse reactions and before leaving the clinic they were counseled to immediately report and seek medical attention for any serious signs or symptoms. A follow up phone call was made the following morning 12/16/20 with soreness at the injection site being the only reported reaction. They returned to work on 12/17/20 with no additional reported signs or symptoms.

Rash, hives and redness, and swelling of the arms that soon improved with benadryl

Dizziness, light headedness, feeling faint. Lasted 1 day. Better with food and water, Tylenol and Ibuprofen alternating every 4 hours, rest.

The morning after the vaccine I had a sore arm, severe headache, 120 HR and felt achy all over. I took tylenol and felt a little better. Sunday my eye irritation began in the right eye. The right eye was hurting, had a little drainage and was severely swollen. Conjuctivitis set up in the right eye and the right side of my head hurted really bad with the right eye area throbbing. Contacted my PCP who prescribed eye drops for me. My eye is still a little swollen and my head still feels really strange and still hurts a little on the right side. I have consulted with the NP and the PCP who is currently monitoring the situation

90 minutes post injection experienced numbness and tingling in all extremities lasting 1 hour. Resolved in all extremities except left arm. Left arm pain radiating from shoulder to forearm became severe. She sought treatment 12/23/2020 PM at a hospital emergency room where she received IV fluids and IV Toradol. On 12/24/2020 the pain persists but has improved with continued Ibuprofen 600mg every 6 hours and a sling for support.

It started with itching hands and feet and then spread over my whole body. It all turned red. I had shaking.

Patient had an elevated temperature.

Soreness in injection site, headache, and tiredness.

1300: Pain to L upper arm 1400: increasing pain to L upper arm 1600: increasing pain from shoulder to elbow 1630: face feels hot, mild sweating, temp of 100.3 1700: fatigue, exhaustion; pain in L arm extends to forearm, pain with lifting L arm 2000: rotating between episodes of chills and sweating 0700 on 12/24/20: continued fatigue; no longer have chills/sweating/fever; significant decrease to L arm pain

12/18/2020: COVID19 vaccine received. 12/19/2020: Patient noticed petechiae/bruising on arms, legs and face. Worsened over next 48 hours. 12/21/2020: Patient had blood drawn (CMP, PT/INR, CBC) at lab. 12/22/2020: Labs resulted; CMP and PT/INR WNL (exceptions: SCr 1.24, TBil 1.7); CBC with platelet count of 1,000 resulting in patient admission to Hospital. At admission he received 80 mg of prednisone, 40 g of IV Ig and a unit of platelets. 12/23/2020: Continued hospitalization. Patient's platelets improved to 20,000 and he received another 35g of IV Ig. 12/24/2020: Patient discharged with platelets of 38,000.

sore arm at injection site, fatugue, general malaise, neck soreness on side of injection

None stated.

Pt c/o lightheaded, elevated BP 180/98. Pt was seated, given snack and water. Felt betterand was discharged 20 minutes later

Chills Fatigue Muscle soreness

Five minutes after the shot she had trouble swallowing her saliva. Dry Cough Tight Lungs

He was fine ate lunch, in a room with a patient, felt light headed and dizziness, passed out, he became unresponsive, he was hypotensive, he is now in the ER.

About 12 hours after receiving the vaccine, I felt weak, achy, and quite dizzy. I awoke approximately 20 hours after receiving the vaccine with a 101 degree fever, worsened body aches, soreness at site of injection, and increased dizziness.

Left infraclavicular and supraclavicular lymphadenopathy, severe myalgias, local injection site swelling and pain. Patient was diagnosed with COVID-19 on September 28, 2020 and was 87 days after diagnosis at the time of vaccine.

After a few minutes tingling in arms, anxious, tongue felt funny. Lasted 10 minutes. Prior medical history of panic attacks. Normal vital signs , verbal felt better sent to the ED for observation

Lightheadedness

EE states that she started feeling dizzy and fatigued but it quickly resolved. Today, 12/24/2020 at 1:20pm EE states that she was driving and started having chest pains, sternum area, pain 3 out 10, the pain comes and goes, it happens when she is moving and resting, when asked about other symptoms, EE states that the chest pain is her only symptom at this time, tested negative for Covid, no travel history. I advised the EE to go to the ER immediately for further evaluation. The EE stated that she prefers to go the Urgent Care.

Pt was dizzy became nausea, and developed a headache. BP was163/105. She was obcerved for almost an hour and then had dry heaves. She was sent to Er for further treatment and observation

10 hours after shot, back pain started then body aches and chills. Fell asleep then woke up feeling like I was on fire but not sweating. Body aches continued through the night. Took Tylenol at 945pm and again at 845am. I went back to sleep and by 1130am I only had a mild headache.

Around 8:00 pm on 12/23/2020, I began to experience headache, fatigue, soreness at injection of site, and nausea. Over the next hour, the headache and nausea intensified dramatically, and at around 9:00 pm, I vomited.

Approximately 20-25 minutes after the vaccine my lips and tip of my tongue started tingling, then approximately 20 minutes after that my nose and forehead started to feel numb. I was instructed to

take Benadryl and come into be observed. The tingling sensation decreased a little after a few hours but continued throughout the night. The numbness of nose and forehead went away later that evening around 9. When I woke up the next morning the tingling sensation of my lips was gone but then returned later in the morning around 11. Breathing and airway were not impaired.

Low grade fever, chills, body aches, sore arm.

It all happened next day when I woke up. My both hands were swollen, swelling went for four days in my hands, now its better, I was nauseated, and had joint pain, it first started on my left ankle I had pain in the joint, next day and still going I have pain in both my joints in the legs, for for four days I had headache but as I was reading that's normal it was controlled with Advil and now feels better. Only joint pain still going but its not something that its terrible pain its just there. I started wearing compression socks hopping that will help.

Patient vaccinated at Nursing home. Transferred to ER the following day when patient developed fever and altered mental status. Found to have acute kidney injury on chronic kidney disease, hyperkalemia. Required emergent hemodialysis for hyperkalemia with ECG findings of peaked T waves.

44 y F referred to clinic after allergic response to COVID vaccine this afternoon. Pt received dose of covid vaccine at 1713. at 1723 pt c/o itching R wrist and neck. 3 small reddened areas noted. Vaccine hypersensitivity protocol initiated; RRT initiated. Allergic reaction to COVID vaccine-pruritic hives without angioedema-resolved with Benadryl

Approx. 35 minutes after the injection Heavy feeling s in his body and light headed. New funny taste. PMH hypertension. No itching no rash no SOB normal VitalS igns . Sent to ED observed and released

2 hour 30 min after injection severe pain radiating down left arm from shoulder to forearm, unable to raise left arm. Persists through 12/24/2020. Acetaminophen start at midnight every 6 hours without relief. Pain exacerbated with any movement of left arm. Injection site high up on upper arm close to shoulder.

pt started having headache and body aches first, then fever 100.6 and chills and a red face

FULLNESS IN THROAT PERI ORIAL NUMBNESS CHEST TIGHTNESS PRESSURE IN CHEST PATIENT WAS GIVEN EPI PEN , TRANSPORTED TO ED DEPARTMENT IMMEDIATELY

Difficulty breathing, palpitations, feeling like she is developing hives

Pfizer-BioNTech COVID-19 Vaccine Slight headache on the morning of 12/22/2020, and feeling exhausted. These two symptoms persisted during the day but did not get worse. In the early morning of 12/23/2020, the headache was worse, I had chills and my fever was 102.1. I was very dizzy at the time when getting up. I took Tylenol and ibuprofen, alternating, to help with the headache and fever. On 12/24/2020, I still have a slight fever of 100.4 but symptoms are getting better.

Pfizer-BioNTech COVID-19 Vaccine Slight headache on the morning of 12/22/2020, and feeling exhausted. These two symptoms persisted during the day but did not get worse. In the early morning of 12/23/2020, the headache was worse, I had chills and my fever was 102.1. I was very dizzy at the time when getting up. I took Tylenol and ibuprofen, alternating, to help with the headache and fever. On 12/24/2020, I still have a slight fever of 100.4 but symptoms are getting better.

Low grade fever, chills, fatigue, headache

99.4 fever, headache, body aches, injection site inflamed , red and a hematoma. Aches especially in my neck

Fatigue, nasal drainage, no treatment, resolved

Parasthesia in left arm within 5 minutes of vaccination. Parasthesia radiated into fingers (tingling but not painful). Parasthesia in left arm resolved in about 1 hour with no treatment. Parasthesia in tongue within 5 minutes of vaccination. Parasthesia in tongue (tingling but not painful) lasted through the evening (~5 hours). Resolved without treatment. Heartbeat increased (bounding heartbeat) onset within 5 minutes of vaccination; resolved within 5 additional minutes with no treatment.

Was scheduled for 3:10 yesterday and received it at 3:25 ish. Did fine at first ? a little flushing/burning around neck and chest about 35 minutes after but then around 10:00 pm I had a full on inflammatory response throughout the entire body. Thankfully it was evening/bedtime but it was an awful night with significant pain everywhere with any kind of movement. Mild headache that has been intermittent. I wouldn?t call it true chest pain but did have intermittent, weird stabbing pains in chest at times. I dosed up on gallons of water and Tylenol and certainly felt better by around 7:00 a.m. but if that was my response to round one I am hesitant to go back for seconds.

The first 5 mins felt dizzy like small fainting I started relaxed. I went home took shower I had a mild fever took Tylenol. The next day some headache and weakness. On day 2 mildness and weakness again. Then on day 3 fever and weakness was almost gone and headache is sill there.

it really started on the 21st when I felt fatigue, wiped out ,runny nose, sore throat, and now I have a dry cough and I still feel it today 12/24/2020, I went to the dr on the 21st and they did not prescribe anything to me

patient felt SOB, coughing and having sensation as if something was in her throat. Epinephrine epi-pen administered VS 130/70 HR 106, O2 Sat = 99% after epi administration

After 15-20 minutes of receiving the vaccine I began to have tingling in my lips that felt almost numbing but not quite. This progressed into my mouth with the slight swelling of my tongue and lips. I had incredibly dry mouth as well. Felt very thirsty. I was given a Zyrtec (10mg I think). Swelling and numbness never progressed into anything serious, could swallow and speak fine. Did develop a small rash on my forehead that went away about an hour after the Zyrtec. 30 minutes after taking the Zyrtec the tingling and swelling in my mouth and lips subsided. Around 7pm my cheeks and face felt tingly so as recommended I took a benadryl. In the morning all symptoms were non existent.

1) rigors without fever; 2) severe HA. These both lasted approximately 6 hours.

numbness and tingling in both hands. after 5 minutes it spread to her body, tongue and lips. Maybe after an hour, left side of face was numb for a little while. Today, feel ok, except left hand still feels the same.

""""Moderna COVID-19 Vaccine EUA""; patient reported jaw and throat area felt numb approximately 30 min following vaccine. Patient vital signs were taken and patient was monitored the entire time: BP and heart rate readings: 140/89, HR 64; 126/85, HR 73; 136/99, HR 69; 139/94, HR 68; 100% pulse oximetry all readings, each approximately every 10 min. Patient stated she was not getting better, but able to speak. EMS was called and arrived; patient was taken to hospital."

Headache and nausea after 15 mins of vaccine. Headache lasted all day, even with taken 1000mg of Tylenol. On 12/23/2020 around 7:30 PM my left arm was extremely sensitive and sore. I could not lay on the arm or touch it. Very hard. This morning when I woke, I had ability to move the arm slightly more than day before. Now my arm is hard and injection sight is red measuring 3 inches wide and 1 inch long. It hurts to touch the upper arm. I cannot stretch my arm all the way or rotate it as normal.

Patient is a 47 y.o. female who arrived by Car presented to the emergency department for Stroke symptoms. Patient awoke at 6:15 this morning, some difficulty seeing out of the right eye and also was stumbling towards the left and to table. Concerned about things not being right so brought to the emergency department. Patient feels her speaking and swallowing are okay. She did drink a bit of coffee earlier. She denies headache or significant vision problems presently. Continues to not feel normal on her left side. No history of stroke and parents or siblings. She does give personal history of an occipital migraine many years ago at which time she did not have a headache but had some vision troubles. Physical Exam Vitals signs and nursing note reviewed. Constitutional: General: She is not in acute distress. Appearance: She is not ill-appearing or diaphoretic. HENT: Head: Normocephalic and atraumatic. Right Ear: Tympanic membrane normal. Left Ear: Tympanic membrane normal. Nose: Nose normal. Mouth/Throat: Mouth: Mucous membranes are moist. Pharynx: No oropharyngeal exudate or posterior oropharyngeal erythema. Eyes: Conjunctiva/sclera: Conjunctivae normal. Pupils: Pupils are equal, round, and reactive to light. Comments: Patient displays absence of left lateral movement Neck: Musculoskeletal: Normal range of motion. No muscular tenderness. Cardiovascular: Rate and Rhythm: Normal rate and regular rhythm. Heart sounds: No murmur. Pulmonary: Effort: Pulmonary effort is normal. Breath sounds: Normal breath sounds. Abdominal: General: Bowel sounds are normal. There is no distension. Palpations: Abdomen is soft. Tenderness: There is no abdominal tenderness. Musculoskeletal: Right lower leg: No edema. Left lower leg: No edema. Lymphadenopathy: Cervical: No cervical adenopathy. Skin: Findings: No rash. Neurological: Mental Status: She is alert. Cranial Nerves: Cranial nerve deficit (left facial droop, dysarthria) present. Comments: Patient's speech seems a bit slurred to me. Absence of ocular movements towards left noted as well as upward movements. Tongue is midline. Patient is unable to shrug the left shoulder or lift the left arm off the bed. Grip strength is 4 out of 5 on the left. Left leg strength is 3 out of 5. Extremity strength on right arm and leg is 5 out of 5. After consultation with a neurologist, the patient is being transferred from the ED.

This resident received the first dose of the Pfizer Covid vaccine at the Covid vaccine clinic at medical Facility. He had a rapid response, experienced low blood glucose and low heart rate. NP and medical director were in attendance. Heart rate remained low despite all measures. He was transferred to Hospital for bradycardia.

numbness soon after vaccine, as the day progressed difficult elevate left arm, resolved by next morning

Febrile 101.3F, body aches and chills.

She got very light headed immediately after vaccine was given. We had her sit and gave her a cold ice pack and bottle of water. I went to get her crackers as she said she didn't eat much today and when I got back from grabbing crackers my intern was attending to her and she ended up throwing up. She continued to throw up and still felt lightheaded for about 20 minutes. I monitored her and she ate a few crackers and had more water and then she started feeling better. No medical treatment was needed. Continue to monitor for remainder of 30 minutes after vaccine.

Patient was very anxious about getting her vaccination. After a couple minutes of receiving the vaccine, the patient went to stand up from the chair she was vaccinated in and became light headed. She then put her head on the table and began shaking. She was safely lowered to the floor and placed on her back. 911 was called and paramedics arrived within 10 minutes. The patient was lucid and responsive, but breathing quickly and shaking. She was taken to the hospital by paramedics and discharged shortly after arriving.

WHEEZING SHORTNESS OF BREATH FULLNESS IN THROAT RAPID PULSE PT WAS GIVEN ALBUTEROL, EPI PEN, TRANSPORTED TO ED DEPARTMENT

Five minutes after receiving the vaccine I started feeling slight nausea, which got progressively worse, started feeling lightheaded and had to sit down at about minute 6, at 7 minutes a clinical assessment team was called because I was feeling like I was about to pass out. Everything seemed far away and removed and sound distorted/muffled , I was extremely nauseated, lightheaded and extremely thirsty and was seeing ?spots? in my vision. When the team arrived only a minute or so later, they checked my vital signs and found that my blood pressure was low, at 89 for systolic, with my normal systolic being 120-130.. I got very pale all over and my arms and especially fingers became weak, numb and tingly, the left arm more than the right. I was told I had a vasovagal response and also that I was expelling too much CO 2 because I had been hyperventilating. I was monitored and given po fluids for about half hour at which point I felt recovered enough to leave. I was offered/recommended being checked out at the emergency room but declined

Went to sleep at 8am. Woke up at 1am with unilateral angioedema. Presented to ER, given 125 mg methylprednisolone, 20 mg famotidine, and 25 extra mg of diphenhydramine (in additional to 50 mg I had already taken). Observed in ER. Swelling decreased. I was not admitted because I'm a doctor. Symptoms resolved 10 hours later.

Whole body aches, fever, loss of appetite. Took Tylenol. Symptoms decreased after about 24 hours, but currently still present (still have a low fever).

Approximately 9 hours post injection, patient developed chills, fever, cough with phelgm production which then progressed into uncontrollable cough. Patient went to ER, treated with albuterol inhaler and released without restrictions. Pt using inhaler but symptoms decreased at this time.

"About 10 minutes after injection, c/o tachycardia and became diaphoretic and stated she felt ""weird"" Taken to ER for eval/tx."

"""Moderna COVID19 Vaccine ""; patient reported she was feeling flushed/hot. Vital signs were taken and patient monitored for over 30 minutes. BP and Heart Rate readings approximately every 10 minutes: BP 142/105, HR 110; BP 139/101, HR 110; BP 132/83, HR 104; 124/94, HR 102; 98 % pulse oximeter readings during episode. Patient's mother works at the facility as well, stayed with patient and decided to leave with patient to go home. Mother returned inside facility and stated daughter was vomiting outside. Dr. advise mother to take daughter to ER."

Temperature of 100.04, head ache, back ache, muscle ache Running nose

1-2 minutes after injection a whole body flush developed along with heart palpitations, tingly throat and tongue, and a rash across the chest and neck.

high fever, severe headache, myalgia, chills

Within 5 minutes of receiving the vaccine, patient experienced anxiety, shortness of breath, and body aches in her elbows, knees, and ankles. Vital signs were normal. No lip/tongue/throat swelling on exam. She was pale and diaphoretic. Symptoms resolved in 35 minutes with laying supine and applying cold cloth/compress to neck and upper chest. She developed a headache at 40 minutes, however it was mild and it did not cause her to stay for monitoring any further.

Lip swelling and tongue tingling

"Physician Assistant texted the Dr. this morning: ""High fever and aching all night. It feels like having the virus all over again. Temperature down now but still pretty achy."" At 1347, he texted clinic: ""My fever is down. I still fee achy, about like when I had the original infection."""

About 10 minutes after vaccine I was extremely hot, dizzy, disoriented. My blood pressure was 30 points higher than usual and 15 minutes after the first episode, I had another episode.

Nausea, bilateral hip joint pain, fever, headache. Currently approaching 42 hours.

Minor sore arm at the site of injection

Felt a rush in my arm 5 minutes after. Then one hour following the injection I started getting dizzy and vertigo. Driving home I felt like something was very wrong like impending doom. My heart started racing

almost pounding out of my chest. I was extremely dizzy and almost fainted. Flushed feeling and tightness in my chest followed. Flushed feeling felt all day. Also had a rash on my neck and chest.

Received vaccine before shift. Within 10-15 mins bilateral back of the tongue numbness and tingling. Walked to ER (my department) and asked charge nurse for Zyrtec. Advised to stay and be monitored, opted not to be checked in to ER. BP 146/105, 126-120 BP, abnormally high. Experienced red lips, itchy hands and feet, 'frog in throat' feeling. Convinced to check into ER. Swollen uvula, tonsils, lips red/swollen, stridorous breathing. Checked in to ER, given IV Benadryl, fluid, prednisone, and Pepcid. Hands and feet were mottled. Confirmed anaphylactic reaction. Became nauseous, given Zofran. Given Epi in left shoulder. Stayed for 4 hours for continued monitoring. Symptoms started to subside. Also given inhaled albuterol. Discharged w/ Benadryl, Pepcid, prednisone 5 days course, and prescription for Epi.

Metallic taste

32 y.o pregnant female (8weeks) receive covid 19 vaccine in left deltoid at 6:45 pm. Around 7:10 pm patient developed tingling/pins/needles feeling and decreased motor coordination of left arm. Tingling/pins/needles sensation progressed to left eye lid, mouth, face, neck, throat, left lower leg and right hand. Pt was monitored in ER for an hour and sensation gradually dissipated

Dizziness, lightheaded was starting 10 minutes after injection and subsiding in about two hours

"Patient received vaccine at 1005 and approx. 20 minutes later reports ""tickle"" in throat feeling the urge to clear throat. and ""tingling' of lips. Benadryl 50g given by mouth per standing order. Monitored for additional 30 min. 30 min after administration of benadry Patient reported no change to symptoms. Patient was escorted to ER to be seen."

Headache

Mild soreness at the injection site noted in the evening of 12/22 and felt chills at 11:50 pm 12/22 but no fever at that time. Woke up the morning of 12/23 at 5:30 am and had a fever of 104 general body aches and shaking rigors. Took Tylenol and the fever came down. I was extremely fatigued and was in sleeping for most of the day on 12/23 and had no appetite . I informed my place of employment on the afternoon of 12/23 that I may not be able to report to work as scheduled on 12/24. Stayed home 12/24 but noticed an erythematous rash on my trunk around 3pm 12/24. I continued to alternate Tylenol and Motrin on 12/23 and 12/24 for general aches.

Severe muscle aches/pain throughout my entire body as well a consistent headache which I believe caused the nausea. For a period of an hour, I was having muscle spasms which them subsided. My body hurt so badly that I had a very difficult time turning from side to side and getting out of bed. At one point, I felt so badly that I thought I would have to be hospitalized. I started feeling a bit better by 8am but then started feeling badly again around 10am or so. I'm feeling better now, 4:25pm.

12/24@5:00pm EST-Caller stated that on Sunday 48hrs after vaccine he was chills, lost of taste and smell, fatigue with fever. Nose and throat dryness with chest pain. Today caller has been spitting up dark

green mucus with red streaks. Caller is taking doxycycline for strep. Caller keeps having elevated temps of 102.0 and chills. Dry cough has been persistent since 12/23/20. Vaers report completed over the phone.

Monday night pain on arm at injection site, Tuesday pain still there, Entire body started to ache. Couldn't stand. Runny nose. Could barely walk that night. Hallucinations sleeping at night, chills, tired. Took1 Tylenol.

Vasovagal syncopal episode, fainted within 10 minutes of vaccine, rapid returned to baseline after episode

Observed for 15 minutes after vaccine. About 30 minutes later in my car, felt sharp shooting pains in left neck. About 8 hours after receiving first dose, started coughing up blood, bright red, with streaks and clots. No cough, fever. Seen in ER with chest xray and ct scan with contrast. No resolve. On second day after receiving vaccine? Continue to experience bright red sputum. No resolve.

Developed Bell's Palsy symptoms on the left side of my face almost exactly 24 hours after vaccine administered

Tingling of face difficulty breathing with a swollen tongue

Right arm tingling, felt as though asleep, improving but lasted at couple hours after

Sore arm & headache. Motrin helped.

Headaches, chills, runny nose sore throat body aches, 5 hours after the Vaccine

ABOUT 5 MINUTES AFTER THE VACCINE, THE PERSON EXPERIENCED LIGHTHEADEDNESS AND NAUSEA AND VOMITING

Since vaccine headache, diarrhea fatigue, dry cough and tinnitus

Starting that night 12/19/20 at approx 8pm I became nauseous with a 100.8f fever. I felt achy for the 2 days with the fever subsided. On Monday 12/21/20 I was at work (Firefighter) when I started to have palpitations. I was able to obtain a 12 lead EKG right away which showed a ventricular rhythm lasting for approx 5 min. After that I was having multiple PVC's / Ventricular beats. I was taken to Hospital where I was admitted. Over night the rhythm subsided, all my labs were good with other test's being done. I was discharged home. I have not had any other episodes since Monday. I was cleared by our Occ Health Doc who suggested I fill this out.

Hives on chest transient noticed at 4:30 pm, diffuse red raised patches and erythema, gone by 8 pm, no pruitis. Site injection deltoid soreness, beginning about 1hour after injection, soreness increasing through today.

I had a intense headache, nausea & vomitting, body aches, joint pain and fatigue.

Patient (RN who works at hospital) complained of jaw tightness about 15 minutes after the vaccination. Diphenhydramine 50mg IM x 1 was administered. Patient then developed a rash across her chest and stated that she was not feeling well. EpiPen x 1 IM was given at 11:17 and Code Blue was called per hospital policy. Patient's vitals were BP 175/99, HR 129, Oxygen 100%. Patient was alert and oriented but anxious. Patient was sent to ER at around 11:20 for observation

15 min after receiving Covid 19 vaccine patient started to feel like her heart was racing / felt faint. Burning feeling in upper thigh and pelvic area. BP 180/100 HR 130. Rapid Response called / transported to ER. Admitted for 24 hr observation.. Solu -medrol, Benadryl and Ativan given in ER. Released home the next day. 72 hrs later patient states she has numbness and tingling in hands and feet. 12/24/2020 patient reports she is feeling better today / no symptoms noted.

I started feeling week and had muscle aches and joint pain about 8hr after the vaccine. Then had stabbing sharp pains all over my chest like it was pain in my lungs. Severe aching for 10 hrs. Severe chills and dizzy for several hrs. Better now. Seemed important to report.

50Y female, with history of PTSD, anxiety and afib. Was seen in covid vaccine clinic during her break on 12/24/2020 at 1113, for covid 19 vaccine. At 1133, she reported scratchy throat and felt her heart was racing. Heart racing symptoms lasted only for a few minutes and then resolved. She reports mild scratchy sensation with swallowing. Reports that she had a lot stress since start of shift today. Also admits to stress while sitting in the clinic for observation, stressors include work related stress and responding to multiple phone calls related to codes. She was on the phone with husband prior to symptoms onset. She denies shortness of breath, dizziness, wheezing, chest discomfort, palpitations, change in vision, weakness or fatigue. She denies history of hypertension. Was previously on coumadin and diltiazem. But currently not on any medications. O: VS at 1140: BP 166/104, HR 75, O2 97% RA 1150: 164/93 HR 70 O2 99% RA 1158: BP158/83 HR 70 RR 17 O2 98% RA 1210: BP 147/82 HR 64 RR 15 O2 100% RA AAOx4. Employee was teary and anxious. Follow commands. Lung sounds clear. Heart sounds normal. No focal weakness, numbness, tingling. No respiratory distress. Able to tolerate fluids. A: Allergic reaction to COVID 19 vaccine. P: Employee was closely observed in clinic for an hour. Employee was provided fluids and emotional support. Symptoms gradually resolved. Her vital signs stabilized. Benadryl was offered but not given because employee reports symptoms improved and wanted to return to work. Employee was advised to monitor her symptoms. If her symptoms recur, she needs to go to urgent care or ED. Advised her to follow up with her PCP for further evaluation of her blood pressure and PTSD. She stated understanding and agreeable to plan. Employee returned to work and left in stable condition.

Fatigue, chills, fever, headache, body ache, right sided chest pain, neck pain, left arm pain at site of injection.

Headache, facial flushing, ears red/hot, nausea, diarrhea, chills, body aches, fatigue, arm pain

2:44p Stated felt dizzy, feet elevated, ice pack to neck and forehead, BP 151/99, HR 60, repeat six minutes later 152/94, and he stated he is not hypertensive. Within ten minutes stated was feeling fine, no longer dizzy. After about 15 minutes more he left the area.

Heart rate from 80 BPM to 128 BPM in 30 mins. and remained > 105 for 16 hours. Headache, Nausea with Vomiting, Shortness of breath. Chills No fever

Pain at sight of injection.

fever, Fatigue and Chills, Treated with Tylenol and Advil to ease the symptoms and lower the fever. Symptoms persisted for two days after taking the first dose of the vaccine.

Hyperacusis

Toes appeared bruised and painful upon touch. 15 minutes later, toes became inflamed and felt hot to touch. Also, experienced burning sensation. 10 minutes later, burning and erythema subsided and bruising reappeared. Bruises are still painful to touch, but both pain and appearance is improving since the event occurred.

Localized soreness and tenderness onset 1.5hrs post vaccination, peak at 12-24hrs post, slow improvement until 23hrs post after which improvement rate quickened. Still mild soreness and tenderness at 53hrs post vaccination. Low grade temperature (100 F), diffuse muscle aches, chills ~26hrs post vax, responsive to acetaminophen. Similar symptoms resurfaced at ~51 hrs post vax but acetaminophen taken prior to temperature elevation if it were to occur.

Angioedema, face swelling. Went to bed feeling fine and woke up with face swelling, mouth, throat and lips swelling. Delayed adverse reaction

Had some chills, headache the evening after vaccine. Next afternoon only had running nose.

Severe body aches and headache. Low back pain. Temperature between 100.6 and 101.8 today. Still 101.3 even after Tylenol.

Localized pain and some swelling. Swelling is approximately 1.5 cm in diameter and red.

nausea, vomiting, lightheadedness, chills, diaphoretic

Severe under arm pain on second, third and fourth day, enlarged lymph nodes.. Redness and swelling of shoulder on second day, Severe itching at injection site on third and fourth day, fever on third day. Urgent care thought it is expected symptoms for some.

Bilateral axillary pain

The Monday night I got the vaccine I had chills and headache all night. The next day (Tuesday) continued having chills and fevers and headache. Wednesday morning I woke up feeling great

On 12/20, I woke up to swollen eyes, ears, and face. I had itchy, red patches and welts on my legs and forearms, and a burning red rash across my forehead that circled my face and went around my chin. I went to the ER, where I was given benedryl, a steroid, and pepcid. I was sent home with a prescription for the same. On 12/21, I woke up with the same rash as described from the day before. I continued my prescriptions. On 12/22, I woke with with the rash only on my legs. I continued with my prescriptions.

On 12/23, I went to an immediate care facility where I asked for a COVID test. My rapid test was resulted as positive. I never had any of the listed COVID 19 symptoms. I continued my prescriptions. On 12/24, I woke up with no rash, no COVID 19 symptoms, and I continued with my prescriptions.

About 1-2 minutes after vaccination, I developed palpitations, tachycardia, tingling, and also a scratchy throat and full sensation in my throat. The palpitations, tachycardia, and sensations of a full throat lasted approximately 10 minutes and tingling several minutes. The scratchy throat lasted approximately 1.5 hours. Also, several minutes after the injection I developed twitching of my fave lasting several minutes as well.

NAUSEA

I started feeling palpitation after 2 minutes then was placed in the observation room. Vital sign showed heart rate of 145 with normal blood pressure and oxygen. Then after few more minutes I started feeling numbness and tingling in the mouth and started feeling dizzy and had cold sweats. Heart rate was 130s and BP was undetectable and my skin was severely pale. I administered my Epipen and rapid response team arrived after few minutes. I felt better 5-6 min after infection of the epipen but was still feeling dizzy and mildly short if breath. I was transferred to emergency room when I was treated with IV steroid, benadryl , pepcid and IVF. I was observed for 4 hours and was discharged with improvement in symptoms .

Pfizer-BioNTech COVID-19 Vaccine EUA Day of vaccine - Fatigue 1 day after - Sore muscle in left arm 4 days after - Achy left shoulder joint, sensation of heat, tingling sensation on left arm just above elbow. Minor swelling just above elbow. 5 days after - Rash on torso, red spotted

Subsequent idiopathic anaphylaxis event 1 1/2 days later

Patient complained about difficulty swallowing, and tongue swelling about 12 minutes after receiving vaccine. 50mg Benadryl given and EMS called. Patient transferred to Hospital.

Fatigue, Headache, myalgia, mild joint pain, extreme right deltoid muscle tenderness

Soreness at injection site.

Fatigue

Few minutes after vaccine heavy right side throat/tonsil, right are very sore and painful raising right arm, and headache next day.

Fever

Severe headache, muscle pain in whole body, fatigue, fever, inability to do any daily work due to sx

Hyperpigmentation of lower extrememities. Dark discoloration of skin from the pelvis down to ankle

Fatigue

Low grade fever

BODY ACHES, CHILLS, AND VIRAL RASH OVER ABDOMEN/BACK/FOREARMS

Swollen and tender at injection site.

"""Pfizer-BioNTech Covid-19 Vaccine EUA"" Had fatigue the morning after receiving the vaccine from 7:00 to approximately 7:00pm. Have injection site pain, swelling, and redness. Noticed on second day after the injection, but injection site was sore the first day after the injection, I just did not check for any swelling or irritation."

Subjective fevers, chills, myalgia, extreme fatigue, headache, severe injection site soreness Have persisted over the day after the vaccine

Tenderness at injection site.

Received dose at 0800. By 1730 was nauseated and achy. Fever of 104 by 2330 with vomiting, severe joint pain, shortness of breath, tachycardia, BP 174/110. Fever down to 101.8 in Emergency Department. Received nausea medicine and Tylenol. Chest X-ray negative. MD felt it was a severe hypersensitivity reaction. Fever continued through today (12/24 low grade, 99.8). I had severe Covid-19 the last week of March and was hospitalized. I?m just resting and waiting for the reaction to pass and have stayed off work.

Bell?s Palsy

Tenderness at injection site.

Injection site sore arm, pounding headache, fatigue, nausea

Headache, tenderness at injection site.

Headaches and body aches

Headaches and body aches

I experienced bleeding bilaterally from my lower gums and the inside of my lower lip ~1.5 hours after receiving the vaccination. I went through several tissues to try and stop the bleeding but it continued for 3-4 minutes at this rate until it spontaneously resolved.

My jaw hurts; feels like TMJ

Tenderness at injection site.

Tenderness at injection site.

Severe fatigue Sore throat Abdominal distention Dyspepsia/GERD Shortness of breath intermittently Moderate to severe headache Left arm pain (mild) Angina at rest Right claviclular/subclavian pain

12/22/20 at 1800 I noted angioedema in my face and itchy/sore gums. I went to two different urgent cares I did not receive any care at due to lack of physician at one and lack of epi at another. After being refused at the second urgent care my throat and chest started to feel tight. I then went to the ER for further evaluation. I received a dose of epinephrine IM and prednisone 125 mg IV at 1930. I was observed for 4 hours then discharged. I returned to the ER 30 minutes later because my throat started to feel tight again. I received a second dose of epinephrine at 2358 and noted some improvement. I was discharged at 0600 on Dec 23rd. I returned to the ER Dec 24 at due to my throat feeling tight and burning sensation in my chest. I got CXR, and troponin that were WNL. I was observed for 4 hours and discharged at 0900. ER physician felt that the sensation in my throat and chest could be related to the reaction from the 22nd.

About 20 minutes after vaccination, patient reported generalized itching and hand swelling (left). Patient had red spots on her face and complained they were itchy. EMS personnel were on-site and and MD administered 50mg oral diphenhydramine and 100mg oral prednisone. BP: 130/90, P: 92, R: 16 with no obvious signs of distress. Lungs were clear to auscultation and patient was sitting on her own and able to hold a conversation. Ambulance was called and arrived about 10 minutes after reaction started. IV with Normal Saline was started and patient was given 25mg IV diphenhydramine. Patient was taken via ambulance to a nearby hospital.

Patient presented with signs and symptoms of sepsis, developing over 12 to 24 hours 6 days after vaccination. was hypotensive and confused (beyond baseline)

Woke up at 0400 on 12/22/20 with tympanic temp of 100.8, chills, body aches, very tender left deltoid injection site pain. Ibuprofen resolved elevated temp. Spent all of 12/22/20 with fatigue and body aches despite ibuprofen - these symptoms fully resolved by 12/23/20. Tender left deltoid persisted for a total of 3 days, then became less tender.

Body Aches, Arm Pain, HA, Fever of 102- 12/24/2020

Initially no pain, then moderate-severe pain at injection site that radiated down towards my fingertips. This started approximately an hour after receiving the vaccine. Tingling in both hands and forearms, which began shortly after midnight. Today (12/24) I have mild swelling, as well as the same pain and tingling.

Fatigue, chills, myalgia, arthralgia, nausea, headache, soreness at injection site

Patient had redness and swelling on her face. Transferred to emergency room for observation

Pain at the injection site, general fatigue, myalgias, and chills starting about 6 hours post-vaccination and lasting for 24 hours

Hypertensive and had tongue and throat swelling. Epi was administered per protocol an d transported to ED.

Lots of physical pain and soreness, red and visibly swollen, hot to touch, pain in limbs and joints continuing for 2 days and counting.

Lymphadenopathy - left supraclavicular. Painful, onset approx 36 hours post vaccine. Arm soreness almost completely resolved at this time

patient has had hot and cold feelings on her body, feels like her chest is heavy, denies short of breath or difficulty. fever, chills, fatigue, arm soreness.

waiting in observation on a 30 minute wait time, reports change in voice, gravelly sensation in throat, clammy hands, not feeling right reports similar reaction to contrast dye, no SOB no audible wheezing

Dizzsiness, orthostatic hypotension, migraine, nausea

Nausea headaches light headed dizzy

Began with fatigue and nausea/stomach upset. This progressed all day and then 12/24/2020 late at night woke up in a sweat and noted a fever of 102F via oral thermometer.

12/21/2020 0200 hrs severe chills & Temp 104.2 F took Tylenol 500 mg , 0400 hrs Temp 103.4F. 0600hrs Temp 104F took Tylenol 500mg . 0700hrs 103.6F. all day temp ranges from 102.8F to 103.4F 12/22/2020 no chills Temp ranges from 101.6F to 103F 12/23/2020 Temp ranges from 99.5F to 102F

Fever, body aches

Begin to feel tingling and some numbness in left arm. Moved over into right also. About an hour after shot feeling chest tightness, winded with activity. Tingling stopped within an hour but tightness and breathing continued Did not feel bad enough to worry We but did not feel good for several days. Continue to have feelings of not being able to get deep breath. Have been in contact with my physician about issues. Have never been bothered with vaccines before but did not feel right pretty quick after this one.

Headache Fatigue Weakness Fever Sore Throat

About 0400 hours became extremely hot, dizzy, and nauseated. Threw up and then became short-of-breath. Felt hot and fever went up to 102.6 (oral). Charge nurse was notified and the house supervisor. Was sent home and told to fill out this form.

Dry, nonproductive cough , first day 12/24, fever 105.2 (temporal) 0700 12/25/20.

immediately after injection, facial flushing, then continuous waves of flushing and chills through body, from abdomen to toes, lightheadedness, cold hands and feet. This occurred for several hours and did not worsen nor did this improve. Tongue felt numb, and mouth was dry. Tongue felt swollen, however, the tongue size was normal. No rash, no fever and no shaking. Blood pressure, Oxygen saturation were normal. No breathing difficulties. I was observed in the ER and administered iv Benadryl 25 mg and pepcid, and iv fluids. I woke up a few hours later. I still had the rushes of chills, numb tongue, and cold

hands and feet. I was discharged to home. I still have the rushes of flushing and chills that flows through my body.

All mild Covid-19/flu like symptoms, in addition to sharp pain in armpit area, into the chest area, down the right side of upper body on side where vaccine was injected. Couldn't move right arm to should level or further without intense pain. Right armpit area swollen and extremely tender. Also experienced dizziness. This all began roughly eight hours after vaccine, lasting throughout the entire next day, and still in existence today.

Received the vaccine on 12/23/2020, felt great after, no allergy reaction, just a sore arm at the injection site. During the night of 12/24/2020, started having my lymph node in my left armpit swelling up, and feeling very tired. Felt like I was breaking a slight fever. Took ibuprofen in the morning, no fever (97.6), still having lymph node swollen and feeling extremely tired. Otherwise no other side effect so far. Will continue to self monitor and treat symptoms with ibuprofen. When i received the flu vaccine and tDap vaccine in my left arm, same situation, lymph node in my left arm pit started swelling within 24 hrs, and went away after 3 days. I'm expecting the same with this one.

Saturday around 2pm I developed intense body aches, progressed to chills, nausea and severe headache by 8pm. Next day improved but still had myalgias. Had some mild pleurisy and congestion starting on Tuesday. This would only be in an and resolve by evening time.

Pain at inhection site, fatigue, chills, fever 101.6, upset stomach, headache

Woke up Dec 24 with fatigue, chills, fever of 100.5, and phlegm, shortness of breath and cough. Tired throughout day and fever lasted til 6pm. Took Tylenol and Ibuprofen to break fever and chills. Recovered on Dec 25.

Reported sensation of tongue swelling during post-vaccination observation at 10 minutes. Epinephrine was refused and she was taken to ED for observation where she was given oral dose of Benadryl and Pepcid. Discharged with instructions to return PRN and follow up with PCP. Elevated BP noted.

red arm, swelling in arm , pain in arm

Pfizer-BioNTech COVID-19 Vaccine . Nausea started around 1:30, vomiting shortly after. Continued to throw up until approx 10am the next morning. Felt feverish as well. Had to lay in my car for several hours before my one hour drive home and threw up in plastic bag while driving. Had to stop and rest and throw up halfway home. Went to bed when I finally got home and continued to throw up all night

Fever 101.3, aches and pain, body Malaise

R arm pain and swelling at injection site starting about 24 hours after injection, still present 48 hours after injection Flushed feeling in face with headache starting about 33 hours after injection, lasting approximately 6 hours

Day 1. Queasy nausea, some soreness at injection site. Day 2 runny nose, itchy throat some cough, day3 muscle cramps up into shoulder a and back. Later day 3 muscle cramps in both calfs and some nerve pain. Left side face. Day 4 bowel cramps, fatigue, congestion and some loose stools. Day 5 symptoms subsiding.

Twenty-fours after injection, experienced fatigue, body aches, chills and high fever of 102.4. Took two Aleve. Fever kept spiking. Took Tylenol PM (that was the only Tylenol I had); it took one hour for Tylenol to take effect, which finally brought fever down to 100.8 then 98.3. Went to bed. Woke with bad headache. Took an Excedrin Migraine for relief from headache. Body aches and fatigue gone. Not looking forward to these symptoms again after the upcoming second dose on January 20, 2021, but will take the second vaccine shot in order to get the full effect.

Patient received Pfizer vaccination in Administration clinic. While in post vaccination observation, patient complained of feeling warm, lightheaded. At that time, patient reported she failed to inform nurse of current penicillin allergy. Proceed out called. Took vital signs at 15:05, 130/83, HR 83, 02 sat 99%. Repeat vital signs 15:24 BP 125/83, HR 83, 02 sat 97%. Patient transferred to ED for further monitoring. In the ED, patient was monitored for few hours where the light headiness has subsided. patient was discharged home.

Nerve pain in upper back started to increase and had a strange numbing feeling in my neck and face. Some pain in my abdomen as well.

C/o stomach ache that started after vaccine. 24 hours. LLQ, dull, no radiation. movement exacerbates and deep breaths. Constant. Mild, reported as a 3-4/10 in severity at it's worst. Responds to tylenol. Denies changes in BM, bloody bowel movements, obstipation.

1756 Pt c/o itchy throat. Vitals taken. 1758 Team alert called. 1759 c/o tingling in fingers . c/o shortness of breath and not feeling well. MD arrived.

10 min after injection hot flash, 1 hour p injection quarter size red welt, raised and hot to touch 24 hrs p injection dollar size red welt, raised size of goose egg and hot to touch. Also, all joints ache. 48 hrs p injection same as above 24 hrs

Hives

"Right side of face (from mid eyebrow-line to below temple) became numb and has a ""pins-and-needles"" sensation when touched."

I woke up around 4am at night because my feet were tingly, like pins and needles. At first I thought maybe I was wearing tight socks, so I took them off, but it wouldn't go away, so then I thought maybe it's just how I have been sleeping so I woke up and started to walk around. I noticed that my feet weren't only just tingly, but they also felt heavy to walk around. It felt like someone had put weights on my feet, and I could hardly pick them up to move. This was on going for about 45 min until I panicked, and I called the ER. They told me since there wasn't much information about adverse effects from the

vaccine to just monitor it, and if it didn't go away to go to the ER. It did take about 3 to 4 hours for the sensation to leave. It did gradually fade, so it wasn't the same height of sensation the whole 4 hours.

swelling and tenderness to left axillary area

Rash all over body

within a few minutes I became overly warm and feeling dizzy, my blood pressure went up to 189/80 and my pulse elevated to 99. My normal levels are usually 120/70 and pulse 54-60. I had acute anxious feeling and overall body shaking. I was taken down to the ED by stretcher, I received the vaccine in the hospital setting, I stayed in the ED for 3 hours and was discharged home. I felt fatigued and weak for 24 hours after.

Pain at injection site, body aches, chills

Sense of Taste and smell going in and out

Shortly after receiving vaccine, experienced soreness at injection site. Soreness continued to spread, encompassing area from shoulder to elbow. Soreness lasted approximately 24 hours. No medications or treatments administered.

I received my shot at 1347 and within 5-10 minutes after receiving the shot I got a hot flush feeling through my body. My heart then began to race and I became dizzy. I started to get a tickle feeling in my throat. Soon after my lips and tongue felt numb. My tongue had the feeling of having been burned by hot soup. I also had red splotches over my entire body (not a rash but redness). When I alerted the vaccination staff that I thought I was having a reaction they all seemed shocked. They didn?t really know what to do and asked me what I wanted to do. I, myself, was having a hard time making choices since I was in a bit of a panic. They wanted to give me oral Benadryl but since I was having the reaction in my throat and mouth one of the nurses suggested IM Benadryl. They gave me that shot around 1405. They watched me for about an hour and I still had the numbness in my lips and tongue and the red splotches over my entire body. (During this entire time no one took my BP or pulse). I had 2 work friends (RNs) come to check on me. It was only then that one of them took my pulse. I was still had tachycardia. Since my symptoms were not fully resolving they sent me to the ER where I got solumedrol and Pepcid. They sent me home still having slight numbness in my lips and tongue.

Individual woke up in the morning at 3:00am with complete numbness of the entire left and right arms/hands with concomitant tingling of both feet and lower legs. Tingling on the feet and lower legs resolved within 15 minutes with movement. Complete numbness on the arms and hands persisted until 7:00am when feeling in arms and hands began to return. Mild tingling in hands and arms persisted throughout the day and would worsen with use of hands and arms. Individual took a dose of ibuprofen 600mg with no improvement in symptoms. Symptoms seemed to improve by resting arms and hands. The tingling in hands and arms dissipated with complete resolution by 5:00pm on 12/24/2020.

Body aches, chills, fever (as high as 101, with 800 mg of ibuprofen) , nausea. Symptoms started around 600 pm. Woke up at midnight 12/25 with a fever still and I woke up 0600 am 12/25 with mild symptoms (body aches, fatigue)

- 5 hours after Covid vaccinated, I had sweating, chilly, and mild muscle ache for 2 hours. After that I had moderate pain at injection site till the next day. - The next day, I felt dizzy and heavy headache for 3 hours; after that I felt normal and no pain at injection site. I took Tylenol 500mg by mouth twice a day and Vit C daily to help for releasing symptoms.

Headaches, muscles pain, joint pain, nausea and fever

Headache, occasional chills, sinus head pressure throat irritation without closure, fatigue

Moderna COVID-19 Vaccine EUA Palpable 5cmx6cm lump/erythema/edema/soreness just inferior to injection site on R middle deltoid. Onset of sx was approx 5 hrs after injection. Localized moderate mm soreness began approx 3 hours after. Approx 1 day after vaccine, experienced chills, fever, generalized body aches, muscle soreness which has continued through Day 2 (today). Then came onset of grumpiness when I realized ...

Injection site soreness starting 12hrs after vaccine Fatigue and body aches starting 20 hrs after vaccine Fever max temperature 101 F after 28 hrs after vaccine

buccal edema herpes blister

Site reaction. Red, swollen, hard and warm. Fever. Severe body aches, chills, shaking, cough, SOA, headache, fatigue.

on 12/24/2020 the resident was sleepy and stayed in bed most of the shift. He stated he was doing okay but requested pain medication for his legs at 250PM. At 255AM on 12/25/2020 the resident was observed in bed lying still, pale, eyes half open and foam coming from mouth and unresponsive. He was not breathing and with no pulse

Moderna COVID-19 Vaccine EUA Received vaccine at 5:03pm 12/23, through night arm became increasing sore. I woke up 12/24 at 6:45 and the injection site was red, raised, and painful. The area then became very hot to the touch. By 9:00am that morning I began experiencing excessive dry mouth and thirst. I drank close to a gallon of water 12/24 and it was not satisfying this. Woke up 12/25 and now the injection site and surrounding area is extremely itchy.

arm soreness: started about 4-6 hours after injection and lasted 3 days; stabbing type stomach/intestinal pain (no nausea, vomiting or diarrhea): started the next day and lasted 3 days (completed this report 3 days after vaccine and still with GI symptoms) ; backache: started the morning after the injection and lasted 3 days. Overall, similar to flu-like symptoms. No significant fever or chills.

patient has a telephone appointment with me on urgent care shift on 12/25/2020 . he works in ICU in COVID positive patient's floors. he received COVID vaccine Pfiser on 12/18 and he had a phone

appointment with me today on my urgent care shift. he reports fever for the last week after getting the vaccine highest around 102 F. today his temp is 100.6F . no cough or SOB or respiratory sx other than generalized body aches.O2 sat is 98%. I consulted with our ID specialist on call today and they recommended that we test the patient for COVID-19 infection which I scheduled for tomorrow . ID specialist also recommended that I report the adverse effects in here . thank you

Client developed itchy rash to face, neck and chest approximately 15 minutes after injection. Client then reported that she had similar experience after her flu vaccination the past 3 years. Client took 25mg of Benadryl and was monitored for an additional 30 minutes at clinic site until rash was resolving. Client denied any issues/ complications with swallowing or breathing. Rash and itching was resolving prior to client leaving vaccination / monitoring site. Her significant other had brought her to the clinic and was available to drive her home. EMS was also on scene but did not need to provide assistance.

High fever Headache Tired Body aches Joint aches

Diarrhea every time since shot given. 5-6 qd

Pfizer-BioNtech COVID 19 Vaccine EUA: Developed throat itching, mild throat swelling, flushing, and mid upper back pain about 24 hours after the vaccine was given

Individual presented to outside hospital after receiving first dose of the Moderna COVID-19 vaccine 2 days prior at Hospital. Individual presented with possible SIRVA from injection. Patient had a stat neuro consult due to being unable to move her arm (same arm that received the vaccine).

Fevers 101F to 102F, severe rigors, diffuse myalgia, headaches leading to Emergency Dept visit at Hospital Rideout on 12/24/2020

Tachycardia Malaise

I was working at the Hospital and around 1000AM, I noticed a ?sideache? on my right side of my abdomen above my waistline going around to my back on the right side. It came and went throughout the rest of my shift. Came home, at dinner and went to bed after taking some Tylenol. I woke my Husband up at 1:30 AM due to worsening pain/discomfort and He took me to Hospital ER.

"Client began feeling flushed approximately 10-15 minutes following vaccination with COVID-19 vaccine. Client stated her ""chest had a heavy feeling"" and she was experiencing heart palpitations (which she also reports are normal for her). She was concerned as the heart palpitations were occurring along with chest pain. EMS on scene at clinic site (precaution) and escorted client to area where EKG was completed. Normal sinus rhythm was noted along with possible infarct age undetermined (as reported on strip)and client was asked if she would like to go to ER for additional evaluation which she refused. (Client signed refusal of medical treatment, transport and/ or evaluation form). Client was advised by EMS and health district staff to seek medical treatment or call 911 if symptoms persist or become worse. Client voiced understanding."

After have the vaccine done and taking my medications, I started have hallucinations of bugs all over my skin and coming out of my skin. the hallucinations lasted for about 20 hours. Called my doctor and he had to increase one of my meds to get the hallucinations to stop.

Fever, body aches, chills, fatigue, nausea around 19 hours after vaccination.

The evening of the 24th, I felt lightheaded, sore, and extremely fatigued. Waking up on the 25th, I had diarrhea, vomiting, headache, coarse cough, asthma exacerbation, chest pain. Chest pain subsided but other symptoms remained. Around 11am, I developed cervical neck pain in the back of neck, and lower pack pain. I started to experience loss of vision upon standing, tachycardia, tactile fevers, chills, and loss of appetite with extreme fatigue.

Vertigo, three episodes in early morning. Then quick episodes of dizziness throughout the day. No further dizziness or vertigo at bedtime nor after that.

Muscle pain all over the body, injection site sore to the point cant lift left arm, nausea, low-grade fever/chill, diarrhea, sore throat, congestion and runny nose.

Perioral and Tongue Paraesthesias-

Diarrhea and fatigue, day after vaccination

Fever, nausea, fatigue, pain at injection site, swelling at injection site, generalized pains

Supraventricular tachycardia--needing to be seen in ER twice before controlled

Fever 100.4 F/ Fatigue/ Headache/Body ache/ Chills.

Massive headache 7/10 take came on after I woke up from a 5hr nap after I got my vaccine I am also feeling tired. My arm is feeling a bit sore (esp if I raise it) but not worried about that. My headache really hurts more then my usual post covid headaches which I've recently gotten under control I took sumatriptan to see if it will help. Will eat and probably go back to sleep. (it's 3pm for reference)

dizziness shortness of breath tachycardia hypertension forceful heart contractions

SEVERE diarrhea

Fatigue/tired, nausea, body aches, chills started dec 23

Began just as sudden sharp headache on 12/21/20 at 6:00 pm, noticed after shift after showering, left upper extremity was slightly red, and slightly tender to touch. Not unbearable. 12/22/20 noticed redness was continuing to spread and arm was beginning to ache, still not unbearable. On 12/23/20 during shift, the redness in my left upper arm had spread from elbow to below injection site, arm was increasingly aching as well as new noticeable left sided facial swelling from directly underneath the left eye throughout the cheek area. and slightly tender. This is when I checked into the urgent care and was examined. At first the mid-level reported she thought I had experienced vaccine induced bellspalsey; however, after consulting with the MD, this was dismissed. Left upper extremity was diagnosed as

cellulitis and treated with bactrim and informed to take zyrtec or benadryl for facial swelling. If symptoms worsened, visit nearest ER. Also informed to report symptoms to CDC for tracking. Today I have been treated with 2 full days of antibiotics and the redness and swelling has reduced. left sided facial swelling remains present.

Moderate to severe unilateral headache unresponsive to Tylenol or Advil on day 3, 4 and 5 (today). The headache gets better after several hours but returns.

Day 1 (day of vaccination): dry mouth Day 2: pain in left arm and body aches Day 3: none Day 4 (today): tingling in lips and mouth, swelling of left side of face with numbness

Cough, fever, chills, diarrhea,fatigue, headache

Rashes/Hives started on the my left hand on the date of vaccination, about 30mins after vaccine administration. Then today, Dec 25, 2020 I have rashes on both forearms that are itchy.

Lightheaded, Metallic taste in mouth, and tingling in my throat for the first 15 min after vaccine given. Then after that just localized injection pain to site

Acute NSTEMI with symptom onset 4 days after vaccination

Sore arm, tingling sensation slightly numb, tingling numb sensation also in left 3 outside fingers (pinky, ring, middle). That started about 15 min after injection. The next day on 12/24, increased pain at site, redness, swelling and hard lump in area of vaccine. It is about 2 inches diameter round spot. Pain in arm continued. Fingers feel slightly improved as of 12/25. The injection site is the same as yesterday.

Moderna Covid -19 vaccine EUA

None

Localized upper lip swelling. No lower lip or tongue swelling. No rash. No shortness of breath. No throat swelling or pain. Resolved in approximately 1 hour with Claritin PO

Bilateral ear pain and ringing in ears. Varies in pain severity from 8/10 to 3/10 depending on activity.

more than usual bowel movements and body tingling all over at random. Body tingling would occur more during strenuous movements and would occur with presyncope sensations without having a syncope episode

Herpes zoster (intraoral - left hard palate and left scalp V2 distribution) which began 4 to 5 days status post vaccination. No prior history of shingles.

Rash on my stomach and legs day after and still present. Day after vaccine I had a light headache and felt very tired.

Immediately after the vaccination I felt warm and clammy. I did not have shortness of breath. I sat down for a few minutes and took off my shoes and I began to feel better. I went straight home and laid down.

Throughout the night I felt anxious to where I felt uncomfortable sitting still. I have anxiousness in my chest which travels down my body. My hands and feet are clammy sporadically.

Pfizer-BioNTech COVID-19 Vaccine EUA On 12/19/20 around 11:15 PM, patient experienced ?pinching? pain in armpit of left arm (arm of injection). Pain persisted throughout night with accompanying generalized underarm swelling (fluctuate). On 12/20, NSAIDs were taken to relieve pain. 1 dose of Advil were taken on 12/21 and 12/22 to manage pain. On 12/22, pain level on 1?10 scale was 8-9 in the morning with increased swelling, warmth, and discomfort. At night, swelling was less than that of morning. On 12/23 pain level was 3. No NSAIDs were taken and patient visited doctor at 10 AM. Upon examination, doctor made diagnosis of a localized lymph node/inflammatory response, possibly Cellulitis and prescribed Keflex to be taken 2 times daily for 10 days. Pain has mostly subsided (level 1 or 2 when it occurs), swelling has gone down but not completely resolved. Left underarm continues to feel fluctuate following day 2 of antibiotic regimen. Possible axillary lymph node reaction suspected. Patient has also experienced persistent redness, swelling, mild pain and itchiness at injection site. Most of swelling and pain has subsided, itchiness remains.

Headache, fever 101.2, chills, body aches, left knee joint pain, right arm lymph nodes swelling and pain.

Got vaccine 12/21/20.@1645. Felt fine until 1500 on 12/23. Started with severe H/A, then started with extreme dizziness. Had to have some drive me 100 yards home from the dog park. Needed my hiking poles to navigate from bed to bathroom. Even had bed spins.

Patient presented to ED states was sleeping when awoke with feeling of rapid heart. Has pulse oximeter at home and states HR was 150s felts sharp chest pain and sweat. Had husband bring her to Emergency room. Emergency room physician states patient is mildy anxious and mildy diaphoretic. Blood pressure 155/83 and pulse rate in 120 upon arrival. Patient was given Ativan 1 mg IV and 1 liter of normal saline HR in 90s upon discharge form ed. Admitted at 2134 discharged at 2353

Febrile to 101.4, vomiting, joint pain.

Extreme injection site pain day 1. Nausea the same night and following morning with vomiting. Massive headaches and extreme fatigue. Injection site pain got worse throughout the day and now I?m having several rounds of diarrhea.

listed before

Approximately 2 minutes after injection, felt flushed and tingly. This subsided, but developed a cough. Felt fine enough to leave the vaccination area after being monitored for 15 minutes. Cough continued, and developed a scratchy throat that eventually led to swelling of the throat at approximately 30-35 mins post administration. Sought care in the ED, where I was tachycardic and hypertensive. Received IV Benadryl, steroids, and IV fluids. Discharged home, but symptoms returned around 2pm. Sought care in a different ED, where I remained hypertensive and tachycardic. Received additional IV fluids, IV Benadryl and steroids. Eventually was treated with IM epinephrine after my heart rate was decreased to about 100bpm with IV metoprolol.

Moderate pain at site. Next day started with fever of 102.3, chills, severe body aches. Headache as well. Fever subsided by end of first day but started again the next day.

Received vaccine at about 0830 on 12/24/20, at about 0100 on 12/25/20 started feeling lethargic then developed nausea and vomiting, additionally had mild to moderate shaking chills and mild myalgias. Went to sleep and resolved when woke up in AM.

Moderate dizziness, nausea, chill, fatigue started around 5 pm lasted throughout evening. Had to take zofran 4 mg ODT for nausea. No known fever. Unable to drive home from work for 2 hours. Went to bed around 11 pm. Felt better the next morning with mild residual dizziness and chill and fatigue. Minimal chill and fatigue ongoing at 55 hours after injection. Left arm injection site pain started at time of injection and ongoing after 55 hours.

36 hours after vaccine, sudden onset tachycardia, shortness of breath, dizziness on the verge of passing out, called covid hotline, sent to ER due to resting heart rate of 130-150. Lasted approximately 9 hours, was going to be kept for observation in ED. Resting HR came down to 90 and sent home, following day unable to perform normal activities and unable to work for two days as of now

Diarrhea starting 12/25/20 at 11:00 am (5-6 episodes in a 24 hour period)

Approximately 10 hours after vaccination I developed sudden onset of fatigue, severe headache, lightheadedness, cyclical chills, tachycardia, bilateral conjunctival erythema, excessive tears and muscle spasm which lasted for about 4hours

Headache and lightheadedness right after vaccination which disappeared after a day. Headache returned 9 pm on Dec 24 with chills and sore throat. Fever of 100.7 on Dec 25 at around 6 am w/ chills, headache, sore throat and body aches.

Tingling og tongue and itchy eyes at 10min post admin Swelling/redness and flushing of head 20mins post admin Shortness of breath at 20mins Whole body hives and itching at 40min pot admin Swelling under the jaw and tightness/burning in chest at 40min After treatment in er...symptoms resolved after 5hrs. 14hrs later, symptoms reoccurred, with increasing severity. Went back to the ER for treatment. Again symptoms resolved after 5hrs. Now on 25mg benadryl 4x/day, 40mg prednisone 1x/day, zertec 20mg 1x/day and 20mg famotidine 1x/day for the next 4 days. Still being treated.

Fever/ runny nose/ sinus pressure/ extreme fatigue for about 36 hours

Pfizer-BioNTech COVID-19 Vaccine EUA: During vaccine administration patient complained of flushing, lightheadedness, dizziness, and arm tingling. No loss of consciousness, respiratory symptoms, or gastrointestinal symptoms reported. Inital vital signs: Blood pressure 147/84 mmHg, heart rate 115 beats per minute, oxygen saturation 95% on room air. Repeat vitals ten minutes later: blood pressure 123/60 mmHg, heart rate 77 beats per minute, oxygen saturation 98% on room air. Patient monitored for 30 minutes. Symptoms improved with time and snack. Patient was discharged in stable condition.

Left lymph node swollen next to breast. Warm to touch and painful to touch. Slightly red area noted as well. Currently taking motrin, did ice first day

Swollen lymph node in L arm pit and above L clavicle

Axillary lymphadenopathy

"Pfizer-BioNTech COVID-19 Vaccine EUA: Patient reports fever, body aches, chills, headache, and chest pain one day after receiving the vaccination. Patient had COVID before (November2020) and reports ""this felt very similar to one of my worst days with symptoms"". Patient reports only persistent symptom was feeling more tired than usual. On 12/22/2020, patient noticed a rash on back and under arms."

Soreness at site 48 hours following vaccine administration. General muscular and joint discomfort beginning approximately 48 hours out. Onset of fever (103.4) and chills at approximately 72 hours out. Fever between 99.4 and 102.0 for the next 48 hours.

At the time of the injection sharp pain across my back , then at about 5 mins after feelings of light headedness, progressing pain across my back, trouble feeling like I could get enough air in with breathing and dizziness and I tried to get to the floor to sit or lay down but passed out. Then the next event I recall was a sharp pain in my thigh(apparently administered Eli pen) . I regained consciousness and was gasping andI was told I had been given a shot of epi.

Sweating on first day, fatigue from first day persistent for 3 days. On day 5 (12/23) pain under the arm pit began. From 12/23-12/25 pain worsened into arm pit, down back, into breast, and into right side of neck. Swelling of lymph nodes in that area

Approx. 18-19hrs after receiving the vaccine I suddenly became nauseous and had an upset stomach, lack of appetite. Then shortly followed a headache, muscle aches, bone/joint pain, weakness, fatigue, dizziness, chills, fever of 102.4f, general feeling of illness or unwell, anxiety, tachycardia, painful breathing and slight SOB with exertion. O2 saturation?s 94% per my Apple Watch. Fever controlled with Tylenol, I have not sought out further medical treatment at this point. Full recovery of this adverse event is pending.

Pfizer-BioNTech COVID-19 Vaccine EUA: Patient reports dizziness, lightheadedness, and mild skin reaction (redness) at injection site soon after receiving vaccination. No respiratory or gastrointestinal symptoms reported. No loss of consciousness reported. Initial vital signs: blood pressure 141/72 mmHg, pulse 121 beats per minute, respiratory rate 24 breaths per minute, oxygen saturation 98% on room air. Repeat vital signs a few minutes later: pulse 105 beats per minute, respiratory rate 20 breaths per minute, oxygen saturation 94% on room air. Juice, snack, and ice pack provided. Vaccine administration site cleaned and patient monitored for one hour after vaccine administration and symptoms resolved. Patient left ambulatory in stable condition.

Headache several hours after injection with mild shortness of breath. I felt warm but did not seem to have an elevated temperature. Sore muscles and tired.

Headache, mild pain at injection site, lymphadenopathy, fatigue, nausea, malaise

Immediately after receiving the vaccine tongue felt fuzzy/a little swollen. Also lightheaded, dizzy, eyes not focusing very well. After 10-15 minutes, eyes focusing better but still lightheaded. ~1 hour later noted swelling of uvula, posterior palatal arches, tongue, neck, face, lips, intermittent wheezing. In addition the next day headache and rash started. Now day 9 with continued intermittent severe swelling, wheezing, rash and headache and some level of oral and facial swelling every day as noted above. Muscle aches started on day 8. Consulted with angioedema specialist; he felt was allergic reaction due to onset of symptoms. Had telemedicine visit with NP on 12/23/20. Had to go to Emergency Department on 12/25/20 for severe uvula, posterior palatal arch, face, lip, neck swelling unresponsive to oral Benadryl and oral steroids.

Severe fatigue, nausea, lightheaded, almost blacking out, eyes getting fuzzy/black around edges, fever 101.5 F, severe arm pain, swollen arm at injection site, chills, slept the whole day after getting the vaccine, rapid heart rate, excessive thirst. Most symptoms resolved by 12/25/20.

Migraine/headache, chills, nauseous/vomiting, body ache,l

Initially, lump and tenderness at injection site, which dissipated within 3 days. Chills, sweats, muscle pain, lightheadedness, headache began 3-4 days following vaccine and lasted approximately 3 full days

Oral ulcers on my looking like Aphthous ulcers with similar ulcer on my urethral meatus 24h after taking my vaccine

Moderna COVID-19 Vaccine EUA Afternoon after receiving the vaccine on 12/22/20, developed arm pain at injection site, 'can't keep eyes open' fatigue and sore throat. 12/23/20 symptoms were continued arm pain, manageable fatigue, and worsening sore throat with new drainage and sinus pressure. 12/24/20 arm pain noted to be much improved as with fatigue & sorethroat- sinus issues worsening. 12/25/20 sinus issues continuing but less severe. No fever at any time during past 3 days.

C8 distribution numbness directly after inject. 4th and 5th digits of hand on injection side felt like tight rubber bands at base of digits, improved with benadryl and dexamethasone). C8 sx followed by 35 min later abrupt onset central facial numbness (felt as if I had received dental block, and lip swelling Mild but noticeable (upper lip more than lower), per ED attending also some blotchy red areas, not hives on the neck same side as injection. No shortness of breath or swallowing difficulties. Bp higher than base line and slightly tachycardia compared to baseline. Treated with benadryl and dexamethasone . Facial symptoms lasted over night took additional 10 mg of prednisone, with improvement over the course of the day.

2 hours after vaccine sudden onset burning and cramping abdominal pain with cold sweat, generalized weakness, lightheadedness and flushed sensation required lying flat for 30 minutes before started improving. Day after vaccine arm moderately painful and hot, generalized headache, occasional sweats. Two days after mild generalized headache, arm mildly sore. Sweats less frequent.

Swelling in the injection site of 0.5 cm, hardness, Redness, Muscle pain for 3 days, Headache,

Injection received at 1330 on 12/24/20. Localized reaction about 2 hours after. By 2000 hours same day, severe muscle aches and joint pain. Nausea and vomiting at 2330 same day. Fever of 101.6, controlled with Tylenol but requires regular redosing. Chills and headache.

Severe swelling, erythema pain at at injection x for first 4 days Headache, first day. Day two fever, body aches started. Third day joint aches, cough, congestion, sore throat started and continue today.

Body/joint ache 18hrs post inj, slight fever 99.2 , 24 hrs later, w/ chills, dull headache, increased heart rate, pressure/heaviness around sternum, cough, tired. Feels like covid! Some dizziness when moving around

Rash to bilateral deltoids for 3 days, slightly itchy, felt like sunburn

I was very tired during the day. More so, as the day went on. Sometimes, I am tired during the day. It was only obvious that this might be a side effect later in the day. 1-2 cm blisters at antecubital site on left arm, which was the extremity of vaccine injection. My neck was sore. At first, I thought I had just slept so long that first night, that I was sore from that. It was more sore than from an odd sleeping position. My left neck/trapezius muscle at insertion in neck.

Received shot at 12:30 PM. Started feeling really tired about 8:30 PM. Severe body aches and chills at 9:30 PM. Wearing layers under blankets and teeth chattering. Started getting a headache. Took Aleve 440 mg at 11:00 PM, did not help. Sleep at midnight, woke at 2:30 freezing and very achy. Woke again at 0630 same symptoms, woke again at 11:00 AM, severe aches, headache, but being so cold was subsiding. Highest temp I had during this was 99.7, so not bad. Felt tired and very achy all day Thursday arm is red and have other red areas now on that arm that are hot and painful, no more chilling. Just feeling tired Friday and still have the red spots on the arm by the injection site. Aches and headache subsided. I still had a post Covid cough and palpitations when I received the vaccine.

Paresthesias, gait disturbance, vision disturbance

I am an RN and I received the Covid Vaccine on Friday, felt some expected fatigue and arm soreness on Saturday, but woke up Sunday for my shift with a dry throat and hoarse voice that progressive worsened that day. I got a Covid PCR swab Monday morning at 0900 and made an appointment to see my doctor that afternoon. At my appointment I had almost lost my voice, had some nasal drainage, slight sore throat, fatigue, and she felt I had decreased lunch sounds that warranted all abs and a chest X-ray. I was swabbed for strep, Flu A & B, and Covid antigen testing was done. All were negative. The CBC was mostly within normal limits. The chest X-ray show inflammatory process, a possible beginning pneumonia, and stranding. She prescribed a ZPak. I received a negative COVID PCR test result on Wednesday. I reported to my employee health nurse at my faculties where I work and received the vaccine and she asked me to fill out a VAERS report. Licensed provider note states ?December 21, 2020 To whom it may concern, This is a note to confirm that patient was seen in my office today for a doctors appointment. Patient was seen in office today, x-rays were taken, does as symptoms consistent with bilateral bronchitis, pre pneumonia right side of concern this started with the COVID vaccine. ?

developed a pruritic red burning rash on hands and arms 1 hour and 23 minutes after Pfizer covid vaccine. Itching all over and mild itchiness of throat. Had premeditated with 10mg zyrtec. Upon reaction took additional 10mg zyrtec and prednisone 10mg. symptoms resolve in 4 hours

Within 10 minutes lips were tingling and small hives on roof of mouth (1635). After 30 minute evaluation I left since I thought it might be anxiety or Placebo. Took 2 Benadryl. At 1830 decided I needed to go to the ER since symptoms were worsening. Tongue swelling, hives on roof of mouth getting larger in size and increasing surface area, larger hives on inside of mouth, lips noticeably swelling to those who didn?t know me, lips tingling, face itchy and discolored, getting harder to breathe to the point of being painful to swallow and talk. In the ER they have me a epinephrine shot in my left thigh and a intravenous dose of steroids in right arm. Observed for roughly 2-2.5 hours then sent home. Have a Rx for prednisone (3 20mg tablets for next 5 days) and instructions to contact allergist/ immunologist within 10 days. To date (12/25) symptoms are: still swollen lips although not as large, itchy face/ neck, sores on inside of mouth, throat still sore but can safely talk and eat without problems.

12/22 - Extreme fatigue 12/23 - Arm pain and swelling at the injection site, Feverish feeling but no actual fever

Hives and scratchy throat

Moderate full body myalgias and low grade fever 100.2 approximately 20 hours later. Resolved spontaneously by 48 hours.

2 days after receiving the injection I noticed a large amount of swelling under my left arm. It is tender and about the size of 2 golf balls. I have had COVID 19 in June and had antibodies in July and October during my blood tests.

24 hours after receiving the vaccine, patient discovered a rash approximately 1/2 inch in width extending from the left corner of their mouth to about halfway down their neck (approximately 5 inches in length). The rash was washed with cool water and soap, and monitored.

Slight weakness/tiredness, muscle soreness, low grade fever, general feeling unwell

20 minutes post vaccine to approximately 1 hour post vaccine: hot flushing from chest up to face. Flushing felt like nose and cheeks were numb. 12 hours post vaccine: left upper arm (injection site) with not only muscle soreness but arm was difficult to lift. 27 hours post vaccine: sudden onset of diarrhea (only 1 episode)

irritation an inch below the injection site. the size of a silver dollar. seems to be increasing size.

"WITHIN 5-10 MINUTES OF GETTING THE VACCINE. I STARTED FEELING LIGHTHEADED WHILE SITTING ON A CHAIR. I FELT LIKE I NEEDED TO LIE DOWN AND PUT MY FEET UP BECAUSE I FELT LIKE MY BP IS GOING UP. I TOLD SOMEBODY AND A NURSE CAME WITH A CRASH CART. I TOLD THE NURSE IF SHE COULD CHECK MY BP BECAUSE I COULD FEEL IT GETTING HIGH (I CAN TELL IF MY BP IS HIGH BECAUSE I TAKE BP MEDS FOR MY HTN.) I TRIED TO TAKE A DEP BREATH TO CALM MYSELF. NEXT THING I KNEW, A

NASAL CANNULA WAS PLACED ON MY NARES. I FELT TACHYCARDIC, AND STARTED TO FEEL PALPITATIONS CREEPING UP MY NECK AND CHEST. THEY DID AN EKG AND FS BLOOD SUGAR ON ME. I HEARD SOMEBODY SAID, 'HER BP IS 200!"". THE DOCTORS AND NURSES WERE STARING AT ME TO ASSES ME FOR ANAPHYLACTIC REACTIONS. I SAID ""I DONT THINK IT'S ANAPHYLACTIC REACTIONS"". A DOCTOR TOLD ME THAT THEY ARE BRINGING ME TO THE ED FOR FURTHER OBSERVATION. ON THE SECOND DAY POST-VACCINATION, I FELT SO TIRED, FEVERISH AND IT'S LIKE I HAD A HANGOVER."

extreme soreness and swelling at injection site, followed by soreness and tenderness up same side of neck

Sores on tongue Fatigue Diarrhea 6 days after shot

On 12/24 I started having muscle twitching in my back, shoulders, eyes and my mouth are felt drawn up. It subsided after about 15 minutes. On 12/25 the same thing happened, bit twitching muscles also affected my arms and hands. It lasted about 35 minutes.

I was at work (I am emergency doc) on the day following the vaccine. That day I woke up with some pain only at palpation of the right deltoid muscle at the site of the injection. At about 1p, I began to feel cold and soon after that my teeth began to chatter and I began to have rigors. I continued to work and left at 330p, as usual. I reached home at about 430p and took my temperature: 102.2F. I took 1000mg acetaminophen and 600mg ibuprofen. At that time I had stopped shivering. I had dinner without problems and went to bed at approx. 1000p, repeating the dose of both meds. I woke up at 5 the following morning and reached to work by 0700a. Symptoms did not reoccur. Deltoid pain was gone by morning as well. I rationalized the event as a boost reaction, as I had Covid-19 in July 2020.

Feeling that something was wrong, headache, racing heart beat, short of breath, dizziness, weakness, inability to stand, hot then cold, shaking, chills,

Fast Heart Rate of 107 24 hours after vaccination; sluggishness

Mild anaphylaxis with angioedema of the tongue within minutes of injection.

1-day post-vaccination, injection site swollen, raised circle about 1.5 inches in diameter, warm to touch. No past reactions to other vaccines.

Intermittent Abdominal cramping on 23rd and 24th. Diarrhea on 25th at night. I?m usual sensitive like this to some antibiotics. Feels similar.

Began experiencing pain in left arm shortly after injection, approximately 12 noon. Pain continued to worsen throughout day. Unable to move arm without severe pain by 5 pm same day. Began taking liquid advil gels approx 9 pm on the same day. . Pain continued throughout night. At approximately 10 pm I called the VAERS toll-free number to report this problem. I left a message and have received no return call as of yet. I have been taking 400 mg liquid advil gels every 4 to 6 hours since. I placed a call to my primary physician on December 25th. I was told this was a common reaction and to take Ibuprofen for pain. I am writing this approx 2:30 am on Saturday December 26th and pain has not subsided.

First and second night rigors, full body cramps. At 30 hrs ageusia following an exercise run with severe knee pain. Dry mouth starting at 48 hours. Chills continue 3 days later. No resp symptoms. Afebrile. Going on 4 days and symptoms continue

"FELT FLUSHED, ""TINGLY"" AND HER THROAT ITCHED"

Itching, urticarial rash, mild shortness of breath, headache, mild nausea.

Right arm is painful with a rash and redness in the area. There is also pain from the elbow to the shoulder. Pain especially with lifting my right arm or lifting something with right arm.

"Headache like I experienced with Covid, painful hips/back like I experienced with Covid - both only on 12/20/2020. I took Ibuprofen. My arm was sore at the injection site and it still is sore 12/22/2020. A small area around the site of the injection became red on 12/20/2020 and the red area continues to grow on 12/22/2020. What was the size of a thumb nail on 12/21 has grown to about 2"" long by 1"" wide."

Dizziness,Nausea, and Tense

low grade fever 99.3, fatigue, achiness, headache, congestion

Patient c/o of overall warm, tingly rush through her body, feeling shaky. Denies difficulty breathing or any other symptoms. BP 133/98, HR 95, O2 100%; BP rechecked after a few minutes, 116/81. POC 114. Reports feeling better right away and returned to monitoring area to be observed for 30 minutes.

fever to 100.8 around 1pm on 12/25, lasted for 1-2 hours.

Developed large hives on face, returned back to clinic. They gave me two doses of 25g Benadryl liquid. Vitals were taken. BP was 170-180/1-teens, pulse between 100-120. Was observed and hypertensive emergency remained, was then sent by ambulance to ED. Treatment given there was liquid Decadron.

RIGHT UPPER ARM STRTED FORMING A REDDENED AREA SATURDAY 12/19/2020. AREA KEPT GETTING BIGGER SITE MORE PAINFUL. tUESDAY 12/22/2020 RIGHT UPPER ARM HAD GRPE SIZE HARD AREA WARM TO TOUCH, VERY TENDER. DR EVALUATED, PLACED ME ON ANTIBIOTICS FOR 10 DAYS. WAS INSTRUCTED TO CALL AND SEE HIM IF ANY CHANGES/ WORSENING OF THE AREA.

Localized raised, reddened area. Warm and tender to touch. Took Benadryl-did not remedy the area but no worse. No systemic reaction. No further swelling of arm I have reacted this way to previous vaccines (tetanus being worse than this one. ----

I had bodyaches, fever of 101.4, nausea, chills, headache that started at 2230 on 12/24/2020. Tylenol was taken and fever continued to increase. Hip joint is stiff and walking is difficult.

Moderna COVID-19 Vaccine EUA Severe body chills(started at 7pm to 10am)) body aches (8pm to 10am)) headache (10pm to 8pm next night) Lethargy 10pm to present)

fatigue nausea vomitting

single episode of diarrhea 20 minute after vaccine administration, no other systemic symptoms, no other complaints or concerns

Stomach cramps, fatigue, diarrhea.

Feeling hot, redness

Dizziness. Lightheadedness. Fever (100.1)

Hypertension, hives on chest, arms and torso, sweating. 50 mg Benadryl administered

Day 2 post vaccination: Tinnitus. Ringing in ears, ears feeling plugged, hearing diminished, and every sound seems to echo around me.

Got covid vaccine around 0745, Driving home from hospital, felt like throat was warm and closing, heart racing and shakey, pulled over call 911 at 0816 and ambulance arrived. Blood pressure was elevated, symptoms subsided and took Benadryl. Minor tingling in throat post- event.

red, hard, painful, raised, warm area at injection site measuring 8cm x 5cm five days after injection

Approx 10 hours after receiving vaccine began feeling nauseous with headache that worsened. Followed by high fever of 102 came down to 100 with use of ibprofuen. Fever was on and off for another 12 hours fever and headache/body aches resolved by 3 pm on 12/25/20

Sharp pain in left arm shortly after injection with ROM of shoulder. Pain progressively worse over the next 48 hours to 5/10 at rest and 8-9/10 with ROM. Unable to work as scheduled as a OT for patient safety reasons due to limitations of left arm use.

I began to have itchiness on my eye lids, around my eyes, and on my neck. I took 2 Benadryl and went to sleep. Today, I continue to have itchy eye lids as well as some itchiness around my chin although that is less severe than my eye lids. I have no rash nor do I feel this possible reaction requires any immediate attention.

Woke up the morning of 12/24/20 and had Developed raised red rash with itching to right shoulder, chest and arm down to the hand. Rash only developed on The right side, did not move down to abdomen or legs at all. Also developed blister in the mouth only on the right side on the roof of the mouth. Took Benadryl and applied cortisone cream topically to rash. At this time 12/26 0800 most of the task has resolved only remaining in on the back of the right hand and wrist and the blisters in the mouth remain.

Patient had a syncopal episode after receiving her first dose of the COVID-19 vaccine.

lLeft arm was warm them whole body got warm. Heart Racing Broke out in hives

Vomiting w/o nausea. Chills

myalgia, chills and drenching sweats

Sore throat, fever , tested positive for covid

Experienced mild bloating, mild abdominal cramping, hyperactive bowel sounds, mild diarrhea, and mild nausea starting at 0130 on 12/23, with the worse of it 12/23, improving on 12/24, and resolved by 12/25. Symptoms were improved with over the counter gas medicine.

Numbness and tingling of face unilateral on same side as injection, nerve like pain shooting thru neck, followed with bilateral reynauds of hands and feet. Started within 15 min on injection side and was bilateral within one hour.

I got the vaccine on Tuesday, on Wednesday night In the middle of the night, I had extreme leg cramps, more severe than I have had before in both legs. I got nauseous and vomited, not sure if due to pain or a reaction. I took potassium and drank more water the next day. Again, I Thursday nIght, I had another EXTREME episode. Felt my whole body was cramping. It lasted about 5 to 10 minutes. I drank a lot again, took several vitamins, potassium and one gabapentin on Friday night. I did not have an episode on Friday night. I am not sure if this is related to vaccine but felt the need to report as I suspect somehow my electrolytes were affected.

I began feeling short of breath, heart palpitations, and dizziness. It felt the same as my reactions to bee stings and fire ant bites. This lasted about 10 minutes and started to subside on it's own. Then, I was also given 25 mg of benadryl by mouth. Within about 30 minutes I was feeling back to normal.

Body aches, fever, headache, sore throat, coughing, congestion, no taste, loss of appetite.

12/23 body aches - generalized all over, just don't feel well. 12/24 body aches, just don't feel well. 12/25 body aches, just don't feel well, skin on back feels itchy and burning - nothing is reliving it. 12/26 body aches, just don't feel well, skin on back feels itchy and burning - difficulty sleeping/getting comfortable.

Low grade fever, muscle soreness, chills, headache, disorientation, confusion

Nausea

Received Moderna COVID vaccination on 12/25/20 at 7:50am. Felt fine with vaccine and immediate period. woke up with pain in arm 1900. Upset stomach 3am. Vomited. Presented to COVID vaccination clinic at 9am. Headache on left side of head, nausea, malaise, achy. Tingling down left arm and into hand. Swelling at the site. Red skin size of a dime at injection site. Reports she worked last night 2300-7am. No fever. Iced the arm. Took Aleve.

Fever up to 100.8, treated with ibuprofen, body aches.

Sore arm about 4 hours after receiving vaccine. Next morning: woke up feeling fatigued and had 3 bouts of diarrhea in total (each time after eating).

Diarrhea, onset about 12-16 hours post dose. Multiple times for roughly 24 hours. Self limiting, not requiring any treatment beyond oral fluids. Injection arm soreness, swelling and small contusion,

starting about 8-12 post dose lasting for 48-72 hours. Self limiting did not require any treatment. Fatigue, developed within 18-24 hours post injection. Self limiting not requiring any treatment.

lightheaded, sweaty, and nausea. Past hx of vasovagal reactions to needles

12/26/2020 Generalized body urticaria/rash, itchy, Fever 100.9¦, headache, GI s/s, Sore arm 12/25/2020 2pm-nighttime Fever 101.1¦ (continued throughout evening), GI s/s, fatigue , Sore arm/shoulder 12/24/2020 7pm Scalp Itch, Sore Arm

Immediate: arm numbness and tachycardia Day 1: injection site swelling swollen, tender, red, and warm; myalgias; occipital headache; general malaise Day 2 & 3: injection site swelling swollen, tender, red, and warm (still ongoing)

intial light headedness. spotty vision and fatigue. Patient felt like they were going to faint. Vitals were taken and patient had elevated HR, and 90% O2. Resolved in 60 seconds from initial response. Patient was observed for 30 minutes post vaccination

severe myalgias, joint pain, bone pain, chills - lasting from hour 15 after vaccination till hour 45; associated with severe fatigue . slept all day on 12/24. took tylenol and ibuprofen every 4-5 hours. 80 % resolution of symptoms by hour 48. complete resolution of symptoms in 72 hours.

16 hours after injection- (6 am) and lasting 10 hours Nausea Vomiting Dry heaves Cold sweats Headache Fatigue Muscle aches

Chills fever over 102f headache cough body pain weakness 48 hours

12/24- bad headache 12/25 bad headache, sore throat, swollen lymph nodes, fever 101.6, chills, nausea 12/26 headache, temp 99.5, sore throat

On the 19 had a horrible headache and then at about the 24 hour mark I had really bad left ear pain almost like an ear infection but worse this lasted about 24 hrs then I felt like crap for 2 more days

LIGHTHEADEDNESS, HEART PALPITATIONS, SHORTNESS OF BREATH, FELT FAINT

Right side of face felt hot and slightly numb. Continued to persist for several hours. Appeared slightly puffy on right side. Muscles on right side of face felt stiff when moving them. Symptoms seemed to resolve but the next morning but returned around 1pm on 12/25. Additionally I noticed slight dropping in my face on the right side of my face.

Patient developed symptoms early the next morning after the Covid vaccine. Started with fever 102.8 and body aches. had fever for 5 days. Extreme low energy for 8 days and continuing. Headaches everyday. cough for the last 2 days. no SOB, no N/V D, no Sore throat, no nasal congestion. no loss of taste and smell. not pregnant.

Shaking chills, sweats, fever

complains of heart racing. Had patient site down checked bp 151/92 and pulse now 72. Patient reported heart rate no longer racing and has history of high BP

Body aches that started within 24 hours Low grade fever tmax 100.3 started late on the 25th and today.

Rapid onset of hoarseness, throat tingling and tightness

diaphoretic, shaky, nausea (transient)

dizziness resolved within 20 minutes

Chills, joint pain with redness and swelling, fever. Fever ranged from 99 to 101.7. Left foot pain causing issue walking for 24 hours, both elbows pain right shoulder. Right hand thumb, index finger and middle finger red and severely swollen. Fever continued off and on from 12 22 to 12-25 as of date. As of 12/25 pm, had episode again of chills, fever up to 100.1 again and left foot started hurting again.

Complains of heart racing. Had her sit down pulse 100 and BP 161/96 at 1120. At 1123 BP 161/96. At 1125 pulse 64 and bp 144/93 and states heart not racing and I feel better

Swollen armpit

Sneezing -12 hours, runny nose- 24 hours, mild cough 24 hours, fatigue for 36 hours, mild headache12 hours, muscle aches. Used OTC multi symptom cold medicine and Allegra.

Really bad reflux all day two days later (I don't get reflux unless I am pregnant, and it's been close to 4 years). Then the next day I had a really bad pain in my chest which occurred every time I swallowed. Was told this was probably an ulcer (I've never had one of these before).

Generalized rash

Injection Site Reactions included: pain, tenderness and swelling of the lymph nodes in the same arm of the injection (left arm) and hardness and some swelling around injection area of said left arm. Started on Wednesday, December 23, 2020 at approximately 5;30 pm and is still ongoing as of December 26, 2020 at time of this report. General Side Effects: Fatigue: Started on Wednesday, December 23, 2020 at approximately 5:30 pm and is still ongoing Muscle Pain, Joint Pain, Chills and Nausea: Started on Wednesday, December 23, 2020 at approximately 5:30 pm and subsided on December 25 at approximately 6 am. headaches and sporadic fevers: Started on Wednesday, December 23, 2020 at approximately 5:30 pm and is still ongoing - taking ibuprofen to keep fever and headaches down.

extreme dizziness a couple hours following the vaccine, headache for around 36 hours, weakness for 36 hours,

Headache, nausea, dizziness, dehydration, weakness, shaking

On 12/25 woke up with chills, body aches ,no appetite, mild nausea & extremely tired. Low grade fever 99.2. Only had orange juice to keep my blood sugar up. I have Type 1 Diabetes. Felt this way all day until I went to bed. Woke up today 12/26 feeling fine

Vomiting 1 week post injection followed by headache lasting 2 days

i developed mild cough at first, then fever and chills and body aches on the 2nd day up to present. I am taking tylenol fort he fever and Mucinex for coughing. Also Albuterol Breathing treatment Q 6 hours PRN Also the high temp and humidity of my CPAP at night helps

15 seconds after administration I felt tingling in my mouth and felt warmth come over my body from my feet to my head. I then experienced a sudden increase in heart rate. I was tachycardia to the 140s and BP 140/90s (high for me). This lasted for about 1 hour then resolved. The same event occurred 3 additional times, resolving in between episodes with a heart rate in the low 100s.. I was taken to my workplace Emergency Department. The entire even lasted over 4 hours.

Experienced numbness and tingling unilaterally to one side of face. Began 45 minutes after vaccination and lasted 4 hours.

Headache similar to migraine in location and intensity, first day of vaccine and every day since receiving vaccine. Nausea the day after the vaccine No appetite every day since receiving vaccine

At 72 hr marl I began having nausea and intermittent vomiting. Voming has subsided but nausea is persistent to the pint ive taken zofran many times.

Approximately 5 days later I began having symptoms which then developed into a shingles rash on the 7th day after receiving the vaccine. I wanted to report this to see if others had the same experience.

headache, upset stomach

Itching with redness and raised welts beginning 36 hours post injection, starting bilateral inner thighs and ascending bilaterally along groins, flanks, axilla, to arms and hands over a 36 hour period.

Fatigue, chills, fever, joint pain and pain at injection site

12/18 afternoon: asthma attack. This was the same as previous asthma attacks and occurred after my normal triggers (exercise in cold air). Symptoms resolved completely with albuterol. I was coughing continuously and strenuously for about 10 min before using albuterol. 12/18 evening: low-grade fever (100.1 F, baseline is <98) with chills. Also with altered mental status/delirium, which is typical for me while febrile. There was also nausea. 12/19: fever decreased to 99.2 F with normal mental status. New general malaise, worsened nausea. Single episode of vomiting, large volume of bile with some blood (streaks of fresh blood, larger volume of coffee grounds emesis mixed with bile). After vomiting I noted tachycardia to 130s--140s but this is a typical finding for me post-vomiting. 12/20: No further vomiting. Subsequent 2 bowel movements with moderate melena, since resolved. Fatigue and cold extremities, improving.

Within minutes of receiving first dose of Moderna COVID-19 vaccine, patient became lightheaded and pale, developed clammy skin, and was confused. He was assisted to a supine position with his feet elevated while his vitals were checked. His symptoms rapidly resolved in this position, and he was noted

to have the following vitals: P: 60; BP: 118/68; O2 Sats: 98% on room air. He remained supine for ~15 minutes and then was able to sit and ultimately stand without return of symptoms. He was monitored for 30 more minutes during which time he remained asymptomatic and was able to tolerate eating and drinking without difficulty. He was released to home with advice to seek immediate evalution for any symptoms.

"After injection patient reported feeling dizzy and ""woozy"". Patient states he is very anxious and nervous about injection today. Patient was assisted to floor x 2 assist with RN and Dr. and feet put up. BP 94/51 HR 90. Patient reported feeling nauseous initially. Patient responsed well to supine position. He requested a drink of water and reports he has not eaten today. Patient remained alert during the entire episode. Repeat BP at 1225 116/72. Patient was offered water with gramham crackers to eat, okay per Dr. Patient was assisted to a sitting position on the floor. Color improved, cheeks pink and patient appears in no distress. Patient was assisted to standing position at 12:30, reports no dizzy or light headedness and repeat BP 130/80 HR 74. Patient was assisted to the observation area with 1 assist. He will continue in observation area for 30mins."

Anxiety and slight shortness of breath that didn?t interrupt my sleep. I used my regular inhaler as scheduled. I felt better the next morning. Just arm soreness.

Full body hives beginning about 36 hours after vaccination. Angioedema in the hands, feet, and lips beginning about 48 hours after vaccination. Hives did not improve with Benadryl so doctor prescribed prednisone. No severe reaction such as anaphylaxis, but reaction was moderate enough to make daily life difficult.

Urticaria rash on bilateral arms and abdomen

Day off sensation going up my left arm to my head Headache dizzy lightheadedness and nausea almost fainting. Bp 115/70 hr 80. Tylenol helped with headache but head still felt heavy. 1st day Chills and extreme fatigue 2nd day fatigue nausea 3rd day fatigue nausea severe headache ?exploding? after getting up from picking up toys off the grown blood pressure 90/60 .

The day after I got my vaccine (a Thursday) my arm hurt really bad, and my body aches started as soon as I woke up, but were not severe. As the day progressed, the body aches got more severe and were accompanied by a headache and fever by around 7 PM. I literally felt like I was dying, and have never had body aches that bad before in my life. I laid on my couch and didn't move until 11 PM, with no apetite, and then went to bed. The day after that, when I woke up the body aches weren't as bad, and my temp was 98.8. Again, around 3 the body aches started getting worse, I was so tired I could barely function, couldn't eat without being nauseous, and laid in bed as still as possible until I could fall asleep. The Saturday following my vaccine, I woke up at 6 and my body hurt so bad it felt like I couldn't move, my head was so bad even the light from the shades felt like it was piercing me, and I still had no apetite. I stayed in bed until 10 until the body aches got a little better, and was able to go about my day almost as normal, just with my body feeling kind of like I slipped and fell on ice. On Sunday, I still had no apetite and was nauseous without even eating. My body still ached, but I was able to do things like the dishes and just hang out at home. My headache was still unbearable. I called the hotline number for my

hospital that was given to me when I got my vaccine, and they scheduled a COVID nasal swab test at 1. I put on sunglasses to drive the 10 minutes to the clinic, got my test, and went home and went to bed. Since I had a COVID test ordered by my employer, I wasn't allowed to work until I got the results and HR cleared me. The results were negative, and I didn't get cleared by HR until Monday morning. When I contacted my supervisor, he wanted me to stay home anyway since the body aches (even though they were getting better), fatigue, headache and nausea were still there, regardless of a negative covid test. He was worried I had the flu. I made an appointment with my primary care doctor for 2:10 on Monday, and he told me it was just serum sickness. I went home and went to bed. My body aches and fatigue fully went away by Wednesday, and my headache still remains, on the following Saturday. I haven't had a headache in maybe 5 years.

Patient received vaccine around 4:15pm on 12/24/20. Around 11pm he was feeling extremely tired, however, patient had been working very hard the week leading up to Christmas. Patient woke up in the early hours of the morning with chills and very fatigued. Chills and fatigue remained on and off through out the day and the patient realized he was running a temperature of 102.8 at some point during the day. Patient stayed at home and rested and took Ibuprofen and eventually started feeling better towards the evening and night. However, the fatigue still remains on 12/26/20.

Initially very mild tingling to nose and lips. Then in ED, BP 170s/110s. Then about 1 hour and 10-15 minutes later had rash start to pop up on random areas of my face. Then next morning with sore throat and rash around the next about 21-22 hours after the vaccine

Bodyaches, weakness, bone pain, lethergy, brain fog

Moderate soreness at injection site.

Moderna COVID-19 Vaccine EUA Severe teeth chattering chills, body aches, muscle & bone pain, temperature 99-101. Diaphoresis, Dizziness, Nausea, Vomiting & Diarrhea lasting 48 hours. Severe body aches, muscle & bone pain persisted.

12/18/2020 I HAD A LOT OF BODY, MUSCLE AND JOINT PAIN. THIS LASTED ALL DAY 9:00 AM - 9PM. I WENT HOME AT 5 AND WENT TO SLEEP FOR 90 MINUTES. SYMPTOMS WERE MILDER. I STARTED TO NOTICE L UNDER ARM PAIN, INTENSIFIED OVER THE WEEKEND. 12/21/2020 CONTACTED PCP; LYMPHNODES SWELLING. PAIN LASTED UNTIL 12/22/2020, LATER EVENING THRU 12/23/2020 12/25-/12/26 NO PAIN TELECHAT WITH PCP NOT VISIT; DR PRESCRIBED TYLENOL

12/23/20 0850 Stinging/burning at injection site right arm; 2000 entire arm right burning and feeling of sunburn across chest down to liver then to left flank and entire back; 12/23 2300 generalized joint pain; 12/24/20 0830 101.3, 1030p 100.6; Friday 12/25/2020 1030am 100.1; 5pm 99.3; Vomited 830p;11pm 101.3 Saturday 12/26/2020 1pm 100.0

C/O of tachycardia, dizziness 20 minutes post vaccine, placed on monitor. HR 80-100, B/P 157/102, SaO2 100%. Progressed to SOB & HR 174 @ 25min post vaccination. Epi auto injector 0.3mg IM x1 given,

called emergency response. Patient awake, alert, oriented x3. Verbalized improvement in SOB after epinephrine, taken to ED via wheelchair.

Patient had fever and malaise that lasted 48 hours

Flush feeling through entire body within 10 min with dizziness associated. Numbness of bilateral hands and feet as well as lips. Rise in Bp up to 150/100. Red, blotchy neck. Within hour, dizziness subsided, but numbness of extremities and lips lasted approximately 10 hours.

12/23/20 0000AM constipated like symptoms started; 0200AM woke up to severe stomach discomfort with refluxing feelings with body chills; 0300AM had bouts (at least4) of violent vomiting with very thin, liquid greenish vomitus, vomiting lasted for about 20 minutes then followed by loose bowel movements consecutively (about 6 times) with very liquid, greenish stools; stomach discomfort somewhat subsided right after but body chills remain and joints and back started to ache. Noticed that exposure to cold air would trigger bowel movement. Was afebrile all this time until about 1100AM where it was recorded to be mildly febrile at 37.8, took some tylenol with gatorade after which mild fever seem to subside. For much of the day of 12/24/20, body aches continues with intermittent loose bowel (especially after eating or drinking anything)still averse to cold, took some tylenol again 6 hrs. later for the body aches mostly. 12/25/20 felt much better for most of the day then at 1100PM reflux symptoms and body aches started again but no vomiting this time, still afebrile. 12/26/20 at the time of this reporting, stomach still feels queasy and still having loose bowel and body aches. No other symptoms experienced except for the ones described above.

Vaccination administration error - equipment syringe failure. While giving the shot, the cap (needle part) of the syringe came off. Nurse vaccinator stated that patient likely received 0.3mL or 0.4mL of the dose (full dose is 0.5mL). The remaining dose was pushed out of the syringe, so unable to see how much of dose was remaining that did not get into the patient. The patient displayed no signs and symptoms at time of this error. We called Moderna manufacturer after error occurred, while patient was still waiting in the room. Moderna Medical information stated that they do not have any recommendations outside of the information published to providers and to wait for call back from their experts regarding next steps. Patient was observed for recommended amount of time and then left the facility. We'll contact her if anything is needed besides the second dose that is scheduled in 4 weeks in order to complete the vaccination series.

Local site reaction: erythema, hard welt, warm to touch, burning at injection site at time of injection. Erythema grew over next 48hrs to a max of 2inches, warm, hard to touch with persistent burning. Resolved 12/25/2020. Beginning at 4:00pm 12/22/2020 generalized body, muscle, and joint pain, increased generalized neuropathy pain and generalized sensitivity to touch. Symptoms resolving 12/26/2020 at 10:00am.

Fever, body aches,

Left supraclavicular lymphadenopathy

Injection given on 12/21/20 at 0830 - Injection site pain noted for 12 hours. 12/22/20, tiredness, nausea, swollen lymph nodes noted and continued through 12/23/20. All side effects resolved by 12/24/20.

Extreme soreness at site of injection that has continued into third day. Pain worst the second day and is waning, but use of arm is still painful. Experienced lightheadedness shortly after injection, but with no bad effects. Like being high. Painful body aches began at end of day of injection and continued for 36 hours, with highest intensity after 24 hours. Body aches diminishing on third day, but arm soreness still quite evident

tingling, dizziness, tunnel vision, nausea

"I have been experiencing overall of ""being unwell"" including intermittent palpitations, nausea, lower GI upset/cramping, dizziness, fatigue, chills, low grade temp of 99.5 F, right sided neck pain, and Headache. Treatments: Tylenol PRN, and PRN Zofran Outcome: ongoing"

Very sore , swollen , red arm below injection site. Headache and chills for 24hrs

I received the shot at 7pm on the 23rd, when i woke up on the 24th i had some soreness around the site but I felt fine otherwise, around 10am on the 24th, I started by first having chills then feeling flushed, I started to have severe muscle and joint aching, headache and body sweats. my fever got up to 103. I was taking tylenol and ibuprofen about every 4-6 hours. this all lasted until 6am on the 25th, on the 25th i had some fatigue and headache, the night of the 25th around 10 pm i noticed a little swelling and tenderness under my left axilla and left upper chest near my collar bone. i think it is lymph node swelling or tenderness. Today is the 26th and i still have the tenderness under my arm and upper chest, but i feel better otherwise. I was told that people usually have worse side effects from the second shot, is there any reason you wouldn't get the 2nd shot??

Lip soreness 12/23 around 6p. Mild Lip swelling 0900pm and took 1000mg of acetaminophen. Severe lip swelling mainly on the left side at 0400am. Took Benadryl and 1000mg of Tylenol. Swelling went down slightly. Went to ED 12/24 around 1130AM with low grade fever of 100 F arm soreness and continued lip swelling. 12/24 at 0900p fever of 101, fatigue, aches, and lip still swollen, but less then AM-took 1000mg of Tylenol and Benadryl. 12/25 at 0500AM 102.2 fever, body aches, sever headache, night sweats, and other side of lip swollen took Benadryl and 1000mg of Tylenol. At 6 AM fever went down to 101.2. 1200pm fever of 100.5, severe head ache, muscle and joint aches, lips mildly swollen-took 100mg more of Tylenol. 6pm 101 fever, headache, and lips itchy/swollen. Benadryl taken and 1000mg of Tylenol. 1200AM fever of 100 and headache, lips sensitive-1000mg of Tylenol and Benadryl. 12/26 at 0930 AM fever broke with temp of 98.6, mild headache, lips sensitive, but minimal swelling.

*A small rash of around 10 mosquito bite size bumps appeared under left armpit and left torso only. Shot was given in left arm. There are no bumps anywhere else on body. *They do not itch, hurt, or bother me. *It has been almost 72 hours since shot and bumps still remain.

Small amount of fluid leaked at needle hub.

10 minutes after dose experienced tachycardia, dizziness shortness of breath, and flushing. It lasted about 30 minutes.

HAD FEVER TO MAX OF 101, BODY ACHES AND CHILLS AND EXTREME FATIGUE FOR ABOUT 36 HOURS AFTER INITIAL SYMPTOMS STARTED

-Arm soreness started almost immediately, worsened within 8 hours, much improved by 48 hours -Bilateral trapezius myalgia, started about 10 hours later, unrelenting with heat/massage/oil/relaxation but still able to go out with a heavy backpack and hike, about 60% improved by 48 hours

sudden onset of pain in throat, base of tongue and increase dry cough. Oxygen saturation 97% which patient reports is at her baseline, no increase work of breathing, slight dry cough x 3 but not other cough

Light headed and dizzy, funny taste(metallic taste),pins/needles in tonsil area, nausea/vomiting

Facial hives, ear ringing, happened around 1 hr and 30 min after vaccination

Patient described feeling flushed. We activated our rapid response and hooked the patient up to the monitor. The patient was observed by our ED physician and observed for ~ 30 minutes. All vitals were normal, the patient reported a Migraine for 1-2 days after.

Experienced High fever chills muscle aches and malaise

Pt had fever and headache within 1 hr. This went away about 9 pm. The next day patient was ok. On day 2 post vaccine (12/20/2020) patient woke up with lymph node swelling in his left armpit. It was about palm size. Pt took meloxicam on that day and next day. Swelling has started to decrease.

Dizziness, syncope, nausea, feeling of going to faint.

Pt stayed for 15 minute observation time and then went to the cafe to eat breakfast. Once she got in her car about 45 minutes after, she noticed her lips were swelling. Pt took 25 mg of Benadryl. She continued to have to take it q4h on day of vaccine. Over the next 2 days she started to cut back on the amount of Benadryl she was taking but lips were still swollen some. She saw her PCP on 12/21/2020 and was told to continue Benadryl as needed and to take Pepcid 20 mg daily until better.

Pt had injection site soreness the next day. On day 2 post vaccination, pt developed a golf ball size knot. Five days post vaccination, the knot is gone but injection site still sore. Pt took ibuprofen as needed and Benadryl at night.

Soreness at injection site 3/10 for 24 hrs. Soreness radiating down to elbow and up to neck and base of skull starting 3 hrs after injection lasting 11 hrs.

Headache and general fatigue

"several minutes after vaccination, complained of shortness of breath. Nurse used standing order protocol to administer epi 0.3 mg into right deltoid. Patient reports feeling a little better BEFORE the epi, but reported feeling ""strange"". Charge nurse notified the emergency department, an ED nurse advised

coming for workup in the ED (which is right down the hallway). Patient walked to ED. Appeared pale. Patient discharged from the ED with a prescription for zyrtec."

Employee had nausea lasting 2-3 hours following vaccination and malaise for the rest of the day

Blister at injection site. Skin peeled. Approximate size green pea. Red line less than an inch.

itching, fatigue

Chills, malaise, nausea, vomiting, diarrhea, currently at a total of 44 hours from symptom onset without significant improvement

Right Shoulder Muscle Soreness

Fever 100.5, shortness of breath, heart racing, wheezing, fatigue

Fever, all over body aches, severe headache and chills, all this started about 11:00PM on 12/23/2020, about 11 hours after I received the vaccine. lasted throughout the night, around 0830 the next morning, felt better, still had a headache. Had low grade fever and slightly achy (not as bad as evening before) on 12/24/2020 evening. Felt completey back to normal by morning of 12/25/2020. I tool OTC extra strength Tylenol and Advil for my symptoms.

fever 101.8, body aches , chills, back pain , cough, shortness of breath , loss of taste and smell, sore throat

Tachycardia, elevated blood pressure, tightness in throat

Body aches and pains (started at 8PM), shaking chills and really cold(1:30 AM), nauseous (1:30 AM), fever 100.5 (8:45AM and throughout the day). The next day, some coughs cause my head hurts, aches and pains, low grade fever. Treatment:aspirin and benadryl. Doing better than the day before.

nausea, cold sweat, dizziness

"Patient entered observation area and upon greeting states ""I feel something"". Patient stated ""feeling something when I swallow"" denies difficulty swalling or breathing. Patient appears comfortable, Dr. speaking with patient who reports similar episode in the past mostly after a long shift at work. Patient states she has a history of SVT and usually has this response when she gets nervous. Initial BP 165/108 HR 112 02 99%. Patient reports feeling anxious and denies all other symptoms including shortness of breath or difficulty swallowing. Repeat BP 143/92 HR 95 O2 99%. Patient offered bottled water and appears to be calm at 15:20. Repeat BP 134/94 HR 83 @ 15:30. Patient speaking on her cell phone with employer re: issues at work. Patient in no apparent distress at this time. BP 139/92 HR 89 O2 98%. Patient without complaints. Will discharge after 30 mins of observation. discharged at 15:45."

None . Just got vaccine shot today the first shot.

metallic taste headache

Period cycle is lasting more than 8 days without relief or a reduction of intensity. This is abnormal and hasn?t changed within the last 24 hours

dose 1 of vaccine at 11am 12/24/20, after vaccination I noticed some pain and burning that radiated down arm, lasted for seconds and resolved. This pain came and went throughout afternoon of 12/24. Upon waking around 730am on 12/25/20 I noticed slightly red erythematous ovoid rash that measured approx 3 in x 1 in in size, was exquisitely tender to touch, but smooth, without vesicles, pustules, non-fluctuant. Took tylenol and applied heat to area without relief of pain. Pain is burning in nature, with a soreness that radiates down the back of my upper arm. Pain worse with raising or using arm. Also have aching in neck and upper back. Also having increased fatigue and slight headache all of 12/25, worst at night and located on right side of head, throbbing. On 12.26.20 I woke and noticed rash has slightly increased from markings made on 12/25/20. I continue to feel tired, achy, with slight headache. Arm very sore and upper back very sore.

"Minutes after getting the vaccine dizziness, flushing, and racing heart present. I was taken to a back room, laid flat, cool washcloth, vitals taken. Rash began to develop on chest and spread across the body. No itchiness, but a mild burning sensation accompanying rash. Throat was hot and scratchy. Within 10 minutes taken down to the ER. Rash came and went in waves and would appear on different parts of body. Each wave had increased heartrate, dizziness, flushing, rash, burning. Was given 50mg benedryl at 10:45, oral 10mg dexamethasone, and 1L bolus of saline solution. Was monitored in ED for 4 hours. Last reaction ""wave"" experienced around 1pm. Discharged around 2pm. No reaction since discharge."

Received Moderna Vaccine at 11:36, waited 30 minutes per Dr. recommendation. Left hospital, starting driving home and felt lips tingling and bilateral sides of tongue feeling thick and words sounding thick. Return to the Vaccine clinic at the hospital in 5 mins . Escorted to the emergency dept. BP 203/95, HR 80s, O2 Sats 94% room air.

Sore throat Fever of 100.4

When I put food in my mouth around 3pm and then again around 5pm, I felt burning/tingling in my mouth which quickly resolved.

Heart rate of 159 with palpatations, tingling on the throat, (red, no hives), surface rash on throat, clear speech, clear lung sounds Local EMS was contacted at 1:17 p.m. and the patient was administered 50 mg of Diphenhydramine at 1:21 p.m. After admininstration visual signs of rash subsided, and patients status improved. Patient was handed off to Local EMS

near syncope, hypotension, nausea/vomiting, tachycardia (120-150) within 5 minutes of administration. did not resolve and worsened within 1 hour. Pt went to ER for workups. Received IV benadryl without improvement. Admitted to hospital overnight for continuous cardiac monitoring. Improved overnight and discharged in the afternoon 12/24/20.

next day mild headache (next morning) for 3 hours inflammation of the inferior lips (1 month ago i was inyected with fillers). for 2 hours

Severe injection site soreness- Start: 0100 12/23- end: 0800 12/24 Fatigue- Start: 1200 12/23- end: 0800 12/24 Nausea- Start: 1700 12/23- end 1900 12/23

Muscle aches. Chills. Fatigue. Started 2 days after the vaccine. Temp 99.4. Had Shingrix shot #2 2 weeks before the COVID shot.

Felt fine day of shot. Next day low fever 100.6 chills, tired , generalized aches rap hand joints. Now arm soreness atvi jection site and a red small rash distal to site

Went hiking in the morning of the 25th.. Got home at 1pm. At around 1;30pm started experiencing nausea and vomited 4 times. Went to bed, felt tired and nauseated but did not vomit again. By 8pm I felt much better and have had no symptoms since.

Chills, fever (101), bodyache, headache

Patient developed rash/hive 1 hours after receiving the vaccine. Patient self medicated with a dose of Benadryl when the hives started. Send to ER and was observed for 2 hours. Hives resolved in 24 hours with no further treatment.

Employee consulted with PCP regarding taking covid vaccine with a know allergy to flu vaccine preservative. PCP recommended taking covid vaccine and pre-medicating with Benadryl 50 mg 30 minutes prior to the injection. The employee followed those instructions. Thirty minutes after covid vaccine administration, employee started to lose her voice and developed some wheezing. Employee was taken to ED where she received a dose of epi and solumedrol. The employe was observed in the ED for 2 hours and symptoms were resolved at the time of discharge.

Within 5 minutes of received the vaccine employee became pale and felt faint. Employee was lowered to the floor and examined. BP 122/64, alert and oriented, HR 100. Employee stated he was nervous and had not had eated that day. Pt. received juice and a cookie. Felt better after ingestion of food. No hives, wheezing, or other symptoms of an allergic reaction.

Severe low back pain, had to take muscle relaxers and pain meds. Couldn't stand up straight and needed help with adls. I also had chills at night a day prior to back pain.

1800 Chills started. 2100 fever 100.8, hr 115, slight sob resp 28, spo2 96, achy, lost appetite Next day fever 100.5, resp 32, spo2 93, very achy, head ache, sob walking around house, bad reflux heartburn Day 3 fever 99.5, resp 28, spo2 93, same symptoms Day 4 normal temp, resp 26, spo2 95, same symptoms, now with loose stool Gradually improved but stayed very fatigued. Day

Swollen lymph nodes left side of neck, rash all over

Felt nausea and headache after receiving the vaccine. She was laid supine and had continuous blood pressure taken for 30 minutes. After that time her symptoms resolved completely.

Headache 5 days now, face flushing 1st day, face swelling 2nd day.

Bilateral lower extremity myalgias and chills lasting 3 hours.

Metallic taste after around 20 mins after the shot Muscle pain around the injection site - 20 mins after Mild headache after around 4 hours after the shot Mild headache on and of until two days after the shot Mild sore throat until two days after No treatment done

Injection site discomfort within 3 hours, increased pain day 1 & 2. Significant headache at 12 hours post-vaccine, persistent through day 3. Significant fatigue and drowsiness on day 2 (none like I've ever experienced before) - slept 18 of 24 hours. Mild on day 3. Sore throat day 3.

Her lips began to feel tingly and became swollen. She also reported a mild headache. Laid supine for about 30 minutes. After which she reports all symptoms resolved.

Fever, chills, sweating, shivers, myalgias, fatigue, headache, not feeling well in general.

Felt as though her throat was closing and fatigue. She was talking the entire time but kept clearing her throat.

this morning I noticed swelling and pain in the lymph nodes under my left arm, no redness or warmth just swelling and pain/tenderness

Felt a flushing sensation, nausea, and reported feelings of anxiety. Laid supine for 30 minutes. After which she reported a resolution of the symptoms.

Painful, extremely sore arm; stomach pain, headache, just feel generally not good

Painful and red contralateral side (right) olecranon bursitis (Ulnar Bursitis)

Vaccine given in Clinic on the 18th. No pain no issues then on 21 st started having nerves on my left leg firing during the day like I had a pinched nerve. Later that night I had lower back pain like sciatica nerve pain like 10/10 Tylenol 500 could not help added 400 md Motrin still no help got to 8/10. and also right hand finger next to the thumb was numb occasionally. I felt tightness on left hamstring area. Massaged it and all pain disappeared on the back after a while. But since that incident I have been having lower leg bil never firing and occasionally same numbness on the same finger . Today got slightly worse as seems like my right hand getting a bit more numb.

On 12/24 @3am I started vomiting and did so on and off for the next 4 hours. A felt very fatigued the rest of the day. On 12/25 I developed a macular pruritic rash to my chest that progressed throughout the day that covered my torso. By 9pm on 12/25 I was experiencing fatigue, headaches, muscle aches and chills. I took Tylenol and ibuprofen and went to bed. I current have a headache, worse pruritic rash and upper tooth pain .

Patient asked for extra monitoring in the observation area due to Sulfa and other antibiotic allergies. Patient states tongue was swelling. No difficulty breathing, no airway obstruction. Assessed by on site provider, 25 mg po Benadryl liquid ordered and given without difficulty BP elevated to high of 151/95. 911 call placed. EMS on site. Patient refused transport to hospital and was picked up by her mom after

signing AMA documents. Advised to not drive, not be alone and was being monitored by mom who was a physician. Patient states tongue swelling improving on discharge to mom. Last BP 140/90. Patient is obese.

Client is 17 year old and vaccine given. Unknown adverse reaction. Underage for vaccine approved.

Second day on December 21 had moderate arm pain extending up neck to base of head. Dec 22 pain was gone but began to have continuous twitching of left eyelid, Dec 23 eye pain. Started prednisone dose pack on Dec 22. Eye twitching gradually improved and am currently having minimal symptoms

APPROXIMATELTY 10 MINUTES AFTER RECEIVING MODERNA VACCINE, SHE REPORTED TO THE MONITORING PHYSICIAN THAT SHE FELT LIKE HER HEART RATE WAS HIGH A LITTLE BIT. DENIED ANY OTHER ISSUES. PHYSICIAN CHECKED MANUAL PULSE=100BPM, THEN DECREASED TO 84 BPM THEN DOWN TO 76 BPM WITHIN A 3 MINUTE TIME SPAN. PATIENT SAID SHE FELT BACK TO NORMAL AFTER THAT AND CONTINUE TO WAIT AN ADDITIONAL 15 MINUTES JUST TO BE SURE. NO FURTHER ISSUES NOTED. PHYSICIAN REPORTING THIS INFORMATION WAS AT THE COUNTY HEALTH DEPARTMENT

Numbness and tingling in lips and tongue - post 1 hour Dizziness day 2-3 Fever Low grade 99.4 post 1 hour Achiness day 4-5 Fever 100.4 day 5

Approximately 4 hours after receiving vaccine, patient broke out in full body hives. Patient took Benadryl and Claritin that night and Claritin the next day and symptoms subsided.

Nausea and intense vertigo

57 hours after vaccine, I woke up with stomach cramps, diarrhea, chills/sweats feeling awful and soon after had a sudden syncopal event while walking back from the bathroom. I recovered, laid in bed and then within 15-20 minutes had diarrhea again so went to the bathroom and had another syncopal episode on the toilet (both witnessed by my husband) with diarrhea during this episode. I then went to the ER and was treated with 3L IV fluids for hypotension, IV zofran and bentyl. I left the ER within about 3 hours. still have been fatigued but was up most of that night. my body all hurts but I fell into my bedframe face first during the first syncope so would relate that to those symptoms/injuries.

Within grove minutes of receiving the injection my throat closed, my heart raced. My pulse was 107 my oxygen was low around 89-90 I believe. My neck became red with a rash and I was shaking. I was taken to the emergency room as the shot clinic was attached to the hospital and received Benadryl 25mg and Predinose 50mg. I have no known allergies that have ever caused an anaphylactic reaction. I have never had vaccine reactions in the past either.

Day of vaccination (Monday) and day after vaccination (Tuesday) experienced a sore, tender arm and mild fatigue. Wednesday morning woke up with tender, swollen lymph nodes and sore throat. Arm still sore as well at injection site. Thought sore throat may have been due to acid reflux so went to work at the hospital as usual. Thursday morning woke up with a worsening sore throat with difficulty swallowing, cough, nasal/sinus congestion, ear fullness, fatigue with dizziness, and nausea. Was unable to perform daily functions. Notified employee health at the hospital who advised a covid test and

exclusion from work. A rapid strep test was also performed which was negative. Friday symptoms still present but slightly improved. Saturday morning received negative covid test result and approval to return to work if respiratory symptoms improved and under control. Today is Saturday afternoon, now returned to work (arrived late). Experiencing mild symptoms currently similar to the common cold.

within 3 min of receiving the vaccine, I experienced flushing, racing heart, lightheadedness, dizziness, mentally fog, winded/ shortness of breath, and felt like an adrenaline rush. All that calmed down by 30 min. Then experienced nasal congestion for an hour. within 3 hours of vaccine, developed a headache and later that day it worsened and chills developed. The next day was just slight headache. The second day was sore arm and fatigue that lasted for 1 to 2 more days.

Severe vomiting and diarrhea to where had to go to ER due to dehydration, lasted 4 days. Body aches, fever, muscle aches

I have a large bruise, found the next morning. Right foot tingling, and soreness on right calf and right leg hamstrings.

Injection site pain, no swelling or redness Fatigue (moderate) Headache Pain with eye movements Nausea Abdominal pain No treatments needed.

"Received Moderna Covid 19 Vaccine EUA Approximately 8 hours after receiving the vaccine I developed a cold sore (not unusual when I have had influenza shots in the past). Approximately 36 hours later, late at night, I developed pruritus on my left arm (near elbow, same are as injection). I examined it in the morning and there were small lesions as well as a circular ""bulls eye"" lesion, similar to when I was told I had contracted Cox Pox when doing surgery on farm workers at Hospital, 10 years ago. Acyclovir helped relieve the puriritis. At this time (60 hours after vaccination and 18 hours after pruritus and lesion developed) the condition has not progressed and has slightly improved."

pain in injection site (few hours after injection, all day), muscle aches(12/24/2020 in the evening into the next day, 12/25/2020, all day), numbness on entire left side (12/25/2020, few mins)

Fever 100.9 approximately 12 hours after injection, body aches, fatigue

Employee was waiting to be observed for the required 15 minutes post vaccination. She started to complain of not feeling well and feeling short of breath. She was immediately assessed by staff and transported to Emergency Department for further evaluation.

Pt began feeling flushed, tremulous, c/o weird sensation in throat. developed rash. Had near syncope. 1-2hrs of symptoms.

Nausea, vomiting, fatigue, muscle aches, headache, chills unrelieved by over the counter medicine lasting over 3 days

Had complete relief of my chronic back and leg pain for one day. Pain gradually returned in three days.

Transient pleuritic pain -- about 3 incidents lasting about 1/2 hour each, day following vaccination. Minor headache a few hours after vaccination. Mild abdominal discomfort off and on for a couple of days. Soreness in the arm at site of injection -- not unexpected. Resolved after three days.

Swelling at injection site with redness that became visible within 12 hours. At 72 hours site is larger, measuring 2 inches in diameter. Area is also swollen, slightly sore, periodically itchy.

lightheadness/weakness

Loss of taste. Body aches coughs

Swelling at injection site, redness, pain

Arm/sight pain pressure weakness x 3 days following vaccination, Nausea, diarrhea x 2 days following vaccination, tiredness, body aches x3 days following vaccination, mouth sore 5 days following vaccination

Migraine with aura and pain 1 hour after injection. Laid down, took OTC migraine medicine and applied ice pack to head pain area. Migraine disappeared after 3 hours.

Tender lymphadenopathy in left axilla. Began 12/24 (one week after vaccine administration on 12/17).

"Moderna COVID-19 Vaccine Vaccine administration was okay and without issue. Patient reports having sensation of ""vice around heart"" that spontaneously resolved less than 5 minutes after injection. No anaphylaxis or shortness of breath, but sensation of tightness in chest that subsequently resolved within the 10-15 minutes after injection."

Began to feel tired in afternoon. Woke from nap and began to vomit several times. Also malaise, fatigue and feeling feverish even with normal temperature.

Tachycardia and Dizziness

Headache, nausea , retroorbital pain, cough, shortness of breath, vomited once

Dysgeusia: a sweet, metallic taste in the mouth that started about 2 hours after the vaccine was administered. This effect lasted for about 3 hours and resolved on its own without intervention.

Shortness of breath and chest tightness

On 12/24- vomiting, severe chills, diarrhea On 12/26- woke up with head cold symptoms- stuffy nose, sinus pressure, fatigue.

Fever 102.8 Myalgia Chili?s Muscle spasm Severe headche

Today I am 36 weeks and 4 days pregnant, due on January 19, 2021. This is my first pregnancy, and going well so far. This is not a bad adverse event just something I noticed: I developed 2 ulcers in my

mouth and one inside my vagina today. I had ulcers pop up in my mouth when I tested positive for COVID on May 1, 2020. Just interesting, not bad.

Day 1/2 - Headache, Pain at injection site/slight arm sweeping, tiredness Day 2 - nausea, tiredness, dizziness, shortness of breath, feeling hot/flushed, fainted (led to a 911 call / ED visit)

swollen and painful possible lymph node on left clavicle left arm sore for 3 days numbness and tingling in left arm following injection for a few hours

Sore arm started ~5hr s/p injection and persisted for 2 days. Mild-moderate headache started ~5-6hr s/p injection and lasted for 2 days. 1 day s/p injection had eye itching that lasted 3 days.

After 5 minutes, tachycardia, lip tingling, tremors

About 25 min after receiving 1st dose, migraine headache, the right side of my body felt heavy and the muscles in my leg, lower back and neck hurt, I also had a lump on my right arm at the injection site. Within 6 hours the heaviness and the pain in my leg and back were gone. As of 12/26, the pain in the neck has decreased but it is still there, the lump in the arm still there and the migraine is still continual

Severe persistent joint pain on right arm extending down to right hip 24hrs after injection was administered.

Skin Rash, itch,inching, haves 12/20/2020 Skin rash, itching, haves 12/26/2020

Within minutes of innoculation, site area became extremely itchy. I brought this to the attention of the medics in the 15-minute observation room, and they immediately took me to an exam room where I was attentively cared for by several nurses, medics, and healthcare staff. I was given liquid Benedryl as my arm began to rash around the site. Within about five minutes of being in the exam room, my tongue began to feel like it was swelling in the back of my mouth, it soon began to feel swollen through the whole tongue, and it became increasingly difficult to swallow. Upon notifying the nurse nearby, I was immediately given an EpiPen injection. I do not know what may vitals were as everything happened very quickly, but I was told that my face, neck, and chest became rashy quickly, but subsided after several minutes from the EpiPen, at which time I was given more liquid Benadryl. Once stable, I was taken to the emergency room for monitoring for two hours. I felt better quite quickly after arriving in the emergency room, but the itching persisted through the evening. After 15 hours of sleep, I awoke to only a sore arm and thigh from each injection site.

Rashes on the neck started on 12/25/2020

Left side only , eyelid heaviness, feeling unable to lift eyelid that developed and has lasted since. Since then my eyelid sometimes droops and sometimes it appears normal but still feels heavy. All other facial movement has been symmetrical & without problems.

throat swelling, itchy eyes, flushed skin and a headache

12/23 Patient reported fever lots of body ache and headache

Day 1 (day of vaccination) - 6 hrs after injection extreme tenderness of left upper arm Day 2 chills, body aches, sore throat, headache, fatigue, sore injection site - sx lasted all day Day 3 sore injection site - no other symptoms Day 4 after doing some housecleaning - in afternoon, chills, body aches, sore throat, headache, dizziness and fatigue. lasted 5 hrs (is this from vaccination or post covid episode?)

A low grade fever started approximately 5 hours after the vaccine paired with overall feeling of being run down and achy muscles. The injection site was very sore and it was hard to move my arm. Symptoms subsided by 36 hours post vaccine.

About 10 hours after vaccine was received, severe headache started. Became terribly headache, no fever but chill even with 5 blankets, skin felt like it had been burned, nausea and vomiting, leg cramps though out night and most of the next day. Headache and fatigue for another 24 hours which are present now.

12/23 injection site pain immediately 12/24 arm pain and slept 11 hours - tiredness 12/25 no symptoms 12/26 returned with injection site stabbing pain

Exhaustion. Nausea joint and body aches mild headache

About 5 hours or so after the injection I began to feel a stiffness and soreness on my left forearm and left shoulder. The soreness in the forearm persisted for about a few hours and the pain was negligible unless I applied a slight squeeze to my forearm, which caused significantly more pain. At that strength I would normally not feel any pain at all, but it was strong enough to cause me to almost instantly release my grasp. The pain in the shoulder was also negligible but caused far less pain when pressed compared to my forearm. My shoulder symptoms lasted until I woke up the next morning.

Loss sense of taste and smell

Red rash, bumps that itch appeared 4 days after, mainly on arms.

I developed generalized pruritus, sore throat, lip and tongue tingling and numbness. Symptoms started 30 min after the injection and progressively got worse. Took Zyrtec without much relief. Took Benadryl 25mg when lip tingling and Buke ness started and went to bed. Symptoms resolved by morning.

12/17 Patient report sore throat, loss of smell, cough, muscle aches, loss of taste, shortness of breath and headache.

Symptoms started after 2-3 mins of vaccine. Started having numbness, tingling on face, arms, legs, tachycardia up to 144 bpm, dizziness, palpitations, chest tightness. Lasted up to 1 hour. Observed in clinic and went home after 2.5 hrs. At home continued to have on and off palpitations for 2-3 hrs with heart rate increasing to 110 bpm.

O had the vaccine at 9 am this morning waited 15 mins after vaccine before leaving while driving I had a pounding heart rate and hot I rolled down the window felt better. 1 hour later while at home.e started with nausea diarrhea rapid heart rate headed to medical office while in care tongue swelled I called 911

pulled over when the ambulance got to me my throat swelled and I had hives on chest they took me emergency while there I had sever pounding heart and vomiting treated with meds sent home with medication and benadryl

12/23 report feeling lightheaded, anxious, body aches, fatigue, headaches, chills without fever, dry cough and nasal congestion

Headache Runny nose Congestion Neck stiffness

Fever (101.1) Chills Headache fatigue

Dizziness, diaphoretic, wheezing, cough, hoarse voice, tingling to my throat and headache. Sent to emergency room, received medication. Decadron IV, Benadryl IV and Pepcid. I was monitored in ER. Eventually was discharged home with medications.

Lip swelling/tingling without airway compromise, full body itching, Covid symptoms. Lasted approx 48hours, took 50 mg benadryl every 4 hours and pepcid twice a day for 5 days

I had several episodes of dizziness on Saturday, December 26th, approximately 6. All of them occurred while I was sitting. In all but one case, I had been sitting for long periods and had not recently stood or moved around. They started in early afternoon and continued through late night. I hope they go away tomorrow.

Aching arm, loss of train of thought, deeper breathing, steady increase in heart rate with the occasional drop in heart rate.

Fever, nausea, dizziness, muscle pain, joint pain, headaches, vomiting

The patient developed palpitations, lightheadedness and nausea and came to the ED and was found to have sinus tachycardia. Unclear if it is a vaccine reaction or due to anxiety or severe iron deficiency anemia.

Left clavicle pain with point tenderness over the bone (not the muscle) no lymphadenopathy. Pain lasted few days and seems to start to improve today.

Approximately 30 minutes post injection experienced left jaw numbness lasting approximately 2 hours. Experienced left ear tingling and bitter taste in mouth lasting approximately 5 minutes. Experienced left sciatic numbness lasting approximately 10 minutes. No treatment. Self-resolved.

body aches, chills, feeling of being unwell, swollen lymph nodes. the body aches, chills and feeling of unwellness, i treated with aleve cold and sinus. but the swollen lymph nodes is on going.

Eyes twitching, headache, and nausea.

reddened rash with hives Benadryl to ED

24 hrs- lymphadenopathy, submandibular, ear pain 36 hrs- primary outbreak of VZV- trigeminal n involvement- tingling/burning 48 hrs- rash and vesicles in trigeminal n distribution

sore upper arm. mild reactoin

Severe chills, headache, lack of appetite and Temp of 101.9 for 5 days following injection.

Fever, chills, body aches. Improved with Tylenol and motrin

Employee states had vaccine on 12/20 and was monitored in Emergency Department for approx. 4.5 hrs r/t which started with metallic taste, then within 10 minutes lips/throat/tongue tingles, full feeling in throat followed by heaviness in chest with self-resolving (only IV fluids administered in the ER). Employee states took 50 mg of Benadryl when she went home after the ER. Employee endorse body/headache post vaccine on 12/21. Patient is unsure to take second dose and seeking advice, has already contacted her PCP.

Sugar spiked increased insulin till comes down to normal, tea and tylenol for the throwing up, fever ,headache body feeling like it weighs 1000pound. Calling Dr. on monday

About 6 hours after injection, sore arm At 3am awoke from sleep shivering uncontrollably. This went on for about 2 hours. Woke at 6am with muscle aches and temp 101.2. Took Tylenol. About 11am took temp - 100.1. Took several naps and laid around most of the day not feeling well. Temp went back to normal. 12/26 woke feeling fine, but took morning nap and afternoon nap, and still did not feel back to normal; tired. No fever and slight muscle aches. 12/27 feel back to normal.

Extreme muscle twitching in the left wrist muscles

Moderna COVID-19 Vaccine. Received the vaccine at 8:30 AM 12/24. Morning of 12/25 I started to feel a slight sore throat and tender lymph nodes. By the early morning of 12/26 I was experiencing a moderate-severe headache, fatigue, swollen/red tonsils, swollen lymph nodes, congestion, sore throat, and trouble swallowing. Around 2:00 AM on 12/26 I took NSAIDS which only mildly helped. I went to an urgent care center at 9:30 AM on 12/26 where after my examination the CRNP ordered a strep test and COVID test. Strep test resulted positive, prescribed amoxicillin 875mg twice daily for 10 days, and prednisone 20mg twice daily for 2 days. As of now, 12/27, symptoms have significantly reduced. Awaiting COVID test results.

Brusing Pain Entire arm soreness Nerve tingling pain Fingers moving on their own

Intermittent parasthesia, numbness and tingling to arm vaccine was administered

Generalized itching/rash, red bumps to arms and neck, scratchy throat.

Severe injection area soreness, mild-moderate fever (100.3 - 101.9), achiness, fatigue, mild headache (later in day)

Patient received Moderna COVID-19 vaccine IM in the Administration clinic. During the observation period, patient reported feeling flushed, warm, sweaty, with lip tingling. Vital signs 138/95, HR98, 02 Sat 98%. Proceed out call. Patient transported via wheelchair to ED for further monitoring. In ED, monitored with resolution of tingling of the lips, cheeks still with slight flushing to them. No sob or abd pain or tongue/lip swelling, no worsening rash. Encouraged followup with working well clinic. Patient was discharged home 4 hours later.

Dizziness, syncope, nausea, fatigue

Patient reported having reaction to flu shot in past so was being monitored closer. Upon her completion of 30 min observation, patient felt lump on throat, slight pain to touch on upper chest, slight headache, some redness to chest area and arms. Patient came prepared and took 25mg of chewable Benadryl at 10:13am, two minutes after symptoms began. 20 minutes later lump on throat was gone and redness to skin had disappeared. Symptoms resolved, patient was monitored for an extra 15min, asymptomatic upon leaving, had husband waiting outside to drive her home. Patient has EpiPen and understands if any sx return, chest pain, trouble breathing, should go to ED.

Patient began reporting of a tingling sensation in right arm approximately 15 minutes after vaccine administration in the right arm. Patient denied shortness of breath, chest pain, palpitations. Patient encouraged to wait in observation room for another 10-15 minutes with enhanced monitoring by MAs and RNs, patient agreed and complied to plan. Patient reported continuation of tingling sensation in right arm with noticeable tingling sensation beginning in left arm and lips as well. Vital signs taken on patient at 1300: BP: 165/84, HR 78, O2 100% on RA. Proceed out called, team arrived and transported patient to ED for further evaluation. In ED, patient was observed for few hours, and was discharged home.

Redness and swelling at injection site and surrounding area noticed ~day 1. Today is day 10 and the redness and swelling (same shape/area) and now warmth to touch (noticed warmth on day 9) have not gone away. No other symptoms of note.

""""PFIZER-BIONTECH COVID-19 VACCINE"" Adverse effects: Swelling under the left arm extending to the back to about under the shoulder blade. The swelling also extends to the left side of the chest area where there is also visible rash/hives with swelling. All of these areas are painful to the touch."

Patient reported tingling sensation in hands and feet ~15 minutes after Moderna Vaccine Administration. Patient states the tingling sensation was not present prior to receiving vaccine.

"Patient was given injection and mentioned she had a warm feeling and had tingling in her face. Patient stated, ""It made me very anxious."" Resp therapist checked her breath sounds no stridor or wheezing. B/P was taken- 116/83 Pulse of 73 bpm. Kept for 15 minutes and the symptoms resolved. Patient was offered Benadryl but stated he mother has had a reaction to Benadryl and patient refuse the medication."

Around 10 that night I felt chills, lethargy, and fever. Next morning a headache. Still have a headache.

Saturday 12/26/2020 received Moderna vaccine dose #1 of 2 at 12:00pm. 15 minute observation required (no symptoms) was able to leave. At 12:30 pm - 30 minutes post vaccine: experienced lip & tongue tingling & numbness, throat felt weird. Jaw line became itchy. Self-resolved 15-20 minutes after. At 2:00pm experienced severe migraine & lightheadedness - unable to perform daily routine due to pain & feeling of passing out. At 3:15 pm tongue became itchy & throat feeling weird again. Self-resolved 15 minutes later. Today 12/27/2020 only symptom is severe pain in left upper arm (where injection was) feels like solid mass & difficulty raising arm due to pain & tight feeling (this is very different than just having sore arm post flu vaccine). Pain in arm constant throbbing heavy pain.

Passed out twice - at 5pm on 12/26 & 8:30am on 12/27

Arm soreness at sight of injection ans involving shoulder. Extreme pain with arm movement. Difficult to move arm especially lifting arm over head.

Arm soreness at sight of injection ans involving shoulder. Extreme pain with arm movement. Difficult to move arm especially lifting arm over head.

Woke up with whole-body muscle aches, chills, and a slight cough. Feeling tired, weak, and fatigued. Headache.

Severe rash. Treated at ER with prednisone and recommended Benadryl.

General Itchiness, fatigue, joint inflammation, worsening hives on trunk and extremeties

Day 9 post vaccine started with local vaccine reaction. Itching, redness and swelling at site of immunization. 5.0 cm of erythema and induration.

Moderna COVID 19 Vaccine EUA Nausea and Bodyaches

Very large and swollen left supraclavicular lymph node

Intense Vertigo and tachycardia lasting for approximately 2 hours post injection, nausea/motion sickness lasting 5 days post injection

High blood pressure Pain in injection site Light headed Fatigue Headache Body aches Shaking

"B/p elevated, states ""feel swooney, like dizzy"""

Within two minutes of injection: started feeling flushed, light headed, elevated pulse, and tightening of my throat. Waited 30 minutes at site while physician monitored my symptoms. Flushness, pulse rate and feeling of throat tightness diminished over the 30 minute period and I was released to leave. On the way home I bought Benadryl and took 50 mg. I began to feel more normal 1-2 hours post injection.

"Patient stated, ""She got pain immediately during injection."" Next day she stated it was swollen at the site."" Went and saw her doctor who confirmed it was red and hot to the touch. Patient stated, ""I tried advil and it helped a little bit. I did not try Benadryl."" Staff stated, Patient's arm was fairly/pretty large (swollen)."

Couch, high fever, chills, body aches, headache, severe fatigue

Fever, chills, sore throat

severe headache and fatigue from 3 days after the shot continuing; the illness has not stopped and is now 8 days after the shot

Waited 15 min without issue. While driving home after approx 10 min developed acute throat fullness, lip tingling, hand tingling, nausea, clammy & lightheaded. Felt like going to pass out. Was able to call 911, pull over. After EMS arrival throat fullness & lightheadedness improved, still with lip tingling. Refused ER went home took Benadryl 50 mg with improvement after a couple hours.

Shingles, left side leg and foot

After 5 min of receiving vaccine felt woozy/dizzy, sudden burst of chills, elevated heart rate. Asked for someone to check HR; obtained VS. Discharged after acceptable HR and BP. Home (day of and after vaccine) - HR elevated after minimal exertion and temperature.

An inflammatory response noted in right hand joints (index and ring finger). Severe swelling and pain.

About 1830 (6 hours post-vax), I developed numbness/loss of sensation in the right side of my face from mid-eyebrow to just below the temple. I continue to have this symptom.

Swelling, redness, and warmth that emerged 8 days after vaccination.

On the next day exp fatigue last mostly that day. I woke up on Thursday no issues at all. The following Sat on 12/19 exp coughing and that was it. I stay home one day to rest but dint miss work.

Day one achy and nauseous. Day 2 sore arm swollen armpit temperature and nauseous.Took Tylenol and went away third day.Temperature up to 101.9F.

shingles, nasociliary branch. started with burning in the inside of my left Nare, vesicular rash appeared which spread to the tip of my nose. I immediately (day 2 of rash) started valtrex 1gm TID. After 48 hours on valtrex no progression of rash. I have not had any visual symptoms (herpes opthalmicus) yet and hopefully don't.

Vertigo started during the night following the vaccination. It felt like the room was spinning, while I was lying in bed and on getting up. It is mild, and I can still go about my regular activities.

Vaccinated member,. Recently received tetanus 9 days ago upon clarification

Received Moderna vaccine at approximately 4:05pm on 12/26/2020. Within 15 minutes, developed flushed feeling throughout body, developed strange taste in mouth, mouth and tongue felt numb and tingly. Was given 2 Benadryl, symptoms improved, resolved within 6 hours.

vesicular rash occurring on right upper arm, not at the injection site. small groups of nodular bumps that are now occurring on my right hand, left arm, back, and neck. they do itch but are not painful. they do not appear to be fluid filled. appeared about 3 days after initial vaccine.

I woke up with a fever 100 it did reach 102 afternoon, I exp alot of muscle ache and pain stayed in bed. I was uncomfortable sitting felt better laying down. After taking Tylenol I felt better also exp nausea and headache it dint feel overwhelming. I felt totally back to normal on 12/17.

Patient developed a feeling of warmth all over within a few seconds of receiving the IM injection. She had no other symptoms initially. Approximately 35 minutes after the vaccination, she had a brief (approximately 3 second) syncopal episode. No other symptoms developed.

Approximately 15 hours after vaccination I awoke with severe pain of the left fourth toe, medial aspect of the proximal phalange. There was a 3 mm pustule on a 1 cm erythematous base. At the time I also had mild routine constitutional symptoms from the vaccine: fatigue, headache, vague malaise. I had no fever. The pustule progressed over the following 15-20 hours. I was prescribed doxycycline 100 mg po bid and the pustule was incised and drained. A wound culture was not sent, but the assumption was that S. aureus was the pathogen. Over the next four days, the lesion resolved without complication.

12/25 10 pm: Chills, fever 100.2 congestion, slight cough, headache 12/26 1 pm: Chills, fatigue, 100.3, headache, fatigue 12/27 1:00 am: fever 102.5, headache, nasal congestion, fever broke after motrin, at 6am. 12/28- 11:00, chills, fever 100.2, fatigue, mild headache

Attempted to sleep but could not focus and kept having problems all night not being able to sleep. Woke up sore and with a headache and a bit of nausea. Was shaking a little in the morning.

"within about 5 minutes of receiving vaccine, pt states that tongue felt ""tight and swollen"". No difficulty breathing and no other airway symptoms. Given Benadryl 50mg IM at 1108. Symptoms quickly improved. By 1150, pt swollen feeling resolved and tongue just feeling dry"

Rash and pain at injection site, chills, fever, headache/neck pain, muscle pain, fatigue

Chest pain followed by Syncope approximately 5 minutes after injection.

Tingling, general flush, BP 132/82, HR 92 O2 98% - positioned supine, administered Benadryl IM

Within first 5 minutes, pt reports feeling dizzy and lightheaded and that throat was tight and it was difficult to swallow. Symptoms did not progress. Benadryl was considered but with medical staff, agreed to observe for worsening over the subsequent 5 minutes. Symptoms slowly resolved and by 12:10 throat just feeling dry. No dizziness reported.

Face became red with hives and swollen., sweating and clammy, chest tight and tachycardia. Went to emergency room. Given Benadryl. Occurred about 8 hours after vaccine

Exacerbation of vertigo associated with nausea and loss of appetite.

Woke up due to arm being very sore- went to get ibuprofen and got very light headed. Needed to sit down, ears began ringing and felt like I was going to faint/pass out. Went into bathroom, felt some what nauseated and weak. Suddenly felt hot, sweating and ears still ringing. Had to keep my head below my knees due to still feeling like I was going to faint. Eventually sat on floor doing deep breaths, feeling weak and hot/sweaty. Then started to feel very cold/clammy. Took temp at this point- no temperature. More deep breaths and eventually after possibly 5 to 10 minutes felt like I could walk to my bed. Still felt very cold but no longer like I was going to faint and ear ringing had stopped. Slept through the remainder of the night until approximately 7am without incident.

Pfizer-BioN Tech COVID19 Vaccine EUA Injection site soreness in deltoid and shoulder region starting next day lasting roughly 24 hours. No treatment other than Advil

I am a healthcare provider, received first dose of Vaccine, had slight tachycardia about 5 minutes after receiving. Tachycardia resolved after about 5 minutes, chills lasted about 5 minutes. Most concerning when driving home about 20 minutes after vaccination right side of my face began tingling and numbness. This numbness and tingling lasted throughout the night until sleeping. There was no facial paralysis. When I woke up symptoms had resolved. Throughout the next 48 hours would have intermittent tingling on right side of face only for a period of a couple minutes. After 48 hours no symptoms.

R temporal tingling, numbness, treated by supine positioning, resolved

Dizzyness, resolved with juice, crackers

Adverse event: developed papular rash to right flank 12/24, treated with topical hydrocortisone cream, rash remained through 12/27. OTC PO benadryl taken the night of 12/26. Developed another papular rash to right neck and subclavian region on 12/27 @0800. Papular rash to left neck smaller but also developed 12/27 @0800-0900.

Moderna COVID-19 Vaccine EUA. Swelling, redness, soreness, itching from the injection site to the elbow. Soreness began 10-11 hours after injection. The injection site-related symptoms have progressed. Had headache and chills followed by a low grade temperature within 24 hours of injection. No longer experiencing any symptoms besides those associated with the upper left arm. Will advise primary care physician of the issue today.

Dizziness, dyspnea, neck swelling

Vaccine administered at 823am; at 0831, patient reported feeling warm and that her throat felt like it was swelling. 0834 pt placed on VSS monitor; 911 called; 0843 Pt was given epi pen 0845/0850 VS repeated; 0851 ambulance arrived and pt taken to ED

Headache Muscle pain Low grade fever Sweating Cough Sore throat

Headache on day 1 evening and all day 2 Day 5-7 tenderness on left side of face in distribution of trigeminal nerve. like trigeminal neuralgia. Gone by day 7 after vaccine. It only occurred on the left side (same side as left upper arm vaccination)

I am experiencing nausea, diarrhea, and a migraine.

Vaccine administered at 0924; 30 minute observation due to past history of allergic reaction to tetanus vaccine; 0948, pt notified RN of tickle in the back of her throat; 0951 VS taken and WNL, remained with tickle in throat. 1016 pt reports having muscle cramps on back of neck, radiating to shoulders; VSS 1026 pt reported new onset chest pain; pt agreed that symptoms were progressing and epi pen was administered at 1031, 911 called. 1034, pt reported improvement; 1036, 911 arrived and pt transferred to ED

About 12 hours after receiving the vaccine, woke up to use the restroom and while standing in the bathroom, I became dizzy, lightheaded, weak, and fell to the floor. My spouse was able to arouse me after a few attempts at shouting my name but informed me that I had lost all the color in my face, lips and face were very pale. I laid on the floor for approximately 30 minutes until I was able to sit up & stand without feeling lightheaded and dizzy.

The patient was vaccinated on 12/17/20. Wife was diagnosis with COVID-19 on 12/18/20. He was diagnosis with COVID-19 on 12/21/20. Symptoms woresen on 12/26/20. And he had chest exam (x-ray's), pneumonia bi-lateral and he was hostipalized on 12/26/20.

Client reported rash on left side of neck and facial tingling/slight swelling about 4 hours after vaccine; HR 88, BP 130/90 RR 18. Assessed by Medical Director - urticaria most consistent with an allergic reaction. Patient offered Benadryl and encouraged to stay at clinic for observation, but chose to go home - explained risks and danger signs to be aware of that would require immediate visit to ED. Client took 25mg Benadryl at 5pm and MD spoke with her at 6pm - she indicated there was improvement with her rash after the initial dose.

Had the expected side effects of arm pain, body aches, headache and chills beginning several hours after vaccination. The morning after the vaccination, I felt like I would be okay to go to work, so got up to take a shower. Felt very lightheaded in the shower and fainted. Fell to the floor outside the shower, hitting my head on the tile floor. Was later able to proceed with going to work. No other ill effects or treatment.

Covid vaccine received, was instructed to go to ?observation area? for 15 minutes. While walking, started to feel faint, sat down and started to feel okay. After 5 minutes, I started to feel faint again and felt my heart rate go up. My Apple Watch showed my heart rate at 144. I asked staff to check my vitals and I was instructed to go to the nurse area. Vitals showed heart rate of 140s-150 (Apple Watch registered my highest heart rate during that period was 160). Blood pressure about 135/90 (my normal is 115/80), SPO2 of 99%. After 5 minutes, heart rate down to 90, BP 120s/90s. Every 5-10 minutes I would feel faint, a sense of ?impending doom,? mild nausea, and my heart rate would go up to 140s, it would last about 2 minutes then go down to 90s. This cycle of heart rate going up and down kept

repeating for 30 minutes. No chest pain, no shortness of breath. Prior to going home, heart rate was 90, blood pressure was 125/98. Total time being observed was 40 minutes from time of vaccine to leaving observation.

Sudden onset of numbness and tingling in Left arm at 11pm (arm that received injection). Arm appeared to be mottled as well.

Progressive pain in arm

Nausea and vomiting

"Besides from the low grade headache, i started to have chills, then fever for 5 days, joint pains and generalized body malaise, observed "" petechiae rash"" on my face"

Splotchy Redness and extreme itching on both left and right arms, hands and feet started itching about an hour later. Took 1 dose of benedryl and redness subsided.

1120 informed staff was feeling lightheaded and dizzy- VS checked BP 83/63 58 100 RA reck at 1130 78/45 52 taken to ER via WC for evaluation

At approximately 11:30PM on 12/25/20, pain in my left axilla woke me from deep sleep. There was (is) a palpable, painfull swollen lymph node . It remains painful at the time of reporting (12/27/20 12noon). The pain is temporarily relieved with NSAID. Other than pain, there are no other associated symptoms. I had mild pain at injection site on day 2 but no other notable events following vaccination on 12/19/20. I will send a message to Dr , (my PCP) but do not think a visit will be necessary. I am scheduled for my second vaccination on 01/08/21 and intend to get it - in my right arm.

c/o dizziness not feeling right very anxious scratchy throat taken to ER via wheel chair

Moderna covid-19 vaccine EUA. Pain at injection site, pains on lifting injection arm next day. Diffuse muscle and joint pains next day. Extremely tired next day. Upset stomach next day. Peculiar feeling on the tongue - not burning just a weird sensation.

About half hour after vaccine had a headache woke up with a 100 temp fever. The next morning fever went away. The night of 12/18 my temp was 102. temp, lost taste/smell and felt fatigue. On 12/19 I went to get a Covid Test results positive. The week of 12/21 started to feel better and then on 12/26 OT started dropping. I had to miss 5 days of work.

About 10 minutes after receiving the injection I felt tightening in my throat. I then felt a hot flush all over, and some chest tightness. I notified one of the nurses at the site who took my VS: BP 200/100, P 100, R 22, O2 sat 99%. Symptoms resolved in about 20 minutes. I went back to work when the symptoms returned. As I was walking to the site where the injections were being given I saw a pharmacist from the hospital. He took me to the pharmacy and recommended Benadryl. Since I was at work and Benadryl makes me sleepy he gave me another Claritin, knowing I had taken one that

morning. He also suggested that I use my Albuterol inhaler, which I did. Symptoms resolved within the hour.

On December 25th at about 8 pm I became extremely lethargic and unable to think clearly. I had a temperature of 103.7. My face and tongue were swollen and I developed a rash on both lower limbs. I went to Emergency Room and was admitted.

did fine at time of vaccination and left after the 15 minute time period and went back to her desk and after 10-15 minutes in registration states started feeling funny dizzy starting to get a HA met her and manager in the hallway instructed to go to ER. Taken to ER via wheelchair for evaluation

Received Pfizer COVID-19 vaccine without untoward effects on 12/18. Given her usual allergy shot by her allergist on 12/22 (she has been receiving these for several years; I was told this is a protein antigen in a glycerine suspension). Within 15 minutes, patient developed anaphylaxis: generalized erythema, swelling, pruritus and hypotension requiring epinephrine, and diphenhydramine. Patient recovered over several hours.

Abnormal heart rhythm, mild tachycardia. 90 to 100 bpm.

c/o came back in after being discharged 10- 15 minutes and stated she was dizziness, scratchy throat, heart racing taken to ER via wheelchair for evaluation

periorbital edema, flushing, itching

Nausea beginning Sun Dec 20, in the late afternoon. Vomiting around 6:00 PM. Nausea a bit relieved then, but persisted until Mon Dec 21 evening. Headaches noticed daily until Dec 27. Soreness in arm for only a few days.

Pfizer-BioNTech COVID-19 Vaccine EUA headache, swollen L tonsil and L ear ache for 4 days post-vaccine; symptom treatment with Dayquil and Nyquil. resolved without further treatment

Fever, muscle aches, hypertension, rapid heart heart

24 hours after the vaccine injection I had severe chest and abdominal pain along with nausea and vomiting. I went to the ER where they did blood work, an ekg, and a chest xray, all of which were within normal limits. I was give IV morphine for the pain and IV pepcid. The symptoms went away after a couple of hours and I was released. The symptoms did not return.

"Received vaccine at 0930... was checked on and feeling well ?. at 0950, she raised her hand and stated she was having tachycardia, ""not feeling right"" and c/o numbness and tingling in legs. METs team called and pulse was 130 and was taken to ER here at MC via wheelchair."

Fever (100.4), chills, myalgia on the next day.

On 12/22/2020 between 2000-2100, while driving, I experienced a definite notice of sensation of absence of my heart beating between 6-10 times. At one point, I was able to safely pull over, but by that

point my right radial pulse palpated was 60 bmp and strong. Prior to this time but after the vaccination, I had felt instances of a similar lack of sensation but am not sure of the times, had paid little attention to the events ? presumably because they were very very short and, though not driving, I was never able to catch them/i.e. palpate my heart rate during the events. On 12/23/2020 at 2005, I again sensed my heart wasn?t beating. I immediately attempted to palpate my right radial pulse and felt no pulse for at least 3 seconds (I was not watching a clock to time). After the 3 seconds, I could suddenly feel a strong right radial pulse, HR was 56 bpm (my pre-vaccine HR). I had not taken my evening dose of Propanolol.

"I received my first dose of the Pfizer vaccine through employee vaccination for medical center at about 6:45 pm on 12/16/2020. The same evening, I had no side effects to report. The next morning, on 12/17/2020, I woke up with a sore arm (know this is a common complaint). As the day progressed on 12/17/2020, I became fatigued and developed joint aches. Took a normal dose of Tylenol, took a bath, and went to bed. Went to work at the hospital the following day, on Friday, 12/18/2020. Was fatigued for my twelve hour shift on 12/18/2020. Following my shift on 12/18/2020, I came home, ate a little supper, showered, and went to bed. I did not have much of an appetite at this time. The following morning, I woke up with vertigo, dizziness, slight nausea, and felt a little shaky. I informed my workplace that I did not feel well and my charge nurse instructed me to ""see how it goes.' I proceeded to go into work at 0630 that morning on 12/19/2020. Upon arrival at work, I stated that I did not feel well or normal and I was instructed to call the employee health hotline to report my symptoms. I did and spoke with a woman, over the phone. She instructed me to go get a COVID test to confirm I did not have COVID. I told her that I really felt like it had to be from my vaccination, but she insisted I get tested for COVID. She scheduled me an appointment at a walk-in across from our hospital and I went and was tested. I went home to wait for my results and ended up missing the rest of my twelve hour day shift. My test came back negative later that day. the following days, until 12/26/2020, I had nausea when I would wake up. I still had some vertigo and dizziness and fatigue. Today, 12/27/2020, I have felt better. I am a little scared to get my second dose and wanted to report what I experienced."

Almost immediately following vaccine administration I had tingling in my lips, followed by swelling and tingling of my soft palate. It was minimal and became worse at around 20min following the vaccine. I had left the facility and was having some increased mucous production. No difficulty breathing, but I had some slight difficulty swallowing. I took 50mg of Benadryl and after about 1.5 hours the symptoms had resolved. Now over 24 hours out. I have some swelling of my right bicep, as well as some tenderness with right elbow and right wrist pain. Some myalgia worse in my right shoulder and right sciatic area and right thigh. Slight fatigue.

Headache, fatigue, body aches, sharp abdominal pains

Progressive and fluctuating hives and red rash on the shoulders, chest, abdomen, back, and upper thighs. Began on December 25 in the afternoon lasting about 30 hours, waxing and waning until a final flare-up in the PM in December 26. No more symptoms Dec. 27

5:00 PM chills, felt freezing, arm sore, muscle aches , headache, congestion, tired. 11:00 pm same symptoms and nausea. 1:30 am dizzy, temperature 97.8, other symptoms slightly better. 8:45 am arm sore, muscles sore, thirsty, nausea, dizzy, mucus.

Red rash on left forearm and back of left hand. Lasted 48 hours. High, uncontrolled blood glucose, unable to correct using insulin pump and additional insulin delivery. (Held over 300 mg/dl) Lasted 30 hours. Within 48 hours all symptoms alleviated.

N/V with severe diarrhea approximately 24 hours after vaccine administration. Symptoms lasted for 36 hours and resolved.

35min after injection. Swollen, numb lips, hoarse voice, difficulty swallowing, nausea. Patient is RN and self treated with 50mg benadryl, zyrtec, and caffeine. Patient was somnolent for several hours with concurrent nausea. Reported full resolution of symptoms within 6 hours. .

"patient reports ""chest pain after 5 minutes of receiving the vaccine""; then in the past 6 days, body aches and intractable headache"

On the day of my injection approximately 20 minutes later i had tingling down the arm I received the vaccine in and in my face which lasted for about 2 hours but went away. Other symptoms began 12/25/20 including body aches, fatigue, chills, and fever.

I am 67 year year old physician and have been inline distance skater for more than 30 years. I normally skate 3-4 times per week ~ 15 miles over about 90 minutes. I only walked for the two days after I received the vaccine (about 5 miles each time)and developed some low grade myalgias following which responded to 600 mg. of ibuprofen. On December 26, 2020 (approximately 72 hours post vaccination) I skated about 15 miles and upon returning home developed more intense systemic myalgias, nausea, fatigue, and general malaise which lasted about 12 hours. Today (December 27), the myalgias resolved. I have never had anything like this before. Since I see firefighters in my practice on a regular basis (as well as other first responders) I was concerned that coincidentally I actually developed Covid. I feel fine now but will get a Covid test on December 28 through my office. Curious if others reported similar side effects after the vaccine with vigorous exercise?

approximately 1.5 hrs after my vaccine I started to feel lightheaded and flushed all over my body. My heart rate was 120's and my temperature was 100.2F. No difficulty breathing, SOB, chest pain or rash. I was checked into the clinic and monitored in the Nurse Treatment Center. I was placed on a bedside cardiac monitor, an EKG was done, labs drawn and IV fluids administered. I was there for approx 1 hr and discharged to home. Temp was 99.1 HR 100's.

Chills and fever for 3 days. Chronic Fatigue and headache starting on 12/25 until today (12/27)

Dizziness, numbness hands & feet (feeling cold) for 2 hours, extreme thirst, chills for 6 hours, injection site pain 2 days

Palpitations, shortness of breath, chest tightness, presyncope, which led to New onset atrial fibrillation with rapid ventricular response and required synchronized cardioversion and hospitalization. Discharged on anticoagulation and beta-blocker.

Site pain, fever ro 102¦F for 2 days, body aches, headache, fatigue, and weakness

10 minutes after the injection while I was sitting and relaxing, I felt my feet tingling with a pins and needles sensation. They also felt cold. The pins and needles and coldness then shifted to my hands as well. It also happened in my lips and nose. I occasionally felt a cold tight feeling in my chest. I felt a little weak and shaky, like maybe I would faint but I did not. This did not improve with eating some candy and drinking water. I later felt anxious but the anxiety was brought on by these symptoms, as I was definitely not feeling anxious prior to the tingling. I tried resting and that did not resolve it. It just eventually stopped after about 6 hours.

approximately 24 hours after administration, I had vertigo and nausea lasting for approx 6 hours. I was treated with zofran with some improvement. I was able to get to sleep and in the morning the symptoms had resolved

Rapid heartbeat, SVT

felt flushed, developed hives on forehead and forearm; took 25mg of Benadryl, symptoms went away.

2 nights on migraines with light headaches continuing during the day. Upset or sour stomach with pain and decreased appetite for several days. Vertigo on December 24. Headaches starting Monday morning and continuing off and on through today, December 27.

24 hours after vaccine: feverish but afebrile, chills, headache, nasal congestion, change in taste and smell, malaise lasting for 5 to 6 hours. 48 hours after vaccine: chills, intense headache, nasal congestion, change in taste ans smell, malaise lasting over 8 hours. 96 hours after vaccine: feverish but afebrile, chills, intense headache, nasal congestion, change in taste and smell, occasional cough, malaise lasting over the next 24 to 48 hours.

Diarrhea, severe cramping, lighter stools, 24 hours duration, improved after loperamide

10 min: light headed, very scratchy throat, flushed hot lasted 2 hrs took Benadryl/Pepcid/Claritin an hr after shot Started Motrin/Tylenol every 3 hours alternating about 4 hours after shot 3 hr: severe global headache lasted 48 hrs 5 hr: nausea/diarrhea last 30 minutes 7 hr: chills/severe body aches lasted 36 hrs 12: hr: fever 100, with Motrin and Tylenol lasted 2 hrs Unable to work the next day

Itching to right forearm and bilateral upper thighs, provided Benadryl 25mg po, and recovered

Stronger than usual hay fever symptoms: rhinitis, sneezing, runny nose, stinging or burning sensation in side if nose

Dec 21- vaccine Dec22- soreness right arm Dec23- nothing Dec24, 4pm... I was cleaning up, getting everything tidy for Christmas Day. All of a sudden, I felt very nauseated and sick and just bad. I laid on

the couch, and around 5, I noticed my left forearm getting swollen and splotchy. It continued to get more swollen, red and hot. I put an ice pack on my arm. It was very tender to touch or graze over. I realized then that I had a temp of 99.8. I had body aches, headache, was still nauseous, and I had diarrhea. Dec 25- felt terrible, fever, extreme fatigue, body aches,and arm still the same. Dec 26- get tested for Covid, only slight headache and little fever Dec 27-Covid test negative, arm still swollen, but not as red

Severe headache, chills, sweating, stomach upset, altered mental state, vision impairment, shaking. Started 30 minutes after injection and increased in severity over the next 48 hours then began to decrease. Headache is still present 4 days after injection.

Fine rash to arms and legs. Red, itch patches to abdomen, back, neck and chin. Hot, burning feeling to palms of hands and soles of feet. The rash started 5 hours after receiving vaccine. The rash improved the next day and was gone by 2 days.

5 minutes post administration complaint of lightheadedness. 15 minutes post administration bilateral hand tingling, hot flushed and sweaty. Oral Benadryl 25mg given. 5 minutes, resolution of sweaty/hot flushing. 15 minutes post Benadryl resolution of all symptoms. Monitored for 60 minutes, full resolution

Soreness at site of injection - 4 days. Soreness and inflammation in right armpit - 5 days, starting 1 day after injection. Pain on right side down to hip/groin area 1.5 days, 3 days following injection. I did not experience any drowsiness, back pain or nausea.

Swelling, redness, pain, itchin, achy

Intractable vomiting (12 episodes in 24 hours) with dizzyness, throat swelling, chills, headache. Took Zofran/benadryl with mild relief. Went to ED on 12/26/2020 and had IV fluids and Zofran. Improved and discharged. Symptoms slowly resolving with no longer vomiting and no dizzyness.

vaccine given 12/23. reported slight swelling and redness on 12/26. on 12/27, tenderness, redness, and warmth noted to the majority of the left upper arm along with slight swelling

Approximately @1900 day after vaccine I started experiencing a headache, stuffy nose, and drainage accompanied with cough. Since then it has steadily been getting worse. My head is achy and stuffy. I am fatigued, running low grade temp, and been sleeping a lot the past 2 days. I have been taking Benadryl liquid and ibuprofen. Symptoms still the same. I feel a bit dizzy but I associate that with Benadryl for 2 days.

Injection site itching (2 hours), redness and swelling (2 days). Chills and fatigue (2 days).

Experienced significant tachycardia (hr ~140) beginning about 5 mins from vaccination, lasting ~5 mins. Self limited.

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Rash

Rash

Left arm soreness, ~5pm Fatigue,8pm Chills, miss nausea ~10pm Fever (110.3') and headache, 12-4am Fever ended following 2 Tylenol tablets ~5am (98.1') Fatigue, mild headache, slight nausea, moderate left arm soreness, and intermittent chills remain 12/27/20

Itching on arms, trunk, legs. Hives on thighs, trunk, and arms. Took Benadryl and they went away and came back about 24 hours later. Took more Benadryl and they have not returned.

Within 12 hours of vaccination I had 24 hours of: fever as high as 103.7, regular tachycardia 120 at rest (likely fever related), generalized headache, malaise, fatigue, diffuse joint pain, severe right arm pain without redness/warmth radiating down my right arm and up to the right trapezius.

On post vaccine day #2, the onset of notable bilateral jaw pain, most intense at TMJ. Muscle fatigue also noted in the jaw and jaw clenching. No treatment has been taken at this time, just close monitoring of symptoms and noting progression of pain and constant symptoms. Currently on day 5 post vaccine and symptoms are still present, worsening since day 2 onset.

severe chills, achiness, fever

Severe body aches, feeling feverish (without elevated temp.), fatigue, headache, extreme arm pain at injection site, welt-appearance under injection site, redness and warmth at injection site. Treated with Tylenol (1000 mg) around-the-clock starting ~18hrs after injection.

Fever on/off up to 101. Tylenol makes temp go down to 98-99. Chills, sharp pain in face, chest pain, muscle pain, joint pain, hx of covid in June, aching, headache, chest feels hot, HR up to 140

redness, tenderness, and warm to touch at injection site (apprx palm-size)

On the morning of the 24th I noticed a large, circular, red, raised lump on the head of my humerus above the injection site. As the day went on, my neck became sore, and I could feel swollen lymph nodes. No fever, no sore throat, no cough.

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Diarrhea stomach cramps on Sunday afternoon Very sore arm Saturday to now Feeling like my nose is stuffy or tender but no congestion or mucus

Headache onset the night of vaccination. Body aches / congestion next day.

Patient reported she had been feeling anxious about receiving the vaccine all day due to its newness. About 10 minutes after receiving the vaccination she reported an elevated heart rate per her watch. Her hands were shaking mildly. She denied chest pain, shortness of breath and/or dizziness. Palpated radial pulse was 130s-140's. BP was 150's/70's. She was taken to hospital emergency room; she declined any medications. Through use of meditation techniques and calming practices, her heart rate lowered to 90's, then returned to 120's then lowered again to normal heart rate.

Within minutes of receiving vaccine, became pale with faint feeling, and elevated BP. Experienced this feeling in waves for an hour after the event.

My tongue & roof of my mouth was feeling numbness & I felt off. I told nurse I was leaving and she said no get reevaluated. An doctor checked my symptoms and vital signs were elevated. He gave me an Benadryl IM. Send me to ER and had me on observation for a couple of hours. My symptoms subsided and my vitals returned to normal. I went back to work.

I developed severe arm pain within 6 hours of getting the vaccine making it difficult to turn to my left side so I could sleep. The following day in less than 24 hours I spiked a 101 fever with chills and fatigue. Took Tylenol and it went away. My arm was still painful with warmth and swelling, noting a red circle approximately 2.5 inches in diameter around the site of injection which was noticed by a friend on 12/26. I continue to have pain in the arm on 12/27 with lessening of warmth and redness but still with swelling.

Patient experienced headache, nausea, and light-headedness after receiving the Pfizer BioNTech COVID-19 Vaccine. She was observed for 30 minutes and her symptoms resolved.

Shingles lasting about 5 days -mild case

Approximately 20 to 30 mins after vaccine i developed feeling of hot all in my body reminded me of broom injected worn contrast dye my heart was pounding tachycardia some chest heaviness jaw popping have self epi pen went to hospital monitored for 4 hours give ativan im had feeling of hot flushing tachycardia chest heaviness impending doom at least 10 or more times before it went away. Slept for 16 hours nausea threw up once. Mild confusion don't remember leaving hospital coming home or talking to some people on the phone

"Moderna COVID-19 Vaccine EUA Patient reported generalized pruritic rash upon waking up the morning of 12/27/20, also reports ""scratchy/itchy"" throat. Patient with stable vital signs, speaking in full sentences and hives over bilateral upper extremities and chest, examined at 815am. Patient given 20mg dexamethasone IM, zyrtec 10mg and sent home to take 50mg oral benadryl."

Arm tingling and soreness first 30 minutes, then just sore. About 6 hours later, extreme chills and pain throughout body, sore joints, lightheaded, fever.

Vision interference, tachycardia, hypertension, flush, rash, sweaty, hot, shakey, light headedness

Shortness of breath, chest pain, itching, near syncope, blood pressure spike

Severe cramping pains in the left calf that woke my up from sleep. I had difficulty moving my leg. I am assuming it was about 2 AM and it kept me up for at leas 20 minutes. However I did not look at the clock. I am an internist. I have not reported this to my PCP's office of to employee health yet as it is the weekend. It did not recur so far and I hope it does not

5 hours after shot administered developed a moderate amount of pain in my left arm that continued into the next day. On 12/25/2020 I developed a pretty constant left sided headache. Pain is moderate and is affected my daily life. Unable to complete household chores.

intermittent headache since vaccine given. Relief with Tylenol

""""Moderna COVID-19 Vaccine"" Developed rapid pulse and flat red rash across chest immediately after vaccination. Within 8 minutes developed metallic taste in mouth. Reported tongue swelling and throat tightness. Taken to Emergency Department after onset of symptoms. Symptoms resolved within 1 hours of vaccine and patient was at baseline with in 2 hours. Patient was discharged home from Emergency Department."

Fever up to 102 degrees Chills Fatigue Headache

Headache Fatigue Nausea

Dizziness, Shaking and Nausea

Received the vaccine on 12/21/20 without a reaction 15-30 minutes after administered. On 12/24/20 experienced flush, and rash on my face with swelling of the eyes and face. The swelling has progressed since then getting larger even after treating with Benadryl and cold compresses. It is now 12/27/20, and swelling is not decreasing. Am not experiencing difficulty breathing or any other symptoms.

Rash on both arms that is itchy

Left arm pain, headache, fatigue

12/24/2020- morning- noticed pain in R deltoid at site of injection (expected) and also L ankle pain not associated with any type of trauma and with no hx of injury to ankle in past. Also noticed mild aching pain to R knee (which has had extensive surgical repair several times) 12/24/2020- by midday, limping noted due to pain in L ankle, negative for swelling, bruising, or decreased range of motion 12/24/2020- 8pm- moderate to severe pain to L ankle, still no swelling or bruising. 12/25/2020- midday- still noticeable limp, however pain was moderate and tolerable all day 12/26/2020- increased pain in L ankle as day progressed, still no bruising, decreased ROM or swelling 12/27/2020- woke at 3 am due to pain, elevated L leg. Swelling noted in lateral aspect of ankle by 7am, decreased ROM and point tenderness had developed around lateral and anterior ankle joint. Took 2 Aleve for pain. Went to walk-in orthopaedic clinic when they opened at 9am for assessment,

Flushed, Headache, Hypertensive Event

Moderna COVID-19 Vaccine EUA dizziness room spinning had trouble standing, light headed, vomiting drinking water made it worse for a short time, shakiness, head ache the lights in the er room made this worse.

Mild Fever (max 100.3), Cough, Fatigue, Runny nose, Congestion, Headache, Dizziness, Nausea. Symptoms started within 3 hours of receiving vaccine. Symptoms continue still today 12/27/20. Taking Tylenol and ibuprofen to control the fever and afrin nasal spray for congestion.

Painful fluid filled bumps in a linear formation discovered this morning 12/27/2020 at 9am. I received the COVID vaccine on 12/19/2020 at 10:15am

Lips & Tongue became numb Tx with Steroids by PCP

Fatigue, Malaise, Back Pain/Joint Pain - From 12/24 at 11 am to 12/25 at 6 pm

rapid heart rate Difficulty breathing dizziness weakness

Body aches and Fatigue

Moderna COVID-19 Vaccine EUA 12/23/2020: Received vaccine at 1:00 pm. Experienced left arm soreness, injection site tenderness, body aches, and chills from 10:00 pm throughout the night. 12/24/2020: Awoke with left arm soreness, injection site tenderness, body aches, chills, and a fever of 100.6 F at 8:00 am. Fever rose to a maximum of 102.0 F at 9:30 am. Took acetaminophen and ibuprofen around the clock starting at 9:30 am until I went to bed that night. Symptoms were completely controlled with the acetaminophen and ibuprofen by about 3:00 pm. 12/25/2020: Arm soreness and injection site tenderness throughout the day. Chills with temp of 99.8 F at 2:00 pm. Took single dose of acetaminophen (1 g). Chills and low-grade fever resolved and did not recur. 12/26/2020: Mild injection site tenderness only (did not require treatment) 12/27/2020: all symptoms resolved

Sluggish , body chills , cold sweats

12/23- began to experience intermittent right lower quadrant pain in the morning, fever of 100.4 F in the evening which subsided with ibuprofen. 12/24- no fever noted but intermittent right lower quadrant pain continued, seen at the Health Clinic, sent to Hospital ER for CT scan, diagnosed with appendicitis, appendectomy performed.

c/o dizziness and increased heart rate. Assessed by attending and hospital MD present. HR went from 138 to 80 beats per min in 3 minutes. Able to walk to reclining chair from straight back chair without incident.

"S: Patient 41Y F unit assistant came to Covid vaccine clinic for vaccination on 12/27/2020. Received injection at 1436. Employee was instructed to sit in clinic for observation. At 1445, employee reported nausea, lightheaded, a ""floating' sensation and sore throat. The floating sensation was also described as a ""oozing sensation"". States that she ate noodle soup for lunch at approximately 1pm. Took Tylenol at 2pm prior to arriving to clinic for vaccine. She denies chest discomfort, palpitation, shortness of

breath, wheezing, or blurry vision. History of craniotomy in 2017 and pulmonary embolism in 2016. No history of HTN or GI conditions. á O: VS at 1445: BP 126/75, HR 75, temp 98.3, O2 sat 96% room air, RR 18, pain 0/10. Reports symptoms onset. At 1455: BP 123/76, HR 72, temp 98.3, O2 97% room air, RR 18, pain 0/10. Nausea resolved. Continue to have mild sore throat, lightheaded, and ""floating sensation."" At 1510: BP: 132/80, HR 69, temp 98.3, O2 96%, RR 18, pain 0/10. Sore throat improved. Denies lightheaded, floating sensation. AAO4, follow commands, lung sounds clear, heart sounds normal. No angioedema. No acute respiratory distress. á A: Adverse reaction to Covid-19 vaccine á P: Employee was closely monitored in clinic for additional 30 minutes. Employee was provided fluids. Employee states that her symptoms has gradually resolved. Employee was advised to monitor her symptoms. If symptoms worsen or persist, she needs to notify her manager and go to urgent care/ED for further evaluation. She stated understanding. Employee returned to work, left clinic in stable condition. No acute distress."

Sever Headache that progressed to a Migraine

Warm feeling all over the body possibly a slight fever and as of now later on in the day a warm tingly sensation on the injected left arm.

8 minutes after vaccine, started to feel dizzy, room got quite, started to feel hot around neck ears chest, red blotchy all over and continued to get worse. Started to feel a cold sensations. Nurse came over to assess had me sit and put legs up, rash got worse dizzines got worse, took me to a cot to lay on, had me take dose of pepcid and claritin, then decided i needed benedryl injection at 713pm. monitored my blood pressure, pulse ox and heart rate. heart rate was tachycardia. just felt off felt like something was wrong. about 30-40 minutes after benedryl injection the redness started to lighten in color. after more time of monitoring me i slowly started to feel a little better, after an hour and half or so i felt ok enough to be dropped off at home. Today 12/27/20 i have felt very jittery, nausea chills and fatigue started around 430p.

Lightheaded, metallic taste in mouth, and tingling in my throat at time of vaccine. Localized injection pain to site the next day, now joint and muscle pain the following day and to this day along with fatigue

WITHIN MINUTES SUDDEN ONSET OF PALPITATIONS AND SUBSEQUENT CLAMMINESS

about 45min after injection time, my lips started to tingle and my throat was scratchy. the muscles in my anterior neck and upper back felt acutely tight. I did not have any trouble breathing. the scratchy throat and muscle tightness lasted about 10 min. the lip tingling lasted about 20 minutes. after those symptoms resolved, I started to feel flu-like and fatigued/diffusely achy. those myalgia/fatigue symptoms lasted 5 hours. I never had a rash. I never had trouble breathing. I was back to normal about 6 hours after injection--other than an expected sore injection site.

Tired, body aches, fevers and cough

Dizziness, dim vision, sweating, flushing, metallic taste in mouth, chest pressure

Moderna COVID-19 Vaccine EUA. Side effects included arm pain at the injection site, chills and low-grade fever to 100.0 starting approximately 10 hours after receiving vaccine. Fever broke a few hours later and symptoms had resolved within 24 hours of vaccination.

At 4:00 today started feeling nauseous and vomited twice so far

Myalgias and mild head discomfort. Scratchy throat and cold symtoms

Extremely sore arm, full body aches, and headache the day after the vaccine. Resolved the following morning. Also presented with hive like raised red itchy rash on lower back starting approx. 9 PM the night of the vaccine on 12/24,. I still have the rash- it hasn't gotten any worse or any better. It hasn't changed in size either. I tried Benadryl spray with fair effect.

Swelling of lower lip 5 hours after injection. Resolved slowly over 9 hours after taking Allegra. Developed 2 hour episode of atrial fibrillation 11 hours after vaccination that lasted 2 hours and was treated with PO Diltiazem and Xarelto.

Localized reaction. Erythema initially 1 in diameter, indurated, sore arm. Worse 12/24. Induration/erythema up to 3 inch diameter. Soreness obviously worse. Took antihistamines, tylenol. Today induration down to 1 inch, bruised not nearly as sore.

Migraine was present at time of vaccination, but evolved and worsened after 36 hours. Nausea and anorexia developed after 24 hours. Severe aching back pain developed after 32 hours. Fever 101.5F developed after 36 hours. Symptoms lasted 24 hours and resolved. Diarrhea developed at 48 hours, was intermittent, and lasted 12 hours. Ondansetron 8 mg PO was taken once. Ibuprofen 400 mg PO was taken after 48 hours.

Had a sudden strong wave of nausea and felt very hot. That went away after a minute. Have had consistent mild nausea since then.

Headache beginning two to three hours after the injection. Generalized malaise approximately 9 pm. Awoke from sleep at 1 AM with severe chills and tremors lasting until 3 AM. Temperature of 103. Back to sleep and awoke at 4:30 with severe headache and N/V. Temperature 100.8. Muscle aches, headache extreme tiredness throughout the day on the 25th. Chills again around 11:00, temp 100.1. Generalized malaise, stomach cramping and headache lasted throughout the day. Awoke on the 26th at approximately 2am with night sweats. Went back to sleep and awoke at 8am on the 26ths with wet blankets and pajamas. Felt better after showering. Still had a headache but didn?t really hurt unless sneezing or coughing. Well enough to go to church. After returning had diarrhea a couple of times. Now only a lingering heaviness in center of my chest and need to cough that I have had since a week before my Covid diagnoses in November

"Pt was vaccinated at approximately 1135, exact time on consent form for vaccination. Pt was visitnig with another pt outside the lobby for about 15-20 min. then came iinto building stating that she had ""chest tightness"" pt was calm and able to descrive sesation. No distress. Pt was instructed to sit in chair and vital signs obtained, 2 sent obtained immedicately after. Pt still awake and alert able to

verbalize needs. Manual blood pressure taken. Dr called by Pharmacist. Pt was anxious and was verbally calmed by RN. 2 RN's and pharmacist at pt side. Pt c/o of dizziness, respirations elevated but able to maintian airway. Pt heart rate elevated. Dr arrived and asessed pt. After stabilation and meds administered, pt taken to urgent care for further monitoring and evaluation. Pt declined EMS transport to ER."

Myalgias, chills, dizziness and restlessness, feeling unwell. The dizziness and restlessness resolved with an antihistamine (Cetirizine 10 ml, one dose) and tylenol was used for myalgias and chills with good response.

Migraine headache, severe. Associated nausea, vomiting, light and sound sensitivity.

Fever (100.4) and chills starting approximately 12 hrs after administration. Temp was back to baseline by noon the following day. Some lymph node swelling to right armpit noted the day following administration. Subsided 2 days later

Employee was given moderna vaccine on 12/24/20. On Friday night, he started to get fatigued and sore. Today, he developed fever of 101 and still feel fatigued and sore.

Within 5 mins of receiving I had systemic tingling and felt very hot. My heart rate went into the 110s (usually 60s). Throat tightness occurred and I was given 50mg IV benadryl. Within 30 mins all of those symptoms subsided

Hot flashes, extreme headaches, extreme fatigue, muscle fatigue, lasting greater than 12 hours

Sore arm, sinus-type headache, and fever for approximately 7 hours.

Pain at injection site 2 days of severe fatigue Yellow/orange urine despite doubling water intake

Fatigue, headache and pain at the injection site all started within 6 hours of vaccination. Headache lasted about 1 day. Sever fatigue later about two days. And pain at the injection site for about 3 days. Yellow/orange urine despite doubling water intake for about 3 days .

All initial symptoms- soreness at site passed at day 3, At day 5 woke up from sleep with headache, did not respond to excedrine, progressed to migraine with photo and sound sensitivity, called out of work for next shift (bedside rn) vomited twice, telehealth urgent care proscribed imitrex and zofran, encouraged ER visit if headache not relieved by first dose of triptan. Migraine lasted about 9-10 hours from onset to pharmacy filling two new prescriptions for me to allowing medications time to work

Experienced L sided visual changes, including decrease in visual field and inability to focus eyes. No intervention, recovered 30-40 minutes after it began.

Headache, nausea, low-grade fever, malaise

Headache, took tlyenol

Subconjunctival hemorrhage in my right eye.

Chills Fatigue Joint Pain Body Aches Started 1800 on 12/27/2020 I took no medication but considering Tylenol

dizziness with horizontal nystagmus, improving the next day. No fatigue, no weakness, no headache, no fever, no aches or pains at any time, no other symptoms.

Flushed, hot feeling, sweating, rapid heartbeat, dizzy starting about 10 minutes after vaccine and lasted over 3 hours.

Pfizer-BioNTech COVID-19 Vaccine EUA: pruritic rash at injection site (localized), appeared 10 days after first dose

fatigue, muscle ache, joint ache, headache, nausea, chills

severe nausea and vomiting lasting 4 hours; moderate headache lasting 12 hours; mild left arm pain at site of injection

Chills, shivering, migraine , body aches, painful tinnitus, fever, elevated resting HR of 90 (normal is 46), bounding heart beat, tightness in chest, elevated resting BP 150/80 (normal 124/72) 600mg ibuprofen & 500mg acetametaphine made me comfortable to get about an hour and half worth of sleep. Went to ED for elevated HR, BP and chest pain. ED took EKG and monitored vitals. ED discharged with 975mg acetametaphine and 800mg ibuprofen with 24hrs quarters. I was able to get about 3 hours of sleep.

Decrease appetite-12/23,12/24, 12/25,,12/26,12/27 Increase Joint pain-same as above General muscle aches-same as above Numbness bilateral arms w/ tingling in fingers-12/24, 12/25, 12/26 Fever w/ chills - 12/25 Headache w/ nausea on and off 12/23, 12/25, 12/27 Dizziness and weakness 12/23, 12/27 Tiredness and feeling unwell 12/25, 12/26, 12/27 Chest tightness 12/27 I didn?t take any other OTC medicine, just tried to Go through

I developed left arm soreness (at the injection site) 12 hours after getting the shot. I also developed a temperature up to 100.7 associated with chills. I took Tylenol 1000 mg and fever subsided for 4 hours but fever and chills came back and now temp was 101.1 which was relieved by Aleve (took 2 of the 375 mg tabs). I had low-grade fevers up to 100-101 for 24 hours, associated with myalgia but no more chills for the whole Christmas Day. All symptoms resolved except for left arm soreness within 24 hours. Left arm is still sore even after 72 hours.

Joint pain. Most significant in hips. Effected my walking / sitting throughout the day.

Received the vaccine at 1038a. 1045 developed minor tongue tingling. Called the RN she gave me 25mg Benadryl. By this time whole tongue became tingly and the roof of my mouth started to feel numb. A minute later throat started to feel full and it became hard to swallow. This feeling of it being hard to swallow, came with a painful headache and some chest pain. Once in ER, was given more Benadryl, Epi, Lorazepam, and Protnox. The feeling in my throat and the difficulty swallowing slightly improved 25min after the oral Benadryl. It took about a little over an hour from the onset of symptoms to start to feel they were resolving.

Small bumps/mild rash on chest and a little itchy (but I?m also on Zyrtec)

Horrible debilitating non stop migraine like headache for three days following 1st dose of vaccine starting 12 hours after dose. Extreme tiredness, muscle pain, nausea three days duration. All symptoms resolved 3 days after vaccine

8:27 Hives, itching all over chest and on tongue, tongue swelling, slight difficulty swallowing. 8:30 epi administered/ benedrly 8:32 pseudo seizures begin off and on till the 27th

IM shot received at 0750. Went to sleep for the day since I work nights. I work up at noon with severe headache and numb bilateral hands. I took Tylenol 1000mg and went back to sleep. I woke up for work at 1630 feeling flushed. I took naproxen and went to work(in the ER). I developed a rash on my chest that evening. Over the next 3 days the rash progressively worsened across torso, back, and extremities. Since I received the vaccine on Christmas eve, employee health has not answered my calls or messages with the holiday. I also am scheduled to see PCP for this after the holiday weekend. I have been medicating with Zyertec BID, Benadry Q4hr, Pepcid BID, Tylenol TID since 12/24. I started a prednisone taper on 12/27.

I am sore throughout my body, muscles and joints, constant. I have never had any issues like this before. Tolerable pain/ discomfort 2-3 out of 10. Iwould guess what arthritis feels like. Also I?m very tired.

"I received the 1st moderna shot on 12/23/20. A couple hours later I experienced extreme fatigue. My memory became cloudy and I was so tired that I had difficulty walking. This fatigue lasted the rest of the day. I awoke the next morning with less fatigue but feeling hungover. I also had blurry vision that morning. The blurry vision abated within 5 hours. The fatigue was much improved within 36 hours. My allergy symptoms were triggered the day after the shot and my dermatitis flared within a couple days of that- super annoying because I have significant allergies and dermatitis that took specialists a couple years to control. All was ""in remission"" until the covid vaccine. Hoping that everything better by tomorrow- fingers crossed."

flushing , rash to face and chest. small bumps on the lips and tip of tongue. Improving symptoms with claritin and benadryl taken by the patient prior to arrival to the ER.

"10 minutes following vaccination, itchiness, ""fullness in face and chest"" She took benadryl and cetirizine due to known adverse reaction to H1N1 vaccine Overall resolved in 30 min no worsening Arm achiness x2 days"

12/18: First hour after vaccine: increased heart rate, felt flush and jittery - like I had drank a lot of espresso. Not debilitating but unpleasant. Then mostly went away, felt drained 12/19: headache and nausea started along with fatigue. Nausea would come in waves 12/20: Fatigued, headache 12/21: Headache, Nausea, waves of feeling flush (never had fever) and increased Heart rate. Worked all day but felt lousy 12/22: Continued symptoms from day before - feeling drained especially after episode of nausea/increased HR. Worked all day 12/23: Heached, Nausea - stayed home from work because they wanted a covid test to rule out that I had not contracted. Slept on and off all day. Cough started PM

12/24: Just headache, no nausea but no appetite, low energy 12/25: started feeling normal. still no appetite.

Facial numbness on side vaccine was given

Pain and generalized swelling to left arm for 3 days post injection. One day after injection fatigue and myalgia, Tylenol taken twice that day. Day 8 post injection a hot and painful red circle at injection site, approximately size of a quarter. Day 9 circle is size of half dollar and still hot and painful.

Weakness/ chills and fever.

Tongue went numb on right side. My face then went numb on the right side and spread to my ear. It then progressed up to my right eye lid. I took a dose of Benadryl and Flonase. Numbness stopped spreading. It lasted about 35 hours. No facial drooping noted. I was able to close my eyelid then entire time.

syncope, anxiety, nausea, vomiting, diarrhea, perceived tongue swelling although no visible swelling

fever of 100.4 deg F, took tylenol

Significant fatigue ~24 hours after vaccination. Muscle aches, joint pain, fatigue ~48 hours after vaccine. No fever noticed.

I took the shot at 11:45. By 3ish my shoulders and neck began to become stiff with slight pain which progressed throughout the evening until I developed a severe headache. By 6pm I had difficulty turning my head due to neck stiffness with a resting HR:98 SpO2:99%. I then developed a cough, SOB, dizziness, and balance deficit. Around 9pm my lips went numb with tingling when touched. I then developed small blisters around my lips. I was awake till around 4am with a severe headache. By 9am all these symptoms subsided except for the tachycardia and lips tingling with paresthesia which resolved by the next morning. 48hrs later I was back to normal.

Left sided facial numbness

Significant pain at injection site that lasted about 36 hours and prevented any touching of the site. Also had mild headache and some generalized myalgias. These also resolved after 36 hours.

Injection site pain, low-grade fever, bodyaches, sore throat, headache, tiredness - lasted from around 10 am to 9 pm, when I went to bed. I had a confirmed negative antibody test 11/24/20

Numbness of the tongue

Moderna COVID-19 Vaccine EUA Excessive shoulder pain with limits on range of motion. Has diminished in the past 36 hours but pain still persists and range of motion is not back to normal. Only took Tylenol, aleve, and albuterol.

Enlarged left cervical lymph nodes. Two palpable nodes that are hard and tender. Measuring about 3 cm in diameter today.

Chills, malaise, nausea, muscles sore, temp 100.1-100.5 13hrs post injection. All s/s gone within 36-48 hrs post injection.

Blood pressure has been 145/80 p.60 since 12/24. I do not have high BP normal pressure for me 110/75 Extreme muscle strain experienced 48 hrs after vaccine given.

12:30 pm injection given to left arm, after 10 minutes of waiting a sudden warm sensation began from left arm traveling across chest to right arm, up my neck and inside throat to my face and head. I found this sensation to be strange and describe the feeling similar to receiving contrast for CT scan and when administered you can feel the warm sensation as it travels through out your body. My vision became a bit blurry I tried to remain calm and asked others in the room if they experience similar symptoms in which no one had. I stood up and walked across the room to get some water. I had an unsettling feeling and coached myself to remain calm. I drank 2 cups of cold water and sat down. After about 5 minutes the hot flush went away. I decided to stay longer than the 15 minute observation time that I was told to do. After 30 minutes from injection I felt okay to leave.

Chills, fatigue, h/a, joint pain, bruising on forearm

-Dec 24: received -Dec 24 evening: fatigue, sore joints -Dec 25th: fatigue, generalized malaise, sore joints - especially those affected by the arthritis.. Moderate symptoms.Last all day. Bed rest. -Dec 26th. Symptoms improving. bed rest -Dec 27th: Much improved. Only symptoms remaining is sore joints (mild) Treatment: 1000 mg Tylenol q 4 -6 hr since Dec 24th

Prolonged symptoms. Pain, swelling to injection site that radiates down arm to fingertips and up arm into shoulder for 5 days and continuing. Swollen, painful lymph nodes in left under arm for 5 days and continuing. Pain so severe unable to sleep.

Within 30 minutes of vaccination, there was tongue numbness and tingling in addition to chest tightness. After 5 hours there was also upper lip numbness and tingling. Benadryl 50mg po was given in Emergency department of Hospital (where patient is a resident physician) and patient took another 25mg po Benadryl before bedtime. Tongue numbness improved by next morning, however upper lip numbness persisted. There was also upper lip swelling the next morning after vaccine, which was noticed when patient woke up (~ 16 hours after vaccination). This was treated with 20 mg cetirizine in AM and 10mg cetirizine at night by patient. Swelling persisted into the following day ~ 48 hours post vaccination before resolving. Patient?s initial chest tightness resolved within the few hours of observation in ED.

Agitated that night starting in 4 hours Resolved by am Mild arm pain and febrile sensation during night after injection Myalgia for 3-4 days

12-14 hours after vaccine, very sore injection site arm, fever, chills, viral syndrome symptoms and intensely sore, burning mouth. All symptoms came on simultaneously. felt great after one dose of NSAID except for sore mouth. Following day looked with flash light and have red based mucoid lesions multiple throughout the oral pharynx. no trouble swallowing. I take valtrex 1 gram daily as my dry mouth causes

chronic HSV outbreaks but these are NOT hsv as there are no central ulcerations and they burn but aren't intensely painful like hsv lesions.

Approximately 30 mins after injection I started to feel my heart racing. Checked my pulse and it was reading 130bpm. This continued on for approximately 60mins. I then started with a migraine that lasted 36hrs. Starting on 12/25/2020 I felt a lump in my throat and have been periodically choking on food and liquids. It feels like my thyroid is enlarged.

Pfizer-BioNTECH COVID-19 Vaccine EUA I had a mild headache 20-30 minutes after vaccine was administered on 12/18/20 that went away 4-5 hours later. I did not take any medication to help with headache. I woke up the next day with extreme fatigue, muscle aches and hot flashes/chills from Saturday-Tuesday morning. I had radiating pain down my arm to my fingers that lasted about a day on 12/19/20.

Arm soreness, Diarrhea, Headache, Nausea, and Fatigue. The last four were exact symptoms I had when I was ill with the virus. The side effects only lasted approximately 12 hours and most were alleviated with Zofran and Naproxen. No medication helped the headache, which was also my experience when I had the virus a month ago.

Muscle/body aches, fatigue/tiredness, and fever

Chills a couple hours overnight. Woke up on 12/17/20 with a moderate headache.

Mild pain and mild headache

Slight runny nose, mild rash, moderate headache lasted 14 hours

With in 5 minutes of receiving the vaccine, my feet began to burn. It continued to get worse throughout the day and turned into numbness and tingling in both feet and both hands. Still continuing to have these symptoms 17 hours post vaccine and unable to sleep.

Received COVID vaccine 12/22 at 1100. Noted hive on right wrist, opposite arm of vaccination at 1700; hive- 1 cm in dimeter, red raised in middle, not itchy. Benadryl at bedtime and when woke up red outline was present but not raised, 24 hours later completely resolved. Some fatigue and slight headache within the first 12 hours, resolved. Also reported mild chills and mild fever lasting less than 12 hours.

Excessive thirst 15mins post Heart palpation with fluttering sensations 30mins post HTN 156/96, 80hr, 1hour post Chills 1hour post Muscle spasms with cramping throughout body 45mins post Muscle weakness to left side 2hour post Facial twitches Treated with tylenol and Gatorade and rest. Symptoms lasted 48hours post.

Vaccinated on 12/23/2020 at 1 PM. Moderate pain and tenderness on injection site. One white pustule on left tonsil. Tender lymph nodes. Moderate generalized body aches. Mild headache, mild fever. Went to urgent care Negative for mono and strep. Got script for erythromycin if symptoms persist.

Developed cough, fever, body aches, and chest pain

Flushed skin, elevated HR, extreme feeling of internal heat, dizzy

nausea/vomiting, elevated heart rate and cough

Patient received COVID 19 vaccination and developed elevated heart rate. It is less likely that this was a reaction to the vaccine given no complaints of nausea, vomiting, itchiness, shortness of breath, abdominal or epigastric pain, wheezing which are typical signs of a reaction. Most likely this was an anxiety event.

Severe nausea/abd pain lasting 24 hours

Developed headaches the week of vaccine, especially Saturday, 12/26/2020. Experienced body aches on 12/26/2020, intermittent in nature and fatigue. Called Nurse to report symptoms and confirm clearance to return to work on 12/28/2020 and was instructed to complete potential vaccine reaction.

Woke with nausea/vomiting, chills, and dizziness

pt with history of anaphylaxis to latex and fruit, presents to ED with urticarial skin reaction with itching, throat itching, cough, lightheadedness soon after receiving Covid vaccine.

Day 1 injection site pain, Day 2 extreme fatigue and temperature of 100.4, injection site red, warm with a 5 cm hardened lump, Day 3 injection site red, warm with a 3 cm hardened lump, day 4 injection site remain red and warm, no longer swollen

Patient developed a soreness and then itching developed. She then noticed a knot to the left of the injection site. She has now developed approximately 2 inch long area of redness across her deltoid.

within minutes of being vaccinated, developed feelings of swollen lymph nodes, fullness and stiffness in her neck. She has redness across her upper chest. She has experienced side effects similar to this from other vaccines she's received in the past. She was observed in the ED but no medications were administered. Her symptoms improved and she was discharged with a prescription for an EpiPen and an appointment to follow up with an allergist.

12/27 woke up with pain in left armpit. Swelling increased throughout the day. Pain was manageable without medication, did hurt when swelling was palpated or I squeezed my left arm down to my side. Woke on 12/28 with same pain, does not appear to be further swelling, but hurts in my armpit to hold my arm above my head.

Approximately 20 hours later, I began getting chills. When I put on a jacket, I began sweating profusely., yet freezing cold. My head was pounding. Came home from work a couple hours later and took a nap for a few hours yet woke up multiple time covered in sweat, yet again freezing cold

Within 10 minutes of receiving the Pfizer COVID vaccine, she complained of chest tightness, feeling flushed, mild headache, and paresthesias in her hands and mouth. Symptoms lasted approximately 10

minutes and resolved spontaneously. No treatment was administered. The patient was observed and discharged to home with no additional treatment.

Erythema and edema at injection site measuring 4 inches by 2.5 inches lasting 3 days. Day 2 had an excruciating headache unrelieved by Tylenol or Aleve.

Patient received the Pfizer Vaccine. Mild rash was noted on the forearms by the patient

10 minutes after receiving vaccine patient complained of head heaviness, palpitations and feeling hot in the ears. BP = 166/97, HR = 129, O2 SAT = 100%, Temp. = 98

10 minutes after receiving vaccine patient complained of head heaviness, palpitations and feeling hot in the ears. BP = 166/97, HR = 129, O2 SAT = 100%, Temp. = 98

Pfizer-BioNTech COVID-19 vaccine EUA on 12/15/2020--12/19/2020 @ 0300 I woke up with joint pain in all joints including hands, feet, fingers & toes, also muscle aches. I had an occasional cough, nasal congestion, nausea and headache. The joint and muscle pain lasted approximately 48 hours and was relieved with Tylenol and ibuprofen every 4-6 hours. The HA lasted until 12/22/20. As of today 12/23/20 I still have some nasal congestion but no other symptoms. I never ran a fever.

Tongue swelling a bit. Postules formed. Bumps all over tongue. No fever or other symptoms

FEVER 100.1, HA, body aches

These are expected side effects, I was told I still need to fill out this form by my boss. Temp 100.2, extreme fatigue, chill, extreme muscle pain, cough, left eye irritaion

Serum sickness syndrome, fever not greater than 101, severe muscle and body aches/pains, nasal congestion, extreme fatigue, cough, nausea, loss of appetite First vaccination in 55 years

"12/23/2020 0200 Severe Tremors and Chills. Nausea, dizziness, & near syncope. Headache. 0700 Softball size lump(edema), 6""x6"" area erythema, hot to touch, and pain at injection site. Difficulty raising arm due to pain. Fatigue. 12/25/2020 0100 Awakened hot and sweating which lasted approximately 6 hours, fatigue. Arm issues continued. 12/26-27/2020 Arm slowly improving but fatigued and headache continued. 12/28/2020-Improved but headache continues."

Bruising at site of injection and multiple areas covering body (limbs, back, abdomen) that was noticed beginning 12/24/20 and has continued over several days

12/20/2020 12:00 PM DEVELOPED LAPID ATRIAL FIB. WENT TO ER WHEN IT PERSISTED, MEDICAL CENTER. ADMITTED TO INPATIENT; 12/21/2020 - ELECTRICAL CARDIOVERSION. MONITORED OVERNIGHT. 12/22/2020 - DISCHARGED *ON CHRONIC BLOOD THINNER

12-23-2020 severe chills, nausea, and severe body aches did not check temp. 12-24-2020 she still feels off, but not as bad. Temp is normal

Local redness, swelling, left upper arm at injection site.

Rash on abdomen approximately 2x4 inches with slight itching that lasted about 3 hours without requiring any treatment.

Almost immediately after vaccination the recipient felt faint. She was helped to lay on the ground, vitals were checked and monitored, and remained stable. She quickly felt better and stayed in observation a total of 25 minutes. She reported that she has experienced this in the past when getting a blood draw or vaccine. She returned to her work unit with a colleague. We checked in with her a few hours later and she was completely fine.

Arm pain

Patient reports developing a mild headache post vaccination within 15minutes that progressed in severity with nausea, dizziness and fainting. Occupational Health is following up with patient and recommending comprehensive provider evaluation

Immediately after receiving vaccine recipient stated that he felt faint. Eyes rolled back and he became limp. Two nurses laid him on floor. He came to within seconds but was diaphoretic. Vitals were checked and monitored (BP 130/70, 118/74, 120/72; pulse 57, 72, 68; pulse ox 98%, 99%, 99%). He quickly felt better (within a few minutes), was given water, chocolate and a granola bar. He stayed in observation a total of 35 minutes. He reports that he had been very nervous about getting a vaccination. He returned to his unit with a colleague. We checked in with him a few hours later and he reported that he felt well.

Muscle aches, fatigue. Treatment rest. Resolved by 12/27/2020

Fatigue on 12.26, fever 101f on the night of 12.26, fevers 101 to 102 from 12.27 to today 12.28. headache beginning 12.28

Moderna COVID-19 Vaccine EUA Headache for 2 days

Vaccine recipient received the vaccine on 12/18/2020. On 12/19/2020 reported that the injection site had prominent redness and swelling. On 12/22/2020, the site was warm to the touch and the pain was mild, but bothersome. Over these 5 days the injection site became swollen with increased redness and pain. On 12/23/2020, the vaccine recipient reported that they were feeling better and has followed-up with occupational health with no further issues.

low grade fever 99.8 F, slight nausea, over feeling not well, fatigue

Redness, swelling at vaccine site

12/25/2020 08:00AM patient awoke with left eye twitching, mouth drawn to left side. Neck severely aching from right earlobe to the back of neck, severe headache. Unable to close left eye. ER visit 12/26/2020 in the morning - discharge diagnosis, Bell's palsy. Prescription Valacyclovir hcl 1 gram tablet, Butalbital, Acetaminophen, Caffeine Oral tablet 50-325-40mg , solution eye drops , Azithromycin cream

Flu symptoms including headache, nausea, chills, joint pain and low grade fever of 99.3 Symptoms began in the middle of the morning about 10:30 - 11:00 am while I was at work; worsened through the afternoon and night; all better by morning; symptoms completed gone

Patient complained of tachycardia about 15 to 20 Minutes after receiving the vaccine

Quarter size swelling at injection site, entire deltoid became quite sore, firm, warm and extremely tender with significant decrease in ability to perform abduction and extension over the next hour. Pain and stiffness progressed to right shoulder blade and right trapezius. At this time these areas remain somewhat tender and sore, however ROM has improved. Of note, also developed some SOB and redness to neck and chest within 30 minutes of injection, Fexofenadine was taken and the SOB and redness to chest resolved by 4pm day of injection.

Within 12 hours of receiving the vaccine I developed sever flu-like symptoms - low grade fever, chills, body aches, extreme fatigue, runny nose

I had a headache, extreme fatigue, achy joints and muscles. I had a scratchy throat also.

who presents with complaint of rash , itching minutes after COVID vaccine. Also notes nausea and fatigue. Pt notes no throat swelling , pain , voice change , shortness of breath , abdominal pain , vd or other concerns. Pt has known allergy to flu vaccine and other medications as noted

Fever 100.1 to 101.5. 24 hours. I was very weak. I could barely walk to the bathroom. At 5 AM when the symptoms started I felt like it was going to faint or just collapse. I felt like I was going to faint on multiple trips to the bathroom. I had no energy .I felt like I had Covid symptoms all over again. I had cold sweats for almost 24 hours had to take my clothes off to get comfortable. I was so warm. exhaustion .slept for almost 24 hours. I just felt miserable my stomach was nauseated and felt very sore in my abdomen. aches and pains in my hips and legs.

After receiving the covid vax, I had shoulder soreness the first couple of days. That night, the vein , was a different color than the rest of my veins in my bicep. The discoloration of the vein was at the top of my bicep. Now, the vein is visually fine now.

Two hours after the injection my tongue started swelling and pain increased throughout the day to the point where I could not eat. The next morning (Dec. 23rd) I had painful white lesions under and on the sides of my tongue. This worsened over the next day and I was seen at an urgent care clinic who took culture swaps for lab test. (eventually negative for oral herpes). Pain and lesions continued to worse and I was admitted to the ER on December 26th. Breathing, heart rate, and blood work all normal. Diagnosed with Herpangina/Coxsackie Virus.

Injection site pain x 2 days, nausea x 5 days, fatigue x 3 days, chills x 2 days, muscle + joint pain x 2 days, headache x 1 day, weird dreams x 2 nights

Hive reaction began on day 7 post vaccine, isolated to left arm, back, trunk.

Experienced nausea, dizziness, felt hot and face flushed, and felt like he was going to pass out 15 minutes after receiving vaccine. Patient assessed in the emergency department and found to be stable but has complaints of nausea and dizziness with headache. Received IV fluids, meclizine, and prochlorperazine. Discharged from emergency department at 1454 after tolerating fluids and foods by mouth without difficulty, no recurrence of symptoms, vital signs remaining stable, and stating he feels like he is back to his baseline status.

pt received a COVID vaccine of moderna and within 15 minutes pt c/o throat feellng itchy and tight down low. Also, c/o of tingling in fingers and toes. Pt noticeably shaking. Pt has a hx of fainting with needles. Pt become more anxious and requested and ambulance to be called. Color was flushed. B/P 169/99 P146 SPO2 99%. For pts comfort gave O2 at 2L/min via NC. Pt remained alert and oriented and talking. EMT administered Benadryl 50mg IM. Ambulance escorted pt to ER where only observation was done. F/U with pt about 2 hours later. Pt states she believes she panicked and was doing fine right now. No other issues.

first start with sore arm and neck-then started hurting in chest- now have blisters on lip and throwing up

Cold extremities, warm face & diarrhea - Monitored for 47 minutes, no abnormal finding except for elevated BP. Client did not have any rash, hives, angioedema, difficulty breathing, wheezing or altered level of consciousness. She reported all symptoms resolved and discharged home. Additionally, she reported diarrhea overnight which had resolved by the next day.

severe cold chills started at 3am no fever used heating pad to get warm then had to work the next day severe aches and chills again with some nausea took ibuprofen at 9am and chills and aches went away for about 5.5 hours then returned but not as severe. right arm pain x 2 days

Muscle aches, subjective fever, headache, sore arm

Arm pain for 2 days and a very bad headache for 2 days and extreme fatigue.

"approx. one hour after receiving vaccine pt started having throat tightness, nausea, lips tingling, SOB and ""feeling weird"". States has had anaphylaxis in the past from nuts and uses an EPI pen. States she used her pen but did not get relief so went to ER where she received IV benadryl, tagment and steroids. EKG was abnormal. States no problems at injection site. F/U with patient appox. 7 hours after incident and pt states she is doing fine and not having any issues now."

Hello I received my Covid Vaccination on 12/23/20 7:56 am at Healthcare Clinic. I waited 15 minutes after the vaccination and then went and stayed home. Six hours later my arm started to become very painful (no surprise) I then felt an overwhelming fatigue and sadness. I had tears just streaming down my face for about 3 minutes. I laid down and awoke later that night still feeling very fatigued. I showered and crawled back to bed I awoke the next day at mid-morning, still tired but 60 % better. I stayed awake for a few hours, showered, changed the bed sheets and went back to bed for several hours more. I awoke tired ate a lite dinner and went back to bed. I awoke at 8:00 on Christmas day feeling fine, just like my old self. If you need any more information just call. Oh my vaccine information

is: PFIZER EJ1685 12/23/20 1st dose. Thank you, Medical Interpreter Center for Advanced Pediatrics Endocrine Department.

Headache, cough, Fever 99.9, wheezing, body aches, fatigue

15 minutes after vaccine pt c/o mild SOB, no tongue swelling noted, rapid response team called

Arms became achy and wasn't able to lift it. Extreme Fatigue, Headache and chills

Moderna COVID-19 Vaccine EUA Side effects started about 12pm on 12/23/20 Nausea, headache, body aches, cough, runny nose, congestion, very tired

Patient reports shortness of breath and persistent cough.

About 10 days after the vaccine, I developed, over the course of 30 minutes, pain/pressure from my left distal forearm to my hand, with stiffness and vague weakness in the area. Over the next hour or so I noted swelling of the wrist; swelling and pain in the dorsal and radial aspects of the left wrist have persisted until the following day when I am submitting this report. I had done some activities with the wrist prior to the onset of symptoms (opened a difficult jar, sat on my hand to keep it warm while using the computer) but these didn't seem outside of my normal daily activities.

For the first day or two after receiving the vaccine I experienced injection site soreness, fatigue and malaise, and sore throat. Symptoms resolved within 2-3 days and I was symptom free by the time I went back to work on 12/24

Initial symptoms included a feeling of slight panic with associated need to take deep breaths. Once I left the facility 20 minutes later, I felt slightly lightheaded with sensitivity to light and sound. These symptoms were mild overall. The feeling of anxiety and mild sensory symptoms persisted for several hours. That night, I experienced night sweats. I have been feeling fine overall since that point.

12/26/2020 Chills, headache, fever 105.00, occasional dry cough, throat tickle, body aches. 12/28/2020 low grade temperature- fever, occasional dry cough.

I am a 46 yo MD who received the Moderna vaccine lot#037K20A exp 6/22/2021 on 12/24/20. I had also just recovered from a COVID infection 5 weeks earlier. 18 hours after receiving the shot, I developed severe chills/fever/tachycardia and muscle aches and headache that lasted about 7 hours. I slowly recovered and was better at about 36 hours post vaccine.

Vomiting, Diarrhea, Fever, Chills, Muscle Aches

Axillary pain and swelling

Eyes started itching. On December 20th eyes itched so bad that contacts were not able to be worn. Redness on hands and were itching which began 12/19 but on the 20th bumps and itchiness on elbows. I suffer from eczema and take self injection shots for it so the rash appeared as if my eczema was triggered.

Dizziness moments after injection, mild-moderate severity. Duration 2 hours. Treatment -rest after driving 15 minutes to home. Resolved without treatment.

facial numbness

The evening I received the shot I spiked a fever and my body started aching really bad. The next morning my head hurt and my body ached. I took some ibuprofen which seemed to help but that evening I spiked another fever and my body ached again.

After receiving the vaccine, 30 mins later. I started feeling dizzy with a rapid heart rate. I started feeling really weak and delirious. Then I had a really bad headache with nausea and fatigue. Then I eventually laid down and fell asleep for about an hour, I had a headache and the other symptoms were gone. All of the symptoms lasted about 3 hours. The headache was the only symptom that lasted longer, about 6 hours.

Mild to moderate widespread muscle and joint pain Temporary localized pain around injection site

Throat itching and light headedness; symptom duration 20 minutes.

When I woke up at 0800AM, noticed with rashes on my back about 25%. I took Loratadine but not relieved. Went to ER at 05:00PM and they give Benadryl IV. Prednisone 60 mg tab & Pepcid 20 mg tab. After 2 Hours rashes resolved. Noticed with rashes also on both legs and adomen when I was in the ER.

PAtient with a history of vision abnormalities reported blurry vision after vax administration. Patient sat for 30min, reported minimal or no improvement and refused to present to ED

Roughly 8 hours after vaccination I had fever to 100.0 and fatigue for about 24 hours. Mild muscle aches. Extremely tender shoulder for 48 hours

Day 5 after vaccine (12/23) severe joint pain only to right upper extremity (shoulder, elbow, wrist, fingers). Day 6 mild joint pain to right upper extremity. Day 7-10 Mild intermittent joint pain along with shooting nerve pain on right upper extremity. Under arm and AC stabbing pain. Numbness and tingling to right upper extremity intermittently. All positional except feeling of ?nerve pain?.

Employee received the Pfizer Covid vaccine. She was feeling nauseous. Soon after she ate, she vomited. She refuse to go to the Emergency room. She felt better to complete her shift.

- R side HA and sinus congestion followed by left sided HA with sinus congestion - Fatigue - muscle and joint aches - resolved after 48hours.

Severe headache onset at 4pm only normal headache at this time, woke me up at 12:30am was severe. Took 2 regular Tylenol eased up after 30 minutes. slight headache lingering on day 3.

Tingling, light-headed, red blotches

Symptoms included fatigue, headache, muscle and joint pain, chills, nausea, dizziness starting approximately one hour after the injection and lasting 4 days for most all the symptoms. The dizziness

lasted for 2 days and the body aches for three. Still with a slight headache and nausea today 12/28/20 5 days after the injection.

Anaphylaxis - epi pen X 2, transported to the ED for evaluation and further treatment.

Dizzy, nauseous, headache, body aches, fatigue, black tary stools., diaphoretic, near syncope

Began spotting period blood, but at least two weeks prior to normal period week.

Moderna COVID-19 Vaccine EUA

Face Started itching, Throat felt weird, rash started appearing on both arms

Tingling in hands and arm soreness, feeling like they are asleep 1 hour after injection. No treatment. Symptoms eventually resolved.

Aching in right arm, then pruritus, then swelling. Went to ED immediately since she was at work when reaction began. In ED was given prednisone, Pepcid, Benadryl.

After 3-4h of the vaccine, patient suffered intermediate headache, 1st dose of Tylenol 750mg PO was given, symptom partially resolved. 15h after, patient had chills followed by high fever, another dose of Tylenol 750mg PO and naproxen 60mg PO were given, 2 hours later, fever and chills resolved. Continuously having fatigue, dizziness, nausea, diarrhea, myalgia, arthralgia for 1-2 days. Lymphadenopathy was felt but unable to touch any swelling lymph nodes in left axillary area. All of symptoms were resolved after 3-4 days. Due to a possible exposure notice, got COVID-19 tested on 12/23/2020, both rapid antigen test and RT-PCR were negative.

Flu like symptoms, HA, sore throat, muscle aches, runny nose, dizziness, chills, felt feverish-but no fever noted.

Vaccine received at 3:29 pm on 12/26/2020. By 4:00 pm she had complaints of a headache, dizziness alog with nausea and vomiting. S/S without resolution or decrease. Sent to Emergency Department for evaluation at 5:35 pm. She was administered the follwing @ 5:39 Sodium Chloris IV, 6:18 pm 1,000 mg IV tylenol, ketorolac 30 mg IV push and Ondansetron 4 mg IV. She was discharged no longer nauseated and headache decreased from a 4 to a 2. discharged in stable condition. on 12/27/2020 she stated she had fatigue, nausea and vomiting, diarrhea and a temp os 102.0. 12/28/2020 N/V, diarrhea and fever resolved. C/o's joint pain and body aches.

Patient came to receive her vaccine. While in the monitoring area. Patient stated her mouth was experiencing numbness/tingling. Patient stated she never has adverse reaction to vaccines. V/S. B/P 130/99 P: 85 O2.98. Patient stated feeling lasted approx 3 mins. Patient was further observed for additional 15 mins. Patient stated feeling had stopped and she was feeling much better. Patient left observation approx 8:10 AM.

After receiving Pfizer vaccine, patient reported some lightheaded ness and some chest tightness. B/P 131/95, P 73, R 16. She was given orange juice, cookies and continued to be observed for an additional 30 minutes. Patient left on her own.

In the evening of Dec. 16, my arm was very tender and hurt to touch or move. It got better by the next afternoon, at which point I shoveled the snow, only to come inside with chills, sweats, low-grade fever (100.5), dizziness and headache. The entire episode was only acute for a few hours and by the next day I felt mostly myself.

10 min-heart palpitations 20 min-heart palpitations, could not catch breath, angst/panicky sensation, all intermittent 1 hour- akathisia, heart palpitations/panicky sensation, all intermittent, resolved with benadryl 24 hours- heart palpitations/panicky sensation, intermittent

3 cold sores appeared by the next morning

Headache, chills, horseness, weakness, cough.

"Day 1: approximately 1 hours after vaccine - dizziness, extremely tired, dosing off, , injection site tender, approximately the size of a dime knot at injection site. Day 2: body aches all over, moderate headache, extremely tired, no energy, about 1700 hours: profuse sweating, full body chills accompanied with entire body shakes, extreme headache, nauseated, unable to eat, lose of taste and smell, extreme body aches, sense of falling. Lasted for 36 hours, lost 7 lbs. Swelling at injection site, followed by a knot in arm approximately size of a quarter, raised approximately 1 "", red rash and extreme itching. Day 3/4: symptoms subsiding, rash and pain in arm increasing. Rash spread from elbow and shoulder, raised approximately 2"" and almost encompassed entire upper arm, approximately 1"" gap on the inside of arm not affected. Day 5: Started feeling human again. Temperature was never higher than 99.5 degrees. Took Aleve and Tylenol"

Developed a rash on abdomen that was discovered at approximately 10 pm on 12/29/20, the day following the vaccination. Personal physician diagnosed it the following day as shingles and an anti-viral (valacyclovir) was prescribed. Last dose taken on 12/27/20. Rash is clearing.

Severe bilateral arm pain, fatigue, fever, chills. Onset 12/24/2020 10:00am until 2:00am. Ibuprofen. Person recovered.

"""Flushing"" feeling felt during monitoring period. Patient requested a Benadryl but then symptoms resolved with no intervention. Pulse- 99 BP 154/99 O2 - 98 R - 22"

Patient experienced/reported nausea post administration, approximately two hours after. Patient had emesis x1, to where Zofran given by mouth, w/ patient reported relief.

Treatment dugs:

None stated.

Treatments dugs:

Treatment dugs:

Treatment dugs:

Treatment dugs:

Treatment dugs:

had hives on back and L arm 1 inch medial to vaccine injection site; no lip or tongue edema, no wheezing or stridor Treatment dugs:

Treatment dugs:

Treatment dugs:

Treatment dugs:

She states that she had immediate pain at the injection site. On Saturday at 7AM, she developed malaise and frequent stools but would not classify them as diarrhea as well as a headache. She has never had a fever. Today, she continues to feel weak but reports that she is improving. Treatment dugs:

25mg po Benadryl given per vo Dr. at 9:20a -- 9:45 symptoms completely resolved Treatment dugs:

I was told to contact you and let you know that I have been having flu like symptoms since my vaccine Monday afternoon at 3:45. Started yesterday with the headache, body aches and chills. I stayed the day yesterday but i will be leaving early today as I am not feeling any better. Treatment dugs:

Treatment dugs:

12/16 - onset of fatigue and runny nose followed by headache and body aches. As of 12/23 he has a mild headache not requiring any medication for relief. He missed a day of work on 12/22. He did not seek medical attention. Treatment dugs:

Treatment dugs:

Throat swelling/closing feeling, outcome is anxiety, will take hydroxyzine. Feeling of throat swelling, throat closing

nausea, vomiting, severe enough to call out of work

headaches, mild but moved around mostly on right side; moderate to at times severe joint pain in hips, knees and hands. Headaches started 12/25/20 and continue today 12/28/2020. Joint pain started afternoon of 12/24/2020- was worst 12/26/2020 but some relieve with high dose ibuprofen. Still joint pain and stiffness, mostly in hips, knees, lower back and hands.

12/25/2020 Patient states that he started experiencing body aches and took Ibuprofen, on 12/26/2020 patient states that he wasn?t feeling well with flu like symptoms: fever 101, loss of appetite, fatigued, vomited once, body aches, continued taking Ibuprofen throughout the day, 12/27/2020 Patient states

fever decreased to 99, still feeling fatigued, shoulders are sore, feeling clammy, patient states that he has never tested positive for Covid, he has never been exposed to his knowledge , went away, still feeling fatigued, shoulders sore, clammy, temp no higher than 99. patient states that because of his flu like symptoms, he went to pharmacy for the PCR Covid Test and is waiting on his results.

Soreness to injection site, fatigue, fever, chills, body ache and nausea.

right after the vaccine she felt light headed felt better in observation after about 7 minutes employee c/o heart racing,Chest pressure, feeling light headed, throat scratchy and tight. allergy to MRI contrast dye only - Gadolinium. Has had lots of vaccines in the past without problems. Taken to ED via W/C was talking all the way not SOB admitted to ED. 12-28 States she was admitted to the hospital overnight for anaphalaxis on a second trip to ED. She will not be able to get her second dose of the vaccine. this should be entered into the VAERS reporting system. She is till using the benedryl.

facial rash - forehead/nasal area/ lips red and decreased swelling. Denies SOB.

Fever up to 102 degrees, muscle aches, fatigue, lymph node pain, injection site reaction, headache, chills, joint pain. Started about 26 hours after the vaccine and lasted about 48 hours. Injection site redness/warmth started about 96 hours after vaccine- large area on upper arm about 6 inches by 10 inches. The redness and warmth are still there, other symptoms have resolved.

Dermatitis.

Approximately 5 minutes after vaccine administration (8:14a) patient felt heart palpitations, Heart Rate up to 90, blood pressure 149/98. At 8:22a blood pressure at 153/98, At 8:37 a Blood pressue at 144/96 Within 30 min (8:43a) patient Heart rate down within normal limits to mid 60s and blood pressure to 130/80 (manually).

nausea and vomiting

Approximately 17 hours following vaccination, recipient experienced fever, chills, shortness of breath, nausea, diarrhea.

Supraclavicular adenopathy

After receiving the vaccine, I laid down at noon. When I woke up at 6:30 in the evening, I felt tired. Then by 9:15-9:30pm, I started getting chills. Then by 1:15am, I started running a temp of 101.5. When I got up this morning at 7:30am, My temp had gone up to 101.7. I took two tylenol at 8:30am and I have not checked my temp yet. Im just sitting in the chair sweating.

After receiving the vaccine, I laid down at noon. When I woke up at 6:30 in the evening, I felt tired. Then by 9:15-9:30pm, I started getting chills. Then by 1:15am, I started running a temp of 101.5. When I got up this morning at 7:30am, My temp had gone up to 101.7. I took two tylenol at 8:30am and I have not checked my temp yet. Im just sitting in the chair sweating.

The morning after the vaccine I woke up with a headache, took some Advil and it helped. On Monday I had the majority of other symptoms: chills, headache, nausea, mild abdominal discomfort, sore throat, congestion, muscle ache, joint pains. No fever.

During injection immediately felt itching at injection site. Over 3--45 minutes, itching spread up the deltoid to the left upper chest towards the mid chest. No airway involvement. Went to the ER and received prednisone, Pepcid, Benadryl. Discharged to home with prescription prednisone, Benadryl, and Pepcid, and Epi-Pen.

"Patient administered vaccine and remained in the vaccine clinic observation area for the recommended time period. Patient at that time had no reactions and returned to her nursing unit. Approximately 10-20 minutes after leaving clinic while working, patient developed: Right lip swelling,R scratchy throat,R tongue feels ""tingley"", No respiratory distress At onset of symptoms patient took her own benadryl 25mg po prior to re-presenting to clinic to notify staff of symptoms. Staff observe symptoms as listed above, again pt had no acute respiratory issues. Epinephrine offered to patient, refused by patient. Patient agreeable to repeat dose diphenhydramine, pt takes 12.5mg oral solution. Staff monitors patient closely, no worsening of symptoms and slight improvement noted within ~15-20 minute of presentation. Patient leaves against medical advice from clinic due to a rapid response call for one of her patients. Follow up with RN within an hour shows resolution of symptoms with diphenhydramine, no additional doses taken after the total of 37.5 mg"

Ran fever of 99 for 2 days

Immediately after vaccine my face started getting hot and itching. swelling to my face and neck area I took zyrtec for the adverse events

Severe chills, aches in hip and body, headache. Lack of energy the following day.

Moderna COVID- 19 Vaccine EUA Patient reported account of vaccination on 12/21/20: I received my 1st dose of the Pfizer Covid-19 vaccine yesterday afternoon and about 2 mins post injection I felt flushed, dizzy, and nauseous which disappeared quickly but then came back about 10 mins post injection and then never happened again. I felt completely normal after that and I feel fine today.

"1006: received vaccine 1022: 15 min observation complete - no difficulties 1034; lightheaded ""wash"" in my head lasting < 30seconds (as though standing too quickly) along w/ fleeting nausea then ""light"" numbness of face. Uncertain if subsequent tachycardia and hand tremors were from the initial lightheadedness and numbness or additional side effects. I was driving my car, alone and became nervous. 11:30 25mcg benadryl capsule taken ~13:00 numbness of face resolved."

15 minute post vaccination observation patient denied any symptoms. Later in the day patient experienced significant nausea and vomiting followed by mild SOB and throat swelling.

Developed red, blotchy, mildly itchy rash to anterior and posterior neck on the morning of 12/25/2020 (rec'd vax afternoon of 12/23/2020). The rash progressed throughout the day; extending to anterior

torso down to waist, right arm, and upper back. Took 25mg benadryl tablet. Rash began improving the next afternoon (12/26/2020) and completely resolved by morning of 12/28/2020.

DIARRHEA, FATIGUE, AND BODY ACHES AND SORENESS

About 8 hours post vaccine, at 2300 as I was going to bed I felt what I would describe as breathing resistance. I would not describe it as chest pain/pressure/tightness or SOB. It was just upper chest resistance to inhalation when lying down for bed. 12/24 started with intermittent gnawing epigastric during the day. Persisted through the night with gnawing epigastric pain radiating through to my spine, i was unable to sleep due to the pain. Attempted tums (I do not have GERD), motrin & tylenol however, nothing was helpful. 12/25 & 12/26 same symptoms persisted both day and night 12/27 asymptomatic 12/28 cramping/twisting epigastric pain returned, much more mild

Vasovagal like reaction after a light 1 mile walk. Lost consciousness.

Numbness in sole of feet. Unable to walk, develop high fever, resp failure resulting in intubation, acute kidney injury

Diaphoresis, syncope, and hypotension.

cold sweats and body aches day after vaccination

Patient had mild wheezing 15 minutes after vaccine injection.

Moderna COVID 19 Vaccination administered IM L deltoid. Client stayed 30 minutes for observation. Left and approximately 15 minutes later experienced numbness in tongue and neck area-felt like throat was constricting. Drove self back to clinic with epi and benadryl administered IM and oxygen placed at 8l. Blood pressure 170/98, HR 108. States felt better but after approximately 15 minutes became flushed and felt like it was returning. Left with practicing MD & NP to go to ER.

1. Injection site pain - more than typical with a flu shot - awakened in the middle of night with aching - took acetaminophine which remedied the problem. Continued general body achiness for 24-36 hours, again resolved withacetaminophine. 2. Next day, December 24 - (a very active day for me) - experienced fatigue as day progressed - had to stop in mid-afternoon and sleep - very uncommon for me. NOTE: The above symptoms were unpleasant but did not prevent me from playing the organ for 3 church services on the 24 and 25.

12/22/2020 Chills, body aches, fever 103.00 fever -- overnight fever unable to break 104.7 fever with Tylenol and Ibuprofen. Morning no change in temperature 104.7 no change -- ER Clinic Visit, XRAY-results: pneumonia , Covid test - positive; medications prescribed : 5day Z-pack

Shortness of breath had a terrible asthma attack very congested in my lungs weezing

Possible Bell's Palsy Rx of Prednisone 60mg Daily x7 days Valacyclovir 1000mg TID x7 days

Fever of 102.9 extreme body aches

About 2 minutes I received the vaccine I felt my right upper lip swelling and tingling, then left start and migrated to my ear and down to my jawline. Difficult to swallow.

Around midnight on day of vaccine, 12/23/20, patient experienced pain at the injection site, which lasted about 20 hrs. Patient also had a severe headache, which he says has abated as of today, 12/28/20. Patient starting having the following problems around midnight on 12/23/20 and is still experiencing them: fever (99+), occasional chills, difficulty in breathing, restless sleep, coughing, burning sensation in nose and sinuses.

12/20/2020 WITHIN MINUTES, I STARTED TO FEEL PINS AND NEEDLES. RADIATED LEFT TO RIGHT SIDE OF ARMS, AND THEN UP TO HEAD. NUMBNESS AND TINGLING. SEVERE PROFOUND WEAKNESS, DIZZINESS AND ORIENTATION. VISION FELT 'FAR AWAY'. HR INCREASED, HX SVT. 3 MINUTES BP WAS 'OK' BUT I BELIEVE IT BOTTOMED OUT. HR WAS 150. STRETCHER, TX TO ER. BLURRY, 'STAY WITH US'. ALERT, AWAKE, VERY IN AND OUT OF FOCUS. FEEL LIKE 'PTSD' FROM THIS EXPERIENCE. 'WHOLE BODY WAS BUZZING'. IV STEROIDS, IV BENADARYL, IV FLUIDS, IV ATTIVAN (NO EPI AS NO DIFFICULTY BREATHING) STILL FEELING 'DAZED' *FLU SHOT REACTION 2013 - BRONCHOSPASM, MILD. 2014 - BRONCHOSPASM, RINGING IN EARS, INCREASED HR, DRY HACKING COUGH, USED NEBULIZER AND TOOK BENADRYL. LASTED 4 HOURS. ALLERGIST APPT 2020 - ADMINISTERED FLU SHOT UNDER GUIDANCE; SCRATCH TEST; BROKEN UP INTO 2 DOSES. INFORMED NOT ALLERGIC TO FLU SHOW 'GOOD TO GET COVID SHOT'. *STILL HAVE TINGLING IN LEFT THUMB

chills, fever, extreme exhaustion

Uncontrollable shaking, muscle tremors, cramping of muscles in legs, calves and thighs, generalized fatigue and body aches, fever 103, diarrhea, vomiting, extreme headache, extreme soreness in arm where injection was given with limited range of motion. Egg size lump, bruising and rash at injection site. Most all symptoms lasting 2 days.

Within 8 minutes of receiving the COVID-19 vaccine, patient developed feeling of throat feeling itchy, tongue tingling, and progressed to throat tightness and difficulty speaking and squeaky voice within 15 minutes of receiving the COVID-19 vaccine. 911 was called with request for the facility's Rapid Response Team (RRT) to assist. While awaiting RRT arrival, patient was administered Epinephrine 0.3 mg IM via EpiPen, first dose within 18 minutes of onset of adverse symptoms, with short-lived improvement of symptoms. The Rapid Response Team arrived on the scene and when the same symptoms started to return, about 7 minutes after the first dose of Epinephrine, a second dose of Epinephrine was administered IM. Patient's symptoms responded positively to the second dose of Epi and patient was transported to the Emergency Department by the Rapid Response Team for observation and further evaluation/treatment as needed.

chills, fever of 103, bodyaches, headaches, and fatigue. Started 12/26/2020 and still active.

developed hives all over arms and thighs, few spots on calf. Slightly itchy at times. Arms were not painful welts, but the leg welt are very painful, feel almost like bruises. This along with generalized muscle aches

and pains. Took an antihistamine with no relief, hives have been gradually fading but pain in legs still persistent. no respiratory issues so did not go to ER.

About 8 hours after receiving the vaccine, I experience a severe migraine the radiated down my neck and was accompanied by nausea. I slept for 12 hours and the symptoms are almost completely resolved.

Severe injection site pain. Went to UC. Followed up with PCP. Supportive measures recommended.

"Left arm tingling down to fingertips within 15 mn of injection. Later down entire left side to toes. Later diffuse tingling. Resolved next morning 12/18. Lump at injection site for 1 week. Strong Left arm pain on 12/18 12/25 swelling and red rash (1.5"")around injection site. Strong itching. Used hydrocortisone x2 on 12/25and 12/26. Swelling and rash resolved. 12/28 lump is gone, minor skin discoloration remains."

Fatigue and arm soreness for 3 days following vaccine

Raised red rash to face, bilateral hands and forearms started approx 30 minutes post vaccination. Patient treated with PO Benedryl at home immediately following reaction. Applied hydrocortisone cream, but burned upon application, so she washed it off. Is now using topical diphenhydramine spray with good effect. Today, 12/28/2020, most of rash has dissipated; some reddened areas persist. Patient reports the rash affected areas feel much better. She will continue the topical spray and Tylenol prn.

Pt reports numbness above lip to right eye. Pt states she had some anxiety about injection and potential side effects, and wasn't sure if it was due to that. She states it resolved and is feeling fine.

Day 1: limited mobility in the left shoulder join, pain at the injection site Day 3,4,5: numbness of the arm and fingers on the left arm, unable to hold fingers together, whole left arm numbness occasionally, limited control of movements

Swelling and numbness around right eye and cheek; hives. Lasted for about 2 hours maximum. Took Claritin and showered.

possible anaphylaxis - throat itching, flushing, felt unwell

Developed a hardmlump at injection site within 1 hour of receiving. Several days later, lump subsided, but area because itchy. On 12-26-20 noticed a discoloration or pigmentation at injection site.

Around 2:00 am exp dull ache from arm to wrist ,tingling in fingers lasted all day. I called employee health was told to go to see PCP. The tingling went away after 3 days and the dull ache lasted 5 days. I was told to take Tylenol for dull ache. I dint have to miss any work.

extreme fatigue, nausea, dry heaving, headache, dizziness (all similar but milder than my covid19 symptoms from April); arm soreness, tender to touch (both expected), large knot in upper arm/injection area

Patient developed a fever 24 hours after vaccine administration

"Employee presented to COVID 19 vaccination clinic and received 1st dose of COVID 19 @ 13:48. Patient proceeded to wait in the waiting area 15 minutes and was about to leave to return to work when the contracted employee reported she developed a cough and flushed face. VSS @ 2:04 BP 172/105 HR 111, she was A&O, Employee was moved to stretcher, given water to drink unable to drink, she stated ""it feels funny"", VSS retaken BP 151/97, HR 91. She continues with intermittent non productive cough and C/O she was unable to clear throat and felt throat tightness. Within minutes, her face flushed, coughing worsened, difficulty swallowing, and she became diaphoretic. Solumedrol 125 mg IM Given to right arm. Patient reported she felt heaviness throughout her body, and was unable to move her Left arm as easy as before, with bilateral numbness to tingling to upper extremities and decrease strength to left arm. Patient crying out, stated she felt as if she could not breath, no hives present, no angioedema. Anxious, crying out that she felt ""heavyness on her chest"". VSS 2:19 158/108 HR 78. This writer attempted to call ED RN several times through operator: NO answer to each call. I left personal message with Unit secretary of COVID 19 reaction and needed to speak with RC or ED MD. I attempted to to call ED MD, no answer. Epinephrine 0.5mg IM given to right deltoid at 14:20 patient was taken to ED triage area, patient taken to room. Report given to RN and ED MD."

Upper lip swelling, associated with herpes labialis. Has history of occasional recurrent herpes labialis, though never with such swelling associated. Suspect possibly due to heightened immune response from recent vaccination. Patient did have slight right axillary swelling, likely lymphadenopathy, some time after vaccination, though this resolved.

Approximately one week after Pfizer Covid vaccine, experienced around 4 cm diameter area with redness, mild tenderness, and itchiness at injection site on left deltoid.

Palpitations felt after 15-20 minutes, subsided within 15 minutes. Fatigue set in after 4-5 hours. Fever the following morning to 100.8 F. Fever accompanied with dizziness and lightheadedness, syncopal event with brief LOC. Overwhelming fatigue until 3:30 pm the following day, with arm pain. On day #3 arm pain persisted, new development of neck pain and mild truncal rash.

Joint Pain, Fatigue, Nausea, Fever up to 102 lasting for two days.

Fever, headaches, myalgia/arthralgia, fatigue, decrease in breast milk production- treated with braids, resolved 3-4 days

Muscle soreness at injection site

Felt like throat was swollen

"C/o throat ""itchiness"" shortly after receiving vaccine - face also flushed. Received relief with Diphenhydramine 25 mg po"

C/o shortness of breath + chest tightness a couple of hours after receiving vaccine

12/22 c/o Low grade fever & malaise

12/22 Body aches, Joint pain, injection site swelling

12/21 PM - c/o headache, chills, night sweats

12/21 PM developed headache & fatigue - improved after Tylenol

12/22 Developed chills; 12/23 Chills, sore throat, body ache, headache by 12/24 only c/o headache

Patient received COVID-19 vaccine at 3:02 pm - approx 26 minutes after vaccine administration patient became dizzy/lightheaded/nausea. B/P-140/102, 98% RA, 98 HR, R 20 even and unlabored. Patient brought to UC for Evaluation. During UC Evaluation vital signs remained stable. Patient drank water. Tylenol was given for headache - 1 gram Acetaminophen at 3:40 pm. Patient had improvement in symptoms ER precaution were discussed, patient verbalized understanding of treatment plan. Patient discharged home.

One hour after administration, patient experienced a nose bleed. Approximately 2 hours after administration she noticed her heart rate fluttering which turned in to a strong throbbing feeling at the base of her sternum. This was regular rate, but very strong, intense feeling. This lasted until the next day when it decreased frequency and ended by afternoon. Also she experienced a mild headache the day after receiving the immunization. She states that she has a hx of seasonal allergies. Also states that she was very anxious about receiving the immunization prior to admin. She states that she was also a little dehydrated.

I received the vaccine on 12/23. I noticed my back was really itchy that day but didn't think much about it. The next day I had a rash on my arms, back, and chest. My eyes were swollen on 12/25. Rash still has not resolved today, maybe even worse.

facial flushing and dizziness experienced by the patient 10 minutes after administration.

Employee is complaining of chills, headache, dizziness, fatigue and feeling faint. She was tested for Covid on a rapid for the ID now and tested negative today.

Left arm was sore from shot and could not lift it, had to keep ice pack on arm. Fatigue, body ache, headache, Oxygen level drop Started on December 25, 2020, took Advil, noticed oxygen level drop on Saturday, December 26, 2020. Have been sleeping since Friday and had a hard time waking up on Saturday, so I started checking my oxygen level and it was 89. I got up and started walking and it helped to bring it up but every time I sit for any length of time it goes back down to 92 - 95. I have called Dr. my Pulmonary Doctor and waiting on him to call me back.

"21 y.o. female who arrived by from on-campus presented to the emergency department for Nausea, face/tongue/distal extremity numbness 5 minutes after receiving Covid vaccine. Patient states that the symptoms are intermittent and ""come in waves."" She states that she was simply sitting in a chair doing nothing on the symptoms started. She does not feel like her tongue is swollen, she has no difficulty with breathing, no new rashes, and her nausea is not persistent. She has no history of anaphylaxis. She has no history of food or other allergies, and has never used an EpiPen. She does not

typically have symptoms after receiving injections and is a phlebotomist and does not have fear of needles. Patient's symptoms resolved within 1 hour of her stay. She felt well, had no difficulty with breathing, did not notice any development of rashes, abdominal pain, nausea. She states that her heart rate is typically 80s/90s when she checks it. á After her fluids are complete, and she is observed for 4 hours, patient has no symptoms, and feels safe to go home."

I felt very dizzy afterward

During 15 minute monitoring time, patient developed throat irritation and tachycardia.

10 hours after vaccine woke with moderate body aches and chills. Tylenol and Motrin take every 3 hours alternating x 48 hours. Symptoms completely resolved after 4 days.

Sore arm with general swelling noted in deltoid and upper shoulder on post-vaccine day 0 and 1. Managed with acetaminophen and resolved by morning of post-vaccine day 2. Headache started in morning of post-vaccine day 2 and increased in intensity throughout day. Initially managed with acetaminophen. Difficult to manage as day progressed. In addition, dizziness and slight vertigo not dependent on position/posture manifested in moderate intensity in late afternoon. Rested in reclined position which did not ease symptoms of headache or dizziness. Was able to sleep and woke up in morning with no symptoms. Dizziness did manifest in mild intensity on post-vaccine day 3 off an o, not dependent on activity or position, but was manageable. No further symptoms since day 3.

Took vaccine 12/21/2020 12/22/20 Slight sore throat, injection site barely sore (left arm) 12/23/20 AM:slight sore throat, discomfort, pain left axilla PM:sore throat gone, pain under left axilla with sore/swollen Lymph Node (golf ball size) 12/24/20 All day: Pain left arm and under left axilla with sore/swollen Lymph Node (golf ball size), swollen Lymph Node left subclavicular, overall feeling of unwell, headache, nausea, hurts to breath deep. No appetite. Fever 99.8 Feel worse than when I had Covid. 12/25/20 AM: Didn?t sleep well, symptoms same as 12/24 with additional swollen and painful Lymph Nodes on left side of neck (pea size), no fever PM: Feeling some better, less pain, Lymph Nodes still swollen, no fever 12/26/20 Feeling better other than Lymph Nodes (still swollen and axilla still sore) 12/27/20 Continuing to feel better, still swollen Lymph nodes less sore

Numbness in fingers Severe pain throughout whole arm Unable to lift arm

On 12/24/20 I received the vaccine at Pharmacy, later that night I woke up feeling very cold. My temperature for the first 2 days of 103.1, chills, body aches, veins in my eyes busted. The fever has continued, today 12/28/20, 100.8, I feel dizzy, tired. Due to the holiday, will be seeing my PCP today.

I exp sore arm, fatigue, body ache and after taking Ibuprofen was gone. The fatigue is still lingering not entirely sure if this is due to vaccine.

Noted tongue starting to swell on 12/24 at 1030. Started on left side, then progressed to right side. No SOB, difficulty swallowing or breathing, but staff noted difficulty understanding her speech. Presented to ED at 1300. 50mg Benadryl given IV on 12/24 at 1328 and 125mg solumedrol given IV at 1327. Pt reported improvement in tongue swelling at 1630.

"09:48am While waiting her wait time, reading emails, she felt flushed, like a ""hot flash"". Heart rate per her apple watch was 152. 09:54am Seated, placed on monitor for BP and O2 sat., 151/90, HR 111, 99% on room air. 10:05 158/87, 111, 99% - RA 10:10 147/85, 102, 100% - RA, States feeling nervous. 10:20 144/84, 96, 100% - RA, States feeling better, less nervous. No shortness of breath, no facial swelling. No other complaints. Allowed to leave facility. With instructions to follow up with Emergency Department if any life threatening symptoms develop and to follow up with Employee Health if needed. She verbalized understanding of above."

12/26/2020 2:00PM ears itching, hives - left wrist to elbow -- Urgent Care Visit -- Solumedrol shot received and Benadryl advised to take. Hives cleared on skin 12/26/2020

Shortness of breath, dizziness, vomiting, increased BP.

About 11:50 I sat down for observation and between 12 and 12:05 I felt tachycardia, I could even hear my heart and felt my heart really racing. I could feel something on my fingertips as well. The nurse came to check on me and at 2:08 my heart rate was 109 and one minute after it was already 110. So they brought 2 RNS to observe me. I did not go to the ER. They came about 10 min later and stayed with me 20 mins. They kept taking my vitals and checking my BP and told me that my vitals were stable. I left and when I went to my car and checked my heart race and noticed that it was stable, around 83 and decided to go home. I left the hospital about 1PM. After I had the vaccine, the next day I felt body aches, I was not sure if it was my sinus issues or related to the vaccine. I also had joint pains, back pains. But sometimes I have it with my sinus but today I feel fine. My arm the soreness increased with each day but by Friday it got better today I don't feel it anymore.

migraine headache, woke up 12/28 with 2 blisters near lower back

I received the Covid 19 vaccine at 12:30PM on Wednesday, 12/23/2020. On 12/24/2020, mid-day, I developed the following S/S (which were similar to a Lamictal rash): Fine raised red rash over my body, but significantly heavier to face, neck and lower legs; throat swelling with a high pitched cough (with no difficulty breathing) productive with clear thin secretions; diarrhea; I took 6 benadryl every 4-6 hours, Pepcid twice daily, and had an epi pen available (but did not need it). The cough and rash resolved by late Sunday evening. I did not report to ED because I felt the symptoms were manageable at home.

experienced nausea, diarrhea and chills about 14 hours after vaccination. Lasted a couple of hours, and by daytime patient was feeling ok.

Moderna COVID-19 Vaccine EUA

The patient experienced jaw tightness and tingling in the face. She felt better lying down. No treatment was given; she was observed for about an hour and went home. The patient did report having plastic surgery with facial fillers approximately 6 weeks ago.

metallic taste in mouth starting 2 minutes after receiving. No shortness or breath or respiratory/cardiovascular symptoms

Patient developed fever, chills, body aches, ocular migraine and then developed cramping and abdominal pain. Symptoms lasted 3 days and then resolved completely.

Right side of tongue was numb and swollen , could fell the right side of my tongue for a day 12/28/2020 5/10 Lost still today at a week post Received Benadryl incase of allergic reaction

Patient had hives on both arms. Assessed by EMT and provider on site 25 MG benadryl admin to right delt.

Chills, body aches, fever 101.8, headache onset 2100-0300.

Paresthesia of the left foot. Feels like water flushing over the outer aspect of dorsal foot. Occurs about every half hour for the last day and a half. Mild headache grade 1/10.

On 12/24/2020 started with slight headache and a sore throat. On 12/24/2020 tiredness and slight sore throat. At 15:30 on 12/24/2020 she noticed tenderness in right groin. By 1730 she had chills. On 12/26/2020 at 0230 she had throbbing in her right groin and 2030 she had cellulitis in the right groin.

Decreased strength and mild tingling in left hand.

Within minutes of the injection I felt very dizzy with associated palpitations. The triage RN took my BP 160/80 HR 110. The sensation quickly subsided and i left the triage area within 10 minutes. Over the course of the next 3 hours that same sensation would come and go every 10-15 mins, again lasting a short time with return to normal, I would feel very dizzy with palpitations lasting about 30secs-1min and then it would subside. At one point I had a metallic taste in my mouth, another time i felt nauseous. My coworker stated I was pale. By 12:30pm that day the sensations stopped and I just felt very tired the rest of the day. By the following day I felt completely back to normal.

General malaise; Body aches; Chills; Fatigue

Covid-type headache unrelieved with tylenol or ibuprofen lasting greater than 12 hours. We finally gone when i got up the next day. Fatigue and loss of appetite until following morning.

Itchy and bottom lip felt swollen. Went to the ED.

numbness and itching in roof of mouth

within 12 hours of the vaccine, developed and hives; 24 hour later wheezing - mild. took benedryl, Zyrtec, Pepcid - symptoms continued Sought care at Urgent Care - 12/27/2020 - was given an inhaler. Symptoms lasting at least 10 days

Patient began felling flush and hot. Throat itching. She was given 50 mg of diphenhydramine. She does carry an Epi-pen due to bee stings. She did not want to take the Epi-pen initially. we watched for about 10 more minutes. Voice was beginning to get raspy, and she reported increased feeling of swelling in vocal chords. We took patient to the ED triage area and she administered her Epi -pen. She was registered in the ED and was placed in a room for observation/monitoring. She was given an additional

25 mg of IV diphenhydramine and also 125mg of Solu-Medrol. Following this regimen, the patient began feeling much better. She was monitored for an additional 2 hours. I stayed with the patient while in ED and she recovered from the reaction with no additional sequalae.

12/17/2020 20 MIN AFTER INJECTION, FELT ITCHY AND WELTS. MEDICAL STAFF ADMINISTERED TYLENOL AND BENADRYL. 12/20/2020 AFTER RASH AND HIVES DISAPPEARED, WOKE UP TO JOINT AND MUSCLE PAIN ALL OVER. PINS AND NEEDLES, FELT LIKE ON FIRE. *MISSED 2 DAYS OF WORK DUE TO ACHES

arm stiffness, cough, dizziness, ringing in ears, muscle aches and spasms. Seeing Primary care for symptoms and dizziness has not improve and ringing in ears has worsen. Recommend from to get a MRI.

Swollen lymph nodes of the right arm with itching and redness began on 12/24/20. No treatment. Swelling is improving, itching and redness remains unchanged.

After vaccine, muscle aches, swollen lymph nodes, low grade temps to 100.5 for 4 days. On morning of 5th day, symptoms improved. Evening of 5th day, fevers to 103.0, severe headaches, cough, sore throat, fatigue x 4 days. Covid tested- negative.

About 20 minutes after receiving the vaccine both hands turned flame red from the wrists to fingertips. No itching or burning. Resolved after about an hour.

I was very lethargic, warm (without a fever), and very achy. This lasted until I went to bed at 9pm and I felt fine when I woke up the next day. I took no medication for this nor did I seek medical treatment.

Mild Flushing/itchiness, blood pressure dropped for a few moments, slight dizziness for a few minutes, then about 15 minutes after symptoms abated then Istomach felt uncomfortable, and a headache started about 45 minutes after injection.

Tingling of tongue, shortness of breath, swollen lip. The patient was observed in the Emergency Department for about an hour and discharged home without further treatment.

blood pressure issues and tightness of throat

recipient complained of feeling lightheaded and thought she would pass out. gotten a snack and drink and then laid down on stretcher. vital signs stable but then symptoms did not improve and began to complain of numbness and tingling in her left arm. transferred to the ED

Paramedic who administered shot gave it too high. I noticed this maybe 10 minutes after administration when I felt that the Band-Aid was high and a nurse practitioner I work with confirmed that it was too high by observing the puncture site. Pain started about 2-3 hours later, with restricted range of motion left shoulder joint

Next morning I woke up with a migraine and stiff neck. Following day I had multiple episodes of diarrhea and significant nausea. I woke up with another migraine and stiff neck on 12/23/20. I still had GI upset. On 12/24/20 I had migraine again with body aches and GI upset.

Pain at injection site, severe body aches, fever raning from 99.3 to 100.8. Hip and knee pain

"She got a Covid vaccine Pfizer at the Health Dept on Dec 18th in her L arm. Within 30 minutes, she felt tingling going down her L arm and in then she felt tingling on the L side of her face. Muscle aches, fatigue and chills lasted about 33 hours. On the 22th she had L leg weakness when she got out of bed, this lasted just a few seconds until she ""worked it out."" Later, she developed a sinus type headache. She developed muscle aches on 25-26th, she went to have a covid test that was negative. The L side of her face is tingly and her L jaw is sore--she describes it as feeling like she has had a novacaine injection for dental work since 4pm yesterday."

Muscle soreness, fatigue

Came to recovery area and within a period of 5 minutes or less complained of a headache. Face became flushed and was taken to lay down on stretcher. BP 142/80, HR 140, RR 20. Patient was given water, Ibuprofen 800mg and Benadryl 50 mg. BP 135/90, HR 78, SaO2 100% room air. Patient sat up and drank juice and ate granola bar. Patient left at 0925

Employee stated that she woke up at midnight with severe nausea and started vomiting intermittently throughout the night. She also experienced fever/chills/body aches and right arm pain. Had to call in sick.

Arm felt very sore for 2 days after the shot, felt feverish, body was very warm.

15 minutes after vaccine, patient starting having itchiness and eye pain, looks like starting to develop hives. Benadryl 50mg IM given x 1 dose.

Slight increase in pulse for approximately 3 hours after the injection. Duration 45 minutes to an hour. Eye lids puffy approximately 20 hours after the injection. Unknown duration.

Patient on left jaw felt dull discomfort from ear to center of jaw Lower lumber/ Spine felt numbness for 20 minutes. Area still remain tight

12/20 - symptoms presented as possible right ear infection. 12/21 - began taking Amoxicillin 875MG 2xdaily 12/25 - presented in urgent care, for treatment of worsening ear infection. In addition to Amoxicillin, Prednisone was prescribed. Did not fill or take the prednisone on 12/25 due to Christmas Holiday and no open Pharmacies. 12/26 Awoke with Bells Palsy on right side of face. Went to ER. Was diagnosed with Bells Palsy and potential ear swimmers ear. Placed on and began taking the following medications on 12/26/2020. Prednisone 10MG Tablets taking 4 tablets every day for 2 days, 3 tablets every day for 2 days, 2 tablets every day for 2 days and 1 tablet every day for 2 days CIPR/DEXAMETH 0.3-0.0% OTIC SUSP - instill 2 drops into right ear twice daily for 7 days. AMOX-CLAV 875MG VALACYCLOVIR 500NG Bells Palsy impacting right side of the face. Symptoms began 12/20, presenting as possible right ear infection.

12/27/20 10:30AM swelling at the injection site, muscle aches, fatigue; 4:30PM sharp, pounding headache; 06:00PM chills, body soreness, night sweats. 12/28/2020 nausea, loss of appetite, fatigue Tylenol, some relief.

severe injection site pain, radiating down the arm, and just not feeling quite right. the headache that was reported last night is still hanging around along with some nausea. experiencing an overall feeling of being really hot, but not running a fever. HR 90s-100s

At 11:20AM Patient returned to vaccination room to show that she had developed hives on the right side of body (back, side, and legs). Patient was experiencing redness and itching--no shortness of breath. Patient was given 25mg of diphenhydramine. At 12:30PM Patient returned to show that the rash had cleared considerably and was not having any other issues. Patient was instructed to be observed by a healthcare provider for 30 minutes, rather than 15, for her second dose.

Dizziness

At 6 hours post vaccine (1400 on 12/26/2020), I woke up from a sound sleep sneezing convulsively and experiencing a headache, nausea, and extremely runny (literally gushing) nose and eyes. Within several hours, I also experienced swollen eyes and face as well as scratchy throat and slight cough. No effect: ibuprofen; ibuprofen; phenylephrine; loratadine; fexofenadine Effective: benadryl 100mg. q6hr(I was unable to take this previously because it puts me to sleep; once I was pulled from the work schedule I was able to take this) I have now taken three doses of 100 mg- as it wears off, some of the symptoms return, but they are gradually lessening. Since I am an RN, I am comfortable doing home treatment with my employer/employee health representative aware of the situation.

Fever, fatigue, pain, weakness

The patient reports developing CP and SOB about 1 hour after receiving the vaccination which resolved within 3-4 minutes. The patient denies seeking medical treatment and these symptoms were reported to employee health on 12/28/2020.

Began to have facial flushing and hives about 5 minutes after the injection, followed by itchy throat, hoarse voice, abdominal cramping, joint pain.

Fever, weakness, aches, tired.

Fevers up to 103.1 (started at hour 10 lasted through hour 48) Nausea (at approximately 24 hours) Vomiting (at approximately 24 hours) Severe headache (hour 20 through Hour 31) Somnolence (started hour 9) Chills (Hour 10- hour 25) Extreme Shivering (Hour 10-25)

immediately upon inj had bad taste in mouth and inside my mouth and lips felt filmy. from there broke out in itchy rash within minutes and my voice was crackly the pharmacist checked on me and had to wait a few extra minutes before leaving of note the APRN i work with was there getting her injection as well and advised on the benadryl. I have used benadryl and claritin since the injection to help with symptoms . after about an hour after the injection my lips were very red I never experienced SOB i did

report to my PCP (MD) the next day and he said to continue as I was doing and to alert him if things worsened (also note I work at my PCP office) Employee from pharmacy called to check in on me on the 23rd and advised I report the event to you and questioned if I should take dose 2 and I told him i WOULD NOT be taking another dose. since the injection i have continued to have the under the skin itchy rash and inside mouth and lips felt irritated after and i have experienced several other persistent symptoms of ha on and off, blurry vision, facial swelling around eyes, nausea no vomiting ,decreased appetite ,fatigue ,upper gastric pain for a few days after, and felt weak in lower back, voice is crackly at times and the tip of my tongue will feel a burn\tingly feeling. AGAIN i have not had what i would call SOB I did let my PCP know today of the persistent symptoms and that I was reporting them over to you as the pharmacy directed. I did not have a formal office visit but my pcp did note the effects in my chart

Patient experienced fever, edema and redness to injection site, neausea, headache, and diearrhea as well as body aches for 3-4 days.

Approximately 6-7 minutes of observation she developed flushing and warm sensation about the face and neck. Also developed red rash, non pruritic about the neck and chest. Also behind both ears right greater than left. No shortness of breath and no wheezing. Rash only on upper chest and neck. Vitals signs taken BP 174/91, pulse 73, 173/86, pulse 68, 163/92, pulse 64. Benadryl 50mgs by mouth. Observed additional 15 minutes. Patient had complete resolution of symptoms. O2 saturations were 97-98% the entire time. Patient discharged ambulatory.

Pediatrician working in the hospital. Was exposed the an office contact wo had covid. Shoulder in soreness. At work on Wednesday. Felt lightheaded had to sit in chair. That's all he reminders. He workup to a CODE team putting oxygen on him. He has a seizure. Took the COVID test has COVID. Admitted to hospital for 2 days. Likely a syncopal event.

REDNESS SWELLING HEAT TO THE RIGHT DELTOID, STILL SPREADING. PT EXPERIENCED CHILLS, FATIGUE, PAIN SWELLING TO EXTREMITY AND NAUSEA.

The evening after receiving vaccine had headache, severe body and joint aches, chills. This lasted for 2 full days. Awoke on day#3 and symptoms were gone. Left arm soreness and tenderness at injection site for 2 days.

I exp arm soreness greater than other vaccines kind of lingered for awhile (48 hrs.) I had fever up to 103.4 couldn't distinguish between the Covid and vaccine. I had a Covid test on 12/21 results positive. I missed work due to Covid not thinking cause of vaccine the timing was odd.

30 minutes after vaccine administered, pt had irregular heart beat (felt like it was going to come out of his chest through his neck). Lightheadedness, and terrible headache. Skin of chest and stomach were red. Pt received treatment in the ER, received IV benadryl, IV steroids, and anti-nausea medicine, and IV fluids. Pt was cold and shaking, couldn't stay warm. 4 days later, patient is still cold and fatigued.

Insomnia Deltoid pain Deltoid induration

dizziness, nausea

Right arm soreness: onset 6-8h after vaccine -- > worsened to full body soreness/aches with point TTP over injection site (couldn't sleep on that side); Injection site redness: No initial redness on day 0 or day 1 post-injection. Slight redness and TTP as above on morning of day 2. Body Aches: began ~18h after vaccine, worsened throughout day 1 before bed; ~36h vaccine symptoms resolved Fatigue: Started morning after vaccine (~18h post-vaccine) -- > peaked ~36h post-vaccine (went to bed early and simultaneously restless but also exhausted) Headache: Moderate, primarily frontal headache (like a head cold with NO congestion); began ~24h after vaccine, continues today (~48h vaccine) but improving without intervention. Fever: Began ~36h after vaccine at peak of fatigue symptoms (peak T: 100.2). No intervention, self-resolved by 48h post-vaccine

shoulder pain day of vax, itching, swelling, warm at injection site, redness. ER on 12/26 stated that vaccination may have been injected incorrectly, possibly lower than should have. ER gave Benadryl to pt.

Reports circumoral numbness and tingling onset about 30 minutes after received vaccine. Then mouth felt numb and tingling and finally symptoms moved to the back of her throat. She states it was hard to swallow and felt as though her uvula was large. States looked in the mirror at uvula, but could not see a difference. She states she considered going to the Emergency Department, but ultimately did not. She states that at about 7:30 p.m. she took 25 mg of Benadryl. She waited a little while and then took an additional 25 mg of Benadryl. She states that by 10:30 p.m. symptoms had resolved and she felt safe to sleep.

Patient received the Covid 19 vaccine on 12/23/2020. Twenty fours after vaccination she started to cough and wheeze (Hx of not well controlled Asthma, DM). Cough and wheezes relieve with nebuilzer. No fever, chills, or HAs. Symptoms have improved significantly and are stable. She has reached out to her PCP and EH. Covid Testing is scheduled on 1/4/2021 but awaiting for a sooner appt at EH.

24 hours after vaccine woke up with significant body aches. Then rash started on left forearm and wrist. Following day it spread to right arm and back.

21 y.o. female normally healthy who arrived by to the emergency department for Post COVID-19 vaccination reaction. Patient states approximate 5 minutes after the vaccine, she started to feel lightheaded and nauseated. She does notice the sensation of throat irritation, but denies any shortness of breath or difficulty breathing. Denies any tongue/lip/airway swelling, abdominal pain, new rash/pruritus, diarrhea, emesis, fever/chills, chest pain. She has no history of anaphylaxis or use of EpiPen. No significant allergic reactions in the past Initial reevaluation approximately 30 minutes after arrival, patient status unchanged. She still felt lightheaded and nauseated with a sore throat. No new rashes, shortness of breath, difficulty breathing. Her voice was normal, and did not report any new GI symptoms. Heart rate was 109 with one half fluids given thus far. á On reevaluation 2 and 3 hours after arrival, patient's heart rate normalized into the 60s?70s, she was asymptomatic. She was slightly fatigued from the Benadryl. She felt safe to go home. Follow-up call a few days later and patient was doing fine with no symptoms.

According to Hospital ED record: This is a 38 yo male present to ED with complaint of tingling sensation and reaction after receiving COVID-19 vaccination. Symptoms started approx 30 min after he received

the initial shot. Patient was on his way home when he noted some tingling in his tongue and strange sensation to the mouth. Pt denieschest painSOB, LOC, AMS, neurological deficits. No abdominal pain, nausea or emesis.

later that night at home about 6:15 I stared to get a red rash across my chest and on to my left arm and was very itchy, then was hard to take deep breaths. I also got a pretty good size bruise on arm I got the shot in and arm was sore for 2 days. I also had lil bit of rash around where shot was.

Fatigue, lightheadedness, achiness, left arm soreness and pain at the site for 48 + hours.

I felt tired couple hrs in the afternoon felt better after laying down.. I started to feel completely around 5 pm. I did not miss any work.

Pfizer-BioNTech COVID-19 Vaccine At approximately 4 pm on December 23 (day of vaccine) I experienced sudden onset of fatigue. I also had a low-grade temperature of 99.0 F with chills. By 5:30 pm, I was also bringing to experience lightheadedness and dizziness. That night at approximately 10 pm I had a temperature of 99.1. On December 24, I experienced lightheadedness and dizziness the entire day, from waking up to going to bed later that night. My eyes were glassy and I would feel an impulse of dizziness go distinctly from the right side of my head to the left, and then feel more dizzy after that. It was constant throughout the entire day and would occur while I was sitting, standing, or moving around. On December 25, I was tired but the dizziness had gone away.

Tachycardia started the morning of 12/28/20 and was distressing enough to lead to calling 911 and then visiting the emergency department. Emergency department work up was negative. No previous history of tachycardia prior to this episode.

BP- 110/62 HR- 78 Temp ? 97.7 Resp ? 22 Reports feeling tingling and shaky, no visible shakiness and no unsteady gait noted

Began experiencing dizziness on 12/26/2020 at around 10:30 am. Dizziness was initially off/on for the remainder of the day. By 12/27/2020, I began experiencing dizziness and feeling ?swimmy headed? with no periods of relief (even when sitting still or laying down).

I received the first dose of the Pfizer Covid vaccine on Tuesday, December 22 at 0730 in my left deltoid muscle. I felt fine that day - just some injection site soreness later that day that radiated to my left neck. On Wednesday, I experienced some fatigue, headache and moderate backache and neck ache which were all side effects that I expected. On Thursday, December 24 at approximately 1330, I experienced tingling of the tongue. It began at the tip of the tongue, but spread to the entire tongue over a five minute period. At the same time, my throat became scratchy/itchy. I realized that this was an allergic reaction and took 2 25mg Benadryl capsules. The symptoms resolved in about 20 to 25 minutes. I never experienced trouble breathing, speaking or swallowing. I also reviewed everything that I ate, drank, etc. in the last 24-48 hours and there was nothing new. About four hours later, I developed an intensely itchy rash. It began on my trunk, then spread to my bilateral upper extremities, then neck. My face and scalp also itched although they did not have a rash. My face was just red. There were no other

symptoms. I took 2 more 25 mg Benadryl at this time. It took about 45 minutes or so for the symptoms to resolve this time. Since that time, I have experienced significant body aches and fatigue (more than initially), mild headache and nausea. Due to the holidays, I was unable to report this incident to employee health until this morning, Monday, December 28. I have received no further instructions. On Friday, December 25, I noticed that I developed multiple apthous ulcers on my gums and hard palate. Since that day, I have experienced extreme fatigue, body aches and a mild persistent headache and nausea.

"Patient received the Covid 19 vaccine on 12/22/2020. Four days after vaccination (12/26/20) she started to notice that she ""loss her sense of smell ""while brushing her teeth. The toothpaste tasted ""weird"". All of the sudden, she lost her appetite. These symptoms persist today. Covid test scheduled on 12/28/2020 at Employee Health."

The patient reported subjective sense of lip and tongue 'tingling', described in intensity of 6/10 prior to EMS arrival, down to 4/10 on EMS arrival, but without interventions. Per EMS report, the patient had stable vital signs and a normal physical exam. The patient refused transport to the hospital, and a refusal of medical aid (RMA) was taken by EMS. The patient was advised to seek medical care should symptoms return.

12/24, I woke up with arm soreness and headache. 12/25, I had a headache, fatigue, arm pain radiating down to my elbow and into my right side. 12/26, I had all the above along with swelling under right axilla. 12/27, all of the above along with pain in right ribs, swelling worse under right axilla, fever of 100.3 (up to 101.2), body aches, and joint pain. The symptoms all continued as 12/27 into 12/28.

Vaccine was received on 12/17/2020. Patient states that he did not start experiencing symptoms until 12/25/2020. Patient states that he doesn?t think his symptoms are related to the vaccine and that he may need to be tested for Covid. Patient states that his symptoms are sore and itchy throat, congestion and runny nose, no coughing, no fever, no chills, no body aches. Patient states that his kids go to daycare and came home with a runny nose, no travel history, no exposure to Covid that he is aware of, never tested positive for Covid.

the day after receiving the vaccine the patient developed a fever TMax 101.7 and loss of taste, these later developed into congestion, general malaise, body aches. the pt sought out her PCP who is running covid and flu testing.

Felt fine to begin with, ate supper per usual, then at 7:10 pm sudden onset of symptoms, nausea & extreme diarrhea and chills for 2 1/2 hours. Temp of 99.9 Then headache, very severe, trouble seeing, disorientated. Sat in chair all night. Left arm and left side hurt into teeth and jaw. Thought about calling ambulance at 4:00 am, but decided not to. Headache lasted through Sunday and Sunday evening, until 3 am on Monday. Now at 11:30 am on Monday it is a 2 on a scale of 1-10. Had Tylenol #3 on hand, and took every 5-6 hours since Saturday night. Missing work today 12/28/20.

Major chills, fatigue, stomach ache, runny nose,

Patient states about 20 minutes after vaccine she developed scratchy throat, itchy all over but no hives and dry cough.

23 y.o. male who arrived by to the emergency department for suspected allergic reaction. Patient received his Covid vaccine 3 hours prior to ED arrival. Initially he was asymptomatic however, as the morning progressed, he developed a redness around the injection site. He then noticed a rash all over his face, that was mildly itchy in nature and felt warm. He denies any associated wheezing, shortness of breath, facial swelling, throat swelling, severe abdominal pain, vomiting, lightheadedness, dizziness, or syncope. He has not taken anything for his symptoms, and they continue to worsen. He has no prior history of allergic reaction to vaccines or other known allergies in the past. He states this is mildly itchy in nature. Patient was given 50 mg of p.o. Benadryl and Pepcid for symptomatic control. He was observed in the ED for 2 hours without any progression of his symptoms, no associated facial swelling, wheezing, shortness of breath, abdominal pain, vomiting, or hypotension to suggest anaphylactic reaction. He was discharged home in stable condition

12/16 EVENING OF VACCINE, VERY SORE SHOULDER. LASTED 24 HOURS. 12/17 - 12/19 VERY FATIGUE, ACHY JOINTS.

The entire reaction was over in an hour started at 115pm 12/19/2020 I had pain in upper back and shoulder, within 5 mins it started hurting my left arm and traveled down to my wrist and then went into my left thigh and I had this sharp headache for 3 mins and then it all went away and I have not had any symptoms since. That day I went to the ER and they kept me for 2 hours for observation and I went back to my work, The only reason I sought care was because I was already in a hospital, I was taken by wheelchair, blood pressure was fine

Fever 101.4F, Chills, nausea, dry heaving, achy joints, Low back pain, headache Treated with Tylenol

EE states that within minutes of receiving the vaccine, she started experiencing itching at the site, tingling down the left arm to finger tips. She did not report her symptoms at that time because she has similar symptoms with the Flu vaccine. Later that evening, EE states that she started experiencing tingling down the left leg to the left foot/toes. The next day, 12/18/2020, the tingling stopped but there was a lump at the injection site. The lump was warm to touch and slightly sore. She did not report this of take anything because her symptoms were similar to the flu shot. On 12/25/2020, EE states that the lump started itching and she scratched it which caused redness and inflammation. She used hydrocortisone on the injection site. The lump is now gone with no itching, just a little discoloration at the site.

12/17/2020 at 1250 Pt complained of itching, noted slight red spots about circumference of small tangerine on right hand, left lateral hand, and lower left leg, S/P COVID 19 #1 Injection; about 5 minutes after injection.

the patient developed symptoms 3 days later which included body aches, headache, cough, runny nose. pt is seeking her pcp for further testing/workup.

Shortly after receiving the vaccine, patient began feeling numbness and tingling down right arm to finger tips and stated that her right arm felt cold. She also reported a hot flash after receiving the vaccine. She waited for 1 hour after receiving the vaccine with no reports of improvement but denied any worsening of symptoms. The RN assessed the temperature and grip of each arm, reporting equal in both sides.

patient developed general malaise, body aches, cough, and diarrhea, temperature 99-100 F. Sought out pcp for testing/workup.

"26 y.o. female who arrived presented to the emergency department for concern of an allergic reaction. Patient reports being at the COVID-19 clinic just prior to arrival receiving her first dose of the vaccine. However, after walking a few minutes later she began to experience an abnormal sensation in the back of her throat, describing it as ""spicy"" accompanied by a general wave of feeling ""hot and heavy"" with some tingling in her fingers and toes. Patient currently states that overall her symptoms are improving with only a continued feeling of ""hot and heaviness."" Denies a history of allergic reactions to vaccinations or medications, besides a possible allergic reaction to Penicillin when she was younger. Denies shortness of breath, nausea, emesis, or any other complaints at this time. Denies a history of GERD, stating that she has not eaten anything today. Patient is otherwise healthy with no use of daily medications. Patient was observed for one hour while here in the ED with no residual symptoms. Patient feels comfortable going home and will return for worsening symptoms. Agrees to follow up with her PCP. Vital signs are stable at time of discharge."

41-year-old male who presents to the ED today with a complaint of weakness in his bilateral arms and legs. He states he fell slightly weak yesterday but this morning when he woke up around 6 AM he was not able to get out of bed because he was so weak. He states he feels like he has no muscle strength in his arms and legs. He denies any fever. He denies any cough or shortness of breath. He denies any chest pain or abdominal pain. He denies any nausea, vomiting or diarrhea. He denies any numbness in his extremities. He denies any neck or back pain. He did receive the first Covid vaccination on December 17.

After I received the vaccine exp nausea at 2:30 pm continued to 1 am. The following day I continued nausea and took Zofran. On 12/17 I left work due to nausea and around evening nausea stopped.

Sore arm at injection site for 3 days

cough got worse runny nose headache sore throat chills body aches teeth sensitive all these symptoms started Wednesday night which is the day I got the vaccine they lasted all Thursday and felt nothing on Friday

12/17/2020 at 1530 Patient states she has a little anxiety from just having received the COVID-19 vaccine. Per patient, she already spoke with her PCP who recommended she get the COVID vaccine. Patient offered ER evaluation for severe or worsening symptoms. Provided patient with phone number to Occupational Health dept to schedule appointment. States she will give them a call before going home. á1545 Patient observed for 30 minutes after vaccination. States she feels fine at this time and does not feel dizzy. No further needs

Woke up at night after vaccine Pain was intense at vaccine site, radiated to shoulders, body aches, headache x3 days Took Acetaminophen, slow resolution then resolved by day 4

Severe Myalgia, Extreme fatigue, mild headache, chills and nasal congestion

Patient lists that she woke up during the night after receiving the vaccine feeling sweaty and feverish. Upon waking the following morning she took her temp and it was 100.8 and 101. Patient also reported injection site tenderness and localized redness.

"PATIENT IS A PHYSICIAN. ALMOST 12 HOURS AFTER INJECTION, BEGAN HAVING BODY ACHES AND CHILLS - RESTLESS ALL NIGHT. IN A.M. WAS 101.0 F, TOOK TYLENOL EVERY 4 HOURS, ABOUT 2100 WAS 104.3F. FEVER STAYED ABOUT 100 TO 101 THROUGH NEXT DAY. SUNDAY, FEVER BROKE, MINOR CHILLS. FEELING ""FINE"" TODAY - NO SX'S."

I am a nurse practitioner here at the facility. I received the vaccine on 12/18/2020 at noon. On Monday evening 12/21/2020 I developed floaters and flashes of light in my right eye. I awoke on 12/22/2020 with continued worsening symptoms. I went to my optometrist. I was diagnosed with Vitreous detachment of the right eye. The optometrist did not feel it was related to vaccine but our health nurse advised reporting.

Chills, Fever middle of the night, headache, sluggish. No appetite.

FLUSHING, HIVES, FACIAL NUMBNESS ON THE LEFT SIDE

Fever, headache, sore arm at injection site, 72 hours after injection. resolved in 48 hours

about 3 hours after injection, began feeling nauseous. the next day at about 8 am temp went up to 102.4. took ibuprofen and temp finally broke about 4 pm that day. had injection site soreness for the first 48 hours then developed large red wheal that covered 3/4 of upper arm. still with red area when this report was filed on 12/28/2020

"reported no s/s of adverse reaction at time of vaccination and for 30 minute post-vaccination monitoring period. States that approximately 4 hours after administration , he had elevated BP (148/92) and heart rate (115bpm). Normal readings are HR in the 60s-70s and ""normal"" BP 120/60s. Had fever of 102 the first night that lingered for 48 hours, accompanied by extreme fatigue, nasal congestion, shortness of breath, decreased appetite, He took tylenol for fever and afrin for nasal congestion. By the 26th, he felt well enough to get dressed. No fever, appetite back to normal. BP on the 26th was normal to low and heart rate 105. Adverse reactions required no further treatment."

Pt recieved the vaccine and was hospitalized the following day with a bowel obstruction.

Employee was vaccinated at 4PM on 12/23. Hives started to develop on 12/23 at 8PM. Employee came back to the vaccination site at 1:15am on 12/24, complaining of hives on trunk of body and arms. No hives on legs or face. Denies shortness of breath , just itching and hives. 50 MG of Benadryl given IM at 1:30am on 12/24 and instructed to go to ER. Employee refused ER attention.

Assigned to work at nursing location. I reported for duty on 12/23/2020 @ 1310 and was offered the vaccine. No reaction at that time. Several hrs into my shift I became ill. Nausea, vomiting, trouble breathing, tongue was feeling funny, dizzy, stomach pain, extreme fatigue and lightheaded. I immediately reported to the charge nurse on the floor then shortly called my registry informing them of the current events. Registry offered to call 911 and I declined. Registry gave permission to end of shift and go home.. However when I notifed the charge nurse on the floor she stated I can't leave because she was leaving for the day. She called supervisor. I spoke to him and explained the situation and he informed me another person whom was a MD also was experiencing the same symtpoms. He instructed me to stay in the room I was at and they will send orange juice it should make me feel better. I waited and waited. I called the sup back and informed him my symptoms are getting worse and need to go. At this time I had developed a severe headache. I was not able to continue with extremely HEAVY workload caring 29 COVID patients in my condition and sup allowed me to go home. He said he would talk to the floor nurse because he had already arranged for 2 nurses to come in 7 pm which was shortly. Once home, my husband said I had a blank stare and dazed. Several hrs later I developed a fever, cough and severe body pain. I remained in bed for several days and most symptoms resolved. However on the 4th day went out and within a few started to become short of breath and heaviness on my chest and attempted the following day going outside and the same thing. I continue to have intermittent stomach pains and coughing.

12/17/2020 at About 2pm pt complained of some blurry vision, slight jitteriness and some queasiness; pt requested water. Nurse assisted pt to Overflow Observation Room. Pt A/O x4, Nurse provided pt water, crackers. Nurse continued to monitor pt: Continuous monitoring; and asked if she need anything periodically/ every 8-10 minutes. Pt refused any further care or assistance from Nurse; Pt stated she is feeling better and will continue to be in observation ; pt continued to be monitored by Nurse. Pt talked on phone during observation time; A/O x4. Pt monitored for about 40 minutes. Pt stated she feels better and fine; pt stated she was going to leave. A/O X4, denies chest pain, SOB, has steady gait.

Fever of 101.0 F that lasted until the next morning. Fever of 101.0 F for 2 hours the next night. Fatigue for 2 days, Chills with the fevers, night sweats for 6 days.

On 12/27/2020, I woke up with body aches and a headache around 0530. At 1230, I began experiencing severe stomach pain. I went into the bathroom and began sweating profusely. I had a bowel movement and started dry heaving. I then fell on the floor, and felt extremely weak. I did not bare down when having a bowel movement, I do not believe this was a vagal response. At this point I was still sweating profusely, my body hurt all over, I couldn't catch my breath, and I was incredibly weak. I crawled down the hall way to get my phone as I was home alone. My arms then began to tingle and my hands completely spasmed, I couldn't move them. My fingers locked completely straight but my palms closed. I activated Siri on my phone because I couldn't use my fingers, and had her call 911. I was having a very hard time catching my breath. By the time EMS arrived (about 20 minutes on the phone with 911), I had started feeling better. I had chills, and still felt out of it, but I was breathing better and my hands unlocked. My arms were still tingling. I let them check me out. My BP was normal, my O2 sat initially said 88% but was 98 by the time they left. EKG was normal. I didn't go to the hospital with them, I stayed

home. I didn't move around much the rest of the day. I felt tired and had lack of appetite. Today on 12/28/20, I'm feeling better but I am still taking it slow, just in case.

Blood pressure rose 190/100; got headaches in 10 minutes and started getting heavy chest; got headaches in 10 minutes and started getting heavy chest; Throat started to get tight, voice changed; Throat started to get tight, voice changed; had heart palpitations; Fast heart beat, difficulty breathing, dizziness and weakness; Fast heart beat, difficulty breathing, dizziness and weakness; Fast heart beat, difficulty breathing, dizziness and weakness; Fast heart beat, difficulty breathing, dizziness and weakness; This is a spontaneous report from a contactable healthcare professional. A 42-year-old female patient received first dose of bnt162b2 (Pfizer-BioNTech COVID-19 vaccine; lot EK5730), intramuscular on 17Dec2020 17:00 at single dose (left arm) for Covid-19 immunisation. Medical history included diabetic, high blood pressure and allergies to fruits such as canaloo, and peaches. Concomitant medications included amlodipine, loratadine, metformin, and ascorbic acid (VITAMIN C). On 17Dec2020 17:15, the patient experienced headaches in 10 minutes and started getting heavy chest, throat started to get tight, voice changed and injection was given; blood pressure rose to 190/100 and had heart palpitations, fast heartbeat, difficulty breathing, dizziness and weakness. The patient was given Epi injection and benadryl shot as therapy for the events. The vaccine was administered at the hospital. The patient did not receive any other vaccines within 4 weeks prior to the Covid vaccine. The patient visited a doctor or healthcare professional office/ clinic due to the event. The patient was not diagnosed with Covid-19 prior to vaccination and since the vaccination, the patient had not yet been tested for Covid-19. Outcome of events was recovering.; Sender's Comments: Based on the compatible time association ,the reported events are possibly related to suspect bnt162b2 injection in this patient. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

joints were aching; nauseous; hot flushes that progressed; feeling really hot; can't recall names; had a glazed look; This is a spontaneous report from a contactable registered nurse A 34-year-old female patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot/batch number: 9899, expiry date: Mar2021), intramuscularly in left deltoid on 18Dec2020 at 10:20 am at 0.3 mL, single for COVID-19 immunization. Medical history included chronic lyme disease and anxiety both from an unknown date and unknown if ongoing. Concomitant drug included vivogen which is a stimulant to keep her awake during the day and took supplements, but reporter didn't have a full list. On 18Dec2020 at 10: 25, the patient had an adverse reaction within 5 minutes felt nauseous, hot flushes that progressed and feeling really hot, as it progress she started getting out of it, the patient also can't recall names, she had a glazed look, within 30 minutes (18Dec2020 10:50) joints were aching. She was asking for common adverse events during clinical trial study. The event was reported as seriousness for being other medically important condition. The reporter considered the events was related to the COVID 19 Vaccine. The patient still had the neuro symptoms. She was still very out of it and her joints were still hurting. The nausea had gone. The outcome of the nauseous was resolved in Dec2020, the outcome of joints were aching was not resolved, the outcome of other events was unknown.; Sender's Comments: The reported

information is limited. Based on the close temporal relationship and the description of the events, nauseous, hot flushes, feeling hot, can't recall names, glazed look and joints aching. there is a reasonable possibility that the events are related to BNT162 vaccine. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

A very slight droop of relaxed right lip (Smile is symmetrical and NO orbital involvement); tightness, swelling and tingling in right jaw; tightness, swelling and tingling in right jaw; tightness, swelling and tingling in right jaw; generalized itching; A small patch (dime-size)of non-raised erythema noted behind right ear; A brief period of feeling hot followed immediately by a chills; A brief period of feeling hot followed immediately by a chills; Rash; This is a spontaneous report from a contactable nurse. A 41-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot number: EJ1685), intramuscularly in the left arm, on 18Dec2020 at 08:45 (at the age of 41-years-old) at a single dose for COVID-19 immunization. Medical history included hypertension (HTN) and seasonal allergies. The patient was not pregnant at the time of vaccination. Concomitant medications, taken within 2 weeks of vaccination, included mometasone furoate (FLONASE) and cetirizine hydrochloride (ZYRTEC). Other concomitant medications included an unspecified antihypertensive. The patient had no known allergies to medications, food, or other products. The patient did not receive any other vaccines within four weeks prior to the vaccination. The patient experienced a very slight droop of relaxed right lip (smile is symmetrical and no orbital involvement), tightness, swelling and tingling in right jaw, generalized itching, a small patch (dime-size) of non-raised erythema noted behind right ear, a brief period of feeling hot followed immediately by a chills, and rash on 18Dec2020 at 09:30. Therapeutic measures were taken as a result of the events, which included treatment with oral diphenhydramine hydrochloride (BENADRYL) 50 mg. The clinical outcome of a very slight droop of relaxed right lip (smile is symmetrical and no orbital involvement), tightness, swelling and tingling in right jaw, a small patch (dime-size) of non-raised erythema noted behind right ear, and a brief period of feeling hot followed immediately by a chills was not recovered and of generalized itching and rash was recovered on an unspecified date. It was reported that jaw tightness and slight asymmetry of relaxed lips continued on 18Dec2020 at 16:15. It was also reported that since the vaccination, the patient had not been tested for COVID-19. No follow-up attempts needed. No further information expected.; Sender's Comments: Based on the close temporal relationship, there is a possibility that the events are related to BNT162 vaccine. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

experienced a strong medicine-like smell; a rush of warmth throughout my body; felt that my hands were swelling and slightly itchy but they did not appear to be swollen; felt that my hands were swelling and slightly itchy but they did not appear to be swollen; panicked; felt that my throat was tight but I didn't feel short of breath; My BP was elevated at 140s/80s; tachycardic; This is a spontaneous report

from a contactable nurse (patient). A 42-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number: EH9899), intramuscularly at the right arm on 18Dec2020 at 13:00 (1 pm) at single dose for COVID-19 immunization. The patient was not diagnosed with COVID-19 prior to vaccination and since the vaccination, the patient has not been tested for COVID-19. The patient was not pregnant at the time of vaccination. The patient's medical history included asthma r/t environmental allergies, anxiety, and known allergies to PCN, Sulfa, grass, trees, ragweed, weeds, mold, dust mites, cat and dog. Concomitant medication included cetirizine hydrochloride (ZYRTEC), venlafaxine hydrochloride (VENLAFAXINE XR), colecalciferol (VITAMIN D), ibuprofen, and montelukast sodium (SINGULAIR). The patient received the vaccine on 18Dec2020 at approximately 1 pm (13:00) and 5 minutes later (18Dec2020 at 13:05), she experienced a strong medicine-like smell and a rush of warmth throughout her body. She then felt that her hands were swelling and slightly itchy but they did not appear to be swollen. She was panicked and felt that her throat was tight but she didn't feel short of breath. Her BP was elevated at 140s/80s and she was tachycardic. She gave herself an epinephrine injection and about 10 minutes later the occupational health nurse gave her 25 mg Benadryl at her request. The adverse events results in Emergency room/department or urgent care. The clinical outcome of the events was recovered on an unspecified date.; Sender's Comments: Based on the close temporal relationship, the association between the reported events with BNT162b2 can not be fully excluded. The history of asthma, allergies, and anxiety may have been contributory. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

diagnosed with Bell's palsy; This is a spontaneous report from a contactable nurse (patient). A 33-year-old female patient received 1st dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number: EK5730, expiration date: Mar2021), via an unspecified route of administration in left arm on 19Dec2020 10:00 at single dose for COVID-19 immunization. No other vaccine administered in four weeks. Medical history included drug sulfa allergy. Concomitant medication included cetirizine, cetirizine hydrochloride (ZYRTEC) from 18Dec2020, and multivitamin from 18Dec2020. No Covid prior vaccination. No Covid tested post vaccination. About 40 min after the vaccine (19Dec2020 10:40) the patient developed left facial/ left tongue tingling/ numbness. By 20:30 at night (19Dec2020 20:30), the patient had a left sided facial droop as well, the patient was diagnosed with Bell's palsy. 20:30 (19Dec2020), she had facial asymmetry. She looked in the mirror and noticed her smile was not symmetrical. She then checked into the Emergency Room and the ER doctors diagnosed her with Bell's palsy. She was not admitted to the hospital. Steroids were given for treatment. The patient was still expirencing. Intermittent tingling but tingling was not constant. Smile was not normal yet. The outcome of event was not recovered.; Sender's Comments: Based on the close temporal relationship, the association between the event Bell's palsy with BNT162b2 can not be fully excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as

well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

bilateral periorbital swelling; Myalgia; Fever; This is a spontaneous report from a contactable physician. A 49-year-old male patient received BNT162B2, via an unspecified route of administration on an unspecified date as single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced bilateral periorbital swelling, myalgia and fever on an unspecified date, which were medically significant. Description was as followed: patient went to the emergency department. The vaccines was given on a Wednesday afternoon, and patient presented with bilateral periorbital swelling this morning, myalgias, and fever. Therapeutic measures were taken as a result of swelling, myalgia and fever; the only treatment given was diphenhydramine (BENADRYL) orally. The batch/lot number for the vaccine, BNT162B2, was not provided and will be requested during follow-up.; Sender's Comments: The reported information is limited. Based on the close temporal relationship and the description of the events, periorbital swelling, myalgia and fever, there is a reasonable possibility that the events are related to BNT162 vaccine. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

Diaphoresis; palpitations of 180-150 beats per minute, and SVT supraventricular tachycardia on the heart monitor.; palpitations of 180-150 beats per minute, and SVT supraventricular tachycardia on the heart monitor.; This is a spontaneous report from a contactable physician. A 56-year-old male patient received the first dose BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 18Dec2020 at 09:00 at single dose for covid-19 immunization. Medical history included hypertension, episode of SVT (supraventricular tachycardia) in the past. There were no concomitant medications. The patient experienced diaphoresis, and palpitations of 180-150 beats per minute, and SVT supraventricular tachycardia on the heart monitor on 18Dec2020. The events were reported as serious per medically significant. Event details: the patient received the vaccine 18Dec2020 at 09:00AM. About 40 minutes later the patient returned to hospital where he worked, where he received the vaccine, with diaphoresis, palpitations of 180-150 beats per minute, and SVT supraventricular tachycardia on the heart monitor. Reporter stated this was temporally related. Patient was given Adenosine 6mg IV with no response; then 12mg Adenosine with no response. Then the patient the spontaneously converted 10 minutes after the last dose of adenosine to 75 beats per minute and sinus rhythm, in one beat. The reporter was an emergency room (ER) physician and the patient was the ER right now. The patient was stable at time of reporting and expected to be discharged. The reporter did order a Troponin and cardiac workup. Troponin result was less than 6 which was normal. With regard to the Adenosine that didn't work reporter stated those vials usually went into a container and after consulting with another coworker stated the Adenosine vial had been discarded at this time and he was unable to provide NDC, lot or expiration date. The outcome of the events was resolved on 18Dec2020. Information on the lot/batch number has been requested.; Sender's Comments: Based on the close temporal relationship and the description of the events,diaphoresis, palpitations and SVT,

there is a reasonable possibility that the events are related to BNT162 vaccine. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

"fainted right after taking the vaccine; This is a spontaneous report from a non-contactable consumer (Pfizer company representative). A female patient of an unspecified age received the bnt162b2 (BNT162B2; also reported as COVID-19 vaccine; Batch/lot number, NDC number, Expiry Date: Unknown), via an unspecified route of administration on 17Dec2020 at a single dose for COVID-19 immunization. The patient medical history was not reported. The patient's concomitant medications were not reported. The patient experienced fainted right after taking the vaccine (medically significant) on 17Dec2020. It was unknown if the patient received other products, and any investigation assessment was unknown. The clinical course was reported as follows: The reporter stated they had seen quite a bit on social media and on the (site name), where people have been sending around a video regarding a healthcare worker who fainted. The caller was just wondering "" if Pfizer has been made aware of this. ""Apparently, this was on the news. This healthcare worker was taking the COVID-19 vaccine and as she was talking to the press, she apparently fainted. It looks as if she fainted as one would do when taking blood tests or faint from fear of a shot or being worried. However, this video has been sent all over social media, as seen as an AE, and telling people to not take the vaccine."" The reporter further clarified the healthcare worker was in (city name) and received the COVID-19 vaccine. As the healthcare worker was talking to the press, she fainted right after taking the vaccine. The reporter further clarified she was sent a link via (site name) from the news channel where it had the video recording. The reporter did not have a specific reporter. The reporter explained it was a "" whole group that was talking about it."" The reporter clarified she was in a (state name) group on (site name) with friends and family. The reporter also saw it on social media. "" People are sending it left and right."" When probed to determine if the reporter had any patient details or further details regarding the event, the caller stated the only information she had was that on (News name), and click on (City name) news and find the video of the healthcare worker taking the vaccine and fainting. The reporter clarified the news article was dated as 17Dec2020 ""so this event must have happened yesterday."" From the reporter's understanding from the news, the patient was fine, she got up. ""However, people are sending out on social media that she is dead"", which the reporter did not think was the outcome. According to the news, when the reporter opened the link, it was just a regular fainting, it was not a death. The reporter felt obligated to report and make sure Pfizer was aware of this since she had been seeing it everywhere on social media. The clinical outcome of the event, fainted right after taking the vaccine, was unknown. No follow-up attempts are possible; information about batch/lot number cannot be obtained."

"throat tightness; tingling of lips; allergic reaction; felt strange; This is a spontaneous report from a contactable Other-HCP (nurse practitioner). A 43-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, NDC, lot/batch number and expiration date unknown), via an unspecified route of administration on 18Dec2020 at single dose for covid-19 immunization (She wanted to be vaccinated against COVID 19). Patient history was no. She has no other history no other history of

reactions to vaccines or flu vaccines, no history of allergies noted before. She thought her weight was probably about 140. She did not have her height either, but she was about 5'4"" probably. Concomitant medication included atorvastatin (LIPITOR) and thyroid medications. It was reported that they have an employee that received the COVID 19 vaccination and experienced an allergic reaction. It had to be a brief call but it was there crazy. Patient received the vaccine and within 30 minutes she had throat tightness and tingling of lips. This happened on 18Dec2020(today) about 20-30 minutes after receiving the vaccine. The throat tightness had resolved after giving Epinephrine (Epi). She said the tingling of her lips resolved as well after Epi. She just said she felt strange but that could be from the Epi. She said it was an employee vaccination so there was no prescriber. She took Lipitor and thyroid medications. She said those were just her routine medications. She did not have a start date for the Lipitor. She had not been on anything new. It was definitely just the COVID vaccine. Outcome of the events tingling of her lips, throat tightness and allergy reaction was recovered on 18Dec2020, of other event was unknown. Information about lot/batch number has been requested.; Sender's Comments: There is a reasonable possibility that the events allergic reaction and throat tightness were related to BNT162b2 based on known drug safety profile and close temporal relationship. Based on the close temporal relationship, the association between the event tingling of lips with BNT162b2 can not be completely excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate."

Temperature up to 102.2; Numbness in fingertips; Chills; Nausea; Soreness in arm; Shaking too badly; This is a spontaneous report from a contactable Registered Nurse (patient) and Consumer (Patient's husband). A 64-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, batch/lot# EK5730), via an unspecified route of administration in Left deltoid on 17Dec2020 14:00 at single dose for COVID-19 immunization. Vaccination Facility Type: Hospital. Vaccine administered at site: No. Medical history included cervical dystonia. The patient had COVID back in Mar2020. Symptoms were similar but she doesn't remember having the numbness in her fingertips. Family medical history: None. The patient's concomitant medications were not reported. Additional vaccines administered on same date of Pfizer suspect: None. The patient previously took povidone-iodine (BETADINE) and experienced allergy to betadine. Prior Vaccinations within 4 Weeks: None. AES follow prior vaccinations: None. The patient experienced temperature up to 102.2 on 18Dec2020 11:00, chills on 18Dec2020 10:00, numbness in fingertips on 18Dec2020 10:45, nausea on 18Dec2020, soreness in arm on 17Dec2020, shaking too badly in Dec2020. No AES require a visit. Relevant tests: None. The patient received shot at 2PM. Had a little soreness in arm and took paracetamol (TYLENOL, Acetaminophen 500mg, Product strength and count size dispensed: 500mg caplets; quantity 100, Provided 0CE3259A above date of Jan2022, Provided 484782EF17 from bottle, NDC: 49035-308-78, Manufacturer is Unknown) as pain reliever before bed, Dose: 1000mg on 17Dec2020 at 9PM. Took Ibuprofen (Product strength and count size dispensed: 200mg tablets; quantity 100, Provided 0DE2612A above date of Feb2022, Provided 604782EF8 from bottle, NDC: 49035-308-78, Manufacturer is Unknown) at dose: 400mg on 18Dec2020 at 4AM this morning. Having chills, temperature up to 102.2, numbness in fingertips and a little nausea. Clarified she is referring to the COVID Vaccine. The patient was shaking too badly. Symptoms started

with Chills around 10AM 18Dec2020. Temperature was checked at 11AM Central time 18Dec2020 and checked now during report. Temperature was the same. Numbness in fingertips began 10:45AM 18Dec2020. Nausea had been on and on due to chills. Chills were aggravating the nausea. Had not thrown up. Temperature was going up and she was worried about getting dehydrated. Clarified EK5730 is from CDC Patient Card. Indication: Front line worker; lead nurse in Intensive Care and is in front of COVID all day long. A sample of the product is available to be returned, if requested, notified of mailer. Packaging is sealed and intact. The patient underwent lab tests and procedures which included temperature: 102.2 in Dec2020 and on 18Dec2020. The outcome of all the events was unknown. Serious: Yes, Seriousness criteria-Other medically important condition: No (as reported). Reporter seriousness for Temperature up to 102.2, Chills, Numbness in fingertips, Nausea: Medically significant. Relatedness of drug to reactions/events: Reaction assessed: Temperature up to 102.2, Chills, Numbness in fingertips, Nausea; Source of assessment: Primary Source Reporter; Source of assessment: Global Introspection; Drug result: Related. Verbatim event relatedness: COVID-19 Vaccine: Temperature up to 102.2, Numbness in fingertips-Related.; Sender's Comments: Based on the close temporal relationship and the description of the events, there is a reasonable possibility that the events, temperature up to 102.2, chills, numbness in fingertips, nausea, soreness in arm, shaking, are related to BNT162 vaccine. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

had a syncopal event and hit her face when falling; had a syncopal event and hit her face when falling; hit her face; This is a spontaneous report from a contactable consumer via Pfizer sales representative. A 41-year-old female patient received BNT162B2 (Pfizer product) , via an unspecified route of administration on 18Dec2020 at single dose for COVID-19 immunization. The patient medical history was none. The patient's concomitant medications were not reported. The patient had COVID vaccine administration yesterday (18Dec2020). She went to bed that night and woke up in the middle of the night to use the bathroom. She had a syncopal event and hit her face when falling. She required a trip to the urgent care and stitches. She was a healthy female with no underlying conditions. Event took place after use of product. Therapeutic measures were taken as a result of hit her face. The outcome of the events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

"Anaphylactic Reaction; felt like something was in throat; felt tingling on both hands and fingers; voice started to change; face turning red to white to purple; everything in mouth as tongue felt like it was growing; having chest pain radiating to left scalpel, and jaw; couldn't think of the words to say as it was hard to breath; chills; heart rate is racing; This is a spontaneous report from a non-contactable nurse via internet source via Pfizer Sales Representative. A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number: EH9899) via an unspecified route of administration on 18Dec2020 at single dose for covid-19 immunization. Medical history included had a lot of food allergies. The patient's concomitant medications were not reported. The nurse told that her manager (patient) had an anaphylactic reaction shortly after receiving Pfizer's COVID-19 BNT162b2

vaccine on 18Dec20. Patient stated via Social Media indicated that she received the Covid-19 vaccine right after work. Easy breezy didn't feel a thing. She was asked to wait for 15 minutes, 5-10 minutes of waiting, she felt like something was in throat, so she kept clearing it. Patient felt tingling on both hands and fingers. Her voice started to change. She informed the ER team there, the ER nurse described her face turning red to white to purple. ER nurse started an IV right on patient's right AC, gave her a shot of Benadryl, steroids and the epi pen right through pants. Patient felt everything in mouth as tongue felt like it was growing, but she can breath. Patient was route to the ED via wheelchair, everything started to look hazy, she was having chest pain radiating to left scalpel, and jaw. Patient couldn't think of the words to say as it was hard to breath. When got to the ED they gave her another dose of Benadryl, solumedrol, decadeon, HHN tx with epi and that worked. Patient felt her throat opening up and started talking but then came the chills. It took almost 3 hours to clear the symptoms, even though her heart rate is racing (prob due to the meds), she opted to go home. The outcome of ""heart racing"" was not recovered, of other events were recovered on 18Dec2020. No follow-up attempts are possible. No further information is expected.; Sender's Comments: A possible causal association between administration of BNT162B2 and the onset of anaphylactic reactions with tongue swelling/voice alteration/hard breath/tingling/something in throat/skin discoloration, chill and chest pain cannot be excluded, considering the plausible temporal relationship and the known adverse event profile of the suspect product. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate."

TTP; This is a spontaneous report from a non-contactable pharmacist. A 22-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), intramuscular on 17Dec2020 as a single dose for COVID-19 immunization. The patient did not have any known relevant medical history. The patient had no allergies to medications, food or other products. Prior to the vaccination, the patient was not diagnosed with COVID-19. The patient's concomitant medications were not reported. It was unknown if the patient received any other vaccines within four weeks prior to the vaccination. On 21Dec2020, the patient experienced thrombotic thrombocytopenic purpura (TTP); which was serious for hospitalization. The clinical course was as follows: The patient went to the emergency room/urgent care and was admitted in the early morning of 21Dec2020 due to TTP. Work-up was ongoing with no known results. On 21Dec2020, the patient also had a COVID-19 test which was negative. The patient was treated with unspecified corticosteroids and platelets. The clinical outcome of the TTP was unknown. The reporter assessed that it was unknown if the TTP was related to the vaccination. The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up.; Sender's Comments: Current limited information does not allow a full medically meaningful assessment, especially lack of medical history, concomitant medications, concurrent illness and diagnostic workups such as coagulation test, Combs test, bacterial/virologic/immunological biomarkers to identify the etiology. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any

appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

injection site pain; tiredness; headaches that come and go; muscle pain; few chill; severe joint pain; fever; This is a spontaneous report from a non-contactable healthcare professional (patient). A female patient of an unspecified age (Age: 60; Unit: Unknown) received single dose of (BNT162B2, batch/lot number and exp date not reported), via an unspecified route of administration on 21Dec2020 (last Monday), around 11amfor immunization. The patient's medical history and concomitant medications were not reported. Patient reported experiencing 7 side effects after receiving the COVID-19 vaccine on an unspecified date in Dec2020. She experienced injection site pain, tiredness, headaches that come and go, muscle pain, few chill, severe joint pain, and fever. Her temperature ranged between 99.9-100, at the low grade. Patient asked how long the symptoms would last and to what point does she assume that they relate to the vaccine. The outcome of the events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

Developed redness, swelling, and itching at injection site 6 days after receiving the vaccine.; Developed redness, swelling, and itching at injection site 6 days after receiving the vaccine.; Developed redness, swelling, and itching at injection site 6 days after receiving the vaccine.; This is a spontaneous report from a non-contactable nurse reporting for a patient. A 29-year-old female patient received first dose of BNT162B2 (Pfizer product, lot number EK5730), via an unspecified route of administration on 16Dec2020 on left arm at single dose for COVID-19 immunization. Medical history was none. The patient's concomitant medications were not reported. The patient was not pregnant. She had no known allergies, no Covid prior vaccination, no Covid tested post vaccination. The patient developed redness, swelling, and itching at injection site 6 days after receiving the vaccine (on 23Dec2020). No treatment was received for the adverse event. The outcome of the events was unknown. The report was assessed as non-serious. No follow-up attempts are possible. No further information is expected.

"chills; extremely dry mouth where she feels like she has no saliva; extremely dry mouth where she feels like she has no saliva; extremely tired; had a strange sensation of tingling in her skull, back of neck, and up her skull. Tingling sensation is more left sided than right/the tingling sensation in her head; This is a spontaneous report received from a contactable nurse (who is also the patient). A 63-year-old female patient started to receive BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899, expiry date: Mar2021), via an unspecified route of administration, on 22Dec2020, at single dose, for COVID-19 immunization. The patient medical history and concomitant medications were not reported. The patient reported that on 23Dec2020, she had a strange sensation of tingling in her skull, back of neck, and up her skull. Tingling sensation was more left sided than right. On24Dec2020, she experienced chills, which she knows is one of the normal effects. She also experienced an extremely dry mouth to where she feels like she has no normal saliva on 24Dec2020. She was constantly drinking ice water. She was also extremely tired. The patient reported that the most concerning to her is the tingling sensation in her head and the extreme dry mouth. The patient wanted to know if what she is experiencing is ok or not. She also reported that ""if it's urgent she cannot wait until USMI reopens, she will go to the ER"". The outcome of the events was unknown."

localized soreness in arm; This is a spontaneous report from a non-contactable physician via Pfizer sales representative. A male (nephew) patient of unknown age received on an unknown date BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) at single dose in the arm for COVID-19 shot. Medical history and concomitant medications were not reported. The patient, who is an ER doc, had localized soreness in arm from vaccination. Outcome was unknown. No follow up attempts are possible, information about batch number cannot be obtained.

"Patient states that she waited her required 15min at the vaccine clinic. She felt no symptoms. One hour later however she felt tired so she took a nap. That night she felt cold and had to grab a blanket. Before bed she felt that the skin on her abdomen was feeling ""tingly."" The next morning she noticed a rash on the abdomen that is itchy. She already takes 25mg benadryl daily for allergies so she started taking it twice a day but that hasn't helped. She now notices the rash in the b/l groin, left thoracic back and left arm (upper and forearm). The rash is still present and itchy 5 days later so she came to my clinic today. I prescribed her a 6 day dose pack of methylprednisolone and to continue benadryl."

Pain at injection site, fatigue

First day had chills, headache, body ache, body sweat, fever, fatigue for two-three days, first day slept for 21 hours, second day for 15 hours. Didn't start feeling normal until the fifth day. Arm swollen where the shot was given on right arm, 3 inches size. Today is the 6th day and still some visible swelling on the area down to two inches but itchy for two days now.

felt tired and had left elbow pain

Non-itchy slighlty raised rash that appeared about 24 hours after vaccine at location of shot that extended up to shoulder and down to elbow. It went away after another 24 hours. 1 week after vaccine, developed lip twitch on side of body that vaccine was administered. Still persists 1 week later, but is not as intense

0654 TACHYCARDIA. LIGHTHEADED, THROAT IRRITATION, HYPERTENSION, & FACIAL SWELLING

Arthralgia, sore throat, dry cough, congestion, pain to back of head and neck, leg pain, lower back pain, fatigue, fever 100.7 on 12/23/20 12/26/20- developed chest pain neck pain left shoulder pain lightheaded and nausea at night-resolved next morning

Severe headache causing mild nausea due to pain. Continues ongoing from 4hrs after dose to present. Itching all over they body from morning after the dose to present. Trouble concentrating, brain fog since morning after the dose to present. Restless from morning after the dose to present. Numbness around mouth, since the morning after the dose to present. Fatigue since morning after the dose to present.

7 days after receiving vaccine I?ve been having nausea without vomiting and headaches. It started on Dec 25 and has continued and is present as of today Dec 28th. I will make an appointment to be Covid tested as soon as possible. On the Vaccination record card it stated to report any possible adverse reaction. I?m unsure if this is related but felt I should report it.

Patient received the Covid 19 vaccine on 12/24/2020. On 12/26/2020 she c/o new onset fatigue, bodyache, cough, headache, sore throat. The dry cough and sore throat are worsening. Denies fever or chills. Covid test scheduled on 12/28/2020 at Employee Health.

vaccine at 11:30 am on 12/18/20 and after 15 mins she felt the room started to spin, dizzy and tunnel vision. nausea and dry heaves also 2-3 mins after. persistent dizziness. pruritic rash and was taken to the ER by wheel chair. About an hour after the vaccine, she felt something in the back of her throat, speech ok, able to swallow. No sob. She was treated with benadryl, pepcid, zofran and fluid. She felt very hot and shaking. In the ER, she noticed that the rash had progressed to her back. Notes chest redness, back with erythematous, raised pruritic bumps on back and arm (smaller size of dime) Within 4 hours of treatment, she had improved. That night at 2am she had a rash -not as pruritic. She took more benadryl. No rash after. No new meds, no nsaids. She has never had any medical problems or rashes before. Her symptoms are concerning for anaphylaxis but it is reassuring that her vitals were ok and that she did not progress and improved with benadryl and pepcid - advised to not get 2nd vaccine dose - will plan on skin testing her in the future

Arm pain and Migraine .. Took Migraine medication and that's when I had a anaphylaxis reaction . I have an appointment to see a specialist to verify if the reaction was caused by the COVID vaccine or the medication I took that day

Pt received COVID 19 Vaccine on 12/16/20. During 15 minute Observation; pt complained of Palpitations about 5 minutes into Observation. The nurse assisted pt to Overflow Observation room. Nurse Manually check Pulse; Pulse 68, A/O x4. Pt provided water and crackers. Pt stated her Palpitations have resolved on their own in about 4-5 minutes.

Around lunch time I felt inside my body a stinging sensation shooting down my body. 5-10 min it got worse and I felt my heart racing. I noticed I started getting a rash, it started on my chest, bottom and legs, I went to the ER where they recommended me a shot of Benadryl and a Pepcid. It took 3- 4 days for the rash to go away and 2 days for the itchiness to go away. It also broke out on my face a day later in the morning.

Approx. 3-5 minutes after receiving vaccine became lightheaded with blurry vision, tongue became thick and numb. About 10 minutes after vaccine pain in right arm and burning down my throat. My hands and arms became numb and tingly and were heavy to move. Symptoms got better with IV Benadryl and Solu-Medrol. Approximate 4 hours after vaccine developed vomiting and diarrhea.

numbness & tingling in tongue & throat after vaccine administration. Immediately taken to the ED, Benadryl & steroid given.

Difficulty breathing, catching breath then face flushing an hour after vaccination. She took her temp which was normal, went to sleep and woke up the next day feeling fine. No history of asthma or COPD. No history of AE from vaccines in the past.

Overall itchiness

Pt. received Covid #1 at 8:20 a.m. , 10 minutes later, she experienced palpitations along with heart rate of 90-100. Other vital signs stable. O2 sat 100% , afebrile. This went on for 1 1/2 hours on and off of wellness then again with the episode. She also experienced diarrhea X2 within the 1 1/2 hour span. This adverse event seems to be a vasovagal reaction to the injection and not to the vaccine itself.

Approximately 5 minuets after receiving Moderna, COVID-19 vaccine, while talking with writer, client became unresponsive and slumped over in chair. Client's extremities became stiff and his eyes rolled to the back of his head. Client was lowered to the floor with assistance and remained unresponsive for a minuet more. EMTs on site responded to event and monitored client for approximately 40 minuets before discharging client home in stable condition. During the monitoring period, client did have emesis x 1. His skin was also clammy after initially becoming unresponsive.

Red raised area to arms and chest that resolved within ten minutes without treatment

Nursing Notes: about an hour after COVID injection, severe vertigo, vomiting, severe headache, left arm completely numb, pt states she is sitting in her car in the parking lot of her apt, but not able to get out and walk bc the dizziness is too much. RN recommended ER disposition. Pt is going to take an Uber

The night of, I had vivid, strange dreams. I thought this was a fluke but have spoken with multiple people who had the same issue. I didn't have any weird dreams any other night, just the night of the vaccination. No treatment needed.

Patient tested positive for Covid-19 on 12/25/2020

angioedema face and hands, rash, fever, chills, fatigue, started menstruation all started about 7 hours post vaccination.

Myalgias, fever x24hrs

Employee developed heart palpitations shortly after receiving the COVID-19 vaccine. Heart palpitations lasted approximately 1 hour. No medical intervention needed. Pulse remained within normal limits (60-100).

Patient developed heart palpitations shortly after receiving the COVID-19 vaccine. Heart palpitations lasted approximately 1 hour. No medical intervention needed. Pulse remained within normal limits (60-100).

Awoke with a significant frontal headache. I considered that it might be sinus related, but decongestant did not help it. Awoke the following morning fine. So potentially could be related to vaccination.

"12.22.20 @ 20:30 injection site pain, radiating pain to right elbow and neck, tingling in right 4th, & 5th finger 12.23.20 @ 05:45 awoke with headache, body aches and continued pain in right arm 12.23.20 @12:45 headache worsened, continued arm pain, fatigue 12.23.20 @ 14:30 elevated temperature 100.2 and chest palpitations and nausea 12.24.20 @ 10:53 ""killer headache, and body aches. No fever since yesterday night w/o taking reducer fever medications."" BP1 164/106 Individual took her BP again in the

other arm: BP2 162/109 She stated she will take Tylenol, and rest for 30 minutes to take her BP again. She stated she will contact her PCP after this. 12.24.20 @ 12:03 BP 129/90 Individual stated she contacted her PCP and PCP is aware of this event."

Patient developed Covid 19 following vaccination.

8 hours after injection: itching, induration, pain @ injection site (left deltoid) Following morning: headache, earache & pressure, Post nasal drip, increased pain & itching @ injection site, ping-pong sized swelling at injection site with redness. Took Motrin for symptoms with some relief. 2nd Day: improvement in pain, swelling, itching, still present. Slight headache/bilateral earache. General malaise. Took Motrin with some relief. 3rd day: left arm tender to touch, swelling/redness further decreased, intermittent itching. Malaise improved. Remnants of headache/earache. No need for Motrin. 4th Day: arm pain/itchiness continues to decrease, no swelling now, no headache, no malaise, some ear pressure.

Patient had mild hypotension, decreased oral intake, somnolence starting 3 days after vaccination and death 5 days after administration. He did have advanced dementia and was hospice eligible based on history of aspiration pneumonia.

pt co fatigue over the weekend and then developed chest pressure and hypoxia per pt on 12/28/20

The sequence of events begins approx. 3:30pm on 12/23/20. 12/23/20 ? headache, nausea with vomiting, brief itching, chilled feeling, temp of 99.9, body/bone aches all over with legs hurting the most, very sore injection arm, husband and I debated on going to the ER, cried 12/24/20- headache, nausea without vomiting, body/bone aches, didn?t take temp, sore arm. 12/25/20- same as 12/24 12/26/20-body/bone aches but not as intense, headache, arm sore, neck was tad stiff. When I put on deodorant it hurt then felt pea sized lump painful to touch in left arm pit. Also felt lump on left side on my neck the size of thumb pad but not painful. Cold sore appeared on bottom lip 12/27/20- sore armpit-lump smaller, neck lump smaller non painful, nauseous 12/28/20-armpit feeling better lump almost gone still painful if I press on it otherwise not an issue, neck lump smaller -pinky pad finger size non painful June 2020 tested positive for COVID was moderate in symptoms

Less than 15 minutes after vaccination alerted lead of itching and hives. Noted rash. Has had similar reactions to medications in the past. No respiratory compromise. Per standing order was given Benadryl 50mg po with water at 1519. 1520 VS: 158/79-82-16-96.9 and 96% on room air. 1534 VS: 140/73-76-16-96.6 and 95% on room air. Employee was observed for an additional 15 minutes with no progression of symptoms. Instructed to call lead if any further symptoms develop. Returned to lab department to work.

I got vaccine tonight ~1750. I felt fine immediately after and stayed for the recommended 15 minutes. During my drive home, ~20 minutes, I had some expiratory wheezing and a sensation of something in my throat. No angioedema or swelling. No skin symptoms. This was mild but made me think twice so I drove back to the er. The wheezing resolved, but I felt like I was going to faint with hot flushing and nausea in the parking lot. I didn?t go in because things seemed better and my stomach was turning like I was going to have diarrhea. Since the wheezing was gone, I decided against going in. I stayed in the

parking lot for ~ 15 minutes and feeling of unease and presyncope waxed and waned, but eased. I continued with some nausea. I had waves of nausea, chills, flushing, and presyncope. The wheezing didn?t return. No tachycardia. I had chills and nausea on the drive home and at home. Took Tylenol and Pepcid when I got home and feel absolutely fine now after ~2 hours of fluctuating nausea, chills and sense of unease/anxiety. None were as severe as they were when I was in the parking lot. Throughout, I didn?t have high or low heart rate. After 8 pm or so, I feel just fine. I have zero symptoms now.

"patient became nauseated and began dry heaving. C/o ""tickle in back of throat"" with repetitive throat clearing. Mild periorbital swelling noted Given Zofran, Pepcid, Benadryl, epi-pen x 1, IV initiated EMS took patient to emergency department for further evaluation"

HR 101, anxious, BP cuff not reading, but patient indicates she has always has a low BP. Pt refused snack, symptoms have resolved. SPO2 100% and HR at 80 at discharge.

34 year old female who reports localized redness and itching within 5 mins after injection. Patient denied any shortness of breath, GI symptoms or rash. VSS. Patient received 50mg of Benadryl. Approx 5 min later patient developed throat tightness. Patient was promptly administered EPI. Patient developed urticarial like lesions. Patient reported improvement in throat tightness but continued to complain of itching at injection site. An additional 50mg of Benadryl was administered. Patient reported improvement of itching approx 5-10 min later. Patient VSS stable throughout but developed tachycardia.

Lightheaded, immediately resolved. HR 80 at discharge

Patient developed wheezing, c/o difficulty breathing. Denies tongue swelling, no visible rash. Treated with albuterol nebulizer and transported to hospital.

sharp pain in all my joints.

Injection site soreness starting on day of injection and has improved today. Headache, nausea and vomiting at least 6 times. Not pregnant but unsure if food poisoning

visible rash to anterior chest and left side of the neck (close to left ear). Client c/o of itching. Allegra 60 po given with water per protocol.

Headache, body aches, joint pains and low grade fever with feeling warm and fatigue x 36 hours. Headache with severe cervical/thoracic spine/neck pain, fatigue, fogginess has persisted x 10 days. Associated nausea when pain is severe. Sometimes headache is improved; but it usually worsens in the evenings.

Upper body flushing and dizziness (arms/face). Dizziness resolved in approximately 20 minutes. Pt left observation area still slightly flushed.

Pfizer-BioNTech COVID-19 Vaccine. Headache and fatigue

Friday patient experienced feeling fatigued and disoriented, Friday she reports muscle aches and headaches and Saturday patient reports feeling headaches and even more fatigue along with a sore throat on Saturday

Patient received the Covid 19 vaccine on 12/24/2020. On 12/27/2020 she c/o new onset fatigue, cough associated with slight itching of the throat and chills. Denies fever. Hx of allergic cough. Covid test scheduled on 12/28/2020 at Employee Health.

33 y.o. female who arrived by on-campus presented to the emergency department for onset of dizziness and a splotchy red rash after receiving the COVID-19 vaccine today. Patient states after onset of her symptoms she further sat down for approximately 15 minutes, but when she went back up to work she was further prompted to come down to the ED for evaluation. Denies wheezing, nausea, or abdominal pain. Denies a history of allergies. Patient tested positive for COVID-19 at the end of this past September. No prior immunization reactions Patient was given PO Benadryl and observed for one hour while here in the ED with no residual symptoms. Patient feels comfortable going home and will return for worsening symptoms. Will discharge patient with a prescription for Prednisone to use if symptoms return

Moderna COVID-19 Vaccine Nausea/Vomiting/Diarrhea upon awakening on 12/24. Lightheaded, near-syncope, diaphoretic. Lasted approximately 3 hours. Vomited then nausea subsided after about 1hr. Chills starting 12/26. Difficulty warming up after being outside in the cold. Prolonged effects that are not normal for me. 12/28 cold/clammy hands despite being in warm environment.

Hives to bilateral arms and chest

"""throat feels tight"" - no obvious signs of distress. Benadryl 50mg Po given and discharged at 1040 feeling better"

Just over 24 hours after receiving vaccine, began running low grade fever. First recorded at 101. Over the next 48 hours (approximately) fever fluctuated between 99-101. Also experienced pain at injection site and muscle soreness in left arm. Issues resolved on their own without medication. V-SAFE 1st check in, did not occur until 4 days post vaccine, at which time, fever had resolved.

Headache (akin to a tension headache, forehead location) almost instantly after injection that has persisted but lessened in severity since injection over the course of one week.

Same day after vaccine I started feeling tired. 2nd day i started having chills and muscle aches. Went to work and tried to work through it. Wednesday i worked 1/2 day. Thursday morning I started feeling light headed that afternoon I started getting hives on my legs. 12/24 I called internal med and spoke with Dr. He called in a rx for me a steroid. I took the 1st day and 1/2 of the 2nd and stopped because I started feeling nauseous and light headed but my hives started getting better(color change) He advised me to go to the ER but I started feeling better andf I told him i would follow up with Dr's office. if I wasn't getting better. I scheduled an appointment with Dr my PCP. I am still very weak and the back of my neck and shoulders are very tender. I still have hives on my legs but they are starting to clear.

5 days after I received the vaccine, I came down with severe abdominal pain, I went to the emergency department and was diagnosed with Acute Pancreatitis without a cause. I do not drink alcohol, and my gall bladder is working well, no gall stones noted to cause pancreatitis.

Shortness of breath, shallow breathing Fatigue Headache some body ache at first I went to the clinic, nothing prescribed but did take a Covid test which came out negative

Headache Fatigue Muscle Aches Nasuea

At 3:00 PM same say I started having arm pain 12:00 AM that night chills , back pain , muscle pain Next morning fever , I could Not stand up , eyes was burning , headache third day- Headache and arm pain

Sever dizziness, headache and nausea

12/17I had severe nausea I never threw up and fatigue and I had to leave work and Dr prescribed zophran, I was fine the next day on 12/18 I went to work I was just a little nauseous

12/23/20 - SEVERE stomach cramps, chills, low grade temperature, mild headache 12/24/20 - Fatigue

VACCINE 12/22 having congestion, cough, runny nose starting 12/24 and current 12/28

Left arm very sore, with some nausea (so far I haven?t thrown up).

Headache, neck pain & pain at injection site starting approx 2 hours after injection and lasting until bedtime on 12/18/20. Headache, swollen glands, neck pain, fatigue, nausea and fever beginning morning of 12/20/20 and resolved 12/22/20.

Fever over 100 degrees F

On 12/21/2020 at 1630, patient complained of anxiousness, feeling hot, and claustrophobia about 8-10 minutes S/P COVID 19 Vaccine administration.

tachycardia

vaso-vagal response to injection

First overnight after vaccination. No fever. Nightmares and vivid dreams all night long. Generalized myalgia and arthralgia (even my fingers and toes). I have had dengue (?break bone?) fever twice ?. It felt almost as bad. It?s like looking at your extremity wishing to move it, but it hurts so much that you just give up! Sounds dramatic but it is the best way I can describe it. Got better as I incorporated into the day. Some residual fatigue for 1-2 days. All resolved.

Patient had Hoarsness in her throat and felt like she could not breathe. Was given Benadryl, Prednisone and Pepcid.

Fever, sore arm, chills

Patient presents to the ED with complaints of an allergic reaction that started approximately 5 minutes after receiving the COVID-19 vaccine. Patient states that she started to experience throat swelling, tingling on her nose and lips, as well as feeling a little dizzy. Patient denies any trouble breathing but states that she has slight chest pain on inspiration. Denies any other symptoms, denies any significant medical history, has not ever had a reaction to a vaccine before.

Approximately 12 hours after the injection - started feeling that the L side of her face was numb and tingling. Also started with nausea (no vomiting); headache (located in the back of her head) and fever (102.2). She noted head felt very heavy and she had difficulty walking by herself (son was at her home to assist). Facial numb ness resolved in ~3 hours. She tried taking 800 mg ibuprofen but didn't have any relief so took Tylenol (this was still on 12/24) and then took another dose of each at around 5:00am 12/25. Fever was still coming/going (responded to the medicine but towards the end of that timeframe her temperature went up again). Last fever was on 12/26 - no fever since (reporting this on 12/28). Headache resolved on 12/27/2020. She also noted that her injection site had small vessicles and was red/tender to touch - as of 12/28 vessicles have resolved and injection area appears back to normal.

I had an elevated BP 218/116, shivering, sweating, light headed and had nausea.

lightheaded, nauseous, feeling faint. Manual BP was taken as automatic BP was unable to be obtained; manual BP was 80/52 mmHg. Water provided, cold pack applied to posterior neck. Patient recovered after 13 minutes and was walked out of building by RN.

Sore throat, body aches, and fever

"Very painful injection site; overall fatigue; muscle cramps in my legs; This is a spontaneous report from a contactable healthcare professional. A 50-year-old female patient started received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot number EH9899), intramuscular into the left arm on 16Dec2020 at 18:30 as single dose for COVID-19 immunization. Medical history included chronic bronchitis, asthma and hypertension from an unknown date. Concomitant medication included losartan (MANUFACTURER UNKNOWN). No allergies to medications, food, or other products were reported. The patient experienced very painful injection site, overall fatigue and "" muscle cramps in my legs "" on 17Dec2020, at 12:00. The events were not serious, and no treatment was required. The outcome of very painful injection site, overall fatigue and "" muscle cramps in my legs "" was recovering."

Muscle aches,Migraine, night sweat; Muscle aches,Migraine, night sweat; Muscle aches,Migraine, night sweat; This is a spontaneous report from a contactable healthcare professional. A 55-year-old patient of an unspecified gender received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), intramuscular on 16Dec2020 at 13:00 as single dose for COVID-19 immunization. Medical history included fibromyalgia, degenerative bone disease from an unknown date. The patient's concomitant medications were not reported. No diagnosis of COVID-19 was noted prior to vaccination. Since the vaccination, the patient has not been tested for COVID-19. There were no allergies to medications, food, or other products. The patient experienced muscle aches, migraine, night sweat on 16Dec2020, at 12:30, which was non-serious. The outcome of muscle aches, migraine, night sweat was recovered in Dec2020. The batch/lot number for the vaccine, BNT162B2, was not provided and will be requested during follow-up .

"The day after I am feeling very tired, achy and weak with a temp of 100.1.; The day after I am feeling very tired, achy and weak with a temp of 100.1.; The day after I am feeling very tired, achy and weak with a temp of 100.1.; The day after I am feeling very tired, achy and weak with a temp of 100.1.; This is a spontaneous report from a contactable healthcare professional. A 44-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), intramuscular on 17Dec2020 at 14:00 as single dose for covid-19 immunization. Medical history included hypertension and being pre-diabetic from an unknown date and unknown if ongoing. No known food or drug allergies noted. Concomitant medication included metformin (MANUFACTURER UNKNOWN), amlodipine besilate (NORVASC), metoprolol succinate (TOPROL). The patient reported "" the day after I am feeling very tired, achy and weak with a temp of 100.1"" on 18Dec2020. No other vaccines within 4 weeks prior to the COVID vaccine were administered. No treatment received for the adverse events. No diagnosed of COVID-19 was noted before or after vaccination. Vaccine Facility information available. The outcome of "" the day after I am feeling very tired, achy and weak with a temp of 100.1"" was unknown. The batch/lot number for the vaccine, BNT162B2, was not provided and will be requested during follow-up."

Sneezing, intermittent cough, congestion, body aches, fatigue, loss of appetite.

Headache, body aches (specifically to back), fatigue; Headache, body aches (specifically to back), fatigue; Headache, body aches (specifically to back), fatigue; This is a spontaneous report from non-contactable consumer, the patient. A 26-year-old non-pregnant female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot Number: EK5730), via an unspecified route of administration on 17Dec2020 at 20:00 (at the age of 26-years-old) in the right arm as a single dose for COVID-19 immunization. The patient's medical history was not reported. Prior to the vaccination, the patient was not diagnosed with COVID-19. Concomitant medications included omeprazole (PRILOSEC) and fexofenadine hcl (ALLEGRA); both for unknown indications from unknown dates and unknown if ongoing. The patient did not receive any other vaccines within four weeks prior to the vaccination. The patient previously took azithromycin (ZITHROMAX) from an unknown date to an unknown date for an unknown indication and experienced drug allergy. On 18Dec2020 at 04:00, the patient experienced headache, body aches (specifically to back), and fatigue; all reported as non-serious. The patient did not receive any treatment for the events. The clinical outcomes of headache, body aches (specifically to back), and fatigue were recovering. It was also reported that since the vaccination, the patient had not been tested for COVID-19. No follow-up attempts are possible. No further information is expected.

Woke up with hive-like bumps that itch; This is a spontaneous report from a non-contactable healthcare professional. A 32-year-old female patient received bnt162b2 (BNT162B2; lot number: EK5730; expiration date: unknown), intramuscular left arm on 17Dec2020 17:00 at single dose for immunization. Medical history included hives a few weeks ago. She is not pregnant. The patient's concomitant medications were not reported. The patient stated that she woke up on 18Dec2020 07:00 AM with hive-like bumps that itch. There was no treatment given. The patient added that it maybe unrelated as she had hives, a few weeks ago. The vaccine was given in a hospital. The patient did not have other vaccine in the last 4 weeks. The patient was not diagnosed with COVID-19 prior to the vaccination and was not COVID tested post vaccination. The outcome of the event was unknown. No follow up attempts are possible. No further information is expected.

Approximately 2 hours post injection, I began to feel fatigued and achy. At 3 hours post injection, I had a headache, muscle & joint aches. I also had slight nausea & a moderately severe stomach ache. These symptoms began to subside approximately 10 hours post injection with the stomach ache taking an additional 2 hours to resolve (12 hours total). The injection site was painful the day following the vaccine and did not resolve until 2 days post administration.

Fever, sore arm

Arm soreness; fever max of 101.9; cough; heart burn; fatigue; chills; headache; This is a spontaneous report from a contactable consumer (patient himself). A 35-year-old male patient received the first dose of bnt162b2 (BNT162B2, lot number: EH9899), via an unspecified route of administration on 17Dec2020 10:30 AM at single dose (left arm) for immunization. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Medical history included MI with Stent and diabetes type 2. The patient received other medications (unspecified) within 2 weeks of vaccination. The patient previously took amoxicilin and experienced allergies. On 17Dec2020 at 07:00 PM, the patient experienced arm soreness, Fever max of 101.9, cough, heart burn, fatigue, chills and headache. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. Therapeutic measures were taken as a result of the events which included Tylenol and Motrin. The events recovered on unspecified date in De2020.

Employee has history of anaphylaxis and was in the 30 min observation. C/O dizziness. Sits on gurney at 45 degree angles. No sob, chest pain or hives. VS obtained and employee hypertensive. Under observation of RN. Able to sip on water, but continues to have HTN and dizziness. Taken to the ED for further evaluation of symptoms.

Pain at injection site x 36 hrs.; This is a spontaneous report from a contactable consumer. A 50-year-old female patient received first dose of bnt162b2 (Pfizer-BioNTech COVID-19 vaccine; lot EK5730), via an unspecified route of administration on 16Dec2020 18:00 at single dose (right arm) for Covid-19 immunisation. Medical history included seasonal allergies, depression, elevated cholesterol and pollen and dust allergies only. The patient had no allergies to medications and food. Concomitant medications included fluoxetine, loratadine, Montelukast sodium (SINGULAIR), fluticasone and mul (as reported). On 16Dec2020 19:00, the patient experienced pain at injection site x 36 hrs. The patient was vaccinated at the hospital. It was reported that the patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient did not received treatment for the event. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, the patient had not been tested for COVID-19. Outcome of event was recovered on an unspecified date.

Reports dizziness started evening of 12/24/20 and ongoing. Reports dizziness is much better today and feels it has almost resolved. Is following up with PCP today, 12/28/20 . no other symptoms reported.

felt warm; blurred vision; light headed; arm pain; This is a spontaneous report from a contactable pharmacist. A 61-year-old male patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EJ1685), intramuscular on the left arm on 18Dec2020 at a single dose for COVID-19 immunization. The patient's medical history included atrial fibrillation (a fib). Concomitant

medication included flecainide and apixaban (ELIQUIS). The patient previously took pantoprazole sodium sesquihydrate (PROTONIX) and experienced allergies to pantoprazole sodium sesquihydrate. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. On 18Dec2020, 5 minutes after injection, the patient felt warm, blurred vision, light headed, and arm pain. No treatment was received for the adverse events. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, the patient had not been tested for COVID-19. Outcome of the events was recovered on 18Dec2020. The events were considered non-serious.

Pt verbalized he felt dizzy. Pt was sitting down at this time. The patient verbalized that the dizziness resolved after a duration of 30 seconds. No epinephrine or diphenhydramine was required for recovery. Pt denied distress or SOA.

10 min after the vaccine had sudden cold hands; palpit; dizziness; BP 150/90 - high for patient; a sensation of chest awareness (not pain, but a bit of tension); anxiety; a clear sensation of chest warmth; presyncopal episodes; chest tightness; Still with waves of chest warmth/heat/burning sensation and chest awareness; This is a spontaneous report from a contactable physician (patient). A 45-year-old female patient (not pregnant) received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 17Dec2020 15:00 at single dose at left arm for immunization. Medical history included hypothyroidism, migraine from an unknown date and unknown if ongoing. Concomitant medications included levothyroxine sodium (SYNTHROID), cetirizine hydrochloride (ZYRTEC), triamcinolone acetonide (NASACORT). There's no other vaccine in four weeks. 10 min after the vaccine patient had sudden cold hands (the kind of inside cold like Propofol gives you), with palpit and dizziness, self-limited in a few mins. BP 150/90 - high for patient. Similar episode but shorter and less intense within next half an hour. Also a sensation of chest awareness (not pain, but a bit of tension, which patient had experienced before with anxiety and put it on anxiety). Decided to go home and while walking patient noticed a clear sensation of chest warmth. Patient decided to stick around the hospital a bit more, pondering about going into the ER. Drank 2 bottles of orange juice and headed home. Then on the way home patient had 2 presyncopal episodes. The fact that patient had not eaten all day and wasn't well hydrated might have contributed. Patient didn't go to the ER. Patient ate, drank juice, took diphenhydramine hydrochloride (BENADRYL) 25 mg. The chest tightness got better. Still with waves of chest warmth/heat/burning sensation and chest awareness. Never had such sxs 2/2 anxiety. Patient received acetylsalicylic acid (ASPIRIN), diphenhydramine hydrochloride, clonazepam as treatment. Outcome of all events was recovering. Patient was not diagnosed with COVID-19 prior to vaccination, and no COVID tested post vaccination. Events were reported as non-serious. Information on Lot/Batch number has been requested.; Sender's Comments: Based on the close temporal relationship, there is a reasonable possibility that the events are related to BNT162 vaccine. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

Pt had Covid vaccine. 5 minutes after vaccine complained of tachycardia. HR initially to palpation was in the 220s. Pt assisted supine. Code Blue called per protocal. Dr. to room. Pts BPs were 160/80, 144/90,

140/84, and 138/80. HR 140, 134, and 123 bpm. O2 sat the whole time was 100% on RA. Pt c/o nausea and dizziness. Assisted to stretcher and brought to ER for evaluation. Pt state she had a previous history of Covid and anxiety but this experience felt different to her then her previous panic attacks. No rash, wheezing, oral swelling, pruitis.

Flushing and hot flashes that have persisted 2 hours after vaccine.; Flushing and hot flashes that have persisted 2 hours after vaccine.; Notable feeling of dizziness; This is a spontaneous report from a contactable consumer (patient) and physician. A 37-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE lot/batch # EH9899), via an unspecified route of administration on the left arm on 18Dec2020 11:15 at SINGLE DOSE for COVID-19 immunization at the hospital. Medical history reported as none. The patient had no allergies to medications, food, or other products. There were no concomitant medications. Prior to vaccination, the patient not diagnosed with COVID-19 and the patient has not been tested for COVID-19 since the vaccination. On 18Dec2020 11:30, the patient experienced flushing and hot flashes that have persisted 2 hours after vaccine. The patient also had notable feeling of dizziness. No treatment was received for the adverse events. Outcome of the events were not recovered.

Reporting on behalf of staff member. She received covid vaccine on 12/24. The following day, she experienced extreme weakness/fatigue, migraine, low grade fever, body aches, and tachycardia. She went to the ER, they gave her IV fluids, pain meds and tylenol with no relief. She was monitored for awhile and then sent home to rest and recover. 3 days later (12/27) she says she feels significantly better, but still a little tired.

No adverse events reported as of yet after patient was vaccinated in right deltoid except a sore arm; pregnant patient was vaccinated yesterday with the COVID-19 vaccine; pregnant patient was vaccinated yesterday with the COVID-19 vaccine; pregnant patient was vaccinated yesterday with the COVID-19 vaccine; This is a spontaneous report from a contactable physician via Medical information team. A 35-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), lot number: EH9899, in right deltoid via an unspecified route of administration on 17Dec2020 10:30 at single dose for routine vaccination. Medical history was reported as none. The patient's concomitant medications were not reported. It was reported that patient pregnant was vaccinated yesterday with the COVID-19 vaccine. She received vaccine while pregnant on 17Dec2020 which was non serious per report. The patient was an MD and her age was 35 years old. She was vaccinated yesterday with COVID 19 vaccine and she was pregnant. She was able to speak to Pfizer Drug Safety. The patient was a frontline Healthcare provider and there was no prescriber for the vaccine. She thinks there should be a pregnancy registry so she wanted to get on it so Pfizer can use her data. Her next dose will be on 07Jan2021. The reason she got it was because she was high risk and a front line healthcare worker. The patient was 21 weeks pregnant. She assumed this was going to be a normal pregnancy and normal delivery. The patient had the vaccination in the hospital. No additional vaccines administered on same date. No adverse events reported as of yet after patient was vaccinated in right deltoid except a sore arm. Onset time of arm being sore was 5pm (17:00) yesterday, 17Dec2020. This did not require a visit to the ER or physician's office. No prior vaccinations within 4 weeks. No AE for prior vaccinations and no medical

history or family medical history relevant and no relevant test. The outcome of the events was unknown.

headaches, back pain, fatigue, nausea, foul taste in mouth

"she got the vaccine 2 nights ago and started to develop itchiness all over her body 30 min post vaccination/head to toe itching; I had serious flu like symptoms, full body aches; Knuckles hurting on both hands; Rash; She stated she had"" body aches but feeling better today""; This is a spontaneous report from a contactable nurse (patient herself). A 61-year-old female patient received first dose of BNT162B2 (lot number: EK5730) via an unspecified route of administration, on 16Dec2020, at single dose, for COVID protection. Medical history included asthma. Concomitant medication included albuterol (SALBUTAMOL) for asthma. The patient mentioned that she got the vaccine 2 nights ago and started to develop itchiness all over her body 30 min post vaccination (16Dec2020). She stated she had body aches but feeling better today. Her body got very itchy and she spent that whole night head to toe itching. Itch was so bad. She had serious flu like symptoms, and full body aches. Patient stated that she understood everything was normal. Patient stated, ""I need to find out from you guys who do I call to find out if I have that itching, if I actually, I had an allergic reaction to the vaccine whether or not if I should take the second dose."" She also stated, ""I was going to say the first day about hour an half my it started with my knuckles hurting on both hands and then I just got rash, I mean not rash itching head to toe and it left with through the night I took some Zyrtec (further clarified as treatment) because I can't take Benadryl. So, I took and it (Zyrtec) helped with the it and itch was resolved by yesterday."" She had lab work two days ago. On the same day, she had the injection and had a test for her thyroid and COVID antigen test both with unknown results. The patient recovered from pain and pruritus on an unspecified date in Dec2020, while for the other events was unknown."

"felt like I was going to pass out; lightheaded/Dizzy; 9 minutes after administration heart rate up to 154; leg shakes; started having chest itchiness; neck rash; facial hives; Injection site sore; This is a spontaneous report from a contactable consumer. A 29-year-old female patient received her first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot: EH9899) via an unspecified route of administration in the left arm on 17Dec2020 08:00 at a single dose for covid-19 immunisation. Medical history included allergies to cephalosphorins. Concomitant medication include unspecified multivitamins. On 17Dec2020 08:09, the patient's heart rate went up to 154 after vaccine administration. On 17Dec2020 08:15, she felt like she was going to pass out, she was lightheaded and dizzy. The patient also experienced leg shakes, started having chest itchiness, neck rash, facial hives and injection site sore on 17Dec2020. The patient was treated with diphenhydramine (BENADRYL) 50mg intramuscularly (IM) for the events ""9 minutes after administration heart rate up to 154"", ""felt like I was going to pass out"", ""lightheaded/Dizzy"", ""leg shakes"", ""started having chest itchiness"", ""neck rash"" and ""facial hives"". The patient's heart rate came down to 130s then down to 90s and the hives subsided. The patient underwent lab tests and procedures which included heart rate: 154, heart rate: 130 and heart rate: 90; all on 17Dec2020. Outcome of the events ""9 minutes after administration heart rate up to 154"", ""felt like I was going to pass out"", ""lightheaded/Dizzy"" and ""facial hives"" recovered on an unspecified date while the outcome of events ""leg shakes"", ""started having chest itchiness"", ""neck rash"" and ""injection site sore"" was unknown."

after the administration of the first dose of the Covid Vaccine presented a leakage of about 2-3ml; the patient was administered Subcutaneously instead of Intramuscularly/maybe the product had been injected Subcutaneous rather than Intramuscular; This is a spontaneous report from a contactable physician. A patient of unspecified age and gender received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), subcutaneous at single dose on an unspecified date for Covid-19 immunisation. The patient medical history and concomitant medications were not reported. On an unspecified date, the patient after the administration of the first dose of the Covid vaccine presented a leakage of about 2-3ml, the patient was administered subcutaneously instead of intramuscularly/maybe the product had been injected subcutaneous rather than intramuscular. Information on the lot/batch number has been requested.

I'm not sure this is entirely vaccine related, but I wanted you to be aware. I occasionally experience unexplained swelling of my lips. It has been investigated by an allergist, but the cause is unknown -- doesn't appear to be a food allergy (no trigger foods identified, and it has never appeared immediately after eating), and may not even be histamine related. It could be something immune-system related, and my experience this weekend might support that. I had normal, expected symptoms on Friday evening (chills, headache). Those resolved Saturday. Saturday night, my lower lip swelled dramatically. Swelling spread into the upper lip as well. I have seen this before, but this was one of the more severe instances I have experienced. Lips remained swollen overnight. When I woke up Sunday morning and went to the restroom, I became suddenly lightheaded and passed out. That's a symptom I have never experienced before. I consulted with my primary care doctor and took it very easy the rest of Sunday. He and I will follow up to further asses what happened. No further light-headedness on Sunday or today. Lips eventually resolved late in the afternoon. This is all about 72 hours after the vaccine, so I can't be sure it is related, but I do wonder if it is related to having my immune system revved up by the vaccine. I reported it on the CDC check-in app and my primary care physician is noting it on his side as well.

fever of 38.6; cold fingers all day; very sore deltoid area from the night of 12/16 thru 12/17, cant raise my right arm; very sore deltoid area from the night of 12/16 thru 12/17, cant raise my right arm; very sore deltoid area from the night of 12/16 thru 12/17, cant raise my right arm; This is a spontaneous report from a contactable consumer (patient). A 48-year-old female patient received the first dose of the bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot Number: EH9899), via an unspecified route of administration in the right arm on 16Dec2020 at 18:15 at 48-years-old at a single dose for COVID-19 immunization; administered in a hospital. Medical history included Vertigo, chronic pruritus from Apr2020 to Jul2020 (Vertigo, chronic pruritus (treated and recovered with gabapentin). Concomitant medications included ergocalciferol (VIT D), krill oil (MANUFACTURER UNKNOWN), niacin (MANUFACTURER UNKNOWN), guaifenesin (MUCINEX), loratadine (CLARITIN); all taken for an unspecified indication from an unspecified date to an unspecified date (received within two weeks of vaccination). The patient previously took ketoconazole and experienced Known allergies, gabapentin for pruritus and vertigo; all from an unspecified date to an unspecified date. On 16Dec2020, the patient experienced: very sore deltoid area from the night of 12/16 thru 12/17, cant raise my right arm. On 17Dec2020, the patient experienced: cold fingers all day (non-serious). On 17Dec2020 at 17:50, the patient experienced: fever of 38.6 (non-serious). Prior to the vaccination, the patient was diagnosed

with COVID-19; and since the vaccination, the patient had been tested for COVID. The patient underwent lab tests and procedures which included body temperature: 38.6 on 17Dec2020, Oral Throat Swab PCR (polymerase chain reaction): positive on 22Nov2020, Oral Throat Swab PCR: negative on 10Dec2020. Therapeutic measures were taken as a result of cold fingers all day, fever of 38.6, very sore deltoid area from the night of 12/16 thru 12/17, cant raise my right arm. The clinical outcome of the events: cold fingers all day, fever of 38.6, was recovered on an unspecified date. The clinical outcome of the event, very sore deltoid area from the night of 12/16 thru 12/17 was recovered on 17Dec2020. The clinical outcome of the event, cant raise my right arm, was unknown.

Pfizer-BioNTech COVID-19 Vaccine EUA; Generalized Itchy rash with hives all over body not relieved by benadryl, zyrtec, claritin and pepcid.

"I got a mild headache. Within an hour it was severe; I became diaphoretic and felt flushed; I became diaphoretic and felt flushed; felt my heart pounding; GI upset; vomited; This is a spontaneous report from a contactable consumer (patient). This 39-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (Lot Number: ej1685), via an unspecified route of administration at single dose in the right arm on 16Dec2020 14:30 for covid-19 immunisation. The patient medical history was not reported. Concomitant medication included estradiol (ESTRACE), levothyroxine in Dec2020. The patient previously took amoxicillin and experienced drug allergy. The patient stated that ""on 17Dec2020 14:30, I got a mild headache. Within an hour it was severe. I became diaphoretic and felt flushed. and felt my heart pounding. Experienced GI upset and vomited once. Took Tylenol and went to sleep for 8 hours. Woke up feeling normal. Therapeutic measures were taken as a result of the events included Tylenol. The outcome of the events was recovered. The vaccine was administered at Hospital Facility. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient was not diagnosed with COVID-19 prior to vaccination. The patient had not been tested for COVID-19 since the vaccination."

"feels sluggish; had a little bit of fever yesterday; Warm feeling shooting in head; developed a warm feeling in his head that turned into a headache; This is a spontaneous report from a contactable consumer. A 57-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EM9899), via an unspecified route of administration (arm left) on 16Dec2020 at single dose for precaution for front line worker. The patient's medical history included blood pressure abnormal, blood cholesterol abnormal, diabetes, enlarged prostate, sleep disorder, on anticoagulant therapy, and migraine. Concomitant medications included lisinopril, simvastatin, metformin hcl, tamsulosin, dutasteride, zolpidem, aspirin [acetylsalicylic acid], and melatonin. It was reported that the patient experienced warm feeling shooting in head on 16Dec2020. It was further reported that the patient developed a warm feeling in his head that turned into a headache on 16Dec2020. The patient also experienced slight fever on 1Dec2020. The patient received the vaccine on Wednesday afternoon (16Dec2020). The patient stated, ""initially it felt weird; for a couple of minutes, it felt ok and then he felt a warm feeling shooting in his head, like when you take strong medications or do MRI. It gives you that strong feeling. It was cold or warm but shoots in head. He felt it, so he went to occupational health and it went away. He went home early and did not finish his shift. Then he got a headache and it did not go away and it is not severe. He feels sluggish and had a little bit of fever yesterday and took Tylenol and

it went away. He still had a headache and it bothers him. He cannot remember the name of the medication that he got the warm feeling shooting in his head, but he believed it was when they did a dye for an MRI. He does not have the name and did not have a lot or expiration. He works at a hospital but not as a healthcare provider. He got the vaccine a few day ago and later stated it was Wednesday, 16Dec2020 warm feeling started an hour after getting the vaccine. As soon as he went to occupational health, it went away and improved. He did not have the headache yet. He did not work his full shift. He got home at night and felt not too bad of a headache. He has a history of migraines and he can feel somehow, he is starting to have a headache. It is not severe though. The headache started that night and it is still there. It is not so severe, but it bothers him. When he had a slight fever, it is gone after taking Tylenol. He never actually checked his temperature, he just felt warm. He takes medications every day, so he took medications the night before and did not take other medications since then. He wanted to find out if there was any interaction with the vaccine before taking them again. The outcome of event fever was recovering, events warm feeling shooting in head and headache was not recovered, and the event feels sluggish was unknown."

35 y.o. female who arrived by to the emergency department for Allergic reaction. Patient got the shot at approximately 8:10 AM and subsequently developed tingling in the back of her throat and felt like she had some swelling. She alerted staff who brought her here for further evaluation. She currently denies any trouble swallowing, voice changes, tongue, lip swelling, rash, abdominal pain, nausea, vomiting, diarrhea. Able to speak in full sentences without difficulty, not in respiratory distress. She is also able to drink water in the emergency department without difficulty. Will dose with Benadryl and observe. Patient was observed for over 2 hours in the emergency department with event of her symptoms. Doubt anaphylactic reaction at this time as she had no other symptomatic involvement. Patient safe for discharge home at this time.

"patient received the vaccination and within a few minutes she developed sore throat, wheezing; patient received the vaccination and within a few minutes she developed sore throat, wheezing; This is a spontaneous report from a contactable nurse. A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 18Dec2020 at 08:30 at single dose for COVID-19 immunisation. Relevant medical history and concomitant medications were not reported. On 18Dec2020 at 08:30, the patient experienced sore throat and wheezing; within a few minutes she developed sore throat, wheezing. Facility where the COVID-19 vaccine was administered was workplace clinic. The adverse events resulted in Emergency room/department visit or urgent care. The patient received ""RT"" treatments. It was unknown if prior to vaccination the patient was diagnosed with COVID-19 and it was unknown if she was tested for COVID-19 since the vaccination. The outcome of the events was unknown. Information on the lot/batch number has been requested."

"a ""funny"" feeling in my mouth/A sore sensation; a ""funny"" feeling in my mouth/A sore sensation; It felt as if it had been burned; slurred speech; loss of taste; This is a spontaneous report from a contactable consumer. A 32-year-old female patient received the 1st dose of bnt162b2 (BNT162B2) at single dose at left arm on 17Dec2020 09:30 for immunization, administered at hospital. Medical history included asthma, allergies: aluminum, pet dander, trees/weeds/grass, seasonal allergy. She had not

Covid prior vaccination. Concomitant medication included montelukast sodium (SINGULAIR), colecalciferol (VITAMIN D [COLECALCIFEROL]), received within 2 weeks of vaccination. The patient had not received any other vaccines within 4 weeks prior to the COVID vaccine. On 17Dec2020 14:30, the patient experienced a funny feeling in my mouth/a sore sensation, it felt as if it had been burned, slurred speech, loss of taste. Course of events: Within 5 hours of injection she started noticing a ""funny"" feeling in her mouth. A sore sensation. By 19:30 her tongue was very sore. It felt as if it had been burned. she had nothing hot to eat that day and nothing new to eat. The soreness increased. She also had some slurred speech and loss of taste. The patient underwent lab tests: Sars-cov-2 test (Rapid nasopharyngeal, nasal swab): negative on 18Dec2020. She received no treatment. The symptoms have stayed steady and have not gotten better. The outcome of events was not recovered. The case was assessed as non-serious. Information on the lot/ batch number has been requested."

"thinks it is COVID toe; thinks it is COVID toe; an itchy toe/Her toe started itching. It is very red; an itchy toe/Her toe started itching. It is very red; This is a spontaneous report from a contactable nurse, the patient. A 49-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot Number: EK5730), via an unspecified route of administration on 16Dec2020 at 07:15 (at the age of 49-years-old) as a single dose for COVID-19 immunization. Medical history was not reported. Concomitant medications included zingiber officinale root (GINGER ROOT), clonazepam (KLONOPIN), progesterone (MANUFACTURER UNKNOWN), fluoxetine hydrochloride (PROZAC), spironolactone (MANUFACTURER UNKNOWN), vitamin D3 (MANUFACTURER UNKNOWN), and zinc (MANUFACTURER UNKNOWN); all taken for unknown indications from an unknown date and unknown if ongoing. On 18Dec2020 at 02:00, the patient experienced an itchy toe/her toe started itching and it was very red, reported as non-serious. The clinical course was as followed: the patient was at work on the night of 18Dec2020 and was having trouble with her toe. Her toe started itching. It was very red. She wondered if it was ""COVID toe"" as the picture she found looked exactly the same. The physician she worked with did not know what it was. She took a diphenhydramine hydrochloride (BENADRYL) and sprayed freezing agent on it to stop the itching. The clinical outcomes of the itchy toe, red toe, and ""COVID toe"" were not recovered.; Sender's Comments: The reported information is limited. Based on the close temporal relationship and the description of the events, there is a possibility that the events are related to BNT162 vaccine. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate."

herpes flair-up; herpes flair-up; I nerve pain, it happends all the time when I am under stress She mentioned this happened last night; I nerve pain, it happends all the time when I am under stress She mentioned this happened last night; This is a spontaneous report from a contactable Nurse reporting for herself. A 61-years-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EH9809, Expiry Date: Mar2021), intramuscular on 17Dec2020 at single dose for covid-19 immunisation (front line worker). Medical history included herpes treated with acyclovir (manufacturer: Calrsbad Tech), oral at 400 mg, as needed. The patient's concomitant medications were

not reported. The patient experienced herpes flair-up on 17Dec2020 with outcome of not recovered. On 17Dec2020 (last night) the patient had nerve pain, it happened all the time when she was under stress with outcome of unknown. The patient took acyclovir as treatment and wanted to know if there's any drug interaction with the covid 19 vaccine and if she will be eligible to get her second dose of Covid 19 vaccine while taking Acyclovir.

lightheadedness/feeling lightheaded/felt herself going backwards and caught herself; disappointed and upset; This is a spontaneous report from a contactable consumer (patient) who reported that a female patient of unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration, on 17Dec2020 at single dose for COVID-19 immunization. Medical history and concomitant medications were not reported. Patient was allergic to aspirin, if she takes it her eyes will come out of her head and quite a few other things will happen to her. Patient reported that she got the COVID-19 Vaccine on 17Dec2020 and it was like 1 hour after (also reported within 1 hour) she got the vaccine that she started feeling lightheaded which she had never experienced before, even today. Patient is an environmental service worker, she had so many discharges and so many COVID rooms to wipe down that she just kept pushing herself because they are just short staffed; but at one point she felt herself going backwards and caught herself, she decided to sit down and drink a water and continued to feel lightheaded. No one was available to relieve her yesterday (17Dec2020), she had to stay at the hospital until midnight and continue her activities with lightheadedness (pending clarification). Patient said, almost a day later, lightheadedness persists, she was still feeling the lightheadedness today (18Dec2020). Her concern is it's like 3-4 days afterwards that you will feel some effects. She wanted to know if this is what they are talking about, if this is expected. Patient initially reported being a healthcare professional (HCP), but clarified her profession is Environmental Service, working at (Institution name). Patient is allergic to aspirin, she wondered if the COVID-19 vaccine contains aspirin. Patient was suggested contacting her doctor to find out if she is allergic to any of the components in the vaccine. Patient was reminded it is possible to consult the ingredients as part of the Vaccine Fact Sheet on (Website name). Patient was disappointed and upset for experiencing lightheadedness after receiving the vaccine (Dec2020). She wishes she hadn't received it. As indicated in previous requests, was referred to an HCP for guidance after experiencing lightheadedness. Outcome of lightheadedness was not recovered, outcome of disappointed and upset was unknown. Information on the Lot/Batch number has been requested.

Fever, mild cough, headache & light-headedness

nausea; dizziness; Progressed to tachycardia; heart rate from 60-120; This is a spontaneous report from a contactable consumer. A 37-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK5730), via an unspecified route of administration at left arm on 18Dec2020 at 07:45, single dose for COVID-19 immunization. Medical history and concomitant medications were not reported. The patient, approximately 15 minutes after shot, experienced mild nausea and dizziness. Progressed to tachycardia, heart rate from 60-120. Felt it racing and pounding. Went to emergency room for evaluation. The patient underwent lab tests and procedures which included heart rate: 60-120. Therapeutic measures were taken as a result of the events and included electrocardiogram (EKG) and telemetry monitoring.

Extreme Vertigo and Dizziness 20 minutes following vaccination. Patient began to slowly feel better.

Right neck pain radiates from shoulder blade to occiput.; Tightness of chest and fluttering in chest that made me cough persistently; Tightness of chest and fluttering in chest that made me cough persistently; BP elevated 150/90; I had EKG report read occasional PVC.; This is a spontaneous report from a contactable nurse reporting for herself. A 45-years-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), intramuscular in the left arm on 18Dec2020 10:15 at single dose for covid-19 immunisation at hospital. Medical history included asthma, eczema, allergies to PCN (penicillin), whey, glutamate, gluten, sulfites. Concomitant medication included isosorbide mononitrate (FLO). On 18Dec2020 at 10:45 the patient experienced right neck pain radiates from shoulder blade to occiput. Tightness of chest and fluttering in chest that made her cough persistently. BP elevated 150/90, no prior history of hypertension. In ED for check-up, the patient had EKG report read occasional PVC. Labs all within normal limits and symptoms and BP better within 1.5 hours so discharged to home. The patient was not treated for the events. Prior to vaccination the patient was not diagnosed with COVID-19 and has not been tested for COVID-19. Information on the lot/batch number has been requested.

numberless shoulder/extends numbness left leg weak when stood(felt numb)/numbness; This is a spontaneous report from a contactable consumer. A 49-year-old female patient (not pregnant) received bnt162b2 (BNT162B2, also reported as Pfizer-BioNTech COVID-19), via an unspecified route of administration on 18Dec2020 13:15, single dose (dose number 1) in left arm, for immunization. Medical history included allergies to food, perfumes, fragrance, smoke and residual odor. Other medical history includes asthma, OSA (obstructive sleep apnea), borderline DM, anxiety and depression. The patient previously took VICODIN and had drug hypersensitivity. She had no other vaccines in four weeks but had other medications (unspecified) in two weeks. The patient reported that on 18Dec2020 at 13:30 she experienced left arm lateral numberless shoulder- last 3 finger, extended numb to pointer finger, extends numbness shoulder up left neck to lips midpoint the complete lips extended to right side of face and neck and then to right temporal, ear and down to clavicle; left leg weak when stood(felt numb). She developed asthma exacerbation by 0900 and started to resolve in ER. About 0018 numbness now in lips, around lips, tongue, and starting down neck. Treatment for the event were Epinephrine IM, Benadryl, Dexamethasone, ab. She also had CXR (chest x-ray), no results reported. The outcome of events was recovered with Sequel. Information on the lot/batch number has been requested.

Bell?s Palsy to the left side of my face. Woke up Wednesday morning with symptoms.

"Increased congestion about 12 hours after receiving the vaccine. Congestion in back of throat and feeling like I need to clear my throat often.; When I clear my throat there is phlegm; Slight nasal congestion; Slight itching and soreness of the throat; Slight itching and soreness of the throat; coughing once through the night; pain and swelling of the injection site; pain and swelling of the injection site; fatigue; This is a spontaneous report from a contactable consumer. A 36-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE) via an unspecified route of administration on 18-DEC-2020 09:00 AM (at the age of 36-years-old) at an unspecified dose in the left arm for COVID-19 vaccination. Medical history was reported as ""None"" and the patient did not

have any allergies to medications, food, or other products. Prior to the vaccination, the patient was not diagnosed with COVID-19. The patient was not pregnant at the time of vaccination.The patient was administered the vaccine in the hospital. Concomitant medication included zolpidem tartrate (AMBIEN), clonazepam (KLONOPIN) and ""MVI"" (not further specified). The patient did not receive any other vaccines within four weeks prior to the vaccination. On 18Dec2020 at 17:00, the patient experienced increased congestion ""about 12 hours"" after receiving the vaccine as well as congestion in back of throat which she described as ""feeling like I need to clear my throat often"" and ""when I clear my throat there is phlegm."" Further, on 18Dec2020 at 17:00 the patient also experienced slight nasal congestion, slight itching and soreness of the throat that lasted for about 30 minutes and she woke up coughing once through the night. Additionally, on 18Dec2020 at 17:00 the patient experienced pain and swelling of the vaccination site and fatigue. The patient did not receive any treatment for the events. The clinical outcomes of congestion in back of throat, phlegm, nasal congestion, sore throat, itchy throat, coughing, vaccination site pain, vaccination site swelling and fatigue were not recovered. It was also reported that since the vaccination the patient had not been tested for COVID-19. The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up."

Employee reports he developed tinnitus 8 hours after injection and has remained 4 days post injection with no history of tinnitus.

Eyelid and nasal bridge swelling; Eyelid and nasal bridge swelling; Swelling of hands and wrists; Swelling of hands and wrists; This is a spontaneous report from a contactable physician. A 35-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Batch/lot number: EJ1685), via intramuscular route of administration (right arm) on 18Dec2020 18:15 at a single dose for COVID-19 immunisation. Relevant medical history included depression, hay fever and acne. Concomitant medication included escitalopram, fexofenadine hydrochloride (ALLEGRA) and doxycycline. The patient was allergic to nickel and fragrance. On 19Dec2020 07:00, patient experienced eyelid and nasal bridge swelling; and swelling of hands and wrists. Patient received allegra due to the event. Outcome of the events was reported as recovering/resolving. Follow-up attempts are completed. The following information on the batch number has been requested.

Elevated heart rate (150-160)/ elevated heart rate of 160; shakiness/ shaky; dizziness; hives on her neck; This is a spontaneous report from a contactable nurse. A 37-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; lot number: EH9899), via an unspecified route of administration on the left arm on 18Dec2020 11:30 at a single dose for immunization. The patient's medical history and concomitant medications were not reported. The patient had no known allergies and did not receive any other vaccines within four weeks prior to the COVID vaccine. The patient wanted to know if she should receive the second dose after experiencing this type of reaction after the first dose. On 18Dec2020, she experienced elevated heart rate 160 (also reported as 150-160), shaky, dizziness and hives on her neck; stated she received the vaccine at 11:30 am and symptoms started at 11:40 am. She was monitored for one hour to make sure heart rate went down and stated that her heart rate went down after 35-40 minutes. The patient was not diagnosed with COVID prior to vaccination and has not been tested post-vaccination. No treatment was given for the events. Outcome

of the events elevated heart rate, shaky and dizziness was recovered and of hives on her neck was unknown.

Joint pain started in right hand, then right arm, to right shoulder and eventually across back to left shoulder.; This is a spontaneous report from a contactable consumer (patient). This 40-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (Lot number: EH9899) on 16Dec2020, via an unspecified route of administration, at a single dose in the left arm, for COVID-19 immunization. The patient had history of positive antinuclear antibody (ANA) without diagnosis. She had known allergies to penicillin. Concomitant medications received in two weeks included ethinylestradiol/ferrous fumarate/norethisterone acetate (JUNEL FE), acetylsalicylic acid (ASA), melatonin (MELATONIN). The patient did not receive other vaccine in the past four weeks. She had not had ever been diagnosed with COVID-19 prior the vaccination, not tested for COVID-19 post the vaccination. On 17Dec2020, the patient experienced joint pain which started in right hand, then right arm, to right shoulder and eventually across back to left shoulder. The event was non-serious. The patient did not receive any treatment for the event. The event was not resolved.

Soreness; Headache; This is a spontaneous report from a contactable Healthcare Professional reporting for herself. A 53-years-old female patient received first dose of BNT162B2 Pfizer-BioNTech COVID-19 Vaccine, Lot number: ER5730, by intramuscular route in right arm, in Hospital, on 17Dec2020 at 08:45, at single dose for COVID-19 immunization. The patient had no known allergies and no relevant medical history. Concomitant medications were taken, but they were unspecified. On 17Dec2020 at 15:00 the patient experienced soreness and headache, both assessed as non-serious and resolved on an unknown date in Dec2020 without any treatment.

unable to lift arm in active range of motion; difficulty sleeping; administered too high on the arm into the subacromial space; This is a spontaneous report from a contactable consumer (patient). A 41-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number: Eh9899), via an unspecified route of administration at the left arm on 18Dec2020 at 15:00 (03:00 PM) at single dose for COVID-19 immunization. The patient was not pregnant at the time of vaccination. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient was not diagnosed with COVID-19 prior to vaccination, and the patient has not been tested for COVID-19 since the vaccination. The patient's medical history was not reported (other medical history: yes). The patient had no known allergies. Concomitant medication included other unspecified medications received within 2 weeks of vaccination. The patient reported that the injection was given and she thought that it was administered too high on the arm into the subacromial space. By end of day, she was unable to lift arm in active range of motion, and had difficulty sleeping. Following day, still unable to lift arm. The events unable to lift arm in active range of motion, and had difficulty sleeping started on 18Dec2020 at 16:00 (04:00 PM). The clinical outcome of the events was unknown.

Developed dizziness, lightheadedness, warmth, sweaty and had a syncopal episode at 8:45pm. All symptoms resolved then within 15 minutes of laying down in bed and having a cold compress on forehead

red splotchy itchy face; red splotchy itchy face; This is a spontaneous report from a contactable consumer, the patient. A 29-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration in the right arm on 17Dec2020 at 16:00 (at the age of 29-years-old) as a single dose for Covid-19 vaccination. Medical history included Premenstrual dysphoric depression syndrome from an unknown date. The patient did not have any allergies to medications, food or other products. The patient was not pregnant at the time of vaccination. Prior to the vaccination, the patient was not diagnosed with COVID-19. The patient was not tested for COVID-19 post vaccination. The patient's concomitant medications included citalopram (MANUFACTURER UNKNOWN) and ibuprofen (ADVIL); all for unknown indications from unknown dates and unknown if ongoing. The patient did not receive any other vaccines within four weeks prior to the vaccination. On 19Dec2020 at 21:00, the patient experienced red splotchy itchy face. Therapeutic measures were taken for the red splotchy itchy face which included allergy medicine (unspecified). The clinical outcome of the events red splotchy itchy face was not recovered. The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up.

Fever 103F, Shaking Chills Responded to Tylenol. Afebrile 12 hours later

Fever 103F, Shaking Chills Responded to Tylenol. Afebrile 12 hours later

ringing in the ear; unable to hear out of the right ear; This is a spontaneous report from a contactable nurse. A 53-year-old female patient (and nurse) started to receive bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot Number: EJ1685), intramuscularly in the left arm on 19Dec2020 at 08:00 at 53-year-old at a single dose for COVID-19 immunization. The vaccine was administered at a hospital. The patient was not pregnant at the time of vaccination. The patient did not receive any other vaccines within four weeks prior to the COVID-19 vaccine. Medical history included asthma, mitral valve prolapse, Sulfonamide allergy, and allergies to tree nuts; all from an unknown date and unknown if ongoing. Concomitant medications included atorvastatin (MANUFACTURER UNKNOWN), escitalopram oxalate (LEXAPRO), fluticasone propionate (FLOVENT); all taken for an unspecified indication from an unspecified date to an unspecified date (received within two weeks of vaccination). On 20Dec2020 at 14:00, the patient experienced: unable to hear out of the right ear (medically significant). On 21Dec2020 at 02:00, the patient experienced: ringing in the ear (non-serious). The clinical course was reported as follows: Approximately 30 hours post-vaccination, the patient was unable to hear out of her right ear. It progressively worsened; however, by 02:00, the patient's hearing returned, and the patient developed a ringing in her ear. By 14:00, all the symptoms had disappeared. There was no treatment received due to the events. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. The clinical outcome of the event, unable to hear out of the right ear, was recovered on 21Dec2020 at 02:00. The clinical outcome of the event, ringing in the ear, was recovered on 21Dec2020 at 14:00.; Sender's Comments: A possible contribution role of bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE) to the onset of event deafness right ear cannot be excluded due to temporal relationship. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as

well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

After vaccine my mouth started to get dry while I was driving home. 1/2 body sore and chest pain felt like heart burn and I was having a heard time breathing. injection site started hurting all the way up to my shoulder. I started getting chills and tired. i started feeling better last night but I did not sleep well. I still have body aches and my chest is feeling better. If I do not feel better in the next 24 hours i will be contacting my HCP.

High blood pressure; heart rate in the 100's/High heart rate; light headed and dizzy; This is a spontaneous report from a non-contactable nurse(patient). This female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) at single dose via an unknown route on Dec2020 (reported as on Thursday) for Covid-19 immunization. Medical history and concomitant drug were not provided. Patient received the vaccine on Thursday and within 15 to 20 minutes, she got light headed and dizzy with high blood pressure with a heart rate in the 100's. She went to the ER and was sent home, but her blood pressure continues to be high. Her primary care physician wanted to start her on some blood pressure medication due to continuous high blood pressure. The reporter was asking if high blood pressure and high heart rate had been reported as an adverse event for the Covid vaccine. Outcome of High blood pressure was not resolved. Outcome of the other events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Sender's Comments: A causal association between BNT 162B2 and the events blood pressure increased, dizziness, and heart rate increased cannot be excluded based on a compatible temporal relation. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

diaphoretic; dizzy; This is a spontaneous report from a contactable nurse. A 51-year-old female patient (not pregnant) received her 1st dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/Lot Number: ek5730) at single dose on 21Dec2020 11:00 AM intramuscular on left arm for Covid-19 immunization. Medical history included known allergies with codeine. Patient reported similar reaction of diaphoretic and dizzy to giving blood. It was unknown if the patient received any other vaccines within 4 weeks prior to the COVID vaccine, or any other medications the patient received within 2 weeks of vaccination. It was unknown if the patient diagnosed with COVID-19 prior to vaccination. Concomitant drug was not provided. Patient became diaphoretic and dizzy approximately 11:15 AM on 21Dec2020 (also reported as 8 min after injection). The adverse event result in doctor or other healthcare professional office/clinic visit, and Emergency room/department or urgent care. Treatment reported as patient was laid down with feet up, cool compress applied, drank some juice. The events were reported as non-serious. Since the vaccination, the patient had not been tested for COVID-19. Outcome of the events was unknown.; Sender's Comments: A causal association between BNT162B2 and the reported events diaphoresis and dizziness cannot be excluded based on a compatible temporal relation. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse

events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

Rash and Hives

Extremely painful legs; abdomen spasms; abdomen spasms and cramps; severe chills; This is a spontaneous report from a contactable nurse (patient). A 52-year-old female patient (not pregnant at the time of vaccination) received her 1st dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) at single dose on 17Dec2020 04:00 PM Intramuscular in Right arm (also reported Arm Left) for Covid-19 immunization. Prior to vaccination, patient was not diagnosed with COVID-19. Medical history included hypothyroidism, hypotension, obesity, and allergies to onions. There were no other vaccines received in four weeks; however other medications received in two weeks. Patient experienced extremely painful legs and abdomen spasms and cramps, severe chills on 17Dec2020 09:00 PM. Patient applied arnica 35% on the affected area and it helped. Since the vaccination, patient had not been tested for COVID-19. Outcome of the events was resolving. The events were reported as non-serious. Information on lot/batch number has been requested.; Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of events of extremely painful legs, abdomen spasms and cramps, and severe chills cannot be excluded. The case will be reassessed if additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

respiratory distress with dyspnea and increased work; respiratory distress with dyspnea and increased work; rapid progression of symptoms; lightheadedness; tingling to right upper and lower arm; pain to mid forearm; generalized weakness; This is a spontaneous report from a non-contactable health care professional. A 72-year-old female patient received her 1st dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot_number= HE9899) at single dose on 18Dec2020 10:00 AM intramuscular in the right deltoid muscle for Covid-19 immunization. Medical history and concomitant drug were not provided. She denied any history of previous adverse reactions to vaccines. Concomitant drug was not provided. During her 15 minute waiting period after the injection, the patient began to experience lightheadedness and tingling to right upper and lower arm. Also complain of pain to mid forearm. She denied hives, difficulty breathing, difficulty swallowing, wheezing, throat tightness, itching and tongue swelling.When walking to the emergency bay reported some lightheadedness and generalized weakness, patient denies facial drooping or weakness. No loss of strength and normal ROM to hand and arms. This provider was notified of patient reaction and she was then assessed in the emergency bay area. Patient was monitored for severe reaction symptoms, including rapid progression of symptoms, respiratory distress with dyspnea and increased work. The events were reported as non-serious. Outcome of the events was unknown. No follow-up attempts are possible. No further information is expected.; Sender's Comments: A possible causal association between administration of BNT162B2 and reported serious events cannot be excluded, considering the plausible temporal relationship. The impact

of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

I received my first dose of Moderna vaccine at around 9:45 am on Dec 24 and I was fine for like 4 hrs after receiving it, until I started feeling similarly to the way I felt when I tested positive for Covid and had it at the beginning of November (feverish, headache, body ache, stuffy mucusless nose, fatigue, hangover sensation like nauseated and weird, etc...) Things got a little bit worse when all of a sudden I started feeling feverish and my heart started beating so fast I could hear it myself. I had to stop doing what I was doing and called (my insurance/MCD) because I was getting anxious and started hyperventilating, which did not allow me to breathe normal. They told me to take Tylenol which I did and little by little my fever started decreasing; it must have been almost 100 F at that moment. Then once again like 5 hrs after I had taken Tylenol I started getting fever again and this time I got extremely cold also and I was shaking so much and felt so weak I had to lay down and call once again; they told me to have someone take me to their urgent care center and I went there and they retested me for Covid but it was negative this time. Since I had taken Tylenol (2nd time same day, 6 hrs apart) just before I left, my fever was not that high when I showed up there. They told me studies have showed some people experience similar symptoms but when they get the 2nd not the 1st dose; however, they thought it could happen too. I had fever nonstop for almost 48 hrs; it was so high (101.7- highest reached). The rest of the time?at night when I was trying to sleep, obviously I could not take my temperature, I was half awake, half sleep hallucinating, shaking, cold, then hot and sweating a lot and speaking non sense in my sleep (according to my spouse)- this happened both nights. On Dec 26 I woke up feeling not great but definitely better but had a little headache and still felt somewhat nauseated. My last dose of Tylenol I took at 8 pm on Dec 25. I have been feeling better for the past two days but I still feel a little bit tired and not back to my normal self.

bells palsy; This is a spontaneous report from a Pfizer-sponsored program. A Consumer reported for herself. A 75-years-old female patient received bnt162b2 (BNT162B2) vaccine , via an unspecified route of administration on an unspecified date at single dose for covid-19 immunisation . The patient medical history and concomitant medications were not reported. The patient previously took mercury and experienced drug hypersensitivity. The patient experienced Bells palsy on an unspecified date with outcome of unknown. The patient is wondering if Bells palsy may be an adverse reaction to the vaccine. Information on the lot/batch number has been requested.

Low grade fever; fast heart rate; she sweated so much; she has body aches still; This is a spontaneous report from a contactable nurse (patient). This 25-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), (Batch/lot number: EH9899) via an unspecified route of administration on 20Dec2020 10:00 at single dose for COVID-19 immunization. There were no medical history and concomitant medications. Patient took COVID vaccine because she was exposure in hospital. Patient said she experienced reaction from the first dose of COVID vaccine. The patient got the first dose of vaccine by injection once on 20Dec2020, later clarified as COVID vaccine, and overnight she had a low grade fever on 20Dec2020, and she checked her heart rate from her Watch, and it said 108 to

like low 100s, stated not her usual resting heart rate, and she woke at 4AM and felt a fast heartbeat, other than that, she thought it was from fever. Low grade fever was right before going to bed around 10PM: she had body aches, headache, she was not feeling well, she was very hot, At 4AM, she thought to sleep it off, as her whole body ached, and she couldn't really move, and she looked at her Watch to check and her heart rate was 103 resting, and she didn't take her temperature again, but she sweated so much, and she turned down the temperature and as of today, she has body aches still, and a little bit of fast heart rate. Outcome of the events was unknown. Reporter seriousness for Low grade fever and fast heart rate was medically significant. Primary Source Reporter assessed Low grade fever and fast heart rate related by Method.; Sender's Comments: A causal association between BNT162B2 and the events pyrexia and heart rate increased cannot be excluded based on temporal association. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

Severe sore throat and tonsillitis, head ache

Vomit; Coughing; Felt like Throat was itchy; This is a spontaneous report from a Non-contactable Nurse. A 41-years-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (lot number: EH9899) intramuscular on Left arm on 21Dec2020 16:30 at single dose for COVID-19 immunization. Medical history included allergies to medications, food, or other products. There were no concomitant medications. The patient did not receive any other medications within 2 weeks of vaccination. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. On 21Dec2020, 10 minutes after the vaccine the patient began to vomit, felt like throat was itchy, and began coughing. Events resulted that she was taken to the ER (Emergency room). She received Epinephrine, Dexamethasone as treatment for events. Events outcome was recovered on 21Dec2020. No follow-up attempts are possible. No further information is expected.; Sender's Comments: A causal association between BNT162B2 and the reported events vomiting, cough, and itchy throat cannot be excluded based on a compatible temporal relation. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

"lost vision and had intense cold sweats for about 2 minutes; Vasovagal response; had intense cold sweats for about 2 minutes until blood flow returned to normal in upper body; This is a spontaneous report from a contactable healthcare professional, the patient. A 36-year-old non-pregnant female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot Number: EK5730), via an unspecified route of administration in the right arm on 16Dec2020 at 09:30 as a single dose for COVID-19 immunization. Medical history included polycystic ovaries syndrome with diabetes, depression, anxiety, attention deficit hyperactivity disorder, iron deficiency anaemia, and vasovagal issues. Prior to the vaccination, the patient was not diagnosed with COVID-19. The patient's received unspecified concomitant medications within 2 weeks of the vaccination. The patient did not receive any

other vaccines within four weeks prior to the vaccination. On 16Dec2020 at 10:00 AM, the patient lost vision and had vasovagal response and intense cold sweats for about 2 minutes until blood flow returned to normal in upper body. The clinical course was as follows: The patient had a vasovagal response 30 minutes after the vaccine and had to lie down. She lost vision and had intense cold sweats for about 2 minutes until blood flow returned to normal in upper body. The entire episode lasted approximately 30 minutes. She felt it coming and knew to sit down so she would not ""black out."" She was unable to elevate her feet above her heart at the time; however, she was able to walk and stand afterward without dizziness. The patient did not receive any treatment. The clinical outcome of the vasovagal response, lost vision, and cold sweats were recovered on 16Dec2020. It was also reported that since the vaccination, the patient had not been tested for COVID-19.; Sender's Comments: The reported vasovagal response with cold sweats and transient visual loss was possibly related to the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE) due to temporal relationship. However, it is worth noting that the patient had medical history including vasovagal issues. The case will be reassessed should additional information become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate."

Arm soreness, 18 hours after vaccine with SOB, CP, fever 99. took Ibuprofen. Numbness to left side of face and hand approx. 36 hours post vaccine, that resolved in 10 hours approx. 48 hours after the vaccine. Lung pain resolved within 72 hours of the vaccine

broke out in hives on face and hoarseness, tightness in throat; broke out in hives on face and hoarseness, tightness in throat; broke out in hives on face and hoarseness, tightness in throat; throat pain, coughing; throat pain, coughing; This is a spontaneous report from a contactable Other HCP. This Other HCP reported for self that the 57-year-old female patient received fist dose of bnt162b2 (BNT162B2, Brand Pfizer), via unknown route of administration in Left arm on 21Dec2020 12:00 PM at single dose for covid-19 immunisation. Medical history included Known allergies to medications, food, or other products: Azithromycin Flushing, Spinach-anaphylaxis, mild allergic reactions to the Ocrevus, azure and Seasonal allergies, Multiple Sclerosis, Irritable bowel syndrome (IBS-C), post herpactic neuralgia. Concomitant medications included other medications the patient received within 2 weeks of vaccination baclophen, clozapine (KLOPIN), ocrelizumab (OCREVUS), sertraline, cetirizine hydrochloride (ZYRTEC [CETIRIZINE HYDROCHLORIDE]), mo. She is not pregnant at the time of vaccination. Facility type vaccine was Hospital. No other vaccine in four weeks. The patient experienced within 15 to twenty minutes of vaccine, broke out in hives on face and hoarseness, tightness in throat then sent to ED where hives continued to form on back the arms, throat pain, coughing, hoarseness increased from 21Dec2020 12:15 AM. AE resulted in: [Emergency room/department or urgent care]. Outcome of the events was unknown. Treatment received included Epinephrine, solumedrol, Benadryl IV. No covid prior vaccination. Covid tested post vaccination. Covid test post vaccination: covid test type post vaccination was Other, covid test name post vaccination was Nasopharyngeal Sofia2 SARS Antigen on 21Dec2020 with result of Negative. Facility where the most recent COVID-19 vaccine was administered was

Hospital. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, has the patient been tested for COVID-19. Test Name was Nasopharyngeal Sofia2 SARS Antigen. Vaccine Facility information available. Information on the lot/batch number has been requested.; Sender's Comments: Based on the close temporal relationship, the association between the reported events with BNT162b2 can not be completely excluded. Medical history of known allergies may have predisposed patient to react this way. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

I elevated heart rate to 159, I was hot, flush, sweating, elevated BP 154/94 which is high for me. I stayed 15 more minutes and everything was back to normal. The next morning I had a headache. By noon, I had vomiting. I went for a COVID 19 test.

Heart racing; Felt flushed and warm; The initial case was missing the following minimum criteria: no adverse event. Upon receipt of follow-up information on 22Dec2020, this case now contains all required information to be considered valid. This is a spontaneous report from two contactable nurses. A 46-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration in right deltoid on 21Dec2020 18:30 at single dose for Covid-19 immunisation. Medical history included Graves disease, hypothyroidism and radiation from an unknown date and unknown if ongoing (all diagnosed about 12 years ago), dental infection (root canal that failed and said she had an infection) and teeth cleaning from an unknown date and unknown if ongoing. Concomitant medication included levothyroxine sodium (SYNTHROID) taking for many years for hypothyroidism, amoxicillin (500 mg tablet) from 21Dec2020 for dental infection. Prior vaccinations within 4 week was none. The patient experienced felt flushed and warm (non-serious) on 21Dec2020, heart racing (medical significant) on 22Dec2020. The patient received the COVID vaccine yesterday (21Dec2020). She called Pfizer Drug Safety yesterday and asked about if she could take amoxicillin with it for a dental infection. She got the vaccine last night (21Dec2020 18:30) and felt a little flushed and warm after receiving it, so they kept her for 15 minutes. Today (22Dec2020), her heart had been racing at 09:00. She was at rest and had not been exercising. Her heat felt like it will beat out of her chest. She had no history of anxiety. She was a little concerned since she got it at around 6pm yesterday and it has been about 18 hours ago. She would like to know if there have been any reports of any elevated heart rates issues occurring the day after. She called her doctor, but he did not have any information. She did start the amoxicillin yesterday before the vaccine. She got a teeth cleaning and had a previous root canal that failed and said she had an infection. She is not symptomatic. They said she needed another one root canal and crown. It is encapsulated and is not causing any issues, but it could down the line. Regarding the feeling warm and flushed, she said the room was warm and there were a lot of people in it, even though they were socially distanced. She said there was just some angst in the room. She did not have a history of getting anxiety. There was also no Air Conditioning on in the room. It subsided and she did not feel like it was alarming. At the facility, they were not documenting it. That went away within 15 minutes. Regarding

the racing heart, she does not know how long it could go on. She did have thyroid issues. She had not done thyroid labs. It could be her thyroid meds too. She took her Synthroid first thing when she woke up so it could be that too. She did not have a lot or expiration to provide. No emergency room or physician's office required. The outcome of felt a little flushed and warm was recovered on 21Dec2020 at 18:45, heart racing was not recovered. Information about lot and batch was requested.; Sender's Comments: The reported information is limited. Based on the close temporal relationship and the description of the events, there is a reasonable possibility that the events are related to BNT162 vaccine.The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

10:30am - Received the Vaccine Shot 11:30am- Warmth throughout face, then right had went all tingly, then numb and swollen. The numbness crept up the arm to the elbow. Then the nose started to get tingly and numb followed by the lips and gums. 12:00pm - Started to not be able to speak a sentence. The words were coming out of my moth very jumbled even though in my mind I knew what I was trying to say. Still numb in right hand, and on right side of face. 12:10 pm- Could not see fully out of the right peripheral of my eye as well to the other symptoms of not being able to speak a full sentence. I was able to speak less words than I had about 10 min prior. Numbness in my hand went away at this time. 1:15pm- I was able to speak mostly full sentences again. I got a pounding headache on the front to left side of my head and felt fatigues. 1:40pm- Finally able to speak full sentences again, I could feel my hand and all the parts of my face. Felt weak, still had headache and felt nauseous and dizzy. 2:15pm- Took 1 advil, fell asleep 4:00pm- Woke up, felt weak, disoriented, still had a headache. 8:00pm- Only a small headache left and a sore arm

Migraine; This is a spontaneous report from a contactable Other HCP reported for self. This 48-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 20Dec2020 via intramuscular at single dose (Lot # EH9899) for Covid 19 vaccine. None medical history and concomitant medications included. She got the first Covid 19 vaccine yesterday (20Dec2020) and got migraine one hour after on 20Dec2020. Stated that it has not gone away. Was not sure if specific course of action for headache since it did not occur until after 15 minutes. Outcome of the event was not recovered. Event assessed as serious (Other medically important condition).; Sender's Comments: The reported migraine was possibly related to the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE) due to temporal relationship. The case will be reassessed should additional information become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Reporting on behalf of patient. He self reported to the Medication Safety Coordinator, that he was woken up from his sleep the night after receiving the vaccination, with his jaw moving side to side

uncontrollably. This lasted for a couple seconds, would stop, and then would happen again. This occurred about 3 times total. He also felt twitching in his forehead a couple times. These episodes self resolved and did not happen again.

"pancreatitis; acute lower abdominal pain; This is a spontaneous report from a contactable pharmacist. A 46-year-old non-pregnant female patient received the first dose of the bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot Number: EJ1685), intramuscularly on 18Dec2020 at 08:00 (as reported) at 46-years-old at a single dose for COVID-19 immunisation. The patient medical history was not reported. The patient had no known drug allergy (NKDA). Concomitant medications included acetaminophen (MANUFACTURER UNKNOWN), propranolol (MANUFACTURER UNKNOWN), sertraline hcl (MANUFACTURER UNKNOWN), sertraline hydrochloride (ZOLOFT); all taken for an unspecified indication from an unspecified date to an unspecified date (which were received within two weeks of vaccination). On 18Dec2020 at 17:00, the patient experienced pancreatitis and acute lower abdominal pain; which required hospitalization and were assessed as medically significant. The patient was hospitalized for pancreatitis and acute lower abdominal pain for 3 days on unspecified dates. The clinical course was reported as follows: The patient received the vaccine "" at some point in the AM on 18Dec2020 (as reported)."" That evening, the patient presented to the emergency department (ED) with acute lower abdominal pain. The patient was diagnosed with pancreatitis and was admitted overnight. It was unknown if the patient received any other vaccines within four weeks prior to the COVID vaccine. Prior to the vaccination, it was unknown if the patient was diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. Therapeutic measures were taken as a result of pancreatitis and acute lower abdominal pain. The clinical outcome of the events was recovering.; Sender's Comments: The information currently provided is too limited to make a meaningful medical assessment. Other than a temporal association , there is no evidence or argument to suggest a causal relationship between BNT162B2 and the events pancreatitis and acute lower abdominal pain. The events are likely due to an underlying medical condition. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate."

Extreme fatigue, muscle weakness

Developed vomiting, four to five times; Diarrhea; Abdominal pain; Slightly flushed face and minimum facial flowing; Numb ears/Numb body; Bleeding; Anaphylaxis; This is a spontaneous report from a contactable consumer. A 43-year-old female patient received bnt162b2, via an unspecified route of administration on 19Dec2020 at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced anaphylaxis on 20Dec2020. Clinical course: the patient received the COVID vaccine on 19Dec2020, and since then she had developed onset of vomiting after 3 o' clock this morning on 20Dec2020, four to five times, numb ears, numb body. She also had diarrhea and bleeding. She had some abdominal pain and she also complained of having slightly flushed face and the minimum facial flowing. The outcome of events was unknown. Information for Lot/Batch number has been requested.; Sender's Comments: There is a reasonable

possibility that the event anaphylaxis was related to BNT162b2 based on known drug safety profile. Based on the close temporal relationship, the association between the event bleeding with BNT162b2 can not be completely excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

She gained some weight and she thinks she was told she was 84 or 86 kg at the clinic. She weighs about 175 pounds; An EKG was done and she was told she had a prolonged qt interval; Her blood pressure went really high to 177/110; This is a spontaneous report from a contactable consumer. This consumer [patient] reported that the 48-year-old female patient received bnt162b2 (BNT162B2, Batch/lot number: EK5730), via intramuscular injection in left upper arm on 19Dec2020 07:30 am at single dose for covid-19 immunisation (Preventative). Medical history and concomitant medications were none. She got the Pfizer Biontech covid vaccine on the 19Dec. She was sent over to ER from the (clinic name) since her blood pressure went really high to 177/110 on 19Dec2020. Her blood pressure stayed around 170/100 and then she would rest for 10-15 minutes, the ER kept her there till her blood pressure went to about 144 or 150 and then she went home. She confirmed she was not admitted. She was told to go back to the ER if her blood pressure went up. An EKG was done and she was told she had a prolonged qt interval on 19Dec2020. She has not had an EKG since and was told to follow up with her doctor. Treatment: declines any, they just monitored her. When querying weight, states she knows she gained some weight and she thinks she was told she was 84 or 86 kg at the clinic. She weighs about 175 pounds. Reports she had some blood work done at the ER and it came back normal. She does not have any health conditions. She has an allergy to Cipro and fexofenadine. Vaccination Facility Type was Hospital. No Vaccine Administered at Facility. History of all previous immunization with the Pfizer vaccine considered as suspect (or patient age at first and subsequent immunizations if dates of birth or immunizations are not available was none. Additional Vaccines Administered on Same Date of the Pfizer Suspect was none. AE(s) required a visit to Emergency Room. No Physician Office. Prior Vaccinations (within 4 weeks) was none. AE(s) following prior vaccinations was None. The outcome of the events was unknown.

Redness, swelling and mild itching at injection site.

"sudden rapid slightly irregular heartbeat; My pulse rate was in 148 and remained in the 140's/rapid heartbeat; associated nausea; This is a spontaneous report from a contactable nurse. This nurse (patient) reported that the 45-year-old female patient received first dose of bnt162b2 (BNT162B2, Covid-19 Vaccine), on Arm left on 19Dec2020 09:30AM at single dose for covid-19 immunisation. She is not pregnant at the time of vaccination. Medical history was none. Known allergies was none. Allergies to medications, food, or other products was none. Concomitant medications were none. Facility type vaccine was other. No other vaccine in four weeks. Other medications in two weeks was none. The patient experienced ""I had just received the vaccination was pulling into the area where you sit and wait in case you have an adverse reaction, was just looking at my phone and felt a sudden rapid slightly irregular heartbeat. Came on very suddenly with associated nausea I am a ER nurse with 22 years

experience and so I began to take my pulse and record it with my phone, I wasn't sure if it was a reaction because I didn't fell like I "" couldn't breathe"" . Just a very rapid heartbeat. My pulse rate was in 148 and remained in the 140's. I beeped my horn on my car in case it was an adverse reaction. They placed a pulse ox on my finger and my heart rate then was 138 and O2 sats 98% . I sat for a bit and then it just went away. My heart rate was back down to the 70's."" The events started from 19Dec2020 09:30 AM and outcome of the events was recoverd. No treatment was received. No covid prior vaccination. No covid tested post vaccination. Facility where the most recent COVID-19 vaccine was administered was Other. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. List of any other medications the patient received within 2 weeks of vaccination was none. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. Vaccine Facility information available. Location of injection information is available for all vaccines received on the same date. Information on the lot/batch number has been requested.; Sender's Comments: A causal association between BNT162B2 and the reported events heart rate irregular, heart rate increased, and nausea cannot be excluded based on a compatible temporal relation. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate."

left eye is getting puffy after receiving COVID-19 Vaccine today; left eye is getting itchy after receiving COVID-19 Vaccine today; This is a spontaneous report from a contactable healthcare professional (patient). A 62-year-old female patient received BNT162B2 (COVID-19 mRNA Vaccine BNT162B2), via an unspecified route of administration on 21Dec2020 at a single dose for COVID-19 immunization. The patient's medical history included allergies to a lot of antibiotics. The patient's concomitant medication included Non-specified anti-inflammatory. The patient's left eye was getting puffy and left eye was getting itchy after receiving COVID-19 Vaccine on 21Dec2020. The events were reported as serious, medically significant. She said she is wondering if her left eye getting puffy and itchy is an allergic reaction and if she needs to seek treatment. Reported she did not have a prescription for the COVID-19 Vaccine. Reported her left eye being puffy and itchy has not gotten worse, but her left eye has not improved. Declined any treatment as she thought if she called Pfizer, Pfizer could tell her if she should get treatment. Reported she took an anti-inflammatory twice in the past 2 weeks, clarifying the last time she took the anti-inflammatory was over 4 days ago. The outcome of the events was not recovered. Information on the Batch/Lot number has been requested.; Sender's Comments: The reported information is limited. Based on the close temporal relationship, there is a reasonable possibility that the events are related to BNT162 vaccine. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

The patient experienced diffuse rash on the upper extremities as well as a scratchy throat 16 hours after vaccination.

Blacked out; Vertigo; Diarrhea; Extreme Fatigue; sicker; This is a spontaneous report from a contactable nurse which is also the patient. A 48-year-old female patient received the first dose in the series of bnt162b2, lot number: EK5730, intramuscular in the left deltoid on 17Dec2020 at a single dose for COVID prevention. There were no medical history and concomitant medications. The patient received her COVID vaccine last Thursday evening, and she has been getting progressively sicker for the past couple of days on an unspecified date in Dec2020. On 20Dec2020, the patient experienced blacked out, vertigo, diarrhea, and extreme fatigue. The patient mentioned that she had extreme fatigue yesterday, with vertigo that started afternoon, and this morning her vertigo was so bad, that she blacked out in the shower, and the room is still spinning for her at this time. Outcome of the events blacked out and sicker was unknown, for the other events was not recovered. The seriousness of events blacked out, vertigo and diarrhea was reported as serious enough that she could not go to work, or get behind the wheel of a car so medically significant. Extreme fatigue was assessed as non-serious. The reported assessed the events extreme fatigue, vertigo, blacked out, and diarrhea as related to bnt162b2. The patient added that vertigo was worsened.; Sender's Comments: The reported information is limited. Based on the close temporal relationship and the description of the events, there is a reasonable possibility that the events are related to BNT162 vaccine. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

severe back pain/ back aches; body aches; inflammatory reaction; This is a spontaneous report from a Pfizer-sponsored program IBCC (Inbound Call Center for HCPs). A contactable female nurse (patient) of unknown age reported that she received BNT162B2 (COVID VACCINE), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. Medical history and concomitant medications were not reported. Patient got the Covid vaccine on Thursday (date not specified). She was taking ibuprofen (MOTRIN) (later clarified as ibuprofen) for anti-inflammatory. She went to a doctor visit yesterday (18Dec2020), and then her doctor told her that because ibuprofen was an anti-inflammatory, she shouldn't be taking it during, right after the vaccine because of inflammatory reaction and so patient stopped taking it and switched over to paracetamol (TYLENOL), now she was in severe back pain/ back aches and body aches, but anyways she was just going to end up taking it if this took much longer. Outcome of the events was unknown. Information about lot/batch number has been requested.; Sender's Comments: From the information provided it is unclear which event is the intended subject of this spontaneous report and what is the reporter's perceived relationship to the vaccine. In addition, the lack of critical information (e.g. immunization date) makes a global medical assessment impossible. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

Patient experienced HA and dizziness approximately 40 minutes after vaccination. Patient was monitored to have diaphoresis with slightly elevated BP ranging from 138/72- 142/88 with HR98. Patient was monitored while standing and had no changes with dizziness but had an elevated HR of 114 with BP 131/84. After sitting again patient's BP 129/81 and HR went down to 88.

hypertension; tired; Headache; This is a spontaneous report from contactable nurse, the patient. A 52-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot Number: EK5730), via an unspecified route of administration on 19Dec2020 as a single dose for COVID-19 immunization. Ongoing medical history included hypothyroidism. Other relevant medical history included anxiety and menopause. Ongoing concomitant medications included estradiol (MANUFACTURER UNKNOWN) taken for menopause, progesterone (MANUFACTURER UNKNOWN) taken for menopause, and venlafaxine hydrochloride (EFFEXOR) taken for anxiety. On 19Dec2020 at 18:00, the patient had a headache. On 20Dec2020, the patient experienced hypertension and was tired. The clinical course was as follows: the patient received her vaccine on 19Dec2020. At 18:00 on 19Dec2020, she started with a headache, and it was not a big deal. In the morning of 20Dec2020, her headache was bad, and then her blood pressure was 180/100. She had a headache and she was tired. She mentioned her baseline was 115/84. She had no coffee or anything, and as the day went by it was 140/90. She reported that the hypertension basically lasted for one day and in the morning of 21Dec2020 it was 120/88. As of 21Dec2020, she did not have a headache. The clinical outcomes of the hypertension and headache were recovered on unknown dates in Dec2020; while that of the tiredness was unknown. The patient assessed the hypertension and headache as serious for being medically significant and related to the vaccine; however, the seriousness and causality assessment were not provided for the tiredness.; Sender's Comments: A causal association between BNT162B2 and the events hypertension and headache cannot be excluded based on a compatible temporal relation. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

The patient felt very hot around 15 min post vaccine, felt anxious. Felt her HR was racing, Watch said it was 103. Let the RN know and HR was then measured at 125 bpm. BP was 140 which is high for the patient (baseline around 100 systolic). She felt shaky. The RN said she saw a few hives on her chest and it was a bit itchy. They gave her some water and juice. She felt better and the hives resolved on their own. She then was given Zyrtec. Her HR is 85 when I spoke to her, 30 min post vaccine, and BP is 130 systolic. No wheezing, no SOB, O2 sat was normal the entire time. She still felt shaky and anxious. Called 2 hours after vaccine administration and she felt normal.

itching really bad; This is a spontaneous report from a contactable pharmacist. A 43-year-old female patient received the first dose of the bnt162b2 (BNT162B2; PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot Number: EH9899 and Expiration Date: Mar2021), intramuscularly on 17Dec2020 at 43-years-old at 0.3 mL, single for COVID-19 immunization. The vaccination was administered in a hospital. There was no history of previous immunizations with a Pfizer vaccine considered as suspect; and there were no additional vaccines administered on the same date of the Pfizer suspect; and there were no

prior vaccinations (within 4 weeks). It was unknown if the patient had adverse events (AEs) following prior vaccinations. Medical history included obesity from an unknown date and unknown if ongoing, hay fever from an unknown date and unknown if ongoing. There was no family medical history relevant to the AEs. Concomitant medications included desvenlafaxine succinate (PRISTIQ) taken for an unspecified indication from an unspecified date to ongoing, metoprolol (MANUFACTURER UNKNOWN) taken for an unspecified indication from an unspecified date to ongoing, montelukast sodium (SINGULAIR) taken for hay fever from an unspecified date to an unspecified date, omeprazole (PROTONIX [OMEPRAZOLE]) taken for an unspecified indication from an unspecified date to ongoing. On 17Dec2020, the patient experienced: itching really bad; which was assessed as medically significant. There were no visits to an emergency room or a physician office as a result of the events. The clinical course was reported as follows: The patient started itching really bad within five minutes of receiving the vaccine. The patient was given a shot of diphenhydramine hydrochloride (BENADRYL) and the itching stopped. This was the patient's first dose of COVID vaccine. It was unknown to the reporter if the patient would continue the vaccine series. Therapeutic measures were taken as a result of itching really bad (pruritus). The clinical outcome of the event, itching really bad, was recovered on 17Dec2020. The causality assessment from the Primary Source Reporter was reported as related; via the Method of assessment.; Sender's Comments: A causal association between BNT162B2 and the event pruritus cannot be excluded based on a compatible temporal relation. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

Approximately 4 hours after vaccine, noted hives/welts on arms, took cetirizine. Went to bed. ~8pm (4 hours later) was very itchy, swollen, discolored face, face felt cold/body hot. No difficulty breathing. Lips purplish, arms swollen. Went to ED. Given benadryl, 2 other pills, watched for 30 minutes. No epinephrine. Hives improved, released, had headache. Next day improved, but still mild headache and groggy. Hives gone completely 48 hours. Mild headache persists. No prior experience like this.

profound dizziness; This is a spontaneous report from a contactable nurse. A 54-year-old female patient received BNT162B2 (lot number: EK5730), intramuscular at the right arm on 17Dec2020 18:00 at 0.3 mL for COVID-19 immunization at a hospital. There were no medical history and concomitant medications. The patient experienced which she described as bizarre side effect of profound dizziness, almost like vertigo, states she was having to hold onto a wall, considered medically significant by the reporter on 20Dec2020 12:00. The patient recovered from the event on 21Dec2020, 10:00.; Sender's Comments: Based on temporal association, the causal relationship between BNT162B2 and the event dizziness cannot be excluded. This case will be reassessed once additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate.

Experiencing some stool that had a little bit of blood and kind of mucus; Experiencing some stool that had a little bit of blood and kind of mucus; This is a spontaneous report from a contactable consumer. A patient of unspecified age and gender received first dose of BNT162B2 via an unspecified route of administration on 18Dec2020 at single dose for COVID-19 immunization. The patient medical history was not reported. The patient's concomitant medications were not reported. This past Friday, so on the 18Dec2020 got the first shot of the COVID 19 Vaccine and starting yesterday (19Dec2020), the patient started experiencing some stool that had a little bit of blood and kind of mucus. So, patient just wanted to know if that is a side effect of the vaccine that could happen or if anyone else have also reported symptoms like that. Events outcome was unknown. Information about lot/batch number has been requested.

freezing and could not get warm; shaking; sick; Chills; tired; lightheadedness; Redness at injection site; Believe the vaccine was given subcutaneous; This is a spontaneous report from a contactable nurse (patient). A 56-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) lot number: EH9899 and expiration date: Mar2021, via subcutaneous route in the back of right arm where the fatty area far away from deltoid, first dose on 17Dec2020 18:15 at a single dose for routine vaccination. The patient's relevant medical history was none. There were no concomitant medications. The reporting nurse was reporting for herself for the covid vaccine. She received the vaccine and believed it was administered subcutaneously versus in her deltoid muscle on 17Dec2020. She had redness at injection site on 18Dec2020. She also reported chills, lightheadedness and was tired on 18Dec2020. She added that the symptoms did not happen until after Friday night (18Dec2020). She doesn't think she could have continued working as sick as she was that night. She did not know if it was medically significant though. She went between not serious and medically significant and then stated she guessed it would be medically significant. She was freezing and could not get warm and was shaking. She did not notice the redness until Friday night around 3pm. The redness has improved, but it was still there. Unknown time for when it first started, but the first that she noticed it was around 3pm. Lightheadedness started around 1pm on 18Dec2020. The tiredness started around 3pm on 18Dec2020. The chill started around 7pm on 18Dec2020. They all improved by Saturday, 19Dec2020. Part of this report is that the doctor said it was in her triceps muscle and she does not think it was. They pinched the skin and put it in. She said her muscle was not sore. As a nurse, she believed it was not in her triceps area. It was not in the deltoid area and that was suggested from Pfizer. The reporting nurse's seriousness for 'believe the vaccine was given subcutaneous' was medically significant, while non-serious for 'Redness at injection site'. The patient had no ER nor physician visit required; she had no prior vaccines within 4 weeks. The patient does not have a positive test for SARS-CoV2. She does not have SARS-CoV2 antibodies at diagnosis as she has had blood test a couple of months ago, either end of Oct2020 or beginning of Nov2020, and there were No antibodies at that time. The patient was not hospitalized nor was she admitted to an Intensive Care Unit (ICU). The patient did not display clinical signs at rest indicative of severe systemic illness. She did not have supplemental oxygen (including high flow or ECMO) nor received mechanical ventilation. She did not receive any additional therapies for COVID-19. The events did not require the initiation of new medication nor other treatment or procedure. The outcome of the events chills, lightheadedness, tired and Redness at injection was recovering while unknown for believe the vaccine was given subcutaneous, freezing and could not get

warm, shaking, and sick.; Sender's Comments: The reported information is limited. Based on the close temporal relationship and the description of the events, there is a reasonable possibility that the events are related to BNT162 vaccine. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

itching; tingly feeling; face appeared more flushed; slight shortness of breath; This is a spontaneous report from a contactable pharmacist. A 63-years-old female patient received 1st dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot# EK5730), intramuscularly in right arm on 18Dec2020 14:30 at single dose for Covid-19 immunisation. Medical history included allergic reactions (allergies to medications, food, or other products: Yes, numerous). No other vaccines administered in four weeks. Other medications in two weeks was numerous. Approximately 10-15 minutes after receiving COVID-19 vaccine (18Dec2020 14:45), patient reported itching, tingly feeling, face appeared more flushed. Seemed anxious due to history of allergic reactions and reported slight shortness of breath. Treated with diphenhydramine 50 mg PO and epinephrine 0.5 mg IM and transported to Emergency Department. Observed in that area and released a few hours later as symptoms resolved. The outcome of events was recovered on 18Dec2020.; Sender's Comments: A causal association between BNT162B2 and the events pruritus, paraesthesia, flushing, and dyspnea cannot be excluded based on a compatible temporal relation. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

Nausea and lightheadedness began about 20 minutes after administration. Lightheadedness abated after about 1 hour, nausea intensified and persisted, abated after about 26 hours. Fatigue began about 2 hours after administration. Fatigue abated after 24 hours. Severe headache (migraine) began about 2 hours after administration, still persists at 28 hours mark. Injection site tenderness, swelling and redness (2-inch diameter, bright red) noted about 8 hours after administration, tenderness persists, redness beginning to abate at 28 hours.

Face swell, Heart rate 108, Blood pressure 133/87, pregnant 35 weeks

Admitted to the hospital with hypertensive basal ganglia bleed, had a head bleed; This is a spontaneous report from a contactable consumer. A male patient of unspecified age received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration in 2020 at single dose for COVID-19 immunization. Medical history included hypertension. The patient's concomitant medications were not reported. After vaccination, the patient was admitted to the hospital with hypertensive basal ganglia bleed, had a head bleed in 2020. The outcome of event was unknown. Information on the lot/batch number has been requested.

Redness around injection site, swollen, hardness at site, fatigue, hot/cold spells, chills.

resp distress; This is a spontaneous report from a non-contactable consumer (patient). An elderly male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration at 16Dec2020 12:00 pm at single dose for covid-19 immunization. Vaccine location was right arm and it was the first dose. The patient medical history and concomitant medications were not reported. No known allergies. Patient was not diagnosed with COVID-19 prior to vaccination. The patient didn't receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient experienced respiratory distress on 19Dec2020, he was hospitalized for three days. Patient received treatment for the adverse event. Since the vaccination, the patient has been tested for COVID-19 with nasal swab on 19Dec2020, it was negative. The action taken in response to the events for BNT162B2 was not applicable. The outcome of events was unknown. The event was serious, the seriousness criteria was Caused/prolonged hospitalization. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

late Friday had sneezing, mild coughing, scratching throat, mild body ache, headache. Still have same symptoms.

blood pressure shot up to 205/112/blood pressure went down to 136/75; head hurt; couldn't hear that well; pulse 137; a heat wave go through her body up to her head; red rash and hives; red rash and hives; This is a spontaneous report from a contactable other healthcare professional (Patient). A 62-year-old female patient (not pregnant) received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, lot number and expiration date not provided), via an unspecified route of administration on 21Dec2020 16:00 at single dose for COVID-19 immunization, vaccine location provided as Left arm. Medical history included Penicillin allergy. The patient's concomitant medications were not reported. After about 10 minutes receiving the vaccine on 21Dec2020 16:15, the patient felt a heat wave go through her body up to her head, couldn't hear that well and head hurt. Her blood pressure shot up to 205/112, pulse 137, red rash and hives. The patient was transported via parametics to the Emergency Room for observation. Her blood pressure went down to 136/75. No treatment was received for all the event. The outcome of the events was recovered on 21Dec2020. Information on the Lot/Batch number has been requested.; Sender's Comments: A causal association between BNT162B2 and the event blood pressure increased cannot be excluded based on a compatible temporal relation. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

Patient evaluated and monitored following vaccine. Developed nausea and lightheadedness approximately 20 minutes after dose given. Patient reports that she hadn't had anything to eat or much to drink in the hours leading up to vaccine as she and her husband were going to get lunch after the vaccination appointment. Patient has a history of syncope/presyncope after a blood draw in the past. Patient had no other stx other than very transient nausea and lightheadedness, which improved significantly in the hour that she was monitored. BP at time of discharge from clinic was 105/73; pulse 67

Pfizer. Only upper lip swelled slightly (noted by coworkers as well) for about 24 hours. Of note, I had Juvaderm filler to the upper lip only late January 2020.

elevated blood pressure/ elevation in blood pressure/ Highest BP 195/93 ranging 180s/90s/ Final BP 155/93; foggy headed/ less foggy; felt flushed/ feeling flushed; metallic taste in mouth; This is a spontaneous report from a contactable pharmacist. A 63-year-old female patient (not pregnant at the time of vaccination) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL0140), intramuscularly on 21Dec2020 15:30 at single dose on right arm for COVID-19 immunization. Medical history included Allergies to medications, food, or other products: IVP Dye, red ants. Concomitant medications received within 2 weeks of vaccination included celecoxib (CELEXA [CELECOXIB]) and atorvastatin calcium (STATIN [ATORVASTATIN CALCIUM]). The most recent COVID-19 vaccine was administered in Workplace clinic. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. On 21Dec2020 15:45, Initially patient felt flushed and foggy headed then developed metallic taste in mouth and elevated blood pressure, required extended monitoring period with continued elevation in blood pressure. Heart rate and respiratory rate stable, no respiratory distress noted. Highest BP 195/93 ranging 180s/90s, however denied need to be seen in ED. Final BP 155/93, less foggy, no dizziness or lightheadedness; feeling flushed remained. Total monitoring time: 83 mins, without significant distress. No treatment was received for the adverse events. The reporter reported the seriousness was no. It was unknown prior to vaccination, if the patient was diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. The outcome of the events was recovered (pending clarification) in Dec2020.; Sender's Comments: A causal association between BNT162B2 and the event blood pressure increased and foggy feeling in head cannot be excluded based on a compatible temporal relation. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

About 7 minutes into my observation period my heart rate rose to 170 bpm and I felt warm and shaky. It took around 15 minutes to return to 70-80; About 7 minutes into my observation period my heart rate rose to 170 bpm and I felt warm and shaky. It took around 15 minutes to return to 70-80; About 7 minutes into my observation period my heart rate rose to 170 bpm and I felt warm and shaky. It took around 15 minutes to return to 70-80; This is a spontaneous report from a contactable nurse (patient). A 36-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration at first dose right arm on 21Dec2020 11:45 am at single dose for covid-19 immunization. The patient medical history and concomitant medications were not reported. The patient previously took Zithromax and morphine both cause nausea and vomiting. Patient was not diagnosed with COVID-19 prior to vaccination nor tested for COVID-19 since the vaccination. The patient didn't receive any other vaccines within 4 weeks prior to the COVID vaccine nor received any other medications within 2 weeks of vaccination. About 7 minutes into patient's observation period, at 21Dec2020 11:45 am, her heart rate rose to 170 bpm and she felt warm and shaky. It took around 15 minutes to return to 70-80. Patient didn't receive treatment for the adverse events. The action taken in

response to the events for BNT162B2 was not applicable. The outcome of events was recovered. The events were non-serious.; Sender's Comments: A causal association between BNT162B2 and the event heart rate increased cannot be excluded based on a compatible temporal relation. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

A day after having the vaccine, I experienced eye soreness in my right eye. The next morning both my eyes were blood shot. I administered eye drops and went on about my day. Late that evening they were really red and watery and my vision was blurred. I went to the optometrist on Monday morning and was diagnosed with Primary iridocyclitis, bilateral. My iris had been attached to my lens from the inflammation, but had detached it self. I was put on steroid drops and made to keep my eyes dilated until my follow up appointment. Went to my follow up appointment today December 28, 2020. My eyes are looking better, but not back to normal yet. Advised to keep administering my steroids drops and only use the dilation drops every other day. I will follow up on Thursday.

New diagnosis of diabetes 5 days after receiving vaccine with no past medical of DM and no family history.; This is a spontaneous report from a contactable Nurse (patient). A 31-year-old female non-pregnant patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number=EJ1685), via an unspecified route of administration on 18Dec2020 14:00 at arm left at single dose for covid-19 immunization. The COVID-19 vaccine was administered at Hospital. Medical history included asthma and hypertension. The patient had no known drug allergies. Concomitant medication included cetirizine, budesonide, formoterol fumarate (SYMBICORT), escitalopram oxalate (LEXAPRO), montelukast and omalizumab (XOLAIR). No other vaccine in four weeks prior to the COVID vaccine. The patient experienced new diagnosis of diabetes 5 days after receiving vaccine with no past medical of diabetes mellitus and no family history. The event result in doctor or other healthcare professional office/clinic visit and Emergency room/department or urgent care. Adverse event start date was 19Dec2020 06:00 AM. Treatment received included fluid bolus, computerized tomogram (CT) scan and labs. The patient underwent lab tests and procedures which included computerized tomogram and laboratory test with unknown results on Dec2020. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, the patient was not been tested for COVID-19. The outcome of the event was recovered with lasting effects.; Sender's Comments: The reported diabetes was unlikely causally related to the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), considering the latency of the onset of the event. A possibility that the vaccination unmarked subject's diabetes cannot be completely excluded. The case will be reassessed should additional information become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Nurse that fainted after the vaccine; This is a spontaneous report from a Pfizer sponsored program received from a non-contactable consumer. A patient of unspecified age and gender received BNT162B2 Pfizer-BioNTech COVID-19 Vaccine, via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. It was reported that the patient was a nurse who received the vaccine and did a live press conference on TV 15 minutes later and, as a result, she fainted. The event outcome was not reported. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

Tightness in chest; This is a spontaneous report from a contactable nurse (patient). A 61-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (Batch/lot number EH9899), intramuscular on 15Dec2020 14:35 in left deltoid at single dose for covid-19 immunization. The patient medical history and concomitant medications were not reported. The patient states that she is on day 7 today, and yesterday, 21Dec2020, she woke up with tightness in her chest, like someone had wringed her rib cage. She states that she wakes up tightness in her chest again this morning 22Dec2020, patient states that as the day continues, it gets a little better. The action taken in response to the event for bnt162b2 was not applicable. The outcome of event was reported as not recovered. The event was reported as serious and seriousness criteria was other medically important condition.; Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of event Tightness in chest cannot be excluded. The case will be reassessed if additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Severe headache and mild nausea started ~ 3 hours after injection. Joint pain and muscle aches started ~6 hours after injection. 1000 mg of Tylenol taken twice over the next 24 hours with some relief. Work was missed the day following injection due to inability to perform daily functions. Mild residual muscle aches 2 days after injection (today).

Bell's palsy/facial paralysis; This is a spontaneous report from a contactable other Health Professional (patient). A 28-years-old female patient received first dose BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot/ batch number: 33121, brand: EJ1685), via an unspecified route of administration at left arm on 18Dec2020 09:30 at single dose for covid-19 immunization at hospital. Medical history included anxiety, depression, diagnosed COVID-19 prior vaccination. No known allergies. Concomitant medication included fluoxetine hydrochloride (PROZAC) in two weeks. No other vaccine in four weeks. The patient experienced bell's palsy/facial paralysis on 21Dec2020 19:00 with outcome of not recovered. The seriousness was reported as no. The adverse event result in doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care. The treatment received for the adverse event was reported as unknown.; Sender's Comments: Based on available information, a possible contributory role of the subject vaccine cannot be excluded for the reported event of Bell's palsy due to temporal relationship. However, the reported event may possibly represent intercurrent medical

condition in this patient. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Sore arm x 36 hours. 1 doses of Acetaminophen; 1 dose of Ibuprofen.

Weakness and tingling down left arm; Weakness and tingling down left arm; Lightheaded; PVC's every 3 beats; emotional too and just very tired; Can not read the vaccination card as she does not have her glasses; Palpitations; Fatigue; Slept a lot; Thready pulse and vertigo; Thready pulse and vertigo; Soreness in left arm at the injection site and down the left arm; Soreness in left arm at the injection site and down the left arm; This is a spontaneous report from a contactable nurse (patient). A 54-year-old female patient received first dose bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, reason for no lot number of COVID Vaccine: Can not read the vaccination card as she does not have her glasses, Expiry Date unknown), via an unspecified route of administration in the left arm on 18Dec2020 at single dose for 'Work with COVID patients'. Medical history included none. There were no concomitant medications. The patient experienced weakness and tingling down left arm (hospitalization) on 22Dec2020, lightheaded (hospitalization) on 22Dec2020, PVC's every 3 beats (hospitalization) on 22Dec2020, soreness in left arm at the injection site and down the left arm on 18Dec2020, thready pulse and vertigo on 19Dec2020, fatigue on 20Dec2020, slept a lot on 19Dec2020, palpitations on 21Dec2020. Details as follows: Caller says she received the vaccine, she is a nurse. She got the vaccine on Friday, 18Dec2020. She had soreness in her arm and at the injection site on Friday but that was it. On Saturday (19Dec2020) she noticed a thready pulse, but went on with her day with only a little arm pain. Sunday (20Dec2020) she was fatigued and the thready pulse continued. She slept a lot on Saturday (19Dec2020) and Sunday (20Dec2020). Yesterday (21Dec2020) she felt a little better, but had palpitations here and there. This morning (22Dec2020) she went into work, was very lightheaded, had tingling down her left arm, and had palpitations. So she hooked herself up to a monitor. Her pulse ox was between 97-99%. Her heart rate would be in the 90s and then drop to 48, so she went down to the ED. She has had a CT, and she is throwing PVC's every 3 beets. She has not been admitted as they are still waiting for results. She is still in the ED. They did a CT to see if there was a possible clot. On 18Dec2020 she received the vaccine around 2 PM. She had soreness at the injections site and down the left arm, which went away by Sunday (20Dec2020). She now (22Dec2020) has weakness and tingling down the left arm. It was never red or anything at the injection site. Saturday, 19Dec2020, she had thready pulse and Vertigo which lasted until Sunday 20Dec2020. She would be laying in bed and try to flip to the other side and having vertigo. When the fatigue started on Sunday (20Dec2020) she did not feel like herself. She was very emotional too and just very tired. Since she went to the ED she has had a CT scan, one with contrast and one without. She had a chest X-ray, and she is on a cardiac monitor. Results are pending. She has Trigeminy PVCs. She says she never goes to the hospital. But she is not admitted yet (pending clarification). Can not read the

vaccination card as she does not have her glasses. Unable to read off the NDC, lot, and expiration date. History: Has been on the same vitamins for two years with nothing new. Blood pressure: Normal base line is 130s/80s maybe lower. Heart rate: Currently within her normal limits of 80s-90s. Depending on what happens, it was asked if she should get the second dose. The patient underwent other lab tests and procedures which included blood pressure measurement: 163/76 on 22Dec2020, chest x-ray: unknown result on 22Dec2020 (Result: Pending), computerised tomogram (CT scan): unknown result on 22Dec2020 (Result: Pending), heart rate: 80s-90s on 22Dec2020, Pulse oximetry: 97-99 % on 22Dec2020, cardiac monitor: results are pending on 22Dec2020. The outcome of events weakness and tingling down left arm, pvc's every 3 beats, lightheaded, palpitations and fatigue was not recovered. The outcome of the event soreness in left arm at the injection site and down the left arm was recovered on 20Dec2020. The outcome of the events thready pulse and vertigo was recovered on 20Dec2020. The outcome of the event slept a lot was recovered on 20Dec2020. The outcome of other events was unknown. Information on the lot/Batch number has been requested.; Sender's Comments: Based on available information, a possible contributory role of the subject vaccine cannot be excluded for the reported events due to temporal relationship. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Shortness of breath; fast heart rate with just activity/increased heart rate; This is a spontaneous report from a contactable nurse. A 47-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EJ1685, expiration date: Mar2021), via an unspecified route of administration on 18Dec2020 10:00 at 0.3 mL, single (0.3ml constituted dose) on left deltoid for COVID-19 immunization. Medical history was none. The patient's concomitant medications were not reported. On 20Dec2020, the patient experienced fast heart rate with just activity, Shortness of breath. Reporter seriousness for Shortness of breath was Medically significant. This patient reported shortness of breath that resolved within hours and fast heart rate with just activity. Fast heart rate with just activity: In the morning around 08:00. It had resolved. Shortness of breath: In the morning as well. Resolved by the evening. Vaccination Facility Type was Hospital and Vaccine Administered not At Military Site. There was no additional vaccines administered on same date of Pfizer Suspect that caller was aware of. The adverse events didn't Require A Visit To. Relevant Tests: Did a COVID-19 test and it was negative. Per (website name), patient should not get a second dose. Wanted to know if this was true. Caller further reported that the patient receiving the COVID-19 vaccine experienced shortness of breath and an increased heart rate for a prolonged period, and was now stable. Caller saw recommendation from the (website name) indicating that the patient should not receive the second dose of the vaccine, and wanted to validate the information. The case safety report was considered as non-serious by the reporter in the further reported information. The outcome of the events was recovered on 20Dec2020.; Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a

possible contributory role of the suspect product BNT162B2 to the development of event Shortness of breath cannot be excluded. The case will be reassessed if additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Developed fever and cough on 12/25/20, tested positive for Covid-19 on 12/26/20

"splotchy rash that started on both of her arms; she was not ok, and she felt weird, and stated something feels wrong; she felt dizziness and like she needed to pass out; she felt dizziness and like she needed to pass out; her knees buckled and she lost her balance; her knees buckled and she lost her balance; hyperventilating and couldn't slow her breathing from fear; hyperventilating and couldn't slow her breathing from fear; This is a spontaneous report from a contactable nurse (patient). A 30-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) lot no: EK5730, via an unspecified route of administration in right arm on 21Dec2020 16:30 at a single dose for COVID-19 immunization. Medical history included bilateral mastectomy, total hysterectomy, breast cancer gene 2 (brca 2), ankylosing spondylitis (AS), allergies to penicillins and latex. The patient was not pregnant at the time of report. Concomitant medications included isotretinoin, estrogens conjugated (PREMARIN), cetirizine hydrochloride (ZYRTEC), meloxicam. The patient previously took ciprofloxacin and experienced allergies. On 21Dec2020 at 16:45, the patient reported that she showed a nurse a splotchy rash that started on both of her arms. At that time, she also stated she was not ok, and she felt weird, and stated something feels wrong. Then she said that she felt dizziness and like she needed to pass out. The nurse asked if she could still breathe and she said ""I think so."" They asked her to stand then when she did her knees buckled and she lost her balance and was dizzier and more fell back into the chair she was sitting in. Then they just lift her onto the gurney. On the way to the emergency department, she began hyperventilating and couldn't slow her breathing from fear. Upon arrival she was asked for her name and birthdate and she slowly was able to say it. She was told she was given epinephrine, 2 rounds she thinks for her hives that had showed and her respiration was in the 39-49 range. Then they gave her methylprednisone (reported as ""methypedisone""), famotidine (PEPSID), and steroids, and lorazepam (ATIVAN) to calm her breathing as well as IV fluids. Then she was able to breathe 20-35 rpm. The patient was not diagnosed with COVID-19 prior to vaccination and has not been tested for COVID-19 since the vaccination. The events were reported as non-serious. The patient recovered from the events.; Sender's Comments: The patient had medical history included allergies to penicillins and latex., and to ciprofloxacin. The reported events were probably related to the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), due to temporal relationship. Patient's drug allergy history and nervousness may have played to contribution role to the clinical manifestations. This case will be reassessed should additional information become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics committees and Investigators, as appropriate."

Autoimmune disorder, it just exacerbated when I got the shot; Autoimmune disorder, it just exacerbated when I got the shot; Joint pain; My immune system overreacted and it was like rash all over my body; This is a spontaneous report from a contactable Nurse for herself. A 32-year-old female patient received bnt162b2 (BNT162B2; Lot #EH9899) vaccine, intramuscular on 18Dec2020 at single dose for covid-19 immunisation. The patient medical history included autoimmune disorder. The patient's concomitant medications were not reported. The patient stated that she suffered from unknown autoimmune disorder, and it just exacerbated when she got the shot, and she had like rash all over her body and had joint pain. The patient was treated with steroids.; Sender's Comments: A possible contribution role of BNT162B2 to the aggravated autoimmune disorder, joint pain and rash cannot be excluded. The case will be reassessed should additional information become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

"low grade fever; Her blood pressure was high/ still really high/ blood pressure was up; headache; Fifteen to twenty minutes after she received the vaccine she became light headed and dizzy/ light headedness and dizziness; This is a spontaneous report from a contactable nurse (patient). A 36-year-old female patient received BNT162B2 (Lot#: EK5730) via an unspecified route of administration on 17Dec2020 afternoon at single dose in the left arm for COVID-19 immunization. Caller was unable to confirm the manufacturer of the vaccine that she received. It is not written on the card, and she didn't see the vial. The patient medical history was not reported. Concomitant medications included oral contraception pill, but the name was unknown. Fifteen to twenty minutes after she received the vaccine on 17Dec2020 she became light headed and dizzy. She had to catch her breath. She couldn't shake it off. The light headedness and dizziness lasted at that intensity for 10 minutes, but it never went away. They encouraged her to be admitted in the emergency room (ER). She would say that the seriousness of being light headed and dizzy was disabling. Caller didn't remember the exact numbers for her blood pressure. It was 160's over 105. Her heart rate was in the low 100's, around 105. She stayed at the first monitoring station in the vaccine area for 2 hours. They were taking her blood pressure every five minutes. She was given diphenhydramine hydrochloride (BENADRYL) there and lots of water. After 3 hours and she was not improving they called a ""code medic"" that got the medical director and nursing supervisor to come. They encouraged her to go to the ER for continual monitoring. She stayed in the ER for4 hours and was given meds to help with the blood pressure. She was discharged from the ER home. She was nervous because of all this stemming from the vaccine. She had a low grade fever on 18Dec2020 (Friday) night. Caller stated her work had already reported her reaction. Occupational safety and the medical director are aware. Caller does not have reference number to provide. On 18Dec2020 (Friday) she was not overly concerned because it was the next day. Her blood pressure was high and her heart rate was in the 100's. They monitored her for a couple of hours and she was given a diphenhydramine hydrochloride (BENADRYL). She went to the emergency room (ER) for a few more hours and received additional treatment. They sent her home to be monitored at home. She has been taking her blood pressure every day since and it had not come down. It was still really high. She called her primary care doctor. He was wanting her to start blood pressure for medication it. She was concerned about starting

it with the assumption that it was related to the vaccine. She would like to know the right thing to do. It seems safe to take the medicine, but it was unknown that whether it was going to mask the blood pressure and something else be going on. On 18Dec2020 she still had a headache and didn't feel well, but she thought she needed to give it some time. She had been anticipating not to feel well on 18Dec2020 (Friday). On 19Dec2020 she felt better considering she didn't have a headache. On 19Dec2020 (Saturday) her blood pressure was 138/90 and she felt good. Then on 20Dec2020 she had the bad headache and her blood pressure was up. On 20Dec2020 (Sunday) she had a bad headache and her blood pressure was 156/100. She came to work today and her blood pressure had been high all day. She still had a headache and the light headedness continued. The outcome of the event low grade fever was unknown, of other remain events was not recovered.; Sender's Comments: A causal association between BNT162B2 and the event dizziness cannot be excluded based on a compatible temporal relation. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate."

Soreness at injection site, severe fatigue

within 5 minutes of vaccination recipient felt lightheaded, pounding HR, and general weakness. recipient laid down, drank some water after 25 minutes, then proceeded to leave. Checked in with recipient at 2:30 PM and the recipient is back to normal no issues

101.5 Fever, HR 155, SOB

"Patient was experiencing congestion and was taking Zyrtec prior to Vaccine. He also states his ""stomach was off"" then night shift before his vaccine. States that his stomach started to feel better so he went ahead with the vaccine. After the vaccine he developed diarrhea in which he had about 6 episodes of, a head ache, nausea, and a dry cough. States he was feeling a little better this morning, but started having diarrhea again and had to take Tylenol for his head ache. States arm is sore from the injection."

Associate returned 45 minutes after receiving the vaccine. She was flush and had already taken 8 puffs of her inhaler. Difficulty breathing. Given two doses of orally Benadryl 25 mg each. Taken to the ER. Stated, She did not take her oral steroid that morning per patient

the following morning after receving the vaccination at around 0300 the patient developed Fv TMax 101.8 F along with chils, body aches, nausea and diarrhea. These symptoms lasted around 36 hours with the patient taking acetaminophen regularly.

5 days of Diarrhea 4 days of left ear pain 4 days of constant headache 5 days of lethargy 2 days of cough 4 days of hip joint pain 4 days of muscle pain TXT: Extra Strength Tylenol & 800 ibuprofen

Arm pain and fever of 100.5 began same day as vaccination. Fever went away after several days, but return on 12/28 with fatigue.

Right arm pain (injection arm) that began at 8:35 AM. Rated pain 6/10. Vital signs: T 98.1 F, BP 145/103, HR 90, RR 18, SPO2 98%. Assessed by onsite MD. Staff also complained of feeling tired. Returned to work after injection. Staff advised to take ibuprofen 800 mg with a meal and monitor symptoms. Advised to contact PCP if not improving over next 3 days. Also advised cool compress to area by MD.

Sun: got vaccine. Tue: 4 am started to have headache. Wed: sore throat until Thu. Thu: Went to work and started to cough, still coughing. no fever. today: cough, congestion, body pain but getting a little better.

Pt. c/o facial redness, flushing, eye puffiness and facial tingling within 30 minutes to 1 hour after receiving the vaccine. States facial symptoms resolved within 1 hour after beginning. Pt. also states started vomiting 2 days after receiving vaccine and lasted for 36 hours. Pt. states went to the emergency room but was unable to be seen. Went to urgent care clinic and had bloodwork drawn and IV fluids were given on 12/28/2020. States feeling much better today on 12/28/20.

My chest was hurting, my heart was racing, I woke up with bleeding from my mouth and nose, a thick film in the roof of my mouth. I was taken by ambulance. I have a cough, headache, fever, nausea, vomiting and diarrhea.

After receiving Pfizer COVID-19 vaccine on 12/18/20, patient c/o nausea.

Raised area with hardness with discoloration to the injection site. Itching occurred on day #2 of administration. Injection site is tender upon palpation.

On day of injection arm soreness, otherwise fine. Woke up at 6:00 am the next morning with my eyes ticking to the right and extremely dizzy. Couldn?t walk down the hall without leaning on the wall. Dizziness persisted all day on the day after injection but got slightly better as the day went on. Using a pulse ox I checked my heart rate which was resting around 100 and when I walked down the hall and back it rose to 135 which is much higher than my normal resting around 85. The following day (12/28), dizziness is gone but heart rate is still higher than normal.

12/16/2020 HEADACHE AND FATIGUE, RASH ON HANDS, RASH ON TRUNK AND ALL EXTREMITIES. 12/20/2020 HA WORSENED PRIMARY AT BASE OF SKULL, DEEP, NOT MUSCULAR. BOTH SIDES. FEVER, BODY ACHE, CHILLS, SKIN HYPERSENSITIVE. COVID TEST; NEGATIVE. 12/21/2020 URGENT CARE; COVID; NEGATIVE 12/21/2020 - AT ER ALL DAY 10/11 AM - 6PM ??? 'ATTRIBUTED TO DRUG ALLERGY; SULFA/BACTRUM' CYPRO, STEROID INJECTION STILL HAVING HA, UPSET STOMACH AND VERY WEAK. VITAL SIGNS WITHIN NORMAL LIMITS 'ROUGH NIGHTS' TELE HEALTH 12/29/2020 DR REQUESTING ANOTHER COVID TEST

Heart palpitations 12/26/20, approximately an hour after vaccine.

Headache and vomiting beginning night of vaccination on 12/24/2020 and continuing to 12/26/2020 accompanied by extreme lethargy. Patient states she was unable to do anything and stayed in bed for days. When I spoke with her today 12/28/2020 she stated she had a headache and was very fatigued still.

Patient had throat tightness and trouble swallowing within 7 minutes of injection. 30 minutes after developed tachycardia and hives. Received prednisone and Benadryl IV symptoms resolved. Patient is 16 weeks pregnant at this time

possible serum sickness 7 days after vaccine: Hand itching, angioedema to lips and face, swelling to hands and genitals, urticaria to chest, inner elbows, groin, genitals, extremities, flushing to face

Itchy throat, gulping to swallow, red eyes, flushed and diaphoresis

12/24/2020 started mild cough, still coughing, sneezing, no fever.

Moderate pain in injection arm. Muscle and joint pain. Headache

Shortness of breath, low oxygen level, cough, fatigue, nausea, vomiting, diarrhea, body aches, headache, chills

Staff received vaccine and sat in observation area at 1405. At 1420, staff complained of right arm pain (4/10) at injection site. Vital signs WNL. Patient was assessed by onsite MD at 2:35 PM and returned back to work at 2:37 PM. Advised by MD that he could use ibuprofen and he should monitor site. No redness or swelling noted at injection site. Normal range of motion

24 hours post vaccination, the patient developed hives. Patient was seen by her PCP for evaluation. Prescribed oral prednisone and OTC antihistamines.

Patient states that a few days after receiving the vaccine, she started to experience a little swelling and irritation at site. She did not report this because she experiences this with the flu shot. She is no longer having the swelling and irritation. On 12/28/2020, patient states that there is a raised, circular rash as the injection site that is similar to a ringworm. She states that is only itches when she touches it. Patient states that she is not experiencing any other symptoms.

Swelling (Lump) and discomfort to left neck area. Noticed it when I woke up Monday 12/28/2020

Experiencing throat congestion with mild tingling on tongue and chest tightness with a slight dry cough

Experiencing throat congestion with mild tingling on tongue and chest tightness with a slight dry cough

numbness below nose, outer upper lip, inner upper lip, tongue. reports symptoms occurred within 30 minutes of receiving vaccine. Took Benadryl and 40 mg of Pepcid. resolved within an hour.

Fever (101.8 - 102.3) and chills Fatigue Headache/stiff neck and pain Lasting 24 hours

I got the vaccine on Monday 12/21. The main symptom that I was having was tachycardia(HR-90?s to 130) for 3 days. Only other symptoms were injection site discomfort, myalgias, fatigue. I had lab work on Tuesday by PCP - normal. EKG showed sinus tachycardia. Resolved by Thursday 12/24.

I went to ER exp redness around the right eyebrow, rash, cheek was swollen. I was placed on Steriods and Benadryl finished the treatment on 12/26. The rash kind of came and went cheeks was swollen and

I felt jittery. I started to feel better on 12/27 and placed a call to my PCP to make sure receiving the second vaccine. My PCP is reaching out to a allergist and contacted Phizer about concerns of the second vaccine. I haven't be able to wear makeup due to my fair skin complexion and don't wont to irritate the rash on my face. I have missed 2 days of work

"Reported ""funny taste in throat."" Stated it was ""metallic"" and occurred five minutes after injection. No unusual foods in the morning prior to vaccination. No food allergies. Upon assessment by onsite MD, patient had mild heaviness in eye and frontal head area that began 15 minutes post-administration of vaccine. Had ""wooziness/lightheadedness"" 15 min after injection as well that resolved. Chest heaviness in left area that lasted 2 minutes, resolved. Reported some anxiety/nervousness. No history of cardiopulmonary disease. Negative EKG and stress test in 2006 that was conducted due to chest pain after walking. No history of GERD. Denied other signs and symptoms."

Possible itchy, red spots over torso and neck

Moderna COVID-19 vaccine EUA Developed throat, cough and throat clearing during observation period. Refused epinephrine. Code assist called and person was taken to ED where received Solumedrol, famotidine, Pepcid, and Benadryl; continued to refuse epinephrine in ED. Symptoms resolved and discharged home.

LocalizedL arm soreness, progressed to fatigue and chills, 12/27 developed severe nausea, fever 12/27 night 100.9, slept for 18 hrs,, awoke this am with a pounding headache,w/mild dizziness, no SOB,has runny nose,post nasal drip and a dry cough, right sinus tenderness

tingling in the back of the throat. Pt was flushed and sweaty. Pt vitals were 179/107, pulse 112.

Day 1-2: malaise, fatigue, muscle aches, chills, sweats, began ibuprofen Day 3 (12/24) sudden onset of severe L sided chest wall pain, lasting for several hours, other symptoms continued requiring ibuprofen. Day 4: moderate L chest wall pain, Day 5: In the AM pain was reduced, but at about noon after a 17 minute exercise program, pain was severe associated with SOB, went to ER and found to have a L pleural effusion, no pneumonia, no PE on CT angio. Due to lack of clear causative process: began augmentin, azithromycin, prednisone, aspirin and Tylenol... Day 6: Much improved, but still L chect pain with deep breathing coughing and recurrent hiccups. Day 7: a little worse in AM until prednisone 40 mg, aspirin 162 mg and 1000mg Tylenol

Muscle Pain, Nausea, Dizziness, Injection site pain

Palpitations, racing heart rate, lightheadedness

On 12/22/2020 we had 1 patient who had a severe allergic reaction to covid 19. after she was administered covid 19 vaccine at about 11 am she went in to the observation area for 15 minutes. while there under the observation of the facility staff members she reported to them that she was having some difficulty breathing and her lower throat was closing up. the staff member came over to the administration area to ask me to bring the epi-pen because they have someone with anaphylactic allergy reaction. I ran over there with a box of epi-pen and patient stated she is having difficulty

breathing and her throat is swelling up and I noticed her lips were turning blue. at that time I administered the epi-pen and asked the facility members to call 911. which the facility members did promptly. I kept her under observation with the 2nd pen ready just in case it was needed. the EMS showed up within 15 minutes and took over from there and transported her to the hospital. The staff members at the facility also called the patients doctor to inform him of the allergic reaction. I followed up with patient on 12/23/2020 at 4.37 pm. and at that time she was doing fine. she informed me that all of her symptoms of the allergic reaction have gone away and all she has is some cough and some shortness of breath. she had been discharged by the hospital and is on some steroids and under her physicians care. I talked to employee at store as he is the one charged with recording this incident and he has informed me that he talked to the facility administrator and facility administrator informed him that both patients have recovered completely and were back to work today on 12/23/2020

Sore Arm x 36 hours

Feeling foggy after vaccine Vitals PO2 100% Temp 36.6 P 85 b/p 112/76 No treatment required left after 30 min observation AMA

Developed itching and redness to bilateral arms and face approximately 20 minutes after vx admin. Admin Benadryl 25mg po x 1 per S.O. 1400-itching nearly resolved, redness decreased.

tingling of posterior tongue flushness of neck and upper arms

Body Aches, Fatigue, Soreness around injection site

Started having chest pain and shortness of breath approx. 10 hours after injection. Symptoms kept Worsening. Taken to the ER. Cardiac workup performed. It was negative. Diagnosed with Pleurisy.

The staff had the Covid vaccine in the morning 12/23/2020. In the afternoon, received a phone call from her boss saying that her boss was COVID positive. Boss only had headaches. Then the staff went to have Covid test, the result was negative. On Thursday she started to expreience headache, still having headache and mild body ache.

Sore arm x 48 hours.

Fatigue, Dizziness, Arm Pain, Redness, Swelling, Light sensitivity, Headache, Muscle Pain in arms and legs, Painful to touch the arms and legs, felt like she worked out extremely long, right knee/leg swollen. Dr. Prescribed cephalexin and Naproxen 500, helped swelling, started taking on 12/25. There was a break in between the pain, from 17th to 20th there were the first symptoms, and then a break, but muscle fatigue started on 12/23.

Received vaccine at work on 12/23/20 at 1600. No problems receiving it. No pain at site or afterwards. about 12 hours later (04am) on 12/24/20, I woke up with body aches and was especially across my shoulder blade area. Had headache. Up that morning. Spiked T-102.5 orally with horrible headache. Temp did break on 12/24/20, but did come back later that day T-101. Continued with horrible headache, body aches, became very sore at injection site. Lethargic. No appetite. Diarrhea.

approximately 3 hours after injection subject developed rapid irregular heart rate consistent with recurrence of her atrial fibrillation which she had not had for at least one year prior. Also noted chest pain and weakness. Took an extra dose of atenolol with some improvement. Symptoms completely resolved overnight without any recurrence since.

Injection site soreness, Heat flashes

Associate developed a rash and tachycardia. Received two doses of po benadryl. Symptoms resolved.

12/21 SITTING IN CHAIR, FELT TINGLING IN EAR, 'FEELING FAINT'. MOVED TO CHAIR AGAINST THE WALL, TOLD MEDICAL STAFF. FAINTED, SWEATING PROFUSELY, 'WANTED TO GO TO SLEEP'. MONITORED HR, BP. VOMITED. BP WAS STILL ELEVATED 136/100. 'FELT BETTER' AFTER VOMITING, COLOR CAME BACK, 'CAME TO'. ER: BASAL EVENT ABOUT TO DISCHARGE, TINGLING CAME BACK. NOTHING ON MONITOR INDICATED ANY PROBLEMS. EVENTUALLY DISCHARGED AS SYMPTOMS DECREASED. DIAGNOSED; SYNCOPE

The day after I received the vaccine, I developed chills, headache, fatigue. Approx. 23 hours after vaccine administration I noticed throat swelling/difficulty swallowing. I took 50 mg of benadryl and went to a local walk in clinic. O2 sat 98%, no respiratory distress, nurse practitioner reported my throat and rest of assessment were within normal limits. Instructed to continue taking benadryl and monitor symptoms. Later that evening I developed congestion, so the morning of 12/24 I called my work's COVID hotline and they instructed me to come in to be swabbed. I received negative COVID-19 results from my works Occupational Health department on the morning of 12/25. The throat swelling/difficulty swallowing has gotten better, but still not back to baseline as of 12/28. I have a appointment with my PCP, to follow up.

Soreness at Injection site

Slight headache for several days following vaccine, resolved as of 12/28. On 12/28 she had a sudden wave of severe nausea, one episode of vomiting and subsequent generalized achiness with mild residual nausea.

Warm, tingling & numbness 10 minutes post injection. Monitoring indicated elevated HR & BP. Team member released after 50 minutes. TM was driving to her clinic and developed left side numbness to her cheek, upper arm and lower left back areas. Supervisor completed incident report and had team member go to urgent care and then went to ER. TM drove herself. ER provider Dr. contacted EH and informed us that TM did not have anaphylaxis and has no known allergies. She also drew CBC, Mag, Urine pregnancy & performed a CT scan w/o contrast to rule out kidney stone. No significant findings were noted.

Patient reports symptoms following COVID-19 vaccine. Patient reports she had brief episode of heart racing, throat tightening, feeling lightheaded. Symptoms already improved within 1-2 minutes by the time this RN reached patient. Denies itching, hives, shortness of breath, or any other symptoms. Has history of anaphylaxis and anxiety attacks, was worried about having anxiety attack with vaccine today. BP and pulse normal on two repeat checks. Patient alert, oriented, speaking clearly and in no apparent

distress. Symptoms resolved and did not return by end of patient's post-vaccination waiting period. Patient works on campus in oncology with healthcare providers nearby for help if any further symptoms.

After receiving the vaccine I was immediately nauseated. I went back to my desk to work and was dizzy and felt like I would vomit. This went away after an hour or so. My arm felt totally normal right after the vaccine, but later in the evening it worsened and I had a dead arm for about 24 hours. The next morning when I awoke I felt there was an elephant sitting on my chest. I couldn't catch my breath or take in a deep breath. I tried to walk down the stairs to get my inhaler, but was so dizzy I had to hang on to the railing in order not to fall. When I got to my medication cabinet I had difficulty opening the cupboard. I took my inhaler and the chest pain seemed to ease up as the day progressed. I had such terrible body aches that I tried to open a bottle of Ibuprofen and had extreme difficulty with my fingers. Throughout the day my fingers were cramped up and I was unable to hold on to anything, even the steering wheel of my car to drive. My hands were so sore that I tried massaging them but nothing helped. I took ibuprofen and Tylenol every 4 hours to help and after about 48 hours the intense burning, aching, and cramping somewhat subsided. Over a week later, I am still struggling to use my cell phone and text messaging. My fingers are not working right so I am hoping that will go away. In addition, I have been achy with chills since the morning after getting the vaccine. I can not seem to warm up. I have tried warm baths and sleeping with hot pads, but I have terrible chills and aches. My joints and muscle hurt all over my body to the point that now I have made an appointment with a doctor to see if the vaccine caused some kind of autoimmune reaction. My fingers, hips, and knees are the areas that hurt the worst still. I am a marathon runner and was currently training and doing well. After the vaccine, my joints and muscles have been so painful that I haven't been able to maintain what I was currently doing with running. I have ended up icing or heating different parts of my body daily and gone through a lot of ibuprofen, naproxen, and Tylenol trying to find relief. My entire body is covered in Icy Hot as that seems to help a little. I am unable to sit for more than a few minutes without pain.

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"Early morning hours 0100 of 12/19/2020, awoke with SOB/dizziness/polyuria/anxious/Heart palpitations/Tachycardia (no tx/went back to bed thought I was just anxious) Afternoon of 12/19/2020 Fatigue/dizziness/HA (Motrin) Early morning hours 0130 of12/22/2020 awoke with SOB/dizziness/Polyuria/anxious/Heart palpitations/Tachycardia 120-130/felt something wasn't (right) (went to Hospital ER, cardiac workup, multiple PVC's some couplets, tachycardia. Given a liter of fluids) Told it was a Large Catecholamine release related to my immune response to the vaccine, Told Heart was ""irritated"""

10 minutes after the vaccination, she began clearing her throat, within 30 minutes began coughing, which led to chest tightness. Was evaluated in the ER and admitted for observation. Given: Prednisone 40mg po, Benadryl 25mg po Duoneb x 3 and Pepcid 20mg

Intractable headache that started 1 day after the vaccine was received. Still having headache as of today, 12/28/2020. Has been taking Ibuprofen around the clock with no relief

Patient woke up the morning after the vaccine and could not get out of bed. She felt horrible and disoriented. Her husband had to help her as she could not stand, was sweaty, nauseated and dizzy. BP 170/107. Did not feel well all weekend and was extremely fatigued and dizzy with a 10 on a scale of 1-10. Patient feels better today and is able to work.

Injection site pain

Injection site pain

Redness, Swelling, Fever, Pain to injection site. Achy and diarrhea for 1 week

"two days post-vaccination on 12/25/2020, had ""COVID sxs of H/A, cough, N/V/D. COVID Swab done early on 12/25/20 was negative. Went to ED for continuing sxs, re-tested for COVID by nasal swab, negative. In ED, states Hgb was 10.1 Gms which she states was a 35% drop from previous Hgb of apprrx. 16 Gms, approx. one year previous. Cponsulted with her PCP on 12/28/2020 and repeat Hgb pending. States her PCP advised against receiving Dose #2 of vaccine ""due to dramatic drop in Hgb. which he felt was due to COVID Vaccine on 12/23/2020."" She plans to decline Dose #2 vaccination."

One day after my COVID-19 injection, I noticed a large growth on my left elbow. It is painless and feels like there is liquid inside. It is about the size of a medium sized egg. The physician at the administration site said it appears to be olecranon bursitis or symovitis.

generalized itching that started in her left hand then spread to the rest of her body. Itchy ears, throat, eyes. Slight coughing and runny nose

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One day after my COVID-19 injection, I noticed a large growth on my left elbow. It is painless and feels like there is liquid inside. It is about the size of a medium sized egg. The physician at the administration site said it appears to be olecranon bursitis or symovitis.

generalized itching that started in her left hand then spread to the rest of her body. Itchy ears, throat, eyes. Slight coughing and runny nose

tingling in arm and hand - fatigue headache

Moderna Inj given: 0830 Pt complaining of difficulty swallowing: 0839 Epi-Pen given: 0840 Pt sx: Original complaint of difficulty swallowing. Upon assessment, glands were noted to be swollen and red. Pt was given Epi-Pen. Pt had notable peri-orbital edema and his face was flushed. Upon assessment of vital signs pt was noted to be tachycardiac with an elevated blood pressure. No adventitious lung sounds. When pt was loaded onto EMT gurney, his BIL LE were noted to be edematous. 0845 0849 0853 0856 T: 96.9 97.5 97.5 97.9 P: 110 95 77 78 R: 24 20 20 20 BP: 151/92 169/80 137/86 137/95 O2: 99% 99% 99% 97% Ambulance arrived at 0856. Pt transported via ambulance to Hospital for assessment and treatment.

Received the vaccine and 8 hours after had nausea. Was scheduled to work and by the time I got inside I also had chills, fever, muscle aches and fatigue. I was sent home. I took Tylenol and went home and went to sleep. The next day the fever was gone but I still had some fatigue and a sore arm at injection site. The next day I only had a sore arm at injection site. No other symptoms after that day.

Soreness at injection site

Soreness at injection site

racing heart, shakiness, dizziness

After vaccine I noticed an immediate metal taste in my mouth, 30 minutes after vaccine I noticed a tingle feeling to my tongue and the metal taste, 45 min after vaccine I noticed my tongue was swollen, Vaccination clinic called and recommended taking diphenhydramine and go to ER if symptoms got worse.

Flu like symptoms, Headache, sore throat, stiff neck, mild cough, fatigue, hot flashes, (left side of face hurts for 3 days and now just tender) and no fever at this time. All the symptoms are continuous even with over the counter meds with no relief.

Pfizer-BioNTech COVID-19 Vaccine Diaphoretic, SOB, Sudden Heat, BP 90/56, 98% O2 Room Air, HR 75 Pt states - likely due to anxiety from vaccine, will continue with 2nd dose in 21 days.

Chills, asthma, fever, congestion, cough, arm pain

tachycardia, hand tremors

The day after I had little bit of soreness on my deltoid, nothing major, but 3 days later, the Saturday I felt a sore throat and by night it was significant enough, I started taking Motrin. My lynphnodes were a little swollen. I contact employee health who set me up with a covid test (negative) and about 3 weeks earlier I had a similar sore throat that prompted me to have a covid test it was negative as well.

Complained of left arm & hand tingling, feeling warm and heavy

Soreness at injection site

Patient was found slumped over in wheelchair, drooling and unable to respond/follow simple instructions; sent to ED for evaluation. CT scans and MRI NEGATIVE for new/recent stroke; resident slurred speech likely due to hypertensive urgency

Blurry vision about 20 minutes after injection when stood up, lasted about 15-20 minutes. No other symptoms noted. Resolved on own. Blood pressure, O2 saturation, and pulse all within normal limits per healthcare provider.

Rt Arm no function/ no feeling.

Pfizer-BioNTech COVID-19 Vaccine headache 5 minutes after IM injection of dose 1, did not recover after 15 minutes of observation.

Extremely tired, chills, and body aches from 3 hours after the vaccine was given, lasting for 2 days. Took ibruprophen 300mg every 8 hours and slept when I was not working.

Nausea, lightheaded, chest pain, vasovagul

Pain at injection site, sore throat

Increased heart rate for several hours following injection Ongoing significant headache - constant dull headache with occasional sharp pain on the lift side of head

Fever (highest 101.5 degrees F while taking 1,000 mg acetaminophen every 6 hours and 600 mg ibuprofen every 8 hours), body aches, joint pains in knees, severe fatigue

Employee received vaccine dose and within 10 minutes developed facial flushing, felt slightly SOB, felt lip tightness, felt like voice was hoarse, with mild lip swelling noted-- reports history of nut allergies/ATBs-- no known history of allergic reaction to a vaccine previously. Employee was brought to ED and received benadryl, epinephrine, decadron, IV fluids in ED and was discharged home.

Fever, Fatigue

""""Pfizer-Bio-Tech COVID-19 Vaccine EUA"" Client given vaccine around 11:30 am, At 11:44 client with c/o increased HR, and flushing. No rash noted , VS monitor, Post 5 minutes she states she feels better , VS stable, 11:59 client left on her own."

Palpitations, chest tightness that has been intermittent, occurring 5-6x/day and lasting 30 minutes before resolving spontaneously since she received the vaccine. She says she has had similar palpitations in the past, with a negative medical workup

Pain at site of injection the next day. Swollen glands in neck/cervical area and armpit on day 2. By day 3 I was feeling better and by day 4 i did not have any soreness at all.

Elevated heart rate and blood pressure, headache and itchiness

Elevated heart rate and blood pressure, headache and itchiness

Fatigue, body aches occurred 1 day after receiving the injection. Symptoms lasted only for that one day. Rest and fluids were the only treatment.

Headache, low grade fever, runny nose starting 6 hours after injection lasting approx 24 hours

Broke out in welts and hives all over body for 4 days.

Stomach Cramps, Diarrhea, dizzy

I felt like I was having a hot flash and felt like I was hungover, tired achey, and nausea, the next day 12/18 I couldn't sleep on my left side because my arm hurt, no rash and Saturday I had horrible itching all over my body, I called the Dr and he had me take Claritin, and it calmed down after 6 hours . I have similar symptoms with extreme stress.

Hives to bilateral arms and chest

The next morning when I woke up I started feeling short or breath like my asthma was exacerbating and used my inhaler. 3- 4 hours later I had to use my inhaler again. And it started happening more often than every 4 hours. So that is when I reached out to my PCP and he prescribed me a nebulizer solution and prednisone.

Pain at injection site, arm stiffness hard to move

10:00 pm - Severe chills 1 am - Temp of 101.1 2 am - take tylenol 3 am - fever 100.4 and excessive sweat 6:30 am - 100.0 temp 8 am - 100.4 temp 9 am - excessive sweat All this time - muscle aches, joint pain

"The employee stated that he started feeling weird. Lips tingling, flushed face, feeling ""fuzzy"" headed, dry mouth, unsteady when standing. BP 130/94 pulse 60 ; at 12:20 Lips numb again and feeling fuzzy; Took to the ER In the ER, patient presented with lip numbness, diaphoresis, leg weakness. Patient states that symptoms were alleviated by sitting down but that the lip numbness returned, Administered- Solu-

Medrol 125mg ivp once; Pepcid 20mg ivpb once ,Benadryl 25mg ivp once Discharged from ER at 13:52 with symptoms improved"

Patient had a head ache, fatigue, loss of taste and smell. Went to doctor and she is being tested for COVID-19.

Injection site sorensss

"Pt received Moderna COVID-19 vaccine at 1023. Approximately 6 hours later, she began to develop ""hives"" which were primarily around her jaw and hairline on the right side. Pt also reports swelling around her eyes. Pt took Benadryl at home with no relief of symptoms. Pt presented to local Urgent Care, they directed her to the Emergency Department. Pt arrived in ED at approximately 8PM. The Pt received 10mg IM dexamethasone, 25mg IM diphenhydramine, and 20 mg PO famotidine. Pt reports resolution of symptoms after medication administration."

I got the vaccine on Thurs and worked the following day. On Sat morning I felt sick with fever, clammy and tired went to get tested results positive. I dint think this was a reaction to the vaccine. I have missed week of work.

Hives. Given benadryl. Taken to ED

12/24/2020 arm pain at injection site, body aches, mild headache, fatigue; 12/25/2020 symptoms worsened next day; 12/26/2020 loose stools, with continued previous symptoms, dizziness, weakness.;12/27/2020 Covid Test - Negative; 12/28/2020 sore throat, head congestion -- all other symptoms continue to persists.

Itchy, feverish, elevated heart rate, light soreness

At the 36 hour I was in severe joint pain with profound myalgia, and fatigue. The pain was an 8 to 9/10 and would have caused me to seek emergency medical care if I were not a physician capable of treating myself. I laid in bed writhing in horrible pain and after analgesics did fall asleep. The next day these pains continued as I had to work and had difficulty walking and maintaining professionalism. The pain continued through Saturday at which time I took a tapering dose of steroids and it seems to finally be letting up. I will not seek the booster injection for covid 19.

Sore arm Sniffles

Soreness at injection site

I was given Moderna Vaccine on 12/26/2020. I had Muscle pain by 11pm on 12/28/2020.Muscle pain was better by Sunday. I felt fine on Saturday 12/27/2020. On 12/28/2020 around 11pm I started with chills, fever and headache. My temp was 99.9. The fever is back to normal as of about 11 am 12/28/2020, but the headache is still lingering. I have not taken any OTC medication. I am drinking a lot of water to stay hydrated and overall feeling better.

Lip tingling, swelling and itching which last approximately 2 days. Treated with 25mg once a day for 2 days. Is now resolved.

11:33 Patient arrived to the observation area with nurse at side. Nurse observed upper body twitching and stated that patient voided in the chair. áPatient looks dazed and pale and requests to lie down. áPatient placed on stretcher with head down andáfeet up. Initials vitals taken. HR 38. Call was placed to EMS. áPatient states that she felt anxious while waiting and has a history of panic attacks. á 11:40 Patient appearance has improved. á2nd set of vitals taken show improvement. áPatient states that she feels better and placed a call to her daughter. Awaiting EMS arrival. 11:45 Patient transported via EMS to ED for further treatment and follow up. 15:00 Follow up call placed to ED. áPatient stable and may be admitted for further observation

Feeling weak, lips numb and tingly progressing up face and to right ear. Hot burning sensation right side of face to right ear. Became numb and tingly from chin to eyes within 5-10 min of shot. Nurse game me Benadryl. Numbness reduced within 30 minutes. Very tired. Slept for 3 hours. Woke up with headache.

PT. REC'D VACCINE AT 2:18PM, WAITED RECOMMENDED 15 MIN. AND CHECKED OUT AT 2:33PM. T/C AT 2:42 PT CALLED AND C/O TINGLING TO LEFT SIDE OF FACE AND LIPS, AND C/O A H/A THAT PT. REPORTS COULD POSSIBLY BE D/T STRESS/ANXIETY OF THE TINGLING SENSATION. STAYED ON THE PHONE WITH HER WHILE SHE COMPLETED HER DRIVE TO THE WORK SITE. SPOKE WITH HUSBAND AND ASKED THAT HE GET BENADRYL AND ADMINISTER ASAP AND TO CALL IF SYMPTOMS WORSEN. T/C TO PT AT 3:12PM HAS TAKEN BENADRYL AND FEELS FINE.

I started with a mild headache with chills body aches and fever of 100 degrees, rash and hives and chest pains. Into the next day I had a sever headache, chest pains and BP 176/126 that caused my cardiologist to add two additional meds to try and get me out of the hypertensive episode.

Kidney Pain

Body Aches

Bruise on back formed, hard to bend over, spinal pain.. chills, muscle aches

12/23 - dry, scratchy throat 12/24 - nasal discharge (mild) 12/25. - nasal discharge 12/26. - sinus congestion 12/27 - loss of taste / smell; diarrhea

Fever and fatigue for approximately 24 hours

Thrush - taking swish and swallow

Patient states she was vaccinated at about 3PM and around 9-10PM she started to feel like she may pass out (shortness of breath, vision changes). Patient states over the next couple of days she felt fatigued and feverish. She reported these symptoms to her DON who encouraged her to report her symptoms to us. Patient has completely recovered from these symptoms.

Tingling in tongue and lips.

patient report symptoms of facial tingling and seemed to have increased secretions with a dry cough. no facial swelling. she contributed to her reflux so she took tums. She was not given any medications while monitoring. The cough and increased secretions resolved and the tingling improved. She reports she took Benadryl and Claritin at home

After receiving the vaccine the patient experienced flushed feeling and perspired under both arms for 10 minutes. Employee began to feel a sharp electrical shooting pain in the axillary/armpit area which extends into upper arm. She is experiencing it intermittently with certain types of movement. She believes that shot was given too low in the arm.

Left side facial swelling, redness, bumps. Improved within 4 hours. Left cheek bone still swollen and red after taking 2 Benadryl. (Have not had any facial filler or anything done to my face what so ever)

Pt reports red itchy rash appeared on bilateral arms approx. 4-5 hours post-vaccination. Dry red rash noted on 12/28/2020. Pt states has been taking Benadryl and using topical hydrocortisone cream. Pt states has seen slight improvement.

"Patient with a history of severe anaphylaxis was observed for 30 minutes post vaccine. Right at the 30 minute mark, patient started to look pale, started with frequent throat clearing followed by sense of shortness of breath and chest tightness. 2:37p: No wheezing, good air movement, breathing was not labored, no cyanosis, no noted lip or tongue edema, able to speak. BP 160/54. P 98, O2 sat 98%. Severity of symptoms per patients = 8/10 ""tightness"" at time of medical evaluation/medical provider response. 2:38p 911 called, 2:39p epipen, benadryl 50mg oral, and solumedrol 125mg IM administered (patient tolerated well, able to swallow) 2:42p patient reports symptoms improved to ~4/10 severity O2 sat 98%, P97 2:46p , O2 96%, P 99, BP 148/52 2:48p patient reports symptoms still at ~4/10 severity/stopped improving, O2 sat 95%, p 85; discussed option of doing 2nd epipen 2:54p EMS arrived prior to administration of second epipen. Patient transported to Emergency Department for further evaluation for possible anaphylaxix"

Pt. Administered vaccine at 1355 at 1358 she complained of throat warmth, anxiety and feeling flushed. Pt. offered Benadryl 50mg, refused but agreed to 25mg. VS's at 1358, HR 84, resp.'s 16, BP148/102. at 1410 146/102, HR 76, resp. 16 1415 states feeling worse, can feel it in throat, to ER via wheel chair.

about 10 mins after the vaccine I had hot flashes started in my feet and went through my whole body , dull headache. It didn't last but a few seconds. the headache lasted a couple hours. I went to the ER for further monitoring and checked blood pressure and vitals for two hours and released me.

Patient received the Covid 19 vaccine on 12/22/2020. On 12/23/2020 she noticed a single, blister-like rash on her right eye. The rash got worse and spread to her face bilaterally and neck. Denies any tingling or numbness of the face. No swelling of the lips noted. Denies respiratory issue or fever, chills, HAs, or fatigue. Denies taking new medications, using new soaps, detergents, fragrance, or lotion, and food allergies, No outdoor activities. She has contacted her PCP and started prednisone 60 mg x 1 on 12/23/2020 - taper to 10 mg Total of 6 days treatment. Also, taking Benadryl 25 mp po q 4-6 hours per pcp. Her facial swelling is improving but not completely resolved. Has a FU appt with PCP .

tingling around body, episodic low-grade joint pains, low-grade foot pain in left foot (resolved), moderate dizziness, pain around head, pronounced left hand weakness, difficulty with daily tasks/had to leave work.

COVID19 Pfizer vaccine given at 10:30am on 12/26 12/27: Itching to left arm and hand at 430am- no treatment Continued itching with swelling of left arm/hand- Benadryl oral at 1230pm 12/28 3:30pm observed swelling to both legs, left leg more than right- leg elevation and rest 12/29 Reduction in swelling, Itching resolved.

Fever 101.1 x 1 day headache x 1 day muscle aches x 3 days fuzzy head x 3 days

patient stayed here for 15 minutes and did well. She went back to her job and developed flushed feeling, hives on neck and tingling on tongue. She improved with no treatment.

Mild Headache remaining

SNEEZING, STUFFY NOSE, LIP SWELLING, TINGLING MOUTH, THROAT CLOSING, UVULA SWOLLEN 1. Allergic reaction (Allergy, unspecified, initial encounter) . Pt. received Moderna COVID vaccine the morning of 12/22/20 and developed angioedema reaction the afternoon of 12/23 Vaccine is only new medication reported by pt. - denies any new products, foods, etc History of hives with spironolactone 2.5 months ago; taking HCTZ now - unknown if reaction is related to this med rather than vaccine? Due to severity of her reaction and uncertainty if all attributable to vaccine versus some other culprit I would recommend Epi pen at time of discharge Has received IM epinephrine, racemic epi neb, Solu-Medrol, Benadryl, Pepcid in the ED Continue with Benadryl 25mg IV q6h, Pepcid 20mg IV q12h, and Solu-Medrol 40mg IV q6h 2. Angioedema (Angioneurotic edema, initial encounter) . Arrived to the ED with R. side lip, tongue, and uvula and oral cavity edema Airway patent, room air O2 sats WNL - monitor throughout the night for any worsening of angioedema or airway involvement Treatment as above

Recipient received her vaccine and was sitting for observation when she reported feeling light headed about 5 min after the administration. 30 seconds after recipient became unresponsive and stopped breathing for 15 seconds, legs were elevated Code blue was called, after about another 30 seconds recipient become aroused and coherent. Vitals were taken- pt. was tachycardic- 120s- came down to 80s, BP 120/80, 90% O2-eventually went up to 98%. Temp 97.3. Med cue was called and took over to evaluate Pt. Pt. did report has had hx of vasovagal syncope.

Atopic reaction. Itching to Left arm, back, head.

Person had tingling and numbness of upper and lower lips, fullness feeling 10 minutes after vaccination given. vaccine given at 1402, started feeling the tingling at 1412. Lips were not swollen. No swelling of tongue. Oxygen sat 99% throughout the event. Blood pressure 150/88. Alert and oriented, injection site not swollen or red. Given Benadryl 25 mg orally at 1415. At 1430 patient feels like the numbness and tingling are getting better.

Metallic taste and dryness in mouth and burning in tongue

Pain at Injection Site

Approximately 30 min after injection pt reported burning in her throat, numbness and swelling of her tongue. At no time did she report shortness of breath. Vital signs were acquired , pt stayed in our vaccine clinic for approximately an hour without improvement and was then taken to our ER to be further evaluated

WOKE UP SNEEZING, RUNNY NOSE, TEETH HURT; SAT/SUNDAY. MONDAY CALLED PCP. PHONE VISIT WITH DR, BROUGHT IN FOR TESTING.

hypertension, tachycardia, lightheadedness, anxiety

Patient reports severe fatigue. Reports unable to walk across room without feeling like his body was giving out.

Had mild chest tightness 10 minutes after vaccination that resolved 10 minutes later. No shortness of breath, no swelling

Nausea, Pain at injection site

Excessive Sneezing, Sore Throat, Headache, Stuffy/Runny Nose. Symptoms started around 6:30pm and have continued through Sunday to Monday and are still on going.

Patient experienced pain at deltoid injection site which extended up to neck. Also report night sweats and rigor. Symptoms have resolved by 12/28/20.

Foreign body sensation in throat. Symptoms resolved and patient was discharged from ED after Benadryl and oral steriods

Eye hurt with pressure Headache body aches Chills Freezing

Headache, arm soreness

Fever, chills, body aches, headache, fatigue, and vomiting

"Headache, lightheaded, nausea, dizziness, muscle aches, malaise, and chest ""squeezing"" prior to syncopal episodes x 3. This occurred in OR where she works. ""I don't know when I passed out."" Rapid Response called s/p sternal rub by MD not effective. Taken to ED via stretcher. In ED, had EKG, IV fluids, Benadryl, and Phenergan. Regained consciousness on arrival to ED. Cleared to return to work on 12/24 by MD in ED. Will follow up with PCP."

Redness and firm area of swelling onset few hours after vaccine, at maximum erythema 25mm, swelling 20mm diameter. Headache reported day of vaccination and 2 days after vaccination, relieved by Tylenol and Benadryl. At day of reporting VAERS, pt vaccine site remain swollen/firm, redness improved but still present.

I had some of the normal side effects: Nausea, body aches, headache, HOWEVER!! the very strange side effect was this: I received the vaccine in my right arm since I am left handed. The following day, the entire right side of my head (the scalp) was burning and painful like a had gotten a bad sunburn. This lasted for three days, with improvement on the third day and my left side of the head being very sensitive. There was absolutely NO pain or burning on the right side of my head (scalp).

Pain at injection site

Patient described feeling light headed, nauseated, dizzy. She developed hypertension and HA over time frame of 5 minutes after vaccine to 1 hour and 30 minutes after vaccine up to a BP of 201/115. Range of BP was 163/94 up to 201/115 with HR 76-89, Patient was alert, oriented, able to move all extremities, transfer to chair and respond appropriately. Major complaint was feeling dizzy and nauseated with feeling of HA emerging.

the night of the 18th my right eye was bothering me so I was itching it in my sleep, when I woke up on the 19th my eye was red and I thought I had injured it in the night and it bothered me all day but I didn't get it checked, I went to urgent care the 20th because I noticed there were vesicles on my right eye. they gave me eye drops and diagnosed me with HSV keratitis, Valtrex was also prescribed trifluridine. I feel almost completely recovered

approximately 5 hours after vaccine the patient developed chills, body aches, cough, head pressure, and the sensation of feeling flushed.

12/20/20 FEVER 102, NO APPETITE, WEAK, VOMIT ONE TIME

Patient felt a sudden severe headache around her forehead, around her eye sockets. When she stood up, the pain worsened. She also felt very weak, but not dizzy or feeling like she was going to pass out.

I woke up at 7AM having migraines, chills, nausea and severe migraine. Contacted PCP for prescription.

Syncopal episode the following morning after received the first COVID19 Moderna vaccine

12/24/2020 COVID Vaccine received (IM injection, L deltoid), 12/25/2020: started with ONE hive on the abdomen 12/26/2020: started with full-body hives (pruritic) without mucosal or face involvement, no respiratory symptoms, no fevers, no swelling - itching improved with Benadryl 12/28/2020 - contacted employee health who said to contact MD; recommending daily Zyrtec with Benadryl at night and steroids if no improvement

Emesis

Reported tightening in face/jaw after vaccine. Subsided on its own with no treatment.

itchiness around the neck

Headache, Pain at injection site

Today fever with muscle and joint pain and fatigue.. feel so run down

Patient started feeling flushed about 30 min after vaccine and developed a headache about 6 hours after vaccine. The morning following vaccine her headache continued and her blood pressure was 168/90. Day 3 168/106 . Day 4 170/106 and has stayed elevated since vaccine given. Her BP was 154/70 in office today - 5 days after vaccine. She is no longer having headache or flushing. Her normal blood pressure is 110-120/70. Last elevated BP in office was in 2012 at 140/88.

Injection at 1109. At 1135 c/o of itchiness of hands and forearms. No other complaints. Benadryl 25 mg given orally. Improved--returned to workplace. At 1250 c/o of worsening symptoms. Tonsils mildly swollen and mildly erythematous. No significant swelling fo tongue and no difficulty swallowing. No redness of skin and no rash noted. Heart rate 118. B/P 118/78 Respirations 18. Oxygen Saturation 100% on room air. I made the decision to send her to the local hospital ER at 1305 as a precaution. At 1408 in ER she received Benadryl and Epinephrine. At 1428 she received solumedrol and Pepcid. Being observed in ER for 4 more hours.

15 min after injection-flushing, heart rate increase. 30 min some lip itching that went away within 30 min. Took Tylenol in morning (12-17)because started having a few muscle aches. Around 10 am- muscles tightening and needed to stretch them most of day. Fatigue but mild. Mild nausea about 11 am . 5 pm chills started. Ibuprofen taken. Muscles aches continued overnight Dec 17 until 10 am 12-18/ Ibuprofen in morning. Mild fever Friday 12-18--99.1-normal temp 97. Next 2 days mild fever continued and normal Monday 12-22. Muscle aches declined and gone 12-21. Heart rate has remained higher than normal since 12-16--normal is low 70's and has been high 80's and low 90's.

Patient reported numbness and tingling in lips and fingers on right hand at 5 minutes post vaccination. She was taken to the Emergency Room by Employee Health Nurse (walked) where tingling/numbness in lips had resolved upon arrival to ER and was decreasing in hand. She had full resolution after 1.5 hours. She was observed for 2 hours, no interventions, symptoms resolved, and then she returned to work.

Tingling in left hand for about 30 minutes Tingling and numbness in lips. Its been a couple hours now, and it feels like it might be starting to subside.

Tingling, Facial flushing, Felt like throat was swelling, Painful in injection site.

Tightening in face/jaw after vaccine. Subsided on its own with no treatment necessary. Somewhat red cheeks.

Patient reports tingling sensation on the right side of head and transferred to the back of the head. Reports knee joint, everything on the right side. Reports right side of body is either feeling pain or tingling sensation.

96hrs following vaccine (12/25/2020)developed acute submandibular gland swelling Visited physician (12/28/2020) performed ultrasound; dx acute Sialadenitis; rx Augmentin

Started plaquenil 12/18 due to new diagnosis of undifferentiated connective tissue disease per rheumatologist. Noticed itching and slight rash. Received Covid Pfizer BioNTech vaccine on 12/22. Rash became increasing worse each day starting 12/23, facial swelling 12/25 and 12/26. Hives in throat

12/26. Hives on tongue, continues head to toe hives and extreme itching 12/29. Last dose of plaquenil was 12/22.

Pain at injections site

Moderna COVID19 Vaccine EUA Metallic taste appeared within 5 minutes of dose. Smell and other taste not affected. Very subtle metallic taste right after injection

Five hours after mild arm soreness, mild chills and day two I was lightheaded

12/21- Vaccine administration 12/22 @ 12am Sore at injection site 12/22 @ 9pm soreness at injection site subsides 12/26 @ 10am severe headache and muscle aches; not relieved with Tylenol; cough, stuffy nose 12/27- headache and muscle aches still apparent, but moderate; not relieved with Tylenol 12/28- headache and muscle aches still apparent, mild.

Heart palpitations, shaking and feeling of adrenaline rush.

12/25/2020 EE states that she started experiencing right ear pain, she has ear frequent ear infections and used her prescribed eardrops for the pain, the pain was not resolved so she took Ibuprofen which helped with the pain. 12/26/2020 EE states that the right ear pain was resolved however, she developed an itchy rash on her right ear and down the right side of her jaw. She took oral Benadryl and used Benadryl ointment to relieve the itching. EE states that she went to her ENT today, 12/28/2020 to discuss her symptoms. Her ENT stated that it may be caused by the vaccine but he was unsure. There was no infection found in either ear. ENT treated it as a fungal infection. EE received steroids for her ear and jaw rash. EE doesn?t report any other symptoms, never tested positive for Covid, never been exposed to her knowledge, no travel history.

Received vaccination early morning (around 7 am). Headache started approximately 5-6 hours post vaccination and continued off and on for 72 hours. Explosive diarrhea approximately 18 hours post vaccination.

Received vaccination early morning (around 7 am). Headache started approximately 5-6 hours post vaccination and continued off and on for 72 hours. Explosive diarrhea approximately 18 hours post vaccination.

Individual was under 18 years of age

12/25/2020 felt funny. 12/26/2020 developed fever of 102, chills and body ache.

Feeling in her arm at the injection site, the pain kept getting worse. She couldn't even move her arm. around 8pm, she started getting chills, no fever with chills. Felt really cold. On the injection side she had pain in her neck and her shoulder blades. Body Aches Feeling fatigue Headache tired Took Ibuprofen around 9pm Stomach cramping and nauseas As of the 28, she is feeling fatigue and still has pain in her arm where the injection site is.

reports rash on back of R hand that started on 12/23 and spread to L hand, face, breast area by 12/26, went to urgent care on 12/26, dx with hives, placed on prednisone, advised to f/u with PCP to document.

Developed a fine maculopapular rash along b/l anterior upper & forearms. Some scattered on posterior, on 12/23/20. Mostly non-pruritic, except after shower on the 1st day. Took Cetirizine on 12/23 with some relief. Dues to persistence on 12/27/20 repeated cetirizine. Photos available.

Patient describes pain at injection, itchiness and experiencing pain. This hasn't had pin since but it did happen within 12 hours of injection

Pain at Injection site

States bruising shortly after injection. States on Dec. 27th around 4pm, developed redness 3-4 in x 2 in with lump (approx 1/4 in diameter in center). Area painful and warm to touch which affected ROM. On 28th states that he showed to a pharmacist that he works with Dr. who said it appeared to be an injection site reaction. At 4 pm on 28th, states bruising improving, but redness is still present, maybe even increased from earlier.

Pfizer-BioNtech COVID 19 Vaccine Left arm pain, mild to moderate from the time of receiving the shot until the next morning at which time left arm pain began to improve. The following morning, woke up with a fever of 102F, intermittent fever all day ranging from 99.9 - 102F. Dulled sense of smell and taste since the injection. Decreased appetite.

Reports that within 24 hours after receiving vaccination had a splitting headache, fatigue and was barely able to lift or move his arm that the injection was administered. The injection site was red and hot to touch, very painful and swollen. After 24 hours the pain started to radiate into that side of his neck as well. He then felt feverish with chills and was very fatigued and unable to get out of bed for 2 days. Also developed diarrhea in that time frame.

After administering the vaccine the Luer Lock needle fell off of the syringe. The nurse stated that a lot of vaccine ran down my arm and was not administered.

I became nauseated and had abdominal cramps for three days.

Headache, dizziness, shortness of breath

Pain at Injection Site

42 year old female who works as a pharmacy tech developed diffuse pruritus and throat tightness, nausea during her wait time. She was given EPIPEN and transferred into the treatment area. She was given 50mg benadryl x2 followed by an additional EPIPEN. Patient reported throat tightness resolution but persistent pruritus and nausea. She was transferred to ED in stable condition with plans to follow up in Allergy.

Pfizer-BioNTech COVID-19 Vaccine: Approximately 90 minutes after receiving vaccine patient returned to clinic reporting dizziness, flushing, nausea, claminess, and hot flashes. Initial blood pressure 133/97 mmHg, other vital signs reported as stable. Patient provided with ice pack, water, and snack. Patient was observed for one hour and symptoms improved. No loss of consciousness or respiratory symptoms reported. Patient left clinic stable.

Moderna Covid-19 Vaccine Patient started vomiting 6 and half hours later, staff reported it and we are reporting it as an ADR

"December 23, 2020, at approximately, 1645 patient noted right eye numbness that tingled into right cheek. At 1730, looked in the mirror and noted no movement in muscles on right side of face. Could raise right eyebrow, but right eyebrow and below numbness and no movement. Patient spoke with physician at Public Health Department and it was recommended patient go to Primary Care to see provider NP. Then at approximately, 1920 went to the local Emergency Department and was seen by Dr. in the ER department. Dr. consulted with on call neurologist. Patient states she was diagnosed with Bells Palsy and given oral steroids (""three pills), then started a Medrol Dose Pak the next morning. As of today, December 28, 2020 patient reports ""Face and eye area feel normal. My mouth is not drooping. I have at least 50% of my movement back."" Patient continues to take Medrol Dose Pak. On day 4 of Medrol Dose Pak has 3 more days. Emergency Department recommended patient follow up with pcp in 5-7 days."

Injection site pain.

"Given vaccine at 1352 on 12/28/2020, employee reports symptoms started almost immediately. Symptoms: tongue felt ""funny"" describes as tingly and thickness feeling that extended down to throat area. Employee did not report symptoms immediately-waited about 30 minutes to notify staff. Vitals taken right away: B/P 138/80, Pulse 64, Respirations 18 at 1425. Given Benadryl 50 mg orally, employee able to swallow. Refuses Epinephrine stating she can still breathe fine, still able to swallow and knows Benadryl will be able to help. Monitored x 30 minutes longer=stayed total of 1 hr post vaccine. Started feeling improvement at 1450 and by 1510 felt significantly better, vitals stable and was released. Aware that benadryl can cause drowsiness and she should not drive. Employee stated she was ""just fine""."

Shortness of breath starting 12:50 on 12/22/20 lasting up to the 5pm hour. Shortness of breath. Monitored O2 sats and deep breathing supine on sofa. Sats stayed in 90s and only for about a 30 min period, sats dropped to 88-93 percent.

Anaphylaxis symptoms starting about 45 minutes after injection. Initial symptoms were severe light headedness and tachycardia. Epi-pen self administered 5 minutes after onset of symptoms. Symptoms resolved within 30 minutes of Epi-pen administration.

Upper shoulder tenderness, appearing days after injection site tenderness fading away, told by coworkers early sign of possible SIRVA.

Patient did not eat prior to vaccination. Felt anxious about vaccine. Felt weak and lightheaded. Patient was brought to ER for monitoring and assessment. Was released back to work without treatment required after a few hours.

Pain at injection site

I am a nurse and I received the Pfizer vaccine on 12/26 at 1030am. I do have a history of food and outdoor allergies. I once got hives on my back from the flu shot, but since have been fine with it if I take Benadryl before it. About an hour after the vaccine, I felt itchy on my upper half of my body. I took a Benadryl without relief. I had a 100.1 fever that afternoon so I took another Benadryl and ibuprofen. It broke my fever, but the itching continued. I also had a couple of hives and a red blotchy rash over my body. I took a hydroxyzine and was able to sleep that night. The next morning I once again felt flushed and itchy. I worked and came home to the same rash, almost mottled looking all over my body. I took a Benadryl and ibuprofen and woke up early this morning itching again. As I was driving into work today (Monday), I noticed my heart fluttering and having palpitations. This continued throughout the morning. My skin rash is still red like I have a bad sunburn all over and is itchy with some red spots. I went to the ER to get checked out. My ekg was normal. They advised me that this is an allergic reaction to the vaccine and to continue 50mg Benadryl q6h for a couple more days and to see a PCP for follow up if it?s not better. I never had respiratory issues or swelling. I will continue to monitor symptoms and reaction.

"Patient received Moderna COVID-19 vaccine and within 5 minutes patient complained of fast heart rate and feeling ""not right"". Patient blood pressure at time 156/88 with heart rate 114. Patient given cool rag and then complained of tingling to her arm and hands and numbness to tongue. Patient was taken to Medical Center Emergency Room and given Epinephrine 0.3 mg per Auto-injector. Patient was then given Solumedrol 125 mg and Bendaryl 25 mg slow IVP. Patient observed in the ER and didn't experience any rash or swelling of lips and/or tongue."

Student went to administer vaccine. An unknown quantity of vaccine leaked out of the hub of the needle and dripped down the patient's arm to the floor. The exact amount given is unknown. Call has been placed to Moderna and CDC for guidance in regards to redosing.

Metallic taste was reported ten minutes after vaccination. Staff reported the reaction was fleeting (seconds long). Patient reported eating dehydrated strawberries just prior to vaccination but not sure if reaction was food related or vaccine related. Onsite MD assessed patient. No angioedema, respiratory distress, or any other complaints. Staff reported being back to baseline quickly after fleeting metallic taste.

Immediately after the vaccine administration had elevated heart rate, dizziness, difficulty breathing. Given a 2 doses of albuterol to help with breathing and transported to ER. Nearly 5 hours after visit, manageable but still difficulty breathing.

Dizzy and Nausea

patient felt a thickening in her throat. Throat also felt sore. IM Benadryl administered. Patient reported feeling better quickly. Monitored for an hour post benadryl.

39 y.o. firefighter, healthy without significant past medical history. He has a hx with cashew allergy in the past (required Epi pen use). He felt light headed, flushing sensation, and mild itchiness on the arm. His light headed felt worse and laid on ground. He remained alert and without apparent distress. There was no respiratory or cardiac complains. Vital signs were normal, O2 sat 100% on RA, BP 119/77, pulse 65, EKG NSR. Paramedics and his colleagues were present and assisted. Benadryl 50 mg IM once was given around 1300 pm. An IV 18 G was placed by paramedics to his right AC and NS tko. Patient left via ambulance.

Nausea, Cold fever, upset stomach, no appetite, pain, headache, vomiting, sore arm

Generalized itchiness, intermittent trunk hives and injection site herpes zoster-like rash. Benadryl 25mg tablets q4-6 prn with moderate relief. From onset (day 2 post vaccination) until present (day 7 post-vaccination)

Reported metallic taste in mouth 5 minutes after vaccination (vaccine received at 11:07 AM). By 11:37 AM, the metallic taste was still present but improving. Staff denied unusual foods prior to vaccination. No other signs/symptoms reported or found when assessed by onsite MD.

Moderna COVID-19 Vaccine EUA Severe sinus reaction - sneezing, congestion, runny nose, chest pain from excessive sneezing.

Body chills, site pain, nausea, and severe headaches.

Patient is a 60yoF who is presenting to ED on 12/28/20 complaining of decreased sensation and itching on left side of face as well as darkening of peripheral vision on the left side. She received her initial COVID vaccine today at 11am, first began noticing symptoms at 1230 and took 2 benadryl around 1pm. In addition, she is reporting some light headedness. She states that her face feels swollen, but knows that it is not. Itching improved after benadryl but face continues to feel numb on left side.

soreness of arm, dry throat

generalized malaise, weak, body aches.

Vaccine administered 10 am 12/26/20. Post vaccine experienced headache, sore arm and fatigue. Approximately 6 hours post injection developed a hot feeling like she was sunburned, pruritis and then a pepper rash/hives started to develop inferior to injection site on right arm, spreading to left arm, chest and neck. Went to ER and treated with IV steroids, diphenhydramine, and hydroxyzine. Discharged on a 5 day course of Famotidine, Hydroxyzine Pamoate, and Prednisone with PRN Diphenhydramine.

chills, slight fever (99.5) and some muscle aches in legs.

nasuea, emesis, throat irritation, hot/cold flashes. The individual was transported to the emergency department for further observation and if necessary treatment.

Injection site pain, Head to toe muscle pain, Joint pain, general unwell feeling

Approximately 5 minutes post vaccine administration, pt reported shortness of breath and chest tightness. Vital signs remained stable BP 100/65, O2 sat 97%, HR 80-100, respirations easy and unlabored. Pt also experienced nausea without vomiting, and possible tightness in the throat, and numbness in the left arm. No swelling, no redness, no rash. EMS was called, EKG showed NSR, pt was transported to the hospital via EMS

Swelling in right axilla, called PCP, no treatment

My left are fell asleep and numb, decreased motor functions and then the tingling sensation moved to my left eye, lips and whole face, left lower leg and right hand. It progressed for an hour or two and then went away. Employee health sent me to the ED for observation. I am due 08/01/2021.

Initial sore arm with associated chills. As day progress worsening generalized myalgias, chills and sweats, mild weakness with position change on standing. Eventually with 10/10 frontal headaches and rigors. Full course lasted ~30 hours.

Headache, fatigue, body aches, sore throat, ear pressure COVID 19 Swab-Neg.

I received the Covid19 vaccine on 12/22 @ 7:00 pm. On 12/23 ~1200 pm, I had a headache that lasted for about 12 hours. I took Tylenol and Motrin and it went away the next day but came back again on 12/24 @ 6:00 pm. On 12/25, 12/26, and 12/27, I just felt unwell. No symptoms but felt unwell and had shortness of breath while walking. I usually walk about 10 miles daily without issue but on those 3 days, I had to take breaks and was not able to walk an talk at the same time.

Woke up with severe nausea 5 days after vaccination. Thereafter, developed lower abdominal pain and constipation. Took a dulcolax that relieved constipation. Then developed retching, vomiting and cramps abdominal pain

Within 2 minutes, Severe allergic reaction, with diffuse erythematous rash, throat tightening, chest discomfort, nausea, and BP240/120. (Normal BP 124/74). Had premedicated with 50 po benedry. Required 50 mg IM benedryl, ambulance ride to the ER, 125 mg of IV solumedrol.

Staff reported a mild tingling in right hand (of injection arm). The tingling lasted for a short period of time and went away once he put his hand in a neutral position. No other signs/symptoms reported when assessed by the onsite MD. Patient was advised to avoid heavy lifting and to seek medical attention if symptoms worsened. Mild to no residual tingling noted at close of observation period (30 minutes).

Weakness, headache, arm ache, back pain, unexpected heavy breakthrough bleeding and cramping LMP was 12/13/2020 not expected to bleed until 01/10/2021

Pfizer-BioNTech COVID-19 Vaccine: One day after receving vaccine patient awoke with myalgias, fatigue, fever (maximum temperature: 100 degrees Fahrenheit), headache, and rhinorrhea. Patient was

evaluated via telehealth two days after vaccine administration and denied throat pain, chest pain, chest tightness, or wheezing. No difficulty swallowing or breathing. Patient was instructed to follow-up with a health care provider immediately for worsening, persistent, or concerning symptoms.

I have history of intermittent episodes of neurological dysfunction, with probable diagnosis of FND. I was symptom-free prior to vaccination today. Within 20?30 minutes my left arm (injection site) began to ache. Shortly after that my face began tingling and my thinking began to feel ?foggy.? By one hour post injection, I was having trouble speaking and walking. These are not brand new symptoms for me, but I do feel the vaccination caused a flare of my dormant symptoms.

Patient reports 2 minute episodes of numbness to hands and feet occurring every 5 minutes s/p receiving COVID-19 vaccine. She further reports associated heart pounding and difficulty breathing General ROS: (-) chills, fever, (-) unusual fatigue or weight loss ENT ROS: (-) nasal discharge, (-) cough, (-) sore throat Respiratory ROS: (+) shortness of breath CV ROS: (-) chest pain, (+) heart pounding Gastrointestinal ROS: (-) abdominal pain Genito-Urinary ROS: (-) dysuria Musculoskeletal ROS: (-) joint/bone pain Neurological ROS: (-) headache, (+) numbness to hands and feet Dermatological ROS: (-) rash Psychiatric: ROS: (-) SI/HI, (-) psych hx Patient improved her symptoms, discharged home

Headache, itchy, joint pain, nauseated, vomiting only twice, body aches, chills, slight fever nothing over 99.3,

generalized malaise, weak, body aches

Headache, extreme fatigue

Difficulty breathing 5 minutes after receiving first dose of Covid-19 vaccine by Pfizer/BioNTech, small erythematous spots to bilateral arms.

Developed a rash on face, neck, arms, stomach ? slight sore arm at injection site

"Initially reported an ""unbrushed teeth"" taste in mouth post-vaccination and for 5 minutes afterward. Reported he did indeed brushed teeth this morning. Unusual taste lasted 10 minutes. Reported no unusual foods consumed prior to vaccination. Onsite MD assessment reported slight headache but staff had prior to vaccine injection, not worsened. However, he has had history of headaches with vaccines. Some tingling also reported in left arm (vaccinated arm). Denied other signs and symptoms. Resolved symptoms after 30 minute observation period (post-vaccination)."

On 12/23 reports feeling fatigued all day. At approximately 4:30 pm on 12/23 began having fever (100.4), body aches, and headache. These symptoms subsided at approximately 11:00 pm on 12/23. On 12/24 had no symptoms and felt fine.

"After receiving vaccination, the staff reported ""cold sweats."" He went home sick after receiving vaccination."

Injection site Pain

Became very flushed in the face. Dizzy and nauseous & felt completely out of my normal. Received a rash all over my upper body. Rash remained until 12/26/2020. Benadryl and Tylenol used. Refuse to get 2nd dose and received documentation for this. Components in vaccine are bothering me and I will not put my body through it again.

fever/chills

Flushing, heart beating fast, pulse ox 96% hr 13-114 . kept for observation 45 min felt well when left pulse ox 99% hr 110.

33 y.o.ámaleáwith no significant past medical history except for obesity who has been working as a nurse in the emergency room department in our hospital and today he received COVID-19 vaccine and 30 minutes later patient started having increased saliva, cold hands and feet, left-sided pressure-like headache and some numbness in his legs at the same time he suddenly started talking only in first language and lost his ability to speak in second language. áHe understand second language but replying first language stating that he is talking in second language. áOn exam he was alert oriented confused by people not understanding his second language stating that his numbness and cold feeling in the hands and feet have improved. áInitially patient received 10 mg of Decadron for possible allergic reaction he had a head CT scan that was negative and his labs were remarkable only for hypokalemia. áPatient had no prior history of any neurological symptoms he was advised admission to the hospital for observation á á Patient symptoms resolved next day,he is alert oriented able to communicate in second language he had a head MRI and head neck MRA that came back negative and had an EEG that showed no seizure activities. Patient was seen in neurology consultation who felt that patient most likely had an episode of migraine headache. Patient is going to be discharged home and to have a follow-up with his primary care physician next week á

Throat itching and tongue swelling

Pt c/o itching at site of injection and back. Denied SOB. Hives, redness at site. Diphenhydramine 25mg po given at vaccination site. Transferred by EMT to ER. At ER, patient given Prednisone 60mg, additional diphenhydramine 25mg and famodidine 40mg. Recommended she take Prednisone x 2 days and diphenhydramine x 24hrs. Patient was discharged to home within one hour.

I had the typical local reaction for the first 3 days following the injection: redness, soreness, swelling at injection site, occasional itchiness and occasional burning, warm to touch. It was resolved by the 4th day. Then on the 8th day, I felt a little itchy and itched the site gently. Three tiny hives appeared and became a moderate-sized red swollen area by the evening with mild pain and some burning. The 9th day it was very red, moderate-to-large sized, some burning, warm to touch. The 10th day, today, it doesn't look angry anymore, is no longer warm to touch, looks like it's resolving but still some swelling that feels like it goes around my upper arm. I had it checked by an NP today and she thinks it's all related to the injection being administered lower than my deltoid, instead went into the subcutaneous/fat area. So we will watch it but she doesn't think it's infected or any reason to not take the 2nd dose when it's time.

Pain at Injection site

Nausea, vomiting, chill, headache. Lasted more than 2hrs. Taken to ED and treated for nausea and rehydrated.

Patient had a vaso vagal event, per the ED notes. Drop in blood pressure and had a fainting spell. Quickly improved after he arrived to the ED

None

Pfizer-BioNTech COVID-19 Vaccine: Patient reported dizziness and shakiness upon arising 15 minutes after receiving vaccination. Vital signs: blood pressure: 115/78 mmHg, pulse 73 beats per minute, temperature 36.8 degrees Celcius, respiratory rate 16 breaths per minute, oxygen saturation 99% on room air. Patient waited five minutes, stated she felt much better, and left vaccine clinic in stable condition. No respiratory symptoms or loss of consciousness reported.

Heart racing (Patient reports pre-existing heart condition) Soreness Aches

Swelling of the lips

Chills Rapid heart beat dizziness Onset of symptoms was within 5 minutes but were mild and subsided after approximately 20 minutes

Nausea, Headaches, Fatigue

Started with very bad cramps which lead to diarrhea, that lasted about 1 hour. Then my SI joint started hurting so bad I couldn't stand it and went to ER. They gave me a shot of Torridol and a prescription for Naproxen. I was also nauseous, lethargic, chills, ringing in my ears, headache . I believe my SI joint started hurting due to having arthritis in the joint. The Naproxen escalated all the above. My arm also very sore, but that I could deal with. Feeling a bet better by 12/28/2020. Going to try and get into doctors on 12/.

low grade fever and sore arm

Headache, strange eye feeling, floaty, dizzy, light headed.

She began to experience body wide tingling, headache and nausea. She did not have lightheadedness, chest pain, shortness of breath, pain at the injection site, rash or wheezing. She went to urgent care in the facility to be evaluated. Patient was placed on a monitor and observed. Vital signs remained stable. She never developed rash. For her nausea she was given Zofran 4 mg as a disintegrating tablet which was helpful. She received 650 mg of Tylenol for her headache pain. Observation continued during which time she was entirely stable. She requested to go home.

Felt like she was breathing fire, flushing, pain ran up left arm to neck, clavicle, joint pain muscle ache, chill, fatigue, swelling under left armpit. Tingling to the face, ringing in ears from covid got worse, neuropathy real intense.

Headache, Tired, Injection site pain

After I received the vaccine my arm was very hot and swollen. Also felt very fatigued, dehydrated, no fever.

Started to feel very dizzy about 3 hours after vaccination. Also felt some nausea and overall head felt very off. Very lethargic and spent many hours sleeping because of the extreme lethargy and woke up a few hours later, still experiencing some dizziness but not as severe as earlier. Also have mild headache but I chronically suffer from migraines so that is nothing out of the ordinary for me. Took one meclizine and two Tylenol after onset of symptoms. Symptoms are tolerable at this time, they were more debilitating earlier. I am still experiencing them now at 6:30 pm.

Phizer-BioNTech Covid-19 Vaccine EUA Nausea and fatigue beginning about four hours after administration. Diarrhea beginning about six hours after administration. Vomiting and chills beginning about eight hours after administration.

WARM SENSATION/FLUSHING ROLLED THROUGHT BODY FROM HEAD TO TOE. FELT DISORIENTED. ABLE TO WALK. DENIES DIZZINESS. THEN FELT TINGLING TO FINGERS ON LEFT SIDE. SYMPTOMS RESOLVED AFTER 5 MINUTES.

Headache, weird eye feelin, like fuzzy headed too

"Approximately 15-20 minutes after vaccine patient reported back to adminitration area complaining of a ""lump in her throat"" with halo vision. Administered 50mg oral benadryl. Patient report nausea and felt flush and lightheaded. Approximatly 20min after benadryl administration she felt better and was able to return to work."

"Approximately 15-20 minutes after vaccine patient reported back to adminitration area complaining of a ""lump in her throat"" with halo vision. Administered 50mg oral benadryl. Patient report nausea and felt flush and lightheaded. Approximatly 20min after benadryl administration she felt better and was able to return to work."

Reported diffused rash to chest and back ~2 hours after recieving Pfizer COVID-19 vaccine on 12/18/2020. Self-medicated with famotidine40 mg, cetirizine 10 mg, and Singulair 10mg at home. Rash improved next day,

Swollen lymphnodes on same side as vaccination site

BAD HEADACHE BEHIND LEFT EAR AND TOP OF HEAD TO RIGHT EAR

Patient complained of feeling dizzy. She had blood pressure checked and it was elevated. Blood pressure did decrease after 15-20 minutes. Patient was observed by 2 local staff nurses and myself. She was counseled to speak to her primary care physician as soon as possible. She was walked to her vehicle by nursing staff. The vehicle was driven by her sister. An administrator at the facility did inform me at about 5pm that patient was at home safe and feeling better

Dec 23 started having right side facial tingling, slight numbness, decreased sensation. Headache, fatigue. This facial symptoms came and went away daily in short intervals. On 12/27 I got dizzy, weakness, blurred vision, right face numbness, slight lip drooping, high blood pressure, trouble swallowing, tongue numbness on right side, and right arm tingling. Went to the doctor on 12/28 and got steroid treatment from being diagnosed with Bell?s palsy, and a ct scan that didn?t show anything abnormal.

I received the vaccine around 7:55 am in my left arm. I waited around the appropriate time then drove home. No problems until 12:30 or so. I was resting in my bed and immediate felt my heart start to race. I checked it with my pulse oximeter and my rate had shot up to 148. I got up and tried some maneuvers to try to get it down. It then went up to 152. I told my husband to call EMS. I also contact my co-worker. She is a physician and she agreed with taking some benadryl. I took 25 mgs of benadryl. EMS arrived about 10 minutes later. they monitor my blood pressure and heart rate. it did come down but remained around 100. I then went to ER by car for evaluation.

Patient developed intense itching 10 minutes following the administration of the COVID 19 vaccination while waiting in the post vaccination recovery area. Emergency personnel present, PO Benadryl and Epipen administered. Patient sent to ER via ambulance for observation.

shortness of breath, diaphoretic, heart racing

Patient reports taking Pfizer Covid vaccine and 2 hours after that she reports feeling not well. She recorded that one of the side effects was heart arrhythmias and hence she had her coworker checked her rhythm and she reported that her heart rate was in 180s and hence she was brought to the emergency department for further evaluation. She reports at the time she had palpitations and felt mild lightheadedness and dizziness. She was found to be in SVT with heart rate in the range of 1 80-220 and she received 1 dose of 6 mg Adenoscan after which she converted to normal sinus rhythm. At the time of my evaluation she is in normal sinus rhythm with heart rate in the range of 90-100. She denies any further palpitations. She reports she had chest tightness for the last 3 days which was assumed to be secondary to asthma and for which she was prescribed prednisone. Currently with the prednisone she does not feel any further chest tightness. She denies any chest pain shortness of breath, fever or chills. She reports remote history of arrhythmia following her foot surgery in the past however does not recall what arrhythmia she had at that time.

Cold sore on lip - used OTC abreva, it is still healing. It has been years since I have had a cold sore. I am not sure if it is related to the vaccine, but thought I should report it for more information.

Vasovagal syncope episode occurred right after receiving the Pfizer COVID-19 vaccine injection, patient became pallor, not diaphoretic, no c/o CP nor SOB, patient felt dizzy, HR in the50's, BP 78/50, glucose = 91, pt given water and OJ. After fluids pulse was stronger, bounding in the 60's, color improved, patient was still feeling faint, taken to cardiac intervention area to lay down, patient refused to go to ER, RRT paged and came to pod - escorted patient to lay down. Of note the patient only had 1 egg for breakfast. Patient continued to be pale, starting shaking and was escorted to the ED for IV fluids and monitoring.

Rash, hot sensation, anxiety Localized reaction in arm, hot, red, swollen

Later in the evening once home, the Eee took Benadryl for initial rash presentation on L arms (vaccination site). Took tylenol next AM for chills, body aches. hives spread to chest. Took more tylenol for itchy, burning sensation. On 12/24 Thursday she noticed new SOB, 101.7F, hives all over the body, Went to a local ED and got solumedrol, famotidine, benadryl, tylenol, IVF. DC'ed from ED on prednisone, benadryl. Had h/o COVID 4/2020.

Dizziness

65 YEAR OLD MALE PRESENTS TO THE EMERGENCY ROOM COMPLAINING OF COUGH WITH CLEAR PHLEGM AND SHORTNESS OF BREATH ONSET 8 DAYS. HE REPORTS SOME CHEST PAIN WITH COUGH. PATIENT REPORTS HE WENT TO SEE HIS PCP ON 12-DEC AND WAS PRESCRIBED PROVENTIL AND PREDNISONE. HE HAD A NORMAL CHEST X-RAY AT THAT TIME. HE STATES HIS SYMPTOMS WORSENED ON 17-DEC AND HE WAS THEN GIVEN LEVAQUIN. PATIENT REPORTS HIS WIFE TESTED POSITIVE FOR COVID-19 ON 05-DEC, BUT HE TESTED NEGATIVE AT THAT TIME AND HAD NO SYMPTOMS.

Patient reports numbness and tingling in both feet, temporary nausea, Sore throat and loss of voice (hoarseness)

Fever and chills

facial itching, flushed. IM Benadryl admined. Patient felt better quickly.

none

Tingling and numbness back and sides of back 1/3 of tongue

Patient developed a red rash on left arm starting at injection site and moving down arm towards wrist/hand. Patient stated her palms felt clammy and numb. Patient expressed feelings of anxiety.

headache all over head, so very tired, body sore, do not want anything to eat.

Dizziness and Headache that took 25 min. to resolve.

Hives. Vitals checked and BP 134/78, pulse 95, SPO2 99. Lungs clear. hives noted on posterior neck, back, upper arms, thighs. Patient given 50mg Benadryl at 630pm. Monitored x 1 hour. Improved. Sent home with scheduled benadryl. Patient already has EpiPen on hand. Instructed to follow-up with PCP.

Pfizer-BioNTech COVID-19 Vaccine EUA

- Fever, Tmax 101.16 occurred 12 hours after injection, febrile at least 2 hours. Afebrile by AM of 12/25, resolved without antipyretics. - Right arm pain: Onset 12/24, up to 6/10. Resolved by 12/26. - Fatigue: Onset 12/25, resolved by 12/26.

Immediately felt warmth and tingling to Left Deltoid at injection site, then started to feel itching and feeling of swelling to throat and mouth. Denies any SOB. No obvious hives. Treated with Solumedrol 125 mg IV, Benadryl 25 mg IV, Pepcid20 mg IV. Given Rx for Benadryl 25 mg PO every 6 hour PRN.

Left axial lymphadenopathy

100-101F fever and chills started on 12/27 @ 945pm 100-103.0F fever, nausea, vomiting, chills and diarrhea on 12/28 @0900am 103.5F on 12/28 @ 0640pm. Advil and Tylenol have been taken

Tachycardia, warmth and flushed body esp face, mucus production (throat), scratchy throat, tingling sensations in feet, pain in R arm and radiated to neck and L arm, weakness, lethargy, dizziness, nausea, and headache.

About 10-15 min after vaccination patient began to experience left side facial numbness and tingling to include her tongue and cheek

Generalized body rash started ~24 hours later; still has 4 days later.

Extremely sore and painful injection site beginning around seven hours post injection. Painful to touch and movement. Sx lasted approx. 36hrs.

Patient presents to the emergency department 12/26 complaining of dry cough associated with fever and chills and headache associated with myalgia and diarrhea for 1 week duration. She had Covid vaccine 12/20 and the symptoms started the same night, she denied any sick contacts at home however she works at the Covid unit and reports constant exposure to sick Covid patients.

Tachycardia (heart rate 90s-110s), adrenaline rush in chest, tingly in chest and neck.. No treatment. Called employee covid HUB and they sent me to get covid swabbed today (12/28/20) . Called NP and she did not want to see me until covid swab back, symptoms worsen or she told me to go to ED.

Patient began to feel nausea after several minutes and then approx. 25 minutes after vaccine patient began to cough. Patient was transported to ER department on same location as clinic to be monitored by ER.

Became dizzy, warm, tachycardic. Lost consciousness (fainted?), quickly regained consciousness and was taken to the Emergency Department. Before transfer, Benadryl IM 25mg administered.

tiredness began the Thursday following immunization, along with sore throat and sneezing. All symptoms were gone by Friday.

He got the COVID vaccine on 12/23/20 at 11. Stayed at the facility for 30 minutes and then drove to another facility. Upon arrival at 12, he started feeling flushed. No SOB, no breathing difficulties. He started feeling itchy about 2 hours post vaccine. He took an Aleve. At home in the evening, took Benadryl with improvement of symptoms The following day also took Benadryl. On 12/25/20 & 12/26/20 he still had some itching, but not bothersome enough to take medications. On 12/27/20 he was working cutting tile and wearing protective eye wear, but the dust that landed on his face caused hives. He has been taking Benadryl since. He says this has occurred in past when his body is hypersensitive, the hives. He has seasonal allergies but no allergies to food or medications. Case discussed with Bolaris and recommendation is to take a Claritin or anti-allergy prior to next vaccine.

After injection felt immediately tingling to bilat arms, face, swelling to face and tongue, Itchy feeling to chest, feeling of palpitations and general unease. HR was 120 BPM, scattered hives over chest. No appreciable airway swelling. Treated with Epinephrine 0.3 mg IM, Solumedrol 125 mg IV, Benadryl 25 mg IV, Pepcid 20 mg IV, Ativan 0.5 mg IV. Rx given for Benadryl 25 mg every 6 hr. PRN

Red spot on arm with knot

Injection site tender to touch and with movement. Fatigue, muscle pain, joint pain, chills.

Scratchy throat. Bendadryl 25mg PO administered. Observed and discharged from vaccine clinic.

"Approximately 7 hours after receiving the vaccine patient who is a L&D Nurse return to work in her area. She describes that after finishing with a C-section she felt burning in both of her eyes (she thought this feels like an allergic reaction, but I am not sweating and haven't rubbed my eyes). She went to the restroom to get a cloth to wash her eyes; afterwards she reports her vision went totally black in both eyes. She reports feeling frustrated that no one came to help and some panic in trying to figure out how to get out of the restroom. She did make it out of the bathroom. Her Staff reports she postured and turned arms inward, head going to one side and passed out. They also report ~ 10 minutes of incoherent conversation and stating ""I got the vaccine, maybe I was given the wrong thing and now I'm blind"". Upon waking, patient vision fully restored and patient does not remember incoherent conversation. Differential diagnosis- TIA vs. CVA > seizure disorder>>> complex migraine"

Injection site pain and headache Tylenol 1000mg taken

Tachycardia 160-170bpm, anxious, carpal pedal spasm. States she took Zyrtec and inhaler this morning (for asthma). Transferred to outpatient clinic for assessment.

"Patient received the covid vaccine on 12/23/2020. She reported that she had chills (temp was 98.0), sore throat, nasal congestion, sneezing, started on 12/25/2020. Chills (shivering lasted for 1 day and ""broke out in sweats""). Still has sore throat., stuffy nose, sneezing as of 12/28/2020. Denies rhinorrhea, cough, or fever. Had negative covid test on 12/28/2020."

"Pt received Moderna COVID on 12/28/2020 without event. She returned 45 minutes later complaining of chest tightness and ""feeling weird"". A code A was called and she was triaged by anesthesia. No angioedema noted. She was moved to nurse stat bay and 911 was called."

Left flank and back pain thats increasing in severity. It is now interfering with acts of daily living such as driving, bending down etc

Symptoms include, hot flashes. palpitations and shortness of breath five minutes after vaccine administration. Patient was given oxygen and Claritin 45 minutes after. Patient was sent to hospital for further monitoring after an hour of administration.

Pt received the covid-19 vaccine from Pfizer and started to experience symptoms 6 days later. Symptoms includes hives, low appetite, wheezing, coughing, and fatigue.

B/L LEG JOINT PAIN, AND MUSCLE PAIN NAUSEA - DRY HEAVING NECK/SHOULDER PAIN ONSET 12.25.20 DURATION/END 12/.27.2020

Chest tightness and flushing. Transferred to outpatient clinic for physician assessment

"PATIENT BEGAN WITH AN ITCHY THROAT AT 15 MINUTES AFTER VACCINE ADMINISTRATION AND LATER DEVELOPED AN ""UNUSUAL SENSATION"" TO THE BACK OF THE THROAT. EPINEPHRINE 0.3MG ADMINISTERED. IV NORMAL SALINE STARTED. DIPHENHYDRAMINE 25MG IV GIVEN. PATIENT'S SYMPTOMS RESOLVED. TRANSFERRED TO ER FOR FURTHER EVALUATION. CONTACTED ER AND WAS INFOMRED PATEINT DISCHARGED WITH NO COMPLICATIONS."

Dizziness, lower left abdominal pain, flushed, heart palpitations. Lasted so long I had to be seen in the ED. New onset of bigeminy. 5 days later I am still having dizzy, feel foggy in my head, overall don?t feel my self.

SHORTNESS OF BREATH, TROUBLE BREATHING, CATATONIC STATE, POTENTIAL SEIZURE

patient noted headache which started within 15 minutes post vaccination, patient was observed for 30 minutes post vaccination and headache remained but did not worsen. Stated she did not have any dizziness of lightheadedness was going back to work. Advised she could treat with OTC pain relievers

Tingling and numb feeling at back of tongue immediately after injection Weird sensation of lump in throat without anaphylaxis that got better with time

patient reported feeling nauseous and dizzy about 15 minutes post vaccination. Was brought to exam room to lay down, was given some apple juice to drink. Vital signs were checked, patient remained onsite for about 1 hour being monitored. Stated she felt better but was still nauseous when she was released to her husband to drive her home. No history of vaccine reaction in the past

She received vaccine and was sitting waiting for 15 minutes. After 10 minutes she came over and expressed that she felt dizzy and was about to pass out. We took her over to bed where she was extremely nauseous and dry heaving repeatedly. She was also extremely flushed and hot but no temperature and no problems breathing. Blood pressure was elevated when ems came. We called 911 and had a Dr. who was at clinic check on her. Ems came after about 10 minutes and took her to hospital.

Itching and mild hives started within 10 mins of the vaccine injection. Patient was treated with antihistamine and responded well. symptoms improved after 2 hours of monitoring.

Worsening, swelling, redness with warmth and itch around injection area and a few inches below

Moderna COVID-19 Vaccine fever, chills, myalgia

Sore throat and body aches began the Saturday following immunization and ended within an hour of starting

severe intractable headache from 12nn 12/23/2020 to 1500 12/24/2020 associated with photo sensitivity, nausea, generalized body malaise, pain & tenderness on injection site. Treated with Tylenol & neurofen tablets, rest in the night & whole morning.

Chills, Fever, body aches, fatigue. Took Tylenol. Resolved in 24-36 hours.

Patient stated had some minor tickle in throat and slight heaviness in chest. Eyes than began swell bilaterally after 25 minutes after vaccine was given.

patient started having dizziness when she got up to leave from the waiting room 15 minutes post vaccination, she also mentioned headache behind her right eye. She was taken to an exam room in a wheel chair as she was unsteady on her feet. She was laid down on an exam table and vitals checked. She states no previous vaccine reactions, has history of seizures and has had them with increased frequency recently. Patient was released to her friend to be driven back to work 1 hour and 27 minutes post vaccination

Tiredness at the second day of vaccination (12/23/2020) and swollen tender left axillary lymph node started (12/26/2020) and still ongoing till the date of filing the adverse event (12/28/2020).

Tiredness at the second day of vaccination (12/23/2020) and swollen tender left axillary lymph node started (12/26/2020) and still ongoing till the date of filing the adverse event (12/28/2020).

10 minutes post-inoculation, I developed an ice cold sensation in my chest that spread throughout body and extremities. I developed a metallic taste in my mouth, nausea, tingling in my hands and feet and lightheadedness. This lasted 15 minutes, then repeated approximately 20 minutes later reccured as I was set to leave vaccinations site.

Severe itchiness with associated hives

chills at about 2:00am, headache, tiredness most of the day

Fainted within a couple minutes of recieving injection. Rapid response team activated and I was lifted onto a bed. Very low blood pressure. And ultimately felt better after 30 to 45 minutes of monitoring by medical team.

Low grade fever and site arm sore

Fever 100 degrees Chills severe Body aches mostly legs Mild soreness in injection area (nothing more than a typical shot)

12/24 ! 13:15 - 15 min after vaccine was administered p t c/o dizziness and shaking. was monitoring for further 15 minutes by vaccine staff. Then apx 06:00 pm that night started c/o chills, N/V, tremors, Fatigue, headache, and feeling flushed. continued thru 12/26. then 12/27 woke up with headache, n/v, chills, tremors and body swelling. 12/28- c/o nausea and headache. Treated with Tylenol OTC 12/24 and 12/26 only. 12/28 Completed rapid COVID 19 test- results negative. EDD 07/30/2021.

Moderate muscle ache,fatigue,sinus congestion

APPROXIMATELY 20 MINUTES AFTER VACCINATION, SHE BECAME ILL, VOMITING THEN COMPLAINING OF CLOSING THROAT, FELT WEAK. EMT AND FACILITY DOCTOR ON SITE WAS CALLED, THEY DETERMINED SHE DID NOT NEED TO BE TRANSPORTED TO THE ER. CONTINUED TO MONITOR PATIENT .

overall body weakness for 3 days and 1 day of severe right leg muscle cramping.

tachycardia, hypertension <15 min post administration

Reported headache and twitching of right cheek. Took Tylenol and headache resolved day of vaccination; twitching resolved day of vaccination (unknown duration). 12/23/20 (day after vaccination) he reported a slight headache upon awakening that worsened as the day passed. He took 2 extra strength Tylenol at 10:00 AM (12/23/20). Tylenol partially effective - headache lessened but still present. 12/28/20 update - chills, nausea, and fatigue from 12/23 - 12/28. Improvement in symptoms but symptoms are not completely resolved as of 12/28/20 per patient.

Anxiety, headache, nausea, sweating approximately 15 minutes after injection. Observed 1 hour emergency room then discharged.

1600 reported petechiae to both upper arms and abdomen 1611 took 25 mg bendryl waiting for 15 min. didn't get any worse went home

Soreness in upper left side of arm where vaccine was injected. Similar feeling to getting soreness in arm after a flu shot.

numbness tingling started in hand moved up the left arm slight numbess r hand site slightly swollen beandyl 25mg given symptoms got better

Vaccination was given at 8:25 and she began itching at 8:32. Itching that progressed from bilateral arms to trunk, bilateral legs and back. She felt wheezes starting. Given 50 mg. Benadryl po at 8:35. Symptoms were getting worse and RN gave Methprednisolone 125 mg. IM at 8:45.Alburteral Inhaler 2 puffs was given at 8:50. At 9:00 patient C/O upper lip tingling. Visual swelling observed. She was transported to ED by WC. ED administered Pepsid po and observed her for an hour. She was then discharged.

Onset of tongue numbness a few hours after vaccination, which was gone the next day. Vaccinated on 12/16 - 10 days later on 12/26/20 tongue numbness recurred & he developed (R) facial droop - seen in ER on 12/17 had normal head CT, negative work up for stroke. Seen in clinic on 12/28 - diagnosed with Bells palsy, started on Valacyclovir. Patient will hold PrEP x7 days (precautionary), no sexual activity during that time.

Onset day 10 post injection of erythema, edema over an area of 5x7cm over the injection site. Associated with mild tenderness, and moderate pruritis. Slight increase in size over first 24 hours (to present).

Chills

Pain at site with Fever (temp. 101 degrees F). Patient was sent to the local hospital ER and returned to the facility with a diagnosis of Fever post vaccination. Tylenol was given and patient received IV HEP saline at the ER.

Pt developed hives on bilateral arms, wrist and hands. Vital signs stable, no other complaints of tongue or throat swelling. No other s/s of anaphylaxis. Pt given Benadryl 50 mg po and observed for 60 minutes. Hives resolved and patient sent home.

Developed localized reaction on day 8 after 1st injection - had no location reaction prior. No intervention needed. 28 weeks gestation at time of vaccine and due date 3/10/21.

Fever, chills, body aches, headache, exhaustion, swollen lymph nodes 12 hours past vaccination to present.

I have had continued ongoing dizziness/vertigo after receiving the vaccine. It has now been a week since my vaccination and I am still feeling this. It it tolerable, but continues and is annoying.

MD Notes in ED Patient is a 35yo female who presents with complaint of allergic reaction. This AM around 0945 received COVID vaccine. Some pain to injection site throughout the day. Today around 1700 started to note dizziness and hives throughout her body. Hives are itchy. Associated with nasal congestion and sore throat. Patient felt difficulty swallowing zyrtec/pepcid. No drooling. Patient without fevers/chills, no recent illness. Denies prior allergies to immunizations. Denies food allergies. No new medications. Another part of the record states she had hives 30 minutes after the vaccine and self-medicated with Zyrtec and Pepcid without relief. Treated in the ED with Epi 0.3 IM Solumedrol 125 mg IV Pepcid 20 mg IV Benadryl 50 mg IV IV fluids Arrived in ED 1836 / Discharged home at 2015

Muscle aches, cramps, paresthesia in extremities and feeling of joint stiffness starting at 3 days after vaccination and continuing intermittently even after 1 week from vaccination. Aches/cramps in the muscles of neck, back of thigh, butt, calves, lower back. Treated with heat pack and hot showers with some temporary relief. No response to acetaminophen.

fever , chills, migrane started around 3 am 12 24 20. Migraine lasted all day. Woke up 12 25 20 with slight headache all day. Physically tired. Woke up 12 26 20 feeling fine.

Intractable nausea, vomiting, fever (101.8), chills

Complaints of gradual joint and bone pain

Angioedema, throat swelling, itching, lungs tight-unable to take a full breath, tachycardia, anxiety, face flushed. I took 75 mg of Benadryl an hour before the injection. Had some caffeine after I became symptomatic. Was monitored for 1.5 hours.

I got the vaccine at 3:30 pm. My right arm where the shot was started to itch extremely bad around 4:30. Then around 4:50 my throat was swelling up and my ear felt congested. A few minutes later it was

hard to breathe. I let my staff know (i work at urgent care) that i was not feeling so good from the vaccine. i was checked into the urgent care and i had hives and i was itching all over.

Tingling in throat, heart pounding and racing, dizziness, flushed skin, sweating, feeling hot

96 hours post injection muscle and joint pain. Injection site pain for 96 hours post injection. 4 days of insomnia.

received COVID vaccine, dose 1, Pfizer, approximately 1600. During observation, became light headed, hot, tingling in hands and feet, with onset of nausea shortly after. given ice packs and encouraged to remain in observation another 15 minutes. denied SOB, itching, no apparent hives or swelling. At approx 1700, symptoms had not resolved, was taken to ED for evaluation.

patient initially complained of headache at 1502, then at 1507 stated tingling in fingertips and toes. Shortly after, complained of dizziness and began crying. Moved patient to cart and vitals taken - BP 160/80, P 104, R 38, SpO2 99% - patient feelings like heart is racing. Patient's hands cold but vitals improved at 1520 - BP 140/78, P 74, R 28, Sp02 99%. At 1527, patient feeling better, headache gone, and tingling improved. BP 120/78, P 73, patient sipping water. Attempted elevating HOB at 1530 and dizziness returned but vitals stable. Continued to improve with slight dizziness with progressive ambulation. By 1548, no dizziness with sitting on edge of cart and ambulated to bathroom, After continued walking with no further symptoms and continued stability of vitals, patient discharged from care at 1558. Final BP 128/78, HR 78.

multiple oral aphthous ulcers and tongue sores without a clear alternative trigger

Headache, nausea, abdominal cramping, elevated blood pressure, 5 mins after vaccination. At home the above symptoms continue plus joint pain, lower back pain, chills for 3 days.

Developed extremely sore arm at site of injection within first hour after vaccination; red rash developed (3 inch diameter) with localized swelling. Mild fatigue for first two days following vaccination. Beginning on Day 3 after vaccination, developed severe fatigue, muscle pain, back pain, joint pain, hot/cold chills, abdominal pain, nausea and diarrhea. Symptoms were severe for three days (Day 3-6 after vaccination) requiring bed rest and supportive care with OTC ibuprofen, benadryl and promethazine. Rash, swelling and muscle pain at injection site persisted through Day 5 following vaccination. Fatigue, muscle and joint pain persisted at moderate intensity through Day 8 following vaccination. Moderate nausea and abdominal pain persisted through Day 8 following vaccination. Still experiencing mild to moderate fatigue on Day 12 following vaccination.

Dull headache on Day 1 of receiving vaccine. Day 2 was primarily a sore arm (moreso than with influenza shot)

Left Shoulder pain that started as ?oh I slept funny? to not going away with ice/heat or rest. Worsening in severity daily and spreading towards base of skull and eventually into clavicle. The pain became excruciating and I was unable to turn my head at all to the left. So bad I had to use my hands to lift my head up. I eventually went to the ED on 12/27/20. And overnight the pain became so unbareable and

functionality so limited I couldn?t go to work or take care of my toddler. I returned the to ED on 12/28/20. Was advised to file adverse event and contact my employee health and safety department. I was initially examined in the ER the first time with a neck spasm. Sent home with an RX which didn?t work. At all. When I returned to the ER th next day, the physician felt my entire neck, shoulder and clavicle an noted swelling and prominent spasm. He diagnosed with a trapezius strain and a vaccine reaction. Gave me an RX for Valium which seems to help take the edge off.

Onset of slight itchiness noted minutes after injection, however did not report to hospital staff because did not realize it was a possible reaction (I have history of rash and skin sensitivity). Noted approximately 2 days later, injection site was increasingly itchy. Then I noticed there was also a red patch surrounding injection site slightly raised that has not subsided since, now 4 days since injection.

Itchy throat, tongue, Numb Lips, Flush, Redness and hives

About 1 hour after getting vaccinated i noticed that my left eye got puffier and I could feel the tingling on my eye. Being little confused and not knowing the cause after reading online I noted that this could be possible from Covid-19 vaccine. At this time few hours later my puffiness is slowly going away . I do have pictures taken at the time of being vaccinated and also when I noticed the possible reaction .

Overdose administered due to improper dilluent

Nausea, Diarrhea, Extreme chills, Fatigue, Bad dreams during nap, waking up in a very excessive sweat, gradually increasing high amount of motivation despite symptoms

low BP/low HR and went to the ER for evaluation

he felt ?oozy? and tingling in feet

Redness, heat, swelling that lasted for a week. Swelling went to around 3 inches circumference around the injection site. Now a lump under the skin and the start of a bruise forming.

Feeling of swelling of the upper lip and throat; Feeling of swelling of the upper lip and throat; Brief tongue tingling; her palms felt sweaty; her throat felt dry; This is a spontaneous report from a contactable consumer (patient). A 50-year-old female patient started to receive BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) Solution for injection (lot number: EH9899 and expiry date unknown) via an unspecified route of administration at the left arm on 19Dec2020 08:45AM at a single dose (dose number: 1) for COVID-19 immunization. The patient's medical history included rare, mild exercise induced asthma with cold a few times in the past; history of pre-eclampsia; and known allergies: wheezing with iodine injected for a hysterogram in 2014. The patient had no concomitant medications. The patient did not receive any other vaccines within 4 weeks prior to BNT162B2 and has not received other medications within 2 weeks of vaccination. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. It was reported that on 19Dec2020, 09:15 the patient experienced a feeling of swelling of the upper lip and throat. There was a brief tongue tingling about a half hour after the injection. Immediately after the injection, her palms felt sweaty and her throat felt dry. Therapeutic measures were taken in response to the

events. The patient took Claritin about 9:15 and Benadryl 50 mg twice so far; the first was taken about 9:30AM. At 1:30 pm, the feeling of lip and throat swelling came back and she took 50 mg of Benadryl again. At the time of the last observation, the outcome of the events was not recovered. The events were reported as Non-serious.

received COVID Vaccine on 16Dec2020 and was asymptomatic for active COVID carrier; received COVID Vaccine on 16Dec2020 and was asymptomatic for active COVID carrier; This is a spontaneous report from a non-contactable nurse. A 35-year-old female patient started to receive bnt162b2 (reported as product=COVID 19, brand=Pfizer; lot number and expiry date unknown), via an unspecified route of administration on 16Dec2020 at 09:30 AM at single dose for COVID-19 immunization. Patient's medical history and concomitant medications were not reported. The patient reported that she received COVID Vaccine on 16Dec2020 and was asymptomatic for active COVID carrier. Covid test type post vaccination was nasal swab on 16Dec2020 with positive results. It was reported that prior to vaccination, patient was not diagnosed with COVID-19. It was further reported that since the vaccination, the patient has been tested positive for COVID-19. The outcome of the events was unknown. Information on the batch number has been requested.; Sender's Comments: Based on the information currently available, a lack of efficacy with the suspect vaccine in this patient cannot be completely excluded.

Fatigue; moderate headache; This is a spontaneous report from a contactable Nurse reporting for herself. A 34-years-old female patient received bnt162b2 (BNT162B2; Lot # EL0140)vaccine , intramuscular in the left arm on 18Dec2020 15:15 at single dose for covid-19 immunisation . Medical history included hypersensitivity to medications including amoxicillin sodium + clavulanate potassium] (AUGMENTIN) from an unknown date. The patient's concomitant medications were not reported. On 18Dec2020 22:00 the patient experienced fatigue and headache (6/10) refractory to caffeine or hydration. The nurse did not try tylenol or NSAIDs as wanted to prevent interference with immune response. The outcome of both the event was not recovered.

lips began tingling; tongue was tingly/numb; tongue was tingly/numb; throat felt fuzzy like needed to clear it; This is a spontaneous report from a contactable nurse reporting for herself. This 36-year-old female patient (non-pregnant) received the first single dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot EH9899) on 19Dec2020 at 08:25, intramuscular, in left arm, for COVID-19 immunization. No other vaccine was given within 4 weeks prior to the COVID vaccine. Medical history included rheumatoid arthritis from 2014. The patient had known allergies to adalimumab (HUMIRA). The patient did not have COVID before vaccination. Family medical history relevant to AEs: none (sister allergic to cashews, dad allergic to bees).Concomitant medications included tofacitinib citrate (XELJANZ XR) from Feb2018, at 11 mg daily, for arthritis, ibuprofen (MOTRIN) at 600 mg, as needed (every day for years 600 mg PRN), vitamins NOS (MVI) daily, for years, omega-3 fatty acids. The patient received the vaccination on 19Dec2020 at 08:25 and waited at the facility 30 minutes. On 19Dec2020 at 09:10 the patient experienced lips began tingling, tongue was tingly/numb and throat felt fuzzy like needed to clear it. Symptoms persisted but did not worsen and at 09:37 she took diphenhydramine (BENADRYL) 25mg as treatment. At 10:30 symptoms were gone at 75%. Emergency room or physician office visit were not required. COVID was not tested after vaccination. Relevant tests: none. The events resolved on an

unspecified date in Dec2020. The reporter considered there was a reasonable possibility that the event was related to suspect product.

Arm swelling; red circle size of a 50 cent piece; severe itching; This is a spontaneous report from a contactable consumer reporting for herself. A 44-year-old female patient received the 1st dose of bnt162b2 (BNT162B2) (Manufacturer Pfizer-BionTech, lot# EH9899), via an unspecified route of administration in arm left, on 16Dec2020 at 01:45 PM, at single dose, for COVID-19 immunisation. Medical history included rheumatoid arthritis, Hashimoto's thyroiditis, vitiligo and alopecia all from an unknown date and unknown if ongoing. The patient had no allergies to medications, food or other products. Concomitant medications included unspecified drugs in two weeks. The patient experienced arm swelling, red circle size of a 50 cent piece and severe itching all on 16Dec2020 at 03:00 PM with outcome of recovering. The events were considered non serious.

right sided numbness; tingling to face,lips and arm to fingertips; slight headache within 15 minutes of vaccination; This is a spontaneous report from a contactable nurse. A 55-year-old female patient (not pregnant) received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, Lot number: elo140), intramuscularly on 19Dec2020 13:15 at single dose for immunization. Vaccine location provided as Right arm. Medical history included asthma. Prior to vaccination, the patient was not diagnosed with COVID-19. The patient's concomitant medications were not reported. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient experienced slight headache within 15 minutes of vaccination on 19Dec2020. On 19Dec2020 13:45, 35 minutes after vaccination reported right sided numbness, tingling to face, lips and arm to fingertips. No treatment was received for all the events. The outcome of the events was recovered in Dec2020. The events were assessed as non-serious.

Fever; chills; body aches; headache; fatigue; This is a spontaneous report from a contactable Other Health Professional (patient). A 42-year-old non-pregnant female patient received first dose of BNT162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number=EH9899) intramuscular at arm Left on 18Dec2020 15:45 at single dose for covid-19 immunization. Medical history included seasonal allergies, eczema, and diagnosed with COVID-19 prior vaccination. Concomitant medication included fluoxetine hydrochloride (Generic Prozac), krill oil, bifidobacterium lactis (PROBIOTIC), sambucus nigra (ELDERBERRY) and multivitamin. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient experienced fever, chills, body aches, headache, fatigue on 19Dec2020 12:00 PM, no treatment received for the events. COVID was not tested post vaccination. The outcome of the events was not recovered.

"Increased blood pressure; Rapid heart rate; Chills(shaking); Chills(shaking); Chest and neck tightness; Chest and neck tightness; Teeth tingling; This is a spontaneous report from a contactable consumer (patient). A 41-year-old female patient (not pregnant at the time of vaccination) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: Ek5730), via an unspecified route of administration on 19Dec2020 12:30 at single dose on left arm for COVID-19 immunization. Medical history included known allergies: Latex. Concomitant medications received within received within 2 weeks of vaccination included acetylsalicylic acid, caffeine, paracetamol (EXCEDRIN [ACETYLSALICYLIC

ACID; CAFFEINE; PARACETAMOL]); ibuprofen. The most recent COVID-19 vaccine was administered at Hospital. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. On 19Dec2020 13:00 (01:00 PM), the patient experienced rapid heart rate, Increased blood pressure, Chills (shaking), Chest and neck tightness, Teeth tingling. The adverse events result in Emergency room/department or urgent care. The patient received ER monitoring, EKG (reported as ""AE treatment"") for the adverse events. The events were non-serious. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient hadn't been tested for COVID-19. The outcome of the events was recovering."

fatigue; Fever 103.6/fever 100.3; headache; chills/chills with fever 100.3 after ibuprofen; Sore at injection site; body aches; This is a spontaneous report from a non-contactable consumer (patient). A 36-year-old female patient (not pregnant) received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, lot number and expiration date not provided), via an unspecified route of administration on 18Dec2020 14:30 at single dose for COVID-19 immunization. Vaccine location was Left arm. Medical history included migraine, transient ischaemic attack (TIA), allergies: Penicillin, the patient had covid-19 prior to vaccination. Concomitant medication included buspirone hydrochloride (BUSPAR), cranberry, vitamin c (ascorbic acid), colecalciferol (VITAMIN D). The patient was not received other vaccine in four weeks. The patient experienced Sore at injection site, body aches, chills with fever 100.3 after ibuprofen, headache on 18Dec2020 19:00. And then the patient had Fever 103.6, headache, chills, fatigue on 18Dec2020 19:30, sore at injection site on 18Dec2020 19:00, body aches on 18Dec2020 19:00. Therapeutic measures were taken as a result of events fever and chills, no treatment was received for the other events. The outcome of the events was recovering. All events were assessed as non-serious. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

About 30 minutes after injection I suddenly felt a rush of heat throughout my body; felt dizzy, weak and a bit nauseated; felt dizzy, weak and a bit nauseated; felt dizzy, weak and a bit nauseated; tired/ fatigue; have some minor injection site pain; This is a spontaneous report from a contactable nurse reporting for herself. A 42-years-old non-pregnant female patient the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE): lot number: EJ1675, intramuscular, in the left arm on 18Dec2020 at 13:15 (at the age of 42 years-old) as a single dose for COVID-19 immunization. The patient received the vaccine at a hospital. Medical history included an allergy to cilantro. Concomitant medication included colecalciferol (VITAMIN D), zinc (ZINC) intermittently, and paracetamol (TYLENOL) once, all within 2 weeks of vaccination. The patient previously took amitriptyline and experienced swelling of eyelid and palmar erythema. The patient did not receive any other vaccines within four weeks prior to the vaccination. On 18Dec2020, the patient experienced a rush of heat throughout her body, felt dizzy, weak and a bit nauseated and minor injection site pain. The clinical course as follows: At 13:45, about 30 minutes after injection she suddenly felt a rush of heat throughout her body, felt dizzy, weak, nauseated. This lasted about 30 minutes and then the warm feeling went away. She still felt a little dizzy, weak, nauseated and very tired. The dizziness lasted about 1.5 hours and the weakness, fatigue and mild nausea lasted about 6 hours. She reported that It felt as though she had taken diphenhydramine (BENADRYL). She stated that had she not been working (RN in an Emergency Department), she just

would have taken a nap and it would have been ok. Having to work through it was not pleasant she said. She never had a fever during this but had some minor injection site pain. She reported that she never experienced an immune response to any vaccine (has had 6 in a day before and was fine). The patient was not hospitalized for the events. The patient was treated with 600 mg of naproxen sodium. The clinical outcome for the events of a rush of heat throughout her body, felt dizzy, weak and a bit nauseated and minor injection site pain, was recovered on an unspecified date in Dec2020. It was also reported that since the vaccination, the patient had not been tested for COVID-19.

"ear infection; This is a spontaneous report from a contactable other HCP (patient). A female patient of an unspecified age received bnt162b2 (reported PFIZER-BIONTECH COVID-19 VACCINE, Covid-19 Vaccine), via an unspecified route of administration on 18Dec2020 at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. PCT asked, ""I got the Covid 19 vaccine yesterday, and this morning I woke up and went to the doctor because I had an ear infection. I was prescribed with oral antibiotics. Is it okay to take the antibiotics?"". Patient stated, ""I had a question about it actually. I got the vaccine yesterday and then today I was at the doctor, I have an ear infection and I was wondering if that would be a bad thing if I took antibiotic while still recovering from the vaccine."" The outcome of the event was unknown. Information on the lot/batch number has been requested."

Numbness on the right side of my face (jaw to just above right eye, not severe); This is a spontaneous report from a contactable consumer. A 44-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (lot number EJ1685), via an unspecified route of administration at first dose right arm on 19Dec2020 07:15 AM at single dose for covid-19 immunization. None medical history. No known allergies. Patient was not diagnosed with COVID-19 prior to vaccination nor tested for COVID-19 since the vaccination. Concomitant medications included cetirizine hydrochloride (ZYRTEC), fluticasone propionate (FLONASE). The patient didn't receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient experienced numbness on the right side of her face (jaw to just above right eye, not severe) on 19Dec2020 07:45 AM. Patient didn't receive treatment for the adverse event. The action taken in response to the events for BNT162B2 was not applicable. The outcome of event was recovering. The event was non-serious.

Classic Herpes Zoster(shingles) left T5 and T6 dermatomes. Received injection at 10AM and noticed rash when I got home from the hospital at 8:00PM same day. Not likely related but felt should report any; rash; This is a spontaneous report from a contactable physician (hospital based neurologist) reporting for a himself. A 64-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot #ELO140) via an unspecified route of administration in left arm on 18Dec2020 10:00AM at single dose for COVID-19 immunization. The patient received the vaccine in hospital. Medical history included coronary artery disease (CAD), status post stent placement right marginal branch in 2015. The patient had no allergies outside of seasonal. The patient did not received any other vaccines within 4 weeks prior to the COVID vaccine. The patient received medications within 2 weeks of vaccination. Prior to vaccination, the patient was not diagnosed with COVID-19. The patient experienced classic herpes zoster (shingles) left T5 and T6 dermatomes and noticed rash when he got home from the hospital at 20:00 on 18Dec2020, same day of vaccination. The patient started on valacyclovir (VALTREX) 1 gm every

8 hours for treatment of events. Since the vaccination, the patient had not been tested for COVID-19. The outcome of events was not recovered. The reporter considered not likely related but felt should report any.; Sender's Comments: Classic herpes zoster (shingles) /rash occurred on the same day of vaccination with BNT162B2 represents a coincidental viral infection caused by Herpes zoster, unrelated to the vaccine use.

"tired/exhaustion; cough; runny nose; fever 100 ""oral""/fever 100.3; This is a spontaneous report from a contactable consumer (patient). A 63-year-old female patient (not pregnant at the time of vaccination) received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899), via an unspecified route of administration on 16Dec2020 08:45 at single dose on right arm for COVID-19 immunization. The patient's medical history reported as none and no Allergies to medications, food, or other products. Concomitant medications received within 2 weeks of vaccination included exemestane, thyroid (ARMOUR THYROID), ergocalciferol (VIT D), ascorbic acid (VIT C), acetylsalicylic acid (ASPIRINE). The most recent COVID-19 vaccine was administered in Workplace clinic. It was reported that nothing on Wednesday. On 17Dec2020 19:00 (07:00 PM) (Thursday evening), the patient was very tired, cough, runny nose and fever 100 ""oral"" (as reported), Friday (18Dec2020) exhaustion and fever 100.3 with cough and runny nose. The events were non-serious and no treatment was received for the events. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient hadn't been tested for COVID-19. The outcome of the events was not recovered."

"Mild maculopapular rash across arms and facial and neck flushing. Rash did not itch; facial and neck flushing; other vaccine same date vaccine date on 17Dec2020; This is a spontaneous report from a non-contactable consumer (patient). A 56-year-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot/batch number and expiration date not provided), via an unspecified route of administration on 17Dec2020 at 07:30 on Right Deltoid at single dose for COVID-19 immunization. Other vaccine was received on the same date on 17Dec2020 Right Deltoid. The patient medical history included Hypertension. Prior to vaccination, patient was not diagnosed with COVID-19. The patient's concomitant medication included Lisinopril (strength: 20 mg). Patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient previously took tramadol and experienced allergy. The patient experienced mild maculopapular rash across arms and facial and neck flushing on 18Dec2020 at 13:30. Rash did not itch and resolved spontaneously in 24 hours. Since the vaccination, patient had not been tested for COVID-19. No treatment was received for the events. The outcome of the events ""mild maculopapular rash across arms and facial and neck flushing"" was recovered in Dec2020 in 24 hours. The report was reported as non-serious. No follow-up attempts are possible; information about lot/batch number cannot be obtained."

"Chills; Headache; Fatigue; injection site soreness and redness; injection site soreness and redness; Shortness of breath; nausea; feeling unwell; This is a spontaneous report from a contactable other health professional (HCP) who reported for herself. A 24-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE) intramuscularly in the left arm on 19Dec2020 at 08:45 (at the age of 24-years-old) as a single dose for COVID-19 vaccination. Medical history included being diagnosed with COVID-19 prior to vaccination, on an unspecified date. Otherwise,

other medical history and known allergies to medications, food, or other products were all reported as ""no"". The patient was not pregnant at the time of vaccination. Concomitant medications were not reported. The patient did not receive any other vaccines within four weeks prior to the vaccination. On 20Dec2020 at 00:30, the patient experienced chills, headache, fatigue, injection site soreness and redness, shortness of breath, nausea and feeling unwell. The events were reported as non-serious and the patient did not receive any treatment for the events. The clinical outcomes of the events chills, headache, fatigue, injection site soreness and redness, shortness of breath, nausea and feeling unwell were all recovering/resolving. It was also reported that since the vaccination, the patient had not been tested for COVID-19. The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up."

Fever 100.5; chills; pain at injection site; muscle soreness; joint pain; very mild nausea; This is a spontaneous report from a contactable nurse (patient). A 32-year-old female patient (not pregnant) received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: 5926710001), intramuscular on 19Dec2020 10:00 at single dose for COVID-19 immunization. Medical history included covid-19. Concomitant medication in two weeks included bupropion, sertraline, ascorbic acid, betacarotene, calcium sulfate, colecalciferol, cyanocobalamin, ferrous fumarate, folic acid, nicotinamide, pyridoxine hydrochloride, retinol acetate, riboflavin, thiamine mononitrate, tocopheryl acetate, zinc oxide (PRENATAL VITAMINS), cetirizine hydrochloride (ZYRTEC), ergocalciferol (VITAMIN D). The patient previously took minocycline, tetracycline and, amoxicillin; experienced drug hypersensitivity. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. The COVID-19 vaccine was administered at Hospital. The patient experienced fever 100.5, chills, pain at injection site, muscle soreness, joint pain, very mild nausea on 20Dec2020 04:30 AM. The patient received paracetamol (TYLENOL) as treatment. The outcome of events was not recovered.

Muscle aches; back pain; nausea; fatigue; headache; This is a spontaneous report from a contactable nurse reporting for the patient. A 32-year-old female patient received dose 1 of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), intramuscular on 18Dec2020 at 14:15 (at the age of 32-years-old) as a single dose in the left arm for COVID-19 vaccination. Medical history included postural orthostatic tachycardia syndrome (POTS), Fibromyalgia, Migraines, Post-traumatic stress disorder (PTSD), anxiety, depression, and gastrooesophageal reflux disease (GERD), all from an unknown date. The patient did not have any allergies to medications, food or other products. The patient was not pregnant at the time of vaccination. Prior to the vaccination, the patient was not diagnosed with COVID-19. The patient was not tested for COVID-19 post vaccination. The patient did receive concomitant medications within 2 weeks of vaccination (unspecified). The patient did not receive any other vaccines within four weeks prior to the vaccination. On 18Dec2020, the patient experienced muscle aches, back pain, nausea, fatigue, and headache. Therapeutic measures were not given for the events. The clinical outcome of the events muscle aches, back pain, nausea, fatigue, and headache was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

Felt body needed to defecate but could not; Severe lower abdominal cramping on day 3 post vaccination. Intermittent pains throughout day but increased at night.; Intermittent pains; Some nausea;

This is a spontaneous report from a contactable consumer, the patient. A 40-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration on 10Dec2020 at 10:45 (at the age of 40-years-old) as a single dose in the left arm for COVID-19 immunization. The patient previously received clindamycin and experienced allergy. The patient had no other relevant medical history or concurrent conditions. The patient was not pregnant at the time of vaccination. Prior to the vaccination, the patient was not diagnosed with COVID-19. Concomitant medications were not provided. The patient did not receive any other vaccines within four weeks prior to the vaccination. The patient did not receive any other medications within two weeks prior to the vaccination. On 05Dec2020 (as reported) at 16:30, the patient experienced severe lower abdominal cramping on day 3 post vaccination. The patient experienced intermittent pains throughout day but increased at night. The patient experienced some nausea. The patient felt her body needed to defecate but could not and pain persisted. The pain improved on day 4. Therapeutic measures were taken as a result of the events and included the patient received Pepto Bismol. The clinical outcome of the events severe lower abdominal cramping, intermittent pains and felt body needed to defecate but could not was recovering. The outcome of the nausea was unknown. It was also reported that since the vaccination, the patient had not been tested for COVID-19. The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up.

Approximately 3 to 4 minutes after injection site I started to get hot with a feeling of an elevated heart rate; Approximately 3 to 4 minutes after injection site I started to get hot with a feeling of an elevated heart rate; This is a spontaneous report from a contactable consumer (patient). A 35-year-old male patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot/batch number and expiration date not provided), via an unspecified route of administration on 16Dec2020 at 12:00 on left arm deltoid at single dose for COVID-19 immunization. The patient medical history included anxiety, depression and prior to vaccination, patient was diagnosed with COVID-19. No known allergy. The patient's concomitant medications received within 2 weeks of vaccination included escitalopram oxalate (LEXAPRO) and cetirizine hydrochloride (ZYRTEC), both on 16Dec2020. Patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient reported that approximately 3 to 4 minutes after injection site he started to get hot with a feeling of an elevated heart rate on 16Dec2020 at 12:00. Took off his hat and noticed his hair was sweaty. Was not clammy anywhere else. Symptoms improved around minute 10 to 12. After sitting in car in parking lot for an additional five or 10 minutes started to feel more baseline. He never experienced any chest pain, shortness of breath, angioedema, hives, difficulty breathing, swelling, he had a history of anxiety, which seemed to coincide with the symptoms. Since the vaccination, patient had not been tested for COVID-19. No treatment was received for events. The outcome of the events was recovered on 16Dec2020. The report was reported as non-serious. Information on the Batch/Lot number has been requested.

had fevers and chills up to 104.7 degrees Fahrenheit for a 36-hour period; lethargy; This is a spontaneous report from a contactable Physician. A 40-year-old non-pregnant female first dose of BNT162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number=EH9899) intramuscular at arm Left on 19Dec2020 11:00 at single dose for covid-19 immunization. The COVID-19 vaccine was administered at Hospital. Medical history included COVID-19 in Mar2020 with 10 days of fevers and chills and bilateral

interstitial pneumonia. The patient had no other medical history and no known allergies. Concomitant medication included silicon dioxide (VIVISCAL), ascorbic acid (VITAMIN C), calcium, colecalciferol (VITAMIN D) and Gummy vitamins. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient was administered at 11am on 19Dec2020, fevers and chills up to 103 Fahrenheit, and lethargy were started around 11pm. It was reported that the patient have had fevers and chills for 36 hrs after getting the first shot of the vaccine. She had fevers and chills up to 104.7 degrees Fahrenheit for a 36-hour period. The patient wanted to know if this response of fevers and chills was related to her being positive last march with accompanying Pneumonia and that if it still safe for her to take the 2nd dose, if it was due to a second time being exposed to Covid which was through the vaccine, could this be a robust immune response. COVID was not tested post vaccination. Outcome of the events was not recovered.

arm soreness at injection site; Body aches; chills; sore throat; This is a spontaneous report from a contactable other health professional (patient). A 43-year-old female patient (not pregnant at the time of vaccination) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: Ek5730), intramuscularly on 17Dec2020 10:15 at single dose on left arm for COVID-19 immunization. The patient's medical history reported as none and no known- allergies. Concomitant medications received within 2 weeks of vaccination included colecalciferol (VITAMIN D [COLECALCIFEROL]), thyroid (ARMOUR THYROID), zinc vitamin, magnesium vitamin. The most recent COVID-19 vaccine was administered at Hospital. On 19Dec2020 19:00 (07:00 PM), the patient's arm soreness at injection site for 2 days. Body aches and chills and sore throat. No treatment received for the adverse events. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient hadn't been tested for COVID-19. The outcome of the events was not recovered.

"Extreme fatigue, slept for most of Saturday; Extreme fatigue, slept for most of Saturday; This is a spontaneous report from a contactable health care professional, the patient. A 27-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), intramuscularly on 18Dec2020 at 13:00 (at the age of 27-years-old) as a single dose in the left arm for COVID-19 immunization. The patient medical history and concomitant medications were not reported. The patient was not pregnant at the time of vaccination. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. On 19Dec2020 at 09:00, the patient experienced extreme fatigue and slept for most of Saturday (as reported). Treatment was not received for the events. Since the vaccination, the patient had not been tested for COVID-19. The clinical outcome of ""extreme fatigue, slept for most of Saturday"" was resolving. Information on the lot/batch number has been requested."

SOB; fever; tired; headache; chills; not feeling well; injection site pain; lymph node swollen under right arm; This is a spontaneous report from a contactable Consumer. This 55-year-old female patient received the 1st dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on right arm on 17Dec2020 at 11:30 am at single dose (lot number: EK5730) for COVID-19 immunization. Medical history included having Covid in Jul2020 and husband had Covid prior to being vaccinated. Concomitant medications included escitalopram oxalate (LEXAPRO), estradiol,

hydrochlorothiazide in two weeks. The patient experienced SOB, fever, tired, headache, chills, not feeling well for over 24 hours than on the 19th noted lymph node swollen under right arm with severe pain along with injection site pain from 18Dec2020 03:00 AM. All events were reported as non-serious. Age at vaccination was 55 years old. Not pregnant at the time of vaccination. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. No treatment was received for the events. Outcome of all events was not recovered.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2020504434 same reporter/same drug/different event

feeling symptoms and that she felt like she had the flu; felling sick; This is a spontaneous report from a contactable consumer (patient). A female patient of an unspecified age received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EY1685), via an unspecified route of administration on 18Dec2020 at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. Caller reported receiving Pfizer Bontech covid 19 vaccine on 18Dec2020. She was feeling symptoms and that she felt like she had the flu (Dec2020). Consumer further stated she work here at the Hospital and Friday she appeared for the shot (Covid Vaccine) and she was just felling sick (Dec2020) and she didn't know what she had to do if it was normal, she had to report it to somebody for this or be around people or can she went back to work tomorrow, she didn't know. The outcome of the events was unknown. No follow up attempts are possible. information about lot/batch number cannot be obtained.

Initially pain at injection site; headache; Next day had body aches; low grade fever 100 degrees; This is a spontaneous report from a contactable consumer. A 27-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration at first dose left arm on 18Dec2020 08:00 at single dose for covid-19 immunization. None medical history. No Known allergies. Patient was not diagnosed with COVID-19 prior to vaccination nor tested for COVID-19 since the vaccination. The patient's concomitant medications were not reported. There was no other vaccine in four weeks or two weeks. The patient experienced initially pain at injection site next day had body aches, low grade fever 100 degrees, and headache on 19Dec2020 07:30 AM. Patient received acetaminophen as treatment for the adverse events. The action taken in response to the events for BNT162B2 was not applicable. The outcome of events was recovered in Dec2020. The events were non-serious. Information on the lot/batch number has been requested.

"Caller states she cant focus/She just can't focus; this is horrible/I have a hard time focusing; I'm like you know fogged; I just want to sleep/I have been sleeping all weekend that was horrible; I have some headache; I just don't feel right this is terrible; This is a spontaneous report from a contactable consumer (Patient). A 58-year-old female patient started to receive BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EJ1685), intramuscular in the arm on 18Dec2020 at single dose for covid-19 immunization. Medical history included seizure. Concomitant medication included celecoxib (CELEXA), levothyroxine sodium (SYNTHROID), phenobarbitone [PHENOBARBITAL] for seizure. The patient stated that she could not focus, this was horrible and had a hard time focusing on 18Dec2020, the patient also stated that ""like you know fogged"" on 18Dec2020, the patient just wanted to sleep and she had been sleeping all weekend that was horrible on an unspecified date in Dec2020, the patient

had some headache on an unspecified date Dec2020, she just took some Ibuprofen for the headache, the patient just didn't feel right this was terrible on an unspecified date in Dec2020. The outcome of 'could not focus' was not recovered and the outcome of the other events was unknown."

"his entire body is hurting; It's flu like symptoms but not really; feeling run down; it's like skin sensitivity/if touch his skin it kind of hurts, more like skin sensitivity versus body ache, touch his arm it hurt; a bilateral inner thigh rash to knee, that was non irritating non itchy but was uniform in pattern; a sore throat but it was like a tickle a throat tickle and then a dry cough; a sore throat but it was like a tickle a throat tickle and then a dry cough; a sore throat but it was like a tickle a throat tickle and then a dry cough; sore arm at injection site; This is a spontaneous report from a contactable nurse (CRNA anesthesia, also the patient). A 39 years old male patient received a dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899), via an unspecified route of administration at arm on 16Dec2020 at single dose for COVID-19 immunization. The patient's medical history included psoriasis (he took biologic for pre-existing psoriasis), arthritis and that ""he thought he had direct exposure"". Concomitant medications included unspecified biologic for pre-existing psoriasis. The patient initially called because he was asking that if it was reaction to the injection or if it was possible Covid 19 because he thought he had direct exposure. The patient mentioned ""his chest and stuff"" and got received a Covid test on 11Dec2020, 02Dec2020 and 24Nov2020 and they were consecutive test and he took these test because they were few of his coworkers down to Covid so he just wanted to be sure that he was not infected with them, these are all negative. So last result he had for Covid was 14Dec2020 and that's two days before he got the vaccine and they were all negative and ""it started like all his activities, it was like going to work, going to get food like at the grocery store or other places for takeout"". He had not been in a situation where he have been gathering with a lot of people or having dinner or lunch and sort of anything like that, just the point that he was not in the one of high risk people. For the possible ""side effects similar to covid 19 from vaccine"", the symptom presentation/progression per patient were are as follows: the patient initially had sore arm at injection site on the day of injection which was Wednesday (16Dec2020) and then the following day (17Dec2020) he started having a sore throat but it was like a tickle a throat tickle and then a dry cough. On Friday (18Dec2020) he had a bilateral inner thigh rash to knee, that was non irritating non itchy but it was uniform in pattern. And then on Saturday (19Dec2020), he continued to have a dry cough and said he did apply some steroid cream that he has for his psoriasis and the rash is going away/almost gone and reported feeling run down, has skin sensitivity, he said that if touch his skin it kind of hurts, it's more like skin sensitivity versus body ache, when he touch his arm it hurt, it's like skin sensitivity. And then on Sunday (20Dec2020, the date of reporting), he still has cough and his entire body is hurting. It's flu like symptoms but not really. The patient's weight was around 175 pounds on an unspecified date. Therapeutic measures were taken as a result of the events included some steroid cream and over the counter Zicam (its tablet for cold). The outcome of the event dry cough was not recovered, bilateral inner thigh rash to knee was recovering, for the other events was unknown. When probed for the causality between events and the suspect product, the patient said ""hope it is not from that"" ."

chills; low grade fever to 38.4; body aches; felt very tired; This is a spontaneous report from a contactable nurse (patient). A 57-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-

19 VACCINE, lot number EK5730), intramuscularly on left arm at 18:15 on 18Dec2020 at single dose for COVID-19 immunization. Medical history included COVID-19 (Prior to vaccination, the patient was diagnosed with COVID-19). There were no concomitant medications (No other vaccine in four weeks, no other medications in two weeks). The patient had chills, low grade fever to 38.4, body aches and felt very tired at 15:00 on 19Dec2020. All events were reported as non-serious. The patient did not receive any treatment for all events. The outcome of events was recovering. COVID was not tested post vaccination.

1.5 hours after the vaccine, one eye vision was down to light perception only. The event lasted 15 minutes and resolved completely. ER eval and Ophthololgy eval did not find a cause for the event.; This is a spontaneous report from a contactable physician. A 66-year-old male patient received bnt162b2 (reported as COVID 19, Covid vaccine, lot/batch number and expiry date were not provided), via an unspecified route of administration from 17Dec2020 12:30 at single dose for covid-19 immunisation. Medical history included gout, abnormal glucose, hyperlipidemia, hypertension. Prior to vaccination, the patient was not diagnosed with COVID-19. No Known allergies. Concomitant medications the patient received within 2 weeks of vaccination included atorvastatin, prednisone, lisinopril, allopurinol, famotidine (PEPCID). The patient experienced 1.5 hours after the vaccine, one eye vision was down to light perception only. The event lasted 15 minutes and resolved completely. ER eval and Ophthololgy eval did not find a cause for the event. CT and labs done. Event onset date was on 17Dec2020 14:00. The patient not received any other vaccines within 4 weeks prior to the COVID vaccine. Since the vaccination, the patient has not been tested for COVID-19. No treatment received for the adverse event. Case was non-serious. Facility where the most recent COVID-19 vaccine was administered at Hospital. The adverse event result in the following: Doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care. The outcome of event was recovered on 17Dec2020 14:15. Information on the Batch/Lot number has been requested.

Mild injection site reaction- red, firm, swollen, tender; Mild injection site reaction- red, firm, swollen, tender; Mild injection site reaction- red, firm, swollen, tender; Mild injection site reaction- red, firm, swollen, tender. Most noticeable day 3 after injection. Note that I had COVID dx 21Apr; This is a spontaneous report from a contactable consumer reporting for herself. This 33-year-old female patient (non-pregnant) received the first single dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot EJ1685) on 17Dec2020 at 07:45, in left arm, for COVID-19 immunization. No other vaccine was given within 4 weeks prior to the COVID vaccine. Medical history included immune thrombocytopenia 2/2, COVID from 21Apr2020, chronic B12 deficiency, ADHD, depression, anxiety and migraine. Allergies to medications, food, or other products: none. Concomitant medications included sertraline HCl (ZOLOFT), lisdexamfetamine mesilate (VYVANSE), lorazepam (ATIVAN), ondansetron (ZOFRAN) and sumatriptan succinate (IMITREX). On 17Dec2020 the patient experienced mild injection site reaction- red, firm, swollen, tender. It was most noticeable on day 3 after injection. No treatment was given. COVID was not tested after vaccination. The events were resolving.

"experienced severe insomnia/some serious felt of insomnia, he did not get a lot of sleep/ tossing and turning all night; This is a spontaneous report from a contactable consumer (patient). A 63-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, lot

number and expiration date not provided), via an unspecified route of administration on 17Dec2020 at single dose for COVID-19 immunization. Medical history included bipolar disorder. Concomitant medication included quetiapine fumarate (SEROQUEL) for bipolar disorder, levothyroxine. The patient received the first dose of the vaccine 17Dec2020 and then last night on 19Dec2020 he experienced severe insomnia. Specifically, it was reported that the patient worked at the front desk and on the Thursday of the 17Dec2020, he received the vaccine from the company and he was fine, he had no real side effects until last night on 19Dec2020 and he was not sure whether it's due to vaccine or not but he did experience some serious felt of insomnia, he did not get a lot of sleep. After about 1'oclock in the morning when he was unable to achieve sleep, he took a ""cup"" ZzzQuil and that usually helps to go sleep but it did not work yesterday (19Dec2020) and the patient was tossing and turning all night. The patient wondering whether it is due to vaccine or not. The patient also tried 10 mg Melatonin and both of the medications didn't work. The patient didn't take them together. He took them separate. He took the Melatonin first and it did not work and then he took ZzzQuil by an hour later and the ZzzQuil did not work either. Neither of them worked. Therapeutic measures were taken as a result of insomnia. The outcome of the event was recovering. Information on the Lot/Batch number has been requested."

muscle aches, pain, and chills that were minor but not fever. He is now experiencing loss of muscle tone in his left foot and feels as if his foot is dropping.; it's hard to walk; muscle aches, pain, and chills that were minor but not fever. He is now experiencing loss of muscle tone in his left foot and feels as if his foot is dropping.; muscle aches, pain, and chills that were minor but not fever. He is now experiencing loss of muscle tone in his left foot and feels as if his foot is dropping.; muscle aches, pain, and chills that were minor but not fever. He is now experiencing loss of muscle tone in his left foot and feels as if his foot is dropping.; This is a spontaneous report from a contactable consumer (patient). A 62-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 18Dec2020 at single dose for covid-19 immunization, carbamazepine (TEGRETOL), via an unspecified route of administration from an unspecified date to an unspecified date at unknown dose and frequency for an unspecified indication. Medical history included ongoing diabetes; ongoing congestive heart problems; ongoing blood pressure high; ongoing mild kidney disease; ongoing gastroparesis; peripheral neuropathy, pain. Concomitant medication included hydrocodone bitartrate, paracetamol (NORCO) for pain, insulin glargine (LANTUS) for diabetes, insulin lispro (HUMALOG) for diabetes, carvedilol (COREG) for congestive heart problem, lisinopril for high blood pressure, spironolactone for high blood pressure, furosemide for high blood pressure, insulin for diabetes. The patient received the Covid-19 vaccine on 18Dec2020. After receiving the vaccine he had muscle aches, pain, and chills on 18Dec2020 that were minor but not fever. He was now experiencing loss of muscle tone in his left foot and feels as if his foot is dropping. The patient noticed on 20Dec2020 that his left foot it's not muscle tone it's kind of flopping there, it's hard to walk. The patient just took Tylenol and took his normal Narcan and Tylenol nothing in addition and one hot shower but it was more of nuisance. The patient stated that the main thing was that the loss of muscle tone in his left foot, that's what bothers him more than chills and everything like that because it was making difficult to walk and he want to walk around. The patient also stated that one of his health problems was peripheral neuropathy and that was what it just seem to make it why he can't feel his foot at all or he can do was move his big toe just a little bit and it was just kind of due to that. The patient just concerned whether that was

supposed to go away in a couple of days. The outcome of the events was unknown. Information on the lot/batch number has been requested.

nausea/sick to stomach; vomiting; sore arm; might be having a Gall bladder issue; This is a spontaneous report from a contactable consumer (patient). A 53-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EJ1685, Expiry Date: Mar2021), via an unspecified route of administration on 19Dec2020 at single dose for COVID-19 immunization. There was no medical history. There were no concomitant medications. The patient experienced nausea, vomiting, sore arm on 19Dec2020. She was feeling better today. She might be having a gall bladder issue, she started feeling sick to stomach yesterday evening (19Dec2020). It had been several hours after she got the vaccine. No treatment received for events. The outcome of events was recovering.

"headaches, weakness, and ""some coughing.""; headaches, weakness, and ""some coughing.""; headaches, weakness, and ""some coughing.""; This is a spontaneous report from a contactable other hcp. A 56-year-old female patient (wife) received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EK5730), via an unspecified route of administration on 17Dec2020 at single dose for covid-19 immunization. The patient was working in hospital, they provided the vaccine and the nurse gave her the vaccine. Next shot will be 3 weeks after that on 07Jan2021. The reporter thought that the patient was the height of the patient was 5 (feet) 6 (inches) and the weight was 68 kg. The patient had no other medical condition or concomitant medication. On the 2nd day on 18Dec2020, the patient experienced headaches, weakness, and ""some coughing."" The patient was taking acetaminophen (Tylenol) 500 mg every 6/8 hours as treatment. The reporter wanted to know if there was anything his wife can do to get rid of these side effects, how long it would last, and what kind of precautions she has to do. The patient was still have them. Just not getting worst or not getting better somehow. She had test for COVID 19 around 09Dec2020 and she was negative. The outcome of the events was not recovered."

Day after the vaccine, I started experiencing throbbing pain on shoulder/arm opposite to the vaccinated arm. Pain became more intense at night and after 48 hours, started experiencing decreased range; Day after the vaccine, I started experiencing throbbing pain on shoulder/arm opposite to the vaccinated arm. Pain became more intense at night and after 48 hours, started experiencing decreased range; decreased range of motion; heaviness on shoulder/arm area all the way to the elbow; This is a spontaneous report from a contactable pharmacist (patient). A 51-years-old non-pregnant female patient the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, lot number=EK5730, intramuscular in left arm on 17Dec2020 at 17:15 (at the age of 51 years-old) as a single dose for COVID-19 immunization. The patient received the vaccine in a hospital. Prior to the vaccination, the patient was not diagnosed with COVID-19 nor was tested. There were no other vaccines within four weeks. Medical history included: hypothyroid, endometriosis, low blood pressure history, anxiety and H pylori. Concomitant medication included sarecycline (SARECYCLINE) for acne, take for 3 days levothyroxine (LEVOTHYROXINE), vitamin c [ascorbic acid] (VITAMIN C [ASCORBIC ACID]), colecalciferol (VITAMIN D [COLECALCIFEROL]), ginkgo biloba (GINGKO BILOBA), and camellia sinensis extract (GREEN TEA [CAMELLIA SINENSIS EXTRACT]). On 18Dec2020 at 0700, the patient experience throbbing pain on shoulder/arm opposite to the vaccinated arm. The clinical course as follows: At 0700, the day after

receiving the vaccine, she started experiencing throbbing pain on shoulder/arm opposite to the vaccinated arm. The pain became more intense at night and after 48 hours, started experiencing decreased range of motion and heaviness on shoulder/arm area all the way to the elbow. The patient was not hospitalized for the events. The patient was treated with OTC obuprofen 400 mg and acetaminophen (TYLENOL). The clinical outcomes of throbbing pain on shoulder/arm opposite to the vaccinated are, decreased range of motion and heaviness on shoulder/arm area all the way to the elbow was not recovered.

24 hours after I received the vaccine I began experiencing terrible body aches all over (muscle aches in my limbs, back, feet, hands, everywhere); 24 hours after I received the vaccine I began experiencing terrible body aches all over (muscle aches in my limbs, back, feet, hands, everywhere); 24 hours after I received the vaccine I began experiencing terrible body aches all over (muscle aches in my limbs, back, feet, hands, everywhere); 24 hours after I received the vaccine I began experiencing terrible body aches all over (muscle aches in my limbs, back, feet, hands, everywhere); fever that reached 101.1 degrees F; chills followed by waking up in a pool of sweat at 6AM on 12/20/20; chills followed by waking up in a pool of sweat at 6AM on 12/20/20; This is a spontaneous report from a contactable health care professional. A 26-years-old non-pregnant female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), lot number-EH9899, intramuscular in left arm on 18Dec2020 at 19:30 (at the age of 26 years-old) as a single dose for COVID-19 immunization. There was no medical history nor concomitant medications. The patient received the vaccine in a hospital. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. There were no other medications received within 2 weeks of the vaccination. On 19Dec2020 24 hours after receiving the vaccination, the patient experienced terrible body aches all over (muscle aches in limbs, back, feet, hands, everywhere), a fever that reached 101.1 degrees F and eventually, chills followed by waking up in a pool of sweat at 0600 on 20Dec2020. She mentioned that she hadn't felt this ill since she was very little. She was a very healthy person, normal BMI, work out every day, eat healthy, have no health conditions. The patient had not been tested for COVID-19 prior to the vaccine and has not been tested after vaccination. The clinical outcomes for experienced terrible body aches all over (muscle aches in limbs, back, feet, hands, everywhere), a fever that reached 101.1 degrees F and eventually, chills followed by waking up in a pool of sweat, was recovering. The patient was not hospitalized for the events. It was noted that the patient had not been tested for COVID-29 prior to vaccination nor after vaccination. The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up.

"Soreness; redness; tenderness just outside of the injection site (not at the site); On my anterior shoulder next to where my arm sits by my armpit. A large red and swollen mark approx 2 on in height, 1 1/2in wide; This is a spontaneous report from a contactable consumer (patient). This 35-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Lot number EH9899) via an unspecified route of administration in the left arm on 19Dec2020 at 11:45 at single dose for COVID-19 immunisation. Vaccination facility type was hospital. The patient did not receive other vaccines in four weeks. Relevant medical history included Graves' disease, hyperthyroidism and chronic spine pain. Concomitant medications included pregabalin (LYRICA), hydroxyzine and buprenorphine hydrochloride/naloxone hydrochloride (SUBOXONE). On 20Dec2020 at 08:00, the patient experienced

soreness, redness, tenderness just outside of the injection site (not at the site). ""On her anterior shoulder, next to where her arm sits by her armpit, a large red and swollen mark approximately 2 on in height, 1 1/2 in wide"" appeared. The events resulted in Doctor or other healthcare professional office/clinic visit. The patient did not receive corrective treatments. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, she had not been tested for COVID-19. The patient had not recovered from the events."

"the rash on her back, more on the flank area/ the upper arms, she got this rash too; had fever, a low grade fever; 24 hour chills; chills was off and on; This is a spontaneous report from a contactable nurse (patient). A 48-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899), via an unspecified route of administration on 17Dec2020 03:40 at single dose for COVID-19 immunization. Medical history (Other medications and other medical conditions) reported as no. The patient's concomitant medications were not reported. Caller initially called to ""report some side effects after getting covid."" Investigation Assessment was No. Consumer (Registered Nurse) further stated Just calling to report side effects because she guessed the data might be needed for study and everything. She went for the vaccine last Thursday (17Dec2020) around 3:40. The first night was the day that she had 24 hour chills (Dec2020). So, just round the clock, Tylenol was taken for that. Then she knew, the rash on her back, more on the flank area that was less than 24 hours that was Friday. And that's in her lower back and now she had more on that lower back and the upper arms, she got this rash too. Chills was off and on. The date when started experiencing rashes was 18Dec2020 and was still experiencing. The patient experienced chills and had fever, a low grade fever (Dec2020), and for chills she took Tylenol. For lab text, the patient stated ""About 2 weeks no, after the COVID vaccine no"". Due date for the next vaccine shot: Consumer believed the due date for the next vaccine shot was 07Jan2021. The outcome of the event ""the rash on her back, more on the flank area/ the upper arms, she got this rash too"" was not recovered, of the other events was unknown."

allergic reaction; dizzy/lightheaded; blood pressure and heart rate skyrocketed; blood pressure and heart rate skyrocketed; fever; sweats; This is a spontaneous report from a contactable consumer reporting for him/herself. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for covid-19 immunisation. The patient medical history and concomitant medications were not reported. On unknown date the patient experienced a mild allergic reaction with unknown outcome. About an hour after getting the shot the patient got dizzy, lightheaded, and her blood pressure and heart rate skyrocketed. She was given 50mg of diphenhydramine hydrochloride (BENADRYL) in the ED and still felt bad. On unspecified date the patient had a fever and sweats but the day after she was feeling good. The patient wanted to know if she could get the second dose. Information on the lot/batch number has been requested.

vomiting; diarrhea; myalgia; headache; face swelling; pain at the injection site; This is a spontaneous report from a contactable physician reporting for one of her patients. A 43-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), lot number: Unknown via an unspecified route of administration on 19Dec2020 at single dose for COVID-19 immunisation. The patient medical history and concomitant medications were not reported. The patient received the COVID-19 vaccine

yesterday (on 19Dec2020) and was experiencing vomiting, diarrhea, face swelling, myalgia, headache, and pain at the injection site on an unspecified date. Expressed being concerned about an anaphylactic reaction and wanted to know how her patient's symptoms compare to it. Then the physician asked for the timing of the anaphylactic symptoms onsets reported in the clinical trials. The event outcome was unknown. Information on the lot/batch number has been requested.

fever; headache; body aches; chills; This is a spontaneous report from a contactable consumer (patient). A 56-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK5730 and expiration date: Mar2021), via an unspecified route of administration on 19Dec2020 at single dose for covid-19 immunization. It was the first dose. Medical history included the patient was Cancer survivor and the patient was not taking any chemo or any radiation. In 2003 the patient took chemo radiation. Concomitant medications included anastrozole, citalopram, alendronate sodium (ALENDRONATE). The patient stated she was having a couple symptoms including fever, headache, body aches, and chills on an unknown date in Dec2020. Treatment included the patient had been taking Excedrin, It had aspirin in it and Tylenol in it and Tylenol is 250 mg and Aspirin is 250 (unit was not specified). The patient was wondering how long her symptoms are going to last. The patient thought the lab test has been about a month. The outcome of the events was unknown.

I felt my left ear become hot and then felt paresthesia of my left ear, side of cheek and jaw, and down side of neck; Felt like numbness after dental procedure; left ear become hot; This is a spontaneous report from a contactable consumer (patient). This 37-year-old female consumer received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) Lot number EH9899, at single dose on 20Dec2020 18:45 on left arm for COVID-19 immunisation. Medical history was none. Concomitant medication was not reported. The consumer had no other vaccine in four weeks. The consumer had no covid prior vaccination. The consumer had no covid tested post vaccination. The consumer had no known allergies. The consumer was not diagnosed with COVID-19 Prior to vaccination. The consumer had not been tested for COVID-19 since the vaccination. Approx 12-15 min after injection (20Dec2020 19:00) the consumer felt her left ear become hot and then felt paresthesia of her left ear, side of cheek and jaw, and down side of neck. She felt like numbness after dental procedure. Waxed and waned over the course of 30-45 minutes. She had mostly resolved after 1.75 hours, though slight abnormal feeling still remained. No treatment was received for all events. The outcome of the events was resolving.

Headache, chills and body was warm; Headache, chills and body was warm; Headache, chills and body was warm; This is a spontaneous report from a contactable consumer reporting for himself. A 37-years-old male patient received bnt162b2 (BNT162B2) , via an unspecified route of administration on 17Dec2020 13:15 at single dose for COVID 19 immunisation. The patient medical history included pre-diabetes. There were no concomitant medications. On 18Dec2020 early in the morning (at about 6-7a.m.) the patient experienced headache, with outcome of not recovered , chills with outcome of recovered and body was warm with outcome of recovered. The patient underwent lab tests and procedures which included blood cholesterol: unknown results on Dec2020 , blood glucose: pre-diabetic but not yet on Dec2020 , body temperature: his body was warm but he did not measure his fever, glycosylated haemoglobin: 5. something, not even 6. on Dec2020 , weight: between 180-190. Information about Lot/batch no has been requested.

felt her heart pounding and took her pulse and it was 158; took her pulse and it was 158; feels fatigued currently; took her blood pressure (BP) and it was 151/113; This is a spontaneous report from a contactable other healthcare professional. A 64-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot# EH9899), intramuscularly in right arm on 18Dec2020 14:05 at single dose for Covid-19 immunisation. Medical history included allergies to penicillin, allergy to mussels (bronco constriction and itch), figs allergy (nausea, vomiting, dizziness, elevated heart rate), allergy to grass (welts), ongoing asthma (asthma environmental triggers (Flowers, perfume, chemicals, soil, grass)), breast cancer left (had radiation and tamoxifen) from 2005 and ongoing, radiotherapy from an unknown date and unknown if ongoing. Concomitant medication included vitamin b complex (VITAMIN B), vitamin C, calcium (CA), Zinc, albuterol [salbutamol] and multivatamins. The patient previously took ampicillin and experienced allergy-rash, previously vaccinated with influenza and experienced weakness in 2010, and previously received tamoxifen for breast cancer female. After one hour later (18Dec2020 15:00), she felt her heart pounding and took her pulse and it was 158 and no other symptoms. Denies chest pain. Staff took her blood pressure (BP) and it was 151/113 on a machine. Recheck 10 minutes later BP 151/112, P 126. EE was brought to the Occupational Medicine Dept, Recheck at 20 min BP 125/68 and an apical pulse of 88. Heart rate (HR) regular, rate and rhythm. Employee states she feels fatigued currently, denies shortness of breath, chest pain, itching, swelling on oral cavity. The outcome of events was recovered on 18Dec2020.

low grade temperature (not fever) within first 24 hours of vaccine; Myalgia resolved with medication; This is a spontaneous report from a contactable consumer (patient). A patient of unspecified age (reported as 28) and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced myalgia resolved with medication, low grade temperature (not fever) within first 24 hours of vaccine on an unspecified date. The outcome of the event myalgia was resolved on an unspecified date, outcome of the other event was unknown. No follow-up attempts are possible. Information about lot/Batch number cannot be obtained. No further information is expected.

itching all over/bottom of his feet were itching too/he was scratching all over, his back, legs everywhere; This is a spontaneous report from a contactable consumer (patient). A 53-year-old male patient received 1st dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot# EK5730), intramuscular in left arm on 18Dec2020 12:45 at single dose for Covid-19 immunisation. Medical history included hypertension and anemia (he only has anemia and hypertension) from 2018 to an unknown date. Concomitant drug included other medications, but he didn't have the list in front of him. Prior vaccinations within 4 weeks was none. He just got the COVID vaccine today (18Dec2020). He started itching about 2 hours ago, once he got home. He was just itching all over. He had a hairbrush just scratching himself because he was itching all over, he was scratching all over, his back, legs everywhere. He confirmed this was his first dose of the COVID vaccine. He was supposed to go back in three weeks to get the second dose. He had not been to an emergency room or physician office yet, but he's getting ready to go. The bottom of his feet were itching too. The itching was everywhere. That was the only symptoms that he had his body was itching. He worked at a hospital, supply them with mask, he was supply technician. He worked

closely with may not be the patient everyday. He was on an esophagogastroduodenoscopy (EGD) done where they put tube down through throat and colonoscopy and EGD, they found some information and they removed it, about a month ago. The outcome of event was not recovered.

Dazed look with nausea; Dazed look with nausea; dry heaving; she looked green; This is a spontaneous report from a contactable consumer. A 61-years-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot Number: EH9899), intramuscular in the left arm on 18Dec2020 07:00 at single dose for covid-19 immunisation. The patient was not pregnant at time of vaccination. Medical history included some metals cause rash, ongoing rheumatoid arthritis and ongoing hypertension. The patient's concomitant medications were not reported. On 18Dec2020 at 08:00 the patient experienced dazed look with nausea and dry heaving: staff standing near her said she looked green. The patient Went to ER at the hospital; EKG done and result normal; seen by ER MD given ondansetron (ZOFRAN); Cleared to return to work same day. The patient recovered from the adverse events.

Numbness in left thumb; Left arm felt heavy and slightly numb; Left arm felt heavy and slightly numb; This is a spontaneous report from a contactable consumer. A 50-year-old female patient received the 1st dose of bnt162b2 (BNT162B2, Manufacturer Pfizer-BionTech) (lot# EH9899), intramuscular in the left arm, on 17Dec2020 at 02:00 PM, at single dose, for Covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient hasn't ever had an adverse event following any previous vaccine administered for immunization. The patient experienced numbness in left thumb on 17Dec2020 at 02:05 PM with outcome of recovered within 30 minutes and left arm felt heavy and slightly numb on 17Dec2020 at 02:05 PM with outcome of recovered within 30 minutes.

joint pain; Dizzy; tired; weak; nausea; This is a spontaneous report from a contactable Other HCP. A 28-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number # EJ1685) on 18Dec2020 at 08:30 AM at single dose via intramuscular on left arm for COVID-19 immunization. Relevant medical history included cancer in 2018 and allergy reaction to bee sting. Concomitant medications were not reported. Prior to vaccination patient wasn't diagnosed with COVID-19 and was not already tested for COVID-19. On 18Dec2020 at 08:45 AM patient experienced dizzy, tired, weak, nausea, and joint pain. At the time of the reporting the patient was recovering. No follow-up attempts are needed. No further information expected.

Sore arm; loss of appetite; nausea; headache; fatigue; This is a spontaneous report from a contactable other health care professional (Other HCP, patient herself). A female patient of unspecified age (reported as 31 also reported as 61) received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) (Lot number EH9899) on 16Dec2020 at single dose for COVID-19 immunization. Medical history and concomitant medications were not reported. Patient experienced side effects reported as sore arm, loss of appetite, nausea, headache, fatigue. All side effects occurred two days after first dose of vaccine (18Dec2020). The outcome of the events was unknown.

Severe pain at site in left arm extending to whole arm, unable to lift arm or do things.; Severe pain at site in left arm extending to whole arm, unable to lift arm or do things.; Severe pain at site in left arm

extending to whole arm, unable to lift arm or do things.; This is a spontaneous report from a contactable nurse (patient herself). A 39-year-old female patient (no pregnancy) received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration at site of right arm at 16:00 on 19Dec2020 at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced severe pain at site in left arm extending to whole arm, unable to lift arm or do things on 20Dec2020. No treatment received for events. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. The outcome of events was not recovered. Information on Lot/Batch number has been requested.

Dizziness; nausea; dry mouth; felt hot; chest tightness; sour taste in mouth; rapid heart rate; tingling on same arm vaccinated (L arm); some numbness in same arm left arm; felt shaky; Blood pressure elevated; This is a spontaneous report from a contactable healthcare professional. A 39-year-old non-pregnant female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot number: EH9899), intramuscularly in the left arm on 17Dec2020 02:25 at a single dose for COVID-19 immunization. The patient had no significant medical history and no concomitant medications. Other illnesses at the time of vaccination and up to one month prior was none. The patient had no allergies to medications, food or other products. On 17Dec2020 02:32, the patient experienced dizziness, nausea, dry mouth, felt hot, chest tightness, sour taste in mouth, rapid heart rate, tingling on same arm vaccinated (L arm), some numbness in same arm left arm, felt shaky and blood pressure elevated. The patient was taken to emergency department and oxygen was provided. The patient underwent lab tests and procedures on 17Dec2020 which included blood pressure measurement: elevated and heart rate: rapid. Therapeutic measures were taken as a result of the events as aforementioned. The patient was observed and discharged to home after 40 min. The outcome of the events was recovered on 17Dec2020.

panic attacks; This is a spontaneous report from a Non-contactable physician. A 30-year-old female patient received bnt162b2 (BNT162B2) at single dose on an unspecified date for immunisation. Medical history included anaphylactic reaction, panic attack and 12 unspecified comorbid conditions. The patient's concomitant medications were not reported. The patient experienced panic attacks on an unspecified date. The action taken in response to the event for bnt162b2 was not applicable. The outcome of event was unknown. According to MD, they are not sure if was a true adverse reaction or a panic attack. No follow-up attempts are possible, information about lot/batch cannot be obtained.

anaphylactic reactions; throat and lip swelling; throat and lip swelling; mild chest pain; This is a spontaneous report from a non-contactable pharmacist. A 34-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration, on an unspecified date at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient previously took terbinafine (MANUFACTURER UNKNOWN) and experienced allergy. The patient experienced anaphylactic reactions, throat and lip swelling, and mild chest pain on an unspecified date. The patient was observed for five hours. The clinical outcome of anaphylactic reactions, throat and lip swelling, and mild chest pain was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Sender's

Comments: There is a reasonable possibility that the events anaphylactic reactions, throat and lip swelling, and mild chest pain were related to BNT162b2 based on known drug safety profile. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

About 30 mins after injection felt brain fog and had a hard time finding words/ like we were having to concentrate more than usual to do routine stuff; About 30 minutes after injection felt brain fog and had a hard time finding words. Another nurse that got vaccinated at the same time felt the same way. It's like we were having to concentrate more t; About 30 mins after injection felt brain fog and had a hard time finding words/ like we were having to concentrate more than usual to do routine stuff; This is a spontaneous report from a contactable consumer. This consumer reported similar events for 2 patients. This is the 2nd of 2 reports. A patient of unspecified age and gender started to receive (PFIZER-BIONTECH COVID-19 VACCINE, Lot number Ej1685), intramuscularly, as first single dose on 20Dec2020 for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. On 20Dec2020, about 30 minutes after injection felt brain fog and had a hard time finding words. Another nurse that got vaccinated at the same time felt the same way. It's like we were having to concentrate more than usual to do routine stuff. Outcome of the events about 30 mins after injection felt brain fog and had a hard time finding words/ like we were having to concentrate more than usual to do routine stuff was unknown.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2020503261 same drug, same event and different patient

"soreness at the injection site; This is a spontaneous report from a non-contactable consumer. A 59-year-old female patient (reporter's mother) received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) (lot EH9899) on 18Dec2020 at a single dose for COVID-19 immunization. Medical history and concomitant medications were not reported. Patient used to receive unspecified vaccines and experienced pain at the injection site. After 8 hours of taking bnt162b2 and into the next day patient reported soreness at the injection site on 19Dec2020. She described it as ""normal"" and like pain felt after other vaccines she has received. The outcome of the event was unknown."

anaphylactic reaction upon receipt of the vaccine; This is a spontaneous report from contactable pharmacist via a Pfizer Sales Representative. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration, in Dec2020 at a single dose for COVID-19 immunization. The patient was reported as a healthcare worker. Medical history included latex allergy. The patient's concomitant medications were not reported. The patient experienced an anaphylactic reaction upon receipt of the vaccine in Dec2020. The reporter called to confirm to confirm the lack of latex in the vaccine and also to inquire about the latex content of the 0.9% sodium chloride (NaCl) used to dilute the vaccine. The clinical outcome of anaphylactic reaction upon receipt of the vaccine was unknown. The batch/lot number for the vaccine, BNT162B2, was not provided and has been requested during follow up.; Sender's Comments: A possible causal association between administration of BNT162B2 and the onset of anaphylactic reaction cannot be excluded, considering the plausible temporal relationship and the known adverse event profile of the suspect

product. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

rash; itchiness; Severe joint pain; nausea; stomach pain; This is a spontaneous report from a contactable Other HCP reported for herself. This 32-year-old female (no pregnant) patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), intramuscular at left arm on 19Dec2020 18:45 at single dose for COVID-19 immunization. Medical history included Auto immune disorder, high-risk medications, asthma, and allergies: Spectrum hand sanitizer. Concomitant medication included adalimumab (HUMIRA) received within 2 weeks of vaccination. No Covid prior vaccination, No Covid tested post vaccination. No other vaccine in four weeks. On 19Dec2020 11:00 PM, the patient experienced severe joint pain, nausea, stomach pain the same day as vaccine. The next day (on 20Dec2020) patient experienced rash and itchiness. No treatment received for the events. The outcome of events was unknown. Information on the lot/batch number has been requested.

she kept having chills and a mild fever; she kept having chills and a mild fever; really bad headaches; She hasn't been able to sleep because of feel warm yet cold and her body aches.; She hasn't been able to sleep because of feel warm yet cold and her body aches.; She hasn't been able to sleep because of feel warm yet cold and her body aches.; She hasn't been able to sleep because of feel warm yet cold and her body aches.; This is a spontaneous report from a contactable healthcare professional. A 28-year-old female patient received BNT162B2 (Lot# EH9899) via intramuscular on 20Dec2020 08:00 AM (anatomical location: arm left, dose number: 1) at single dose for COVID-19 immunization. Medical history and concomitant medications were none. The patient did not have allergies to medications, food, or other products. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine, and did not have any other medications within 2 weeks of vaccination. The patient was not diagnosed with COVID-19 prior to vaccination. Since the vaccination, the patient has not been tested for COVID-19. It was reported that at around 17:00 on 20Dec2020, patient started having really bad headaches. She took a two-hour nap and when she woke up she kept having chills and a mild fever (on 20Dec2020 19:00). She hasn't been able to sleep because of feel warm yet cold and her body aches. No treatment received for the adverse events. Outcome of events was not recovered.

"Tingling throat; This is a spontaneous report from a contactable physician. This physician reported same event for two patients. This is second of two reports. A patient of unspecified age and gender started to receive bnt162b2 (BNT162B2; also reported as COVID-19 vaccine; unknown lot number, NDC number and expiration date), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. It was reported that it was unknown if other products were received or if an investigation assessment was performed. On 16Dec2020, the patient experienced tingling throat (non-serious). The physician called regarding COVID 19 vaccine since they had two events that happened yesterday (16Dec2020), however, the physician stated that she needs to ask a question before speaking with DSU and reporting the events. the physician mentioned that two patients complained of tingling in their

throat during the observation period after the vaccine was administered. The physician thought ""they just panicked and overreacted "" and she did not think they had a reaction. The patients did go the ER (emergency room) and were discharged the same day. The physician wanted to be able to give the second dose. The physician wants to ask about the side effects of the vaccine. The outcome of the event was unknown. The following information on the lot/batch number has been requested; Sender's Comments: Linked Report(s) : US-PFIZER INC-2020502608 same reporter/event, different patient"

Fever; Chill; whole muscle ache; Headache; Runny nose; This is a spontaneous report from a contactable Other HCP reported for herself. This 32-year-old female (no pregnant) patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number: EH9899), intramuscular at left arm on 20Dec2020 11:00 at single dose for COVID-19 immunization. None medical history reported. The patient's concomitant medications were not reported. No Covid prior vaccination, No Covid tested post vaccination. No other vaccine in four weeks. On 20Dec2020 02:00 PM, the patient experienced fever, chill, whole muscle ache, headache, runny nose. No treatment received for the events. The outcome of events was unknown.

Itchiness and small rash on forehead; Itchiness and small rash on forehead; This is a spontaneous report from a contactable nurse (Patient). A 35-year-old female patient received bnt162b2 (lot number: EJ1685), intramuscularly at left arm, 1st dose on 20Dec2020 08:00 AM, at single dose, for COVID-19 immunization. No COVID prior vaccination, COVID tested post vaccination, known allergies, or other medical history. No other vaccines within 4 weeks prior to the COVID vaccine. No other medications the patient received within 2 weeks of vaccination. The patient was not diagnosed with COVID-19, prior to vaccination and after vaccination. Not pregnant at the time of vaccination. There were no concomitant medications. The patient experienced itchiness and small rash on forehead on 21Dec2020 01:00. The event was reported as non-serious. Therapeutic measures were taken as a result of itchiness and small rash on forehead, treatment included: allergy medicine PO (Oral). The outcome of the events was unknown.

Joint pain; Muscle pain; Headache; Fever (100.7 F); Fatigue; This is a spontaneous report from a non-contactable Other Healthcare professional (HCP). A 61-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot # EK5730), intramuscular, on 18Dec2020 at 12:30 PM at single dose for COVID-19 immunisation. Vaccine location was right arm. The patient was vaccinated at hospital, age at vaccination was 61-years-old. Medical history included the patient diagnosed with COVID 19 before vaccination. On 19Dec2020 at 06:00 PM, the patient experienced joint pain, muscle pain, headache, fever (100.7 F) and fatigue. No treatment was administered for the events. The patient recovered from the events on an unknown date in Dec2020. No follow-up attempts are possible. No further information is expected.

Bitter taste with food and drink for 2 hours post injection; This is a spontaneous report from a contactable other Healthcare Professional (HCP, patient). A 49-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot # ej1685), intramuscular, on 19Dec2020 at single dose for COVID-19 immunisation. Vaccine location was left arm. The patient was vaccinated at hospital, age at vaccination was 49-years-old. No other vaccines were administered within 4 weeks prior

to the COVID vaccine. Medical history included allergies to iodine, migraine, and gastrooesophageal reflux disease (GERD). Concomitant medications included duloxetine, erenumab aooe (AIMOVIG), and ubrogepant (UBRELVY) The patient experienced bitter taste with food and drink for 2 hours post injection on 19Dec2020 at 05:30 PM, reported as non-serious. No treatment was received for the event. The patient recovered from the event on an unknown date in Dec2020.

feeling tingling in my lips & face.& tongue; feeling tingling in my lips & face.& tongue; This is a spontaneous report from a contactable nurse (patient). A 61-year-old female patient received her first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot:EL0140) via an unspecified route of administration at the right arm on 19Dec2020 08:30 at a single dose for covid-19 immunisation. Medical history included allergies to medications: sulfa drugs. Concomitant medication included zinc, magnesium, calcium phosphate, colecalciferol (CALCIUM+D), ascorbic acid (VITAMIN C) and clarithromycin (CLARITIN). On 20Dec2020 21:00, the patient felt tingling in her lips, face and tongue. The patient reported that she took diphenhydramine (BENADRYL) orally, 25mg when she got home as treatment. Outcome of events recovered on an unspecified date in Dec2020.

nausea; Headache; This is a spontaneous report from a contactable Nurse (patient). This 60-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot # EK5730), via an unspecified route of administration, on 17Dec2020 at 09:30 AM at single dose for COVID-19 immunisation. Vaccine location was left arm. The patient was vaccinated at hospital, age at vaccination was 60-years-old. No other vaccine was received in four weeks. Medical history included colorectal cancer in 2008, and idiopathic thrombocytopenic purpura (ITP) in 1991 recovered on an unknown date. Concomitant medications included gabapentin, omeprazole, duloxetine. On 17Dec2020 at 01:00 PM, the patient experienced headache and nausea the first day, severe nausea the second and third day, nausea continuing but not as severe as the second and third day. The patient was treated with Zofran. Outcome was not recovered.

headache on left side of head which was similar to migraine; This is a spontaneous report from a contactable other healthcare professional reported for herself. A 43-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number EJ1685, expiry date unknown) intramuscular on left arm on 19Dec2020 11:30 at single dose for COVID-19 immunization. Medical history included penicillin allergies, allergies to sulfa drugs and allergies to cephalosporins. Concomitant medication included vitamin D3 and amylase, ascorbic acid, cellulase, folic acid, lipase, protease nos (JUICE PLUS); both from unspecified date for unspecified indication. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. On 19Dec2020 13:00, the patient experienced headache on left side of head which was similar to migraine and went away on Dec2020 by taking 2 Aleve. The event was considered non-serious and did not results in death, not life threatening, did not caused/prolonged hospitalization, not disabling/incapacitating, not a congenital anomaly/birth defect.

A large raised whelp (welt) at the injection site painful itchy hard and still there 5 days post injection; A large raised whelp (welt) at the injection site painful itchy hard and still there 5 days post injection; A large raised whelp (welt) at the injection site painful itchy hard and still there 5 days post injection; A

large raised whelp (welt) at the injection site painful itchy hard and still there 5 days post injection; This is a spontaneous report from a contactable other healthcare professional, patient. A 56-year-old female patient (non-pregnant) received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 09Dec2020 16:00 in the right arm at single dose for COVID-19 immunization. Patient medical history included hypertension (htn), obesity, chronic pain, arthritis, and season allergies chronic. Concomitant medications were not reported. The patient previously took tramadol, tizanidine and duloxetine hcl (CYMBALTA) and experienced drug allergies. On 09Dec2020 17:00, the patient developed a large raised whelp (welt) at the injection site, painful, itchy, hard and still there 5 days post injection. The events were assessed as non-serious. Outcome of the events was not recovered. Information on batch number has been requested.

Chilled; headache; blurred vision; This is a spontaneous report from a contactable Other Health Professional (patient). A 64-year-old female patient receivef bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) lot number: EJ1685, intramuscular in the right arm, first dose on 18Dec2020 10:15 at a single dose for immunisation. Medical history included cervical dystonia wherein she takes botox treatments quarterly for this. Concomitant medications included estradiol, rosuvastatin calcium (CRESTOR), gabapentin and montelukast sodium (SINGULAIR). The patient was not pregnant. The patient was not diagnosed with covid 19 prior to vaccination nor been tested since vaccination. The patient experienced chilled, headache, and blurred vision on 18Dec2020 at 12:00 PM with outcome of recovered on an unknown date in Dec2020. The patient did not receive any treatment for the events. The events are considered non-serious by the reporter. No follow-up attempts are possible. No further information is expected.

experienced itchy and tight throat that felt like a tickle in throat; experienced itchy and tight throat that felt like a tickle in throat; This is a spontaneous report from a contactable nurse. A 46-year-old non-pregnant female patient received 1st dose of bnt162b2 (brand = Pfizer, lot number: EJ1685), intramuscular in the left arm on 20Dec2020 09:00 at a single dose for COVID-19 immunization at the hospital. Medical history included atrial septal defect repair in 2011 to an unknown date. The patient has no known allergies. Concomitant medications included hydrocodone bitartrate, paracetamol (VICODIN) and diclofenac. The patient experienced itchy and tight throat that felt like a tickle in throat on 20Dec2020 09:00. Airway remained patent and no rash/hives. The AEs resulted in a visit to emergency room/department or urgent care. Outcome of the events was recovered in Dec2020. No treatment was given for the events. It was unknown if patient had COVID prior to vaccination. The patient was not tested for COVID post vaccination.

Injection site pain level 7 to 8 about 6 hours after injection; Very tired and sleepy 4 hours after injection; Very tired and sleepy 4 hours after injection; This is a spontaneous report from a contactable healthcare professional. A 54-year-old male patient received first dose of BNT162B2 (lot number: Ek5730), intramuscularly at the right arm, on 19Dec2020 09:00 at a single dose for COVID-19 immunization at a public health clinic/veterans administration facility. Medical history included continuous positive airway pressure (CPAP), high cholesterol, and high blood pressure (BP). Patient has no known allergy. The patient was no previously diagnosed with COVID-19 not was tested for it. Also the patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Concomitant medication included

atorvastatin calcium (LIPITOR). The patient was very tired and sleepy 4 hours after injection on 19Dec2020 13:00 and experienced injection site pain level 7 to 8 about 6 hours after injection on the same day of 19Dec2020, 15:00. Therapeutic measures were taken as a result of injection site pain which included acetaminophen (TYLENOL). The patient recovered from the event injection site pain by the next day of 20Dec2020 and from the event tired and sleepy after a nap on the same day of 19Dec2020.

Arm soreness; Fatigue; General malaise; Low grade temp; Headache; This is a spontaneous report from a contactable nurse (patient). A 46-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK5730, expiry date: not provided) solution for injection at a hospital, via an unspecified route of administration (on left arm) on 17Dec2020 14:00 at a single dose for COVID-19 immunisation. Medical history included allergy to Sulfa, and FS (flushing and sweating). Concomitant medication included estrogens esterified, methyltestosterone (ESTRATEST) daily. The patient received the vaccine on left arm, dose number 1. The patient experienced arm soreness, fatigue, general malaise, low grade temp, and headache on 17Dec2020. No treatment was given. The events were reported as non-serious. Patient was not pregnant. The patient did not receive any other vaccines within 4 weeks prior to the Covid-19 vaccine; patient has not been tested or diagnosed of Covid-19. Outcome of the events was recovering. No follow-up attempts needed. No further information was expected.

chills; flulike symptoms; cramping in left leg; fatigue; This is a spontaneous report from a contactable other healthcare professional which is also the patient. A 41-year-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 18Dec2020 at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. In Dec2020, the patient experienced having cramping in left leg that has resolved and fatigue, chills that began last night from the time of report, and flulike symptoms since getting the vaccine. The reporter asked if he should be worried and get a COVID test. He was given paperwork and knows these are possible symptoms of the vaccine. Information on lot/batch number has been requested.

Ear pressure and swelling on same side as vaccine injection; Ear pressure and swelling on same side as vaccine injection; This is a spontaneous report from a contactable nurse (patient). A 27-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE lot/batch number EJ1685), via an unspecified route of administration on the right arm on 21Dec2020 08:30 at SINGLE DOSE as COVID-19 immunization. The patient had allergies to tree nuts. Prior to vaccination, the patient was not diagnosed with COVID-19 and patient had not been tested for COVID-19 since vaccination. The patient's concomitant medications were not reported. On 21Dec2020 08:45, the patient had ear pressure and swelling on same side as vaccine injection resulting to doctor or other healthcare professional office/clinic visit. It was unknown if treatment was received for the adverse event. Outcome of the events were unknown.

nausea; headache; fatigue; muscle pain; feeling unwell; This is a spontaneous report from a contactable nurse who reported for herself. A 51-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), intramuscular in Left arm on 17Dec2020 at 11:30 am at single dose for COVID-19 immunization. Patient was not pregnant. No known allergies. Concomitant medication included

unspecified drug: patient received other unspecified medication in two weeks. No other vaccine in four weeks administered. On 17Dec2020 at 11:45 am, the patient experienced nausea, headache, fatigue ,muscle pain and feeling unwell, all non serious. No treatment given. Outcome of the events was reported as recovered in Dec2020. No follow-up attempts are possible, information about batch number cannot be obtained.

Immediate headache followed by total body itching. Itching began 4-5 hours after dose. Itching lasting overnight into early morning. Felt like hives, but skin did not break out into hives.; Immediate headache followed by total body itching. Itching began 4-5 hours after dose. Itching lasting overnight into early morning. Felt like hives, but skin did not break out into hives.; Immediate headache followed by total body itching. Itching began 4-5 hours after dose. Itching lasting overnight into early morning. Felt like hives, but skin did not break out into hives.; This is a spontaneous report from a contactable consumer. A 62-year-old female patient received first dose of bnt162b2 (BNT162B2; lot number: EK5730), via an unspecified route of administration on 20Dec2020 14:00 on right arm , SINGLE DOSE for COVID-19 immunization. Medical history included Known allergies: Contrast dye, sulfur drugs. The patient's concomitant medications were not reported. The patient previously took erythromycin and experienced Known allergies: Erythromycin. No COVID prior vaccination. The patient has not been tested for COVID-19 since the vaccination. On 20Dec2020 18:30, the patient experienced Immediate headache followed by total body itching. Itching began 4-5 hours after dose. Itching lasting overnight into early morning. Felt like hives, but skin did not break out into hives. The events was assessed as non-serious. The outcome of the events was recovered.

Injection site pain; tiredness; headache; muscle pain; chills; injection site swelling; nausea; swollen lymph nodes; feeling unwell; onset of menstrual cycle; This is a spontaneous report from a contactable nurse (patient). A 29-year-old female patient started received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE lot/batch number not provided), intramuscular on the left arm on 17Dec2020 17:00 at SINGLE DOSE as COVID-19 immunization at the workplace clinic. Medical history included Hashimoto's Thyroiditis & Environmental Allergies. The patient also had allergies to ibuprofen, penicillin, & sulfa. Concomitant medications included levothyroxine (LEVOTHYROXINE), montelukast (MONTELUKAST), ethinylestradiol, norgestimate (TRINESSA) and multivitamins. Prior to vaccination, the patient was not diagnosed with COVID-19 and not tested for COVID-19 since vaccination. On 18Dec2020 12:00, the patient experienced injection site pain, tiredness, headache, muscle pain, chills, injection site swelling, nausea, swollen lymph nodes, feeling unwell, and onset of menstrual cycle (as reported). The patient did not receive any treatments for the events. The patient recovered from the events in Dec2020. Information on the lot/batch number has been requested.

hives, urticaria mostly over torso, face; This is a spontaneous report from a contactable physician (patient). A 29-year-old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number: EK5730), intramuscular on the left arm on 15Dec2020 19:30 at a single dose for covid-19 immunization. The patient's medical history included persistent depressive disorder and known allergic reaction to wood varnish. The patient was not pregnant. Concomitant medications included escitalopram oxalate (LEXAPRO) and bupropion hydrochloride (WELLBUTRIN). The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to

vaccination, the patient was not diagnosed with COVID-19 and had not been tested for COVID-19 since the vaccination. The patient experienced hives, urticaria mostly over torso, face on 17Dec2020 18:00. Therapeutic measures were taken as a result of hives, urticaria mostly over torso, face and included treatment with dexamethasone. Outcome of the event was recovering.

intense arm pain, migraine, nausea w/ vomiting; intense arm pain, migraine, nausea w/ vomiting; intense arm pain, migraine, nausea w/ vomiting; intense arm pain, migraine, nausea w/ vomiting; This is a spontaneous report from a contactable other healthcare professional. A 44-year-old female patient received the first dose of bnt162b2 (Covid-19 vaccine, manufacturer: Pfizer, lot no: EJ1685) intramuscular in left arm on 18Dec2020 13:00 at a single dose for COVID-19 immunization. Medical history included type 2 diabetes mellitus, known allergies to sulfa, penicillin group, tetracycline analogues group. Concomitant medication included metformin, fluoxetine hydrochloride (PROZAC), lisinopril, semaglutide (OZEMPIC), and insulin glargine (TOUJEO). The patient experienced intense arm pain, migraine, nausea w/ vomiting on 19Dec2020 04:00. The patient recovered from the events in Dec2020. The events were reported as non-serious. The patient did not receive treatment for events, had no covid prior to vaccination, and was not covid tested post vaccination.

Severe, watery diarrhea; This is a spontaneous report from a non-contactable other healthcare professional. A 30-year-old female patient received bnt162b2 (BNT162B2, lot no and expiry date was unknown), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. The patient is not pregnant. The patient experienced severe, watery diarrhea on 18Dec2020. No treatment received for the event. The outcome of the event was not recovered. No follow-up attempts are possible, information about batch number cannot be obtained.

Really bad body aches the next day.; Itching at site and then itching went to rest of body. No hives.; Itching at site and then itching went to rest of body. No hives.; This is a spontaneous report from a contactable nurse (reported for herself). A 47-year-old female patient (not pregnant) received bnt162b2 (BNT162B2 also reported as COVID 19 brand Pfizer, lot/batch number and expiry date not reported), intramuscular on 18Dec2020 16:45 at single dose (dose number 1) in the right arm for immunisation. Medical history was none. Patient was allergic to medication sulfa, food, or other products. She had no other vaccine in four weeks, no covid prior vaccination. The patient's concomitant medications included unspecified multivitamins. The patient experienced itching at site and then itching went to rest of body (no hives) on 18Dec2020 16:45. She had really bad body aches the next day (19Dec2020). No treatment was given. No hospitalization reported. The outcome of events was recovered on unknown date in Dec2020. Information on the Lot/Batch number has been requested.

mother received BNT162B2/while the mother was breast feeding this 5-month-old patient; vomiting (throwing up); not eating. Not nursing, Not breastfeeding and not taking her bottle; her 5month old baby is lethargic; all of a sudden took ill; This is a spontaneous report from a contactable consumer (parent). This consumer reported information for both mother and baby. This is baby report. This is a case for a 5-month-old patient of an unspecified gender whose mother of unspecified age received first

dose of BNT162B2 (PFIZER/BNT162 Covid-19 Vaccine), via an unspecified route of administration on 18Dec2020 13:15 at a single dose for COVID-19 immunization, while the mother was breast feeding this 5-month-old patient. The patient's medical history and concomitant medications were not reported. On 19Dec2020, all of a sudden took ill. The patient was lethargic, vomiting (throwing up) and not eating. Not nursing, Not breastfeeding and not taking her bottle. The outcome of events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2020503099 mother/baby case

"Received the vaccine last Friday. Having fever. Temperature high as 101.4F .; I have a body ache; This is a spontaneous report from a contactable nurse. A 60-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, batch/lot number EH9899, Expiry Date: 30Mar2021), via an unspecified route of administration on 18Dec2020 at single dose for covid-19 immunisation. Medical history included blood pressure, cholesterol, covid-19 (Had Covid-19 in March). Concomitant medication included amlodipine for Blood pressure, rosuvastatin calcium (CRESTOR) for Cholesterol. Nurse calling on behalf of herself. 60 years old almost 61. Received the vaccine last Friday. Having fever. Temperature high as 101.4F. Still having it lingering between 99F and 100F. How long will it last? Had Covid-19 in March. Compared with her colleagues and they had no side effects except pain at injection site. Lab test: Nurse stated, ""I did a Covid swab on the 14th its negative."" Treatment: Nurse stated, ""When I had a fever I had something, Yes, I did, I took Tylenol."" Causality: Nurse stated, ""Yes, because I was fine before COVID Vaccine."" Nurse further stated, ""Besides the fever I have like my body is aching, my whole body is aching. I have a body ache."" The outcome of the events was unknown."

doesn't feel good; migraine level headaches; body aches; injection site pain; Tiredness; headache; muscle pain; Chills; Nausea; arm is still a little sore; bottom of the arm hurt; she couldn't move it; This is a spontaneous report from a contactable other healthcare professional (patient). A 46-year-old female patient received first dose of bnt162b2 (Pfizer Biontech COVID 19 vaccine), Lot number: EH9899, intramuscular in the deltoid on 17Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. She works in Urgent Care and has to swab people with COVID all day long. The caller had the injection on 17Dec2020 and still doesn't feel good. The patient is a medical assistant calling because of herself. She did not want to go back to work, she does not feel good, she has a headache that is horrible, migraine level headache and a few body aches. This happened two hours after the injection- she had injection site pain, tiredness, headache, muscle pain, chills, nausea. She also stated that her arm is still a little sore, she got it in the deltoid, and the bottom of the arm hurt, she couldn't move it, but the next day, her arm was fine. The outcome of body aches, tiredness, muscle pain, chills, nausea was recovering; migraine level headaches and headaches was not recovered; doesn't feel good and injection site pain was unknown; arm is still a little sore; bottom of the arm hurt and she couldn't move it recovered on an unspecified date.

"Tenderness and slight swelling in my left neck and left armpit; Tenderness and slight swelling in my left neck and left armpit; This is a spontaneous report from a contactable nurse. A 44-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), lot number: EK5730, first dose via an unspecified route of administration in left arm on 17Dec2020 20:30 at single dose for COVID-19 immunization. Medical history included COVID-19 prior to vaccination and penicillin allergy from an

unknown date and unknown if ongoing. On 19Dec2020, the patient stated, ""tenderness and slight swelling in my left neck and left armpit on day 2 after vaccine. The patient had no other vaccine in four weeks. The patient had taken other unspecified medications in two weeks. No treatment was given to patient for the events. The patient had COVID prior vaccination to vaccination and not had COVID test post vaccination. The events were reported as non serious as it did not result in death, not life threatening, did not cause prolonged hospitalization, not disabling or incapacitating and no congenital anomaly or birth defect. The outcome of the events was not recovered."

"injection site pain; This is a spontaneous report from a contactable pharmacist. An adult (reported as 39, unit unknown) female patient received first dose of BNT162B2 (Pfizer-BioNTech COVID-19 mRNA vaccine, batch/lot number and expiry date were unknown), via an unspecified route of administration on 18Dec2020 at a single dose for COVID-19 immunization. The patient received COVID-19 vaccine in a hospital facility. The patient's medical history and concomitant medications were not reported. The patient previously experienced vaccination site pain from flu vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient had 1st dose of COVID-19 vaccine and experience injection site pain. She described it as ""more painful than any flu vaccine received"". The patient did not receive treatment for the adverse event. The outcome of the event was recovered in Dec2020. No follow-up attempts are possible. Information on lot/batch number cannot be obtained. No further information is expected."

Got hot; flushed; weakness; few minutes of itchy throat and back; few minutes of itchy throat and back; lips tingling; a lump in the throat feeling; This is a spontaneous report from a contactable nurse (patient). A 40-year-old male patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number: ek5730), intramuscular on the left arm on 20Dec2020 12:00 at a single dose for COVID-19 immunization. The patient's medical history included irritable bowel syndrome (IBS), attention deficit hyperactivity disorder (ADD), and lactose intolerance. Concomitant medications included hyoscyamine and amfetamine aspartate, amfetamine sulfate, dexamfetamine saccharate, dexamfetamine sulfate (ADDERALL). The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. On 20Dec2020 12:00, the patient experienced got hot, flushed, weakness, few minutes of itchy throat and back, lips tingling, and a lump in the throat feeling. No treatment received for the adverse events. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, the patient had not been tested for COVID-19. Outcome of the events was recovering. The events were considered non-serious.

Low grade temp; headache; achy; diarrhea; tiredness; This is a spontaneous report from a contactable nurse (patient). A 41-year-old female patient received the first dose of bnt162b2 (Pfizer Biontech COVID 19 vaccine), Lot number: EJ1685, via an unspecified route of administration on the left arm on 19Dec2020 11:30 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient was not pregnant. The patient has no allergies to medications, food, or other products. On 20Dec2020 11:00, the patient experienced low grade temp, headache, achy, diarrhea and tiredness. The patient did not receive any treatment for the events and were reported as non-serious. The vaccine was administered in a hospital. The patient has not received

any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. The outcome of events low grade temp, headache, achy, diarrhea and tiredness was recovered on an unspecified date in Dec2020.

lymphadenopathy; joint pain; muscle pain; chills; fatigued; sore, pain at site normal for vaccine admin; This is a spontaneous report from a contactable pharmacist. An adult female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot: EJ1685) intramuscularly on 17Dec2020 at a single dose for covid-19 immunization. The patient's medical history and concomitant medications were not reported. On 17Dec2020 21:00, the patient was fatigued and had sore pain at the site of vaccine administration. On 18Dec2020, the patient experienced joint pain, muscle pain and chills. On 19Dec2020, the patient developed lymphadenopathy. The events were reported as non-serious. Outcome of events recovered on an unspecified date on Dec2020.

purple discoloration to her right arm and right fingers; chills; redness across her chest and stomach; cap refill was sluggish; This is a spontaneous report from a contactable nurse. A 37-year-old female patient received the first dose of BNT162B2 (Pfizer-BioNTech COVID-19 vaccine, lot# EJ1685), via intramuscular on 18Dec2020 11:00 in right arm at single dose for covid-19 immunization. The patient's medical history and concomitant medications were not reported. The most recent COVID-19 vaccine was administered in hospital. Prior to vaccination, the patient was not diagnosed with COVID-19. Employee reported purple discoloration to her right arm and right fingers. She reported her cap refill was sluggish. She stated she had chills and redness across her chest and stomach on 18Dec2020 at 16:00. The events result in Emergency room/department or urgent care. The patient received the treatment for the events. Outcome of events were unknown.

My arm pit is swollen and a little painful; My arm pit is swollen and a little painful; This is a spontaneous report from a contactable consumer (patient). A male patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 18Dec2020 at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient noticed that his arm pit was swollen and a little painful on 20Dec2020. The outcome of the events was unknown. Information about the lot/batch number has been requested.

not being able to smell anything/Cannot smell anything; Sinus issues; Cough; Congestion; Feels hot; backache; fatgue; headache; This is a spontaneous report received from a contactable other health professional (who is also the patient). A 41-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK5730), via an unspecified route of administration in left arm, on 15Dec2020, at single dose, for COVID-19 immunization. There was no medical history. The patient's concomitant medications were not reported. The patient reported that she got the COVID vaccine last Tuesday, on 15Dec2020. She is a psychologist and works close with patients all the time. She has had symptoms since last Wednesday (16Dec2020). She clarified that her symptoms were back ache shortly after the vaccine, fatigue, headache, sinus issues and cough. Then her backache went away. She also had congestion and felt hot on 16Dec2020. She had an appointment last Friday (18Dec2020) and they took her temperature, but she did not have a fever. And then since yesterday (20Dec2020), she

cannot smell anything. She has a baby and cannot smell the dirty diapers. She cannot smell her perfume. She asked other people who received the vaccine if they experienced this, and they did not. She was wondering if this is the vaccine or does she possibly have some other infection or should she get tested for COVID or is it possible this is from the vaccine? The patient clarified that at first her back ache went away but it is still ongoing now. It has persisted at the same level as well as all of the other symptoms. The outcome of the events was not recovered.

Sore arm at injection site and headache at bedtime.; Sore arm at injection site and headache at bedtime.; This is a spontaneous report from a contactable nurse (patient). A 62-year-old female patient (non-pregnant) received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number: EH9899) via unspecified route of administration on 20Dec2020 at single dose for COVID-19 immunization. Patient medical history and concomitant medications were not reported. The patient experienced sore arm at injection site and headache at bedtime on 20Dec2020. Outcome of the event was recovered on unspecified date in Dec2020. No treatment received for the events. The events were assessed as non-serious.

fever; body malaise; Body aches; muscles hurt; sharp eye pain/If she turns her eyes to the right or to the left; chills; This is a spontaneous report from a contactable consumer. A 24-year-old female patient (daughter) received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899), via an unspecified route of administration at 18:00 on 17Dec2020 at single dose for COVID-19 immunization. Medical history included asthma and anxiety. Concomitant medication included sertraline hydrochloride (ZOLOFT) for anxiety. The patient experienced fever, body malaise, body aches, muscles hurt, sharp eye pain/if she turned her eyes to the right or to the left, and chills on 18Dec2020. At time of reporting, the outcome of events was not recovered.

Rash spreading started at the neck slowly progress to the entire neck, then the scalp, torso, legs and arms. Started within 4 hours over night then at 0830 am started getting worse.; This is a spontaneous report from a contactable nurse reporting for herself. A 40-years-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration in the left arm on 20Dec2020 16:15 at single dose for COVID-19 immunization. Medical history included hyperlipidaemia, antiphospholipid syndrome and migraine. Concomitant medication included metronidazole benzoate (FLAGYL), butalbital, caffeine, paracetamol (FIORICET), iron (IRON) and multivitamin. The patient experienced rash spreading started at the neck slowly progress to the entire neck, then the scalp, torso, legs and arms on 20Dec2020 21:30 with outcome of not recovered. On21Dec2020 at 08:30 am it started getting worse. The outcome of the events was not recovered. The patient took Benadryl as treatment for the events. The patient did not undergo COVID test and did not have COVID prior to vaccination. Information on the lot/batch number has been requested.

tingling on roof of mouth, watery eyes, and itchy throat; tingling on roof of mouth, watery eyes, and itchy throat; tingling on roof of mouth, watery eyes, and itchy throat; This is a spontaneous report from a contactable nurse. A 34-years-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number EJ1685), intramuscular in the left arm at hospital on 18Dec2020 09:00 at single dose for COVID-19 immunization. The patient medical history and

concomitant medications were not reported. On 18Dec2020 at 09:15 the patient experienced tingling on roof of mouth, watery eyes, and itchy throat with outcome of unknown. The events required emergency room visit and the patient received treatment.

sore arm following vaccination; This is a spontaneous report from a Pfizer sponsored program, Pfizer First Connect, received from a contactable consumer (patient). A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot/batch number and expiry date were not provided) solution for injection, via an unspecified route of administration on 20Dec2020 at a single dose for COVID-19 immunisation. Medical history included bone pain and arthritis (patient received a prescription of Prednisone today for bone pain and arthritis). The patient's concomitant medications were not reported. The patient reported receiving the first dose of the COVID-19 vaccine yesterday morning (20Dec2020). She mentioned experiencing a sore arm following vaccination. She then explained receiving a prescription of Prednisone today for bone pain and arthritis, after consulting with her foot doctor. She asked if she should she take this steroid treatment, and also asked if she should receive her second dose of the Shingle vaccine while being on the COVID-19 treatment. Outcome of the event was unknown. Information on lot/batch number has been requested.

Tachycardia, heart rate remained higher than 100 bpm throughout the day at rest. Readings ranged from 110-117; This is a spontaneous report from a contactable Nurse. This 25-years-old female Nurse reported for herself (pregnant: No) received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899) on 18Dec2020 01:00 PM at Right arm at single dose for covid-19 immunization. Medical history was allergy to ham. Concomitant drug was Omeprazole. No other vaccine in four weeks. Adverse event reported as Tachycardia, heart rate remained higher than 100 bpm throughout the day at rest (non-serious). Readings ranged from 110-117 on 19Dec2020 09:00 AM with outcome of Recovered. No treatment. No COVID prior vaccination. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. Follow-up attempts have been completed and no further information is expected.

"elevated heart rate of 113; Itching to roof of her mouth; numbness to right side of her throat; This is a spontaneous report received from a contactable nurse. A 24-year-old female patient received her first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EJ1685), intramuscular in right arm, on 18Dec2020 10:45, at single dose, for COVID-19 immunization. The patient medical history and concomitant medications were not reported. It was unknown if the patient was pregnant. It was reported that the patient experienced itching to roof of her mouth, numbness to right side of her throat and had elevated heart rate of 113 on 18Dec2020 at 11:00. The adverse events resulted in ""Emergency room/department of urgent care"". It was unknown if the patient received treatment for the events. The outcome of the events was unknown."

dizziness; weakness; loss of balance; brain fog; lethargy; Dizziness and loss of balance led to a fall where an injury was sustained (leg weakness, loss of balance led to a fall down a flight of stairs with injury to right shoulder); Dizziness and loss of balance led to a fall where an injury was sustained (leg weakness, loss of balance led to a fall down a flight of stairs with injury to right shoulder); Dizziness and loss of balance led to a fall where an injury was sustained (leg weakness, loss of balance led to a fall down a

flight of stairs with injury to right shoulder); This is a spontaneous report from a contactable nurse. This 41-year-old female nurse (patient) reported for herself that she received the first dose of BNT162B2 (Lot# EH9889) intramuscularly at left arm at single dose for COVID-19 ((PFIZER-BIONTECH COVID-19 VACCINE) immunisation on 17Dec2020. Relevant history was unknown. Relevant concomitant drug included multivitamin and ergocalciferol (VIT D). No known allergies. No allergies to medications, food, or other products. Relevant medical history was none. After receiving first dose, the patient experienced dizziness, weakness, loss of balance, brain fog, lethargy on 18Dec2020, 07:00 AM. The dizziness and loss of balance led to a fall where an injury was sustained (leg weakness, loss of balance led to a fall down a flight of stairs with injury to right shoulder). No treatment was received. The patient resolved with sequel from the events. No covid prior vaccination. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. The events were considered as non-serious.

headache; chills; fatigue; This is a spontaneous report from a non-contactable nurse. This nurse reported for a 32-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number=EK5730) Intramuscularly at Left arm at single dose for COVID-19 immunisation on 19Dec2020 (02:30 PM). Relevant history and concomitant drugs were unknown. The patient experienced had chills, fatigue, headache in the morning of 20Dec2020 at 7:00 am. The patient received Tylenol as treatment and the outcome of events was resolved in unknown date of Dec2020. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. No follow-up attempts are possible. No further information is expected.

"amount of blood on his Band-Aid after the injection; This is a spontaneous report from a contactable pharmacist. A male patient unknown age received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) at single dose for COVID-19 immunisation on 20Dec2020. Relevant history and concomitant drugs were unknown. The patient had a significant (then rephrased to ""small"") amount of blood on his Band-Aid after the injection on 20Dec2020. Outcome of the event was unknown. The information on the lot/batch number has been requested."

feeling kind of bad; low grade fever; chills; muscle aches; Arm is still sore at the injection site. It's sore to touch and can tell it's still sore with movement.; swollen lymph nodes; spontaneous report from a contactable nurse. This 47-year-old nurse reported for self that she received her first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) intramuscularly at right arm at single dose for COVID-19 immunisation on 18Dec2020. Relevant history included gestational diabetes history; Her daughter was 14 years old and she had never had diabetes. No signs of diabetes after birth of daughter. The patient was not a smoker/former smoker. The patient had tested positive with COVID antibodies probably in Apr2020, both she and her husband and both wound up getting symptomatic with COVID symptoms about the 14Mar2020. They were unable to get tested and just kind of figured they had it. Her husband also had pneumonia. They both recovered in Apr and decided to get the antibody test done and it was positive for the antibodies and they had also given blood since then and that was also positive for antibodies. The patient considered wondering with this being the first vaccine dose was considered as a

good immune response. Relevant concomitant drug was unknown. The patient reported having the Pfizer-BioNTech COVID-19 Vaccine 685 on Fri and was having some symptoms. Got it about 12:45 Fri (18Dec2020) and around 11PM that evening she was feeling kind of bad, low grade fever, chills, and muscle aches. This was only the first vaccine she had. The symptoms ended up lasting up to 24 hours and the fever went away the next morning, but she still had chills. Only thing she had was the swollen lymph nodes at right axillary, the same side of the site of the injection. The patient mentioned she didn't feel very good Sat, but at the reporting time she could work today. The patient clarified that her husband did not have the Pfizer-BioNTech COVID19 Vaccine 685 vaccine. And she did not test positive for COVID and didn't have the actual testing done because they didn't have the test available it was only for if someone were hospitalized. The patient's arm was still sore at the injection site. It's sore to touch and could tell it's still sore with movement. There was no pre-existing diseases worsened during the SARS-CoV2 infection. The patient was not treated with immunomodulating or immunosuppressing medications or received any other vaccines around the time of COVID-19 vaccination. The patient did not have a positive test for SARS-CoV2. The patient did not display clinical signs at rest indicative of severe systemic illness. The patient did not taking any medications routinely prior to the event being reported. The outcome of event feeling kind of bad, low grade fever and muscle aches was resolved, the outcome of events swollen lymph nodes, chills and sore at the injection site was not resolved. The events were assessed as non-serious. The patient stated she had been positive with Covid in Mar, which may have caused her to be more symptomatic with the vaccine, but was unsure if that was the case. She also heard a lot of people had the first dose, never exposed to Covid, and had no symptoms after receiving the vaccine. The patient asked if she should still take the second dose even though she has been positive with Covid before. Information on the lot/batch number has been requested.

arm started to feel sore; injection site pain; This is a spontaneous report from a contactable consumer (patient). A 76-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number E9899, expiry date Mar2021) intramuscular on left arm on 17Dec2020 at single dose for COVID-19 immunization. The patient has no prior vaccinations within 4 weeks. Medical history included and concomitant medications were none. The patient got the COVID vaccine on Thursday (17Dec2020), her arm was still really sore (17Dec2020). The patient asked on how long will this last and was referred to healthcare professional. Full EUA PI, discussed incidence of injection site pain. No information on duration after 1st dose. The patient received the Covid vaccine around 10:30 on Thursday morning and her arm started to feel sore Thursday evening. The patient clarified that the vaccine was administered around 10:30AM to 11:00AM. The patient was advised to follow up with healthcare professional. The patient did not receive treatment for the events. The outcome of the events arm started to feel sore and injection site pain was recovering. The reporter informed that the vaccination facility type was a hospital and was not administered at a military facility.

"Making me just kind of loopy too kind of light headed; Weakness; Ringing in ears; Headache; pain at the injection site; I could not even turn onto my other side last night from pain; pain at the injection site; I could not even turn onto my other side last night from pain; Chills; fatigue/Tiredness; low grade temperature; I couldn't even sleep; Extreme muscle and joint pain generalized; Extreme muscle and joint pain generalized; This is a spontaneous report from a contactable nurse. A female patient of an

unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), lot number: EH9899, via an unspecified route of administration on 19Dec2020 at single dose for COVID-19 immunization. Medical history was reported as none. There were no concomitant medications. The patient stated, ""I am a Registered Nurse, an RN here in (city name) and I received your Pfizer vaccine (Covid 19 Vaccine) yesterday morning. I just wanted to report some issues with the vaccine. All through the night in Dec2020, I had the muscle pains, generalized muscle pain all over, even Tylenol (later clarified as Ibuprofen 200 mg, lot number: 9FE3019A and expiry date: Mar2021) wouldn't even work. I have a low grade temperature, headache, and real pain at the site of the injection, some chills earlier yesterday on 19Dec2020. So, I am afraid to get the next Pfizer one because to get some more side effects. This one is making me just kind of loopy too kind of light headed, and I am just really tired, really fatigue on 20Dec2020. With this Pfizer vaccine, I thought it was approved by the certain drug and (Center Name) and according to your message that I just got on another phone number has not been approved. But it was rushed out just for emergency use. Is that correct?"". When informed about the role of Pfizer Medical Information and offered the number, the patient stated, ""Well one number that I got, it was all loopy. I mean it was just all over the page, I couldn't leave a message. They gave me so much information that. So, which number you are talking about?"". The due date for the next shot: 06Jan2021. I am a healthcare provider and I also go into the COVID unit probably in January sometimes. So, I wanted, I am kind of one of your guinea pig. ""When I initially got it on 19Dec2020, of course I had pain at the injection site. I could not even turn onto my other side last night from pain at the injection site. Yesterday on 19Dec2020, I got some chills, I got a low grade temperature, feeling fatigue after a while. At first, I didn't feel that other than injections site. Through the whole night I had low grade temperature, extreme muscle and joint pain generalized, which I couldn't even sleep, I had insomnia. Tylenol wouldn't even help with that. Of course tiredness but I couldn't sleep. So I can't really feel okay, not a very good sleep yesterday. Low grade temp when I got up in the morning and dizziness and weakness this morning definitely and ringing in my ears kind of like.Yes I am generally, but the dizziness and the weakness is kind of new one. I had Tylenol during the night because I couldn't sleep, because I had such muscle and joint pain all over my joint in Dec2020."" The outcome of the events was unknown."

headache; had soreness/pain at the injection site between 24-48 hours; muscle aches; fatigue; malaise; low grade fever; This is a spontaneous report from a contactable consumer (patient). A 28-year-old non-pregnant female patient received first dose of BNT162B2 (Pfizer-BioNTech COVID-19 mRNA vaccine, lot number: 1703), via an unspecified route of administration at left arm on 18Dec2020 10:00 at a single dose for COVID-19 immunization, and second dose of hepatitis b vaccine, via an unspecified route of administration at left arm on 11Dec2020 at unknown dose for an unspecified indication. The patient received COVID-19 vaccine in a hospital facility. Medical history was not reported. The patient has no known allergies. The patient's concomitant medication included birth control. The patient previously received first dose of hepatitis b vaccine on unspecified date. Since the vaccination, the patient has not been tested for COVID-19. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient was fine the morning she received the vaccine (up until the evening). Then she started to feel muscle aches, fatigue, malaise, and had a low grade fever on 18Dec2020 19:00. This persisted for about 48 hours. She also had soreness/pain at the injection site between 24-48 hours

(started on 19Dec2020). The 3rd day (today, 21Dec2020), she had a slight headache, but that could be unrelated. The patient did not receive any treatment for the adverse events. The outcome of the events was recovering. The report was considered non-serious.

fatigue; chills; arm soreness; This is a spontaneous report from a contactable pharmacist. This 34-year-old female pharmacist (patient) reported that she received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK5730), via intramuscular on left arm on 18Dec2020 at 12:45 PM at single dose for COVID-19 immunization. Facility where the most recent COVID-19 vaccine administered was hospital. Prior to vaccination, the patient was not diagnosed with COVID-19. Medical history and concomitant medications were not reported. It was reported patient had no other vaccine in four weeks; she had oral contraceptive in two weeks. Since the vaccination, the patient had not been tested for COVID-19. The patient experienced fatigue, chills, arm soreness on 18Dec2020 at 03:00 PM. No treatment was received. Outcome of events was recovered in Dec2020.

arm pain; low grade fever of 100; This is a spontaneous report from a contactable nurse. A 46-years-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK5730), intramuscularly at the left arm on 20Dec2020 10:30 at a single dose for COVID-19 immunization at a hospital. Medical history included migraine and asthma. Allergy with only certain nausea medications (unspecified). There were concomitant medications but were unspecified which the patient received within 2 weeks of vaccination. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient was not diagnosed with COVID-19 prior to vaccination and was not tested for it since the vaccination. On 20Dec2020, 22:00, after almost 12 hours, patient had a low grade fever of 100 (unit unspecified) and had an arm pain with no treatment while fever responded to acetaminophen (TYLENOL). The patient recovered from the events on an unknown date.

redness and swelling to right wrist; redness and swelling to right wrist; Itching to left side neck and back.; This is a spontaneous report from a contactable nurse. A 25-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), lot number: EJ1685, first dose via intramuscular in left arm on 21Dec2020 09:30 at SINGLE DOSE for covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced redness and swelling to right wrist and itching to left side neck and back on 21Dec2020 09:45. The facility where the most recent COVID-19 vaccine was administered was in the hospital. The events resulted in emergency room or department or urgent care. The case was reported as non serious by the reporter, and did not result in death, not life threatening, did not cause prolonged hospitalization, not disabling or incapacitating and no congenital anomaly or birth defect. The outcome of the events was unknown.

Injection site was very painful and it's blowing and my whole arm was hurting; Injection site was very painful and it's blowing and my whole arm was hurting; I have swelling in my whole arm; Weakness; Muscle soreness; Headache; This is a spontaneous report from a contactable consumer (patient, nurse's assistant). A 48-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on Friday 18Dec2020 at about 09:58 at 0.3 ml, single for covid-19 immunization. This was the first dose. None medical history. There were no concomitant medications. In 2020, the patient stated the injection site itself, was very painful and it's blowing and in fact her whole

arm, the whole arm was hurting and she has swelling in her whole arm and also she had like muscle soreness and weakness. The only other thing she felt was like headache and that's it. The patient was given aspirin for treatment. The action taken in response to the events for bnt162b2 was not applicable. The outcome of events was unknown. Information on the lot/batch number has been requested.

"numbness and tingles in armed or pant in all my fingers; numbness and tingles in armed or pant in all my fingers; This is a spontaneous report from a contactable consumer. A 44-year-old female patient received the bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot Number: EK5730 and Expiration Date: Mar2021), via an unspecified route of administration on 18Dec2020 at 44-years-old at a single dose for COVID-19 immunization. The patient's medical history was reported as none. Concomitant medications included estradiol (MANUFACTURER UNKNOWN), misoprostol (MANUFACTURER UNKNOWN); both taken for an unspecified indication from an unspecified date to an unspecified date. On 19Dec2020, the patient experienced: ""numbness and tingles in armed or pant in all my fingers."" The patient stated, ''I got my shot (COVID Vaccine) at work yesterday around 3 pm. Since 1 O 'clock this morning I have numbness and tingles in armed or pant in all my fingers, can won't go away.'' There was no treatment received. The patient reported that she worked in an emergency department as a technician. The patient underwent lab tests and procedures which included body weight: about 190 on an unspecified date. The clinical outcome of the events was not recovered."

Woke up in middle of night; severe muscle pain entire body; chills/fever; chills/fever; debilitating headache; This is a spontaneous report from a contactable nurse (patient). A 61-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot/batch number and expiry date were not provided) solution for injection, intramuscular (left arm) on 20Dec2020 10:00 at a single dose for COVID-19 immunisation. Medical history was reported as none. Concomitant medication included aspirin [acetylsalicylic acid] (ASPIRIN [ACETYLSALICYLIC ACID]), hydrochlorothiazide, losartan potassium (LOSARTAN HCTZ), metoprolol succinate (METOPROLOL SUCCINATE), and estrogens conjugated (PREMARIN). The patient reported she woke up in middle of night, had severe muscle pain on entire body, chills/fever, and debilitating headache on 21Dec2020 02:00. No treatment was received. The events were reported as non-serious. The patient was not pregnant. The patient has not been diagnosed of Covid-19 prior to vaccination and has not been tested. Outcome of the events was recovering. Information about lot/batch no has been requested.

Back pain radiating down to the L buttocks, down the L leg and ending at the ankle.; Back pain radiating down to the L buttocks, down the L leg and ending at the ankle. Rating 5/10 pain.; Back pain radiating down to the L buttocks, down the L leg and ending at the ankle.; Back pain radiating down to the L buttocks, down the L leg and ending at the ankle.; Back pain radiating down to the L buttocks, down the L leg and ending at the ankle.; This is a spontaneous report from a contactable nurse (patient). A 29-year-old female patient received 1 dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899) intramuscular on right arm on 19Dec2020 10:00 AM, single dose for COVID-19 immunization at 29-year-old. Medical history included: COVID-19 diagnosed prior to vaccination. No known allergies. Concomitant medications included: drospirenone, ethinylestradiol betadex clathrate (YAZ); ibuprofen; cetirizine hydrochloride (ZYRTEC); diphenhydramine hydrochloride (BENADRYL); melatonin. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. On

20Dec2020, 10:00 AM, the patient experienced back pain radiating down to the L buttocks, down the L leg and ending at the ankle, rating 5/10 pain. No treatment received for the adverse events. Lab data included: COVID-19 (positive) diagnosed prior to vaccination; pain 5/10 on 20Dec2020. Since the vaccination, the patient had not been tested for COVID-19. Action taken for BNT162B2 was not applicable. Outcome of the events was not resolved. It was reported as non-serious.

feeling light headed; blotchy spots on neck and chest; tingling to the back of the throat; This is a spontaneous report from a contactable nurse. A 42-year-old female patient received 1 dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EJ1685) intramuscular on left arm on 21Dec2020 10:15 AM, single dose for COVID-19 immunization at 42-year-old. Medical history and concomitant medication were not reported. On 21Dec2020 10:30 AM, the patient was reported feeling light-headed, blotchy spots on neck and chest, and tingling to the back of the throat. Emergency room/department or urgent care visited. Action taken for BNT162B2 was not applicable. Outcome of the events was unknown. It was reported as non-serious.

"lips tingling and ""on fire""/tingling ""8/10"", ""2/10""; lips tingling and ""on fire""/tingling ""8/10"", ""2/10""; This is a spontaneous report from a contactable other healthcare professional. A 39-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), intramuscular on 18Dec2020 at single dose for COVID-19 immunization at hospital. The patient's medical history and concomitant medications were not reported. It was reported that the patient received first dose of Pfizer COVID-19 vaccine. After ""10:00 minutes"" of observation phase, patient complained Of (c/o) lips tingling and ""on fire"". Lips not swollen, denies short of breath (SOB), ""skin WNLs"", denies difficulty swallowing. The Medical Emergency Response Team (MERT) was called. Patient was assessed, stated tingling 8/10, no other symptoms. Patient was given bottle of water and was tolerating that fine. Allegra 60mg was ordered and administered at 8:52 A.M. Patient stated was at a 2/10, 10 minutes after getting the Allegra. Patient was drinking water without difficulties. Patient remained without further symptoms, lips still 2/10 with tingling. Outpatient lab work was ordered. Patient left at 10:00 A.M ambulatory to outpatient lab. MERT educated her to notify administrator of her symptoms prior to her second vaccine. The outcome of the event was reported as recovered (in Dec2020). No follow-up attempts are possible; information about lot/batch number cannot be obtained."

incontinence (urine); Tiredness/ exhausted; woke early; numbness down her arm/ numbness went up to her neck/ numbness on the tip of her fingers; soreness on her neck; both her arms since she was so sore; both her arms since she was so sore/ sore at the injection site; sweats; extremely hot; headache; lightheadedness; This is a spontaneous report from a contactable consumer (patient). A 44-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EJ1685) intramuscular on left arm on 19Dec2020 18:00, single dose for COVID-19 immunization at 44-year-old. Medical history was not reported. Concomitant medications included: meloxicam (15mg tablet) oral 15mg once a day for arthritis. The patient had not taken any other medications today (21Dec2020) or yesterday (20Dec2020). The patient experienced numbness down her arm the first day she received the injection (19Dec2020), stated it was like someone was holding her hand tight, stated she thought this was normal. The numbness went up to her neck on 19Dec2020. By Sunday (20Dec2020) she had the

numbness on the tip of her fingers in both hands. The patient stated she also had soreness on her neck on 19Dec2020. The patient stated that when she woke up it felt like someone pulled down on both her arms since she was so sore on 19Dec2020. Treatment received, the patient took paracetamol (TYLENOL), no visit to emergency room or physician office. Currently (21Dec2020), the patient was still sore at the injection site, but she did not have any pain or numbness. The patient had the sweats on 19Dec2020, stated she was extremely hot (19Dec2020). Her back was so wet. She was warm. The patient woke up incontinent (urine) this morning (21Dec2020). The patient stated it was not that she fully emptied her bladder, but she woke up wet this morning. The patient found it odd she did not wake to use bathroom, when she woke up she still went to empty her bladder. She felt like she had recovered completely from the incontinence, she only had it when she woke up. The first night after she took the vaccine (19Dec2020) the patient woke early, like 6 am which she didn't usually wake up so early. The patient stated for two nights she slept and did not move, she woke up the way she fell asleep laying down. It didn't look she changed position, woke up as if the patient did not sleep at all. The patient stated she must have been exhausted because she did not move at all. The patient started to experience the tiredness by the time she left work around 8 pm on 19Dec2020. The patient stated she was regularly tired, not overly tired but she worked two 12-hour shifts. The tiredness was better today (21Dec2020) than the first two days. The patient had a headache, lightheadedness (in Dec2020). Action taken for BNT162B2 was not applicable. Outcome of the event numbness down her arm/ numbness went up to her neck/ numbness on the tip of her fingers was resolved on 21Dec2020; outcome of the events soreness on her neck, both her arms since she was so sore, sore at the injection site was resolving; outcome of the event sweats was resolved on 19Dec2020; outcome of the event incontinent (urine) was resolved on 21Dec2020; outcome of the event tiredness was resolving; outcome of the other events was unknown.

severe dizziness; horrible nausea and vomiting; horrible nausea and vomiting; muscle soreness; headache; This is a spontaneous report from a contactable nurse (patient). A 40-year-old female nurse received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899) via unspecified route in left lower deltoid on 17Dec2020 10 am, single dose for COVID-19 immunization at 40-year-old. Medical history included: surgery and lipoma removed from upper deltoid in Nov2020. Family medical history included: Her mother had colorectal cancer at age 40. When the patient turned 40, she had colonoscopy earlier this year (2020) and it was negative. Concomitant medication included: levothyroxine 100ug daily from 2001. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. She had pretty severe muscle soreness Thursday night (17Dec2020) and the next two days. On 19Dec2020 it was not as severe. It was mild and it started to dissipate on 19Dec2020. The only thing she had been taking was acetaminophen 650mg that night for the muscle soreness. The patient awoke at 3:00 am on 20Dec2020 out of a dream with severe dizziness that turned into horrible nausea and vomiting. She had vomiting for a little while the third night (20Dec2020) into the fourth day. The patient (nurse) considered the muscle soreness and dizziness was non-serious and not medically significant. She didn't feel the need to go to the hospital because it did improve. After she threw up, the dizziness kind of went way. Even today (21Dec2020) she felt fine and no more nausea, but still felt kind of off and dizziness, lingering dizziness. It wasn't extreme dizziness but when texting she could feel, and it was hard to focus. She was not one hundred percent her normal self. She was not sure if it was related to the

vaccine. She was eating and drinking normally. The night that she received the vaccine, she had one beer and one margarita at dinner. She did have alcoholic beverages, a beer and a margarita. It was nothing excessive with dinner. She was not overly drunk. She didn't know if alcohol could have contributed. She had never had that kind of reaction before from drinking. That was very odd. She just wouldn't drink any alcohol. She took acetaminophen for a headache (in Dec2020) that she was experiencing. She was pretty healthy. All of this was so new with the COVID vaccine. That night into this morning she started her menstrual period as well. She had never had any horrible side effects like migraines or cramping when getting her menstrual cycle. It could have been the alcohol or her period. No visit to emergency room or physician office. Action taken for BNT162B2 was not applicable. Outcome of the event muscle soreness was resolved on 19Dec2020; outcome of the event severe dizziness was resolving; outcome of the other events was unknown. Causality assessment between the event muscle soreness and the suspect product BNT162B2 per the patient was reported as related.

Headache; body aches; chills; low grade fever 100 degrees Fahrenheit; Soreness to the right arm where vaccine was administered.; This is a spontaneous report from a contactable consumer. A 60-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via unspecified route on right arm on 18Dec2020 03:00 PM, single dose for COVID-19 immunization at 60-year-old. Medical history included: COVID-19 diagnosed prior to vaccination. Concomitant medication was not reported. No other vaccine received within 4 weeks prior to the COVID vaccine. On 19Dec2020 12:00 PM, the patient had headache, body aches, chills and low-grade fever 100 degrees Fahrenheit. At the same time (19Dec2020 12:00 PM), the patient had soreness to the right arm where vaccine was administered. No treatment received for above adverse events. Lab data included: COVID-19 (positive) diagnosed prior to vaccination; 100 degrees Fahrenheit low-grade fever on 19Dec2020. Since the vaccination, the patient had not been tested for COVID-19. Action taken for BNT162B2 was not applicable. Outcome of the events was resolved in Dec2020. It was reported as non-serious. Information on the lot/batch number has been requested.

swelling of eyelids and cheeks; swelling of eyelids and cheeks; swelling of hands; This is a spontaneous report from a contactable pharmacist. A 58-year-old female patient received 1 dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK5730) intramuscular on left deltoid on 16Dec2020 11:00 AM, single dose for COVID-19 immunization at 58-year-old. Medical history included: Sulfa allergy; diabetes, hypertension, high cholesterol. Prior to vaccination, the patient was not diagnosed with COVID-19. Concomitant medications included: metformin, valsartan and pantoprazole. No other vaccine received within 4 weeks prior to the COVID vaccine. On 17Dec2020 morning, 06:00 AM, the patient had swelling of hands and then 18Dec2020 morning, the patient had swelling of eyelids and cheeks. Doctor or other healthcare professional office/clinic visit. Treatment received as: Diphenhydramine 50mg and prednisone 40mg orally. Since the vaccination, the patient had not been tested for COVID-19. Action taken for BNT162B2 was not applicable. Outcome of the events was resolved in Dec2020. It was reported as non-serious.

Diarrhea, dizziness, swollen tongue and lips. Sore joints for multiple days, headache; Diarrhea, dizziness, swollen tongue and lips. Sore joints for multiple days, headache; Diarrhea, dizziness, swollen tongue and lips. Sore joints for multiple days, headache; Diarrhea, dizziness, swollen tongue and lips. Sore joints for

multiple days, headache; Diarrhea, dizziness, swollen tongue and lips. Sore joints for multiple days, headache; Diarrhea, dizziness, swollen tongue and lips. Sore joints for multiple days, headache; This is a spontaneous report from a non-contactable consumer (patient). A 34-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date not reported), via an unspecified route of administration on left arm at 08:30 AM.on 18Dec2020 at single dose for COVID-19 immunization. Medical history reported as none, no known allergies. The patient's concomitant medications were not reported. The patient experienced diarrhea, dizziness, swollen tongue and lips. Sore joints for multiple days and headache in Dec2020 (reported as 11Dec2020 at time 08:45 AM). All events were reported as non-serious. The patient self administered Benadryl. Acetaminophen and ibup (ibuprofen) as treatment. The outcome of events was resolved with sequel. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. No follow-up attempts are possible. information about lot/batch number cannot be obtained.

urticaria on inside of both arms; This is a spontaneous report from a contactable Physician. This physician reported for a female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) at single dose for covid-19 immunization. Medical history was urticaria. Physician stated that I have a female patient in good health with a history of urticaria. She got the vaccine and developed urticaria on inside of both arms - looking for information on whether this patient should receive the 2nd dose. Outcome of the event was unknown. Information about batch/lot number has been requested.

"I woke up and my left eye is swollen and my face is kind of swollen; I woke up and my left eye is swollen and my face is kind of swollen; rash/ rash on and off on my back and on my arm and around my face; allergic symptoms; kind of like itchiness on my ears and my scalp and also like on and off on my back and also on both of my arms like my wrist area on both arms/All night I was up with scratching my face; The initial case was missing the following minimum criteria: unspecified product. Upon receipt of followup information on 20Dec2020, this case now contains all required information to be considered valid. This is a spontaneous report from a contactable physician (patient). A 30-years-old female patient received first dose bnt162b2 (BNT162B2), intramuscular on 2020 at single dose for covid-19 immunisation. Medical history included On nose, had prior to getting the vaccine, was experiencing some kind of she got through the contact dermatitis rash like her arms and behind her ears and it was all over her neck (she thought it was related to mat because she was getting it on neck and ears taking medication for that it just allergy medication and it had gotten better). There were no concomitant medications. The physician reported she have been experiencing some allergic symptoms following it since Dec2020, she had itchiness, it was like a rash on and off on back and on arm and around face and itchiness on calp and face/ experiencing kind of like itchiness on ears and scalp and also like on and off on back and also on both of arms like wrist area on both arms and then in the morning like 20Dec2020, it was kind of all night she was up with scratching face,; In the morning 20Dec2020, she woke up with some mild facial swelling, noticed like eyes swollen and little bit droopy. The events were still going on, she just took medicine for it. It's kind of persistent. Physician stated, ""I guess I can report the worsening of my symptoms that was in the morning of reporting date like 8 AM."" Treatment included just took medicine, Prednisone, Benadryl and Zyrtec. Weight: About 103. The event outcome was not recovered. Information on lot/batch number has been requested."

flushed; warm face and ears; This is a spontaneous report from a non-contactable other health care professional. A 57-year-old female patient received bnt162b2 (BNT162B2; lot number: HE9899), intramuscular on arm (reported as left arm) dose number 1 on 17Dec2020, SINGLE DOSE for COVID-19 immunization. Medical history included mild history of anxiety, and panic attack. She has medication to treat this at home if needed. The patient's concomitant medications were not reported. She was given the Pfizer vaccination in the right deltoid muscle (pending clarification). During her 15 minute waiting period after the injection, the patient began to experience flushed, warm face and ears. She denied rash, difficulty breathing, difficulty swallowing, wheezing, throat tightness, lightheadedness, lip swelling and tongue swelling. This APP was notified of patient reaction and she was then assessed in the emergency bay area. (Name withheld) was observed x 35 minutes after receiving vaccination. All symptoms resolved within 20 minutes. No treatment was required. The outcome of the events was recovered. No follow-up attempts are possible. No further information is expected.

feeling nauseated, hot; feeling nauseated, hot; headache; difficulty breathing; itchy all over the body, with redness and blotchiness in the face, neck and arms; itchy all over the body, with redness and blotchiness in the face, neck and arms; itchy all over the body, with redness and blotchiness in the face, neck and arms; Blood pressure elevated along with heart rate.; Blood pressure elevated along with heart rate.; This is a spontaneous report from a contactable other healthcare professional (HCP), who is also the patient. This 34-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 19Dec2020 at single dose for COVID-19 immunisation. Vaccination facility type was hospital. Relevant medical history included polycystic ovaries, gastrooesophageal reflux disease, Hashimoto's disease and allergy to sulfa, penicillin, latex and hornets. Concomitant medications included thyroid (ARMOUR THYROID), omeprazole and vitamin D3. On 19Dec2020 at 12:15, 10 minutes after the injection, the patient started feeling nauseated, hot and developed a headache. A couple of minutes after that, she started experiencing difficulty breathing and itchy all over the body, with redness and blotchiness in the face, neck and arms and blood pressure elevated along with heart rate. The events resulted in emergency room/department visit or urgent care. Corrective treatments taken as a result of the events included methylprednisolone sodium succinate (Solu-medrol), diphenhydramine hydrochloride (BENADRYL) and famotadine along with intravenous (IV) fluids. The patient recovered with sequel from the events on an unspecified date. The information on the lot/ batch number has been requested.

Soreness at the injection site; This is a spontaneous report from a contactable nurse (patient). A 62-year-old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number: EJ1685), intramuscular on the left arm on 18Dec2020 13:00 at a single dose for covid-19 immunization. The patient's medical history included hypertension (HTN) and elevated triglycerides. The patient was not pregnant. The patient have no allergies to medications, food, or other products. It was unknown if the patient was diagnosed with COVID-19 prior to vaccination. The patient had not been tested for COVID-19 since the vaccination. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Concomitant medications included metoprolol and fenofibric acid. The patient experienced soreness at the injection site on 19Dec2020 05:00. No treatment was received for the adverse event. Outcome of the event was recovered on Dec2020.

Minor headache; chills; This is a spontaneous report from a contactable other healthcare professional (patient). A 31-year-old male patient received the first dose of bnt162b2 (BNT162B2, lot no. and expiration date were unknown), via an unspecified route of administration on 18Dec2020 23:45 on the left arm at single dose for COVID-19 immunization. Medical history included heart stent. The patient had no known drug allergies. The patient's concomitant medications were not reported. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. On 19Dec2020 01:00 AM, the patient experienced minor headache and chills. No treatment received for the events. The events recovered on unspecified date in Dec2020. Information on the lot/batch number has been requested.

"When they put the shot it's been hurting me ever since then; This is a spontaneous report from a contactable consumer. A 40-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), via an unspecified route of administration on an unspecified date as single dose for COVID-19 immunization. Medical history included diabetes and headache from an unknown date. Concomitant medication included metformin (MANUFACTURER UNKNOWN) for diabetes. On an unspecified date, the patient reported that "" when they put the shot it's been hurting me ever since then "" with outcome of unknown. Details were as follows: Patient indicated that when he got the shot, everything was good but when they put the shot it's been hurting ever since then. There were no lab tests, or treatment given for the event. The outcome of "" when they put the shot it's been hurting me ever since then "" was unknown. The batch/lot number for the vaccine, BNT162B2, was not provided and will be requested during follow-up ."

Heart palpitations and severe fatigue for 48 hours; Heart palpitations and severe fatigue for 48 hours; This is a spontaneous report from a contactable other healthcare professional (patient herself). A 37-year-old female patient received bnt162b2 (BNT162B2 also reported as COVID 19 brand Pfizer, lot EK5730), intramuscularly in the left arm on 18Dec2020 10:30 at single dose (dose number 1) for immunisation. Medical history was none. There were no concomitant medications. The patient experienced heart palpitations and severe fatigue for 48 hours on 18Dec2020 18:00. The events were reported as non-serious. No treatment was given. The outcome of events was recovered on unknown date in Dec2020.

my arm hurt for 4 Hours later and peaked that evening; headache; tiredness; lethargic/pretty lethargic.; This is a spontaneous report from a Pfizer-sponsored program IBCC (Inbound Call Center for HCPs). Contactable Physicians (one was patient) reported that a 72-years-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EH9899, Expiry Date: Mar2021) on 18Dec2020 at single dose for covid-19 immunization. Medical history and concomitant drug were not reported. The caller is a MD. He had the vaccine on Friday. His arm hurt 4 hours later, and then peaked that evening. It was very painful. It hurt and was painful. By Sunday it was 95 % gone. Today (21Dec2020) the pain is completely gone. He received the vaccine Friday. He is supposed to get an MRI Wednesday morning. He will be getting Gadolinun. He wanted to know if there was any adverse reaction with that. Will this material interfere with the immune response of COVID vaccine? He is considering canceling his MRI. The caller confirmed the details provided by the transferring agent. He

doesn't have a prescribing doctor. He was looking at his CDC vaccination record log. He was given 0.3cc. He received the injection, and the pain started 4 hours later. It peaked in the evening. It was the worst arm pain he has ever had from a shot. He couldn't elevate his arm from pain. It was interesting because there was very little heat at the injection site. The amount of arm pain was not proportionate to a local reaction. He did take Tylenol that night. He got up the next day, Saturday, and it was painful but a little less painful. Then on Sunday 20Dec2020, it was 95% essentially. He started to get lethargic that Friday at about 9-12 hours later. Then he had a headache about 11 hours later that lasted 5-10 minutes. He was surprised but it went away. Saturday, he was pretty lethargic. He felt more lethargic from the shingles shot. No details on the shingles shot provided by the caller. He said the tiredness may have been a placebo effect because everyone says you will get tired. He was fine yesterday and today. He is glad he got it. He has recovered completely from all side effects he had. He never had a fever. His question about the MRI was escalated by the Medical information associate. Follow-up attempts have been completed and no further information is expected.

left eye was irritated; left eye was sensitive to light; left eye was painful weeping and red.; left eye was red; left eye weepy; entire left side was sore, achy, including her jaw and stuff; entire left side was sore, achy, including her jaw and stuff; This is a spontaneous report from a contactable consumer. A female patient of unspecified age (reported as 59 with no unit) received BNT162B2 (Pfizer-Biontech COVID-19 Vaccine), via an unspecified route of administration on right arm on 16Dec2020 at single dose for COVID-19 immunization. Medical history and concomitant medications were not reported. It was painless on 16Dec2020. On 17Dec2020, her entire left side was sore, achy, including her jaw and stuff, 18Dec2020 evening, her left eye was irritated, sensitive to light, painful weeping and red (left eye was painful, red, and weepy). She called her doctor on 19Dec2020 and he gave her some eye drops. On 20Dec2020, the eye drops seemed to irritate her eye more. She woke up in the morning and it was seeming to get better as she had been taking Excedrin. She was supposed to wait 6 hours between drops, then her eye again was sensitive to light and painful, so she took another Excedrin, which helped again. She was trying to see an eye specialist the day after the time of the report. She had asked around at work and nobody else had any issues. She was wondering if this was vaccine related. She wanted to get tested for COVID, not that she thought she had it now, but might be she had it before she got the vaccine. She had not even talked to her workplace about this or anything. They asked everyone the first day after, if there were any issues and to report them to HR/Employee Health. She had not done so yet, so she wanted to do that first. Outcome of the events left eye was irritated, sensitive to light, painful weeping and red, and left eye weepy was resolving, and of other events was unknown. Lot/batch number has been requested.

Nausea; headache; fatigue; This is a spontaneous report from a contactable healthcare professional. A 31-year-old male patient received BNT162B2 (Lot number: EJ1685), intramuscularly on right arm on 20Dec2020 07:00 at single dose for COVID-19 immunization. Medical history was not reported. Concomitant medications in two weeks included emtricitabine/tenofovir disoproxil fumarate (TRUVADA), bupropion hydrochloride (WELLBUTRIN), lamotrigine (LAMICTAL), and valaciclovir (VALACYCLOVIR). Patient experienced nausea, headache, and fatigue on 21Dec2020 07:00. No treatment received for these events. Outcome of the events was not resolved.

headache; take BP. My usual normal is 125/80. 164/93 just mow; This is a spontaneous report from two contactable pharmacists. A 53-year-old female patient received BNT162B2 (lot number: EJ1685), via an unspecified route of administration on left arm on 21Dec2020 07:00 at single dose for COVID-19 immunization. Medical history and concomitant medications were not reported. Patient began getting a headache (H) on 21Dec2020 09:00 (around 9:30), felt like a different kind of headache that progressed. At 2:30, patient went back to monitoring area and asked them to take blood pressure (BP). Her usual normal was 125/80, but 164/93 just now (21Dec2020 09:00). COVID-19 vaccine was administered in the hospital. Patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Outcome of the events was resolving.

anaphylaxis; This is a spontaneous report from a non-contactable consumer. This consumer reported similar events for six patients. This is the first of six reports. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot number: AK 5730, EG 1685), via an unspecified route of administration in Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced anaphylaxis in Dec2020. The clinical outcome of anaphylaxis was unknown. No follow-up attempts are possible. No further information is expected.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2020505821 different patient/same drug/event;US-PFIZER INC-2020505822 different patient/same drug/event;US-PFIZER INC-2020505823 different patient/same drug/event;US-PFIZER INC-2020505824 different patient/same drug/event;US-PFIZER INC-2020505825 different patient/same drug/event

anaphylaxis; This is a spontaneous report from a non-contactable consumer. This consumer reported similar events for six patients. This is the second of six reports. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot number: AK 5730, EG 1685), via an unspecified route of administration in Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced anaphylaxis in Dec2020. The clinical outcome of anaphylaxis was unknown. No follow-up attempts are possible. No further information is expected.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2020505820 different patient/same drug/event

anaphylaxis; This is a spontaneous report from a non-contactable consumer. This consumer reported similar events for six patients. This is the third of six reports. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot number: AK 5730, EG 1685), via an unspecified route of administration in Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced anaphylaxis in Dec2020. The clinical outcome of anaphylaxis was unknown. No follow-up attempts are possible. No further information is expected.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2020505820 different patient/same drug/event

anaphylaxis; This is a spontaneous report from a non-contactable consumer. This consumer reported similar events for six patients. This is the fourth of six reports. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot number: AK 5730, EG 1685), via an unspecified route of administration in Dec2020 at a single dose for COVID-19 immunization. The

patient's medical history and concomitant medications were not reported. The patient experienced anaphylaxis in Dec2020. The clinical outcome of anaphylaxis was unknown. No follow-up attempts are possible. No further information is expected.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2020505820 different patient/same drug/event

anaphylaxis; This is a spontaneous report from a non-contactable consumer. This consumer reported similar events for six patients. This is the fifth of six reports. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot number: AK 5730, EG 1685), via an unspecified route of administration in Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced anaphylaxis in Dec2020. Therapeutic measures were taken as a result of the event and included administration of epinephrine (MANUFACTURER UNKNOWN). The clinical outcome of anaphylaxis was unknown. No follow-up attempts are possible. No further information is expected.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2020505820 different patient/same drug/event

anaphylaxis; This is a spontaneous report from a non-contactable consumer. This consumer reported similar events for six patients. This is the sixth of six reports. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot number: AK 5730, EG 1685), via an unspecified route of administration in Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced anaphylaxis in Dec2020. Therapeutic measures were taken as a result of the event and included administration of epinephrine (MANUFACTURER UNKNOWN). The clinical outcome of anaphylaxis was unknown. No follow-up attempts are possible. No further information is expected.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2020505820 different patient/same drug/event

Rash on throat, chest, back and legs; This is a spontaneous report from a contactable healthcare professional. A 38-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899), intramuscular on the left arm on 19Dec2020 07:45 at single dose for COVID-19 immunisation. Medical history included known allergies: penicillin. The patient's concomitant medications were not reported. The patient experienced rash on throat, chest, back and legs on 19Dec2020 11:30. Patient does not receive any treatment. The outcome of the events was recovering.

gut pain; headache; cramping; diarrhea/7 bouts of diarrhea over 3 hours; facial flushing; This is a spontaneous report from contactable nurse. A 58-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK5730), via an unspecified route of administration, at the left arm on 19Dec2020 10:30 at a single dose for COVID-19 immunization at a hospital. Medical history included hypertension and obesity. The patient has no known allergies. The patient was not tested for it since the vaccination. The patient's concomitant medications were not reported. Adverse event: On 21Dec2020, 12:00, patient experienced gut pain, headache, cramping, 7 bouts of diarrhea over 3 hours, and 3/7 also coincided with facial flushing with no treatment. The patient did not recover from the events.

itching on back; hives in a small area; This is a spontaneous report from two contactable consumers (patient and patient's mother). A 22-year-old female patient received BNT162B2 (Pfizer-BioNTech COVID-19 mRNA vaccine, lot number: EH9899, expiry date: 31Mar2021), intramuscular in left arm on 21Dec2020 (about 9:45 -09:50 a.m. this morning) at a single dose for COVID-19 immunization. The patient has no other patient history, no concomitant medications, and no investigation assessment provided. The patient has no previous immunizations. The patient received the COVID vaccine about 9:45 -09:50 a.m. this morning (21Dec2020). She noticed just recently that she was starting to itch on her back and has hives and did not know if it was a side effect. Time of onset of itching on back was around 15:00-15:30 (estimated at within past 30 minutes), while the hives started around 5 minutes later than the itching. No ER or physician's office required. She is a nursing student, so it was recommended she receive the vaccine by the college of nursing. She received it at the hospital. They put Neosporin on her back, and it helped. She does not feel the itching. When asked to provide outcome of the hives, she stated it looks like the hives are getting smaller, but they are still there. The outcome of the events was recovering.

Nasal swab for COVID 19 test; Sore throat. First noticed Saturday morning and not to the point where it's painful to swallow.; Burning from the back of left nostril and down throat; This is a spontaneous report from a contactable healthcare professional (patient). A 40-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK5730, expiry date was not provided) solution for injection, via an unspecified route of administration (on left arm) on 17Dec2020 17:00 at a single dose for Covid-19 immunisation. Medical history was reported as none. Patient had no known allergies. Concomitant medication included ibuprofen. The patient experienced sore throat, he first noticed it Saturday morning (19Dec2020 04:45) and not to the point where it's painful to swallow. Patient reported there was burning from the back of left nostril and down the throat (19Dec2020 04:45). No treatment was administered. The patient underwent nasal swab for Covid 19 test on 21Dec2020 with pending result. Outcome of the event Suspected COVID-19 was unknown while for the other events was recovering.; Sender's Comments: The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

I felt slight dizziness immediately after injection/dizziness increased; feel my heart beating quickly; achiness in my joints; soreness at the injection site; feeling strange; remain uncomfortable; This is a spontaneous report from a nurse (patient herself). A 57-year-old female patient (not pregnant) received bnt162b2 (BNT162B2 also reported as COVID 19 brand Pfizer, lot EH9899), via an unspecified route of administration in the left arm on 21Dec2020 14:45 at single dose, for immunisation. Medical history included rheumatoid arthritis, osteoarthritis, anaemia, bipolar disorder II, hypertension, and GERD. She had no Covid/ Covid test prior to vaccination. She had other medications in two weeks. The patient previously took hydrocodone and experienced drug allergy. The patient felt slight dizziness immediately after injection. When she walked to the 15 min. waiting area, the dizziness increased and she began to feel her heart beating quickly. She drank 8 oz. of water and told the attendant she was feeling strange.

She took a pulse and oximetry reading - 110 and 95%. A nurse came over to check on her. The patient wanted to sit where the patient was for a few minutes longer. After about 20 mins. the dizziness immediately subsided and patient felt her pulse decreased. She got her things and left. After a few minutes, the patient began to feel achiness in her joints and felt soreness at the injection site. She had taken two Acetaminophen and remain uncomfortable. She planned to go home and rest. The events were reported as non-serious. No treatment was reported for dizziness and increased heart rate. The outcome of events Dizziness, Heart rate increased was recovered on 21Dec2020; for other events was unknown.

Employee reported thickness of tongue and dry mouth.; Employee reported thickness of tongue and dry mouth.; This is a spontaneous report from a contactable nurse. A 55-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), Batch/lot number: EJ1685, intramuscular in the right arm on 21Dec2020 12:30 at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The employee reported thickness of tongue and dry mouth on 21Dec2020 12:30. The events resulted in emergency room/department or urgent care. The outcome of the events was unknown.

hypoglycemia; dizziness; This is a spontaneous report from a non-contactable Other HCP. A 33-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) lot number HE9899, intramuscularly in the left arm on unspecified date at single dose for COVID-19 immunization. Patient medical history and concomitant medications were not reported. The patient previously took spironolactone and experienced drug allergy. During her 15-minute waiting period after the vaccination, the patient began to experience feelings of hypoglycemia. She checked her blood glucose with her own monitor and had 77 at 11:04. She chewed 1 glucose tab that she had in her purse. She noted some difficulty with swallowing it and notified clinic staff. The patient also experienced dizziness and was escorted by clinic staff to the emergency bay. This provider was notified of patient reaction and she was then assessed in the emergency bay area. She denied difficulty breathing and chest pain, history of adverse reactions with prior vaccinations or allergies to medications with the exception of spironolactone. Patient had already been given a bottle of water by clinic staff and reported that the glucose tablet went down easier following the water. She took a second glucose tab sometime before 11:13. The event was assessed as non-serious. Outcome of the events hypoglycemia and dizziness was unknown. No follow-up attempts are possible. No further information is expected.

thin red line on back of neck/redness at her right eyebrow and in the midline of her forehead/reddened area above eyebrow along with puffiness, redness on nose, cheeks and left hand; Rash; dot markings on her left hand and redness which is where she received vaccine in her left arm; dot markings on her left hand and redness which is where she received vaccine in her left arm; reddened area above eyebrow along with puffiness, redness on nose, cheeks; This is a spontaneous report from a contactable nurse (patient). A 62-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), lot number: EK5730, via intramuscular in left deltoid on 19Dec2020 10:30 at single dose for COVID-19 immunization. Medical history included hypertension diagnosed when she was 47, hypothyroidism diagnosed 20 years ago and allergic to penicillin and sulfur; all ongoing. Concomitant medication included ongoing metoprolol succinate for hypertension. The patient received her first dose of vaccine

on Friday 19Dec2020 at her job. Stated that she woke up Saturday with redness at her right eyebrow and in the midline of her forehead between her eyebrows and nose. Stated that she had dot markings on her left hand and redness which is where she received vaccine in her left arm. Stated that she had went to ER and was put on Prednisone 60mg for 5 days and Benadryl 50mg prn. Stated that a few people said few different things. Stated that she is allergic to penicillin and sulfur. No further details provided. The patient wanted to know if sulfur is in the vaccine to know if in three weeks should she take the second vaccine. On 19Dec2020, states she had a rash when she woke up. The patient had reddened area above eyebrow along with puffiness, redness on nose, cheeks and left hand. The patient went to the emergency department and an HCP saw a thin red line on back of neck. The patient was prescribed prednisone and benadryl and now symptoms have resolved. The patient was asking about more information regarding this type of reaction. The outcome of the event rash was recovered on unspecified date and the remaining events was recovered on 20Dec2020. The events were reported as non serious.

"a funny metallic taste in her mouth; she felt like she had cotton mouth; This is a spontaneous report from a contactable consumer (patient). A 62-year-old female patient received the first dose of bnt162b2 (COVID 19 vaccine) lot no: EH9899, via an unspecified route of administration in left arm on 21Dec2020 08:00 at a single dose for COVID-19 immunization. Medical history included diabetic type 2 and allergic to metal, both from an unknown date and unknown if ongoing. Concomitant medication included ongoing metformin hydrochloride (METFORMIN ER) for diabetes, taking for a couple of years. The patient received the vaccine on 21Dec2020 8am at her hospital, and by 10:30AM or 11:00AM she noticed ""a funny metallic taste in her mouth."" She stated it was like a metal cup a tin taste like that and she wanted ice water. The patient is a phlebotomist, she continued with her patients and asked a co-worker did you taste/experience that, coworker stated ""I've had covid""; she didn't get the vaccine taste metal in your mouth. The reported wanted to know if that is an expected side effect of the vaccine. She can smell everything. She still has taste buds. It was still there but not as strong. She stated that she felt fine, and doesn't feel anything. She doesn't feel bad. She was just wondering about the side effects. She drank a lot of water. The patient added that all of the sudden her mouth was tasting funny like nickel. She added that she is allergic to metal; stated she can taste the tin in a tin can. She was working in the ER after having received the first dose injection at 8:00AM on 21Dec2020. She started to taste the funny taste about two hours later, 10:30AM or 11:00AM. She drank some ice water and it kind of rinsed her mouth out then she only tasted it a tiny bit. Then she felt like she had cotton mouth. It has improved but not gone away. She received the injection in her left arm. She is scheduled 11Jan2021 for the next dose. The patient was recovering from the events. The sample of the product is not available to be returned."

she started with ringing in her ears and it has not gone away; This is a spontaneous report from a contactable nurse (patient). A 57-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot/batch number and expiry date were not provided) solution for injection, intramuscular (left deltoid) on 19Dec2020 18:00 at a single dose for COVID-19 immunisation. Medical history was reported as none. There were no concomitant medications. The patient reported it was nothing severe, but she had the first dose of the vaccine on Saturday evening at 6pm and about 6 hours after, she

started with ringing in her ears and it has not gone away. She would like to know if that was one of the side effects. It was not listed on the sheet that was given to her; will it go away and should. She was just concerned. She does not want it to progress. It was like a ringing. It was not like a headache but was a steady discomfort from ear to temple. She works at a hospital and got invited to take it. It was just an annoyance since it was still there. Outcome of the event was not recovered. Information on Lot/Batch has been requested.

she started getting really bad body aches; she got really dizzy; nauseous; throw it up; her arm was sore where they gave the vaccination; The initial case was missing the following minimum criteria: no adverse effect. Upon receipt of follow-up information on (21Dec2020), this case now contains all required information to be considered valid. This is a spontaneous report from a contactable nurse (patient reporting for herself). A 21-year-old female patient received bnt162b2 (also reported as PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899), via an unspecified route of administration on 19Dec2020 18:00 on the left arm at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient stated that she got the vaccine, the Covid-19 vaccine, Saturday 19Dec2020 around 6PM. On Sunday 20Dec2020, she went about her day and around mid day, about 5PM she started getting really bad body aches and then after she showered she got really dizzy, states she would try to eat and she would get nauseous and throw it up. She wanted to know how fast the symptoms are showing after vaccination. She went to get a COVID test today as well because she is not sure if this is due to the vaccine or what. She took Ibuprofen 400mg around 10PM last night 20Dec2020 because the body aches are so bad. States she took a shower last night and got really dizzy but that has resolved and has not happened since. On 21Dec2020, she ate some breakfast and at 11AM she got very nauseous and threw up. Initially (in Dec2020), her arm was sore where they gave the vaccination which she was expecting and then it started going all over her body, states it is like menstrual cramps but like all over. The events did not require a visit to Emergency Room and Physician Office. The event dizzy recovered on 20Dec2020. The outcome of her arm was sore where they gave the vaccination was unknown and the rest of the events was not recovered.

aching/he is feeling a little achy/ he feels achy; he has not slept well; he is just tired; His arm did hurt for 2 days after; This is a spontaneous report received from a contactable consumer (patient). A 50-year-old male patient started received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK5730, expiry date: 31Mar2021), via an unspecified route of administration in left arm, on 16Dec2020, at single dose, for COVID-19 immunization. There were no medical history and concomitant medications. The patient reported he got the COVID Vaccine on 16Dec2020 (Wednesday) and now he is feeling a little achy. He is wondering if that is a side effect. He said it is not a big deal and that maybe he is just tired. He also reported he has not slept well so maybe he could just be tired. Although it could be a side effect. He clarified he did not start feeling achy until 21Dec2020 (today). He reported his arm did hurt after for 2 days. The outcome of the event vaccination site pain was recovered on an unspecified date in Dec2020, pain was not recovered, and the remaining events was unknown.

Cough; congestion/stuffed nose; runny nose; chills; sore arm; decreased sense of smell; decreased sense of taste; This is a spontaneous report from a contactable physician. A 49-year-old female patient receive first dose of bnt162b2 (BNT162B2), intramuscular on left arm on 17Dec2020 10:15 SINGLE DOSE for

COVID-19 immunization. Medical history included Cough variant of asthma, prediabetes. The patient's concomitant medications were not reported. On 18Dec2020 10:00, the patient experienced Cough, congestion, runny nose, chills, sore arm, stuffed nose, decreased sense of smell, decreased sense of taste. No COVID prior vaccination. The patient has been tested for COVID-19 post vaccination. The patient underwent lab tests and procedures which included nasal swab test: pending on 21Dec2020. The outcome of the events was recovering.

broke out in hives on my chest and upper back.; This is a spontaneous report from a contactable other healthcare professional (patient). A 25-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot: EJ1685) intramuscularly on 18Dec2020 10:45 at a single dose for covid-19 immunisation. Medical history included moyamoya disease, asthma and allergies to crustaceans. Concomitant medication included acetylsalicylic acid (ASPIRIN (E.C.) and azithromycin. The patient previously took prochlorperazine maleate (COMPAZINE) and experienced drug allergy. On 18Dec2020 23:59, the patient reportedly broke out in hives on the chest and upper back. Outcome of the event recovered on an unspecified date on Dec2020.

102.5 F fever; Chills; Headache; Dizziness; Body aches; Fatigue; Nausea; This is a spontaneous report from a contactable Other HCP (patient). This 24-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 19Dec2020 12:00 at single dose on left arm for COVID-19 immunization. Medical history was not reported. Concomitant medications included vortioxetine hydrobromide (TRINTELLIX) and levothyroxine, both received within 2 weeks of vaccination. Facility that the most recent COVID-19 vaccine was administered in Hospital. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient hasn't been tested for COVID-19. The patient experienced 102.5 F fever, chills, headache, dizziness, body aches, fatigue, nausea on 19Dec2020 23:00. The outcome of 102.5 F fever, chills, headache, dizziness, body aches, fatigue was recovering, of nausea was unknown. No treatment received for the adverse event. The events were assessed non-serious. Information about lot/batch number has been requested.

arm pain; Fever; body aches; fatigue; This is a spontaneous report from a contactable other HCP (patient). This 29-years-old female patient started to receive BNT162B2, on 17Dec2020 09:15 at single dose for COVID-19 immunisation. The patient medical history and the concomitant medications were not reported. Multi vitamins received in in two weeks. Prior to vaccination, the patient was not diagnosed with COVID-19. Facility that the most recent COVID-19 vaccine was administered is Hospital. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient experienced Fever, body aches, fatigue, arm pain on 18Dec2020. The outcome was not recovered. The patient underwent lab tests and procedures which included sars-cov-2 test (Nasal Swab): negative on 11Dec2020. The events were assessed non-serious. No treatment received for the adverse event. Information on the Lot/Batch number has been requested.

Flushing and Dizziness within 10 minutes of administration that resolved after drinking water.; Flushing and Dizziness within 10 minutes of administration that resolved after drinking water.; Injection site tenderness; Tiredness; headaches/headaches were markedly increased; muscle aches; fever to 101.1;

Slight chest discomfort; chest pain/chest pain and headaches were markedly increased; This is a spontaneous report from a contactable nurse. This nurse reported for a 35-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), (Lot number: EK5730) via intramuscular route on 20Dec2020 10:30 at single dose on the right arm for COVID-19 immunization. Medical history included COVID in Apr2020, post COVID syndrome and migraines. No allergies to medications, food, or other products. Concomitant medications included topiramate (TOPAMAX), topiramate (TROKENDI), gabapentin, magnesium, vitamin b complex (VITAMIN B), all received within 2 weeks of vaccination. Facility that the most recent COVID-19 vaccine was administered in Hospital. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was diagnosed with COVID-19. Since the vaccination, the patient hasn't been tested for COVID-19. On 20Dec2020 10:30, the patient experienced flushing and dizziness within 10 minutes of administration that resolved after drinking water. Injection site tenderness. Tiredness, headaches, muscle aches, fever to 101.1. Slight chest discomfort (patient had COVID in April 2020. She had all these symptoms with in the acute phase and still have intermittent chest pain/headaches. With the vaccine, the chest pain and headaches were markedly increased on the day after receiving it). Outcome of the events was recovered in Dec2020. No treatment received for the adverse events. The events were assessed non-serious.

sore at site of injection; had a knot there where it was given; This is a spontaneous report from a contactable consumer (patient). This 67-years-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), on unknown date in Dec2020 at single dose for COVID-19 immunisation. The patient medical history and the concomitant medications were not reported. The patient received vaccine last Wednesday, didn't have any side effects. It was sore at site of injection. Same day, it had a knot there where it was given. The outcome was unknown. Information on the lot/ batch number has been requested.

sore throat; runny nose; This is a spontaneous report from a contactable consumer (patient). A 20-years-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (lot number: EL0140) via an unspecified route of administration on left arm on 18Dec2020 at single dose for COVID-19 vaccination. There was no medical history. There were no concomitant medications. The patient is asking if this is part of the documented side effects of the vaccine. She received the Covid19 vaccine last Friday (18Dec2020), at noon, the first in the series of two. She says on Saturday (19Dec2020) she woke up with a runny nose, and then on Sunday night (20Dec2020) she had a sore throat. She says she would like to know if her body fighting is fighting something off or building antibodies. She received the vaccine from work and it was optional, not prescribed. She has her vaccine card and all it has on the back is the name Pfizer and the LOT. She didn't take any new medications or receive any other injections at the time of the COVID-19 vaccine. She didn't do any treatments for the sore throat and runny nose. Events outcome was unknown.

nodule formed at the injection site; the injection along with localized pain; reddened, warm area remained around the injection site; reddened, warm area remained around the injection site; This is a spontaneous report from a contactable nurse (patient). A 42-years-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (lot number: EH9899) intramuscular on right arm

on 18Dec2020 17:30 at single dose for COVID-19 immunization. Medical history included hypertension. Concomitant medication included the medications the patient received within 2 weeks of vaccination: Amlodipine, hydochlorathiazide, bupropion hydrochloride (WELLBUTRIN), zolpidem tartrate (AMBIEN). The patient previously took albuterol sulfate and experienced drug hypersensitivity. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. On 19Dec2020, a nodule formed at the injection site about 12 hours after the injection along with localized pain. The nodule started to disappear, but a reddened, warm area remained around the injection site. The reddened area is about the diameter of an egg. It has been about 72 hours since the injection. No treatment was received for the adverse event. Events outcome was not recovered.

test positive post vaccination; test positive post vaccination; This is a spontaneous report from a contactable Nurse (patient). A male patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 17Dec2020 at single dose for COVID-19 immunization. The patient medical history was not reported. The patient's concomitant medications were not reported. The patient got the Pfizer Covid-19 vaccine on the 17Dec2020. He would like to how likely is he to test positive post vaccination. He wants to know if the test results would be a false positive post vaccination. He is going to get tested at two different facility. Event outcome was unknown.; Sender's Comments: Based on the current available information and the consistency with the known safety profile of the suspect product BNT162B2, a possible contributory role of the suspect product to the development of Drug ineffective and COVID-19 cannot be excluded. The case will be reassessed if additional information becomes available.

sweating; itching palms; elevated HR; headache that lasted 24 hrs; fatigue; foggy feeling that also lasted 24 hrs; This is a spontaneous report from a contactable nurse (patient). A 39-year-old female patient received the first dose of BNT162B2 (lot number: EJ1685) intramuscular on right arm on 19Dec2020 14:45 at single dose for COVID-19 immunization. Medical history included DM type 2, irritable bowel syndrome, restless legs syndrome, insomnia. Other unspecified concomitant medications received in two weeks. The patient previously took thiomersal and experienced drug hypersensitivity. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. On 19Dec2020, within 10 minutes of the reaction she experienced sweating and itching palms with elevated HR. Within 1 hr of the vaccine she had a headache that lasted 24 hrs with fatigue and a foggy feeling that also lasted 24 hrs. No treatment received for events. Events outcome was recovered. No follow-up attempts are possible. No further information is expected.

felt hot; felt achy; Chills; generalized myalgias; high fever/her highest recorded temperature was 102.5; Deltoid soreness; This is a spontaneous report from a contactable Other HCP. This other hcp (patient) reported for herself that the 32-year-old female patient received bnt162b2 (BNT162B2, Solution for injection, Covid-19 Vaccine manufacturer: Pfizer BioNTech), intramuscular into her left deltoid on 17Dec2020 07:30 at single dose for covid-19 immunisation (Prophylaxis). Medical history included Hypothyroidism, mood and sleep. Concomitant medications included Levothyroxine at 100mcg daily by mouth ongoing for Hypothyroidism started taking at 19 years old, escitalopram oxalate (LEXAPRO) at 10mg once a day by mouth from Dec2020 started it about 2 weeks ago ongoing for mood, zolpidem tartrate (AMBIEN) at 10mg as needed by mouth for sleep and was not taking this at the time. The

patient experienced Deltoid soreness from 17Dec2020 to 18Dec2020, Chills from 20Dec2020 to 21Dec2020, generalized myalgias from 20Dec2020 to 21Dec2020, high fever from 20Dec2020 to 21Dec2020. The outcome of the events was recovered. Her vaccination cared is at her house. She received the product at the hospital she works at. The causality of the events Deltoid soreness, Chills, generalized myalgias and high fever was related. Caller is a nurse practitioner that reported that she wanted to report a possible side effect for herself with the Covid-19 vaccine. She said that she herself got vaccinated on Thursday 17Dec2020. She was doing fine except for the deltoid soreness that showed up about 12 hours after receiving the vaccine and lasted for about 12 hours and then it went away. On Sunday, she had sudden onset of chills, generalized myalgias, and a high fever. Caller said that her highest recorded temperature was 102.5. Her symptoms started at about 1430 and she said she had no other symptoms aside from what she reported. She said that her chills went away after about 3 hours and then she felt hot, and then she just felt achy and had the generalized myalgias. All were subsided by 0900 this morning. She said that she also had a low grade fever of 99.8 this morning, but it was all gone by 0900. Caller said that she is a emergency room employee and was given the vaccine at the hospital and they was no prescribing physician. Caller said that she has never had a reaction like this to a vaccine before. Vaccination Facility Type was hospital. Vaccine Administered at Military Facility was No. Additional Vaccines Administered on Same Date of the Pfizer Suspect was none. No AE(s) was require a visit to ER or physician office. Prior Vaccinations (within 4 weeks) was none. AE(s) following prior vaccinations was none. Family Medical History Relevant to AE(s) was none. Relevant Tests was None. Information on the lot/ batch number has been requested.

Headache, muscle and joint pain,Chills and Fever-102.9 day after; Headache, muscle and joint pain,Chills and Fever-102.9 day after; Headache, muscle and joint pain,Chills and Fever-102.9 day after; Headache, muscle and joint pain,Chills and Fever-102.9 day after; Headache, muscle and joint pain,Chills and Fever-102.9 day after; This is a spontaneous report from a contactable Nurse (patient). A 66-years-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (lot number: EJ1685) intramuscular on arm left on 18Dec2020 12:45 at single dose for COVID-19 immunization. Medical history included osteoarthritis. The patient was not allergic to medications, food, or other products. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Concomitant medication received within 2 weeks of vaccination included Atorvastatin, Ibuprofen, sambucus nigra (ELDERBERRY), Krill Oil, One A Day VitaCraves Women's, ergocalciferol (VITAMIN D), ascorbic acid (VITAMIN C). On 19Dec2020 08:00, the patient experienced headache, muscle and joint pain, chills and Fever-102.9 day after, gradually went down over night. No treatment received for the adverse event. There was no Covid prior vaccination, received COVID tested post vaccination via nasal swab on 20Dec2020 with result of negative. Events outcome was recovered.

tested (nasal swab done) on Sunday; received positive test result; Patient had COVID, did not know she had COVID and got the vaccine; This is a spontaneous report from a Pfizer-sponsored program Pfizer First Connect via a contactable pharmacist (patient). This 41-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), (lot number: EH9899) via an unspecified route of administration on 19Dec2020 at single dose for COVID-19 immunization. There were no medical history and concomitant medications. Patient had COVID, did not know she had COVID and got the vaccine. Patient

received vaccine on Saturday, tested (nasal swab done) on Sunday. Patient received positive test result on 21Dec2020. Outcome of the event was unknown.; Sender's Comments: Based on the information currently available, a lack of efficacy with BNT162B2 in this patient might not be completely excluded.

R sided facial numbness; tingling; muscle weakness; This is a spontaneous report from a contactable pharmacist reporting for herself. This 32-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via intramuscular route at right arm on 21Dec2020 at single dose (lot number: EJ1685) for COVID-19 immunization. Medical history and concomitant medications were unknown. The patient reported R sided facial numbness, tingling, and muscle weakness roughly 20 minutes after receiving the COVID-19 vaccine on 21Dec2020. The sensation was improving over the next 10-15 minutes. The patient was asked to monitor her signs and symptoms and report to her doctor if no improvement/worsening. Events were reported as non-serious. No treatment was received for events. Outcome of the events was recovering. Information about lot/batch number has been requested.

Having a lot of bone pain in the arm that I got the injection at; Having a lot of bone pain in the arm that I got the injection at; This is a spontaneous report from a contactable consumer (patient). This patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose in the arm for COVID-19 immunization. Medical history and concomitant medications were not reported. Patient stated it was the COVID-19 Vaccine. Patient was having a lot of bone pain in the arm that patient got the injection at. It was not 'muscle' (not clarified). The outcome of events having a lot of bone pain in the arm that patient got the injection at was unknown. Information on the Lot/Batch number has been requested.

"bleeding coming from the injection site after the needle was removed his arm; This is a spontaneous report from a contactable other HCP (anesthesiologist) reported for himself. This male patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose on the arm for COVID-19 immunization. Medical history and concomitant medications were not reported. Patient stated after receiving COVID vaccine on an unspecified date (reported as ""today"") he noticed bleeding coming from the injection site after the needle was removed his arm. Patient said he had the vaccine he took the needle out he bleed a little bit he said he was afraid he was injected wrong possible into a vein nothing was swollen nothing was bruised red. Patient stated he was unsure if the vaccine was administered intravenously or intramuscularly. Outcome of the event was unknown. The report was assessed as non-serious. Information on the Lot/Batch number has been requested."

patient received BNT162B2 vaccine that had been through a temperature excursion; patient received BNT162B2 vaccine that had been through a temperature excursion; This is a spontaneous report from a contactable healthcare professional. This healthcare professional reported similar events for ninety patients. This is one of ninety reports. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), via an unspecified route of administration in Dec2020 as a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. In Dec2020, the patient received BNT162B2 vaccine that had been through a temperature excursion. This was further elaborated as the patient received the vaccine that had been

exposed to -50 degrees Celsius for about 20 minutes before being transferred to the refrigerator and then administered within 5 days. The clinical outcome of patient received BNT162B2 vaccine that had been through a temperature excursion was unknown.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2020502898 same reporter reporting similar events in different patients with the same vaccine

severe headache with nausea; severe headache with nausea; This is a spontaneous report from a contactable nurse (patient) who reported for herself that a 56-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EH9899) via an unspecified route of administration on 17Dec2020 at single dose for COVID-19 immunization. Medical history included pulmonary sarcoidosis, thyroid, mild depression. Concomitant medication included famotidine, ibuprofen (DUEXIS). Nurse called in to report side effects, she got her shot on 17Dec2020 and she had a severe headache with nausea about 45 minutes after getting the shot. When probed if still experiencing the event, nurse stated, about 15 minutes it was gone on 17Dec2020. She just took Ibuprofen (MOTRIN) for treatment. Outcome of severe headache with nausea was recovered on 17Dec2020.; Sender's Comments: The reported information is limited. Based on the close temporal relationship and the description of the events,headache with nausea, there is a reasonable possibility that the events are related to BNT162 vaccine. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

Headache; malaise; diarrhea; This is a spontaneous report from a contactable nurse (patient). A 38-year-old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number: Ek5730), intramuscular on the right arm on 19Dec2020 16:15 at a single dose for covid-19 immunization. The patient's medical history included reflux and anxiety. The patient had no known allergies to medications, food, or other products. Concomitant medications included sertraline hydrochloride (ZOLOFT), spironolactone, loratadine (CLARITIN), ascorbic acid, betacarotene, calcium sulfate, colecalciferol, cyanocobalamin, ferrous fumarate, folic acid, nicotinamide, pyridoxine hydrochloride, retinol acetate, riboflavin, thiamine mononitrate, tocopheryl acetate, zinc oxide (PRENATAL VITAMINS), vitamin d3, and famotidine (PEPCID). The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient was not diagnosed with COVID-19 prior to vaccination and had not been tested for COVID-19 since the vaccination. The patient experienced headache, malaise, and diarrhea on Dec2020 (reported as 18Dec2020 19:00, pending clarification). No treatment was received for the adverse events. Outcome of the events was recovered on Dec2020.

He has a temperature of 100.1 but a lot of muscles aches and pain; He has a temperature of 100.1 but a lot of muscles aches and pain; He has a temperature of 100.1 but a lot of muscles aches and pain; This is a spontaneous report from a non-contactable Nurse. This Nurse reported for a male patient (Son) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 19Dec2020 at 08:20 at single dose for covid-19 immunisation. Medical history was not provided Concomitant medications included Lisinopril for a little hypertensive. He received a shot (COVID Vaccine) yesterday (19Dec2020 at 08:20), today he called on for work, and he says that he has a temperature of 100.1 but a lot of muscles

aches and pain. Outcome of the events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

Tiredness; Pain injection site; Headache; muscle pain; Joint pain; Nausea; just isn't feeling good; feels like face and around eyes are swollen; feels like face and around eyes are swollen; This is a spontaneous report from a contactable consumer reported for self. This 53-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 17Dec2020 in her right arm at single dose for required to at work. None medical history and concomitant medications. She is at work right now. She doesn't have a prescribing doctor. She works at the ER, and they were provided to employees. There is pain at the injection site, which she expected. She has had tiredness, headache, muscle, and joint pain. No chills. She has had nausea. She just wasn't feeling good. She feels like her face is swollen. Like around her eye lids is swollen, but she asked her kids, and they said it doesn't look swollen. She can feel it, but not see it. She got the vaccine on 17Dec2020. She started having all the side effects on the 18Dec2020. They have just persisted. She took something for nausea. She took Ibuprofen for pain, Headache, muscle pain, Joint pain. Outcome of the events was not recovered. Information on the lot/batch number has been requested.

She does have a significant muscle ache and joint ache; She does have a significant muscle ache and joint ache; This is a spontaneous report from a contactable physician (Patient's husband). A female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 19Dec2020 at single dose (Lot # EH9899) for covid-19 immunisation. Medical history, concomitant medications or past drug history were not provided. She has received the first injection of the Covid 19 Vaccination, she received it 24 hours ago (19Dec2020) and she doesn't have a fever but she does have a significant muscle ache and joint ache. So the question if it is okay for the patient to take anti-inflammatory medication like non-steroidal. Outcome of the event was unknown.

tested positive for Corona Virus/ symptomatic and has been sick; tested positive for Corona Virus/ symptomatic and has been sick; This is a spontaneous report from a Pfizer-sponsored program by a contactable other HCP reported for self. This 35-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on an 18Dec2020 10:45 am on left arm at single dose (Lot # EK5730) for routine vaccination. No additional vaccines received on the same date. Vaccination facility type was hospital. None medical history, concomitant medications or past drug history. She has a patient on the line who got the COVID vaccine on Friday (18Dec2020 10:45), and on Sunday (20Dec2020) she tested positive for the Corona Virus. The main reason she called is to figure out what to do about the booster. There is not really enough data to determine this at this point. There was no prescriber. She just received it at the hospital. She is symptomatic and has been sick on 18Dec2020 all weekend. Saturday (19Dec2020) is when she began to have more significant symptoms and on Sunday (20Dec2020) as well. Today, she is better, but still symptomatic. She became symptomatic on Friday night 18Dec2020, and experienced loss of smell, extreme fatigue, mild cough, nasal congestion. She states all were related to COVID. This all started around 7:30 pm. Relevant test included Positive for Corona Virus on Sunday, 20Dec2020. Relevant test included Positive for COVID test (Corona Virus) on Sunday, 20Dec2020. Outcome of the events was unknown.; Sender's Comments: Based on the information currently available, a lack of efficacy with BNT162B2 in this patient might not be completely excluded.

arm tingled; a little pain around the injection site; This is a spontaneous report from a contactable consumer. This female consumer (patient) of an unspecified age received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), intramuscular on 20Dec2020 at 4:00 pm at single dose for COVID-19 immunisation in her left arm. The medical history and concomitant medications were not reported. At 4:00 pm a nurse placed the vaccine in her left arm. When she placed the medication the patient felt a zing and a burning sensation with a tingle down her arm. She didn't say anything, she thought maybe the medication was just a thicker consistency like Betamethasone, which can sometimes burn when injected in the muscle. The patient's arm tingled for about 3 to 5 minutes and then it stopped. The patient felt the medication go in and felt burning and tingling. It's 6pm and the patient feel fine, just a little pain around the injection site. The skin surrounding the injection site was normal in color and cool to the touch. No visible swelling. She personally think she placed the vaccine a little too high and hit a nerve. The outcome of the events was recovered on 20Dec2020 6pm. Information about Lot/Batch number has been requested.

Muscle ache; Fatigue; Headache; feels Achy; This is a spontaneous report from a contactable Physician. A female patient started to receive started to receive BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 17Dec2020 at single dose for covid-19 immunisation. This is unknown to her, but she would imagine the second dose is around 07Jan2021. Medical history, concomitant medications or past drug history were not provided. The patient was experiencing that she was referring to is muscle aches, fatigue, and headache. She doesn't feel sickly but feels achy. It is unknown if the patient ever test positive for Covid, or had antibodies prior to the vaccine. Outcome of the events was unknown. Information about Batch/Lot number has been requested.

entire tongue began to itch; entientire tongue began to itch, tingle; A small bruise-like spot appeared on the tip of her tongue; This is a spontaneous report from a contactable Nurse reported for self. This 65-year-old female patient (not pregnant) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on an 19Dec2020 14:30 on Arm left at single dose (Lot # EKS730) for covid-19 immunisation. Facility where the most recent COVID-19 vaccine was administered: hospital. Medical history included Gastrooesophageal reflux disease. Concomitant medications included omeprazole. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Past drug history included Allergies to medications, food, or other products: Bactrim, Ceftin. On 20Dec20200 8:30 AM, 18 hours after receiving the vaccine her entire tongue began to itch, tingle. No swelling noted. A small bruise-like spot appeared on the tip of her tongue. 5 hours later the itching stopped (20Dec2020 13:30) and the bruise-like spot began to fade. The spot was completely gone the next morning. There was no trauma to the tongue at any point that would account for the spot. Prior to vaccination, was the patient did not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. No treatments were received for the events. Outcome of the event tongue itching was recovered on 20Dec2020 13:30. Outcome of the event a small bruise-like spot appeared on the tip of her tongue was recovered on 21Dec2020. Outcome of the event tingling tongue was recovered in Dec2020. Events assessed as non serious.

developed a slight cough; This is a spontaneous report from a contactable nurse reported for herself. This 25-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an

unspecified route of administration on 19Dec2020 at single dose for COVID-19 immunization. Medical history and concomitant medications were unknown. The patient received the COVID Vaccine on 19Dec2020. The following day she developed a slight cough on 20Dec2020, and she felt completely fine otherwise. Outcome of the event was recovered. Information on the Batch/Lot number has been requested.

feeling ok not perfect; This is spontaneous report from a contactable nurse reporting for herself. This female patient of unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 21Dec2020 at single dose for COVID-19 immunization. Medical history and concomitant medications were unknown. The patient got the Pfizer Covid-19 vaccine on 21Dec2020 and wanted to know if she was contagious. She stated she knew it's not a live vaccine and it's an MRNA vaccine. Her pharmacist told that she was not contagious, but she just wanted to make sure. The patient was feeling ok not perfect. The patient did not state any side effects. Outcome of the event was unknown. Information about lot/batch number has been requested.

heaviness in the chest; trembling of the mouth like teeth went on chatter like it is real cold; This is a spontaneous report from a contactable consumer (patient). This 57-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 17Dec2020 at single dose (lot number: EJ1685) for COVID-19 immunization. Medical history included blood pressure abnormal. Concomitant medications included cetirizine hydrochloride (ZYRTEC) and acetylsalicylic acid (ASPIRIN 81) as blood pressure pills. The patient was informing the side effect that she had when she had got the vaccine (Unspecified vaccine). The patient experienced heaviness in the chest and also trembling of the mouth like teeth went on chatter like it was really cold on 17Dec2020. When probed for the lot number, EJ1685 with Pfizer was reported. The patient worked at the hospital. It was just happened between the first 4 hours after receiving. It was not still experiencing. No treatment received for the problem because they left like within the first 4 hours and after that the patient didn't feel anything. Outcome of both events was recovered in Dec2020.

Some chills, temperature; Some chills, temperature; Soreness in the administration site; This is a spontaneous report from a contactable nurse reported for himself. This 51-year old male patient started to receive BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 20Dec2020 at single dose for COVID-19 immunization. Medical history and concomitant medications were unknown. On 21Dec2020, the patient experienced some chills, temperature, and soreness in the administration site. The patient was vaccinated at 51 years old. The patient wanted to know if he should isolate himself again, and if he will get Covid again after receiving the vaccine. Outcome of the events was unknown. Information about lot/batch number has been requested.

Runny nose; Congestion; Malaise; Fever; Chills; This is a spontaneous report from a Pfizer-sponsored program from a contactable consumer (patient). This male patient of unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 18Dec2020 at single dose for COVID-19 immunization. Medical history and concomitant medications were unknown. The patient received the vaccination on Friday, 18Dec2020. The patient was experiencing fever and chills Friday night on 18Dec2020. Then he proceeded to receive a runny nose and

congestion still at the time of reporting along with a little bit of malaise. He was wondering if he should get tested for COVID-19 due to the symptom or if the symptoms were due to the vaccination. Outcome of the events runny nose, congestion and malaise was not recovered. Outcome of the events fever and chills was unknown. Information on the Lot/batch number has been requested.

left deltoid hurt a lot for a while; got left actual swelling like in his armpit; This is a spontaneous report from a contactable consumer (patient). This 49-year-old male patient received the 1st dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration at left deltoid on 18Dec2020 at single dose for COVID-19 immunization. Medical history and concomitant medications were unknown. The patient received the COVID vaccine Friday morning as part of work. The patient had a lot of, kind of significant actual swelling in the (incomplete sentence). The patient was too much concerned about this, but it was out of the ordinary enough that the patient felt it was worth reporting. So the patient got the vaccine in his left deltoid and the left deltoid hurt a lot for a while but currently the patient got left actual swelling like in his armpit it's, where the lymph nodes were, the patient got a very significant swelling. The patient stated he was experiencing it on 20Dec2020. So his age was 49 years. The patient was assuming it was a normal immune response, but he never had it with the flu vaccine or anything, so the patient wanted to report it. It's a COVID-19 Vaccine. No treatment was received for events. Outcome of the events was unknown. Information about lot/batch number has been requested.

sore and heaviness on the injection site; heaviness on the injection site; This is a spontaneous report from a contactable Nurse (patient) via Pfizer sales representative. This female patient of unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. Medical history and concomitant medications were unknown. The patient posted on Social Media that she was injected with COVID 19 vaccine. As per her comment, after 8 hours she experienced sore and heaviness on the injection site. Outcome of the events was unknown. Information on Lot/Batch number has been requested.

mild COVID symptoms; front line nurse and received it because of that; This is a spontaneous report from a contactable nurse. A female patient of unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on an unspecified date at single dose for treating COVID patients. Medical history included COVID. Concomitant medications were unknown. The patient had COVID previously, received the vaccine, and was currently experiencing mild COVID symptoms. The patient received vaccine from the hospital, so there was no prescriber. Patient was a front line nurse and received it because of that. Outcome of the events was unknown. Information about batch/lot number has been requested.

"Cough; Got a COVID test; positive; 4 hours after, my arm became sore; body aches; Still feel sick but not as sick as I was; shortness of breath; fever; Developed like pretty bad symptoms; This is a spontaneous report from a contactable nurse reported for himself. This 38-year-old male patient received 1st dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration at arm on 16Dec2020 at single dose (lot number: PAA156051) for vaccinated against COVID 19. Medical history included HIV. Concomitant medications included bictegravir sodium/emtricitabine/tenofovir

alafenamide fumarate (BIKTARVY) for HIV. The patient had received the Pfizer vaccine for COVID 19 on 16Dec2020 (Wednesday). And then the patient developed like pretty bad symptoms. Then, when the patient went to get tested because he suddenly started having like a cough at night on 16Dec2020 and got a COVID test and it was positive on Dec2020. The patient was a nurse in the emergency room and just wanted to report that. The patient knew scientifically it couldn't give him the virus. The patient didn't have any symptoms of COVID. So, after the patient got the shot, 4 hours after, his arm became sore and then 12 hours after, he had body aches, fever, cough, shortness of breath on Dec2020. About Lab Work, the patient stated, ""Just the COVID one."" And the patient got positive results for COVID test. Due date for the next shot was 06Jan2021. When asked if he was still experiencing cough, the patient stated he still felt sick but he was not as sick as he was. The first 2 or 3 days were really bad. About treatment, the patient stated, ""Nothing for the cough but I took Tylenol."" Outcome of the events was unknown. Information about batch/lot number has been requested."

Hives; felt itching to her scalp; This is a spontaneous report from a contactable other hcp (patient). This 38-years-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (lot number: EK5730), intramuscularly on 21Dec2020 06:40 at single dose on left deltoid for COVID Prevention. Medical history included Polycystic ovarian syndrome, was diagnosed with this in her early 20's and ongoing, Hypothyroidism from 2015 and ongoing, Corneal abrasion from 2020 and ongoing (Patient got a corneal abrasion to her right eye, about a week ago and is currently using eye drops for prophylaxis against infection), and anaphylaxis. Concomitant medication included metformin tablet oral at 750mg, once daily for Polycystic ovarian syndrome, she has been taking the product on and off since being diagnosed with PCOS and ongoing, thyroid (ARMOUR THYROID) oral at 60 (unsure if the product is MG or MCG) once daily for Hypothyroidism, started product four or five years ago and ongoing, moxifloxacin hydrochloride (VIGAMOX) at 1 drop to right eye, three times daily for Infection prophylaxis from Dec2020 and ongoing, patient got a right corneal abrasion last week and is using the product as infection prophylaxis. The patient was a Physician Assistant, who works in the ER, who just received the COVID vaccine at work. The patient stated that she got hives after her injection. The patient received the vaccine today at about 6:40AM. She stated that she was instructed to wait 30 minutes after receiving the vaccine because she does have a history of anaphylaxis, but not to vaccines. So it was about 5 to 10 minutes before her 30 minute wait time was up, that she started getting the hives on 21Dec2020. She stated that the hives she got started on her left wrist, and then they worked to bilateral upper arms, and then she also felt itching to her scalp but states she did not feel a rash on her scalp. She took 50mg of Benadryl orally for treatment. It was stated that the hives have resolved at this time, but patient was unsure as far as outcome goes, because she took Benadryl and the hives are gone now, but she does not know if they will return or not. She stated that she only had to take Benadryl and she declined checking in to the ER, so she considers this, not serious. The outcome of hives was recovered, of felt itching to her scalp was unknown.

fatigue; This is a spontaneous report from a non-contactable consumer (patient) via Pfizer sales representative. This patient of unspecified age and gender received first dose of BNT162B2, from an unspecified date at single dose for COVID-19 immunisation. The patient medical history and the concomitant medications were not reported. The patient experienced fatigue the day after the first

dose. The outcome was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

body aches; pregnant patient received BNT162B2 for COVID Prevention; pregnant patient received BNT162B2 for COVID Prevention; pregnant patient received BNT162B2 for COVID Prevention; This is a spontaneous report from a contactable physician (patient). This 35-years-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (lot number: EH9899), intramuscularly on 19Dec2020 at single dose in right upper arm for COVID Prevention. Medical history was none. Concomitant drug included unspecify drugs. The patient got the vaccine on 19Dec2020, and then that evening she had body aches. She stated that she took 1000mg of Tylenol by mouth because she was really achy, but she was fine by the next day. She was pregnant. Patient last menstrual period date was 08Sep2020. She does take another medication but she does not think it was associated with the body aches she experienced. The outcome of Body aches was recovered on 20Dec2020, of other events were unknown. Primary Source Reporter assessed Body aches related by Method of assessment.

Weakness; Lightheadedness; fast heart beat/heart rate is 101; coughing a little bit; panic attack; he was not acting well and his blood pressure was 158/98; he feels silly then has nervousness; he feels silly then has nervousness; feeling tired; not feeling well; This is a spontaneous report from a Contactable consumer (patient). This 52-years-old male patient received first dose of BNT162B2(PFIZER-BIONTECH COVID-19 VACCINE) (lot number: AK5730), on 20Dec2020 at single dose on left arm for COVID-19 immunisation. Medical history included Blood pressure high. The patient's concomitant medications were not reported. He had one injection given in his left arm around 08:30 or 08:40 in the morning on 20Dec2020, before 9 o clock. He says that they let him rest for 15 minutes after his injection, and it is a delayed reaction that just started this morning and he tried to go to work and had to go home. The patient got the vaccine on yesterday morning then tried to come to work on this morning but he was feeling weak and having light headedness, and his heart beat is so fast. He did go home to try to relax. He said he experienced a panic attack at some other times where his heart beat fast and he was quite light headed at some other times gone from rest and get up to walk or try to do something, and that's why he had gone home after he reported to work earlier. He says just now also trying to have something to do he is feeling it. He says that he took Tylenol and some cough syrup for feeling lightheaded and weak. He clarifies that he took Tylenol yesterday and then after he took vaccine and this morning the nurse gave him Tylenol also. He says he told them he was not feeling well, he felt silly and weak. They told him to go home because he told them he was not acting well and his blood pressure was 158/98. He has been doing Lisinopril 20mg for his high blood pressure, and he has been on it for a long time. He says that the label says discard after 01Oct2021. He says he takes 20mg once a day by mouth, and he keeps refilling it every 30 days. The patient took the cough syrup because he was coughing a little bit. He says that the EXP date on the Tylenol he took that he has at home is Mar2022. He provides EA013 as LOT and dose strength as 500mg. He says he took this last night and this morning at the facility they gave him the 500mg dose too. He says that he took vitals with his nurse, and his heart rate is 101. The patient asks what can he do since he is worried about reading side effects of vaccine so now he is feeling fine, then some other times it comes like first time this morning at work he feels silly then has nervousness or something and a panic attack, so they let him go home. He says he got home, and was

feeling fine again. He says he tries to go to the bathroom, or tries to do something in his garage, and feels light headed and is feeling tired. He says he would like to know if that is normal, should he take anything. Lab data on 21Dec2020 included Blood pressure was 158/98, Heart rate was 101. The outcome was unknown.

rigors; This is a spontaneous report from contactable physician via Pfizer sales representative. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), on an unspecified date at single dose for COVID-19 immunisation. The patient medical history and the concomitant medications were not reported. The patient had rigors that subsided in 12 hours after receiving the Pfizer-BioNTech COVID vaccine. The outcome was recovering. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

"General weakness; body ache; Muscle ache; Headache; This is a spontaneous report from a contactable Nurse (patient). A 56-years-old female patient received first doe of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (LOT#: EK5730), on 17Dec2020 at single dose for COVID-19 immunisation. Medical history was none. There were no concomitant medications. The patient received a Pfizer's Covid vaccine on 17Dec2020 and have got some side effects which is general weakness, headache and it just started second day after received the Vaccine on 18Dec2020. The patient had done Covid test several times and all the time it was negative. The patient stated, ""You mean is it worsened from the start date, it's the same when it started on the second day it continued with the headache and body ache, muscle ache and I am taking some Tylenol 500 every 6 hour but not all the time after that."" The outcome was not recovered.P rimary Source Reporter assessed General weakness; body ache, Muscle ache, Headache were related."

"she has almost a sinus headache; the injection site was very, very sore; Chills/She couldn't get warm; cold; body aches; This is a spontaneous report from a contactable consumer (patient). This 64-years-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (lot number: EK5730) on 19Dec2020 15:15 at single dose on Left Arm for COVID-19 immunisation. Medical history included She had COVID on 10Nov2020. There were no concomitant medications. The patient received the COVID vaccine on 19Dec2020, the first dose. She didn't have much side effects or feel symptoms except the next morning on 20Dec2020, the injection site was very, very sore. As the day progressed, she had chills. No fever, but chills. She couldn't get warm. This morning when she woke up she has almost a sinus headache on 21Dec2020. It's not really a headache, but around her eyes. ""Injection site was very, very sore"" didn't really start until yesterday after lunch. She has not had chills this morning, just body aches. She feels like she is about to get a cold. She had COVID on 10Nov2020. She wasn't as cold this morning like she was when she went to bed last night. She thinks the chills stopped some time in the night. When she went to get in the shower this morning she felt the headache. She still has the sensation around the eyes. She took some Tylenol about 11AM on 19Dec2020. The outcome of the injection site was very, very sore was recovering, of other events were unknown."

tachycardiac; Low grade like a 99.8; This is a spontaneous report from a contactable nurse (patient). A 32-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EH9899), via an unspecified route of administration on 17Dec2020 at single dose at the left deltoid for

immunization. Medical history included tachycardia heart condition (had an underline heart condition that was a tachycardia heart condition). There were no concomitant medications. Patient got Pfizer vaccine on 17Dec2020. Patient really had not had any side effects except had a low grade like a 99.8 yesterday (in Dec2020). Which was probably just the vaccine patient was assuming probably just the vaccine had to do like kid when they get in then they get a little fever. On 19Dec2020, though however patient had tachycardia. Like right now patient was in 130 and blood pressure didn't read when went to stand. And patient had drink plenty fluids all day on 18Dec2020. Patient previously did have an underline heart condition that was a tachycardia heart condition. Patient had not had any issues with heart for about. Because the last time had it was about 2 years ago. Patient had a cardiac condition that caused her to be tachy-cardiac. But it was usually only when she was pregnant. But patient was not pregnant and it had been about 2 years since last episode of this. And the only this that changed was this on 17Dec2020. So, this was the first time patient had had anything that changed after getting that vaccine. Patient did not take any medication. She used to be on a beta blocked but she was recently taken off of that (She don't know 3 months ago). Outcome of events was unknown.

Tingling down entire left side of body, from face to foot.; Numbness and tingling of left side of face.; Had headache temporarily (resolved). Mostly on right side behind eye; This is a spontaneous report from a contactable Other HCP. This Other HCP reported for herself that the 48-year-old female patient received fist dose of bnt162b2 (BNT162B2, Batch/lot number: EK5730), via unknown route of administration in left arm on 21Dec2020 07:45 PM at single dose for covid-19 immunisation. She is not pregnant at the time of vaccination. Medical history included History of breast cancer. Past drug event included Known Allergies to medications, food, or other products: Codeine. Concomitant medications included tamoxifen. Facility type vaccine Hospital. No other vaccine in four weeks. Other medications the patient received within 2 weeks of vaccination included Tamoxifen, multi-vitamins, hair, skin and nails. The patient experienced Tingling down entire left side of body, from face to foot. Numbness and tingling of left side of face. Feel like I got Novocain shot in face. Had headache temporarily (resolved). Mostly on right side behind eye from 21Dec2020 08:00 PM. Outcome of the events was not recovered. No covid prior vaccination. No covid tested post vaccination. Facility where the most recent COVID-19 vaccine was administered was Hospital. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. No treatment was received for the adverse event. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, has the patient has not been tested for COVID-19. Vaccine Facility information available. Location of injection information is available for all vaccines received on the same date.

"I have had an excruciating back and hip pain; I have had an excruciating back and hip pain; I can barely walk around; This is a spontaneous report from a contactable consumer. This consumer (Respiratory therapist) reported that the 64-year-old male patient received bnt162b2 (BNT162B2, Pfizer BioNTech Covid 19 Vaccine), via unknown route of administration on 16Dec2020 at single dose for covid-19 immunisation (""It helps so that I won't get Covid.""). Medical history included Blood pressure. Consumer stated, ""I need it to report that I have had an excruciating back and hip pain. This is the fifth day and I still have pain but its slightly better but I don't think I am going to work today or tomorrow. I can barely walk around."" Consumer stated, ""It was given to me by a nurse at hospital."" Consumer

stated, ""I take a high blood pressure medicine."" Consumer stated, ""I didn't take any Lab work."" Treatment was received and consumer stated, ""Yes I tried Ibuprofen."" The outcome of the events was unknown. Information about lot/batch number has been requested."

arm pain; fatigue; severe nausea; This is a spontaneous report from contactable Physician via Pfizer Sales Representative. This Physician (patient) reported that the patient of unknown age and gender received bnt162b2 (BNT162B2, reported as Pfizer-BioNTech COVID vaccine), via unspecified route of administration on arm on unknown date at single dose for covid-19 immunisation. Medical history was none. Concomitant medications were unknown. Physician reported arm pain, fatigue and severe nausea after receiving the Pfizer-BioNTech COVID vaccine. Patient is a HCP with no prior medical history. The outcome of the events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

"Headache; shivers; coldness; body aches; mouth hurts; feel very weak; This is a spontaneous report from a Pfizer-sponsored program Pfizer First Connect. A contactable consumer reported for self that the female patient of unknown age received bnt162b2 (BNT162B2, reported as PFIZER-BIONTECH COVID-19 VACCINE), via unspecified route of administration on 18Dec2020 at single dose for covid-19 immunisation. Medical history and concomitant medications were unknown. She had a COVID vaccine shot on Friday, on 18Dec2020, now she is experiencing a headache. She would like to know if headache is normal or if she should go to a doctor. Upon callback, consumer states she received the Covid19 vaccine on Friday 18Dec2020, and is experiencing ""shivers, coldness, body aches, headache, mouth hurts, I feel very weak"". Consumer wants to know if these things are normal, and if she needs the second dose. She wants to ""make sure she's not dying"". ""Can I use antipyretics before or after vaccination with the Pfizer-BioNTech COVID-19 vaccine?"" Response: The interim ACIP guidelines note that, "" Antipyretic or analgesic medications (e.g., acetaminophen, nonsteroidal anti-inflammatory drugs) may be taken for the treatment of post-vaccination local or systemic symptoms, if medically appropriate. However, routine prophylactic administration of these medications for the purpose of preventing post-vaccination symptoms is not currently recommended, as information on the impact of such use on Pfizer-BioNTech COVID-19 vaccine-induced antibody responses is not available at this time.& quot; If you are a patient, you should discuss this with your healthcare provider. The outcome of the events was unknown. Information about Batch/Lot number has been requested."

She woke up miserable and is still miserable now; she has had a fever of 101.6/It spiked to 103.1; Dry cough; neck pain; swollen lymph node and glands; headache; napped a lot; hot flash; sweaty; off balance and shaky; felt tired all day; joints felt a bit achy/achy joints/shoulder pain; This is a spontaneous report from a contactable Nurse (patient). A 43-years-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (lot number: E10140) intramuscular in her left deltoid on 20Dec2020 08:25 at single dose for COVID-19 immunization. There was no other additional vaccines administered on same date of the pfizer suspect. Medical history included had COVID from Aug2020 to an unknown date and had a pulse-ox. The patient did not have any other medical history. She has had no reactions to any other vaccines before. Her father died of heart attack but with no other medical history prior to that. Her mom died of a brain tumor. In her extended family there is high blood pressure and high cholesterol. She has not personally be diagnosed with any of these conditions. She is healthy.

She has no history of any allergies and again repeats she has never had this side effect with anything. Concomitant medications included over the counter vitamins regularly. The patient has had a fever of 101.6 about 24 hours after getting the shot. It spiked to 103.1. She has had a dry cough and all the other common sides effects reported with the vaccine. There is nothing to do but treat the symptoms. She has let her primary care doctor know via email but he is out of the office through today so she hasn't heard back. She had a Fever of 101.6 that was noticed at 2am after the shot, on 21Dec2020. When she woke up about 10 minutes ago is when she noticed a fever that spiked to 103.1, it is about 1:20pm where she is located. The dry cough started around 8am 21Dec2020, she took cough medication and has used her inhaler to stay on top of the cough. Her pulse-ox readings have been fine and she is at 97-98%. She has a pulse-ox because she had COVID Aug2020 and was out of work 6 weeks and on home oxygen. She felt if she got COVID again she would die so she would rather have the vaccine. She notes that about 15 minutes after getting the shot while they were monitoring her, she was joking with the nurse, she experienced what felt like a hot flash and was sweaty on 20Dec2020. She was off balance and shaky on 20Dec2020. This lasted about 15- 20 minutes and then she was fine. Afterward, she did notice she felt tired all day on 20Dec2020 and napped a lot. Also it was reported that her joints felt a bit achy throughout the day. She has never had a reaction to a vaccine before. Other events experienced were neck pain, swollen lymph node and glands, neck and shoulder pain, headache on 21Dec2020, and achy joints on 20Dec2020. All the events have gotten worse since starting. The fever, neck pain, swollen lymph node and glands, neck and shoulder pain, and headache were noticed about 2am. She woke up miserable and is still miserable now. The patient received Tylenol, Benadryl, Advil, cough medication and an inhaler as treatment for events. No any event required a visit to emergency room or physician office. Seriousness criterial for events fever, dry cough, neck pain, swollen lymph node and glands, Aching joints, Headache, felt tired all day, hot flash and was sweaty, off balance and shaky was medically significant. Events outcome of fever, dry cough, neck pain, swollen lymph node and glands, aching joints, headache, felt tired all day was not recovered (reported as worsened), events outcome for hot flash and was sweaty, off balance and shaky was recovered on 20dec2020, while for other events was unknown. Relatedness of drug to reactions for fever, dry cough, neck pain, swollen lymph node and glands, aching joints, headache, felt tired all day was related per primary source reporter.

Arm is getting redder today and sore. Was not red or sore yesterday after the injection.; Arm is getting redder today and sore. Was not red or sore yesterday after the injection.; This is a spontaneous report from a contactable Nurse. This Nurse reported for self that the 59-year-old female patient received first dose of bnt162b2 (BNT162B2), via unspecified route of administration on Left arm on 20Dec2020 07:45 AM at single dose for covid-19 immunisation. She is not pregnant at the time of vaccination. Medical history included known allergies to medications, food, or other products: PCN, cedar, mold and Hashimotos disease. Concomitant medications included other medications the patient received within 2 weeks of vaccination:ibuprofen (ADVIL [IBUPROFEN]), Levothyroxine and ergocalciferol (VIT D). Facility type vaccine was Hospital. No other vaccine in four weeks. The patient experienced Arm is getting redder today and sore. Was not red or sore yesterday after the injection from 20Dec2020 07:45 AM. The outcome of the event was not recovered. No treatment received. No Covid prior vaccination. Covid tested post vaccination. Covid test type post vaccination was Nasal Swab on 15Dec2020 with result of Negative. Facility where the most recent COVID-19 vaccine was administered was Hospital. The patient

did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has been tested for COVID-19. Vaccine Facility information available. Information on the lot/batch number has been requested.

"I was achy and tired; I was achy and tired; I was really, severely dizzy, like vertigo. My head was swimming; I was really, severely dizzy, like vertigo. My head was swimming; This is a spontaneous report from a contactable consumer. This consumer reported for self that the 56-year-old female patient received bnt162b2 (BNT162B2, reported as Pfizer-Biontech Covid-19 Vaccine, Batch/lot number: EJ1685, Expiry Date of COVID Vaccine: Mar2021), via unspecified route of administration on 18Dec2020 12:30 at single dose for covid-19 immunisation. Medical history was none. Concomitant medications included cyanocobalamin (VITAMIN B12 [CYANOCOBALAMIN]) Injections. She is a respiratory therapist. She states she got the vaccine on 12:30 PM on Friday. She states that Friday night by 09:30 pm was really bad. Her head was swimming. She said by Saturday she was achy, tired. Also, on Friday night she was severely dizzy and felt like she has vertigo. She is better now."" Consumer stated, ""It was just a shot."" Th outcome of the events was recovering. Treatment was received and consumer stated, ""The only thing I took was 800 mg Ibuprofen Friday evening."" Consumer further added, ""I was, just like in chart second vaccination I guess I am okay to take it. I talked to my doctor."" Consumer stated ""I got the covid vaccine on Friday and it was a bad night. I was really, severely dizzy, like vertigo. My head was swimming. I got the shot at 12:30 that day, but the symptoms didn't start until 9:30 that night. On Saturday I was achy and tired. But I'm better now."" Consumer questioned if dizziness was a reported side effect."

"My arm is sore; I have really weird red like bump blister that formed on my right hand on my index finger; This is a spontaneous report from a contactable Physician. This Physician(patient) reported that the 48-year-old female patient received bnt162b2 (BNT162B2, Batch/lot number: EJ1685), via unknown route of administration on arm on 19Dec2020 01:30 at single dose for covid-19 immunisation. Medical history was none. Concomitant medications were unknown. Physician stated, ""I took the Pfizer Vaccine (COVID Vaccine) yesterday at 1:30 and I am fine. My arm is sore, but I have really weird red like bump blister that formed on my right hand on my finger, on my index finger. I don't have any 'trauma to it'. I don't why it's there? I haven't seen it but its unusual looking."" No treatment received. The causality was assessed by Physician stated, ""No, I don't know. I have no idea if this it is just a rare coincidence."" The outcome of the events was unknown."

"felt more like a burning especially in my neck; Minutes after shot some sweating, first thought perhaps it is some anxiety related to having a vaccination. After monitoring period went back to the office. Started to get severe nausea; Minutes after shot some sweating, first thought perhaps it is some anxiety related to having a vaccination. After monitoring period went back to the office. Started to get severe nausea; Minutes after shot some sweating, first thought perhaps it is some anxiety related to having a vaccination. After monitoring period went back to the office. Started to get severe nausea; muscle pain that started in my neck, shoulder and then moved on to both legs; felt weak and had to go home; pain in my neck; leg pain; arm pain; This is a spontaneous report from a contactable Nurse. This Nurse reported for self that the 50-year-old female patient received first dose of bnt162b2 (BNT162B2, reported as PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EK5730), via Intramuscular on left arm on

18Dec2020 03:15 PM at single dose for covid-19 immunisation. She is not Pregnant at the time of vaccination. Medical history included Known allergies to medications, food, or other products: Dust mites, nickel and recent iron deficiency anemia, esophageal ulceration, reactive airway disease. Concomitant medications included other medications the patient received within 2 weeks of vaccination included Omeprazole 40 mg BID (Twice a day), colecalciferol (VITAMIN D [COLECALCIFEROL]) and Albuterol. Facility type vaccine was Hospital. No other vaccine in four weeks. No other vaccine in two weeks. The patient experienced ""Minutes after shot some sweating, first thought perhaps it is some anxiety related to having a vaccination. After monitoring period went back to the office. Started to get severe nausea and muscle pain that started in my neck, shoulder and then moved on to both legs. I felt weak and had to go home. The muscle pain was not like exercise pain - it felt more like a burning especially in my neck. The pain in my neck got better after Tylenol , the leg pain continued until 10 pm. The nausea was severe until 7:30 and was gone by 10 pm. I had to leave work 2 hours early because of side effects. The arm pain continued for two days, locally, minor and was gone on day three (21Dec2020)"". The event started from 18Dec2020 03:30 PM. The outcome of the events was recovered. No treatment received. No covid prior vaccination. No covid tested post vaccination. Facility where the most recent COVID-19 vaccine was administered was Hospital. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. The events were assessed non-serious."

left arm started to feel numb first, and then she started to feel it in her face/numbness on the side of her face; worried; This is spontaneous report from a contactable other healthcare professional (patient). A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection) via an unspecified route of administration on 21Dec2020 at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient was having a side effect after taking the COVID vaccine today (21Dec2020). The patient experienced numbness on the side of her face on 21Dec2020. The patient added that she had to wait for 15 minutes and didn't have anything. The patient when driving on the way home, she started to feel numbness on her face. The patient clarified within 20 minutes of receiving the vaccine her left arm started to feel numb first, and then she started to feel it in her face. The patient has been trying to exercise it and move it because she was worried it would become weak. The patient was unsure what to do or if this is expected. The patient, while providing contact information she stated she was really worried (21Dec2020), and she can't finish the report at this time. The full report details were unable to be obtained. The outcome of the events was unknown. Follow-up activities are possible, information on the batch number has been requested.

moderate myalgia; This is a spontaneous report from a non-contactable consumer. A 30-year-old female patient (daughter of a friend) received bnt162b2 ((Pfizer-BioNTech COVID-19 mRNA vaccine) lot number and expiration date were not reported, via an unspecified route of administration on 17Dec2020 at a single dose for COVID vaccination. The patient's medical history and concomitant medications were not reported. The patient experienced moderate myalgia following her COVID vaccination last Thursday on

17Dec2020 with outcome of recovering. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

"Injection site pain; Tiredness; Headache; Muscle pain; Chills; I have fever 100.3; Injection site is swelling; injection site have redness; feeling unwell; This is a spontaneous report from a contactable Nurse (patient). The patient received first dose of bnt162b2 (BNT162B2, lot number: EH9899, Expiry Date: Mar2021), unknown on 19Dec2020 18:00 at single dose for covid-19 immunisation. Medical history was reported as Patient History: No. There were no concomitant medications. Nurse stated, ""I have received the vaccine, the Pfizer COVID vaccine yesterday at 06:00 PM. I have side effects is injection site pain, tiredness, headache, muscle pain, chills and I have fever 100.3 (I got the fever after 24 hours of receiving the vaccine) and injection site is swelling, injection site have redness and feeling unwell. I would like to know how long it takes to, the side effects is going to be gone."" The outcome of the events was unknown."

"Dizzy; I felt really weak; Shortness of breath in getting up the stairs; The shortness of breath freaks me out, I think that's where the anxiety comes in; I think the midsternal chest pain was my anxiety but like a little bit; started feeling very like flu; Headache; Weakness; Fatigue; Muscle ache; I also have like really swollen lymph nodes, my lymph nodes feels like draining right now; The shortness of breath must have pain and issue for me; This is a spontaneous report from a contactable nurse (patient). A 32-years-old female patient received bnt162b2 (BNT162B2), via an unspecified route of administration on 19-DEC-2020 07:30 at single dose for covid-19 immunisation. The patient medical history was not reported. Concomitant medication included buspirone hydrochloride (BUSPAR), omeprazole (OMEPRAZOLE), lithium (LITHIUM), doxycycline (DOXYCYCLINE) for infection right now in her toe. The lithium cause 'sinus' reflux asthma. Nurse reported an adverse effect, was kind of confuse if it is related or not. She felt good for first 15 minutes and when she was about to leave. she was not afraid of shot. she felt dizzy and then she had to go upstairs and she felt really weak and Shortness of breath getting up the stairs, to get to her car. The shortness of breath freaks her out, she think that's where the anxiety comes in. she started driving home and she had bad shortness of breath. she think the midsternal chest pain was her anxiety but like a little bit. she am not sure. In '12' hours later she went to work she started feeling very like flu, she started flu like with headache, weakness, fatigue, muscle ache. she was working in ER and it is hard to work and then 20Dec2020 she was still feeling bad but little bit better than first day and shortness of breath that was still there like all day the day before. she also had like really swollen lymph nodes, her lymph nodes feels like draining right now. Nurse stated she was taking Omeprazole. That was wired because she have 'sinus' (Further not clarified, hence not captured in tab) reflux asthma, so the shortness of breath must have pain and issue for her but Omeprazole have stopped it, so before taking the vaccine she thought she was completely fine but then after taking the vaccine, it was like she have the issue again like it was controlled before the vaccine. Result of lab test: TSH was 8. So it was elevated but that was because of lithium and then she reduced the dose so it should be better now. So every result was normal."" Results of tests and procedures for investigation of the patient: Test: CBC, CMP, Lithium level, TSH: Thyroid panel unknown result."

generalized weakness; headache; right sides numbness/bilateral hand numbness/bilateral face numbness; This is a spontaneous report from a contactable other healthcare professional reported for

herself. A 43-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number EH9899, expiry date unknown) via an unspecified route of administration at the right arm on 18Dec2020 10:00 at single dose for COVID-19 immunization. The patient medical history was none. The patient was not diagnosed with COVID-19 prior vaccination. Concomitant medication included influenza vaccine inact split 3v (FLULAVAL, lot number 542MY, expiry date unknown) on 20Nov2020 for immunization. On 18Dec2020 at 16:00 (day 1), the patient experienced headache and right sides numbness. On day 2 (19Dec2020), patient has headache. On day 3 (20Dec2020), the patient has overall improvement. On day 4 (21Dec2020), the patient experienced generalized weakness, at 1300 bilateral hand numbness, at 1540 bilateral face numbness that has persisted into the afternoon (pm). The outcome of the events headache, right sides numbness/bilateral hand numbness/bilateral face numbness and generalized weakness was not recovered.

Headache; Chills; Body ache and little bit congested; Body ache and little bit congested; This is a spontaneous report from a contactable consumer (patient). A 50-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for immunization. Medical history included high blood pressure, seizure disorder. Concomitant medication included metoprolol, aripiprazole (ABILIFY). The patient experienced headache, chills, body ache and little bit congested on an unspecified date with outcome of unknown. No treatment was received for events. Information about Lot/Batch number has been requested.

a little bit of chill; like a slight bit of dizziness; This is a spontaneous report from a contactable consumer. A patient of unspecified age and gender received bnt162b2 (BNT162B2, Batch/lot number: EH9899), via an unspecified route of administration on 18Dec2020 at single dose for covid-19 immunisation. The patient medical history was not reported. The patient's concomitant medications were not reported. The patient experienced a little bit of chill and like a slight bit of dizziness on Dec2020 with outcome of unknown.

really uncomfortable, my stomach is alarming; This is a spontaneous report from a contactable consumer (patient). A 57-year-old female patient received BNT162B2 (COVID Vaccine, manufacturer not clarified), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunisation. Medical history included hypertension, diabetes, atrial fibrillation. The patient had some concomitant medications. When probed for any concomitant, patient stated, that was her other concern. She was seeing there was an issue with if you won't blood thinner (further not clarified). Patient stated, she got her own injection (COVID Vaccine) on Friday and It was not been major but she had been to the bathroom since Friday and she was change her diet or anything. This was really uncomfortable, her stomach was alarming. Patient asked if that was normal. Outcome of the event was not reported. Pfizer is a marketing authorization holder of COVID Vaccine in the country of incidence or the country where the product was purchased (if different). This may be a duplicate report if another marketing authorization holder of COVID Vaccine has submitted the same report to the regulatory authorities. Information on the lot/batch number has been requested.

fatigue, nasal congestion and body aches/tested positive with infection; fatigue, nasal congestion and body aches/tested positive with infection; This is a spontaneous report from a contactable physician. A

male patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 16Dec2020 at single dose for COVID-19 immunisation. The patient medical history and concomitant medications were not reported. On 15Dec2020, the patient reported possible personal exposure (close contact / dinner with friend who tested positive on 18Dec2020, both unmasked) and received Covid vaccine on 16Dec2020. The patient reported fatigue on 17Dec2020, nasal congestion and body aches on 18Dec2020. He tested positive with infection control MD and had monoclonal Ab administered same day (18Dec2020). He wanted to know, what this means for his scheduled second vaccine and if needs to wait 90 days from positive Covid. The outcome of the events was unknown. Information on the lot/ batch number has been requested.; Sender's Comments: The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

"Arm was a little sore; a little dizziness; This is a spontaneous report from a non-contactable consumer (sister). A female patient of an unspecified age received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration from Dec2020, at an unknown single dose for an unspecified immunization. The patient's medical history and concomitant medications were not reported. The patient works as an RN in (Place name), received the Pfizer vaccines (COVID-19 vaccine) on Saturday; she stated that her arm was a little sore and experienced a little dizziness ""but otherwise just fine"". Outcome of events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained."

I have good and bad side effects, first of all I have trouble, pain in my knees and today I relieved from much pain in knees,; Pain in the arm; Headache; Diarrhea; started with a feel and now it was more, it was a pain, it was like a crack in her abdominal; This is a spontaneous report from a contactable consumer (patient). A 52-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 17Dec2020 08:15 at single dose for COVID-19 immunization. The relevant medical history included thyroid disease and arthritis (have problem with her knees and they said it arthritis). Concomitant medications included vitamin c, vitamin d3 and vitamin e, all from an unspecified date for thyroid disease. The patient stated that first moment it was okay, not feeling much just the pain in the arm on 17Dec2020 and in the next day she had good and bad side effects, first of all she had trouble, pain in her knees on 18Dec2020 and at the time of the report she relieved much from pain in knees, they came back but that was okay. She had a little headache, not much on 17Dec2020. But at the time of the report like an hour prior to the report she started with diarrhea in Dec2020. Diarrhea was getting worse, it started with a feel and now it was more, it was a pain, it was like a crack in her abdominal, she had gone to the bathroom few minutes prior to the report and almost she felt like she had to go again. The patient did not ask the dose and stated that they were supposed to give her a one dose, it was her first dose, her second dose coming on 07Jan. The outcome of the event pain in the arm was unknown, for event arthralgia was recovering, while the other events were not recovered. Information about Lot/Batch number has been requested.

"Lost weight; Achiness; Tired; Headache; her daughter was tested positive for COVID/ she was around her daughter; Blurriness; I could hardly see; A little bit of vision changes; eyes, both days, yesterday they were swollen, 'puffy' and draining a little bit; eyes, both days, yesterday they were swollen, 'puffy' and draining a little bit; eyes, both days, yesterday they were swollen, 'puffy' and draining a little bit; Nauseous; This is a spontaneous report from a contactable Nurse (patient). A 54-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 17Dec2020 at single dose for COVID-19 immunization. The relevant medical history included blood cholesterol and sinus problem. Concomitant medications included pravastatin for cholesterol. The patient stated that she received the immunization on Thursday at the hospital that she worked at and Saturday and then at the time of the report her eyes, both days, yesterday they were swollen, 'puffy' and draining a little bit on 19Dec2020. Today they were too this morning. So, that got better than yesterday because she cold compresses on them. For the next shot, the patient stated that she was not so sure, it was within 21 days. An appointment was set-up, she just had to look. It was during work, so she was working. She went downstairs, she got the show. She sat there while they watch her for several hour, observation time and she got on her phone and scanned in something. Maybe appointment but she got to work. She didn't write it down. The patient stated that her daughter was tested positive for COVID on Monday. And they said her to get test it because she was around her daughter. And then they weren't so sure whether or not to give her the vaccine. But they said it was okay so they did. She was negative at that time. The patient stated Friday at work, she didn't feel anything because she was working around, almost 3:30 or 4 O' clock on Thursday. She was nauseous all day at work on 18Dec2020. And just the minor ones that they had. That was to be expected, the achiness, felt a little swollen, tired, headache. But she was okay to work. But then at the time of the report after her eyes been swollen yesterday. She got up to get ready for work but her eyes were like. At that time in the morning on 19Dec2020 she could hardly see out of them. But they were much better at the time of the report. The patient had this mask that was a gel pack. So, it was bit of like a cold compress. And put Vaseline and they told her to get another COVID test. The patient had some vision. Some blurriness and just a little bit of vision changes on 19Dec2020. That she had not noticed at the time of the report. So that was resolved she thought. The patient underwent lab test included COVID test on an unspecified date which showed negative; weight on an unspecified date which showed about 186 pounds (she lost weight, so she might be a little more, she just hadn't checked). Therapeutic measures were taken as a result of the events ""eyes, both days, yesterday they were swollen, 'puffy' and draining a little bit"". The outcome of the events ""eyes, both days, yesterday they were swollen, 'puffy' and draining a little bit"" was recovering, for the event ""Blurriness; I could hardly see; A little bit of vision changes"" was recovered on an unspecified date, the other events were unknown. Information on Lot /Batch Number has been requested."

"I was not feeling well and I actually was like feeling really sick; I was feeling really like weak; I was not feeling well and I actually was like feeling really sick; I was feeling really like weak; I was not feeling well and I actually was like feeling really sick; I was feeling really like weak; I had to throw up; I ended up falling on floor; Arm started hurting; I was getting like crampy; I had to throw up; I ended up falling on floor; This is a spontaneous report from a Contactable consumer. This consumer (patient) reported that the 59-year-old female patient received (BNT162B2), via an unspecified route of administration on

18Dec2020 (yesterday morning about 6:30) at single dose for covid-19 immunization. Medical history included Allergy and consumer stated, ""No, I take Zyrtec D for my allergies. But I have not taken any because I was feeling better from it. So, my doctor said you don't need to take it all the time, just take as you needed."" Concomitant medications included cetirizine hydrochloride/pseudoephedrine hydrochloride (ZYRTEC-D) for Allergy. The patient experienced ""I was not feeling well and I actually was like feeling really sick, I had to throw up, I was getting like crampy. And usually when I throw away I lie down but I didn't and I ended up falling on floor, I was feeling really like weak, Arm started hurting, I was getting like crampy"". No Investigation Assessment. Consumer stated, ""Actually I was just calling to report because I have taken the COVID shot, yesterday morning about 6:30 and I got some side effects from it. So, I was just calling, I guess it is just pamphlet and stuff."" Consumer stated, ""Yes I called off my work because I rescheduled my job today but I couldn't go because I was not feeling well and I actually was like feeling really sick. And I had to throw up. And then I was getting like crampy. And usually when I throw away I lie down but I didn't and I ended up falling on floor. So, I am okay but I didn't go to work because I was feeling really like weak."" Consumer stated, ""Actually they had it done it with the hospital. So, I didn't go to the doctor. They just had a, had to just go on the computer and go to that setup. And then I had an appointment yesterday at 6:30, that's when I got the shot taken at 6:30 in the morning. Consumer stated, ""What is that for? They gave me an envelope, I don't know they gave me a card too. Is that on that card? They schedule me my other appointment, I mean to get my other shot. When I have to get the other one I guess. I don't know why I can't find it. We found the card. It says dose COVID-19, it's Pfizer and then it's looks like E and then it's a J or a T, looks like a J or a T the way wrote it, we'll just go ET1685, I guess. Due date for next shot is 08Jan2021 at 9:15 am."" Consumer stated, ""That's the vaccine because I work around, I work in Intensive Care Unit. And it is pretty much second floor and in COVID unit. So, that's why I wanted to get it for my safety. Consumer stated, I did get them like 2 O' Clock this morning. My arm started hurting towards later in this evening and then I woke up and it didn't help me."" Consumer stated, ""No I feel better when I got up because I didn't go to work because I was a little not, you know weak and kind of. So, I called off my job because I don't want to be going over there and. Yeah I feel better, my stay close to bed because I fell."" No treatment was received. The outcome of the events was unknown. Information on the Batch/Lot number has been requested."

Hives around the injection site; This is a spontaneous report from a contactable consumer (patient). A 38-year-old male patient received the 1st dose of bnt162b2, Pfizer vaccine, lot number: EK5730, expiry date: Mar2021, via an unspecified route of administration in the right arm (deltoid) on 20Dec2020 11:10 at a single dose for COVID-19 immunization. Medical history included hypertension and diabetes mellitus. Concomitant medications included metformin since diabetic, aspirin [acetylsalicylic acid] on 20Dec2020, and ongoing zinc. The patient experienced hives around the injection site on 21Dec2020 05:30. The event was described as follows: after getting the vaccine, he woke up with hives around the injection site. It is itchy, crater-ish like. If you touch it is tough and it feels like one was bit by ants. This on the arm and head. It is bigger on the head. It is like huge bumps. He has been calling his HCP all morning, but has not heard anything back from the doctor. He is calling to see if there were any recommendations, ointments, or anything he can take. He mentioned he took Benadryl this morning for it. He went on to further explain when he woke up 5:30 am this morning he had a bunch of bumps that

were itchy, like ants or mosquitoes biting. They were pretty big. He has one on his collar bone. It is stiff and hard. The bumps are spreading towards the back of his back. He also has it on his left shoulder as well. He provided the hives as the same to worse. He added on his arm near the injection site is a lot worse compared to his forearm. Near the injection site it is also warm to touch. He stated this was typical symptom from what he read. He received the vaccine at 11:10 am. The patient is scheduled to get the second dose on 10Jan2021. The event did not require patient to visit the Emergency Room and the Physician Office. The reporter stated he has been trying to contact his physician to determine if his events are severe enough to go to the ER. He was informed that his doctor has been booked all day. He may have to go to the night clinic if does not get better. Outcome of the event was not recovered.

urticaria to bilateral upper extremity (BUE); This is a spontaneous report from a contactable nurse (patient). A 33-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE lot/batch number not provided), via an unspecified route of administration on 19Dec2020 21:00 at SINGLE DOSE for COVID-19 immunization at the hospital. Medical history included diabetes mellitus (DM), hypertension (HTN), depression, obesity, hyperlipidaemia (HLD), migraines, and degenerative disk disease (IDD). The patient also had allergies with sulfa, oyesters, and adhesives. Concomitant medication included insulin aspart (NOVOLOG), bupropion hydrochloride (WELLBUTRIN), metformin (METFORMIN), sumatriptan (SUMATRIPTAN), and losartan potassium (LOSAR) for unknown dates and indications. Prior to vaccination, the patient was not diagnosed with COVID-19 and had not been tested for COVID-19 since vaccination. On 19Dec2020 17:00, the patient experienced urticaria to bilateral upper extremity (BUE). The patient did not received any treatment for the event. The patient was recovering from the event. Information on the Lot/batch number has been requested.

Soreness in left upper arm; This is a spontaneous report from a non-contactable consumer. A 28-year-old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number and expiration date were not reported), via an unspecified route of administration on the left arm on 20Dec2020 at a single dose for covid-19 immunization. There were no medical history and concomitant medications. The patient had no known allergies to medications, food, or other products. The patient was not pregnant. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient was not diagnosed with COVID-19 prior to vaccination and had not been tested for COVID-19 since the vaccination. The patient experienced soreness in left upper arm starting several hours after administration on 20Dec2020. Soreness was worst the next morning. No treatment was received for the adverse event. However, the outcome of the event was recovering. The event was considered non-serious. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

lightheadedness for 2 hours after vaccine; Flushing and tongue numbness within 2-3 minutes of vaccine administration; Flushing and tongue numbness within 2-3 minutes of vaccine administration; This is a spontaneous report from a contactable Physician (patient) A 42-year-old female patient received,at hospital, the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) intramuscular on arm left on 17Dec2020 (reported as at 01:15 PM) at a single dose for COVID-19 immunization .Medical history prior history of allergies requiring allergy shots, GERD , GERD and Sulfa and environmental/food allergies , food allergy .Concomitant medication included ibuprofen and cetirizine hydrochloride (ZYRTEC). No

Covid prior vaccination and no covid test vaccination provided . On17Dec2020 at 01:15 PM , the patient experienced Flushing and tongue numbness within 2-3 minutes of vaccine administration and lightheadedness for 2 hours after vaccine.All events were reported as non-serious. Patient received treatment with Benadryl 25 mg PO (per oral).The outcome of the events was recovered in Dec2020. Information on the lot/batch number has been requested.

a few blisters near the injection site; Arm soreness; This is a spontaneous report from a contactable consumer. A 29-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 19Dec2020 at single dose for immunization. The patient medical history was not reported. The patient's concomitant medications were not reported. The patient experienced a few blisters near the injection site in addition to arm soreness on 20Dec2020. Outcome of events was unknown. information about lot/batch number has been requested.

Dizziness; Fatigue; got the injection his left arm was a little sore/Severe left arm pain, soreness, throbbing; intermittent kind of dyslexia; This is a spontaneous report from a contactable consumer (respiratory therapist - patient himself). A 52-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE lot/batch number EK5730) via an unspecified route of administration on the left arm on 17Dec2020 at SINGLE DOSE for COVID-19 immunization (also reported as vaccination). Ongoing medical history included type 2 diabetes mellitus since Dec2003, renal disorder (reported as kidney prevention) and blood cholesterol abnormal (cholesterol was not high, but because of Type II Diabetes his doctor wanted to keep it at bay). Ongoing concomitant medications included metformin (METFORMIN) since Jan2004 for type II Diabetes, lisinopril (LISINOPRIL) since May2020 for kidney prevention and atorvastatin (ATORVASTATIN) since May2020 for cholesterol. On 17Dec2020, the patient had first dose administered of BNT162B2. When he got the injection, his left arm was a little sore (like if he leaned against his left arm or rubbed it he would notice the soreness). About mid-morning on 20Dec2020, his left arm just started throbbing like he had just blocked a lacrosse ball shot, severe left arm pain, and soreness. He also had onset of dizziness and fatigue as well on 20Dec2020. He went on, did a heating pad and ibuprofen and all that stuff and all that went on. He found it odd because these events did not start until around like 3 days after the injection was administered though the paperwork showed that these kind of events are expected in the first couple of days after product administered. On 21Dec2020 when he woke up around 11:30am, the throbbing went away, he was not as dizzy as before but still super fatigued and tired (then further stated that maybe a little bit better because he does not have that constant pain constantly draining him). The patient also mentioned that he wondered if there was an intermittent kind of dyslexia that he has because he will transpose words and just last week learned how to spell received without having to tell himself 'i before e except after c'. He also mentioned that he was tested like 4 times for COVID-19 and was negative every time in 2020. The outcome of the event of dyslexia was unknown while recovering for the remaining events.

Tiredness throughout the day; slight lightheadedness; slight headache; This is a spontaneous report from a contactable pharmacist (reporting for himself). A 38-year-old male patient received the first dose of bnt162b2 (BNT162B2, lot number and expiry date were unknown), intramuscular on 21Dec2020 09:30 on the left arm at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. Prior to vaccination, the patient was not diagnosed with

COVID-19. Since the vaccination, the patient has not been tested for COVID-19. On 21Dec2020, the patient experienced tiredness throughout the day, slight lightheadedness and slight headache. There was no treatment that was received for the events. The events were considered non-serious. The most recent COVID-19 vaccine was administered in the hospital. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The outcome of the events was recovering. Information about Batch/Lot number has been requested.

Soreness in the arm more than any other vaccine in the past; This is a spontaneous report from a contactable Other Health Professional (patient). A 31-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) lot number: EJ1685, via an unspecified route of administration in the left arm, first dose on 19Dec2020 14:15 at a single dose for immunisation. The patient's medical history and concomitant medications were not reported. The patient is not pregnant. She had not had other vaccines within four weeks prior to vaccine and she had no other medications in 2 weeks. Adverse event reported was soreness in the arm more than any other vaccine in the past. The onset was on 20Dec2020 with outcome of recovered in Dec2020. She took an over the counter ADVIL. She did not have covid prior vaccination nor had she tested post vaccination. The event was reported as non-serious.

"Chills; I felt like I am getting a fever; like flu like symptoms; nausea and that is why my voice is like this; nausea and that is why my voice is like this; felt like fatigued and tired; Numbness; This is a spontaneous report received from a contactable consumer (patient). A 41-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK5730), via an unspecified route of administration, on 18Dec2020, at single dose, for COVID-19 immunization. Medical history included hypertension (also reported as borderline hypertension, which was before, and the patient got better). The patient reported exercising, he was heavier, but he is losing weight now. There were no concomitant medications. The patient reported, ""I got my COVID vaccine last Friday, that would be on the 18Dec2020. So I feel like I see the side effect of having it, (voice incomprehensible). The day that I got it, when I got back, on 18Dec2020, I felt like fatigued and tired. And then on Saturday (19Dec2020), which I was off, I felt a little better. But then, you know, I had a little numbness (Dec2020) but it disappeared. And then on Sunday, I went to work and last night (20Dec2020), I just woke up and I had chills and I felt like I am getting a fever, like flu like symptoms like nausea and that is why my voice is like this. Is it normal to feel after 3 days this side effect? I mean actually I was reading the paper that I got it because I need to, because I have work today, I need to inform my manager that I cannot go to work because I am feeling this side effect and I don't want him to think that you know."" The patient did not have lab work done and did not receive treatment for the events. The outcome of fatigue was recovering, numbness was recovered on an unspecified date in Dec2020, and the outcome of the remaining events was unknown."

"Woke up 2 days later with painful swelling under both eyes and pain around my chin. these are all areas, and the only areas that I have had dermal filler injections; Woke up 2 days later with painful swelling under both eyes and pain around my chin. these are all areas, and the only areas that I have had dermal filler injections; Woke up 2 days later with painful swelling under both eyes and pain around my chin. these are all areas, and the only areas that I have had dermal filler injections; This is a

spontaneous report from a contactable physician. A 45-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899), intramuscular on the left arm on 16Dec2020 10:45 at single dose for COVID-19 immunisation. Medical history included hypertension and dermal filler injections. Concomitant medication included losartan. The patient stated, ""woke up 2 days later with painful swelling under both eyes and pain around my chin. These are all areas, and the only areas that I have had dermal filler injections. I started steroids and pain and swelling resolved in 3 days"". The outcome of the events was recovered on Dec2020."

she was running a temperature of 100.3 degrees Fahrenheit/highest her temperature got up to last night was 101.9 degrees Fahrenheit; Left arm sore; Left arm was just a little swollen; A little swollen in her left underarm and armpit; Started getting hot and cold and hot and cold; Achy; Nauseous/Feeling like she was going to throw up; This is a spontaneous report from a contactable consumer (patient). A 50-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) lot number and expiration date were not reported, via an unspecified route of administration in the left arm, first dose on 19Dec2020 07:30 at a single dose for vaccination. Medical history included ongoing colitis ulcerative when she was 23 years old (1993), POTS (Postural Orthostatic Tachycardia Syndrome) from 2017 and ongoing, had thyroid problem, with heart medication. Concomitant medication included prednisone, levothyroxine sodium (SYNTHROID), irbesartan, bisoprolol fumarate, fluticasone and potassium. The patient stopped prednisone about 4-5 days before COVID-19 Vaccine administered. She talked to her doctor about prednisone use and getting COVID-19 Vaccine, doctor told her to go ahead and get COVID-19 Vaccine. The patient is a Certified Nursing Assistant who received the Pfizer COVID-19 Vaccine at her place of employment on 19Dec2020. This was her first dose of 2 dose series of the vaccine. She reported after she received the vaccine injection, she had onset of 'achy, nauseous, left arm sore, left arm was just a little swollen, a little swollen in her left underarm and armpit, she started getting hot and cold and hot and cold, feeling like she was going to throw up and was running a temperature. She added that at the night of 19Dec2020 she felt achy and a little nauseous but it was not bad so she took some TYLENOL and she was feeling fine. She stayed at work Saturday. Starting morning of 20Dec2020 she woke up and her left arm felt like she had gotten a tetanus shot, left arm was sore and just a little swollen and she was a little swollen in her left underarm and armpit; she felt achy all over again; so she took some more TYLENOL and went to work and was feeling fine until about lunch time on 20Dec2020. Around lunch time on 20Dec2020, she started getting hot and cold and hot and cold, feeling like she was going to throw up; by about 4:30pm on 20Dec2020 she was running a temperature of 100.3 degrees Fahrenheit. The highest her temperature got up to last night was 101.9 degrees Fahrenheit. She took a Tylenol PM to knock her out to sleep because she was achy. The outcome of the events achy, nauseous, left arm sore, left arm was just a little swollen, a little swollen in her left underarm and armpit, started getting hot and cold and hot and cold, feeling like she was going to throw up, and she was running a temperature of 100.3 degrees Fahrenheit/highest her temperature got up to last night was 101.9 degrees Fahrenheit was recovering. Information about Batch/Lot number has been requested.

headache; fever of 100/mild fever 99.5; fatigue; non productive cough; tested Covid 19 positive; tested Covid 19 positive; This is a spontaneous report from contactable consumer. A 23-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via unspecified route of administration on

unspecified date at single dose for COVID-19 immunization. Medical history and concomitant medications were not reported. It was reported that the patient was a 23 years old nurse and received the Covid 29 vaccine on Saturday morning. Sunday she developed a headache fever of 100 and fatigue. Monday she developed a non productive cough as well as mild fever 99.5, fatigue, and the headache was reduced. It was also reported that the patient was tested Covid 19 positive on 22Dec2020. The outcome of the events were unknown. Information on the lot/batch number has been requested.

Diarrhea; she could feel her stomach again; This is a spontaneous report from a contactable consumer. A 64-year-old female patient received the first dose of BNT162B2 (Pfizer-BioNTech COVID-19 mRNA Vaccine BNT162B2; lot number: EH9899), via an unspecified route of administration on 17Dec2020 at a single dose by injection once so she doesn't get COVID. The patient's medical history was not reported. There were no concomitant medications. The patient experienced diarrhea on 19Dec2020. The patient just thought about it, she had diarrhea, she had said everything is good, but she didn't think about it when answering the questions, when she eats the food, she notices, she got the COVID vaccine. She doesn't know how to change responses to the questions. She answered no to them, but this could be tied together. Every time she eats, she gets diarrhea. Patient got the COVID test. She wanted to change answers, but it wouldn't let her. Patient could feel her stomach again in Dec2019, but she hasn't eaten. This was the first time she received the vaccine. The outcome of the events was unknown.

mild rash around the injection site; This is a spontaneous report from a non-contactable consumer. A 50-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE lot/batch number not provided), via an unspecified route of administration in 2020 at SINGLE DOSE for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. In 2020 (five days after vaccination), the patient experienced mild rash around the injection site. Outcome of the event as unknown. Information about lot/batch number cannot be obtained. No further information is expected.

Rash/rash did have a pretty discreet or distinct area around the injection site; She says it was pretty red and you could tell the area was swollen at first, and it has faded; She says it was pretty red and you could tell the area was swollen at first, and it has faded; She says that the rash this morning has spread to her left chest wall and breast area, and she was looking at her body in other places and saw the reaction was on the rest of her body too/rash had maybe a little mild itch; injection site may bleed longer which was the only thing notable; This is a spontaneous report from a contactable physician (patient). A 28-year-old female patient received single dose of BNT162B2 (lot number: EK5730, exp date not reported), via an unspecified route of administration (one injection to left deltoid) on 18Dec2020 07:00 for primary prevention. Medical history included rare bleeding disorder from 2016, and seasonal allergies. She says she had no effects from it but knows of it from genetic testing. Patient did not receive any other vaccines at the same time as this one, or any other medications. Patient was a resident doctor at the hospital and was calling as consumer. She received her first dose of the Pfizer BioNTech COVID-19 vaccine on 18Dec2020 (Friday morning at 07:00AM). She had gotten sort of a whole body generalized rash which the morning of reporting was worse nearer the site and left chest wall area. She says she would like to see if this has happened to and been reported by others. The vaccine was offered by her employer to any staff who wanted to get it, and she was in phase one. She says that there wasn't a

specific provider who prescribed it. She has the card that they gave her following the injection and says that it doesn't have an expiration date on it, just the date given and the name of the clinic site. She says it just says Pfizer on this part, on the card. She says on the other form it says Pfizer BioNTech COVID-19 vaccine. She says that there was no dose information provided for the injection. Patient further reported that the rash did have a pretty discreet or distinct area around the injection site up through probably the day before reporting (onset date: Dec2020). It was pretty red, and you could tell the area was swollen at first, and it has faded. She says that the rash the morning of reporting had spread to her left chest wall and breast area, and she was looking at her body in other places and saw the reaction was on the rest of her body too. She says that the rash had maybe a little mild itch, she hadn't noticed if there was anything, just a mild itch, not significant. She didn't do any treatment for the rash specifically, she did take loratadine (CLARITIN) the morning of reporting, but not for that reason, as it was for seasonal allergies, not because of the rash. She provides potential LOT 9HE36498, and says there was no UPC, she got the loratadine and it could have been in original package as one of two, there was no bar code on the label. She provides a second potential LOT 61282ZYF3, and EXP May2021. She says she was told the injection site may bleed longer, due to rare bleeding disorder, which was the only thing notable. No investigation assessment performed. The patient recovered from site swollen on Dec2020. The outcome of other events was unknown.

Fever of 102.4; chills; full body muscle aches; fatigue; nausea; injection site pain; swollen lymph nodes; This is a spontaneous report from a contactable healthcare professional. A 21-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), Batch/lot number: ek5730, intramuscular in the left arm on 21Dec2020 08:45 at single dose for COVID-19 immunization. Medical history included COVID-19 diagnosed prior vaccination. The patient has no known allergies. The patient was not pregnant at the time of vaccination. The patient's concomitant medications were not reported. The patient experienced fever of 102.4, chills, full body muscle aches, fatigue, nausea, injection site pain, and swollen lymph nodes on 21Dec2020 at 19:00. No treatment was given for the events. The vaccine was administered at the hospital. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine and no other medications was received within 2 weeks of vaccination. Since the vaccination, the patient has not been tested for COVID-19. The outcome of the events was not recovered.

"Cold sensation down her right arm; Began ""seeing stars""; Metallic taste in her mouth; This is a spontaneous report from a contactable pharmacist. A 40-year-old female patient received the first dose of bnt162b2 (Pfizer Biontech COVID 19 vaccine), Lot number: EJ1685, intramuscular at the right arm on 21Dec2020 09:00 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient was not pregnant at the time of vaccination. On 21Dec2020 09:00, the patient experienced cold sensation down her right arm, began ""seeing stars"", followed by a metallic taste in her mouth. The patient was not hospitalized for the events but required emergency room/department or urgent care visit. The patient did not receive any treatment for the events. The events were reported as non-serious. The vaccine was administered in a workplace clinic. It was unknown if the patient has received any other vaccines within 4 weeks prior to the COVID

vaccine. Prior to the vaccination the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. The outcome of the events was unknown."

Severe ear and eye pain; Severe ear and eye pain; This is a spontaneous report received from a contactable nurse. A 51-year-old female patient received her first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiry date not reported), intramuscular in left arm, on 21Dec2020 15:15, at single dose, for COVID-19 immunization. Medical history included hypertension, depression, and known allergies to eggs, latex, nuts and codeine. The patient is not pregnant. Concomitant medication included aspirin (ASPIRIN), ascorbic acid (VITAMIN-C), hydrochlorothiazide, lisinopril (ZESTORETIC), venlafaxine and zinc. The patient previously took codeine and experienced allergy. The patient experienced severe ear and eye pain on 21Dec2020 at 18:30. It was also reported that the patient did not receive any vaccines within 4 weeks prior to BNT162B2. The patient was not diagnosed with COVID-19 prior to vaccination. The patient has not been tested for COVID-19 since vaccination. Treatment included ibuprofen and rest. The outcome of the events was recovering. Information on the Batch/Lot number has been requested.

was up and down all night; Nausea; so out of breath/was having some shortness of breath; feeling bad; low grade fever, with the highest temperature being 99.8 degrees; Abdominal cramping; pooped in her pants/did another poo right after/a little more diarrhea; This is a spontaneous report from two contactable nurses (patient and daughter). A 65-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number EH9899, expiry date unknown) intramuscular at right deltoid on 17Dec2020 (10:30) at single dose for COVID-19 immunization. The patient did not have any other vaccines on the same day as receiving the COVID vaccine. Medical history was none. The patient's concomitant medications were not reported. The patient on this past Thursday (17Dec2020), around 10:30 AM, the caller had her COVID vaccine. The patient informed that she lives 20 minutes (address), and on the way home after getting the vaccine that morning, the patient started having abdominal cramping (17Dec2020 17:15) like she needed to go to the bathroom. Due to construction and traffic, she was unable to stop to use the bathroom anywhere and by the time she got home, she had pooped in her pants and when she got inside the house and looked, it looked like a cow patty. The patient got the bathroom and did another poo right after that. The patient that night, she had a little more diarrhea, but then she was okay on Friday and went to work. The patient informed that on Saturday (19Dec2020), after lunch, she started feeling bad and was having diarrhea again, but it was sporadic. The patient informed that yesterday (21Dec2020) afternoon, she got diarrhea again. The patient informed that last night (20Dec2020) she was up and down all night, and also had associated nausea and a low grade fever, with the highest temperature being 99.8 degrees. The patient's daughter informed that the low grade fever started Saturday (19Dec2020) and was on Saturday and Sunday evenings, but daughter informed that the patient has not had fever this morning so far. The patient did not go to work today (21Dec2020). The patient informed that over the weekend (20Dec2020), she had gotten a ham into her daughter's (nurse too) refrigerator, and the daughter asked the patient why she was so out of breath. The patient informed that she was having some shortness of breath as well. The patient would say it was not ongoing but she also was still in bed at this time so she was unsure. The reporter informed that the patient was not specifically prescribed the vaccine, but was given the

product as part of a hospital policy. The patient did provide her Primary Care's name and phone number but did not have address or email address to provide at this time. The outcome of the events abdominal cramping was recovering, pooped in her pants/did another poo right after/a little more diarrhea and Nausea was not recovered, feeling bad, was up and down all night, so out of breath/was having some shortness of breath was unknown, low grade fever, with the highest temperature being 99.8 degrees was recovered on Dec2020.

sore throat before she got the shot, but it made it worse; sore throat before she got the shot, but it made it worse; Body aches; She couldn't swallow; This is a spontaneous report from a non-contactable consumer (patient's coworker). A female patient of an unspecified age received bnt162b2 (BNT162B2, lot no. and expiry date were not reported), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient medical history included sore throat. The patient's concomitant medications were not reported. The patient got the shot on Tuesday and on Thursday (unspecified date) she got sore throat and body aches. She gargled with salt water and drank tea and felt better the next day. It was clarified that the patient had the sore throat before she got the shot, but it made it worse. She said she couldn't swallow. The outcome of the events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

she felt a little more local soreness than she did with the regular seasonal influenza shot; This is a spontaneous report from a non-contactable consumer (patient's husband). A female patient in her mid 30s received her first BNT162B2 (Pfizer-BioNTech COVID-19 mRNA vaccine), via an unspecified route of administration on 20Dec2020 at a single dose for COVID-19 immunization. The patient's medical history was not reported. The patient's concomitant medications were not reported. The patient noted that she felt a little more local soreness than she did with the regular seasonal influenza shot on an unknown date in Dec2020. The outcome of the event was unknown. No follow-up attempts are possible, information about lot/batch cannot be obtained. No further information is expected.

"hot flash; itchy throat; This is a spontaneous report from a non-contactable pharmacist. A female patient of an unspecified age received first dose of BNT162B2 (COVID-19 mRNA Vaccine BNT162B2), via an unspecified route of administration on an unspecified date at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced a ""hot flash"" 5 minutes after COVID-19 vaccination and then ""itchy throat"" 30 minutes after vaccination on an unspecified date. They would liked to know if patient should receive the second dose. She is otherwise fine with all symptoms resolved and never had respiratory distress of any kind. The outcome of the events was recovered on an unknown date. No follow-up attempts are possible; information about lot/batch number cannot be obtained."

she felt dizzy; This is a spontaneous report from a contactable Nurse (patient). A 50-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), on unknown date via unknown route of administration at unknown dose for unknown indication. Medical history and concomitant medications were not reported. Patient received the COVID vaccine. Later in the day she felt dizzy. The outcome of the event was unknown. Information on the lot/batch number has been requested.

"Pain in upper two shoulders and neck/upper body joint pain, both sides; Generalized weakness; Pain in upper two shoulders and neck; This is a spontaneous report from a contactable physician reporting for herself. This 63-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (lot/batch number not provided) on the morning of 20Dec2020, intramuscularly in the left arm at a single dose, for COVID-19 immunization. The patient's medical history included arthritis, esophagitis and esophageal ulcer, from unspecified date and unspecified if ongoing. The patient's concomitant medications were not reported. On 20Dec2020, the patient (physician) called to report two side effects: pain in upper two shoulders and neck, generalized weakness. She developed an upper body joint pain, both sides. She got the injection on the left but both her shoulders had joint pain and weakness. She did not receive treatment for the events. She had the COVID test on 19Dec2020 or 18Dec2020 (reported as ""yesterday"" and ""2 days ago"") but the results were not back as of 20Dec2020. The outcome of the events was unknown. The reporter assessed the events as related to the vaccine. Information on the lot/batch number has been requested."

Facial swelling; Low grade fever around a 100; Got my eye supposedly my eye lids like little swelling and they looks like they are bruised and they itch like crazy; Got my eye supposedly my eye lids like little swelling and they looks like they are bruised and they itch like crazy; I have swelling in both of my eyes; It is getting pretty bad actually, it has got worse; This is a spontaneous report from a contactable nurse (reporting for herself). A 41-year-old female patient received bnt162b2 (BNT162B2 also reported as Covid vaccine by Pfizer, lot EJ1685), via an unspecified route of administration on 17Dec2020 at single dose for immunisation. Medical history included depression and anxiety. The patient's concomitant medications were not reported. The patient got the COVID vaccine on Thursday of last week (17Dec2020) and had low grade fever around a 100. On Friday (18Dec2020) she started getting little bit of facial swelling not a whole bunch. After the weekend, her eye lids had little swelling and they look like they were bruised and they itch like crazy. She does not have any drainage like conjunctivitis or anything like that but it looks like she have swelling in both of my eyes and that doesn't happens to her. She does not have any but was probably going in today because it was getting pretty bad actually, it has got worse. The outcome of events was not recovered.

Headache- lasted 12 hours; 24hrs after injection Tachycardia at rest (hr 106); chest pain; flushing/feeling very warm; flushing/feeling very warm; elevated BP 136/96; This is a spontaneous report from a contactable Nurse reporting for himself. A 52-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899), intramuscular on 17Dec2020 10:45 AM at single dose for covid-19 immunization. Vaccine location was Right arm and it was the first dose. The COVID-19 vaccine was administered at Hospital. Medical history included mild coronary artery disease (CAD), Migraine, Psoriasis, and allergy to Sulfa Medications. Concomitant medication included atorvastatin (LIPITOR), finasteride, cetirizine hydrochloride (ZYRTEC]), aspirin, melatonin, biotin, zinc, ergocalciferol (VIT D), ascorbic acid (VIT C), ubidecarenone (COQ10), fremanezumab (AJOVY), and adalimumab (HUMIRA). The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient experienced headache- lasted 12 hours, 24hrs after injection tachycardia at rest (heart rate (HR) 106), chest pain, flushing/feeling very warm, elevated blood pressure (BP) 136/96 on 18Dec2020 10:30. Symptoms lasted for about 2 hours. No treatment received for the events. Prior to vaccination,

the patient was not diagnosed with COVID-19 and since the vaccination, the patient was not been tested for COVID-19. The outcome of the event headache was recovered on 18Dec2020 22:30 (lasted 12 hours), the outcome of the other events tachycardia at rest (heart rate (HR) 106), chest pain, flushing/feeling very warm, elevated blood pressure (BP) 136/96 was recovered on 18Dec2020 (lasted about 2 hours).

Severe rigors and fevers; Severe rigors and fevers; other vaccine same date product; other vaccine same date product; This is a spontaneous report from a contactable physician (patient). An adult male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration in arm left on 21Dec2020 08:00 at single dose for COVID-19 immunisation. Facility where the most recent COVID-19 vaccine was administered was hospital. Medical history included covid (if Covid prior vaccination: Yes/Prior to vaccination, was the patient diagnosed with COVID-19?: Yes). No allergies to medications, food, or other products. Concomitant medications the patient received within 2 weeks of vaccination included gabapentin (NEURONTIN), ibuprofen (MOTRIN), other vaccine same date product=Pfizer, other vaccine same date vaccine location was left arm. The patient experienced severe rigors and fevers on 22Dec2020 02:00. The patient not received any other vaccines within 4 weeks prior to the COVID vaccine. Since the vaccination, the patient has not been tested for COVID-19. Therapeutic measures were taken as a result of severe rigors and fevers (Tylenol). This case was non-serious. The outcome of events severe rigors and fevers was not recovered. The outcome of other events was unknown. Information on the lot/batch number has been requested.

I had severe body rigors/Chills; I threw up; I had a 101.8 fever; I was pretty much out all day yesterday, like I was out sleeping with a fever; pretty much out; This is a spontaneous report from a contactable Nurse. A 59-year-old female patient started to receive first dose of BNT162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot/batch number: EJ1685, Expiry Date: 31Mar2021) intramuscular on 19Dec2020 at 0.3 mL, single for covid-19 immunization from her work. Patient history was reported as no. The patient didn't have really anything. Concomitant medication included paracetamol (TYLENOL), the patient had been taking some Tylenol. The patient had a vaccination Saturday morning on 19Dec2020 and had a very bad reaction during the night. The patient had severe body rigors and chills. She threw up. She had a 101.8 fever. She was pretty much out all day yesterday, like was out sleeping with a fever. Investigation assessment was no. The patient just would like to know if she can get the second injection. Outcome of the events was unknown. The events were considered as related by the reporter via global introspection (Method of assessment).

anaphylactic reaction; This is a spontaneous report from a contactable physician via a sales representative. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot/batch number and expiration date not provided), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced an anaphylactic reaction 8 hours after receiving the Covid-19 vaccine. The outcome of the event was unknown. Information about Batch/Lot number has been requested.; Sender's Comments: Based on the compatible temporal association and the drug's known safety profile, the Company considers the anaphylactic reaction is possibly related to BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE)

vaccination. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

"Runny nose; Headache; Joint pain I guess kind of, small moderate pain; Really bad sore throat; This is a spontaneous report from a contactable consumer (patient). A 31-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number EKS730), intramuscular on 17Dec2020 at single dose for COVID-19 immunization at hospital. The patient's medical history included seasonal allergy (Seasonal allergies he guess, that's it). Concomitant medications were not reported. The patient previously took cetirizine hydrochloride (ZYRTEC) from an unspecified date to Sep2020, not currently, he had not been taken it since summer but he had not currently taken it, he have stopped taking it, three months before the vaccine. The patient was a paramedic (further not clarified) and received the vaccination at a hospital, not a pharmacy. Patient guessed that they vaccinated there whole front line staff. The patient got the vaccine on Thursday (17Dec2020), Pfizer vaccine, Covid 19 vaccine and he was just having side effects mostly sore throat, he was having a really bad sore throat and he was expecting. He knew they said fever, chills, headache, joint pain was normal and things like that they are normal. But he just wasn't sure of this sore throat part of it and was also wondering if he was able to take like, anything to help with the symptoms. He also had other symptoms, on 20Dec2020 (started yesterday by the time of reporting), he experienced runny nose, headache, ""joint pain he guessed kind of, small moderate pain"" and really bad sore throat. As a treatment to the events, he took DayQuil on 20Dec2020 and was not sure what that dosage was. The events were quite persisting, which started yesterday. The patient had general lab work of Cholesterol on date that he didn't remember and did not know the result of it. The outcome of the events was not recovered."

Pain at injection site; Tachycardia like 120 heart rate; Dizziness; Fatigue; Fever; Stressing; Threw up; This is a spontaneous report from a contactable Other healthcare professional (Nurse Practitioner, also the patient). A 32-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, lot number: EK5730), intramuscularly on 20Dec2020 at single dose on right deltoid for COVID-19 immunization. Medical history reported as none. There were no concomitant medications. The patient experienced tachycardia, dizziness, fatigue, fever, stressing, threw up on an unspecified date in Dec2020, and pain at injection site on 20Dec2020. The patient received Covid vaccine yesterday on 20Dec2020 and he woke up and he threw up twice and he have fever 102 and tachycardia like 120 heart rate and some dizziness and he took some Tylenol (taken as treatment) and just drinking water. Feeling a little better right now. Tylenol was taken this morning as a treatment for fever of 102. For Causality, consumer stated, he believed so, because like he hasn't been around, he obviously worked around people who were sick, but he was fully gown and fully PPE. He was fine until this morning. Last night the only symptom he was having was pain at injection site which was expected. Of course, he can expect a low grade fever or maybe just some fatigue, he thought he was just stressing, he had fever went to 102 and he developed tachycardia and dizziness which was getting better after medicine and drinking fluid.

Therapeutic measures were taken as a result of tachycardia, dizziness, fever. The outcome of the events tachycardia, dizziness, fever was recovering, the outcome of the other events was unknown.

Left arm soreness, myalagias and low grade temp 100.5 the morning after the dose.; Left arm soreness, myalagias and low grade temp 100.5 the morning after the dose.; Left arm soreness, myalagias and low grade temp 100.5 the morning after the dose.; This is a spontaneous report from a contactable physician (patient). A 44-year-old female patient received the first single dose of BNT162B2 (Lot number: EH9899, exp date not reported), intramuscular (Anatomical Location: Arm Left) on 21Dec2020 13:45 for immunization. The COVID-19 vaccine was administered at the hospital. The patient was diagnosed with COVID-19 prior to vaccination. The patient had no known drug allergies (NKDA). The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. There were no other medications the patient received within 2 weeks of vaccination. The patient experienced left arm soreness, myalagias and low grade temp 100.5 the morning after the doses (22Dec2020, 04:30 AM). Treatment received for the adverse events included paracetamol (TYLENOL) and naproxen (ALLEVE). The event was considered as non-serious by the reporter. Since the vaccination, the patient had not been tested for COVID-19. The outcome of the events was not recovered.

""""sweaty feeling""; Developed headache; flushing after injection; redness; This is a spontaneous report from a contactable nurse. A 24-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number=EJ1685), intramuscularly on left arm at 12:00 PM on 21Dec2020 at single dose for COVID-19 immunization. Medical history included exercise-induced asthma. The patient's concomitant medications were not reported. The patient experienced headache, redness and flushing after injection, also reported ""sweaty feeling"" at 12:15 PM on 21Dec2020. Ae resulted in: Emergency room/department or urgent care. All events were reported as non-serious. The outcome of events was unknown."

Soreness at injection site; Soreness at injection site The night of vaccine being given, noted fever, chills, malaise, and fatigue. Resolved next morning.; Soreness at injection site The night of vaccine being given, noted fever, chills, malaise, and fatigue. Resolved next morning.; Soreness at injection site The night of vaccine being given, noted fever, chills, malaise, and fatigue. Resolved next morning.; Soreness at injection site The night of vaccine being given, noted fever, chills, malaise, and fatigue. Resolved next morning.; This is a spontaneous report from a non-contactable Physician. A 25-years-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number:9899), intramuscularly on 21Dec2020 12:00 PM at left arm, single dose for covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced fever, chills, malaise, and fatigue from 21Dec2020 16:00. Resolved next morning on 22Dec2020. No treatment was received for the adverse event. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. No seriousness criteria: no Results in death, no Life threatening, no Caused/prolonged hospitalization, no Disabling/Incapacitating, no Congenital anomaly/birth defect. No follow-up attempts are possible. No further information is expected.

Moderate left arm pain, radiating into upper back; Moderate left arm pain; This is a spontaneous report from a non-contactable nurse (patient). A 36-year-old male patient received first dose BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EH9899), via an unspecified route of administration at left arm on 21Dec2020 10:45 at single dose for covid-19 immunization at hospital. Medical history included allergy to penicillin (PCN). Concomitant medication included fish oil, cetirizine hydrochloride (ZYRTEC), fluticasone propionate within 2 weeks of vaccination. The patient experienced moderate left arm pain, radiating into upper back on day 2 (22Dec2020), the adverse event start time was 21Dec2020 08:00 PM. No treatment received for the adverse event. No COVID prior vaccination, no COVID tested post vaccination. The event outcome was not recovered. The was not reported as a serious report. No follow-up attempts are possible. No further information is expected.

Mild soreness left arm at injection site for 1 day, no redness or swelling; This is a spontaneous report from a contactable other healthcare professional (patient). A 56-year-old male patient received the first dose of bnt162b2 (Pfizer Biontech COVID 19 vaccine), Lot number: EH9899, intramuscular in the left arm on 18Dec2020 14:15 at a single dose for COVID-19 immunization. Medical history included Psoriatic Arthritis, HTN, HLD and known allergies: Sulfa. Concomitant medication included losartan and gabapentin. On 18Dec2020 14:15, the patient experienced mild soreness left arm at injection site for 1 day, no redness or swelling. The patient was not hospitalized for the event and did not receive any treatment for the event. The event was reported as non-serious. The vaccine was administered in a hospital. The patient has not received any other vaccines within 4 weeks prior to the COVID vaccine. Since the vaccination, the patient has not been tested for COVID-19. The event recovered on an unspecified date in Dec2020.

Headache; Soreness; Exhaustion; This is a spontaneous report from a contactable healthcare professional. A 45-years-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899), via an unspecified route of administration at the right arm on 21Dec2020 08:15 at a single dose for COVID-19 immunization at a hospital. Medical history included breast cancer, blood pressure abnormal, blood cholesterol abnormal. Concomitant medication included hydrochlorothiazide (HCTZ) and unspecified medications for blood pressure, cholesterol. The patient experienced headache, soreness, and exhaustion on 21Dec2020, 10:15. with no treatment The patient was recovering from the events.

started getting severe abdominal cramping; This lead to diarrhea, nausea with vomiting; This lead to diarrhea, nausea with vomiting; This lead to diarrhea, nausea with vomiting; Afterwards, was feeling tired, but ok.; This is a spontaneous report from a contactable Pharmacist reported for herself. A 51-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EJ1685), intramuscular on 21Dec2020 15:45 at single dose for covid-19 immunization. Vaccine location was Arm Right and it was the first dose. The COVID-19 vaccine was administered at Hospital. Medical history included Hypertension, asthma, obesity and Seasonal allergies - mold/dust etc.. Concomitant medications included losartan, indapamide, omeprazole, montelukast. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. About 9pm on 21Dec2020, the patient started getting severe abdominal cramping. This lead to diarrhea, nausea with vomiting. This lasted about 60-90 minutes of not being able to leave the restroom. Afterwards, she was feeling tired, but ok. No lingering

effects this morning (22Dec2020). No treatment was received for the adverse events. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, the patient was not been tested for COVID-19. The outcome of the events was recovered on 22Dec2020.

Fever, nausea/covid test result= Positive; Fever, nausea/covid test result= Positive; This is a spontaneous report from a contactable nurse (patient). A 24-year-old female (no pregnant) patient received first dose bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot/batch number and expiry date were not provided), via an unspecified route of administration in arm Left on 17Dec2020 02:30 at single dose for COVID-19 immunisation. Facility where the most recent COVID-19 vaccine was administered was hospital. The patient's medical history and concomitant medications were not reported. Prior to vaccination, the patient was not diagnosed with COVID-19. The patient experienced fever, nausea on 20Dec2020 12:00. Since the vaccination, has the patient been tested for COVID-19. The patient underwent lab tests and procedures which included PCR: positive on 21Dec2020, POCT: positive on 21Dec2020, Nasal Swab: positive on 21Dec2020. (reported as '[{covid test type post vaccination= Nasal Swab, covid test name post vaccination= PCR, covid test date= 21Dec2020, covid test result= Positive}, {covid test date= 21Dec2020, covid test type post vaccination= Nasal Swab, covid test name post vaccination= POCT, covid test result= Positive}]'). No treatment received for the adverse event. The patient not received any other vaccines within 4 weeks prior to the COVID vaccine. The outcome of events was not recovered. Information on the Batch/Lot number has been requested.; Sender's Comments: Based on the information currently available, a lack of efficacy with BNT162B2 in this patient might not be completely excluded.

Fever 99.9f, arm soreness, malaise; Fever 99.9f, arm soreness, malaise; Fever 99.9f, arm soreness, malaise; This is a spontaneous report from a contactable nurse (patient). A 32-year-old female patient (not pregnant) received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899), Intramuscularly on 21Dec2020 11:45 AM in left arm at single dose for COVID-19 immunization. The COVID-19 vaccine was administered at hospital. Medical history included COVID prior vaccination. Concomitant medication in two weeks included minerals nos, vitamins nos (PRENATAL VITAMINS), probiotics, levothyroxine. It was unknown if the patient received any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. The patient experienced fever 99.9f, arm soreness, malaise on 22Dec2020 04:00 AM. The patient received paracetamol (TYLENOL) as treatment. The outcome of events was unknown.

Arm soreness for 48 hour; Fatigue; muscle aches; chills; This is a spontaneous report from a contactable physician (patient). A 62-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number:20201216-830), via an unspecified route of administration on 16Dec2020 15:00 at arm left at single dose for covid-19 immunization. The COVID-19 vaccine was administered at Hospital. No other vaccine in four weeks. Medical history included hypothyroidism and hyperlipidaemia. The patient had no known allergies. Concomitant medication included levothyroxine, atorvastatin, ergocalciferol (Vitamin D) for an unspecified indication. The patient experienced arm soreness for 48 hour then fatigue, muscle aches and chills on 3rd and 4th days after vaccination on 19Dec2020 at 08:00 AM. No treatment was received for the event. Prior to vaccination, the patient was

not diagnosed with COVID-19 and since the vaccination, the patient was not been tested for COVID-19. Outcome of the event was recovered.

muscle aches; Chills; This is a spontaneous report from a contactable other health professional (reported for himself). A 56-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number not provided) (Pfizer EH 9899), intramuscularly on 21Dec2020 10:30 at single dose on right arm for COVID-19 immunization. Medical history included hypertension (HTN) and No known drug allergies (NKDA). The patient's concomitant medications were not reported. The most recent COVID-19 vaccine was administered at Hospital. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient experienced chills and muscle aches on 22Dec2020 02:30. The events were non-serious and no treatment received per the reporter. The outcome of the events was recovered on 22Dec2020. Information on the Batch/Lot number has been requested.

Arm pain; This is a spontaneous report from a contactable other health care professional. A 38-year-old female patient received bnt162b2 (BNT162B2; lot number: EJ1685), via an unspecified route of administration on 22Dec2020 09:15 in left arm for COVID-19 immunization. Medical history included allergic rhinitis. Concomitant medication included oseltamivir phosphate (TAMIFLU), meloxicam (MOBIC). The patient previously took dexilant and experienced drug hypersensitivity. No COVID prior vaccination. The patient has not been tested for COVID-19 post vaccination. On 22Dec2020 09:30, the patient experienced arm pain. The event was assessed as non-serious. The outcome of the event was recovering.

Neck also sore muscles; Neck also sore muscles; nausea; very bad HA, almost migraine; This is a spontaneous report from a contactable nurse (patient). A 45-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number=EL0140), intramuscularly on left arm at 05:30 AM on 21Dec2020 at single dose for COVID-19 immunization. Medical history reported as none. There were no concomitant medications (No other-vaccine-in-four weeks, no other-medications-in-two weeks). 21 hours post injection (02:45 AM) on 22Dec2020, the patient experienced very bad HA (headache), almost migraine. Then added nausea. HA was bad for 3 hours, then slowly better. Neck also sore muscles. All events were reported as non-serious. Excedrine and advil taken intermittently. Slept/rested in dark for 8 hours. Prior to vaccination, it was unknown if the patient was diagnosed with COVID-19. Since the vaccination, the patient had been tested for COVID-19. The outcome of events was recovering.

PVCs developed about 20 mins after administration of vaccine; This is a spontaneous report from a contactable Pharmacist. A 35-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, batch/ lot number: EL0140), intramuscularly on 21Dec2020 13:45 at right arm, at SINGLE DOSE for covid-19 immunization. Medical history included ongoing chronic back pain. Concomitant medication included escitalopram oxalate (LEXAPRO), amfetamine aspartate, amfetamine sulfate, dexamfetamine saccharate, dexamfetamine sulfate (ADDERALL). The patient was not pregnant at the time of vaccination. The patient experienced PVCs about 20 mins after administration of vaccine. Placed on Zoll cardiac monitor on 21Dec2020. Vitals to include BP, heart rate, respiratory, pulse ox

several times during additional monitoring period. No respiratory distress or other issues during this monitoring period. No treatment was received for the adverse event. It was unknown if the patient was diagnosed with COVID-19 prior to vaccination. Since the vaccination, the patient had not been tested for COVID-19. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The outcome of the event was recovered in Dec2020.No seriousness criteria: no Results in death, no Life threatening, no Caused/prolonged hospitalization, no Disabling/Incapacitating, no Congenital anomaly/birth defect.

feeling hot and diaphoretic; diaphoretic/ sweaty; massive headache; sleep 13 hours; swollen face; joint pain; chills; start wheezing with a dry cough; start wheezing with a dry cough; 101.8 fever/ mild fever 99.6; swelling in my lymph nodes happened immediately/ swelling; some chest tightness; hard to breathe it was like breathing through a straw; Unable to go to work; uncomfortable; Never shown allergic reaction to vaccines before this; This is a spontaneous report from a contactable other Health Professional (Patient). A 26-years-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 17Dec2020 08:00 at single dose for covid-19 immunization in hospital. Medical history included polycystic ovary syndrome (PCOS) and possibly rheumatoid arthritis. No Known Drug Allergies. Concomitant medications in two weeks included birth control and iron supplements. The patient got the vaccine at 8:00 am on 17Dec2020 Thursday and experienced swelling in her lymph nodes happened immediately and some chest tightness. It was never hard to breathe it was like breathing through a straw. At 10:00 am hits and she got joint pain, chills, start wheezing with a dry cough and a 101.8 fever. Unable to go to work. She sleep and wake up 18Dec2020 Friday with a mild fever 99.6 and some chest tightness/swollen Lymphnodes but nothing else. On 19Dec2020 Saturday she took antihistamines to see if that would help her swelling and go to bed. The patient wake up with a swollen face which was a new reaction to this medicine I've taken before. Chest tightness was gone/ lympnodes still swollen. On 20Dec2020 Sunday she sleep 13 hours. On 21Dec2020 Monday happened and she awake to feeling hot and diaphoretic. She drank water and remove clothes/blankets go back to sleep. Wake up still sweaty with a massive headache but no fever. Lymphnodes still swollen and uncomfortable currently. Never shown allergic reaction to vaccines before this. No COVID prior vaccination, no COVID tested post vaccination. Therapeutic measures were taken as a result of swelling in lymph nodes and included antihistamines, no treatment received for the other adverse event. The outcome of the event fever was recovered in Dec2020; of the event sweaty was not recovered; of unable to work, swollen face, headache, sleep 13 hours, uncomfortable, shown allergic reaction was unknown; of the other events was recovered/resolved with sequel. The seriousness was reported as no. The information on the batch number has been requested.

Pink eye,eye drainage; Pink eye,eye drainage; Chills; Muscle Aches; This is a spontaneous report from a contactable nurse reported for herself. A 50-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: Ek5230), intramuscular on 17Dec2020 16:00 at single dose for covid-19 immunization. Vaccine location was at Right arm and it was the first dose number. The COVID-19 vaccine was administered at Workplace clinic. The patient's medical history was not reported. Concomitant medications included fluoxetine hydrochloride (PROZAC), atorvastatin, buspirone hydrochloride (BUSPAR). The patient did not receive any other vaccines within 4 weeks prior to the

COVID vaccine. Patient's known allergies included Erythromycin. The patient experienced Chills, Muscle Aches, pink eye, eye drainage on 21Dec2020 19:00. Adverse event result in Doctor or other healthcare professional office/clinic visit. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, the patient was not been tested for COVID-19. The outcome of the events was unknown.

I experienced slight heaviness and then a tingling parasthesia in the feet that traveled up to my knees. I stayed for one hour, it began to feel like a cold sensation. I was able to walk and did not f; I experienced slight heaviness and then a tingling parasthesia in the feet that traveled up to my knees. I stayed for one hour, it began to feel like a cold sensation. I was able to walk and did not f; I experienced slight heaviness and then a tingling parasthesia in the feet that traveled up to my knees. I stayed for one hour, it began to feel like a cold sensation. I was able to walk and did not f; anxiety; This is a spontaneous report from a contactable nurse (patient). A 32-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (lot number EK5730), intramuscularly on 15Dec2020 07:45 at single dose for covid-19 immunization. Vaccine location was left arm and it was the first dose. None medical history. No known allergies. Patient was not diagnosed with COVID-19 prior to vaccination nor tested for COVID-19 since the vaccination. There were no concomitant medications. The patient didn't receive any other vaccines within 4 weeks prior to the COVID vaccine nor received any other medications within 2 weeks of vaccination. At 22Dec2020 07:45 am, the patient experienced slight heaviness and then a tingling parasthesia in the feet that traveled up to her knees. She stayed for one hour, it began to feel like a cold sensation. She was able to walk and did not feel dizzy and left work. The patient reported them to the MD who said it could be a coincidence and anxiety. Patient didn't receive any treatment for the adverse events. The action taken in response to the events for BNT162B2 was not applicable. The outcome of events was unknown. The events were non-serious.

had a sudden lightheadedness/a bit lightheaded; slurred speech; extreme sleepiness; feeling like was under anesthesia and unable to move the legs; unable to move the legs; Blood pressure dropped to 80/60mmHg and pulse was at 50; Blood pressure dropped to 80/60mmHg and pulse was at 50; This is a spontaneous report from a contactable pharmacist. A patient of unspecified age and gender received a dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization in their facility. The patient's medical history and concomitant medications were not reported. It was reported that patient (doctor) in their facility received the vaccine and had a sudden lightheadedness, slurred speech and extreme sleepiness. Feeling like was under anesthesia and unable to move the legs. Blood pressure dropped to 80/60 mmHg and pulse was at 50. The episode lasted 2h and then became alert but a bit lightheaded and was normal next day. The outcome of the events was recovered. Information on the lot/batch number has been requested.

migraine; Vomiting; low grade fever and headache; headache; chills; light sensitivity; This is a spontaneous report from a contactable Nurse (patient). A 54-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK5730), via an unspecified route of administration on 18Dec2020 around 07:45 at single dose for COVID-19 immunization. Anatomical location of administration provided as left upper arm; deltoid. Medical history included migraines

(Hasn't had one in a while). There were no concomitant medications. There were no prior vaccinations within 4 weeks. The patient previously took FLU VACCINE and had a low grade fever. The patient experienced low grade fever and chills on 19Dec2020, Headache with Light sensitivity: Woke up in the night with the headache after going to bed on Saturday, 19Dec2020. The patient has been vomiting off and on since Sunday, 20Dec2020. Caller stated she got the vaccine on Friday the 18Dec2020 and now has a low grade fever and headache and asked if she can take Tylenol or Ibuprofen for her symptoms. She also asked if she is allowed to take these before her next dose. Caller asked since she was experiencing symptoms with first dose is it likely she will experience them for second dose or it would be worse. Specifically, it was reported that late Saturday, the patient started running a fever and chills between 4PM and 5PM on 19Dec2020. She knew it was a potential side effect and minor. Got a headache since then and with light sensitivity. She wasn't sure what she could do to break it. Turned into a migraine on an unspecified date and has had vomiting. Vomiting occurs with her migraines, but hasn't had a migraine in a long time. The patient wasn't sure if she could take Ibuprofen or Tylenol with the vaccine. The light fever and chills is listed on the potential side effects she received. She can't focus with the headache she has. Called in to work. The patient knew COVID Vaccine could cause headaches. Think the headache started and ballooned into a migraine. Has been vomiting off and on since Sunday, 20Dec2020. Thinks the vomiting is from the headache and not the vaccine. Not due for next dose of COVID Vaccine until 08Jan2021. Wants to know if she is likely to experience the same symptoms with the second dose. Or if the symptoms will worsen. The outcome of the events was unknown. The seriousness provided as between not serious and medically significant. The causality assessment for events fever and chills, headache with light sensitivity with suspect vaccine provided as Related by Primary Source Reporter via Method of assessment Global Introspection.

Joint pain and swelling 3 days after the first dose. Affected joints: right elbow, right wrist and right third interdigital joint; Joint pain and swelling 3 days after the first dose. Affected joints: right elbow, right wrist and right third interdigital joint; This is a spontaneous report from a contactable consumer (patient). A 60-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number=EK5730), via an unspecified route of administration on left arm on 17Dec2020 at single dose for COVID-19 immunization. Medical history included wasp venom with anaphylaxis. There were no concomitant medications (No other-vaccine-in-four weeks, no other-medications-in-two weeks). The patient previously Stage 4 breast cancer in remission on Xeloda. The patient experienced joint pain and swelling 3 days after the first dose. Affected joints: right elbow, right wrist and right third interdigital joint on 20Dec2020. All events were reported as non-serious. The patient did not receive treatment for the adverse events. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. The outcome of events was not recovered.

dizziness/lightheadedness; severe nausea; rash/hives on chest and back and forearms; rash/hives on chest and back and forearms; severe chills/shivering; This is a spontaneous report from a contactable nurse (patient). A 28-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), intramuscularly on 18Dec2020 11:30 AM at Left arm, at SINGLE DOSE for covid-19 immunization. The patient's medical history and concomitant medications were not reported. The

patient was not pregnant at the time of vaccination. The patient experienced dizziness, lightheadedness, severe nausea, rash/hives on chest and back and forearms, severe chills/shivering on 18Dec2020 11:45 AM. The patient received treatment fluids, pepcid, Benadryl for these events. There events resulted in: Emergency room. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The outcome of the events was recovered in Dec2020. No seriousness criteria: no Results in death, no Life threatening, no Caused/prolonged hospitalization, no Disabling/Incapacitating, no Congenital anomaly/birth defect. Information on the lot/batch number has been requested.

maculo-papular rash on neck and trunk with itchy skin; maculo-papular rash on neck and trunk with itchy skin; This is a spontaneous report from a contactable physician reported for herself. A 52-years-old female patient received first dose BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EH9899), via an unspecified route of administration at left arm on 18Dec2020 20:00 at single dose for covid-19 immunzation at workplace clinic. Medical history included seasonal and dust allergies, allergies to medications doxycycline and erythromycin. Concomitant medication included acetaminophen and ibuprofen. The patient experienced maculo-papular rash on neck and trunk with itchy skin on 19Dec2020 10:00 with outcome of recovered in Dec2020. No treatment received for the adverse events. No COVID prior vaccination, no COVID tested post vaccination. The was seriousness was reported as no.

reports getting the vaccine on Friday and then tested positive for for covid infection on the following Monday; reports getting the vaccine on Friday and then tested positive for for covid infection on the following Monday; This is a spontaneous report from a contactable other healthcare professional (HCP) reported for herself. A 60-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 18Dec2020 (Friday) at single dose for covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient got the vaccine on Friday (18Dec2020) and then tested positive for covid infection on the following Monday (21Dec2020). She asked if this would interfere with getting the second dose and if she should or could get the second dose of the covid vaccine after testing positive for covid infection. The outcome of the events was unknown. Information about lot/batch number has been requested.; Sender's Comments: Based on the current available information and the consistency with the known safety profile of the suspect product BNT162B2, a possible contributory role of the suspect product to the development of Drug ineffective and COVID-19 cannot be excluded. The case will be reassessed if additional information becomes available.

Patient felt lethargic and lightheaded (starting 18Dec, more significant 19Dec-20Dec) post-vaccine administration; Patient felt lethargic and lightheaded (starting 18Dec, more significant 19Dec-20Dec) post-vaccine administration; This is a spontaneous report from a non-contactable pharmacist. A 52-year-old male patient received first dose bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EK5730), intramuscular on 17Dec2020 14:30 at single dose for COVID-19 immunisation. Facility where the most recent COVID-19 vaccine was administered was hospital. The patient medical history was not reported. Concomitant medications the patient received within 2 weeks of vaccination included budesonide (PULMICORT), cetirizine hydrochloride (ZYRTEC). The patient experienced 'Patient felt

lethargic and lightheaded (starting 18Dec, more significant 19Dec-20Dec) post-vaccine administration' on 18Dec2020. It was unknown if the patient received any other vaccines within 4 weeks prior to the COVID vaccine. It was reported unknown whether treatment received for the adverse event. The case was non-serious. The outcome of the events was reported as unknown. No follow-up attempts are possible. No further information is expected.

Dry mouth and throat; Dry mouth and throat; This is a spontaneous report from a contactable nurse (patient). A 24-year-old female patient (not pregnant) received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number: EJ1685), via an unspecified route of administration on 22Dec2020 08:15 in left arm at single dose for COVID-19 immunization. The patient medical history was not reported. Concomitant medication in two weeks included venlafaxine, famotidine. There was no other vaccine in four weeks. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. Facility type vaccine was hospital. The patient experienced dry mouth and throat on 22Dec2020 at time of 08:30 AM. No treatment received for the adverse event. The outcome of event was recovering. No follow-up attempts are possible. No further information is expected.

itching skin; injection site immediately red and hot; injection site immediately red and hot; could not locate hives or welts; This is a spontaneous report from a contactable pharmacist. A 36-year-old female patient (pregnant at the time of vaccination) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK5730), intramuscularly on 21Dec2020 13:15 at single dose on left arm for COVID-19 immunization. Medical history included anaphylactic reaction to food, Anaphylaxis to sesame and lidocaine, had never had anaphylactic reaction to vaccines in past. The patient's concomitant medications were not reported. The most recent COVID-19 vaccine was administered at Hospital. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. On 21Dec2020 13:15 (01:15 PM), the patient experienced itching skin, could not locate hives or welts, injection site immediately red and hot, no wheezing observed, no tachycardia observed. Treatment included observed for an hour, ice pack on injection site x2, 50mg diphenhydramine hydrochloride (BENADRYL), 1 10mg cetirizine hydrochloride (ZYRTEC), 20mg famotidine (PEPCID). Advised to pre-medication prior to booster dose and alert vaccinator of this reaction to be prepared. The events were non-serious. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient hadn't been tested for COVID-19. The outcome of the events was recovered in Dec2020.

"congestion; throat hurts, she has a sore throat; a sore arm where it was administered. It is not swollen or red but hurts to the touch; diarrhea and has gotten a little worse since starting/having to get up and go to the bathroom often; uncomfortable; This is a spontaneous report from a contactable consumer (patient). A 25-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (lot number unknown because the patient was sent a picture of the paper provided for vaccine administration but it did not include any product details), via an unspecified route of administration at arm on 21Dec2020 at single dose for COVID-19 immunization at hospital. The patient's medical history included seasonal allergy, she had no allergies other than season allergies. She had no reactions to any vaccines previously. Prior Vaccinations within 4 weeks was reported as none, and no events following prior vaccinations. Concomitant medications included unspecified medication for birth control daily and

has been on this for a couple months. No additional vaccines administered on same date of the Pfizer suspect. The patient is a medical assistant, an employee at a hospital. She received the vaccine at work yesterday (21Dec2020) around 10 or 10:30 and she was having side effects. She had contacted her employer but wanted to know if it is ok to go to work or should she stay home and treat the symptoms. Afterward she experienced diarrhea which started last night and has gotten a little worse since starting. She also has congestion and her throat hurts, she has a sore throat, that started this morning, on 22Dec2020. There had been no treatment for above symptoms. After getting the shot she had a sore arm where it was administered. It is not swollen or red but hurts to the touch. This started 30 minutes after administration and she had to take pain medication. It was worse on 22Dec2020 (today). She did not require a visit to the doctor at the point when reporting, it was just uncomfortable having to get up and go to the bathroom often. No emergency room or physician visit due to the event. No relevant tests. The outcome of the event ""uncomfortable"" was unknown, and for the rest of events was not recovered. Information on the lot/batch number has been requested."

Increased heart rate; Increased heart rate and blood pressure; Feeling hot; Cold fingers; This is a spontaneous report from a contactable nurse (patient). A 48-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE lot/batch number EH9899), intramuscular on the left arm on 22Dec2020 08:00 at SINGLE DOSE as COVID-19 immunization at the workplace clinic. The patient had no medical history and no allergies to medications, food, or other products. The patient previously had COVID-19 test on 24Aug2020 and showed negative. Concomitant medication included levothyroxine (LEVOTHYROXINE). On 22Dec2020 08:00, the patient experienced increased heart rate and blood pressure, feeling hot and cold. Since the vaccination, the patient had been tested for COVID-19 in Dec2020 with unknown results. The patient did not receive any treatments for the events. The patient was recovering from the events.

tingling in hands and feet; This is a spontaneous report from a non-contactable other healthcare professional. A 48-year-old female patient receives first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: HE9899), intramuscularly on 18Dec2020 12:45 at single dose for immunization. vaccine location provided as Right arm. Medical history included fibromyalgia, rheumatoid arthritis. The patient's concomitant medications were not reported. No history of vaccine or medication reaction previously. During her 15-minute waiting period after the injection, the patient began to experience tingling in hands and feet on 18Dec2020. She denied rash, hives, difficulty breathing, difficulty swallowing, wheezing, throat tightness, hoarseness, lightheadedness, dizziness and tongue swelling This provider was notified of patient reaction and she was then assessed in the emergency bay area. Review of Systems included: Constitutional: Negative for chills and fatigue. HENT: Negative for congestion, facial swelling, rhinorrhea, sinus pain, sneezing, sore throat and trouble swallowing. Respiratory: Negative for cough and shortness of breath. Musculoskeletal: Negative for back pain, myalgias and neck stiffness. Skin: Negative for rash. Neurological: Tingling in hands and feet bilaterally. The outcome of the event was unknown. All events reported as non-serious. No follow-up attempts are possible. No further information is expected.

"Feeling under the weather; Nausea; Headache; Muscle ache; This is a spontaneous report from a contactable other healthcare professional (HCP), who is also the patient. This 63-year-old female patient

received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Lot number EL0140) via an unspecified route of administration on 19Dec2020 at single dose for COVID-19 immunisation. Relevant medical history included hypertension (hypertensive for years and takes medication for that), muscle aches (she got muscle aches once in a while) and headaches (she got some headaches from wearing a mask). Concomitant medications included unspecified drugs for hypertension. On 21Dec2020, the patient experienced nausea; in Dec2020 she experienced headache and muscle ache and on 22Dec2020 she experienced feeling under the weather. The patient specified that she has had light symptoms of nausea, headache, and muscle ache. Nausea was the most prevalent symptom. She said she got some headaches from wearing a mask, and the headaches she has experienced since receiving the COVID-19 Vaccine could be related to her mask wearing, and not the vaccine. She said she was at the age where muscle aches are not uncommon, and she got muscle aches once in a while, so she was unsure if her muscle aches were from receiving the COVID-19 Vaccine. She further specified that the she had a little nausea, saying the nausea was not very noticeable. The nausea was a little heavier at the time of the report, and she had some toast and some things to help settle her stomach. She said she was feeling ""blah."" She clarified she was feeling under the weather, like she just wanted to get in bed and sleep. The patient reported that the symptoms she was experiencing could be stress, and she just wanted to get the rapid COVID test to make sure she doesn't have the virus. She would take the rapid test as a requirement for travel. Treatment: the patient took 2 Extra Strength Tylenol 500mg (Lot Number: SHA086, and Expiration Date: Jun2024). The patient had not recovered from nausea and feeling unwell; the outcome of the headache and muscle ache was unknown."

"Day after vaccine, developed itchiness; Then I began breaking out in hives throughout my body; Also suffered from bouts of nausea and have trouble keeping things down; This is a spontaneous report from a contactable other HCP (patient) . This 24-year-old female patient received,at hospital, the first dose of BNT162B2 (also reported as Pfizer-BioNTech COVID-19) intramuscular on arm left on 20Dec2020 (reported as at 02:30 PM) at a single dose for COVID-19 immunization.No Allergies to medications, food, or other products; No other Medical history Concomitant medication Omeprazole, Terbinafine. No Covid prior vaccination and no covid test vaccination provided . Day after vaccine, on 21Dec2020 at 12:00 PM, the patient developed itchiness. Then she reported ""I began breaking out in hives throughout my body. Also suffered from bouts of nausea and have trouble keeping things down"". The adverse events resulted in Doctor or other healthcare professional office/clinic visit. The patient was tretated with Steroid shot and was prescribed with medication for nausea.All events were reproted as non serious.The outcome of the events was recovering at the time of the report. Information about lot/batch number has been requested."

Bloody nose; Blood in urine (slight tinged); This is a spontaneous report from a contactable pharmacist. A 48-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), lot number: EK5730, first dose via intramuscular in left arm on 17Dec2020 10:30 at single dose for COVID-19 immunisation. Medical history was reported as none. Concomitant medication included atorvastatin (LIPITOR) and estradiol (ESTROGEN). On 18Dec2020 07:00 AM, the patient experienced bloody nose and blood in urine this morning (slight tinge) and has not exhibited any other side effects at the time of this report. Noted in afternoon on 18Dec2020, the patient urinated and no blood present. It was unknown if

patient received treatment for the events. It was unknown if patient had COVID and tested COVID prior vaccination. The patient had no known allergies. The case was reported as non serious as it did not resulted in death, not life threatening, no prolonged hospitalization, not disabling/Incapacitating and no congenital anomaly/birth defect. The outcome of the events was unknown.

Headache fever 100.0 body aches fatigue nausea; Headache fever 100.0 body aches fatigue nausea; Headache fever 100.0 body aches fatigue nausea; Headache fever 100.0 body aches fatigue nausea; Headache fever 100.0 body aches fatigue nausea; This is a spontaneous report from a contactable nurse reported that a 46-year-old female patient received bnt162b2 (BNT162B2 also reported as Covid 19 vaccine), intramuscular in the right arm on 17Dec2020 12:00 at single dose for immunisation. It was in the hospital where the most recent COVID-19 vaccine was administered. Medical history included Hep B chronic carrier. She had no other vaccine/ medications in four weeks, no covid tested post vaccination, no known allergies. The patient's concomitant medications were not reported. The patient experienced headache, fever 100.0, body aches, fatigue and nausea on 20Dec2020. No treatment was given. The outcome of events was recovered on unknown date in Dec2020. Information on the Lot/Batch has been requested.

Feeling tiredness/unwell; Feeling tiredness/unwell; Arm pain/soreness at injection site (expected); Arm pain/soreness at injection site (expected); This is a spontaneous report from a contactable nurse, who is also the patient. A 31-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration in the left arm on 21Dec2020 at 10:30 at single dose for COVID-19 immunisation. Vaccination facility type was hospital. The patient had no relevant medical history. Concomitant medications were not reported. On 22Dec2020, the patient experienced feeling tiredness/unwell and arm pain/soreness at injection site (expected). The patient did not receive corrective treatments. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination she has not been tested for COVID-19. The outcome of the events was unknown. The information on the lot/batch number has been requested.

Headache; Nausea; Ear ache; Injection site pain that started 7 hours after injection and has continued to now; This is a spontaneous report from a contactable nurse (patient herself). A 26-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on right arm on 21Dec2020 at 10:45 AM at single dose for COVID-19 immunization. The patient medical history was not reported. Concomitant medication included vitamin D3 and progesterone, both listed as other medications the patient received within 2 weeks of vaccination. The patient experienced injection site pain that started 7 hours (onset on 22Dec2020 at 17:45 AM) after injection and has continued to now. Pain was lessening as time went on. Tylenol had helped. Headache, nausea and ear ache all started this morning on 22Dec2020 at 07:00 AM. Headache was continuous; nausea and ear ache were intermittent. The patient did not receive any treatment for these events. All events were reported as non-serious. The outcome of event vaccination site pain was recovering. The outcome of rest events was not recovered. Information on the lot/batch number has been requested.

dizziness; tachycardia; fatigue; This is a spontaneous report from a contactable other health professional (patient). A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19

VACCINE), via an unspecified route of administration on an unspecified date at SINGLE DOSE for covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced reported dizziness, tachycardia, and fatigue after taking the COVID vaccine on an unspecified date. The patient's symptoms didn't seem severe. Information on the lot/batch number has been requested.

Redness of skin, especially on face; itching of head and arms; some swelling in feet; This is a spontaneous report from a contactable nurse (patient). A 58-year-old non-pregnant female patient received first dose of BNT162B2 (Pfizer-BioNTech COVID-19 mRNA vaccine, lot number: EH9899), intramuscular at arm left on 21Dec2020 at 12:30 at a single dose for COVID-19 immunization. The patient received COVID-19 vaccine in a hospital facility. The patient has allergies to medications, food, or other products. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. The patient is receiving unspecified concomitant medications within 2 weeks of vaccination. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. On 21Dec2020 at 01:00 PM, the patient experienced redness of skin, especially on face, itching of head and arms, some swelling in feet. The patient received Benadryl 50 mg PO as treatment. The outcome of the events was recovering.

Nauseous; I got a really strong headache; Really intense headache right no/ headache was on her left side of her head; something weird going on with right eye/ very blurry for like 3 minutes/ really blurred up/ blurriness was the right corner of her right eye; This is a spontaneous report from a contactable consumer (patient). A 57-years-old female patient started to receive BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 18Dec2020 at single dose for COVID-19 immunization. The patient medical history and concomitant medications were not reported. On Saturday 19Dec2020, the patient had something weird going on with her right eye. It was very blurry for like 3 minutes, she kind of let it go. But she got a headache afterwards on 19Dec2020. And it happened again at night, same night around 10 o' clock. Not on 20Dec2020, but 21Dec2020, she just got it really blurred up again and she got a really strong headache. But the headache was on her left side of her head whereas the blurriness was the right corner of her right eye. And she just came on very hard headache and she was just very nauseous on an unspecified date. The patient just was in a really intense, she didn't know why she was having such trouble. She just had a little trouble. The patient just wanted to know if this was something normal to get a bad headache like this. The headache outcome was not recovered, of the other evens was unknown. The information on the batch number has been requested.

body aches; fever; This is a spontaneous report from a contactable Other Healthcare Professional (HCP, an x-ray tech who is the patient). A male patient of unknown age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, on 21Dec2020 (reported as ''yesterday'') at single dose for COVID-19 immunisation. Medical history included he had coronavirus in May2020, treated with plasma infusion, and still had detectable antibodies in his system based on lab test administered last month. Concomitant medications were unknown. On 21Dec2020, the patient received the vaccine and has had body aches and a fever. He wanted to know if this was expected after being vaccinated. The reporter asked if there are precautions in patients getting the vaccine who have had

coronavirus previously and been treated with plasma infusions. Outcome was unknown. Information on the Lot/Batch number has been requested.

general malaise; Ringing in both ears; headache; dizziness; nausea; This is a spontaneous report from a contactable Nurse (patient). This 62-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot # EH9899), intramuscular, on 18Dec2020 07:30 AM at single dose for COVID-19 immunisation. Vaccine location was left arm. The patient was vaccinated at hospital, age at vaccination was 62-years-old. No other vaccine was received in four weeks. Medical history included hyperlipidemia, Coronary artery disease (CAD), Barrett's Esophagus. Concomitant medications included unspecified medications the patient received within two weeks of vaccination. On 18Dec2002 at 02:00 PM, the patient experienced ringing in both ears, headache, dizziness, nausea, general malaise, started 5 hours after injection, it still continues 4 days post injection, all reported as non-serious. The adverse event resulted in Doctor or other healthcare professional office/clinic visit. No treatment was received for the events. Outcome of the events was not recovered.

Chills; Muscle aches and pain; joints hurt (her body aching); Muscle aches and pain; joints hurt (her body aching); Muscle aches and pain; joints hurt (her body aching); She has a headache; Sleeping the whole morning. She didn't get up; Doesn't want to eat; Fever; Temperature of 100.4; Doesn't feel good; Little soreness at injection site; This is a spontaneous report from a contactable nurse (patient). A 52-year-old female patient started to received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE lot/batch number not provided), via an unspecified route of administration on the right arm on 21Dec2020 15:00 at SINGLE DOSE as COVID-19 vaccination at the hospital. It was reported that the patient had COVID-19 in May2020 (until 2020). Then had COVID-19 test again in Jul2020 and still tested positive. The patient did have COVID-19 test last week (Dec2020) and it was negative. The patient also had the flu shot every year as immunization and never has a side effect. The patient was also on unspecified supplement. On 21Dec2020 at 15:00, the patient received COVID-19 vaccine. Around 20:00-21:00 (8-9 o'clock), she felt nothing and perfectly fine. Didn't feel anything until 23:00-24:00 (11-12 o'clock), she felt injection site hurting and started to have fever up to 100.4. She doesn't feel good. She was also was afraid to touch the injection site hard or rub it. On 22Dec2020 (that morning), she has chills, muscle aches and pains, and her joints were hurting (her body aching). The patient also had headache this morning and was sleeping the whole morning. She didn't get up. The patient also doesn't want to eat but was drinking water. The patient wanted to know if other people reported side effects like she has. She mentioned that she had 2-3 coworkers, but these coworkers did not have symptoms after COVID-19 vaccination. Outcome of the events were unknown. Information on the Lot/batch number has been requested.

developed congestion in nose; joint aches; This is a spontaneous report from a contactable physician (patient). A male patient of an unspecified age received BNT162B2 (Pfizer-BIONTECH Covid-19 Vaccine), via an unspecified route of administration on 18Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. On an unspecified date in Dec2020, within the next 18 hours, the patient developed congestion in nose, over the next 72 hours the patient developed joint aches and the symptoms have lasted for 96 hours. The outcome of events was unknown.

feeling dizzy/dizziness; tachycardic/tachycardia; This is a spontaneous report from a non-contactable Nurse. A female patient of an unspecified age received bnt162b2 (BNT162B2) vaccine , via an unspecified route of administration on 22Dec2020 at single dose for covid-19 immunisation . The patient medical history was not reported. There were no concomitant medications. After receiving the vaccine on 22Dec2020, after 15 minutes of sitting and waiting, the patient started feeling dizzy and tachycardic which lasted for 1 minute and 30 seconds, then it subsided. No follow-up attempts are possible. Information about lot/batch number cannot be obtained.

Nausea and Headache 1.5-2 hours administration; Nausea and Headache 1.5-2 hours administration; This is a spontaneous report from a contactable other healthcare professional (HCP) reported for herself. A 31-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL0140), via an unspecified route of administration on 22Dec2020 11:30 at single dose for covid-19 immunization. Vaccine location was Left arm and it was the first dose. The COVID-19 vaccine was administered at Nursing Home/Senior Living Facility. Medical history included hypertension (HTN), bipolar disorder, Known allergies included PCN and cefixime (BIOXIN). Concomitant medications included metoprolol, celecoxib (CELEXA), and Multivitamin one a day. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient experienced nausea and headache 1.5-2 hours administration on 22Dec2020 13:00. No treatment received for the events. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, the patient was not been tested for COVID-19. The outcome of the events was unknown.

"Headache only; This is a spontaneous report from a contactable healthcare professional. A 61-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, lot number: EK5730 and expiry date not reported), intramuscular on the right arm on 22Dec2020 07:30 at single dose for COVID-19 immunisation. Medical history included diabetes mellitus (reported as ""diabetic""), gastrooesophageal reflux disease (GERD), and neuropathy peripheral. Concomitant medications included tramadol, alprazolam, cyclobenzaprine, celecoxib, losartan, ropinirole, oxybutynin, gabapentin, metformin hydrochloride (METFORMIN ER), pantoprazole, cetirizine, hydrochlorothiazide, calcium, magnesium, and iron. The patient previously took erythromycin and experienced drug allergy. The patient experienced headache only on 22Dec2020 10:00. Clinical outcome of the event was recovering."

Fever 102, shakes, chills, headache and nausea; Fever 102, shakes, chills, headache and nausea; Fever 102, shakes, chills, headache and nausea; Fever 102, shakes, chills, headache and nausea; Fever 102, shakes, chills, headache and nausea; This is a spontaneous report from a contactable Nurse reporting for herself. A 55-years-old female patient received bnt162b2 (BNT162B2; Lot # EJ1685) vaccine , via an unspecified route of administration in the left arm on 18Dec2020 09:15 at single dose for covid-19 immunisation . Medical history included , coeliac disease from an unknown date and hypertension from an unknown date. Concomitant medication included progesterone (PROGESTERONE), nebivolol hydrochloride (BYSTOLIC), vitamin d3 (VITAMIN D3). The patient previously took codeine and experienced drug hypersensitivity. The patient experienced fever 102¦F, shakes, chills, headache and nausea on 18Dec2020 19:15 with outcome of recovered.

Fatigue beginning the night of the vaccine into early morning. Severe fatigue inability to get out of bed in the morning.; This is a spontaneous report from a contactable Nurse. A 25-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot # EL0140) on 21Dec2020 at 10:00 via intramuscular on left arm for COVID-19 immunization. The patient hd no relevant history. Concomitant medications included unspecified vitamins. The patient reported fatigue beginning the night of the vaccine (about 11:45) into early morning, described as severe fatigue inability to get out of bed in the morning. The patient was recovering from the event.

her throat hurts; She reported that her mouth is raw.; her chest is a little heavy/feels like a chest cold is coming on in her chest; She has a little bit more of a cough; severe joint; achiness; felt a little bit tired, but reported that she has felt increasingly tired and out of it/more fatigue; got possibly exposed to covid from a patient who tested positive after getting random swabbed; like all of her lymph nodes are swollen; she felt like she was getting the flu; the throat pain is throwing her though; The throat pain is up to her ears; She stated her mouth is a little red.; This is a spontaneous report from a contactable nurse, who is also the patient. This 56-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number EK5730; expiration date 01Mar2021) intramuscular in the left deltoid on 19Dec2020 at 15:00 at 0.3 mL single for COVID-19 immunisation. Vaccination facility type was hospital. Relevant medical history included hypertension, breast cancer, obesity, high cholesterol and ex-tobacco user (former, quit over 10 years ago). Concomitant medications included atorvastatin calcium (LIPITOR), amlodipine, losartan and ubidecarenone (CO Q10). The patient got possibly exposed to COVID from a patient who tested positive after getting random swabbed in Dec2020 with outcome of unknown; she also experienced felt a little bit tired, but reported that she has felt increasingly tired and out of it/more fatigue on 20Dec2020 with outcome of not recovered, severe joint (arthralgia) on 21Dec2020 with outcome of not recovered, achiness on 21Dec2020 with outcome of not recovered, her throat hurts on 22Dec2020 with outcome of not recovered, like all of her lymph nodes were swollen on Dec2020 with outcome of unknown, she reported that her mouth was raw on 22Dec2020 with outcome of not recovered, she has a little bit more of a cough on 21Dec2020 with outcome of not recovered, her chest was a little heavy/feels like a chest cold was coming on in her chest on 22Dec2020 with outcome of not recovered, she felt like she was getting the flu on Dec2020 with outcome of unknown, the throat pain was throwing her though on Dec2020 with outcome of unknown, the throat pain was up to her ears on Dec2020 with outcome of unknown and she stated her mouth was a little red on Dec2020 with outcome of unknown. She said that the vaccine was administered on Saturday 19Dec2020. She was at work the next day and felt a little bit tired, but reported that she has felt increasingly tired and out of it. On Monday, she felt very tired and took it easy. She said that she woke up with no fever, but had severe joint and achiness, more fatigue, and her throat hurts, like all of her lymph nodes are swollen. She reported that her mouth was raw. She had a little bit more of a cough and said that her chest was a little heavy. She did not feel like herself. Just spoke to a colleague and one of the people she was working with tested positive for COVID. She was working with her on Sunday 20Dec2020. Caller said that she received the vaccine at the hospital. She was able to work, but felt disconnected and tired. She said that she slept great the night before. Attributed the way she was feeling to the shot or maybe working. She said that she felt like she was getting the flu. She felt like she was hit by a bus. She said that the throat pain was throwing her though. It was throat pain right side. The throat pain was up to her ears. She said

that she was taking 1 gram Tylenol every 6 hours with a lot of water. She stated her mouth was a little red. She said that it was like a thrushy feeling like when you take antibiotics. It was that kind of sensation. She said that she almost felt like a chest cold was coming on in her chest. She had no shortness of breath, just an awareness when you get a chest cold. She used to get bronchitis all of the time. She said that she was speaking to a friend from work and a girl that she works with tested positive on a random swab for COVID-19. Caller said that the girl was asymptomatic and she did not receive the vaccine.

vertigo; dizziness; nausea; This is a spontaneous report from a contactable physician. A 41-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), intramuscular, on 21Dec2020 at 10:00 AM at single dose for COVID-19 immunisation. Vaccine location was left arm. The patient was vaccinated at hospital, age at vaccination was 41-years-old. Medical history and concomitant medications were unknown. On 22Dec2020 at 12:30 PM, the patient experienced abrupt onset vertigo, dizziness nausea - self resolved but then second wave of similar symptoms also self resolved. Th events were reported as non-serious. No treatment was received for the events. Information on the lot/batch number has been requested.

Headache over the front of the head; This is a spontaneous report from a contactable unspecified healthcare professional reporting for herself. This 60-year-old female patient received on 22Dec2020 11:15 first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot EH9899) at single dose intramuscular in the right arm for COVID-19 immunization. Medical history and concomitant medications were not reported. She denied any history of previous adverse reactions to vaccines. On 22Dec2020, during her 15 minutes waiting period after the injection, the patient began to experience headache over the front of the head. The event required an emergency room visit. Outcome was unknown. Neurogical examination was positive on an unknown date. No follow-up attempts are possible. No further information is expected.

Headache; This is a spontaneous report from a contactable nurse. A 38-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, lot number: EK5730), via an unspecified route of administration the right arm on 22Dec2020 12:30 at a single dose for COVID-19 immunisation. Medical history was not reported. Concomitant medications included amfetamine aspartate, amfetamine sulfate, dexamfetamine saccharate, dexamfetamine sulfate (ADDERALL). The patient experienced headache on 22Dec2020 14:30. No therapeutic measure was taken as a result of the event. Clinical outcome of the event was recovered on an unspecified date.

slight nasal congestion; This is a spontaneous report from a contactable other healthcare professional (patient). A 53-year-old male patient received 1st dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot# EJI685), intramuscularly in left arm on 22Dec2020 13:45 at single dose for Covid-19 immunisation. The patient's medical history and concomitant medications were not reported. No Covid prior vaccination. No Covid tested post vaccination. No known allergies. The patient experienced slight nasal congestion (non-serious) on 22Dec2020 14:30 with outcome of recovering. No treatment received for the event.

Fever of approx 101 F; body chills; injection site pain; This is a spontaneous report from a contactable unspecified healthcare professional reporting for himself. This 45-year-old male patient received on 21Dec2020 13:00 first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) at single dose in the left arm for COVID-19 immunization. Medical history included allergies to penicillin and sulfa drugs and hypertension. Prior to vaccination, the patient was diagnosed with COVID 19. Concomitant medications were not reported. On 22Dec2020 03:00 am, the patient had fever of approximately 101 F, body chills, injection site pain. No treatment was provided. Outcome was not recovered. Information on the batch number has been requested.

headache; pain in arm; dizziness; This is a spontaneous report from a contactable consumer. A female patient (wife) of unknown age received on 21Dec2020 11:15 BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) at single dose for COVID-19 immunization. Medical history and concomitant medications were not reported. In Dec2020, she reported headache, pain in arm and dizziness. Outcome was unknown. Information on the batch number has been requested.

Severe crushing headache in bilateral temporal lobes; Severe fatigue day after; This is a spontaneous report from a contactable nurse which is also the patient. A 36-year-old non-pregnant female patient received 1st dose of bnt162b2, intramuscular in the left arm on 18Dec2020 12:00 at a single dose for COVID-19 immunization at the hospital. Medical history included polycystic ovaries (PCOS), anxiety, depression and attention deficit hyperactivity disorder (ADHD). The patient has no known allergies. Concomitant medications included amfetamine aspartate, amfetamine sulfate, dexamfetamine saccharate, dexamfetamine sulfate (ADDERALL), bupropion hydrochloride (WELLBUTRIN), and escitalopram oxalate (LEXAPRO). It was reported that the morning after vaccine, 19Dec2020 08:00, the patient awoke with severe crushing headache in bilateral temporal lobes that resolved in a couple hours with acetaminophen (TYLENOL) and rest. The patient also had severe fatigue day after. Added that there's also fatigue on 2nd day after vaccine but much more mild than 1st day. All symptoms resolved at 48hrs. The patient was not diagnosed with COVID-19 prior to vaccination and since the vaccination. The events were assessed as non-serious. Therapeutic measures were given for the events. Outcome of the events was recovered in Dec2020 after 48hrs. Information on the lot/batch number has been requested.

Tingling in lower arm and hand that lasted from time of vaccine until the following morning.; This is a spontaneous report from a non-contactable other health care professional. A 30-year-old female patient received bnt162b2 (BNT162B2), via an unspecified route of administration on 20Dec2020 13:00 at SINGLE DOSE at right arm for COVID 19 immunization. Medical history included allergies: sulfa drugs. The patient's concomitant medications were not reported. On 20Dec2020 13:00, the patient experienced Tingling in lower arm and hand that lasted from time of vaccine until the following morning. The patient did not receive treatment. No COVID prior vaccination. The patient has not been tested for COVID-19 since the vaccination. The event was assessed as non-serious. The outcome of the event was recovered. No follow-up attempts are possible. Information about lot/batch number cannot be obtained.

Injection site pain; headache; body aches; feeling generally unwell; joint pain; This is a spontaneous report from a contactable other-hcp reporting for herself. A 35-years-old non-pregnant female patient

received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number EH 9899), via an unspecified route of administration in the left arm on 21Dec2020 14:00 at single dose for covid-19 immunisation. The patient medical history was not reported. Concomitant medication included celecoxib (CELEXA, 20mg). The patient previously took thimerosal and experienced drug hypersensitivity. The patient experienced injection site pain, headache, body aches, feeling generally unwell and joint pain all on 22Dec2020 03:00 with outcome of recovering. No treatment was performed. The patient did not have COVID prior to vaccination nor COVID test post vaccination.

"Strange brain fog; forgotten her medications at home, she forgot to do something with her dogs that she usually does; was pretty sure she forgot to brush her teeth; Right arm soreness; This is a spontaneous report from a contactable nurse (patient). A 31-year-old female patient received 1st dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot# EJ1685), intramuscularly in right arm on 18Dec2020 11:00 at single dose for Covid-19 immunisation. Medical history included ulcerative colitis from 2018 and ongoing, birth control from 2018 and ongoing, seasonal allergies from an unknown date and unknown if ongoing, multivitamin (supplementation therapy) from an unknown date and unknown if ongoing. Concomitant medication included HPV vaccine on 11Dec2020, mesalazine (LIALDA, exp: 29Sep2021, Manufacturer: Zydus) from 2018 and ongoing for ulcerative colitis, cetirizine hydrochloride (WAL ZYR, exp: Dec2021, NDC: 0363049547) from 2018 and ongoing for seasonal allergies, probiotics (lot# 20540N0, exp: Apr2022, Company: Seed.) from 2018 and ongoing, fluticasone propionate (Nasal spray, strength: 50 ug, lot# RR7350, exp: Apr2022) from 2018 and onoging for seasonal allergies, ascorbic acid, biotin, calcium pantothenate, calcium phosphate dibasic, colecalciferol, cupric oxide, cyanocobalamin, ferrous fumarate, folic acid, manganese sulfate, nicotinamide, phytomenadione, potassium iodide, pyridoxine hydrochloride, retinol acetate, riboflavin, selenium, thiamine mononitrate, tocopheryl acetate, zinc oxide (FORVIA, tablet, lot# B0115, exp: May2023, UPC: 835134000202) from 2018 and ongoing for multivitamin, ethinylestradiol, ferrous fumarate, norethisterone acetate (LO LOESTRIN FE, exp: Nov2021, barcode:04300420149) from 2018 and ongoing for birth control, and turmeric (exp: Feb2023, barcode #:074312803673) at 1000 mg daily from 2018 and ongoing. The patient previously received tetanus vaccine 10 years ago. The patient experienced right arm soreness on 18Dec2020,""strange brain fog"" on 21Dec2020, she was not sure if it was a reaction to the vaccine, because it was not in the packet that it has been reported; but she wanted to ask if brain fog had been reported. She further described that the brain fog included having forgotten her medications at home, having had a really weird day, she forgot to do something with her dogs that she usually does; was pretty sure she forgot to brush her teeth; and she had a needle stick at work with Heparin after administration of Heparin to patient (little mark on her left middle finger from the needle stick). She had already given the patient the Heparin, then the needle stick to her left middle finger happened after dose to patient was administered the full dose on 21Dec2020. She did not think there was any Heparin left when she got the needle stick; if so it was very very small amount. She washed the needle stick site out really vigorously for 5 minutes, wrapped the site, it was not bleeding or anything; She reported having recovered completely from this event probably 21Dec2020; but clarified that the only lasting effect she has had from this event was since yesterday there is a little mark on her left middle finger from the needle stick; but there is no pain, no swelling and no redness. The hospital drew her blood and the Heparin patient's blood 21Dec2020. She did not notice any of the brain fog or related events on

20Dec2020, not until onset on 21Dec2020. She did not know if these brain fog related events were a side effect of the COVID-19 Vaccine. She felt fine otherwise. She knew that the actual COVID-19 virus had brain fog. She received the tetanus vaccine 10 years ago. The patient received the HPV vaccine a week before the COVID one. She planned on getting the second dose as scheduled, no changes made. Brain fog: She thought she recovered completely by about 21Dec2020. It was better. She had not really done much as of report date. Forgotten her medications at home: These medications were her concomitant products. The outcome of right arm soreness was recovered on 20Dec2020, the other events was recovered on 21Dec2020."

Nausea and diarrhea; Nausea and diarrhea; This is a spontaneous report from a contactable nurse (patient). A 36-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 19Dec2020 at 08:45am at single dose in left arm for COVID-19 immunization. No known allergy to medications, food or other products. Concomitant medications included Multivitamin (unspecified) received within 2 weeks of vaccination. On 21Dec2020 at 02:00 am the patient experienced nausea and diarrhea. Patient was treated with unspecified medication.The outcome of the events was recovering. Information about lot/batch number are requested.

positive test to the COVID-19 infection; This is a spontaneous report from a contactable Other HCP reporting for herself. A 35-years-old female patient received bnt162b2 (BNT162B2; Lot# EL0140) vaccine , via an unspecified route of administration in the left upper arm on 21Dec2020 at single dose for covid-19 immunisation . The patient medical history and concomitant medications were not reported. The patient resulted positive to the test to the Covid-19 infection on the same day she got the vaccine 21Dec2020 with outcome of unknown. The patient was wondering if her symptoms could worsened and if she could receive the second shot as scheduled.

have a really bad headache; This is a spontaneous report from a contactable consumer (patient). A 22-year-old female patient received the first dose BNT162B2 (Pfizer-BioNTech COVID-19 Vaccine, Batch/lot number: EL1284), via an unspecified route of administration on 21Dec2020 at single dose for covid-19 immunization. Medical history included GERD (Gastrooesophageal reflux disease), obsessive-compulsive disorder. Concomitant medication included omeprazole at 40 mg for GERD, fluoxetine at 40 mg for obsessive-compulsive disorder. The patient had a really bad headache in Dec2020. The reporter stated she was a 22 years old pharmacy intern working in a hospital. She received the covid vaccine yesterday (21Dec2020) and she had a really bad headache. The patient further described this as a 'very, very bad headache.' The patient didn't receive treatment for headache. She was wondering if she could take Tylenol for headache. The outcome was unknown.

COVID-19 confirmed by positive COVID-19 test; COVID-19 confirmed by positive COVID-19 test; This is a spontaneous report from a contactable other health professional (reported for himself). A 30-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899), via an unspecified route of administration on 17Dec2020 10:00 at single dose on left arm for COVID-19 immunization. Medical history known allergies: PCN (Penicillin). The patient's concomitant medications were not reported. The most recent COVID-19 vaccine was administered at Hospital. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to

vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has been tested for COVID-19 via Nasal Swab and the test name was PCR with the result of positive on 22Dec2020 (12:00). This wasn't really an adverse event but the reporter thought it may be useful for studies taking place. On 22Dec2020 12:00 PM, the patient was diagnosed with COVID-19 5 days after vaccination and was currently self-isolating. The adverse event result in Emergency room/department or urgent care. No treatment was received for the adverse events. The events were considered as non-serious by the reporter. The outcome of the events was recovering.; Sender's Comments: Based on the current available information and the consistency with the known safety profile of the suspect product BNT162B2, a possible contributory role of the suspect product to the development of Drug ineffective and COVID-19 cannot be excluded.

substantial back pain in her mid back and spine; substantial back pain in her mid back and spine; This is a spontaneous report from a non-contactable Nurse (patient). A female patient of an unspecified age received bnt162b2 (BNT162B2) at single dose on 21Dec2020 for immunisation. The patient medical history and concomitant medications were not reported. The patient experienced substantial back pain in her mid back and spine on an unspecified date. The outcome of events was unknown. No follow up attempts are possible; information about lot/batch number cannot be obtained.

Severe headache; This is a spontaneous report from a contactable pharmacist, who is also the patient. This 37-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number EK 5730; expiration date Mar2021) intramuscular in the left arm on 21Dec2020 at 17:30 at the age of 37 years at single dose for COVID-19 immunisation. Vaccination facility type was hospital. Relevant medical history included Major Depressive Disorder (MDD), anxiety and foramen ovale patent. Concomitant medications were not reported. Past drug history included allergy with sulfamethoxazole/trimethoprim (BACTRIM) and aripiprazole (ABILIFY). On 22Dec2020 at 06:00, the patient experienced severe headache resistant to butalbital/caffeine/paracetamol (FIORICET) and ibuprofen, which were taken as treatments. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, she had not been tested for COVID-19. The patient was recovering from the event.

Diarrhea; Body ache; Spike fever of 99; not a low grade fever; Headache; This is a spontaneous report from a contactable consumer (patient). A 58-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EH9899), via an unspecified route of administration on 18Dec2020 at single dose for immunization. When probed for the due date for the next shot, consumer stated it was on 08Jan2021. Medical history included anxiety, acid reflux and eyes just not really great. Concomitant medication included topiramate (TOPAMAX) at 25 mg, daily for weight loss, fluoxetine for anxiety, omeprazole (PRILOSEC) for acid reflux. The patient experienced body aches, spikes fever of 99, it was not a low grade fever, headache on 18Dec2020, and diarrhea on 19Dec2020. Patient received acetylsalicylic acid (EQUATE, lot number: think it was 0B3076C, Expiry Date of Equate: Dec2022, NDC# 4903552378) for events body aches and the headache and the spike fever. It's Equate pain reliever, a (Company name) brand and it was 325 mg. Outcome of events body ache and headache was not recovered, and outcome of other events was unknown.

Nausea; Chills; This is a spontaneous report from a contactable consumer via a Pfizer-sponsored program,. A female patient of an unspecified age received bnt162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), via an unspecified route of administration on 19Dec2020 at a single dose for COVID-19 immunisation. Medical history and concomitant medications were not reported. The patient experienced nausea and chills on an unspecified date. Clinical outcome of the events was unknown. Information about lot/batch number has been requested.

she is better but still not good; not to be able to breath; sore right arm; This is a spontaneous report from a contactable nurse (patient herself). A 62-year-old female patient received bnt162b2 (BNT162B2, lot EK5730), intramuscular on 18Dec2020 at single dose for immunisation. Medical history included asthma (hospitalized on Jan2020 and has not had any issues since that time, referring to her asthma) diabetes, high blood pressure, swelling, sciatica, blood cholesterol abnormal, rosacea, reflux, allergies, sinus congestion, shingles and post carpal tunnel surgery. Concomitant medications included lisinopril, hydrochlorothiazide, gabapentin, rosuvastatin, metformin, glipizide, doxycycline, sucralfate, cetirizine hydrochloride (ZYRTEC), pseudoephedrine, ascorbic acid, ergocalciferol, nicotinamide, retinol, riboflavin, thiamine hydrochloride (VITAMINS) and tramadol. The patient reported that she not to be able to breath (seriousness criteria-life threatening) on 22Dec2020. She woke up this morning and could not breathe and there was no reason for her to not be able to breath. She thought she may have had a reaction to the COVID vaccine. It was the only thing she could think of that might have caused her not to be able to breathe this morning. As treatment for not to be able to breath, she used Budesonide and Levosalbutamol in her nebulizer. She had sore right arm on 18Dec2020. She informed that she had done everything she can and she was better but still not good. She planned to take the second dose of the COVID Vaccine because she thought it was more important to be protected. She suspected that the vaccine was related to the events sore right arm and could not breathe. The outcome of the event not to be able to breath was recovering; for sore right arm was recovered on unknown date in Dec2020; for she is better but still not good was unknown.; Sender's Comments: Severe allergic reaction including anaphylaxis is the known risk factor; a possible causal association between administration of BNT162B2 and the onset of not being able to breath cannot be excluded, considering the plausible temporal relationship and the known adverse event profile of the suspect product. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Headache; pain in her arm; Dizziness; This is a spontaneous report from a contactable consumer (patient's husband). A 45-year-old female patient started to receive bnt162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, lot number: N9899, expiry date: 01Jan2021), via an unspecified route of administration on the right arm on 21Dec2020 at a single dose for COVID-19 immunisation. Medical history included ongoing high blood pressure. Concomitant medication included ongoing alprazolam for high blood pressure. On 22Dec2020, the patient experienced headache, pain in her arm and dizziness. Clinical outcome of the events was not recovered.

positive COVID-19 test with symptoms; positive COVID-19 test with symptoms; Soreness at injection site; This is a spontaneous report from a contactable nurse (patient). A 40-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 18Dec2020 17:30 in the left arm at single dose for COVID-19 immunization. There was no medical history or concomitant medications. The patient experienced soreness at injection site, cough, body aches on 19Dec2020; sore throat, voice changes from coughing on 20Dec2020; tested positive for covid on 21Dec2020; mild low congestion, loss of taste and smell on 22Dec2020. The nurse stated that he got the vaccine on Friday (18Dec2020). The next day (19Dec2020) he had common side effects: Soreness at the injection site and body aches, which were expected. He also had a cough on top of that, which progressed to the next day. His body aches and coughing were infrequent. The afternoon of Sunday (20Dec2020), he developed sore throat. Yesterday(21Dec2020), he said he could not work because he was still coughing and had a sore throat. His voice was also changing due to the coughing. He was getting better now. The doctor from Employee Heath said that the cough was concerning so he got a COVID swab test yesterday(21Dec2020), and today (22Dec2020) it came back positive. This morning (22Dec2020) he had loss of taste and smell. He no longer had sore throat or cough. He had the vaccine before the test. He wanted to know where they were at with information on this. Was this being monitored? How did this happen? Was it possible that the test was a false positive because he had the vaccine prior? He would like someone to give him an answer, if the test was a false positive due to the vaccine? His doctor could not tell if the test was legit a positive because of the vaccine. He was not able to work right now. He did not even know if the COVID was from the vaccine or not. Will he get compensation for this? Will his workplace cover his absences? In the case he went to the hospital, will this be considered a work related or vaccine related issue? The outcome of event soreness at injection site was recovered on 21Dec2020. The outcome of event tested positive for COVID was not recovered. The nurse considered the cough was disabling as this was not part of the symptoms to watch for after getting the vaccine. All of the symptoms currently besides the cough are not serious as of now, but it has put him out of work. The nurse considered all other events as non-serious except for cough (disabling). Information on the lot/batch number has been requested.; Sender's Comments: Based on the information currently available, a lack of efficacy with BNT162B2 in this patient might not be completely excluded.

hands were tingly and both hands were tingly; lips got numb; both hands were tingly and kind of numb feeling; both hands were tingly and kind of numb feeling and then became itchy; This is a spontaneous report from a contactable nurse (patient). A 58-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot/batch number and expiry date unknown), via an unspecified route of administration on 18Dec2020 17:13 at single dose for covid-19 immunization. Patient history was no. There were no concomitant medications. The patient didn't notice anything until the Saturday on 19Dec2020, at about the same time at 24 hours later, it was noticed that hands were tingly and both hands were tingly and kind of numb feeling and then became itchy and lips got numb during that time frame, the patient just took anti-histamines, only one dose Loratadine on 20Dec2020. Issue still persisting, it's not as bad on 21Dec2020 but it still as numb, fingers were especially numb. The outcome of the events was not recovered. No investigation assessment. When asking the causality, the patient

said it was fine until, that's what she was presuming, the Covid shot. Information on Lot/Batch number has been requested.

Severe headache; photophobia; eye pain; myalgia; diarrhea; skin sensitivity; lesions and blisters around mouth and lips, oral lesions; lesions and blisters around mouth and lips, oral lesions/intra-oral lesions/Buccal lesion; inflammation; pharyngitis; lymph node inflammation in neck; BL earache; nausea; diaphoresis; fatigue; This is a spontaneous report from a contactable consumer (patient). A 50-years-old female patient received first dose of BNT162B2 (Lot# EH9899), via an unspecified route of administration, in right arm, on 18Dec2020 15:00 at single dose for COVID -19 immunization. The patient was not pregnant at the time of vaccination. Facility where the most recent COVID-19 vaccine was administered was workplace clinic. Medical history was none, good health. No allergies to medications, food, or other products. Prior to vaccination, patient was not diagnosed with COVID-19. Since the vaccination, patient had not been tested for COVID-19. No other vaccines was received within 4 weeks prior to the COVID vaccine. The other medication that the patient received within 2 weeks of vaccination was amfetamine aspartate, amfetamine sulfate, dexamfetamine saccharate, dexamfetamine sulfate (ADDERALL) at 30 mg orally daily. The patient experienced severe headache, photophobia and eye pain, myalgia, diarrhea, skin sensitivity, lesions and blisters around mouth and lips, oral lesions and inflammation, intra-oral lesions, buccal lesions, pharyngitis, lymph node inflammation in neck, BL earache, nausea, diaphoresis, fatigue, all on 19Dec2020 05:00 AM. The events were reported as non-serious. No treatment was received for the events. The outcome of the events was recovering.

Hives all over his body, on his tummy, his legs, his wrist; did a cold compress, it seemed to work but it came back again; This is a spontaneous report from a contactable consumer (patient's wife). A 47-year-old male patient received BNT162B2 (Lot# EK5730), via an unspecified route of administration on an unspecified date at single dose for COVID -19 immunization. Medical history included type 1 diabetic, blood pressure high and cholesterol. Concomitant medication included insulin. The patient got the vaccine on Friday. On 21Dec2020, the patient had hives all over his body, on his tummy, his legs, his wrist. He started getting it at midnight and the reporter wondering do she need to take him in or can she just give him Benadryl. she was looking at the documents trying to find a number to call. He got the COVID Vaccine on Friday and no trouble till this morning, now at midnight. The treatment included he did a cold compress on it, it seemed to work but it came back again. It's still the same. Cold compress last night or this morning, it seemed to help. The outcome of the event was not recovered.

"Soreness at the site for the first 24 hours; Swelling underneath my right arm; Inflammatory response or immune response from the vaccine; Right breast had swollen areas in it almost being at lymph nodes; Right breast had swollen areas in it almost being at lymph nodes; Around nipple was very swollen and had about three knots; This is a spontaneous report from a contactable Nurse (patient). A 34-year-old female patient received first dose of BNT162B2 (lot number not provided), via an unspecified route of administration on an unspecified date at single dose for COVID -19 immunization. Medical history and concomitant medication were reported as none. The nurse stated she had received the first dose of the Pfizer Covid Vaccine on Thursday. It didn't really had anything other than some soreness at the site for the first 24 hours but on the Saturday, she started noticing a bit of swelling like underneath her right arm. She didn't think anything of like that was probably just the inflammatory response or immune

response from the vaccine. So, she thought it was all a normal side effect. The next morning, next Sunday morning, she woke up and her right breast had swollen areas in it almost being at lymph nodes and that's kind of where she just thought - Okay the breasts have lymph drainage and vessels and all these things. And she could palpate it like from her arm pits, she could palpate and can find out another one that was the area but it was around her nipple that was the concern because it was very swollen and had about three knots and again she was like probably it's just the lymph nodes. She reported ""But they wanted us to report anything. You are at Hospital, like little health area and I was told that you need to call Pfizer too. I am saying that is something out of the ordinary because I am like they are not ordinary, they are in the breast area. don't want to call it as nothing, it might be something else as it is kind of hard to tell if it related to the vaccine or is it not or something I need to talk to my OB-GYN about. I didn't know if that was something else did anybody else is experiencing"". The event onset date was unspecified. The treatment of the events included Motrin. The outcome of the events was unknown. Information on the Batch/Lot number has been requested."

Severe headache; headache was very bad; it was so much that I am scared to take the second dose; Muscle pain; joint pain; This is a spontaneous report from a contactable nurse (patient). A 55-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EK5730, Expiry Date: 31Mar2021) via an unspecified route of administration on 18Dec2020 at single dose to prevent Covid 19, to get antibodies; folic acid via an unspecified route of administration from an unspecified date at 1 mg, daily for Thalassaemia minor; levothyroxine sodium via an unspecified route of administration from an unspecified date at 50 mg, daily for an unspecified indication; zinc oxide via an unspecified route of administration from an unspecified date at 50 mg, daily for an unspecified indication; nifedipine (NIFEDIPINE XL) via an unspecified route of administration from an unspecified date at 60 mg, daily for blood pressure high; valsartan via an unspecified route of administration from an unspecified date at 80 mg, daily (one morning one in the evening) for blood pressure high; paroxetine via an unspecified route of administration from an unspecified date at 10 mg, daily for an unspecified indication; cyanocobalamin (VIT B12) via an unspecified route of administration from an unspecified date at 1000 mg, daily for an unspecified indication; ascorbic acid (VIT C) via an unspecified route of administration from an unspecified date at 1000 daily for an unspecified indication; acetylsalicylic acid (ASPIRIN) via an unspecified route of administration from an unspecified date at 81 mg (once in week or every other day) for an unspecified indication. Medical history included hyperthyroidism; anxiety; Thalassaemia minor; Blood pressure high; patient was diagnosed with Covid-19 earlier, she stated she was a survivor, she recovered on 06Apr2020, she was sick on 21Mar2020 and she was ruled out positive on 25Mar2020 when they bought out the test first time, she said she might have been positive before but they did not have the test. The patient's concomitant medications were not reported. Patient stated she took the vaccination (Pfizer Covid 19 vaccine) in the hospital, she worked there she was a nurse, and she got the side effect, she got severe headache. She had headache but her mistake she did not take Tylenol that time but it got eased after may be 5 hours but the problem was (statement incomplete), and then she started having muscle pain, joint pain and that was okay but headache was very bad, out of all this. Her question was she was a survivor Covid-19 but this one took on her, the headache and she was on blood pressure medications too (further not appropriately paraphrased and clarified hence captured as unspecified medications) so she didn't know what were the ingredients which caused her

such a severe headache. So now her question was that was it okay for her to take the second dose after 3 weeks. The start date of headache was not even half an hour within 15 minutes of taking vaccine. For headache, patient was okay now, that time it was so much that she was scared to take the second dose, the booster dose, so that was why she want to check with them that it was okay or not because she had severe headache. After 5 hour it was improved without taking anything, it subsided on it's on. No treatment received. The action taken in response to the events for folic acid, levothyroxine sodium, zinc oxide was unknown. The outcome of the event Headache was recovered on 18Dec2020, of the other events was recovering. Pfizer is a marketing authorization holder of [folic acid, levothyroxine sodium, zinc oxide] in the country of incidence or the country where the product was purchased (if different). This may be a duplicate report if another marketing authorization holder of [folic acid, levothyroxine sodium, zinc oxide] has submitted the same report to the regulatory authorities.

Fever; injection site mild pain; This is a spontaneous report from a non-contactable other healthcare professional (patient) via a Pfizer sales representative. A 51-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number and expiration date were not reported), via an unspecified route of administration on an unspecified date at a single dose for covid-19 immunization. There were no medical history. Concomitant medications were not reported. The patient experienced fever and injection site mild pain on an unspecified date. Outcome of the events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

rash; This is a spontaneous report from a Pfizer-sponsored program IBCC (Inbound Call Center for HCPs). A contactable consumer (patient) reported that a 64-years-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number EJ1685) , via an unspecified route of administration on 20Dec2020 at single dose for covid-19 immunisation . Medical history reported as none. There were no concomitant medications. The patient experienced rash on 20Dec2020 about an hour after receiving the vaccine. The patient did put some lotion on rash. The outcome of event was not recovered.

headache; soreness on injection site; hives; This is a spontaneous report from a contactable nurse (patient). A 47-year-old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number: EK5730), intramuscular on the left arm on 20Dec2020 10:30 at a single dose for covid-19 immunization. The patient's medical history included chronic cough, post nasal drip, asthma, sinusitis, and allergies to sulfa. The patient was not pregnant. Concomitant medications included levocetirizine dihydrochloride (XYZAL), amoxicillin, clavulanic acid (AUGMENTIN), omeprazole (PROTONIX), fluticasone propionate, salmeterol xinafoate (ADVAIR), budesonide (PULMICORT), albuterol [salbutamol] (ALBUTEROL [SALBUTAMOL]), and guaifenesin. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. On 20Dec2020 16:00, the patient experienced headache, soreness on injection site, hives started on the day of injection in the afternoon until current day. The patient underwent lab tests and procedures which included COVID-19 Nasal Swab was negative on 13Nov2020. The patient was not diagnosed with COVID-19 prior to vaccination and had been tested for COVID-19 on Dec2020 since the vaccination. No treatment was received for the adverse events. Outcome of the events was recovering. The events was considered non-serious.

coughing; chills; cold; This is a spontaneous report from a contactable consumer (patient). A 76-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), lot EJ1685, Expiration Date 31Mar2021, via unspecified route of administration, on unspecified date, at single dose for COVID-19 immunization. The patient medical history included blood pressure high. Concomitant medications included unspecified medication for high blood pressure. The patient experienced coughing, chills, and cold on 20Dec2020. The events were non serious. The outcome of the event coughing was unknown. The outcome of the events chills, and cold was not resolved.

"muscle soreness; This is a spontaneous report from a contactable physician. A male patient of an unspecified age (age: 43; Unit: unknown) received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 16Dec2020 at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient had muscle soreness for about 24 hours after the shot. The patient stated, ""I received the Pfizer vaccine on 16Dec at my hospital, (Institute Name Withheld). I think our hospital management wanted to first vaccinate some key clinicians who felt very comfortable with it - I personally wanted it as soon as possible since I see patients with COVID-19 every day. Twelve hours before I received the vaccine, I took information survey and signed the consent form. At my appointment, I was asked to confirm that I was feeling OK, was given the injection, and then waited about 15 minutes to make sure I didn't experience any side effects. I had a little muscle soreness, sort of like a punch to the arm, for about 24 hours. Other than a little muscle soreness that felt similar to a punch, I felt perfectly fine. The hospital administrator said they'd be in touch to schedule the second dose, which will be within a 96-hour window about three weeks later. I believe the science behind this type of vaccine - the messenger RNA platform - is strong. Understanding the basic science of it, I have very few concerns about the efficacy of the vaccine or the long-term complications. As a mechanism, there is no live COVID -19 virus in the vaccine: It's just giving you the code for spike protein so that your immune system will be able to make antibodies. To me, it's an even safer platform than many previous types of vaccines. Many infectious diseases are managed through vaccines. Infectious diseases that we don't think of as being a big issue anymore, like polio, even chickenpox, have been all but wiped out in the US thanks to vaccines that most people now get as babies. One or two people are not going to stop the COVID-19 pandemic. It's really when we get a good majority of the population fully vaccinated that we'll start to see a major effect. Until then, I plan to still wear my face mask, practice social distancing, and observe safety and sanitary precautions. The outcome of the event was unknown. Information on the lot/batch number has been requested."

Fatigue; Dizziness; Tachycardia/heart rate is 115 laying down and her heart rate is 123 walking around; patient may be having an allergic reaction; This is a spontaneous report from a contactable other healthcare professional (hcp). A 31-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 Vaccine, lot number: EL0140, NDC number: 59267-1000-1, Expiry Date: 31Mar2021), via intramuscular on 21Dec2020 09:15 at 0.3 mL, single (0.3ml intramuscular injection in arm) for preventative (COVID-19 immunization). There were no medical history or concomitant medications. The patient did not receive any other vaccines prior vaccinations (within 4 weeks) or on the same date. The reporter worried the patient may be having an allergic reaction. The patient experienced dizziness, tachycardia, and fatigue, all on 21Dec2020, started about 45 minutes after receiving the injection

around 10:00 am. The patient's heart rate is 115 laying down and her heart rate is 123 walking around on 21Dec2020. It is not life threatening and is kind of minor. The patient does get motion sickness easily. The reporter also received an injection from the same lot number. The patient she was reporting on is the only patient she has had that had an adverse reaction. There had not been any issues with any of her other patients. Treatment: The patient took Advil pm last night and it did not help, states Advil PM has benadryl in it. States it did not help. The outcome of events was not recovered. The causality between events dizziness, fatigue, tachycardia and BNT162B2 is considered related by Primary Source Reporter per Global Introspection.

hives all over her body; Itching; This is a spontaneous report from a contactable Pharmacist. A 32-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), lot EH9899, Expiration Date Mar2021, via intramuscular route of administration in right arm, on 18Dec2020 15:55, at single dose for COVID-19 immunization. The vaccine was administered at Hospital Facility. The patient medical history and concomitant medications were not reported. The patient experienced hives all over her body and itching on 18Dec2020 at 19:00. The events required visit to Emergency Room. The patient was treated with Benadryl PO and Prednisone 60mg PO. The patient did not have any respiratory distress or anything. They said this was related to the vaccine. The events were non serious. The outcome of the events was unknown.

tingling in her arm at the injection site; hand turned red; soon after had tingling up and down her entire arm; This is a spontaneous report from a contactable consumer. A 27-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration, on 24Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced tingling in her arm at the injection site, hand turned red, and soon after had tingling up and down her entire arm. Therapeutic measures were taken as a result of the events, which included diphenhydramine hydrochloride (BENADRYL). The clinical outcome of tingling in her arm at the injection site, hand turned red, and tingling up and down her entire arm was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

migraine; This is a spontaneous report from a contactable consumer. An adult female patient (middle-aged) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration in Dec2020, at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced migraine in Dec2020. The patient was not responding to their usual migraine medicines. The clinical outcome of migraine was unknown. No follow-up attempts are possible; information about batch/lot number cannot be obtained.

he felt very achy and tired with a sore arm; he felt very achy and tired with a sore arm; he felt very achy and tired with a sore arm; This is a spontaneous report from a contactable physician (patient) via Pfizer Sales Representative. A male patient of an unspecified age received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) Batch/Lot number unknown, via an unspecified route of administration on 21Dec2020 at single dose for COVID-19 immunisation. The patient medical history and concomitant

medications were not reported. The patient reported he felt very achy and tired with a sore arm on 21Dec2020. The events were non serious and the patient completely recovered from the events on 22Dec2020. Information about batch/lot number has been requested.

Sore left arm at injection site. Pain started 8-10 hours after injection; resolved by 3 days after injection; This is a spontaneous report from a contactable physician (patient). A 49-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Lot EH9899) intramuscular in left arm on 18Dec2020 at 07:45 am at single dose for COVID-19 immunization. Medical history included Cluster headaches, Osteoarthritis of right shoulder and gastrooesophageal reflux disease (GER). No Known allergies to medications, food or other products. Concomitant medication included ascorbic acid (VITAMIN-C), omeprazole and fish oil. The patient experienced sore left arm at injection site on 18Dec2020 at 04:00 pm; pain started 8-10 hours after injection and resolved by 3 days after injection. Patient was treated with ibuprofen and recovered from the event in Dec2020. Case is non serious.

Mild arm soreness; This is a spontaneous report from a contactable physician. A 34-years-old female patient started to the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), lot number: EJ1685, intramuscularly on 22Dec2020 14:00 (at the age of 34-years-old) as a single dose in the left arm for COVID-19 immunization. Medical history included allergies to medications, food, or other products: shellfish from an unknown date and unknown if ongoing. Concomitant medication included clomifene citrate (CLOMID), folic acid (FOLATE). The most recent COVID-19 vaccine was administered in the hospital. It was unknown if the patient was pregnant at the time of vaccination. On 23Dec2020, the patient experienced mild arm soreness. The event mild arm soreness did not result in death, was not life-threatening, did not cause/prolonged hospitalization, was not disabling/incapacitating and did not cause congenital anomaly/birth defect. No treatment was received for the event. Outcome of the event mild arm soreness was recovering. Since the vaccination, the patient has not been tested for COVID-19.

He is sleeping a lot of side effect, I mean all day; This is a spontaneous report from a contactable consumer (patient's wife). A 52-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: AJ1685), via an unspecified route of administration on 17Dec2020 at single dose for covid-19 immunization. Medical history was none. There were no concomitant medications. The patient got his first shot on 17Dec2020 and he was sleeping a lot of side effect, all day. No treatment received and he just slept all day. Due date of next short was 08Jan2021 to 10Jan2021. The outcome of the event was unknown.

throat tightness; sore throat; This is a spontaneous report from a contactable consumer (patient herself). A 61-year-old female patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration in Dec2020 at single dose for immunization. The patient's medical history and concomitant medications were not reported. The patient reported that 4 hours later she started to have throat tightness that lasted through the night. Caller reported during the call that the tightness was no longer present but she now had a sore throat. Outcome of event throat tightness was recovered in Dec2020, and outcome of event sore throat was unknown. Information on the lot/batch number has been requested.

"basically thought she had COVID all over again; basically thought she had COVID all over again; Pain at the injection site; Joint pain; Feeling unwell; This is a spontaneous report from a contactable physician (patient). A 45-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EK5730), via an unspecified route of administration on an unspecified date in Dec2020 at single dose for COVID-19 immunization. Medical history included COVID a month ago in 2020. There were no concomitant medications. The patient experienced pain at the injection site, headache, myalgia, joint pain, chills, nausea, feeling unwell, fatigue in Dec2020. The patient basically thought she had COVID all over again. The patient stated, ""I was calling because I just had the COVID vaccine which has caused so many adverse reactions which is the side effects? I am experiencing all the side effects but it is calming down because today is day three. Pain at the injection site, headache, myalgia, joint pain, fatigue, chills, nausea, feeling unwell. Basically I had COVID a month ago and I had vaccine three days ago (Dec2020) and I basically thought I have COVID all over again. I took the vaccine on Friday started with the symptoms pretty much on Saturday."" The patient received ibuprofen (ADVIL) as treatment. The outcome of events was unknown. The physician assessed events pain at the injection site, headache, myalgia, chills, nausea, feeling unwell, fatigue was related with vaccine.; Sender's Comments: Based on the information currently available, a lack of efficacy with BNT162B2 in this patient cannot be completely excluded."

I have like muscle pain; I am having like chest pain, pain in my chest; This is a spontaneous report from a contactable consumer (patient). A 47-year-old female patient received BNT162B2 (Pfizer-BioNTech COVID-19 Vaccine, lot number EJ1685) on 21Dec2020 for COVID-19 immunization. The patient's medical history included high blood pressure and asthma. Concomitant medications were not reported. On 21Dec2020, the patient reported that she had like muscle pain, and had like chest pain/ pain in her chest. The outcome of the events was unknown.

chronic cough; Itchy welt in the lower of my back, its more like swell; whelps; This is a spontaneous report from a contactable nurse reported for herself. This 66-years-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (Lot number: EJ1685, Expiry Date: 31Mar2021) via an unspecified route of administration at single dose in the right deltoid on 22Dec2020 08:00am for Covid-19 immunisation. Medical history included stage 0 breast cancer, she had a lumpectomy and radiation in 2016, she also just her Zyrtec for her seasonal allergies a few minutes. Concomitant medications were not reported. The patient experienced whelps on 22Dec2020 02:00pm with outcome of not recovered, chronic cough on an unspecified date with outcome of unknown, itchy welt in the lower of my back, its more like swell on an unspecified date with outcome of unknown. The events were described as follows: After getting the vaccine she noticed raised whelps on her lower back. They are about 1-2 cm in length and that was the largest and the smaller ones are about 1/2 a centimeter long. There are 4-5 on her lower back and there is one right around her upper scapula area. She describes them as itchy, red, and raised. She has never had this happen to her before and so she immediately took Benadryl. The patient also reported that she has a chronic cough which has been described as a combination of things. It is an asthma variant cough, she has drainage and a hyper-reactive airway but doesn't not have asthma technically. The vaccine was administered at Hospital Facility. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine.

left arm soreness; extreme fatigue for 4 days; severe headache day 3,4; This is a spontaneous report from a contactable physician, who is also the patient. This 44-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration in the left arm on 18Dec2020 at 07:00 at single dose for COVID-19 immunisation. Vaccination facility type: hospital. Relevant medical history included penicillin allergy. There were no concomitant medications. On 18Dec2020 at 15:00, the patient experienced left arm soreness and extreme fatigue for 4 days and in Dec2020 she experienced severe headache day 3, 4. The patient did not receive corrective treatments. She recovered from the events in Dec2020. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, she had not been tested for COVID-19. No follow-up attempts are possible, information about batch number cannot be obtained.

I had a fever last night; This is a spontaneous report from a contactable consumer (patient). A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), via an unspecified route of administration on 21Dec2020 at a single dose for Covid-19 immunization. The patient's medical history was and concomitant medications were not reported. The patient had the Pfizer vaccine yesterday (on 21Dec2020) and had a fever at night. The patient asked if patient has to quarantine because of that. The outcome of the event was unknown. Information on the lot/ batch number has been requested.

severe headache; This is a spontaneous report from a non-contactable consumer (patient husband). A female patient of an unspecified age received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for immunization. The patient's medical history and concomitant medications were not reported. The patient experienced severe headache on an unspecified date with outcome of unknown. No follow-up attempts are possible, information about lot/batch cannot be obtained.

she woke up this morning with vomiting, loose stool and her chest wall muscles are extremely painful; she woke up this morning with vomiting, loose stool and her chest wall muscles are extremely painful; she woke up this morning with vomiting, loose stool and her chest wall muscles are extremely painful; nausea; This is a spontaneous report from a contactable consumer (patient). A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient wanted to know about her symptoms after receiving the covid 19 vaccine. The patient reported that she woke up this morning (an unspecified date) with vomiting, loose stool and her chest wall muscles were extremely painful, and she wanted advice on what to do about her nausea. The outcome of the events was unknown. Information on the lot/batch number has been requested.

metallic taste in mouth; general malaise; This is a spontaneous report from a contactable other HCP (Nurse anesthetist) reporting for himself. A 42-year-old male patient received bnt162b2 (BNT162B2, Batch/lot # EL0140) at single dose at left deltoid on 21Dec2020 08:30 for immunisation. Medical history and concomitant medications were none. On 22Dec2020 he was feeling just some general malaise that has since improved. On 23Dec2020, he woke up with a metallic taste in his mouth around 6:30 am and it

is persisting. The patient stated he felt fine, he was afebrile, could still smell, went for a 7 mile run, but still had this metallic taste in his mouth. The outcome of malaise was recovering, of metallic taste in mouth was not recovered.

intractable vomiting; This is a spontaneous report from a contactable physician (patient). A 38-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number EK5730), intramuscular on 22Dec2020 at 13:00 at single dose in right deltoid for covid-19 immunization. There were no medical history or concomitant medications. The patient experienced intractable vomiting on 22Dec2020. The reporter was a physician, she received the Covid-19 vaccine on 22Dec2020 at 1:00 pm. At night on 22Dec2020, she started experiencing intractable vomiting, it was less frequent at time reporting, happening every 2-3 hours. The outcome of the event was resolving.

"dry throat; arm feeling sore; This is a spontaneous report from a contactable consumer. This consumer reported similar events for two patients. This is the first of two reports. A 43-year-old female patient received bnt162b2 (BNT162B2; lot number: EH9899), via an unspecified route of administration on 21Dec2020 at SINGLE DOSE for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. On 21Dec2020, it was reported that she had a ""weird very dry throat 3 hours after the vaccine at the same time that my arm started feeling sore."" She also commented that her coworker also had a dry throat 2-3 hours after the shot and thought it was just talking to his student too much. The outcome of the event was unknown.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2020510803 same reporter, suspect drug, event, different patient"

"dry throat; This is a spontaneous report from a contactable consumer. This consumer reported similar events for two patients. This is the second of two reports. A male patient of an unspecified age received bnt162b2 (BNT162B2), via an unspecified route of administration on an unspecified date at SINGLE DOSE for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. On an unspecified date, it was reported that the patient experienced dry throat 2-3 hours after the shot and thought it was just talking to his student too much. The outcome of the event was unknown. Information on the lot/ batch number has been requested.; Sender's Comments: Agree with the reporting consumer, the reported dry throat reported as "" just talking to his student too much"" is considered unrelated to the administration of BNT162B2 for COVID-19 immunization,Linked Report(s) : US-PFIZER INC-2020510790 same reporter, suspect drug, event, different patient"

fatigue; headache; sore throat; feeling crummy; This is a spontaneous report from a contactable physician (patient). A 32-year-old male patient received first dose of BNT162B2, via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced fatigue, headache, sore throat, feeling crummy all on an unspecified date with outcome of unknown. Caller stated that he got the COVID vaccine on Saturday, got fatigue, headache and sore throat, kind of feeling crummy. Wanted to know if this was a side effect of the vaccine. Wanted to know if it was worth getting a test. Wanted to know will the test come up positive due to the vaccine. Wanted to know if he needed to quarantined. Wanted to know if what he got was good. Stated that this was his first dose. Information on lot/batch number has been requested.

chills; body aches; runny nose; This is a spontaneous report from a contactable consumer (patient himself). A male patient of an unspecified age received BNT162B2 (Pfizer-BioNTech COVID-19 vaccine), via an unspecified route of administration on an unspecified date at single dose for covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced chills, body aches and runny nose on an unspecified date. All events were reported as non-serious. Outcome of events were unknown. Information on the lot/batch number has been requested.

Feeling a bit unwell/I am not feeling good; Chills; little weak; Little bit tired; This is a spontaneous report from a contactable consumer (patient herself). A 56-year-old female patient received the first dose of (Pfizer-BioNTech COVID-19 vaccine, lot# EK5730), via an unspecified route of administration on 20Dec2020 at single dose for covid-19 immunization. Medical history included allergy. Consumer stated, she guessed its environmental allergies. Concomitant medication included cetirizine hydrochloride (ZYRTEC) for allergy. Patient had the vaccine on Sunday and was feeling a bit unwell on 22Dec2020. Consumer further stated, because she had the vaccine the first shot on Sunday and today (22Dec2020) she was not feeling good, she was wondering it could be a side effect. When probed for the adverse events, Consumer stated, she was feeling like little bit like chills, little bit tired and a little weak. Consumer stated she got it from work at the hospital. Outcome of events were unknown.

"Developed sore muscle pain after the injection; Little more tired than normal/had to go to bed earlier than usual, around 10-10:30pm instead of midnight to 1am; This is a spontaneous report from a contactable other healthcare professional. A 46-year-old female patient received bnt162b2, via an unspecified route of administration on 21Dec2020 at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. It was asked that if patients develop sore muscle pain at site of injection, did that mean the body was mounting an immune response to the vaccine? The patient developed sore muscle pain after the injection on 21Dec2020, it continued 22Dec2020, but it is gone and better on 23Dec2020. It was also reported that the last few nights, she had been a ""little more tired than normal"". She had to go to bed earlier than usual, around 10-10:30 pm instead of midnight to 1am. The outcome of event tiredness was unknown; of another event was recovered on 23Dec2020. Information on the lot/batch number has been requested. ."

back pain has been getting worse; This is a spontaneous report from a contactable other healthcare professional (patient herself). A female patient of an unspecified age received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 18Dec2020 at single dose for COVID-19 immunization. Medical history included back pain. The patient's concomitant medications were not reported. The patient back pain had been getting worse on 20Dec2020. The outcome of event was unknown. Information on the lot/batch number has been requested.

he felt weakness; fever/100.1 degrees; chills; nausea; tiredness; headache; This is a spontaneous report from a contactable consumer (patient himself). A 25-year-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL0140), via an unspecified route of administration at site of left arm (reported left shoulder) at 11:00 on 22Dec2020 at single dose for COVID-19 immunization. Before vaccination, patient was recently COVID-19 positive by a nasal swab COVID-19 test and had

ended his quarantine period a few days before receiving the COVID-19 vaccine. There were no concomitant medications. After vaccination, he had chills, fever, nausea, tiredness, and headache around 10:00 PM on 22Dec2020, and throughout today, he had been experiencing these side effects. The side effects all hit at once. He felt weakness this morning on 23Dec2020, and then had a severe headache and chills. He had a headache and fever of 100.1 degrees. he had taken a generic dextromethorphan hydrobromide guaifenesin paracetamol pseudoephedrine hydrochloride (DAYQUIL, liqui-gels for his symptoms. and about 30 minutes later, his symptoms dissipated, and he was good for 3 hours until the symptoms came back. The outcome of event 'felt weakness' was unknown, of rest events was not recovered.

sore throat and L ear pain about 22 hours after vaccination; sore throat and L ear pain about 22 hours after vaccination; This is a spontaneous report from a contactable pharmacist. A 48-year-old female patient started to receive BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot# eL1284), intramuscular from 22Dec2020 15:45 to 22Dec2020 15:45, single for COVID-19 immunisation. Medical history was none. The patient's concomitant medications were not reported. Vaccine location was left arm. No other vaccine was received in four weeks. The patient experienced sore throat and left ear pain about 22 hours after vaccination on 23Dec2020 13:30. No treatment was administered. The action taken in response to the events for bnt162b2 was not applicable. The events outcome was unknown.

Muscle aches; Chills; Fever little over 100; This is a spontaneous report from a contactable nurse. A female patient of an unspecified age received bnt162b2 (BNT162B2, lot number and expiry date were not reported), via an unspecified route of administration on Dec2020 at a single dose for immunization. The patient's medical history and concomitant medications were not reported. The patient experienced muscle aches, chills and fever little over 100 on Dec2020 with outcome of unknown. Information on the lot/batch number has been requested.

"metallic taste in my mouth; tongue feels like it's being coated with something; This is a spontaneous report from a contactable consumer reported for himself. This 52-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (Lot number: EL0140), via an unspecified route of administration at single dose on 22Dec2020 for Covid-19 immunisation. Medical history included cholesterol. Concomitant medication included colecalciferol (VITAMIN D [COLECALCIFEROL]). The patient stated, ""I get the vaccine about an hour ago and I didn't see anything stating with the side effects but I have got the metallic taste in my mouth and now my tongue feels like it's being coated with something"" on 22Dec2020 with outcome of unknown. No treatment was performed."

fatigued; disoriented; This is a spontaneous report from a contactable physician (patient) via a Pfizer sales representative. A male patient of an unspecified age received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number and expiration date were not reported), via an unspecified route of administration on Dec2020 at a single dose for covid-19 immunization. The patient's medical history and concomitant medications were not reported. On Dec2020, the patient was fatigued and disoriented for 3 days. He felt fine now. Outcome of the event was recovered on Dec2020. Information on the lot/batch number has been requested.

when they were drawing the needle back out of her arm there was unusual amount of blood that came out; This is a spontaneous report from a Pfizer-sponsored program IBCC (Inbound Call Center for HCPs), by a contactable pharmacist. A male patient of an unspecified age received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration at 0.3 mL, single on 22Dec2020 for Covid-19 immunisation. The patient medical history and concomitant medications were not reported. The patient experienced that when they were drawing the needle back out of her arm there was unusual amount of blood that came out on 22Dec2020 with outcome of unknown. We don't know if we needed to re-dose or revaccinate her since it was unusual amount that came out. Information on the Lot/Batch number has been requested.

Headache; Muscle pain; Chills; This is a spontaneous report from a contactable consumer (healthcare medical assistant) reporting for herself. This 39 years old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot EK5730, expiry date 03Jan2021) on 21Dec2020, at single dose, for COVID-19 immunization. Medical history included thyroid (no other information reported). The patient was exposing herself to patients with COVID, she worked in a health care. Concomitant medication included an unspecified thyroid medication. The patient experienced headache, muscle pain and chills on an unspecified date in Dec2020. The reporter asked if she could take like paracetamol (TYLENOL). Events outcome was unknown.

general body aches; discomfort; This is a spontaneous report from a contactable physician reporting for himself, received via a Pfizer sales representative. This healthy 31-year-old male patient received the first single dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 19Dec2020, for COVID-19 immunization. Medical history and concomitant medications were not reported. On 22Dec2020 the patient experienced general body aches during the day. Aches may have begun a day or two before 22Dec2020. Aches caused discomfort but did not interfere with ability to perform normal tasks / activities. Events outcome was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

her tongue felt a little weird; she got nervous; her arm was really sore; something about her tongue was like feeling lazy or heavy or something like that; she had like a taste of metal, like a lingering taste of metal; she was starting to feel a little weird, overall she was getting weird; This is a spontaneous report from a non-contactable consumer. An approximately 47 years old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on an unspecified date in Dec2020, at single dose, for COVID-19 immunization. Medical history and concomitant medications were not reported. On an unspecified date in Dec2020 the patient experienced her tongue felt a little weird, she got nervous, her arm was really sore, something about her tongue was like feeling lazy or heavy or something like that, she had like a taste of metal, like a lingering taste of metal and she was starting to feel a little weird, she just said overall she was getting weird. Last night, on 21Dec2020, the reporter was speaking to her sister who took the COVID vaccine and she said her tongue felt a little weird and she was starting to feel a little weird and she got nervous and she got up and started walking around just to like clear herself and just to make sure there was nothing going on. She said it took about half an hour, it happened about half an hour but sure went ahead. No treatment was given. Events outcome was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

sinus infection; This is a spontaneous report from a non-contactable consumer. A 52-years-old female patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 17Dec2020 at single dose for covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced sinus infection in Dec2020. The patient wanted to know the efficacy of the covid vaccine after getting the first dose. The outcome of the event was unknown. No follow-up attempts are possible. Information about lot/batch number cannot be obtained. No further information is expected.

anaphylaxis; This is a spontaneous report from a contactable physician reporting on behalf of patient. A patient of unspecified age and gender received single dose of BNT162B2 (batch/lot number and exp date not reported), via an unspecified route of administration on an unspecified date for immunisation. The patient's medical history and concomitant medications were not reported. On an unspecified date, the patient experienced anaphylaxis with a very protracted course requiring an epi dose for 4.5 days and was still in the ICU (date/s unspecified) following administration of the COVID vaccine. The physician would like to use a drop of leftover vaccine from one of the vials to do a future skin test after the patient is stable. They were unsure if they needed permission as this was standard practice in allergy to test afterwards but wanted to check in with the company. The outcome of event was unknown. Information about batch/lot number has been requested.; Sender's Comments: A possible causal association between administration of BNT162B2 and the onset of anaphylaxis cannot be excluded, considering the plausible temporal relationship and the known adverse event profile of the suspect product. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Had a sore arm after receiving Pfizer's Covid 19 vaccine; This is a spontaneous report from contactable consumer received via a sales representative. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient medical history and concomitant medications were not reported. The patient experienced sore arm after receiving Pfizer's COVID-19 VACCINE. The patient outcome of the event was unknown. No follow-up attempts are possible, information about batch number cannot be obtained.

mild injection site soreness; This is a spontaneous report from a contactable nurse received via a Pfizer sales representative. A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 22Dec2020 at single dose for COVID-19 immunization. The patient medical history and concomitant medications were not reported. The patient experienced mild injection site soreness on Dec2020. The patient outcome of the event was unknown. Information about Lot/Batch number has been requested.

Sense of taste is gone; This is a spontaneous report from a contactable nurse reporting for himself. A 49-year-old male patient received the 1st dose of bnt162b2 (BNT162B2, Manufacturer Pfizer-BionTech), via an unspecified route of administration, on 20Dec2020, at single dose, for COVID-19 immunisation.

Medical history included asthma from an unknown date and unknown if ongoing. Concomitant medication included procaterol hydrochloride (PRO-AIR) as needed (inhaler) for asthma. The patient experienced sense of taste is gone on 21Dec2020 with outcome of unknown. The information on the lot/batch number has been requested.

Tongue feel tingly; This is a spontaneous report from a contactable consumer reporting for herself. A 27-year-old female patient received bnt162b2 (BNT162B2) (lot# EK5730), via an unspecified route of administration, on 22Dec2020, at single dose, for COVID-19 immunisation. Medical history and concomitant medications were none. The patient experienced tongue feel tingly on 22Dec2020 1 hour after vaccination with outcome of unknown. Therapeutic measures were taken as a result of the event and included treatment with Tylenol.

Sore throat; Headache; Left arm pain; This is a spontaneous report from a contactable nurse. A 39-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK5730), intramuscular on the left arm on 22Dec2020 18:15 at single dose for COVID-19 immunisation. Medical history included she was COVID positive a few months ago. There were no concomitant medications. The patient previously got flu vaccine in Oct2020 for immunisation. The patient experienced sore throat and headache on 23Dec2020 and left arm pain on 22Dec2020. The outcome of sore throat and headache were recovering and left arm pain was not recovered.

Substantial back pain; This is a spontaneous report from a contactable consumer (the patient) A patient of unspecified age and gender received bnt162b2 (BNT162B2; Lot # EK5730) vaccine , via an unspecified route of administration on 21Dec2020 at single dose for Covid-19 immunisation . The patient medical history and concomitant medications were not reported. The patient experienced substantial back pain on an unspecified date with outcome of unknown.

experienced loss of taste; Cannot taste or smell red wine vinegar or bleach respectively.; This is a spontaneous report from a contactable other healthcare professional. A male patient of an unspecified age received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 20Dec2020 at a single dose for COVID-19 immunization. The patient's medical history includes wears a CPAP (ongoing). Concomitant medications were not reported. The patient received vaccine 20Dec2020 and experienced loss of taste. He wears a CPAP. He went to the doctor on 21Dec2020 and was prescribed amoxicillin. The patient cannot taste or smell red wine vinegar or bleach respectivel. Outcome of the events was unknown. Information on Lot/Batch has been requested.

"threw up about 3 hours ago; fever which started last night; This is a spontaneous report from a contactable other healthcare professional (reporting for herself). A female patient (Age: 22; Units: unknown) received bnt162b2 (also reported as PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiry date were unknown), via an unspecified route of administration on 23Dec2020 11:30 at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient got Covid vaccine yesterday at around 1130 am and had fever which started last night (23Dec2020) and ""threw up"" about 3 hours ago this morning (24Dec2020) and mentioned that it

was just on 1 occasion, but it was a lot. She wanted to know if it's normal. The outcome of the events was unknown. Information on the lot/batch number has been requested."

I had a headache quite severe and arm pain; I had a headache quite severe and arm pain; Dizziness; Hot flashes; This is a spontaneous report from a contactable consumer for herself. A 55-years-old female patient started to receive bnt162b2 (BNT162B2; Lot # EJ1685) vaccine , via an unspecified route of administration on 18Dec2020 at single dose for covid-19 immunisation . The patient medical history was not reported. Concomitant medication included liraglutide (VICTOZA). The patient had a headache quite severe, arm pain, dizziness and hot flashes on 19Dec2020 with outcome of recovered. The patient also stated that everything was fine by Sunday.

fever; This is a spontaneous report from a contactable other health professional received via Medical Information Team. A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 23Dec2020 at 09:00 at single dose for COVID-19 immunization. The patient medical history and concomitant medications were not reported. The patient experienced fever on 23Dec2020. The patient outcome of the event was unknown. Information about Lot/Batch number has been requested.

lymphadenopathy in her cervical area; This is a spontaneous report from a contactable consumer (parent). A female patient of an unspecified age (reported as 59, unit unknown) received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 22Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. It was reported that patient noticed lymphadenopathy in her cervical area yesterday (23Dec2020). Outcome of event was unknown. Follow-up attempts are completed. The following information on the batch number has been requested.

slight fever; cold; This is a spontaneous report from a contactable other health professional received via Medical Information Team. A 24-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 23Dec2020 at single dose for COVID-19 immunization. The patient medical history and concomitant medications were not reported. The patient experienced slight fever and cold on Dec2020. The patient outcome of the events was unknown. Information on the lot/batch number has been requested.

Flushing after an hour of receiving the vaccine; This is a spontaneous report from a contactable consumer (patient). A patient of an unspecified age and gender received BNT162B2 (Pfizer-Biontech Covid-19 Vaccine) on 21Dec2020, at single dose, for COVID-19 immunisation. Relevant medical history and concomitant medications were unknown. On 21Dec2020, the patient experienced flushing after an hour of receiving the vaccine and on 22Dec2020, the episode was lasting quite a bit longer. Clinical outcome of the adverse event was unknown at time of this report. Information on the lot/batch number has been requested.

the injection site is extremely painful; bleed a lot; there was lot of blood, it was more than usual; I could barely move; Rest of the arm feels cold like really cold; This is a spontaneous report from a contactable nurse (patient). This 48-year-old female patient (weight 68.04 kg, height 160 cm) received BNT162B2

(Pfizer-Biontech Covid-19 Vaccine) on 22Dec2020, at single dose, for COVID-19 immunisation. Relevant medical history included asthma and allergy from an unspecified date and ongoing. Concomitant medications were none. On 22Dec2020, the injection site was extremely painful and bleed a lot; there was lot of blood, it was more than usual. She could barely move and rest of the arm felt cold like really cold. Patient put 3 band aids on injection site. Clinical outcome of the events was unknown at time of this report. Information on the lot/batch number has been requested.

Swelling reported around mouth and eyes; Swelling reported around mouth and eyes; rash; This is a spontaneous report from a contactable consumer (patient). A female patient of an unspecified age received bnt162b2 (Pfizer-BIONTECH COVID-19 vaccine), via an unspecified route of administration on 22Dec2020 16:30 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient previously took doxycycline in 2019 and experienced swelling reported around mouth and eyes and rash. On an unspecified date in Dec2020, the patient experienced swelling reported around mouth and eyes and rash. The outcome of the events was unknown. Information on the lot/Batch number has been requested.

"Armpit is swollen; This is a spontaneous report received from a contactable consumer (patient). A 45-year-old male patient (also reported as female, pending clarification) received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number reported as ""It is hard to read this handwriting EIP5730. This one it might be A or K, EK5730"" (clarification pending), expiry date not reported), via an unspecified route of administration in gluteus, on 18Dec2020, at single dose, for COVID-19 immunization. Medical history included sexually transmitted disease (STD). There were no concomitant medications. The patient reported, ""I took vaccine shot (COVIDvaccine) on 18th and I noticed my, yesterday (20Dec2020), my armpit is swollen is like big hill, it is like swollen."" The patient stated, ""Armpits, under my arm is swollen."" The patient underwent lab tests and procedures which included blood work (unspecified date) with unknown results, the patient reported that this was for his STD. The outcome of the event was unknown. Information about lot/batch number has been requested."

body aches and fever; body aches and fever; This is a spontaneous report from a contactable nurse. A patient of unspecified age and gender received bnt162b2 (BNT162B2), via an unspecified route of administration on an unspecified date at SINGLE DOSE for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. On an unspecified date, it was reported that the patient was having body aches and fever. The outcome of the events was unknown. Information on the batch/lot number has been requested.

"ear ringing; This is a spontaneous report from a contactable consumer. A male patient of an unspecified age (age: 63; Unit: unknown) received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 20Dec2020 at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient received vaccine on Sunday 20Dec2020 and indicated experiencing ear ringing started Monday 21Dec2020 that has been persistent. The patient's blood pressure was ""fine"". The outcome of the event was not recovered. Information on lot/batch number has been requested."

I had body hives for 24 hours; This is a spontaneous report from contactable nurse (patient). A female patient of an unspecified age received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 16Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. On an unspecified date in Dec2020, the patient had body hives for 24 hours. The patient recovered from the event on an unspecified date in Dec2020. Information on the lot/Batch number has been requested.

headache; nausea; cough; fatigue; This is a spontaneous report from a contactable nurse. A male patient of an unspecified age received bnt162b2 (BNT162B2, lot number and expiry date were not reported), via an unspecified route of administration on 18Dec2020 at a single dose for immunization. The patient's medical history and patient's concomitant medications were not reported. On 22Dec2020, the patient experienced cough and fatigue. On 23Dec2020, the patient got severe nausea, severe headache that continued through the night. The outcome of the events was recovering. Information on the lot/batch number has been requested.

"sore throat; This is a spontaneous report received from a contactable other healthcare professional (who is also the patient). A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiry date not reported), via an unspecified route of administration, on 21Dec2020, at single dose, for COVID-19 immunization. The patient medical history and concomitant medications were not reported. The patient reported, ""I received my vaccine on Monday the 21st and on Tuesday (22Dec2020) I had a sore throat. I don't see on the fact sheet this as a commonly reported side effect. Should I get tested?"" The outcome of the event was unknown. Information about Lot/Batch number has been requested."

hurts to breathe or move; severe pleuritic pain at the right ribcage; abdominal pain; This is a spontaneous report from a contactable consumer. A female patient of an unspecified age received bnt162b2 (BNT162B2), via an unspecified route of administration on left arm on an unspecified date at SINGLE DOSE for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. She experienced abdominal pain 14 hours after receiving the vaccine (went away after 6 hours). At 26 hours after she experienced severe pleuritic pain at the right ribcage (vaccine was injected on her left arm), saturation is at mid 90s, and it hurts to breathe or move. The outcome of the event abdominal pain was recovered, while unknown for the other events. Information about lot/batch number has been requested.

"flu like symptoms; fever 99.5 this morning; feel weak; fatigue; injection site pain; upper arm pain; breathing heavier now; This is a spontaneous report from a contactable consumer (patient). A 27-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on an unspecified date at a single dose for covid-19 immunization. Medical history included COVID-19 in Jul2020. The patient's concomitant medications were not reported. On 24Dec2020, the patient experienced flu like symptoms, fever 99.5 this morning, feel weak, fatigue, injection site pain, upper arm pain and was breathing heavier. The patient took paracetamol (TYLENOL) for the events injection site pain and upper arm pain. Outcome of the events ""upper arm pain"" and ""injection site pain"" was recovering while the outcome of the events ""flu like symptoms"", ""fever

99.5 this morning"", ""feel weak"", ""fatigue"" and ""breathing heavier"" was unknown. Information on the lot/batch number has been requested."

Sore arm; This is a spontaneous report from a contactable nurse, the patient. A 39-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, lot number El0140), via an unspecified route of administration in the left arm on 23Dec2020 at 19:15 (at the age of 39-years-old) as a single dose for Covid-19 vaccination. Medical history included Fibromyalgia from an unknown date. The patient did not have any allergies to medications, or other products, was allergic to milk. The patient was not pregnant at the time of vaccination. Prior to the vaccination, the patient was not diagnosed with COVID-19. The patient was not tested for COVID-19 post vaccination. The patient's concomitant medications were not reported. The patient did not receive any other vaccines within four weeks prior to the vaccination. On 24Dec2020 at 09:30, the patient experienced sore arm. Therapeutic measures were not taken for the sore arm. The clinical outcome of the event sore arm was recovering.

Swollen painful axillary lymph node, malaise, constant headache, nausea for several days; Swollen painful axillary lymph node, malaise, constant headache, nausea for several days; Swollen painful axillary lymph node, malaise, constant headache, nausea for several days; Swollen painful axillary lymph node, malaise, constant headache, nausea for several days; Swollen painful axillary lymph node, malaise, constant headache, nausea for several days; This is a spontaneous report from a contactable consumer, the patient. A 50-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE) solution for injection in the left arm on 18Dec2020 at 09:00 (at the age of 50-years-old) as a single dose for COVID-19 vaccination. The patient was not pregnant at the time of vaccination. Medical history included celiac disease and hypothyroidism. Concomitant medications included levothyroxine sodium (SYNTHROID) and paroxetine hydrochloride (PAXIL). Past drug history included known allergies: minocycle, tetracycline and acetylsalicylic acid (ASPIRIN). The patient did not receive any other vaccine within 4 weeks prior to the vaccine. Prior to the vaccination, the patient was not diagnosed with COVID-19. On 22Dec2020, the patient experienced swollen painful axillary lymph node, malaise, constant headache, nausea for several days. No treatment was provided for the events swollen painful axillary lymph node, malaise, constant headache, nausea. The outcome of the events swollen painful axillary lymph node, malaise, constant headache, nausea was not recovered. Since the vaccination, the patient has not been tested for COVID-19. The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up.

get hot with a feeling of an elevated heart rate /she also experienced similar reactions to her vaccine; get hot with a feeling of an elevated heart rate/she also experienced similar reactions to her vaccine; This is a spontaneous report from a contactable consumer (nephew of the patient). A female patient of unknown age received BNT162B2 on unknown date at single dose for COVID-19 immunisation. Medical history and concomitant medications were unknown. Approximately 3 to 4 minutes after injection site, the patient started to get hot with a feeling of an elevated heart rate. The action taken with BNT162B2 was not applicable. The outcome of the event swas unknown. Information for Lot/Batch number has been requested.

Diarrhea; Nausea; This is a spontaneous report from a contactable Other health care professional (HCP) (patient). A 20-year-old female patient, not pregnant, received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 23Dec2020 at 06:00 PM at single dose in Right arm for COVID-19 immunization, Lot number: EK9231. Medical history included covid. No known allergy to medications, food or other products. Concomitant medications included amfetamine aspartate, amfetamine sulfate, dexamfetamine saccharate, dexamfetamine sulfate (ADDERALL) and trazodone. On 23Dec2020 patient experienced diarrhea and nausea. Patient received anti diarrheal as treatment. Since the vaccination patient had not been tested for COVID-19. Patient was recovering from the events.

hives all over her arms and legs; This is a spontaneous report from a contactable nurse. A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 21Dec2020 at single dose COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient reported on Monday 21Dec2020 that she got the COVID-19 vaccine. Last night 23Dec2020, she got hives all over her arms and legs. The doctor was thinking of putting her on Prednisone and she wants to check to make sure that won't decrease the effectiveness of the vaccine. It was not provided if a sample of the product was available to be returned, if requested and if packaging was sealed and intact. The outcome of the event was unknown. Information on lot/batch number has been requested.

Right lower quadrant pain; back of throat tight and full and moved to tongue; fullness in ears; some itching and fullness on the right side near the back of her tongue; This is a spontaneous report from a contactable nurse (patient). A 50 years old female patient (weight 81.65 kg and height 173 cm) received BNT162B2 (Pfizer-Biontech covid-19 vaccine, Lot. EL1284) on 22Dec2020, at single dose, for COVID-19 immunisation. Relevant medical history and concomitant medications were none. It was reported that she had no allergies to anything. On 22Dec2020, the patient experienced a sharp pain in her lower right quadrant of her abdomen, then her ears started getting full, then the back of her throat started getting tight and full and moved to her tongue. It was also reported that she started feeling some itching and fullness on the right side near the back of her tongue. Her airway was intact. Nurse clarified that her reaction last night after the vaccination all happened within 12 minutes of receiving the shot. She went to the emergency room for observation and was treated with epi and Benedryl. She went home after a couple of hours. Clinical outcome of the events was recovering at time of this report. The adverse event, right lower quadrant pain, was assessed as serious (medically significant).; Sender's Comments: By close temporal relationship ('within 12 minutes of receiving the shot') and absence of factors which may provide an alternative cause, the company cannot exclude a contributory role of the BNT162B2 administration in the development of the serious event reported as 'sharp pain in her lower right quadrant of her abdomen'. The impacts of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Itching - injection site and left side of body, throat, back and neck Slight soreness off & on - inj site. Sore body, tired, headache

Fatigue x 3 days, SOB x 4 days (history of asthma; used inhaler multiple time daily). Headache - motrin/Tylenol x 7 days. Upset stomach x couple of days. Arm, red swollen, hard, painful with some itching x 1 wek.

Started feeling unwell Monday night and sick by Tuesday night. Extreme fatigue Tuesday AM, nausea & fatigue & headache. By Tuesday night, very sore throat and extreme fatigue. Wednesday very congested, sore throat, swollen and painful lymph nodes. Went to urgent care & swabbed for COVID and strep. Both negative (tests were rapid and PCR). Since Wednesday continuing through today 12-28-20 - congestion, sore throat, coughm, swollen painful lymph nodes, some GI issues, headache, and fatigue. Return to PCP on 12-29-20

- light headedness, headache started later Some itchiness but did not last BP - 118/84 Headache not resolved

itchiness around vaccine 5-10 mins - resolved with cold compress intermittent dizziness (did resolve) + headache (did not resolve) at 15 mins - 60 mins

On December 23rd, around 5:30-6:00 p.m. I received the Moderna COVID-19 Vaccine EUA at the Vaccination Site. I did not have any adverse symptoms until the night of December 24th around 11:30 p.m. It started that night with nausea. I initially thought it was something I had eaten. I went to bed feeling nauseous but fell asleep. I slept through the night, and work up the next morning, December 25th, still nauseous. I did not ever vomit, even though I very much thought I would. As the day progressed, I developed chills and a low-grade fever. This continued through the day. The nausea was terrible! I could not eat anything because the mere thought of food made me feel sicker. I drank very little as well. I also developed flu like symptoms. I could not stand to be touched, as my skin was highly sensitive to touch. (The same feeling you get if you have a bad case of the flu.) I used a cold wet washcloth all day, as I felt hot, but my fever never went over 99.7 degrees. I eventually fell asleep that night, but I was restless. I woke up several times to noises in my home. Each time it felt like my body was trembling or my heart was racing or fluttering, but these episodes did not last long, nor could I tell you for sure that was exactly what it was. I just felt shaky. Each time I fell back asleep. The next morning, December 26th, I awoke, and the nausea was gone, but the chills and the fever were still hanging on. I just felt bad! I used a cold wet washcloth on my forehead, face, and neck all day. I did eat maybe 5-10 dry saltine crackers and drank a glass or two of sprite. As the day progressed, I felt worse!! The nausea came and went all afternoon and into the night. I eventually fell asleep around 10-11:00 p.m. I slept all night. I awoke the next morning, December 27th, initially feeling nauseous again. I made it a point to drink a lot of Gatorade and sprite throughout the day. I found that I felt some better when I sat up but felt worse when I laid down. So, I sat for about an hour on the side of my bed. I eventually got up and walked around my house. I began to feel better and thought I might be able to shower and possibly eat. So, I did? and it was like my body did a 180! I quickly felt so much better. I ate some soup and drank some sprite. I didn?t completely go back to my normal routine, but I did stay up the remainder of the day and did not get sick. The next day, December 28th, I felt like myself again and pretty much went back to my normal routine. The most interesting side effects that I had that are not mentioned in the CDC COVID-19 Vaccine common side effects are: *My feet were ice cold, but they were wet with sweat

(I put on socks to try to warm them up, but it did not help as my socks would get damp thus making my feet colder) *My tongue became coated white (I did not lose my sense of taste or smell) *My skin felt hot to me, even though it was not hot to the touch (I used a cold wet washcloth for 2-3 days straight)

1 hour after vaccination, itchy eyes, swollen lip, tickle/scratchy throat. Went to ED. Took 25mg benadryl. Observed x 5 hours. Symptoms improved.

Headache the evening after , migraine overnight, soreness at the injection site, fatigue the next day, mild myalgia

Dizziness, itching of entire arm for days, migraine and nausea, sore muscles and fatigue for days, sinus pressure and pain, small rash at site

Started with lower back pain in the morning when I woke up. Then my back and hamstring muscles tighten up. All that went away as the day went on. Just a lingering discomfort remained. That night I was awaken by 10/10 dull pain in both my hips. I don?t have arthritis, but I imagine that is what the pain must feel like. That eventually subsided over the course of the night and then the following morning I woke up with a stronger lower back pain and major stiffness in my hamstrings, but the hip pain was gone. Throughout the day the pain would come and go and move up and down my back and along my spine. It was the strongest on the night of the 22 and has since gotten weaker and the tightens in my back and hamstrings has since left. Now I just get random aches throughout my back that come and go during the day. Yesterday, the 27th, I was hiking down a hill and the impact from that caused instant discomfort in my spine, it felt like it was compressing like an accordion. Never had this happen before. After that my back was sore for hours. Today, the 28th, I tried jogging and the spinal discomfort was instantly there. Went about thirty yards before I stopped and my back has been aching down my spine for hours. Also been experiencing a couple mild headaches through the day since the 22nd. This also has fired up the endothelial dysfunction in my heart which causes some strong chest pain throughout the day. I?ve gone back in my heart medication, so hopefully that will fix that issue. I will be contacting my cardiologist in regards to this and seeing if the vaccine can affect that.

Fever, chills, bodyaches

Burning eyes bilateral one hour after injection. Sore throat 4hours after injection.

Hives on neck. Swollen throat. Nausea.

Numbness and tingling all the way from injection site to the pinky and ring fingers foe few days. Nausea since injection off and on.

Fever and body aches. It feels like when I had covid a month and a half ago.

About 24 hours after the vaccine moderate soreness/pain in the area of the injection on the left upper arm. It disappeared 48 later without treatment. Also, 48 hours after the vaccine, a slight pain in the right ear/upper right mandible, especially when chewing, presented itself. it disappeared without treatment three days later, about five days after the vaccination.

I recieved vaccine on 12/22 at 1500 and awoke 12/24 at 0500 with a broken blood vessel in my R eye that did not involve pain, blurred vision or irritation.

headaches, severe myalgia, fatigue for over 24 hours

fever, nausea, vomiting fatigue starting 12/25 2 hrs after vaccination, fever 100.8 starting 12/26 at 2 pm, improved with acetaminophen, emesis x 1 around 9 pm, symptoms resolved by 12/27 9 am

Headache, lightheadedness, nausea, pain at injection site

Tiredness first thru day 5 Injection site soreness next for 24 hours Fever and chills at 12 hours thru day 6, highest fever 101.5 at day 5. Sweating and skin paleness day 4 thru 5. Headache at 12 hours thru currently, piercing behind right eye day 3 thru 6, eye watering on day 5 during worst fever, occasional nausea when headache is worst. Fatigue at 12 hours thru day 6.

Malaise, persistent fever 99.3-101.8 defF. Chills, diarrhea, body aches. All since the vaccination day to present.

The day after getting the vaccine I started having an intermittent tremor in my lower lip. This has continued through 12/29/20.

Within minutes of receiving my first vaccination, I developed a metallic type taste in my mouth. Currently experiencing altered smell and greatly reduced or altered taste.

Numbness and swelling of left upper lip

Fever 101 the first night , achy muscles and occasional dry cough

Woke up from being asleep with moderate pain in injection site, mild headache that has rapidly intensified into a moderate headache, body aches and chills began around 130 am and have continued. Took advil around 1 am for headache and has not helped. Low grade temp was recorded at 150 am of 99.9.

Presyncopal with hypertension and tachycardia . Resolved after observation . Was given oral Benadryl

Mild Bell's Palsy affecting right side of face. Mild assymetry noted, mild decreased muscle strength and tone, and slight right eye irritation. Symptoms with minimal progression by day 2. Started course of Prednisone on day 3 (12/28/20.) Currently symptoms persist but early in treatment course.

Left arm soreness, Chills since around 1:30pm on 12/28/2020, nausea around 4:00 am, low temp fever 99.1

Patient experienced a syncopal episode after receiving the COVID-19 vaccine. Patient transferred to the emergency department. Upon arrival to the emergency department, patient was awake and alert with GCS of 15. Patient did state she felt a little dizzy. Patient denied any nausea, vomiting, or abdominal pain. Patient received IV fluids. Patient was reassessed and stated she felt significantly improved. Patient discharged at 1300 on 12/23/2020.

Moderna COVID?19 Vaccine EUA 10 minutes after vaccine : injection site pain, feeling warming of entire body. 1 hour after vaccine: fatigue, worsening injection site pain. 15 hours after vaccine: woken up to mild head ache, mild body ache, moderate chills, restlessness. General malaise. Worse injection site pain

Within a couple minutes I had a metallic taste. Within about 15 minutes of vaccine my lips started feeling tingly and numb, after 20 minutes it spread to my mouth, nose area and eventually my whole face. My face felt numb. My eyelids felt like they were turning in. I was advised to take a Benadryl. I took one and within 20mins symptoms improved. After about 40mins the numbess started to come back. I then realized my Benadryl had expired in July 2020. I went back to vaccine site and they gave me pepcid & advised to take more Benadryl. I took pepicid & went to pharmacy & got new Benadryl. Within about 20 mins my symptoms improved. I was advised to take another pecid and did so that evening. I stayed with the metallic taste for another day. Symptoms have not returned.

Slurred speech, crooked walking, slow thought process, unable to spell words that I've never had a problem with before.

Patient reported flushing in the face, tingling on the left side down the left arm and then began to break out into hives on their chest. The individual also had a rapid heart rate and needed a wheel chair due to feeling slightly faint.

start time 03:00 am 12/29/2020: headache, neck pain, fatigue, injection site pain - treating with over the counter ibuprofen and rest

Headache, body aches, chills

Cold sore

Generalized Warm sensation x 3 min

"5 to 10 minutes after receiving vaccine started feeling ""drunk"", anxious, paranoid. Muscles became mildly tense and teeth clenched. The physical aspects only lasted a short time (10-15 minutes)the anxiousness paranoia and ""drunk"" feeling lasted approximately another hour. An hour after receiving vaccine started experiencing nausea and vomiting with extreme muscle soreness that was generalized and fatigue. After napping the nausea and vomiting resolved. Woke up shivering in cold sweats and shivering. Began experiencing forgetfulness and having problems thinking correctly. Issues with finding words, conversing and conveying information to other people. Shortly after waking up began experiencing severe back pain in lower to mid left back. Pain was shooting and it did not seem to matter on positioning. Back pain has resolved. Day 2 still experiencing severe fatigue, extreme muscle soreness, forgetfulness and not thinking correctly. Having issues finding words to use and communicate. Thinking process seems slow. Occasional cold sweats and shivering. Day 3 still feeling of forgetfulness, unable to find words and communicate correctly, slow thinking process, occasional cold sweats and shivering, occasional bouts of anxiety (lasts only 2-3 minutes at a time), short bouts of shortness of breath with exertion resolved quickly. Some muscle soreness seems to be resolving."

shanking chills (fever taken = 101.9), body aches, fatigue, nausea & vomiting

very bad palpitations for a short time frame

Parathesia in left foot. Did not seek medical treatment yet.

swelling and tingling sensation of left eyelid

Injection sight began to become sore around 6:30pm on 12/28, which kept me up all night with the soreness worsening. Throughout the night, I had severe chills, which is not normal for me.

3 Hours after injection left arm swollen from shoulder to elbow. 2 days after injection arm still swollen and rash on 20 percent of left arm

Pt c/o mottling of palms, tingle in arm; pt became hypertensive with headache within 15 minutes of vaccine; symptoms resolved and pt dc from ED

12/24 @3pm - tingling and heat sensations throughout body, tingling in mouth. Sore arm. 12/25 @5am - total body aches, joints, bone pain , mild headache, increased heat and tingling sensation to face, bright red cheeks. Body temp normal to low-grade 99F. Fatigue. Self-treated with Tylenol x3 doses. 12/26 - body pain resolved, heat and tingling sensation continued until late morning. Arm was red/hard/itchy 12/24 through 12/26.

40 min after vaccine was given my face turned red and tight on left side. Then something happened next day. Face on left side felt weird like tight skin and a little numbness on left side that comes and goes on left side since and a little swelling on left side of face.

Feels extremely fatigued, body weakness, and a migraine.

Lumbar back pain for 12-14 hours

Pt experience leg cramps post vaccination.

loss of smell

Pt became diaphoretic, tachycardic, nauseous 10 minutes after vaccination; juice given; symptoms resolved

Around 2pm, developed itchy, blotchy, red rash on left elbow, spreading to neck and face, lips began to tingle, went to ED, ED provide PO Benadryl, discharged home, symptoms resolved.

C/O of right sided numbness and tingling. No SOB, NO Diaphoresis, No Chest pain. Pt transferred to the ED in no distress.

HEADACHE, NAUSEA, VOMITING, FATIGUE

Pt had tachycardia later in the evening after vaccination and tachycardia next morning

Worsening itchy rash on the belly (20cm x 13cm). loratadine 10mg Bid, triamcinolone 0.1% cream applied QID. Limited efficacy. Affecting sleep and daily activities.

Lightheadedness and fatigue. The following afternoon nausea, chills, body aches, severe headache and fever of 101F which lasted till Sunday night 12/20/2020. Monday 12/21/2020 the patient started experiencing hot rash all over the body, and burning Itching two days afterwards and lasted Friday 12/25/2020

DIZZINESS

At 30 minutes after vaccination patient informs she felt palpitations, blurry vision and headache. The day after she noticed a lump on her left supraclavicular area, no other swelling noted.

1 hour after administration the left side of my face is numb, specifically my cheek

Patient stated she felt tingling/scratchiness in throat. BP 96/65, Pulse 71 , Pulse Ox 99%. Shortly afterwards, patient stated that her throat was feeling a little more swollen but that she did not want to go to convenient care. Patient stated she was fine and she didn't want conveneint care doctor to come see her. Patient was talking and no dyspnea noted throughout. Kept for 30 minutes to monitor. At end of 30 minutes, patient started to itch and wanted to go to convenient care. Went to convenient care, received methylprednisolone 125 mg IM x 1 and diphenhydramine 50 mg PO x 1. Stayed for 20 minutes and reprted relief from treatment. Discharged to home.

Pfizer-BioNTech COVID-19 Vaccine Soreness at injection site, generalized body aches and malaise, headache/neck ache, low grade fever (99.3), mild chills.

Awoke with Flu-like symptoms: nausea, vomitting, fatigue, muscle soreness

Received SARS-CoV-2 Moderna vaccine in left deltoid. Pain at injection site and developed stiff/sore trapezius about 12 hours after injection. Got worse for about 12 hours after that before starting to get better. Fully recovered after 3 days.

localized reaction at site of injection redness and itching

On 12/26, I woke up with a headache, nausea, and feverish without a temp. They resolved by 12/28. I was tested for Covid on 12/26, results pending

throat tightness

Pain, burning, redness and heat at injection side and upper arm to shoulder

Extreme fatigue, headaches, and body aches since day of vaccination given. Taken Tylenol. Symptoms go away for couple hours and then come back.

"I had tingling/swelling in tongue and body itching for 30 minutes post vaccine, then felt light headed/dizzy and almost passed out. Then about 8 hours later I noticed my arm was swollen, hard, red, puffy and hot at injection site. It continued to get worse the next day. I was extremely tired and felt "" like I was hit by a truck "" for almost 2 days later. Pain in arm continued for a couple days later."

After having covid 4 weeks ago, I got the covid vax. After an hour, arm was sore. I went through my work day. Got home and was tired, showered, and was tired. I woke up at 1am and was shivering and shaking . It was intense. I had a better reaction with the actual virus. The CDC stated that I should be 10 days out from having covid, to get the vaccine, and I did so. My arm is swollen, there is a lump where the injection was. I did not take any thing for pain or symptoms.

Extreme fatigue. I slept close to 24 hours, woke for about 10 min and had horrible muscle/joint aches. Returned to bed for another 5 hours. Had a lingering headache (pain behind my eyes) for about 2 days afterwards.

Received vaccine on 12/28/2020 at 12:30 PM. Experienced injection site soreness by 6:00 PM. Experienced fever and chills in the night at 02:00 AM. On 12/29/2020 @ 06:00 AM I experienced perfuse sweating. At that time I took (2) Tylenol 500 mg tablets PO. Shortly thereafter the symptoms resolved.

Pt received injection in left arm. Pt had no initial pain. Approximately 5 minutes after injection became flushed, started seeing spots, felt like he may black out, felt numbness and tingling in the left arm that radiated up into the left side of the face and jaw.

Began with feeling fatigued around 6pm, had chills, palpitations and severe body aches with 101.3 fever. Fever resolved with Tylenol . Woke up then next morning (24 hours later) still with low grade 99 fever with weakness and fatigue. Fever spike again at 1pm 101F. Tylenol resolved fever again. The next day (48 hours after) fever free still with general aches and fatigue.

About 9 hours post vaccine, started to get extreme fat. 12 hours post vaccine, started getting chills and body aches. About 15 hours post vaccine, woke up with worsening body aches, headache, chills, nausea and a fever of 101.4. Took 600mg Ibuprofen at this time. 22 hours post vaccine, still having body aches, headache, nausea and temp 100.2. Took another 600mg Ibuprofen. 23 hours post vaccine, I feel exactly how I felt when I was infected with Covid-19 a few weeks ago. Temp 100.5.

dry cough, headache, body ache, feverish the following morning

rash all over chest to neck and lower face, started resolving on own, but took allergy med before bed. Mostly gone in am

Employee reported feeling shortness of breath and chest discomfort. Employee was taken to ED for evaluation.

Noted to have difficulty swallowing approximately 1-2 minutes after injection. Palpitations noted as well as being shaky. This lasted about 1-2 hours after. Difficulty swallowing did not worsen. Became light headed for about 1/2 hr after above symptoms subsided. Then all symptoms disappeared. Towards evening soreness in right arm started... throughout night soreness increased to the point of alternating Tylenol and naproxen. Soreness continue to increase throughout 2nd day... 3rd day soreness lessened and today(day4) almost nonexistent

I received my vaccine on 12/22 around noon. I woke up at 4am this morning 12/25 with tingling in my lips and tongue, in addition to the left side of my face being swollen. Not entirely sure what these side effects are from exactly but thought it best to report my experiences I was hospitalized on 12/25 to 12/26 because my reaction did get worse. I was experiencing numbness on the left side of my body and swelling, numbness, and redness on the left side of my face as well. The hospital didn?t really give any explanations but I?m only now have mild swelling and numbness on the left side of my face. Everything else has resolved at this point in time.

Slight lip swelling sensation, scratchy throat, her skin felt itchy (no visible hives).

muscle pain in both arms, R worse than L. Slight dizziness for first 4 hours after vaccine. On and off minor headaches for the first 48 hours post vaccine

tiredness, extreme nausea, pain in arm of injection, horrible headache

At 1234 am I developed fever, chills, severe night sweats and whole body aches. It lasted approx. 6-630 hours. I also have had increase in GERD/acid reflux since about 2 hours after the injection.

Achy body Extreme tachycardia (HR in the 180s). Unable to get below 90. Uncontrollable shaking Migraine

whole body hives, responsive to diphenhydramine

Became diaphoretic a few minutes after receiving the vaccine. Said his throat was 'scratchy' and was dizzy when he stood up. Sent to ED for evaluation. Discharged from ED without incident.

chills, achiness, diarrhea, fatigue

Moderna COVID-19 Vaccine EUA Experienced injection site soreness, Body and Joint aches, Fatigue, Sleeplesness

"Two minutes after vaccine was give to left arm was painful and swelled about 1"" diameter at injection site 2-3 mm out from skin. No redness present."

body hives

Left upper additional pain and left shoulder pain. Palpable mass under left anterior ribs. Tiredness.

Patient experienced episode of severe leg cramping on 12/22/2020 that began in early AM and lasted until noon. Patient experienced another episode on 12/24/4040 of cramping that began in the legs and went up to the head that felt like muscle tension. This episode also began in the early AM and lasted until noon. However, patient did have residual minor leg cramping. Patient did follow-up with his PCP, who obtained bloodwork on patient. On 12/28/2020, patient states all symptoms have been resolved.

58 y/o female with history of severe seafood allergy presented to ED on 12/24 at 933am with hoarseness, sensation of throat closing. Stated received Covid vaccine at 0730 this morning. Patient took claritin and prednisone prior to vaccine and 20 minutes prior to arrival to ED took benadryl. Symptoms

have improved since arrival to ED. Presenting with symptoms of difficulty swallowing. No difficulty breathing, no itching, no rash, no swelling and no wheezing. One dose of Prednisone 40mg tablet given orally at 0955am. Patient monitored and then discharged to home at 1027am with prescription for Prednisone 20 mg by mouth daily for 4 days and to follow-up with primary physician.

waited 20min. got up to leave and while walking out had a little side step/unbalance moment. thought nothing of it and got to car. waiting in car for an extra 10 min. left hand started tingling. same tingling like if it was asleep and was waking up. started to drive home, on the way home, noticed tingling in left foot and left side of face. neck on left side felt like someone had hit it. about 50 min after receiving injection, was at home, injection site and whole deltoid was numb. left side of face, left foot and left ear all felt numb but with tingles. I had stopped timer after 2 hours. tingling and numbness subsided sometime after 2 hour of receiving vaccine. Today, everything feels fine. Injection site just feels like I got a shot, can barely notice it.

Pain at time of administration, right upper arm, continued throughout day. Nauseated appprox, 0100 29 December. Still Nauseated at 0815, Pain in upper arm increased.

Cold Chills Muscle aches Heart rate 110-150BPM for 5-6 hours that started approx 36hrs after the vaccine was administered Axillary swelling the size a baseball, swelling was also noted in left pectoral muscle and in left shoulder blade

Dose given was 1mL vs. 0.5mL

Pain at injection site, trouble sleeping.

"Tingling tongue and numbness and tingling on R cheek and jaw; R jaw line pain and R sided teeth pain--pain rated 8/10 initially; Provided 50 mg of Benadryl orally; tingling tongue symptom resolved; after 45 minutes pain 2/10 with ""mild"" jaw and teeth pain and R-cheek numbness and tingling"

headache, lower back pain, inject local site achiness.

I received the covid vaccine on 12/23. Since then I have had a fever, chills, body aches, sore throat, headaches, sinus pressure and have been very fatigued. My symptoms seem to come and go, they are currently less severe, but last night a had a fever of 103.2 with chills and shakes.

Patient became dizzy / weak a few minutes after getting the dose. Had slight flushing on chest and rapid heart rate. ER physician feels it is likely vaso vagal response and not a medication reaction. Patient recovered quickly.

The employee's primary care provider's office contacted our office this morning saying that she received the vaccine on 12/22/2020, on 12/26/2020 she began experiencing facial drooping, came into their office on 12/28/2020, had MRI performed (that was negative), and was diagnosed with Bell's Palsy.

Intermittent Fever, cold sweat, cough, congestion, fatigue, stomach upset, loss of appetite, and diarrhea resolved with Tylenol, PO fluids, and light diet of soup and saltine crackers

Already did: 2:30 p.m. until about 6:30 p.m., leg cramps and unusual joint pain in hip and knees. Subsided. From about 10 pm to 8 am, localized discomfort at injection site, on upper left arm.

1mL was given instead of 0.5mL

headache feeling unwell pain and swelling at injection site muscle pain fatigue fatigue

Patient presented to the ED ~ 14 hours post dose. Chest discomfort, dyspnea, fatigue, and malaise. Had prolonged covid hospitalization April-May. Had some sinus tachycardia between 110 and 117. Administered methylprednisolone 40 mg IV. Was discharged from the ED with no outpatient prescriptions.

pt was given 1mL instead of 0.5mL

Vomiting and diarrhea for 2 days. Chills, body aches, sore throat on left side only, ear ache left side only, low grade temps up to 99.9 F taken temporal, lasting 4 days.

Around 4:30 pm on day if vaccination I started feeling nauseous and had the chills. Then around 8 pm my arm became extremely sore to the point where I could not lift it without 10/10 pain and when I touched it my pain was also 10/10. As the night progressed my body not only had the chills but I got a temperature of 102 and I was on fire. I could not cool down until my significant other put cold compresses on my forehead chest and arm. I felt all of those symptoms until about 5am when my fever finally broke. The next day I continued to have a headache and mild soreness in my arm. Then that night I had mild chills and night sweats and a mild temperature. I was therefore out of work for two days following the vaccine.

Alergi

Throat tightness and tingling , itchy mouth within 15 minutes post-vaccination. Received diphenhydramine 50 mg PO and hydrocortisone 20mg PO. VS stable throughout observation period with O2 Sat at 99%. D/C'd in stable condition. Will be evaluated by Allergy Clinic for Dose #2 recommendations.

Extreme fatigue; intermittent episodes of vertigo; intermittent episodes of tachycardia - all started on 12/28 at approximately 7 p.m. The tachycardia appears to be resolving today; the vertigo remains and the fatigue continues. Localized reaction has lessened.

MUSCLE PAIN, CHILLS, LOW GRADE TEMPERATURE, TIREDNESS, HEADACHE

Ibuprofen

Ibuprofen

Patient woke up in the night, walked downstairs to get water, walked back upstairs and became nauseous, laid down and became unresponsive. Eyes were open but not focused, breathing was irregular and snoring-like. this lasted less than a minute and he regained consciousness.

red, raised, hard, swollen. painful area at the site of injection. Area of swelling was approximately 3 inch circular shape. Treated with ice pack and Tylenol for pain After about 2 days, the pain and swelling gradually subsided

I received the injection at 11:00am and around 4:00p, I began to feel like my heart was racing. It continued until about 7p. At one point I thought I should go to the Emergency room but I began to feel better. That was about an hour and a half later but then it started again increasing but by 7p, it went away.

Swollen and discomfort left armpit lymph nodes

Day of injection uncontrollable diarrhea for 36 hours Saturday and Sunday night- nausea , abdominal pain, Sunday I starting vomiting Monday went to the hospital

Day 1: Arm pain 5/10, neck stiffness, tension headache 5/10 (occipital and temporal) Day 2: Arm pain 5/10, neck stiffness, throbbing headache 5/10 (occipital and temporal) Day 3: Arm pain 1/10 Day 4: no symptoms

I broke out in hives Sunday morning. The convenient Care would not see me and sent me to the ED. I was given a muscle relaxer and benadryl. I was prescribed prednisone and benadryl. It took 3 days for the hives to go away. I still have spots and swelling.

Moderate muscle pain/soreness of left arm- started approximately 6 hours post injection and present even after 24 hours

Nurse at vaccine clinic injected subcutaneously and did not reach the muscle. Did not have information to know what to do. Observed patient who was asymptomatic.

Panic attack following, both cheeks red. symptoms left. 6 hours after L side of face started swelling, pain at cheek bone followed by numbness of entire left side of face. numbness lasted for 5 hours. Today face is still swollen. I went to the ER and was kept for two hours for observation, no intervention

After I received the vaccine. Approx 24 hours after the shot, I started having a headache. As my headache got worse, the ache muscle and joint pain came. When the headache started, I started feeling really tired. I was feeling like I was having flu symptoms. I started taking IB prophen on Wednesday morning. It lasted aprox 2 days, and I started feeling better on Saturday morning. Symptoms lasted about 3 days. Symptoms got better with IBprophen.

12/24- fatigue, joint aches, cough, diarrhea, headache 12/25- fatigue, less cough and aches, headache, some diarrhea 12/26- same 12/27 slightly better 12/28 loss of taste and smell. Positive Covid nasal swab test 12/29 headache, cough, fatigue, diarrhea

7:48 am hot, difficulty swallowing, numbness/tingling lips, raspy/hoarse, 50mg benadryl given- symptoms did not resolve so sent to ER, Initial Blood pressure 166/117 Given 50mg IV benadryl, IV dexa

methasone, and IV pepcid Difficulty swallowing resolved in about 1 1/2 hours, numbness and tingling lips resolved approximately 8 pm 12/28/2020 continued raspy/hoarse and day 2

30 minutes after receiving the vaccine I developed pain in my left upper gumline, swelling started and over the next 12 hours included my entire left cheek. I sought medical treatment and 12/24/2020 was prescribed prednisone 50mg PO daily for five days. The swelling has decreased but not resolved, the pain has resolved.

Dizziness/Headache Swollen right elbow (tender to touch) Fatigue High Temperature

Patient reported numbness and tingling to bilateral hands. Patient was transported to ED for evaluation.

I am Health Care worker (Security Officer) at Hospital. On 12/28/2020 around 9am I received my Covid Vaccine (1st) After the shot, I sat the required 15 minutes and felt no ill effects Around 530 pm. I was out shopping after work and almost passed out. It was not a gradual feeling -It felt more like someone had punched me in the head. I was too dizzy to walk for 30 seconds or so. After about 5 minutes I felt okay and drove home. I feel absolutely fine today (12/29/2020)

Chills, Aches, Fever of 101, HA

Extreme soreness at injection site, hard to lift arm above shoulder. Chills, low grade fever, nausea

Muscle soreness, chills, fever, body aches

Diarrhea, headache, chills, body aches, chest pain, shortness of breath, finger on hands and toes get cold. All the symptoms happened at 4:30pm.

Employee reported numbness and tingling to left arm, fingertips and both feet. Left hand is shaky. Employee was transported to ED for evaluation.

For the first day after vaccination I was so fatigued I couldn't get out of bed. My arm was too sore to use for about 48 hours, and I had a headache starting 12/23 and lasting through 12/25. Both arms were very sore then on 12/25. Nausea started 12/26.

Vaccine receieved 12/21/20 at 10 am. Glucose in evenening 12/21/2020 120. Patient reports hypoglycemic event at 8 am 12/22/2021 - glucose of 80 followed by 3 hours of glucose of 40. Glucose then stabilized for remainder of week with no repeat events.

Hives and itching developed about 230pm on 12/28/20. patient self treated with oral Benadryl. presented to clinic about 830 am on 12/29/20 with continued c/o hives and itching . She was sent to ED at Hospital for evaluation. patient denied any other symptoms

102 fever that wouldn't break until about 10 hrs later, severe nausea and headaches, dizziness, extreme body pain

Patient became dizzy, lightheaded, pale, diaphoretic and hypotensive approx. 5 minutes after receiving vaccine. Also c/o nausea without vomiting.

Heat flash Elevated BP

"At 8:50 AM she developed nausea, diffuse headache, malaise, tingling of her hands, elevated blood pressure and metal taste in mouth. She denied any trouble breathing. No swallowing difficulty, swelling of the tongue or lips observed. Subject stated she did not feel safe driving and was brought to ED by EMS. She has a history of fibromuscular dysplasia and is on aspirin and Plavix. Emergency Department ASSESSMENT and PLAN This is a 58 y.o. female who presents with vaccination side effects. She is well-appearing on exam. There is no evidence of airway swelling or anaphylaxis. Will observe. 11:34 AM Has been observed for 2 hours and her symptoms have not worsened. She did take her own dose of Tylenol for headache. She is comfortable returning home. She does have the Moderna fact sheet and we discussed signs and symptoms of when to return. She is comfortable with plan. All questions were answered."""

Itching, redness, rash, difficulty breathing

I received COVID vaccine on December 23rd and had tongue swelling one hour later. I took Tylenol and benedryl and swelling went away

Employee became dizzy at time of check out from observation area. Employee was taken to ED for evaluation.

fever 102.7 in the evening of 12/28, in the morning 99.6 with stuffy nose/chills, soreness at injection site, COVID + 12/14

Employee received the Pfizer covid vaccine @ 0752. @ 0800 employee began to feel flushed, SOB, increased HR. Patient also had some throat tightness and itchiness. BP 147/95. O2 100% HR 149 @ 0755. Symptoms worsened by 0805 and EPI pen given at this time. By 0807 patient was feeling much better- HR 81, BP 134/75, no SOB. Patient chest and face flushed. Taken to ED at 0812.

Chills, fatigue and L shoulder soreness at injection site

Acute headache for 48 hours Acute lethargy for 48 hours Minor pain at injection site for 36 hours

Soreness of left arm radiating to left upper neck and numbness of left hand, pulling sensation of left side of neck

called to observation area at 1020. 98/60 p 100. stated felt shaky, tongue feels thick and not changing, skin warm, hands, face, neck mottled. respirations not labored. oriented. rapid response called and arrived at 1025. transported to ER per wc as stated throat getting tighter.

Severe nausea Esophageal spasm. Could not swallow

Nausea and lightheadedness on day of the vaccine. By that night, fever, chills, headache, shaking, body aches and local pain at site of injection. Nausea gone the next morning. Fever lasted 36 hrs. Body aches and headache lasted 48 hrs. Fatigue lasted 3 days. Side effects resolved by 4 days.

Facial Flushing, throat constriction, feeling faint

12/27/2020 joint pain, body aches, sinus congestion, chest and throat soreness; . l cheek numb, sluggish.; left eyelid more raised and sluggish than other 12/28/2020; l armpit swollen armpit.

Nausea; vomiting; diarrhea; fatigue; headache

She was vaccinated 12/23. Initially she had some soreness, nausea, diarrhea, extreme fatigue, but no fever. Two days later, she developed a diffuse erythematous rash on her bilateral arms, chest and neck with sharply delineated white patches. She also describes that her hands were purple, almost cyanotic appearing. The rash was not itchy or painful and lasted about 6 hours before going away completely.

Vaccine administered via SubQ pinching technique in upper left posterior arm, midway between shoulder and elbow. NOT an IM injection. Site red, swollen and tender. Concern raised for less immune response. No training given to administration staff by hospital clinic.

paresthesia along ipsilateral arm (ulnar nerve distribution) a few minutes after vaccination soreness at injection site, mild headache, & lightheadedness 1-2 hours after vaccination chills 4 hours after vaccination (but no fever) * most symptoms improved/resolved 8 hours after vaccination

Moderna COvid-19 vaccine eua

6 days after receiving my initial covid vaccine, I began to develop an itchy rash. The rash started in the morning of 12/28/2020, beginning with itchy, red ankles. Progressed over the next 8 hours over my whole body. Red, raised, itchy patches. No other associated symptoms and no other means of explaining allergic reaction (no new meds, foods, clothing, detergents). Left work, took Benadryl and a shower. Rash subsided. I feel fine today.

Developed headache rated 9/10, feeling hot and light headed.

Pain both right and left arms and left side of neck with tingling of the lips, palms of hand and soles of the feet. Mild headache. Mild chest pains at 1900 same day. Performed breathing exercises and yoga. Took a 1.5 mile walk. Took 1000mg of Tylenol and 12.5mg of Benadryl at 1900. Pain was relieved but tingling around the mouth persist even today 12/29/20 with leg muscle tingling and stiffness in the left neck . I had to take off work 12/28/20 due to severe pain left neck. Same symptoms I have when I take the tetany vaccine.

Moderate arm pain and swelling at site of injection.

Patient reports freezing and sweating for 2 days after immunization 12 days ago. Body aches and headaches have persisted since then. Also reports numbness going down left arm to all fingertips since vaccine.

2-3 minutes after injection, experienced what felt like a drop in blood pressure, tachycardia, tongue tingling and taste, and for a few seconds, my nose stuffed up but then all symptoms went away within a few minutes. I felt completely fine 5 minutes later.

Went to hair appointment and water aerobics after vaccination. Arm started to hurt a lot. Went to bed at 10pm and at 12am was feeling really hot with a headache, chills, and shivering. Temp was 99.4.

trouble breathing

ON THE THIRD DAY I FEEL LIKE PINS ON MY BACK AND A SLOPE CAME OUT OF MY NOSE AND ON MY LIP. I TAKE BENADRYL TABLETS 50MG TWO TIMES.

muscle pains, shakes, 100.3 temp, headache, nausea

Fever, body weakness, headache, sinus drainage

Drooping of the Right side of her face. Started 12/26/20. MRI to rule out Stroke negative. Diagnosed with Bell's Palsy. RX with a Prednisone taper and Valtrex.

called to observation area 10:50 - report that patient passed out, was on stretcher, reported did not fall, 'came to' in less than 1 minute. 108/68, P 70 and strong, alert and oriented. states feels anxious about flu shots. felt lightheaded, hot, sweaty, skin pale and warm. at 1052 rapid response arrived. states feeling better, had had food/fluids today. assessed that not allergic response - vaso/vagel. 1055 sat up and feeling good, skin pink. 1100 to chair. 1115 left area walking.

Patient felt lightheaded, flushed and nauseous.

Approximately 1 and 1/2 hours after the injection, her tongue became thick, lips swelled, chest pain, short of breath and headache. Injections site was red and swollen. She was traveling out of town and called an urgent care and was advised to take 50 mg of Benadryl q 4 hours till swelling was gone. She took it for 4 days. She saw here PCP on 12/21/2020.

Didnt feel good, soreness on arm Monday I had chills , Unconformable at work Took Antibiotics Chills Possible UTI the following Wednesday I discovered a cold sore on lip

Called and spoke with patient, the received her COVID vaccine yesterday. Since the vaccine she had a temp of 99.9 last night, has not checked today, feeling a little warm today but not as warm as last night. The area is hot and red and swollen in the size of a golf ball, was bigger yesterday. Her entire body feels itchy. She did take benadryl approx 5 hours ago, it helped a little bit right away but now she feels no relief again. She states she has small little bumps that have slowly been spreading from the arm of injection to back and now onto other arm. á Does report she felt like she needed her inhalers, now denies and swelling or itching of mouth throat or tongue. No difficulty breathing at this point.

RASH AND HIVES TO NECK. BENEDRYL AND PREDNISONE. SYMPTOMS STARTED AT 4:00 VACCINE ADMINISTERED AT 1:00

5 hours after injection my legs from the knee to the ankle joint became very itchy, I wrapped them both in a cool wet towel to keep the itching down. This lasted for 48 hours and then went away.

5 hours after injection my legs from the knee to the ankle joint became very itchy, I wrapped them both in a cool wet towel to keep the itching down. This lasted for 48 hours and then went away.

During first few minutes after the vaccination, the client began to cough repeatedly. She stated that her throat was tingling and she was noted to be diaphoretic, with Shortness of breath, an increased heart rate and hives. Epinephrine 0.3 mg IM given to client. Client responded with less diaphoresis and cough subsided. However, noted in 5 more minutes that the symptoms progressed. (As we were in a hospital area administering the vaccine), a rapid response team was activated and she was sent to the ER for further evaluation monitoring and treatment.

intermittent itching, some blotchy rednesss no hives or raised rash that lasted about 3 hours, went away on its own without any treatment

Employee reported numbness and tingling in upper lip 10 minutes after receiving vaccine. Employee was transported to Emergency Department for evaluation.

low grade fever- 99.9 sore arm

Hot flush Dull headache

Day 1-after immunization covid 19 moderna vaccine-headache, sneezing, low grade temp 99 when she arrived home Day 2-102F-took tylenol as needed, she continue to experience headaches, body aches Day 3- No signs or symptoms, temp 97.6F with out tylenol

Local reaction: Pain and swollen arm in the injection spot for over 2 days

14 hours after injection woke up with swollen upper lip and extreme systemc itching. Took 50 mg Benadryl. 12/26/2020 at 0900 continued itching took claritin 10mg and 25 mg Benadryl lip still swollen.12/26/2020 @2000 took 25mg benadryl for itching lip no longer swollen. 12/27/2020 itching has now become burning sensation systemically took 25 mg benadryl and 10mg Claritin. Upper lip swollen 12/27/2020 @ 2000 took 25 mg benadryl for continue burning and itching Lip no longer swollen. 12/28/2020 @ 0600 took 10 mg claritin till itching no burning. 12/28/2020 at 2100 took benadryl 25 mg for continued itching. 12/29/2020 0600 took claritin 10 mg for itching.

Vomiting within 15 minutes Fever 1 hr post vaccination Continued vomiting

Rash on chest

Scratchy throat within minutes. Left thigh pain and spasms, left arm pain. The next morning I can't lift my arm above shoulder, thigh pain not as bad, diarrhea at 9:30 am.

Erythematous rash over anterior torso, groin, flexor aspect of elbows/knees/hips

12/28/2020 weakness, fatigue, chills, tongue swollen, left arm pain at injection site 12/29/2020 fever 101.00 headache, loss of appetite, weakness, fatigue, dizziness, throat swollen

Injection site swelling (~6 cm across), redness, and tenderness beginning 12/28, resolved when patient took benadryl

developed raised red bumps on arms and legs several hours after receiving vaccine.

Debilitating, severe neck and shoulder pain the next day that continued for a week Stiff neck, spread to back pain Unable to work/left work early Still have stiff neck and feel strain doing my normal day-to-day tasks

Day 1-after Covid 19-Moderna injection-employee experienced an extreme pounding headache, her blood pressure was elevated 161/93. Evening hours employee reported fatigue, rash to chest/back no itching, along with fever 102F Day 2-Employee continued with fever 100.2 F and rash to chest/back no itching-taking Motrin and Tylenol Day 3-No fever, no rash, pain to injection site and generalized body aches Day 4-No symptoms

38 y.o. female who arrived by Clinic/physician office presented to the emergency department for Concern for possible allergic reaction. Patient was receiving the Covid vaccine today and while waiting during the observation. She felt some palpitations and was found to have some tachycardia. She was sent here for further evaluation. Currently she says she feels fine and denies any swelling, rashes, difficulty breathing or wheezing. She has not had any allergic reactions in the past and has never had any issues with shots or vaccinations before. She does not have any pain or swelling at the injection site. She was initially heart rate in the 120s but during exam is 100-105. She denies any shortness of breath, chest pain, lightheadedness and does not think she is feeling anxious at all. o ECG (My read): Sinus tachycardia, normal intervals, no ST elevations or depressions and no T wave inversions or signs of right heart strain o Patient did start to feel palpitations again, her heart rate periodically drops into the 90s and then jumps back up into the 1 teens. Considering this, did obtain basic labs all of which were completely normal. Her heart rate has improved, did order Zio patch for monitoring over the next 7 days and recommend she follow-up with her PCP for results on this. Otherwise appears well with no signs of allergic reactions or other emergent concerns. Discharged in stable condition with return precautions given

Developed a severe headache around 1 PM of the day she received her vaccine, some general tingling non-specific; sever headache lasted until 9 PM that evening, relieved with medication but in the morning continued to have headache although more mild then previously. Was better by the 3rd day.

Pain at injection site

Numbness in nose tip of tongue; earlobes warm

Severe right arm soreness inability to have range of motion cannot pick up items over 5 lbs numbness and tingling and cooler fingers in rt hand

Fatigue, chills, body aches, mild cough, headache, sweats for 36 hours Arm soreness for 5 days

Injection site pain

Approximately 5 minutes after administration of vaccine, patient felt nauseated and vomited with some relief. Blood pressure was checked (171/94). Approximately 50 minutes @09:20am after administration of vaccine, patient complained of mild headache. Blood pressure was checked (148/96). At 09:35am, patient reports no nausea. Continues with mild headache. Patient clinically stable. No medications administered. At 10:05am patient reports headache still present but is gradually subsiding. Patient was released at 10:10am.

2 minutes after injection patient c/o head heaviness, nose tightness. VS: BP 159/88, HR 101, O2 SAT 99%, RR 24

Approximately 15 minutes after administration of vaccine, patient experienced twitching on left upper eyelid off-and-on for approximately 10 minutes. Twitching resolved. Blood pressure was checked at 09:50am (161/109). HR=76. Patient clinically stable. No medications were administered. Patient was advised to follow-up with PCP regarding blood pressure concerns and released at 10:10am.

Injection Site Pain

Experienced fever, chills, sweats, joint pain and soreness in Right arm

Fever, chills, headache, arm soreness

After receiving the vaccination, I experienced slight soreness at the site of the injection and a mild headache every day until Friday 12/25. Starting Friday evening 12/25 I started to experience tingling around my jaw after flossing my teeth. It continued when I woke up the next day and spread to my chin and around my lips. I now feel the sensation on my forehead as well. In addition to this I have been having chills, runny nose, pressure in my face, head, and ears, had diarrhea X1 and have been nauseous . I tested COVID negative on 12/28 and had my electrolytes checked along with CBC which all came back normal. Today 12/29 I took 2 Benadryl in the event it could help an allergic reaction.

Patient began with muscle/body aches and chills on 12/24. Highest temperature recorded was 99.8, took ibuprofen. On 12/25, lymph nodes near right clavicle and right axilla swollen and stiffness in neck and shoulder. Right foot also became swollen. On 12/27, developed pain behind eyes, swelling began decreasing on 12/27. Began having headache on 12/28.

Nausea, Headache, arm pain, Neck pain, Swelling, Headache

Swollen, tender lymph node under left armpit

Loss of taste

Resident found unresponsive in her room. Note from earlier: Resident appears to be weak today. Resident ate a few bites of dinner before refusing the tray. Writer encouraged fluids. Vitals 123/72 80HR BS 166. Will log for Doctor and continue to monitor. Was sent out 911.

Flush and dizziness ,Increased heart rate and elevated BP 8 mins after the shot. Evening of the shot 12/18/20,patient c/o blurry vision and joint pains.

First symptom was body ache, headache, fatigue, loss of taste

Runny Nose, Sore Throat, and Fatigue

Patient with tongue and throat swelling, some shortness of breath

developed fever,chills, shaking and body aches. Very sore arm

Dizzy/lightheaded at 8pm 12/28, nauseous. 12/29 6:30am dizzy, lightheaded, fainted in shower

Chills, back pain, severe headache, muscle pains

no symptoms

Started with mild headache the evening of vaccine administration. 12/27/20 woke up with severe body aches, severe chills, sorethroat, sinus congestion and sinus discomfort, and extreme fatigue. Took temp once and it was 99.5 oral. Symptoms were gone within 28 hours of onset. Minor discomfort at vaccine site as expected.

Injection site soreness

When leaving post vaccine, numbness and tingling of right foot, over the next 7 days spread numbness to both lower extremity extending into calf?s. Burning nerve sensation started at day 7 increased up legs into hips. Numbness and burning sensation bilateral from feet to hip

One week following the COVID 19 vaccine, patient developed a psoriatic arthritis flare up. She has history of psoriatic arthritis; however reports it has been well controlled. She had a change in her medication in 11/2020 and was started on Ixekizumab. She is also taking Hydroxychloroquine. States psoriasis rash under her nails is severe. She also reports bilateral shoulder pain. Taking Tylenol.

Right arm and neck are very sore and has a headache.

muscle pain in arm, headache, fatigue

Injection Site Pain, Fatigue

After i received my vaccine 11:00am, i was ok until 8:30 PM, i started to unusual to my body, particularly in my stomach. I didn?t hqve the appetite to eat. By 2am, i woke up with chills and my body was shivering. Temperature 98.3, i took tylenol ES. After an hour, my chills went away. I feel lack of energy. This morning, i still have feelings of being cold, body malaise and mild headache and still no energy to do house chores.

Pt was experiencing shortness of breath, sweating, and racing heart, and dizziness. Code A was called and RN and MD came to attend. Vitals 1st set 90/41, pulse was 50, and O2 was 100%. Vitals 2nd set, 10 min later 100/60, pulse was 60, and O2 was 100%. Pt was given apple juice and given the okay to discharge home after waiting 10 more minute for observation.

Extreme dizziness with nausea and vomiting that starting on 12-26-2020 after receiving the vaccine on 12-24-2020

Lip swelling, left 4th digit swelling, pruritic palms, headache

I received the vaccine shot on 12/23/20 at 3 pm. By 12/24/20, I had pain in my left arm that radiated to my neck and back on the left side. Over the past 4/5 days, I continue to have pain in my left arm, back and neck

soreness on injection site, headache, fatigue, muscle pain, joint pain, chills

Fever, Body aches, fatigue, Nausea

On monday 12/28 i started to feel fatigue/ weakness Body ache Headache Slight feverish On tuesday morning between 1-5am i had Fever Body ache Chills

Nausea, extreme fatigue, headache, swelling left arm

within 15 minute waiting period after vaccine, employee felt like she was going to black out, no LOC. Increased BP 180/130 and tachycardia, HR 120's. After sitting/resting, VS returned to normal and employee felt weak but better. On 12/29 called employee and she had called in ill to work today for h/a, vomiting and is now reporting severe dizziness that she cannot stand up, chills with the h/a and vomiting. She is taking Tylenol/ibuprofen.

I received the Moderna COVID-19 Vaccine EUA on December 28 at 3:30 PM. Starting at 4:30 AM today (December 29), I started to have chills, followed by fatigue, headaches, muscle pain, joint pain, chills, nausea and vomiting. I vomited twice.

Nausea, Injection Site Pain, Vomiting, Diarrhea

Severe myalgia, chills, fever, nausea, vomiting

"Employee reported ""racing heart and ""feeling like passing out"". Employee was transported to Emergency Department for evaluation."

Pfizer-biontech covid-19 vaccine eua 15 minutes after receiving shot my head became itchy. that resolved within 15 minutes. around 1430 that day i developed nausea and diarrhea, which lasted until 12/25/20 at 2130.

It started with a cough that night went to work. The cough was consistent at work the coworkers asked me to call employee health. I was informed to get Covid test at 11:00 am when I got home took a nap. Upon waking had a fever, cough had gotten worse, exp breathing problems, abdominal pain, muscle ache and joint in knee/wrists swelling. I took Tylenol for fever went away and still feel exhausted. On this morning my fever was 99.7,still have cough, and trouble breathing after Nebulizer treatments. I have missed over 5 days of work.

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Severe Headache x4 days Sinus pressure x3 days Nausea and vomiting x 2 days

Hives, Benadryl 25 mg given, itching has decreased, but is moving from original area.

Patient is four months pregnant. She received the vaccine at an employee immunization clinic. Ten minutes post-vaccination, she reported feeling lightheaded and dizzy, HR of 121. She was provided an area to rest and given juice and peanut butter crackers. At 30 minutes post vaccination, she continued to feel lightheaded and dizzy. Vitals: BP 122/64, P 71. Continued rest, juice, and crackers provided. EMS and RN observation at bedside. 1 hour post vaccination, she reported feeling much better and feels safe to drive home. Discharge vitals: 120/66, HR 75.

Pt complaint of mild symptoms ie. itchy mouth. Interview and vs taken as noted. Pt given Benadryl 25mg PO x1. Per standing order. Emergency medication management of vaccine reactions. Symptoms Remain present after 10 min of observation. Pt taken to urgent care and checked in. She stated that her face was starting to feel itchy while being checked into UC. Report given to Urgent care RN.

Fever, Injection Site pain

"vaccine. She was waiting about 15 min after vaccination when closer to 4:45 complained of headache, cold and chills. She was asked to lay down on stretcher where her BP was checked 134/94,P=74 Pulse OX 100% on room air. She drank two small juice box and continued laying down. Raised her feet up and while she was resting she felt increased heart rate BP=143/104, P 97, Pulse OX 100%. Pt has no medical history, denies any environmental, food or vaccine allergies previous to this vaccine. She was alert, awake and oriented through the process yet escalated to transfer to ED since her BP remained elevated above her normal level of 120/80. Paramedic arrived at 17""35 and she was transferred to ED. BP 144/93 P=80, T=99.2(tympanic), Pulse Ox=100% at the time of transfer. Her chest was clear to auscultation and heart is regular with occasional iregular heart beat on auscultation. Her headache decreased yet still had mild headache."

1. soreness on my right arm beginning at injection site and expanding to the entire area from the shoulder down to the elbow 2. I am feeling extremely tired 3. sore/stiff muscles

Severe hives and itching to lower abdomen, lower back,buttocks and left hip.

Fever, Chills, lasted 24 hrs

Fever, Chills, lasted 24 hrs

Neck/shoulder stiffness; all over body aches; severe fatigue; nausea; chills; high temperature; migraine, and loss of appetite.

dejavu symptoms throughout the week after the dose. On Thursday Morning approximately 2.5 days after the dose, I had a seizure in my sleep at approximately 4am.

Day after receiving the vaccine - Headaches, heart palpitations, chills, loss of appetite, severe nausea, and fatigue.

Patient called after events occurred. She was administered the shot on 12/21. She stated that evening, she became short of breath however did not seek medical treatment. She stated she instead went to sleep and Tuesday 12/22 she was experiencing a back ache but also had a dull ache in her neck and forehead. I suggested patient be seen by their PCP. Whether or not patient followed up with medical care is unknown. I also encouraged her to call back if symptoms do not improve or if any new symptoms occur. Have not heard back from individual.

Patient called after events occurred. She was administered the shot on 12/21. She stated that evening, she became short of breath however did not seek medical treatment. She stated she instead went to sleep and Tuesday 12/22 she was experiencing a back ache but also had a dull ache in her neck and forehead. I suggested patient be seen by their PCP. Whether or not patient followed up with medical care is unknown. I also encouraged her to call back if symptoms do not improve or if any new symptoms occur. Have not heard back from individual.

Employee received vaccine, c/o shortness of breath, throat tightness, difficulty swallowing, difficulty breathing and hoarseness. METS team called and Employee taken to Emergency Room.

about an hour afterward began experiencing diarrhea up to 6 times that day. around 11:30PM at work I began feeling a whole body tingling/pins and needles sensation along with muscle/joint pain in my back, neck, and hands. The tingling lasted about 3 hours then subsided, on the 19th night again I felt the tingling for about an hour. patient replied yes, she had MIS as result of Covid vaccine.

Injection site redness and increase skin temp at site which occurred 8 days after 1st dose of vaccination. No itching present. Slightly tender and no swelling at this time.

Headache Fever Body aches Fatigue

I had three days of fatigue, chills, aches, and intermittent night sweats. 1 day after the vaccine was administered I developed a rash (red bumps/itchy) over my chest, back, and inner ankles. The chest rash was relieved with Benadryl administration and lasted 2 days, I still have a very mild rash within my inner ankles 6 days later (tiny red itchy bumps).

Fatigue, Body aches

Vaccine error: Vaccinator administered COVID 19 vaccine however some of the liquid of vaccine splashed onto the patients arm and thus the patient did not receive full first dose. The vaccinator likely

did not secure the needle to the syringe well enough. Incident was filed on the date of occurence. Patient did not have any symptoms.

throat tightening and scratchy

Modern a COVID-19 Vaccine. Swelling in the right eye lid. Muscle pain. Headache. Injection site throbbing in pain. Labored breathing (with burning discomfort). Fatigued.

Hives and itching to left bicep on Morning of 12/28, Hives spreadin to all four extremeties by 0500 on 12/29. Mild Shortness of breath

states she had nausea and diarrhea afternoon that she received the vaccine and into the following day with lack of appetite; had not eaten anything

Severe Headache

Moderna COVID-19 Vaccine EUA Fever (99.8 - 100.4 F over course), body aches, chills - took 2 tylenol (650mg each) about 1-2 hours after onset, symptoms resolved within 2 hours, temperature back down to 98.6F.

Tuesday, rash started on Wed with no new meds/food/lotion/soap/detergent. Rash is raised, wide-spread to left arm, abdomen and upper back/shoulders. + Itching/irritation. Denies blistering, SOB, cough, fever, chills. Using topical triamcinolone which helps with itching START ON Prednisone for 9 days, Claritin 10mg AM for 7 days,Benadryl 25-50mg PM for 7 days.

After injection, within 1 hour, started having left arm muscle tightening, up to left shoulder. Following morning: facial numbnes/decreased sensation; mild facial droop. Onset 9am on 12/28/2020. Went to ED for evaluation. Sensation started to resolve, continues to be slightly diminished on left side of face. Droop has since resolved.

Pt came in for vaccination for COVID-19 at 4:03 . She received Moderna vaccine at 4:15. She experienced palpitation, worsening chills, headache, and presyncope. No loss of consciousness. Denies chest pain, shortness of breath but feels heavy to push air in and pulse OX 100%, No angioedema, No rash, No pruritus, No throat swelling, denies hoarse voice, or difficulty breathing. She traveled to MD on 12/14/20 to receive antibiotics. She was treated with Erythromycin dose for 6 days from MD. á The patient was +COVID19 on 12/11/20 with fever, scratchy throat, congestion, cough, and SOB and was seen in urgent care on 12/13/20 where was DX + for COVID19. She was quarantine for 10 days when she was returned to work on 12/22/20. Her Chest X-ray was negative on 12/13/20. She was negative for nausea, vomiting, diarrhea. She denies any recent vaginal bleeding, or abdominal pain. Denies any history of cardiac disease, or history of arrhythmias. Denies any history of prolonged immobility, or history of clots.

Headache for 48 hours, fever x 12 hours, fatigue x 5 days, severely enlarged lymph nodes to left arm started Monday 12/28, continues today 12/29

Employee reported by bedtime of 12/28/2020 which was the date she received her 1st dose of the COVID-19 vaccine she had the following symptoms: Arm was sore as a boil and she had upper respiratory symptoms similar to a cold, drainage, nasopharyngeal irritation and cough lasting a good while.

Pt. received vaccine, at 640pm... at 705 pm, c/o throat tightness, nausea, mouth tasting like chemical. METS team called, taken to Emergency Room

Pfizer-BioNTech COVID-1 Vaccine Patient presented to ED 10 minutes after receiving COVID vaccine with mild redness around injection site and some chest tightness that may be attributed to being nervous and anxious over vaccination. no erythema or swelling noted around injection site. Patient had just worked 14 hours night shift. 0823 redness improved along with chest tightness. IM dexamethasone 8 mg given in ED 0837 significantly improved after ED observation and stable for discharge Prescription for hydroxyzine 50 mg po TID x 7 days Follow up with PCP

Sore Throat, Coughing, started 16hrs after injection

Uterine/pelvic cramping, nausea. Third pregnancy, EDD 6/8/21, 16 weeks pregnant

Hives, angioedema, and periorbital edema.

hand tingling, itching all over, chest feels hot or flushed, nausea, rash Went to the ER after advised by staff -treated with benadryl 50 mg IV solu medrol 125 mg IV/zofran 4mg IV/Pepcid 20 mg IV/Tylenol 975 mg po stable after IV meds, discharged home with epi pen and steroid dose pack

"Woke up the morning after vaccination and had ""blisters"" in mouth and itching all over. States wife saw some ""red spots"" on his back but no other place. Also immediately after injection felt the need to take inhaler. Itching to hands and ""all over"" continues as of 12/28/2020 without evidence of hives or rash."

Vomiting at 10:30. Watery diarrhea until about 1:00 am

Injected into tricep instead of deltoid

Runny Nose, No smell

Patient c/co - lightheadedness, tingling on L side of jaw, w/ peripheral tingling in bilateral feet. Pt given water for hydration, VS taken: 121/75 BG of 105 HR of 85 w/ O2 sat. of 98%. ED (Dr.) contacted, assessed for anaphylactic events - none noted. After 20 mins, patient reported relief w/ only dry mouth remaining. Pt believes it may have been an anxiety attack. Continuous monitoring applied. Patient washed face w/ water and relayed he was feeling fine and will now get something to eat. Pt released w/ no s/s reported.

headache backache neck ache dizzy about 30 min. after vaccine

heart rate of 40; dizzy; really tired; This is a spontaneous report from a non-contactable consumer (patient's friend). A male patient of an unspecified age received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date were not reported), via an unspecified route of administration on 16Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient was having some symptoms that wanted to check out. On Dec2020, he was really dizzy, he was really tired, and he had a heart rate of 40. No questions, they just want to make sure that he was not going to die. Outcome of the events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

immediate chills, shaking, low BP (82/60), low grade fever (99.8) when covered with blanket in following 48 hrs - fever 102.7 before meds. chills, shaking, severe diarrhea, abdominal cramping, nausea

Chills, body aches, dizzy, migraine, vomiting, low grade fever, neck pain. Took Tylenol and Advil to relieve the pain.

Diaphoretic, felt like she was going to pass out. Lost pulse momentarily, stopped breathing momentarily. Spontaneously recovered.

Left side of face Numbness, Gone after 24 hrs

Injection into tricep instead of deltoid. Discovered next day by patient based upon pain location.

I was being monitored for 30 minutes. At 20 minutes after the vaccination, I began having difficulty swallowing and within minutes of that began experiencing numbness around my mouth, including my lips, with minimal swelling wound my lips and mouth. Then I had a tingling sensation as if pins were sticking me in my face, especially around my eyes and forehead. I immediately ported my symptoms to the nurse standing next to me for observation. My entire body felt as if it was on fire, with a burning and itching sensation. I was administered 25 mg of Benadryl IM and was transported to the Emergency Department, where I was given oral prednisone. I left the Emergency Department is about 2 hours. At 24 hours after the, I still have itching around my scalp, back and lips.

7:30PM flu like symptoms with severe shaking and fever ranging from 102 to 104 the first night. At approximately the same time for the next two nights fever ranging from 101 to 103 and flu like symptoms . These symptoms lasted 3 days during the evening hours only.

Sore arm, Joint Aches

Sore arm, Joint Aches

The vaccine was administered on the following date: 12/28/20áand at approximately the following time: 12:20pm á The symptoms began 5 min after administration of the vaccine.á The symptoms were: 5 min after vaccine had hives, felt itchy and warm. Symptoms were on chest, face and scalp. Tingling in her arm and left jaw tingling. She did not have swelling, wheezing, SOB, dysphagia, GI symptoms. She went to the ER- given IV benadryl, pepcid, solumedrol. 30 min it felt much better By the time she left 2 h later, she felt much better. She had some blotchiness and itcihng on her skin this AM (24h later) so she took

allegra. She was prescribed prednisone but has not yet picked it up. The treatment of the reaction was:áá o Antihistamines:ábenadryl 25mg, famotidine 20mg o Steroids:ámethylprednisolone 125mg in the ER o Epinephrine:ánone á Other medications taken on day of reaction:áázoloft and MVI- taken for years. Other possible exposures (e.g.áfoods):ánone Was this the first dose of the vaccine?: yes Location of injection site:áLeft upper arm Other pertinent past medical history: noneá History of COVID infection: no History of systemic allergic reactions to drugs, foods, vaccine:ánone Other pertinent medications:ánone

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Extreme arm soreness, pain with any/all arm movement > 24 hours

First I had a really bad muscle ache , chills, fatigue headache, fever, ear ache , sore throat

Chills,Lightheaded, Nauseated, Left leg pain and body aches.

Soreness of Arm, cold like symptoms for 3hrs day after, joint pain

Developed hives on face and both arms. Released after 30 minutes of monitoring with no further progression of symptoms. Returned one hour later reporting scratchy throat and feeling of being swollen all over. Also presented with increased redness on face (blushing). No difficulty with shortness of breath. Escorted to ER for monitoring.

Moderna Covid-19 Vaccine EUA Swollen lymph node in right arm pit: starting 12/27/20 at 11:00 pm

severe vertigo

When I got the vaccine, I observed redness on both arms immediately and severe itching all over my body. I had nausea, I vomitted, I felt like I was drowning, I had tightness left side of my body from neck to foot, The Director of Nursing observed that rashes reached up to my neck, BP was elevated as well

Became hot, flushed and felt dizzy,. Had slight weakness in rt face

Hives 4 hours post-vaccine. Improved with diphenhydramine. Resolved by the following day

Adverse reaction post Covid vaccine. Waited for 20 min post vaccine. Experienced S/S Heart palpitations, shortness of breath, tingling in extremities, diaphoretic after leaving clinic observation. Drove back to hospital, escorted by pre surgical testing hospital staff and taken by wheelchair to ED.

Body Chills, Joint pain

major confusion 9 hours after first administration continuing on to the next day, pain at wound site, itchy feeling

"Patient reported developing a ""butterfly rash"" across the bridge of nose and cheeks approximately 24 hours after COVID-19 vaccine. Rash resolved without treatment within 10 days. Also experienced some fatigue."

Within 1 hr of receiving shot felt heaviness and pain in lungs, gradually getting worse then swollen face and clearing of throat constantly by hr 4. By hr 7 gradual lung pain and face swelling reduced. Today 12/29 still have some lung pain little face swelling but still have trouble breathing while walking and talking.

Throbbing, constant pain with burning from L) shoulder joint to fingertips plus shoulder joint up to left neck; nausea, dizziness, headache, joint pain (all body), muscle aches, throwing up, loss of appetite

headache

Achiness, chills and fatigue for 2 days. Better for 1 day, worked and went for a run, then woke up in middle of night going into 4th day post vaccine with severe aches. Got Covid tested on day 4, came back negative on day 5. I am now on day 11 post vaccine and am still having aches in my hip joints. I?m unsure if it?s related to the vaccine but I haven?t been able to run (I am a regular runner) without pain. I did not have any pain from running prior to the vaccine.

Injection site soreness in the AM 12/23. Later in the day on 12/23, body aches and general malaise. On 12/24 continued malaise and painful headache.

Low grade fever and body aches onset approx 14-16 hours post vaccine

Lightheaded, body aches, hot flashes, chills, developed a 101 fever, shortness of breath

Almost a week later after the first dose, still experiencing intense shaking / chills at night. Fatigue during the day with headaches.

The patient was given the Moderna vaccine. She then felt very hot around 15 min post vaccine, felt anxious. Felt her HR was racing, so she looked at her Apple Watch, which said it was 103bpm. She let the RN know and it went up to 125 bpm. BP was 140 which is high for the patient, baseline is around 100 systolic. She then felt shaky. The RN said she saw a few hives on her chest and it was a bit itchy. They gave her some water and juice. She felt better and the hives resolved on their own. She then was given

Zyrtec 10mg. About 30 min post-vaccine, her HR was 85 and BP was 130 systolic. No wheezing, no SOB, O2 sat was normal the entire time. She still feels shaky and anxious. 2 h later she felt asymptomatic.

Low grade fever to 100.1 the morning after receiving the vaccine, mild body aches and headache. Symptoms dramatically improved within 12hrs and by the following morning (48hrs post receipt of vaccine), I was symptom free.

Experienced numbing of right face and jaw for half a day 2 days post vaccination. Took ibuprofen 400mg and symptoms eventually resolved.

Arm soreness Feverish Chills Body Aches

Pt felt lightheaded. Pt did not eat breakfast or lunch prior to vaccine. Pt commonly becomes nauseated after flu shots with no additional adverse effects. Pt was positioned in supine and given Sprite and crackers. After eating, symptoms resolved.

Red itchy spots/hives across abdomen and chest. Have used topical anti-itch cream, taken over the counter benadryl and zyrtec. Topical cream and benadryl did not seem to have any effect. Just took zyrtec this morning so results tbd.

within 2 minutes after receiving vaccine I became flush, tightness in base of my throat and chest and heart starting racing faster and faster. A few nurses came over and saw my fit bit heart rate going higher (max 136 BPM) my fingertips started to get numb. They quickly injected me with .05 epinephrine. They brought me up to the emergency room and put me on a heart monitor. The racing heart subsided after approx. 7 min then started again. It happened 3 times in the emergency room. They ran a few EKG's to try to catch the tachycardia episodes. They started an IV and ran fluids. After 2 hours the symptoms stopped and they released me from the hospital.

Mild rash all over the body the evening post-vaccination. Alleviated by diphenhydramine. Heart palpitations for 2 days post-vaccination

Sore arm, body aches that are as bad as when I had covid, chills, stomach ache.

12am I woke up with a headache chills body aches and sore arm

Sore arm, Heart skipping Beats, Body pain

Itching, redness, hives to right side of face and neck, abd pain. Right upper back pain started almost immediately after vaccination. Continued through the night. Itching, redness, and hives resolved in approximately 2 hours with administration of dexamethasone. Abd pain continues today. Right upper back pain is full today, instead of sharp, and is intermittent today.

The employee reported difficulty breathing. She transferred to the Emergency Department for elevated heart rate and possible syncopal episode. Symptoms self resolve with no medications required.

Received vaccine on 12/28/2020 @ 930am. By 7:00pm left deltoid was tender to touch. Redness , swelling at site. on 12/29/2020 the redness and swelling had increased to 1 inch wide x 3 inch like a band across my deltoid , It is tender to touch and itchy.

Facial numbness,redness

terrible headache, pain in the joints, chest tightness.

Sweating then chills. Back to back. Two days.

Swelling redness and soreness at injection site

Swelling redness and soreness at injection site

Soreness in arm immediately. 13 hours after injection- sweats, chills, increased arm pain, body aches, extremity pain, palm sensitivity, nausea, trouble sleeping. 14 hours after injection- fever, shortness of breath, fatigue, redness in arm, swelling in injection site. 18 hours after injection- stiffness in injection site, extreme fatigue, increased nausea.

6 hours post vaccine: sore arm, chills 24 hours post vaccine: fever (101-102), chills, myalgias, headache, severe soreness at injection site (no other symptoms). All symptoms resolved by 48 hours post vaccine.

cough and a little difficulty breathing rash in the torso (of abdomen and back

Red circle about 3 inches wide and 3 inches long bruising itching, swelling, dizzy headache

Headache and injection site pain, Nausea

shingles

Moderna has an EUA from the FDA for patients aged 18 and older. This vaccine was used inappropriately to vaccinate a 17 year old staff member at a clinic hosted by Pharmacy. Patient experienced no adverse effects, but this improper usage of the vaccination requires reporting to VAERS.

hives down bilateral exposed skin - Benadryl oral tab provided with relief. Hives disappeared by 12:45PM

elevated blood pressure to 156/92 following injections. Experienced dizziness. BP checked 5 hours after vaccine: 143/88.

lightheaded, left lower arm pain chest pain with burning sensation , increase heart rate to over 190 and High blood pressure lasting for 2-3 hours

Fever, Nausea, Diarrhea, covid test was negative

On December 27th I began to have uticaria on my chest, back, legs and neck that respond to oral diphenhydramine but return after 6-8 hours. This is ongoing for three days so far.

Anaphylaxis requiring epinephrine

Body aches, low grade fever 99.5

Injection sight soreness

Body aches, chills, slight fever

a couple days after the vaccine, I developed a rash on the bottom of my abdomen, my neck, and my elbow creases. The rash was worst along my abdomen especially the right hip. The rash is red and looks like tiny red circles.

Patient presented five days after first COVID vaccine with complaints of tingling running down her arm (peripheral paresthesias per MD report) and also swelling and redness at injection site. She does also complain of feeling a little achy the day following her vaccination. She was given prednisone and diphenyhdramine while in the ED. She was prescribed prednisone (20 mg x 3 days) upon discharge.

Fatigue, joint pain, muscle aches, headache, nausea and vomiting for three days. Treated at home with over the counter pain relievers.

Neck swelling, labored breathing

Fatigue, Muscle pain and redness at injection site

moderate rash to left arm, mild to right arm. Also rash to trunk and legs. Benadryl was taken

Hives to face for 1.5 hours - improved after 1 course of Benadryl

5 minutes after the injection I developed tinnitus in both ears. This has continued on since the injection. It varies in intensity but is constantly there. I had never experienced tinnitus prior to the shot.

Vaccine recipient received vaccine on 12/17/2020. Reported that they felt tired the next day. Three days after receiving the vaccine, reported to develop headache and neck/should pain. This was still bothering the vaccine recipient. Directed to follow-up with occupation health.

Rapid heart rate, achy, fever 101, flu like symptoms started about 7 hours after vaccine. She did have Covid on 11/1/2020. She is going to give it today and see how she feels and will let me know if she goes to the DR or ER.

Pain at injection site, muscle pain, redness around injection site

Fever, shortness of breath, headache, myalgias

itching, face and eye swelling, wheezing, H/A. Treated successfully with Epi X 2 and Benadryl.

Anaphylaxis requiring epinephrine

tenderness in armpit, specifically upon touch

Patient received the covid vaccine on 12/20/2020. She reported that she started to have chills (temp reading were in 98.0s), headache, bodyaches, and swelling of the Right groin on 12/21/2020. She was evaluated by her PCP (in person) and treated with Ampicillin x 7 days . She did NOT inform her PCP about her covid vaccination status. HAs, bodyaches, chills, and R groin swelling resolved by 12/26/2020. On 12/28/2020 she c/o new onset of nasal congestion. Denies fevers or cough. She tested positive for covid on 12/28/2020 at Employee Health. Has FU appt with PCP in one week and EH on on 1/7/2021.

Hives on abdomen, back, and ankles; associate reports taking loratadine 10 mg PO from personal stock

Fell light headed, muffled hearing, flush, warm.

Jittery, Increase heart rate with 20 min after shot.

Light Headed, Cold, burning sensation inside, nausea, felt like she was going to pass out, rash on chest/neck, she could hear people talking but felt she didn't feel like she was present - elevated BP 200/110. Staff member took Metoprolol 25mg. 1/2 hour took medication feels better but feels foggy

Rash on the upper chest and neck

Increased heart rate and blood pressure, syncope, nausea, sore throat, fever

I received the Pfizer EK5730 shot at about 11:30 am on 12/28/2020. When I walked out of the office from getting the shot I started feeling like I had walked mile but I was ok. At about 4:00 PM I started feeling some tightness on my chest and some aching like a pulsing aching on my chest. I felt like I had some energy but I also felt I was paying to mush attention to my symptoms. I lay down at 8:30 PM and I fallen to sleep on the couch. When I got up this morning as stood up from my bed my legs were hurting and I feel exhausted. I just want to cuddle and go back to sleep. I force myself to make it to work but I am dealing with leg pain and very very tired with a slight headache and chills.

"My temperature, it is 100.6; I was feeling chills; I am having body aches/full blown body aches; I was starting to feel achiness/achiness was not going away; I am congested all of a sudden; I felt like I was developing a headache that just got worse as the day progressed/now I woke up this morning and my head is hurting; I was not feeling well; This is a spontaneous report from a contactable nurse who reported for herself. A 56-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot #: EH9899; Expiry Date: Mar2021) via an unspecified route of administration on 18Dec2020 at 09:59 (at the age of 56-years-old) as a single dose for COVID-19 vaccination. Medical history was reported as none. The patient reported ""no, I do not have any health issues."" Concomitant medications included estradiol taken as hormone therapy from an unspecified date at 0.1 mg, once daily. The patient experienced ""I felt like I was developing a headache that just got worse as the day progressed/now I woke up this morning and my head is hurting"" and ""I was not feeling well"" on 18Dec2020, ""I was starting to feel achiness/achiness was not going away"" on 18Dec2020 at 18:00, ""I was feeling chills"" and ""I am having body aches/full blown body aches"" on 18Dec2020 at 19:00, ""I am congested all of a sudden"" on 18Dec2020 and ""my temperature, it is 100.6"" on 19Dec2020. It was reported that the ""symptomatology began immediately after I got the vaccine (COVID Vaccine)"". The

clinical course was reported as follows: ""I received a vaccine (COVID Vaccine) at work. I am a nurse, I received a vaccine at 09:59 today morning and within probably 5 or 10 minutes, I felt like I was developing a headache that just got worse as the day progressed. By the time, I got home, I get off at 6 O'clock, I started to feel achiness and then eventually I was feeling chills and I was congested all of a sudden as well. So, I took a 1000 mg of acetaminophen last night probably around 9 PM. Initially, I thought it was just side effects from the shot and I would ride it out, but the achiness was not going away. So, I took the acetaminophen and went to bed. When I took the acetaminophen within about two hours the symptoms improved, the achiness had diminished, but I woke up this morning and my head was hurting, I am having chills, I am having body aches. I just took my temperature, it was 100.6."" The nurse stated that she took acetaminophen as treatment for the side effects. When asked about the primary/prescribing Healthcare Professional details the patient stated ""well, it was not a doctor it was a nurse at our hospital, it was a room full of people giving the shot."" The patient also stated ""I read correctly under side effects that the vaccine cannot cause you to contract COVID. Is that true?"" The nurse was informed about Pfizer Medical Information department. When asked about the dosage, the patient stated ""No, I don't think that is on here."" When asked about the causality, the patient stated ""I think it is possible, but it is also possible I mean I just got the vaccine yesterday, I mean we test patients for COVID in my department. My department is responsible for testing all procedures on surgical patients at the hospital and there is always a chance that I have contact with COVID but it is odd that the symptomatology began immediately after I got the vaccine (COVID vaccine), I mean within 10 minutes, I was not feeling well. When I woke up yesterday I was having no symptoms whatsoever and then almost immediately after I took the vaccine it seemed that I had a headache again and it just lasted the entire day, all day until I got home it was so bad and I still have not taken anything because I thought it was just the side effects and like 7 O'clock I was having full blown body aches and chills."" (as reported). The clinical outcome of the event ""I felt like I was developing a headache that just got worse as the day progressed/now I woke up this morning and my head is hurting"" was not recovered/not resolved; the outcome of the event ""I was starting to feel achiness/achiness was not going away"" was recovering/resolving; while the outcomes of the events ""I was feeling chills"", ""I am congested all of a sudden"", ""my temperature, it is 100.6"", ""I was not feeling well"" and ""I am having body aches/full blown body aches"" were all unknown."

parasthesia in injected arm including ring and pinky fingers; parasthesia in injected arm including ring and pinky fingers; weakness in injection arm up to the tricep muscle; He also experienced mild weakness; This is a spontaneous report from a contactable nurse (patient). A 33-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number: EK5930), via an unspecified route of administration in left arm on 21Dec2020 09:00 at a single dose in TB size syringe for COVID-19 immunization. The patient has no medical history. There were no concomitant medications. The patient is a nurse anesthetist calling about himself, stating that he thinks he has had a reaction to the Pfizer COVID Vaccine. He took a dose about 9am this morning and about 2.5 hours later he experienced paresthesia in his injected arm including his ring and pinky fingers. He also experienced mild weakness. The symptoms lasted about 45 minutes. Stated that the symptoms lasted about 45 minutes and has completely resolved thus far; however, he cannot attest if these symptoms will return or not. Stated that it was given with a TB size syringe and so assumes that it was the standard dose that

he received, but does not know for sure. No treatment was received for the symptoms. He just monitored himself. Caller wants to know if he should move forward with the second dose. He heard about Bells Palsy. If he had paresthesia with his first dose in the injected arm, could the paresthesia come to his face next? He wants to know if he is in the normal category to advance with the second dose. The events were reported as not serious. The events recovered on 21Dec2020.

Severe heartburn; abdominal pain; Agita; swelling; chest tightness; generalized redness; itching; sore throat; severe weakness; fatigue; headache; muscle pain; nausea; malaise/feeling unwell; increased temp but not febrile; This is a spontaneous report from a contactable nurse, the patient. A 63-year-old non-pregnant female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), intramuscular in the left arm on 18Dec2020 at 14:15 (at the age of 63-years-old) as a single dose for COVID-19 immunization. Medical history included chronic pain, hypertension, diabetes, depression, and broken vertebra. The patient was allergic to many antibiotics and benzodiazepines which caused dystonia. The patient also had an allergy to all anti-emetics except ondansetron (ZOFRAN) in the form of dystonia. Prior to the vaccination, the patient was not diagnosed with COVID-19. Ongoing concomitant medications included diclofenac (MANUFACTURER UNKNOWN) from an unknown date for an unknown indication, esomeprazole magnesium (MANUFACTURER UNKNOWN) from an unknown date for an unknown indication, fentanyl (MANUFACTURER UNKNOWN) for a broken vertebra from an unknown date, gabapentin (MANUFACTURER UNKNOWN) from 2019 for an unknown indication, misoprostol (MANUFACTURER UNKNOWN) from an unknown date for an unknown indication, oxycodone hydrochloride/paracetamol (PERCOCET) from an unknown date for an unknown indication, and fentanyl (FENTANYL PATCH) from an unknown date for an unknown indication. The patient did not receive any other vaccines within four weeks prior to the vaccination. On 18Dec2020 at 14:30, the patient experienced generalized redness, itching, swelling, and chest tightness; which required her to go the emergency room for 6 hours and was treated with epinephrine (MANUFACTURER UNKNOWN), diphenhydramine hydrochloride (BENADRYL), and fluids. On an unknown date in Dec2020 (reported as later), the patient had sore throat, severe weakness, fatigue, headache, muscle pain, nausea, malaise/feeling unwell, and increased temperature but not febrile. On 22Dec2020, the patient had severe heartburn, abdominal pain, and agita. Since the vaccination, the patient had not been tested for COVID-19. The clinical outcomes of generalized redness, itching, swelling, chest tightness, sore throat, severe weakness, fatigue, muscle pain, nausea, malaise/feeling unwell, and increased temperature but not febrile were recovering; while that of the headache, severe heartburn, abdominal pain, and agita were not recovered. The events were reported as non-serious and assessed as possibly related to the vaccine. The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up.; Sender's Comments: The patient was allergic to many antibiotics and benzodiazepines and had an allergy to all anti-emetics except ondansetron (ZOFRAN) in the form of dystonia. Based on information available, the reported chest tightness and swelling together with generalized redness and itching were possibly related to the BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), considering temporal relationship and clinical course. This case will be reassessed should additional information become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any

appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Severe headache woke me from sleep approx. 6 hrs later, continued till the next day; Severe headache woke me from sleep approx. 6 hrs later, continued till the next day; severe neck and back stiffness, just did not feel well; severe neck and back stiffness, just did not feel well; This is a spontaneous report from a contactable nurse (patient). A 47-year-old female patient received bnt162b2 (Pfizer Biontech COVID 19 vaccine), lot number: EJ1685, via an unspecified route of administration at the left arm on 20Dec2020 06:30 at a single for COVID-19 immunization. Prior to vaccination the patient was diagnosed with COVID-19. Concomitant medication included levothyroxine sodium (SYNTHROID), carvedilol (COREG), ergocalciferol (VIT D), vitamin b complex (VIT B COMPLEX) and bupropion hydrochloride (WELLBUTRIN). On 20Dec2020, the patient experienced severe headache that woke her from sleep approximately 6 hours later and continued till the next day. She started having severe neck and back stiffness and just did not feel well. The patient was not hospitalized for the events and did not receive any treatment for the events. The events were reported as non-serious. The vaccine was administered in a hospital. The patient has not received any other vaccines within 4 weeks prior to the COVID vaccine. Since the vaccination, the patient has not been tested for COVID-19. The events recovered on an unspecified date in Dec2020.

Her BP went down to 80/60 with a pulse of 50.; sudden light headiness/light headedness; pulse of 50; Slurred speech; extreme sleepiness/sleepiness that there was no other focal deficit; felt like she was under anesthesia, was unable to move her legs/felt like she was under general anesthesia trying to wake up but unable to open her eyes or move her arms or legs; This is a spontaneous report from a contactable pharmacist. A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) lot number and expiration date were not reported, via an unspecified route of administration on unspecified date at a single dose for immunization. Medical history was none. The patient's concomitant medications were not reported. It was reported that the patient (a doctor) received the vaccine and had a sudden light headiness, slurred speech, and extreme sleepiness with outcome of recovered. She felt like she was under anesthesia, and was unable to move her legs. Her BP went down to 80/60 with a pulse of 50. All of these episode lasted about 2 hours. The patient became alert, but she still felt a bit light headed. She felt normal the next day. The patient said that at the sudden onset of the side effects: light headedness, slurred speech, and sleepiness that there was no other focal deficit. She felt like she was under general anesthesia trying to wake up but unable to open her eyes or move her arms or legs. The outcome of the events Her BP went down to 80/60 with a pulse of 50, sudden light headiness/light headedness, Slurred speech, extreme sleepiness/sleepiness that there was no other focal deficit and felt like she was under anesthesia, was unable to move her legs/felt like she was under general anesthesia trying to wake up but unable to open her eyes or move her arms or legs was recovered on an unknown date. Information about lot/batch number has been requested.; Sender's Comments: A possible causal association between administration of BNT162B2 and the onset of low blood pressure/ low pulse with dizziness cannot be excluded, considering the plausible temporal relationship. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for

adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate

Midbottom of foot to toes is completely numb; tingling in toes of both feet; paresthesias (numbness, tingling) right arm; paresthesias (numbness, tingling) right arm; This is a spontaneous report from a contactable nurse practitioner, the patient. A 56-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot Number: EK5730), intramuscular in the left arm on 18Dec2020 (at the age of 56-years-old) as a single dose for COVID-19 immunization. The patient did not have any relevant medical history. Ongoing concomitant medications included levothyroxine sodium (SYNTHROID) and unspecified vitamins. On 18Dec2020, the patent experienced paresthesia (numbness, tingling) in right arm. On 19Dec2020, the patient had tingling in the toes of both feet. On 21Dec2020, the mid bottom of foot to toes was completely numb. The clinical course was as follows: The patient received the vaccine in the left arm on 18Dec2020 and 9 hours later, she had paresthesias (tingling/numbness) in right arm. It was stemming from her shoulder down her arm. Around mid-morning on 19Dec2020, she had started having tingling in the toes of both feet. On 21Dec2020, the mid bottom of foot to toes was completely numb. The patient reported that the paresthesias (tingling/numbness) in right arm was getting better and was more intermittent and the tingling in the toes was only in the left foot as of 22Dec2020. The clinical outcome of the paresthesia (numbness/tingling) in the right arm was recovering; while that of the numbness in mid foot to toes and tingling in the toes were not recovered. The reporter assessed the events as serious for being medically significant and assessed the events as related to the suspect vaccine.; Sender's Comments: The Company cannot completely exclude the possible causality between the reported paresthesia (numbness, tingling) in right arm, tingling in the toes of both feet, the mid bottom of foot to toes was completely numb, and the administration of the BNT162B2 for COVID-19 immunization, based on the plausible temporal association. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified, as appropriate.

Hypotensive (diastolic 43, sistolic 103); neurological tingling -upper spine/between shoulder blades; felt crummy; This is a spontaneous report from a contactable consumer. A female patient of an unspecified age received 1st dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration in left arm on 21Dec2020 15:45 at single dose for Covid-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient experienced hypotensive (diastolic 43,sistolic 103), neurological tingling - upper spine/between shoulder blades and generally felt crummy on 21Dec2020 at 15:45 (also reported as occurred within 5 minutes of shot). The patient underwent lab tests and procedures which included blood pressure measurement: 103/43 on 21Dec2020. Event resulted in emergency room and physician's room visit. Treatment received intravenous (IV) fluid replacement, lab tests (unspecified), 6 hour observation. The outcome of events was unknown. Information on the lot/batch number has been requested.

"Immunocompromised; Flushing; This is a spontaneous report from a contactable other healthcare professional which is also the patient. A 37-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration not provided), via an unspecified route of administration on 21Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient received the COVID-19 vaccine yesterday (21Dec2020) and experienced flushing since Dec2020. Added that patient was also immunocompromised. The events were reported as non-serious. Outcome of the events was unknown. Information on the Batch/Lot number has been requested.; Sender's Comments: Limited information was provided for the mentioned ""immunocompromised"". Based on the information currently available, pending further clarification, the Company deems the reported ""immunocompromised"" unlikely related to the administration of BNT162B2. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RA, IEC, as appropriate."

chills all night and syncope; chills all night and syncope; This is a spontaneous report from a contactable other health professional (patient). A 39-year-old male patient received the first dose of the bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot Number and Expiration Date: Unknown), intramuscularly in the left arm (also reported as the right arm) on 22Dec2020 at 15:00 at 39-years-old at a single dose for COVID-19 immunization. The facility where the most recent COVID-19 vaccine was administered was reported as: other. Medical history included Penicillin allergy from an unknown date and unknown if ongoing. Concomitant medications included estrogens conjugated (PREMARIN), progesterone (MANUFACTURER UNKNOWN), estradiol (MANUFACTURER UNKNOWN), montelukast (MANUFACTURER UNKNOWN); all taken for an unspecified indication from an unspecified date to an unspecified date (all of which were received within two weeks of vaccination). The patient did not receive any other vaccines within four weeks prior to the COVID vaccine. On 23Dec2020 at 00:00, the patient experienced: chills all night and syncope. The event syncope was considered medically significant; and the event chills was non-serious. There was no treatment received due to the adverse events. It was reported that prior to vaccination, the patient was not diagnosed with COVID-19; and since the vaccination, the patient had not been tested for COVID-19. The clinical outcome of the events, chills all night and syncope, was recovering. The batch/lot numbers for the vaccine, bnt162b2, were not provided and will be requested during follow up.; Sender's Comments: Based on temporal association, a possible contributory role of suspect BNT162B2 vaccine cannot be excluded for reported event syncope. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

"vomiting; nausea/felt like she was going to vomit; headache/bad headache was reported as worsened; arm and joint pain in injection arm/Joint pain; arm and joint pain in injection arm; arm and joint pain, mostly in the left arm where she received the COVID vaccine/left arm pain at injection site; had a history of a pain conditions in her back/ but got worse after the shot""; This is a spontaneous report from a

contactable nurse (reported for herself). A 26-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899), via an unspecified route of administration on 22Dec2020 11:30 at single dose at arm for COVID-19 immunization. Medical history included complex regional pain syndrome from Dec2019 and ongoing, back pain ongoing. Concomitant medications included naproxen sodium (ALEVE) ongoing, duloxetine hydrochloride (CYMBALTA) from 20Dec2020 and ongoing. Caller wanted to know if she should receive the second dose of the Covid vaccine. She received the vaccine yesterday (22Dec2020) at 11:30 (11:30 a.m.) by 21:30 (9:30 p.m.) she was experiencing side effects of vomiting, nausea, headache, arm and joint pain in injection arm, and continued to feel as if she was going to throw up. HCP was called to get Zofran prescribed. Caller further reported that she got the COVID Vaccine yesterday, 22Dec2020, at 11:30 (11:30am). At 21:30 (9:30 pm) last night (22Dec2020), she started vomiting and has had nausea since that time. Caller also stated that she had a really bad headache. Caller stated that she also had arm and joint pain, mostly in the left arm where she received the COVID vaccine. She went to sleep at 8:30 last night and woke up vomiting at 9:30pm and then had had nausea and a headache since then. If she tried to get up, she felt like she was going to vomit. She had a history of a pain conditions in her back and ""let"" (as reported, pending clarification). Stated that she cannot say that this was entirely due to the shot, but got worse after the shot (Dec2020). Caller reported that last night, she took Zofran which help the vomiting. The vomiting stopped around 3 o'clock this morning (23Dec2020 03:00), but she was still having nausea that made her feel like she was going to throw up. She could not stop vomiting for a few hours during the night. Caller asked how she know if she should be taking the 2nd dose of the COVID vaccine. Events Vomiting, Nausea, bad headache, left arm pain at injection site, Joint pain all reported as started from 22Dec2020 (21:30). Patient recovered from vomiting with lasting effects of nausea which made her feel like she was going to vomit, started on 23Dec2020. Reporter seriousness for Vomiting, Nausea, bad headache was Medically significant and bad headache was reported as worsened. Reporter seriousness for left arm pain at injection site and Joint pain was not serious. No Investigation Assessment. The reporter considered events Vomiting, Nausea, bad headache, left arm pain at injection site, Joint pain were related to the suspect product. The outcome of the event vomiting was recovered on 23Dec2020 03:00. The outcome of ""had a history of a pain conditions in her back/ but got worse after the shot"" was unknown. The outcome of the other events was not recovered.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the vomiting, nausea, headache and other reported events due to temporal relationship. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate."

hypertensive emergency; felt like the swelling was progressing into the back of her throat; swallowed harder; she felt like she was hot in her face and felt like something was squeezing her neck like a tight collar on her shirt; she felt like she was hot in her face and felt like something was squeezing her neck

like a tight collar on her shirt; shivering on and off; This is a spontaneous report from a contactable pharmacist. This pharmacist reported similar events for two patients. This is the first of two reports. A 67-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot number: EH9899), intramuscularly in an unspecified arm on 21Dec2020 14:30 at 0.3 mL single for COVID-19 immunization. Medical history included sulfa allergy. The patient's concomitant medications were not reported. There were no prior vaccinations within 4 weeks prior to the first administration of the suspect vaccine. The patient did not have a history of reactions to any other vaccines. On 21Dec2020, the patient experienced hypertensive emergency, which was reported as being medically significant. On 21Dec2020, the patient also felt like she was hot in her face and felt like something was squeezing her neck like a tight collar on her shirt, shivering on and off, felt like the swelling was progressing into the back of her throat and she swallowed harder. Clinical details were reported as follows: the patient received the vaccine on 21Dec2020 at 14:30 and fairly quickly the patient started saying she felt like she was hot in her face and felt like something was squeezing her neck like a tight collar on her shirt. She was given 25mg of diphenhydramine hydrochloride (BENADRYL), orally. The patient was shivering on and off and patient said she felt like the swelling was progressing into the back of her throat. She was having to clear her throat and swallow harder. She was taken to the emergency department around 15:11 and given intravenous (IV) famotidine (PEPCID) 20mg at 15:27. The patient did not have issues oxygenating. It was noticed that the patient's blood pressure was 232/100 on 21Dec2020 and they started treating her for the hypertensive emergency with amlodipine (MANUFACTURER UNKNOWN) 5mg orally, one time of IV labetalol (MANUFACTURER UNKNOWN), 10mg , IV labetalol (MANUFACTURER UNKNOWN) 20mg once, Clonidine (MANUFACTURER UNKNOWN) 0.1mg, orally. The patient was sent home around midnight and was not admitted to the hospital. The outcome of hypertensive emergency was recovering and of patient also felt like she was hot in her face and felt like something was squeezing her neck like a tight collar on her shirt, shivering on and off, felt like the swelling was progressing into the back of her throat and she swallowed harder was unknown. When querying causality, the reporter stated this patient did not have a history of hypertension, so she thinks it is suspicious.; Sender's Comments: The 67-year-old female patient had sulfa allergy medical history. Throat swelling and hypertensive emergency were possibly related to the BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), considering temporal relationship and clinical course. This case will be reassessed should additional information become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.,Linked Report(s) : US-PFIZER INC-2020510772 Same reporter/different patient/similar events

had a patient receive COVID vaccine and 3 days later developed bilateral pulmonary embolisms; This is a spontaneous report from a contactable physician. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration at single dose on an unspecified date for COVID-19 immunisation. The patient medical history and concomitant medications were not reported. The physician had a patient receive COVID vaccine and 3 days later developed bilateral pulmonary embolisms on an unspecified date with outcome of unknown. Have there

been any similar reports of such events within short time frame of receiving the vaccine? Information about lot/batch number has been requested.; Sender's Comments: The information provided is limited and doesnot allow a full medically meaningful assessment. This case will be reassessed should additional information, especially patient age, relevant medical history, concomitant drugs and clinical course, become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

facial itching; throat swelling; lump in throat; hoarse voice; This is a spontaneous report from a contactable nurse. A 37-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: ELO140), via intramuscular on left arm on 23Dec2020 at 09:45 at single dose for COVID-19 immunization. The relevant medical history and concomitant medications were not reported. The patient experienced facial itching, throat swelling, lump in throat and hoarse voice, all at 11:30 on 23Dec2020. The most recent COVID-19 vaccine was administered at hospital. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The events resulted in doctor or other healthcare professional office/clinic visit for the patient. The patient received IV benadryl and Epi pen as the treatment for the events. Prior to vaccination, the patient was unknown if diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. The outcome of the events was recovered on an unspecified date in Dec2020.; Sender's Comments: Based on temporal association, the causal relationship between BNT162B2 and the events pruritus, pharyngeal swelling, sensation of foreign body and dysphonia cannot be excluded. This case will be reassessed once additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate.

Exaggerated immune response and rigors; Exaggerated immune response and rigors; Fever and night sweats; Fever and night sweats; Sustained tachycardia between 100-105; This is a spontaneous report from a Pfizer sponsored program. A contactable 31-year-old male physician reported that he received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Lot number EH9899) via an unspecified route of administration in the right deltoid on 19Dec2020 at 10:30 at single dose for COVID-19 immunisation. Vaccination facility type: hospital. Relevant medical history included COVID-19 (recently had COVID prior to receiving the COVID-19 Vaccine). There were no concomitant medications. Five minutes after the COVID-19 Vaccine, on 19Dec2020, the patient experienced sustained tachycardia between 100-105 that lasted about 40 minutes and then dissipated by itself; the patient recovered from tachycardia on 19Dec2020. Early morning on 20Dec2020 at 03:30, he had an exaggerated immune response and rigors, which lasted about 30minutes to 40minutes, followed by fever and night sweats, which continued for 30 minutes and then it was all over. Reactions were spontaneously over. The patient recovered from the events exaggerated immune response and rigors, fever and night sweats on

20Dec2020. The physician believed that it was a hyper immune response. Recently, he had COVID prior to receiving the COVID-19 Vaccine and he wanted to know whether he should have waited after experiencing COVID to have received the first dosage of the COVID-19 Vaccine. The physician considered the reported events related to the COVID-19 Vaccine.; Sender's Comments: Based on available information, a possible contributory role of the subject product cannot be excluded for the tachycardia and other reported events due to temporal relationship. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics including EKG at baseline and during subject drug therapy, echocardiogram, electrolytes, chemistry panel, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

patient's anaphylactic reaction persisted longer than expected; This is a spontaneous report from a contactable pharmacist. A 45-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration in Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient's anaphylactic reaction persisted longer than expected in Dec2020. The outcome of the event was unknown. The batch/lot number for the vaccine, BNT162B2, was not provided and will be requested during follow-up.; Sender's Comments: The causal relationship between BNT162B2 and the event anaphylactic reaction cannot be excluded as the information available in this report is limited and does not allow a medically meaningful assessment. This case will be reassessed once additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate.

heart racing/her heart beat was 140 BPM; felt flush, hot; tired; soreness at the injection site; This is a spontaneous report from a contactable consumer. An adult female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 22Dec2020 at single dose for COVID-19 immunization. The patient medical history was not reported. The patient's concomitant medications were not reported. The patient received the vaccine and with 10 minutes felt flush, hot, and her heart racing on 22Dec2020. At one point she looked at her watch and her heart beat was 140 BPM. She was sent immediately to the ER (emergency room). Since then she was tired and had soreness at the injection site. She would have to see an allergist before getting the 2nd shot. The outcome of the events was recovered on unspecified date in Dec2020. Information about batch/lot number has been requested.

tunnel vision; Shortness of breath; headache; couldn't move arms/legs; This is a spontaneous report from a contactable other health professional via a Pfizer sales representative. A patient of unspecified

age and gender received bnt162b2 (BNT162B2), via an unspecified route of administration, on an unspecified date, at single dose, for Covid-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient experienced tunnel vision, shortness of breath, headache and couldn't move arms/legs all on an unspecified date with outcome of unknown. The information on the lot/batch number has been requested.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the reported events of tunnel vision, shortness of breath, headache and couldn't move arms/legs due to temporal relationship. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics including eye examination at baseline and during subject drug therapy, Head CT/MRI, chemistry panel and chest x-ray , counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

hallucinations; pain in right arm; headache; fever; chills; This is a spontaneous report from a contactable pharmacist via Regulatory Authority (Regulatory Authority report number not provided). A 35-year-old female received the 1st dose of bnt162b2 (BNT162B2, Manufacturer Pfizer-BionTech), intramuscular, on 18Dec2020 morning, at single dose, for Covid-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient has never had an adverse event following any previous vaccine. On 18Dec2020 afternoon, 12 hours after receiving vaccine, the patient experienced hallucinations, pain in right arm, headache, fever and chills. The patient underwent lab tests and procedures which included body temperature: fever (18Dec2020). The events recovered in Dec2020, 36 hours after. The information on the lot/batch number has been requested.

She woke up with a burst blood vessel in her eye; This is a spontaneous report from a contactable other healthcare professional (hcp) (patient). A 35-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 Vaccine), via an unspecified route of administration on an unspecified date in 2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. After receiving the Covid-19 vaccine in 2020, she woke up with a burst blood vessel in her eye. There was blood throughout the white portion of her left eye. The outcome of event was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Based on available information, a possible contributory role of the subject vaccine cannot be excluded for the reported event of eye hemorrhage due to temporal relationship. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics including including eye examination at baseline and during subject drug therapy, Head CT/MRI, chemistry panel, CBC and coagulation panel, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events.

Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

tenderness when pressure applied under left arm pit

Elevated temp 1?.2, chills, aches, nausea

Throat tightness, hoarse voice

Patient stated her throat felt tight and she was having trouble swallowing and her heart was racing. She was given diphenhydramine 50 mg IM and taken to the emergency room for observation. She was not given any additional medication in the emergency room and was discharged to home approximately 3 hours later.

nausea, headache, pain and swelling in arm, and weakness

Felt dizzy/faint and heart pounding. Given ice water and cool wash cloth, rest. Monitored, blood pressure 102/76. After 30 minutes continued to feel faint and dizzy with heart pounding feeling. Brought to Emergency Department for further evaluation.

Mild generalized, erythematous rash noted on patient's abdomen and back. The rash is pruritus.

Near Syncope

swollen gland in left armpit? tenderness to touch

Dry Cough

Client complained of numbness in arm, SOB, throat closing per onsite party, medical rendered by ambulance service, client given a Benadryl, condition improved, client released to self and drove self from the waiting parking lot.

Chills, body aches. He did have Covid on 11/11/2020

When rec'd injection on 12/23, it hurt more than any I've ever had and expected discomfort for several hours. By evening on 23rd my upper arm and shoulder were very painful and deltoid area swollen. By 24th, the pain was affecting entire left arm, shoulder, left back and neck. Then had pain/discomfort throughout body through the 25th, Ibuprofen taken as needed, by end of 26th I was feeling a bit better, and the 27th near all symptoms resolved. I do still have a good sized bruise around injection site.

7 AM - severe arm pain and swelling (for about 24 hours) 12:00 PM - 10 PM: chills, fever, fatigue, malaise

Patient reports elevated heart rate of 147 (normal: 70-120) and dizziness about 20 minutes after receiving vaccine.

shoulder pain with movement.

Patient was vaccinated for COVID-19 on 12/27/20 at 11am. 2 days later, upon waking up she developed pain at the injection site (left deltoid), and a rash on her right hand and right side of her stomach, not itching reported. The patient reported to employee health the reaction, she was seen in urgent care and given prednisone, benadryl, and famotidine.

Golf ball size swelling lymph nodes. Swelling in shoulder, chest, N/V.

Throat swelling, hard to breath, wheezing, went to employer ER. Prescribe a steroid and antihistamine.

"Patient reports that at about 30 minutes after she received her vaccine, her lips began feeling numb and tingling, mouth dry. She reports her face starting itching and developed a red rash, her face felt like it was ""on fire"". She denied any shortness of breath or difficulty breathing. She walked back into the clinic office at 1240, a set of vitals were taken and at 1250 25mg of PO benadryl was administered. Patient was held for observation and at 1325 she reported that the itching had improved. She did have an itching sensation in her through but no feelins of constriction or difficulty breathing. She stated that she did not feel drowsy and was okay to drive herself home. Her husband would be at home with her for the remainder of the day and she was told that if she developed any new or worsening symptoms to report to the ED immediatley."

Vaccine recipient received vaccine on 12/18/2020 at 7:30 am and at 9:00 am reported their bottom lip had swelling and around the chin had tingling that lasted 1.5 hours. At the occupational health follow-up visit on 12/28/20, the vaccine recipient reported that the injection site has been soar with occasional numbness and weakness that has not changed in intensity. Pfizer-BioNTech COVID-19 Vaccine

Received vaccination 12/23/20. On 12/28/20 began having fever 102+ and shortness of breath. Decided to go to ED for evaluation and COVID tested. Discharged from ED.

Back started itching, noticed huge red spot warm to the touch, hives. Neck and face become blotchy looking. Called NP, took 50mg of diphenhydramine. The hives and rash subsided by the end of the day on December 24th.

minutes after had flushed feeling all over body (similar to when I had dye injected for a cat scan).. felt lightheaded and extreme dry mouth.. lasted for about an hour. blood pressure when check on floor had a high diastolic number (120/94)

Approx 25 minutes after vaccination, client developed mild, red, raised rash with itching on lateral left wrist distal to injection site. Client denies any other adverse signs/symptoms of angioedema or anaphylaxis 1 hour after administration of vaccine.

Fever (102): body aches, chills, nausea, lightheaded (vertigo) All symptoms have subsided EXCEPT Vertigo/dizziness

Severe arm pain the following day. Resolved after about one day.

"Dizziness, warmth, ""just not normal"", scratchy throat. Resolved in about 1 hour."

Dizziness and nausea 10 minutes after injection, continued to wax and wane over approx 90 minutes. No vitals taken. Patient ambulated back to work at 1800.

tenderness to touch under right arm/armpit area. pain pressure felt when running.

Swelling of palate approx. 5 minutes post COVID Vaccine Dose #1. VS normal and stable. Received diphenhydramine 50mg PO with symptom resolution within 20 minutes. Observed for 40 minutes and D/C'd in stable condition with no sxs present.

Rash developed on forehead. Felt itch on other part of body. Felt hot and prickly. Took diphenhydramine and subsided within 45 minutes.

Weird rash to both lower legs, chest and neck area about 2 hours after administration.

Patient describes a tingling feeling all over the body, especially in the hands in face and it came in 2 waves lasting not more than a few seconds. She no longer is having these symptoms

Symptoms started 2 days after I got my injection. I had a massive migraine, body aches, chills, fever with temperature reaching 102. Symptoms lasted 24 hours. The following day I felt fine again.

Soreness in the arm achness around injection site itchy around the ears, in ears and itchy spots in throat around lips and face body felt numb

Near Syncope, dizziness

Near Syncope, dizziness

While, receiving the Covid vaccine with the needle still inserted, felt a significant amount of liquid drip down my arm and unsure how much of vaccine was administered.

Extremely stiff joints and joint pain.

Ipsilateral (to side of vaccination, i.e. left) supraclavicular adenopathy (painful, swollen, very tender to palpation for 3 days) Itchy throat Congestion Left arm soreness (this was immediately after, resolved after 3 days around the time the adenopathy began)

On December 25th developed a rash that started on the stomach, spread down legs then up the back on December 26th, all over body by the December 28th. Started off as a blistery area then turned to dry flakey skin, on the 28th started itching. by December 29th the itching had started to subside. Rash did not occur on the face but was in the scalp area. Patient took diphenhydramine but it die not help. As of the time this report is being filed has not contacted any healthcare provider.

facial swelling and hives; hives to right arm - zyrtec and prilosec taken. Ice administered. subsided by next day.

About 7 hrs after the vaccination I've experienced the side effect of tense pain on neck, lower back, thighs, calves and got more intense with time throughout the night and in the morning, daytime (now

12:34pm). Hard to sleep, kept waking up at night. I took Advil and Tylenol and couldn't tell if one was helpful then the other. The pain was still there but not as intense.

metallic taste in mouth

sore arm, chills, body aches; lasted 2 days after the vaccine date

Chills, joint pain, and headache starting 4 hours after the covid vaccine. S/S have yet to subside.

Patient received the covid vaccine on 12/19/2020. C/O new onset on sore throat and diarrhea on 12/28/2020. Sore throat is worsening. Hx of colitis by well controlled with Xeljanz. Diarrhea is unusual this time. Last diarrhea was almost 1 year ago. Denies fever, cough, loss of smell, rhinorrhea, nasal congestion, abdominal pain Awaiting PCP at medical center for evaluation and testing. Declined Employee Health Service

Systemic reaction. 3 days after injection. Severe, worsening macular-papular rash. Started on Abdomen and groin area. Now diffuse and encompasses chest, neck, and both legs. Very pruritic/itchy. Been taking daily Claritin and Benadryl. Not improving after >4 days.

Severe, disabling myalgias of lower back, flank, then lower abdomen resulting in extreme difficulty with standing and ambulatory.

"tingling in fingers approx 5 minutes after injection which resolved approximately 2 minutes later. At 0954, complaint of feeling ""clammy"", 1001 states feeling ""weak"" overall, denies lightheadedness, dizziness while sitting up on cart with HOB elevated. At 1011 no complaints and discharged from care."

Recipient reported to Employee Health Nurse: Pain at injection site, severe fatigue, headache, muscle pain, severe chills, joint pain, fever exceeding 101.0 for 2 days, increased heart rate, rash, dizziness, weakness, tightness in throat, difficulty breathing, nausea, swelling of face/lips.

8PM: Extremely nauseous 4AM: 101.5 fever 11AM: 100.3 fever 11AM: extreme body pain

12/29 c/o fatigue, heavy eyes, and numbness, tingling and swelling to left arm. Also numbness, tingling to left leg and foot. She was seen in ED , prescribed naproxen and sent home.

24 hours after receiving vaccine, Patient started to experience fever, tachycardia, chest pressure, excessive sweating, cough. Patient presented to ER for evaluation. Patient received EKG, blood tests and Covid Rapid antigen test. Patient tested positive for Covid on Rapid Antigen test in ER. Patient was having no symptoms of covid and reported no exposure to covid on pre-vaccine questionnaire the day prior. Patient released from ER to home in stable condition with instructions to call physician immediately if condition worsens.

On 12/28, start getting a really bad headache. Within two hours, I started developing aches all over my body. Developed chills for a few hours. Chills were gone by morning, but headache and some of the aches remained by noon.

Was given the vaccine and about 5 minutes later started having swelling and my eyes and face. It was watched for a few minutes and was assessed by EMS and taken to the emergency department. I was given epinephrine, Benadryl, Solu-Medrol, Pepcid, IV fluids, DuoNebs and observed overnight. I was given multiple rounds of Benadryl, steroids, Pepcid, DuoNebs

She arrived at 12:30 and was vaccinated shortly after while waiting 15 for observation within the 1st 10 min she C/O tingling of her throat and lower lips, felt palpitation. No chills, No headache, + palpitations, and No presyncope. Tells me that she did not experience any loss of consciousness. Never had any chest pain, shortness of breath, or angioedema, rash, pruritus, throat swelling, hoarse voice, or difficulty breathing. The patient has had no recent illnesses, fevers, chills, nausea, vomiting, diarrhea, or flu-like illnesses. She has had no cough, rhinorrhea, or congestion. She denies any recent vaginal bleeding, or abdominal pain. Denies any history of cardiac disease, or history of arrhythmias. Denies any history of prolonged immobility, recent travels, or history of clots. In ED:32 year old female with PMHx as listed in HPI presents with concern for allergic reaction to mod chair and a COVID-19 vaccine, felt tingling in the back of her throat and lower lip, no swelling, wheezing, shortness of breath, throat tightening, rash, nausea vomit or dizziness. Vitals reviewed found to be within normal limit. Physical exam as per above, no signs of mucosal or oral swelling, no hives or rash and no wheezing on exam. Given above findings, low suspicion for allergic reaction this time but plan to observe patient in the ED for any delayed reaction. á

Nausea 10-15 mins after dose. Pain at injection site ~10 hours later. Generalized severe myalgia (thighs and buttocks), chills & rigors ~12 hours after. Headaches, mild nasal congestion and persistent myalgia 24 hours post vaccine with fevers of 38.7 C max 36 h post vaccine. Now ~48h post vaccine and continue with headaches and myalgia especially of lower limbs. However, now also feeling fatigued.

C/o itching and redness to arms and face approx. 20 minutes post vaccine administration.á Admin Benadryl 25mg po x1 per S.O.á 1400-Pt reports itching is nearly resolved; redness improving.

extreme arm soreness, extreme body ache

Fever, chills, recently was positive for Covid on 11/29/2020

Myalgia Dizziness Nausea Fatigue Fever

Pressure in ears that started approximately 3 hours and 40 minutes after vaccination. Pressure is reported in both ears but more prominent in the left ear. Patient came back to immunization clinic under direct observation for additional 30 minutes after symptoms started. Symptoms still present.

Tachycardic, flushing

"Dizzy, nausea at 1 hour Throat tightness, felt ""swollen"" Worked x 2 1/2 hours then reported to nurse, sent to ER"

Around 4am exactly a week after getting the vaccine; I woke up in a sweat, went to the bathroom with extreme nausea thought I may throw up. No throw up came but severe nausea persisted. Along with a

lot of dizziness and light headedness. My balance feels off. My body feels strange, very sensitive to touch. Extreme exhaustion. No motivation. Head ache that seems to not go away with Tylenol. Stomach pain. And my body hurts on the inside my joints. I have metal in my back and it seems to be increased in pain. I had to take the day off and could not work. I feel miserable. Very flu like.

12hours after shot -mild to moderate pain at injection site (no redness or swelling). 12/27/20 (day 5) Skin reaction to few mosquito bite (1 inch red spot around bites). Its the first time I react to mosquito bites. Resolved overnight. 12/28/20 (day 6) Dark reddening around both eyes (specially in eyelids) when removing my makeup. Same routine/products as always. Also resolved overnight.

Dizziness. Light-headed. Given water & mint candy. Took blood pressure. Reading normal. Offered opportunity to lie down. Refused. Sat in chair until about 11:00 AM when felt better to drive.

Dizziness. Light-headed. Given water & mint candy. Took blood pressure. Reading normal. Offered opportunity to lie down. Refused. Sat in chair until about 11:00 AM when felt better to drive.

Dizziness. Light-headed. Given water & mint candy. Took blood pressure. Reading normal. Offered opportunity to lie down. Refused. Sat in chair until about 11:00 AM when felt better to drive.

12 hours after vaccination I started chilling and had intense body aches, terrible joint pain. I do have arm soreness but nothing worse than with other vaccinations. These symptoms have continued for 24 hours after the injection

"Vasovagal response. Pt requested to lie down following vaccination. Reported feeling faint, nauseous and ""seeing stars."" Team applied cool compresses, patient instructed to lie on the floor with feet on a chair. Vitals were BP: 124/82, hr 53, o2 97% at 1200. Pt moved to sitting shortly thereafter. Then, at approximately 1210 requested to lie down 2/2 ringing in ears, sweating, and feeling nauseous again. At 1212 vitals were bp 124/78, hr 58, o2 97%. At approximately 12:25 symptoms abated, pt moved to sitting. Continued to monitor until 12:50 with no recurrence of symptoms."

12/23/2020 - VACCINATION 12/24/2020 - WOKE UP AT 6AM WITH HEADACHE. LASTED 12 HOURS; NO RELIEF WITH TYLENOL (TOOK 2 BRANDS); NAUSEOUS. 'WAS NOT THE NORM'. FELT BETTER AFTER THE 12 HOURS. PREGNANCY HISTORY; 12 WEEKS,; DUE DATE JULY 11/12TH 2021.

About 45 minutes post injection I experiences the sensation of heat all over my body, my heart rate increased rapidly and I had tingling in my mouth. This passed after about 10 minutes, since then I have been experiencing exhaustion and feeling foggy. No additional reactions at this time.

Feeling of wanting to pass out, dizziness and fell at home, severe headache, body aches, scratchy throat and SOB.

Localized urticaria on day 7 post vaccine with generalized swelling, itching, and tenderness. No prior reaction until day 7.

"She arrive at 3:43 and she was nervous before the vaccination for COVID19 (Morena) because has had anaphylactic reactions to Flonase. She was feeling well up to 15 min post vaccination when she felt she is going to pass out w/o loosing consciousness. She felt weak and feeling fainted when we transferred her to the stretcher. Her BP was 163/106 P=112, Pulse Ox 100% at 16:09. She was resting, received O2 lit per min, she was feeling chest tightness when she used her inhaler Albuterol 2 puffs X2 within 5 min. She was feeling weak and stating ""I am going to pass out."" Her repeat BP=152/110, P=94 with pulse Ox 100% at 16:12 repeat at 16:30 BP=139/100, P=99 pulse OX 100% She then C/O chills later. Paramedics were called and transferred in to ED. She takes AMLODIPINE 5 MG DAILY FOR HTN. She has family HX of HTN. Negative for headache, + palpitations, + presyncope, + shortness of breath, slight difficulty brathing. She did not experience any loss of consciousness. Never had any chest pain, angioedema, rash, pruritus, throat swelling, hoarse voice. The patient has had no recent illnesses, fevers, chills, nausea, vomiting, diarrhea, or flu-like illnesses. She has had no cough, rhinorrhea, or congestion. She denies any recent vaginal bleeding, or abdominal pain. Denies any history of cardiac disease, or history of arrhythmias. Denies any history of prolonged immobility, recent travels, or history of clots. á In ED: 36 year old female presents with dizziness and presyncopal like symptoms approximately 15 minutes after receiving the Medina vaccine at this hospital the patient who is mildly tachycardic mildly hypertensive but otherwise normal and stable vital signs and is overall nontoxic appearing. Of note the patient's oxygen saturation was 97% while I was in the room and not the 2% that is documented here. á EKG notable for a rate of 87 normal axis normal sinus rhythm T-wave inversion in V1 otherwise no evidence of Brugada interval abnormality or evidence of electrolyte abnormality that would require further workup at this time. Patient counseled to follow up with her primary care. Patient given EpiPen given her EpiPen has expired. Patient requested to go back to work I feel this is fair given patient will be on campus and can return to the emergency department should she develop any further symptoms. á Patient states her symptoms have completely resolved and she has normal vital signs currently heart rate in the 80s blood pressure 138 systolic feeling well and requesting to be discharged."

Upon registration, pt informed staff she normally gets hives and itching with flu vaccine. Pt received COVID vaccine at 1205. Pt sat down in monitor area at 1209. At 1221, pt stated she started to feel slight itching. At 1230, pt stated itching had increased. RN also noted redness to neck. Pt denied any SOB, difficulty breathing, tingling in mouth, or any other anaphylactic symptoms. At 1234, RN gave 25mg Benadryl orally. Pt requested to receive smaller dose instead of the entire 50mg. Pt stayed to be monitored until 1255. No other symptoms noted. Pt educated to monitor for further signs of anaphylaxis.

Immediately injection site was itchy, but no distress. within 10 minutes, throat became very dry; back of tongue started to tingle and feel as if it were swelling. No shortness of breath noted.

Full body hives approximately 12 hours after injection, resolved with oral diphenhydramine

Shortness of breath, wheezing, throat tighness, body aches without fever beginning 3 days ago lasting 2 days resolved spontaneously overnight

reported throat closing

She stated she had hives appear on her face and had to take Benadryl.

Large red lump that was very sore to the touch, the site is warm and 7 days later a bruise has formed. Lump appears to be very slowly getting smaller.

I woke up on the morning of Dec 26th with significant eye swelling. It was somewhat relieved with loratidine anithistimine 10 mg po daily x 3 days . The swelling was bilateral, symmetrical and was not accompanied by significant reddening of the eyes. Swelling was above and below the eyes. Swelling is slowly resolving but still present today 12/29. A small amount of skin sloughing occurred below the eyes and on the eyelids. Swelling was accompanied by watery eyes, itching with foreign body sensation.

Fever- Started in the middle of the night around 1:00 am and dizziness felt like I was going to pass out. Woke up at 8 with a slight cough, dizziness and faint feeling.

Patient felt lightheaded and dizzy about 5-10 minutes after receiving his first COVID vaccine. His blood pressure was elevated (160/96 mmHg) and he was tachycardic (143 bpm). He said he felt some tingling in his arm. The injection site appeared normal. The patient sat for 30 minutes and his blood pressure and pulse normalized (134/86 mmHg and 84 bpm). He said he began to feel better and eventually left the building.

Approximately 2 and a half hours after vaccine administration, I had the sudden onset of abdominal cramping, multiple episodes of diarrhea, nausea, and tingling in my hands and lips. I recognized these symptoms as a potential allergic reaction and took cetirizine 20 mg and famotidine 20 mg. These symptoms subsided approximately one hour after onset. Approximately 4 hours later, I experienced moderate fatigue and mild muscle soreness of my left arm (where the vaccine was administered). The fatigue and soreness persisted into the next day and gradually subsided.

Sudden onset. Chills, low-grade fever. Myalgia, arthralgia I did have the Covid virus in June. I still have adequate IgG. This began while I was seeing patients today. I do not feel very good. No cough, nasal congestion, no fear of contamination.

Redness of both arms, mild cough, temp 99F

12/22/2020 Received vaccination at approximately 1000 in left deltiod area. Approximately 1700 12/22/2020 developed parethesia 3rd, 4th and 5th fingers diagonally to ulnar area of left palmar surface. 12/23/2020 noted paresthesia alone vertebrea with outward extension to all areas of back.

None stated.

c/o tingling in nose/throat, dizziness, Chills administered 25mg Benedryl PO @ 1225 v/s 98% RA HR 81 126/82 c/o Cough and itching of throat @ 1246 93% RA, 124/84, HR 83 c/o Tightness in R/chest, symmetrical chest, diminished throughout, with wheezes and faint crackes on RUL clears with cough. 1306 1306 called EMS - sent to ER for Eval

Very tired the first day; pain in my arm for two days; sporadic palpitations; This is a spontaneous report from a contactable nurse (patient). A 28-year-old female received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) lot number: Ek5730, via an unspecified route of administration in the left arm, first dose on 18Dec2020 08:15 at a single dose for immunization. Medical history included hypothyroidism. Concomitant medication included levothyroxine sodium (SYNTHROID). The patient previously took oral aspirin but had intolerance. The patient was not pregnant. The patient did not receive any other vaccines within 4 weeks prior to the vaccine. The patient was not diagnosed with covid-19 prior to vaccination and she has not been tested since the vaccination. The patient was very tired the first day, she had pain in her arm for two days and sporadic palpitations that continued. The events started on 18Dec2020 at 10:30 AM. The outcome of the events 'very tired the first day, she had pain in her arm for two days and sporadic palpitations' was unknown. The patient did not receive any treatment for the events.

Numbness and swelling of the right side of the face; Numbness and swelling of the right side of the face; This is a spontaneous report from a contactable pharmacist. A 39-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899) via intramuscular on 15Dec2020 12:45 on left arm at a single dose for COVID-19 immunization. The patient has no medical history and not allergy to medications, food, or other products. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine and did not receive any other medications within 2 weeks of vaccination. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, the patient has not been tested for COVID-19. The patient experienced numbness and swelling of the right side of the face on 22Dec2020 12:30. The adverse events result in emergency room/department or urgent care. There is unknown whether treatment received for the adverse events. The outcome of the events was unknown.

High Blood pressure; tachycardia; This is a spontaneous report from a contactable nurse (patient). A 36-year-old male patient received first dose of BNT162B2 (Pfizer-BioNTech COVID-19 mRNA vaccine, lot number: EK 5730) intramuscular in the left arm on 18Dec2020 17:00 at a single dose for COVID-19 immunization. The patient received COVID-19 vaccine in a hospital facility. Medical history included asthma, high blood pressure, and allergy to seafood. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. The patient is taking unspecified concomitant medications. The patient previously had allergies to acetylsalicylic acid (ASPIRIN) and iodine (IODO). The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient experienced high blood pressure and tachycardia then 2 minutes after receiving the vaccine. The patient did not receive treatment for the adverse events. The outcome of the events was recovered in Dec2020. The report is considered non-serious.

Pain and numbness in the left arm, from the shoulder to the fingers.; Pain and numbness in the left arm, from the shoulder to the fingers.; Pain and numbness in the left arm, from the shoulder to the fingers.; Cannot raise arm, nor leave it down.; This is a spontaneous report from a contactable pharmacist. A 55-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK5730), intramuscular on 17Dec2020 14:15 at single dose for covid-19 immunization. Vaccine location was left arm and it was the first dose. The COVID-19 vaccine was administered at Hospital. Medical

history included Right breast cancer. Concomitant medication included vitamin Vitamin C, Vitamin D, anastrozole (ARIMIDEX). The patient experienced pain and numbness in the left arm, from the shoulder to the fingers. Can not raise arm, nor leave it down on 19Dec2020. Relief with a sling. Also, to manage pain she was taking Tylenol every four hours. By medical order she started diclofenac potassium 50 mg tablet. Adverse events resulted in: Doctor or other healthcare professional office/clinic visit. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, it was unknown if the patient was been tested for COVID-19. The outcome of the events was unknown.

Nausea; colic; diarrhea; This is a spontaneous report from a contactable pharmacist. A 51-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number EK5730), intramuscular at left arm on 21Dec2020 11:15 at single dose for COVID-19 immunization at a hospital. The patient's medical history and concurrent conditions was reporter as none. The patient had no known allergy (NKA) to medications, food, or other products. There were no concomitant medications (no any other vaccines within 4 weeks prior to the COVID vaccine, no any other medications received within 2 weeks of vaccination). The patient was not diagnosed with COVID-19 prior to vaccination, and had not been tested for COVID-19 since the vaccination. On 21Dec2020 15:00, the patient experienced nausea, colic, and diarrhea. The events lead to doctor or other healthcare professional office/clinic visit. No treatment was received for the events. The outcome of the events was recovered in Dec2020.

joint pain in both knees and elbows/pain in both hips/some joint pain on the right knee and hip; This is a spontaneous report from a contactable physician(patient). A 35-year-old male patient received the first dose of BNT162B2 (lot number: EKS730), via intramuscular in left arm, on 18Dec2020 09:45 AM at single dose for COVID-19 immunization. Facility where the most recent COVID-19 vaccine was administered was hospital. The patient was not diagnosed with COVID-19 prior to vaccination. Since the vaccination, the patient was not tested for COVID-19. Relevant medical history was none. No allergies to medications, food, or other products. No other vaccines were received within 4 weeks prior to the COVID vaccine. The medications received within 2 weeks of vaccination included CBD oil drops. On Monday 21Dec2020 06:00 AM the patient started experiencing joint pain in both knees and elbows. Pain was moderate and fluctuating, the patient took some Tylenol and intensity of pain improved. On Tuesday, 22Dec2020 pain intensity decreased, however at night time the patient started experiencing pain in both hips, mostly on the right side. Today 23Dec2020 pain has disappeared from both elbows, left hip and left knee. The patient was still experiencing some joint pain on the right knee and hip, mostly when he was walking, if he was sitting down or not moving at all, pain is not present. Treatment Tylenol 500 mg P.O. (oral) q (every) 8 hours and CBD oil was received for the events. The outcome of the event was recovering.

Bell's Palsy; This case has been considered invalid as non-serious event was not reportable in clinical study. This is a report from an interventional study. A 51-year-old female non-pregnant subject received blinded therapy (BNT162; PLACEBO) first dose on 24Aug2020 at 13:15 and second dose on 15Sep2020, via an unspecified route of administration on left arm at single dose for COVID-19 immunization. Medical history included allergy to some foods. No other vaccine in four weeks and no other medications in two weeks. The subject experienced bell's palsy on 03Dec2020 which considered as non-

serious by investigator. Clinical course was as follows: on 03Dec2020, the subject had a diagnosis of bell's palsy post 2nd vaccine. The subject had no COVID prior vaccination. A nasal swab post vaccination on 30Nov2020 was negative. After visit 3 (13Oct2020), the subject reported the Bell's Palsy. She went to her doctor, but mot hospitalized. The investigator did not think this was an SAE and was not considered life threatening. The action taken in response to the event for blinded therapy was not applicable. Event treatment included an unspecified medication. The outcome of the event was not recovered. The investigator assessment with blinded therapy, concomitant drugs and clinical trial procedure not reported. Follow-up (21Dec2020): New information received from site included: updated report type, patient ID, event seriousness (non-serious).

Headache for 4 days now; 10 hours post vaccination, patient's entire arm (not injection site) hurt horribly, unable to lift; 10 hours post vaccination, patient's entire arm (not injection site) hurt horribly, unable to lift; At times her face will feel tight; 30 min post starting itching very bad; Have experienced insomnia since the injection, followed by exhaustion; Have experienced insomnia since the injection, followed by exhaustion; eyes itch and have been red; eyes itch and have been red; This is a spontaneous report from a contactable nurse. A 45-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK5730), via an unspecified route of administration (left arm) from 18Dec2020 09:45 at a single dose for COVID-19 immunization. Medical history included migraine, depression, anxiety, allergies, poly cystic ovary syndrome, asthma, different food allergy and sensitivity to all antibiotics. It was reported that 30 min post vaccination, patient started itching very bad and none of her allergy meds would calm it. Have experienced insomnia since the injection, followed by exhaustion. The itching decreases daily but even 10 hours post vaccination, patient's entire arm (not injection site) hurt horribly, unable to lift. She had headache for 4 days now. At times her face will feel tight. She added that she has allergies and sensitivity to many medications/ environmental/ scents. Outcome of events was recovering. No treatment was received due to events. Follow-up attempts are completed. The following information on the batch/lot number has been obtained.

Muscle aches in legs; This is a spontaneous report from a contactable nurse. A 50-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), intramuscular from 18Dec2020 07:45 to 18Dec2020 07:45 at a single dose for COVID-19 immunisation. Medical history included sinusitis, HLD, and penicillin (PCN) allergy. Concomitant medication included vitamin c [ascorbic acid], tocopheryl acetate (VITAMIN-E), ergocalciferol (VIT D), magnesium and calcium. The patient experienced muscle aches in legs from 2 to 12 hours post vaccine administration (18Dec2020 10:00). Outcome of event was reported as recovered. No treatment was received due to the event.

redness above eyebrow, nose and cheek and left hand had few reddened marks on skin, neck had a thin red line; right eyebrow was swollen and neck had a thin red line; The initial case was missing the following minimum criteria: unspecified event. Upon receipt of follow-up information on 23Dec2020, this case now contains all required information to be considered valid. This is a spontaneous report from a contactable nurse. A 62-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot number: EK5730), intramuscularly in the left deltoid on 18Dec2020 10:30 at a single dose for COVID-19 immunization. Medical history included hypertension (diagnosed at 47 years old), hypothyroidism, Hashimoto's disease from 2000 to an unknown date (diagnosed 20 years ago), anxious

person and weight loss. Concomitant medication included hydrochlorothiazide (MANUFACTURER UNKNOWN), taken for blood pressure from 2000 to an unspecified date, levothyroxine sodium (SYNTHROID), taken for hypothyroidism and Hashimoto's disease from 2015 to an unspecified date, rosuvastatin calcium (CRESTOR), taken prophylactically from 2010 to an unspecified date and semaglutide (OZEMPIC) taken for weight loss from May2020 to an unspecified date. Family history included; the patients mother had an allergy to Sulfa and allergy to penicillin and the patients father had unspecified allergies and hay fever. There were no prior vaccinations within 4 weeks. On 19Dec2020, the patient experienced redness above eyebrow, nose and cheek and left hand had few reddened marks on skin, neck had a thin red line and right eyebrow was swollen. The reporter considered the events to be non-serious. The patient was worried about anaphylaxis, so they went to the emergency room (ER) for the reported events but was not admitted. The patient was treated in the ER for the events with diphenhydramine hydrochloride (BENADRYL), prednisone (MANUFACTURER UNKNOWN) and famotidine (PEPCID). Relevant tests were none. The outcome of the events was recovering. The reporter stated that there was a reasonable possibility that the events were related to the suspect product.

left arm began having generalized weakness and difficulty holding pen.; Mild tremors of left hand and fingers.; This is a spontaneous report from a contactable pharmacist. An adult female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number: EJ1685), intramuscular on 18Dec2020 at a single dose for COVID-19 immunization. The vaccine was administered in the hospital. The patient's medical history and concomitant medications were not reported. Around 6 hours post-administration on 18Dec2020, patient's left arm began having generalized weakness and difficulty holding pen. Mild tremors of left hand and fingers. Lasted approximately 2-3 hours and resolved spontaneously. No other symptoms. No treatment was given. The events were reported as non-serious. Outcome of the events was recovered in Dec2020.

Was exposed to someone positive and then 2 days later tested positive; Was exposed to someone positive and then 2 days later tested positive; Was exposed to someone positive and then 2 days later tested positive; This is a spontaneous report from a contactable pharmacist. A male patient of an unspecified age received the first dose of BNT162B2 (Pfizer-BioNTech COVID-19 mRNA vaccine), via an unspecified route of administration in Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient received the first COVID-19 vaccine last week in Dec2020, then was exposed to someone positive and then 2 days later, patient tested positive. Reporter inquired whether they can vaccinate patient on schedule 3 weeks after the first dose or if they have to wait 90 days. The outcome of the events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

Extreme dizziness that is still ongoing; This is a spontaneous report from a contactable nurse (patient). A 54-year-old female patient received the first dose of bnt162b2 (Pfizer Biontech COVID 19 vaccine), Lot number: EK5730, via an unspecified route of administration at the left arm on 18Dec2020 15:15 at a

single dose for COVID-19 immunization. The patient medical history includes migraine and known allergies to Latex and sulfa drugs. Concomitant medication included levothyroxine, gabapentin, calcium, colecalciferol (CALCIUM & VITAMIN D). On 05Dec2020 03:00 (pending clarification), the patient experienced extreme dizziness that is still ongoing. The patient was not hospitalized for the event, did not receive any treatment for the event and event was reported as non-serious. The vaccine was administered in the workplace clinic. The patient has not received any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination the patient was not diagnosed with COVID-19. Since the vaccination, the patient has been tested for COVID-19 (Dec2020-unknown results). On 14Dec2020, Nasal Swab (COVID 19) Result was Negative. The outcome of the event was not recovered.

tightness in throat; This is a spontaneous report from a non-contactable Other Health Professional. A 51-year-old female patient started to receive bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) lot number: HE9899, intramuscular in the right arm, first dose on 16Dec2020 10:21 at a single dose for immunisation. The patient's medical history and concomitant medications were not reported. The patient is not pregnant. The patient had been escorted from observation area to emergency area with complaints of tightness in throat. The patient was eupneic, p/w/d, ambulatory, NAD. Vitals #: P72, 100% pulse ox, RA Vitals #: P72, 98% pulse ox on RA, 112/78 seated. She was administered with 25mg diphenhydramine PO per verbal order (VO)/D. (Name) PA #, pt swallowed with water. Vitals #: 98% pulse ox on RA, P74, denies shortness of breath or pain. She was presented to vaccination clinic. Patient received her vaccination at approximately 1021. Patient reported symptoms onset at approximately 1038 with tightness of the throat. The outcome of tightness in throat was recovered on an unknown date. No follow-up attempts are possible. Information about lot/batch number cannot be obtained. No further information is expected.

tongue tingling and swelling specific to the left side of her tongue; tongue tingling and swelling specific to the left side of her tongue; This is a spontaneous report from a non-contactable other hcp. A 57-year-old female patient received 1st dose of bnt162b2, lot number: HE9899, intramuscular in the right deltoid muscle on 16Dec2020 13:30 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient was seen at the clinic today for her first dose of the COVID 19 vaccination. She denied any history of previous adverse reactions to vaccines. She reports that she also had shingles and pneumonia vaccination on Monday, 14Dec2020. She was given the Pfizer vaccination in the right deltoid muscle. During her 15 minute waiting period after the injection, the patient began to experience tongue tingling and swelling specific to the left side of her tongue. She denied rash, difficulty breathing, difficulty swallowing, wheezing, throat tightness, dizziness and lip swelling. She reports similar reactions after receiving other vaccinations. States that those symptoms always resolved with time and never required any treatment. Outcome of the events was recovered. The events was assessed as non-serious. No follow up attempts are possible. No further information is expected.

Red itchy rash around injection site; Red itchy rash around injection site; Red itchy rash around injection site; This is a spontaneous report from a contactable nurse. A 38-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: Eh9899), intramuscular (Arm Left) from 18Dec2020 18:45 at a single dose for COVID-19 immunisation. Medical history included hypothyroidism

and pre diabetes. Patient had no known drug allergies (NKDA). Concomitant medication included levothyroxine. On 20Dec2020 23:45, the patient experienced red itchy rash around injection site. The patient underwent lab tests and procedures on 16Dec2020 which included nasal swab with negative result. Outcome of events was recovered. No treatment was required/involved. Follow-up attempts are completed. Information on the batch/lot number has been obtained.

lymphadenopathy/I was having reaction of lymphedema; This is a spontaneous report from a contactable consumer (medical dosimetrist and patient herself - pending clarification). A female patient of an unspecified age received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE lot/batch number EJ1685), via an unspecified route of administration in Dec2020 at SINGLE DOSE for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. In Dec2020, the patient was having reaction of lymphedema/ lymphadenopathy and was wondering how long it last generally. The patient also inquired if she would get the next vaccine in different arm. Outcome of the event was unknown. No follow-up attempts are possible. No further information is expected.

Left sided lip numbness; Left hand and foot tingling; This is spontaneous report from a contactable physician (patient). A 29-years-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (lot number EH9899) intramuscular in left arm on 20Dec2020 17:45 at single dose for COVID-19 immunization. There was no medical history. The patient was not allergic to medications, food, or other products. There were no concomitant medications. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient experienced left sided lip numbness, left hand and foot tingling on 20Dec2020 18:00. No treatment was received for the adverse events. Events outcome was not recovered.

Itching and tingling to right arm that traveled to elbow; Itching and tingling to right arm that traveled to elbow/itching to flank area; Itching and tingling to right arm that traveled to elbow; Itching and tingling to right arm that traveled to elbow; This is a spontaneous report from a contactable nurse. A 30-year-old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EJ1685), intramuscular at the right arm on 22Dec2020 07:45 to 22Dec2020 07:45 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. On 22Dec2020 8AM, the patient experienced itching and tingling to right arm that traveled to elbow, employee reported sensation was 'easing up' 5 minutes after it started. She also reported itching to flank area, no rash was noted. The patient was not hospitalized for the events but had an emergency room/department or urgent care visit because of the events. The events were reported as non-serious. The vaccine was administered in a hospital. The outcome of the events was recovering.

throat tightness; This is a spontaneous report from a non-contactable other healthcare professional. A 36-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), lot number HE9899, intramuscular Right arm (right deltoid muscle) from 18Dec2020 12:45 to 18Dec2020 12:45 as single dose for COVID-19 immunization. Medical history included mild anxiety. The patient's concomitant medications were not reported. Patient was given the Pfizer vaccination in the right deltoid muscle. During her 15-minute waiting period after the injection, the patient began to experience throat

tightness. She denied rash, hives, difficulty breathing, hoarseness, lightheadedness, dizziness, facial swelling, lip swelling and tongue swelling. Review of Systems Constitutional: Negative for activity change, appetite change and fever. HENT: Negative for congestion, facial swelling, rhinorrhea and trouble swallowing. Initially with some throat tightness. Resolved within 10 min Respiratory: Negative for cough and shortness of breath. Neurological: Negative for dizziness, weakness, light-headedness and headaches. The outcome of the event was recovered on 18Dec2020. No follow-up attempts are possible, information about batch number cannot be obtained.

bumps; This is a spontaneous report from a contactable consumer. A 58-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EJ1685 & expiration date: 30Dec2069), via an unspecified route of administration at the left arm on 17Dec2020 15:30 at a single dose for COVID-19 immunization. Medical history included border line diabetic, ovarian cancer over 25 years ago, high blood pressure, depression, all under control. The patient has no known allergies. Concomitant medications included metformin, sertraline, lisinopril, ibuprofen, vitamin c, and ergocalciferol (VITAMIN D). Sunday of 20Dec2020, around 16:00, patient noticed bumps on her arms, then the next day more came out and some on her upper legs, which were not painful or red, just bumps. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient was not diagnosed with COVID-19 prior to vaccination and was not tested for it since the vaccination. The patient has not recovered from the event.

tachycardia; This is a spontaneous report from a contactable nurse. A 25-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number: EL0140, expiry date: 31Mar2021), intramuscular on the left deltoid on 17Dec2020 13:22 at 0.3 mL, single for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient had tachycardia on 17Dec2020 13:25, post vaccine but it went away quickly. Reporter stated that she didn't know if patient was anxious. Outcome of the event of tachycardia was recovered on 17Dec2020. The reporter assessed the event as non-serious.

diarrhea; shortness of breath; tachycardia; elevated blood pressure; flushing; chills; 101F fever; weakness; fatigue; muscle aches; This is a spontaneous report from a contactable nurse. A 24-year-old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EJ1685, expiration date unknown) via an unspecified route of administration on 19Dec2020 ast 14:15 at a single dose for COVID-19 immunization in the hospital. The patient has no medical history. There are no known allergies. Concomitant medication included ethinylestradiol, ferrous fumarate, norethisterone acetate (JUNEL FE) for birth control. The patient was not diagnosed with COVID-19 prior to vaccination. The patient experienced diarrhea, shortness of breath, tachycardia, elevated blood pressure, flushing, chills, 101F fever, weakness, fatigue, muscle aches all on 20Dec2020 at 10:00. No treatment was received in response to the events. The patient has not been tested for COVID-19 since vaccination. The patient recovered from diarrhea, shortness of breath, tachycardia, elevated blood pressure, flushing, chills, 101F fever, weakness, fatigue, muscle aches all on an unspecified date.

diagnosed with COVID-19; diagnosed with COVID-19; This is a spontaneous report from a contactable physician, the patient. A male patient of an unspecified age received the first dose of BNT162B2 (PFIZER-

BIONTECH COVID-19 mRNA VACCINE), via an unspecified route of administration on 21Dec2020 as single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. On 22Dec2020, the patient was diagnosed with COVID-19. The clinical outcome of diagnosed with COVID-19 was unknown. The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up.; Sender's Comments: The patient was diagnosed with COVID-19 one day after he received vaccination with BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE). There was not a reasonable possibly that the event was related to vaccination considering the temporal gap between the vaccination and the event onset.

hives; she had an achy left arm (injection arm); fatigue; This is a spontaneous report from a contactable nurse (patient). A 67-years-old female patient started to the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), Batch/lot number was not provided, unspecified route on 17Dec2020 (at the age of 67-years-old) as a single dose in the left arm for COVID-19 vaccination. Medical history and concomitant medication were not reported. On unspecified date in Dec2020, the patient experienced she had an achy left arm (injection arm) and fatigue which she states that she expected. On 22Dec2020, the patient experienced hives. She woke up and had hives. Outcome of the event fatigue was recovered in Dec2020. Outcome of the events hives and she had an achy left arm (injection arm) were unknown.

rash to both forearms, thigh and private area/developed a rash on both arms, thighs, and kind of near the private area. Areas are red and bumpy/rash now is flat, red, and pinkish; rash to both forearms, thigh and private area/developed a rash on both arms, thighs, and kind of near the private area. Areas are red and bumpy/rash now is flat, red, and pinkish; rash to both forearms, thigh and private area/developed a rash on both arms, thighs, and kind of near the private area. Areas are red and bumpy/rash now is flat, red, and pinkish; This is a spontaneous report received from a contactable nurse (who is also the patient). A 62-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EJ1685, expiry date unknown), intramuscular in left deltoid, on 19Dec2020 at single dose for COVID-19 immunization. The patient medical history and concomitant medications were not reported. The patient reported she received the COVID-19 vaccine on Saturday (19Dec2020). Everything was fine all day on Saturday and when she took a shower on Sunday morning (20Dec2020), she noticed she developed a rash on both arms, thighs, and kind of near the private area. Areas are red and bumpy, and she still has the rash on the arms. She called her primary care provider and was instructed to use Benadryl at bedtime and Zyrtec in the morning to help. She was wondering because in 20 some odd days she is to get the second shot and wants to know if she should expect this type of adverse reaction. She mentioned that the rash now is flat, red, and pinkish. She stated she has never had COVID-19 testing or symptoms. Just this rash from the vaccine. The reporter assessed the events as non-serious. The outcome of the events was not recovered (reported as ongoing).

Patient woke up with forehead and back of hand rash; she had swelling in the morning after being vaccinated; This is a spontaneous report from a contactable pharmacist. A 29-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) lot number: unknown, via an unspecified route of administration on 21Dec2020 at a single dose for immunization. The patient's medical history and concomitant medications were not reported. It was reported that the patient woke up with forehead and back of hand rash and she had swelling in the morning after being vaccinated. She took a

BENADRYL and went to the ED (Emergency Department). Event onset date was on 22Dec2020. The event was reported as non-serious. The outcome of forehead and back of hand rash and she had swelling was unknown. Information on Lot/Batch number has been requested.

my lt. arm felt like lead , so heavy and very sore; my lt. arm felt like lead , so heavy and very sore/felt soreness if she lifted up her arm; This is a spontaneous report from a contactable healthcare professional (patient). A 58-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EUA), intramuscular in the left arm on 21Dec2020 16:45 at single dose for COVID-19 immunization. Medical history included the patient being pre-diabetic. The patient's concomitant medications were not reported. The patient previously took epinephrine, norethindrone, and comtrex cold medicine and experienced drug allergy. The patient didn't have anything until around 2:00am on 22Dec2020 - her lt. arm felt like lead, so heavy and very sore. Her arm felt better after getting up - having shower around 6:30am. By 2 pm she only felt soreness if she lifted up her arm. No treatment was given for the events. The patient was not diagnosed with COVID-19 prior to vaccination and was not tested for COVID-19 post vaccination. The patient also did not receive any other vaccines within 4 weeks prior to the COVID vaccine and have not received any other medication within 2 weeks of vaccination. The outcome of the events was recovering. Information on the Lot/batch number has been requested.

achiness; Fatigue; patient was administered 0.3ml of undiluted covid vaccine intramuscularly.; patient was administered 0.3ml of undiluted covid vaccine intramuscularly.; This is a spontaneous report from a Pfizer-sponsored program, IBCC (Inbound Call Center for HCPs). A contactable pharmacist reported that a 28-year-old female patient received bnt162b2 (BNT162B2; lot number: EH9899; NDC number of Covid vaccine: 59267-1000-1 Expiry Date of Covid vaccine: Mar2021), intramuscular on right deltoid on 18Dec2020 at 0.3 mL for COVID-19 immunization. There were no medical history and concomitant medications. On 18Dec2020, a patient was administered 0.3ml of undiluted covid vaccine intramuscularly. The patient experienced achiness, fatigue. The patient received the covid vaccine injection Friday afternoon. When querying seriousness regarding the patient receiving the undiluted dose, he states she has not had very many side effects from it thus far. Clarifies that achiness and fatigue were her main side effects which started Friday night and continued into Saturday. Treatment: She received IV fluids this weekend in the ER as a precautionary measure He does not have time to continue with report and requested to be transferred. No further details. The outcome of the events was unknown.

localized tingling at the injection site that radiated into her 4th and 5th digits and proximally along the sternomastoid muscle; localized tingling at the injection site that radiated into her 4th and 5th digits and proximally along the sternomastoid muscle; This is a spontaneous report from a non-contactable healthcare professional. A 45-year-old female patient received bnt162b2 (BNT162B2; lot number: EH9899; expiration date: unknown), intramuscularly left arm on 22Dec2020 11:15 at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. During her 15-minute (22Dec2020 11:30) waiting period after the injection, the patient began to experience localized tingling at the injection site that radiated into her 4th and 5th digits and proximally along the sternomastoid muscle. The patient denied rash, hives, difficulty breathing, difficulty

swallowing, wheezing, throat tightness, hoarseness, stridor, itching, dizziness, facial swelling, lip swelling and tongue swelling. This reporter was notified of patient reaction and she was then assessed in the emergency bay area. Monitored patient for severe reaction symptoms, including rapid progression of symptoms, vomiting, hypotension and chest pain. The patient was observed for approximately 30 minutes post injection with no evolution of symptom. Injection site tingling that extended along the ulnar nerve distribution was improving at the time of discharge. The outcome of the events was recovering. No follow-up attempts are possible, information about batch number cannot be obtained. No further information is expected.

Hives torso, abdomen, neck and leg; This is a spontaneous report from a contactable nurse. A 50-year-old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number: EH9899), intramuscular on the right arm on 22Dec2020 08:30 at a single dose for COVID-19 immunization. The patient's medical history included penicillin allergy. The patient was not pregnant. There were no concomitant medications. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient was not diagnosed with COVID-19 prior to vaccination and had not been tested for COVID-19 since the vaccination. The patient experienced hives torso, abdomen, neck and leg on 22Dec2020 12:00. Therapeutic measures were taken as a result of hives and included treatment with oral antihistamine. Outcome of the event was recovered on 22Dec2020. The event was considered non-serious.

Severely swollen, hard and painful lymph nodes in the L axillary region. / other swollen glands; fever; muscle aches; chills; headache; This is a spontaneous report from a contactable nurse (patient). A 52-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EJ 1685, expiry date was not provided) solution for injection, via an unspecified route of administration on left arm on 17Dec2020 12:00 at a single dose for Covid-19 immunisation. Medical history included Covid-19. Concomitant medication included sertraline hydrochloride (ZOLOFT). Prior to vaccination, patient was diagnosed with COVID-19. The patient received the vaccine at a workplace clinic and experienced severely swollen, hard and painful lymph nodes in the L axillary region, other swollen glands; fever; muscle aches; chills; and headache, all on 18Dec2020 12:00. It was unknown if patient received treatment for the events. The events were reported as non-serious. Outcome of the events was not recovered. No follow-up activities are needed. No further information is expected.

"BNT162B2 was given to the patient subcutaneously instead of intramuscular; upset; crying; This is a spontaneous report from a contactable nurse via medical information team. A 42-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via subcutaneous on 19Dec2020 at single dose for COVID-19 immunization. Medical history included deep vein thrombosis (DVT) from 3 years ago and unknown if ongoing. Concomitant medication included acetylsalicylic acid (ASPIRIN (E.C.) for DVT and multivitamins. The patient stated ""BNT162B2 was given to me subcutaneously instead of intramuscular (IM)."" She stated she works at (Name withheld) and it was administered by an employee and her hospital employee health will not talk to her and she was being brushed off. The patient asked what's needed to do moving forward. She stated she does not know the efficacy for subcutaneous administration. After providing information in attached document the patient asked what should her next steps be since the hospital will not answer do anything about this incorrect administration.

BNT162B2 was administered her incorrectly. The patient was little upset and was crying about it in Dec2020. The outcome of the events was unknown. Information on the lot number/batch number has been requested."

Having some raised bumps in the back of the hand, multiple small bumps very very small/The bumps are very very small, like an 8th of a centimeter; almost like hives and chicken pox; almost like hives and chicken pox; This is a spontaneous report from a contactable nurse (patient). A female patient of an unspecified age received BNT162B2 (Pfizer-BioNTech COVID-19 mRNA vaccine, lot number: EJ1685, expiry date: Mar2021), intramuscular in the left deltoid on 21Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced a mild side effect after receiving the COVID Vaccine yesterday on 21Dec2020. The patient is having multiple raised bumps, almost like hives and chicken pox, on the back of her hand. The bumps are very very small, like an 8th of a centimeter. The outcome of the events was unknown.

dizziness; throat dryness; nausea; This is a spontaneous report from a non-contactable healthcare professional . A 23-year-old male patient received bnt162b2 (BNT162B2, lot number:EH9899), intramuscularly in his left arm on 22Dec2020 11:00 at a single dose for covid-19 immunization (reported as covid-19 vaccination). The patient's medical history included GI symptoms that he was currently being worked up for. Patient reported onset of similar signs around time of vaccine injection. The patient's concomitant medications were not reported. During his 15 minute waiting period after the injection, the patient began to experience dizziness, throat dryness, and nausea. He denied rash, hives, difficulty breathing, difficulty swallowing, throat tightness, hoarseness, stridor, itching, facial swelling, lip swelling and tongue swelling. The provider was notified of patient reaction and he was then assessed in the emergency bay area. Monitored patient for severe reaction symptoms, including rapid progression of symptoms, respiratory distress with stridor, vomiting, abdominal pain and hypotension. Outcome of the events was unknown. No follow-up attempts are possible; information about batch number cannot be obtained.

I feel weird, kind of spacey; metallic taste; Blood pressure 133/90.; This is a spontaneous report from a contactable nurse. A 53-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE lot/batch number: EJ1685), intramuscular on the left arm on 22Dec2020 14:15 at SINGLE DOSE as COVID-19 vaccination at the hospital. Medical history included reactive airway disease, attention deficit hyperactivity disorder (ADD) and asthma. The patient also had allergies to sulfa. Concomitant medications included losartan potassium (LOSARTA), methylphenidate hydrochloride (CONCERTA) and unspecified inhaler for asthma. On 22Dec2020 14:25 (10 minutes after injection), the patient felt weird, kind of spacey and had metallic taste. The patient also had blood pressure of 133/90 (unit of measure not reported) on 22Dec2020 but denies urticaria, itching, pain, shortness of breath, and chest pain. The patient was brought to the emergency room/department or urgent care further evaluation due to the events. It was unknown if treatments were received for the events. Outcome of the events were unknown. No follow-up attempts are possible. No further information is expected.

Fatigue; The initial case was missing the following minimum criteria: No adverse effect. Upon receipt of follow-up information on (23Dec2020), this case now contains all required information to be considered

valid. This is a spontaneous report from a contactable healthcare professional. A 23-year-old female patient started to receive BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EJ1685), first dose via intramuscular on 22Dec2020 15:00 in left arm at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The facility where the most recent COVID-19 vaccine was administered in a hospital. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. The patient experienced fatigue on 22Dec2020 18:00. The outcome of the event was unknown. The event was considered non serious as it did not results in death, was not life threatening, did not cause/prolonged hospitalization, was not disabling/Incapacitating and had no congenital anomaly/birth defect.

now COVID positive with symptoms; now COVID positive with symptoms; This is a spontaneous report from a contactable consumer(patient). A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 16Dec2020 at single dose for COVID-19 immunization. The patient medical history and concomitant medications were not reported. The patient received the vaccine on 16Dec2020 and now COVID positive with symptoms as of 19Dec2020. The patient asked that should he (she) still get the second vaccine. The outcome of event was unknown. Information on lot/batch number has been requested.

my lymph node is really swollen/and it hurts; headache/a mild headache; had a little bit of dizziness; sick for a little bit; had a little bit of chills; soreness in my arm; This is a spontaneous report from a contactable other hcp (patient). A 40-year-old female patient received 1st dose of bnt162b2 (Pfizer-Biontech Covid-19 Vaccine, lot number: EH9899), via an unspecified route of administration into the left arm on 19Dec2020 at a single dose for COVID-19 immunization. Medical history included high cholesterol diagnosed in maybe 2016 or 2017, but stated that she has the hereditary type, so she can never get rid of it. Concomitant medication included acetylsalicylic acid (BABY ASPIRIN) for high cholesterol; the patient started taking this last year, but then she stopped for a while because her cholesterol was ok, and then her cholesterol went back up and she started taking this again 3-4 months ago. The patient had the COVID vaccine on Saturday and 20 min in, she had a headache and didn't think much of it, had a little bit of dizziness and they gave her Tylenol and she was fine. She was sick for a little bit and just a mild headache. She had a little bit of chills and soreness in her arm. The next day she woke up and notice her neck, between her shoulder and collar bone and woke up and said 'oh that hurts me' and looked and her lymph node was really swollen. It does not bother her but she took a Tylenol and that seems to help with the swelling and it swells up again after the Tylenol. The caller asked if that was a normal side effect or adverse side effect and should she take the next dose 09Jan2021. She also asked if this is a serious adverse reaction or just a side effect. The patient has an appointment today at the time of report with her doctor. The reporter further added that she is a healthcare worker and she took the COVID vaccine this last Saturday; she received the vaccine in her left arm, and on the left side of her body, where she got the vaccine, she is having a reaction. She was fine right after she got the vaccine, like maybe within 20 minutes of getting it she had a headache a little bit of dizziness, and so she was kept in observation for an hour, but she took some Tylenol and was fine. Then, the next day, the caller woke up and on the left side of her body, she has a lymph node that is swollen, and still has not gone

down, and she is wondering if that is normal for the product. She does not really have the headache anymore, but the dizziness is still coming and going, not as bad as it was on that first day, but it comes and goes. She also did have the chills for a bit the day she got the vaccine, but it was just for a few hours and then it went away. The headache she had, was a different type of headache, it was not severe, but it was like a wave where it would come on strong, but not where she couldn't tolerate it, and then the dizziness would come at the same time, and then it would all just go away, and then come back like a wave; caller states that it was weird. The swollen lymph node started the next day, and it hurts. It was pretty swollen when she found it, but she took Tylenol and with the Tylenol, the swelling went down a little bit, but when the Tylenol works its way out of her system, the lymph node swells back up. The patient stated that the lymph node hurts and is painful. The patient does not know the actual dosage amount she received, she just knows it was the first dose in the series. The patient confirms that she did not take any other vaccines on the same day as the COVID vaccine. The patient is due for her second dose of the COVID vaccine next month, and she is wondering if the swollen lymph node would be something that would disqualify her from getting the second dose. Therapeutic measures were taken as a result of headache, dizziness, lymph node is really swollen and it hurts. Outcome of the events headache and chills recovered in Dec2020, for the events dizziness, sick, and soreness in arm was unknown; and for the event node is really swollen/and it hurts was not recovered.

Diarrhea; This is a spontaneous report from a contactable other healthcare professional (patient). A 46-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number EL0140, expiry date unknown) intramuscular at the left arm on 21Dec2020 13:30 at single dose for COVID-19 immunization. The patient received Covid vaccine in a hospital. Medical history included high blood pressure, penicillin allergies. Concomitant medications included clonidine, bupropion hydrochloride (WELLBUTRIN XL), pantoprazole, topiramate, alprazolam (XANAX), cetirizine hydrochloride (ZYRTEC [CETIRIZINE HYDROCHLORIDE]), ascorbic acid (VIT C), fish oil, lactobacillus nos (CULTURELLE), ox bile; all from unspecified date for unspecified indication. The patient previously took ceftriaxone and experienced allergies. The patient did not receive other vaccine in four weeks. The patient has no diagnosis of Covid-19 prior to vaccination. On 22Dec2020 07:00 AM, the patient experienced diarrhea. The patient was not Covid tested post vaccination. No treatment was administered due to diarrhea. The outcome of the event diarrhea was not recovered. The reporter considered the event non-serious.

Allergic reaction; full body rash; fatigue; This is a spontaneous report from a contactable nurse. A 48-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) lot number: EK5730, intramuscular, first dose on 20Dec2020 at a single dose for immunization. Medical history included diabetes mellitus (DM), depression, gastrooesophageal reflux disease (GERD) and hypercholesterolaemia. The patient had no known allergies. The patient have unspecified concomitant medications. She had other vaccines in two weeks (unspecified). The patient experienced allergic reaction- full body rash, fatigue on 21Dec2020 with outcome of not recovered. Treatment received for the events included steroid and antihistamines. The events are reported as non-serious. The patient had doctor or other healthcare professional office/clinic visit. She had no covid prior vaccination. She was tested for covid post vaccination through nasal swab on 21Dec2020 with negative result.

Body aches; fatigue; headache; not feeling well; Muscle aches; elevated temperature; This is a spontaneous report from a contactable nurse (patient herself). A 43-year-old female patient received the first dose of bnt162b2 (BNT162B2 also reported as Covid-19 vaccine by Pfizer, lot EK5730), intramuscular 20Dec2020 15:15 at single dose in left arm for Covid-19 immunisation. Medical history included High blood pressure and interstitial cystitis interstitial. Concomitant medications included losartan and hyoscyamine sulfate, methenamine, methylthioninium chloride, phenyl salicylate, phosphoric acid sodium (URIBEL). The patient previously took doxycycline and experienced drug allergy. The patient experienced body aches, fatigue, headache, was not feeling well, muscle aches, elevated temperature, all on 21Dec2020 12:00. The events were reported as non-serious. Prior to vaccination, patient was not diagnosed with COVID-19 and since the vaccination, the patient was been tested for COVID-19 via nasal swab on 22Dec2020 with pending results. The outcome of events was unknown. No follow-up attempts are possible. No further information is expected.

headache; body aches; chills; fatigue; fever of 102; This is a spontaneous report from a contactable nurse (patient). A 28-year-old male patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE; lot/batch number unknown), via an unspecified route of administration on the left arm on 21Dec2020 07:30 at a single dose for covid-19 immunization. Medical history included anxiety and Covid-19. Prior to vaccination (covid-19 vaccine), patient was diagnosed with COVID-19 (Covid prior vaccination: Yes). The patient has no known allergies. No allergies to medications, food, or other products. Concomitant medications received within 2 weeks of vaccination included sertraline hydrochloride (ZOLOFT), ascorbic acid (VITAMIN C), zinc and colecalciferol (VITAMIN D). The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. On 21Dec2020 at 18:00 hour, the patient experienced headache, body aches, chills, fatigue and fever of 102 around 6pm the same day receiving vaccine. The events were considered non-serious by the reporter. Since the vaccination, the patient has not been tested for COVID-19 (Covid tested post vaccination: No). No treatment was received for the events. The outcome of the events was recovering. Information on the lot/batch number has been requested.

Moderate to severe lower back pain; This is a spontaneous report from a contactable physician (patient). A 38-year-old male patient started to receive BNT162B2 (Solution for injection, lot number and expiry date unknown), via an unspecified route of administration on 18Dec2020 08:30 at single dose in the left arm for COVID-19 immunization. The patient's medical history was not reported. Concomitant medication included vitamin C and multivitamins. The patient was not diagnosed with COVID-19 prior to vaccination and since the vaccination, the patient has not been tested for COVID-19. On 18Dec2020 19:00, the patient experienced moderate to severe lower back pain approximately 9-10 hours after receiving vaccine. He was feeling well prior to that, no strenuous activity. Symptoms progressed over 1-2 hours, then resolved over 4 days with tylenol/motrin use. Therapeutic measures were taken as a result of moderate to severe lower back pain. The outcome of the event was recovered on an unspecified date. The following information on the batch number has been requested.

runny nose; sore throat; This is a spontaneous report from a Pfizer-sponsored program. A contactable consumer (patient) reported that a 44-year-old male patient started to receive BNT162B2 (Solution for injection, lot number and expiry date unknown), intramuscular on 18Dec2020 at single dose in the left

deltoid for COVID Prevention. There were no medical history and concomitant medications. The patient called and stated that he took the COVID vaccine first dose, on Monday, and now he is getting the side effects of running nose and sore throat. Stated that the running nose and sore throat starting this morning on 22Dec2020, right as he woke up, and then it went away, and now it just seems to have gotten worse. He wondered if those are common side effects because he couldn't find them on the facts sheet. He stated that he is just trying to gather more information because he knows that it is currently cold and flu season, and it could also just be allergies. Also he wanted to make sure this is a common side effect, because if not, he has family coming to town to visit him for the holiday and he wants to be safe if he is sick. The outcome of the events was not recovered. The following information on the batch number has been requested.

Tachycardia; This is a spontaneous report from a contactable physician (patient). A 41-year-old male patient started to receive BNT162B2 (Solution for injection, lot number and expiry date unknown), via an unspecified route of administration on 21Dec2020 12:30 at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient was not diagnosed with COVID-19 prior to vaccination and since the vaccination, the patient has not been tested for COVID-19. The patient experienced tachycardia on 22Dec2020 02:30. No treatment received for the event. The outcome of the event was not recovered. The following information on the batch number has been requested.

Fever (39.1 C); chills; headache; body aches; nausea; This is a spontaneous report from a non-contactable nurse. A 37-years-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899), intramuscular at the left arm on 21Dec2020 10:45 at a single dose for COVID-19 immunization. Medical history included COVID-19 prior to vaccination. The patient has no known allergies. There were no concomitant medications. The patient experienced fever (39.1 C), chills, headache, body aches, nausea on 21Dec2020 20:00 with no treatment. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient was not tested for it since the vaccination. The patient recovered from the events on an unknown date. No follow up attempts are possible. No further information is expected.

Nausea; body aches; night sweats; headache; tired; This is a spontaneous report from a contactable other healthcare professional (patient). A 37-year-old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number: EJI685), intramuscular on the arm (reported as location was in the left and right arm, pending clarification) on 21Dec2020 15:30 at a single dose for COVID-19 immunization. The patient's medical history included celiac disease and wheat, gluten, chicken, nightshades, yeast allergy. The patient was not pregnant. Concomitant medication included vortioxetine hydrobromide (TRINTELLIX). The patient previously took chlorhexidine (CHLORAPREP) and experienced allergies to chlorhexidine. The patient was not diagnosed with COVID-19 prior to vaccination and had not been tested for COVID-19 since the vaccination. On 21Dec2020 17:00, the patient experienced nausea, body aches, night sweats, headache, and tired. Therapeutic measures were taken as a result of the events and included treatment with ondansetron (ZOFRAN) and paracetamol (TYLENOL). Outcome of the events was not recovered.

Diarrhea; Vomiting; dry heaves; This is a spontaneous report from a contactable nurse (patient). A 48-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK5730), intramuscular (left arm) on 21Dec2020 17:00 at single dose for Covid-19 immunization. The patient's medical history included high blood pressure. Concomitant medications were not reported. The patient was not diagnosed with COVID-19 prior to vaccination. The patient has no allergies to medications, food, or other products. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient experienced diarrhea, vomiting, and dry heaves on 22Dec2020 (06:00 AM). There was no treatment received for the adverse events. The patient has been tested with COVID-19 since the vaccination. The patient had nasal swab (test) on 22Dec2020 with pending result. The outcome of events was unknown.

"positive COVID-19 test with symptoms; positive COVID-19 test with symptoms; This is a spontaneous report from a contactable physician (patient). A male patient of an unspecified age received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration in Dec2020 at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced tested positive for COVID in Dec2020. The patient got the first dose of the vaccine on the day before the date of this report, started coughing on the day before the date of this report and tested positive for COVID on the date of this report. Caller requested guidance regarding whether he should receive the second vaccine dose, specifically will it be effective. Caller stated that he was ""an ER doc"" and understand that he did not get COVID from the vaccine. The patient underwent lab tests and procedures which included tested positive for COVID in Dec2020. The outcome of events was unknown. Information about lot/batch number has been requested.; Sender's Comments: Considering the temporal gap between the vaccination and the event onset, there was not a reasonable possibility that the COVID-19 infection was related to vaccination with BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE)."

"""pins and needles type tingling"" of the face; Chills; malaise; fever (101F); scratchy throat; headache; lack of appetite; pain of entire body; my feet hurt as soon as they hit the ground; This is a spontaneous report from a Pfizer Sponsored Program IBCC (Inbound Call Center for HCPs) from a contactable physician reported for herself. A female patient of unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via unspecified route of administration on 21Dec2020 at single dose for COVID-19 immunization. Patient medical history and concomitant medications were not reported. Patient reported that she received vaccine yesterday, 21Dec2020. Approximately 24 hours later, on 22Dec2020, she started experiencing ""pins and needles type tingling"" of the face, chills, malaise, fever (101F), ""scratchy throat"", headache, lack of appetite, ""pain of entire body"" and feet also hurt as soon as they hit the ground. She asked with the reaction that she was having, when do she seeks help and how long does it lasts. ""With the reaction that I'm having, when do I seek help? How long does this last? Are there any reports of fever? Are these common side effects?"" Outcome of the events was unknown. Information about lot/batch number has been requested."

Sore arm within an hour; Chills; body aches; fatigue overnight and throughout the next day; slight headache; This is a spontaneous report from a contactable nurse (patient). A 24-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) lot number: Eh9899, via intramuscular route

in the right arm, first dose on 21Dec2020 11:00 at a single dose for immunization. Medical history was none. The patient's concomitant medications were not reported. The patient is not pregnant. She has no known allergies. The patient did not have Covid prior vaccination and was not tested post vaccination. She did not receive other vaccines with 4 weeks prior to covid vaccine. The patient experienced sore arm within an hour on 21Dec2020 with outcome of recovering. She also had chills, body aches, fatigue overnight and throughout the next day with outcome of recovering. Almond with slight headache which was recovering. No treatment received for the events. The seriousness of the events was reported as non-serious.

12 minutes after vaccination, pt experienced jaw discomfort on left side and sharp intermittent pain in L ear.; 12 minutes after vaccination, pt experienced jaw discomfort on left side and sharp intermittent pain in L ear.; This is a spontaneous report from a contactable pharmacist. A 44-year-old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number: EL0140), intramuscular at the left arm on 22Dec2020 at a single dose for COVID-19 immunization. The patient medical history was not reported. The patient was not pregnant at the time of vaccination. Concomitant medications included baclofen, vitamin d3 and pitavastatin. The patient previously took tramadol and experienced drug allergies. On 22Dec2020, 12 minutes after vaccination, the patient experienced jaw discomfort on left side and sharp intermittent pain in L ear. The patient was not hospitalized for the events. It was unknown if patient receive any treatment for the events. The events were reported as non-serious. The patient has not received any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination the patient was not diagnosed with COVID-19. Since the vaccination, it was unknown if the patient has been tested for COVID-19. The outcome of the events was unknown.

pain in the arm of injection site; numbness and pins and needle tingling in the lower arm and hand; numbness and pins and needle tingling in the lower arm and hand; loss of feeling in hand and loss of sensation and strength; difficulty holding onto objects; loss of feeling in hand and loss of sensation and strength; difficulty holding onto objects/weakness; loss of feeling in hand and loss of sensation and strength; difficulty holding onto objects; dizziness; severe joint pain; throbbing headache; This is a spontaneous report from a contactable other healthcare professional (patient). A 41-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number EJ 1685, expiry date unknown) via unspecified route of administration at left arm on 19Dec2020 07:30 at single dose for COVID-19 immunization. The reporter informed that the covid-19 vaccine was administered in a hospital. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient was not diagnosed with COVID-19 prior to vaccination. Medical history included asthma, allergies to penicillin, allergies to milk, seasonal allergy, allergies to bees, allergies to latex. Concomitant medications included montelukast, fluticasone, budesonide, formoterol fumarate (SYMBICORT) and cetirizine; all from unspecified date for unspecified indication. The patient previously took Bactrim and experienced allergies. On 19Dec2020 15:00, the patient experienced pain in the arm of injection site including numbness and pins and needle tingling in the lower arm and hand, loss of feeling in hand and loss of sensation and strength; difficulty holding onto objects, dizziness and weakness, severe joint pain and throbbing headache. The patient underwent lab test and procedures post vaccination which included nasal swab/Covid-19 RNA rapid: negative on 22Dec2020. No treatment was

received due to the events. The outcome of the events pain in the arm of injection site, numbness and pins and needle tingling in the lower arm and hand, loss of feeling in hand and loss of sensation and strength; difficulty holding onto objects, dizziness, weakness, severe joint pain, throbbing headache was not recovered. The events were assessed as non-serious which did not results in death, not Life threatening, did not cause/prolong hospitalization, was not disabling/incapacitating, and not a congenital anomaly/birth defect.

Fever/ got up to 102 degrees Fahrenheit; Body aches; Sore throat; Feels like she has got just a regular cold; This is a spontaneous report from a contactable other hcp (patient). A 59-year-old female patient started to receive BNT162B2 (Solution for injection, lot number and expiry date unknown), intramuscular on 21Dec2020 19:00 to an unspecified date at single dose in the right arm for vaccination. Medical history included menopause from an unknown date. Concomitant medication included levothyroxine sodium (SYNTHROID), fenofibric acid, metformin, escitalopram and unspecified hormones for menopause. The nurse practitioner called to report on herself as the patient. She received her first dose of COVID-19 Vaccine on 21Dec2020 around 7:00pm. Starting about 10:00 am today, 22Dec2020, she had onset of fever, body aches and sore throat. She is hoping that this is all a normal part of the COVID-19 Vaccine; but she called to verify if that is all normal because she has to work tomorrow. Stated that her fever got up to 102 degrees Fahrenheit. She mentioned regarding seriousness criteria of all events that they are not serious, that she feels like she has just got a regular cold. She is scheduled to get the second dose of this vaccine 21 days after first dose. Causality of all events reported as yes, she really believes it is related to product. The outcome of the events was not recovered. The following information on the batch number has been requested.

Sore arm at injection site; This is a spontaneous report from a contactable healthcare professional reported for himself. A 41-year-old male patient started to receive BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number: EJ1685, expiry date: unknown), intramuscular on the left arm on 22Dec2020 01:30 at a single dose for COVID-19 immunization. There was no medical history. The patient's concomitant medications were not reported. The patient experienced sore arm at injection site on 22Dec2020 02:00. Outcome of the event was not recovered. No treatment was given. Patient had no COVID prior to vaccination and was not tested for COVID post vaccination. The event was considered non-serious.

back is achy; Injection site pain; Body achy; body feels like after you have a workout; Muscles are sore; My close coworker who works with me in the same company cubicle as me when we document, tested positive for COVID; This is a spontaneous report from a contactable other health professional (patient). A female patient (Age: 35; unit unknown) received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EH9899), via an unspecified route of administration on 21Dec2020 at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient received COVID vaccine on 21Dec2020 and experienced side effect of the vaccine. Stated 'achy feeling. The patient's abdomen and trunk like after a workout.' She move suddenly her back was achy. She had injection site pain. Consumer stated, her close coworker who worked with her in the same company cubicle as she, tested positive for COVID and he had been having symptoms since Saturday. And she was body achy at the time of this report, like she kind of feel like, her body felt like after she

had a workout and her muscles are sore. So, she did not know what to do because she do not know if this body achiness is a symptom of COVID or a symptom of the vaccine. And if she went get tested, whether she will show like a positive because she had the vaccine. The outcome of events was unknown.

she was freezing one minute, and then she was hot the next minute; dizzy; soreness throughout body/achy; stated her eyes feel heavy; Chills; This is a spontaneous report from a contactable consumer (patient herself). A 50-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), lot number: EK5730, expiration date: Mar2021, intramuscular in left upper arm from 21Dec2020 10:00 to 21Dec2020 10:00 at 0.3 mL for Covid-19 immunization. Medical history included COVID-19 in Jul2020. She said she had a real bad case of COVID-19, and didn't get over it until Oct2020. The patient's concomitant medications were not reported. The patient stated she received the COVID-19 Vaccine yesterday at her employer, which is a hospital. She said she got the COVID-19 Vaccine at around 10:00AM on 21Dec2020. She said she had a few chills not too long after receiving the COVID-19 Vaccine. She said last night the chills got worse, saying she had chills all night. She said the chills are not as bad now. Reported she is sore and achy, clarifying she has more of a soreness throughout her body. She stated her eyes feel heavy too. Caller asked if what she was experiencing were side effects of the COVID-19 Vaccine and how long were the symptoms going to last. The reporter stated she is not a healthcare professional. She said she works in the surgery area at the hospital, and the hospital was offering the COVID-19 Vaccine yesterday, so she got the vaccine. Reported after receiving the COVID-19 Vaccine, she noticed she felt cool at work. She said last night she felt like she was freezing one minute, and then she was hot the next minute, and kept going back and forth between freezing and hot. She said she woke up at 1:00AM and felt really hot. She said she wished she had a thermometer at the time to check her temperature because she thought she had a fever. She said her husband told her what she was experiencing was part of having the chills. She said when she woke at 1:00AM, she got out of bed to go to the bathroom, and her eyes felt heavy, and she thought she may have been a little dizzy. She said now she doesn't think she was dizzy at the time, but maybe it was because she just woke up and got out of bed. She said she hasn't had any dizziness today. Treatment: Reported she took an Ibuprofen 200mg at 2:00AM and another Ibuprofen 200mg at 8:30AM. She clarified it was Equate Brand Ibuprofen 200mg. The event chills with outcome of recovering; the rest of the events was unknown. Therapeutic measure has been given as a result of the events. Information about the lot/batch number and expiration date has been requested.

Dry mouth; rapid heart rate; fuzzy feeling in middle of forehead; This is a spontaneous report from a non-contactable other healthcare professional (patient). A 23-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899, expiry date was not provided) solution for injection, intramuscular from 21Dec2020 11:15 at a single dose for Covid-19 immunisation. Medical history included PVC's (Premature ventricular contractions). Concomitant medication included ibuprofen. The patient received the dose number 1 of the vaccine at a hospital and experienced dry mouth, rapid heart rate, and fuzzy feeling in middle of forehead on 21Dec2020 11:15. No treatment was administered. The events were reported as non-serious. Patient was not pregnant. Patient was not

diagnosed with Covid-19 prior to vaccination and has not been tested. Outcome of the events was recovering. No follow-up activities are needed. No further information is expected.

4 days after first vaccine started to get left cheek and left arm numbness without weakness. Also had left vision spotting. Different pattern than pts usual migraine

Left arm pain on first 2 days; extreme fatigue; chills/ All night chills; flu like illness; This is a spontaneous report from a contactable Physician (patient himself). A 40-year-old male patient received his first dose of bnt162b2 (BNT162B2 also reported as COVID 19 vaccine brand Pfizer, lot/batch number and expiry date were not reported), via an unspecified route of administration in left arm on 18Dec2020 11:45 at single dose for Covid-19 immunisation in a hospital. Medical history included High cholesterol. Concomitant medication included influenza vaccine (FLU). Prior to vaccination the patient was not diagnosed with COVID-19 and had not been tested for COVID-19 post vaccination. The patient experienced left arm pain on first 2 days (21Dec2020) 12:00, had extreme fatigue, chills described as all night chills and flu like illness on 21Dec2020 12:00. The patient took Tylenol as treatment. The outcome of events was not recovered. Information on the Lot/batch number has been requested.

Nausea; injection site soreness; fatigue; chills; general feeling unwell; This is a spontaneous report from a non-contactable healthcare professional. A 33-year-old female patient received bnt162b2 (BNT162B2; reported as COVID-19 vaccine; solution for injection; unknown lot number and expiration date), intramuscular right arm on 21Dec2020 04:30 at single dose for COVID-19 immunization. The patient had no medical history and concomitant medications. The patient was not pregnant at the time of vaccination. The patient has no allergies to medications, food, or other products. On 21Dec2020 at 08:30 PM, the patient experienced nausea, injection site soreness, fatigue, chills and general feeling unwell. The patient did not treatment for the adverse event. The patient had her most recent COVID-19 vaccine was administered in a hospital. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient had no other medications the patient received within 2 weeks of vaccination. The patient was not diagnosed with COVID-19 prior to vaccination and has not been tested for COVID-19 since the vaccination. The outcome of the events was not recovered. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

Cold/Flu/COVID symptoms, skin rash around injection site and left side of back

Injection site pain; myalgia; abdominal pain; This is a spontaneous report from a contactable physician. A 40-year-old male patient (not pregnant) received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, batch/lot number: unknown), via an unspecified route of administration on 21Dec2020 (19:15 PM) at single dose for COVID-19 immunization. There was no medical history. Concomitant medications were not reported. The patient has not been diagnosed with Covid-19 prior to vaccination. No know allergies. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. There was no other vaccine in four weeks and other medications in two weeks. The patient experienced injection site pain, myalgia, and abdominal pain on 22Dec2020 (09:00 AM). There was no treatment received for the adverse event. The patient was not tested for Covid-19 post vaccination. The outcome of events was

recovering. This case is reported as non-serious. Information on the lot/batch number has been requested.

Soreness at the injection site, Joint pain, including hip, leg soreness with a change in mobility.

aches; chills/shivering; generally not feeling well.; don't fall asleep; I have been feeling tired and like funny like a you have a cold or something/fatigue; I have been feeling tired and like funny like a you have a cold or something/cold; The initial case was missing the following minimum criteria: Unspecified product. Upon receipt of follow-up information on 23Dec2020, this case now contains all required information to be considered valid. This is a spontaneous report from two contactable consumers (including the patient). A 70-year-old female patient received BNT162B2 (Pfizer-BioNTech COVID-19 mRNA vaccine, Solution for injection; lot number and expiration date were not provided), via an unspecified route of administration on 20Dec2020 at single dose for immunization. Medical history included hot flashes. There were no concomitant medications. The patient stated that she just got the shot yesterday (20Dec2020) at the hospital she just went. Today (21Dec2020), she was feeling like a kind of funny and further described she had been feeling tired and like funny like she had a cold or something. She had a shot in the arm. It was further reported that she received the vaccine on Sunday (20Dec2020) at the hospital she works at; reported side effects of aches, chills, and generally not feeling well. She also stated tiredness and fatigue, she didn't fall asleep even if she did a night shift. For 2 days, she felt achy, chills were bad, she was cold, and was shivering, then they went away. The patient had hot flashes before, but it wasn't like that. She was having cold. Then it would go away, took a while. She had them (feeling tired, feeling cold, generally not feeling well, didn't fall asleep) since Monday (21Dec2020), then yesterday (22Dec2020), she felt the chills, aches and fatigue. The patient wanted to know how long to expect the side effects to last. The outcome of the events was not recovered. Information about lot/batch number has been requested.

shingles; This is a spontaneous report from a contactable Nurse. A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), via an unspecified route of administration in Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient was vaccinated with the Pfizer-BioNTech COVID-19 Vaccine last week (in Dec2020). She claimed being diagnosed with shingles and has asked the nurse if it could be related to the vaccine. The outcome of the event was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.

left hip pain; This is a spontaneous report from a contactable physician. A 71-year-old male patient received bnt162b2 (BNT162B2), via an unspecified route of administration on 17Dec2020 at, SINGLE DOSE for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. Caller stated that he got the coronavirus vaccine last Thursday and on midday Saturday that he got left hip pain. reported that he has sticky hips. Stated that he does not experience pain normally. Stated that the day before on Wednesday that he did yoga at home. Stated that he has done yoga for years. Stated that every time that he does it the he could strain something. Stated that the pain was bad enough that he took 3 doses of Advil over the next 24 hours and it went away. Stated that it did not

cause any major limping. Stated that he took 75 minutes walks on Saturday and Sunday and did yoga that evening. Stated that he is not sure that it is not related to the vaccine. Stated that this is his first dose of the vaccine. Stated that he is happy that he got the vaccine. Stated that he would get it again in a heartbeat. The outcome of the event was recovered. Information on Lot /Batch Number has been requested.

I am diabetic on a CGM and insulin pump. My blood sugar started to rise mid-afternoon and I couldn't get it below 200 despite giving myself increased amounts of insulin. It was up to 289 at bedtime. I count carbs and was very careful about what I ate yesterday. This morning I was back down to 169 when I got up, but I had increased my basal rates during the night. Second event that I'm not sure is related, but FYI, last evening I got some sharp pains in my left hip and continual aching in my left buttock while sitting watching TV. It continued until after I went to bed. It's back to normal this morning.

injection site pain-minor; tiredness-moderate/fatigue; headache-mild to moderate; muscle pain-minor/muscle aches; chills; fever-low grade; injection site redness light pink; nausea-comes and goes; feeling unwell-mild to moderate; muscle weakness; weak; This is a spontaneous report from a contactable consumer (patient). A 49-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899), via an unspecified route of administration on 18Dec2020 12:15 on the right arm at a single dose for COVID-19 immunization. Medical history included allergies to anxiety medication. The patient's concomitant medications were not reported. On 18Dec2020 20:00, the patient experienced mild to moderate side effects: injection site pain (minor), tiredness (moderate), headache (mild to moderate), muscle pain (minor muscle aches), chills (sometimes), fever (low grade), injection site redness (light pink), nausea- (comes and goes), feeling unwell (mild to moderate), muscle weakness and feeling fatigue which were moderate Friday, Saturday, and Sunday and Monday. If patient was active, for example Christmas shopping for about an hour, she was very fatigue, weak and the nausea was strongly moderate and it would come and go. Outcome of the events was recovering. No treatment was received for the events. The events were considered non-serious. The patient was not diagnosed with COVID-19 prior to vaccination and had not been tested post vaccination.

dry mouth; peculiar sensations running through extremities/trunk/abdomen (akin to IV contrast administration); elevated BP; tachycardia; lower abdominal cramping; This is a spontaneous report from a contactable physician (patient). A 46-year-old male patient received the first single dose of BNT162B2 (Lot number: EH9899, exp date not reported), intramuscular (vaccine location: left arm) on 21Dec2020 15:00 for Covid-19 immunisation. Medical history included hyperlipidaemia. The patient had no known allergies. Concomitant medication included atorvastatin (LIPITOR), and omeprazole (PRILOSEC). The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The COVID-19 vaccine was administered at a Hospital. On 21Dec2020 at 3:00 pm (also reported as within minutes of receiving vaccine), the patient developed dry mouth, peculiar sensations running through extremities/trunk/abdomen (akin to IV contrast administration), elevated BP, tachycardia, and lower abdominal cramping. The patient considered the events as non-serious. AEs resulted in doctor or other healthcare professional office/clinic visit. No treatment was given for the events. The patient had no

prior COVID vaccination and did not undergo COVID testing post vaccination. The patient recovered from the events on an unspecified date Dec2020.

Patient with a nut allergy, tongue became tingly 20-30 minutes following vaccine. Patient was given 50 mg of diphenhydramine and was able to transport home with his wife.

is 'fibril' until today/ fever; This is a spontaneous report from a contactable pharmacist. A patient of unspecified age and gender received BNT162B2, via an unspecified route of administration on 18Dec2020 at single dose for COVID -19 immunization. The patient medical history and concomitant medications were not reported. The reporter asked to just call her back to give info Covid vaccine was administered to a physician last 18Dec2020 and was 'fibril' until today (pending clarification). Asking if there is info on the duration of the fever that occurs. The outcome of the event was not recovered. Information on the Batch/Lot number has been requested.

Sore throat, mild bronchial congestion, mild muscle aches, soreness in left arm; Sore throat, mild bronchial congestion, mild muscle aches, soreness in left arm; Sore throat, mild bronchial congestion, mild muscle aches, soreness in left arm; Sore throat, mild bronchial congestion, mild muscle aches, soreness in left arm; This is a spontaneous report from a contactable nurse (reported for herself). A 62-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899), via an unspecified route of administration on left arm on 21Dec2020 08:45 at a single dose for immunization. Medical history included rosacea, primary hypertension, Hashimoto's Thyroiditis and penicillin allergy. The patient's concomitant medications were not reported. The patient experienced sore throat, mild bronchial congestion, mild muscle aches, and soreness in left arm; all on 22Dec2020 at 06:30. The patient did not receive treatment for the events. Outcome of the events was recovering.

patient called to report nausea, vomiting headache low grade fever abd pain

Extreme fatigue; nausea; lightheadedness; diarrhea; muscle ache; inability to sleep; sickness; This is a spontaneous report from a contactable physician (patient). A 41-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, batch/lot number: unknown), intramuscular (left arm) on 21Dec2020 16:00 at single dose for COVID-19 immunization. The patient has no medical history. No known allergies. The patient has no allergies to medications, food, or other products. Concomitant medications were not reported. The patient has received other medications (unspecified) within 2 weeks of vaccination. The patient was not diagnosed with COVID-19 prior to vaccination. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. On 21Dec2020 (18:00), the patient experienced extreme fatigue, nausea, lightheadedness, diarrhea, muscle ache, inability to sleep, and worst sickness of entire life (as reported). The patient received over the counter medication as treatment for the adverse events. The patient has not been tested for COVID-19 since the vaccination. The outcome of events was not recovered. This case is non-serious (as reported). Information on the lot/batch number has been requested.

"arm stiff and sore two hours after getting vaccine/muscle is stiff in her right arm; arm stiff and sore two hours after getting vaccine, at right arm; she didn't get to sleep last night since it felt heavy and stiff with

discomfort; she didn't get to sleep last night since it felt heavy and stiff with discomfort; Couldn't raise her right arm/couldn't lift her right arm/ farthest she can lift her right arm from her side is 2 inches; she didn't have strength to open the bottle it was new and she cannot open it; This is a spontaneous report from a contactable consumer. A 69-year-old female patient started to receive BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 21Dec2020 15:00 at single dose, at right arm for COVID-19 immunization. Medical history included ongoing hypertension (controlled), ongoing prediabetes (controlled), blood thinner, stroke (it was a very mild trace of a very mild stroke) and MRI on 2015. Historical vaccine included flu vaccine on an unspecified date. Concomitant medication included clopidogrel bisulfate (PLAVIX) from 2015 as blood thinner. After the patient got the vaccine on 21Dec2020, she was instructed to sit for 15 minutes and was given flyers and the card that stated the next scheduled dose is on 11Jan2020. She mentioned that the card she was given is the COVID-19 appointment card with a return flyer attached regarding Pfizer vaccine recipients and care givers. She reported that all that she can see on there is that, there was no lot, batch or serial number, just the name of the vaccine. She stated that the vaccine was shipped in the morning and they started giving it around noon and she got hers at three o'clock in the afternoon. She stated this is their facility's second batch, and the first was consumed last week. She stated she made a mistake, and that she should have requested they inject her left arm because she is right handed. The patient reported that she experienced arm stiff and sore two hours after getting vaccine (17:00). It was tolerable at first, but when she got home, she couldn't raise her right arm. She thought it would just be like the Flu vaccine and tolerable but she couldn't lift her right arm. The farthest she can lift her right arm from her side is 2 inches. She tried putting a cold compress on it but it was not working. She doesn't know if she can take TYLENOL. She would like to know if she can take TYLENOL for the pain since it was the only medication she has. Her supervisor advised her to take Advil, but she only has TYLENOL. She says she does feel better and that she was fine, there was nothing else, just her arm is so sore. She has nothing negative, no other side effect, no redness, just her muscle is stiff in her right arm and it feels sore. She stated maybe if she had taken TYLENOL the night before, but last night or today she didn't have strength to open the bottle it was new and she cannot open it. She stated at least the pain is lesser than last night, she didn't get to sleep last night since it felt heavy and stiff with discomfort. She was supposed to get a mammogram on reporting time, but since she couldn't raise her arm she was trying to reschedule. She is supposed to have a blood test the following day. Therapeutic measures were taken which includes cold compress. Outcome of the event ""arm stiff and sore two hours after getting vaccine, at right arm"" was recovering while outcome of all other events was unknown. Information on the lot/batch number has been requested."

Subject received vaccination Wednesday Dec 16th in the afternoon. He became symptomatic (shortness of breath, low grade fever) the next day. Went to the Emergency room on Saturday Dec. 26th, 2020 due to shortness of breath, had an 02 Sat of 60%, and was hospitalized in the ICU at another hospital (due to bed unavailability).

Brown spots in the shape of a circle at different locations in the body all appearing within a few hours; This is a spontaneous report from a contactable nurse (patient). A 29-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE lot/batch number: EH9899), via an

unspecified route of administration on the right arm on 22Dec2020 07:45 at SINGLE DOSE for COVID-19 immunization at the hospital. The patient had allergies with detergent and soap products. Concomitant medications included fenofibrate (FENOFIBRATE) and vitamin D from unknown dates and indications. Prior to vaccination, the patient was not diagnosed with COVID-19 and has not been tested for COVID-19 since vaccination. On 22Dec2020, the patient experienced brown spots in the shape of a circle at different locations in the body all appearing within a few hours. No treatment was received for the event. Outcome of the event was not recovered. No follow-up attempts are possible. No further information is expected.

Fever; Chills/rigors; Nausea; Vomiting (one episode); Headache; Myalgia; Change in taste; Generalized weakness; This is a spontaneous report from a non-contactable physician (patient). A 44-year-old male patient received one dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number: 1647, expiration date not reported), via an unspecified route of administration (left arm), on 21Dec2020 at 12:30 at a single dose, for COVID-19 immunization. Medical history included hypertension and COVID-19 from an unknown date. Concomitant medication included lisinopril and amlodipine. On 22Dec2020 at 04:30, the patient experienced 8 hours of severe symptoms: fever, chills/rigors, nausea/vomiting (one episode), headache, myalgia, change in taste, generalized weakness. The patient took Tylenol and naproxen as treatment. The patient was recovering from the events. No follow-up attempts are possible. No further information is expected.

"Patient became visibly flushed within five minutes after inoculation, and she reported having ""waves of nausea."" A cool compress was applied to her neck. While she was closely being monitored, she admitted feeling ""dizzy right after the shot bit didn't want to tell anyone because she [ic] was embarrased."" At 1532, patient denied that she was allergic to Benadryl, so Benadryl 50 mg/mL IM was injected into her right deltoid. At 1545, patient reported an alleviation of symptoms. She was advised to go home to rest, but to immediately contact 911 or go to the ER if symptoms worsened. Patient voiced understanding and left the facility with coordinated ambulation and in stable condition. RN 12/29/2020 @ 1318"

"tingling in injection arm, left arm, left neck, around the lips/tingling through arms, hands, fingers, and legs/worsened by sitting on legs/dense tingling in anterior shins upon standing; tingling in injection arm, left arm, left neck, around the lips/tingling through arms, hands, fingers, and legs/worsened by sitting on legs/dense tingling in anterior shins upon standing; tingling in injection arm, left arm, left neck, around the lips/tingling through arms, hands, fingers, and legs/worsened by sitting on legs/dense tingling in anterior shins upon standing; This is a spontaneous report from a contactable physician (who is also the patient). A 37-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK5730, expiry date not reported), via an unspecified route of administration in left arm, on 19Dec2020 09:30, at single dose, for COVID-19 immunization. There were no medical history and no known allergies. The patient's concomitant medications were not reported. The patient reported that about 30 minutes after vaccination on 19Dec2020 at 10:00, while driving home, tingling was noted in injection arm, traveling up the left arm into the left neck and around the lips. Tingling resolved but the next day, tingling was noted to be diffuse, light and scattered through arms, hands, fingers, and legs equally and bilaterally. No dermatomal or distinct nerve distribution. Tingling worsened by sitting on

legs, became dense tingling in the anterior shins upon standing, but then resolved a few minutes later to the more diffuse light tingling. No notable difference in strength (able to hike and cook) and no notable numbness. No rashes, no shortness of breath, no changes in heart rate. The events resulted in ""doctor or other healthcare professional office/clinic visit"". No treatment was received for the events. The patient was not diagnosed with COVID-19 prior to vaccination. The patient has not been tested for COVID-19 since vaccination. The patient did not receive any other vaccines within 4 weeks prior to BNT162B2. The reporter assessed the case as non-serious. The outcome of the events was recovered (as reported)."

"light headache; Low grade fever; Muscle ache; Pain; This is a spontaneous report from a contactable consumer (parent) reported that a 49-year-old female patient received single dose of (BNT162B2, Solution for injection, lot number was not provided), via an unspecified route of administration on the left arm on 18Dec2020 for covid-19 immunization. Medical history included ongoing hypertension that was diagnosed when she was 32-years-old, after she gave birth to her second child; she was diagnosed with COVID-19 on 25Aug2020, and now was 4 months out from having COVID-19; reportedly she was tired and had a lot of ""nervously"" feeling, like heart palpitations before she took the COVID-19 vaccine. There were no concomitant medications. On 19Dec2020, the patient experienced light headache, low grade fever, muscle ache and pain. The patient underwent lab tests and procedures which included weight: 212-213 lbs on an unspecified date. The outcome of the events was recovered on 19Dec2020. Information about lot/batch number has been requested."

Raspy voice, body and joint pain, pain at injection site, fatigue, headache

myalgia; chills; headache; fatigue; Loss of appetite; This is a spontaneous report from a non-contactable physician. A 44-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899), via an unspecified route of administration on 21Dec2020 14:30 in left arm at single dose for COVID-19 immunization. Medical history included COVID-19 from an unknown date and unknown if ongoing. Concomitant medication included omeprazole. After vaccination, 12-15 hours later, the patient pronounced myalgia joined 18 hours later with chills, headache, fatigue and loss of appetite. The patient experienced myalgia on 22Dec2020 05:00; chills, headache, loss of appetite and fatigue on 22Dec2020. Treatment such as acetaminophen and rest was given to patient for the events. The facility where the most recent COVID-19 vaccine was administered was in the hospital. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. The patient had no allergies to medications, food, or other products. The events were considered non serious as it did not results in death, was not life threatening, did not cause/prolonged hospitalization, was not disabling/Incapacitating and had no congenital anomaly/birth defect. The outcome of the events was not recovered. No follow up attempts are possible. No further information is expected.

Metallic taste in mouth.

Headache; nausea; mild body aches; hot flashes; This is a spontaneous report from a contactable nurse (patient). A 39-year-old female patient (not pregnant) received the first dose of BNT162B2 (PFIZER-

BIONTECH COVID-19 VACCINE, lot number EJ1685), intramuscular at right arm on 21Dec2020 17:45 at single dose for COVID-19 immunization at a hospital. The patient's medical history included migraines, bipolar II, anxiety, attention deficit hyperactivity disorder (ADHD) and insomnia. No allergies to medications, food, or other products. No other vaccines within 4 weeks prior to the COVID vaccine. Concomitant medication received within 2 weeks of vaccination included amfetamine aspartate, amfetamine sulfate, dexamfetamine saccharate, dexamfetamine sulfate (ADDERALL), diphenhydramine hydrochloride (BENADRYL), lamotrigine (LAMICTAL), nortriptyline, alprazolam (XANAX) and multivitamin. The patient was not diagnosed with COVID-19 prior to vaccination, and since the vaccination, the patient been had not tested for COVID-19. It was reported that on 22Dec2020 17:45, the patient experienced headache, nausea, mild body aches, and hot flashes. Treatment for the reported events included that the patient took ondansetron (ZOFRAN) and acetaminophen (Tylenol) that she had at home. She took them on her own. No doctor needed. The outcome of the events was recovered in Dec2020.

Arm pain/Pain in arm was so severe; Pain in arm was so severe I could not sleep; Extreme body aches the aches intensified throughout the day; Headaches; sore throat; head and chest congestion; head and chest congestion; This is a spontaneous report from a contactable other hcp (patient). A 49-year-old female patient received bnt162b2 via an unspecified route of administration on arm left, first dose on 16Dec2020 12:45 at single dose for COVID-19 immunization. Other vaccine same date product included Pfizer-Biontech first dose on 16Dec2020 on left arm (pending clarification). Medical history included COVID-19 prior vaccination from an unknown date. Not pregnant at the time of vaccination. No known allergies. No other medical history. Concomitant medication included bupropion from 2020. No other vaccines within 4 weeks prior to the COVID vaccine. The patient experienced arm pain. Pain in arm was so severe she could not sleep. Applied an ice pack throughout the night. Extreme body aches the aches intensified throughout the day. Headaches, sore throat, head and chest congestion. Adverse event start date was on 16Dec2020. The event was reported as non-serious. Therapeutic measures were taken as a result of arm pain/pain in arm was so severe, treatment included ice pack. No treatment was received for other events. The outcome of the events was recovering. Information about Lot/batch no has been requested.

Significant arm soreness, headache.

"muscle soreness; This is a spontaneous report from a contactable physician (patient). A patient of an unspecified age (reported as 35, unit unknown) and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration from 15Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient reported that after he got the shot (Dec2020), he had experienced ""just a little muscle soreness"". The outcome of event was unknown. Follow-up attempts are completed. The following information on the batch number has been requested."

muscle soreness; This is a spontaneous report from a contactable physician (patient). An adult patient (Age: 44; Unit: Unknown) of an unspecified gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE lot/batch number: not provided), via an unspecified route of administration on 14Dec2020 at

SINGLE DOSE for COVID-19 immunization. Medical history and concomitant medications were not reported. It was reported that the patient had side effects that were minimal - muscle soreness in Dec2020 for 24 hours, that's about it. The patient recovered from the event in Dec2020. No follow-up attempts are possible, information about batch number cannot be obtained.

I started getting profused rhinitis; I am got a little hoarse and it lasted all night long; I started getting profused rhinitis; I am got a little hoarse and it lasted all night long; I had enough Postnasal drip that I got a little bit of cough and no fever and didn't know if this was related to the vaccine; I had enough Postnasal drip that I got a little bit of cough and no fever and didn't know if this was related to the vaccine; This is a spontaneous report from a contactable physician who was also the patient. A 71-year-old male patient received bnt162b2 (BNT162B2 lot: EK5730, expiry: Mar2021), intramuscular in left arm on 17Dec2020 at a singe dose for covid-19 immunisation. The patient's medical history included hypertension from an unknown date and unknown if ongoing. Concomitant medications included olmesartan medoxomil (BENICAR) for hypertension and unspecified vitamins. On a unspecified date, the patient started getting profused rhinitis, he got a little hoarse and it lasted all night long. Patient actually had enough Postnasal drip (Captured as suspect conservatively) that got a little bit of cough and no fever and didn't know if this was related to the vaccine or not and needed to find out if that's the case. It was also reported that the patient took a rapid Covid test in the morning and whould like to know if that would to be 'false' positive because of taking the virus shot or Covid shot. It was reported that an RN administered the vaccine. The outcome of the events was unknown.

"Pain in arm; Kind of allergy you know like sneezing a lot, the whole day I have been sneezing; Kind of allergy you know like sneezing a lot, the whole day I have been sneezing; This is a spontaneous report from a contactable consumer. A patient of unspecified age and gender received bnt162b2 (BNT162B2), via an unspecified route of administration on 18Dec2020 at SINGLE DOSE for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. Consumer stated, ""I have a question about, I just had Pfizer on last Friday so I didn't have any symptom anything, the next day on 19Dec2020 I have like my arm pain, not swollen just pain and then I have kind of allergy you know like sneezing a lot, it is the whole day I have been sneezing and just like the whole day. Is it allergy to the Pfizer or should I just have another like second shot should I have it or is it the allergic reaction or what is that? It is the COVID the one COVID I had from Pfizer (COVID Vaccine). Because of I am afraid to have second shot if I have like more allergy or."" The outcome of the events unknown. Information on the Batch/Lot number has been requested."

Spiked the temperature during the night; Body ache; Fatigue; This is a spontaneous report from a contactable nurse (patient). A 58-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number EH9899), via an unspecified route of administration on 21Dec2020 at a single dose for COVID-19 immunization. There were no medical history and no concomitant medications. The patient was not having any serious side effects but she was having like probably spiked temperature during the night, body ache, and fatigue on 22Dec2020. The patient want to make sure if it is okay to take paracetamol (TYLENOL) or ibuprofen (MOTRIN) generally. Outcome of the events was unknown. The reporter assessed that the events were related to the suspect drug.

bad headache; This is a spontaneous report from a contactable consumer. A male patient of an unspecified age received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), via an unspecified route of administration on 22Dec2020 as a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. On 22Dec2020, the patient experienced bad headache. The clinical outcome of the bad headache was unknown. No follow-up attempts are possible; information about lot number cannot be obtained.

I have COVID after getting the vaccine. Fever, chills, and I feel very bad.

Respiratory: Laryngeal stridor going into the trachea and the central bronchial tubes. No wheeze out on the periphery. , Respirations: Tachypneic, Breath sounds: Stridor.

lightheaded/dizzy; This is a spontaneous report from a contactable consumer. A 35-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK5730), first dose via an unspecified route of administration on 21Dec2020 at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient was vaccinated yesterday with the Pfizer COVID-19. The patient felt lightheaded/dizzy after the injection and for many hours after in Dec2020. The patient felt these events before with other vaccines. The outcome of the event was unknown.

chills; malaise; raynauds in left fingers cold,blue; tingling; This is a spontaneous report from a contactable physician (patient). A 42-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EH9899), via an unspecified route of administration on 21Dec2020 06:15PM, at right arm, at single dose for covid-19 immunization. Medical history included Guillain barre after flu vaccine in 2010, covid-19 prior vaccination. The patient's concomitant medications were not reported. The patient previously received flu vaccine in 2010. The patient experienced chills, malaise, raynauds in left fingers cold, blue, tingling on 22Dec2020 08:00 AM. No treatment received for all events. The outcome of events was recovering. Patient had not tested for COVID-19 post vaccination. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. No seriousness criteria: no Results in death, no Life threatening, no Caused/prolonged hospitalization, no Disabling/Incapacitating, no Congenital anomaly/birth defect.

Headache Fever (101.3) with chills body aches/malaise nausea/decreased appetite site injection-arm pain

headache; Tachycardia; chills; body aches; This is a spontaneous report from a contactable nurse (patient). A 25-year-old female patient received her first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number: EH9899), intramuscularly on right arm at 07:30 AM on 18Dec2020 at single dose for COVID-19 immunization. The patient medical history was not reported. Concomitant medication included ethinylestradiol, ferrous fumarate, norethisterone acetate (LO LOESTRIN FE). The patient experienced tachycardia, chills, body aches, headache at 12:00 AM on 19Dec2020, events resulted in: Emergency room/department or urgent care], events were reported as non-serious. Prior to vaccination, the patient was not diagnosed with COVID-19. The patient was tested COVID post vaccination on

19Dec2020; COVID test type: Nasal Swab, COVID test name : Covid PCR, Covid test result: Negative. The patient did not receive any treatment for events. The outcome of events was recovered in Dec2020.

Episode of nausea; Right-sided preauricular and superficial cervical lymphadenopathy; This is a spontaneous report from a contactable physician (patient herself). This 36-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number EJ1685), via an unspecified route of administration, at single dose on 19Dec2020 at 08:45 AM for COVID-19 immunisation. Vaccine location was left arm. The patient was vaccinated at hospital, age at vaccination was 36-year-old. No other vaccine was received in four weeks. The patient was not pregnant. The patient did not have a relevant medical history. Relevant concomitant medications included ibuprofen and 20 Ethinyl Estradiol-3 Drospirenone. On 21Dec2020, the patient developed right-sided preauricular and superficial cervical lymphadenopathy. On 22Dec2020, the patient had an episode of nausea. The patient did not perform COVID test before and after vaccination. No therapeutic measures were taken as result of the events. The outcome of the events was unknown.

On day to the left arm had some redness at the injection site and was sore. This was listed as unknown possible side effect. On the days following a became increasingly red and itchy. I took Benadryl to help resolve the itching. Redness and itching continued and then on Sunday 12/27/20 The site became increasingly read painful to touch and warm to touch. On Monday morning I contacted my immediate supervisor advised her that I was having something outside of what I believed to be a ?normal? reaction or side effect. I went to urgent care to see occupational health. I was given prescriptions for keflex and naproxen for cellulitis. My arm is extremely painful to touch. I was advised if the area worsens or spreads to see the ER because I may need IV antibiotics.

Sore arm; This is a spontaneous report from a contactable nurse (patient). A 24-year-old female patient (no pregnant at the time of vaccination) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EH9899) via intramuscularly on 22Dec2020 06:15 AM on left arm at single dose for COVID-19 immunization. The patient's medical history included hyperthyroidism/goiter and not allergy to medications, food, or other products. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine and did not receive any other medications within 2 weeks of vaccination. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, the patient has not been tested for COVID-19. The concomitant drug included vitamins within 2 weeks of vaccination. The patient experienced sore arm on 22Dec2020 06:15 AM. No treatment for sore arm. The outcome of the events was recovering.

"In Clinic: Pt received Moderna vaccine on right arm. She immediately felt numbness and tingling sensation on both shoulders and right neck. Neck felt tight, pain and + weakness on left wrist and 4th / 5th digit. BP was 149/ 78, O2 sat 99%, pulse 82. Pt then felt nausea, dizziness, burning sensation of left thigh, ""not feeling well"". Pt abvle to move all extremities, denies SOB. Hx of allergic reaction to Reglan and compazine. Repeat Vitals: 160/74, pulse,83,O2sat 100%, 2 pm: 135/85, pulse 75, O2 sat 99% Paramedics was called and arrived at 2:11 pm. Pt to be further evaluated in ER. In ED: Gen: Patient is in NAD, non-toxic appearing, cooperative HEENT: NC/AT, MMM, no conjunctival injection, b/l sclera anicteric. Mallampati 1 oropharynx clear, no exudates, tonsils within normal limits. No edema or

erythema. Neck: Supple. Cardiovascular: RRR Pulmonary/Chest: CTAB, no increased WOB, no respiratory distress, no wheezes/rhonchi/rales, chest wall tenderness. Abdominal: Soft. NT/ND, no r/g, no masses Extr/MSK: Well perfused, distal pulses intact. No tenderness. No LE edema. Back: No CVAT Neuro: No evidence of facial droop, normal speech, mentation appropriate, steady gait. Sensation intact to light touch to upper lower extremities. Cranial nerves 2-12 within normal limits. Psychiatric: Normal affect. Mood not labile nor depressed. Skin: No rashes, lesions, or wounds appreciated on exposed skin. á ED Course & Clinical Decision Making: 43 year old female with PMHx as listed in HPI presents with intermittent numbness after receiving the coronavirus vaccination. á - History of present illness also notable for symptoms started 20-30 minutes after receiving the coronavirus vaccination. á - Vitals reviewed and all wnl á - Physical exam notable for neurologically intact, no rashes, no airway abnormalities, otherwise unremakrable. á - Given above findings, presentation is concerning for side effects from the coronavirus vaccination, electrolyte abnormality. Will check basic lab work here in the emergency department. Will give symptomatic control with 1 L of IV fluids and Zofran for the nausea. Will monitor here in the emergency department. Disposition pending clinical improvement. á Lab work grossly unremarkable here in the emergency department. Mild hypo phos of 2.6. Electrolytes otherwise within normal limits. No leukocytosis. Hemoglobin of 10.2, no baseline but the patient does have a history of chronic anemia given uterine fibroids. á The patient was able to ambulate with steady gait. She continues to have burning sensation to her left leg and her right arm. She will be given lidocaine patches for symptomatic control. She also be given ibuprofen 600 mg. á Return precautions returning to the patient. At this time presentation does not appear consistent with anaphylaxis. Min presentation most consistent with side effects from coronavirus vaccination. á Patient tolerated p.o. here in the emergency department. She was able to ambulate with steady gait. Symptoms mildly improved after lidocaine patch and ibuprofen. Return precautions given. á Patient re-evaluated and is stable for discharge. á At this time, suspicion is low for acute injury/illness requiring hospital admission or emergent intervention. No indication for inpatient management; No medical or surgical emergent care needed at this time. á However, it was stressed to the patient that symptoms may persist or worsen, in which case she should be reevaluated. Patient should also get appropriate and timely follow up for further evaluation and continuation of care. The patient indicates understanding of these issues. Patient is ready for discharge. Return precautions (advised to return to ER if their symptoms persist, change, or worsen) and follow up plan reviewed with patient and understood. á á"

Left deltoid soreness; This is a spontaneous report from a non-contactable physician (patient). A 28-year-old female (not pregnant) patient received first dose bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EJ1685), intramuscular in left arm on 22Dec2020 08:15 at single dose for COVID-19 immunisation. Facility where the most recent COVID-19 vaccine was administered was Hospital. Medical history included asthma (Prior history of asthma). No allergies to medications, food, or other products. Prior to vaccination, the patient was not diagnosed with COVID-19. Concomitant medications included ethinylestradiol, norethisterone acetate (JUNEL), ascorbic acid, betacarotene, biotin, capsicum annuum fruit, colecalciferol, collagen marine, curcuma longa, cysteine hydrochloride, equisetum arvense, fallopia japonica, hyaluronic acid, iodine, keratin, lysine, methionine, piper nigrum, selenium, serenoa repens, tocotrienols nos, withania somnifera, zinc (NUTRAFOL). The patient not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient experienced left

deltoid soreness (non-serious) on 22Dec2020 10:00. No treatment received for the adverse event. Since the vaccination, the patient has not been tested for COVID-19. The outcome of the event was not recovered. No follow up attempts are possible. No further information is expected.

""""whole body aches everywhere.""/whole body is so sore today, my breast, my back, shoulders, my neck; My throat gets a little sore; I just threw up everywhere; This is a spontaneous report from a contactable consumer (patient). A 65-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK5730), via an unspecified route of administration on 22Dec2020 08:20 at single dose for COVID-19 immunization. The patient medical history was not reported. There were no concomitant medications. The patient reported that her ""whole body aches everywhere/her whole body hurts."" Healthcare professional (HCP) had not been made aware of this at time of call. The patient further reported that her whole body was so sore today (23Dec2020), my breast, my back, shoulders, my neck. Also, her throat gets a little sore and she just threw up everywhere on an unspecified date in Dec2020. The patient was working in a nursing home. No treatment was given for the events. ""Lab test: Consumer stated, ""No, just the Covid test but I passed it so (sentence incomplete)."" The outcome of the events was unknown."

Anxious, dizzy, hypertensive, lightheaded for 30 min-- monitored throughout -- resolved without intervention -- discharged home

"Facial Tingling 25 minutes after injection. Still with mild tingling.; Face and ears felt very warm; This is a spontaneous report from a contactable nurse (patient). A 55-year-old non-pregnant female patient received her first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899), via an unspecified route of administration on 21Dec2020 13:30 at single dose on her left arm for covid-19 immunization. Medical history included gastrooesophageal reflux disease (GERD) and known allergies included Latex, epinephrine (""epi""), shell fish. Concomitant medication in two weeks included fexofenadine hydrochloride (ALLEGRA), lansoprazole (PREVACID), plantago ovata (METAMUCIL), dextran sulfate sodium (DSS). The patient previously took epinephrine and experienced drug hypersensitivity. The patient experienced face and ears felt very warm. Facial Tingling 25 minutes after injection on 21Dec2020 14:00. No treatment was received. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, the patient has not been tested for COVID-19. The outcome of the events was recovering."

2 inch diameter at injection site; swelling, redness, tender for 3 days after; 2 inch diameter at injection site; swelling, redness, tender for 3 days after; 2 inch diameter at injection site; swelling, redness, tender for 3 days after; This is a spontaneous report from a contactable other health professional (patient). A 40-years-old female patient (not pregnant at the time of vaccination) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), intramuscularly on 17Dec2020 16: 30 at single dose on left arm for COVID-19 immunization in hospital. Medical history included attention deficit hyperactivity disorder (ADHD), idiopathic retinitis. Concomitant medication included amfetamine aspartate, amfetamine sulfate, dexamfetamine saccharate, dexamfetamine sulfate (ADDERALL), gabapentin, naproxen sodium (ALEVE), ergocalciferol (VIT D), magnesium supplement and multivitamin.

The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient experienced 2 inch diameter at injection site; swelling, redness, tender for 3 days after, stated from 18Dec2020 12:00 PM. Then gone. No treatment received for the adverse events. The events outcome was recovered in Dec2020. No COVID prior vaccination, since the vaccination, the patient hadn't been tested for COVID-19. The seriousness was reported as no. The information on the batch number has been requested.

Tachycardia up to 160 with exertion. Some shortness of breath noted. Returns to normal heart rate with rest. Cardiac monitor, CXR, CBC, TSH, CMP in the Emergency Department and physician evaluation. Returned to work same day without restrictions. Will follow up with personal provider.

left arm soreness a little; This is a spontaneous report from a contactable nurse (patient). A 55-year-old female patient (not pregnant at the time of vaccination) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK5730), intramuscularly on 22Dec2020 16:30 at single dose at left arm for COVID-19 immunization. Medical history was none. The patient's concomitant medications were not reported. The most recent COVID-19 vaccine was administered at Hospital. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient did not receive any other medications within 2 weeks of vaccination. The patient experienced left arm soreness a little on 22Dec2020 16:30. There was no any treatment received for the adverse event. The case safety report was non-serious per the reporter. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient hadn't been tested for COVID-19. The outcome of the event was recovering.

joint pain; fatigue; headache; sore arm; This is a spontaneous report from a contactable pharmacist (patient). A 27-year-old female patient (not pregnant) received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number= EH9899), via an unknown route of administration on 22Dec2020 09:00 AM in left arm at single dose for COVID-19 immunization. The COVID-19 vaccine was administered at hospital. The patient's medical history and concomitant medications were unknown. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient experienced joint pain, fatigue, headache, sore arm on 23Dec2020 09:00 AM. The patient received Ibuprofen as treatment. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, the patient was not been tested for COVID-19. The outcome of events was unknown.

oral lesions; This is a spontaneous report from a contactable nurse. A 48-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (lot number EH9899), via an unspecified route of administration on 21Dec2020 at single dose for covid-19 immunization. Vaccine location was right arm and it was the first dose. The facility type vaccine was hospital. None medical history. No known allergies. Patient was not diagnosed with COVID-19 prior to vaccination nor tested for COVID-19 since the vaccination. Concomitant medication included acetylsalicylic acid, caffeine, paracetamol (EXCEDRIN MIGRAINE) within 2 weeks of vaccination. The patient didn't receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient experienced oral lesions on 22Dec2020 with outcome of not recovered. Patient didn't receive treatment for the adverse event. The action taken in

response to the events for BNT162B2 was not applicable. The date report was first received from source was 23Dec2020. The event was reported as non-serious.

I woke up in the middle of the night after my vaccine; experienced a rapid heartbeat; This is a spontaneous report from a contactable healthcare professional. A 50-year-old female patient received BNT162B2 (Pfizer-BIONTECH Covid-19 Vaccine), via an unspecified route of administration on an unspecified date at a single dose for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient stated that she received the first injection of the vaccine on Monday and experienced a rapid heartbeat on Monday night (unspecified dates). She further stated that she woke up in the middle of the night after her vaccine with her heart rate at 127. She wanted to know about this side effect if it was the true side effect and if it could happen again after receiving the second dose of the vaccine. Outcome of the events was unknown. Information on the lot/batch number has been requested.

chills, muscle soreness, left arm pain/injection site pain. injection site hard started around 7pm 12/28/20, currently 12/29/20 no longer have chills still have generalized muscle soreness, left arm pain/injection site pain, injection site hard

fever accompanied by severe chills for 12 hours; fever accompanied by severe chills for 12 hours; This is a spontaneous report from a non-contactable Other healthcare professional (HCP) reporting for herself. A 25-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 22Dec2020 at single dose for covid-19 immunization. Vaccine location was Right arm and it was the first dose. The COVID-19 vaccine was administered at Hospital. Medical history included the patient was diagnosed with COVID-19 Prior to vaccination. Concomitant medications included escitalopram oxalate (LEXAPRO), trazodone, acetylsalicylic acid (BABY ASPIRIN), ibuprofen. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient experienced fever accompanied by severe chills for 12 hours on 22Dec2020 07:00 PM. Since the vaccination, the patient was not been tested for COVID-19. No treatment received for the events. The outcome of the event was recovering. No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.

drop in platelets; This is a spontaneous report from a Pfizer-sponsored program. A contactable pharmacist reported that a patient of unspecified age and gender started to receive bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE; lot/batch number not reported), via an unspecified route of administration on an unspecified date at a single dose for covid-19 immunization. The patient's medical history and concomitant medications were not reported. Pharmacist on the line calling about COVID 19 Vaccine. He was doing some administrative work and noticed they have patient who received the COVID 19 vaccine and has since experienced a drop in platelets. He wanted to know if we have any information about any other reports of this occurring. The COVID 19 vaccine was given and then noticed patient had a drop in platelets. The reporter stated he does not know when the patient experienced the drop in platelets. He was provided with this question yesterday, so it's possible the drop occurred yesterday, but he does not know. It was unknown to the caller if the drop in platelets is still ongoing or has resolved. The outcome of the event was unknown. Information on the lot/batch number has been requested.

Pain at injection site

nausea; Headache; fever; chills; body aches; This is a spontaneous report from a contactable Nurse (patient). A 42-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number E12573C) , intramuscular in Left arm on 21Dec2020 at 19:00 at single dose for COVID-19 immunization. Medical history included COVID-19 (the patient diagnosed with COVID-19 prior to vaccination); since the vaccination, the patient has not been tested for COVID-19. No known allergies to medications, food or other products.Concomitant medication included cetirizine hydrochloride (ZYRTEC) and ibuprofen, received within 2 weeks of vaccination. On 22Dec2020 at 17:00, the patient experienced nausea, headache, fever, chills and body aches, all non serious. No treatment was given and patient recovered from all the events in Dec2020.

"Urgency, repeated episodes of diarrhea; GI symptoms; Cramping; This is a spontaneous report from a contactable physician (patient). A 58-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number EJ1685), via an unspecified route of administration at right arm on 19Dec2020 07:15 at single dose for COVID-19 immunization at a hospital. The patient's medical history included hypertension (HTN), obesity, had hx of stroke 2007 and COVID-19 (diagnosed prior to vaccination). No allergies to medications, food, or other products. No other vaccines within 4 weeks prior to the COVID vaccine. Concomitant medication received within 2 weeks of vaccination included hydrochlorothiazide, valsartan (VALSARTAN HCTZ), rosuvastatin calcium (CRESTOR), acetylsalicylic acid (ASA 81) and multivitamin. Since the vaccination, the patient had not been tested for COVID-19. It was reported that on 20Dec2020 09:00, the patient experienced gastrointestinal (GI) symptoms, cramping, and ""urgency, repeated episodes of diarrhea"". No fever. No treatment was taken as a result of the events. The outcome of the events was recovering."

Severe fatigue/malaise.; Severe fatigue/malaise.; This is a spontaneous report from a contactable Other Health Professional (patient). A 32 years old male patient received the 1st dose BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, lot EH9899), intramuscular at 21Dec2020 11:00 AM at single dose in left arm for COVID-19 immunisation. Medical history included Asthma, ADHD and Known allergies: Sulfa. Concomitant medications included salbutamol sulfate (PROAIR), fluticasone propionate, salmeterol xinafoate(ADVAIR), montelukast sodium (SINGULAIR) and amfetamine aspartate, amfetamine sulfate, dexamfetamine saccharate, dexamfetamine sulfate (ADDERALL). The patient experienced Severe fatigue/malaise on 22Dec2020 06:00 AM. Remained afebrile during symptoms. The patient did not receive any treatment. Outcome of events was recovering.

Sore/tender arm; headache; This is a spontaneous report from a contactable other hcp (patient). A 67-year-old female patient received bnt162b2 (lot number: ek5730), intramuscularly at left arm, first dose on 18Dec2020 13:45, at single dose, for COVID-19 immunization. Medical history included high blood pressure from an unknown date. No known allergies. The patient is not pregnant at the time of vaccination. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Concomitant medication included blood pressure medication. The patient experienced Sore/tender arm and headache the day after the vaccine on 19Dec2020 01:00. The event was reported as non-serious. No treatment received for the

adverse event. The patient underwent lab tests and procedures which included blood pressure measurement: high on an unspecified date. The outcome of the events was recovered.

Symptoms started the morning after (12/29/2020), the injection site is very sore. Sudden onset of headache.

Initial flushing in face and slight metallic taste in mouth lasting less than 5 min; Initial flushing in face and slight metallic taste in mouth lasting <5 min; tiredness; mild nausea; Next 1-2 days bruising more than my normal at site of injection; This is a spontaneous report from a contactable Other healthcare professional(patient). A 39-year-old female patient received first dose BNT162B2 via Intramuscular at Arm Left on 20Dec2020 11:00 at the 39-year-old at single dose for COVID-19 immunization. The medical history included Sulfonamide allergy, Varicose veins, 1/2 thyroid removed no meds, chronic sinuses take nasacort for and COVID-19. The concomitant medication was Vitamins. The patient previous took levaquin, chloraprep and both Allergies to them. On 20Dec2020 11:15 the patient Initial flushing in face and slight metallic taste in mouth lasting less than 5 min. Then tiredness for 12-24 hours as well as mild nausea and in well feeling. Next 1-2 days bruising more than my normal at site of injection. After that fine. Over all fairly mild symptoms. There was no treatment received for the adverse events. The outcome of the events Initial flushing in face and slight metallic taste in mouth was recovered on 20Dec2020 11:20, the other events was recovered in Dec2020. Information on the lot/batch number has been requested.

mild injection site soreness; mild light headed; tiredness; This is a spontaneous report from a non-contactable nurse (patient). A 39-year-old female patient the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EK5730), intramuscularly on 22Dec2020 at left arm, at single dose for covid-19 immunization. Medical history included hypothyroid, migraine and known allergies: Penicillin. The patient's concomitant medications were not reported. The patient was not pregnant at the time of vaccination. The patient experienced mild injection site soreness, mild light headed, tiredness on 22Dec2020. No treatment received for all events. The outcome of the events was recovered in Dec2020. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. No seriousness criteria: no Results in death, no Life threatening, no Caused/prolonged hospitalization, no Disabling/Incapacitating, no Congenital anomaly/birth defect. No follow-up attempts are possible. No further information is expected.

Fever, chills, body aches, low back pain, pain at injection site

"feeling her face numb; funny; flushed; Also felt 'a little bit' of nausea; tired; low joint pain the next morning; This is a spontaneous report from a contactable other health professional (patient). A female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications was not reported. The patient experienced after 30 minutes to 1 hour of receiving the injection she described ""feeling her face numb, funny, flushed, but then that kind of went away an hour or 2, less and less and less."" Also felt 'a little bit' of nausea and

tired, low joint pain the next morning, that went away in one and a half days. The outcome of the events was recovered on an unknown date. Information on the batch number has been requested."

"Patient with HA / ""Mucous"" sensation in throat. Progressed to patient frequently coughing / clearing throat. Felt like something in throat, difficult to swallow water ICC called for ER MD to eval. IV started. Benadryl, Pepcid, and Solumedrol given as per protocol. Pt taken to ICC for monitoring."

Headache; tinnitus; This is a spontaneous report from a contactable physician (reported for herself). A 41-year-old female patient (not pregnant at the time of vaccination) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK5730), via an unspecified route of administration on 21Dec2020 12:15 at single dose at left arm for COVID-19 immunization. Medical history included endometriosis, sinus disease, allergies, and known allergies: NSAID. Concomitant medications received within 2 weeks of vaccination included cyclobenzaprine, doxepin, ergocalciferol (VIT D), cetirizine hydrochloride (ZYRTEC [CETIRIZINE HYDROCHLORIDE]), Ocp. The most recent COVID-19 vaccine was administered in Hospital. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. It was reported that headache developed at 48 hours with tinnitus on 23Dec2020 11:00. Treatment received for the adverse event included Tylenol. The events were non-serious per the reporter. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient hadn't been tested for COVID-19. The outcome of the events was not recovered.

Rash swelling primarily to arm injected.; Rash swelling primarily to arm injected.; Chills; fatigue; mild nausea; This is a spontaneous report from a contactable nurse. A 50-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number= EH9899), Intramuscularly on 17Dec2020 08:15 AM in left arm at single dose for COVID-19 immunization. The COVID-19 vaccine was administered at hospital. Medical history was not reported. The patient had unknown allergies. Concomitant drugs in two weeks included Glucosamine, curcuma longa rhizome (TURMERIC). The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient experienced rash swelling primarily to arm injected, chills, fatigue, mild nausea on 18Dec2020 08:00 AM. No treatment received for the events. The adverse events resulted in doctor or other healthcare professional office/clinic visit. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, the patient was not been tested for COVID-19. The outcome of events was recovering. No follow up attempts are possible. No further information is expected.

Tachycardia, ?hot?, ?jittery? and chest tightness. Lasted ~45 minutes.

Body aches; Joint Pain; low grade fever; This is a spontaneous report from a contactable nurse (patient). A 37-year-old female patient received the first dose of BNT162B2 (Lot number: EJ1685), via intramuscular, in arm left, on 21Dec2020 15:00 at single dose for COVID-19 immunization. Facility where the most recent COVID-19 vaccine was administered was hospital. Medical history included HTN(Hypertension). Prior to vaccination, the patient was diagnosed with COVID-19. Since the vaccination, patient was not tested for COVID-19. Known allergies included PCN. No other vaccines were received within 4 weeks prior to the COVID vaccine. The other medication that the patient received within 2 weeks of vaccination was HCTZ, alprazolam(XANAX), paracetamol(TYLENOL),

colecalciferol(VITAMIN D), Ibuprofen, naproxen sodium(ALEVE). The patient experienced body aches, joint pain, low grade fever on 22Dec2020 09:00 AM. The events were reported as non-serious. No treatment was received for the events. The outcome of the events was recovering.

Client was leaving the building after her 15 min wait. She became dizzy and got a headache. She returned to the monitoring room. B\P 142/80 Respirations even and unlabored. Skin pink warm and dry. Reported dizziness and a headache. Client monitored an additional 15 min. No further headache or dizziness. B]P 138/78 pulse 60. Respirations even and unlabored. Skin pink, warm and dry. Released informed to report to V-safe and to seek medical advise if in symptoms reoccurred.

Headache; Runny nose; Sore throat; mild fever; fatigue; This is a spontaneous report from a contactable other hcp (patient) from a Pfizer Sponsored Program. A female patient of an unspecified age received bnt162b2 (lot/batch number and expiration date not provided) via an unspecified route of administration, first dose on 16Dec2020 (reported as last wednesday of 23Dec2020), at single dose, for COVID-19 immunization. The patient medical history and concomitant medications were not reported. Stated that she got her first dose COVID vaccine last wednesday and experienced mild fever and fatigue on 16Dec2020. Stated that this morning (23Dec2020) she woke with a headache, runny nose and sore throat. Stated that she had wanted to know if the side effects are normal for the time frame and if she would have to be tested. The patient underwent lab tests and procedures which included body temperature: mild fever on 16Dec2020. The outcome of the events mild fever, fatigue was unknown, of the other events are not recovered. Information on the lot/batch number has been requested.

joint pain; fever; nausea; stomach pain; This is a spontaneous report from a contactable physician (patient). A 76-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 22Dec2020 at left arm, at single dose for vaccination. Medical history included ongoing diabetes. Concomitant medication included dulaglutide (TRULICITY) for diabetes. The patient the vaccine on 22Dec2020 and had developed joint pain, fever, nausea, and stomach pain on 22Dec2020. The patient had taken Pepto bismol and Tylenol in response to these events and what to know if these medications are safe to take or what recommendations to treat side effects. He called to ask if those products were safe to take relative to having gotten the COVID-19 Vaccine; and if there are any recommendations on medications to or not to take relative to having gotten the COVID-19 Vaccine. The patient stated his was also on Trulicity for diabetes and that medication can cause stomach pain too. He stated the pain is in the center of his abdomen. COVID-19 Vaccine next dose is scheduled in 3 weeks, no dose change made. The patient specified that there is no relevant information to provide regarding concomitant products or medications or other medical conditions. He took medication for diabetes but that was not relevant. The outcome of the events was not recovered. Information about Lot/Batch number has been requested.

Heart Racing, lump in the throat, facial swelling

Fever; chills; nausea; injection site pain; body aches; This is a spontaneous report from a contactable nurse (patient). A 33-year-old female patient (no pregnant at the time of vaccination) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: Ek5730) via an unspecified

route of administration on 22Dec2020 06:45 PM on left arm at single dose for COVID-19 immunization. The patient's medical history included chronic low back pain and not allergy to medications, food, or other products. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine and did not receive any other medications within 2 weeks of vaccination. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, the patient has not been tested for COVID-19. The concomitant drug was not reported. The patient experienced fever, chills, body aches, nausea, injection site pain on 23Dec2020 11:30 AM. No treatment for adverse events. The outcome of the events was recovering.

Headache; soreness to the injection site; This is a spontaneous report from a contactable nurse. A 55-year-old female non-pregnant patient received her first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK5730), via intramuscular on 21Dec2020 07:30 at single dose on her left arm for covid-19 immunization. Medical history included hypertension. No allergies to medications, food, or other products. Concomitant medication was received within 2 weeks of vaccination included lisinopril. The patient experienced headache and soreness to the injection site on 21Dec2020 10:00. Treatment included Tylenol 500mg. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19, since the vaccination, the patient had not been tested for COVID-19. The outcome of the events was recovered in Dec2020. No follow-up attempts are possible. No further information is expected.

fever, headache, nausea, extreme fatigue lasting 24 hours No treatment besides ibuprofen. Symptoms began aboue 20 hours after injection and gone 26 hours later

12-26-2020 uncomfortable heart palpitations, tired and disruption of sleep x 2 days.

Extreme body aches, has to stay in be, severe headache, eyes hurt, swollen lymph nodes under right arm, fever to 99.2

Moderate/severe fatigue; muscle discomfort at injection site; muscle discomfort at injection site; This is a spontaneous report from a non-contactable other health professional (patient). A 25-years-old female patient (not pregnant) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number: EH9899), intramuscularly on 22Dec2020 08:00 at single dose on left arm for COVID-19 immunization. Medical history included polycystic ovarian syndrome (PCOS), sinus tachycardia, anxiety. Concomitant medication included propranolol, fluoxetine hydrochloride (PROZAC), spironolactone (ALDACTONE A), all from Dec2020. The known allergy included metoclopramide (REGLAN). The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient experienced moderate/severe fatigue, muscle discomfort at injection site on 23Dec2020 05:45 AM. No treatment received for the adverse events. The events outcome was not recovered. No COVID prior vaccination, since the vaccination the patient hadn't been tested for COVID-19. It was not reported as serious. No follow-up attempts are possible. No further information is expected.

she felt cold, then hot; she felt tired and weak; feel hot; she felt tired and weak/weakness; she felt cold/cold sensation; chills; headache; have a temperature of like 99 to 99.1/temperature went to 99.1; This is a spontaneous report from a contactable physician (patient). A 41-year-old female patient

received first dose bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EK5730, Expiry Date: Mar2021), intramuscular in left deltoid on 16Dec2020 around 2:00 or 2:30 in the afternoon at single dose for COVID-19 immunisation. Medical history included none. Concomitant medications included colecalciferol (VITAMIN D), ascorbic acid, ergocalciferol, nicotinamide, retinol, riboflavin, thiamine hydrochloride (VITAMINS [ASCORBIC ACID;ERGOCALCIFEROL;NICOTINAMIDE;RETINOL;RIBOFLAVIN;THIAMINE HYDROCHLORIDE]). The patient previously took flu shot on 16Oct2020 at age of 41-year-old for immunization. Caller asking if is possible to see side effects days later after getting the vaccine. Caller report her symptoms which the caller reports started 4-5 days after receiving the vaccine. Symptoms included were chills, weakness, headache and temp. Caller on the line a doctor, MD, calling about the COVID Vaccine. She mentioned she got the shot last week, 16Dec2020. Almost like the fourth day after getting the vaccine, that Sunday (20Dec2020), she started to experience chills and have a temperature of like 99 to 99.1. She did not get the vaccine through her doctor. She got the vaccine at the hospital she works at. She explained on Sunday (20Dec2020) night, she felt cold. She had to use a couple of blankets and wear a sweatshirt which was not usual for her. On Monday 21Dec2020, she felt tired and weak. That afternoon and evening she felt chills as well. It was like all of a sudden she had a cold sensation. She commented her normal temperature always runs like 97.6 to 98. Her temperature went to 99.1, something like that. However, she confirmed it did not go above that. She would feel hot at times and chilly at times. She also mentioned she experienced headaches. Yesterday (22Dec2020) morning she felt better. Last evening it was not that bad. She mentioned with chills she felt cold, then hot. She checked her temperature and it was 98.8 something like that. Just a little higher than her normal. Outcome of chills: Stated this morning she was fine, but in the evening it is worse. Felt weak: She mentioned there was time where she was fixing lunch and after it was cooked she felt weak and like she had to sit right away. Headache: Had an episode Sunday (20Dec2020) night and it happened again yesterday. The headaches for short periods. Caller confirmed this was the first dose received of the COVID vaccine. She confirmed she does not know if the chills, feeling weak, headache, or temperature is related to the COVID vaccine. She mentioned she has no other symptoms like cough. She also added she was tested for COVID and it was negative. She had the test done on 22Dec2020. At end of call, caller questioned, it was asked if it is possible to have side effects days later after getting the COVID vaccine and it be related to the vaccine. She stated she's read it's common for it to occur like two days after, but not this long afterwards. Vaccination Facility Type was Hospital. Vaccine Administered at a Military Facility was No. Additional Vaccines Administered the Same date of the Pfizer Suspect was None. No AE(s) require a visit to the Emergency Room or Physician Office. The outcome of the event weakness was not recovered. The outcome of the event have a temperature of like 99 to 99.1/ temperature went to 99.1 was recovering. The outcome of other events was unknown.

lump in armpit and sore; sore collar bone swollen on side that received vaccine; lymph node and collar bone swollen; collar bone swollen; fever; chills; shakes; This is a spontaneous report from a contactable nurse. A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 21Dec2020 at single dose for covid-19 immunization. The patient medical history and concomitant medications were not reported. The patient stated she was noticing possible side effects in Dec2020, with lymph node and collar bone swollen,

fever, chills, shakes, this morning (23Dec2020) lump in armpit and sore collar bone swollen on side that received vaccine. The action taken in response to the events for bnt162b2 was not applicable. The outcome of events was unknown. Information on the lot/batch number has been requested.

Moderna COVID-19 vaccine EUA

Sore arms; light headed; This is a spontaneous report from a contactable Other Healthcare professional (HCP) reported for himself. A 55-year-old male patient received (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK5730), intramuscular on 22Dec2020 18:30 at single dose for covid-19 immunization. Vaccine location was Right arm and it was the first dose. The COVID-19 vaccine was administered at Doctor's office/urgent care. Medical history reported as none. The patient's concomitant medications were not reported. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient experienced sore arms, light headed on 22Dec2020. No treatment received for the events. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, the patient was not been tested for COVID-19. The outcome of the events was recovered on an unknown date in Dec2020.

I hard time swallowing Tingling in my face

SEVERE chills/shivering; significant nausea; tachycardia- mid to upper 120's; dizziness; fatique; headache; body aches; This is a spontaneous report from a contactable nurse (patient). This 50-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: Not available/provided to reporter at the time of report completion) via an unspecified route of administration on 21Dec2020 06:30 on right arm at a single dose for COVID-19 immunization. The patient no known allergy and no medical history. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Concomitant medications received within two weeks included methyprednisolone, azithromycin, celecoxib (CELEXA) and fish oil. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, the patient has not been tested for COVID-19. The patient experienced severe chills/shivering, significant nausea, tachycardia- mid to upper 120's, dizziness, fatigue, headache, body aches on 21Dec2020 08:00. The patient received Zofran to treat nausea. The outcome of the events was recovering. Information on Lot/Batch number has been requested.

Patient reported chest pain and tingling/numbness to face. HR 60 Respirations 18. Monitored and chest pain resolved - did have evaluated n Emergency Room and was discharged home and advised to return if symptoms worsen. 12/29/2020 spoke with patient and feeling good, no symptoms at all.

"Left armpit 7.5centimeter long x 4.5 centimeter tender mass; This is a spontaneous report from a contactable nurse (patient). A 55-year-old female patient (not pregnant) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number EH 9899), via an unspecified route of administration at left arm on 21Dec2020 15:15 at single dose for COVID-19 immunization at a hospital. The patient's medical history included arthritis, known allergies: Penicillin (Pcn) and COVID-19 (diagnosed prior to vaccination). Concomitant medication received within 2 weeks of vaccination included golimumab (SIMPONI), methotrexate and meloxicam (MOBIC). No other vaccines within 4

weeks prior to the COVID vaccine. It was reported that on 23Dec2020 09:00, the patient experienced ""left armpit 7.5centimeter long x 4.5 centimeter tender mass"". The event led to doctor or other healthcare professional office/clinic visit and patient consulted the event. The outcome of the events was unknown."

arm soreness starting seven or eight hours after injection; Pregnant at the time of vaccination?: Yes; Pregnant at the time of vaccination?: Yes; Pregnant at the time of vaccination?: Yes; This is a spontaneous report from a contactable consumer (patient). This consume reported information for both mother and fetus/baby. This is a mother report. A 39-year-old female patient received bnt162b2 (lot number: EJ1685), intramuscularly at left arm, on 22Dec2020 11:00 at single dose for COVID-19 immunization. Medical history included asthma, migraines from an unknown date. The patient is pregnant at the time of vaccination. The patient date of LMP is 09Oct2020. The mother was 10 weeks pregnant at the onset of the event. The mother was due to deliver on 16Jul2021. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. No allergies to medications, food, or other products. Concomitant medication included ascorbic acid, betacarotene, calcium sulfate, colecalciferol, cyanocobalamin, ferrous fumarate, folic acid, nicotinamide, pyridoxine hydrochloride, retinol acetate, riboflavin, thiamine mononitrate, tocopheryl acetate, zinc oxide (PRENATAL VITAMINS). The patient experienced arm soreness starting seven or eight hours after injection on 22Dec2020 21:00. The event was reported as non-serious. No treatment received. The outcome of the event was recovering.

rash on upper chest, itching in both arms, pt reported she felt short of breath

Fever up to 100; myalgias; chills; wheezing; coughing; some shortness of breath; This is a spontaneous report from a contactable Other Healthcare professional. A 41-year-old female patient received first dose BNT162B2 via Intramuscular at Arm Left on 18Dec2020 15:00 at the 41-year-old at single dose for COVID-19 immunization. The medical history included Asthma, GERD, insomnia, bladder pain syndrome and COVID-19(Prior to vaccination, was the patient diagnosed with COVID-19). The concomitant medications were Amitriptyline, Trazodone, diphenhydramine hydrochloride (BENADRYL), Omeprazole, macrogol 3350(MIRALAX), mometasone furoate (ASMANEX), Naproxen. Symptoms started 7 days after injection. On18Dec2020 12:00 the patient experienced Fever up to 100, myalgias, chills, wheezing, coughing, some shortness of breath. The patient received treatment Naproxen for the adverse events. The outcome of the events was recovering. Information on the lot/batch number has been requested.

Patient left eye felt like sand was in it, she tried eye drops and eye wash and nothing worked. She also reports left leg pain

None, just a sore arm; This is a spontaneous report from a contactable nurse (patient herself). A 43-year-old female patient started to receive her first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot Number: EJ1685), intramuscularly on right arm at 14:45 on 22Dec2020 at single dose for COVID-19 immunization. Medical history included hypothyroidism and psoriasis, no allergies to medications, food, or other products. Concomitant medication included ibuprofen (MOTRIN). The patient experienced sore arm on 23Dec2020, event reported as non-serious. Prior to vaccination, it was

unknown if the patient was diagnosed with COVID-19; Since the vaccination, the patient had not been tested for COVID-19. The patient did not receive any treatment for events. The outcome of event was unknown.

Headache; This is a spontaneous report from a contactable Other Health Professional (patient). A 38-year-old female patient (no pregnant at the time of vaccination) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899) via intramuscular on 22Dec2020 10:00 AM on left arm at single dose for COVID-19 immunization. The patient's medical history included allergy to cefdiner and augmentin and no other medical history. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine and did not receive any other medications within 2 weeks of vaccination. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, the patient has not been tested for COVID-19. The concomitant drug was not reported. The patient experienced headache on 23Dec2020 05:00 AM. No treatment for adverse event. The outcome of the events was recovered in Dec2020.

tiredness, headache, hot flashes, chills, reduced appetite. Conditions started approx 22 hours after inoculation and lasted for 15 hours. After that just minor hot and cold spells on the second day, today.

5 days post-vaccination, temperature ranging from 99.0-99.6F.; 4 days post-vaccination noticed lymphadenopathy behind right ear.; Mild swelling; sensitive to touch; This is a spontaneous report from a contactable nurse (patient). A 22-year-old female (not pregnant) patient received first dose bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: Unknown), intramuscular in arm left on 17Dec2020 17:30 at single dose for COVID-19 immunisation. Facility where the most recent COVID-19 vaccine was administered was hospital. Medical history included none. No allergies to medications, food, or other products. Prior to vaccination, the patient was not diagnosed with COVID-19. The patient's concomitant medications were not reported. The patient experienced 4 days post-vaccination (21Dec2020) noticed lymphadenopathy behind right ear. Mild swelling, sensitive to touch. 5 days post-vaccination (22Dec2020), temperature ranging from 99.0-99.6F. No treatment received for the adverse event. Since the vaccination, the patient has not been tested for COVID-19. The patient not receive any other vaccines within 4 weeks prior to the COVID vaccine. The case was non-serious. The outcome of events was recovering. Information on the Lot/batch number has been requested.

can't smell or taste anything; can't smell or taste anything; Head cold; This is a spontaneous report from a contactable nurse (patient). A 63-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EK5730), via an unspecified route of administration on 18Dec2020 at single dose for immunization. Medical history and concomitant medications were no. Patient got the Covid vaccine on 18Dec2020, towards the end of her shift around 1800 on 22Dec2020, she felt like she was getting a head cold. On 23Dec2020 morning, patient stated she cannot smell or taste anything. Outcome of all events was not recovered. Reporter seriousness for cannot smell or taste as not serious.

Feeling tired after the vaccine; This is a spontaneous report from a contactable consumer (Patient). A 34-year-old male patient received (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK9231), via an

unspecified route of administration on 23Dec2020 09:00 at single dose for covid-19 immunization (Front line health care worker). Vaccine location was left arm and it was the first dose. He was scheduled to get the second dose in Jan2021. The COVID-19 vaccine was administered at Hospital. Medical history included attention deficit hyperactivity disorder (ADHD). Concomitant medication included ongoing methylphenidate hydrochloride (CONCERTA) for ADHD taking for five years. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient was feeling tired after the vaccine on 23Dec2020, Stated he just got the vaccine and he was now just really tired, not sick or anything and he was at work. He was considering going home from work and they told him he had to call Pfizer. Reported he received the COVID 19 vaccine today at work at the at 0900 23Dec2020 in the left arm. About 20 minutes after the injection he started to feel tired and like he wanted to go home from work. His feeling was staying the same. The outcome of the event was not recovered.

I started feeling a lump in my throat, not really bad but it got worse it did not affect my speech or my breathing. But after a while I realized I was having a hard time swalowing, I asked the nurse for Benadryl and it took about 10 min to receive, they took my vitals, they watched for about 45 min and once I told them my throat was feeling better I was realized to go back to work.

Sore arm only; This is a spontaneous report from a non-contactable other HCP (patient). A 39-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EJ1685) via intramuscular on 22Dec2020 08:30 on left arm at a single dose for COVID-19 immunization. The patient allergy to Percocet and medical history included hypothyroidism. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine and did not receive any other medications within 2 weeks of vaccination. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, the patient has not been tested for COVID-19. The patient experienced sore arm only on 23Dec2020 18:00 and no treatment received. The outcome of the event was recovered in Dec2020. No follow-up attempts are possible. No further information is expected.

Difficulty breathing, itchy mouth rash, very bad cough, fever (103)

chills; fatigue; headache; arm pain; body aches; Fever; This is a spontaneous report from a contactable nurse(patient). A 29-year-old female patient received the first dose of BNT162B2 (Lot number: EL0140), via intramuscular, in arm left, on 22Dec2020 18:15 at single dose for COVID-19 immunization. Facility where the most recent COVID-19 vaccine was administered was hospital. Medical history included Covid 19, pneumonia, anxiety/depression. Prior to vaccination, the patient was diagnosed with COVID-19. Since the vaccination, patient was not tested for COVID-19. No allergies to medications, food, or other products. No other vaccines were received within 4 weeks prior to the COVID vaccine. The other medication that the patient received within 2 weeks of vaccination was MULTIVITAMIN, sertraline hydrochloride(ZOLOFT), VITAMIN D3, ZINC, VITAMIN C. The patient experienced fever, chills, arm pain, body aches, headache, fatigue on 23Dec2020 09:00 AM. No treatment was received for the events. The outcome of the events was not recovered.

"Chills; sweats; aches and pain; Reports she was up all night opening the window and tuning on the heating blanket during the night; This is a spontaneous report from a contactable consumer (patient). A

67-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number ""CJ1685 and 228255"" pending clarify), via an unspecified route of administration on 22Dec2020 08:30 at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. It was reported that she got the covid-19 vaccine yesterday (22Dec2020) at 08:30 A.M. Reported that all night long (22Dec2020) she had chills, sweats, aches and pains. She was told that she should be fine by Christmas. She was up all night opening the window and tuning on the heating blanket during the night. She was wrapped in blankets. Patient was advised to contact healthcare professional for treatment recommendations. Patient declined any treatment to the events. Patient also mentioned that her doctor did not want her to get the vaccine. She works as a certified nurse assistant (CNA) in the hospital. For the lot number, NDC number, and expiration date, she provided details from the card she was given for the vaccine. She read first dose COVID-19: ""CJ1685 and 228255"". She put her glasses on to read the card. The patient she wanted to lay down. The outcome of the event chills, aches and pains was not recovered, for event sweats was recovering, for the rest of event was unknown."

At about 15 minutes the patient experienced nausea, headache, then face flushing.

fever/steady fever/Caller says his fever got as high as 101.5 degrees Fahrenheit; This is a spontaneous report from a contactable Other Health Professional (patient) from a Pfizer-sponsored program IBCC (Inbound Call Center for HCPs). An 82 years old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, lot EL0140) via an unspecified route of administration on 21Dec2020 at single dose in left arm for COVID-19 immunisation. Medical history and concomitant medications were none. Warm transfer in regards to the COVID vaccine which he received Monday morning. Agent reports caller said since then he has had a steady fever and has questions in regards to side effects. As for Height: Caller says he is shrinking, he is about 5 feet 9 inches tall. No further details provided about shrinking. Caller clarifies his doctor title and says that he is not a physician or medical doctor, he has a PhD in psychology. Caller says he doesn't have a prescribing provider, he got the vaccine at a retirement home called (facility name and location). Caller says that his fever started the day he got the shot. He says he got the shot that morning, clarified to being about noon, and had a fever that evening. Caller clarifies that he takes Advil, not Aspirin for his fever. He says when he takes the Advil it goes away, it gets rid of it, but when the Advil wears off the fever comes back again. He says he has no idea what side effects of this drug are, so he thought he would give a call because others were worried about it and pressured him to ask. Caller says the only information he has is the card, the COVID-19 Vaccine Record Card, which says Pfizer, then below it EL0140, which could be either 0 or letter O, probably 0. He says it has the date 21Dec2020 on it from when he got it and he got it in his left arm, it was his first injection of it, he has another to come. Caller says his fever got as high as 101.5 degrees Fahrenheit on 22Dec2020, and he also has a fever right now. Therapeutic measures were taken as a result of fever and included treatment with Advil. Outcome of event was not recovered.

after 2 hours headache lasted for 3-4 hours; left arm injection site soreness worse at night unable to raise arm due to pain lasted up to 48 hours from time of injection; unable to raise arm due to pain; This is a spontaneous report from a contactable other hcp (patient). A 64-year-old male patient received bnt162b2 (Lot: EK5730), via an unspecified route of administration at Left arm, first dose on 20Dec2020

10:30 at single dose, for COVID-19 immunization. Medical history included diabetes, high cholesterol and hypertension (HTN) from an unknown date. Prior to vaccination, the patient was not diagnosed with COVID-19. No Known allergies. Concomitant medication included metformine, lisinopril, atorvastatin and finasteride. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. It was reported that after 2 hours headache lasted for 3-4 hours left arm injection site soreness worse at night unable to raise arm due to pain lasted up to 48 hours from time of injection. The adverse event start on 20Dec2020, at 12:15 PM. The events are reported as non-serious. Therapeutic measures were taken as a result of after 2 hours headache lasted for 3-4 hours left arm injection site soreness worse at night unable to raise arm due to pain lasted up to 48 hours from time of injection, treatment included ibuprofen. The outcome of the event was recovering.

After a few minutes started experiencing a headache pressure feeling and dry mouth

redness at the site that was more noticeable; some tenderness; This is a spontaneous report from a contactable nurse (patient herself). A female patient of an unspecified age received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot #: EH9899), via an unspecified route of administration on 21Dec2020 at single dose for immunization. The patient's medical history and concomitant medications were not reported. The patient experienced redness at the site that was more noticeable, and some tenderness in Dec2020 with outcome of unknown.

Patient woke up with nausea, vomiting, and a headache this morning. OTC treatment, not see by physician.

Groggy/sleepy; mild cognitive impairment; mild unsteady gait; light headed; malaise; tired; This is a spontaneous report from a contactable other health professional (patient). A 55-year-old female patient received the first of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot/batch number: EJ1685), intramuscularly on 22Dec2020 06:30 AM at left arm, at single dose for covid-19 immunization. Medical history included Rheumatoid arthritis, hypothyroid and remission of DM2, known allergies: Penicillin. Concomitant medication included arginine hydrochloride, ascorbic acid, calcium, calcium pantothenate, cyanocobalamin, ferrous fumarate, folic acid, magnesium, methionine, nicotinic acid, phosphorus, potassium, pyridoxine hydrochloride, retinol, riboflavin, selenium, thiamine hydrochloride, tocopheryl acetate, triticum aestivum, zinc (MULTI VITAMIN), methotrexate, thyroid, sertraline. The patient previously took tramadol and experienced drug hypersensitivity. The patient was not pregnant at the time of vaccination. The patient experienced Groggy, mild cognitive impairment, mild unsteady gait, light headed, malaise, tired, sleepy on 22Dec2020 11:00 AM. No treatment was received for all events. The patient underwent lab tests and procedures which included covid test: negative on 21Dec2020 (Nasal Swab). The outcome of the events was recovering. Prior to vaccination, the patient was not diagnosed with COVID-19. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. No seriousness criteria: no Results in death, no Life threatening, no Caused/prolonged hospitalization, no Disabling/Incapacitating, no Congenital anomaly/birth defect.

Sore injection site; This is a spontaneous report from a contactable other HCP. A 45-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), Intramuscularly on 22Dec2020

02:45 PM in left arm at single dose for covid-19 immunization. The COVID-19 vaccine was administered at hospital. Medical history included diabetes. The concomitant drugs were not reported. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient experienced sore injection site on 23Dec2020 05:00 AM. No treatment received for the event. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, the patient was not been tested for COVID-19. The outcome of event was recovering. No follow-up attempts are possible. Information on Lot/Batch number cannot be obtained.

Extreme headache, as bad as I has while sick with covid. Exhaustion, shortness of breath while talking

Slightly elevated heart rate - most of that afternoon through early morning Slightly elevated blood pressure - most of that afternoon through early morning Palpitations at night - when I went to bed that's when I noticed it up until 1:30'ish in the morning I took one (1) 500 mg tylenol at around 1:00 am and felt a bit better; that was it

headache; ear neck back pain; ear neck back pain; ear neck back pain; chills/shivers; sweaty; nausea; vomiting; diarrhea; dizzy; weak; sore muscles; heavy feeling in both arms; tingling in lower legs; This is a spontaneous report from a contactable Nurse reported for herself. A 62-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, EK5730), intramuscular on 21Dec2020 08:30 AM at single dose for covid-19 immunization. Vaccine location was Right arm and it was the first dose. The COVID-19 vaccine was administered at Hospital. Medical history included rheumatoid arthritis and high blood pressure. Concomitant medication included quetiapine, metoprolol succinate, cyclobenzaprine, levothyroxine, omeprazole, tofacitinib citrate (XELJANZ). The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient's Known allergies included Iodine, Morphine. The patient experienced headache, ear neck back pain, chills, shivers, sweaty, nausea, vomiting, diarrhea, dizzy, weak, sore muscles, heavy feeling in both arms, tingling in lower legs on 21Dec2020 11:00 AM. No treatment received for the events. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, the patient was not been tested for COVID-19. The outcome of the events was recovered on an unknown date in Dec2020.

Headache; felling warm; This is a spontaneous report from a non-contactable other HCP. A 23-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899) via intramuscular on 22Dec2020 15:30 on left deltoid at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient denied any history of previous adverse reactions to vaccines. The patient was given the Pfizer vaccination in the left deltoid muscle. During her 15 minutes waiting period after the injection, the patient began to experience headache and felling warm. She denied rash, hives, welts, difficulty breathing, difficulty swallowing, wheezing, throat tightness, hoarseness, stridor, itching, lightheadedness, dizziness, facial swelling, lip swelling and tongue swelling. This provider was notified of patient reaction and she was then assessed in the emergency bay area. Monitored patient for severe reaction symptoms, including respiratory distress with stridor, wheezing, dyspnea, increased work of breathing, persistent cough and cyanosis. The patient was told to receive Tylenol and no side effects.

The patient was stable to go home and follow up with PCP. The outcome of the events was unknown. No follow-up attempts are possible. No further information is expected.

heart rate increased to 100BPM; This is a spontaneous report from a contactable Other Health Professional (patient). A 47-year-old female patient received 1st dose BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, lot EJ1685) via an unspecified route of administration on 18Dec2020 04:30 PM at single dose in left arm for COVID-19 immunisation. Medical history included Asthma, Known allergies: Sulfa, Peanuts, Shell Fish and Peas. Concomitant medications included cetirizine hydrochloride (ALEGRA), montelukast sodium (SINGULAIR), fluticasone propionate (FLOVENT) and ascorbic acid, tocopheryl acetate, xantofyl, zeaxanthin, zinc (AREDS) and Probiotics. The patient previously took Iodine and Erythromycin and experienced known allergies. At 18Dec2020 04:45 PM, her heart rate increased to 100BPM and continued for 45 min, and this result in Emergency room/department or urgent care. The patient underwent lab test and included EKG and heart rate count. Therapeutic measures were taken as a result of event and included treatment with Pepcid, Benadryl, EKG and Monitored her heart rate. Outcome of event was recovered on Dec2020.

3 hours after patient received vaccine on 12/27/2020 @ 2pm she started to feel flushed in the face and hands. She also started to get blisters on both hands. Pt. took a 25mg tab of Benadryl by mouth and symptoms resolved. She awoke at 3:30 am and felt that her carotid artery was pulsating. Patient informed Primary Care Physician's office on 12/28/2020 of symptoms who then prescribed patient an Epi-pen. Advised to receive emergency medical service if symptoms worsened. On 12/29/2020 patient feels good and all symptoms have subsided.

her upper face was swollen, clarifying more on the left side, and mostly around her eyes.; her upper face was swollen, clarifying more on the left side, and mostly around her eyes.; her eyes are a little red; This is a spontaneous report from a contactable consumer(patient). A 61-year-old female patient received BNT162B2 via an unspecified route of administration at Deltoid Right on 22Dec2020 14:00 at the 61 years old at single dose for COVID-19 immunization. The medical history included Type 2 diabetes mellitus from 1995 and ongoing(diagnosed about 25 years ago, controlled diabetic with a Hemoglobin A1C of 5) and Blood pressure high from 1995 and ongoing (diagnosed with high blood pressure about the same time as her diabetes, clarified as 25 years ago. She stated she has controlled blood pressure). The concomitant medications were not reported. The patient previously received a flu shot in Oct2020. On 23Dec2020 the patient reported her upper face was swollen, clarifying more on the left side, and mostly around her eyes. She said her eyes were a little red, too. She said she does not have any swelling around her mouth. The patient reported the facial swelling had slightly improved. She said she keeps looking at her face, so it was hard for her to tell, but her boss said her face was swollen. The patient reported she took a generic Benadryl 30 mg tablet this morning. She said she normally takes a Benadryl 30 mg tablet every night along with Melatonin for sleep. She said she has a big bottle of the generic Benadryl 30 mg at home and the bottle is almost empty. She said she rather take the Benadryl and Melatonin. The outcome of the events upper face was swollen and mostly around her eyes was Recovering, the event eyes were a little red was Not Recovered. Information about batch/lot number has been requested.

Employee c/o of sudden loss of vision and fell forward on the floor. Employee states he did not have any lunch yet. Emergency team called and assess the employee. Client refused to be taken to the ER for further evaluation. VS monitored and stable . No SOB, no difficulty of breathing. No Taking po fluids. Client d/c with steady gait and no c/o.

Anxiety; Anxiety; dizziness; rapid breathing; This is a spontaneous report from a non-contactable other health professional. A 34-year-old female patient received the first of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EH9899) intramuscularly on 22Dec2020 14:00 at left arm, at single dose for covid-19 immunization. Medical history included anxiety and took Hydralazine prn (As needed). The patient's concomitant medications were not reported. The patient denied any history of previous adverse reactions to vaccines. The patient was given the vaccination in the left deltoid muscle. During her 15 minute waiting period after the injection, the patient began to experience dizziness on 22Dec2020. She denied rash, hives, welts, difficulty breathing, difficulty swallowing, wheezing, throat tightness, hoarseness, stridor, itching, facial swelling, lip swelling and tongue swelling. This reporter was notified of patient reaction and she was then assessed in the emergency bay area. The patient presented with rapid breathing and anxiety. Monitored patient for severe reaction symptoms, including respiratory distress with stridor, wheezing, dyspnea, increased work of breathing, persistent cough and cyanosis. The patient's breathing slowed and felt less anxious by the time she left. The outcome of the events rapid breathing and anxiety was recovering, the outcome of the other event was unknown. No seriousness criteria: no Results in death, no Life threatening, no Caused/prolonged hospitalization, no Disabling/Incapacitating, no Congenital anomaly/birth defect. No follow-up attempts are possible. No further information is expected.

The day after on 12/18 soreness at at the injection site. On 12/19 symptoms exp headache and fatigue. Then on 12/20 started chills, fever and headache. I went to see the doctor on 12/21 and got several test Covid ,Flu and Strep results positive for all. Since then symptoms has continued. I have had to miss 6 days of work.

muscle aches; chills; Fatigue; This is a spontaneous report from a contactable nurse (patient). A 51-year-old female patient received 1st dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, expiration date: 31Mar2021), via an unspecified route of administration on 19Dec2020 19:30 at single dose to prevent Covid. Medical history included COVID-19 from 30Oct2020 to 24Nov2020. There were no concomitant medications. Eight hours after getting the vaccine (20Dec2020 03:30), she had muscle aches and chills, she also had fatigue on 20Dec2020. She was worried. She was concerned that she had done something crazy. She was through Covid for sure. She wasn't able too much. She was off work that day and didn't have to do anything. She would not have been able to work. The muscle aches were rivaling the worst days of Covid. She had Covid for 3 weeks. Then she had to wait another 10 days to get over the symptoms. She never had to go to the hospital. These muscle aches that she experienced after the injection were as intense as when she had Covid. The Lot on the patient card was difficult read. The information was hand written and squished in. She was unsure if it was EK5B30 or EK5030 or EK5730. The patient underwent lab tests and procedures which included COVID test: positive on 30Oct2020, negative on 24Nov2020. The outcome of muscle aches and chills was recovered on 21Dec2020, fatigue was recovering. The event muscle ache reported as serious, with serious criteria medically significant.

Information about lot/batch number has been requested.; Sender's Comments: The Company considers there is a reasonable possibility that the reported muscle ache is related to the administration of BNT162B2, based on the plausible temporal association and the known safety profile of the suspect. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RA, IEC, as appropriate.

Low-grade fever and chills (99.5 Fahrenheit); Low-grade fever and chills (99.5 Fahrenheit); headache; This is a spontaneous report from a contactable nurse (patient). A 29-year-old female patient received her fist dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number not provide), intramuscularly on right arm at 09:30 AM on 21Dec2020 at single dose for COVID-19 immunization. Medical history included deep vein thrombosis (DVT), covid-19 prior vaccination. Concomitant medication included escitalopram oxalate (LEXAPRO), rivaroxaban (XARELTO), atenolol, multivitamins. The patient experienced severe headache at 18:00 on 21Dec2020. Low-grade fever and chills (99.5 Fahrenheit) Q (every) 90 mins from 22:00 21Dec2020 till 04:00 22Dec2020. The events were assessed as non-serious. Since the vaccination, the patient had not been tested for COVID-19. The outcome of event headache was recovered in Dec2020, the outcome of events chills and low grade fever was recovered at 04:00 on 22Dec2020. Information on the Lot/Batch number has been requested.

dizziness; This is a spontaneous report from a non-contactable healthcare professional. A 21-year-old male patient started to receive bnt162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, lot number: EH9899, expiry date not reported), intramuscular on the right arm (right deltoid muscle) on 22Dec2020 18:15 at a single dose for COVID-19 immunisation. Medical history and concomitant medications were not reported. The patient experienced dizziness on 22Dec2020. He denied rash, hives, welts, difficulty breathing, difficulty swallowing, wheezing, throat tightness, hoarseness, stridor, itching, facial swelling, lip swelling and tongue swelling. The provider was notified of patient's reaction and he was then assessed in the emergency bay area. The patient was monitored for severe reaction symptoms, including rapid progression of symptoms, respiratory distress with stridor, wheezing, dyspnea, increased work of breathing, persistent cough and cyanosis, vomiting, abdominal pain, hypotension, dysrhythmia, chest pain and collapse. Therapeutic measures were taken as a result of dizziness that included water and rest. The patient was stable to go home. Clinical outcome of the event was unknown. No follow-up attempts are possible. No further information is expected.

I felt a little flushed; My heart is breathing; This is a spontaneous report from a contactable consumer (patient). This female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration at single dose on 21Dec2020 for Covid-19 immunisation. The patient medical history and concomitant medications were not reported. The patient stated: I felt a little flushed and my heart is breathing on an unspecified date with outcome of unknown. Information on the lot/batch number has been requested.

dizziness; This is a spontaneous report from a non-contactable healthcare professional. A 72 year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, lot number: EH9899),

intramuscular on the right leg (right deltoid muscle) on 22Dec2020 17:30 at a single dose for COVID-19 immunisation. Medical history and concomitant medications were not reported. The patient experienced dizziness on 22Dec2020 17:45, during her 15 minute waiting period after the injection. She denied rash, hives, welts, difficulty breathing, difficulty swallowing, wheezing, throat tightness, hoarseness, stridor, itching, facial swelling, lip swelling and tongue swelling. This provider was notified of patient reaction and she was then assessed in the emergency bay area. The patient was monitired for severe reaction symptoms, including rapid progression of symptoms, respiratory distress with wheezing and dyspnea, vomiting, abdominal pain, hypotension, dysrhythmia, chest pain and collapse. On an unspecified date, the patient underwent lab tests and procedures which included blood sugar: 108 and vital signs measurement: normal. No therapeutic measure was taken as a result of the event. Clinical outcome of the event was unknown. No follow-up attempts are possible. No further information is expected.

About 10 minutes after vaccine a red injection site appeared and then also was red further up around the shoulder (noticed because shoulder was itchy). I also felt warm. I have been diagnosed in the past with exercise induced asthma. Asthma started to flare up shortly after but did not require intervention. Was monitored by a doctor at facility where vaccine was given and symptoms did not worsen. No medication required. I noticed unusual muscle aches starting the next morning and persisted for a week after vaccine. Left arm where vaccine was given did not hurt, but other right arm, shoulders and thighs were aching. Hands seemed arthritic with movement at work. Feet occasionally felt tingly when walking for 5 days after vaccine. Asthma flare-ups continued after vaccine. Had to stop and rest after climbing stairs which is unusual for me. The worst asthma flare-ups persisted for up to 5 days. After 10 days at time of reporting adverse effects, asthma is still triggered but to a lesser extent. Can climb stairs without pause now. Airways have not fully recovered yet and I have a residual cough. Started self treating with albuterol rescue inhaler if needed.

Developed swollen lymph node under right arm; This is a spontaneous report from a contactable nurse (patient). A 35-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number: EK5730) intramuscularly at right arm on 20Dec2020 at 10:15 a.m. at a single dose (dose number=1) for COVID-19 immunization. Medical history and concomitant medications were not reported. The patient was not pregnant. Facility type vaccine was at hospital. No other vaccine in four weeks. The patient developed swollen lymph node under right arm on 21Dec2020 at 11:00 a.m. The event was reported as non-serious. with outcome of recovering. No treatment received for the event. No COVID-19 diagnosed prior vaccination and no COVID-19 tested post vaccination. No known allergies (no allergies to medications, food, or other products). No follow-up attempts are possible. No further information is expected.

Chills and body aches

Headache; nausea; This is a spontaneous report from a contactable other health professional (other HCP) (patient). A 60-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK5730) via an unspecified route of administration at right arm on 21Dec2020 at 10:00 a.m. at a single dose (dose number: 1) for COVID-19 immunization. Medical history included hypothyroid and

hyperlipidemia. Concomitant medications in two weeks included levothyroxine, simvastatin (ZOCOR), ergocalciferol (VITAMIN D), ascorbic acid (VITAMIN C) and calcium (reported as calcium mul, to be clarified). No other vaccine in four weeks. The patient was not pregnant. Facility type vaccine was hospital. No COVID-19 diagnosed prior vaccination and no COVID-19 tested post vaccination. No known allergies (no allergies to medications, food, or other products). The patient experienced headache, nausea on 22Dec2020 at 12:00 p.m. with outcome of resolved in Dec2020. The events were reported as non-serious. No treatment received for events.

Bilateral parasthesia to fingers 4 hours post injection. This passed in 15 minutes, About 7 Pm on 12/28/20, bilateral parasthesia to hands & feet. On 12/29/20 (AM) foot pain--painful to walk, went away in about 5 minutes, but still felt tingling to both feet. Still having tingling sensation to both feet (constant) and both hands (intermittent)

Pain injection site; numbness in both hands; This is a spontaneous report from a contactable consumer (patient). A 30-years-old male patient started to receive first dose bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, Lot number: EK5730), via an unspecified route of administration on 22Dec2020 14:00 at single dose (Anatomical Location of Administration: right shoulder) for COVID-19 immunization. Medical history included ongoing allergy, allergic to Sulfa drugs, Clindamycin, and Vancomycin. Concomitant medication included ongoing fluticasone propionate (FLONASE [FLUTICASONE PROPIONATE]) for Allergy and ongoing loratadine for Allergy. Prior vaccinations within 4 weeks was none. The patient experienced numbness in both hands on 22Dec2020 about ten minutes after the injection, pain injection site on 23Dec2020 09:00. He had an interesting side effect that was not listed on the fact sheet. He mentioned he did not want his information going to any third parties. He clarified the interesting side effect that he did not see listed on the fact sheet as, received the COVID 19 vaccine yesterday (22Dec2020) around 2 pm, after getting the shot he felt fine initially, but then he started to experience both of his hands go numb. He was not sure if had any effect on the nerves, but it effected his hands. Then he noticed today (23Dec2020) he had some pain at injection site. He stated that was normal and saw it listed. It was the numbing of his hands that was weird to him. His left hand felt better, but right hand felt the same. He was calling to see if due to this if he should still take the booster shot or not. He also wanted to see if these details had been reported before. Pain at injection still hurts a good amount and unable to provide outcome. He mentioned the card he received with the lot number the person who wrote on it had terrible hand writing, so he was not sure of the lot number. He stated these reactions are not severe, it is kind of annoying. The action taken in response to the events for bnt162b2 was not applicable. Relevant Test was None. The outcome of the events was not recovered.

anxiety; chills; generalized feelings of not feeling quite right; nausea; nervousness; This is a spontaneous report from a non-contactable other hcp. A 34-years-old female patient received first dose bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, Lot number: EH9899), intramuscular on 22Dec2020 13:45 (vaccine location: Right arm) at single dose for covid-19 Vaccination. Past medical history includes anxiety for which she took venlafaxine (Effexor) on a daily basis as well as type 2 diabetes, diagnosed approximately seven or 8 years ago during a pregnancy, she was on oral medication during the day and insulin at nighttime. Concomitant medications were not reported. She did take her oral medication today (22Dec2020) and last ate a pasta lunch right before arriving to the vaccine clinic. Last A1c was 6.

During her 15-minute waiting period after the injection, the patient began to experience generalized feelings of not feeling quite right as well as anxiety/nervousness, nausea and chills. She denied difficulty breathing, throat tightness, dizziness, chest pain, or other GI complaints. This provider noticed her raising her hand from across the waiting area and tended to her where she noted the above complaints. she was then assessed in the emergency bay area. She was monitored for severe reaction symptoms, including rapid progression of symptoms, vomiting, hypotension, chest pain, collapse and Respiratory distress. The action taken in response to the events for bnt162b2 was not applicable. The outcome of the events was unknown. No follow-up attempts are possible. No further information is expected.

Upset stomach; Nausea; Mild headache; This is a spontaneous report from a contactable nurse reporting for herself. This 26-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (lot number: EJ1685) on 22Dec2020 14:25 at a single dose intramuscularly in the left arm for COVID-19 immunization. The patient medical history was not reported. Concomitant medication included sertraline hydrochloride (ZOLOFT). Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. The patient experienced upset stomach, nausea and mild headache on 23Dec2020. The events were non-serious, no treatment received for the events. The patient was recovering from the events.

Patient was under the age of 18 when Covid-19 vaccine was administered

dizziness; This is a spontaneous report from a non-contactable healthcare professional (HCP). A 63-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (lot number EH9899) on 22Dec2020 17:30 intramuscularly at a single dose in the left arm (in the left deltoid muscle) for COVID-19 vaccination. No relevant medical history. The patient denied any history of previous adverse reactions to vaccines. The patient's concomitant medications were not reported. During her 15 minute waiting period after the injection, the patient began to experience dizziness. She denied rash, hives, welts, difficulty breathing, difficulty swallowing, wheezing, throat tightness, hoarseness, stridor, itching, facial swelling, lip swelling and tongue swelling. She was then assessed in the emergency bay area, monitored for severe reaction symptoms, including rapid progression of symptoms, respiratory distress with stridor, wheezing, dyspnea, increased work of breathing, persistent cough and cyanosis, vomiting, abdominal pain, hypotension, dysrhythmia, chest pain and collapse. Vitals were normal, glucose was 100. The event dizziness was non-serious. The outcome of the event was unknown. No follow-up attempts are possible. No further information is expected.

Swollen lymph nodes; Injection site pain; Tiredness; This is a spontaneous report from a contactable Nurse(patient). A 31-year-old female patient received first dose of BNT162B2(PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL0140), via an unspecified route of administration on 22Dec2020 20:45 at single dose at left arm for COVID-19 immunization. The patient was not pregnant. There were no known allergies or other medical history. There were no other vaccine in four weeks. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. Concomitant medication included ascorbic acid (VITAMIIN C), ergocalciferol (VIT D), vitamin b complex (SUPER B COMPL); reported as prenatal. The patient experienced swollen lymph nodes,

injection site pain, tiredness; all on 23Dec2020 14:00 with outcome of not recovered. The events were non-serious. No treatment received for the events.

Moderna COVID-19 Vaccine EUA Day1- none Day2- Injection site: soreness, firmness, and weakness. General symptoms: none Day3- Injection site: bruising, tenderness. General symptoms: fatigue Day4- Injection site: bruising, tenderness. General symptoms: fatigue, body aches, joint pains, difficulty waking in the morning Day5- Injection site: bruising, tenderness. General symptoms: fatigue, body aches, joint pains, difficulty waking in the morning Day6- Injection site: bruising, tenderness. General symptoms: fatigue, body aches, joint pains, difficulty waking in the morning I am currently on day 6 from getting the Moderna COVID-19 Vaccine and the injection side bruising and tenderness still persist along with the general symptoms of fatigue, body aches, joint pains, and difficulty waking up in the morning.

had only a sore arm; muscles were sore.; This is a spontaneous report from a contactable physician (patient, psychologist, work as a healthcare provider in a prison system). A 69-year-old male patient received a single dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (Lot number reported as: E316, either 05 or 85) via an unspecified route of administration on 21Dec2020 (between 13:15 and 13:30) in the right arm for COVID-19 immunization. Medical history included flu, not recently, several weeks ago. Concomitant medications were reported as none. The patient had only a sore arm on 21Dec2020 as a side effect. The patient also reported muscles were sore on 21Dec2020. The outcome of the events was unknown. Caller stated he wanted to check and make sure he wasn't supposed to have side effects. He had seen on TV people complaining of chills, fever and headache. As he was looking at the document he was given, he may have called the wrong number for the question to ask: he was lucky enough as a healthcare professional to be administered his first shot of Pfizer's COVID vaccine, and with the exception of where the site where it was injected, his right arm being a little sore, like with any shot, he had not experienced side effects, like headaches or nothing, and today he noticed he didn't get a check in, he got texts. But his question was: if he didn't feel side effects, did it mean the vaccine was not necessarily taking, if no side effects, did it mean it will not be effective? Stated it was just minor, like any other shot. He did not mind participating in this study, for information, since Pfizer may be counting soreness in the arm, but he did not perceive this as a problem. He got the vaccine on Monday 21Dec2020, between 13:15 and 13:30, and then it was just like, he had a flu shot, not recently, several weeks ago, and to the same point. No further details provided. Like within a couple, three hours, it started, and it was difficult to sleep on it, just sore, no redness/inflammation, he could not tell where the skin was punctured, just his muscles were sore. He called the number on the sheet, he was just real curious, he did not feel bad, like he hears on TV, and he knew personally people who got symptoms and he no symptoms, that he can ascertain. No further details provided. His appointment was 1:15, it may have been in his arm at 13:25, or 13:30 or something, he went and sat for his 15 minute wait time, at 1:30, so it was between 13:15 and 13:30. Outcome reported as it was OK during the daytime, but to sleep on that side, it can feel sore, and he turned to the other side, it did not keep him from typing, lifting, writing, working, emptying the dishwasher. He had a registration code, was given a card. Read from his vaccination card: provided date of vaccination 21Dec2020, vaccine name Pfizer COVID 19, stated lot was written in ink, looked like it was E316, stated he can't read, it was smeared, but then said next dose is 11Jan2021. States it was E316, either 05 or 85. He didn't have the sore arm before he got it,

and it is going away now, or it would go away. Information on the lot/batch number has been requested.

she broke out in hives 4 hours after she received the vaccine; This is a spontaneous report from a contactable other-healthcare professional (HCP) (patient). A 34-year-old female patient received a single dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (Lot #: EL1284) as the first dose via intramuscular on 23Dec2020 13:00 in the right arm for COVID-19 immunization. The patient medical history and concomitant medications were not reported. The patient did not receive any other vaccines within 4 weeks prior to the vaccine BNT162B2. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. The patient reported that she broke out in hives 4 hours after she received the vaccine on 23Dec2020 (also reported as at 16:00). The event was reported as non-serious. No treatment was received for the event. The outcome of the event was recovering. No follow-up attempts are possible. No further information is expected.

"This is a spontaneous report from a contactable nurse (patient). A 33-year-old female patient received BNT162B2 (Pfizer-BioNTech Covid-19 vaccine) on 22Dec2020 11:30AM at left arm for COVID-19 immunization. The patient had known allergies to sulfa and was currently breastfeeding. The patient had concomitantly received ascorbic acid, honey, melatonin, zinc gluconate (ZARBEE'S ALL NATURAL COUGH SYRUP NIGHTTIME) (reported as "" Zarbees elderberry immune syrup"") in two weeks. The patient experienced fatigue, myalgias, headache, arm soreness, brain fog at 3:00PM on 22Dec2020. Patient received ibuprofen 400 mg as treatment for the adverse events. The outcome of the events was resolving at the time of reporting. Information on the lot/batch number has been requested."

headache; fatigued; lightheaded/dizzy(the room was spinning); nauseous; chills; hot flashes; This is a spontaneous report from a contactable nurse reported for herself. A 24-year-old adult female patient (pregnant: no) was received the first dose BNT162B2 (brand: Pfizer, Batch/lot number: EK5730) via unspecified rout of administration on left arm on 23Dec2020 13:00 at single dose for COVID-19 immunization. Medical history included asthma, Bipolar Disorder, known allergies: Latex, milk, bananas, blue dye 2&, COVID-19 (Prior to vaccination, was the patient diagnosed with COVID-19? :Yes). Concomitant medication in two weeks included lamotrigine (LAMICTAL), fluoxetine hydrochloride (PROZAC), cetirizine hydrochloride (ZYRTEC [CETIRIZINE HYDROCHLORIDE]) and ascorbic acid, ferrous fumarate, folic acid, retinol (PRENATAL [ASCORBIC ACID;FERROUS FUMARATE;FOLIC ACID;RETINOL]). No other vaccine in four weeks. After the vaccination patient became lightheaded, dizzy (the room was spinning), nauseous and got chills and hot flashes. After 30minutes or so she began to get a headache while the other symptoms wore off and then became fatigued. Adverse event start date was 23Dec2020 01:00 PM. the most recent COVID-19 vaccine was administered in Hospital. Since the vaccination, the patient has not been tested for COVID-19. Treatment received for the events included ibuprofen (MOTRIN), Meclizine, ondansetron (ZOFRAN) and paracetamol (TYLENOL). Patient was recovering from the events. It was reported as non-serious. No results in death, life threatening, caused/prolonged hospitalization, disabling/Incapacitating nor congenital anomaly/birth defect.

woke up with mild fever, and severe headache, lasted through the day, was gone upon waking next morning.

Joint ache and tiredness on the next day after vaccination; Joint ache and tiredness on the next day after vaccination; This is a spontaneous report from a contactable other healthcare professional (patient). A 27-years-old female patient (not pregnant) received BNT162B2 (lot number: EK5730) first dose on 18Dec2020 12:45 PM intramuscularly on Left arm at single dose for COVID-19 immunization. Medical history and concomitant medications were not reported. No Known allergies to medications, food, or other products. Facility type vaccine was Hospital. Other medications in two weeks was No. Patient experienced Joint ache and tiredness on the next day after vaccination (19Dec2020). Patient had no covid prior vaccination. Patient had covid tested post vaccination on 21Dec2020, Nasal Swab, the result was negative. Patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. No treatment received for the events. The outcome of the events was recovering. The seriousness was reported as no.

soreness at site of injection; This is a spontaneous report from a contactable nurse (patient). A 39-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 17Dec2020 intramuscularly on right arm at single dose for COVID-19 immunization. Medical history included ongoing Psoriatic arthritis, patient received allergy shots (Unable to provide the names, NDC. Lot, or expiry for the allergy injections she received. It's the regular one for pets (cat and dog dander), trees, mold and dust. No food allergy. Mentions having an allergy to sulfur), unspecified sulfur products-wheezing, rash, itching. Concomitant medications included adalimumab (HUMIRA) and methotrexate, both ongoing for Psoriatic arthritis. She Is having soreness in her arm where she received it and she got it last Thurday (17Dec2020). Today (23Dec2020), she went to get her allergy shots and not sure if she should have waited or if she is missing something in the literature about doing the allergy shots after. It didn't say. She knows that it is the same when she has to get a flu shot she waits about a week to get her allergy shots. Received the vaccine early last Thurday evening and the allergy shots today at 2pm. Received the vaccine through her workplace. The soreness started on Friday morning (18Dec2020) and by Monday afternoon (21Dec2020) and it had gone away. She is just worried because she got the allergy injection today in the same arm that the vaccine was given. Clarifies that the soreness is around the injection site of where the vaccine was given, not where the allergy shots given. Worried that she should have waited and doesn't want to go to bed and wake up with something wrong. States this is her first shot. Unable to provide the names, NDC. Lot, or expiry for the allergy injections she received. It's the regular one for pets (cat and dog dander), trees, mold and dust. No food allergy. Mentions having an allergy to sulfur. Has wheezing airway and the first time was when she was a kid and she got a rash, redness, and itching. The doctor now knows not to prescribe anything with sulfur because the second time was when she was 20 something she had the wheezing. Vaccination Facility Type was Hospital. Vaccine Administered at Military Facility was No. History of all previous immunization with the Pfizer vaccine considered as suspect (or patient age at first and subsequent immunizations if dates of birth or immunizations are not available) was none. Additional Vaccines Administered on Same Date of the Pfizer Suspect was none. No AE(s) require a visit to Emergency Room or physician office. Prior Vaccinations (within 4 weeks prior to the first administration date of the suspect vaccine(s)) was none. The outcome of the event was recovered on 21Dec2020. The seriousness was reported as no. Information on the Batch/Lot number has been requested.

woke up with mild fever, and severe headache, lasted through the day, was gone upon waking next morning.

Severe body aches; chills; low grade fever 100.7; fatigue; muscle pain; This is a spontaneous report from a contactable nurse (patient). A 34-year-old female patient (pregnant: no) was received first dose BNT162B2 (brand: Pfizer BioNtech, lot number: EJ1685), via unspecified route of administration at arm right on 17Dec2020 12:30 PM at single dose for COVID-19 immunization. Medical history included Complex Migraines, prior to vaccination, the patient was diagnosed with COVID-19. Concomitant medication in two weeks included verapamil, amitriptyline, fish oil, magnesium, vitamin b2 [riboflavin], no other vaccine in four weeks. Patient previous took amoxicillin clavulanic acid (AUGMENTIN), butalbital caffeine paracetamol (FIORICET) and eletriptan hydrobromide (RELPAX) and had allergies to them. Patient experienced severe body aches, chills, low grade fever 100.7, fatigue, muscle pain on 18Dec2020 03:00 AM. the most recent COVID-19 vaccine was administered in Hospital. Since the vaccination, the patient has not been tested for COVID-19. No treatment received for the events. Patient was recovered from the events. It was reported as non-serious. No results in death, life threatening, caused/prolonged hospitalization, disabling/Incapacitating nor congenital anomaly/birth defect.

soreness at site of injectio and droziness

"Fever up to 100.4; Headache; Chills; Muscle pains; This is a spontaneous report from a contactable physician (patient). A 57-year-old male patient was received first dose BNT162B2 (reported ""Active Drug substance names: COVID 19"", lot number: EJ1685), via unspecified route of administration at left arm on 18Dec2020 05:15 PM at single dose for COVID-19 immunization. Medical history included hyperlipidaemia and COVID-19 (Prior to vaccination, was the patient diagnosed with COVID-19?:Yes), No known allergies. There are no other medications in two weeks and no other vaccine in four weeks. Patient experienced fever up to 100.4, headache, chills, muscle pains on 19Dec2020 12:00 PM (20Dec2020 00:00). the most recent COVID-19 vaccine was administered in Hospital. Since the vaccination, the patient has not been tested for COVID-19 (COVID was not tested post vaccination). Treatment for the event included paracetamol (TYLENOL). Patient was recovered from the events. It was reported as non-serious. No results in death, life threatening, caused/prolonged hospitalization, disabling/Incapacitating nor congenital anomaly/birth defect. Pfizer is a marketing authorization holder of COVID 19 vaccine in the country of incidence or the country where the product was purchased (if different). This may be a duplicate report if another marketing authorization holder of COVID 19 vaccine has submitted the same report to the regulatory authorities."

Patient reports that about 25 minutes after receiving the vaccine she began to feel like her throat was swollen and the her voice was changed and she had a feeling of pressure on her vocal chords. She also noted that she seemed to have an increase in heart rate. She took a dose of Benadryl and no further symptoms were experienced. She reports that these symptoms resolved by next day but she felt extreme fatigue for the next few days.

fever; Headache; fatigue; This is a spontaneous report from a contactable Other healthcare professional (patient). A 59-year-old male patient received BNT162B2 (lot number: EJ1685) first dose on 22Dec2020 07:30 AM on left arm at single dose for COVID-19 immunization. Medical history included HTN (Hypertension) and Allergies to PCN (Penicillin) and Sensitive to morphine. Concomitant medications included venlafaxine hydrochloride (EFFEXOR), atenolol, ergocalciferol (VIT D) and multivitamin. Facility type vaccine was Hospital. Patient had other vaccine (Trial) in four weeks, patient had it on 02Dec2020 first dose on Left Arm. Patient had other medications in two weeks: Effexor, atenolol, multivitamin, vit D. About 16 hrs (22Dec2020 11:00 PM) after injection patient began fever 100-101. Lasted about 20 hours. Relieved with ibuprofen. Headache and fatigue also. All resolved about 36 hours after injection. Patient did not have covid prior vaccination and no covid tested post vaccination. No treatment received for the adverse event. The outcome of the events was recovered. The seriousness was reported as no.

Patient received the vaccine, waited 15 minutes and had no difficulties. He presented back to the injection area with complaints of dizziness, slight chest and neck tightness. BP was slightly elevated. He was given 2 benadryl an taken to the ED where they monitored him. No further medication intervention needed.

Felt a little achey and a sore arm; This is a spontaneous report from a contactable consumer. An adult female patient of unspecified age was received first dose of BNT162B2 (Brand: Pfizer/BioNTech, lot number: unknown) via unspecified route of administration at single dose for COVID-19 immunization. Medical history and concomitant medication were unknown. It was unknown if other vaccine in four weeks. Patient felt a little achey and a sore arm on 21Dec2020. It was unknown if the patient diagnosed with COVID-19 prior to vaccination, it was unknown if the patient been tested for COVID-19 since the vaccination (unknown covid tested post vaccination). It was unknown if treatment received for the event. Outcome of the events was unknown. It was reported as non-serious. No results in death, life threatening, caused/prolonged hospitalization, disabling/Incapacitating nor congenital anomaly/birth defect. Information on the Batch/Lot number has been requested.

"Vertigo; Dizziness; Sore arm; This is a spontaneous report from a contactable Other healthcare professional (patient). A 63-year-old female patient received BNT162B2 (lot number EL0140) on 21Dec2020 2:30""pm on arm left at single dose for COVID-19 immunization. Medical history was none. Concomitant medications included multivitamin. She doesn't know if it is a side effect but today she has had vertigo that she has never had before, and a little bit of dizziness on and off. The vertigo started about 4:30am this morning (23Dec2020) when she got up to go to the bathroom. Everything was just spinning so she didn't go to the bathroom, she just laid down. She had it 2 more times but not anymore after that. Now she is just having some dizziness from time to time (Dec2020). She also specified that soreness is ""normal"" for her to experience ""after injection"". She has takes multivitamin but nothing that would be related to this event. She has just never had this happen before. It was given in his left upper biceps area. With previous vaccines she has had a sore arm but with this vaccine the sore arm wasn't that bad. It was sore that day (21Dec2020) and yesterday but today there is nothing, no soreness. She received no other vaccines that day or within 4 weeks of the vaccine. There is no significant family history. There have been no treatments for the events. The outcome of event vertigo and sore arm recovered on 23Dec2020. The outcome of event Dizziness was not recovered."

Shaking chills; body aches; nausea; vomiting; vertigo; This is a spontaneous report from a contactable Other-healthcare professional (patient). A 57-year-old female (not pregnant) patient received BNT162B2 (lot number: EH9899) first dose on 17Dec2020 02:00 PM intramuscularly on left arm at single dose for COVID-19 immunization. Medical history included Colon Cancer, Hypothyroidism, Allergic Rhinitis, Weight Loss Surgery, GERD, BPPV. Concomitant medications in two weeks included Levothyroxine, cetirizine hydrochloride (ZYRTEC), Escitalopram, MVI, Calcium, colecalciferol (VIT D3), cyanocobalamin (VIT B12). No Known allergies to medications, food, or other products. Facility type vaccine was Other. No other vaccine in four weeks. Patient experienced Shaking chills, body aches, nausea, vomiting and vertigo on 18Dec2020 03:30 AM. Patient received Zofran, Meclizine, Phenerga as treatment. Patient did not have covid prior vaccination and no covid tested post vaccination. The outcome of the events was recovering. The seriousness was reported as no.

Within two days of vaccine, shortness of breath on light exertion (talking, walking), ?revved up? like on steroid or medrol. Anxiety, increased resting HR, abdominal cramping, diarrhea, agitation, palpitations, fatigue, dazed, premenstrual spotting.

Temp 103, and very sore arm for 3 days; Temp 103, and very sore arm for 3 days; This is a spontaneous report from a contactable nurse reported for herself (patient). A 57-year-old female patient (pregnant: no) was received BNT162B2 (brand: Pfizer, Lot number: unknown) via unspecified route of administration on 19Dec2020 10:30 AM at single dose for COVID-19 immunization. Medical history included COVID-19 (Prior to vaccination, was the patient diagnosed with COVID-19?:Yes). Concomitant medication in two weeks of vaccination included simvastatin, acetylsalicylic acid (BABY ASPIRIN), docusate sodium (COLACE) and fish oil (FISH OIL OMEGA 3). no other vaccine within 4 weeks prior to the COVID vaccine. Patient used took ciprofloxacin (CIPRO) and had allergy. Patient experienced temp 103, and very sore arm for 3 days on 20Dec2020 02:00 AM. the most recent COVID-19 vaccine was administered in Hospital. Since the vaccination, the patient has not been tested for COVID-19. Since the vaccination, the patient has not been tested for COVID-19. Treatment received for the events included ibuprofen. Patient was recovered from the events in Dec2020. It was reported as non-serious. No results in death, life threatening, caused/prolonged hospitalization, disabling/Incapacitating nor congenital anomaly/birth defect. Information on the lot/batch number has been requested.

"12/28/20 called to observation area at 12:05. she had already waited 15 minutes after vaccine. reports tingling top of tongue, tingling ums, back of mouth/throat scratchy. 12:10 states no change, 12:12 rapid response and supervisor arrived - talked with her. decided to not go to ER unless worse, agreed will not go back to work or leave for home until sx resolved. 12:20 states gum tingling decreasing. 12:30 states sx resolved - left observation with instruction to return if sx. 12/29/20 came to vaccine area at 1045 to report injection site with 1"" redness, firm to touch. blanches, tender w/ pressing outer edge redness. arm size unchanged, noted when got up this morning. states sore, able to move arm. 1050 evaluated by rapid response and nursing supervisor. states otherwise feeling ok, no sx. supervisor drew circle around redness. suggested ice/anti-histamine. talked with her - to wait 30 minutes, to contact PCP if spreads. 1130 states no change, decided to RTW"

Severe arm pain at injection site.; No swelling but can barely move arm; Chills; fatigue; moderate headache; This is a spontaneous report from a non-contactable nurse (patient). A 27-year-old non-pregnant female patient receive first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EH9899), via an unspecified route of administration at left arm on 22Dec2020 at 10:00 AM at single dose for COVID-19 immunization at pharmacy or drug store. Medical history was none and there was no known allergies. Concomitant medication included oxybutynin hydrochloride (OXYBUTYNIN) and birth control received within 2 weeks of vaccination. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient experienced severe arm pain at injection site, there was no swelling but can barely move arm, chills and fatigue and moderate headache, all on 22Dec2020 at 09:00 PM. There was no treatment for the events. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. The outcome of the events was not resolved. No follow-up attempts are possible. No further information is expected.

He was diagnosed with COVID 19; He was diagnosed with COVID 19; This is a spontaneous report from a contactable consumer (front line hospital worker) reporting for himself, received via a Pfizer sales representative. This male patient of unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on an unspecified date in Dec2020, at single dose, for COVID-19 immunization. Medical history and concomitant medications were not reported. On an unspecified date in Dec2020, after vaccination, the patient was diagnosed with COVID 19 with unknown outcome. Information on the lot/batch number has been requested.

Pain at the injection site; This is a spontaneous report from a contactable Other Health Professional (patient) via Pfizer sales representative. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced pain at the injection site after Covid 19 vaccine on an unspecified date with outcome of unknown. Information on the Batch/Lot number has been requested.

Lightheadedness; This is a spontaneous report from a contactable Nurse (patient). A 60-year-old female patient (not pregnant at the time of vaccination) received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EL1284), intramuscularly in arm left on 23Dec2020 16:30 at single dose for COVID-19 immunization. The patient medical history was not reported. Concomitant medication the patient received within 2 weeks of vaccination included colecalciferol (VIT D3), smilax aristolochiifolia (SARSAPARILLA), ascorbic acid (VIT C), dioscorea villosa (WILD YAM), multi collagen protein. The patient previously took codeine and experienced allergies: Codeine. The patient experienced lightheadedness on 23Dec2020 17:15 with outcome of recovered in Dec2020. Facility where the most recent COVID-19 vaccine was administered: Hospital. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. No treatment received for the adverse event. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. Identification of the case safety report: Serious: No; Seriousness criteria-Results in death: No; Seriousness criteria-Life threatening: No; Seriousness criteria-Caused/prolonged hospitalization: No;

Seriousness criteria-Disabling/Incapacitating: No; Seriousness criteria-Congenital anomaly/birth defect: No.

I begin chilling the next day after I received the vaccine and started running a low grade fever of 100.5-body aches, headache, fatigue and pain in the arm where I received vaccine x 2 days.

Tiredness; Chills; mild joint pain; Nausea; feeling unwell; he hasn't eaten; threw up; This is a spontaneous report from a contactable consumer (patient). A 28-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration by injection once in the left arm, near shoulder on 18Dec2020 at single dose for COVID-19 immunization. Medical history included asthma from 2009 and ongoing (Has asthma but he has no breathing symptoms, no runny nose, no dry cough, no shortness of breath, no COVID symptoms). There were no concomitant medications. The patient experienced tiredness on 20Dec2020 with outcome of not recovered, chills on 20Dec2020 with outcome of recovered on 20Dec2020, mild joint pain on 20Dec2020 with outcome of recovered on 20Dec2020, nausea on 20Dec2020 with outcome of not recovered, feeling unwell on 20Dec2020 with outcome of not recovered, he hasn't eaten in Dec2020 with outcome of unknown, threw up in Dec2020 with outcome of unknown. No runny nose, cough or anything. Investigation Assessment: No. The patient took the COVID vaccine and was having mild symptoms, which he wished to report, and he was seeking recommendations. He had the print out thing given with all the symptoms that may happen, he had tiredness, chills, mild joint pain, nausea, and feeling unwell. He was a COVD tester, which is why he got it last week. This is not his first date of symptoms. Nausea: He threw up Sunday and Monday, was nauseous on Tuesday, is nauseous now but feels better, he missed work on Monday, he went for 2 hours yesterday and was sent home, he didn't go in today, but is feeling more normal, but has been perpetually nauseous since Sunday, like 24/7, in the middle of the night, middle of day, for no reason. He ate yesterday, he hasn't eaten today, because he feels nauseous. States feeling unwell goes along with nausea, he can't separate the two. What kind of medicine should he take, like over the counter or Pedialyte. What would a person potentially take if they were nauseous. Pedialyte, fluid or something. States this is Pfizer, he guesses any guidance is medical. Information on the Lot/batch number has been requested.

"positive rapid COVID testing positive/COVID-19 PCR test positive; positive rapid COVID testing positive/COVID-19 PCR test positive; This is a spontaneous report from a contactable nurse (patient herself). A 42-year-old female patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899, Expiration date: Mar2021), intramuscularly at site of right deltoid at 08:00 on 16Dec2020 at single dose for COVID-19 immunization. Medical history included ongoing high blood pressure. The patient received a flu shot in Oct2020. The patient's concomitant medications were not reported. The patient was tested positive for rapid COVID-19 testing on 21Dec2020 and was also positive for COVID-19 PCR test on 22Dec2020. No treatments after positive testing and patient was not hospitalized. The outcome of events was not recovered.; Sender's Comments: The reported ""tested positive for rapid COVID-19 testing"" after 4 days of immunization with BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) is considered related to BNT162B2 administration."

soreness at the injection site; slight fever; tiredness; This is a spontaneous report from a non-contactable consumer. A female patient of an unspecified age received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 22Dec2020 at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced soreness at the injection site, slight fever and tiredness on 22Dec2020. The outcome of events was recovered in Dec2020. No follow-up attempts are possible; information about batch/ lot number cannot be obtained.

Mild symptoms such as muscle soreness; This is a spontaneous report from a Pfizer-sponsored program. A contactable physician (patient himself) reported that a 31-year-old male patient received the first dose of BNT162B2 (Pfizer-BioNTech COVID-19 vaccine, lot# EJ1685), via intramuscular on 17Dec2020 20:00 in right arm at single dose for routine vaccination. There were no medical history and concomitant medications. Vaccination facility type was hospital, not a military facility. No additional vaccines were administered on same date of the Pfizer suspect. Prior Vaccinations (within 4 weeks) was none. Event following prior vaccinations was none. Relevant test was not tested. Patient was calling about COVID vaccine. He got the vaccine last Thursday and experienced mild symptoms such as muscle soreness around 6 am on Friday, 18Dec2020. On Sunday, his family became symptomatic and got tested for COVID and tested positive. He wanted to know if the COVID vaccine could produce false positive and if he can get the second dose. Caller did provide medical information's number and patient would need to be transferred over. There was no prescriber. It was given as routine from the hospital that he worked at. ER (emergency room) or physician's office required was none. Outcome of event was recovering.

Just letting you know it felt like a bad flu shot, sore enough to avoid sleeping on, but it went away after a few days :) thank you for your hard work, let?s hope after Jan 20 you can do your jobs without restriction.

felt weak; Nauseated; unable to sleep; was sick for about 2 hours; got so cold and couldn't get warm/felt cold to her bones; This is a spontaneous report from a contactable consumer (patient herself). A 64-year-old female patient received BNT162B2 (Pfizer-BioNTech COVID-19 vaccine), via an unspecified route of administration on 21Dec2020 at single dose for covid-19 immunisation. There were no medical history and concomitant medications. Investigation assessment was no. Caller received the Covid-19 vaccine Monday (21Dec2020). She was sick for 2 hours yesterday (22Dec2020). She got so cold and couldn't get warm, after a while she felt better. She felt cold to her bones. Today (23Dec2020) she felt weak and was nauseated. She worked at hospital. She was a tech at the hospital. She was a frontline worker. When a vial became available, she was given the vaccine. She was also unable to sleep last night (22Dec2020). She was up most of the night. She clarified that when she said she was sick for about 2 hours she was referring to being cold. Outcome of cold was recovered on 22Dec2020, and outcome of other events were unknown. Information on the lot/batch number has been requested.

Lymphadenopathy; Injection site pain/pain and tenderness under her arm; Lethargy; tired/did not feel like getting out of bed; Headache; arm was swollen/her sleeve was tighter, 1.5-2 inches bigger than her other arm; This is a spontaneous report from a contactable nurse reporting on behalf of herself. This 50 years old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot EJ1685) on

19Dec2020 at 11:15, at single dose, in right deltoid, for COVID-19 immunization. No other vaccine was given on the same date or within 4 weeks before. Medical history included ongoing epilepsy, ongoing depression and anxiety, COVID in late Oct2020 early Nov2020 (so her manager advised her to get the vaccine), allergies as a child, ongoing allergy to penicillin that showed up on an allergy test, ongoing allergy to house dust and trees, things like that. She previously received influenza vaccine in Oct2020, for immunization. AE(s) following prior vaccinations: none. Family medical history relevant to AE(s): none. Concomitant medications included topiramate (TOPAMAX) and brivaracetam (BRIVIACT), both for years, for epilepsy and duloxetine HCl (CYMBALTA) from Aug2020, for depression and anxiety. The reporter related Cymbalta use to COVID. The patient experienced lymphadenopathy on 21Dec2020, headache on 20Dec2020, injection site pain on 20Dec2020 at 03:00, lethargy on 20Dec2020, tired on 20Dec2020, arm was swollen on an unspecified date in Dec2020. Lymphadenopathy was reported as medically significant. The other events were reported as non-serious. The reporter stated it was painful but everyone told her it would be so she expected that. At about 3 A.M. on 20Sun2020 she woke up to her arm hurting when she tried to turn on her right side. She had taken 2 of the arthritis strength paracetamol (TYLENOL) the night before because she was told it was going to hurt, that might have been the reason she did not notice it before then. This was just injection site pain. At this point, she still had some injections site pain and it was tender if bumped but it was better than before. On 20Dec2020 she did not go to church because she felt tired and did not feel like getting out of bed, she also had a headache but these things were expected by her. She stayed in bed till noon. She went to work on 21Dec2020 and in that morning when she went to apply deodorant she noticed pain and tenderness under her arm. Her arm was swollen and she noticed that her sleeve was tighter so she had her husband measured her arm and it was 1.5-2 inches bigger than her other arm. It was tight and tender, actually at this point it was more than tender when she put her deodorant on. She was also giving the vaccine. No other treatments were given and she had not called her doctor about this. No emergency room or physician office visit were not required. Relevant tests: none. Headache and lethargy resolved on 20Dec2020. Injection site pain was resolving. Lymphadenopathy had not yet resolved and was reported as aggravated. The outcome of the other events was unknown. The reporter considered there was a reasonable possibility that headache, injection site pain, lymphadenopathy, lethargy were related to BNT162B2 vaccine.; Sender's Comments: Based on available information, a possible contributory role of the subject drug cannot be excluded for the lymphadenopathy and the other reported events due to temporal relationship. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Tachycardia

was tired and slept more than usual; was tired and slept more than usual; Soreness in left arm; This is a spontaneous report from a contactable consumer reported for himself. A 71-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration in left arm on 22Dec2020 13:50 at single dose for covid-19 immunisation. There were no medical history or concomitant medications. The patient got it at 1:50 pm, and got home and was really tired, so he said he was going to bed at 6pm and woke up at 7:30 feeling pretty refreshed. He then told himself, if he didn't get up, he wouldn't sleep at night, so he got up until 11:00 and slept until 8am. The patient was tired and slept more than usual on 22Dec2020 at 16:00. The only side effect was that he got a little bit more rest than normal. The other side effect is he got soreness in left arm and it was pretty sore unspecified date in Dec2020. He did not have any headaches or anything else. He was pretty satisfied. The outcome of the events was tired and slept more than usual was recovering while for other event was unknown. Information on lot/batch number has been requested.

rash on his forearm by his elbow/He said that the rash is also on the back of his of calf; injection site soreness; a little achy; tired; itching; could not sleep well; This is a spontaneous report from a contactable consumer (reporter). A 50-year-old male patient received bnt162b2 (BNT162B2, lot number EK5734), via an unspecified route of administration on 18Dec2020 18:30 at single dose for COVID-19 immunization. Medical history included asthma. He said that he took no other medication except for a multivitamin and his asthma medication. The patient said that within 5 hours of receiving the vaccine, he was a little achy and had injection site soreness. He said that he felt a little tired on Friday (18Dec2020) and Saturday (19Dec2020), but by Sunday (20Dec2020) it was gone. He said that starting Monday (21Dec2020), he noticed a rash on his forearm by his elbow. He said that his skins was normally sensitive and dry. He thought maybe it was not the vaccine and said that he used hand sanitizer that may have bothered it. He said that the rash was on the back of his tricep now though. He said that the rash was also on the back of his of calf. He said that it was itching. He stated that he treated it with triamcinolone cream for rash from his kid and it did not do anything. He said that he was following up with this primary care physician about this. He stated that it was so itchy and he could not sleep well. The outcome of the event tired was recovered on 20Dec2020 while for other events was unknown.

test positive for COVID-19; test positive for COVID-19; This is a spontaneous report from a contactable consumer (patient). A 26-year-old female patient received the first dose BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 20Dec2020 at single dose in left arm for covid-19 immunization. There was none medical history or concomitant medications. The reporter reported that she got the vaccine on the 20Dec2020 and found out Monday (21Dec2020) that she was exposed to someone who was positive so they used a rapid test post exposure on the 22Dec2020 that the result was positive for COVID-19. She reported she knew that the vaccine would not have given her COVID, and it was likely she had it before she got the vaccine and didn't know she had it because she didn't have symptoms. The outcome was unknown. Information about lot/batch number has been requested.

Sore left arm the day of the vaccination near the site. Throughout the next morning I felt a progressively worsening sore neck, that evolved into a stiff neck by early afternoon. My neck is a bit swollen, on the same side I received the vaccination (Left).

arm feels sore and heavy; arm feels sore and heavy; This is a spontaneous report from a contactable nurse (patient). A 36-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient reported that arm felt sore and heavy on an unspecified date after vaccination. The outcome was unknown. No follow up attempts are possible; information about lot/batch number cannot be obtained.

the arm was quite sore; This is a spontaneous report from a contactable consumer (patient's friend). A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK5730, expiration date: Mar2021), via an unspecified route of administration on an unspecified date at single dose in arm for covid-19 immunization. The patient's medical history was and concomitant medications were not reported. The patient was a frontline healthcare worker, the patient said the arm was quite sore (far more than expected) after vaccination, but no problem after an hour or so. The outcome of the event was resolved.

head ache; sore arm; This is spontaneous report from a contactable nurse (patient). A 43-year-old female patient (non-pregnant) received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot #: lot number Eh9899), via an unspecified route of administration on 22Dec2020 at single dose for immunization. Medical history was none. The patient's concomitant medications were not reported. Patient didn't receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, patient was not diagnosed with COVID-19. Since the vaccination, patient has not been tested for COVID-19. The patient experienced head ache after 24 hours, sore arm on 23Dec2020 18:00 with outcome of unknown. Patient didn't receive treatment for events. The report is considered non-serious. Information on Lot/ Batch number has been requested.

Slight alteration in smell. Smells are not as pungent and some smells are different then what they should be.

lymphadenopathy in left lower neck area above clavicle/swelling of lymph nodes; sick; sore throat; This is spontaneous report from a contactable other-healthcare professional (patient). A 45-year-old female patient (non-pregnant) received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot #: lot number Eh9899), via an unspecified route of administration on 16Dec2020 19:00 at single dose at left arm for immunization. Medical history included known allergies/shellfish. The patient's concomitant medications were not reported. Patient didn't receive any other vaccines within 4 weeks prior to the COVID vaccine, patient didn't receive other medication within 2 weeks of vaccination. Prior to vaccination, patient was not diagnosed with COVID-19. Since the vaccination, patient has not been tested for COVID-19. On 21Dec2020 07:00 AM, the patient experienced lymphadenopathy in left lower neck area above clavicle. Patient had never had this before but had felt sick since patient took the vaccine mainly the first day but sore throat not sure if related, then the swelling of lymph nodes. Patient didn't receive treatment for events. Outcome of events was not recovered. The report is considered non-serious.

Arm soreness; slight aches; slight fatigue; Large lump (lymph node maybe) under arm pit left arm; This is a spontaneous report from a contactable other health professional (patient). A 47-year-old male patient received first dose of BNT162B2 (Lot number: Eh9899) intramuscularly in left arm on 21Dec2020 10:00 at single dose for COVID-19 immunization. Medical history included COVID-19 from an unknown date and unknown if ongoing (COVID prior vaccination: Yes). There were no concomitant medications. The patient experienced arm soreness, slight aches, slight fatigue, large lump (lymph node maybe) under arm pit left arm all on 23Dec2020 03:00 AM. Treatment was not received. The patient underwent lab tests and procedures which included COVID test: COVID on an unspecified date. The outcome of events was not resolved. Facility where the most recent COVID-19 vaccine was administered in hospital. Prior to vaccination, the patient was diagnosed with COVID-19.

pain that worsened at injection site; pain that worsened at injection site; This is a spontaneous report from a non-contactable consumer (patient). A 43-year-old patient of an unspecified gender received BNT162B2 via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced pain that worsened at injection site over time on an unspecified date with outcome of unknown. No follow up attempts are possible; information about lot/batch number cannot be obtained.

dry mouth; my arm is sore at the injection site; my temperature is also slightly above baseline; It feels like I am dehydrated; my arm is sore at the injection site; This is spontaneous report from a contactable other health professional (Patient). A 32-year-old male patient received first dose of BNT162B2 (lot number: EJ1685), via an unspecified route of administration in left arm on 22Dec2020 17:45 at single dose for COVID-19 immunization. Medical history included psychiatric history, partially empty selle tursica, no other major Illnesses. Concomitant medication included testosterone, emtricitabine, tenofovir disoproxil fumarate (TRUVADA) for prevention. On 23Dec2020 09:00 AM, the patient was experiencing a dry mouth. This was unique because he never had this problem but his arm is sore at the injection site and he had a dry mouth, his temperature is also slightly above baseline, but not significantly. It felt like he was dehydrated but he was drinking lots of water. He had about 3/4 of a gallon today and his mouth was still dry. Almost like a cotton mouth feeling but very mild. It was only 3/10 on how bad it's bothering him. Treatment was not received. The patient underwent lab tests and procedures which included body temperature: slightly above baseline on an unspecified date. The outcome of events was not resolved.

--- 12/29/2020 11:02 AM by NOT AUTHENTICATED--- 1809: Patient is a 54 year old female presents requesting vaccination for COVID-19. Patient's identity was verified utilizing two patient identifiers. Allergies reviewed and patient has no history of severe allergic reactions. Patient reviewed vaccine information and given opportunity to ask questions: Yes Patient wants vaccine: Yes Pfizer-BioNTech COVID-19 vaccine # 1 in series administered, see Immunizations activity for vaccine details. Patient tolerated well and will remain for observation period to monitor. 1815: Patient is a 54 year old female COMPLAINED OF NO FEELING STRANGE, WITH TINGLING IN NECK ON BOTH SIDES. ADULT EMERGENCY WAS CALLED AND WATER WAS OFFERED TO PATIENT. RADIAL PULSE READ 110 BPM. SHE WAS TRANSFERRED TO HOSPITAL FOR EXTENSIVE OBSERVATION. NO APPOINTMENT WAS MADE FOR

SECOND VACCINE. 1817: Staff present and transported via w/c for eval. Pt. treated as noted below. Triage Note: C/O feeling ? Strange?. Tingling in neck. Pulse:110 Upon arrival, (Triage Note) Member received COVID vaccine, and shortly thereafter began to experience SOB, tingling in bilateral hand and back of neck and head, and elevated heart rate. Feels like symptoms have improved. Pt speaking in complete sentences, in no acute distress. Given Benadryl 25mg IV, Famotidine 40mg PO. Improved, Observed. D/C home at 2242.

area of swelling, erythema, induration, one inch by 2.5 inches from the injection site and downwards, noted 24 hours after injection; area of swelling, erythema, induration, one inch by 2.5 inches from the injection site and downwards, noted 24 hours after injection; area of swelling, erythema, induration, one inch by 2.5 inches from the injection site and downwards, noted 24 hours after injection; This is a spontaneous report from a non-contactable physician (patient). A 31-year-old female patient received BNT162B2 (lot number: e51685), via an unspecified route of administration in left arm on 22Dec2020 at single dose for covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced area of swelling, erythema, induration, one inch by 2.5 inches from the injection site and downwards, noted 24 hours after injection in Dec2020. The outcome of events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

muscle soreness; fatigue; This is a spontaneous report from a contactable nurse (patient herself). A 42-year-old female patient (non-pregnant) received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number: EK5730), intramuscular on 22Dec2020 07:30 at single dose at left arm for immunization. Medical history included PCOS, allergy to ragweed, grass. The patient's concomitant medications were not reported. Patient didn't receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, patient was not diagnosed with COVID-19. Since the vaccination, patient has not been tested for COVID-19. On 22Dec2020 10:00 AM, the patient experienced muscle soreness and fatigue. Patient was unsure if the fatigue was from lack of sleep before working 12 hours and then getting the vaccine, or from the vaccine itself. Patient was recovered from all events in Dec2020, and didn't receive treatment. The report is assessed as non-serious. Information on the lot/batch number has been requested.

Woke up next morning after vaccine with chills and sweats and bodyaches. He has been fatigued. He has been nauseated and headache as well. Fever of 102.4 degrees and chills and sweats back and forth.

Headache; muscle aches; fatigue; possible fever; This is a spontaneous report from a contactable other healthcare professional (hcp) (patient). A 26-year-old female non-pregnant patient received first dose of BNT162B2 (Pfizer-BIONTECH Covid-19 Vaccine, lot number: EH9833), intramuscularly on 22Dec2020 10:30 at a single dose in left arm for COVID-19 immunization. There was no medical history. Concomitant medication included fluoxetine received within 2 weeks of vaccination. There were no other vaccines received in four weeks. No known allergy. The patient experienced headache, muscle aches, fatigue, and possible fever, all on 23Dec2020 18:30. No treatment received for these events. The patient did not have COVID prior vaccination. Since the vaccination, the patient had not been tested for COVID-19. The outcome of events was unknown.

severe myalgias, fever of 100.6*F, malaise, fatigue for the past 12 hours (approximately 12-18 hours after receiving the vaccine). Patient of note, had COVID19 infection in July 2020. She tested negative for COVID19 this morning (screening done/ordered after reporting her initial symptoms).

skin reaction of circles on forearm and trunk; This is a spontaneous report from a contactable nurse (patient). A 46-year-old male patient received BNT162B2 (Pfizer-BIONTECH Covid-19 Vaccine), via an unspecified route of administration on 22Dec2020 09:15 at a single dose for COVID-19 immunization. He is fair skinned. There were no medical history or concomitant medications. The patient experienced skin reaction of circles on forearm and trunk on 23Dec2020. The outcome of event was unknown. This case is reported as non-serious by reporter. The causality between event skin reaction of circles on forearm and trunk and BNT162B2 is related by Primary Source Reporter per Global Introspection. Information on the lot/batch number has been requested.

Cough; voice sounded different; not feeling great; Chest congestion; Nasal congestion; sore arm; Fatigue; body ache; This is a spontaneous report from a contactable consumer, the patient. A 27-year-old non-pregnant female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot Number: EK5730), via an unspecified route of administration in the left arm on 20Dec2020 (at the age of 27-years-old) as a single dose for COVID-19 immunisation. The patient did not have any relevant medical history. She never had any reactions to any vaccines prior. Prior to this vaccination, the patient was not diagnosed with COVID-19. The patient's concomitant medications included loratadine (CLARITIN) and unspecified birth control. The patient did not receive any other vaccines within four weeks prior to the vaccination. On 21Dec2020, the patient experienced sore arm, fatigue, and body ache. On 22Dec2020, the patient developed nasal congestion and chest congestion. On 23Dec2020, the patient had a cough, her voice sounded different, and was not feeling great. Since the vaccination, the patient had not been tested for COVID-19. However, in May2020, she was tested for COVID-19 antibodies and was negative. The clinical outcomes of fatigue, body ache, nasal congestion, chest congestion, cough, voice sounded different, and not feeling great were not recovered; while that of the sore arm was recovered on 22Dec2020.

Employee started exhibiting sx 10 minutes after vaccine administration. She started having chest heaviness, difficulty breathing and became tachycardic. Employee was sent to the emergency room.

Fever 100; cough; fatigue; This is a spontaneous report from a contactable Nurse (patient). A 33-year-old female patient (not pregnant) received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot# EJ1685), intramuscularly in right arm on 20Dec2020 16:15 at single dose for COVID-19 immunization. Medical history included Hashimotos, PCOS, hyperlipidemia. Concomitant medication the patient received within 2 weeks of vaccination included levothyroxine sodium (LEVOTHYROXIN), neomycin hydrochloride;polymyxin b sulfate (neomycin and polymyxin b sulfates otic solution). The patient previously took ciprofloxacin hydrochloride (CIPRO) and experienced drug allergy. Facility where the most recent COVID-19 vaccine was administered: Hospital. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. The patient experienced fever 100, cough, fatigue, all on 22Dec2020 13:00 with outcome of not recovered. The

patient underwent lab tests and procedures which included pyrexia: fever 100. AE resulted in: None of the above. It was unknown if treatment received for the adverse event. Serious (NO). Seriousness criteria-Results in death (NO). Seriousness criteria-Life threatening (NO). Seriousness criteria-Caused/prolonged hospitalization (NO). Seriousness criteria-Disabling/Incapacitating (NO). Seriousness criteria-Congenital anomaly/birth defect (NO).

Symptoms clarified as body aches and pains like her bones aching; Symptoms clarified as body aches and pains like her bones aching; This is a spontaneous report from two contactable consumers (one was patient herself). A 54-year-old female patient received the first dose of NT162B2 (Pfizer-BioNTech COVID-19 vaccine, lot# EJ1685), via an unspecified route of administration on 21Dec2020 in right arm at single dose for vaccination. Medical history included hypertension. Concomitant medication included lisinopril from 2017 and ongoing for hypertension. This Medical Assistant called to report on behalf of herself, not a healthcare professional. She had her first dose of Pfizer COVID-19 Vaccine on 21Dec2020. She reported she developed symptoms which she clarified to be body aches and pains like her bones aching. Symptoms clarified as body aches and pains like her bones aching: onset 22Dec2020 around 10:00am. By around 8:00pm on 22Dec2020 this event pretty much went away, but she can still feel the body aches and pains like her bones aching on and off; event had improved now. She was taking paracetamol (TYLENOL) 1000mg every 6 hours for this event. She was scared she was gonna not be alive after getting this vaccine; because she was very sensitive with flu shots. She clarified that she got flu shot on 30Oct2020 at the institution where she worked and did not get sick with that flu shot. Second dose in series scheduled for 11Jan2020-she did not plan to change dose at this time. Outcome of events were recovering.

Myalgias; Left leg sensitivity; Fatigue; This is a spontaneous report from a non-contactable Other Health Professional. A 38-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot# EJ1685), intramuscularly on 21Dec2020 at single dose for COVID-19 immunization. Medical history included COVID from an unknown date and unknown if ongoing (Prior to vaccination, was the patient diagnosed with COVID-19: Yes). The patient's concomitant medications were not reported. Facility where the most recent COVID-19 vaccine was administered: Hospital. Did the patient receive any other vaccines within 4 weeks prior to the COVID vaccine: No. Was treatment received for the adverse event: No. Since the vaccination, has the patient been tested for COVID-19: No. The patient experienced myalgias, left leg sensitivity, fatigue on 21Dec2020 with outcome of recovered in Dec2020. AE resulted in none. Serious: No: Seriousness criteria-Results in death: No. Seriousness criteria-Life threatening: No. Seriousness criteria-Caused/prolonged hospitalization: No. Seriousness criteria-Disabling/Incapacitating: No. Seriousness criteria-Congenital anomaly/birth defect: No. No follow-up attempts are possible. No further information is expected.

Pt reports approximately 5-6 hours after waking he begins to feel very flushed and hot. After that, he begins to have severe dizziness, to the point that he is unable to ambulate, instead having to crawl across the floor. He checked his blood pressure and blood sugar, both of which were within normal limits. The dizziness can last several hours and is only resolved if he goes to sleep.

Injection site soreness; This is a spontaneous report from a contactable other healthcare profession (hcp) (patient). A 54-year-old non-pregnant female patient received first dose of BNT162B2 (Pfizer-BIONTECH Covid-19 Vaccine, lot number: EJ1685), intramuscularly on 21Dec2020 16:30 at a single dose in left arm for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. No known allergies. The patient experienced injection site soreness on 21Dec2020 17:00. No treatment received for this event. The patient underwent lab tests and procedures which included COVID test type post vaccination (Nasal Swab): negative on 14Dec2020. Prior to vaccination, the patient was not diagnosed with COVID-19. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. This is a non-serious report. The outcome of event was recovering.

Dizziness for about 1 hour; This is a spontaneous report from a contactable other health professional (patient herself). A 43-year-old female patient (non-pregnant) received the first dose of BNT162B2 (Pfizer-BioNTech COVID-19 vaccine, lot# EJ1685), via an unspecified route of administration at 23Dec2020 01:00 in left arm at single dose for covid-19 immunization. Medical history included slightly elevated BP (blood pressure) and gastrooesophageal reflux disease (GERD). Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. Concomitant medication included omeprazole (PROTONIX) and lisinopril. The patient experienced dizziness for about 1 hour on 23Dec2020 01:30 with outcome of recovering. No treatment was received for the event.

rash; This is a spontaneous report from a contactable pharmacist. A patient of unspecified age and gender received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for immunization. The patient's medical history and concomitant medications were not reported. The patient experienced rash after first vaccine on an unspecified date with outcome of unknown. Information on the lot/batch number has been requested.

Pt reports approximately 5-6 hours after waking he begins to feel very flushed and hot. After that, he begins to have severe dizziness, to the point that he is unable to ambulate, instead having to crawl across the floor. He checked his blood pressure and blood sugar, both of which were within normal limits. The dizziness can last several hours and is only resolved if he goes to sleep.

Chills; dizziness; high blood pressure; This is a spontaneous report from a contactable nurse (patient). A 50-year-old female patient (not pregnant) received first dose of BNT162B2 (lot number: EJ1685), via an unspecified route of administration in right arm on 22Dec2020 16:45 at single dose for COVID-19 immunization. Medical history included GERD (gastrooesophageal reflux disease) from an unknown date and unknown if ongoing. Concomitant medication included omeprazole (PRILOSEC), cetirizine, ascorbic acid (VIT C), ergocalciferol (VIT D), zinc, magnesium. The patient experienced chills, dizziness, high blood pressure on 22Dec2020 17:30. Treatment fluids was received. The patient underwent lab tests and procedures which included blood pressure: high on 22Dec2020. Facility type vaccine: Hospital. The patient didn't receive any other vaccines within 4 weeks prior to the COVID vaccine. The adverse event result in emergency room/department or urgent care visit, treatment was received for the adverse event (fluids). The outcome of events was resolving.

Experienced right arm tingling and the tingling went up into the right side of her neck. Experienced a few minutes of chills and heart racing.

Dizziness; Headache; chest pain; This is a spontaneous report from a non-contactable physician (patient). A 40-year-old female non-pregnant patient received BNT162B2 (Pfizer-BIONTECH Covid-19 Vaccine), intramuscularly on 23Dec2020 13:00 at a single dose in arm for COVID-19 immunization. Medical history included known allergies: roasted chestnuts. Concomitant medication included ascorbic acid, betacarotene, biotin, calcium carbonate, calcium phosphate, chlorine, colecalciferol, cupric oxide, ferrous fumarate, folic acid, iodine, magnesium oxide, manganese sulfate, molybdenum, nickel sulfate, nicotinamide, pantothenic acid, phosphorus, potassium chloride, pyridoxine hydrochloride, retinol acetate, riboflavin, selenium, silicon, thiamine, tin, tocopherol, vanadium, vitamin b12 nos, zinc oxide (MULTIVITAMINS & MINERALS PLUS LUTEIN) within two weeks of vaccination. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient experienced dizziness, headache, chest pain, all on 23Dec2020 21:30. No treatment received for the event. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. The outcome of events was recovering. This is a non-serious report. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

Swollen, firm, tender infraclavicular lymph node on side ipsilateral to injection site. Swollen to the extent where it is visible without need for palpation.

I had a very mild soreness on my right jaw at about 10 mins about my shot.

Headache; Pain and swelling at the injection site.; Pain and swelling at the injection site.; This is a spontaneous report from a contactable nurse (patient) from a Pfizer sponsored program. A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 19Dec2020 at single dose for COVID-19 immunization. The patient medical history was not reported. The patient's concomitant medications were not reported. The patient experienced pain and swelling at the injection site on 19Dec2020. They told her she could only take paracetamol (TYLENOL). Then she was reporting a headache on 23Dec2020 and was asking if she could take ibuprofen (ADVIL) as well. The outcome of the event was unknown. Information on the lot/batch number has been requested.

Minor headache; This is a spontaneous report from a contactable nurse (patient). A 39-years-old male patient started to receive bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) , intramuscular at 10:30 22Dec2020 at the first single dose for covid-19 immunisation. Vaccine location was Left arm. The patient medical history was not reported. No covid prior vaccination; No covid tested post vaccination. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient's concomitant medications were not reported. The patient experienced minor headache in Dec2020. The outcome of event was unknown. Information on the lot/batch number has been requested.

Mild/moderate nausea starting 24 hrs after vaccine, continuing for 10 hours now and has not subsided. Mild injection site soreness; Mild/moderate nausea starting 24 hrs after vaccine, continuing for 10 hours now and has not subsided. Mild injection site soreness; This is a spontaneous report from a contactable

other health professional reported for herself. A 40-year-old female patient (pregnant at the time of vaccination was reported as No) received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), intramuscularly on 22Dec2020 13:00, on Right arm, at single dose for COVID-19 immunization. Medical history included migraines, anxiety. Concomitant medications included fluoxetine, Vit B complex, ergocalciferol (VIT D), cetirizine hydrochloride (ZYRTEK). The patient previously took Iohexol and experienced allergies. The patient reported mild/moderate nausea starting 24 hrs after vaccine on 23Dec2020 13:00, continuing for 10 hours now and had not subsided. Also reported Mild injection site soreness on 23Dec2020 13:00. No treatment was received for the adverse events. The outcome of the events were not resolved. Information on the lot/batch number has been requested.

Went to the PMD a day later for routine blood work and found I have significantly elevated LFTs with ALT and AST 400s

Within 6-8 minutes of receiving vaccine, looked at cell phone to text husband and could not focus on the keys (Blurred vision), then felt a rush/tingling sensation thru whole body, as if the medication starting/moving from my arm all the way down my legs, some dizziness and heart rate increased - I believe to 120. No increased BP, SOB, itchiness, closed throat feeling, hives. Heart felt like it was racing for about 10 minutes. RN at site checked BP and heart rate 5 times in 40 minutes. Left facility and was able to drive myself home. Later that evening, soreness at injection site for 36 hours. No fever, chills, body aches.

"Fast heart rate, heart rate kept fluctuating went to 120 then 112 then 90 and 80, it went high for like at least half an hour, I kept feeling that palpitation; Sweaty; Tired; Body pain and ache; This is a spontaneous report from a contactable Consumer (patient). The 39-years-old female patient received bnt162b2 (BNT162B2), unknown on unknown date in Dec2020 at single dose for COVID-19 immunisation. Medical history and concomitant medications were none. Consumer stated, ""I am calling because I got the COVID Vaccine yesterday morning and then after I got the vaccine I had a fast heart rate and then my heart rate kept fluctuating, it went to 120 then 112 then 90 and 80 and it kept, it went high for like at least half an hour not more and then I kept feeling that palpitation and then today I am still feeling sweaty, tired, body pain and ache. So, I want to see what should I do regarding that? Is that considered like a severe allergic reaction and I need to do something about it or what should I do? So, I contact my employee health and they told me I need to contact you guys."" The outcome of the event Palpitation was unknown and was not recovered for the rest events. Information on the lot/batch number has been requested"

Moderna COVID-19 Vaccine EUA: injection site soreness for 36 hours

Chills/chills in the night; Headache, very severe headache very painful; Pain at the injection site; Little bit of stomach cramping and pain; probably a fever too; Little pain; This is a spontaneous report from a contactable consumer (patient). A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK5730), via an unspecified route of administration on 22Dec2020 at single dose for Covid-19 immunisation. The medical history and concomitant medications

were not reported. The patient experienced chills, headache, very severe headache very painful, pain at the injection site, little bit of stomach cramping and pain and probably a fever too, little pain and chills in the night in Dec2020. The outcome of the events was unknown.

notable pain at the injection site; This is a spontaneous report from a contactable consumer (patient) via Pfizer Sales Representative. This 40-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 23Dec2020 at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient received the COVID vaccine on 23Dec2020, that evening he was having notable pain at the injection site. The outcome of the event was unknown. Information on the lot/batch number has been requested.

body aches, chills, rigors, headache, fatigue, lymphadenopathy on the side of the injection

"I started getting achy; Headache; Joint pain; I started developing congestion; Cough; Sore throat; Fatigue; This is a spontaneous report from a contactable consumer (patient). A 23-years-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (lot number: EH9899) via an unspecified route of administration in right arm on 17Dec2020 at single dose for COVID-19 immunization. There was no medical history. There were no concomitant medications. The patient got the vaccine (Covid vaccine) on this past Thursday the 17 and he first didn't show any symptom or anything like that and then later at night and then in the beginning of morning of 18Dec2020, he started showing some symptoms. He started getting achy, he guessed little bit joint pain and started to get headache and didn't take too much of it neither of those side effects and as he found out last night apparently he had a positive exposure on the 18th the following day and didn't find out until last night but after the 18th he started showing different symptoms, he can't find better with the vaccine so he started developing congestion, cough, sore throat and a little bit of fatigue (all on Dec2020). He is going to get tested now and they have told him that the test, the vaccine should not affect the test itself. He received a medication for his headache. Treatment reported as the only thing he took was Tylenol. His height was about 5""8 or 5""9. Events outcome was unknown."

Continued fevers after 24 hrs after injection and body aches; Continued fevers after 24 hrs after injection and body aches; This is a spontaneous report from a contactable nurse(patient). The 25-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), intramuscular on 22Dec2020 09:45AM at single dose(dose number was 1) at left arm in workplace Clinic for covid-19 immunisation. Medical history and concomitant medications were none. She was not pregnant, no known allergy to medications, food, or other products. There is no Covid prior vaccination, no covid tested post vaccination. There is no other vaccine received in four weeks, no other medications in two weeks. The patient experienced continued fevers after 24 hours after injection and body aches on 23Dec2020 06:00AM. There is no treatment received. Outcome of events was not recovered. Case considered non-serious. Information on the Batch/Lot number has been requested.

soreness in the injection; headache; This is a spontaneous report from a Non-contactable Nurse reported for herself. This female patient of an unspecified age received the first dose of BNT162B2

(PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for Covid-19 immunisation. The medical history and concomitant medications were not reported. The patient had the first dose of the vaccine and mentioned that she experienced the expected adverse events of soreness in the injection site and headache. She said she felt better after multiple ibuprofen (ADVIL). The outcome of the events was recovering. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

Moderna COVID-19 Vaccine EUA

she felt sleepy and cold; she felt sleepy and cold; a bit dizzy; This is a spontaneous report from a contactable consumer reported for cousin. A female patient of unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 23Dec2020 at single dose (lot number: Ek5730) for COVID-19 immunization. Medical history and concomitant medications were unknown. The patient got the vaccine on the morning of 23Dec2020. She said she felt sleepy and cold. The patient said she felt better this afternoon. A pinch, the patient felt cold and sleepy. She could take a nap. The patient felt a bit dizzy when she got out of her chair just now. Outcome of the events was recovering. No follow-up attempts are possible. Information about lot/batch number cannot be obtained.

Drowsiness; This is a spontaneous report from a contactable pharmacist reported for self. This 43-year-old female patient (not pregnant) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on an 23Dec2020 14:15 on Arm left at single dose for covid-19 immunisation. Medical history included Seasonal allergy. No allergies to medications, food, or other products. Concomitant medications were none. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. No any other medications the patient received within 2 weeks of vaccination. The patient experienced drowsiness on 23Dec2020 16:30. Prior to vaccination, was the patient did not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. No treatments were received for the event. Outcome of the event was Not recovered. Information about lot/batch number has been requested.

"Patient notified me this morning that his clavicle (on the same side as injection) is ""very swollen."" Patient was advised to follow up with his PCP and report event through V-Safe."

Left arm/shoulder pain; Left arm/shoulder pain; Sternal pain; Fatigue; Headache; This is a spontaneous report from a contactable Other HCP (patient). A 33-years-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on left arm on 23Dec2020 16:00 at single dose for COVID-19 immunization. The patient medical history was not reported. There were no known allergies, no allergies to medications, food, or other products. The patient's concomitant medications were not reported. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19, since the vaccination, the patient has not been tested for COVID-19. The patient experienced left arm/shoulder pain, headache, sternal pain, and fatigue on 24Dec2020. No treatment was received

for the adverse events. Events outcome was not recovered. Information on the lot/ batch number has been requested.

Night sweat; Soreness of the thighs; This is a spontaneous report from a contactable Nurse (patient). A 47-years-old female patient received bnt162b2 (Batch/lot number: EJ1685), via an unspecified route of administration on 22Dec2020 16:30 at single dose for covid-19 immunisation. Medical history was none. There were no concomitant medications. The patient experienced night sweat on 22Dec2020 with outcome of unknown, soreness of the thighs on 22Dec2020, which was ok with outcome of recovered on Dec2020.

Onset of body aches 12h after vaccination, lasted for 24h; This is a spontaneous report from a contactable other healthcare professional reporting for a patient. A 26-year-old female patient (no pregnant) received her dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (Batch/lot number: EH9899), via an unspecified route of administration on 21Dec2020 at single dose for COVID-19 immunization. Medical history was not reported. The patient had no allergies to medications, food, or other products. The patient's concomitant medications were not reported. The patient experienced onset of body aches 12h after vaccination on 21Dec2020, lasted for 24h. No treatment received for the event. The event was reported as non-serious. The most recent COVID-19 vaccine was administered in Hospital. The patient had not received any other vaccines within 4 weeks prior to the COVID-19 vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. The outcome of the event was resolved in Dec2020.

Arm soreness lasting 24 hours; This is a spontaneous report from a contactable Nurse reporting for herself. A 48-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) Lot number EK5730, intramuscularly on 15Dec2020 14:00 at the right arm at single dose at workplace clinic for COVID-19 immunisation. There were no medical history and no concomitant medications. There were no allergies to medications, food, or other products. The patient did not receive any other medications within 2 weeks of vaccination. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient had no COVID prior vaccination. The patient did not have COVID tested post vaccination. The patient experienced Arm soreness lasting 24 hours on 15Dec2020 16:00. The event was reported as non-serious. Treatment was not received for the adverse event. The outcome of the events was recovered on an unspecified date in Dec2020.

Tenderness in injection site; This is a spontaneous report from a non-contactable Other HCP (patient). A 34-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) Lot number EJ1685, via Intramuscular route of administration on 23Dec2020 11:15 at single dose on left arm for COVID-19 immunization. Medical history included Gastrooesophageal reflux disease (GERD), Postpartum Depression. Concomitant medication included sertraline. The patient previously received nickel, amoxicillin, penicilline, hepatitis b vaccine and had allergies. The patient had not received other vaccine in four weeks. The patient had no covid prior vaccination. The patient had no covid tested post vaccination. The patient experienced Tenderness in injection site on 24Dec2020. The outcome of the event was resolving. No follow-up attempts are possible. No further information is expected.

105 degree fever, chills, fatigue, pain in injection site that extended to neck, shoulder, right breast, and right leg and thigh. Headache. These symptoms were at there worst for first 48 hours. I am now at day 5 and continue with headache, arm pain and right leg tingling.

Body aches and weakness; Body aches and weakness; Really fatigued; Sore arm; Chills; This is a spontaneous report from a contactable consumer (patient). This 25-years-old female patient (no pregnant) received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number: EH9899) on 23Dec2020 02:15 PM on Right arm for COVID-19 immunization. Medical history and concomitant drug were not reported. Past drug was known allergies with pethidine hydrochloride (DEMEROL). No other vaccine in four weeks, no other medications in two weeks. It was reported that patient experienced really fatigued, sore arm, chills and slight body aches and weakness (all reported as non-serious) on 23Dec2020 08:00 PM with outcome was Recovered in an unspecific date in Dec2020. No treatment. No COVID prior vaccination. No COVID tested post vaccination. Prior to vaccination no diagnosed with COVID-19. No follow-up attempts are possible. No further information expected.

Ten minutes after vaccine administration, employee started feeling very nauseated. She became tachycardic and became very blotchy across her chest and left arm. Employee was sent to the emergency room for evaluation.

Right nipple soreness and swelling; Right nipple soreness and swelling; This is a spontaneous report from a contactable physician (patient). This 73-year-old male patient reported that he received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EK5730), via intramuscular at arm right on 19Dec2020 03:00 PM at single dose for COVID-19 immunization. Medical history was none. Prior to vaccination, the patient was not diagnosed with COVID-19. No allergies to medications, food or other products. Concomitant medication was not reported. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient received no new medications within 2 weeks of vaccination. Since the vaccination, the patient had not been tested for COVID-19. Patient experienced right nipple soreness and swelling on 22Dec2020. No treatment was received for the adverse event. It was reported as non-serious. Outcome of event was not recovered.

swelling right under the arm (mentioned axilla); This is a spontaneous report from a contactable consumer (patient herself). A female patient of an unspecified age received bnt162b2 (BNT162B2 also reported as PFIZER-BIONTECH COVID-19 VACCINE) , via an unspecified route of administration on unspecified date at single dose, for immunisation. The patient's medical history and concomitant medications were not reported. The patient experienced swelling right under the arm (mentioned axilla) on an unspecified date. The outcome was unknown. Information about batch/lot number has been requested.

Sore arm a few hours after injection but very mild on first day. Day 2 arm soreness was worse and throbbed at times and was slightly warm to touch with mild swelling but relieved with ibuprofren. Day 3 arm sore but just barely noticeable. Soreness gone on day 4. No treatment needed other than the ibuprofren.

Arm soreness for 24 hours. Muscles aches and chills in the evening after the vaccine.; Arm soreness for 24 hours. Muscles aches and chills in the evening after the vaccine.; Arm soreness for 24 hours. Muscles aches and chills in the evening after the vaccine.; This is a spontaneous report from a non-contactable physician reported for self. This 26-year-old female patient (not pregnant) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot#: EH 9899) at single dose on 18Dec2020 at 07:00 on arm left for COVID-19 immunization. Medical history and concomitant medication were not reported. There was no allergies to medications, food, or other products. Concomitant medication was not reported. There was no other vaccine in four weeks. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. The patient experienced arm soreness for 24 hours, muscles aches and chills in the evening after the vaccine. Onset was 18Dec2020. There was no treatment for the events. The outcome of events was resolved in Dec2020. No follow-up attempts are possible. No further information is expected.

Shortly after injection started itching. Then when she got home she started a rash on face, chest.

Non productive cough; diarrhea; This is a spontaneous report from a contactable other healthcare professional (HCP). A 36-year-old male patient received 1 dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot Number: EJ1685) intramuscular on right arm on 23Dec2020 03:15PM, single dose for COVID-19 immunization at 36-year-old. Medical history included: allergies: promethazine hydrochloride (PHENERGAN). Prior to vaccination, the patient did not diagnose with COVID-19. Concomitant medication was not reported. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. On 24Dec2020, 05:00AM, the patient experienced non-productive cough, diarrhea. No treatment received. Since the vaccination, the patient had not been tested for COVID-19. Action taken for BNT162B2 was not applicable. Outcome of the events was not resolved. It was reported as non-serious. No follow-up attempts are possible. No further information is expected.

Fever, 100.4, sore arm

Injection site soreness 10 hours post administration; Still sore injection site this morning; Mild headache, muscle achiness and chills also 10 hours post administration of vaccine; Mild headache, muscle achiness and chills also 10 hours post administration of vaccine; Mild headache, muscle achiness and chills also 10 hours post administration of vaccine; This is a spontaneous report from a contactable other HCP. This 47-year-old female other HCP (patient) reported for self that she received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number=EK9231) intramuscularly at the right arm at single dose for COVID-19 immunization on 23Dec2020; 09:45 AM. Relevant medical history included Asthma, Ulcerative Colitis and allergies to Penicillin, Fiorinal with Codeine. The patient received Ibuprofen, Mesalamine, Pantoprazole within 2 weeks of vaccination. The patient experienced injection site soreness 10 hours post administration on 23Dec020, mild headache, muscle achiness and chills also 10 hours post administration of vaccine. The patient felt better in the next morning on 24Dec2020, while she still had sore injection site this morning. No treatment was received. The final outcome of events was resolved. All events were considered as non-serious. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19.

About 5 min after receiving IM Pfizer COVID injection, patient developed flush feeling, dizziness, and sore throat. Taken to ED for evaluation. Monitored for approximately 1 hour with resolution of symptoms.

Received vaccine at 1:30 pm yesterday, noted onset of symptoms at 8:45 pm. Numbness and tingling to mouth and bilateral upper and lower extremities, mild vision change, feeling of some swelling to bilateral eyelids. Also swelling to lips. She also did take zinc gluconate 50 mg last night and this morning. Has never taken zinc 50 mg, but has taken zinc as component of multivitamin/pre-natal vitamins. Patient was prescribed Pepcid 20 mg BID, Medrol 4 mg dose pack 21 pill taper until complete. Also given Benadryl 25 mg - 50 mg every 4 - 6 hours for allergy symptoms. And provided with an Epi-Pen for home.

Tingling in upper body, heat, warm

Medium area of redness, lump, itchy and sore around area of injection.

Headache, body aches, fatigue, injection site pain; Headache, body aches, fatigue, injection site pain; Headache, body aches, fatigue, injection site pain; Headache, body aches, fatigue, injection site pain; This is a spontaneous report from a contactable Nurse (patient). A 55-year-old female patient (No pregnant) received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) Intramuscular on 22Dec2020 10:30 AM on Right arm for COVID-19 immunization. Medical history was diagnosed with COVID-19 prior to vaccination. Concomitant drug was not reported. No other vaccine in four weeks. Adverse event reported as Headache, body aches, fatigue, injection site pain (all was non-serious) on 23Dec2020 12:00 AM with outcome was Recovering. No treatment. No COVID prior vaccination. No COVID tested post vaccination. Since the vaccination, the patient was not been tested for COVID-19. Information about lot/batch number are requested.

went to observation area at 1045. called to observation area 1100. states sx started at 1055: inside ears tingling, itching and warm. sweaty armpits. states has eaten peanutbutter, snacks and coffee for intake today. not lightheaded, dizzy, states no other sx. 1102 seen by, RN from rapid response. decided to wait 10 minutes to see if sx resolve. 1115 still no change in sx, ed called and transported to ED at 1125.

Chills; Fever 101.1¦F; Body Aches; This is a spontaneous report from a contactable physician, the patient. A 34-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE) Lot: EJ1685, via an unspecified route of administration in the left arm on 21Dec2020 (at the age of 34-years-old) as a single dose for COVID-19 immunization. Medical history included a diagnosis of COVID-19 (COVID positive) on 31Aug2020. The patient did not have any allergies to medications, food or other products. Concomitant medications were not reported; however, it was reported that the patient received unspecified medications within 2 weeks of the vaccination. The patient did not receive any other vaccines within 4 weeks prior to the vaccination. On 22Dec2020, the patient experienced a fever of 101.1¦F, body aches and chills. Treatment was not received for the events. Since the vaccination, the patient had not been tested for COVID-19. The clinical outcomes of the fever of 101.1¦F, body aches and chills were recovered on an unspecified date in Dec2020.

Headache; fatigue; nausea; muscle soreness; injection site pain; This is a spontaneous report from a contactable healthcare professional, the patient. A 32-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, Lot EH9899) solution for injection in the left arm on 23Dec2020 at 13:30 (at the age of 32-years-old) as a single dose for COVID-19 vaccination. The patient was not pregnant at the time of vaccination. There was no medical history. Concomitant medications included amfetamine aspartate/amfetamine sulfate/dexamfetamine saccharate/dexamfetamine sulfate (ADDERALL) and sertraline. The patient had no known allergies. The patient did not receive any other vaccine within 4 weeks prior to the vaccine. Prior to the vaccination, the patient was not diagnosed with COVID-19. On 23Dec2020 at 18:00, the patient experienced headache, fatigue, nausea, muscle soreness, and injection site pain. No treatment was provided for the events headache, fatigue, nausea, muscle soreness, and injection site pain. The outcome of the events headache, fatigue, nausea, muscle soreness, and injection site pain was recovering. Since the vaccination, the patient has not been tested for COVID-19.

12/23 @ 2000: severe chills 12/24 @ 0100: severe chills, nausea, vomiting, body aches, fever of 102.4 12/24 @ 0900: body aches, fever of 101.5 12/25 @ 0800: body aches, fever of 100.8

headaches; dehydration; nausea; vomiting; diarrhea; This is a spontaneous report from a contactable healthcare professional, the patient. A 33-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, Lot EJ1685) solution for injection in the right arm on 22Dec2020 at 15:45 (at the age of 33-years-old) as a single dose for COVID-19 vaccination. The patient was not pregnant at the time of vaccination. Medical history was unknown. Concomitant medications included amoxicillin, diphenhydramine hydrochloride (BENADRYL) and birth control. Past drug history included known allergies: cyclobenzaprine. The patient did not receive any other vaccine within 4 weeks prior to the vaccine. Prior to the vaccination, the patient was not diagnosed with COVID-19. On 23Dec2020 at 08:15, the patient experienced headaches, dehydration, nausea, vomiting and diarrhea. No treatment was provided for the events headaches, dehydration, nausea, vomiting and diarrhea. The outcome of the events headaches, dehydration, nausea, vomiting and diarrhea was unknown. Since the vaccination, the patient has not been tested for COVID-19.

Diarrhea , nausea, 'feeling unwell', fatigued began at 9am the next day - it is currently 3pm - continuing to feel symptoms

lightheadedness; confusion; This is a spontaneous report from a non-contactable healthcare professional. A 34-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, Lot EH9899) solution for injection intramuscular in the left arm on 22Dec2020 at 15:45 (at the age of 34-years-old) as a single dose for COVID-19 vaccination. Pregnancy status was not provided at the time of vaccination. Medical history and concomitant medications were unknown. Past drug history was unknown. On 22Dec2020 during her 15 minutes waiting period after the injection, the patient began to experience lightheadedness and confusion. The patient denied rash, hives, welts, difficulty breathing, difficulty swallowing, wheezing, throat tightness, hoarseness, stridor, itching, facial swelling, lip swelling and tongue swelling. The patient was discharged stable to go home and follow up with PCP (primary care physician). The patient was released at 16:39 with no symptoms at that time. No treatment was

provided for the events lightheadedness and confusion. The outcome of the events lightheadedness and confusion was recovered on 22Dec2020. No follow-up attempts are possible. No further information is expected.

Employee developed a severe headache approximately 10 minutes after vaccine administration.

Extreme fatigue and nausea and vomiting; Extreme fatigue and nausea and vomiting; Extreme fatigue and nausea and vomiting; This is a spontaneous report from a contactable nurse. A 40-years-old female patient started to the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), Batch/lot number: Unknown, intramuscularly on 23Dec2020 11:30 (at the age of 40-years-old) as a single dose in the right arm for COVID-19 immunization. The patient did not have allergies to medications, food, or other products. Concomitant medication included metformin, zolpidem tartrate (AMBIEN), venlafaxine hydrochloride (EFFEXOR XR). The most recent COVID-19 vaccine was administered in the hospital. The patient was not pregnant at the time of vaccination. Prior to vaccination, the patient was not diagnosed with COVID-19. On 23Dec2020 14:30, the patient experienced extreme fatigue and nausea and vomiting. The extreme fatigue and nausea and vomiting did not result in death, was not life-threatening, did not cause/prolonged hospitalization, was not disabling/incapacitating and did not cause congenital anomaly/birth defect. No treatment was received for the event. Outcome of the event extreme fatigue and nausea and vomiting was recovering. Since the vaccination, the patient has not been tested for COVID-19. Information on lot/batch number has been requested.

muscle ache, fatigue, hoarse throat, flushed skin, chills

Sore arm; nausea; This is a spontaneous report from a contactable nurse reporting for self. A 43-years-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), Lot# EH9899, via an unspecified route of administration in the right arm on 19Dec2020 at 15:30 (at the age of 43-years-old), as a single dose for COVID-19 immunization. The patient was not pregnant at the time of vaccination. The vaccine was administered in a hospital facility. There was no prior COVID-19 vaccination. The patient was not diagnosed with COVID-19 prior to vaccination & not COVID tested post vaccination. Medical history was none. Concomitant medications were not reported; however, there were no other medications the patient received within 2 weeks of the vaccination. The patient did not receive any other vaccine within 4 weeks prior to the COVID vaccine. There were no known allergies to medication, food, or other products. The patient experienced sore arm for 24 hours, then from about 34-72 hours had nausea. The onset date and time for the events was reported as 19Dec2020 at 15:30. The events were reported as non-serious. There was no treatment for the events. The patient recovered from the sore arm and nausea on an unspecified date.

"hearing in his left ear started sounding muffled; I was given the shot and instantly, within 30 seconds felt a slight numbing feeling radiating up my arm, then to my neck and up the left side of my face.My tongue felt a little numb but not swollen; had that ""metal"" taste in my mouth, but that did not return; This is a spontaneous report from a contactable other HCP. A 58-year-old male patient received BNT162B2 (Pfizer-BioNTech COVID-19 mRNA vaccine) (lot number EL1284), intramuscularly in the left arm on 23Dec2020 at 07:00 (at the age of 58-years-old) as a single dose for COVID-19 immunization.

Medical history included high blood pressure from an unknown date and unknown if ongoing and latex allergy from an unknown date and unknown if ongoing. There were no other vaccines received within 4 weeks of the BNT162B2 vaccination. Prior to the vaccination, the patient was not diagnosed with COVID-19. Concomitant medication included nebivolol hydrochloride (BYSTOLIC), fish oil (FISH OIL), naproxen sodium (ALEVE) and bifidobacterium lactis (PROBIOTIC [BIFIDOBACTERIUM LACTIS]). On 23Dec2020 at 07:00 (within 30 seconds of the vaccination as reported), the patient felt a slight numbing feeling radiating up his arm, then to his neck and up the left side of his face. Then, within 15 minutes, his hearing in his left ear started sounding muffled. His tongue felt a little numb but not swollen. It was reported when he first started feeling the numbing feeling, for about a split second, he had a metal taste in his mouth, but that did not return. It took about 1.5 hours for the numbness to go away. No therapeutic measures were taken as a result of the events. Clinical outcome of the numbness was resolved on 23Dec2020 at 08:30. Clinical outcome of the metal taste in his mouth and hearing in his left ear sounded muffled was unknown. It was also reported that since the vaccination, the patient tested negative for COVID-19 on 23Dec2020."

Headache, body aches and pain, lower back pain, high blood pressure, injection site soreness

severe shoulder pain/injection in left shoulder once, close to shoulder higher up; states it was not on the deltoid, it was given higher than normal; This is a spontaneous report from a contactable consumer (patient). A 61-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) Lot number EJ1685, on 23Dec2020 13:30 at single dose by injection in left shoulder once, close to shoulder higher up for COVID-19 immunization. Medical history and concomitant medication were none. The patient received the shot yesterday, and her only experience she was having was severe shoulder pain, and she was wondering if it was possible to just take Aleve, they mentioned taking Tylenol, but she was wondering if Naprosyn was ok to take. Towards yesterday evening, she noticed the severe shoulder pain, she received it at 1:30 in the afternoon, and noticed probably around 9PM, all night was just pain like as if someone or else you overexert with exercise, that kind of pain. She hadn't taken anything, she wondered if it was ok to take Aleve, no one seemed to know. She stated the dose was not given on the deltoid, it was given higher than normal. The outcome of severe shoulder pain was not resolved.

Weakness in the left side of face; and fatigue. 1112 am went to observe patient in her room. Laying in the bed with left side droopiness to face. Weakness on left side only, nurse taking care of her stated just happened. On observation it appears to be Bells Palsy reaction. No treatment at the time, Hospice nurse is to visit her today and check on her. Staff will check on her every 30 min for the next few hours and do a pulse oximeter check every hour for next few hours. 1205 second check on patient in room prior to staff leaving. Patient squeezed my hand and opened her eyes on command. Pulse saturation was 95 per staff. Patient resting comfortable with no signs of trouble breathing.

"I don't feel so good; This is a spontaneous report from a non-contactable consumer, the patient. A female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration on an unknown date as a single dose for COVID-19 vaccination. Medical history was unknown. The patient's concomitant medications were not reported. On an unknown date, the

patient reported ""I don't feel so good and I don't want to go to the hospital."" The clinical outcome of "" don't feel so good"" was unknown. No follow-up attempts are possible. Information on the lot/batch number cannot be obtained."

pruritic rash in pubic area moving up; This is a spontaneous report from a contactable nurse (patient). A female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, lot number:EH9899), via an unspecified route of administration in the left arm on 21Dec2020 at 11:00 AM as a single dose for COVID-19 vaccination. Medical history included cardiomyopathy and hypothryroid. The patient did not have any allergies to medications, food, or other products. The patient was not pregnant at the time of vaccination. Prior to the vaccination, the patient was not diagnosed with COVID-19. The patient's concomitant medications were not reported; however, there were other medications the patient received within 2 weeks of the vaccination. The patient did not receive any other vaccine within 4 weeks prior to the vaccine. On 22Dec2020 at 08:00 AM, the patient experienced pruritic rash in pubic area moving up. The report was reported as non-serious. The patient was not treated for pruritic rash in pubic area moving up. The clinical outcome of pruritic rash in pubic area moving up was not recovered. It was also reported that since the vaccination, the patient had not been tested for COVID-19.

chills; body aches; fatigue; This is a spontaneous report from a contactable consumer. This consumer reported that a 54-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration in the right arm on 23Dec2020 at 03:00 PM ((at the age of 54 years-old) as a single dose for COVID-19 vaccination. Medical history was unknown. The patient was not pregnant at the time of vaccination. Prior to the vaccination, the patient was not diagnosed with COVID-19. The patient's concomitant medications were not reported. The patient did not receive any other vaccine within 4 weeks prior to the vaccine. On 23Dec2020 at 10:00PM, the patient experienced chills, body aches, fatigue. The report was reported as non-serious. The patient was not treated for chills, body aches, fatigue. The clinical outcome chills, body aches, fatigue was recovered on an unknown date in Dec2020. It was also reported that since the vaccination, the patient had not been tested for COVID-19. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

Fever; Headaches; Chills; Aches and pains; This is a spontaneous report from a contactable consumer (patient herself). This 60-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, on 23Dec2020 at 08:30 AM at single dose for COVID-19 immunisation. Vaccine location was left arm. The patient was vaccinated at hospital, age at vaccination was 60-year-old. She was not pregnant. No other vaccine was received in four weeks. Relevant medical history included diabetic, allergies to eggs, chicken and latex. It was reported that prior to vaccination, she was diagnosed with COVID-19. Relevant concomitant medications included insulin aspart (NOVOLOG) for diabetes. On 24Dec2020, at 02:30 AM, the patient developed fever, headaches, chills, aches and pains. The patient was treated for the events. Nasal swab, COVID test (rapid) was performed on 24Dec2020 and was negative. The outcome of the events was unknown. Information on the lot/batch number has been requested.

I noticed onset of a mild rash down my bilateral arms and along my hips, back and legs. This rash worsened upon inspection on 24Dec2020 with associated itching and warmth along the rash site; warmth along the rash site; I noticed onset of a mild rash down my bilateral arms and along my hips, back and legs. This rash worsened upon inspection on 24Dec2020 with associated itching and warmth along the rash site; This is a spontaneous report from a contactable Other HCP. A 25-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, Batch/lot number: EK5730) via an unspecified route of administration on 22Dec2020 at 18:15 (at the age of 25-years-old) at an unspecified dose in the right arm for COVID-19 vaccination. Medical history was not provided. The patient had no allergies to food or medications but reported having seasonal allergies and it was reported that prior to vaccination the patient was diagnosed with COVID-19 on an unspecified date. The patient was administered the vaccine in the hospital. Concomitant medication included an unspecified oral contraceptive. The patient did not receive any other vaccines within four weeks prior to the vaccination. On 23Dec2020 14:00, the patient noticed the onset of a mild rash down her bilateral arms and along her hips, back and legs. This rash worsened upon inspection on 24Dec2020 with associated itching and warmth along the rash site. The patient did not receive any treatment for the events. The clinical outcomes of the events were reported as not recovered. It was also reported that since the vaccination the patient had not been tested for COVID-19.

Aches; Headache; Fever 102 degrees; This is a spontaneous report from a contactable physician, the patient. A 59-year-old non-pregnant female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot Number: EJ1685), via an unspecified route of administration in the left arm on 23Dec2020 at 08:00 (at the age of 59-years-old) as a single dose for COVID-19 immunization. Medical history included asthma and penicillin allergy. Prior to the vaccination, the patient was not diagnosed with COVID-19. Concomitant medications included naproxen sodium (ALEVE) and unspecified multivitamins (MANUFACTURER UNKNOWN). The patient did not receive any other vaccines within four weeks prior to the vaccination. On 24Dec2020 at 07:00, the patient aches, headache, and fever of 102 degrees Fahrenheit, reported as non-serious. The patient was not treated for the events. Since the vaccination, the patient had not been tested for COVID-19. The clinical outcomes of aches, headache, and fever of 102 degrees Fahrenheit were not recovered.

"Lightheadedness an dyspnea after receiving COVID 19 vaccine. Patient states that 5 minutes after receiving the vaccine, he felt ""out of it."" He felt like he was ""in a dream."" He reported feeling palpitations, shortness of breath, and chest pain. He denies feeling overly anxious. He states that the chest pain is substernal with no radiation. He reports it is pleuritic in nature. He states it is currently a 4/10, feels like a pressure on this chest; He received 50mg Benadryl and 0.3mg epi x2 by EMS and was brought to the ED for further evaluation. Admitted from ED for observation on 12/18/2020 and discharged on 12/20/2020."

"Lymphadenopathy: 0.5 cm left arm tender lymph node and 2 cm left infraclavicular tender lymph node; Lymphadenopathy: 0.5 cm left arm tender lymph node and 2 cm left infraclavicular tender lymph node; This is a spontaneous report from a contactable physician reporting for herself. A 49-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot #: EH9899), via an unspecified route of administration on 16Dec2020 at 09:00 (at the age of 49-years-old)

as a single dose in the left arm for COVID-19 vaccination. Medical history and concurrent conditions were reported as ""none"". The patient was not pregnant at the time of vaccination. Prior to the vaccination, the patient was not diagnosed with COVID-19. Concomitant medications (""other medications in two weeks"") included valaciclovir hydrochloride (VALTREX) taken for an unspecified indication from an unspecified date and unspecified if ongoing. The patient did not receive any other vaccines within four weeks prior to the vaccination. The patient previously received sulfa (sulfonamide) on an unspecified date for an unspecified indication and experienced allergy. On 22Dec2020, the patient experienced lymphadenopathy: 0.5 cm left arm tender lymph node and 2 cm left infraclavicular tender lymph node. It was reported that the event was non-serious and did not require hospitalization. The patient did not receive any treatment for the event. The clinical outcome of the event lymphadenopathy: 0.5 cm left arm tender lymph node and 2 cm left infraclavicular tender lymph node was not recovered/not resolved. It was also reported that since the vaccination, the patient had not been tested for COVID-19."

""" Code called for a 36 YOF complaining of anaphylactic reaction after receiving COVID vaccine. Per staff, patient began to have hives around mouth and a tingling in mouth. RN on scene administered epi pen at 1310. Patient found awake and alert, in no distress. Team took over care of patient to bring down to ER. Pt VS WNL: BP 158/80, HR 122, RR 18 (post epi pen). Skin parameters WNL with vanishing hives. Patient brought to ED 09 for evaluation. """

vomited; muscle pain.; severe flu symptoms for about 4 hours; This is a spontaneous report from a contactable healthcare professional, the patient. A 58-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, Lot# EL1284), via an unspecified route of administration in the right arm on 23Dec2020 at 10:45 (at the age of 58-years-old) as a single dose for Covid-19 vaccination. Medical history was not reported. The patient did not have any allergies to medications, food or other products. The patient was not pregnant at the time of vaccination. Prior to the vaccination, the patient was not diagnosed with COVID-19. The patient was not tested for COVID-19 post vaccination. The patient's concomitant medications were unspecified (had received other medications in two weeks). The patient did not receive any other vaccines within four weeks prior to the vaccination. On 24Dec2020 at 00:00, the patient experienced severe flu symptoms for about 4 hours, vomited and had muscle pain. Therapeutic measures were not taken for the severe flu symptoms for about 4 hours, vomited and had muscle pain. The clinical outcome of the events severe flu symptoms for about 4 hours, vomited and had muscle pain was recovered.

Fever; chills; arm was sore; extreme body aches; This is a spontaneous report from a contactable consumer, the patient. A 51-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), intramuscular in the left upper arm on 21Dec2020 at 11:00 (at the age of 51-years-old) as a single dose for Covid-19 vaccination. Medical history included COVID in May2020 for he knows he has detectable antibody levels; body aches in his shoulder, hip joints, knee joint and elbow joint for the last month and a half after recovering from COVID virus from an unknown date and weight loss of about 27 to 28 pounds since having COVID from an unknown date in 2020. The patient's concomitant medications included vitamin C, oral from an unknown date and ongoing for supplementation; Vitamin D, oral from an unknown date and ongoing for supplementation and aspirin (unspecified) since middle

of Jun2020 after having COVID per recommendation of his doctor. The patient previously received flu shot Flublok Quadrivalent a couple months ago (did not receive any other vaccines within four weeks prior to the vaccination). On 21Dec2020, the patient experienced extreme body aches around 8:30 to 9:00pm (described as more like the ones he experienced when he had COVID virus) and chills around the same time; and arm was sore. The patient experienced fever on an unknown date (in the middle of the night). The patient underwent lab tests which included body temperature which included 99.5 degrees F (last night), up to 100.8 degrees F (this morning) and 98.8 degrees F; and blood tests on an unknown date with unknown results. Therapeutic measures were taken for the events pain, pyrexia, chills and arm was sore which included paracetamol (TYLENOL) in the morning around 8am. The clinical outcome of the events pain, chills, pyrexia and arm was sore was recovering (improved with treatment). Information on the lot/batch number has been requested.

About 12 hours following the vaccine, I suddenly felt like I had the flu - shivers, shakes, nausea, headache, fatigue but no fever. I went to bed and woke up the next morning and felt back to normal. I was fatigued the second day and had a very sore arm.

Severe headache; fever; chills; fatigue; This is a spontaneous report from a contactable nurse, the patient. A 40-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), intramuscularly on 23Dec2020 at 18:15 (at the age of 40-years-old) as a single dose in the left arm for COVID-19 immunization. Medical history included multiple sclerosis and hypothyroidism. The patient had no known allergies. The patient was not pregnant at the time of vaccination. Prior to vaccination, the patient was not diagnosed with COVID-19. Concomitant medication included duloxetine hydrochloride (CYMBALTA), gabapentin, cefixime (FLEXERIL), tolterodine, levothyroxine, liothyronine; all for unknown indications from unknown dates and unknown if ongoing. The patient did not receive any other vaccines within 4 weeks prior to the vaccination. The patient experienced severe headache, fever, chills, and fatigue on 23Dec2020 at 18:30. No treatment was received for the events. Since the vaccination, the patient had not been tested for COVID-19. The clinical outcomes of the severe headache, fever, chills, and fatigue were recovering. Information on the lot/batch number has been requested.

Armpit of injected arm swollen and sore; Armpit of injected arm swollen and sore; This is a spontaneous report from a contactable healthcare professional, the patient. A 29-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, Lot ek5730) solution for injection in the left arm on 19Dec2020 at 14:00 (at the age of 29-years-old) as a single dose for COVID-19 vaccination. The patient was not pregnant at the time of vaccination. Medical history included fibromyalgia, depression, anxiety and ADHD (attention deficit hyperactivity disorder). Concomitant medications were unknown. The patient did not receive any other vaccine within 4 weeks prior to the vaccine. Prior to the vaccination, the patient was not diagnosed with COVID-19. On 20Dec2020, the patient experienced armpit of injected arm swollen and sore. No treatment was provided for the event armpit of injected arm swollen and sore. The outcome of the event armpit of injected arm swollen and sore was recovering. Since the vaccination, the patient has not been tested for COVID-19.

Reported paresthesia on the left side of her face and swelling of the lower part of her mouth an hour after administration of the Moderna COVID-19 vaccine. These symptoms resolved by this morning. She was observed for 15 minutes (as directed) following the vaccine and symptoms were not observed by clinic staff. She was advised to contact her personal physician for recommendations.

Unsure if side effect of vaccine but experiencing sweating, abdominal cramps and diarrhea.; Unsure if side effect of vaccine but experiencing sweating, abdominal cramps and diarrhea.; Unsure if side effect of vaccine but experiencing sweating, abdominal cramps and diarrhea.; This is a spontaneous report from a contactable Nurse. A 41-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, lot and batch number unknown) via an unspecified route of administration at an unknown dose in the right arm on 23Dec2020 at 12:45 (at the age of 41-years-old) for COVID-19 immunization. Medical history included asthma, anxiety, arthritis, fibromyalgia and surgical menopause all from unknown dates and unknown if ongoing. The patient did not have any allergies to medications, food or other products. Prior to the vaccination the patient was not diagnosed with COVID-19. The patient was not pregnant at the time of vaccination. The patient was administered the vaccination in the hospital. Concomitant medication included meloxicam (MELOXICAM), estradiol (ESTRADIOL), gabapentin (GABAPENTIN), phentermine (PHENTERMINE), melatonin (MELATONIN), aminobenzoic acid, biotin, calcium pantothenate, choline bitartrate, cyanocobalamin, folic acid, inositol, nicotinamide, pyridoxine hydrochloride, riboflavin, thiamine mononitrate (B COMPLEX), collagen (COLLAGEN). The patient did not receive any other vaccines within four weeks prior to the vaccination. The patient stated that she was unsure if these were side effect of vaccine but on 25Dec2020 at 10:00 she was experiencing sweating, abdominal cramps and diarrhea. The clinical outcomes of sweating, abdominal cramps and diarrhea were reported as recovering. It was also reported that since the vaccination the patient had not been tested for COVID-19. The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up.

"Describes left face, arm, leg felt numbness/tingling Had first COVID shot on 12/20/2020 19:36 then while driving home felt L face numbness at 20:37 Went to ED, BP 167/107 ""...driving home she states that she developed a strange, difficult to describe sensation when she was swallowing in her car, this started around 8:37 p.m.. She states that her numbness generalized to involve the entire left side of her face on the left side of her body including her left upper and left lower extremity. She denies any weakness. She denies any dysarthria or noticeable facial droop, she does not feel like she is walking differently. She denies any headaches or visual changes, denies any dizziness, chest pain, shortness of breath, palpitations. She states she has never had anything like this before."" ED notes had a normal neuro exam POCT glucose was normal at 83 resolved after minutes to hours in ED"

Vaginitis; This is a spontaneous report from a contactable healthcare professional. A 22-month-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration at the left arm from 23Dec2020 13:00 at a single dose for COVID-19 immunization at a hospital. The patient medical history was not reported. The patient's concomitant medications were not reported. The patient experienced vaginitis on 24Dec2020 13:00 which was reported to be treated with an unspecified OTC. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient was not diagnosed with COVID-19 prior to vaccination

and was not tested for it since the vaccination. The patient was recovering from the event. Information on the batch number has been requested.

Headache; This is a spontaneous report from a contactable consumer (patient). A 61-year-old female patient received the first dose on BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), on 18Dec2020 at single dose for COVID-19 immunization. Medical history was reported as none. Concomitant medications were not provided. Patient stated that she had her COVID shot on 18Dec2020 (reported as last Friday) and she had a headache ever since. Patient was just taking Ibuprofen trying to get rid of the headache. Outcome of the event was unknown. Information on lot/batch number has been requested.

developed some tingling, kind of a shock that comes and goes in her arms and in her back; This is a spontaneous report from a contactable nurse (patient). A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899) via an unspecified route of administration on 23Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient took the vaccine yesterday on 23Dec2020 and she developed some tingling, kind of a shock that comes and goes in her arms and in her back. She watched it for a long time, as nurses like to watch, and she finally feel asleep, so she wanted to tell this, she didn't know if this is any danger to her, she didn't think so, she was breathing well and can talk, but she was concerned because the tingling was almost like a little shock that comes and goes, not permanent. The reporter wanted to know if anyone has reported this. She was about to go out, but decided to call, agent can't say if this is something reported and she need to go to the local hospital. The outcome of the event was unknown. Information on the Lot/batch number has been requested.

UTI; This is a spontaneous report from a contactable consumer. A 65-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899), via an unspecified route of administration, left upper arm on 22Dec2020 12:30 at a single dose for COVID-19 immunization at a hospital. Medical history included urinary tract infection (UTI) in 2018 (2 years ago). There were no concomitant medications as the patient does not take any prescription drugs. Patient thinks her urinary tract infection (UTI) started to develop, 28-29 hours after receiving the vaccine so the onset was 23Dec2020. Patient stated the UTI came on fast and she has an appointment with an urgent care and may need antibiotics to treat the UTI. Patient was drinking a lot of fluids to try to flush the UTI out of her system. She said she doesn't feel as bad and felt like the UTI was getting better, and just woke up a short time ago. Patient also stated that she is concerned the antibiotic will mess up the vaccine, and wanted to know if she can take an antibiotic so soon after receiving the vaccine. The patient was recovering from the event. . .

Rash all over body, very itchy; Rash all over body, very itchy; This is a spontaneous report from a contactable nurse reporting for herself. A 62-year-old female patient received bnt162b2 (BNT162B2, Batch/lot # EJ1685) at single dose at left deltoid on 20Dec2020 in the afternoon around 13:30-13:45 for covid-19 immunisation, administered by a nurse at a tent outside of the hospital. The patient medical history was not reported. There were no concomitant medications. No additional vaccines administered on same date of BNT162B2. No prior vaccinations within 4 weeks. The patient got Flu shot a long time ago for immunisation. No events occurred following prior vaccinations. The patient experienced bad

rash all over body, very itchy on 20Dec2020 in the evening. The rash was driving her crazy.The reporter assessed the events were not really life threatening, not requiring hospitalization. Therapeutic measures were taken as a result of events: patient just bought Benadryl cream. No invesitgations. The outcome of events was unknown. She wanted to know if she has to get the second dose.

Arm pain on the left side, back pain, neck pain, headaches and then a dry cough developed several days later.

Headache; Body ache; Joint pain; This is a spontaneous report from a contactable consumer (patient). A 31-year-old male patient received the first dose BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), intramuscular, on 22Dec2020 at 11:00 AM at single dose for COVID-19 immunisation. Age at vaccination was 31-years-old. Medical history and concomitant medications were reported as none. On 22Dec2020, the patient developed headache, body ache, and joint pain. The patient reported the body ache has gotten worse, headache is still the same. The patient was treated with Advil. Outcome of all events was not recovered. Information on lot/batch number has been requested.

Shortly after vaccination (within 15 min), patient experienced warmth and itching at injection site, some radiating pain. Patient asked to stay longer to be observed, but eventually returned back to work without progress in symptoms. Approximately an hour later, she was prompted by her supervisor to return to vaccine area when she developed a headache and tingly lips. She was given 50mg of diphenhydramine PO. In no apparent distress after dosing

Fatigue, Headache, Nausea, sore throat

Achy pain at injection site; This is a spontaneous report from a non-contactable Other health care professional (HCP) (patient). A patient of an unknown age and gender received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), on unknown date at single dose for COVID-19 immunization. Medical history and concomitant medications were not provided. On unknown date patient experienced achy pain at injection site. Outcome of the event was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

GI problems; This is a spontaneous report from a contactable consumer (patient). A 46-year-old female patient (weight 74.39 Kg) received the first dose of BNT162B2 (Pfizer-Biontech covid-19 vaccine, Lot. EK5730) on 18Dec2020, in the left upper arm, at single dose, for COVID-19 immunisation. Relevant medical history included thyroid disorder. Concomitant medications were unknown. On 18Dec2020, the patient experienced gastrointestinal (GI) problems. Clinical outcome of the adverse event was unknown at time of this report.

Some problem with my arm; that is red; This is a spontaneous report from a non-contactable consumer (patient) This patient of an unknown age and gender received BNT162B2 (Pfizer-BioNTech COVID-19 at a single dose for COVID-19 immunization.Medical isotry and concomitant medication were not provided.The patient stated as follows:I have some problem with my arm that is red .The patient was wondering if it was an allergic reaction.The outcome of the event was unknown at the time of the report. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

Patient experienced dizziness/lightheaded, pale, body wide shaking, face tingly, hypertensive, tachycardic from patient reported baseline.

"Paresthesia in right hand (received covid-19 vaccine in right arm); Numbness; ""pins and needles""; This is a spontaneous report from a non-contactable nurse, who is also the patient. This 25-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration in the right arm on 23Dec2020 at 13:00 at single dose for COVID-19 immunisation. Vaccination facility type: workplace clinic. The patient did not receive other vaccines in four weeks. Relevant medical history included allergy to latex, mango and naproxen. Concomitant medication included unspecified oral contraceptive pill. On 23Dec2020 at 13:30, the patient experienced paresthesia in right hand (received COVID-19 vaccine in right arm), numbness and ""pins and needles"" which continued on and off for 48 hours. The patient did not receive corrective treatments for the reported events. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, she had not been tested for COVID-19. The patient recovered from the events in Dec2020. No follow-up attempts are possible; information about lot/batch number cannot be obtained."

headache; This is a spontaneous report from a contactable consumer received via Medical Information Team. A 61-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 18Dec2020 at single dose for COVID-19 immunization. The patient medical history and concomitant medications were not reported. The patient experienced headache on 23Dec2020. The patient outcome of the event was not recovered. Information about Lot/Batch number has been requested.

The following day had arm pain and fatigue for three and a half days, nasal congestion, dry eyes and itchy throat. Got tested for COVID one week later and is positive.

fever on and off; arm pain; body aches; chills; joint pain; This is a spontaneous report from a contactable nurse who was also the patient. A 55-year-old female patient received bnt162b2, lot:EK9231, via an unspecified route of administration on 23Dec2020 at an single dose for covid-19 immunisation. The patient's medical history was none. The patient's concomitant medications included unspecified vitamins. On 23Dec2020, the got the vaccine and the fever (on and off) started that night and had some arm pain too. The patient also had body aches, some chills and joint pain in Dec2020. The nurse stated that the thing should have gone better. She was just wondering how long she could have that side effects because it's been 3 days. Therapeutic measures were taken as a result of fever on and off pyrexia, body aches pain and chills were Tylenol and Motrin (patient did not clarify the improvement after taking the treatment). The outcome of the events was not recovered at the time of the report.

Feeling nauseous, throwing up; Feeling nauseous, throwing up; don't have the strength to keep talking right now; This is a spontaneous report from a Pfizer-sponsored program. A contactable female consumer, who is also the patient, of an unspecified age reported that she received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 23Dec2020 at single dose for COVID-19 immunisation. Relevant medical history and concomitant medications were not reported. In Dec2020, the patient started been feeling nauseous, throwing up and she wanted to double check if

she needed the second dose of the vaccine. The patient further specified that she didn't have the strength to keep talking. At the time of the report, the outcome of the events was unknown. The information on the lot/batch number has been requested.

"Tingling in her tongue and in her arm; Tingling in her tongue and in her arm; This is a spontaneous report from a contactable other health professional (patient) from Pfizer-sponsored program. A 33-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), intramuscular on Dec2020 at single dose for COVID-19 immunization. The patient medical history and concomitant medications were not reported. On Dec2020, the patient experienced tingling in her tongue and in her arm, the patient reported that: ""after getting the vaccine but it looked like the tingling in my arm was probably within an hour and the tongue was all like that in evening"". The patient outcome of the events was recovered. Information on Lot/Batch number for the product has been requested.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2020516692 same reporter, different patient/drug/event"

Pt woke up morning on 12/23 at0800 with rash on arms, thighs and legs. Called Nurse Manager, and primary doctor. Took 25mg PO Benadryl at 0815. Claritin 10mg PO at 0820. Took Pepcid 20mg at 0915. Had telehealth visit with primary doctor at 1000. Primary doctor informed patient that he believed this was an allergic reaction as the rash was spreading, patient was itching and had trouble swallowing pills in AM (unusual for patient to have that problem, resolved 1 hr post benadryl). MD informed patient to take 25mg PO of benadryl Q4H until rash disappeared. Ordered steroid dose pack if patient felt the benadryl did not help. Rash went away after 5 doses of 25mg PO Benadryl.

24hrs Soreness at injection site; This is a spontaneous report from a contactable consumer. A female patient of unknown age received on an unknown date BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) at single dose for COVID-19 immunization. Medical history and concomitant medications were not reported. On an unknown date the patient had 24hrs soreness at injection site. Outcome was unknown. Information on the batch number has been requested.

Patient received Pfizer vaccine at approximately 12:00 PM and drove to observation area. Observer reviewed safety measures with patient. Observer stated that patient c/o tingling at injection site. At approximately 12:05PM observer stated that she saw patient slightly waving paddle and went to assess patient, upon arrival to patient's car, patient was unresponsive. Emergency measures implemented. Epi administered via IM route, Oxygen applied, vital signs taken and EMS called. Patient remained unresponsive up EMS arrival. Patient was transported to the ER via EMS.

"I started running a fever; This is a spontaneous report from a contactable consumer (patient). A 63-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot EH9899) intramuscular in the arm on 22Dec2020 at single dose for COVID-19 immunization. Medical history included depression, allergy, high cholesterol, asthma, thyroid disorder. Concomitant medication included sertraline, bupropion and atorvastatin for High cholesterol. The patient started running a fever (non-serious) on Dec2020. Patient worked at the day care center that provided care for the Doctor's and Nurses Children. She worked at a healthcare site, she was not a doctor or a pharmacist, so that's how

she got a vaccine.Patient stated she got vaccine on 22Dec2020 and on 26Dec2020 she took her son, he was 24, to the doctor and he tested for Covid, now up to that point she had no side effects or anything, he did not get a vaccine so she wasn't surprised when he came down with it on his own but well she was surprised, last night she started running a fever so she was wondering ""will the vaccine effect a Covid Test?"" (as reported). Patient was treated with paracetamol (TYLENOL) and final outcome of the event was unknown."

Constant headache; This is a spontaneous report from a contactable nurse (patient). A 42-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number: EH9899) on 24Dec2020 at 09:00 at single dose for COVID-19 immunization. Medical history was none. Concomitant medication included multivitamin (unspecified) . The patient experienced constant headache on 24Dec2020 at 15:00. The patient, who was a health care worker front line (nurse), received the vaccine on 24Dec2020. She started having a headache, bad like afternoon around 6 hours after she was given the vaccine. The headache has not gone away. It was not like a terrible headache. It was a constant headache like if she took some paracetamol (TYLENOL) it went away but it came back. Patient stated she did not suffer from headaches and she had been having a constant headache since 24Dec2020, when she received the vaccine. The final outcome of the event was reported as not recovered.

Rushed to ER. Has now been tubed and put into the ICU and has had full-cardiac arrest less than 24 hours after receiving the vaccine.

nausea; chills; This is a spontaneous report from a Pfizer-sponsored program a contactable consumer (patient). This female patient of unknown age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route od administration, on 19Dec2020 at single dose for COVID-19 immunisation. Medical history and concomitant medications were unknown. She's experiencing symptoms like nausea and chills. She wants to know how long the symptoms will be. Outcome was unknown. Information on the lot/batch number has been requested.

Nauseous; I did start throwing up; Headache; This is a spontaneous report from a contactable consumer (patient herself). This 65-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, on 27Dec2020 at 07:30 AM at single dose for COVID-19 immunisation. The patient was vaccinated at hospital, age at vaccination was 65-year-old. Relevant medical history included diabetes, blood pressure abnormal and thyroid disorder. Relevant concomitant medications included insulin for diabetes, levothyroxine for thyroid disorder, and lisinopril for blood pressure abnormal. She was a MRI tech. She stated ''I had COVID Vaccine this morning at 7:30 and a little while ago like about 4'o clock. I work mid night, I got up from bed and I stand little nauseous and I did start throwing up and I have bad headache now but that's it. It is not emergent, but I just want to make sure, I am just checking in because I haven't. I can't get my smart phone to work because it keeps discharging so fast, but I was in bed. I am all right.' She stated ''there is no rash or anything. I just got nauseous which surprised me.'' The second dose is planned for 19Jan2021. No therapeutic measures were taken as result of the events. The outcome of the events was unknown. Information on the lot/batch number has been requested.

Aching in left deltoid hear injection site

Patient received vaccine around noon. She immediately felt numbness and tingling after injection. She reported back to clinic an hour later due to numbness and tingling persisting. She was given oral Benadryl and referred to the emergency department for evaluation.

Pain in left fingers and elbow that occurred within 15 minutes of injection. Numbness in left hand and forearm

0915 Generalized itching walked pt over to EMS Administered 50 mg of diphenhydramine PO

injection site pain, redness around injection site, Fatigue

Pt received first dose of Pfizer Covid 19 vaccine at around 12:45 and within 20 seconds, pt reported feeling sensation of tightness in his throat. Pt was observed for 15 minutes and his symptoms persisted but did not progress. Patient was taken to ED for evaluation. At 30 minutes post injection symptoms resolved. Monitored in ED for approx. 3 hours and discharged.

"Pt began c/o ""not feeling right"" with her tongue ""feeling funny"" and her lips tingling approximately 5 minutes after the administration of the Moderna COVID19 vaccine. Pt was transported to the Emergency Department for care and monitoring and was discharged when symptoms had resolved after approximately one hour."

Severe injection sure pain, jaw pain, hip pain, headache, palpitations, chills, nausea/vomiting, dizziness, fatigue

Left lip, cheek and nare swollen very visible to others. No difficulty breathing or swallowing . She has been taking zertec and this has resolved some but not all of the swelling.

Left eye bloody area lateral from iris, approximately 2cm x 2cm

Peripheral sensation loss

Swollen upper arm. Fever, chills with nausea

Extreme chills, muscle aches, joint pain, headache, fever, fatigue

On 12/28, reported that on 12/25 she had swollen lymph glands in her clavical and neck areas. Also, reported extreme fatigue (slept 16 hours following vaccine on 12/24) and significant arm soreness. Is seeking medical attention.

numbness on my right foot right after the injection (it went away) 30 min after swelling of right side of my face and droopy right eye (swelling went away but my eye is still droopy) little body pain, head ache and body felt warm (took Tylenol and it all went away). I'm just a little worried about my eye. Not sure how long it will take this to go away. I didn't take any allergy med because I'm not sure if I can.

High blood sugars, vision change, hearing issues, anxiety

Chest/arms itchy, tingling tongue

Itchiness after her first dose of COVID-19 vaccine this afternoon. Received vaccine around 2:15 PM and may be 30 minutes later just got diffusely itchy. No rashes not swollen anywhere no nausea or vomiting or belly pain no trouble speaking or swallowing or breathing. She got some oral Benadryl 50 mg prior to ED arrival.

Patient received the vaccine Monday, December 21. Patient started getting flu like symptoms on Thursday including cold, cough and headaches. Patient reports on Saturday the left ear and the left side of the throat began to hurt. Today Monday , December 28th, the patient states to waking up with a sore throat and the left side of the neck was swollen as big as a golf ball and remains swollen.

Patient received the vaccine Monday, December 21. Patient started getting flu like symptoms on Thursday including cold, cough and headaches. Patient reports on Saturday the left ear and the left side of the throat began to hurt. Today Monday , December 28th, the patient states to waking up with a sore throat and the left side of the neck was swollen as big as a golf ball and remains swollen.

Cold Like Symptoms

At 9 PM on December 22 I became absolutely exhausted extreme fatigue I went to bed I was woken around 11 1115 something like that every part of my body hurt it hurt to move my fingers it hurt to move everything every joint hurt and if I did move I felt nauseous then I started to throw up I did that for half an hour or so it was if you need to know it was violent and then I got back into bed with a cool cloth on my head at about 4 AM I got back to sleep I woke up at 6 AM to my alarm for work and I felt absolutely fine except my arm was sore just like it is from any regular inoculation.

area around injections, red, raised, warm, tender to touch

Hospitalized 12/29, has now been tubed and put into the ICU

May be in no relation at all but day after vaccination patient woke up with ankle pain. It was hard for the patient to walk/run. During the evening time he reports possible pulling of muscle/ligament while walking in a parking lot at the store during a snow storm.

Approximately 29 hours after the vaccine I developed fatigue, myalgias and chills. Lasted until I went to bed that night (4 hours or so). Resolved as of when I woke up the next morning.

Approximately 29 hours after the vaccine I developed fatigue, myalgias and chills. Lasted until I went to bed that night (4 hours or so). Resolved as of when I woke up the next morning.

Developed a rash on her face and arms; took Benadryl 50 mg immediately when the rash emerged at 9:15 AM; she notified the Employee Health office of the rash at 9:45 AM and was immediately referred for evaluation by an Employee Health medical provider at 9:50 AM; she took Benadryl 25 mg at 7:00 PM and then went to bed; the rash was gone upon waking at 8:00 AM on 12-29-2020; she had a follow-up

evaluation at 9:00 AM on 12-29-2020 with an Employee Health medical provider and was cleared to return to full duty and was discharged from care.

9:30pm on 12/23/20 i started with a severe headache and then an immediate onset of fatigue, i was unable to stand up and felt like i could not walk. thru at the night i had bodyaches, nightsweats, chills and fever. i had a fever or 101.3 on 12/24/20 for most of the day I rotated tylenol and ibuprofen and was only able to get it too 100.3 . bodyaches and headache continued . 12/25/20 fever and burning of eyes. 12/26/20 -12/27/20 fever and headache. all symptoms subsided on 12/28/20

Moderna COVID-19 Vaccine EUA. Around 25 min after injection I started feeling dizzy then had tachycardia, sweating, numbness and tingling in extremities. Given Oxygen and taken to the ER. Symptoms subsided 5 min after arriving in ER except numbness and tingling in hands. About 30 min later I started having dizziness and tachycardia again which lasted a few minutes. EKG, CHest X-ray and labs all normal. Just feel tired.

Patient observed for 15 minutes in the clinic after vaccine with no issues. Patient is a NP and left clinic. 10 min after leaving, was in physician lounge and had tachycardia, dizziness, flushing. Hospitalist in lounge recorded pulse as 180 normal rhythm. Patient taken to ED. In SVT - heart rate eventually reduced. Patient released on cardiac monitor to home. Later that night, patient had increased heart rate again - 160's - while in bed. Admitted to hospital.

Cough, diaeresis; initially only injection site soreness then other symptoms developed

Patient had tingling and numbness of the mouth and throat 20 minutes after receiving the COVID vaccine

Patient reports 2 hours after getting vaccination that she had difficulty moving left arm. Reports having decreased strength in left arm, and decreased ability to lift any amount of weight with left arm. Reports having numbness in left arm that is ongoing. Pt reports symptoms are improving .

Directly after receiving the vaccine I tasted a metallic taste and my tongue started to tingling. My face flushed. Last about ten minutes.

Lethargy & fever 12/29/2020

12/29/20 came to vaccine clinic to report. states had vaccine 7:10 pm, waited 15 minutes, 'felt edgy' but thought maybe nerves. 7:25 pm walked back to her office, felt slightly lightheaded, had worked 12 hours, sx subsided. 7:45 pm walked to her car felt right side jawline numbness that extended to forehead and whole side of face, able to smile, swallow, drove home (30 min) and sx stayed the same. states lingered over the evening, went away by 10 pm. states eyelid felt heavy, was not puffy. did not keep her awake - did report night sweats. 0700 awoke, states no sx, no residual. states arm slightly sore and general joint aches. 1205 came to clinic to report. states feels pretty good, concern is about next shot. Will contact PCP, did vsafe and will complete report.

Right side tongue numbness, tingling and burning in/around lips, elevated heart rate 136+, Blood pressure spike 165/105. Shortness of breath believed to be r/t elevated heartrate. Within 10 mins of shot. Face flushed, redness worsened with some swelling to ears and tongue skin felt like a sun burn rawness. Throat tugging noted. Dispatched an ambulance, had my husband take me around corner to ER where I was treated for anaphylaxis with 1 dose of Epi IM, IV solumedrol, and two rounds of benadryl IV. I was monitored and sent home on steroids, benadryl, and cimetidine for several days. I was issued an Epi Pen at that time. The rash and redness with feeling of burning has come and gone since as well as the tongue numbness on right side.

Red bump, painful and itchy

Cough and injection site soreness

Patient is a physician. He reported palpitations and tachycardia the evening of vaccination (about 4 hours after vaccination) when he was at home. It did subside within 2-3 hours.

I'm not sure if it was the vaccine, I'm a chaplain at the hospital I didn't eat or drink anything before the vaccine. I had a trauma that day and after the shot my arm was tingling when I was driving home I couldn't focus I had a headache, when I got home I ate and immediately went to bed, I slept for 10 hours and the next day I was getting my son ready and I fell asleep sitting up and by lunch time I felt completely normal again.

Generalized itching

Itching and rash/ hives. Itching started approximately 5 minutes after injection, slight at first then itching increased throughout body. Rash hoed later. Mostly only on areas scratched (face, chest and neck). Rash and itching present for 5 days including day injection given. Used over the counter antihistamines round the clock. Used inhaler once evening of injection day and once 3 days later. (Albuterol)

Deltoid pain with movement of arm.

"Co-worker reported a ""sever headache"" and later at 2:05pm she reported she was ""unable to open her right eye due to the severe pain in her head"". She took Benadryl 25mg by mouth. Her mother came and picked her up to take her home after an hour without any additional symptoms. The co-worker reported she still had a ""headache"" the next day, but it was much better."

12/19/2020 0630 AM WOKE UP AND WENT TO REACH FOR PHONE, COULD BARELY LIFT LEFT ARM. HURT ALL WAY DOWN TO WRIST. WHOLE ARM WAS SWOLLEN, HARD. SEVERE HA. GOT UP TO GO TO BATHROOM; BODY ACHES, CHILLS, DIARRHEA. 12/20/2020 AFTERNOON FELT WORSE. FELT LIKE HAD THE FLU BUT 50 MILLION XS WORSE; BODY DIDN'T 'FEEL RIGHT'. GETTING TO POINT OF FEELING WORSE. CALLED HOSPITAL, PHARMACIST. SCARED. COULDN'T STAY AWAY, COULDN'T STOP SLEEPING. COULDN'T WORK. CALLED PCP. TEMP SLIGHT ; 99.5 12/21/2020 WEDNESDAY MIDDAY ALL SIDE AFFECTS WENT AWAY LIKE SOMEONE FLIPPED A SWITCH. 'NOT A GOOD EXPERIENCE' 'I DON'T THINK I CAN GO THRU THIS AGAIN WITH THE SECOND SHOT'

general body itching

Hives, nausea, headache. Given benadryl. Hives resolved. Residual dull headache. Patient sent home with scheduled Benadryl x 24 hours, has Epipen. Encouraged to use prn and to seek medical attention prn.

Day of vaccine- extreme fatigue, pain at injection site Day 1- scratchy throat, extreme fatigue, muscle pain Day 2 - scratchy throat, extreme fatigue, chest tightness, muscle pain, headache Day 3 all symptoms as above with sore throat and fever

Palpitations, dry eyes, vertigo, rash on chest several hours after receiving vaccine. Resolved within a few hours.

Patient reported on 12/29/2020 that she experienced right hand numbness 15-20 minutes after vaccination and this lasted about 5-10 minutes. About 20 minutes after the vaccination she experienced lip tingling which then progressed to mild swelling and redness of the lips. This has persisted to this day and is gradually improving. She has experienced lip swelling in the past, not triggered by any event, medication, or substance, however has never experienced hand numbness or reactions to vaccines in the past. She has not received fillers.

Woke up with a rash over stomach, back, thighs and arms that were like goosebumps and itchy. They would get red and were painful and that would come and go. on the 25th the rash was constant, The rash was not relived with multiple doses of Zyrtec, Allegra or hydrocortisone cream and has persisted and worsened through the weekend. Prednisone was started on Sunday the 27th which seems to have helped however still itchy and the goosebump like rash is still on stomach, back and thighs.

SOB, Asama attack

Headache, muscle pain, joint pain, fever 100.6, fatigue,chills

Sensation of a racing heart

Employee came and report/showed me a raised rash that is on her face, neck and chest that developed the evening of her vaccine. Has been utilized OTC Benadryl. Able to still work.

low grade fever 99.2 after taking Ibuprofen headache sudden hot feeling and then fast cooling off, almost chilled, but I am fine, very mild

Noticed a rash around mouth and cheeks

5-10 minutes after vaccine got mild numbness/heaviness feeling corner of left side of mouth (very pinpoint without migration) that 1-2 hours after vaccine progressed to similar feeling on lateral left side of face and corner of left eye-no motor weakness in face, facial drooping or clinical change in sensation on palpation of skin, intermittent gritty/sandy feeling on tongue/mouth that started about 30 minutes or so after received the vaccine. Intermittent very mild scratchy/sore throat that start 30+ minutes after vaccine, frontal pressure-like headache-forehead/temples/cheeks on face-started within about 30 mins-

1 hr of getting vaccine-can get extremely strong at times. Approximately 12-14 hrs after vaccine got tingling/burning sensation on tongue with complete 100% loss of taste that was transient and 1-2 hours after started has slowly been improving and taste is slowly returning since then. no loss of smell. no tongue swelling or throat closing up sensation. all symptoms improve with taking over the counter antistamines-Zyrtec or benadryl, but haven't resolved yet. all symptoms overall mild (except headache at time) and are waxing and waning in severity (including headache) the entire time since receiving the vaccine. I feel completely fine otherwise.

Tachycardia and throat tightening

I developed a maculopapular rash over my chest, abdomen, back and proximal extremities but sparing my face, hands and feet. I was otherwise asymptomatic and the rash was not painful or itchy. It resolved on its own after 24 hours.

Patient reports arm tingling down from elbow to hand of left arm. A little numbness in left hand. Few hours later patient reports numbness moving down to arm and hand and up to eye with somewhat lessening on the lip. Patient currently experiencing some tingling on the right arm.

I actually am having a hard time lifting up my arm. Cannot put any pressure on the arm or take off clothes in shower. I cannot carry my son. I cannot lift anything. I cannot put my arm in pocket or jacket. If I get beyond 15-30 degrees abduction, I cannot do very well. Beyond that I can.

Sore arm for a week, redness and bump at injection site

Sore arm for a week, redness and bump at injection site

patient had body aches, head ache and shortness of breath. symptoms resolved on own no treatment necessary.

12/19/20 Employee's written report/description of events: shoulder injection site, left shoulder. Including shooting pain from my left wrist into the left side of my face. I have shooting pain into my chest from the injection site which also has included involuntary muscle movement in my neck and face, involuntary muscle movement is painful and this occurs with dizziness. All the pain stems from the injection site itself and always starts there when the pain happens. 12/23/20 saw OHS RN and was improved: states symptoms are better today & no involuntary muscle movements experienced today. Pain at injection site is less also. Has been using OTC Aleve, 1-2 every 12 hours. CMS left hand intact; all digits both hands have pale nail beds with > 2 sec cap refill; skin temp cool to warm. States has been on a medication that can cause Reynaud's disease; and has been concerned this may be occurring. Work comp MD appt. for 12/30/20; has not confirmed.

2:30 PM vaccine listed above given, 3:02 PM cheeks flushed with slight swelling of lips, Benadryl & Pepcid taken per employee. 4:35 PM symptoms resolved, 6:34 PM employee to ER with rash, itching, and trouble swallowing. Treatment received of Benadryl and Solu-Medrol, symptoms improved and employee DC to home. FU this am, employee states she has a HA and has taken med for, no further problems noted.

Strange taste in mouth, heart felt like it was pounding out of chest, blood pressure 195/100 (elevated), dry/burning mouth Was brought to ED and given Benadryl and Lorazepam

Tachycardia. Fever. Sweat. Body aches. Weakness

After I received the vaccine, after I went upstairs to go back to work (about 30 min later) I felt my hands and feet very cold and numb. I also felt dizzy and my hands and feet kept cold. Kept trying water and coke and I was continuously dizzy, a weird dizzy, like I had taken some kind of drug. My coworkers said I had slurred speech, my BP was 180/120 and my heart rate was 140. They sent me down to the ER. As soon as I laid down at the ER I started feeling better and within one hour my symptoms were gone. I also felt very sleepy throughout, as soon as I started feeling dizzy. I was fighting the sleep.

Fever Chills Rash and hive Fatigue

Noticed redness and swelling to vaccination site upon waking up. Site is warm to the touch and hard now about the size of a quarter.

Swelling redness and bump at injection site

Swelling redness and bump at injection site

Patient reported that his arm is tingling, has nausea, chills (no fever) and vomiting. These events all occurred as the patient woke up the morning after vaccination on 12/29/20.

Headache, light headed, dizziness for about 10 minutes

itchy tongue/throat

Right side of face swollen

Palpitations, tachycardia, anxiety several hours after vaccine while at home after awakening from a nap. Resolved after 2 hours.

Chest pain, short of breath. Morphine, sublingual Nitro, IV Nitro drip & Heparin drip

Severe headache, mild fatigue

Tension headache

Patient developed persistent nausea one day after vaccination with Pfizer COVID-19 vaccine. Nausea is ongoing 7 days post vaccination. Patient has not had any vomiting, diarrhea, myalgias, fever, and endorses no pain or tenderness in her abdomen. She has taken promethazine oral with minimal relief of nausea.

Headache body aches dizziness low back pain sore throat diarrhea

fever, fatigue, cough/dyspnea, muscle aches, headache, dizzy

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12 hrs after vaccine. symptoms runny nose, tenderness on left arm, headache, dry cough

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About 7-10 minutes after receiving covid vaccine, I was just talking with other nurses and suddenly felt a rush came over me. Felt lightheaded and dizzy. My pulse and blood pressure spiked. After about 5 more minutes, my forehead became numb. My pulse and BP had come back down. Later on that evening and into the next day my palms of my hands were bright red and itchy.

Flushing for 5-10 minutes

General Hives, sunburn effect, itching

General Hives, sunburn effect, itching

"Blurry vision, RIGHT arm weakness, shortness of breath, feels ""sick."""

Pain at injection site the night after injection. Swelling, pain, heat in the muscle around the injection site the next day.

12/18/2020 9:00PM Body aches, fatigue, headache and chills; Tylenol dose. Symptoms have not subsided; have continued to today 12/29/2020. 12/28/2020 Swollen lymph nodes left armpit, extremely fatigued and headache. 12/29/2020 Clinic visit with NP, Flu -- negative and COVID 19 test taken -- no results yet. Advised to continue Tylenol for treatment.

Received vaccine in left arm at 7:20 am sat for 15 minutes without any incident. At approximately 7:50 am I felt an intense burning sensation to outer aspect of right eye and eyelid. My eye was burning and watering continuously.Reported back to department where vaccine was administered nurse gave my 25 mg of P.O Benadryl. No other symptoms at that time. At approximately 2:00pm same day right eye partially opens,swelling persists to right eyelid with burning sensation and eye watering.

Loss of appetite/nausea

Vertigo, nausea, altered vision within minutes of receiving vaccine. Observed in clinic for 1 hour. Symptoms resolved. Returned to work. Vaccine received around 1150 am - patient had not had anything to eat that morning.

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stiff and inflamed joints where i have had previous injuries. Also sore throat and hot flashes.

Fever 103.5, body aches, chills, nausea, vomiting

22 mins after , I was light headed, Accelerated heartrate 170/101. I felt weak and shaky . Chills, I was given Iv fluid. In injection of Benadryl Slight Fever of 98.7

After 24 hours. Chills diarrhea and fever

RASH ON NECK AND LEFT HAND BUMP/ITCHYNESS

"Felt ""fine"" initially, then became ""lightheaded and dizzy"", felt like having an asthma attack. This occurred approximately 20 minutes after immunization. Went to ER, given rescue Albuterol inhaler, given Benadryl IV, Pepcid IV , monitored vitals"

Chest pains and short of breath within one hour of vaccine

Low grade temp 99.5

"Mental confusion. Couldn't gather thoughts. Mental ""fog"". Dizziness while sitting."

Patient received the vaccine on 12/23. Patient reports fever and fatigue from 12/24 ? 12/27 and developed hives on 12/26 and a diffuse red rash on 12/28. Patient was treated in the ED 12/28. On 12/28/20 patient was diagnosed with Diverticulitis, Allergic Reaction. Patient discharged with antibiotics and corticosteroid.

Fever this morning of 103 F. Took 1,000mg of Tylenol and fever went down to 101 F. 4 hours later took another 1,000mg of tylenol and fever is currently down to 100 F. Chills Soreness at injection site Fatigue

Patient received Pfizer Vaccine at approximately 1430 and was in observation area. At approximately 1435 observer stated that patient started to c/o dizziness and became pal.. Patient maintained LOC. Emergency measures implemented. Patient was place on oxygen, vital signs taken, EMSA called. EMSA present and evaluated patient. Patient was able to leave clinic site after evaluation.

Hospitalization 12/26 for Covid PNA

generalized edema, facial redness, slow resolution over next 18 hours

After injection developed swelling in cheeks and under eyes -

Moderna covid-19 Vaccine. Moderna was given to pt Im Left Deltoid 2 10:06 am . during her observation period for 15 min @ 10:20 she complained of itching and red spots on left arm and started on her back until 10:30 when 50 mg of Benadryl given in RD Im . started itching and red spots on rt arm noted. no other c/o , no shortness of breath noted, pt alert, oriented x4, sitting in chair talking to husband and drinking water. 11:00 am pt says I am no longer itching, my husband is going to drive me home. Instructed pt if any other symptoms develop go to Hospital ER . Pt walked out to car with husband to go home. I called pt 3:50 no answer at home number. spoke to pt at 4:10 pm , she also vomited X1, Slight headache.

Left arm put swollen and tender, lymph node

injection site pain

Pt called on 12/29 to report she is in pain. Reports at around 9:30 PM on 12/28 she had headache. They woke up at around 4 AM in severe pain. Her head hurt all over as well as the back of her neck down in her legs. Her entire body ached. She felt like she could not get a good breath. Her SaO2 was decreased. Today she is still in pain. Her pulse is 108 lying down and SaO2 88-92%. Will be going to the ER. Her oncologist is concerned about pneumonnia.

Fever-100.3

prolonged pain at the injection site, the pain increased in intensity 72 hours after the vaccine was administered and is persistent after 10 days. no systemic symptoms, evaluated locally, no findings on exam.

Multiple episode of irregular HR for about 7 hours. Severe pain in the left shoulder and joint, with muscles involvement. The pain extended down the arm to the wrist. Muscles were weak and unable to lift arm higher than chest, unable to perform ADL's with left arm as there wasn't any muscle strength to lift a thin blanket covering. Severe pain lasted about 48 hours with continued joint pain, although much less severe, in the left shoulder. Used Benadryl and Motrin. Didn't notice any different outcomes. Arm remained elevated on a pillow for some pain diminishment.

Near syncope, palpitations, tachycardia, elevated blood pressure

received vaccine at 02:30 pm 12/26/20, by 09:30 12/27/20 had chills, muscle aches, headache, sinus pressure, fatigue, and moderate soreness in arm of injection, symptoms resolved as of 12/28/20 09:30

Patient stated she had her Covid Vaccine on Friday 12/18 at 930am. On Friday night she reports she had a terrible migraine, on Saturday she felt very fatigued. She reports Sunday was her worst day and she felt very achy & her body felt like it was on fire. On Monday (12/21) she reports feeling better, but today 12/22 she reports that she has a bad cough and chest tightness.

Loss of appetite/nausea

"Co-worker reported she brought her ""epi pen"" with her to receive vaccine as she has allergies. Pt was given vaccine and waited 30 minutes and did not report any symptoms. Co-worker returned the next day to the vaccine clinic at approximately 11Am and reported that she was having symptoms of a reaction ""(unable to walk), "". She was taken to the emergency room. Co-worker had already taken Benadryl prior to coming to report the adverse reaction. Co-worker was called the next day by co-worker health 12/23/2020 and she reported that she had symptoms the evening of the day she received the vaccine that consisted of hives on her arms, shortness of breath and felt like ""something was coming on"" and she was disoriented. Co-worker was treated and released from the ED the same day."

"Patient stated that 2 hour after shot stated to develop ""brain fog,"" fatigue, and pain/burning in injection arm. In am, was nauseated, slept all day, arm pain improved as did ""brain fog."" Did not feel this was an allergic reaction, but side effects that needed to be reported"

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Night sweats, body aches, temp 100, severe fatigue. Symptom onset approximately 6 hours after vaccine, resolution within 24 hours

Patient is first responder (EMT) did not disclose symptoms of illness at time of vaccination or would have been denied. Reported that he developed headache and sinus issues on 12/26/2020. Developed extreme arm soreness in arm of injection site and night-time onset of extreme chills. Presented at local health department 12/29/2020 9 AM for PCR testing and tested positive for SARS-CoV2 negative for Influenza A&B. Chills have subsided was of short duration - arm remains sore. Patient denies known route of exposure . Was active over the recent holiday - significant other (GF) scheduled for PCR during AM 12/30/2020 currently asymptomatic.

Significant exhaustion, headache, flu like symptoms, body and muscle aches, fever, chills

Swollen supraclavicular lymph nodes (2 bumps) 12/28/2020 7:00 pm 1 week after. None other side effects

EE developed tingling in left arm, tingling of tongue and roof of mouth, started feeling like her tongue/mouth was swelling. Was given 50 mg of Benadryl PO at 1255. Symptoms continued to worsen, to Emergency Dept at 1300. Was given IV solumedrol and Pepcid. Oral Zyrtec and discharged home. OK to RTW with out restrictions. Upon f/u EE did report a hive like rash on the right side of her body but this has since resolved as well.

Numbness, tingling of low lip, tongue, right side of face for 5 minutes. Hours later developed temp, 101.2, headache. Took a Claritin.

Fevers-101.3, 99.3, 99.1

On 12/28/20 at approximately 1700 hours I felt slightly drowsy and warm. I checked my temperature with a tympanic thermometer which read 98.4. At around 1900 hours I began to feel I had a fever and chills. Temperature was checked again and it read 101.2. I went to bed around 2200 hours where I continued to experience moderate fever and chills. At around 0100 hours on 12/29/20 I had profuse sweating, headache. I took tylenol PM and awoke at around 0730 hours on 12/29/20 and found I no longer had any symptoms.

Itchy Hands were red Itchy at injection site 2 days later got a migraine. from her elbows up everything was red, not hot or didn't break out in a rash.

Dizziness, migraine, neck pain, jaw pain? all on the right side

12/28/2020 flushed neck to face and R side face paralysis (duration for 30 minutes). symptoms resolved and pt feeling better No further symptoms to report

Nausea, which started around 1pm on the same day of vaccination.

Nausea, which started around 1pm on the same day of vaccination.

Loss of appetite/nausea

Approximately 35 minutes after the patient received the vaccine, she reported a muscle spasm and tremor in her right arm, numbness in her lower lip, nausea, jaw heaviness; numbness, tingling and weakness bilaterally in legs.

5 days after injection have a red welt around injection site 2 in wide by 1 in up and down

5 days after injection have a red welt around injection site 2 in wide by 1 in up and down

Loss of appetite/nausea

10:05am injection of moderna covid vaccine into left arm 1010am- started with tingling of left fingers 10:15 tingling increasing up arm, pressure feeling on left side of head and tongue 10:20am tongue feeling numb on left side 10:21am Benadryl 50 mg given PO Liquid 1030am Cetirizine 10 mg tablet given PO Physician observation for 30 minutes, symptoms resolved, still felt groggy, sent home

She has an area measuring 3x2 inches of red, warm tissue. The area is itchy, but I am concerned with a possible cellulitis brewing.

Loss of appetite/nausea

Stated she developed itching all over her body and a rash on her left side of her body. Was taken to ER for further evaluation. Reported to ER provider history of anxiety and panic attacks and stated she was unsure if she could possibly having and anxiety attack. Reported also having chest tightness. . Given Benadryl 50mg po, Ativan 1mg po, and Solu-Medrol 125mg IM. Relieve of symptoms

Fever, severe headaches, body aches, fatigue

On 12/19 when I got my vaccine at 5:00 pm. When I woke up tingling feeling fingers, feet, face and scalp of head. The following morning I notice a rash around my hairline. I called my associate health was informed to take Benadryl multiple times throughout the day and was prescribed Ativan. The itching is still occurring in my scalp of the head and feet. I dint have to miss any days of work.

Vaccine scheduled for 6:30 pm on 12/28/20. only new loss of taste and smell the next morning approx. 5:15 am of 12/29/20.

itcing and welp/hive at injection site

Pain in right arm lasting two days, headache lasting two days, dizziness lasting two days, and fatigue lasting three days

Pain in right arm lasting two days, headache lasting two days, dizziness lasting two days, and fatigue lasting three days

Pt presented to COVID Vaccine Clinic for first dose of Pfizer vaccine, which was administered. Pt complained of throat swelling and itching approx. 1 min later. Patient transferred to ED.

"A few minutes after receiving the Moderna vaccine, pt reported feeling ""warm and heavy,"" seeing spots. Felt faint right away. Pt pale and clammy. Does have a hx of anxiety and reports taking propranolol 40 mg prior to vaccination. She had this reaction prior to a Hepatitis A vaccine"

Approximatley 2 hours after injection, after arriving home and starting some housekeeping activities, vertigo started with nausea and sensitivity to light. It is going on 2 hours while lying down with eyes covered and some improvement in that eye motion is no longer sensitive.

Developed high fever of 103.2; body aches, headache at 7:00pm; this morning fever down to 99.7; continues with body aches and fatigue.

Pt described starting to have warm, red, swollen, tingly fingers on both hands and felt that her ears and back of her neck were hot/red. Upon examination - there was no warmth or redness noted on ears or neck; lungs were clear to auscultation. Her hands were a little pink but did not appear swollen. She was able to drink a large cool water and said holding the container in her hands felt good. She also noted her lips were a little tingly. A decision was made to offer her 25 m.g. benadryl p.o. - and she felt some relief within ~ 20 minutes of dose. She was able to return to work but did note she developed a headache and did take excedrin for that. Since this initial episode - she has felt extreme fatigue and body aches and those appear to continue to today (29Dec2020). She also has been experiencing chills and some itching on her torso. She also reported starting to have a bit of a cough and sore throat - so will see if she should go to COVID testing.

severe chills fevers and myalgias.

Diarrhea , 102Temp, Nausea and vomiting

Extreme pain at injection site, fever, headache, nausea, vomiting, metallic taste in mouth, muscle aches

Extreme pain at injection site, fever, headache, nausea, vomiting, metallic taste in mouth, muscle aches

Headache, nausea, stomach cramps, diarrhea

Client was vaccinated approx 10:00am at the Health Dept. Client left after 15min without incident. Client went to report to work and began feeling nauseated, dizzy, and feeling as if was going to faint. Client returned to Health Department approx 12:30. Client was diaphoretic, HR was 140bpm, and BP was 178/120. Client was given 50mg/20mL of diphenhydramine PO and EMS was called and client taken to local ER. Client remained A+Ox3 at time of EMS transport. Spoke with client evening of 12/28/2020. He reports he was transferred to another facility and was told was in a-fib. He reports that he is feeling much better but heart still fluttering. Spoke with client afternoon of 12/29/2020. He reports that he is

being discharged in a few hours and is being sent home on metoprolol and a baby ASA. He reports they had been working on getting his BP down. He reports that he is feeling better and is going to be scheduled for a heart cath outpatient. He reports that he was initially in a-fib, then a-flutter, and then arrhythmia. He reports that he has been seen by Dr. a Cardiologist, while hospitalized.

"Pt presented to COVID vaccine clinic for 1st dose of Pfizer, which was administered at 0739. Pt complained of itchy throat and ""unable to speak."" Pt was transferred to ED"

Rash on both thighs, hypersensitivity to touch, burning pain when walking and thighs touching, chills of feeling like getting sick

828a- covid injection left arm 836a- itchiness at site of injection in left arm 839a-hives at site of injection left arm physician notified 840a-benadryl 50 mg PO liquid given, zyrtec 10 mg given po 852a-symptoms resolving, pt feeling fine, no difficulty breathing or swallowing, no further increase in hives

Throat started to swell. Did not affect my breathing, but made it difficult to swallow. The employee health nurse gave me a Benadryl and monitored me for an additional 30 minutes or so. By the time I left, my throat was starting to feel a bit better. Never got any worse.

Swelling and pain at injection site, nausea, headache, muscle aches, chills but no fever

After 25 minutes started coughing, shortness of breath, wheezing, vitals taken,albuterol inhaler administered, wheezing and shortness of breath improved

Fever spiked at 102.6 then broke after 6am and tylenol 1200 po, blotchy red raised rash to rt side of body(harlequin in nature) only mainly torso and back extending to some anterior upper thigh and neck region went away around 1300 on 29th, severe HA, shakes, N/V, dizziness, severe body aches especially to neck amd ankles, injection site swollen x4 camaraderie to rt arm with heat for 12+ hours.

Patient began with a rash to trunk 20 minutes after vaccine Benadryl IM given as no other symptoms. Within 5 minutes he stated his throat itched and was sractchy Epinephrine 0.3 mg given IM then sent to ER as he needed monitored

Fatigue, chills, fever and now headache.

Employee reports Myalgia and SOB

dizziness, nauseas, dry mouth, Shortness of breath, see light spots Solu-Medrol 125mg IVP slowly Benadryl 50mg IVPB refer to ED

Monitored x 15 min per guidelines. Began to experience SOB and throat swelling, after which pt presented to the ED for tx, dx acute hypertensive urgency with severe hypertension.

Patient presented back at work with a rash on her chest, mouth felt tingly, had red blotches on her arm about an hour after receiving injection. Patient returned to ER and was given Benadryl and monitored for 3.5 hours.

"Pt presented to receive 1st dose of Pfizer COVID Vaccine, which she received at 1130. She emailed hospital leadership to describe a reaction which is as follows: I feel the need to inform you about a likely reaction I had to the COVID vaccine I received yesterday around 11:30 am. I was feeling fine after the immunization, drove home and took some Tylenol in case of any arm pain (of which I have had none). I ate some lunch, was on the phone talking with a friend and developed sudden onset of lightheadedness, slurred speech and extreme sleepiness. No other focal deficit. I actually got up and walked around to try to shake it off. But I suddenly felt so tired that I could not keep my eyes open. I called my husband and asked him to come home immediately. I laid down and tried to reassure my kids that I was fine. I don't remember much thereafter. Just bits and pieces. It felt like I was under general anesthesia, trying to wake up but not able to open my eyes or move my arms/legs. I could hear some things going on but could not talk. There were times I would ""wake up"" in my mind and I would check to make sure I could swallow and I was breathing ok. I remember mumbling to my husband that I could breathe. He says he was checking my vitals throughout this time and monitoring things. He said my Blood pressure was initially 80/60, pulse 50, and as he keep checking it gradually improved. This lasted about 2 hours and then finally I was able to wake up. I felt a little lightheaded and tired for the rest of the day, but I feel essentially normal today. Please note: age not provided in internal system report; unsure of person's age"

Upper lip numbness, bilateral midline. Possibly associated with very minimal swelling to the upper lip. Lasted a few hours. No other associated reaction.

Dizziness, racing heart , short of breath

Fogginess in the head, dry mouth, increased heart rate 120s-140s No treatment Lasted approximately 3 hours

Weakness, Headache, Chills, Fever, Nausea, Vomiting, Diarrhea

dizziness, chills, fever, muscle aches, tachycardia

Body aches, left arm soreness, chills

Received vaccine 12/26/2020, by 4:45 pm 12/27/2020 started feeling a headache. On 12/28/2020 it had become a migraine with nausea. On 12/29/2020 it is still a migraine with some vomiting and nausea.

The symptoms began 20 min after administration of the vaccine. The symptoms were: throat tightening and tongue swelling which self-resolved within 15 min. He did feel that there was difficulty swallowing which persisted. He had a sneezing fit when he got back to the vaccine clinic. He got very anxious. He felt that his hand was swelling and was cold. He felt that he was having itching in his arm where the vaccine was given.He was in his car when the symptoms began so he turned around and went back to hospital. His BP 153/98, HR 128. At this point, he felt that he had no blood in his hands and he felt he needed to do deep breathing. He was observed for 1.5 hours and the symptoms self-resolved with the exception of his HR which has persistently been > 100. He feels very anxious. No treatment was given. He has no symptoms at this moment, 3.5 h after vaccine administration.

Redness about 2 inches diameter swelling after hour Following several hours tenderness and swelling to bicep to lift and move and tenderness in armpit

Hot flash, tightening to throat, tingling to tip of tongue and lips. Mild to moderate. Began 5 minutes post injection. Increased for about 10 minutes, then leveled off but did not resolve. Seen in ER and given Benadryl 50 mg IV and Solu-Medrol IV, dose of Solu-Medrol not listed on ER visit summary. Observed for about an hour and a half symptoms resolved,and discharged. Rx for Prednisone 40 mg po x 4 days and Epi pen given.

Chills, Headache, Cough, Body Aches

Pain to right leg

So that night throughout I felt feverish around 100.9 the highest was 101F. I would break though and then 1-2 hours later again it would come back. Body chest, couldn't move my arm, the pain was severe. Tuesday I could not even sit down I felt so weak, I had rashes in my face, legs, chest. I was so weak, I fainted and hit my head twice while going to the bathroom and kitchen. I felt like I was constipated, ant then I had diarrhea, I did not have appetite but could not hold anything in, I would throw up. My left side was all numb. I could not feel anything. It was like that the while Tuesday. Wednesday body aches, rashes, numbness, but I had a little bit of a body strength and could walk on my own. Thursday I was able to start eating a little bit and constipation were stating to go way. Friday was just body aches. Sunday the rashes finally went away.

After vaccine started with dyspnea \Tx: Pepcid 20mg Benadryl 50mg Atrovent 0.5mg

Arm was very sore for several days. 6 days after injection -- upper left arm broke out in a red, itchy rash (12/28). On 12/29 the rash is more spread out on the left upper arm and is lighter red.

Chest heaviness, chills, headache, fatigue

ask for auscultation before she goes, found with wheezing Solu-Medrol 125mg IVP slowly Refer to ED

PATIENT STATES FEELS LIGHTHEADED AND FLUSH AFTER INITAL 15 MINUTE WAIT TIME. PATIENT HAD NO INCREASE IN HEARTRATE. PATIENT STATES HAS NOT HAD ANYTHING TO EAT TODAY. PATIENT GIVEN WATER AND PEANUT BUTTER CRACKERS AND OBSERVED ADDITIONAL 15 MINS WITH NO OTHER COMPLAINTS AND FEELS BETTER.

Chills, Shortness of Breath, Chest Pain, Arm Pain

Swelling, warmth, redness to left deltoid at injection site started 12/29/2020. Measures 3.5 inches vertical and 2 inches wide. Ice and advil.

After 15 minutes observation I drove home, ate almonds and took a hot shower. My face turned bright red over my cheeks and forehead and broke out in hives all over my face. I never had a reaction like this to nuts before and believe it may be from the vaccine. The redness lasted one hour the hives slowly subsided after a full day.

Within a short period of time my neck became stiff. I developed a headache and became unsteady on my feet. After sitting longer while being observed by our nurse I was allowed to leave. That night I woke up nauseous and vomited. The next day I develped muscle and joint pain. Similar to flu symptoms. Everytime I ate I felt nauseous again. All the symtoms disappeared about 42 hour later. I have had an annaphilatic shock to penicillin as a child.

Patient felt tachycardia, was hypertensive, HR 200, O2 wnl, skin with red blotches throughout shoulders, face and chest and had cold hands and more blotches on shoulder area, transported to ED urgently for further evaluation

Heachache, chills, muscle pain, and temp of 100.9

Nausea, face tingling

Patient received a Hepatitis B booster within 2 weeks of COVID vaccine.

Slight arm soreness, nausea and decreased appetite

TEN MINUTES AFTER VACCINATION, PERSON BECAME LIGHTHEADED, PALE, NAUSEATED AND C/O HEADACHE. SHE ALSO C/O OF BEING HOT AND COLD. HR AND BP ELEVATED AT 157/100 AND 130 BPM. PERSON SITTING WITH LOWER EXTREMITIES ELEVATED, ICE PACK GIVEN TO POSTERIOR NECK, JUICE AND ICE WATER GIVEN TO PT TO DRINK. RAPID RESPONSE TEAM ACTIVATED. PERSON RESTED AND MONITORED AT VACCINE SITE FOR ONE HOUR WITH IMPROVEMENT IN SYMPTOMS. PERSON STABLE AFTER THIS TIME AND ABLE TO GO HOME.

"Immediately Following vaccine: light headed (resolved) & left jaw pain 1 Day following vaccine: nausea, dizziness, headache - all resolved 2nd day following vaccine: fatigue- all resolved 12 days after vaccine: continued left jaw pain- described as consistent dull ache with intermittent ""nerve shock"", weird taste in mouth, left ear pain feeling full with ""crackles"". Patient has not reported symptoms or seen any health care provider since vaccination."

Patient reports having symptoms of nausea headache and Low grade fever.

1237pm- injection of covid vaccine into left deltoid 1240p-hives noted on left arm Benadryl 50 mg given po liquid 1241p-hives spreading rapidly on body physician notified, rapid response called epipen 0.3 mg IM given 1242p tingling of left arm noted 1245- transferred to observation unit on floor with RN/ physician present 1Pm-3pm, itchiness noted, some shakiness due to epipen, hives resolving 145pm 25 ng Benadryl po given one hour post epiepn given itchiness increasing on body, saying throat is itchy 245pm increasing itchiness, discomfort with swallowing solids, taking liquids, says he feels funny, sl lightheaded, did walk to bathroom to void Famotidine given 40 mg PO per Dr 330- remains very itchy, with dysphagia, some hoarsness, breathing comfortably, ambulance called and take to hospital.

CHILLS LIGHT FEVER MUSCLE PAIN ALL OVER MY BODY JOINT PAIN ALL OVER MY BODY GAIT BALANCE

Rash, itching

Itching, cough. Given benadryl 50mg and epinephrine 0.3 in vaccine clinic, and taken to ED for further tx.

Intense arm pain, site redness and swelling, site was warm to touch, increased nausea, decreased appetite, slight shortness of breath, and fatigue

Patient stated she felt experiencing potential angioadema and scratchy back of throat, additionally she was tachycardic and hypertensive

Elevated Blood pressure, dizziness, fatigue, Headache, Light headed , Nausea .

Headache, Fatigue, light chills. taking Tynenol. it is improving slowly.

Headache, Fatigue, light chills. taking Tynenol. it is improving slowly.

With five minutes of vaccine Increased heart rate shot up to 198 bpm. Regular resting heart rate for me is in the 50s. Left pupil dilated completely, right people constricted to pin size. Extremities went numb and ice cold. Went to emergency room Per request of EMTs at vaccination center. Was given high-dose Benadryl and Saline IV. Heart rate return to normal and all other symptoms disappeared after treatment.

Headache, Chills, vomiting

All other symptoms resolved, continued arm redness

Developed chest tightness, slight fever and headaches

Patient experienced hives all around her body she was give benadryl and within 5 minutes the allergic reaction seemed to resolve

After vaccine started with chest pain, dizziness and dry mouth Tx: Solumedrol 125mg Benadryl 50mg

PATIENT FELT LIGHTHEADED AFTER INITIAL 15 MINUTE WAIT TIME. PATIENT WAITED ADDITIONAL 15 MINS UNTIL HE FELT BETTER. PATIENT SYMPTOMS RESOLVED BEFORE HE LEFT.

Swollen lymph node under clavical on left side

Soreness at injection site starting 30 min after the infection.

Itching in hands, head and back of neck, dizziness. Benadryl 25mg given and taken to ED for further tx.

Patient is reporting injection site discomfort, body aches and a tactile fever (unable to measure fever due to no thermometer).

Chills, fever, running nose, fatigue, joint pains, muscle pain, nausea, loss of appetite; lasted two days. Took Tylenol

"Significant redness/rash to chest and back with itching, lips numb, dry mouth, itchy hands, ""feels like I've been hit by a truck"" 2 doses of Benadryl 25 mg IM administered at 11:42 am and at 12:19 pm. 3 hours later, patient still reports feeling like she'd been hit by a truck"

Pt reported feeling of lightheadedness, dizziness and had sweating a few minutes after receiving the injection. Pt is breastfeeding just an FYI.

Right arm pain. Nausea, body and joint aches.

Jaw pain Numb lips Hives over face and neck Hard to breath

Jaw pain Numb lips Hives over face and neck Hard to breath

Tingly lips and around mouth Swollen bottom lip 10 minutes post infusion Right top of mouth tingly

n/v headache T 101 on 12/27/20

soreness in arm of injection, about a 6 inch area

fever of 103F the morning after the vaccine, chills

covid vaccine given at 1030am 12/28/20 bed ridden from pain, dizziness, nausea, and lightheadedness from 2pm 12/28/20 to 4pm 12/29/20. severe muscle pain in L upper pain which peaked around 1230am generalized muscle aches dehydration even though constant fluid drinking nausea, lightheadedness, dizziness if speaking more than one sentence at a time, shortness of breath vitals (taken 5pm 12/29/20) BP 131/87 (normal is usually 116/56) HR 95-105 (normal resting is around 70s-80s)

Client received vaccine,while scheduling next appointment got hot , heart felt like it was pounding, felt like her throat was slightly tight. She immediately took a benadryl from her purse. When writer arrived client's B/P was 150/78 heart rate 98. Respirations even and unlabored. Skin pink,warm and dry. Client was kept for further monitoring. Upon discharge B/P 110/68 no signs or symptoms of distress. Informed to seek medical advice if any further problems.

Metallic taste in the mouth for 10-15 minutes post vaccination; started 10 minutes after vaccination. About 5.5-6 hours after vaccination, experienced rhinorrhea and epiphora for about 1-2 hours, which then progressed to mild nasal congestion and mild chest congestion. Also experienced mild headache and mild fatigue around the time of the congestion. Notable puffiness/swelling of the hands and face set in about 10 hours post vaccination; resolved by the next morning upon waking.

The evening following administration of the vaccine, patient had left-sided rib 2-7 muscoskeletal pain.

Severe cold symptoms beginning 2 days post vaccine, runny nose, cough, shortness of breath leading to ER visit on 12/28, covid test results still pending as of time of this submission

Received COVID vaccine on 12/19/2020. On 12/20, she experienced chills and fever (100.9) and body aches (shoulders, HA). UC visit on 12/21 and doing much better, essentially normal. Clinical Impression: Post-vaccination syndrome. Tested for COVID and flu on 12/21, received negative results on 12/22

Nausea, Fatigue, Minor Chest Pain

I got it on the 21st and ten mins after I had tingling sensation all the way down to my hands, dizzy 190/101 blood pressure, I was sent to Urgent Care and they did a EKG and it was normal I was discharged with BP 180/90, I had cold clammy hands that day, weakness, the next day I was week and fatigued. The 23rd I started having chills and numbness on the left arm. I never had a fever. I'm still not 100% back I'm still tired and I've been having palpitations. I have an appt with my primary Dr today 12/29/20 in the evening.

Patient reports dizziness, hot/flushed, and ears ringing; Patient placed supine x 15 minutes and provided water as requested. BP 128/72 HR 76 O2 sat 100% Patient denies any symptoms after 10 minutes. Observed sitting for another 15 minutes

Patient is a 40 y.o. female with no known past medical history brought to ED with concern for ALOC after getting the COVID vaccination 30-40 minutes PTA. Pt is a nurse and experienced decreased level of consciousness following her COVID vaccinationn. Pt reports h/o anaphylaxis. She was given epinephrine PTA. Denies SOB, oral swelling, CP. BGL within normal limits. Pt denies any other complaints or symptoms at this time.

"got flushed, trying to ""clear"" throat, labored breathing, bp elevated, pulse 120's 15 minutes after vaccine administration. Given 50 mg of po benadryl and at the advice of her physician, 0.3mg epi im in R thigh. After epi, patient breathing slowed, flushing slowed, BP and pulse remained elevated. Pt. expressed feeling better. History of multiple allergies and seen in clinic. Encouraged by physician to receive vaccine."

Strong migraines, fatigue, muscle pain, chills. Pain, tenderness, and swelling at vaccine sight.

Patient received the Moderna Vaccine within 5 minutes complained of throat tightness and not feeling well. The patient was noted to be pale and hypertensive. She was placed on a stretcher, placed on oxygen and a Rapid Response was called. MD responded and initiated IV fluids and administration of Pepcid 20 mg IVP. Patient was transported to the Emergency Department (ED) for further evaluation. In the ED, patient received Methylprednisolone succinate 125 mg IV x 1 dose and Diphenhydramine 25 mg IV x 1 dose. Patient reported relieve of throat tightness and upper chest pressure. Patient was discharged with prescriptions for oral Prednisone x 3 days, Pepcid 20 mg oral twice daily and Benadryl 25 to 50 mg every 6 hours as needed for and recurrent symptoms.

12/29/2020. 0430 I awoke with facial swelling including eyes/nose/lips. Slight wheezing, coughing & my skin felt like I had been sunburnt. I took Benadryl 25mg, Pepcid 20mg, Prednisone 10mg and I did an Albuterol Neb treatment. When I awoke at 0830, the swelling ,wheezing & burning had subsided. I was extremely fatigued & I had a 99 degree fever. The fever subsided ,but I remain fatigued. (12/29/20 @ 1615) It's important to note my past severe allergic reactions have always been delayed by 8-14 days. I do carry an epi-pen.

Body aches & sore left upper and lower arm.

About 28 minutes after receiving I started getting hot, I could feel my heart racing in my chest, my breathing quickened, rapid response was called taken into another room by then my fingers had cramped up to where I couldn't work then arms and legs felt like pins & needles. Sent by ambulance to nearest ER where I was given benadryl and Solu-Medrol by IV, given another dose before being discharged with a prescription for Methprednisolone a few hours later.

Difficultly breathing sweats then passed out

Cloudy vision in left eye

Immediately after getting the vaccine she complained of headache. She had warm feeling at injection site She H/A Thursday, Friday and Saturday at mid-day her boyfriend called and said weakness in Right arm right face droop, no speech she was taken to the ER at 1 pm approximately. She was admitted and was dx was CVA . 2 TIA on left side of brain. Stopped Birth control and physician said it could be a combination of both birth control and vaccine.

26 hours after injection, the person had hives on bilat upper ext, pt's back had some redness

Patient (aRN) felt dizzy was tachycardiac stayed in area for 1 hr symptoms persisted then was taken to ED there was no evidence of Anaphylaxis is. Patient stateds she was given to large of dose RN administering denies states gave 0.5 IM she was monitored for several hours because patient has cardiac history

We requested pt wait 30 min due to her hx of severe allergies. Initially after vaccination, she felt nauseated and looked a little flush. Gave her cold compress and she felt better and wanted to leave. We made her wait and around 20-25 post vaccination, she reported feeling itchy all over and then said her throat felt funny. We were administering the vaccine for a clinic for their hcp staff. Rather than using our benadryl and ER kit, we walked her down to the ER since we were right in the hospital.

Fever, chills, arm pain, horrible body aches and congestion

Headache, chills, vomiting

Difficulty catching my breath, stiff joints in legs

5 minutes post-vaccination, struggled to breathe, felt itchiness in throat, light-headed, dizziness, & tightness in chest.

I have had intermittent numbness in my left hand for about 1 week. The first 2 days were the worse. It is also resolved but still feels different from my right hand. I have not had any weakness.

Pt reported her lip swelling and lip tingling a few minutes after receiving the injection.

Throat numb and swollen metallic taste back of tongue numb chest tightness

Pt c/o nausea and headache. Reported very nervous about getting vaccine. 1013 Vital Signs - 139/80; HR 96, Spo2 99. 1018 reported I may be hungry VS - 129/75; HR 86: SPO2 100. 1025 VS 125/75; HR 86, sp02

100 reported HA, Warm, I am so nervous. At 1030 VS 130/83, HR 97 SPO@ 100 pt reported All I want to do is eat.

Body aches, chills, L arm pain (lasted 2 days-until 12/26) Swollen lymph nodes L arm (lasted at least 5 days, current)- have added warm compress.

"Received the COVID-19 vaccine 12/19/2020 and felt great the next few days with zero symptoms. About 3-4 days later I felt some chest discomfort especially when taking a deep breath in. This occurred on both the front side and back side of chest. This continued for the next 5-7 days. Kept experiencing pain with deep breaths and my exercise tolerance was diminished. When I would hike up a small incline I felt I was not getting enough air and was a bit winded. Finally made an e-visit with my healthcare provider on 12/28/2020 after 5-7 days of symptoms. Knowing I work in healthcare my provider asked if my pain felt like, ""pleuritic chest pain"" and I think that is a spot on description of how it felt. Based on my symptoms he told me the most likely diagnosis is a mild case of pericarditis and prescribed me ibuprofen 400 mg by mouth 3 times daily for a few days. After ~36 hours of ibuprofen I'm feeling 80-90% better but still have some discomfort with deep breaths or exertion."

Soreness in injection site arm, headache, sore throat

Headache, chills, vomiting, temp 100.3

I had my vaccine at 0910 and was instructed to wait 15 minutes post-injection to monitor for any reaction. While seated, at 0920 I felt suddenly extremely lightheaded, dizzy, and nauseous. I had a feeling in my chest like my heart was racing and I check my HR on my watch and it read 120-125 bpm. My baseline HR is 60-70 at rest. I notified staff immediately and was placed onto a stretcher. The rapid response team was called and I was brought to the emergency department on site for evaluation. In my recollection, my heart rate came down to the 70?s/80?s within the hour at which time the feeling like my heart was racing had subsided. The nausea was treated with 4mg IV Zofran. My lightheadedness, dizziness, and nausea resolved with a 1,000 mL NS Bolus. I was discharged home at approximately 1145 with a mild to moderate headache and generalized fatigue.

metallic taste, tongue tingling and numbness began within minutes and numbness took the longest to resolve--hours

patient received a dose of Moderna vaccine after receiving the Pfizer vaccine.

1037 Pt c/o dyspnea, metal taste in mouth and dizziness; 50 mg Benadryl given.. 1039 vs 160/112, HR 123; rr 20; spo2 98 - pt reports metal taste gone. 1044 VS 148/107; hr 94; rr 20; sp02 96; 1052 vs 162/106, 90 sp02 97 - pt said he felt fine and wanted to drive home. no further reports of any s/s first reported.

Started with nausea and racing heart rate on 12/21/20 then lymph node under left arm became swollen, warm and tender on 12/23/20 and continued through 12/28/20

I started on Sunday 12/27/20 with chills, body aches, headache (that was all over) reaction on my arm, felt like my arm was the size of baseball. I figured it was all from the shot because I, myself work in the health field so I knew these were all reactions. However, as the day went along the worse I got to feeling. I kept taking Tylenol (only thing I can take because of not having a spleen and having a bleeding disorder) and my headache would not go away. So, then at midnight I ended up checking my temperature and it was 100.4. As the night went on I still wasn't able to get rid of my headache and I had even started adding Benadryl along with my Tylenol and still wasn't able to get rid of it. I ended up talking to my Hematologist and she had recommended me to go to the ED to be checked out.

Chills and temp of 101

Pfizer-BioNTech COVID-19 Vaccine EUA About 3.5 hours after vaccine was administered pimple like rash appeared on right hand and wrist. Slight itch associated with rash. Rash still present on second day after administration.

"Patient felt a migraine aura that started about 8-10 min post-vaccination. She was experiencing pain around her left eye and some vision disturbance although no nausea which she stated she usually has. Patient was still at clinic waiting since it had not been past her 15 min time yet. We gave her some tylenol and had her move to a room that was a little darker and quieter and kept her for another 30 min (45 min total). Patient said she still felt like it was the ""beginning of a migraine"" and not feeling well. We called someone to come drive her home and sent her home for the rest of the day."

"12/29/20- Spoke to CG. Received Pfizer COVID-19 vaccine, dose #1 on 12/23/20 @ 4pm. Stayed in Observation area for 15 minutes without any problem. Suddenly, on 12/26/20 (3 days after receiving the COVIID vaccine), CG felt ""itching to throat, gum, mouth and body; itching head to toe"", also noticed ""lip, mouth swelling"" as well as ""wheezing"". Stated she has history of ""asthma"". CG then self-medicated with ""Claritin and Albuterol inhaler"" without much improvement on 12/26/20. Then the next day, on 12/27/20, itching to throat and mouth is resolving but still had shortness of breath and itching body. On 12/28/20, CG came to work but still experienced itching body and ""hard to breath"" when wearing surgical mask (required at work). CG was sent home and saw primary care physician (PCP) via virtual visit. Per PCP's evaluation, CG has had ""delayed allergic reaction"" to COVID-19 vaccine. PCP recommended CG to continue with Benadryl and Albuterol inhaler until recheck on January 4 for re-evaluation and discussion on preparation of 2nd dose with steroid and EpiPen. CG would like to complete the vaccination series to receive 2nd dose. As of today, 12/29/20- CG stated she still has shortness of breath and itching and will be off work until re-evaluation by PMD on Jan 4, 2021. Reviewed CG?s consent form of COVID-19 Vaccine- Date received 12/23/20 @3:37pm. Answer of NO to question ?Do you have a history of severe allergic reaction (e.g. anaphylaxis) to another vaccine or injectable medication??"

Fatigue Headaches Muscle pain Joint pain Fever Soreness at injection site

throat discomfort/ irritation

Arm soreness, same day Fever and chills, same day and 1 day after Fatigue, same day and 1 day after

Sore arm at injection site, about 6 hours after injection, ongoing Next morning stiff neck on left side, about 19 hours after injection, ongoing Swollen lymph node in neck area, collar bone, left side about 21 hours after injection, ongoing Tiredness, off and on, about 7 hours after injection, sporadically ongoing

Hot flushes with rash to chest

headache, 100.0 temperature

I got the shot at 115PM I waited and within a couple of mins I tasted metal on the left side of my tongue. the back of my tongue and my left cheek started to go numb and I was taken to the ER, my vitals were taken and was normal and was monitored for a couple hours, triptase was taken and they did bloodwork, the numbness climbed to the left side of my face from my eye to my jaw, they gave me antihistemines for the next 48 hours and was sent home. Saturday morning I went to the gym and felt fine and 24 hours later I felt complete fatigue like I had been hit by a bus, Sunday I had congestion and still numbness on my face. On Monday I got a call from an allergist, they couldn't figure out if it was an allergic or adverse reaction. I was put on a high dose of Allegra to see what it could be. Tuesday the congestion went into my lungs and was out of breath and was having trouble breathing. My PCM called me and asked me to video call and said I looked terrible. my pulse oximeter was 99. Wednesday when I woke up my difficulty breathing was starting to get better. I was tested for covid twice on Wednesday and both were negative. Wednesday to 12/28 I continued to have serious fatigue and I'm very active I feel much better 12/28 and 12/29 I feel better but I've had the numbness on my left side of my face this whole time and it feels like I've had Novocain I can't get rid of it.

PATIENT received the covid vaccine on 12/28/2020. He had two episodes of nausea and vomiting at 2 pm and at 3:30 pm on 12/28/2020 (about 3 hours after vaccination). Nausea and vomiting have resolved. Has bodyaches today. Denies fever, chills, cough, sore throat or HA.

SHORTLY FOLLOWING THE VACCINATION, PATIENT COMPLAINED OF ITCHING, REDNESS ON HER FACE, SCALP AND MOUTH. LEGS AND TORSO ITCHING ALSO.

Patient rec'd first dose of the Pfizer Covid-19 vaccine. About 5 minutes after she reported a hot peppery taste and her tongue felt hot. No other reported symptoms. Had the patient sit in observation for a total of 45 minutes with no worsening or new symptoms. Called patient 2 hours after event and symptoms have resolved.

Client reported dry mouth occasional cough and feeling warm after. Water provided leg elevation cool compress to neck reports feeling much better

sore throat, cough

2 minutes after she received the vaccine, she felt numbness at injection site that radiated across her chest and down her right arm. She was sent to the ED, no treatment needed and symptoms had resolved prior to her leaving the ED.

First day of vaccine, I had a really sore arm. Next day after vaccine, felt very fatigued that continued for 3 days. On 3rd day after vaccine, developed mild cold symptoms/sinus congestion. Day 5 after vaccine, lost taste and smell and tested positive for COVID-19.

1st day - muscle tenderness in injection site. 2nd day - around 11am headache, fatigue, chills, joint pain

Patient was nauseated and warm Ice pack to neck Denies further symptoms

Anxiety, arm soreness and chills

No adverse event. The vaccine was given 22 hours after the vial was punctured. The event was discovered three days later which was a Sunday at 10pm at night. The patient was notified the next day (12-28-20). The patient reported no side effects and was feeling felt great.

Took Benadryl at home before arriving at shot clinic - began to feel tightness & burning sensation in throat shortly after injection - taken to ER for observation and was administered prednisone

Extreme fatigue, fever, chills, headache, body aches and pain at injection site. I know they are all listed I just didn?t know if I needed to report them

headache, chills 100.0 temperature

"Patient was monitored for >15 minutes after vaccination. Patient told a nurse that her knees felt weak. Patient then fainted and was laying on the floor when i arrived. Patient reported she felt like she was ""floating"" and she did not want to ""fall"". She was also nausea and wanted to vomit and did not end up vomiting anything up. Patient fainted several more times. Her BP was around 143/80 and unsure about the pulse. Patient then become unresponsive for 20-30 seconds."

1:00 am to 5:00am the night after vaccine in morning. Chills and shivering severely. Body ache. Headache. No fever. Chills subsided. Mild Headache only symptom for remainder of day.

Moderna COVID-19 Vaccine EUA Approximately 16 hours after receiving the vaccine (8 AM), I was woken to hot flashes, sweating, and fever-like symptoms. My arm was also very sore and slightly bruising had occurred. My temperature at this point was 99 degrees. After taking Tylenol at 4 AM for arm soreness and Motrin at 8 AM, symptoms of aching and soreness subsided. At 2 PM I had not had medicine since 8 AM and symptoms resumed. My temperature was 100 degrees and I experienced chills and body aches. It is currently 6 PM and symptoms have mostly subsided, however, my arm is still sore and I feel faint fatigue and soreness all over.

Developed 2 hive like welts on chest that I thought might be bug bites because they were very painful itchy and swollen with fluid in them. After a few days more of them developed until there were about 22 on my legs, arms and chest. Very painful and inflamed and itchy. They are as painful as shingles but there are none on the midline or abdomen. I saw physician and he determined it was a reaction to the vaccine. I have never had a reaction to a vaccine before nor have I ever had welts as painful or like these. He prescribed prednisone which I am taking now. I have only finished one day of oral prednisone

and the swelling on the site have started to improve but I still have pain itching and have 3 new ones that have come up. One on the lateral breast and the other two on the anterior breast (superior).

headache, chills, temp 100.7

headache, chills, temp 100.7

Within 1-2 minutes: left hand felt numb and my body became very warm. Within 5-10 minutes: a huge headache. Within 30 to 45 minutes: Blood Pressure fluctuated, headache became worse, and chills started to occur. Within 1 hour to 1.5 hours: the headache became a huge migraine and my head felt like a bowling ball (I was still at work at this time.) Eventually, I could not lift my head off the desk. About 2 hours to 2.5 hours later, I felt so bad that I could not continue to work and head to leave work and go home. Upon arrival at home, the chills, aches, pains, migraine, some fever, eyes could barely stay open, and diarrhea started. About 7 hours later, a full blown Lupus flareup seemed to have started and/or it seemed to feel like a full blown case of the flu (if that makes any sense at all.) By the time I wrote this, all the symptoms have remained the same. I have had chicken soup, Gatorade, and bananas and treating this like the flu. I have continued to take my medication except for the Prednisone because I was told not to take the prednisone at the time that I was given the COVID19 shot at 9am this morning. I have stayed at home since I arrived at home around 1:30 or so...

Headache, body aches, chills, nausea and vomiting. Tool Ibuprofen at start of symptoms, and an additional dose later in the day.

Approximately 10 minutes after administration of vaccine, patient reports having dry mouth and some tightness and closure of esophagus (similar to what happens when patient eats shell fish), but not as severe. Patient was offered Benadryl, but declined. Patient drank some water to help relieve dry mouth. Blood pressure @4:30pm was 136/84. At approximately 35 minutes after symptoms started, patient reports being able to produce a little more saliva. Blood pressure @4:55pm was 118/87. Clinically stable. Symptoms are not progressing.

Individual began feeling dizzy and reported feeling painful sensation in her neck within approximately 5 minutes after receiving the vaccine. She was tachycardic in the 120s. She was encouraged to take deep breaths, offered water, and given 50 mg Benadryl IM in the right deltoid. After several minutes post Benadryl administration, her symptoms resolved. She was taken home by a family member.

Approximately 7 minutes after administration of vaccine, patient reports having tingling sensation on head and face. Symptoms lasted for approximately 10 minutes. Blood pressure @4:34pm was 140/87, HR=71. Blood pressure @16:52 was 150/73, HR=105. At 5:10pm, patient clinically stable. Symptoms have completely resolved. Patient released from vaccination clinic at 5:14pm.

headache

Vaccine administered at 7AM on 12/26/20. 12:00 noon, 101 fever, chills, joint and muscle aches same day. Took Ibuprofen to reduce fever, temp down to 99 by 6PM 12/26/20. Next day, 12/27/20, at 5AM temp back up to 101. Took Ibuprofen again and fever was gone by 5PM. Muscle aches and fatigue

continued through 12/28/20. 12/29/20 woke up feeling like I have a minor cold with some congestion. No fever as of 3:20PM on 12/29/20

During the observation time after receiving the vaccine, the employee report that her ears were read and warm. Employee noted to be squeezing her ears at time of concern. Employee evaluated by RN staff, no swelling, SOB or difficulty swallowing noted. Employee then reported onset of itching to her neck and ears. Employee was escorted to the Emergency Room for evaluation. Per ED physician note: 46 yo F c/o R ear redness, swelling and generalized itching. sudden onset just PTA. pt had COVID-19 vaccine approx 20 min ago. denies throat/tongue tingling/swelling or SOB. O2 sat = 100%, no acute distress, lungs clear, respirations non-labored, breath sounds equal, speaking in full sentences, no pharyngeal erythema or exudate.. Treated with diphenhydramine 50mg IV, famotidine 40mgIV, methylprednisolone 125mg IV and NS 1000 ml x 1.

patient experienced dizziness, lightheadedness approx 20 minutes after dosing. VS WNL BP 100/70, HR 80. Pt sat and drank water and put ice on her neck for approx 30 mintues

After administration of vaccine at 1:00 pm, I looked up and saw patient had fainted in chair, that time was maybe around 1:01 pm. When I rushed over to her, she regained consciousness, noticed she was not able to speak well, nurses removed her mask and we noticed her lips were swollen and was having an anaphylactic reaction, I then administered one dose of Epi-pen at 1:04 pm and called 911. We took her BP but it was high due to the Epipen injection, we tested her blood sugar. When the EMT arrived, they took over and took her to the ER.

Hives on neck takes Benadryl and refused to be seen

Loss of taste that evening only, some dizziness at time of vaccination - fatigue, muscle aches, nausea and declined in appetite. Symptoms have cont as of time of generating this report 12/29/2020 but has lessened in severity each day.

DAY ONE 12/22/2020- SORE INJECTION SITE, DAY 2 TOTAL BODY ACHES ON 12/23/20, FELT FINE ON 12/24/2020, 12/27/20 SWOLLEN LYMPH NODES AROUND THE CLAVICAL AREA WITH SORENESS IN THE INJECTION SITE, NUMBNESS AND TINGLING TO THE EXTREMITIES.

received injection at 13:04, went to observation area. reported brief dizzy spell at 13:20. Drank water, BP right arm 184/101, BP left arm 166/90 at 13:25. Patient reported only brief episode of dizziness and no further dizziness. User reports they ate lunch 1.5 hours earlier. BP 173/90 at 13:30. User reports she feels fine and will recheck BP when she gets home and follow up with her PCP. User waited 5 additional minutes before leaving with no further adverse effects. Total time of observation post injection was 30 minutes.

About 15 hours after the injection I developed sudden onset of chills, headache, nausea, dizziness and low back pain. The site of the injection was also throbbing. I had no side effects prior to this. It was severe enough that I had to call off of work. Symptoms resolved about 6 hours later. I have had no further symptoms since that time.

Fever 102.1 Chills Muscle aches Cough Headache

Fever, coughing, tachypnea, tachycardia

Right after vaccine, felt like she was freezing. Got home from work, took Tylenol felt achy, went to bed, woke up about 11:00 pm shivering really bad, breathing heavily, temp was 102.3, took more Tylenol. Up all night off and on with body aches, headaches, chills and fever. Felt the same way as when she had COVID.

Frontal headache, shivers, body aches, fever to 101.6F.

Received vaccine at 13 15. At 1351 c/o mild chest pain. 1353 c/o throat fullness and anxiety; 1354 bp 148/81 HR 99 O2 sat 100% c/o difficulty swallowing, SOB and itching. Rapid response called. Benadryl 50 mg IVP given at 1355. 1356 Solumedrol 125mg given IV; 1357 Epinephrine given; 1358 Pepcid 20 mg given. 1400 Normal saline 250 mg IV; 1415 transported by ambulance to local ER. In waiting area in local ER no attention. Came back to Hospital and admitted to observation

Developed skin reaction (hives). Treated with 25 mg of Diphenhydramine orally and observed for additional 30 minutes. Hives subsided and patient released.

developed headache, body aches and fever - has since resolved

headache/chills/weakness

Patient reported that immediately after receiving the vaccine she felt lightheaded, dizzy, like she might pass out. She felt as though her throat was more swollen and she had difficulty swallowing. She had no hives, shortness of breath, or difficulty breathing. No myalgias, sore throat, cough, or wheezing.

Facial/ arm numbness and tingling

Soon after IM vaccine c/o sore & swollen arm for 2 days. Also felt weak, shaky and tired for those 2 days

About 4 hours after injection, pain at injection site started. 5 hours after injection, fatigue, body aches, and fever and chills occurred. Symptoms subsided for several hours until night time. Severe nausea occurred sometime around 1:30 am, a little 12 hours after injection. Vomiting happened at 5am. The entire next day after injection I experienced nausea, fatigue, sore throat, headache and fever.

High fever to 102 with uncontrollable shivering and chills beginning apx 12 hours after injection, improved with ibuprofen but not resolved, fever continued x 16 hours

18 min after injection. Throarlt began tonitch and feel tight, chest pressure. Light headed. Epi 0.3 given, sent to er, provided with solumedrol, benadryl, pepcid, ativan and 1750 cc of fluid. Released from hospital at 330.

- arm tenderness. Initially felt like routine flu vaccine. After 12 hours, arm started to increase in tenderness, more similar to other vaccines such as TdaP or tetanus. Gradually resolved at 72 hours. - Mild malaise developed at 24 hour mark (1st day post injection). Checked temperature at 28 hour post

injection with 1 degree Fahrenheit higher than normal forehead temperature using Exergen thermometer. Subtle myalgia during the evening. Symptoms resolved after sleeping, which should be at 40 hours after injection. Slightly less than normal physical stamina between 40-50 hours post injection (2nd day post injection). Symptoms have completely resolved after the second night sleep (66 hours post injection or 3rd day post injection). Injection was on Saturday 2:00pm. Completely symptom free on Tuesday.

Next day after the vaccination, the patient(staff member) came back to the vaccination clinic and stated that she felt numbness and tingling along the smile lines of her face and around her lips. She was monitored for about 40 minutes then she reported difficulty of swallowing. At first reported symptom of swallowing difficulty she as administered diphenhydramine 50 mg oral liquid by mouth. After about 30 minutes of continued monitoring, epinephrine 0.3 mg IM was administered. At the same time 911 emergency response was called and the patient was transferred to the acute care hospital.

Four hours later after received vaccination he complaints of tingling sensation in both cheeck with associated edema and redness. Treated with Solumedrol 125 mg IV and Benadryl 50 mg IV. Patient improved and was discharge with instruction .

Sustained slight but rapid muscle twitching in the deltoid muscle of the injection (left) arm. Noticable the afternoon of post injection day #1. Twitching continued for approximately 1 hour then ceased. No other side effects reported other than minimal arm soreness that didn't interfere with daily activity

Received dose @ 1445; 1458 had a cough and itchy throat and flushed; Bp 162/103 HR 86 Sat 99%; At 1459 gave IV push solumedrol 125 mg; 1510 bp 150/93 hr 80; sat 99%; feeling better

Hives on neck, face, upper chest, and back. Increased heart rate. Metal taste in mouth. Zyrtec given and monitoring Relief after about an hour

Onset of herpes zoster (shingles) - right anterior thigh

Moderna COVID- 19 Vaccine: During observation period after receiving the vaccination patient reported headache, nausea, and dizziness. Vital signs: blood pressure: 111/73 mmHg, pulse: 56 beats per minute, oxygen saturation 100%. Patient reports that she is typically hypotensive and does become nauseous somewhat frequently. Patient offered water and snacks. No loss of consciousness or respiratory symptoms reported. Patient observed for at least 30 minutes and left vaccine clinic in stable condition.

fever 102

nauseated; sensitivity to light; sweaty; hypertensive; tachycardic.

Received vaccine on 12/22/20, on 12/25/20 noticed redness, hives, and itching on the left arm where received vaccine. Took Benadryl on 12/25/20 and 12/26/20. Reported on 12/29/20, and feels itching with some redness subsiding, no pain.

12/24 EVENING c/o being so cold causing shivering. Not normal for pt. Also arm pit area swelling for a bit. All symptoms resolved on 12/25/20.

Morning of day after vaccination had headache, fever, chills, joint pain, muscle aches. 2 days after vaccination same symptoms also diarrhea and positive COVID-19 test.

Moderna COVID - 19 VACCINE Sorearm in left arm Chills Severe headaches Nausea and vomiting

flushed and nauseous and anxious and dry cough; dizzy; hypotensive

METALLIC TASTE IN MOUTH ABOUT 10 MINUTES AFTER VACCINE. NO OTHER SX.

Feeling dizzy and light headed 30 mins after injection. One hour later felt nausea and dizzy. BP 177/73, and 156/70-72 w/ repeat. Symptoms improved with Tums.

fever 103'

"Patient received the covid vaccine on 12/22/2020. No problem with the vaccination. Reported new onset of ""dry cough"" and nasal congestion started on 12/29/2020. Denies fever, chills, HA, body aches, or fatigue. Last covid test on 12/17/2020 was negative."

Complains of left arm swelling and pain. She had the COVID-19 vaccine on December 23. The next day she had some mild pain at the injection site. She massaged it and use Tylenol. On December 24 he developed pain down all of her left arm. On the 25th she had complete loss of sensation and feeling in her left hand for about 3 hours. Then the arm seemed to tingle and feeling came back. That night she developed pain down in her wrist. Complains of some swelling in the left forearm. That area is burning and throbbing. Pain is affecting her sleep. She has tenderness to palpation on her wrist area. She also has pain with with wrist movements. . .

Pain in area of inyection (left arm), mild rash in chest area

Approximately 5-7 minutes after receiving vaccine, I experienced a rapid increase in heart rate along with a head rush. I then was shaky and lightheaded and was told extremely pale. I then noticed the back of my tongue was slightly swollen and I had a tightness/itchy feeling so n my throat. My pulse was checked at 120bpm, Approximately 10 minutes later my lips were tingling and numb. I was given Benadryl and prednisone. 1.5 hours later since my symptoms did not go away I was escorted to the ER for epinephrine.

12/28 Difficulty falling asleep, Awake in middle of night w/ achiness - couldn't get comfortable. This morning c/o headache, feeling exhausted and weak.

staff member received his first injection in the left arm. As staff was waiting for his time of observation, he stated he could feel his blood pressure rising. When assessed, his blood pressure was 196/119. Staff member stated to the MD he takes medications for hypertension but was unable to state what that medication was. He says he just takes what he was given. Staff member stated he was having a hard time breathing due to his blood pressure and was given supplemental oxygen at 3L per nasal cannula.

O2 was 98% throughout. 911 was called to assist staff member to ED for evaluation of symptoms. While taking staff member to meet the ambulance, via wheelchair, he stated he believes he forgot to take his medication for the day. Ambulance took staff to ED with no noted complications.

Immediately after receiving the dose, I developed lightheadedness, nausea, sweating. This worsened for 15 minutes, then slowly subsided over several hours. The next day, I was a little fatigued, but returned to baseline by the evening. On the 2nd day after vaccination, I developed uncontrollable violent rigors and PACs, along with fatigue and vertigo. These symptoms improved on days 3-5 after the vaccine, but returned on day 9 with worsening rigors and PACs. I also developed substernal chest pain on day 5. Now, day 9 post vaccination, and I'm feeling unwell. Main symptoms are chest pain, PACs, intermittent rigors, vertigo.

Pfizer-BioNTech COVID 19 Vaccine Starting at 20-minutes post vaccination and lasting for approximately two hours, patient experienced episodic tachycardia (HR 123-200), flushing of face and arms, and tingling sensation in upper body lasting up to 5-minutes per episode. Episodes were 20 minutes apart and decreasing in severity. Patient medicated after second episode with 25mg/Benadryl, 40mg/prednisone, and 20mg/pepcid. Side effects resolved within 40 minutes of medicating.

Pfizer-BioNTech COVID-19 Vaccine: Soon after vaccine administration patient reported dizziness, trouble swallowing, paresthesias in both hands, shortness of breath, anxiety, and one episode of vomiting. Patient was transferred to the emergency department where initial vital signs were: blood pressure 161/84 mmHg, pulse 97 beats per minute, temperature 36.9 degrees Celcius, respiratory rate 16 breaths per minute, and oxygen saturation 98%. The patient presented alert and oriented in no acute distress. On exam no rash, edema of the uvula or tongue, respiratory distress, wheezing, rhonchi, or rales were noted. Patient was administered one dose each of lorazepam and ondansetron and was discharged.

I previously had covid the first 2 weeks of november** Symptoms of adverse reaction included: -severe pain and limited movement of injection site - large amount of redness and swelling at injection site - fever of 101.2 - body aches and chills - headache

drooping OF LEFT EYE, twitching, weeping of left eye. Upper eyelid of left eye puffy and red. Chest tightness

"""Pfizer-BioNTech COVID-19 Vaccine"": left-sided facial bell's palsy; facial drooping mostly resolved, minimal eye drooping on left side; headache; Tylenol taken for headache; headache has resolved;left-sided sensitivity to loud noises; hearing sensitivity resolved"

Mild headache, significant fatigue, runny nose

Severe headache, nausea almost to vomiting, body aches, injection site inflamation/pain,

itching (full body), sore throat, L ear pain

Diarrhea

physician/patient with history of anaphylaxis to shellfish - symptoms of tingling tongue & syncope. no longer carries epi pen sue to ability to avoid food. 10 minutes post vaccination pt/physician experienced tongue tingling similar to prior anaphylactic events. administered 25 mg. Benadryl po. no further issue, vital signs stable throughout & later in evening.

chest tightness, tongue tingling, tachycardia, hives on left arm

Unilateral facial numbness, tingling, and swelling

"Metallic taste in mouth, dizziness, weakness, altered mental status, difficulty raising arms, ""heavy like a slug"", HR 81, BP 112/78. reaction immediately after vaccination. Symptoms did not resolve after an hour. Patient taken to ER for evaluation."

rash, dizziness, neck pain, hypertension, vomiting, mydriasis, diaphoresis: neck pain started within 10 mins, while other symptoms proceeded after about 20-30 mins.

Temporary Numbness of facial muscles

Days 1-4 - low grade fever (100.8) swollen lymph nodes and extreme sore throat and lethargic. Day 5 no fever but swollen lymph nodes and sore throat. Day 6 congestion, no taste or smell.

10 MINUTES FOLLOWING VACCINE - SOB, COUGH, TIGHTNESS IN CHEST, THRAOT SWELLING, DIFFICULTY SWALLOWING, LIGHT HEADEDNESS, AND ELEVATED HEART RATE. ORAL AND IM BENADRYL ADMINISTERED, 2 DOSE OF EPINEPHRINE, 2 NEB TREATMENTS, O2 PLACED. 911 CALLED AND TRANSPORTED TO EMERGENCY FOR FURTHER TREATMENT AND MONITORING. AT HOSPITAL IV STEROID ADMINISTERED. SYMPTOMS SUBSIDED WITH SECOND DOSE OF EPINEPHRINE, HOWEVER RETURNED 3 HOURS LATER AND ANOTHER DOSE OF BENADRYL ADMINISTERED. ELEVATED HEART RATE CONTINUED AND IV FLUIDS ADMINISTERED TO ATTEMPT IN BRINGING DOWN HEART RATE. IV FLUIDS WERE NOT EFFECTIVE. HEART RATE (118-120) REMAINED ELEVATED INTO THE OVERNIGHT HOURS AND SUBSIDED AROUND 1:30A ON 12/29/2020. CONTINUED HEADACHE, NAUSEA ONSET, FATIGUE, DIFFICULTY SWALLOWING AND COUGH ON 12/29/2020.

Shingles outbreak mostly lesser occipital nerve distribution

Got shot on Tuesday. On Sunday night had cough and congestion and little fever. Going to do COVID testing this morning. Is feeling better today.

I received my Moderna vaccine 12/28/2020. First symptom began that day with pain, soreness of injection site. Later throughout the day I began to have chills, and body aches. I had a sleepless night. The following morning 12/29/2020, I still felt chills, body. Then, I felt nausea, and headache. I slept most of the day today since I felt fatigue too, but it's better than going through Covid .

Face turned red,sweating,cold clammy skin, throat constricted

Atrial fibrillation

The morning after getting vaccine, patient had high BP 213/159, 92% on room air, shaking, chills, LCTAB with diminishment at bases, emesis. Admitted to hospital for pneumonia.

Muscle tightness to bilat shoulders and neck. Tension headache. Rash across shoulders and chest.

Sore arm, body aches, mild fevers for 48 hours

Bad Headache, nausea, extreme body aches

Pt had felt little tingling effect in mouth and mentioned about having an allergy shot today.

Hives from Head to toes. Swollen ears, slight lip swollen, fever 101

12/23/2020 developed left ear pain and next day experienced drooping of left side of face, difficulty blinking left eye Bells Palsy

Chills, fever, fatigue, headache

Vaccine administered with no immediate adverse reaction at 11:29am. Vaccine screening questions were completed and resident was not feeling sick and temperature was 98F. At approximately 1:30pm the resident passed away.

Injection site pain 4-36 hours after dose. Headache 12-36 hours after dose. Joint pain 12-36 hours after dose. Fatigue 12-36 hours after dose. Chest tickle 24-36 hours after dose. Tooth ache 4-36 hours after dose.

His wife ended up contracting Alpha-Gal by Ticks; This is a spontaneous report from a Pfizer-sponsored program Pfizer First Connect via contactable consumers (patient's husband, and patient herself). A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient medical history and concomitant medications were not reported. The patient ended up contracting alpha-gal by ticks on an unspecified date. The reporter asked about the ingredients of the COVID-19 vaccine, if it contains mammalian cells, dairy, guinea pig 1 cell, or cholesterol origin. Outcome of the event was unknown. Information on the lot/batch number has been requested.

near syncope episode, orthostatic; feels a little foggy; This is a spontaneous report from a contactable Physician. A 38-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), via an unspecified route of administration on unspecified date in 2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The emergency medicine physician was monitoring a patient that came in from a vaccination event, stated that it was Pfizer BioNTech Covid 19 vaccine. The patient had a near syncopal episode. They did orthostatics (unspecified) and found that she was orthostatic (near syncope episode, orthostatic). There was no anaphylaxis reaction or allergic reaction. She still felt a little foggy. The physician did a blood glucose, labwork and EKG that look good. The physician wanted to know if there was any data for things that they should looking for with the vaccination and will direct the patient to

contact Pfizer to report it. The outcome of the events was unknown. Information on the lot/batch number has been requested.

Sore arm; Dizziness; Tiredness; nausea; fever of 102¦F; severe headache; This is a spontaneous report from a contactable consumer (patient). A 20-year-old female patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899, expiration date unknown) intramuscular at the left arm on 18Dec2020 at a single dose for COVID-19 immunization in the hospital. Medical history included allergy to Sulfa from an unknown date. Concomitant medications included escitalopram and clonazepam. The patient did not receive any other vaccines within 4 weeks prior to the vaccine. It was unknown if the patient was diagnosed with COVID-19 prior to vaccination. The patient experienced sore arm after first 8 hours; dizziness, tiredness, nausea, fever of 102 F and severe headache all on an unspecified date in Dec2020 (reported as 12Dec2020 at 01:15 AM). The patient was tested for COVID post vaccination and had a nasal swab with negative results. The patient recovered from sore arm, dizziness, tiredness, nausea, fever of 102 F and severe headache all on an unspecified date in Dec2020.

Fever of 101.0; sore throat; light headedness; aches; chills; excessive sweating; nasal congestion; This is a spontaneous report from a contactable healthcare professional. A 32-year-old female patient received BNT162B2 (lot number and expiry date unknown) at a hospital, at age 32-year-old, intramuscular, on the left arm on 21Dec2020 19:45, at single dose (dose 1), for COVID-19 immunization. Medical history included anemia, anxiety, and urticaria. Patient was also diagnosed with COVID-19 prior to vaccination. Patient is not pregnant at the time of vaccination. Patient did not receive any other vaccines within 4 weeks prior to the COVID-19 vaccine. Concomitant medication included ethinylestradiol, norgestimate (ORTHO TRI-CYCLEN), lorazepam (ATIVAN), clonazepam (KLONOPIN), and diphenhydramine hydrochloride (BENADRYL) from unspecified dates. The patient previously took hydrocodone/acetaminophen (VICODIN), oxycodone / paracetamol (PERCOCET), pseudoephedrine hydrochloride (SUDAFED) on unspecified dates and had known allergies. On 21Dec2020 at 23:00 , the patient experienced fever of 101.0, sore throat, light headedness, aches, chills, excessive sweating and nasal congestion. No treatment was received for the events. Since the vaccination, has the patient has not been tested for COVID-19. The outcome of the events was recovering. Case is reported as non-serious. Information on the lot/batch number has been requested.

hives and sore throat the day after receiving COVID19 Vaccine; hives and sore throat the day after receiving COVID19 Vaccine; This is a spontaneous report from a contactable Nurse. A 46-year-old female patient started to receive BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Lot number: EL0140, Expiry Date: 31Mar2021), intramuscular (injection left deltoid) on 18Dec2020 (around 1621) at single dose for COVID-19 immunization. The patient medical history and concomitant medications were not reported. The patient has no prior vaccinations. The patient experienced hives/ She had body hives all over and sore throat the day after receiving COVID19 vaccine on 19Dec2020, within 24 hours. The patient took BENADRYL and was fine. Reporter was not sure if the patient would receive the second dose. The adverse event did not require a visit to the emergency room nor physician office. Outcome of the event was recovered on 19Dec2020.

headache; fever/as high as 102.9 degrees Fahrenheit, now (22Dec2020) it's just over 100.0 degrees Fahrenheit; This is a spontaneous report from a contactable nurse. A 31-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), lot number: EK5730, via an unspecified route of administration, at the right arm, from 17Dec2020 18:30 at a single dose for covid-19 immunization. Medical history included attention deficit hyperactivity disorder (ADHD), osteoarthritis (OA); patient already suffer joint pain and her current joint pain is no worse than usual, Raynaud's, palpitations and joint pain. Concomitant medications included amfetamine aspartate monohydrate, amfetamine sulfate, dexamfetamine saccharate, dexamfetamine sulfate (MYDAYIS); amfetamine aspartate, amfetamine sulfate, dexamfetamine saccharate, dexamfetamine sulfate (ADDERALL); and ibuprofen (IBUPRO). It was reported that the patient has had fever daily. Initially on 18Dec2020 at 9:00, it was as high as 102.9 degrees Fahrenheit, now (22Dec2020) it's just over 100.0 degrees Fahrenheit. She also has had a headache daily(reported as started on 18Dec2020 at 9:00), but today's headache is much worse than previous days. The patient underwent lab tests and procedures on 18Dec2020 which included sars-cov-2 test/COVID-19 test/nasal swab with negative result. Outcome of events was reported as not recovered. Therapeutic measures were taken as a result of events headache and fever included OTC medications (unspecified). Follow-up attempts are completed. The information on the batch/lot number was obtained.

Chills; joint pain; muscle pain; This is a spontaneous report from a contactable other healthcare professional (patient). A 21-year-old female patient (not pregnant) received first dose BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899), intramuscular (Left arm) on 22Dec2020 09:30 at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient was not diagnosed with COVID-19 prior to vaccination. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. There were no other medications received within 2 weeks of vaccination. The patient experienced chills, joint pain, and muscle pain on 22Dec2020 (19:00). There was no treatment received for the adverse event. The patient has not been tested for COVID-19 since the vaccination. The outcome of events was recovering. This case is non-serious.

Fever; chills; body aches; headaches; malaise; chest pain in side-lying; cough; diminished appetite; This is a spontaneous report from a contactable healthcare professional. A 30-year-old male (also reported as female) patient received the first dose of BNT162B2 (Pfizer-BIONTECH Covid-19 Vaccine; Lot number: EH9899), intramuscular in the left arm on 17Dec2020 at 15:45 at a single dose for immunization. The patient had no relevant medical history. The patient din not have Covid prior to the vaccination and had no known allergies to medications, food, or other products. The patient's concomitant medications were not reported. It was reported that the patient had no other medications in two weeks and did not receive any other vaccines within four weeks prior to the COVID-19 vaccine. The patient experienced fever, chills, body aches, headaches, malaise, chest pain in side-lying, cough, and diminished appetite starting at 11pm (23:00) on 17Dec2020 and gradually decreasing mild symptoms still present on 22Dec2020. The patient received no treatment for the adverse events and was not tested for COVID-19 after the vaccination. The facility where the most recent COVID-19 vaccine was administered was at the hospital. The outcome of the events was recovering. The case was reported as non-serious (did not

result in death, was not life-threatening, did not cause or require prolonged hospitalization, was not disabling/incapacitating, and did not result to any congenital anomaly/birth defect).

Left arm pain; generalized malaise; i was wiped out and wanted to sleep all day; This is a spontaneous report from a contactable Nurse. A 52-years-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Lot number: EJ1685), via an unspecified route of administration on 22Dec2020 07:15 at a single dose (dose number 1, left arm) for COVID-19 immunization. Medical history included HIV+ and COVID-19 from an unspecified date. Concomitant medication included bupropion hydrochloride (WELLBUTRIN), trazodone, oxazepam (SERAX), valaciclovir hydrochloride (VALTREX), and ibuprofen from an unspecified date for an unspecified indication. The patient has allergies to Tegretol and AZT. The patient was diagnosed with COVID-19 prior to vaccination. The patient had no other vaccine in four weeks. The patient experienced left arm pain, generalized malaise (he was wiped out and wanted to sleep all day) on 22Dec2020 09:00. Treatment was not given. Event outcome was recovering. Since the vaccination, the patient has not been tested for COVID-19. The events were assessed as non-serious.

"vertigo; left facial tingling; lip tingling/tingling in the left corner of the mouth; he feels hazy/Haziness; facial numbness; heaviness and tingling in the left corner of the mouth; This is a spontaneous report from a contactable physician (patient). A 32-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (lot number EL0140), via an unspecified route of administration on 18Dec2020 08:15 am at single dose for covid-19 immunization. Vaccine location was left deltoid and it was the first dose. The facility type vaccine was hospital. Medical history included raynaud from an unknown date. The patient clarified that Raynaud's is not officially diagnosed. When he was in medical school and would take Methylphenidate to study his fingers would get pale and in cold weather he gets it in his hands. No known allergies. Patient didn't do relevant test. There were no concomitant medications. The patient didn't receive any other vaccines within 4 weeks prior to the COVID vaccine. Physician stated that received COVID-19 Vaccine on Friday. A couple of hours later he had left facial tingling and lip tingling that lasted about an hour. The left facial tingling and the lip tingling started between 9AM and 10AM. It felt like facial numbness and heaviness and tingling in the left corner of the mouth. It was less tingling and more of a heaviness. Vertigo started on the second night (19Dec2020). Whenever he sit back in a chair quickly he has vertigo as well as when he laid back in the bed at night. He took no medications. Throughout the day he felt hazy. Haziness that is consistent. The best way to described it is if you drank a lot of alcohol and were well hydrated. The next morning you feel fine, but there is something there and feels off, but you can't put a finger on it. There was no adverse event require a visit to emergency room or physician office. The action taken in response to the events for BNT162B2 was not applicable. The outcome of events ""left facial tingling"" and ""lip tingling"" was recovered on 18Dec2020 and were reported as non-serious. The outcome of event Vertigo was not recovered, it was reported as serious-Medically significant. The outcome of other events was unknown. The drug result of events ""Vertigo"", ""left facial tingling"" and ""lip tingling"" was Related.; Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of event Vertigo cannot be totally excluded. The case will be reassessed if additional information becomes

available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate."

cold tingling sensation in right hand; sore right arm; This is a spontaneous report from a contactable consumer. A 56-years-old female patient receive BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Lot number: EK5730), via an unspecified route of administration on 18Dec2020 at a SINGLE DOSE (injection to right arm one time) for COVID-19 immunization. Medical history included Pencillin allergy, diagnosed with a sulfur allergy in her 20s and developed a rash (ongoing). There were no concomitant medications. The patient experienced cold tingling sensation in right hand in hand in same that had the injection, and sore right arm, few minutes after the injection on 18Dec2020. Treatment for sore right arm included, 24 hours after took ALEVE and did gentle stretching exercises. Event outcome was recovered completely on 18Dec2020. Event outcome was recovered on 18Dec2020.

Head cold; cannot smell or taste anything; cannot smell or taste anything; This is a spontaneous report from a contactable nurse (patient herself, ICU nurse). A female patient of an unspecified age received bnt162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, lot number and expiry date not reported), via an unspecified route of administration on 18Dec2020 at a single dose for COVID-19 immunisation. Medical history and concomitant medications were not reported. After receiving the vaccine on 18Dec2020, she had a head cold, she cannot smell or taste anything. Clinical outcome of the events was unknown. Information about Lot/Batch number has been requested.

hoarseness; throat tightness; flushing; This is a spontaneous report from a contactable consumer. An adult female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, lot number and expiry date not reported), via an unspecified route of administration on 23Dec2020 at a single dose for COVID-19 immunisation. Medical history was none. Concomitant medications were not reported. On 23Dec2020, the patient experienced hoarseness, throat tightness and flushing. Therapeutic measures were taken as a result of the events that included epinephrine, steroid, and Benadryl. Clinical outcome of hoarseness was recovering, while for the other events was unknown. Information on the lot/batch number has been requested.

experiencing tingling sensation in my throat and some tightness; experiencing tingling sensation in my throat and some tightness; This is a spontaneous report from a non-contactable pharmacist. A 41-year-old female patient started to receive BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Lot number: EK5730), via an unspecified route of administration on 22Dec2020 15:30 at SINGLE DOSE (right arm, dose number 1) for COVID-19 immunization. The patient has no medical history. The patient's concomitant medications were not reported. Patient has no known allergies. The patient experienced experiencing tingling sensation in her throat and some tightness on 22Dec2020 15:30, 1 to 2 minutes after vaccine administration. After 10 min symptoms started going away and completely disappeared in 30 minutes. Patient did not had other vaccine in four weeks nor other medications in two weeks. Patient has no prior COVID vaccination and was not tested for COVID post vaccination. Patient is not pregnant.

Treatment was not received. Outcome of the event was recovered on 22Dec2020 16:00. Events were reported as non-serious. No follow-up attempts are possible. No further information is expected.

Fatigue; This is a spontaneous report from a contactable nurse (patient). A 50-year-old male patient received first BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899), intramuscular (left arm) from 21Dec2020 (09:45 AM) to 21Dec2020 at single dose for COVID-19 immunization. The patient's medical history included hypertension, hyperlipidemia, and Type 2 diabetic. No known allergies. Concomitant medications included amlodipine besilate, olmesartan medoxomil (AZOR), atorvastatin calcium (LIPITOR), metformin, insulin glargine, lixisenatide (SOLIQUA), and empagliflozin (JARDIANCE). The patient was not diagnosed with COVID-19 prior to vaccination. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient experienced fatigue on 22Dec2020 12:00 with outcome of recovering. There was no treatment received for the adverse event. The patient has not been tested for COVID-19 since the vaccination. This case is non-serious.

I have some aches which feels like the same I had; This is a spontaneous report from a contactable Other HCP (patient). This 52-year-old female patient reported that she received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via intramuscular at left arm on 23Dec2020 at 12:45 AM at single dose for COVID-19 immunization. Medical history included patient diagnosed with COVID-19 in Oct2020. No allergies to medications, food, or other products. Concomitant medication was none. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient received no other medications within 2 weeks of vaccination. Since the vaccination, the patient had not been tested for COVID-19. After vaccination, patient had some aches on 24Dec2020 07:00 AM, which felt like the same she had since she did have Covid the first part of Oct2020. It was reported as non-serious. No treatment was received. Outcome of event was unknown. Information about Lot/Batch number has been requested.

severe body aches; chills; fatigue; cervical and left axillary lymphadenopathy; left axillary lymphadenopathy; muscle weakness; This is a spontaneous report from a contactable physician reported for herself. A 48-year-old female patient received first dose of BNT162B2 (Pfizer product), intramuscular on 21Dec2020 10:15 at single dose on left arm for COVID-19 immunization. Medical history included High cholesterol, insomnia, ongoing penicillin allergy, covid-19 from 13Nov2020 to an unknown date and pneumonia from an unknown date (the patient was tested positive for covid on 13Nov2020 and was hospitalized on 23Nov2020 with pneumonia). Concomitant medication included atorvastatin calcium (LIPITOR), zolpidem tartrate (AMBIEN), escitalopram oxalate (LEXAPRO), colecalciferol (VITAMIN D), fish oil (FISH OIL OMEGA 3) , zinc (ZINC), ascorbic acid, dexpanthenol, ergocalciferol, nicotinamide, pyridoxine hydrochloride, retinol, riboflavin, thiamine hydrochloride, tocopheryl acetate (MVI) and bifidobacterium lactis (PROBIOTIC). The patient previously took niacin and experienced drug allergy. The patient received injection at 1015 am at 0300 am on the following day (22Dec2020) she experienced chills, severe body aches, fatigue, cervical and left axillary lymphadenopathy and muscle weakness, woke up the next day and was asymptomatic except the left axillary lymphadenopathy which is still present today on 24Dec2020. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. No covid tested post vaccination. No treatment was received for the events. The outcome of the event left axillary lymphadenopathy was not

resolved while of other events was resolving. The reporter assessed the events as non-serious. Information about lot/batch number has been requested.; Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of event severe body aches cannot be totally excluded. The case will be reassessed if additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

back pains; back spasms; This is a spontaneous report from a contactable physician. A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), via an unspecified route of administration on 21Dec2020 as a single dose for COVID-19 immunization. Medical history and concomitant medications were not reported. It was not reported if the patient was pregnant nor if any other vaccines were received 4 weeks prior to the vaccination. The patient reported that she had the COVID-19 vaccine last Monday (22Dec2020) and was told to stop taking NSAIDS. Now, she is experiencing back pains, so she wants to know when she could restart taking NSAIDs. She doesn't think her back spasms are from the COVID-19 vaccine. The clinical outcome of the back pains and back spasms was not reported. It was also not reported if the patient had been tested for COVID-19. The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up.

Tingling sensation in my fifth digit that radiates up to my arm; This is a spontaneous report from a contactable physician, the patient. This 28-year-old female patient received BNT162B2 (Pfizer-BioNTech COVID-19 mRNA vaccine) (lot number: EK5730), intramuscularly in the left arm on 23Dec2020 at 12:00 (at the age of 28-years-old) as a single dose for COVID-19 vaccination. It was unknown whether the patient received any other vaccine within 4 weeks prior to the vaccine. Medical history included asthma from an unknown date and unknown if ongoing. The patient was not pregnant at the time of vaccination. Prior to the vaccination, the patient was not diagnosed with COVID-19. The patient did not have any allergies to medications, food, or other products. The patient did not receive any other vaccines within four weeks prior to the vaccination. Concomitant medication included escitalopram oxalate (LEXAPRO). On 24Dec2020 at 06:00, the patient experienced tingling sensation in her fifth digit that radiates up to her arm. No therapeutic measures were taken as a result of the events. The clinical outcome of the tingling sensation was not resolved. It was also reported that since the vaccination, the patient had not been tested for COVID-19.

"Small itchy blister/zit like bumps. Started on back of legs and back. Now some sporadically showing up on arms, belly, shin.; Small itchy blister/zit like bumps; This is a spontaneous report from a contactable Other Health Care Professional (HCP). A 48-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, Batch/lot number: EJ1685), intramuscularly at an unspecified dose in the left arm on 18Dec2020 at 04:00 (at the age of 48-years-old) for COVID-19 immunization. Medical history included allergy to sulfa drugs from an unknown date and unknown if ongoing. The patient did not have any allergies to medications, food or other products. Prior to the vaccination, the patient was not diagnosed with COVID-19.The patient was not pregnant at the time of

vaccination.The patient was administered the vaccine in the hospital. Concomitant medication included cetirizine hydrochloride cetirizine hydrochloride (ZYRTEC). The patient did not receive any other vaccines within four weeks prior to vaccination. On 21Dec2020 at 20:15,the patient experienced small itchy blister/zit like bumps which started on back of her legs and on her back. Some are sporadically showing ""now"" up on arms, belly and shin.The patient did not receive any treatment for the events.The clinical outcomes of small itchy blister/zit like bumps was not recovered. It was also reported that since the vaccination the patient had not been tested for COVID-19."

woke up with Chills, body/ joint pain, chest pain with mild difficulty to breath; woke up with Chills, body/ joint pain, chest pain with mild difficulty to breath; woke up with Chills, body/ joint pain, chest pain with mild difficulty to breath; woke up with Chills, body/ joint pain, chest pain with mild difficulty to breath; take smaller breaths because Rib cage hurts every time she took a deep breath; An hour after the vaccine developed a headache; woke up with Chills, body/ joint pain, chest pain with mild difficulty to breath/mild body aches; back also had moderate pain.; This is a spontaneous report from a contactable other healthcare professional (HCP) reporting for herself (patient). A 45-years-old female patient started to the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), lot number unknown, intramuscularly on 22DEC2020 13:45 (at the age of 45-years-old) as a single dose in the left arm for COVID-19 immunization. Medical history included drug allergy to vancomycin. Concomitant medication included nebivolol hydrochloride (BYSTOLIC), duloxetine hydrochloride (CYMBALTA), hydrochlorothiazide, levothyroxine. The patient previously took vancomycin and experienced drug allergy. The most recent COVID-19 vaccine was administered in the hospital. The patient was not pregnant at the time of vaccination. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. An hour after the vaccine the patient developed a headache and mild body aches on 22Dec2020 14:45. Two days after (24Dec2020) she woke up with chills, body/ joint pain, chest pain with mild difficulty to breath. She had to take smaller breaths because her rib cage hurts every time she took a deep breath. Her back also had moderate pain on unspecified date in Dec2020. The events an hour after the vaccine developed a headache, woke up with chills, body/ joint pain, chest pain with mild difficulty to breath/mild body aches, take smaller breaths because rib cage hurts every time she took a deep breath and back also had moderate pain did not result in death, were was not life-threatening, did not cause/prolonged hospitalization, was not disabling/incapacitating and did not cause congenital anomaly/birth defect. No treatment was received for the events an hour after the vaccine developed a headache, woke up with chills, body/ joint pain, chest pain with mild difficulty to breath/mild body aches, take smaller breaths because Rib cage hurts every time she took a deep breath and back also had moderate pain. Outcome of the events an hour after the vaccine developed a headache, woke up with chills, body/ joint pain, chest pain with mild difficulty to breath/mild body aches, take smaller breaths because Rib cage hurts every time she took a deep breath and back also had moderate pain were unknown. After the vaccination, the patient has not been tested for COVID-19. Information on the lot/batch number has been requested.

developed a tingling sensation 45 minutes post vaccination. Came on gradually and increased in sensitivity; Lips also had a tingling sensation similar to a sunburn feeling on lips/But lips Continue to have a weird sensation to lips; This is a spontaneous report from a contactable nurse (patient). A 49-

years-old female patient started to the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), lot number EK5730, intramuscularly on 23Dec2020 16:00 (at the age of 49-years-old) as a single dose in the left arm for COVID-19 immunization. Medical history included hyperactive thyroid for which was treated with radioactive iodine thus makes her hypothyroid. Concomitant medication included levothyroxine sodium (SYNTHROID). The patient previously took hydrocodone/acetaminophen (VICODIN) and experienced drug allergy. The patient did not have allergies to food.The most recent COVID-19 vaccine was administered in the hospital. The patient was not pregnant at the time of vaccination. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. On 23Dec2020 16:45 the patient developed a tingling sensation (45 minutes post vaccination). It came on gradually and increased in sensitivity. Her lips also had a tingling sensation similar to a sunburn feeling on lips. Tingling sensation gradually subsided to body lasted 4 hours. Tingling sensation to lips also gradually decreased 6 hours later but lips continue to have a weird sensation to lips. The events developed a tingling sensation 45 minutes post vaccination. Came on gradually and increased in sensitivity, Lips also had a tingling sensation similar to a sunburn feeling on lips/but lips continue to have a weird sensation to lips did not result in death, was not life-threatening, did not cause/prolonged hospitalization, was not disabling/incapacitating and did not cause congenital anomaly/birth defect. No treatment was received for the events tingling sensation 45 minutes post vaccination. Came on gradually and increased in sensitivity, lips also had a tingling sensation similar to a sunburn feeling on lips/but lips continue to have a weird sensation to lips. Outcome of the event developed a tingling sensation 45 minutes post vaccination. Came on gradually and increased in sensitivity was recovered on 23Dec2020 20:45. Outcome of the event lips also had a tingling sensation similar to a sunburn feeling on lips/but lips continue to have a weird sensation to lips was not recovered. Since the vaccination, the patient has not been tested for COVID-19.

left arm pain at injection site throbbing pain; This is a spontaneous report from a contactable other HCP (healthcare professional) who reported for a patient. A 53-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot #: EJ1685) intramuscularly on 23Dec2020 at 15:45 (at the age of 53-years-old) as a single dose in the left arm for COVID-19 vaccination. Medical history included known allergies to shrimp from an unspecified date and unspecified if ongoing. The patient was not pregnant at the time of vaccination. Prior to the vaccination, the patient was not diagnosed with COVID-19. Concomitant medications were not reported; however, there were no other medications the patient received within 2 weeks of the vaccination. The patient did not receive any other vaccines within four weeks prior to the vaccination. On 23Dec2020 at 20:00, the patient experienced left arm pain at injection site throbbing pain. It was reported that the event was non-serious and did not require hospitalization. The patient did not receive any treatment for the event. The clinical outcome of the event left arm pain at injection site throbbing pain was recovering/resolving. It was also reported that since the vaccination, the patient had not been tested for COVID-19.

Minor rash on chest; This is a spontaneous report from a contactable health professional, the patient. A 20-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration in the left arm on 22Dec2020 at 02:00 or 14:00 as

reported, pending clarification (at the age of 20-years-old) as a single dose for COVID-19 immunization. The patient medical history and concomitant medications were not reported. The patient was not pregnant at the time of vaccination. The patient did not have any allergies to medications, food, or other products. Prior to the vaccination, the patient was not diagnosed with COVID-19. On 24Dec2020 at 08:00 the patient experienced a minor rash on chest. The patient did not receive treatment for the event. Since the vaccination, the patient had not been tested for COVID-19. The clinical outcome of the minor rash on chest was resolving. Information about lot/batch number has been requested.

numbness of the lower left face, cheek and area around the mouth (peri-oral and mandibular numbness); numbness of the lower left face, cheek and area around the mouth (peri-oral and mandibular numbness); This is a spontaneous report from a contactable physician reporting for a patient. A 37-years-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), intramuscularly on 19Dec2020 (at the age of 37-years old) as a single dose for COVID-19 vaccination. The facility where the most recent COVID-19 vaccine was administered was a hospital. Prior to vaccination, the patient had not been diagnosed with COVID-19. The patient's medical history and concomitant medications were not reported. It was unknown if the patient received any other vaccines within 4 weeks prior to the COVID-19 vaccine. On 19Dec2020, the patient experienced numbness of the lower left face, cheek and area around the mouth (peri-oral and mandibular numbness). No treatment was received for the adverse events. The patient was recovering from the events.Since the vaccination, has the patient has not been tested for COVID-19. The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up.

"Ongoing fever spikes starting on Day 5 from 101-103 along with moderate to severe chills; Ongoing fever spikes starting on Day 5 from 101-103 along with moderate to severe chills; diarrhea; excess fatigue; This is a spontaneous report from a contactable physician. A 47-years-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), Lot number EJ1685, via an unspecified route of administration on 16Dec2020 12:30 as a single dose (dose 1) in the left arm for COVID-19 vaccination. The facility where the most recent COVID-19 vaccine was administered was a hospital. Prior to vaccination, the patient was not diagnosed with COVID-19. Medical history included type 2 diabetes mellitus and hyperlipidaemia. There were no allergies to medications, food, or other products. Concomitant medication included metformin, eicosapentaenoic acid ethyl ester (VASCEPA), and losartan. The patient did not receive any other vaccines within 4 weeks prior to COVID-19 vaccine. The patient experienced ongoing fever spikes starting on Day 5 from 101-103 along with moderate to severe chills, diarrhea and excess fatigue. The adverse events' start date & time was reported as 21Dec2020 at 12:30. The events were reported as non-serious. ""Today"" (24Dec2020) was day 8 and none of these symptoms have improved. The patient underwent treatment for the adverse event which included paracetamol (TYLENOL) and fluids. The outcome of the events fever spikes, moderate to severe chills, diarrhea, and excess fatigue was not recovered. Since the vaccination, the patient has not been tested for COVID-19."

lost my sense of taste/smell.; lost my sense of taste/smell; This is a spontaneous report from a contactable other hcp, the patient. This 44-year-old female patient received BNT162B2 (Pfizer-BioNTech COVID-19 mRNA vaccine) (Lot number: EH9899), intramuscularly in the right arm on 16Dec2020 at 18:30

(at the age of 44-years-old) as a single dose for COVID-19 vaccination. The patient's medical history was not reported. Prior to the vaccination, the patient was not diagnosed with COVID-19. The patient previously took ceclor for an unknown indication and experienced drug hypersensitivity. The patient did not receive any other vaccines within four weeks prior to the vaccination. The patient was not pregnant at the time of vaccination. Concomitant medication was reported as none and no other medications were received within 2 weeks of the vaccination. On 24Dec2020 at 12:00, the patient experienced losing her sense of taste and smell. It started changing over the course of the day. Things tasted and smelled different or oddly before the senses going away. No therapeutic measures were taken as a result of the events. The clinical outcome of the loss of sense of taste and smell was not resolved. It was also reported that since the vaccination, the patient had not been tested for COVID-19.

headache, chills and muscle pain and a slight dizziness; headache, chills and muscle pain and a slight dizziness; headache, chills and muscle pain and a slight dizziness; headache, chills and muscle pain and a slight dizziness; This is a spontaneous report from a contactable consumer, the patient. A 57-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), Lot: Ek9231 via an unspecified route of administration on 24Dec2020 at 10:00 (at the age of 57-years-old) as a single dose in the left arm for COVID-19 immunization. Medical history included an allergy to sulfa drugs as of an unspecified date and unknown if ongoing; Covid-19 diagnosed prior to the vaccination on 24Nov (year unspecified) and not ongoing (patient had recovered from COVID, was sick and quarantined until 04Dec (year unspecified)). The patient was not pregnant at the time of vaccination. Concomitant medications included calcium carbonate/colecalciferol (CALCIUM & VITAMIN D3), garlic [allium sativum], omeprazole magnesium (PRILOSEC), ascorbic acid (VIT C) and an unspecified multi-vitamin; all for unknown indications from unknown dates and unknown if ongoing. The patient did not receive any other vaccines within 4 weeks prior to the vaccination. The patient previously took meloxicam and doxycycline; all from unknown dates to unknown dates for unknown indications and experienced allergy. On 24Dec2020 at 23:00 (reported as later in the evening), the patient experienced headache, chills, muscle pain and a slight dizziness. The patient did not receive treatment for the events. Since the vaccination, the patient had not been tested for COVID-19. The clinical outcomes of the headache, chills, muscle pain and a slight dizziness were resolving.

Very sore arm for about one day.; Dizzy for one hour, five hours after the vaccine; Chills and body aches for about one hour 10 hours after vaccine with one hour of fatigue also; Chills and body aches for about one hour 10 hours after vaccine with one hour of fatigue also; Chills and body aches for about one hour 10 hours after vaccine with one hour of fatigue also; This is a spontaneous report from a contactable healthcare professional. A non-pregnant 48-year-old female received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration in the left arm on 21Dec2020 09:15 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. There were no other vaccines within four weeks of the suspect product. The patient previously took mefloquine hydrochloride (LARIAM) and experienced allergies. On 21Dec2020 14:15, the patient experienced very sore arm for about one day, dizzy for one hour, five hours after the vaccine. On 21Dec2020, the patient experienced chills and body aches for about one hour 10 hours after vaccine with one hour of fatigue also. There was no treatment received

for the events. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, the patient has not been tested for COVID-19. The outcome of the very sore arm for about one day was recovered in Dec2020 and of dizzy for one hour, five hours after the vaccine and chills and body aches for about one hour 10 hours after vaccine with one hour of fatigue also was recovered on 21Dec2020. The batch/lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up.

can't raise her arm up; pain at the site of the injection; During the night she couldn't sleep; This is a spontaneous report from a contactable nurse (patient herself) via the Pfizer Sponsored Program. A 69-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), lot number: EK9231, via an unspecified route of administration on left arm from 23Dec2020 10:10 to 23Dec2020 10:10 as single dose for COVID-19 immunization. The patient medical history was not reported. There were no concomitant medications. The patient previously took tetanus toxoid and got red and was itching (clarified she had a reaction to a tetanus shot several years ago). Reports she received the first dose of COVID 19 vaccine at the hospital where she works on 23Dec2020 at 10:10AM in left upper arm. She started having pain at the site of the injection in the afternoon at around 3PM or 4PM 23Dec2020. During the night she couldn't sleep because of the pain no matter where she turned. The patient states the pain was probably 8 out of 10 on the pain scale. Adds she had no redness or swelling. The pain today (24Dec2020) is still the same and now she can't raise her arm up. No treatment has been applied. No cold or heat applied. The outcome of the event pain at the site of the injection was not recovered; while the other events was unknown. Information about lot/batch number and expiration date requested.

headache; Had soreness in arm; This is a spontaneous report from a non-contactable consumer. A female patient in her 60s received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), lot/batch number and expiration date not reported, via an unspecified route of administration from 23Dec2020 to 23Dec2020 as single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced had soreness in arm and a headache on 24Dec2020. The outcome of the events was unknown. Information about lot/batch number has been requested.

Fever; Chills; Myalgia; Headache; Feeling weak; anorexia; This is a spontaneous report from a contactable consumer. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot number: EH9899), via an unspecified route of administration on 22Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced fever, myalgia, feeling weak, anorexia and headache in Dec2020. The patient reported that the symptoms lasted over 48 hours. The outcome of the events was unknown.

"Vertigo; Headache; High temperature; Woke up in the morning with vivid nausea and vomiting and threw up constantly; Woke up in the morning with vivid nausea and vomiting and threw up constantly; Body aches; This is a spontaneous report from a contactable consumer (patient). A 70-year-old female patient (weight: 81.65 Kg, height: 173 cm) received BNT162B2 (Pfizer-Biontech covid-19 vaccine, Lot. EL0140) on 21Dec2020, at single dose, for COVID-19 immunisation. Relevant medical history included

pulmonary arterial hypertension. Concomitant medications included furosemide (LASIX) 20 mg, daily and potassium 20 meq, daily. The patient experienced the following reactions: body aches on 22Dec2020; nausea and vomiting on 23Dec2020 at 02:00 described as ""she woke up in the morning with vivid nausea and vomiting and threw up constantly all on the 23rd and most of the day 24th""; headache and high temperature on 24Dec2020 and vertigo on 25Dec2020. The patient recovered from nausea and vomiting on an unspecified date, in Dec2020, while clinical outcome of the other events was unknown."

Resident extremely confused. BP 125/66; Pulse 124, Temp 99.7; 02 at 92% (around 10:00a.m.) BP 138/84; Pulse 125, Temp 99.5, O2 at 95% (around 1:00p.m.)

Increased heart rate majority of day, low bld sugar, nausea and headache late evening of vaccine. Hives appeared Rt arm - elbow, neck to eye. Took Benadryl 50mg at 7:30 pm another dose at 10pm. Awoke 12-29-20 all hives gone but feels hot, fluctuating heart rate, stiff neck, short of breath. Called MD, will monitor symptoms next 24 hours.

In middle of night had strong headache, then day following vaccination was headache-y (mild), light-headed, tired and with body aches. Two days after had mild body aches and mild light headed-ness; day 3 I was clear.

"Patient contacted our pharmacy and noted that ""the day after his Moderna dose, he experienced fever and chills of 100.3 Deg. Pain at the site of injection, and Vomitting."""

Pt experienced Weakness, dizziness, vomiting, headache soreness @ inj. site.

Pt developed a rash about an 30mins to an hour after receiving vaccine. Pt took Loratadine & Benadryl. Next day pt felt better. Soreness @ inj. site.

Patient left hospital and complained of dizziness outside. Patient brought back to vaccine Pod. Patient's blood pressure taken, patient given snack and water and felt better.

Patient felt tingling in left hand. Patient's blood pressure taken. Patient monitored by RN and seen by Resident. As per patient tingling went away

Patient complained of dizziness. Patient's blood pressure taken. Patient given water and snack and felt better.

Bell?s Palsey about 4.5 hours after injection.

10 minutes after receiving vaccine patient complained for being jittery and having an elevated heart rate. monitored BP, heart rate and 02 saturation; patient chose to leave with her friend and drive to Medical Center for evaluation

Starting around 1700 the day I was vaccinated, I started to experience body aches and a sore throat. As the night progressed, I had a fever of 102F. The fever lasted throughout the night until it broke the next

morning. It is currently 2125 the day after vaccination and I still am experiencing body aches and fatigue after sleeping for 18 hours. I have taken Tylenol to help relieve these symptoms.

1 hour after vaccine itching, redness, elevated small bumps in arms. 6.5 hours after the vaccine had flushing and tachycardia up to 130. Had to call FIRE RESCUE .,Took tachycardia meds

headache, nausea, light headed, swelling of the hands Patient was given 1000mg of acetaminophen and 25mg diphenhydramine. Patient was monitored for 60 minutes.

Fevers, chills, night sweats, fatigue, malaise, body aches

Approximately 5 minutes after the injection, I suddenly began experiencing tachycardia (felt like I had way too much coffee). The nurse took my pulse and summoned the attending physician who sat with me for more than 30 minutes. I felt good enough to leave but did experience a somewhat rapid heart rate on and off through the afternoon. Upon leaving, I was told to call my allergist to have my Epi-Pen refilled (my current Epi-Pen had expired), which I did. Eleven hours post injection I'm feeling fine except for the expected arm soreness. In terms of my allergic history, I had previously discontinued allergy shots last year due to repeated systemic reactions to very low dose vials (itchy roof of mouth, swollen throat, etc).

I received my vaccine on 12/18/2020. The side effects I experienced were initially as expected. Mild headache, muscle pain at the injection site. However, the muscle issues have not subsided, and have actually gotten worse. Day 3 I began having a burning sensation in my underarm area radiating back towards my triceps. Muscle spasms continued to increase and spread to include deltoid, trapezius, and SCM muscles. Yesterday I developed a fever and began having a burning sensation down my triceps muscles and radiating into my forearm (radial side). No visible rash noted. Slight weakness in left arm.

On the second day I had a sore arm and I woke up with a headache that lasted 2 hours.

Muscle aches, headaches, chills, vomiting, shakes

Developed metallic taste in mouth within 5 minutes of vaccine administration that persisted for 1 to 2 hours. Developed palpitations and flushing within 10 minutes of vaccine administration that resolved after 1 minute. Palpitations and flushing recurred along with development of burning sensation in distal extremities within 15 to 20 minutes of vaccine administration. Palpitations were forceful and pronounced enough to cause chest tightness, lightheadedness, and weakness. These symptoms resolved without intervention after less than 5 minutes.

Maculopapular Rash beginning not long after vaccine, began with hives and itching on hands, did not speculate vaccine relation until following day, hives appeared on hands and continued non-uniform across forearms, armpits, chest, abdomen, pelvic/thigh crease, buttocks, and behind knees, approx 50-60% of body experienced hives and maculopapular rash within 0-4 days after vaccine, minor swelling occurred where rash was present and was most prevalent 3 days post injection.

Short-term memory loss consistent with Transient Global Amnesia

Had shot at 7:45am and around 3:45pm started having severe itching in mouth , ears and skin. Took oral zyrtec without relief. Was scratching myself raw and bleeding. Went to ER and got solumedrol 125 and 25mg IV Benadryl. Next day had wheezing and rash on chest. Went on prednisone oral taper and albuterol.

One week after vaccine administration I developed lymphadenopathy on the left side - very painful and has lasted 4 days and is ongoing. Antibiotics were started on day 4.

Swollen Lips, throat, foot, sore throat, body aches, chills, head aches, Feeling that can not keep eyes open, pain on administration site, on/off body itching.

Fever within 16 hours of vaccine lasting for 48 hours, general muscle aches lasting under 48 hours, fatigue, non-productive cough persisting more than 3 days

severe chills, hot sweats, muscle and joint pain, headache, fever, vertigo

pt received dose 1 of pfizer/biontech covid-19 vaccine on 12/29/20 at approx 14:04. after 10 minutes of observation pt developed a left upper trunk rash. patient's HR was elevated and BP elevated. pt was nervous. Benadryl 25 mg PO and Pepcid 20 mg PO was given and patient had no other reactions. after 30 additional minutes of observation, pt was able to go home as spouse was driving her home

10:30 AM After receiving the COVID-19 vaccine, the patient experienced an anaphylaxis reaction that included, throat closing and tongue swelling sensation, itchiness, and hives on her bilateral arms and legs. Patient received 65 mg of Benadryl IV, 125 mg SoluMedrol IV, two doses of 0.3 epinephrine IM, 1 mg of Ativan, and 4 mg of Zofran, then taken to the ED for further monitoring. Patient was on 2L NC for comfort, sats in mid 90s off oxygen, and monitored the patient for a few hours. Patient discharged to home with stable vital signs off oxygen and a steady gait.

Unusually high level of fatigue / exhaustion. Feeling ?fluish? Headache Feeling feverish but no actual fever. Has lasted So far from 12/24 to 12/29. Six days. A bit better day 6.

Extreme gas and diarrhea.

Arm started hurting a few hours after injection. A headache and nausea a few hours after that.

Pt. developed tachycardia, hypertension and felt weak with decreased verbal responsiveness, alert but lethargic. She complained of dry throat, took a sip of water then began persistent coughing and wretching also C/O itching of her throat. She denied difficulty breathing, there were no cutaneous signs of edema, tongue enlargement, etc.

Pt. began to feel weak with palpitations about 8-10 minutes after vaccination, her pulse was extremely fast, she then began to complain of lower mid-esophageal burning

LEFT AXILLARY LYMPH NODES TO LEFT ARM SWOLLEN AND PAINFUL. WARM COMPRESS APPLIED. CONTINUE TO MONITOR

Pfizer-BioNTech COVID-19 Vaccine EUA Itching and hives on upper arms, upper legs, and sides of torso x48 hrs thus far, controlled with oral otc Benadryl and pep I'd.

Muscle pain in left deltoid, vomited at 1:22am. No treatment taken

Syncope, severe bradycardia followed by 20+ hours of chills, fatigue, weakness, body aches

Began developing flu-like symptoms about twelve hours after receiving first dose. I started having body aches, chills, fever, and fatigue. Ibuprofen has helped manage symptoms.

About 15 hours after I received the vaccine I started getting body aches and chills. Low grade fever. After 24 hours I was shivering, aches and temp of 102.4. Symptoms lasted a total of 48 hours from first onset of body aches.

On Dec 28th I received the shot & initially didn't feel anything. When I woke up on the morning of Dec 29th I had a really bad headache, felt burning up & cold at the same time. My right arm (shot arm) and my left hip were super soar. I couldn't keep liquids down. I passed out the first time between 6:55 A.M. & 7:05 A.M. Later that morning I passed out a second time for 2 mins. I still plan to get the second dose on Jan 25th 2021. Since I'm a contact tracer I texted my supervisor. I was advised to take the day off & report it just in case it was related to the vaccine.

Started with sudden headache which gradually worsened. Dizziness/light headed followed by progressive foggy thought process, severe arm soreness, and general aches all worsening through the night.

I received the vaccination on Saturday morning. The following day around 10:00a.m., I started feeling weak with a headache and severe left arm pain around the injection site. Around 2:00p.m., I started getting chills and spiked a temperature of 100.6. I was taking ibuprofen and Tylenol interchangeably. The fever and chills resolved that night but still with a headache and weakness. Only the headache remained the following day but the rest of the symptoms subsided.

30 seconds following IM injection, felt warm, flushed, lightheaded, vision dimming., near syncope. Symptoms improved lying supine. Blood pressure measured to be 90's systolic, Heart Rate 60's. NO RASH, NO ANGIOEDEMA, NO Shortness of breath. Symptoms resolved completely within in 3 minutes.

Rig he arm sever pain at elbow. Swelled and painful right axilla lump nodes

mild arm soreness low grade headache

Large lymph node about size of lime in left armpit

lost of taste and smell

Swollen lymph nodes in armpit and side of chest, extreme pain in swollen area Pain at injection site, but not nearly as severe as armpit pain

Large red, swollen area at site of injection Nausea, diarrhea, stomach cramping

"""Increased skeletal pain, Shinbone, back, muscle tightening swelling in back, sharp pains throughout knees and shinbones. These are ongoing medical issues but over the pat week they increased to the point where I stayed in bed with warm compresses and analgesic topic creams from Christmas through Monday the 28th. Currently working and taking 3 advils every six hours to deal with back pain."""

2 days after vaccine had significant back pain. Lower back with excruciating pain. Chest muscles became stiff Was difficult to walk or sit. Then the next day was having breakfast and had an allergic reaction to food that I have eaten regularly. I had an allergic reaction for the first time in September to a different food but it was same reaction. Significant periorbital edema to where my eyes were almost completely swollen shut. No breathing issues.

lethargy chills/sweats pain at injection site for multiple days nausea headache

Moderate myalgia of arms, shoulders, neck and upper back; milder myalgia of lower back and thighs. Treatment is rest, acetaminophen and massage. Outcome to be determined; symptoms still present at 48 hours.

Patient c/o of tingling in the legs about 15 mins after receiving the vaccine. Patient also c/o of warmst in the chest area

My arm was very sore all night and when I woke up I had two raised, red patches on my right arm. One patch was at the injection site, one was slightly below the injection site. The injection site is also still very sore and hard.

Developed a lump in my throat soon after receiving the injection. Feel like I have to keep swallowing and clearing my throat. Some fullness in my ears that resemble having water in your ears when swimming. Some chest tightness, but mild. No shortness of breath. No rashes. Reported this to the nursing staff at the Covid Pod site around 12:15pm. Ate lunch, drank water, and took Benadryl at 1230. Developed chills and fever of 100.1 at 2:30pm.

Fever to 101.5F reported evening of vaccination. No other symptoms reported yet.

Red, raised rash noted to right arm, hands bilaterally, and neck area. Swelling noted to bilateral hands 6 days post injection. Patient given Decadron for symptom relief per PCP.

Patient reported headache immediately after injection. Within 5 minutes, reported headache radiating down neck and arms to elbows with tingling down arms lasting about 10 seconds. 30 minutes after injection, patient declined further care while complaining of persistent sharp frontal headache radiating down neck. Patient was very anxious prior to receiving vaccine.

103.5 fever Vomiting Chills Muscle spasms Headache Difficulty walking

I got the vaccine around 12:35 on 12/29/2020. Around 3 in the morning I started having sever body aches. Now its 12/30/2020 7:32 in the morning, I have sever body pain, Dont have fever but I feel very

warm, My hands are very warm it feels like I have a high fever, chills and very tired with no energy. It feels like I have flu.

Severe Chills, fatigue, blinding headache, pain at ejection site,

Arm pain, chills, headache, fatigue

hives, itching; seen in ED given po Benadryl,, Pepcid with relief discharged on po Benadryl, Rx Decadron if needed Improved and back to work in 2 hours; will follow up with health clinic.

Moderna COVID?19 Vaccine EUA Pain, swelling, warmth to injection site. Chills, body aches and headache onset the next morning.

Fatigue, low grade fever 99.3, chills, muscle and joint pain ,and nausea. At vaccine site bruise and right arm pain

On his drive home, his cheeks started to swell up, throat swelled, the roof of his mouth didn't feel right & he had difficulty swallowing. He went to the ED and his throat closed.

2hours after receiving injection developed a uticarial rash on upper body. Treated with zyrtec 10mg and 25mg of benadryl. Resolved after 30 minutes of receiving benadryl.

Symptoms started on Monday when the test site of my arm was extremely sore and I had a mild headache. Tuesday I started getting additional symptoms of respiratory symptoms with a runny nose and cough, chills, and headache.

Itching to face and legs. Rash to left leg. States she applied Hydrocortisone cream to areas. Side effects have improved.

Fever (100.1 F when first taken), chills, body aches, headache, soreness at injection site. Fever and chill started during the night, woke up about 1am with sweats, chills, and headache. Took 400 mg ibuprofen and headache went away. Low grade fever and chills still persist.

8 hours post injection developed mild injection site/arm pain and soreness 13 hours post injection developed fever, tax 102.7F, chills/rigors, severe body aches

Confused, dizzy, heavy tongue feeling, pale skin, weakness.

Pt developed anaphylaxis, was given IM Benadryl, and was sent to the ED. Pt spent 1 night in the hospital, went home, and has come back and is in the ICU. Pt had hives, itching, chest tightness, swollen lips.

Shortness of breath Hives, Fever, chills joint pains. I was Tx in the ER with Pepcid IV Solumedrol IV, Benadryl IV ,Tylenol and IV fluids. I was discharged on prednisone , Benadryl and Tylenol.

12/29/2020 07:00AM Mild body aches, low grade fever 100.0; 12/29/2020 PM same day-- fever 102.6, severe body aches and fatigue and headache, Tylenol and ibuprofen-- some relief to fever. 12/30/2020 mild headache, left armpit swollen, tender knot -- all other symptoms have resolved.

Approximately 15 minutes after IM injection, patient developed chest tightness. Patient was taken to the Emergency Department for treatment. Was given sublingual nitroglycerin and subsequently admitted to the hospital for observation. Patient discharged home the following morning in good condition.

Several minutes after vaccine started feeling tightness in her throat and a rapid heart rate. Administered epinephrine pen and when to the emergency department. Received oral Benadryl and steroids. Was discharged home later.

My grandmother died a few hours after receiving the moderna covid vaccine booster 1. While I don?t expect that the events are related, the treating hospital did not acknowledge this and I wanted to be sure a report was made.

About 3 am after the injection I woke up with severe chest pains and headache and went to the ER. I was admitted for 2 days and was released with a prescription of Isosorb Monoer, Metroprol, aspirin which is used as a blood thinner. The diagnosis and prognosis was severe migranes and cardioartery disease.

Shortness of breath , Erythema within 30 minutes of vaccine per provider note

Left side of my face went numb. 5 minutes later tongue was dry and tingly. Went back to place of work and went to monitoring room. Went to ER to be checked out. Got better over that day. I was admitted the same day and discharged the next day.

anxiety, tachycardia, flushing, diaphoresis, HTN, SOB

Patient administered Pfizer-BioNtech vaccine, dose #1 in series at 810AM, without notable concerns for 10 minutes. At 10 minutes post vaccination, patient developed itching and some blotching, throat becoming scratchy. No known allergies to components listed in vaccine, though does have a listed allergy to contrast dye, does not carry an epi-pen. Patient was walked to urgent/emergency care in the clinic, where she was seen immediately. Patient was given diphenhydramine 25 mg IV, pantoprazole 40 mg IV, with mild uticaria continuing. Patient notes she feels her 'back is on fire'. Patient was then given methylprednisolone 125 mg IV. At this time, no SOB is noted, uticaria is still present. 0930 patient reports swelling in throat and respiratory difficulties at this time with visible edema in the neck. 0.3 mg Epinephrine given at 0935, epinephrine drip and racemic epinephrine neb given. 1006 Patient on epinephrine drip 2.5 mics/hour. Patient transferred to Medical Center ICU, where she remains at the time of this report.

BP of 176/126mmhg/persistent severe hypertension/continued severe elevation of BP of 178/130mmHg; intermittent chest pains; severe nausea; rash and hives on left side of arm where injection site was, as well as left side of face; rash and hives on left side of arm where injection site was,

as well as left side of face; rash and hives on left side of arm where injection site was, as well as left side of face; rash and hives on left side of arm where injection site was, as well as left side of face; mild progressive headache; body aches; chills; fatigue; fever of 100 degree F; This is a spontaneous report from a contactable Other Health Professional (patient). A 29-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) lot number: unknown, intramuscular in the left arm, first dose on 18Dec2020 12:30 at a single dose for immunisation. Medical history included ongoing gestational hypertension in 2016 that never recovered, with controlled hypertension, asthma/COPD, and seasonal/animal allergies. Concomitant medication included sertraline hydrochloride (ZOLOFT) and losartan. The patient is not pregnant. The patient previously took and had allergies to erythromycin and nitrous oxide. It was reported that within 20-30 minutes of receiving covid vaccine on 18Dec2020, the patient developed mild progressive headache, body aches, chills, fatigue, fever of 100 degree F. At approximately 8:00 p.m. same day of vaccination, she developed rash and hives on left side of arm where injection site was, as well as left side of her face. Immediately following this, she had intermittent chest pains in which she took a BENADRYL 25 mg with some relief. Next day (19Dec2020), progressive headache persisted to a severe headache, severe nausea, persistent chest pains and a BP of 176/126mmhg. Reported to a place for evaluation with persistent severe hypertension and severe headache treated by toradol, compazine, and Benadryl. She was released from the ER with improved blood pressures and reduced headache. The following day Sunday Dec2020, progressive and severe headache occurred with continued severe elevation of BP of 178/130mmHg. Current treatment of losartan 50 mg was increased to 100 mg to attempt control. She was then placed on chlorthalidone/amlodipine. The events resulted in doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care. The outcome of the events mild progressive headache, body aches, chills, fatigue, fever of 100 degree F, rash and hives on left side of arm where injection site was, as well as left side of face, intermittent chest pains, severe nausea, and BP of 176/126mmhg/persistent severe hypertension/continued severe elevation of BP of 178/130mmHg was not recovered (reported as symptoms persist). The patient was not diagnosed with Covid 19 prior to vaccination and she had not been tested since vaccination. Information on the lot/batch number has been requested.; Sender's Comments: Based on the compatible time association, the hypertension aggravated is possibly related to bnt162b2 administration. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

blood pressure was super elevated, in the 190/110 range; It was getting close to stroke level; woke up and felt restlessness and agitation; Headache; felt really restless and anxious; felt really restless and anxious; was not able to sleep/ could not go back to sleep; This is a spontaneous report from a contactable consumer (patient). A 53-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) lot number: EK5730, expiration date: Mar2021 intramuscularly in left deltoid from 17Dec2020 at single dose for COVID-19 immunization. Patient medical history included seasonal allergy. Concomitant medication included mometasone furoate (FLONASE) via nasal from 2018 (about 2 years ago) and ongoing at 1 spray each nostril, 1x/day for seasonal allergy. The patient previously received flu

shot, on Oct2020 (2 months ago) for immunization. Patient was a firefighter and reported that he received the vaccination in the afternoon of 17Dec2020. On that afternoon, he was on duty and felt really restless and anxious and was not able to sleep. He did not sleep at all that night. He maybe got like an hour or 2 on Friday after his shift. Friday night he had the same kind of deal and it continued on into Saturday. He did crash and burn (pending clarification) on Saturday night. On Sunday, he got up and felt normal again. A few hours later on Sunday, it started up again and then it went away. He said that after dinner Sunday evening it started up again, but he was able to get some sleep. He said that Yesterday, 21Dec2020, he was fine. He took off yesterday. This morning on 22Dec2020 at 0200 he woke up and felt restlessness and agitation and he could not go back to sleep. He said that he had a headache and his blood pressure was super elevated, in the 190/110 range on 22Dec2020. It was getting close to stroke level. He said that he thought about going to the ER, but did not experience any stroke or cardiac symptom's, although his blood pressure is still high, but not as high as it was. He has not gotten any sleep since then. He said that he has an appointment to see his physician this afternoon at 1300 22Dec2020. It was reported that all events require physician office visit. Got his flu shot like 2 months ago and nothing like this happened. He said that he heard with the second round there are supposed to me more symptoms like flu like symptoms with the Covid vaccine like fever, muscle aches. Outcome of the events was reported as unknown.

"diagnosed with COVID-19; diagnosed with COVID-19; This is a spontaneous report from a contactable pharmacist. A female patient of an unspecified age (reported as 62 without unit) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot/batch number and expiration date not provided), via an unspecified route of administration on 16Dec2020 at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. Reporter requested information on the administration of the second dose of the COVID-19 vaccine to a patient. The patient received vaccine first dose 16Dec2020; she was diagnosed with COVID-19 on 18Dec2020; started taking the medication ""Bamlanivimab"" on 21Dec2020. The outcome of the events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: There is not a reasonable possibility that reported ""diagnosis with COVID-19"" is related to BNT162B2 vaccine. Event developed 2 days after vaccination. The event is most likely intercurrent medical condition."

Patient had dizziness when she got down to the emergency department.; transient ischemia attack (TIA); Hypertensive emergency; This is a spontaneous report from a contactable pharmacist reporting for two patients. This is the second of two reports. A 53-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (Lot number: EH9899), intramuscular at 0.3 mL, single in the arm on 23Dec2020 for Covid-19 immunisation. Medical history included hypertension, allergies to sulfa, morphine and cipro. There were no concomitant medications. The patient experienced hypertensive emergency on 23Dec2020 with outcome of unknown, patient was getting her blood pressure checked and the patient was in the 170s systolic on an unspecified date with outcome of unknown, patient had dizziness when she got down to the emergency department on an unspecified date with outcome of unknown. The events were described as follows: Patient was getting her blood pressure checked and the patient was in the 170s systolic. She was taken down to the emergency department. She had a blood pressure of 191/105 in the emergency department. Patient had dizziness when she got down to the

emergency department. She does not have further details to provide since the patient is being worked up right now to see if she experienced a transient ischemia attack (TIA). Patient has a history of hypertension. The vaccine was administered at Hospital Facility. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine.; Sender's Comments: While the patient is a known hypertensive and events may be intercurrent events, the causal relationship between BNT162B2 and the events hypertensive emergency, dizziness and transient ischaemic attack cannot be completely excluded due to temporal association. This case will be reassessed once additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate.,Linked Report(s) : US-PFIZER INC-2020510735 Same reporter/different patient/similar events

positive COVID-19 test with no symptoms; positive COVID-19 test with no symptoms; This is a spontaneous report from a contactable other HCP. A 93-year-old male patient received fist dose of BNT162B2(PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 18Dec2020 at single dose by injection at arm for COVID-19 immunization. Medical history and concomitant medications reported as none. The patient was not been treated with immunomodulating or immunosuppressing medications or received any other vaccines around the time of COVID-19 vaccination. The patient, nursing home had turned positive after the getting the vaccine. The patient was tested negative for COVID 19 before getting the vaccine on 18Dec2020, then took his first dose of COVID vaccine. The patient had no reaction to the vaccine. The patient got on the plane on 19Dec2020 and tested positive on 22Dec2020. PCR test for COVID 19 was done on 22Dec2020 and received the results on 23Dec2020 and it was detected(PCR test was positive). Event reported as non-serious. The patient still had had no symptoms before the test and none after the test came back detected. He was pretty healthy. It was unknown if patient would receive the second dose but he was scheduled to receive it. Patient was not admitted to an Intensive Care Unit. Patient did not display clinical signs at rest indicative of severe systemic illness. Patient did not require supplemental oxygen (including high flow or ECMO) or receive mechanical ventilation. Patient had no any new or worsened symptoms/signs during the COVID-19 illness experienced (including date of onset/worsening). The patient did not receive any additional therapies for COVID-19. The event did not require the initiation of new medication or other treatment or procedure. Patient's outcome with COVID-19 reported as not currently ill. The outcome of the event was unknown. Information on the Batch/Lot number has been requested.; Sender's Comments: The patient received BNT162B2 on 18Dec2020 and took plane on 19Dec2020. The patient was tested positive for COVID-19 on 22Dec2020. The event occurred only 4 days after first vaccination and therefore the patient was not under full protection by vaccine.

"patient tested positive for COVID 19 the same day; patient tested positive for COVID 19 the same day; This is a spontaneous report from a non-contactable Nurse. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The relevant medical history and

concomitant medications were not reported. The COVID 19 vaccine was administered to the patient and the patient tested positive for COVID 19 the same day. Patient did not have a fever and reported feeling tired. The nurse wanted to know if the immune response would be affected by having COVID 19 at the time of vaccination and will the symptoms be exacerbated because of receiving the vaccine. The outcome of the events was unknown. No follow up attempts are possible. Information on Lot/Batch could not be requested. No further information is expected.; Sender's Comments: The patient tested positive for COVID-19 on the same day when receiving BNT162B2 vaccine. And therefore there is not a reasonable possibility that reported ""tested positive for COVID 19"" is related to vaccine."

tested positive for COVID; positive for COVID; positive for COVID/asymptomatic; This is a spontaneous report from a contactable nurse reporting for herself. A female patient of an unspecified age received the 1st dose of bnt162b2 (BNT162B2) at single dose on 18Dec2020 for Covid-19 immunisation. The patient medical history and concomitant medications were not reported. She was tested positive for COVID, through the rapid COVID test on 27Dec2020. She stated being asymptomatic and being scheduled for her 2nd dose on 08Jan2021. She asked can she still receive the 2nd dose of the vaccine or should she repeat the vaccination series. The outcome of event was unknown. Information on the Lot/batch number has been requested.; Sender's Comments: Based on the information currently available, a lack of efficacy with suspected vaccine in this patient cannot be completely excluded. Further information like confirmative COVID 19 Nucleic acid/ PCR test are needed for full medical assessment.

10 minutes after receiving vaccination, a significant increase in HR was noted, along with a tingling sensation through out body. Also, scratchy throat was noted. Alert by patient made to staff at vaccination site. Sweating noted and shortness of breath at that time. Epi pen given via L thigh IM. PIV started and benadryl and solumedrol given. Relief of symptoms noted very shortly after Epi administration. Taken to ER for 4 hour observation. Sent home after 4 hours and given prednisone to be taken at home, 50mg daily for 4 days. No further adverse symptoms noted.

decreased range of motion in vaccinated arm: unable to raise left arm above shoulder x 72 hours now due to pain. no associated numbness or swelling. I am a surgeon and this impacts my work and driving. I would not have been able to operate during these last 3 days and while the pain is better 72hrs later, my arm is still out of commission. I think we need to inform healthcare providers who perform procedures that they may want to schedule the vaccine when no planned procedures for at least 72 hrs. Due to this issue I will be unable to proceed with the second dose, unless I can take it a week later than the scheduled January 24, 2021. It is taking too long to regain full function of the arm but i expect it will be back to normal as it is better today 72 hrs later.

Facial numbness radiating down left side of neck to left arm, elbow and chest. Went to ED, admitted for observation overnight.

Bell's palsy; experienced sudden flushing; tachycardia; the left side of my tongue became numb and tight. The numbness and tightness radiated to my left cheek, ear, jaw, and neck; the left side of my tongue became numb and tight. The numbness and tightness radiated to my left cheek, ear, jaw, and

neck; the left side of my tongue became numb and tight. The numbness and tightness radiated to my left cheek, ear, jaw, and neck; The numbness lasted for approximately 45 minutes with resulting jaw and ear pain for 3-4 days after injection; The numbness lasted for approximately 45 minutes with resulting jaw and ear pain for 3-4 days after injection; New lymph node tenderness at day 4.; This is a spontaneous report from a contactable other healthcare professional (patient). A 31-year-old female patient received her first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899), via an unspecified route of administration on left arm at 11:30 AM on 18Dec2020 at single dose for COVID-19 immunization. Medical history included seasonal allergy. Concomitant medication included fluticasone propionate (FLONASE), loratadine (CLARITIN) both for seasonal allergies. The patient had sudden generalized flushing, tachycardia, and the left side of her tongue became numb and tight. The numbness and tightness radiated to her left cheek, ear, jaw, and neck at 11:45 AM on 18Dec2020. She hadn't found any similar reports/reactions documented. Spoke briefly per document below regarding Bell's palsy. The numbness lasted for approximately 45 minutes with resulting jaw and ear pain for 3-4 days after injection. New lymph node tenderness at day 4 in Dec2020. No shortness of breath, dysphagia, or facial drooping associated. All events were reported as non-serious. The patient was not diagnosed with COVID-19 prior to vaccination. Since the vaccination, the patient had not been tested for COVID-19. The patient did not receive any treatment for events. The outcome of events was unknown. Explained that Pfizer would not be able to provide treatment recommendations and referred to her HCP to discuss the 2nd dose.; Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of event Bell's palsy cannot be totally excluded. The case will be reassessed if additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

lips were tingly and swollen; lips were tingly and swollen; fatigued; allergic reaction; passed out; breathing fast; her brain felt like a rock, like she was there but not there; head was so heavy,wouldn't open her eyes; her throat started to tighten up; chest pain; nauseous; headache; felt a little lightheaded, a little wobbly; palpitations; sweaty; This is a spontaneous report from a contactable consumer (patient) via Pfizer Sponsored Program. A 48-year-old female patient (no pregnant at the time of vaccination) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EH9899) via an unspecified route of administrationon 22Dec2020 on left shoulder at single dose for COVID-19 immunization. The patient's medical history included pernicious anemia and She had problems with B12 and Vitamin D like 10 years ago, she had none in her body, everyone said she was deficient and this year with her new primary care, they sent her to do some antibody tests, and found out she has pernicious anemia, allery to MRI and CT contrast. MRI and CT contrast NDC, lot, expiry unknown. Her CT contrast allergy happened when she was 9 and 12 years old. It turns out to be her dad has an allergy the same way, his airways close. Whenever she needs a CT, they do without contrast, if she does need, they prep and give her Benadryl and keep an eye on her. This only happened once, that she needed with contrast, and with prep she was ok. With the MRI, this happened 4 or more years ago, maybe like 5 years ago. She

needed an MRI, they said she would be fine, they injected contrast, she felt pretty hot, then she doesn't know, 20 minutes into it, she couldn't handle her gown, she looked at her chest, her whole chest was red like a burn. They gave her the IV Benadryl, she guesses, and it went away, now she knows, she doesn't know if her dad is allergic to MRI dye, but she knows she got the allergy from him for the CT contrast. The concomitant drugs was not reported. The patient was taken to ER with a severe allergic reaction. She had an allergic reaction on 22Dec2020: she passed out, said her brain felt like a rock, like she was there but not there, she then received an Epi Pen shot, when she got to the ER, her throat started to tighten up, lips were tingly and swollen, she was breathing fast, she had chest pain, she scaled it from a scale of 1-10, as about a 3 to 4 for chest pain, she felt nauseous, sweaty, and had a headache. She went to bed last night, and woke up, feeling better but a little fatigued on 23Dec2020. She is wondering if she should take the second dose, and wants to be in the clinical trial for this type of reaction. She needs transfer to Regulatory Authority. Caller confirmed details. Caller states she works in a hospital, and all this happened at the hospital, and her doctor was not involved. Outcome of allergic reaction: asks what does lasting effects mean? Right now she has a little fatigue and headache, but she knows they are regular symptoms she can have with the vaccine, are those lasting effects? She was discharged from the ER to home. She mentioned to the nurse she has, she went to get the shot, she told the registration nurse, she said she has a severe allergic reaction to CT contrast, her airway closes and she has a severe reaction to MRI contrast, her skin burns, it turns red and feels like a horrible burn, she cannot handle anything to contact her skin, it burns, and she mentioned that to the nurse, she said, instead of staying 15 minutes, said to stay 30 minutes there to observe just in case. She got the vaccine, and 10 minutes after the vaccine, she felt a little lightheaded, a little wobbly, but she didn't think much, it was mild, and on the mark at 30 minutes, the nurse asked her to stand, and that is when she started feeling, like her head was so heavy, the only way to describe, was like her brain was like a rock, she had to lay down, and when they laid her down, she wasn't there, she was there but wasn't, and they didn't wait at all to give her the Epi Pen, she had a feeling of heaviness that got worse, she wouldn't open her eyes, she was able to answer questions, but it was not her there, it was weird, then she didn't have. she breathed fast, had palpitations, chest pain, so they called a Rapid Response team, they were keeping an eye on her breathing, which was super fast, and they rushed her to the ED, and the doctor did what they were doing, giving her IV of whatever medication, and she was also very nauseous, then at one point in the ED, she started feeling, like imagine if fists were on throat, pushing her throat, a little bit, and she tried to tell to the ED doctor, but guessed she was calling everyone to give her things, and didn't catch it, but it didn't last long, at the same time, she started to feel her lips tingly, so she thinks that, because they gave the Epi Pen so quickly, they wasted no time, she didn't have the airways closing like she does when she gets the CT contrast, they were quick. NDC/lot/expiry: She reads from the card they gave her: states first dose COVID-19 EH9899, states it doesn't specify lot, but she can find that out, they just gave her a vaccine record card. EPi Pen: NDC, lot, expiry unknown, states everything happened so quickly, she didn't think to get this information before calling, but she can get it. There at the hospital, she went to see the occupational health doctor, and based on guidelines from the CDC, he read supposedly she cannot get the second dose, but the doctor said because it is so new, and she has to wait the 3 weeks she guesses, things can change, and she wanted to be proactive. The outcome of the events, allergic reaction, passed out, throat started to tighten up, lips were tingly and swollen, chest pain, nauseous,

headache, lightheaded, palpitations, sweaty was recovering. The outcome of other events was unknown.

COVID test positive two times; COVID test positive two times; Pain in bum, back; Pain in bum, back; Last night I was feeling so bad; Skin like a rash; This is a spontaneous report from a non-contactable consumer (patient). This patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot EK5730) on 21Dec2020 at 1:36 P.M., at single dose, for COVID-19 prevention. Medical history and concomitant medications were not reported. On an unspecified date in Dec2020 the patient experienced pain in bum, back, last night was feeling so bad, skin like a rash. On 22Dec2020 the patient did COVID test which was negative. She did another test on 23Dec2020 and it was negative. The patient did not feel any fever. But last night, on an unspecified date in Dec2020, when the patient went to the emergency for work, the lady did COVID test two times and the patient was positive. Events outcome was unknown. No follow-up attempts are possible. No further information is expected.

Tested positive for covid after the first dose of the vaccine; Tested positive for covid after the first dose of the vaccine; This is a spontaneous report from a contactable Pharmacist. A patient of unspecified age and gender received the 1st dose of bnt162b2 (BNT162B2) at single dose on 18Dec2020 at single dose for Covid-19 immunisation. The patient medical history and concomitant medications were not reported. The patient experienced Tested positive for covid after the 1st dose of the vaccine on an unspecified date. The outcome of unknown. Reporter wanted to know if the patient should receive the 2nd dose. Information on the lot/batch number has been requested.; Sender's Comments: The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

Patient presented to the ER on 12/26/2020 with complaints of fever, chills and SOB for about 3 days. Stated it was a gradual onset and has been intermittent. Also reported some nausea and chronic loose stools, mild loss of smell and sinus drainage, non productive cough. Discharged to observation and then home on 12/27/2020. Patient readmitted to hospital on 12/30/2020.

Within 3 minutes of vaccination patient became fully flushed head and neck, with rapid heart rate (112), and feeling like her airways were tightening.. Nurse immediately called for response, administered Epipen, when response arrived applied oxygen and transported to ED. Solumedrol 125 mg, Bendadryl 25 mg, and Famotidine 20 mg, she responded well and was released home with Rx Prednisone 40 mg x 3 days. Only residual effect was a dry/sore throat.

12/30 9:30 am developed angioedema. Swelling of face, lips, tight throat. Also had bright red rash over body trunk and arms. Both palms were red, hot and painful.

Weakness, fatigue, decreased appetite, upper extremity shaking, sternal red blotchy rash, decreased mental status, non-verbal, decreased level of conscious, mottling, left side facial droop, hypertensive, fever, unable to follow commands

headache 15 minutes after receiving vaccine, 3 to 4 hours later broke out in rash on upper extremities, ABD pain, itchy, and arm swelling, throat hurts. SOB

Left sided weakness, fatigue for 3 days post immunization. Patient was seen by health care provider on 12/30/2020. Provider transferred patient to Hospital ER for further evaluation.

At about 6am after receiving the shot I felt very tender at the injection site almost as if it was bruised. Then over the course of the day I started to feel very itchy all over my body but mainly on my right side. 10pm I got up for work, and could barely move, I'm feeling intense back pain on my lower back on the right side. I can walk but its all very limited motion, I can really only manage by putting all my weight on my left side.

I developed severe abdominal pain and was diagnosed with colitis. I was seen in ER. I have no idea if the vaccine called this.

Patient presents with ? Altered Mental Status ? Headache á á HPI Patient presents to ER by EMS ambulance after family called 911 as patient was incomprehensible with slurred speech and moaning on the phone this evening. On arrival of EMS patient was asleep in bed and reportedly unresponsive other that to localize to pain. EMS transferred patient to ER. On arrival to ER patient had GCS 7. Reportedly patient is locum nurse who works in a Nursing Home and patient reportedly received COVID vaccination 2 days ago and that night reportedly began complaining to family on the phone of headache, nasal congestion, sore throat, cough, fever, chills, nausea, emesis, myalgias, and lethargy. Per the medical record patient has history of seizures, migraines, and sciatica. No other information is known on patient arrival to ER. 1. Peripheral IV right dorsal hand placed by EMS in route to ER. 2. On arrival to ER GCS 7 (E1M5V1) and roving eye movements with episodic lateral conjugate and at times disconjugate gaze concerning for seizure activity. Arms and legs with moderately increased tone but no clonic movements and patient able to localize bilaterally. 3. Ativan 1 mg IVP for seizure, then further 2 mg IVP for persistent seizure. 4. Fosphenytoin 1,000 mg IVPB in ER for loading dose of antiseizure medication. 5. Patient had significant improvement following completion of Ativan 3 mg IVP and GCS improved to 14 (E3M6V5) from GCS of 7 (E1M5V1). 6. Patient able to communicate after improvement as above and reports she has had headache or migraine for past several days as well as dysuria with bilateral CVA pain and has significant pain on percussion of bilateral CVA and moderate pain on palpation of bilateral flanks. No nuchal rigidity or pain with ROM of neck. Additionally, she complains of severe headache and diffuse pain of back and abdomen/pelvis. She reports a history of seizures in the past and reports she had one last month and was treated at a hospital in her home state. She denies antiseizure medications. Additionally, patient reports nonproductive cough, sore throat, nasal congestion, fever, chills, myalgias, lethargy, nausea, and episodic emesis over the past 2 days. She has anterograde amnesia following seizure and does not recall events. 7. Normal saline 1,000 mL IV bolus, then 100 mL/hour in ER. 8. CT of head with and without contrast performed and negative for intracranial hemorrhage, lesions, stroke, or other acute pathology. 9. CT of chest/abdomen/pelvis with IV contrast shows no acute pathology or notable abnormalities. 10. Lactic acid drawn and normal. 11. UA and urine microscopy collected by straight catheterization and culture collected and pending. 12. Blood cultures x 2 collected and pending. 12. Rocephin 2 mg IVPB in ER after blood cultures collected. 13. Vancomycin 20 mg/kg (1,500 mg) IVPB

following Rocephin. 14. Dexamethasone 10 mg IVP in ER. 15. Duoneb nebulizer in ER. 16. Called to discuss with patient's daughter and the family's preferred contact who is 23 years old. She reports patient had COVID vaccination 2 days ago and beginning that night patient has complained of headache, fever, chills, nonproductive cough, sore throat, nasal congestion, myalgias, and lethargy. Additionally, she reports patient has history of seizures on at least 1 occasion in the past a few months ago but is not on antiseizure medications. She reports patient had MRI and MRA of her brain at that time and reportedly and intracranial aneurysm was identified at that time. 17. Called to request transfer to another facility and spoke with hospitalist who states there is no neurologist there and suggests transfer to larger tertiary care facility with neurology. 18. Called to request transfer and accepted by ER provider. 19. Transfer by ALS ground ambulance with telemetry, pulse oximetry, O2 to keep > 02%, vitals every 30 minutes, normal saline at 100 mL/hour, Rocephin 2 grams IVPB, vancomycin 20 mg/kg (1,500 mg) IVPB in ER. á DISPOSITION Patient Stabilized and Transferred Data Unavailable Wed Dec 30, 2020 2:12 AM CST

PATIENT WAS OBSERVED FOR 15-20 MINUTES IN THE PHARMACY POST INJECTION, AND HAD NO SYMPTOMS. PATIENT ALSO HAD BROUGHT ALONG HER EPI-PEN TO THE APPOINTMENT AS SHE WOULD BE PREPARED IF SHE HAD ANY PROBLEMS. ON HER WAY HOME, APPROXIMATELY 30 MINUTES AFTER HER VACCINATION, SHE HAD SOME MILD CHEST PAIN AND FELT SOME THROAT TIGHTNESS. SHE DID ADMINISTER 1 DOSE OF HER EPI-PEN 0.3 MG INJECTION AT THAT TIME. SHE EXPERIENCED RELIEF OF HER SYMPTOMS, AND APPROXIMATELY 1 HOUR AND 30 MINUTES LATER WHEN I CALLED HER, SHE WAS STILL FEELING UNUSUAL SENSATION IN HER THROAT, BUT WAS MUCH BETTER. I ENCOURAGED HER TO TAKE SOME HYDROXYZINE , WHICH SHE HAD AVAILABLE AT HOME, AND TO CONTACT THE EMERGENCY ROOM IF HER SYMPTOMS DID NOT RESOLVE COMPLETELY OR SEEM TO BE GETTING WORSE.

Anaphalaxis reaction, stridor an unable to breathe. Happened in 30 seconds

Spouse awoke 12/20 and found spouse dead. Client was not transferred to hospital.

Resident in our long term care facility who received first dose of Moderna COVID-19 Vaccine on 12/22/2020, only documented side effect was mild fatigue after receiving. She passed away on 12/27/2020 of natural causes per report. Has previously been in & out of hospice care, resided in nursing home for 9+ years, elderly with dementia. Due to proximity of vaccination we felt we should report the death, even though it is not believed to be related.

Within 24 hours of receiving the vaccine, fever and respiratory distress, and anxiety developed requiring oxygen, morphine and ativan. My Mom passed away on the evening of 12/26/2020.

Near syncopal episode approximately 2.5 hours after vaccination. Sudden onset of dizziness, nausea, and diaphoresis. Was admitted to ED and observed overnight. Full cardiac work up was done and shown to be within normal limits. I have no pre-existing conditions and considered to be a healthy adult.

On Dec. 20, 2020 around 11:30 PM, 2 days after patient received her COVID-19 vaccination, she was found on the bathroom floor , obtunded, very pale, diaphoretic, nauseous, and complaining of severe chest pain. Paramedics was called and patient was transported to the nearest emergency room.

According to paramedics, on the way to the ER while patient was in the ambulance,she was noted with a sudden drop in heart rate about 19 beats/minute and have to be given Atropine IV Push, oxygen and was connected to transcutaneous pacing which improves her heart rate. In the ER patient continued to have chest pain and she was given Morphine, Oxygen, Nitroglycerine and Aspirin. IM had an EKG which showed Sinus Bradycardia with a Right Bundle Branch Block. She had serial ekgs, a chest x-ray, laboratory testing which included Troponin. Her first Troponin level came back elevated prompting her hospital admission to Telemetry. Her next 2 Troponin level improved and return to normal range and her chest pain has resolved.. She underwent a Stress Test which came back negative. Patient was admitted for a total of 20 hours in the Telemetry unit with Cardiology consultation before being discharged home last . She was re-evaluated by the cardiologist yesterday which diagnosed her a chest pain of unknown origin.

RESIDENT CODED AND EXPIRED

Rash, Itching and swelling of left arm. Progressed to tachycardia in the 150's, hypertension 200/114. Tingling of lips, dizziness

Went to Emergency room on 12/28/20 because he was short of breath. Tested positive for COIVD_19 and was admitted with hypoxia.

Approx 20 min after vaccination patient developed itching at the site and this progressed to include chest, neck. EMS evaluated patient who recommended transport and patient agreed. Benadryl offered by EMS and IV started. Pt with concurrent treatment for valley fever noted. ED administered medications - famotidine 20mg iv, methylprednisolone 125mg iv, NS 1000ml bolus. Prescribed prednisone 20mg po daily x 2 days.

Injection given on 12/28/20 - no adverse events and no issues yesterday; Death today, 12/30/20, approx.. 2am today (unknown if related - Administrator marked as natural causes)

Death by massive heart attack. Pfizer-BioNTech COVID-19 Vaccine EUA

Moderna COVID?19 Vaccine EUA - Metalic taste - Lump in her throat- felt like swelling - Nausea and then vomiting - Shaking and started to become unresponsive.

pt passed away with an hour to hour and 1/2 of receiving vaccine. per nursing home staff they did not expect pt to make it many more days. pt was unresponsive in room when shot was given. per nursing home staff pt was 14 + days post covid

pt was a nursing home pt. pt received first dose of covid vaccine. pt was monitored for 15 minutes after getting shot. staff reported that pt was 15 days post covid. Pt passed away with in 90 minutes of getting vaccine

The patient had COVID19 infection diagnosed 12/14/2020, and he stated 5 to 10 days after this, he developed shortness of breath. Had vaccine on 12/24/2020. Hypoxic and short of breath with COVID19

pneumonia on 12/29/2020. I do not know if this is an adverse effect or temporally related or if the vaccine activated prior infection.

"my left arm and breast were tender with some mild body aches and low grade headache/Arm soreness; my left arm and breast were tender with some mild body aches and low grade headache/ left breast was increasingly painful with swollen palpable lymph nodes; my left arm and breast were tender with some mild body aches and low grade headache/ left breast was increasingly painful with swollen palpable lymph nodes; my left arm and breast were tender with some mild body aches and low grade headache/ left breast was increasingly painful with swollen palpable lymph nodes; my left arm and breast were tender with some mild body aches and low grade headache; body soreness and stiffness; This is a spontaneous report from a contactable healthcare professional. A 34-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899), via an unspecified route of administration on 18Dec2020 at single dose for COVID-19 immunisation. The patient medical history and concomitant medications were not reported. The patient stated, ""the day after the injection, my left arm and breast were tender with some mild body aches and low grade headache. Sunday Arm soreness went away but left breast was increasingly painful with swollen palpable lymph nodes, with body soreness and stiffness. Monday left breast is still remarkably tender with palpable lymph nodes"" on 19Dec2020 (reported as Seriousness criteria-Caused/prolonged hospitalization: Yes, on an unspecified date in Dec2020). The outcome of the event was not recovered.; Sender's Comments: The reported information is limited. Based on the close temporal relationship and the description of the events, there is a reasonable possibility that the events are related to BNT162 vaccine. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate."

got COVID vaccine from Pfizer, next day got COVID tested with mild symptoms and positive; got COVID vaccine from Pfizer, next day got COVID tested with mild symptoms and positive; This is a spontaneous report from a contactable physician (patient). A patient of unspecified age and gender received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on an unspecified date at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient reported that he is a physician and got COVID vaccine from Pfizer, next day got COVID tested with mild symptoms and positive. The patient stated so he got vaccinated probably while having COVID. The patient wanted to know any concerns from the vaccine standpoint efficacy side effects. Outcome of the event was unknown. Information on the lot/batch number has been requested.; Sender's Comments: The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

"asking on how to differentiate between side effects from COVID vs vaccine side effects/also wondered if he needs to quarantine; asking on how to differentiate between side effects from COVID vs vaccine side effects/also wondered if he needs to quarantine; swelling of glands in throat/lymphadenopathy in throat; headache; Feeling a little fluish; This is a spontaneous report from a contactable healthcare professional (patient). A 61-year-old male patient received BNT162B2 (Pfizer-BioNTech COVID-19 mRNA vaccine, batch/lot number and expiry date were unknown), via an unspecified route of administration on 21Dec2020 18:06 at a single dose for COVID-19 vaccination. Medical history included diet controlled Type 2 Diabetic diagnosed 5 years ago in 2015. There were no concomitant medications. The patient previously got Shingles vaccine and it was a two dose vaccine. He felt a little bit like he did now after receiving the second vaccine. He felt fluish for 8-12 hours the day after receiving the vaccine. He has gotten lots of vaccines like Flu and has no responses. The patient does not have prior vaccinations within 4 weeks. The patient received the vaccine yesterday (21Dec2020), and maybe an hour ago on 22Dec2020, he started feeling swelling of the glands in throat or lymphadenopathy in throat and a little bit of headache. He has a question that he cannot find the answer to anywhere. The patient is asking on how to differentiate between side effects from COVID vs vaccine side effects? His temperature was 98.1 on unspecified date. He did not have an exact time frame for when it began. He stated, ""you get swelling in glands and then you notice it."" He noticed about 2 hours ago and it is getting worse. Now he is feeling like he is sick. He has been volunteering and giving the vaccines over the past two days himself. He is feeling now a little fluish. He doesn't know how to say it other than tired and just doesn't feel good. He would go to work like this and does not feel it is medically significant. He does feel like he is deteriorating but that is only a guess. He felt a little worse than an hour ago. He also wondered if he needs to quarantine because he is signed up to give the vaccines and would not want to do that if he should not. No ER or physician's office required. The outcome of the events was not recovered. Information on batch/lot number has been requested.; Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of reported events cannot be totally excluded. The case will be reassessed if additional information becomes available."

tested positive for Covid; tested positive for Covid; This is a spontaneous report from a contactable consumer (patient) from a Pfizer-sponsored Program Pfizer First Connect. A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) Lot number Unknown, via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunisation. The patient medical history and concomitant medications were not reported. The patient was upset. She was part of the COVID Trial in and this past week (in Dec2020) she started to get sick and tested positive for COVID. They gave her a diary which she had to fill out weekly, so she filled it out and put that she had COVID. She never heard from anyone. She stated the testing site people and snarky attitudes and when they went no one was wearing masks. She was told by the testing site, they couldn't make people wear them. Relayed that she could do an escalation and have someone reach out to her in regards to this. The patient underwent lab tests and procedures which included Covid test: positive on unspecified date in Dec2020. The event outcome was unknown. Information on the Batch/Lot number has been requested.

Itchy throat, red eyes after 30 minutes. EMS on site gave IV Benadryl, epi pen shot and took to ER for monitoring. Vitals were good so he was discharged.

Hives/swelling/itchiness/redness at injection site about 5 inches long a week after injection.

"Chills, Fatigue, ""hot"" feeling eyelids when I close eyes, muscle/joint pain, injection site pain. No treatment besides rest and a hot shower."

Pt felt hot and short of breath . Pt recieved EPI in office and EMS was called . Pt was transported to the Hospital

Sore arm-2days , headache -current on and off , light sensitivity 2 days

Currently have shortness of breath, chest pain, fatigue, nausea, body aches, joint pain, and injection site pain.

Dizziness, Equilibrium was off. This started within an hour of the vaccine and lasted 24 hours. Had to take the following day off of work. Also, burning in the chest (like heartburn) lasted 48 hours.

Weakness, headache, high level myalgias, fever, nausea, cold intolerance, shaking

Onset was 10 min post vaccination. Symptoms experienced over an hour, in this order. Went to the ED. Some still continuing within 14 hrs past time of shot. Severe headache. * same night Dizziness and lightheaded. * same night Nauseous Clammy Cheeks flushed Itchy Chills Short of breath / slight wheezing * same night Fatigue * same night

Extreme vertigo occurred suddenly around 9:00 pm. Continuous dizziness continues. Unable to walk straight lines. Wobbling and loss of balance when I walk. I have eaten and been drinking fluids. Side effect still continues.

Normal resting heart rate of 58-61. At 10 PM, heart rate increased to 137 while watching TV, heart rate continues to average at 102 bpm for 120 minutes + and counting. Body feels warmer than usual

About 4 hours after receiving this vaccine I experienced burning down my left arm and up into my chest. I had chest tightness and over the course of the day it became worse. I developed a fever of 100.9 and I woke in the night to SEVERE body aches and a migraine headache. Fever and chills I also had a runny nose earlier that day. It is now the second night after the vaccine and I am still experiencing severe pain in my joints back and kidneys. Also muscle pain If I have a fever in the am, should I wait to go back to work?

Fever of 102 with onset at midnight after vaccination,a long with chills, muscle aches, some nausea,--subsided after a few hours. headache and tiredness the morning after

Raised, hardened, hot bump on arm 24 hrs post injection with pain and swelling

I have an autoimmune disease, psoriatic arthritic and osteoarthritis. This caused my flare up. My knees and ankles swelled to the size of grapefruits. I could not move legs for about 18 hours. From Friday to

Sunday, I could not get out of bed. Monday night, I really started feeling better and was able to take care of my kids again on Tuesday. I went back to my normal shift on Wednesday. I was under the care of my PCP and Rheumatologist.

10 minutes after receiving vaccine, patient reported numbness across upper lip which progressed to her tongue. Felt tingling and dryness of tongue and swelling. No difficulty breathing or swallowing, no chest pain, no wheezing, no rash, no itching. Taken to ED and given methylprednisolone 125mg IV, diphenhydramine 50mg IV, famotidine 20mg PO. Patient improved and monitored x 4 hours with resolution of symptoms. Prescribed prednisone 50mg po x 4 days.

erythema, tachycardia, tachypnea, headache, uncontrolled dystonic shaking

Developed sudden onset of shaking chills and fevers as high as 103.0. She has developed a small circular 5 x 5 area of erythema and firmness at the injection site of her left upper arm.

Dizziness, Hives on entire body

pt received vaccine at covid clinic on 12/30 at approximately 3:30, pt vomited 4 minutes after receiving shot--dark brown vomit, staff reported pt had vomited night before. Per staff report pt became short of breath between 6 and 7 pm that night. Pt had DNR on file. pt passed away at approximately 10pm. Staff reported pt was 14 + days post covid

Sent home from work after receiving vaccine. I immediately developed sore throat. First 3 days I was miserable and then this whole week everything has bad. Outside of ears were burning. Stomach turned immediately. I thought I was going to vomit. Top of my head started spinning. I am still foggy. Breathing was never altered.

Received my vaccine on December 22nd, 2020 at around 830 Am. That afternoon, about 3 PM, I started to have a reaction. It started with tingling/numbness in my right hand which progressed up my arm into my elbow. About 10 minutes later, it then progressed into my right foot, and my left foot. About 10 minutes after that, I started to get flushed and a neck rash (diagnosed from Dr.). I took Benadryl and Ibuprofen 800mg PO every 6 hours for the next 24 hours. The numbness in my right foot and left foot along with the flushness went away a couple hours later. Although, the numbness in my right hand never went away. It came and went for the next 4 days until December 27th and 28th when it started getting worse. On December 28th evening, it got so bad that I was debating going to the emergency room around 1 am. The numbness and tingling was in my right hand and started shooting up my arm. The nerve pain around my wrist was unbearable. I finally fell asleep and the next morning, it was not nearly as bad, but was still there. The numbness and tingling moved from my right hand mainly to right hand, right foot, right leg, left foot and left hand today (12-30-2020).

angiodema. hospitalized overnight. During the hospitalization pt was started on an epi gtt and given MTP 125 mg. He had subsequent hyperglycemia, and increased his rate on his insulin pump to 2 U/hr (from 0.83 U/hr). Pt then decreased his rate to 1.4 U/hr while on the epi gtt, and then to 1.1 U/hr when off of the epi gtt. He also strengthened his carb ratio from 1:12 to 1:10 last night.Pt reports he had

postprandial hyperglycemia overnight after his meal, but then BG corrected overnight. Pt reports fasting this morning is in the 110s. This morning's breakfast on 1:10 CR with well controlled BG.

Resident received vaccine per pharmacy at the facility at 5 pm. Approximately 6:45 resident found unresponsive and EMS contacted. Upon EMS arrival at facility, resident went into cardiac arrest, code initiated by EMS and transported to hospital. Resident expired at hospital at approximately 8 pm

Due Date unknown/6-7 wks pregnant -nausea -Body felt heavy -headache -in & out consciousness -Fatigue, severe -Heart Racing

Patient had an anaphylactic reaction to the vaccine the day after it was given and went to the nearest ER.

Patient stated he stopped his blood pressure medications 3 days prior to vaccination due to a previous reaction to losartan, a medication he was no longer taking. Patient took aspirin and a MVI on day of vaccination and drank lemon water. Patient developed tingling sensation in his mouth after eating dinner around 18:00. Patient stated he ate tacos with apple cider and noticed tingling after dinner. Patient stated he took two benadryl with no relief. His tongue continued to swell and he took two additional benadryl at 22:00. Once he developed difficulty swallowing he went to the emergency department. Patient presented to the ED with tongue swelling and difficulty swallowing. At 23:57 he was adminsitered 0.3mg of epinephrine IM, diphenhydramine 25mg IV, famotidine 40mg IV, dexamethasone 10mg IV at 0114, methylprednisolone 60mg q6hrs started at 0417, diphenhydramine 25mg q6hrs IV started at 0416, albuterol 2.5mg via neb q6hrs started at 0710

Patient died within 12 hours of receiving the vaccine.

Resident received vaccine in am and expired that afternoon.

Started feeling a reaction immediately after the vaccine, felt blurred vision, dizziness, racing heartbeat, chest rash and face, itching all over, difficulty swallowing, tongue tingling and wheezing. Sent to ED. EPI and Benadryl. 1800 Went to see her in the ED, room 33. She has red rash to neck, shaky hands itching to neck and chest. ED Dr to discharge, she stated husband to pick her up and she will follow up with OH tomorrow. ----------RN ED gave her Epinephrine 0.3 mg, Methylprednisolone 125mg, Diphenhydramine HCL 50 mg, Zofran 4mg, Lorazepam 1 mg, Hydroxyzine HCL 50 mg Sumatriptan 6mg , Discharge from ED at 1902 ---------- ---------- RN 12/29/2020 1715 called to check on patient. left voicemail for her to call OH. ???????..? 12/29/2020 1838 left voicemail for patient to call OH. ??????????????????????. 12/30/20 2030 spoke with her. Tuesday 12/29 3pm-4pm dizziness, confusion, sob. Wheezing. Ambulance called. Hospital admitted. Intubated for less than 24 hours. Breathing treatments, epi drip. Now just on steroids and walking around and feeling better. Still admitted at hospital. Hoping discharged tomorrow. ----------RN

Patient received dose 1 of COVID vaccine 12/24. He developed symptoms consistent with COVID infection on 12/25. He was seen in the emergency room at Hospital on 12/27,was diagnosed as COVID positive, and was discharged to home. He returned to the emergency room on 12/29 and was admitted to the hospital for treatment related to COVID infection. He is currently admitted to Hospital.

10 minutes after vaccine numbness and tingling in left foot, hand and left side of face. Spacing out feeling. Feel like i'm going to pass out.

EDD - 4/1/2021 - Contractions at 26 w 3 days sent to L&D to be monitored on 12/28/20. Covid-19 Sars Vaccine given 1st dose 12/27/20. Patient was diagnosed with Fetal Hydrops. Patient Hospitalized 12/28/20 - current MFM consulting in hospital & outpatient

EE has a history of anaphylaxis reaction to Latex. EE states she was intubated in Mexico over this in the past. Pfizer-BioNTech vaccine given, 20 minutes later EE c/o dizziness. EE places on cot and starting wheezing and being short of breath. Lungs sound tight and wheezy throughout. á 1052- Epi 0.3mg IM given in Right Deltoid 1053- Benadryl 50mg IM given in Left Deltoid á 1054- EE getting restless and starts feeling chest tightness. Epi 0.3mg IM given in Right Deltoid á Code Green Team arrived at 1054. á BP 197/126, HR 88, RR 44, blood sugar 109 á 1058- EE getting wheezing and short of breath again. Epi 0.3mg IM given in Right Deltoid and Benadryl 50mg IM given in Left Deltoid. á 1059- EE transferred to ED on stretcher, escorted by ICU RN and ICU MD. In ED- patient given solumedrol, epi, benadryl, phemodidine, ativan, zofran x 2 and ee sent home with medications as well.

Redness about 1 1/2 inches around injection site, edema to right arm, r side of neck, r breast, r shoulder, temp 99.3, increased blood pressure. Patient went to primary care physician. She was then sent to the ER. She was Covid (+) in July 2020

Shortly after receiving the vaccine (within 10 minutes) the patient's tongue swelled, facial redness, gasping for air. This resident was marked for a 30 minute observation due to previous anaphylaxis type reaction. Immediately administered 0.3mg epinephrine x 1 dose. Then administered 50mg IM Diphenhydramine. This treatment course resolved the adverse reaction. Patient was monitored onsite at facility. Her husband came to pick her up and take her home. Tried to reach patient several hours after but was unable to at this time.

I had shortness of breath

approximately 30 minutes after receiving vaccination i began to develop tongue and lip swelling as well as difficulty swallowing and breathing , i then proceeded immediately to the nearest er

Patient complained of a headache, then patient was losing consciousness and gasp for air. EpiPen was utilized due to being unresponsive then began to seizing. Patient started to flatline and an AED was used while a paramedic came. Patient was put on her side then facility gave something for seizures. Lastly, ,ambulance took her to the hospital.

Patient started having myalgia, chills, nausea on the next day of the vaccination. on 2nd day (12/29) patient had chest pressure which made her present to Hospital ED. She had troponin elevation to 1.14.

Cardiac Catheterization was done which was negative. On Trans Thoracic Echocardiogram, patient was found to have hypokinesis of the mid and distal segment with some sparing of apex proving Takotsubo (stress induced) cardiomyopathy. Patient did not have any underlying emotional or physical stress going on in her life or family. Till now extensive infectious as well as inflammatory work up is done to rule out any secondary causes of cardiomyopathy which till date have remained negative. As a diagnosis of exclusion, her presentation seems to be COVID-19 vaccine induced Takotsubo Cardiomyopathy

Pt received 1st dose of Moderna vaccine in am at COVID vaccination clinic. On presentation to clinic he stated he was feeling well. Pt was brought to ER in pm with hypoxic, requiring 15L supplemental O2. Per pt's family, pt was not feeling well for the last couple of days but didn't think it was related to COVID. Abbott COVID + in ER. Possible vaccine reaction, though seems unlikely.

"15-20 mins after receiving the vaccine she reported she had difficulty swallowing and difficulty breathing and was ?shaking."" a PA wrote in her note that when she ran in to help, she found the patient to be tachypneic, diaphoretic, warm with some red blotchy patches on face, chest & neck. Able to speak easily c/o trouble breathing & sensation of throat swelling & extremities feeling abnormal. No stridor. No facial edema noted by that clinician. Administered epi-pen 0.3mg - IV started , Benadryl 50mg IVP and solumedrol 125mg IVP. Patient reports she subsequently arched her back and had rigidity of her arms/legs and tremors. Clinic PA reports that while she was there, pt was never hypotensive. Initially hypertensive after epi as expected with some favorable response after 10-15 min Staff there gave her IM epinephrine, IV Solu-Medrol and 50 mg IV Benadryl. EMS was contacted and transported to the emergency room. She arrived at the ER, was monitored for 2 hours, was started on pepcid and benadryl and discharged from the ER. She had a diffuse itchy rash. The following day she again developed recurrence of throat swelling. Went back to a different ER. Developed dyspnea immediately prior to arrival at ER. There was again given solumedrol and benadryl and pepcid and developed muscle rigidity and arched back for 10 minutes. Symptoms of SOB and dyspnea resolved with epinephrine. Was discharged from the ER with prednisone after being monitored for 5 hours. Is continuing to take prednisone and benadryl. Rash is still present but improving with scheduled benadryl. Has new redness at injection site today. Continues to feel some throat swelling but no tightness today. This information was gathered from talking with pt today for a phone appt and also from her medical chart regarding her vaccination visit and two ER visits."

Acute appendicitis, onset morning of 1/1/2021 (Reporting this because Pfizer covid vaccine had 3-4x higher risk of appendicitis, although data not reported for Moderna covid vaccine)

on dec 22 I felt some myalgias, chills, fatigue, HA --quite normal. That evening, noted small amount swelling R hand --I iced and took acetaminophen. By Dec 25, hand very swollen and painful with decreased ROM all fingers

Within 15 minutes of receiving the vaccine I began to get very itchy and blotchy with a hoarse voice. The paramedic downstairs walked me up to the emergency room. I was treated with medications to help calm the itching and burning feeling. By 940 I went anaphylactic and had several doses of epinephrine to help calm this. I continued to have rashes and the feeling of my throat closing. I was transferred by

ambulance to medical center in the ICU. I am still here and have had two toner anaphylactic episodes since. I have been on a epi drip, steroids, famotidine, Ativan and Benadryl. I also had a picc like placed.

Anaphylaxis. Immediately experienced shortness of breath, rapid heart rate, and rash. I am a Nurse Practitioner in the emergency department. Had went down to the temporary vaccine station to receive my vaccine, immediately returned to the ER and began to experience symptoms of anaphylaxis. Was immediately placed in a treatment room and received treatment by the ER physician, which included oxygen, intravenous Benadryl, Solumedrol, and Normal Saline. Was observed for several hours and then eventually sent home with prescription for Prednisone and Pepcid. I do have a allergy to shellfish, was never asked about my allergies and nothing on the paperwork I was given prior to the injection noted a concern for shellfish allergies.

Vaccine on 12/22/2020 and started feeling bad on 12/27/2020 and tested positive on 12/30/2020 for COVID 19 Was advised to fill this out by my PCP

Flushing, sweating, increased heart rate proceeded to feel difficulty swallowing and clearing my throat. I was taken to the ER. The symptoms progressed to feeling dizziness, difficulty speaking, and chest pressure with increased SBP/DBP. General nausea and feeling very unwell.

CAREGIVER RECEIVED FIRST VACCINE DOSE AND SOON AFTER BEGAN TO FEEL DIZZY AND HER EYES BEGAN TO TWITCH, FOLLOWED BY UNCONTROLLED SHAKING, WITH HIGH FEVER FOLLOWED BY SEVERE SHORTNESS OF BREATH AND GASPING, WITH TIGHTNESS AROUND THE CHEST. TRANSPORTED TO EMERGENCY DEPARTMENT. HAD MULTIPLE EPISODES OF ITEMS LISTED ABOVE WHILE IN ED, INCLUDING HEAVINESS IN HER LEGS AND TINGLING IN ARMS. SHE WAS DISCHARGED FROM ED AT 10:30PM BUT WAS READMITTED ON 12/24 TO ED FOLLOWING SIMILAR ISSUES. TO DATE SHE HAS HAD 5 RAPID RESPONSES IN HOSPITAL DUE TO REPEAT OF SIGNS/SYMPTOMS. CT AND PULMONOLOGY CONSULT SCHEDULED FOR 12/28/2020.

Patient is a 55 year old male with no past medical history who presents with complaint of sudden onset of left-sided nonradiating chest discomfort of sudden onset approximately 1 hour prior to presentation while doing administrative work at rest. He describes the pain as a dull heaviness sensation and approximate 3/10 pain severity. Chest discomfort was associated with a feeling of flushing that was quite transient but chest discomfort was persistent. Patient immediately presented to the ED for further evaluation. He denies experiencing any chest pain upon waking up this morning. Does note that he did have a transient episode of epistaxis on his way to work for which he had to pull over and apply pressure to his nose but this subsequently subsided and he attributed this to dry air as he has experienced epistaxis in the past but with less severity previously. In the ER, vital signs noted for BP 133/76, pulse ranging 91-114, respiratory rate 16-20, 96% on room air. Initial laboratory parameters were completely normal including normal CBC, CMP, LFT, lipase, UA, and normal D-dimer. Initial troponin was negative x1. EKG with sinus tachycardia, heart rate of 115. Noted Q waves inferiorly. No acute ST or T wave changes appreciated. Chest x-ray with mild increased density in the left lower lobe. Given this, patient was tested for rapid Covid which was negative but PCR was positive for COVID. CT of the chest noted for focal subsegmental groundglass infiltrate at the superior segment of the LLL, likely infectious versus

inflammatory. Also noted small nonspecific groundglass attenuation with focal septal thickening at the right upper lobe which could be infectious or inflammatory, bibasilar atelectasis. Patient was treated with aspirin 324 mg in the ED. Of note, patient actually just received the COVID-19 vaccination on 12/24/20. He denies any shortness of breath, no cough, denies any nausea or vomiting, denies any change in taste or smell nor change in appetite. Does note 1 single episode of loose stool but otherwise denies any diarrhea. Does report that he had approximate 48 to 72-hour period of fatigue and soreness at the site of the left deltoid injection following the vaccination but otherwise no further symptoms. It is also noted that he does have a positive family history of coronary artery disease as his dad had an MI at the age of 49. Patient has never undergone a cardiac catheterization in the past but does report having a negative stress test at the age of 42. He is being admitted under the hospitalist service for further management Patient was initially admitted under observation for chest pain obs. However patient's Covid test came back positive and patient also had dynamic EKG changes concerning for possible unstable angina. Patient was treated with aspirin Plavix full-strength Lovenox along with beta-blocker and a cardiology consult. Serial troponins were negative. Echocardiogram revealed normal EF of 55 to 60% with no hemodynamically significant valvular disease. Cardiology felt that patient likely has underlying coronary artery disease have recommended discharge home with aspirin and Plavix with outpatient stress testing given his positive Covid testing. At the time of discharge patient denied any chest pain or shortness of breath. Patient was borderline diabetic with a hemoglobin A1c of 6.1. Patient was discharged home with Metformin along with glucometer, glucose strip, lancets. Given patient's tachycardia patient's Metformin 25 mg twice daily was changed to Toprol 25 mg daily. (Please note clarification in comparison to discharge home med list. Toprol XL 25 mg daily was called to pharmacy in place of the metoprolol.)

The vaccine was received at 1:12 PM, and I felt fairly fine, aside from injection site pain and some tingling in my left arm until I had sudden significant elevation of heart rate, with shortness of breath, and throat swelling/tightening at approximately 1:26PM. I cold compress was applied to my forehead and I was put in a reclining position & then received Epinephrine at 1:28PM. EMS (present onsite) arrived for transport at 1:31PM. 4L of oxygen was applied after O2 sat of 89% noted by EMS. Blood pressure was elevated to >200/100 initially by EMS. Symptoms improved quickly following epinephrine, with some residual feelings of very mild throat fullness, and I developed chills which improved over time. I was transported to emergency department where I was evaluated (symptoms mostly resolved at that time, but ED physician noted a little swelling remaining in my uvula), then IV Benadryl and Decadron were given. Later acetaminophen was also given for headache that developed during my ED stay. My vitals were monitored throughout and observation occurred until I was discharged at approximately 5:00PM, as symptoms had not recurred.

HIVES, SOB, THROAT CLOSING UP, WHEEZING

12/28/2020, Pharmacy staff administered Moderna COVID Vaccine. 12/29/2020, he had not eaten breakfast or lunch but did consume fluids and take his medications. BP =150/70, Temp. = 101.6, Pulse= 102, Respirations= 18 and Oxygen saturation= 97%. Tylenol 650 mg given. It was difficult for him to swallow. Also had no use of right upper extremity and unable to move lower extremity, mouth was drooping and was drooling. Physician in attendance and ordered to send to ER. 1/1/2021, received

information from nurse at hospital that patient received a Peg Tube this afternoon and Clinical indication of a stroke.

I received the vaccine at 6:30pm on 12/27. I worked atb7pm and took lunch at 2:00am. After lunch, I immediately felt sick to my stomache and threw up. I went home after my shift and went to bed. After 5 hours, I woke up and went to the couch to lay down while kids watched TV. Next, I woke to several people in my house. I had a seizure and my son had called 911. I was taken to emergency department. I was admitted and stayed 2 nights in the hospital.

After vaccination, patient tested positive for COVID-19. Patient was very ill and had numerous chronic health issues prior to vaccination. Facility had a number of patients who had already tested positive for COVID-19. Vaccination continued in an effort to prevent this patient from contracting the virus or to mitigate his risk. This was unsuccessful and patient died.

A little over ab hour after receiving the vaccine I noticed a burning sensation in my sinuses. By 130am 1/1/2021 I awoke from my sleep terribly dizzy, shaking violently and experiencing a fever of 101.3 F. I took advil and tylenol and fell asleep about an hour later. I woke up with similar symptoms at approximately 830am on 1/1/2021 took an additional dose of advil and tylenol and slept till 12p. I woke up with a bad headache and coughing fits similar to when I had covid back in March. I went to an urgent care who assessed me and ordered me to the ER. medical center administered IV fluids, an inhaler, steroids, epinephrine and benadryl and a few hours later my symptoms had subsided for the most part and a dose of IV antibiotics was administered. I am currently admitted for observation with likely discharge on 1/2/2021.

30YO F ICU nurse obesity (BMI 35) COVID 19 on Dec 2 symptoms, Dec 3 tested positive for COVID-19. never hospitalized, outpatient only. 12/12 completed isolation 12/21 received vaccine 12/7 developed Fever chills diarrhea SOB cough Urgent care visit. RLL consolidation on CXR given doxycycline 100 mg po bid worse, fever 40 targetoid lesions to LE (started before doxy) WBC 22K tachycardic tachypneic admitted requiring 2-4L oxygen CT angio without clot, diffuse ground glass and RML dense infiltrate DDimer 7.8 LDH 599 CRP 41 procal 0.67 ferritin 500 Viral respiratory PCR negative Sputum cx with oral flora (pending) COVID ag testing neg COVID PCR 1/3 targets positive (called as indeterminate).

Within 5 minutes of the vaccine, patient had wheezing, shortness of breath and chest pain. patient given epi x 4, decadron, fluids with some improvement and then hospitalized. IN the hospital, patient continued to have chest pain and satting well but with protracted course and is still in the hospital.

Vaccine given at 7:05am 12:00noon, 5 hours later, I started experiencing severe chest pain, jaw pain and shortness of breath in which EMS was called and I was taken to the hospital. Since then, I lost feeling in my hands and feet, numbness and tingling. I've improved however, during my recovery suffered with spinal pain, shortness of breath, very winded, muscle pain and loss of appetite to especially meat.

Soreness and weakness of left arm for more than 5 days. Intermittent headaches and runny nose

On 12/29: lightheadedness, flushed, felt like I was going to pass out, numbness/tingling down arms and hands, chest tightness, clammy hands and feet.

Anaphylaxis. The COVID shot was given, no reaction then. After 7 minutes, congestion, severe cough, vomiting phlegm, feeling like throat closing started happening. Code was called, Benadryl was immediately given intramuscular in the left arm, blood pressure, pulse ox was taken, and then was taken to the Emergency Department. In the ED, I was given prednisone, one EPI, anti-nausea medication all through I.V. and many more medications given to me via I.V. that I don't sincerely remember. I was under observation for 4 hours. I was discharged after all symptoms dissipated and was given Prednisone 20 MG (3 tabs a day) to take to help my lungs. Management followed up almost immediately, everyone from the moment I had the anaphylactic reaction was quick and prepared.

Patient with a history of thalassemia and Gilbert's disease, developed severe jaundice three days after vaccination. Had mild headache and sore arm but otherwise felt well. Had labs drawn - found to have highly elevated bilirubin (23) and LFTs in the 700s. Was admitted to the hospital and had CT showing Cholelithiasis, choledocholithiasis and minimal intrahepatic biliary ductal dilatation. Left hospital and was admitted to another facility where plan was for ERCP and cholecystectomy. Ultimately unclear if at all related to the vaccination - may be coincidental.

Pt had vaccination at city site. Waitied 15 min after shot and was cleared to go. Reported to wife that he was very thristy, so they stopped at a convenience store on the way home. While there, he felt worse and asked to go to the Emergency room. They chose Methodist to enter. Pt went to triage and while at triage, had syncopal episode, then full arrest. After short course of CPR and defib, he had ROSC. Was taken to cath lab for intervention (stents) and is now in ICU.

At the time of vaccination, there was an outbreak of residents who had already tested positive for COVID 19 at the nursing home where patient was a resident. About a week later, patient tested positive for COVID 19. She had a number of chronic, underlying health conditions. The vaccine did not have enough time to prevent COVID 19. There is no evidence that the vaccination caused patient's death. It simply didn't have time to save her life.

Prior to the administration of the COVID 19 vaccine, the nursing home had an outbreak of COVID-19. Patient was vaccinated and about a week later she tested positive for COVID-19. She had underlying thyroid and diabetes disease. She died as a result of COVID-19 and her underlying health conditions and not as a result of the vaccine.

Tactile fever ,arm pain, headache and malaise in 24 hrs following injection Next day generalized achiness ,retrosternal chest pain and bilateral forearm tingly pain similar to Nov 2019 and went to Hospital UC,CXR and EKG normal but with short PR interval on EKG ,elevated troponin 3.5 Transferred to hospital troponin 12.1 ng/ml IVIG given SARS IGG positive on admission PCR negative

ON 1/1/21 THE DAY AFTER I RECEIVED THE VACCINE I WAS TAKING A NAP AND MY WATCH KEPT SENDING ME ALERTS. HOWEVER I DID NOT CHECK MY WATCH UNTIL 5:30 WHEN I WOKE UP AND I FELT LIKE I WAS HAVING HEART PALPITATIONS. I WENT TO THE EMERGENCY ROOM WHERE I WAS TREATED. I

WAS TOLD THAT I WAS FEBRILE WITH A TEMPERATURE OF 102. I WAS GIVEN IV FLUIDS, CHEST X-RAY, EKG AND LAB WORK. I WAS RELEASED ON 1/2/21 AT APPROXIMATELY 0030 (MIDNIGHT).

"Patient is hospital employee who completed screening form for COVID-19 vaccine by answering ""no"" to all contraindication questions. Approx 10 minutes after receiving COVID-19 vaccine dose # 1, patient was still in vaccine clinic area and complained of dizziness, palpitations and flushing. I observed patient fanning herself with papers. She was escorted out of the immediate clinic room, and assessed by paramedics present as having an anaphylactic reaction. Epinephrine 0.3 mg IM and diphenhydramine 50 mg IV given in clinic, Rapid Response was called overhead and patient immediately transported down the hall to the Emergency Dept. In ED, pt was noted as having swollen tongue, large areas of erythema on face, arms and chest, shortness of breath, nausea, dizziness (per ED physician notes). Pt reported being hospitalized in ICU with COVID disease more than 3 months ago, including intubation (not treated at this hospital), and has been back at work since August 2020. ED physical exam noted bilateral wheezing and patient in acute distress. In ED, pt administered racemic epinephrine 2.25% 0.5 mL via neb, epinephrine 0.3 mg IM, diphenhydramine 50 mg IV, Solu-Medrol 125 mg IV, famotidine 20 mg IV and epinephrine 5 mg/250 mL IV drip (started at 0.118 mcg/kg/min). Acute symptoms reported to resolve in ED. COVID test was negative. ED physician discovered that pt had history of multiple medications, including previous anaphylactic reaction to radiocontrast dye requiring intubation (which was not disclosed on the vaccine screening form). Pt admitted to Telemetry floor for observation. Overnight course was unremarkable, and patient was discharged the following day with prescription for Prednisone taper and prescription for Epi-pen. Advised not to return for second dose of COVID vaccine. EMR updated to reflect possible anaphylactic reaction to Moderna COVID-19 vaccine."

25 minutes after receiving the injection, there was a sudden onset of facial swelling, hives, itching and airway constriction. I had already left the drive-thru vaccination clinic and was driving to the hospital emergency room where I work. I informed my colleagues of my symptoms and was treated for anaphylaxis with IV diphenhydramine and famotidine over several hours. I was given a prescription for a prednisone taper for the next 6 days.

I suffer from lingering SOB with exertion after COVID infection. On the night of 12/31/2020 I began to feel more SOB than usual and was unable to correct my SOB with rescue inhaler. Became more SOB with exacerbated tachycardia and tachypnea, My family had to call 911 because I became aphasic and showing signs of possible stroke. I was taken to the ER and admitted for respiratory recovery and to role out stroke. The stroke was ruled out and I recovered with IV prednisone therapy, twice daily and supplemental oxygen. Released after HR, BP, & respiratory effort returned to normal: 01/03/2021

I was 28 weeks and 5 days pregnant when I received the first dose of the COVID19 vaccine. Two days later (12/25/2020 in the afternoon), I noticed decreased motion of the baby. The baby was found to not have a heartbeat in the early am on 12/26/2020 and I delivered a 2lb 7oz nonviable female fetus at 29 weeks gestation. I was 35 years old at the time of the fetal demise and the only pregnancy history for this pregnancy included a velamentous cord insertion that was being closely monitored by a high risk OB. My estimated due was March 12, 2021.

At around 40 hours post vaccination, developed severe abdominal pain and went to an emergency room for evaluation on 1/1/21. Abdominal pain was eventually diagnosed as appendicitis requiring appendectomy on 1/2/21. Emergency room visit and hospital discharged patient early on 1/2/21. It was then determined that the on-call team covering mis-read the CT scan and acute appendicitis was found. Patient then went to Medical Center on 1/2/21 for appendectomy and was discharged later that night following operation.

Headache, muscle pain on the site of injection, chills, nausea, fever. Started time 01.03.2021 8:15pm.

15 min after the vaccine I was flushed and felt hot , ears felt hot as well. I had a macular rash on chest and arms. My throat felt itchy and they immediately gave me benedryl. I was tahycardic as well. When I got home from the ER that night I had to take more benedryl and then the next morning I was still itchy and my voice was hoarse so I took more xyzal and famotidine. The rash subsided and I continued taking xyzal twice a day , benedryl and famotidine for a week. After my vaccine the itching did not subside for about 48 hours and it was very difficult to control. I had to take max doses of antihistamines to control the hoarseness In my voice and itching

High fever (104.2 degrees) at present, fatigue, chills

Blood pressure and pulse rate increased to 164/64, 85

1/1/2020: Residents was found unresponsive. Pronounced deceased at 6:02pm

Approximately 11:00pm on 12/29/20: Hives/itching on bilateral hands/wrists/forearms/lower legs/ankes, red face/swelling on face, rapid pulse, headache, nausea, extreme fatigue.

At about almost 4 hrs after receiving the injection I started to experience a tingly feeling to my lips, some lip swelling and tightness in my throat. I had my epi pen on hand incase I needed it but I ended up taking 25mg of Benadryl, then 50 mg of Benadryl 5 hrs later. The following morning my lips where feeling tingly again so I took 25mg of Benadryl again and continued for the next 48 hrs at the advice of my doctor.

About 5 minutes after injection: fast growing wave of internal burning sensation throughout body, feeling that I would pass out, lightheafdedness, increased heart rate and blood pressure, mild difficulty with speech/thought/concentration, freezing hands, wabbly/shaky., chest tightness, very slight throat soft tissue sensation

Fatigue, sore muscle

extreme body aches, fever of 101 degrees F, pain at injection site, severe headache

Swollen painful lymph node left clavicle

Redness and swelling an inch away from the injection site, hives on face

Migraine with nausea and dizziness preceded by visual aura, severe left arm pain (could not raise arm without significant pain), left wrist pain

about 1 hour and 15 minutes post injection (I waited in area as recommended for thirty minutes because of hx), I had the sudden onset of itchy runny nose and chest tightness and wheezing of significant intensity that I needed to use inhaler then and again later in the day. Noteworthy, I had as a precaution taken prednisone 20mg p.o about 2 hours before the injection. I had to take more later that afternoon because of symptoms. I then seem better but several times since the vaccine I have needed to uses the inhaler and take prednisone more than I have except after an infection about 6 years ago that precipitated similar symptoms to now. Today I had a flare significant enough that except for covid I might have gone to the ER or urgent care.

Resident noted with right sided facial swelling and lip droop. diagnosed as bells Palsy

Slight headache a few ours later after vaccination. The next morning I had headache, some joint/muscle pain, right arm pain and a Fever. That evening/night Fever and chills. The following morning still had a fever and chills. All symptoms were gone later that evening (within 48 hours of initial vaccination time)

4 hours after vaccine, sore arm, fatigue, headache, blurred vision 12 hours after vaccine, full body tremors, fever of 102, extreme muscle weakness, fatigue, deep chest cough, shortness of breath. fatigue, weakness and cough continued for three days after vaccine before subsiding

on the following day after the vaccination, I developed chills, awful headache, body aches, extreme fatigue, malaise, no fever

Fatigue, headache, body aches, chills, localized rash

I received the shot around 0730 on 12/30/2020. Went home and got ready for work. Around 12am 12/31/2020 my arm started to radiate at the injection site and was very tense. I placed a heat pack on the right harm but the pain did not dissipate. My arm continued to be in pain for the rest of the night. Around 0240 I ate dinner, had water and still had some arm pain. Around 0345 my arm started to flare up and sent pain sensations throughout my body. My right arm was increasingly discomforting, I could barely move it. The sensations spread to my legs, numbing them and my throat had felt as if it were closing up. I got up to get the attention of the nurse and was able to flag her down. She said I was pale as a ghost. My vision was very blurry, I could not hear anything because my ears had filled up and everything was muffled. My head had begun to ring and I was on the brink of fainting when a chair was given to me. My eyes had become extremely sensitive to the light, I was given water and spoken to about what had happened leading up to the event. I was greeted by the paramedics who drew my blood, placed an IV and transferred me to the Acute Care portion of the Emergency Department. My vitals were 76/49, 80/50, 90/56, 100/60 before being brought to the ER. On 1/1/2021 My thighs have been sore/tense, my knees and ankles have been stiff and just feeling sickly. On 1/2/2021 much of the same symptoms are present. The soreness in the muscles isn't as prevalent, however joints still are stiff On 1/3/2021, congestion and runny nose are still present, stiffness in ankles and now shins are prevalent.

On 12-22-2020, approx. 2 days after vaccine, I noticed several non-tender lumps under my chin/adjacent to left jaw line ~ small gum drop size lumps seemed to congeal together over next 9 days into a single half-dollar dollar sized lump - not completely round.

Headache Chills Temp (101.6) Body aches Skin hurts to touch Soreness in arm (injection site)

Hospitalized with COVID-related pneumonia on 03 Jan 2021. Close contact exposure on 25 Dec, with positive COVID PCR test on 29 Dec... managed as outpatient until respiratory sxms prompted hospitalization on 03 Jan. Care team anticipates at least 4 inpatient days... but patient remains hospitalized at date of this report.

Patient developed SVT 15 minutes after receiving vaccine. Admitted to ICU. ER presentation: BP: 160/109 heart rate 132. No e/o anaphylaxis or allergic reaction.

Sore throat, cold symptoms 3 days after, bone pain

The vaccine was given in the deltoid tendon/shoulder bursa area NOT in the deltoid muscle.

Jan 3, 2021 mild pain at injection site, diarrhea all day, chills in morning , no fever, temp 97.6 Jan 4, 2021 significant arm pain at injection site (awakened by it at 3 am) with chills, temp 99.6. Took One tablet ALEVE followed by temp 98.6

Rash on sides started Thursday. Woke up Friday and rash is all over body itching red and hurts. Taken Benadryl, pepsid and hydrocortisone cream. Called tele doc they gave prednisone nothing is working getting worse

Patient is a 49 y.o. female with a PMHx of AAT deficiency, HPV infection, DVT, Vitamin D Deficiency, Hypercholesterolemia and Anxiety with complaints of acute left arm numbness that radiates into her left digits and chest tightness that began 12-13 min after receipt of the COVID-19 vaccine. She noted numbness radiation into the left side of the neck and the bilateral ears. She voices she has also developed chest tightness and wheezing. Evaluated in the emergency department treated with diphenhydramine 25mg, epinephrine 0.3mg and dexamethasone 10mg

sore arm at injection site for about 1 day

"Pain and swelling in arm where injection was received. Lymph nodes in axilla and in neck were also swollen and painful. Eyes were described as ""glassy"", Two medications prescribed Lidocaine Patch and Naproxen"

Patient had swollen lymph nodes under his left arm 3 days after injection was administered. He stayed he had surgery to remove lymph nodes in June 2020.

Arm pain at injection site, fatigue, mild headache, swollen lymph nodes

riggors, fever,, severe body aches, flank pain, headache, eyes hurt

"Patient was anxious when arrived. After receiving the vaccine, felt light headed and revealed he has ""spells"" of anxiety similar to current experience. Became diaphoretic and needed to lie down."

itching, redness and swelling at injection sight. Took Benadryl on 12/31. Reappeared on 1/1, visited Er, got dexamethasone, Pepcid po and bendaryl

Itchy around the vaccine site, stiff muscle, sore arm

Muscle aches, palm size red ring for 3 days, day 4 rash, Diarrhea, vomiting, arm sore 3 days.

shortness of breath, hypotension, presumed anaphylaxis

Pain at site of injection

Painful/sore joints (shoulders and elbows) for two days. Almost went for treatment after about 48 hrs, but got through a rough night and the next morning it was gone.

Moderate local reaction. Swelling, redness, pain, hot to touch, itchy for 5+ days.

Mild swelling, pain, and itching at the injection site 8 days after injection

MODERNA COVID 19 VACCINE EUA PAIN TENDERNESS SWELLING/ FATIGUE, HEADACHE, MUSCLE PAIN, JOINT PAIN, CHILLS/ THEN CAME THE ALL OVER BODY RASH AND I STILL HAVE THIS

Pfizer-BioNtech COVID-19 Vaccin EUA-. Severe Dizziness, light- headed.

Redness to the area after a week. resolved

Thursday 12/29/20 : Started wheezing, I am using my nebulizer but the wheezing seems to be getting worse My throat also is swollen and red. Fatigue/sleeping a lot Headache

Very swollen lymph node in front of my left ear.

Flue like symptoms but no fever.

I am currently breastfeeding my 11 month old son. On Thursday, December 31st, 2020 (2 days after receiving my vaccine), my son developed a fever x24-36hours and diarrhea that is still on going as of today (1/4/2021). There are no known exposures for my son and his illness. I am reporting this as a possible reaction to the Moderna COVID 19 vaccine I received that could have some how passed through the breastmilk to him.

About 1 week after receiving the vaccine (on 12/31/2020) I developed an itchy, raised, and red hive-like rash at the injection site. It got worse over the next day, and I put some steroid cream on it. It went away gradually and was completely resolved by 1/03/2021

redness and swollen to inj site, rash to hands Benadryl given for sysmptoms

Arm soreness at injection site, worse than a flu shot and starting an hour after the shot and lasting approx 2 days. Increased phelgm production for approx 24 hours following injection.

Moderna COVID-19 Vaccine On day 9 after injection, began to get itching at the injection site. Now on day 10 with red area ~ 5 cm x 3 cm. Mild fatigue on day 9 as well.

Pfizer-BioNTech COVID-19 Vaccine EUA - Patient witnessed another patient with syncope prior to her injection. She was already anxious about receiving vaccination and this increased her anxiety, though she proceeded with immunization. Patient was in 15 min observation window in a chair and began to feel light-headed like she may pass out. A SWAT was called. With RN assistance, patient was lowered to the floor, with no loss of consciousness. Patient was pale and reported anxiety, racing /pounding heart, and felt hot with facial flushing. Patient was transferred to ED and was noted to be tachycardic (120s), but dropped to 80s. She noted that this episode felt different than her prior syncopal episodes associated with anemia. Patient was observed for 5 hours and discharged to home. Patient returned to ED roughly 2.5 hours later complaining of continued dizziness and unsteady gate. Patient was pale and anxious. Patient reported had not eaten/drank enough during her shift and received vaccine immediately post a stressful shift. Additionally, patient witnessed another patient have syncopal episode prior to her receiving her vaccine which made her anxious. Patient was given IV fluids and had electrolytes replacement. Patient additionally received diazepam. Patient was discharged at 2358 on 12/23. Patient returned to ED on 12/24 at 0239 complaining of near syncope and lightheadedness. Patient had tachycardia and self-reported palpitations. Received IV fluids and observation on telemetry with no rhythm disturbance. Patient discharged 1428 on 12/24. On 12/29, patient returned to ED at 0326 for continued dizziness, fatigue and near syncope. Was admitted for cardiac evaluation. Noted to have unprovoked tachycardia and was discharged with a Halter Monitor to evaluate cardiac symptoms. patient was discharged 12/31 at 1619

Received the injection on Wednesday afternoon. I woke up around 3am with an excruciating headache, started vomiting around 6am and continued until 7:30pm. The headache continued and as of this morning 1/4 the headache is still there and my stomach is not settled completely.

Patient received the vaccine and had slight chest tightness, had a slight headache and has mild nausea. He worked the day and still has the symptoms at 1:30 pm

Pt developed urticaria on both arms 4 hours after COVID vaccine administration. Pt received dexamethasone 10mg IM for treatment and diphenhydramine PO 25 mg. Symptoms subsequently resolved.

I received the Moderna COVID-19 vaccine on Tuesday, December 29th at work and on Wednesday, December 30th when I woke up my entire neck had broken out in hives. I did not have hives anywhere else or any other reaction. After taking 25 mg of Benadryl po and applying hydrocortisone cream, the hives had cleared up about 75%. I continued to use the hydrocortisone cream throughout the day, but the hives/redness had fully cleared up by Saturday, January 2nd.

Swollen L armpit, medial, at same side of vaccine. Resolved in 2 days with ibuprofen

Circular redness at injection site about 2 inch in diameter.

Flu like symptoms (fever, chills, aches, fatigue, headache); redness, swelling, warmth and firmness at injection site

Stuffy nose tingling lips tingling face i took 50 mg of over the counter benedryl..symptoms resolved

Arm soreness Arm swelling Headache Right side neck pain Bumps on both cheeks (face)

Patient experienced feeling flushed and nauseated after receiving covid vaccine injection. Declines ED evaluation. No further symptoms reported on 12/19 follow-up

"Pfizer-BioNTech COVID-19 Vaccine EUA - Patient with history of anaphylaxis requiring intubation to benzonatate. Patient answered ""no"" to questionnaire about allergic reactions prior to vaccination. 11 minutes after vaccination, patient reported tingling of lips and swelling of face. Developed hoarseness. SWAT was called and patient given benadryl and taken to ED (1055). Patient received steroids and H1/H2 blockers in addition to epinephrine. Patient brought to ICU for monitoring. Patient continued on therapy and was discharged 1/2 at 1113. Patient returned to ED on 1/3 at 1558 with macular papular rash on leg, chest and back with itching on eyelids and face. No respiratory involvement. Patient given benadryl and predinisone and discharged from ED at 2016."

Generalized body aches that evening, same day as injection. Woke up the next morning, 12/31/2020 with a headache, fever of 100.2, and fatigue

Patient had chills and a fever that started on 12/30/2020 @ 12:00am. The highest fever recorded was 100.6. He took Tylenol on 12/30/2020 @ 6:00am. His symptoms resolved on 12/30/2020 at 8:30pm.

Anterior cervical lymphadenopathy on the ipsilateral side of the vaccination. It seemed to begin on the third day but was most pronounced and painful on the fourth day.

Increasing redness and itchiness, swelling, and discomfort at injection site on R arm, delayed response not present at time of injection, symptoms began 12/27/20 and gradually worsened since then, no improving. Tried Benadryl and cold compresses, as well as Tyelnol.

Body aches, stomach cramping, rash on abdomen, arms. Start of period early (last period 12/22). Itchy all over

Patient developed muscle twitching, fatigue, dizziness and headache minutes after vaccine was given. Day after vaccine given, patient developed small red area around injection site that also had swelling and was warm to touch. No fever or other complication.

Hives and facial swelling. Swelling within the ears. Migrain. Nausea.

Severe joint pain, especially in hips, knees and hands lasting approximately 72 hours after first onset of symptoms. Treatment Tylenol/NSAIDs. Resolved on its own.

Upon injection, vaccine leaked out of syringe at hub site. Stopped injection after noticing after ~0.1mL expelled. Syringe removed, needle noticeably noted to have a curve and retracted into the syringe partially engaged safety.

I received the COVID vaccine on Monday Dec. 21, 2020 at 14:30. By 17:00 I was not feeling well. I was tired, had a headache, muscle aches, nausea and a fever of 101 F. The headache, low grade fever and significant malaise continued through Tues Dec 22 and Wed Dec 23. On Thursday morning Dec 24 at 2:30 AM, I woke from sleep with the urge to use the bathroom. I suddenly felt light-headed and dizzy and had a diaphoresis that soaked my hair and PJs. Fortunately my husband who is a nurse anesthetist helped me through the episode safely and was able to get me back to bed. I am not sure if that event was related to the vaccine or if I happened to be a little dehydrated and had a vaso-vagal event. I did not take any medications because I was allowing my body to have a natural response to the vaccine.

Woke up with a case a vertigo that lasted 30-45 minutes, Headache that lasted around 6 hours that same day

2 Red Area-, itching, burning-the size of a golf ball, the other the size of a quarter- Located at the front of my neck I had vaccine on 12/30/20 at 1:30 pm, and woke up on 01/01/21 at 7am with the red areas.

Patient developed a headache one to two hours post vaccination that lasted approximately 24 hours.

I felt like I was having palpitations, and my blood pressure shot up to 169/119.

About 6 hours after receiving dose, experienced aching in both arms that extended down into both hands - hands was resolved by next morning. Achiness in both arms remained x 48 hours

* TESTED POSTIVE FOR COVID ANTIBODIES 06/2020 - 'STILL HAVE RESIDUAL COUGH' 12/21/2020 - VACCINATION 12/22/2020 9:30 WERE AT WORK; FELT SUPER FLUSHED, SOB, COULDN'T FOCUS, FELT FEVERISH, FELT NAUSEOUS. OCCUPATIONAL HEALTH REFERRED TO URGENT CARE; DR STATED 'NOT TYPICAL RESPONSE'; COVID TEST; NEGATIVE

12/26/20 started to experience covid -19 symptoms.

patient developed fatigue approximately 24 hours after immunization that lasted for about 24 hours. Patient also had soreness at injection site 24 hours after that lasted 24 hours.

first 24 hours: nausea, left arm pain and heaviness 1/2/2021 until present: body aches, very strong headache, sore throat, very tired, coughing with pain, flushed, feel as if my eyes are on fire.

6 days after injection, left supraclavicular lymph node swelling and tenderness and axillary tenderness and swelling

52 year old female received the Pfizer vaccine on 30 Dec 2020. Noticed a slight left sided facial droop as left lower lip numbess on 31 Dec 2020, which has become more pronounced over the past 2 days. She states she spoke to the nurse hotline right before speaking to me who told her to go to the ED (she was on her way). Denies any extremity weakness, numbness, HA or dizziness. No pain to face or ear. Speech

clear on the phone. No recent illness or history of Bell's palsy. NKDA or any prior adverse reactions to immunizations.

Client called clinic on 12/30/2020 in the am requesting us to call in prescription pain medication due to having severe arm pain at the injection site. He stated he had not slept any for the last two nights. Encouraged client to see his PMD if he was in the kind of pain that required a Rx pain medication. Encouraged client to ice down his arm for pain.

"Patinet is a 37 y.o. female ER nurse who received her Covid vaccine just prior to arrival. While being observed at the vaccine site, she developed itching and a rash. She was brought down to the ER for evaluation. Mainly she is itchy all over. She notes a rash across her chest. But she has no cough shortness of breath wheezing. There is no problem swallowing there is no facial swelling. She does not have a history of anaphylaxis, or medication allergies. Review of Systems Constitutional: Negative for chills, diaphoresis and fever. HENT: Negative for congestion, trouble swallowing and voice change. Eyes: Negative for redness and itching. Respiratory: Negative for cough, shortness of breath, wheezing and stridor. Musculoskeletal: Negative for myalgias. Skin: Positive for rash. Pruritus Allergic/Immunologic: Negative for environmental allergies, food allergies and immunocompromised state. Neurological: Negative for headaches. 01/04/2021- Speaking with the patient she states noticed ""hives"" accross chest, right lower extremity, and left upper extremity."

I am breastfeeding-Milk supply significantly decreased (<50% of typical) day of vaccine. Milk supply still decreased 5 days later,

Patient developed fatigue approximately 24 hours after immunization that lasted a couple days.

Approx 25 min after injection I became dizzy and my HR went to the 130?s, at around 30 min post injection my tongue started to swell

Left arm warm, red, sore, swelling noted

dizziness, itching/small hives on forearm (not at injection site) , 30 minutes after vaccine given. Vitals monitored, were normal, sent home and advised to take Benadryl. More hives on upper lip/chin appeared 36 hours after vaccine given. Patient was at home, self-treated with benadryl, zyrtec, famotidine and ice pack applied to area.

Significant neck and upper back pain as soon as 1 hour post vaccine lasting until at least 24 hours - tylenol and heat/ice (no change) chills without fever overnight the night of - no treatment soreness in arm 1 hr post to up to its worst at 24 hours later when I could not abduct >90 degrees for 24 more hours

I got moderna COVID19 vaccine on 12/26/2020. Day 1-3 local pain and swelling, no redness. All resolved after day 3-4. Very tired all week post vaccine,. Day 5-6 noticed ipsilateral axillary lymph node swelling. On day 7 post vaccine I got a localized area of itching swelling and redness as if I had been bitten by a few mosquitoes at injection site that was new. Milder on day 8, less itchy and swollen, but still red and a little raised. Mild shortness of breath.

Really bad headache first 3 days Horrible Chills still ongoing Disoriented and almost like hallucinations Most interesting randomly talking to himself. I mean like a full conversation with someone that isn?t there. He also sometimes feels like when holding something he doesn?t see it or feel it and drops it or vice versa ?.. thinks holding something and isn?t Balance is off Shortness of breath No fever thank goodness and taste and smell are normal

After got vaccinated, I walked out of the clinic to monitoring area approximately 15 walking steps, I felt a little off balance but I was able to make to the chair and sat down. Few seconds later, my heart beat increased faster and faster, my neck turned red. I called for help, they gave me some apple juice to drink and talked to me. About 5 minutes later, my heart beat went back to normal rate and my redness turned back to normal skin color. I only had a little vertigo symptom but I was able to manage myself. About 2 hours later, symptoms disappeared and I was back to my normal health

12/31/20 - cough, sneezing, weakness. Felt ill all weekend. 1/3/21 - called Employee Health with low-grade fever, chills, nausea, weakness and elevated blood pressure 165/104, which had come down by the afternoon to 155/95

Developed Tachycardia approximately 40 minutes post vaccine

patient developed fatigue day after vaccination that lasted about 1 day.

After receiving the vaccine, my arm was in a lot of pain. Then that night and the next day, it was extreme pain, I couldnt lay on it. Then about 3-4 days later, the color is blue and black. Then I started having cold symptoms. Like a head cold. On my left side, my arm and my leg is sore. In addition, my face broke out too. I did not go to the ER. I let Employee health examine my arm . No ER visit

Warm to touch, redness, hard area, sore to touch

patient developed headache and arm pain day after vaccination. Patient stayed and worked from home on this day as a result.

1/2/21 @ 1030: EE called to report she received the vaccine on 12/31/20 between 1030 and 1100. And then around 2330 on 12/31/20 she experienced facial swelling, arm swelling, headache, chills, and dizziness. EE stated she felt it was an allergic reaction to the vaccine and took Benadryl for the next 24 hours to help with the symptoms. EE reported she hasn't had anything since the initial 24 hours, but is concerned about taking the next vaccine. Encouraged EE to contact PCP regarding concern for taking next vaccine. After speaking with Administration, EE encouraged to report vaccine side effects to CDC via V-Safe (https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html).

about two inches around the site was red and outlined. Felt slightly raised and was itching. Is still red today 1/4/21

"C/O of ""smokey vision"", outside in parking lot. Sat in car for about 10 minutes before coming into the building. A&O, ambulatory, denies dizziness, HA or lightheadedness. States feels SOB with exertion, ""heaviness in trachea"" increasing with inspiration. Hand off to EMTs. EKG performed, Sinus Tach 108

initially then NSR 80s-90s with occ MF PVCs, couplets. BP 162/94, O2SAT 100% RA, BS POC 208. Patient brought to ER by EMTs"

Within 10 mins. Tongue was tingling lips were swelling and tingling left arm fingers were tingling , headache

Itching, redness and swelling on the injection site. Dr. Prescribed antiniotic Bactrim DS 800-160 Tab

Chills and shaking consistent with flu-like symptoms began about 12 hours following vaccination. The next morning, I had a headache and vomited about 5 times. Over the next several hours, I began to feel better and by that evening, was feeling pretty much normal, except for some lingering fatigue.

This patient is a 56 y.o. female presenting to the emergency department with a chief complaint of a possible reaction to the COVID vaccine onset 2 days ago. The patient states that she has had a fever, chills, adenopathy, and body aches since her vaccination. Her highest recorded temperature was 101F, and she has been taking Tylenol. She states that her biggest concern is the adenopathy under her right armpit which is painful to touch. She denies any masses. She saw her PCP on 12/24 and had blood work done, which showed an elevated white count of 17.

patient developed arm pain day after vaccination that lasted about 1 day.

Left arm soreness, Headache 30 mins after, Fever 100.9 T 5am and 9am, monitoring until now

After initially receiving vaccine 12/28/2020 my arm was sore and slightly red for approx 2 days and resolved on 12/30/20. When I awoke this morning my right shoulder ached and I thought massage might make it feel better - at that time I noted it was swollen and warm tender to touch at site and again appeared red. I did report this to the clinic who administered vaccine

Patient developed arm soreness at injection site day after vaccination

Migraine for 2 days controlled with medication, Severe swollen eyes with discharge from eyes, itchy, red watery eyes began the evening of the vaccine and ongoing. using BENEDRYL and ALLEGRA to decrease symptoms.

Weakness, almost paralysis both lower extremities worse than baseline paresis from ms.

Arm itchy at injection site, warm feeling at injection site

Patient c/o feeling tachycardia, flush and dizziness, flushness upper torso neck region and bilateral upper arms. Rash/hives not present. Placed on stretcher , monitored immediately with BP 156/100, HR 88, O2 99%, alert and oriented x3, verbalizing clearly. Placed on EKG monitor, noted in NSR 80. POC 102. Shortly after at 1001, redness subside ,briefly noted with tingling of bilateral feet and hands for only seconds. Patient was monitored for 40 minutes, returned to baseline 142/81 HR 58 O2 100%. Nutrition given . Discharged to home, ambulatory feeling well.

Asthma-like fatigue, cough due to fatigue, mild.

Noticed itching and slight rash on distal portion of extremities the evening of Dec. 30, rash became worse over next few days and became more inflamed/raised even with Benadryl taken as directed on box. I went to urgent care on Jan 1, 2021 and was started on Steroid taper of 60-40-20 each dose for 3 days. Improvement noted after 2nd steroid dose. No respiratory involvement with vaccine or rash episode

Modern a covid 19

Moderna vaccine received on 12/21 from my workplace. Rash (reddened skin not raised) appeared after vaccine was given (within 24hrs) the size of a quarter and was gone 3 days later. Now on 1/3 the rash (red bullseye not raised) came back the size of a baseball and is warm to the touch. Went to urgent care and physician called it a delayed adverse reaction to the moderna vaccine 1st dose

I got the shot, didn?t feel it at all so it went good. I went to the bathroom and went pee and got my arm back in my long sleeve shirt under my scrub top. I wasn?t anxious about getting the vaccine. Then I went to sit down and be monitored. After about another minute I felt very weird like a warm feeling going all over my body. I started pulling my mask away from my face to get a deep breath. Then I broke out in a sweat from head to toe. I think I became pale (I apparently didn?t look good). I started feeling more ?weird? as I had never felt this way before and I stood up to walk because the nurse there wanted me upstairs near the ED but I was weak so I sat down and had tunnel vision. After that it?s a bit of a blur. After I stopped sweating I got very cold and shaky but vitals were ok. It scared me because I have never had a reaction before to a vaccine.

fever 100.6- 100.5, chills, headache, general weakness, sweating, and loss of appetite.

felt hot, prickly, right arm red. Later felt chest tightness

Starting on Thursday, Dec. 31, patient began having shoulder and neck tightness. That night patient began having chills, and noticed redness at the vaccine sight and then the redness started streaking. Also complaints of itching at the vaccine sight. Started taking Tylenol for the two days following the vaccine, states feels like it is improving. Referred to PCP for evaluation. Has appt. Monday, January 4th

Triage for COVID 19 SEVERE post Vaccine Reaction VAERS reportable Your concerns: Vaccine at noon without immediate effect. Driving home at 1400 developed itching and redness at scalp, face, neck, chest, back, arms and sides. Reports that she did not feel warm but looked like she had a sunburn. It appeared to fade over the next two hours but re-occurred at 1700 with all previous symptoms. She took 50mg of Benadryl and went to sleep. She woke at 0200 the re-occurrence of all symptoms, she did not take any Benadryl as that would make her too sleepy to come to work. The symptoms subsided and when we spoke at 1050 she had only small bumps/hive like spots on her fore arms and cleavage. They do not itch or burn at this time. Discussed with PA and Dr. after which I spoke with patient again regarding pending plan. She will call the clinic if she has any further symptomatic episodes in the near future. We will investigate moving her second dose ahead 2 days from 1/12/2021 (day off) to 1/14/2021 this way she will be here at work should it happen again, she works 0630-1900. Med provider will consult with allergy to determine if further steps are needed for dose #2. Dept: Respiratory Therapy

Have you missed work? #shifts: none Did you seek emergency care? none Date and Time of Vaccine: 12/22/2020 at 1200 Age at time of vaccination, 46 years 6 months Sex: female Was the vaccine received at facility? yes Site of vaccine (LD or RD): RD Type of Vaccine Pfizer (X) Moderna ( ) Other _____ 1st or 2nd dose: first When did your symptoms start? 12/22/2020 at 1400 Please note reported symptoms yes or no, these symptoms are considered mild to moderate and are NOT VAERS reportable Injection site pain no Tiredness no Headache no Muscle Pain no Chills no Joint Pain no Fever (note temp if known) no Injection Site Swelling no Injection Site Redness no Nausea no Feeling Unwell no Swollen Lymph Nodes (lymphadenopathy) no Other: no Employee reports THE FOLLOWING SEVERE post vaccine ADVERSE reactions (reportable): Difficulty breathing no Swelling of your face and throat no A fast heartbeat no A bad rash all over your body yes, see above Dizziness and weakness no If COVID-19 symptoms persist and/or worsen beyond 48 hours consider COVID-19 testing Treatment/Advise: see above Plan: see above If employee was vaccinated at another facility, they need to contact that facility , it is an expectation that the facility that gave the vaccine complete the VAERS report. N/A Employee verbalizes understanding and agreement with plan. yes VAERS report is completed electronically vaccine given at facility. Pending further review. 12/24/2020 01:51pm Follow up to VAER 12/23/2020 Patient called this morning to update regarding vaccine reaction. Yesterday she went home and did some shoveling. Later, around 1900, she developed a itchy, red rash that started on her chest and the right side of her neck which later covered her entire body. The skin on her face was bright red and very hot to the touch, there were small raised hives on her face which were likened to 'petechia if they were raised'. She took pictures of the raised/red areas. She took 50mg of Benadryl and went to sleep, when she woke at 0230 she was asymptomatic. Regarding the bumps on her forearms and cleavage, she has residual mottling on her arms. Updated providers.

Moderna vaccine given 12/28/2020, 6 days after injection have left supraclavicular lymph node swelling and axillary swelling and tenderness

Extreme fatigue, weakness, lightheaded, malaise

Began noticing itching and redness on left had on 1/3 PM. When I woke up on 1/4 the itching in the had was persistent and the redness was about the same. I also noticed a raised, red patch of skin on my right anterior ribs. The rash on the ribs is less itchy than the hand.

receive vaccine on 12/24/2020 arm was red and sore few days. then on 1/1/2021 at injection site a rash developed and had HA, tired , weakness, chills. I continue to feel this way on 1/4/2021

About 1 hour after receiving my first dose of the Moderna vaccine for COVID-19, I started feeling extreme pain in my left shoulder and arm, where the shot was administered. The pain continued to intensify throughout the day and night and was 10/10 on a pain scale. In addition, I began to lose my ability to lift my left arm or use it. It became so weak that I had to use my right hand/arm to pick up my left arm to move it. My left arm was 'hanging and drooping' and my left shoulder was very noticeably lower then my right shoulder. I called my primary care and employee health. My primary care doctor advised me to take advil and go to urgent care if the pain persisted and worsened. I could not sleep at all that evening of 12/29/20 because the pain was so intense and I had to keep picking my left arm up with

my right arm to keep re-adjusting to try and get comfortable. The next morning I went to an orthopedic urgent care where I was diagnosed with nerve damage from the shot and prescribed Methylprednisolone 4mg dosepack. The doctor who saw me explained that he could not assess the extent of the damage at this time because my nerves were so agitated and inflamed. He scheduled a follow up visit with me for Thursday, January 7th and stated he will then proceed with an MRI and further investigation to assess the extent of the nerve damage. During the days that followed my immunization, I was unable to do anything with my left arm and was dependent on my husband to help me get dressed, showered, household chores, etc. It is unknown at this time whether this will be temporary or permanent damage and disability.

swelling, redness that started 1 wk after injection

Moderna COVID-19 Vaccine Vaccine on day 0 GI symptoms on days 1, 2, 3, and 4 including abdominal cramps, constipation, gas Uterine cramps (not related to menstruation) and light spotting on day 2 Soreness at injection site days 0, 1, 2, and 3

arm pain

Injection received at 0815. At 0900 I started getting diaphoretic, clammy, nauseas and my face was flushed. At 0930, I developed hives on my neck, chest and arms. I immediately went back to the vaccination site (I was still in the hospital at work) and was administered 25mg oral Benadryl and monitored for 30 minutes. The hives resolved, but I still felt unwell. At 1600 I noticed a swelling in my right upper thigh about the size of my hand. It was about 2 inches inferior to my inguinal crease and was the width of my thigh. It was mildly painful to the touch. My injection site was red, inflamed and itchy. I continued taking 25-50mg Benadryl Q4 and took 100 mg at night due to itchiness on my eyes, face, neck, chest and arms. This is still present, although less each day, as of Monday 1/4/21 morning. I have felt feverish but have not had a recorded fever. I took some Ibuprofen for the pain in my arm at the injection site. The redness, swelling and itchiness has decreased each day at the injection site, but is also still present as of Monday 1/4/21 morning. I still feel unwell and have continued diarrhea throughout the weekend.

The day of the vaccine I had a initial diarrhea and headache, minimum pain on the site of the injection but at 2AM on the 22nd I woke up from my sleep with chills, and shaking even my teeth were clacking. Took Tylenol and it got better around 30 min later. Felt very fatigued and still nauseated almost threw up. By the end pf the day it resolved itself.

patient developed headache, nausea and abdominal pain day of vaccination that continued for two days post vaccination.

Flu-like symptoms - nausea, sweat. Arm sore immediately after injection - sore for 2 days.

12/17/2020 VACCINE 12/18/2020 SWOLLEN LYMPHNODES IN GROIN, FATIGUE 12/21/2020 EXPERIENCED A STEMI; RUSHED TO ER; FELT LIKE COULDN'T BREATHE, INCREASED HR CARDIAC CATH

Employee states reaction to every vaccine she receives. Employee states ticks, perseveration, uncontrolled laughing and crying which resolve on own. This happened today immediately after vaccine administered. Employee given water, cold pack. Symptoms resolving on own as stated. Will keep longer for observation.

patient developed headache, nausea and abdominal pain day of vaccination that lasted two days following administration.

EE received Covid-19 Moderna vaccine on 12/29/20 at 5:10 p.m. at Covid vaccination site. 12/30/20 at 3:00 a.m.EE had pain in left side, hip and leg waking EE up from sleep . Lesions times two, one on hip and one on posterior upper leg. MD insructed EE to double Vitamin C orally and to place Bacitracin on the two lesions, which at first appeared to contain bloody drainage. Lesions are now dry. VAERS document completed.

fever 100.6, chills, headache

patient developed flu like symptoms such as body aches, chills, fever, as well as arm pain day after vaccination.

Resident found unresponsive without pulse, respirations at 04:30 CPR performed, expired at 04:52 by Rescue

Patient complained of increased shortness of breath, generalized weakness and fatigue with mild cough worsening today and was admitted on 12/25/20. Patient is an employee of the hospital in the ICU and received the covid-19 vaccine on 12/25/20. Patient believes symptoms started after the vaccination. On admission, patient was in sinus tachycardia with O2 saturation 91% on room air. Tested SARs CoV 2 RNA, RT PCR positive on 12/24/20. Transferred to ICU for closer monitoring after transitioning to high flow nasal cannula on 12/26. Patient recovered and discharged on 12/31/20.

Resident became SOB, congested and hypoxic requiring oxygen, respiratory treatments and suctioning. Stabilized after treatment and for the next 72 hours with oxygen saturations in the 90s. On 1/3/2021 was found without pulse and respirations. Resident was a DNR on Hospice.

Two days post vaccine patient went into cardiac arrest and passed away.

syncopal episode - arrested - CPR - death

Severe diarrhea, cold chills, 101 fever, and nausea

""""Pfizer-BioNTech COVID-19 Vaccine"" 12/29 patient developed SOB, fever tmax 103 degrees F, diaphoretic, dry heaves all started approximately 16 hours after vaccination given. patient then transferred to Hospital for further treatment and observation. 12/30 seen at injection site- erythema, swelling, warmth and tenderness Discharged back to home on 1/1 with RX for cephalexin to treat cellulitis of injection site"

"Tingling in lower legs- neuropathy like; Fever 102.9; Tingling in lower legs- neuropathy like; Severe cramping in hands and feet; Severe bone pain; This is a spontaneous report from a contactable other healthcare professional (patient). A 39-year-old female patient received the first dose of bnt162b2 (COVID-19 vaccine) lot no: EL0140, via an unspecified route of administration in left arm on 18Dec2020 15:15 at a single dose for COVID-19 immunization. Medical history included acid reflux and known allergies to PCN, both from an unknown date and unknown if ongoing. The patient was not pregnant at the time of report. Concomitant medication included omeprazole (PROTONIX), ibuprofen (MOTRIN). No other vaccines were administered in four weeks. On 19Dec2020 at 14:30, the patient experienced fever 102.9 ""normal for vaccines i know"", tingling in lower legs neuropathy like, severe cramping in hands and feet, and severe bone pain. The patient recovered from the events in Dec2020. The patient did not receive treatment for the events. The events were reported as non-serious. The patient didn't have COVID prior to vaccination and was not tested post vaccination.; Sender's Comments: A possible causal association between administration of bnt162b2 and the onset of neuropathy like cannot be excluded, considering the plausible temporal relationship. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate."

Scratchy throat; itching lips; This is a spontaneous report from a non-contactable nurse. A 36-year-old patient of an unspecified gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), lot number EK5730, via an unspecified route of administration on Right arm from 22Dec2020 to 22Dec2020 as single dose for COVID-19 immunization. Medical history included food allergy (Shrimp). The patient's concomitant medications were not reported. The patient experienced scratchy throat and itching lips for approximately 1.5 hours starting 20 mins post vaccine on 22Dec2020. The event caused prolonged hospitalization. The outcome of the events was recovered on 22Dec2020. No follow-up attempts are possible. No further information is expected.; Sender's Comments: Based on temporal association, a possible contributory role of suspect BNT162B2 vaccine cannot be excluded for reported events throat irritation and lip itching. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

delirious; hypoxic; fever; ataxic; incontinent; confused; Chills; HA; anorexia/had no appetite; myalgias; extreme fatigue; slept all and had no appetite; This is a spontaneous report from a contactable physician. A 74-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 15Dec2020 16:00 at single dose for COVID-19 immunization. Medical history included diabetes mellitus (DM). The patient has no known allergies. The patient's concomitant medications were not reported. He was an ER doctor and the medical director of his hospital. The patient was asymptomatic when he got the vaccine on 15Dec2020. 3 hours after the vaccine he began to get chills, HA, anorexia, myalgias, and extreme fatigue. This worsened and he slept

all and had no appetite. On 19Dec2020 he woke up delirious with a fever and was ataxic, hypoxic, incontinent, and confused. The patient was hospitalized due to the events on 15Dec2020. The events also caused prolonged hospitalization due to the events. The patient was not diagnosed with COVID prior to vaccination. The patient was tested for COVID via nasal swab post vaccination with unknown results. The patient did not receive any other vaccines within 4 weeks prior to COVID vaccine. The outcome of the events was not recovered. Therapeutic measures were taken as a result of the events as the patient required oxygen, plasma, and remdisivir. The batch/lot numbers for the vaccine, BNT162B2, were not provided and will be requested during follow up.; Sender's Comments: A possible causal association between administration of BNT162B2 and the onset of reported serious events might not be excluded, considering the plausible temporal relationship. Fever, chills, headache, fatigue and muscle pain are the known adverse event profile of the suspect product. More information such as detailed underlying medical conditions and concomitant medications are needed for fully medical assessment. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Allergic reaction; Diarrhea; Chills; Palpitation; Tongue and throat swelling; Tongue and throat swelling; This is a spontaneous report from a contactable other healthcare professional (patient). A 38-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number: ELO141), via an unspecified route of administration on 21Dec2020 at a single dose for covid-19 immunization. The patient's medical history included asthma and allergy. Concomitant medication included levosalbutamol hydrochloride (XOPENEX) for asthma and cetirizine hydrochloride (ZYRTEC) for allergy. About hour and a half to two hours after the vaccine, on 21Dec2020, the patient experienced had an allergic reaction with symptoms set of diarrhea, chills, palpitations, and tongue and throat swelling. The patient took diphenhydramine (BENADRYL) 25 mg as treatment. It helped some. She woke up this morning (22Dec2020) and still had the symptoms. So, she went to the emergency room. They gave her diphenhydramine 25 mg IV, methylprednisolone (SOLUMEDROL), and famotidine (PEPCID). The patient underwent lab tests and procedures which included blood count and chemistry and lab work which showed normal on 22Dec2020. Outcome of the events was unknown. The patient thinks that the product had causality to the events. Information on the lot/batch number has been requested.; Sender's Comments: The patient's medical history included asthma and allergy. Based on information available, the reported allergic reaction with symptoms set of diarrhea, chills, palpitations, and tongue and throat swelling was likely related to the use of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), due to temporal relationship and clinical course. The case will be reassessed should additional information become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

shaking uncontrollably/she was full of shakes to the point the bed was shaking; chills; Woke up in the middle of the night; body aches; as painful as a strep infection; sore throat that was as painful as a strep infection/throat feels sore to the point of Strep/Throat soreness: Felt like sharp razor blades; Feels like she is having an extreme immune response; Feels congestion; severe serum sickness/weird serum sickness; high fever/Had a fever over 101; This is a spontaneous report from a contactable nurse(patient). A 32-year-old female patient received BNT162B2(lot number EH9899) via an unspecified route of administration at Arm Left on 21Dec2020 (from 16:30 to 17:00) at the age of 32 years old at single dose for doesn't want to bring COVID home to her family. The medical history included Migraine headaches. The concomitant medications were not reported. The patient had so many immunizations for international travel, had Yellow Fever vaccine, all of the Guardasil vaccines, had MMR vaccine four times because she never developed immunity to it until the fourth round, got a flu shot yearly,got TDap vaccine every five years because she was an HCP, did Emgality shots(not done it this month. Emgality had a protein inhibitor, was supposed to get Emgality shot on 21Dec2020). On 22Dec2020 the patient experienced severe serum sickness, high fever, body aches to the point that she was shaking uncontrollably, sore throat that was as painful as a strep infection; Caller mentioned she was taking tylenl and benadryl for her symptoms. The patient was a Nurse Midwife. She got the vaccine on Monday evening at 4:30PM. Feeling like she was having a weird serum sickness. Woke up in the middle of the night and she was full of shakes to the point the bed was shaking. She had a fever over 101. Felt like she was having an extreme immune response. She was taking Tylenol and Benadryl around the clock. Woke up this morning and her throat feels sore to the point of Strep. Wondering if she need to distance and get some kind of test. Has been wearing a mask all of the time and doesn't know of anyone people who have COVID that she has been in contact with. Feels congestion and sore throat. Shakes and chills: Began at 02:30. Hard core chills and shakes. High fever over 101: same time as chills and shakes. Woke up from a dead sleep. Didn't have a working thermometer but knows her temperature must have been over 101 by the way she felt. She didn't feel that crappy unless her fever is over 101. She can gauge her own temperature. She experienced throat soreness: Felt like sharp razor blades. The patient was taking numbing throat lozenges. Seriousness: Would say serious. Didn't require hospitalization. She self-treated. Had she not had to work, she would probably have stayed in bed. Has been taking round the clock medicine. The outcome of the events was unknown. The information on the batch number has been requested.; Sender's Comments: The Company cannot completely exclude the possible causality between the reported serious events including severe serum sickness, high fever, body aches, shaking uncontrollably, sore throat that was as painful as a strep infection, feels like having an extreme immune response, congestion, chills, woke up from a dead sleep and the administration of the COVID 19 immunization with BNT162B2, based on the reasonable temporal association. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to those, as appropriate.

Have a fever with a high of 99.6 Fahrenheit; felt winded like she has exerted herself more than expected/shortness of air; Coughing/cough got worse; She is covid positive/Tested positive for COVID 19; She is covid positive/Tested positive for COVID 19; Shortness of breath/Shortness of breath was

reported as worsened/feels winded; Tachycardia; Has been sick ever since; Felt like she was in a fog, on a cloud, heavy and out of it; She felt hot and weird but had no fever; Headache; Burning sensations in her legs; Extreme fatigue, want to go to bed; headache went away and she felt like the congestion was clearing up some; Arm was sore; This is a spontaneous report from a contactable ICU nurse (patient [Registered nurse ADN]) via Pfizer-sponsored program. A 38-year-old female patient received single dose of BNT162B2 (lot number: EK5730) , via an unspecified route of administration (right arm) on 16Dec2020 20:30 for immunization (for front line health care worker). Medical history included allergies; acid reflux; patent foramen ovale (PFO); supraventricular tachycardia (SVT) without treatment, vitamin D low and ongoing smoker. The patient had no other history/family history. Concomitant medication included loratadine (CLARITIN) taken for at least 5 years for allergy, famotidine from Dec2020 for acid reflex, and vitamin D taken for 5 or more years for vitamin D low; all given orally and were ongoing. The patient had no other prior vaccines within 4 weeks of Covid vaccination. Patient had been taking Covid tests on and off due to her immunocompromised daughter. On 15Dec2020 she took the PTR that took three to four days for results; she tested negative for Covid and was completely asymptomatic. She then received the COVID 19 vaccine 16Dec2020. Her test was positive for COVID 19 on 18Dec2020 and she had been sick ever since. She received the vaccine at the hospital where she works. The vaccine was not administered at facility. She further reported she was fine after getting the COVID 19 vaccine. Her right arm was sore/ started to hurt about four or five hours later on 16Dec2020 but then was fully after 24 to 48 hours. She started to feel sick on 18Dec2020 (Friday evening). States she went to bed Friday morning after the night shift. She felt fine, better than normal. That same day (18Dec2020) she woke up at 1700 and felt like she was in a fog, on a cloud, heavy and out of it. She walked around for a while and that sensation didn't go away. She felt hot and weird but had no fever. Then at 1830 she got the alert on her phone that told her she was positive for COVID 19. She started to feel other symptoms on 18Dec2020 including headache, shortness of breath, tachycardia, burning sensations in her legs; extreme fatigue, wanting to go to bed that persisted from Friday to Sunday. Then on 20Dec2020, Sunday afternoon, her headache went away and she felt like the congestion was clearing up some. Mentions she did have a fever (onset date unspecified) with a high of 99.6 Fahrenheit; but it went back down to 99.0 Fahrenheit (date/s unspecified). On 20Dec2020 the patient experienced coughing. On 21Dec2020 (Monday) she started coughing more but states her O2 was fine and her breathing was okay. However, when walking around she felt winded like she has exerted herself more than expected. She then clarified that on 21Dec2020, she experienced shortness of air and the cough got worse but it has now plateaued. She did call her HCP and they were holding off on treatment at the time. No investigation assessment was performed. The patient was not admitted to an Intensive Care Unit. The patient did not display clinical signs at rest indicative of severe systemic illness nor did she require supplemental oxygen or receive mechanical ventilation. No preexisting diseases worsened during the SARS-CoV2 infection. The patient considered shortness of breath, and tachycardia as serious: medically significant while the events headache, burning sensations in her legs, fatigue, Coughing, and feels winded were considered as not serious. The events headache, shortness of breath, tachycardia, burning sensations in her legs, fatigue, Coughing, and feels winded were ongoing at the time of reporting. Shortness of breath worsened. The patient recovered from arm was sore on an unspecified date in Dec2020; and was recovering from tachycardia, sick, headache and congestion. The outcome of felt like she was in a fog, on a cloud, heavy and out of it; felt hot, and fever was unknown while not

recovered for the other events.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the reported events due to temporal relationship. However, the reported events may possibly represent intercurrent medical conditions in this patient. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics including chest x-ray, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

General weakness requiring assistance to stand.; General weakness requiring assistance to stand; Rash on chest/neck; This is a spontaneous report from a contactable Pharmacist. A 33-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (lot number EK5730), intramuscularly on 22Dec2020 13:15 at single dose for covid-19 immunization. Vaccine location was right arm and it was the first dose. The facility type vaccine was hospital. None medical history. No known allergies. Patient was not diagnosed with COVID-19 prior to vaccination nor tested for COVID-19 since the vaccination. There were no concomitant medications. The patient didn't receive any other vaccines within 4 weeks prior to the COVID vaccine nor received any other medications within 2 weeks of vaccination. The patient experienced rash on chest/neck. General weakness requiring assistance to stand on 22Dec2020 17:00 with outcome of recovered in Dec2020. The date report was first received from source was 23Dec2020. Patient received Fluid bolus, IV benadryl, IV steroid as treatment for the adverse events. The action taken in response to the events for BNT162B2 was not applicable. The events were reported as non-serious.; Sender's Comments: The reported events rash on chest/neck and general weakness requiring assistance to stand were likely related to the use of first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), due to temporal relationship and clinical course. The case will be reassessed should additional information become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Flushing; she noticed that there was a ringing in her left ear; Experienced a weird heaviness on her upper chest and arms/ heavy legs and arms/really heavy arms and legs; experienced a weird heaviness on her upper chest and arms; really cold hands; felt really hot at the injection site/really hot sensation at injection site; lightheadedness/Light-headed; Palpitations; Feeling faint; shortness of breath; Her blood pressure went up to 134/100; paleness; went up to her face; felt tired/She was really tired and slept it off; This is a spontaneous report from a contactable nurse, who is also the patient. This 34-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Lot number EK5730) intramuscular in the left deltoid on 20Dec2020 at single dose for COVID-19 immunisation. Relevant medical history included ongoing asthma (diagnosed as a teenager with sports asthma and uses an

inhaler). There were no concomitant medications. The patient experienced lightheadedness/light-headed (medically significant) on 20Dec2020 with outcome of recovering, palpitations (medically significant) on 20Dec2020 with outcome of recovered on 20Dec2020, feeling faint (medically significant) on 20Dec2020 with outcome of recovered on 22Dec2020, flushing (medically significant) on 21Dec2020 with outcome of recovered on 22Dec2020, she noticed that there was a ringing in her left ear (medically significant) on 21Dec2020 with outcome of recovering, shortness of breath (medically significant) on 20Dec2020 with outcome of recovering, her blood pressure went up to 134/100 (non-serious) on 20Dec2020 with outcome of recovered on 20Dec2020, she experienced a weird heaviness on her upper chest and arms (non-serious) on 21Dec2020 with outcome of recovering, really cold hands (non-serious) on 21Dec2020 with outcome of not recovered, paleness (non-serious) in Dec2020 with outcome of unknown, felt really hot at the injection site/really hot sensation at injection site (non-serious) on 21Dec2020 with outcome of recovered on 23Dec2020, went up to her face (feeling hot) (non-serious) in Dec2020 with outcome of unknown, heavy legs and arms/really heavy arms and legs (non-serious) on 21Dec2020 with outcome of not recovered and felt tired/she was really tired and slept it off (non-serious) in Dec2020 with outcome of unknown. The patient specified that she experienced a moderate reaction after having the COVID-19 vaccine. She had the vaccine last Sunday morning 20Dec2020. She was told to wait 20 minutes before leaving. In the waiting area, she felt lightheaded, had palpitations and was feeling faint. After 20 minutes she started feeling better. Then she started to have more intense light headedness. She went to the ER and was given oxygen. Her blood pressure was 134/100 on 20Dec2020. She had an EKG on 20Dec2020 that was normal. They gave her steroids and Benadryl. She had another episode while being injected with the steroids. On Monday 21Dec2020, she experienced a weird heaviness of her upper chest and arm. She had really cold hands and flushing. On Monday night 21Dec2020 she went to work. She experienced a really hot sensation to the injection site that went to her neck and face. Her left ear was ringing. This lasted until Tuesday 22Dec2020. She took Benadryl again on Tuesday 22Dec2020. She had shortness of breath which started on 20Dec2020 and on 22Dec2020 she had shortness of breath that lasted until 11am. She had really heavy legs and arms and went back to the ER. She had a chest X-ray and D-dimer on 22Dec2020 that were normal per the ER. The night before the report, she had some of the same symptoms. She was really tired and slept it off. She didn't take anything. The morning of the report, she was feeling good and better. She still has heavy feeling on upper chest and arms. Caller clarifies that she did not have a heavy feeling in her legs. Her arms feel heavy if she holds her phone too long. She continues to have ringing in her ear. The flushing went up to her face. The patient specified that she developed sports asthma as a child and uses an inhaler. She gets short of breath if she overexerts herself. Additional laboratory investigations on 20Dec2020 included blood work with unknown results and Troponin which was normal. She was provided with a general steroid. She did not know the name of it. She was also given Benadryl and monitored on telemetry. She was given IV fluids again on 22Dec2020.; Sender's Comments: Based on the compatible temporal association and the known pattern of response, the Company considers the reported events are possibly related to vaccination with BNT162B2. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

just kind of having blackout; Severe fatigue/fatigue; Severe myalgia; Some congestion; Severe headache; Haziness; This is a spontaneous report from a contactable other healthcare professional (HCP), who is also the patient. This patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration in Dec2020 at single dose for COVID-19 immunisation. Relevant medical history and concomitant medications were not reported. In Dec2020, the patient experienced just kind of having blackout, severe fatigue, severe myalgia, some congestion, severe headache and haziness. On day six, symptoms improved and suddenly he/she was having symptoms again, severe myalgia, some congestion severe headaches and fatigue. The outcome of the events was unknown. The information about batch/lot number has been requested.; Sender's Comments: This report fails to include the basic information that is required for an independent medical evaluation. Assessment is postponed after receipt of a more complete case report. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

Flu like symptoms like myalgia, achy head, mental cloudiness; Flu like symptoms like myalgia, achy head, mental cloudiness; Flu like symptoms like myalgia, achy head, mental cloudiness; Flu like symptoms like myalgia, achy head, mental cloudiness; Deep cough; This is a spontaneous report from a non-contactable physician. A female patient of unspecified age received the first single dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on an unspecified date in Dec2020, in left upper arm like deltoid, for COVID-19 immunization. Medical history and concomitant medications were not reported. On an unspecified date in Dec2020, immediately after receiving the vaccine, the patient experienced a deep cough which came on all of a sudden, followed 31 hours post vaccine by flu like symptoms like myalgias, achy head and mental cloudiness. She was feeling a bit better on 22Dec2020 morning and she was back at work. So, it was like a short couple of hours, maybe 24 hours turnaround. The events were resolving at the time of report. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Sender's Comments: The Company cannot completely exclude the possible causality between the reported flu like symptoms like myalgias, achy head and mental cloudiness and the administration of the COVID 19 vaccine BNT162B2 based on the plausible temporal association. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified, as appropriate.

Urination bleeding; This is a spontaneous report from a contactable consumer (patient). A patient of unspecified age and gender received BNT162b2 (Solution for injection, lot number and expiration date not provided), via an unspecified route of administration at single dose on 22Dec2020 for COVID-19 immunization. The patient medical history and concomitant medications were not reported. The patient experienced urination bleeding in Dec2020 and wanted to know if it was going to be a side effect. The outcome of the event was unknown. Information on the lot/batch number has been requested.

"severe fever; chills; severe night sweats; hives throughout my body; a rash on my face; This is a spontaneous report from a contactable nurse. This nurse reported for helf that the 37-year-old female patient received first dose of bnt162b2 (BNT162B2, product: COVID 19, brand: Pfizer), via an unspecified route of administration on Left Arm on 19Dec2020 10:30AM at single dose for covid-19 immunisation. No Pregnant at the time of vaccination. Medical history included Known Allergies to medications, food, or other products:Cocoa butter. Concomitant medications were unknown. Facility where the most recent COVID-19 vaccine was administered was Hospital. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient reported that ""Starting seven hours after the vaccine, I experienced severe fever and chills. The next morning, despite multiple anti-pyretics, the fevers/chills were worse. Also I experienced severe night sweats, likely related to the fevers. Three days after the vaccine, I began to have hives throughout my body and a rash on my face. Responds to Benadryl, but eventually reappears."" The event started from 19Dec2020 05:30 PM. Treatment was received for the adverse event included Anti-pyretics, anti-inflammatories, anti-histamine. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. Facility type vaccine was hospital. No other vaccine in four weeks. The patient recovered with lasting effects. No Covid prior vaccination. No Covid tested post: vaccination. The outcome of the event was recovered/resolved with sequel in Dec2020. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Sender's Comments: The reported events severe fever and chills, severe night sweats, and hives and a rash on face were likely related to the use of first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), due to temporal relationship and clinical course. The case will be reassessed should additional information become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate."

Left sides shock like pains in head. Lasts 3-5 seconds and go away. It's a stabbing shock like pain. Started on Thursday 17Dec2020 at 7:45 pm; Left sides shock like pains in head. Lasts 3-5 seconds and go away. It's a stabbing shock like pain. Started on Thursday 17Dec2020 at 7:45 pm; This is a spontaneous report from a contactable nurse reported for herself. A 28-year-old female patient (no pregnant) received her first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), intramuscularly in left arm on 16Dec2020 14:00 at single dose for COVID-19 immunization. Medical history was none. The patient's concomitant medications were not reported. The patient experienced left sides shock like pains in head, lasted 3-5 seconds and went away. It's a stabbing shock like pain. The events started on Thursday 17Dec2020 at 19:45. It was unknown whether treatment was received for the events. The events resulted in doctor or other healthcare professional office/clinic visit. The events were reported as non-serious. The most recent COVID-19 vaccine was administered in hospital. The patient had not received any other vaccines within 4 weeks prior to the COVID-19 vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. The outcome of the events was not recovered. Information on the lot/batch number has been requested.; Sender's Comments: Based on the compatible time association, the event left sides shock like pains in head is possibly related to suspect BNT162B2 administration. The impact of this report on the

benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

patient began to experience dizziness/shakiness.; patient began to experience dizziness/shakiness.; This is a spontaneous report from a non-contactable other hcp reporting for a patient. A 58-year-old female patient received first dose of BNT162B2 (Pfizer product, lot number: EH9899), intramuscular on 21Dec2020 16:00 at single dose on left arm for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. It was reported that during her 15 minute waiting period after the injection (21Dec2020 16:15), the patient began to experience dizziness/shakiness. This provider was notified of patient reaction and she was then transferred to the emergency bay via wheelchair where she was assessed. Monitored patient for severe reaction symptoms, including rapid progression of symptoms, respiratory distress with dyspnea, increased work of breathing, persistent cough and cyanosis, vomiting, hypotension, dysrhythmia, chest pain and collapse. Treatment included no therapy, but did continue with vital checks at approximately 5 minute intervals. Patient discharge: stable to go home and follow up with PCP. The outcome of the events was unknown. No follow-up attempts are possible. No further information is expected; Sender's Comments: Based on the compatible time association, the dizziness and shakiness are possibly related to suspect BNT162B2 administration. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Small bowel obstruction with diffuse bowel and pelvic lymphadenopathy 36 hours after injection; Small bowel obstruction with diffuse bowel and pelvic lymphadenopathy 36 hours after injection; This is a spontaneous report from a contactable physician (patient). A 61-years-old female patient (not pregnant) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number: EH9899), intramuscularly on 21Dec2020 12:30 to at single dose on left arm for COVID-19 immunization in hospital. Medical history included crohn's disease. No known allergies. Concomitant medications within 2 weeks of vaccination included estradiol, progesterone, colestipol hydrochloride (COLESTID), ustekinumab (STELARA), cyanocobalamin (B12). The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient experienced small bowel obstruction with diffuse bowel and pelvic lymphadenopathy 36 hours after injection on 22Dec2020 22:00 with outcome of recovered in Dec2020. The adverse events resulted in emergency room/department or urgent care, hospitalization for 3 days. Therapeutic measures were taken as a result of event included inpatient observation, nothing by mouth (reported as NPO), intravenous fluids. No COVID prior vaccination, COVID test nasal swab was negative on 23Dec2020 post vaccination. It was not reported as serious.; Sender's Comments: There is not a reasonable possibility that reported events small bowel obstruction and lymphadenopathy are related to BNT162B2 vaccine. The patient had underlying Crohn's disease, which put patient at risk of developing the event. The impact of this report on the benefit/risk profile of the Pfizer product is

evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

"burst blood vessel in left eye/blood in her eye; This is a spontaneous report from a contactable physician (patient). A 35-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (lot number EH9899, expiry date 01Mar2021), via an unspecified route of administration on 23Dec2020 at single dose for covid-19 immunization. Vaccine location was left deltoid. The facility type vaccine was hospital. Medical history included ongoing rheumatoid arthritis for about 8 years. No known allergies. Patient didn't do relevant test. Concomitant medication included duloxetine hydrochloride (CYMBALTA) for rheumatoid arthritis for 2 years, sulfasalazine for rheumatoid arthritis for 4 months, it's unknown if they were ongoing. The patient didn't receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient received the vaccine yesterday (23Dec2020), which she was very excited about, but today (24Dec2020) she woke up with a burst blood vessel in her left eye, she appears to have blood in her eye. This has never happened to her before. She knows this can occur with patients that have COVID but didn't know if it was a side effect to receiving the vaccine. Patient didn't receive treatment for the adverse event. The action taken in response to the event for BNT162B2 was not applicable. The outcome of event was not recovered. The relatedness between COVID vaccine and event ""burst blood vessel in left eye"" was related by reporter. Pfizer is a marketing authorization holder of [BNT162B2] in the country of incidence or the country where the product was purchased (if different). This may be a duplicate report if another marketing authorization holder of [BNT162B2] has submitted the same report to the regulatory authorities.; Sender's Comments: ""Burst blood vessel in eye"" is not uncommon in general population, and there are many causes of the event. Considering temporal relationship, a contribution role of the injection of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) to the reported Eye haemorrhage cannot be excluded. The case will be reassessed should additional information become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate."

Tachycardia; Intermittent palpitations; Low grade fever/fever; muscle aches; This is a spontaneous report from a contactable physician. A 27-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), intramuscularly in unknown arm on 17Dec2020 at single dose for routine mass immunizations (covid-19 immunization). The COVID-19 vaccine was administered at Hospital. Not a military facility. The patient's medical history was reported as none and concomitant medications was none (he was on no other medications). The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient experienced tachycardia, intermittent palpitations, low grade fever/fever all started somewhere in the morning of 18Dec2020 and muscle aches on 17Dec2020. Physician assessed tachycardia and intermittent palpitations as serious due to medically significant. Physician stated that one of his workers had the vaccine and proceeded to have tachycardia and low

grade fever. He would like to know if patient should get the second dose. The patient had mostly tachycardia with some intermittent palpitations. Patient was seen in his office on 18Dec2020, and got the COVID vaccine on 17Dec2020. He also reported fever and muscle aches, although the fever was subjective and was not documented. Tachycardia improved and sent him to cardiology on 21Dec2020. It was not life threatening and they did an Electrocardiogram (EKG). His initial heart rate was 130. When he was seen again in their office on 21Dec2020, it was 93, which was baseline. It improved. He never got his temperature. The highest in office was 99.5 degrees Fahrenheit. He had some muscle aches. The physician just sent patient to cardiology because he was having intermittent tachycardia and intermittent palpitations. Two visits to physician office. He was seen on 18Dec2020 and again on 21Dec2020. Relevant tests: they did testing for tachycardia but not related specifically. They did thyroid and EKG in office and he did not know if test were back. EKG was ok. The Thyroid, Complete blood count (CBC) and lipid (all were on an unknown date in Dec2020) were not back and were just done to make sure there were no cardiac issues. The outcome of the events was recovering. The lot/batch number has been requested.; Sender's Comments: Based on temporal association, the causal relationship between BNT162B2 and the events tachycardia and palpitations cannot be excluded. This case will be reassessed once additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate.

Cellulitis: below left elbow; Soft tissue swelling; This is a spontaneous report from a contactable nurse (patient). A 63-year-old female patient (62 years old at time of vaccination) received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Lot number: EH9899), intramuscular in left upper arm on 21Dec2020 13:00 at a single dose for COVID-19 immunization administered in the hospital. Medical history included ongoing hypertension and cervical cancer from 2015 and ongoing. The patient has been taking unspecified concomitant medication/s. The patient previously took amoxicillin and had allergies and nausea. On 24Dec2020 16:00, patient had cellulitis below left elbow and soft tissue swelling. On 25Dec2020, patient went to ER and X-ray was taken and patient was prescribed Keflex 500mg 3x day. Prior to vaccination, the patient was not diagnosed with COVID-19: Since the vaccination, the patient has not been tested for COVID-19. The outcome of the events was recovering.; Sender's Comments: Based on the information currently provided, the vaccination with BNT162B2 might play a contributory role in triggering the onset of cellulitis. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

congestion in the throat and upper lungs; congestion in the throat and upper lungs; This is a spontaneous report from a contactable other healthcare professional (patient). A 61-year-old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number: EK5730), intramuscular on the left arm on 21Dec2020 09:30 at a single dose for COVID-19

immunization. The patient's medical history included herpes 2. The patient was not pregnant. The patient had no known allergies to medications, food, or other products. There were no concomitant medications. The patient was not diagnosed with COVID-19 prior to vaccination and had not been tested for COVID-19 since the vaccination. On 26Dec2020 09:00, the patient experienced congestion in the throat and upper lungs. Oxygen level was 98 and temperature was 97.7. She had a good diet, no dairy, and no Christmas junk food, so for the patient, it was inexplicable. She was also consistent at mask wearing and all the precautions. No treatment was received for the adverse events. Outcome of the events was not recovered. The events were reported as non-serious.; Sender's Comments: Considering the temporal gap between the vaccination and the event onset, the Company considers the event pulmonary congestion is unlikely related to vaccination with BNT162B2. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

She was hospitalized for a month Occurred after a flu two months prior and a stomach flu 2-3 weeks prior; She was hospitalized for a month Occurred after a flu two months prior and a stomach flu 2-3 weeks prior; This is a spontaneous report from a contactable consumer. A 75-year-old female patient received bnt162b2 (BNT162B2, lot number and expiry date were not reported), via an unspecified route of administration on an unspecified date at a single dose for covid-19 vaccination. Medical history included guillain-barre syndrome from 2011 at the age of 65 and Levaquin allergy. The patient's concomitant medications were not reported. On an unspecified date, the patient was hospitalized for a month that occurred after a flu two months prior and a stomach flu 2-3 weeks prior. The outcome of the events was unknown. Information about lot/batch number has been requested.

I got my left arm pit, lump on it, I have bigger than 1 cm 2 lumps, hidradenitis/Pain under my arm; Patient received Pfizer Covid-19 Vaccine who is a nursing mom; Patient received Pfizer Covid-19 Vaccine who is a nursing mom; Mastitis; I got Myalgia all over the body, especially on my shoulders and back; I had chills but my temperature was normal; This is a spontaneous report from a contactable physician (patient herself). This physician reported information for herself (mother) and baby. This is the mother case. A 40-year-old female patient received her first dose of bnt162b2 (BNT162B2, also reported as Pfizer Covid-19 Vaccine, lot/batch number and expiry date were not reported), via an unspecified route of administration on 20Dec2020 18:30 at single dose for Covid-19 immunisation. The patient medical history and concomitant medications were not reported. The patient informed that she got in her left shoulder and left arm pit, lump on it. It was bigger than 1 cm 2 lumps, hidradenitis under her pits arm same size on 21Dec2020. She also reported that she was nursing mom to her self-kid which is 16 months old. She had Mastitis right now (20Dec2020) and informed that she hadn't it her life before. She got her vaccine on Sunday (20Dec2020) in night. She started to have pain under her arm on monday afternoon (21Dec2020) and then since yesterday (20Dec2020) she had mastitis. The mastitis in the right side, lump and the in the left side, which was the site of the vaccine. She never got a fever but got myalgia all over the body, especially on her shoulders and back and also she had chills but her temperature was normal. The outcome of events was unknown. Information on the Lot/Batch Number has been requested.;

Sender's Comments: Based on the close temporal relationship, the association between the event mastitis with BNT162b2 can not be completely excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.,Linked Report(s) : US-PFIZER INC-2020520371 Fetal case

26Dec2020 continued decreased perfusion added bilateral knee joint pain; 26Dec2020 continued decreased perfusion added bilateral knee joint pain; 25Dec2020 added facial edema; 24Dec2020 ++6 pitting edema on ankles and feet +3 pitting legs and abdomen; 24Dec2020 ++6 pitting edema on ankles and feet +3 pitting legs and abdomen; throat scratchy and tight; throat scratchy and tight; 23Dec2020 slight swelling on feet and ankles; 23Dec2020 slight swelling on feet and ankles; Tingling and best flutter 5 minutes after administration; Tingling and best flutter 5 minutes after administration; This is a spontaneous report from a contactable nurse (patient). A 48-year-old female patient (not pregnant) received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot/batch number: EJ1685, expiration date: Mar2021), intramuscularly on 22Dec2020 at 09:45 at single dose for COVID-19 immunization in hospital. The patient medical history included known allergies: Sulfa, Penicillin; fibromyalgia; hypertension; high cholesterol. Prior to vaccination, patient was not diagnosed with COVID-19. The patient's concomitant medications included other medications was received within 2 weeks of vaccination. Patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient experienced on 22Dec2020 09:45 tingling and best flutter 5 minutes after administration; 23Dec2020 slight swelling on feet and ankles; 24Dec2020 ++6 pitting edema on ankles and feet +3 pitting legs and abdomen, throat scratchy and tight; 25Dec2020 added facial edema; 26Dec2020 continued decreased perfusion added bilateral knee joint pain. Since the vaccination, patient had not been tested for COVID-19. Therapeutic measures were taken as result of the events included diphenhydramine hydrochloride (BENADRYL) 50 mg every 6 hours. The outcome of the events was not recovered. The report was reported as non-serious, with seriousness criteria-Results in death: No; Life threatening: No; Caused/prolonged hospitalization: No; Disabling/Incapacitating: No; Congenital anomaly/birth defect: No.; Sender's Comments: Flutter occurred 5 minutes after vaccination; a possible causal association between administration of the suspect vaccine bnt162b2 and the serious event onset cannot be fully excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

dizzy/feel faint; perspiring; like blood not getting to my head; had to get on hands and knees, crawl; felt like my heart may be racing 10 min after vaccine/heart felt off beat and like blood not getting to my head/heart rate was 142; felt like my heart may be racing 10 min after vaccine/heart felt off beat and like blood not getting to my head/heart rate was 142; arm sore day #1 and #2- not unexpected; This is a spontaneous report from a contactable Physician(patient). A 48-year-old female patient received first

dose (BNT162B2, lot number EK5730) , intramuscular at Arm Right on 18Dec2020 14:15 at the 48-year-old at single dose for COVID-19 immunization. The medical history included elevated blood pressure , allergic to sulfa, hypertension and Covid. The concomitant products included alprazolam, diphenhydramine hydrochloride (BENADRYL), spironolactone, metoprolol for hypertension, colecalciferol (VITAMIN D 3). The patient previously took nubaine and experienced drug allergy. The patient also happened to be a physician in private practice and received the vaccine at her local hospital. The patient had hypertension which was under excellent control on metoprolol 25 mg. She took it as prescribed every day surrounding the vaccine. On day #1 at the vaccine she felt like her heart may be racing 10 min after vaccine was about 80 on 18Dec2020 14:25. nothing serious. The patient experienced arm sore day #1 and #2 and not unexpected. On about 7 pm the day after the vaccine 19Dec2020 she was tachy at rate of about 105. She took her metoprolol heart rate never came down. At about 9:30 pm on 19Dec2020 when her rate should have been about70- she got up from couch after falling asleep. Upon standing felt like she was very dizzy. Walked upstairs, started to feel faint, perspiring, heart felt off beat and like blood not getting to my head. She had to get on hands and knees, crawl and heart rate was 142 and sustained for almost a minute. It took over an hour for it to come back to 86 and stayed there all night. There was not treatment to all of the adverse events. The outcome of the events was Recovering.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the palpitations, tachycardia and other reported events due to temporal relationship. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics including EKG, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Severe rash; This is a spontaneous report from a contactable healthcare professional (patient). A 42-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number: EK5730 (pending clarification)), intramuscularly at the left arm on 21Dec2020 at 16:00 (04:00 PM) at single dose for COVID-19 immunization. The patient was vaccinated at a hospital. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient was not pregnant at the time of vaccination. The patient's medical history included Diabetic, type 1, allergies to penicillin, and the patient diagnosed with COVID-19 prior to vaccination. The patient was not tested for COVID-19 since the vaccination. The patient previously took codeine and experienced allergies. The patient received other unspecified medications within 2 weeks of vaccination. The patient experienced severe rash on 23Dec2020 at 21:30 (09:30 PM). The adverse event resulted in emergency room/department or urgent care: the patient was treated at local ER with prednisone and benadryl. The event was reported as non-serious. The patient recovered from the severe rash on an unspecified date in Dec2020.; Sender's Comments: Based on the information currently provided, the vaccination with BNT162B2 might play a contributory role in triggering the onset of severe rash. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety

evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Diarrhea persisted 24 hours with mucous and bloody mucous after all fecal material was exhausted.; Did have one episode of chills; This is a spontaneous report from a contactable physician. A 51-year-old female patient received the first dose of bnt162b2 (BNT162B2) lot no: EK9231, intramuscular on 23Dec2020 09:45 at a single dose for COVID-19 immunization in workplace clinic. Medical history included hypothyroid, allergies from bee sting, and covid-19 from Apr2020, all unknown if ongoing. Concomitant medication included levothyroxine sodium (SYNTHROID). The patient did not receive other vaccine in four weeks. On 25Dec2020, in the late evening at 11:45 PM-almost midnight, the patient experienced diarrhea, severe, without nausea or vomiting. Did have one episode of chills that resolved. Diarrhea persisted 24 hours with mucous and bloody mucous after all fecal material was exhausted. The patient had COVID-19 in Apr2020 and had positive antibodies in Jun2020 with high titers. She confirmed with their ID chief that she should proceed to receive the vaccine. Diarrhea resolved in 24 hours. Some lingering increased GI activity. No fever (temp 99.0F) (Dec2020). The patient recovered from events without treatment in Dec2020. The events were reported as non-serious. The patient was not tested for COVID-19 post vaccination.; Sender's Comments: A possible causal association between administration of BNT162B2 and the onset of diarrhea, severe cannot be excluded, considering the plausible temporal relationship and the known adverse profile of the suspect product. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate

Difficulty breathing; This is a spontaneous report from a contactable pharmacist. A 54-year-old female patient received her first dose of intramuscular BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 22Dec2020 at 04:15 PM at single dose in left arm for COVID-19 immunisation at the age of 54-year-old. Lot number was ELO140. Medical history was unknown, concomitant medications were unspecified. Patient was not pregnant at the time of vaccination. On 22Dec2020 at 04:30 PM, the patient experienced difficulty in breathing, and she was hospitalized for one day. The patient was treated with EPI for the event. The patient was recovering from the event.; Sender's Comments: Based on the compatible temporal association, the Company considers the event difficulty in breathing is possibly related to vaccination with BNT162B2. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

short of breath; Intense headache; tiredness; body aches; This is a spontaneous report from a contactable other healthcare professional (patient). A 47-year-old female patient (not pregnant) received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number: ELO124), via an unspecified route of administration on 23Dec2020 at 14:30 on Left arm at

single dose for COVID-19 immunization in hospital. The patient medical history included Rheumatoid arthritis, lupus. No known allergy, no allergies to medications, food, or other products. Prior to vaccination, patient was not diagnosed with COVID-19. Concomitant medications included baricitinib (OLUMIANT), hydroxychloroquine, prednisone. Patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient experienced Intense headache, tiredness, body aches, short of breath on 24Dec2020; events were resulted in: Doctor or other healthcare professional office/clinic visit. Since the vaccination, patient had been tested for COVID-19 on 27Dec2020: Nasal Swab, result was unknown. No treatment was received for the events. The outcome of the events was not recovered.

"have COVID; have COVID; bone-crushing-pain; fever; This is a spontaneous report from a contactable consumer reporting for a patient (nurse). A 47-year-old female patient received first single dose of BNT162B2 (Solution for injection, batch/lot number and exp date not reported), via an unspecified route of administration on 20Dec2020 for immunization. The patient's medical history concomitant medications were not reported (unknown). Patient was an ER Nurse and took first dose of vaccine and then described mild/moderate symptoms on day one only. On 23Dec2020, patient posted they have COVID (positive COVID test). Contracted from spouse who got it from work. She further described it as ""hit by a truck."" On Day 4 she describes her COVID symptoms: bone-crushing-pain when fever rises. Symptoms were COVID symptoms, not directly related to vaccine. The events/symptoms started on 20Dec2020. Patient had no Covid prior vaccination. The patient was COVID tested post vaccination. The patient considered the events as non-serious. The outcome of events was not recovered. Information on Lot/Batch number has been requested."

abdominal pain; nausea; high blood pressure; This is a spontaneous report from a contactable consumer. A 93-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL0140), via an unspecified route of administration on 22Dec2020 at a single dose for COVID-19 immunization. Medical history included diabetic and irritable bowel. The patient's concomitant medications were not reported. The patient received the COVID vaccine and had abdominal pain, nausea and high blood pressure within 12 to 18 hours of vaccine received. The events lead to nursing home to emergency room and admitted to hospital. The patient was hospitalized due to events since 23Dec2020. Outcome of the events was recovering.

Golf ball size lump in armpit of injection arm; This is a spontaneous report from a contactable nurse. A 49-year-old female patient received bnt162b2 (BNT162B2), via an unspecified route of administration on left arm on 19Dec2020 18:15 at SINGLE DOSE for COVID-19 immunization. There was no medical history reported. Concomitant medication included estradiol (ESTROGEN), and meloxicam. On 26Dec2020 08:00, the patient experienced golf ball size lump in armpit of injection arm. The patient did not receive treatment for the adverse event. The outcome of the event was not recovered. Information on the lot/batch number has been requested.

I had seizure like 3 times; Vasovagal reaction; Fever; Headache; Weakness; It's just little bit shaky and breathless; It's just little bit shaky and breathless; allergic reaction; This is a spontaneous report from a contactable consumer. A 40-year-old female patient received bnt162b2 (BNT162B2, lot number:

EK5730), via an unspecified route of administration on 24Dec2020 at a single dose for covid-19 vaccination. There were no relevant medical history and concomitant medications. The patient reported that on an unspecified date, she had an allergic reaction. She had vasovagal reaction and seizures. Vasovagal was an allergic reaction that happened, and added that basically it's an allergic reaction. The patient experienced fever, headache, and weakness like right now. It was just little bit shaky, ever since yesterday and she had been way off like she take it as instruction yesterday, weakness, headache and breathless did not stopped from yesterday. The patient had been taking Tylenol for fever and headache. The patient reported that the events persisted. On 24Dec2020, lab work was done at the hospital, and she was told that the lab work was okay and they did CT scan of head because she developed seizure. She had seizure like 3 times so they scanned her brain. The outcome of the events was not recovered.

developed a migraine; nausea; sensitivity to light and sound; sensitivity to light and sound; she developed significant loss of mental clarity (brain fog); On 18Dec in the AM, developed progressive severe soreness at injection site, worse than any other vaccine, hurt even just the the touch. This lasted about a total of 36 hours and progressively improve; brain fog; retroorbital headache/intermittent mild tension type frontal headache; This is a spontaneous report from a contactable physician (patient). A 29-year-old female patient received first dose BNT162B2 (lot number EH9899), via an unspecified route of administration on 17Dec2020 12:00 at 29 years old at single dose at Left arm for COVID-19 immunization. Medical history included Mirena IUD, personal and family history of retinal migraines (without headache). The concomitant medications were magnesium citrate, melatonin, ademetionine (SAME) and fish oil. On 18Dec2020 in the AM, developed progressive severe soreness at injection site, worse than any other vaccine, hurt even just the touch. This lasted about a total of 36 hours and progressively improved. There was no swelling, redness, or other local symptoms. In the afternoon on 18Dec2020, she developed significant loss of mental clarity (brain fog) while at work. In the evening on 18Dec2020, developed mild retroorbital headache (this was actually the first headache of my life). All day 19Dec2020 and about half the day of 20Dec2020 developed a migraine (also the first of my life), experienced as retroorbital pounding headache, sensitivity to light and sound in 19Dec2020, nausea without vomiting in 19Dec2020, and loss of mental clarity. She had intermittent mild tension type frontal headache on 20Dec2020 PM with all other symptoms resolved, all symptoms resolved by 21Dec2020 AM. The patient used naproxen 440 mg and Tylenol 1000 mg on 19Dec2020. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. The patient was not Allergic to medications, food, or other products. The outcome of the events was recovered on 21Dec2020. The information on the batch number has been requested.; Sender's Comments: Based on information available, the reported loss of mental clarity together with other events was likely related to the first dose BNT162B2 due to temporal relationship and clinical course. The case will be reassessed should additional information become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

"husband and daughter tested positive/after taking the shot, she was feeling sick and had a fever/wondering if the vaccine can give the reaction, or maybe she has the virus; husband and daughter tested positive/after taking the shot, she was feeling sick and had a fever/wondering if the vaccine can give the reaction, or maybe she has the virus; having a lot IO symptoms; fever; has been feeling ""sick""; This is a spontaneous report from a contactable consumer. A 56-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899), via an unspecified route of administration on the left arm on 22Dec2020 at single dose for COVID-19 immunisation. The patient's husband and daughter tested positive (COVID-19). There were no concomitant medications. The patient stated, ""had the first vaccine shot, later clarified as Pfizer COVID vaccine, on 22Dec2020, and didn't have any symptoms before that, her husband and daughter tested positive, but she was staying away from that, had no symptoms, but after taking the shot, on 24Dec2020, she was feeling sick and had a fever, and has had a fever ever since, and she is taking Tylenol and Motrin every six hours, and even then she still gets the fever, it hasn't stopped, she is having a lot IO symptoms, and is wondering if the vaccine can give the reaction, or maybe she has the virus. On 24Dec2020 is when the fever started and she was feeling sick. States she filled out a report online, on (Website)"". The outcome of the events was not recovered."

his gums became discolored and turned purple/gums (both sides up and down) remain purple/discoloration to the gums in his mouth; his mouth started hurting; feeling hot; Body aches; Fever; Pain to the gums in his mouth; muscle aches; sore throat; neck pain; This is a spontaneous report from a contactable nurse (patient). A 26-year-old male patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number and expiration date were not reported), via an unspecified route of administration to right shoulder on 24Dec2020 11:30 at a single dose for COVID-19 immunization. There were no medical history and concomitant medications. The patient received vaccine on 24Dec2020. He experienced body aches, fever, and feeling hot with onset of about 3-4 hours after he was administered (24Dec2020). Next day (25Dec2020), his mouth started hurting, his gums became discolored and turned purple. Gums (both sides up and down) remained purple. He will be seeing a dentist. He also reported pain and discoloration to the gums in his mouth on 25Dec2020. He had been experiencing some of the regular side effects such as muscle aches, sore throat, neck pain on an unspecified date in Dec2020. Outcome of the event gum discoloration was not recovered, of the events feeling hot, generelized aching, and fever was recovered on 26Dec2020, of the event gum pain was recovering, and of the remaining events was unknown. He reported seriousness criteria as what he thinks to be medically significant at this point; that they could be medically significant. He is scheduled to receive the second dose of the product which at this point he does not plan to change. Dose change is unknown until he determines cause of these events and on what the doctor and dentist he is going to see recommend. He believes events could be caused by the vaccine. Information on the lot/batch number has been requested.; Sender's Comments: A causal association between BNT162 and the reported events cannot be excluded based on a compatible temporal relation. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

extreme muscle ache that she couldn't move; I couldn't take the pain/severe body ache severe like I couldn't walk; I couldn't take the pain/severe body ache severe like I couldn't walk; extreme muscle ache that she couldn't move; High fever; Lot of chills; Itchiness; Hives; she was crying; This is a spontaneous report from a contactable Nurse (patient). A 44-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiry date unknown), intramuscular on an unspecified date at single dose for covid-19 immunization. Patient history was no and investigation assessment was no. There were no concomitant medications. The patient had hives and itchiness and then that was the first day that was after 8 minutes and then the next day the patient had severe body ache severe like I couldn't walk, she cried. The patient took Tylenol and Ibuprofen as she couldn't take the pain (further clarification was unknown). The patient had high fever 102.4 and was having a lot of chills. Start date of event was 24th, the 23rd she had the hives and the 24th she had the extreme muscle ache that she couldn't move and she was crying and she had the chills and the fever on the 24th. So it on started 23rd with the hives so then it started with the body aches and the fever on the 24th. Outcome of the events was recovered. The causality between the events and drug was considered as related by the reporter via Global Introspection. Information on the batch/lot number has been requested.; Sender's Comments: The Company cannot completely exclude the possible causality between the reported body ache severe like I couldn't walk, extreme muscle ache that she couldn't move, and the administration of BNT162B2, based on the reasonable temporal association. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RA, IEC, as appropriate.

"left sided weakness; it has weakened his heart; stutter; severe stroke like symptoms; Ventricular tachycardia/help keep his heart rate at bay; Loss of balance; extreme numbness and tingling in left hand and foot; tingling in left hand and foot; oral motor impairment; mouth weakness and not coordinated/mouth is fatigued easily; Issues finding words and trouble speaking; Issues finding words and trouble speaking; Ejection fraction down to 25%; The initial case was missing the following minimum criteria: adverse event. Upon receipt of follow-up information on 28Dec2020, this case now contains all required information to be considered valid. This is a spontaneous report from a contactable other healthcare professional (HCP). A 29-years-old male patient received bnt162b2 (lot number: EJ1685), intramuscular (deltoid left) on 21Dec2020 at 05:30 at 0.3 mL single (first dose) for Covid. Medical history was reported as ""none"". Concomitant medications were not reported. The patient previously received Flu vaccine in Oct2020 for immunization. The patient is an Occupational Therapist, and he called to report an adverse event that he experienced with the first dose of the COVID Vaccine. He received the vaccine last Monday, 21Dec2020 at 5:30AM before his shift at work, then 20 minutes later, he was having severe stroke like symptoms. He experienced severe left sided weakness, loss of balance, extreme numbness and tingling in his left hand and foot, he had issues finding his words and he couldn't speak, and he had an oral motor impairment where his mouth was weak and not coordinated. The staff at the hospital did a neurological exam on him, and he failed, so he had to go to the emergency room (ER). The patient added that he was already in the hospital when this happened, and the ER doctors suspected that he had a CVA, and they gave him TPA to prevent any permanent brain damage and it

worked. The patient then added that due to the shock of this whole event, from everything that happened, it has weakened his heart. Reportedly, he is a healthy 29 year old man, with no preexisting conditions, and he works out, and he has no heart conditions, but he had to get a cardiology follow up a few days after he got the vaccine, because he started going in to Ventricular Tachycardia, which he had never had in his life. So, the doctors at the hospital went ahead and did an Echocardiogram and an EKG, and he was told that his Ejection Fraction is down to 25%. He stated his heart is so weak, that he cannot work right now, but the structure of his heart is fine and has not had any damage. The hospital staff thought that maybe the patient had a chronic heart issue that he just did not know about, and that the stress of this event maybe made it kick into overdrive, but he states that the cardiologist said that was not the case, because the structure of his heart is fine, and the only thing they can see is that the heart is pumping weak. One physician even suggested that due to the shock of the event, he might have Takotsubo Cardiomyopathy, which is a broken heart, but because the structure of his heart is okay, it should be reversible. He stated that he is hoping he will heal up good, because he is young and has no pre-existing conditions. He added that his heart is in such a state right now; he has to wear an external defibrillator. The patient stated that all these happened about 20 minutes after he received the vaccine, and he was admitted to the hospital from 21Dec2020 to 25Dec2020. His neurological symptoms have resolved except that he has a stutter that he did not have before and his mouth is fatigued easily, so he has to slow down when he is eating, but now he can eat regular for the most part. The patient confirmed that he was not specifically prescribed the product; it was administered to him at his place of work, but it was optional. He stated he considered how he is working with COVID patients every day, and given the circumstance, he thought that it would be a best practice for him to get the vaccine. He had not gone to his primary care doctor in a while because he had been fine and healthy, but he called them and found out that his primary care had retired, so he has to find a new one now. Regarding the issues finding words and trouble speaking, he stated that he has improved, but it is still ongoing, he is just stuck in a plateau zone. With the Ventricular Tachycardia, he stated that this is an ongoing issue, as he has to wear the life vest even though he has no need to activate it yet. He did have one minor bought of the VTach, but because he is a therapist, he knows how to take care of it with relaxation techniques, he knows how to manage it. He had one bought of VTach the evening prior, but he was able to get it under control. The doctors have him on medication to help keep his heart rate at bay. He has never had to use medication before and is on the following medications to help keep his heart rate at bay: Metoprolol 25mg one tablet once daily by mouth and Lisinopril 5mg one tablet once daily by mouth. The VTach has improved, it was good enough he was able to discharge home, but it is still a concern. His cardiologist said that, basically his hope, is that once his body recover from the whole shock of everything, then his ejection fraction will heal, and his heart will heal. He again stated that the doctor told him that the structure of his heart is perfectly fine; he has thick walls in his heart, no leaking valves, and the heart was not conducting any abnormal signals. The doctor just said that right now, his heart is super weak and that it is an acute problem. With the Takotsubo Cardiomyopathy, he states that two doctors mentioned this diagnosis, but he confirmed that he was not actually diagnosed with this issue, he was just diagnosed with Ventricular Tachycardia. The outcome of the ejection fraction down to 25% was unknown to the patient at this time as he has not had another EKG or echocardiogram, but the cardiologist told him that the cardiologist expects that this will not be resolved quickly anyway. The patient confirmed that he did not receive any other vaccines on the same day he received the COVID

vaccine. The only other vaccine he had this year was the flu vaccine which he got back in Oct2020. He has gone on to his online portal and there are the bloodwork results and all the imaging results on there from his CTs and MRIs, but he did not see the EKG or Echocardiogram results yet. He does not have this pulled up at this time, but he does have access to this stuff and can provide it later, if requested. He is curious about the next steps from here to how his case is processed. He is also curious if this information would help Pfizer make modifications to the vaccine if it is found that a lot of people are having the same reaction as he did. He is also wondering, given his situation, that probably he is not going to get the second dose, for his safety, but he is wondering what percentage of effectiveness the first dose does having just covered. The events left sided weakness, loss of balance, extreme numbness and tingling in left hand and foot resolved on 25Dec2020; severe stroke like symptoms and oral motor impairment; mouth weakness and not coordinated/mouth is fatigued easily resolved in 2020. The events ventricular tachycardia/help keep his heart rate at bay and issues finding words and trouble speaking were resolving, stutter had not resolved while the outcome of the events it has weakened his heart, and ejection fraction down to 25% was unknown.; Sender's Comments: The reported information is unclear and does not allowa meaningful assessment of the case. It will be reassessed upon receipt of follow up information. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate."

Left sided hearing loss; This is a spontaneous report from a contactable physician who was also the patient. A 42-year-old non-pregnant female patient received bnt162b2, lot number and expiration date were unknown, via an unspecified route of administration on 16Dec2020 , 8:30 at a single dose for covid-19 immunization. The patient's medical history included antiphospholipid antibody from an unknown date and unknown if ongoing. The patient's concomitant medications were not reported. On 22Dec2020, the patient experienced left sided hearing loss. It was unknown if patient received treatment for the event. The outcome of the event was not recovered. The patient was not diagnosed with COVID prior to vaccination and has not been tested for COVID-19 since vaccination. Patient has no allergies. Patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Information on the lot/batch number has been requested.; Sender's Comments: As an individual case report there is not enough evidence to establish a causal relationship with the suspect vaccine. Currently there is no clear biological plausibility between the vaccine use and the even onset. More information such as complete medical history and concomitant medications are needed for fully medical assessment. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

severe hearing loss; This is a spontaneous report from a contactable physician (patient). A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an

unspecified route of administration on 16Dec2020 at single dose for covid-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient experienced severe hearing loss on Dec2020 and was inquiring if it was a reported side effect of the vaccine. Outcome of event was unknown. Information about lot/batch number has been requested.; Sender's Comments: A causal association between BNT162 and the reported event cannot be excluded based on a compatible temporal relation. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

tightness in throat and lump in throat/had a tightness and lump in her throat; tightness in throat and lump in throat/had a tightness and lump in her throat; allergic reaction like rash, tightness in throat, and lump in throat; allergic reaction like rash/red rash on her chest and rash was on her arms too; cheeks were flushed; This is a spontaneous report from a contactable nurse (patient). This nurse reported similar events for 3 patients. This is the first of 3 reports. A 23-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) lot number: EK9231, intramuscular in the right deltoid, first dose on 27Dec2020 14:15 at a single dose for covid-19 prevention. Medical history included ongoing asthma and reactive airway which she was diagnosed when she was like 5 years old (2002). Concomitant medication included albuterol [salbutamol] for asthma which started when she was 8 years old or so. The patient wanted to know if she can receive the second dose of covid vaccine after experiencing symptoms of allergic reaction like rash, tightness in throat, and lump in throat. She wanted to know the ingredients and specific proteins in the covid vaccine. The patient received the COVID Vaccine and she developed a reaction. On 27Dec2020, she had a red rash on her chest, and her cheeks were flushed, and the rash was on her arms too, and she had a tightness and lump in her throat, it was not painful to swallow but she could feel the pressure with swallowing. She stated that she did not experience shortness of breath, but regardless, she was seen in the ER and she was given IV SOLUMEDROL, and BENADRYL, and she was watched for 5 or 6 hours and then she was sent home with an Epi Pen, around the clock Benadryl, and prednisone. She asked the ER doctors if they thought it was okay for her to receive the second dose of the product, and they told her to contact employee health for that question. She mentioned that she contacted that employee health and was told to contact her primary care provide which she did. Her primary care doctor instructed the caller to call Pfizer and gather some more information regarding ingredients, as the she may have had the reaction to a particular protein filler. She was also wondering if this is a known reaction to the product. She received the vaccine on 27Dec2020 at 2:15 PM. She reported that the red rash on her chest and arms, and her cheeks being flushed, resolved yesterday after receiving IV BENADRYL. Had a tightness and lump in her throat which was still ongoing, and it was kind of off and on and when the she takes Benadryl it goes away. She reported that this one is medically significant because even though she did not have shortness of breath, it could have affected her airway. She confirmed that she received no other vaccines on the same day as the COVID vaccine. The outcome of the events 'had a tightness and lump in her throat', allergic reaction was not recovered (a s reported); while recovered on 27Dec2020 for allergic reaction like rash/red rash on her chest and rash was on her arms too and cheeks were flushed.;

Sender's Comments: Based on temporal association, the causal relationship between bnt162b2 and the events throat tightness, sensation of foreign body, allergy to vaccine, rash erythematous and flushing cannot be excluded. This case will be reassessed once additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate.,Linked Report(s) : US-PFIZER INC-2020517134 different patient, same drug and same event;US-PFIZER INC-2020517133 different patient, same drug and same event.

Fever up to 120F; Bodyaches; Headache; dulled taste and smell; dulled taste and smell; Pain at the injection site; This is a spontaneous report from a contactable other HCP. A 25-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (reported as COVID 19 vaccine), intramuscular on 27Dec2020 12:00PM at single dose for covid-19 immunization. Vaccine location was left arm and it was the first dose. The patient medical history was not reported. Concomitant medication included influenza vaccine (FLU) on 16Dec2020 at right arm. Patient was not diagnosed with COVID-19 prior to vaccination nor tested for COVID-19 since the vaccination. The patient didn't receive any other medications within 2 weeks of vaccination. The patient experienced fever up to 120F, bodyaches, headache, dulled taste and smell, pain at the injection site on 27Dec2020. Patient didn't receive treatment for the adverse events. The action taken in response to the events for BNT162B2 was not applicable. The outcome of events was not recovered. The events were reported as non-serious. Pfizer is a marketing authorization holder of [BNT162B2] in the country of incidence or the country where the product was purchased (if different). This may be a duplicate report if another marketing authorization holder of [BNT162B2] has submitted the same report to the regulatory authorities. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Sender's Comments: A causal association between BNT162B2 and the event hyperpyrexia cannot be excluded based on compatible temporal relation. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

High blood pressure 187/95; Heart rate at one time 210 bpm; chest pain; Shortness of breath; This is a spontaneous report from a contactable pharmacist (patient) reported for herself that a 45-years-old female patient received first dose of BNT162B2 (lot number: EH9899), via intramuscular in left arm on 22Dec2020 07:00 AM at single dose for COVID-19 immunization. The patient was not pregnant. No known allergies. No allergies to medications, food, or other products. No other vaccine was received within 4 weeks prior to the COVID vaccine. No other medications were received within 2 weeks of vaccination. The patient was not diagnosed with COVID-19 prior vaccination and patient was not tested for COVID-19 since the vaccination. There were no medical history or concomitant medications. The patient experienced high blood pressure 187/95, heart rate at one time 210 bpm, shortness of breath and chest pain on 23Dec2020 10:00 AM. The events resulted in doctor or other healthcare professional

office/clinic visit, emergency room/department or urgent care. Treatment was received for heart rate at one time 210 bpm which included lab works and medication given propranolol to decrease heart rate. The outcome of the event was recovering.; Sender's Comments: Based on temporal association, the causal relationship between BNT162B2 and the events hypertension, heart rate increased, chest pain and dyspnoea cannot be excluded. The information available in this report is limited and this case will be reassessed once additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate.

She had an immediate reaction of accelerated heart rate and elevated blood pressure; She has very slightly elevated heart enzymes.; She had an immediate reaction of accelerated heart rate and elevated blood pressure; She's very anxious and very anxious tonight being alone at the hospital.; This is a spontaneous report from a contactable consumer (patient's father). A 30-years-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 18Dec2020 at single dose for COVID-19 immunisation. The patient medical history and concomitant medications were not reported. The patient had an immediate reaction of accelerated heart rate and elevated blood pressure. She was monitored for an hour and it subsided. On unspecified date in Dec2020 at 1:00am in the morning she had racing heart rate and went to ER. She was still in hospital. Things were not entirely stabilized. She had very slightly elevated heart enzymes in Dec2020 with outcome of unknown. They keep her overnight for an echocardiogram in morning. The patient was very anxious being alone at the hospital. Caller questioned if this has been reported with the vaccine. Lot/Batch and Expiry date has been requested.

mental cloudiness; bruising of injection site; arm pain; fatigue; This is a spontaneous report from non-contactable Pharmacist (patient). A 33-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection) intramuscular at right arm on 19Dec2020 08:15 at single dose for Covid-19 immunization. The Covid-19 vaccine was administered in a hospital facility. Medical history included seasonal allergies, heartburn, and allergies to ethanol. The patient has no Covid prior vaccination. Concomitant medication included cetirizine, esomeprazole, melatonin; all from unspecified date for unspecified indication. The patient did not receive other vaccines in four weeks prior to the Covid vaccine. On 19Dec2020 at 15:00, the patient experienced bruising of injection site (x 1 week), arm pain, fatigue, mental cloudiness (approximately x 1 day). The patient was not tested post vaccination. The patient did not received treatment due to the events. The outcome of the events mental cloudiness, bruising of injection site, arm pain and fatigue was recovered in Dec2020. No follow-up attempts are possible. Information about lot/batch number cannot be obtained.; Sender's Comments: Based on temporal association, the causal relationship between BNT162B2 and the event mental impairment cannot be excluded. The information available in this report is limited and this case will be reassessed once additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as

part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate.

30 minutes after receiving vaccine, patient reported heart racing, dizziness, flushing, burning pain in her chest, dizziness. tachycardia, nausea and throat tightness; 30 minutes after receiving vaccine, patient reported heart racing, dizziness, flushing, burning pain in her chest, dizziness. tachycardia, nausea and throat tightness; 30 minutes after receiving vaccine, patient reported heart racing, dizziness, flushing, burning pain in her chest, dizziness. tachycardia, nausea and throat tightness; 30 minutes after receiving vaccine, patient reported heart racing, dizziness, flushing, burning pain in her chest, dizziness. tachycardia, nausea and throat tightness; 30 minutes after receiving vaccine, patient reported heart racing, dizziness, flushing, burning pain in her chest, dizziness. tachycardia, nausea and throat tightness; 30 minutes after receiving vaccine, patient reported heart racing, dizziness, flushing, burning pain in her chest, dizziness. tachycardia, nausea and throat tightness; 30 minutes after receiving vaccine, patient reported heart racing, dizziness, flushing, burning pain in her chest, dizziness. tachycardia, nausea and throat tightness; This is a spontaneous report from a contactable pharmacist. A 58-year-old non-pregnant female patient received first dose of BNT162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number= EH9899), intramuscular on 19Dec2020 07:00 at SINGLE DOSE at Left arm for covid-19 immunization. Medical history included breast cancer female and allergies to shell fish and Latex. The patient's concomitant medications were not reported. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. 30 minutes after receiving vaccine on 19Dec2020 07:30 am, patient reported 'heart racing, dizziness, flushing, burning pain in her chest, dizziness. tachycardia, nausea and throat tightness. Patient was taken to the ED where she received IV Benadryl and was observed for 4 hours. Patient was discharged home and symptoms subsided. The events resulted in emergency room/department or urgent care. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, the patient was not been tested for COVID-19. Outcome of the events was recovered in Dec2020.; Sender's Comments: There is a plausible temporal relationship between immunization and onset of allergic reaction in a subject with a positive medical history for allergy to food (shellfish); causality cannot be completely excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

exacerbation of cryptogenic organizing pneumonia; fever; malaise; wheezing; This is a spontaneous report from a contactable physician reported for himself. A 60-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection) via an unspecified route of administration from an unspecified date at single dose for Covid-19 immunization. Medical history included rheumatoid arthritis. The patient's concomitant medications were not reported. The patient experienced having fever and malaise after vaccination and then a few days later he has been wheezing. The patient believed it was an exacerbation of cryptogenic organizing pneumonia. The outcome of the events exacerbation of cryptogenic organizing pneumonia, fever, malaise and wheezing was unknown. Follow-up activities are possible, information on the batch number has been requested.; Sender's Comments:

The association between the event cryptogenic organizing pneumonia with BNT162b2 can not be fully excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

Sudden onset Acoustic Neuritis without Labyrinthitis, hyperacusis, loss of hearing, fullness in ears, dizziness and tinnitus.; Sudden onset Acoustic Neuritis without Labyrinthitis, hyperacusis, loss of hearing, fullness in ears, dizziness and tinnitus.; Sudden onset Acoustic Neuritis without Labyrinthitis, hyperacusis, loss of hearing, fullness in ears, dizziness and tinnitus.; Sudden onset Acoustic Neuritis without Labyrinthitis, hyperacusis, loss of hearing, fullness in ears, dizziness and tinnitus.; Sudden onset Acoustic Neuritis without Labyrinthitis, hyperacusis, loss of hearing, fullness in ears, dizziness and tinnitus.; sore arm; nerve related hearing loss; This is a spontaneous report from a contactable physician reporting for himself. A 69-years-old male patient received bnt162b2 (BNT162B2; Lot : EKS730) vaccine , intramuscular in the left deltoid on 21Dec2020 15:30 at single dose for covid-19 immunisation . Medical history included atrial fibrillation from 2009. There were no concomitant medications. The patient stated he experienced sore arm on the same day 21Dec2020 and this was not a big deal. On 26Dec2020 the patient experienced sudden onset of acoustic neuritis without labyrinthitis, hyperacusis, fullness in ears, dizziness and tinnitus . The patient also experienced nerve related hearing loss from Dec2020. Sore arm was considered non serious events, while the remaining were considered Important Medical Events. The outcome of nerve related hearing loss was recovered, the outcome of sore arm was unknown, while the outcome of the remaining events was recovering.; Sender's Comments: Based on the temporal association, it cannot be fully excluded that the vaccination with BNT162B2 might play a contributory role in the events onset. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

I have lost hearing in my right ear; the right side of my face was numb; This is a spontaneous report from a contactable consumer (patient). A 58-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) Batch/lot number number EJ1685, expiration date Mar2021, on 25Dec2020 09:30 at single dose on left arm for Covid-19 vaccination. Medical history and concomitant medications were none. The patient had not received other vaccine in four weeks. The patient had no covid prior vaccination. The patient had no covid tested post vaccination. The patient received her first Covid-19 vaccination on Christmas morning. She worked at a medical center. Within an hour of when she got home, she lost hearing in one ear and also had some numbness on the same side of her face, She was wondering if that was something she should be concerned and she still didn't have hearing in her right ear. Treatment received for the events included Tylenol. The outcome of the events was not resolved.

She suspected that she had an undiagnosed autoimmune disease.; Spinal pain that elicits nausea; spinal pain that elicits nausea; Headache that is worse at night/Headache worse at night time, sometimes gets better during the day/bad head ache; Body aches; Feeling crappy; Low grade fever; Pressure in the head; Terrible pain; Neck pain; This is a spontaneous report from a contactable other health professional (patient). A 43-yearsold female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 19Dec2020 at single dose for covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient received Covid19 vaccine on 19Dec2020 and reported that at 36 hours she had body aches, feeling crappy, and low grade fever in Dec2020, she had since developed at headache that is worse at night, and spinal pain that elicits nausea. She suspected that she had an undiagnosed autoimmune disease. She was inquiring about duration of the reported AE's from clinical trials, and tried to decide how long she will feel this way. And going on 10 days and she's just struggling, bad headache and neck pain headache worse at night time, sometimes gets better during the day. Terrible pain and nausea. Any info on length of side effects: 36 hours- body aches feeling crappy. Low grade fever. Nausea with the spinal pain, pressure in the head. Difference in people with autoimmune issues- infertility - suspected autoimmune. The outcome of the events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Based on the information currently available, there is no biological plausibility to implicate the suspect vaccine to the occurrence of the serious event autoimmune disease. More information such as medical history and concomitant medications and confirmative diagnostic workups are needed for full medial assessment. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Heart rate high; Blood pressure high; bruise at the site of the vaccination; This is a spontaneous report from a contactable other health professional reporting for herself. A female patient of an unspecified age received the 1st dose of bnt162b2 (BNT162B2, Manufacturer Pfizer-BioNTech), via an unspecified route of administration, on 22Dec2020, at single dose, for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. On 22Dec2020, 1-1.5 hours after vaccination, the patient experienced heart rate high with outcome of unknown , blood pressure high with outcome of unknown and bruise at the site of the vaccination with outcome of unknown. The patient underwent lab tests and procedures which included: blood pressure, high (22Dec2020); heart rate, high (22Dec2020). She returned to the emergency room (ER) of the hospital where she received the vaccine due to all the events. Therapeutic measures were taken as a result of heart rate high and blood pressure high and included treatment with a beta blocker. The patient was also prescribed with a blood pressure medicine from the ER physician. The events heart rate high and blood pressure high were considered medically significant. The information on the lot/batch number has been requested.; Sender's Comments: Based on the compatible temporal association, the Company considers the events heart rate high and blood pressure high are possibly related to vaccination with BNT162B2. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety

concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

tingling of the lips/Lips tingled; Throat got tight; This is a spontaneous report from a contactable other hcp(patient). The 49-year-old female patient received first dose BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EK5730, Expiry Date: 31Mar2021), via an unspecified route of administration at left arm on 21Dec2020 at single dose for COVID-19 immunization. There were no concomitant medications nor medical history. Patient got first dose of the COVID vaccine and experienced her lips tingled/ tingling of the lips and her throat got tight, both on 21Dec2020, led to medically significant, lasted about 20 minutes. They observed her and she did not need any further treatment. Outcome of events was recovered in 21Dec2020.; Sender's Comments: A possible causal association between administration of BNT162B2 and the onset of her lips tingled/ tingling of the lips and her throat got tight cannot be excluded, considering the plausible temporal relationship and the known adverse event (anaphylactic adverse reaction) profile of the suspect product. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate

"disoriented; hit her head and cut herself; hit her head and cut herself; Passed out at night; This is a spontaneous report from a contactable consumer (patient). A 67-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK5730), via an unspecified route of administration on 23Dec2020 at single dose at left arm for COVID-19 immunization. Medical history included Atrial fibrillation/heart problems diagnosed prior to the vaccine, got the COVID virus on 18Nov2020, disoriented in Nov2020. Concomitant medications included her heart medication every day and vitamins, nothing out of the normal. Caller stated she had heart problems. The heart problems were diagnosed prior to the vaccine. Caller also stated that she got the COVID virus this year before the vaccine as well and she was off, of work for like a month. On 23Dec2020 she got the vaccine. Then on Thursday 24Dec2020 and Friday 25Dec2020 she had a reaction. She had passed out in the night, hit her head and cut herself, she was then disoriented for 1 full day. Caller stated that the last time she was disoriented like this was when she had the COVID Virus, because she had heart problems. Caller stated that she was fine now. Caller stated that she had been off, of work so much. The heart problem she had was Atrial Fibrillation. Caller clarified that she had the COVID virus this year in Nov2020, it was before thanksgiving, on 18Nov2020 she had the virus, then on 19Nov2020 she got tested and it was positive. She got the vaccine on the 23Dec2020 Wednesday then on 24Dec2020 at night she passed out and on 25Dec2020 she was disoriented all day. Investigation Assessment: No. On 24Dec2020 she was going to bathroom, and found herself on the floor, then the following day 25Dec2020 was when she was disoriented. She knew this because when she had the actual COVID virus previous in Nov2020 this happened previously. When queried outcome of being disoriented she stated that she still felt a little weird but if getting better very, very slow. The Second dose was schedule for 13Jan2021. Caller confirmed that she did have a Positive Test for Covid Previously. Her treatment at the time was in the Emergency Room, they gave her an Antibody infusion, she had to schedule it because it was actually a

clinical trial. Caller was asked if she knew the name of covid test, she stated that she does not know, she only recalled that she opened her mouth and they test her that way. The outcome of the event ""disoriented"" was recovering, of the other events was unknown."

Bells Palsy; This is a spontaneous report from a contactable consumer. This consumer reported similar events for three patients. This is 1st of three reports. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (also reported as Comirnaty), via an unspecified route of administration on an unspecified in Dec2020 at single dose for COVID-19 immunization. The patient medical history and concomitant medications were not reported. The patient experienced bells palsy on Dec2020. The action taken in response to the event for bnt162b2 was not applicable. The outcome of event was unknown. No follow-up attempts are possible; information about batch/lot number cannot be obtained.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2020519118 same reporter/drug/event, different patient;US-PFIZER INC-2020519119 same reporter/drug/event, different patient

Bell's Palsy; This is a spontaneous report from a contactable consumer or other non HCP. This consumer reported same events for three patients (nurses). This is 2nd of 3 reports. A patient of an unknown age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, also reported as COMIRNATY), via an unspecified route of administration on unknown date in Dec2020 at single dose for covid-19 immunization. The patient's medical history and concomitant medications were unknown. Healthcare worker reported that 3 nurses who work in her facility received Pfizer's COVID vaccine last week (Dec2020) came in with Bell's Palsy in Dec2020. Event took place after use of product. The outcome of event was unknown. No follow-up attempts are possible. Information about batch/Lot number cannot be obtained.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2020519105 same reporter, same drug, same event, different patients;US-PFIZER INC-2020519119 same reporter, same drug, same event, different patients

Bells Palsy; This is a spontaneous report from a contactable consumer or other non HCP. This consumer reported same events for three patients. This is a 3rd of 3 reports. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, also reported as Comirnaty), via an unspecified route of administration on an unspecified in Dec2020 at single dose for COVID-19 immunization. The patient medical history and concomitant medications were not reported. Healthcare worker reported that 3 nurses who work in her facility received Pfizer's COVID vaccine last week (Dec2020) came in with Bells Palsy. Event took place after use of product. The outcome of event was unknown. No follow-up attempts are possible; information about batch/lot number cannot be obtained.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2020519118 same reporter, same drug, same event, different patients;US-PFIZER INC-2020519105 same reporter, same drug, same event, different patients

Gallbladder removed, septic, 11mm axillary lymph node.

she got the COVID 19 vaccine on the 16Dec2020 and got tested positive on the following day; she got the COVID 19 vaccine on the 16Dec2020 and got tested positive on the following day; This is a

spontaneous report from a Pfizer-sponsored program IBCC (Inbound Call Center for HCPs). A contactable nurse (patient) reported that a female patient of an unspecified age received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 16Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient reported that she got the COVID 19 vaccine on the 16Dec2020 and got tested positive on the following day (17Dec2020). She is scheduled to take her second dose on 20Jan2021. The patient wanted to know what Pfizer recommendations are. Outcome of the event was unknown. That information on the lot/batch number has been requested.; Sender's Comments: A causal role of BNT162B2 would seem unlikely based on the temporal gap between the vaccination and the event onset.

being tested positive; being tested positive; felt very sick; congestion; This is a spontaneous report from a contactable other healthcare professional (patient herself). A female patient of an unspecified age received her first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date not reported), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient felt very sick and that's not her normal. The patient felt great after getting the vaccine she hadn't felt that in a while. Today (23Dec2020) the patient had this congestion and 4 -5 people came back positive post covid-19 vaccination on unknown date. All of them sent home after being tested positive. The patient just someone to keep track, she just wanted Pfizer to know. She didn't have any problems, she was working COVID patients. They had a lot new cases. She just didn't feel 100%. The patient wanted to know if it's safe for her to get the second dose after being tested COVID positive post vaccination. The outcome of events was unknown.; Sender's Comments: The information available in this report is limited and does not allow a medically meaningful assessment of the case. The company cannot completely exclude a causal relationship between the reported events and vaccination with BNT162B2. Additional information regarding therapy vaccination date, lot number and investigation results will aid in comprehensive assessment of the case.

she reported on 18Dec2020 got vaccine later that day tested positive; she reported on 18Dec2020 got vaccine later that day tested positive; This is a spontaneous report from a contactable nurse. A female patient of an unspecified age received the 1st dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration at single dose on 18Dec2020 for Covid-19 immunisation. The patient medical history and concomitant medications were not reported. She reported on 18Dec2020 got vaccine later that day tested positive with outcome of unknown. She asked can she still receive the 2nd dose of the vaccine or should she repeat the vaccination series. The patient underwent lab tests and procedures which included Sars-Cov-2 test: positive on 18Dec2020. Information on the lot/batch number has been requested.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the reported events due to temporal relationship. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile

of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

received the (1st dose of) COVID-19 vaccine 5 days ago and tested positive; received the (1st dose of) COVID-19 vaccine 5 days ago and tested positive; This is a spontaneous report from a contactable pharmacist. A patient of unspecified age and gender received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Device Type: Vial), intramuscularly on 18Dec2020 at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient received the (1st dose of) COVID-19 vaccine 5 days ago and tested positive on 23Dec2020. PharmD asked if it's possible to administer Bamlanivimab to a patient who received the (1st dose of) COVID-19 vaccine 5 days ago and tested positive. Pharmacist mentioned that as Bamlanivimab was an EUA drug, they cannot go outside of the recommendations, and given that no information was available about its use after a dose of the COVID-19 vaccine, it is possible that Bamlanivimab may not be administered. Explained Pfizer MI is unable to provide a direct recommendation, was referred to the patient's Docton for guidance: Before receiving the next dose of the COVID-19 vaccine, and to clarify if Bamlanivimab should be administered. The outcome of events was unknown. Information on the Lot/Batch number has been requested.; Sender's Comments: The reported tested positive 5 days after COVID-19 vaccine is considered related to the administration of BNT162B2.

PCR test positive for COVID-19 but no signs of COVID-19; PCR test positive for COVID-19 but no signs of COVID-19; This is a spontaneous report from a contactable physician reporting for himself. A 70-year-old male patient received the 1st dose of bnt162b2 (BNT162B2), via an unspecified route of administration in arm left, on 17Dec2020 at 09:00 AM, at single dose, for Covid-19 immunisation. Medical history included hypertension, high cholesterol, benign prostatic hyperplasia, drug allergy and food allergy all from unknown date and unknown if ongoing. The patient had not been diagnosed with COVID-19 prior to vaccination. The patient received unknown medications within 2 weeks of vaccination. Historical vaccine included typhoid vaccine (unknown trade name) on unknown date and the patient experienced drug allergy. The day after vaccination with bnt162b2, on 18Dec2020 at 04:00 PM, the patient experienced PCR test positive for COVID-19 but no signs of COVID-19. The patient did not receive any treatment as a result of the event. The event resulted in doctor or other healthcare professional office/clinic visit. The patient underwent lab tests and procedures which included: COVID-19 PCR test positive (18Dec2020), nasal swab positive (18Dec2020). Outcome of the event was unknown. The information on the lot/batch number has been requested.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the reported events of COVID-19 PCR test positive and suspected lack of efficacy due to temporal relationship. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for

adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

guillain barre syndrome; stroke; left thigh burning; Left b/l gluteal burning/bilateral gluteal burning; paresthesia; mid back burning; right side burning / right thigh burning; b/l hand numbness/bilateral hand numbness; left facial numbness; b/l foot numbness/bilateral foot numbness; This is a spontaneous report from a contactable physician (patient). A 39-year-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EK5730), via an unspecified route of administration on 19Dec2020 at single dose for prevention. Medical history included none. There were no concomitant medications. Caller states, he received the covid vaccine 19Dec2020 and on 25Dec2020 he was experiencing left facial numbness, b/l foot numbness, b/l hand numbness on 26Dec2020, right side burning on 28Dec2020, Today (29Dec2020) he has had left thigh burning, and Left b/l gluteal burning and paresthesia. No motor issues and no tendon issues, all intact. Also had mid back burning on 28Dec2020 that comes and goes. He has heard that there is a described neuropathy with the virus and/or with the vaccine and wants more information on that. Curious if anyone has anything similar? and makes mention of possible Gillian Barre Syndrome. States that he has had a potential reaction. He had his dose on 19Dec2020. On 25Dec2020 he developed left facial numbness, then later that day he developed bilateral foot numbness. On 26Dec2020, he developed bilateral hand numbness, on 28Dec2020 he developed right thigh burning, and today (29Dec2020) he has developed left thigh burning, and bilateral gluteal burning and paresthesia. States that he has been kind of freaking out about it. He doesn't have any motor issues. States that he heard that there is a described neuropathy with the virus, but not with the vaccine, is that true? The left facial numbness resolved on either 26Dec2020 or 27Dec2020. States that the symptoms were concerning because it could have been a stroke. States his symptoms were moderate. States that due to the bilateral foot and hand numbness, he had a LP, brain and spine MRI, and blood work done on 26Dec2020. All came back completely normal. When asked about causality, caller states that it makes the most sense for his symptoms to be caused by the vaccine due to his age and the fact that all his testing was completely normal. Reporter seriousness for left facial numbness, bilateral foot numbness, bilateral hand numbness, right thigh burning, left thigh burning and bilateral gluteal burning and paresthesia: Medically significant. The outcome of the event left facial numbness was recovered in Dec2020. The outcome of the events guillain barre syndrome, stroke and mid back burning was unknown. The outcome of the other events was not recovered.; Sender's Comments: Based on the temporal relationship the association between the reported serious adverse events with BNT162b2 can not be fully excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

Approximately 4 days after vaccine I started experiencing sharp lower back and left hip pain. Also my left foot feels like pins and needles.

Complete loss of vision in the left eye 12 hours after receiving second dose (Moderna mRNA-1273) while having a fever of 102 F for 6 hours. Loss of vision lasted for 1 minute. Loss of vision occurred while standing. Referral to primary care and ophthalmology specialist found normal eye exam and MRI of orbits but presence of tachycardia especially while standing (fluctuations between 60 beats at rest/laying down to 130 beats per minute standing). Postural tachycardia syndrome (POTS) is suspected. Currently pursuing cardiac workup with cardiologist and Covid POTS specialist. POTS specialist believes autoantibody development after vaccination could be suspected as recovering covid patients similarly present to clinic with POTS like symptoms.

Patient with extreme nausea and vomiting that started soon after receiving the Moderna vaccine. Patient with loss of consciousness, diaphoresis and garbled speech during a foley catheter exchange thought to be from dehydration. Patient was admitted to Hospital for observation for 2 days

12/18 VACCINATION 12/19 WOKE UP, RINGING IN BOTH EARS. CALLED PCP, CONSULTED ENT ABNORMALITY - L INNER EAR; HIGH DOSE STEROIDS, 10 DAYS, 60 MG/DAY. WEEK 2; TINNITUS GOT WORSE. DR. PRIMARY CARE PHYSICIAN MEDICAL EXAM ON 1/6/2021 INJECTION OF STEROIDS.

Acute Pericarditis. Patient was admitted from 12/27-12/28/2020 at hospital by cardiology team who strongly felt the acute pericarditis was due to the Pfizer Vaccine (Dr. was senior cardiologist).

Fever, Malaise

After the 15 min monitoring, I went back to work 15 min later. the left side of my face started tingling which went to a numbing feeling down the left side of my body affecting my neck, shoulder, arm, elbow and up the upper left torso. My face and neck was numb for about 48 hrs and the rest came back to sensation within 24 hrs. D/T the numbness I was admitted into the hospital for a 24hr observation.

""""Pfizer-BioNTech COVID-19 Vaccine EUA."" Patient received first dose of vaccine on 12/21/2020. Patient called on 1/3/2021 to notify that she developed symptoms on 12/27/2020 and had an appendectomy on 12/28/2020 at another facility. Patient also reports that CDC V-Safe Application was used to report event as well. Patient reports that she is recovering well."

Patients adverse reactions started day of vaccination with right arm pain up to right ear as well as complete tongue numbness. On 1-1-21 patient had increased Bell's Palsy symptoms including; inability to raise left eyebrow, inability to close left eye in its entirety, teeth being numb on left side, and numbness and tingling in left foot and left hand (from palm to fingers). ER physician prescribed on 1-1 Prednisone, Keflex and Valtrex. Patient went to ER again on 1-2-21 with lower extremity numbness on left side that is moving proximally toward her hip. Patient went home on 1-3-21 with an RX for Prednisone as well as Valtrex. Symptoms have improved but have not fully resolved at this time.

She was hospitalized on 01/04 but exact situation unknown. COVID +. Hospitalized at Medical Center.

Employee received COVID 19 vaccination at 9:45am on 12/30/20. ~15 min. later she developed a rash down her left arm, then down her Rt. arm. about 4 hours later she decided to go to the emergency room

for Hearty Palpitations, Fever, Chest discomfort and feeling of generalized sunburn. Later developed severe headache..

Right arm swelling very bad right after shot, next day woke up to get ready to work I started to get light headed, dizzy, sweating, felt like I was going to pass out. My husband then called 911. They took me to Hospital ,I stayed there for a couple hours then released. They told me to stay home and the next day I felt fine. I did a televisit with my Nephrologist (Kidney doctor) the following week.

noticed twitching in L arm shortly after receiving vaccine, numbness , weakness and pain in arm and shoulder girdle, diagnosed with parsonage turner syndrome by neurologist, currently taking neurontin for pain as steroids not tolerated

Felt slight warmth throughout body about 5 minutes after vaccine. Disappeared 2 minutes later. Arm started to feel sore as the day went on and was very sore by nighttime. Next day, arm started to feel better and over the next 3 days was no longer sore. On the morning of the 30th, woke up feeling fine, took a 3.5 mile walk and felt fine. Around 12:30 pm, experienced sudden pain and a burning sensation in the chest and both upper arms. Thought it was possibly heartburn ; took a Prilosec. The discomfort (mild but steady) continued so checked blood pressure which was 141/91. Called cardiologist and went to emergency room per instruction, around 1:30. Admitted overnight with the diagnosis of a mild heart attack and performed a heart catheterization where they found no major blockage. One artery noted 30% blocked but that overall heart function looked good. Discharged on 12/31/2020. -reported by patient via email, on 1/3/2021 @ 4:49pm

Bell?s palsy, right side of face is numb, with difficulty closing eyes, smiling, raising eyebrows, eating, drinking, swallowing.

12/21 had covid vaccine (dose 1). On evening of 12/29 had sudden onset of mild neck pain and significant weakness and numbness of left arm, weak hand grip, clumsiness in hand . Did not improve after trying to shake arm/move around , and took prednisone 40mg oral. Went to ER and had CT Cspine which did not show evidence of cervical pathology. Continued with corticosteroids, sought consultation with PMR and neurology specialists, and steroid dose increased to 60mg/day. Some improvement in strength , but still have diminished sensation and strength in left hand/arm. Unable to perform full job tasks as I am left hand dominant. Likely brachial neuritis / parsonage turner syndrome per both specialists seen. Continuing with corticosteroids at this time, pending bloodwork and OT evaluation

Resident exhibited no adverse events during 30 minute monitoring following vaccine administration. Resident found without pulse at 1900.

thrombotic stroke -necessitating hospitalization; and craniotomy; required mechanical ventilator for 2 days. Patient now extubated, breathing on her own. Patient remains hospitalized with marked deficits (aphasic)

Pt experienced nausea, shortness of breath, chest tightness and anxiety and then lost consciousness. Vitals were obtained several times during the medical intervention. Respirations were within normal

limits throughout, BP was 135/89 initially, then rose to 210/110, then declined to 180s/? prior to EMS assuming care. Heart rate was 47 initially, then rose to normal limits. Treated with epinephrine, Benadryl and ammonia smelling salts and transported by ambulance to hospital.

Lightheadedness, throat tightness. Increasing chest tightness. History of atrial fibrillation and bilateral breast implants. Received two doses of epinephrine and one dose of diphenhydramine.

Patient developed a septic knee (history of arthroplasty) need for immediate surgery, hospitalization and months to years of antibiotics in his future now.

Presented to the ED after developing chest tightness, cough, lightheadedness, and throat closing sensation. She received the Moderna COVID-19 vaccine on the morning of presentation. Within 15 minutes of receiving the vaccine she developed pain and numbness, starting at the injection site traveling down the ulnar aspect of her arm, and nausea. Over the next several hours she continued to develop worsening nausea, chest tightness, cough, lightheadedness, and the sensation that her throat closing. She took PO Benadryl 25mg; however, her symptoms were not alleviated. She was subsequently evaluated in the ED. á Received PO Benadryl 25mg, IV Benadryl 25mg, Epinephrine 0.3mg x 2, IV Famotidine 20mg, IV Solumedrol 125mg & 60mg, DuoNebs x 3, Racepinephrine x 1.

Decompensation and temp 103.6.

Around 10 or 11 pm, arm pain, chills, fatigue, headache, nausea, swollen lymph nodes, lightheadedness, fainted in tub. Next day, fatigue all day, couldn't talk, or eat. Went back to bed again. The following day hot flashes, weakness. went to ER. Felt like blood pressure was dropping, tingling in legs, difficulty lifting her head.

20 minutes after receiving the vaccination the resident started to not feel well. She said she felt very far away and just kept repeating I don't feel well. She was diaphoretic and her chest was very red and she kept scratching and rubbing it at it. I asked if she wanted IM Benadryl or epipen and she at first denied. She also said she felt like she needed to focus on her breathing. At this time we decided it was best to administer Epipen x 1 dose. Immediately after she felt better. She was observed for another 30 minutes and then went home. at 7:17pm I called and spoke with her. She said her arm was sore and that her oxygen levels were about 88-89% which is low for her but she said she felt fine and is currently working right now.

Presented to the ED with cc of left sided facial and LUE numbness and weakness x 1 days. Patient received her COVID-19 vaccination on 12/30/2020 around 1PM. Immediately after the injection in her left shoulder, she began to feel warmth and numbness in her left shoulder, arm, neck, face, and chest. She reports later experiencing nausea, palpitations, and left arm weakness. Her symptoms persisted, and her family noted a left sided facial droop which prompted her ED visit. á In the ED, patient was noted to have some left sided facial droop and left arm and leg weakness. CT head and CTA showed no acute abnormalities. Tele-neurology was consulted who recommended admission to rule out acute stroke. Ultimately, work up was negative and symptoms resolved. Symptoms appear to be related to the vaccine.

Severe joint aches, fever-type symptoms, nausea

Cough began approx 5 min post vaccine, then pt experienced flushing of neck, chest tightness and SOB. Placed on O2 mask at 8L/min, given 1 dose of Epi and transferred to ED

On 12/24 at around 10 PM, circulation to my 4th left digit significantly decreased after being outside of my car for around 15 minutes during a temperature of about 50 degrees. I realized when sharp pain was felt at the digit. After about 5 minutes the digit felt numb. I got in my car, turned on the heater, and massaged my finger. Sharp pain was felt again as circulation returned to the digit. The event last approximately 10 minutes from the moment I realized the finger was pale until color returned. This occurred again on 12/27 at around 2 PM as I walked from my car into a store at a temperature of about 40 degrees. This time, discoloration occurred bilaterally on my left 3rd, 4th, and 5th digits and my right 2nd, 3rd, 4th, and 5th digits. The event lasted more than 15 minutes with constant massaging. This has occurred two more times since then, both times occurring bilaterally with minimal exposure to cold.

Fever to 103.4F for approximately 4 hours. Myalgias.

within 20 of the injection I strted to salivate and feeling nauseated. returned to clinic and was monitor there. my blood pressure was noted to be low at 115/41. HR 74. reepat BP was 121/48 which is much lower than my usal BP. i was observed for about 1 hrs. the sx's did not go away but the BP improved a little to 130/64 standing. I went home develop injection site pain, fatigue, headache and the pesistent salivation did not go away. after 1 wk it decreased in frequency but still present today. I can not do my normal activity as this worsen the symptom. and my blood pressure has not normalized. still run in 110's/60's. the headaches and fatigue are becoming a burden.

7 days post injection developed significant hives and edema at injection site

Left antecubital rash and pruritic lasting last 5 days, self treated with hydrocortisone 2.5% cream two times partially relieving the pruritic and redness, but still present at time of report.

At 17:00, the injection site started to itch and was warm to the touch. At 4:00 on 01/04/2021, I experienced extreme vertigo while washing my hands at a sink. I returned to bed to get the vertigo to pass, but then vomited at 4:30. I was extremely tired the remainder of the day, sleeping often and have been flushed all day as well.

after the injection I became lightheaded and my blood rose to 155/94. after a hour both my pressure and lightheadness went away. on 1/1 I felt fatigue at work and the injection site began to hurt. On 1/2 I stood home and was still fatigue and had some tension in my neck area. On 1/3 began to feel better no pain at the injection site, no longer fatique, and no tension on my neck.

"15 minutes after patient received her #1 Pfizer vaccine, she started to feel flushed with some throat irritation. She states she feels "" a bit shaky inside "". Given juice and crackers. BP 143/84. heart rate 89. O2 sat 99%. She was moved into another quieter observation area. She claims she felt better. Given H20 to drink. States she had a bit of chest discomfort but this was nothing new to her. She has been having chest discomfort for the past 1-2 weeks periodically. Upon observing patient for 40 minutes, patient

states, she felt better. BP 115/78, heart rate 80. Patient was then released. She states this is the first time this has happened while taking an IM injection."

One hour post shot, heart beat went up to 120 at rest. Slight dizziness. This passed. Later in the evening compared injection sites with others in the household. Mine is redder, more swollen and seems more tender than others.

Fever, nausea, body aches

Received covid vaccine 1/2 at 2pm. Around 7pm that night, left arm pain and slight itching of whole body. did not think much of it. woke up once in middle of night at 4am with racing heart but went back to sleep. Around 9 am next morning started getting chills, initially mild then severe and developed severe myalgias; could not get out of bed or lift arms or limbs. having chest tightness and shortness of breath. pressing on chest wall hurts, hard to take deep breath. Temps of 99.5 most of morning. started taking tylenol total of 1 gram. 1 hour after tylenol shaking and rigors with sweating. had temp of 101 after tylenol. HR 110 at this time (my baseline is around 60s). O2 sat remained normal. Went to ER for testing for covid in case this was covid--test negative. Felt a little better morning of 1/4--no fever. tried to work 1/2 day; called out sick. lots of brain fog, fatigue mental slowing. still having intermittent chest tightness and sob; feel like i cannot expand my lungs. deep breath makes me cough. had few small red bumps on left antecubital fossa that resolved. i'm a physician, i'm concerned this was a severe reaction and was advised to report this.

About 3 minutes after getting the injection, my heart rate elevated, I was dizzy and felt faint with some chest tightness. I told RN, the nurse who gave me the injection and I was told to lay down on my back and she lifted both of my legs perpendicular to the floor. My hands and feet were tingling. My blood pressure was taken and the first reading was elevated and hear rate was 102. I was given a can of apple juice and I felt better after drinking it. Since the blood pressure cuff was too large for me, I was able to go downstairs to urgent care and get a reading with a smaller cuff. The last BP reading was had lowered and I was able to leave. I did not feel well for a good 45 min. My left arm was very sore for the first 48 hours. It did not go away for at least 5 days.

Injection sight pain and swelling, headache, fatigue, omalaise.

I developed severe hives all over my body hours about 19 hours after the shot. Intense itching woke me up at 4:40am the day after receiving the vaccine. The reaction worsened for the next 3 days and began to settle/decrease at the end of the 3rd day. I also felt somewhat disoriented through the allergic reaction period, and on the day after the vaccine I felt slight pain on my chest. I did not experience shortness of breath or have trouble breathing at any point.

High grade fever with chills almost like rigors 103.8 F Happened after 9 pm Initially started with malaise Fever being monitored throughout the night

Numbness in right cheek of face almost immediately after injection.

tiredness, headache muscle pain, chills, nausea, feeling unwell

paleness, weakness, then a few hours later chills, fever, extreme pain at the injection site, body aches, malaise

Soreness of deltoid resolved 2 days after vaccine. Normal shoulder for 7 days. Day 8 post vaccination onset of itching, swelling and redness of left should, continuing now x2 days. No other systemic symptoms. No pain.

Began experiencing nausea and general stomach pains the morning after receiving the vaccine. After one day of pain and discomfort I woke the following morning (~44hrs after receiving the vaccine) to extreme acute abdominal pain in the lower right abdomen. Went to Urgent Care facility and was diagnosed by CT scan as having acute appendicitis. An emergency appendectomy was scheduled and performed for later that evening. I stayed at the Hospital overnight on 12/24/2020 post operatively on IV antibiotics to recover from the appendectomy. Was discharged from the hospital on 12/25/2020 and have been recovering for about 10 days now with limitted activity.

Fever 101.0

At time of injection and for about 30 minutes after, had light tingling to left arm to fingertips, face flushed and warm. Resolved without intervention. No other side effects except muscle soreness to this arm. (Wouldn't report but a coworker had a similar but more severe reaction and is still having effects 3 wks out)

Patient reported swelling on the injection site, itchiness, warmth and soreness.

12/31, 08:30pm: Immediate pain & welt developed at sight 12/31, 08:45pm: Slight numbness & tingling in left hand, persisted approximately 12 hours 12/31, 09:30pm (the following s/s persisted in varying degrees until 01/02): exhaustion/fatigue, headache, dizziness, nausea, chills 01/02, 08:30am: chills/cold sweat/fever (temp not confirmed, as my home thermometer had died, but I woke up later that night drenched in sweat as though a fever had broken, and since then my body temp has been normal (no cold chills or hot flashes) and other s/s have also decreased significantly) 01/03: minimal s/s - lingering fatigue, mild 01/04: 03:00a: woke up with cough - uncertain if related (seasonal allergies?)

Symptoms were chills, fatigue, body aches, headache, fever, tachycardia that started about 12 hours after receiving the vaccine and lasted for about 3 days.

Age at the time of vaccination was 16. Not identified until after the vaccine was administered.

light headed and nausea for 3 days

"10 minutes after receiving vaccination, patient reported rapid heart rate, fatigue, felt weak, hot, and palpitations. Patient reported tachycardia with heart rate 160-170's. Transient numbness to hands and perioral region. Presented to ED, was monitored with resolution of symptoms. On 1/4/21 patient presented to ED with tachycardia with HR up to 160s, Episode was severe, causing lightheadedness, ""throat squeezing"", with bilat UE paresthesias. Episode lasted 20 minutes. Patient evaluated in ED and discharged with outpatient follow up with cardiology and endocrinologist."

Tight throat.Drank 1 pill benadryl.After few hours the symptoms were gone

less than 24 hours after getting shot #1 i felt as if i was coming down with a cold, very congested, stuffy nose, slight sore throat probably from drainage. injection site pain which is normal, but i just felt under the weather. it cleared up within 48 hours of time of injection.

Cold legs, Fever, bodyache including fingers ache, chills, nausea, body weakness, headache. From Saturday to Tuesday. Tylenol

tested positive for COVID19 via antigen test; tested positive for COVID19 via antigen test; having no sense of taste and smell; having no sense of taste and smell; fever; scratchy throat; This is a spontaneous report from a contactable nurse. A 26-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EJ168J), via an unspecified route of administration on 21Dec2020 at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. After getting vaccinated, patient developed a fever on 22Dec2020. On 23Dec2020, the patient has no taste and smell and tested (used the Sofia test) positive for COVID. The patient was told to quarantine and take off work for 10 days. The patient has felt like she has had a scratchy throat. Patient has not taken her allegra. The outcome of events was unknown.; Sender's Comments: A causal role of BNT162B2 would seem unlikely based on the temporal gap between the vaccination and the event onset.

"patient received the PFIZER-BIONTECH COVID-19 MRNA VACCINE and then tested positive for COVID; patient received the PFIZER-BIONTECH COVID-19 MRNA VACCINE and then tested positive for COVID; This is a spontaneous report from a contactable pharmacist. A 40-year-old female patient received the bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot Number and Expiration Date: Unknown), via an unspecified route of administration on 18Dec2020 at a single dose for COVID-19 immunization. The patient's medical history included high body mass index (BMI) from an unknown date and unknown if ongoing. Concomitant medications were not reported. On 22Dec2020, the patient received the PFIZER-BIONTECH COVID-19 MRNA VACCINE and then tested positive for COVID; and showed symptoms. The events were assessed as medically significant. The clinical course was reported as follows: The 40-year-old female patient, with comorbidities ""like high BMI"", received the Pfizer BioNTech COVID vaccine on 18Dec2020 and she had tested positive for COVID on 22Dec2020 and she was showing symptoms; however, they were not severe. The pharmacist did not describe the symptoms. In response to further probing, the pharmacist stated, ""can I do this tomorrow because I need to call patient and ask her about if they have an opinion regarding the monoclonal antibodies treatment."" The pharmacist wanted to know if there was information on consumers receiving antibodies after receiving the vaccine. The pharmacist stated the patient was eligible for antibody treatment. The patient underwent lab tests and procedures which included SARS-CoV-2 test: positive on 22Dec2020. The clinical outcome of the events was unknown. The batch/lot numbers for the vaccine, BNT162B2, were not provided and will be requested during follow up.; Sender's Comments: The reported tested positive for COVID after immunization with BNT162B2 is considered related to the administration of the suspect, BNT162B2."

tested positive for covid; tested positive for covid; coughing; congestion; could not sleep that night; her temperature is still low/temperature was lower around 96 or 97; fever; This is a spontaneous report from a contactable consumer (patient). A female patient of an unspecified age received first dose of BNT162B2 (Pfizer-BIONTECH Covid-19 Vaccine, lot number: EH9899), via an unspecified route of administration on 15Dec2020 at a single dose, for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient received the Covid-19 shot 8 days ago on 15Dec2020. She tested positive for COVID on 23Dec2020. She worked in the emergency room, clarified she was a certified Nurse Assistant (CNA). She was hesitant about taking the COVID-19 vaccine. She was curious since she has been around the virus 24/7 since the pandemic started since she works in the emergency room. When she took the COVID-19 shot, stated she felt great the next day and could not sleep at night in Dec2020 which is not normal for her. It's nothing like the flu shot. It was strange since she has been around the virus all this time, she felt like she had COVID in Feb2020, but she was not tested then. She does not ever get sick and she was down for two days with a fever in Dec2020. After those two days, she always had a low-grade fever of 98 or 99 which was constant. After she took the COVID vaccine her temperature was normal, her temperature was lower around 96 or 97 in Dec2020. She woke up on 23Dec2020 and she had congestion and her temperature was still low. She went to work, and she was told she looked like she had no sleep. She was coughing 23Dec2020 morning, but she did not have any symptoms as far as temperature. She realized that the COVID 19 shot is only 50% effective. She is asking if she should get the second dose. The outcome of events was unknown.

30 mins after vaccination caller was notified patient tested positive for covid; 30 mins after vaccination caller was notified patient tested positive for covid; This is a spontaneous report from a contactable pharmacist. A patient of unspecified age and gender received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for immunization. The patient's medical history and concomitant medications were not reported. 30 mins after vaccination caller was notified patient tested positive for covid on an unspecified date with outcome of unknown. Information on the lot/batch number has been requested.; Sender's Comments: Based on the information currently available (30 mins after vaccination Covid test found positive), no effect of the suspect vaccine could be reasonably achieved to protect from the targeted infection/disease due to the very short time lag. Instead, the positive COVID represents the pre-existing infection prior to vaccine use. Further information like confirmative COVID 19 Nucleic acid/ PCR test together with any associated symptoms are needed for full medical assessment.

tested positive COVID; tested positive COVID; nasal congestion; loss of smell; This is a spontaneous report from a contactable physician (patient). A 46-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number EK5730, Expiration Date Mar2021), via an unspecified route of administration in her right deltoid on 19Dec2020 at single dose for COVID-19 immunization. Medical history included ongoing Crohn's disease from 2007/ diagnosed at 33 years old. There were no other concomitant drugs. The doctor who received the COVID vaccine stated that she must had been exposed to the virus prior to receiving the vaccine because she became symptomatic 48 hours after getting the vaccine. She noted that on Pfizer website recommended that a person not get the vaccine until 6 weeks after active infection but she of course did not know she had been exposed and when her second dose

was due, she would not be 6 weeks after active infections. The vaccine was received on 19Dec2020 and she tested positive on 22Dec2020. The only symptoms she had experienced after testing positive are nasal congestion and loss of smell and they started on 21Dec2020 in the morning. She had had no worsening of her Crohn's disease. The only testing she had had done was the PCR testing for COVID. No treatments for the symptoms at this point. The outcome of the events tested positive COVID was not recovered, while for other events was unknown.; Sender's Comments: A causal role of BNT162B2 would seem unlikely based on the temporal gap between the vaccination therapy and the event onset.

Tested positive for covid; Tested positive for covid; This is a spontaneous report from a contactable nurse (patient). A 33-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899) intramuscularly at right arm on 18Dec2020 14:30 at single dose for COVID-19 immunization. Medical history included asthma. No allergies to medications, food, or other products. The patient's concomitant medications were not reported. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient developed severe nasal burning sensation the first two days of injection along with severe headache that lasted for 4 days. He lost his sense of taste and smell (23Dec2020) 5 days after vaccine was administered, tested positive for Covid (23Dec2020 16:30) with use of ABBOTT rapid test which was performed at his employment. Pending Covid nasal swab fulgent which was obtained on 23Dec2020 and sent out to reference lab. Patient was just wondering if any of these symptoms and/or testing positive after administration was a rare side effect. The adverse event resulted in doctor or other healthcare professional office/clinic visit. No treatment received for the adverse events. Prior to vaccination, the patient was not diagnosed with COVID-19. The outcome of the events was not recovered.; Sender's Comments: Vaccine BNT162B2 provides protection to COVID-19 after at least 7 days have elapsed from the second dose (21 days post first injection). These conditions are not met in the present report. The reported symptoms are compatible with COVID-19 illness.

positive for Covid with symptoms; positive for Covid with symptoms; positive for streph; positive for influenza; This is a spontaneous report from a contactable physician and nurse. A 68-year-old female patient received bnt162b2, via an unspecified route of administration on 17Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced positive for COVID with symptoms, positive for streph and positive for influenza in Dec2020. Additional Context: caller stated that she had a patient that got Covid vaccine on 17Dec2020 who was complaining of muscle aches, no fever, sudden loss of taste and smell in the last 24 hours, sore throat and a cough. Stated that she cannot attribute the cough to the vaccine. Stated that she was screened for COVID, streph and influenza. Stated that she was positive for covid and streph. Stated that she does not think that and wanted to know if the vaccine would cause a positive from a rapid test. Outcome of the events was unknown. The Lot/Batch and expiry date has been requested.; Sender's Comments: The reported positive for COVID with symptoms after immunization with BNT162B2 is considered related to the suspect, BNT162B2.

Chills, fever and a headache; Chills, fever and a headache; Chills, fever and a headache; tested positive; tested positive; This is a spontaneous report from a contactable nurse. This nurse reported similar events for two patients. This is 1st of two reports. An adult female patient of unspecified age (30-40 yrs

of age) received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 17Dec2020 at single dose for COVID-19 immunization. The relevant medical history and concomitant medications were not reported. The nurse stated that they gave the vaccines to the patient the past week and the patient was COVID-19 positive at the time of the report. The nurse needed some guidance and needed to know if the patient could receive the second dose or what they were supposed to do. The patient tested positive for COVID-19 on 24Dec2020 after having chills, fever and a headache. The outcome of the events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Based on the information currently available, a lack of efficacy with BNT162B2 in this patient might not be completely excluded. The case will be reassessed should additional information become available.,Linked Report(s) : US-PFIZER INC-2020513401 different patient, same drug and event

had another COVID test with positive results on 23Dec; had another COVID test with positive results on 23Dec; This is a spontaneous report from a contactable consumer. A 43-year-old female patient received bnt162b2 (BNT162B2, lot number and expiry date were not reported), via an unspecified route of administration on 18Dec2020 at a single dose for covid-19 vaccination. The vaccination was done in the hospital. The patient's medical history and concomitant medications were not reported. The patient was initially tested negative for covid-19 on 13Dec2020. The patient was not pregnant. The patient believed she may have been infected with COVID as early as 13Dec2020 based on symptoms but test results at that time came back negative. She had vaccine on 18Dec2020 and when symptoms hadn't resolved had another COVID test with positive results on 23Dec2020. The event resulted to a doctor or other healthcare professional office/clinic visit. There was not treatment for the event. The reporter considered the events as non-serious. The outcome of the event was recovering. Information about batch/lot number has been requested.

Received the vaccine and tested positive for Covid today; Received the vaccine and tested positive for Covid today; This is a spontaneous report from a contactable nurse. This nurse is reporting similar events for two patients. This is the first of two reports. A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date were not reported), via an unspecified route of administration on 17Dec2020 at single dose for Covid Vaccine/ COVID-19 immunisation. The patient medical history and concomitant medications were not reported. It was reported that the patient received the vaccine and tested positive for COVID today (24Dec2020). She was having symptoms on Saturday (unspecified date in Dec2020), she received her vaccine on Thursday 17Dec2020. The reporter asked several questions, if do they get the second vaccination in 3 weeks and what will be the process, does it do anything to it, or if does it make it worse or better. The outcome of the event was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Based on the information currently available, a lack of efficacy with BNT162B2 in this patient might not be completely excluded.,Linked Report(s) : US-PFIZER INC-2020513377 same reporter, same drug, similar event, different patient.

Received the vaccine and tested positive for Covid today; Received the vaccine and tested positive for Covid today; This is a spontaneous report from a contactable nurse. This Nurse reported similar events for two different patients. This is second of two reports. A female patient of an unspecified age received

bnt162b2, via an unspecified route of administration on 21Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient received the vaccine and tested positive for covid today (24Dec2020).It was further reported that the patient showed up positive today (24Dec2020) and her symptoms have been on and off, she just got her vaccine 21Dec2020. The outcome of the event was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Preventive effect of BNT162b2 is documented after 7 days from the second dosing. This case does not match this requirement.,Linked Report(s) : US-PFIZER INC-2020513367 same reporter/drug. different patient and event.

Drug ineffective; tested positive; chills; fever; headache; This is a spontaneous report from a contactable nurse. This nurse reported similar events for two patients. This is 2nd of two reports. A female patient of an unspecified age (30-40 year-old)started to receive bnt162b2 (BNT162B2) , via an unspecified route of administration on 02Dec2020 at single dose for covid-19 immunisation . The patient medical history and concomitant medications were not reported. The patient was tested positive to COVID-19 on 24Dec2020 after having chills, fever and a headache. The outcome of the events was unknown. The reporter stated that these were worse than just side effects. The reporter is wondering if the patient can receive the second dose. Information on the lot/batch number has been requested.; Sender's Comments: Preventive effect of BNT162b2 is documented 7 days after the 2 dose. This case does not match this requirement,Linked Report(s) : US-PFIZER INC-2020512742 different patient, same drug and event

tested positive for covid; tested positive for covid; This is a spontaneous report from a Pfizer-sponsored program, Pfizer First Connect. A contactable consumer (patient) reported that a female patient of an unspecified age received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number and expiration date were not reported), via an unspecified route of administration on 23Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient received the COVID vaccine on Wednesday this week (23Dec2020) and she tested positive for COVID yesterday (25Dec2020). She wanted to know if she should take the second dose of the vaccine. Outcome of the events was unknown. Information on the lot/batch number has been requested.

"I received the covid-19 vaccine and then afterwards contracted covid-19; I received the covid-19 vaccine and then afterwards contracted covid-19; This is a spontaneous report from a contactable nurse. A female patient of an unspecified age received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for covid-19 vaccine. The patient medical history and concomitant medications were not reported. The patient stated on an unspecified date, ""I received the covid-19 vaccine and then afterwards contracted covid-19. I was told by my hospital that because of this I needed to defer the second dose for 90 days. Is this best practice? Or should I take the second dose in 3 weeks as scheduled?"". The outcome of the events was unknown. Information on the batch/lot number has been requested.; Sender's Comments: BNT162b2 provides protection against COVID-19 seven days after the second dose is administered. This case does not match this condition"

"tested positive for Covid; tested positive for Covid; No symptoms at present time; This is a spontaneous report from a contactable nurse (patient). A 50-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EV1685) via an unspecified route of administration on 22Dec2020 at single dose for COVID-19 immunization. The patient's medical history included Covid-19 12 weeks before 25Dec2020. The concomitant drug was reported as levothyroxine sodium (SYNTHROID), hydrochlorothiazide and vitamins. The patient got the vaccine (Covid 19 Vaccine) on 22Dec2020 (Tuesday) and then on 25Dec2020 (today) had to be tested at work and was tested positive for Covid. So, she was wondering if that might have something to do with the vaccine or it was not for sure. Patient had already had Covid once and this is the first time she got tested since for 12 weeks. It just happened to be three days after the vaccine. So, the lady she work with told her a study was done and people were shown to test positive like two days after they got the vaccine. So, that's what she wanted to find out. If that could be."" She states the test on 25Dec2020 was a routine follow up Covid-19 test. No symptoms at present time. The outcome of the events was unknown.; Sender's Comments: BNT162b2 provides protection against COVID-19 after 7 days from the second dose. This case does not match this condition."

received the vaccine on Friday and tested positive; received the vaccine on Friday and tested positive; This is a spontaneous report from a Pfizer-sponsored program Pfizer First Connect from a contactable other healthcare professional. A 27-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date not reported), via an unspecified route of administration in Dec2020 (reported as on Friday) at single dose for COVID-19 immunization. The patient medical history was not reported. The patient's concomitant medications were not reported. The patient received the vaccine on Friday and tested positive today 26Dec2020. The outcome of event was unknown. Information about batch/lot number has been requested.; Sender's Comments: Based on the information available, a possible contributory role of the suspect BNT162B2 cannot be excluded for the reported event COVID-19 virus test positive based on the known safety profile.

Moderna COVID-19 Vaccine EUA Injection site redness, swelling, itching, discomfort the size of a fist 7 days after injection.

tested positive for COVID with symptoms such as nasal congestion, sore throat, weakness, and flu-like symptoms; tested positive for COVID with symptoms such as nasal congestion, sore throat, weakness, and flu-like symptoms; This is a spontaneous report from a contactable physician (patient). A 46-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (lot number EJ1685), via an unspecified route of administration on 20Dec2020 at single dose for covid-19 immunization. Vaccine location was left deltoid. The facility type vaccine was hospital. Medical history included polycystic ovarian diseases from an unknown date. Concomitant medication included metformin, omeprazole, apremilast (OTEZLA). Patient stated she got the vaccine on the 18th. She took the vaccine on 20Dec2020. Yesterday (25Dec2020) she started to feeling sick and today (26Dec2020) patient got tested and she have Covid. She reported to have tested positive for COVID today (26Dec2020) with symptoms such as nasal congestion, sore throat, weakness, and flu-like symptoms yesterday at around 4:00pm. This was the first time she has taken the Covid test. The physician stated she didn't know the causality between the event and vaccine. The action taken in response to the events for BNT162B2 was not

applicable. The outcome of events was unknown.; Sender's Comments: Based on the information available, a possible contributory role of the suspect BNT162B2 cannot be excluded for the reported event positive test for COVID based on the known safety profile. However the short duration of 5 days since the vaccine first dose is given it is unlikely patient would have fully developed immunity.

Got vaccinated and contracted COVID the following week; Got vaccinated and contracted COVID the following week; This is a spontaneous report from a contactable consumer (patient). A patient of unspecified age and gender received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number unknown as the reporter did not have any of that information at the moment of reporting), via an unspecified route of administration on 15Dec2020 at single dose for COVID-19 vaccination. The patient's medical history and concomitant medications were not reported. It was reported that the patient got vaccinated on December 15th and contracted COVID the following week (Dec2020). Treatment included regeneron infusion last night (24Dec2020). Patient was wondering if zinc supplements should be taken or how to handle own's immune system because the patient had the first immunization. The outcome of the event was unknown. Information on lot/batch number has been requested.

had a testing, came up positive; had a testing, came up positive/sporadic coughing and a little short of breath. Maybe a little sore throat; This is a spontaneous report from a contactable consumer. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EJ1685), via an unspecified route of administration on 20Dec2020 at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient received Pfizer COVID Vaccine (further clarified) on 20Dec2020. And maybe two days after that, the patient kind of developed a little like very sporadic coughing, it was very mild and a little short of breath. Maybe a little sore throat so that's why the patient was concerned. The patient had a testing in Dec2020, they did swab the patient's throat, it came up positive. The outcome of events was unknown.

Very tired; Cold/head cold; upset stomach; she was not feeling well; it got her all congested and she got the head cold in Dec2020; little whooping cough; I had severe headaches and it was just too uncomfortable; my head was so congested; worst headache; it was just too uncomfortable; This is a spontaneous report from a contactable consumer(patient). A 59-year-old female patient received BNT162B2 via an unspecified route of administration on 22Dec2020 at the 59-year-old at single dose for Covid virus. The medical history included Congested, head cold and Covid virus. There was no concomitant medication. The patient work at a hospital and she went for a Covid shot (clarified as Covid 19 vaccine) on 22Dec2020 and she got a very bad reaction from it which bothered her, she had severe headaches in Dec2020 and it was just too uncomfortable and on 24th she was very tired, she didn't had too much of upset stomach in Dec2020 but it was not all that bad by 9 in the clock by morning she was at work and everything and she was told by if she was not feeling well she can walk by a day, but her question and her concern was back on November okay she had called in sick around, she had a funeral that she gone too and people that were at the funeral, unfortunately were smoking outside and smoke bothers me very much, she get congested and she get head cold from it you know and I was thinking it's nothing it's just a cold and somebody told her no (name) you better go get yourself to the employee health office and get checked out and she didn't bother doing that, she said no it's just the cold she will

be fine but then it just got worse down the road and she said to herself may be she better just to say she did it, so she called in sick on 24th because she had the cold still and she called and she went to employee health office on 25th she still had the headache and she still had the cold, however when she went to the health office they said to her well stay out of work and we will get back in touch with her and she said okay and she will do that so when they got back in touch with her they said they do have the Covid and she said ohhh she said okay so she stayed out of work and she went to work on the 07Dec so she was wondering whole time, so her confusion was this she was told if you already had the virus in her which at that time, she did not know what it was she just thought it was from cigarette smoke because it got her all congested and she got the head cold in Dec2020 and the whole thing that went along with it and the health employee officer know you had the virus and it's just the virus and she go oh great and that's when they told her to stay out of work and she said okay fine then she just have to that, so in the meantime everybody in the work said hi calling me checking up on her and she said it's so nice of you people, she appreciate it but then she went back to work she was still feeling you know much better than she was but she had little whooping cough in Dec2020 but that was not really that bad, so they said you going to get the shot or not, and she said she don't know she kind of debatable, she don't know if she should get it, because she work in the hospital or she should not get, she said she don't know she was kind of up and some people like she get it sometime your health was not that good but on the other hand everybody that is working here in the hospital working with patients because was work right in the ICU, all over the floor you know spreading right there so she said oh alright so she kicked myself and said go get the shot, get it just over with and get it out of here so that is when she took her shot that was on 22nd and on 24th she was very tired all day no she was tired all day but she was kind of dragging most of the day but she had on the 20th no that was fine on the 20th okay for some reason she guess it was after work that week on 19th, she came home and her head was so congested and she had the worst headache and she felt like a wand had hit her over the head, it was horrible and all she could smell was cigarette smoke, like is her neighbor smoking here so she went down the hall because in live in building that used to be hotel but now they turned that into Condominium and she walk up and down the hall and she was like was somebody smoking or why this or why smell this so strong and the all the lights off in a hallway and she don't want to offend anybody but they had to go to work and somebody elsewhere and she am like she can't stand this smell and they gave this shot and she went for this shot, and they told us to come back she think it was a week or something like that to get the second shot, and she am saying if this going to cost her going to feel this way again, she don't want to get the second shot, she told them that and they told her to call this number and talk to them.The only reason she got it because they encouraged to get it. Even though she had the Covid virus, people said if you already have the virus you don't need to get a shot but people were encouraging because that's she thought well she guess she will get it. But she was mad that she got because it made her sick in Dec2020. And because we already got it they want us to go back and get the second shot and what she was m trying to say to you is, without take and hour 3 hour of conversation here she just want to say she don't want to get back and get the second shot and if it is okay by you guys somehow send her a letter or whatever it is, whoever she have to talk to because she don't want to go back and get the second shot just because of getting sick. She took Excedrin because that works for my headache. She didn't understand why you need all this information history with all this when all she want to say was she didn't want to get a second shot. The outcome of events Head

cold and Headache was not recovered, the other events was unknown. Information on the lot/batch number has been requested.

Coworker who received the shot is positive too; Coworker who received the shot is positive too; This is a spontaneous report from a contactable consumer. This consumer reporter similar events for two patients. This is the second of two reports. A patient of unspecified age and gender received bnt162b2 (BNT162B2, lot number and expiry date were not reported), via an unspecified route of administration on an unspecified date at a single dose for covid-19 vaccination. The patient's medical history concomitant medications were not reported. The reporter's coworker who received the shot was positive too. The outcome of the event was unknown. Information about lot/batch number has been requested.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2020513735 same reporter/product, different patient, similar event

Caller stated that she received covid vaccine on Tuesday and was tested positive on Friday.; Caller stated that she received covid vaccine on Tuesday and was tested positive on Friday.; This is a spontaneous report from a contactable nurse reporting for herself. A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE lot number and expiration date not reported), via an unspecified route of administration on Dec2020 at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient stated that she received the vaccine on Tuesday (Dec2020) and was tested positive on Friday (Dec2020). The patient stated she was told that vaccine was contraindicated in people who have COVID-19. The outcome of the events was unknown. Information on the Lot/Batch number has been requested.; Sender's Comments: Based on the information currently available, a lack of efficacy with BNT162B2 in this patient might not be completely excluded.

hypersensitivity reaction to COVID-19 Vaccine; throat pain that progressed to a little bit of tightness; ear pain; wheals develop on her back bilaterally; This is a spontaneous report from a contactable pharmacist. A female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EJ1685 and Expiry date: 31Mar2021, strength: 0.3ml) (NDC number: 59267-1000-2) via Intramuscular on 21Dec2020 12:21PM at 0.3ml single dose for COVID-19 immunization. The patient's medical history and concomitant drug was reported as none. The patient experienced a hypersensitivity reaction to COVID-19 Vaccine late last night on 21Dec2020. Hypersensitivity reaction: Further described as patient developed throat pain that progressed to a little bit of tightness; some ear pain; and had wheals develop on her back bilaterally. She was transported to the emergency room on 21Dec2020 where she received treatment and was under observation. The outcome of events was unknown. Since whether outcome recovered completely, recovered with lasting effects or just improved is unknown. She was not admitted to the hospital; she was sent home from the emergency room after 2.5 hours. Caller reported seriousness criteria as medically significant because event required medical intervention. Causality was very likely. Patient at time of this report is scheduled to receive the second dose of vaccine; they have not determined if she will receive the second scheduled dose or change/stop dose in response to this event. First dose; scheduled to receive a second dose; have not determined if will be continuing with it.; Sender's Comments: Based on the compatible time association, the hypersensitivity reactions are reasonably related to suspect BNT162B2 administration.

positive COVID-19 test with symptoms; positive COVID-19 test with symptoms; This is a spontaneous report from a contactable nurse, who is also the patient. This 31-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration in Dec2020 at single dose for COVID-19 immunisation. Relevant medical history and concomitant medications were not reported. The reporting nurse stated that she received her first dose of the COVID-19 vaccine on Saturday (e.g. Dec2020). She had taken a PCR test on Thursday and received a negative result on Saturday, the same day she received her vaccination. She reported developing a fever on Monday night and testing positive for COVID-19 on Tuesday. At the time of the report, the outcome of the events was unknown. The information about lot/batch number has been requested.; Sender's Comments: Based on the information currently available, a lack of efficacy with the suspect vaccine BNT162B2 in this patient cannot be completely excluded. More information such as laboratory findings on viral nucleic acid /PCR test needed for meaningful medical assessment.

All of a sudden I did not have any taste or smell; All of a sudden I did not have any taste or smell; Tested positive; Tested positive; This is a spontaneous report from a contactable nurse reported for herself. A 29-year-old female patient received bnt162b2 ((PFIZER-BIONTECH COVID-19 VACCINE, batch/lot EH9899), via an unspecified route of administration on 22Dec2020 at single dose for covid-19 immunisation. Medical history included seasonal allergy. Concomitant medication included cetirizine hydrochloride (ZYRTEC [CETIRIZINE HYDROCHLORIDE]). The patient was taking a multivitamin a day. The patient experienced typical symptoms no taste, smell on 22Dec2020, Slight tingling, body aches, chills, all the other symptoms for Covid and now positive for Covid in Dec2020. Outcome of events was unknown.; Sender's Comments: Based on the information available, a possible contributory role of the suspect BNT162B2 cannot be excluded for the reported event positive for Covid based on the known safety profile.

"I am not feeling well; had a Covid PCR done swapped on yesterday and I am Covid positive; had a Covid PCR done swapped on yesterday and I am Covid positive; This is a spontaneous report from a contactable nurse. This nurse reported for herself that the 35-year-old female patient who received bnt162b2 (BNT162B2), via unknown route of administration on 23Dec2020 at single dose for covid-19 immunisation. Medical history was none. Concomitant medications were none. Nurse stated, ""I received the Pfizer Vaccine this Wednesday and right before getting the vaccine, I had a Covid test (captured as per verbatim) on before the vaccine on Tuesday (22Dec2020) was negative. I had a Covid PCR done swapped on yesterday (25Dec2020) and I am Covid positive. So I have the vaccine and I am Covid positive"" Nurse stated ""It's ""140"" ""130"" pounds (further bot clarified)."" The patient was not feeling well. The outcome of the events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Based on the limited available information, the company considers that a causal relationship between the SARS-CoV-2 test positive and vaccination with BNT162B2 cannot be excluded."

positive with Covid; having Covid symptoms; positive with Covid; having Covid symptoms; This is a spontaneous report from a contactable nurse. A 54-year-old female patient (mother) received BNT162B2 (Batch/lot number: EK5730), via an unspecified route of administration on 18Dec2020 at single dose for COVID-19 immunisation. Medical history included asthma. Concomitant medications

were not reported. Patient got the vaccine administered on 18Dec2020 and after that she was diagnosed positive with Covid on 24Dec2020, so now she was having Covid symptoms obviously after the vaccine but like not due to the vaccine. Reporter was just concerned what her next dose supposed to be scheduled for 08Jan2021, was she still supposed to get the second dose or what. No treatment received. Patient was just taking vitamins. Reporter also reported that typically it was not supposed to be but was trying to get the information on enhanced immune response. Outcome of the event was unknown.; Sender's Comments: The reported positive with Covid after COVID-19 immunization is considered ineffective of BNT162B2, and the Company cannot completely exclude the possible causality between the reported event and BNT162B2 administration.

sinus issues; positive COVID-19 test with symptoms; positive COVID-19 test with symptoms; right arm sore; This is a spontaneous report from a Pfizer Sponsored Program. A contactable consumer (patient) reported that a 58-year-old male patient received the first dose of BNT162B2 (lot number: EH9899; Expire Date: 31Mar2021), via an unspecified route of administration, in arm, right upper, on 16Dec2020 11:10 AM at single dose for COVID-19 immunization. The vaccination facility type was hospital. The vaccine was not administered at military facility. Patient's medical history (including any illness at time of vaccination) was none. The patient got ill from all pain medications- from prescription strength pain killers to OTC products such as tylenol, ibuprofen and aspirin. All of them make him sick- experienced hot flashes and nausea. No additional vaccines administered on same date of the Pfizer suspect vaccine. Prior vaccinations (within 4 weeks) was none. The concomitant medication included 2 different blood pressure pills, mentioning Lisinopril, but stated he did not think his blood pressure pills were relevant to what he was experiencing with the COVID-19 Vaccine. A MRI tech (clarified by caller as MRI technologist) at a hospital who received the COVID-19 Vaccine on 16Dec2020 (caller clarified he received the vaccine at 11:10 AM on 16Dec2020). Caller stated on 17Dec2020 he had signs of aches and pains allover, a sore arm (clarified as his right arm), no fever. He also experienced sinus issues and a loss of sense of smell. Clarified his right arm was sore for only a day, his sinus issues started on 20Dec2020, and his loss of the sense of smell gradually started on 22Dec2020. He stated on 23Dec2020 he had a COVID-19 test performed and the test result was positive for the COVID-19 virus. Caller asked since he had the first COVID-19 Vaccine dose, and has now tested positive for the COVID-19 virus, should he get the second COVID-19 Vaccine dose scheduled for 06Jan2021. Patient's Height: 5' 8'' as provided by caller, who stated he has shrunk 1''. No further details provided. Patient's Weight: 169 lbs. as provided by caller, who stated his weight was as of today. Reported he worked an overnight shift, clarifying he was injected with the COVID-19 Vaccine after his overnight shift was finished on the morning of 16Dec2020. He stated he came back to work later in the day on 16Dec2020 to work another overnight shift from 9:00 PM to 7:30AM. He said after he finished is overnight shift on the morning of 17Dec2020, he went home to bed, and woke up around 12:00 PM on 17Dec2020. He said when he woke up, he started to feel aches and pains allover, and after that noticed he was getting chills periodically. Clarified he experienced the aches and pains allover for a couple of days, and then the aches and pains went away. He said he then started to get the feeling a sinus infection was coming on, but he never got a sinus infection. He said the aches, pains, and chills came back. Reported his co-worker received the COVID-19 Vaccine on Saturday, 19Dec2020, clarifying his co-worker did well with the COVID-19 Vaccine. He clarified his employer was concerned that he may have exposed his co-worker to COVID-19 when the

two worked together on the overnight shift of 22Dec2020. He said both he and his coworker kept their PPE on the whole time they worked except when the two ate dinner. He said the two of them sat at a round table about 6 feet apart, and took off their masks to eat. He said his partner agreed that the two of them were right at 6 feet apart when the sat at the table to eat dinner, so their employer deemed his coworker as low risk. Reported on 22Dec2020 he had to go back to work, so he was asked for his temperature at the time, which was 98.8 degrees. He did have a flu shot previously. He was instructed as long as he doesn't have a fever over 100 degrees, he can work. The caller said he went to work on 22Dec2020, and read an email from his employer's wellness office. He said the wellness office email spoke about the COVID-19 Vaccine side effects, and instructed employees to contact the wellness office with any COVID-19 Vaccine side effects experienced. He said he left a voicemail with his employer's wellness office explaining exactly what his COVID-19 Vaccine side effects were. He said he instructed his employer's wellness office call him in the afternoon because he was going to go home, go to bed, and wake up at noon on 23Dec2020. He stated he spoke with his employer's wellness office at around 11:30 AM on 23Dec2020, and the wellness office asked for him to go to the hospital, and have a COVID19 test. Caller stated his employer performed a COVID-19 nasal swab test, and on 24Dec2020, he was told he was COVID-19 positive. He said his employer backed up his quarantine start date to 17Dec2020 (the first day he experienced symptoms), and had him follow a 10-day quarantine until 27Dec2020. He stated today, 28Dec2020, was the first day he has been off quarantine. Reported he was not saying he got COVID-19 from receiving the COVID-19 Vaccine, but should he have the second COVID-19 Vaccine injection. Clarified his symptoms were intermittent, and started coming back around 20Dec2020. Reported he was not experiencing any scratchiness in his throat, and his eyes were not watering. He said he has had no cough, no sneezing, and no trouble breathing. He said in general, it felt like something was coming on, saying it was building up, but not getting out. Clarified he had gone back to work on 23Dec2020 to have his COVID-19 nasal swab test performed, and was told by his employer on 24Dec2020 that the COVID-19 nasal swab test was positive. No AE required a visit to emergency room or physician office. The outcome of the event right arm sore was recovered on 18Dec2020 and the other events was unknown.

patient had COVID two days after vaccination; This is a spontaneous report from a non-contactable consumer. A male patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number/expiration date unknown) via an unspecified route of administration on 26Dec2020 at a single dose for COVID-19 immunization. Medical history and concomitant medications were not reported. The patient had COVID two days after vaccination (28Dec2020). The outcome of the event was unknown. No follow-up attempts are possible, information about lot/batch number cannot be obtained.

four days after getting her first COVID vaccine injection, she had a COVID positive test result (antigen rapid response test); four days after getting her first COVID vaccine injection, she had a COVID positive test result (antigen rapid response test); This is a spontaneous report from a contactable consumer. A 29-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number EK5730/expiration date unknown), dose number 1 via an unspecified route of administration on 23Dec2020 09:00 at a single dose on the left arm for COVID-19 immunization. Medical

history included vaccination of unspecified flu vaccine in Oct2020. No vaccines or new medications were received on the day of the vaccination. The patient stated that on 27Dec2020, four days after getting her first COVID vaccine injection, she had a COVID positive test result (antigen rapid response test). The patient stated that she had been mostly asymptomatic for COVID. The outcome of the events was unknown.

angioedema; swelling of the lips; This is a spontaneous report from a non-contactable nurse (patient). A 45-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on an unspecified date at a single dose as COVID-19 vaccine. Medical history included angioedema 23 years ago. Concomitant medications were not reported. The caller wanted to report AE for the COVID-19 vaccine. AE reported that she took the COVID-19 vaccine and after 23 hours, she developed angioedemia on unspecified date. Additionally, she said that she woke up with swelling of the lips on an unspecified date. Given the AE from the first request, it was inquired if it was recommended to get a second dose. The outcome of the events was unknown. No follow-up attempts are possible. Information about lot/batch number cannot be obtained.; Sender's Comments: A possible causal association between administration of BNT162B2 and the onset of angioedemia with lip swelling cannot be excluded, considering the plausible temporal relationship and the known adverse event profile of the suspect product. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate

she had a rapid test performed which indicated a positive test result; she had a rapid test performed which indicated a positive test result; This is a spontaneous report from a contactable nurse (patient). A female patient of unspecified age received the first dose of BNT162B2, via an unspecified route of administration on 18Dec2020 at a single dose for immunization. The patient's medical history and concomitant medications were not reported. The patient indicated she received the first dose of the vaccine on the 18th and due to a family member testing positive, she had a SARS-CoV-2 rapid test performed in Dec2020 which indicated a positive test result. Her employment was questioning as to whether this is due to her receipt of vaccine. The outcome of the events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: The reported information is limited. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

resident (patient) tested positive for COVID, 10 days after the first dose of COVID vaccine; resident (patient) tested positive for COVID, 10 days after the first dose of COVID vaccine; This is a spontaneous report from a contactable physician via a Pfizer sponsored program Pfizer First Connect. A 29-year-old female patient received their first dose of BNT162B2 (lot number and expiry date not reported), via an unspecified route of administration on 17Dec2020 at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The reporter wanted to know

how long they have to wait for the second dose of the COVID vaccine as her resident (patient) tested positive for COVID on 27Dec2020, 10 days after the first dose of COVID vaccine given to her on the 17Dec2020. The patient underwent lab tests and procedures which included SARS-CoV-2 test: positive on 27Dec2020. The outcome of the events was unknown. Information on the lot/ batch number has been requested.; Sender's Comments: Based on available information, a possible contributory role of subject vaccine cannot be excluded for the reported events of LOE and SARS-CoV-2 test positive, based on temporal relationship. There is very limited information provided in this report. This case will be reassessed upon receipt of follow-up information.

tested positive for COVID-19; was given the first COVID-19 dose. After some time, the employee got symptomatic and was tested positive for COVID-19; This is a spontaneous report from a contactable pharmacist. A patient of unspecified age and gender received the first dose of bnt162b2, via an unspecified route of administration on an unspecified date at a single dose for Covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient who is employed in a hospital tested negative for COVID-19 then was given the first COVID-19 dose. After some time, the patient got symptomatic and was tested positive for COVID-19. The outcome of the events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: The reported information is limited. The case will be reassessed upon receipt of follow up information. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

Angioedema of lips, throat, eyes, hands. Flushing of hands; Angioedema of lips, throat, eyes, hands. Flushing of hands; Dizziness; Fatigue; Legs became heavy; Joint stiffness of hands; This is a spontaneous report from a contactable healthcare professional (patient). A 36-year-old female patient received the first dose of BNT162B2 (Pfizer-BIONTECH Covid-19 Vaccine; Lot number: EJ 1685), intramuscular on the left arm on 23Dec2020 at 06:30 AM in a hospital at a single dose for COVID-19 immunization. Medical history included known allergies of seasonal allergies, cats, and metals; migraines, chronic idiopathic urticaria, and angioedema. The patient was not pregnant and did not have any other vaccine in four weeks. The patient did not have COVID prior to the vaccination and did not test positive to COVID post vaccination (also reported as not been tested for COVID-19 after the vaccination). Concomitant medication included propranolol, cetirizine hydrochloride (ZYRTEC), and sertraline (reported as other medications in two weeks). On 23Dec2020 at 06:45 AM, the patient experienced immediate symptoms of angioedema of lips, throat, eyes, hands; flushing of hands, dizziness, fatigue, legs became heavy, and joint stiffness of hands. She was monitored by colleagues for an hour, prescription for Epi pen refilled, and available angioedema and fatigue persisted for three days. It was reported that the patient was not treated for the adverse events but it was also reported that the AE treatment also included X-ray and antibiotic. Outcome of the events was recovered in Dec2020.; Sender's Comments: A possible causal association between administration of BNT162B2 and the onset of immediate symptoms of angioedema of lips, throat, eyes, hands, flushing of hands, dizziness, fatigue, legs became heavy, and joint stiffness of hands cannot be excluded, considering the plausible temporal relationship and the known adverse event

profile of the suspect product. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate

Angioedema; This is a spontaneous report from a contactable Other Health Professional (patient). A 40-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) lot number: EL1284, intramuscular in the right arm (also reported as right shoulder), first dose on 22Dec2020 00:30 at a single dose for Covid-19 immunization. The patient's relevant medical history included severe reaction to some animal dander and pollen, severe reactions to poison oak, possible drug induced reactions (unspecified) post C-section, mild rash with influenza vaccine this year (2020) (with no other hx of adverse reaction to a vaccine); had allergies to pollen, mold, some animals. The patient previously took influenza vaccine (split virion, inactivated) and experienced rash. The patient had no covid prior vaccination nor was she tested post vaccination. Adverse event reported was angioedema on 24Dec2020 with outcome of recovering. Systems started appearing on 23Dec2020 evening with slight rash and fluid collection under right eye. Developed more rash on 24Dec2020. In the evening to early morning of 25Dec2020, symptoms worsened significantly. Rapid swelling to face occurred. Swelling was concentrated around eyes and cheeks the most. Both right and left side of the face and neck were affected. However, the right side face had a more pronounced reaction. MD ordered oral prednisone and Benadryl as treatment plan. Also, ordered episode-pen for a worst case scenario. Symptoms have been improving under treatment but still persist some. The events were reported as non-serious. The adverse event start date was 24Dec2020 (as reported). The event resulted in doctor or other healthcare professional office/clinic visit.; Sender's Comments: There is a reasonable possibility that the event angioedema was related to BNT162b2 based on known drug safety profile and temporal relationship. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

tested positive for the COVID virus/she was having a symptom, she lost her sense of smell; tested positive for the COVID virus/she was having a symptom, she lost her sense of smell; sinus infection; tested positive for the COVID virus/she was having a symptom, she lost her sense of smell; Her nose being stuffed; tension headache on the back of head; her deltoid was hurting for 24 hours; active infection after getting the first dose; This is a spontaneous report from a contactable pharmacist (patient). A 37-year-old female patient received her first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on the right deltoid on 18Dec2020 at single dose for COVID-19 immunization. Medical history reported as none. There were no concomitant medications. The patient had active infection after getting the first dose, consult if it was still recommended to get the second dose next week or she should be delaying getting the second dose. The patient got the COVID vaccine on the 18Dec2020. Then on the 24Dec2020 she tested positive for the COVID virus. She was due to get the second vaccine on 08Jan2021. She was asking should she still get the 2nd dose of the

vaccine since came up positive. The patient was having a symptom, she lost her sense of smell of 22Dec2020. She lost her sense of smell on the evening on 22Dec2020, it still had not come back at all. She did have sense of taste on the tongue. She thought it was sinus infection, because her head didn't hurt and she was not stuffed anymore. She stated that after the vaccine, she had a tension headache on the back of head, and her deltoid was hurting for 24 hours. Her headache started the same day in the evening, went on till lunch time next day. Her nose being stuffed which she thought was a sinus infection started on Tuesday 22Dec2020, it was more located in the front middle of her forehead. Her nose being stuffed which she thought was a sinus infection started on Tuesday 22Dec2020, it was more located in the front middle of her forehead. She did not have her Card to provide Lot and Expiry, it was at work at the hospital. She was administered the vaccine on the right deltoid, since she didn't want to sleep on it. Prior to vaccine she has had no positive test for Covid. Caller stated that this was super unfortunately coincidental. She had had no antibody test. She had no reactions to vaccines in the past. Test: Respiratory Panel. Result: Negative on unknown date. The outcome of events drug ineffective, COVID-19 and sinus infection was not recovered. The outcome of event tension headache and muscle pain was recovered in Dec2020. The outcome of rest events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Based on available information, a possible contributory role of subject vaccine cannot be excluded for the reported events of LOE, COVID 19 and other events, based on temporal relationship. There is very limited information provided in this report. This case will be reassessed upon receipt of follow-up information.

tested positive; tested positive; Symptoms experiencing include having no taste, smell and slight bodyache; Symptoms experiencing include having no taste, smell and slight bodyache; Symptoms experiencing include having no taste, smell and slight bodyache; This is a spontaneous report from a Pfizer-sponsored program IBCC (Inbound Call Center for HCPs). A contactable other-healthcare professional (patient) reported that a female patient of an unspecified age received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 17Dec2020 at single dose for covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient was tested positive on 24Dec2020, and symptoms experiencing include having no taste, smell and slight body ache in Dec2020. The patient asked if she could get the second dose. The outcome of the events was unknown. Information about the Lot/batch number has been requested.; Sender's Comments: Based on the limited available information, the company considers that a causal relationship between the COVID-19, with symptoms of having no taste, smell and slight body ache, and vaccination with BNT162B2 cannot be excluded.

Positive rapid test and PCR test after 1st vaccination; Positive rapid test and PCR test after 1st vaccination; This is a spontaneous report from a contactable nurse reporting for her/himself. A patient of unspecified age and gender received the 1st dose of bnt162b2 (BNT162B2), via an unspecified route of administration, on 15Dec2020, at single dose, for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient tested positive on 27Dec2020 on a rapid test and on 28Dec2020 on a respiratory panel by PCR. Next dose was scheduled on 05Jan2021. The information on the lot/batch number has been requested.; Sender's Comments: Based on the information available, a possible contributory role of the suspect BNT162B2 cannot be excluded for the

reported event Positive rapid test and PCR test based on the known safety profile. However the short duration of 12 days since the vaccine first dose is given it is unlikely patient would have fully developed immunity.

tested positive for coronavirus; tested positive for coronavirus; This is a spontaneous report from a contactable physician (patient). A female patient of an unspecified age received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 22Dec2020 at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced tested positive for coronavirus on 24Dec2020. The patient worked in a hospital. She got the first dose of Pfizer coronavirus vaccine on Tuesday, 22Dec2020. She tested positive for coronavirus on Thursday 24Dec2020 after exposure to patients and staff. She had mild symptoms. Her 2nd dose was scheduled for 12Jan2021. The patient was inquiry whether she should receive it, or should she take an antibody test first, but it would be less than 3 weeks from the onset of illness. The outcome of event was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Based on the information available, a possible contributory role of the suspect BNT162B2 cannot be excluded for the reported event tested positive for coronavirus based on the known safety profile. However the short duration of 2 days since the vaccine first dose is given it is unlikely patient would have fully developed immunity.

"tested positive for covid; tested positive for covid; This is a spontaneous report from a Pfizer-sponsored program Pfizer First Connect. A contactable Pharmacist reported similar events for 2 patients. This is the first of two reports. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 14Dec2020 at single dose for covid-19 immunization. The patient medical history and concomitant medications were not reported. Caller is a pharmacist asked if there is a contraindication for administering antibody therapy to a person after they have received the first dose of the covid vaccine. He reported that there are 2 patients that received the covid vaccine the week of 14Dec and subsequently tested positive for covid on the 23rd and 24th of December. He was trying to determine the safety of administering antibody therapy for those patients even though they already got the first vaccine dose. He reported this question has some urgency and needed the information within 48 hours. Attempted to warm transfer but caller reported that he does not have any patient specific information or identifiers at this time. Escalating Urgently for additional research. Outcome of event was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Based on the limited available information, the company considers that a causal relationship between the event ""tested positive for COVID"" and vaccination with BNT162B2 cannot be excluded.,Linked Report(s) : US-PFIZER INC-2020516661 same reporter/ drug/ AE, different patient"

meningitis; headache; fever; weakness; rash; This is a spontaneous report from a contactable consumer (patient). A male patient of an unspecified age received bnt162b2 (lot/batch number and expiration date not provided), via an unspecified route of administration, on 16Dec2020, at single dose, for COVID-19 immunization. The patient medical history and concomitant medications were not reported. The patient received the Pfizer-BioNTech COVID-19 Vaccine on 16Dec2020, he experienced headache, fever, weakness and rash; went to the ER and after testing blood work and suspecting of meningitis. They did a spinal tap. Test came out negative for Flu and COVID; was told the rash could be due to a drug reaction

and they attributed side effects to a generic bactrim, so he stopped taking all medications. If he continues to have issues the primary concern is whether he should get the second dose of the COVID-19 vaccine or not. The outcome of the events were unknown. Information on the lot/batch number has been requested.

High fevers (103/104 degree F) with chills for five days followed by low fevers (upto 101) for another six days and still ongoing; High fevers (103/104 degree F) with chills for five days followed by low fevers (upto 101) for another six days and still ongoing; headaches; fatigue; This is a spontaneous report from a contactable physician, the patient. A 49-year-old non-pregnant female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot Number: UNKNOWN), via an unspecified route of administration in the left arm on 18Dec2020 at 15:15 (at 49-years-old) as a single dose for COVID-19 immunization. Medical history included severe iron deficiency, hypothyroidism, osteoporosis, and low baseline IgM antibodies levels (unknown cause). The patient did not have any allergies to medications, food, or other products. Concomitant medications included gabapentin (MANUFACTURER UNKNOWN), iron (MANUFACTURER UNKNOWN), calcium (MANUFACTURER UNKNOWN), and biotin (MANUFACTURER UNKNOWN). The patient did not receive any other vaccines within four weeks prior to the vaccination. On 19Dec2020 at 18:00, the patient experienced high fevers (103/104 degrees Fahrenheit) with chills for five days followed by low fevers (up to 101 degrees Fahrenheit) for another six days, headaches, and fatigue; all reported as non-serious. On 24Dec2020, the patient had a post vaccination nasal swab rapid antigen test and SARS-CoV-2 PCR test with negative results. The patient took paracetamol (TYLENOL) and ibuprofen (ADVIL) for treatment for the events. The clinical outcomes of the fever, chills, headaches, and fatigue were recovering. The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up.; Sender's Comments: Based on the compatible temporal association and the drug's known safety profile, the vaccination with BNT162B2 might play a contributory role in triggering the onset of high fevers with chills. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

"tested positive for Covid; tested positive for Covid; This is a spontaneous report from a contactable other healthcare provider. A 44-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration at single dose on 21Dec2020 for Covid-19 immunisation. The patient medical history and concomitant medications were not reported. The patient said that she received the Pfizer-BioNTech Covid-19 Vaccine last Tuesday, 21Dec2020, then tested positive for Covid on 26Dec2020. She said the symptoms started on 24Dec2020. Now, she wants to know if it is still okay to get the 2nd dose of the vaccine on the scheduled date. The outcome of events was unknown. Information about Lot/Batch number has been requested.; Sender's Comments: Based on the limited available information, the company considers that a causal relationship between the event ""tested positive for COVID"" and vaccination with BNT162B2 cannot be excluded."

difficulty thinking; brain fog; Injection site pain and swelling; Injection site pain and swelling; axillary lymph node swelling; wrist pain and swelling/joint pain; wrist pain and swelling; muscle and joint pain;

skin pain; kidney and liver pain; kidney and liver pain; dizziness; nausea; weakness; fatigue; chilling; This is a spontaneous report from a contactable nurse (patient). A 49-year-old female patient (not pregnant) received first dose bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot/batch number and expiry date were not provided), intramuscular in right arm on 22Dec2020 14:30 at single dose for COVID-19 immunisation. Facility where the most recent COVID-19 vaccine was administered was hospital. Medical history included asthma. Prior to vaccination, the patient was not diagnosed with COVID-19. No allergies to medications, food, or other products. Concomitant medication included fluticasone propionate, salmeterol xinafoate (ADVAIR). The patient experienced Injection site pain and swelling, axillary lymph node swelling, wrist pain and swelling, muscle and joint pain, skin pain, kidney and liver pain, dizziness, nausea, weakness, fatigue, chilling, difficulty thinking, brain fog on 23Dec2020 01:15. Symptoms lasting x 6 days. The patient not received any other vaccines within 4 weeks prior to the COVID vaccine. No treatment received for the adverse event. Since the vaccination, the patient has not been tested for COVID-19. The outcome of events was reported as recovering. Information about lot/batch number are requested.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the difficulty thinking, brain fog and other reported events due to temporal relationship. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics including head CT/MRI and chemistry panel, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Got first vaccine dose on the 18th and came out Covid test positive; Got first vaccine dose on the 18th and came out Covid test positive; This is a spontaneous report from a non-contactable consumer (patient). A female patient of an unspecified age received first dose of BNT162B2 (Pfizer-BioNTech COVID-19 mRNA vaccine; lot/batch number and expiry date were unknown) via an unspecified route of administration on 18Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient got the first dose on the 18th, and she came out Covid test positive yesterday (unspecified date in Dec2020). She wanted to know if she should get the second vaccine or what is the protocol into that. The outcome of the event was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.

Diagnosed with COVID after receiving first dose of COVID-19 Vaccine; Diagnosed with COVID after receiving first dose of COVID-19 Vaccine; This is a spontaneous report from a contactable nurse (patient). A 61-years-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, lot number PAA156051, expiration date unknown), via an unspecified route of administration on 15Dec2020 16:00 at a single dose at the right arm for COVID-19 immunization. The patient has no medical history, no family medical history and no concomitant medications. The patient is a nurse in the Emergency Room. She had a first dose of COVID-19 vaccine on 15Dec2020. She was diagnosed with

COVID after receiving first dose of COVID-19 vaccine on 23Dec2020. Due for second dose of COVID-19 vaccine on 04Jan2021. She wanted to know if she should go through with second dose if her symptoms subside. The COVID swab was done in the Emergency Room and was not admitted to hospital. The outcome of the event was unknown.; Sender's Comments: Based on the information currently available, a lack of efficacy with BNT162B2 in this patient cannot be completely excluded.

tested positive for covid; tested positive for covid; This is a spontaneous report from a Pfizer-sponsored program Pfizer First Connect. A contactable Pharmacist reported similar events for 2 patients. This is a 2nd of two reports. A patient of unspecified age and gender received BNT162B2, via an unspecified route of administration on 14Dec2020 at single dose for covid-19 immunization. The patient medical history was not reported. The patient's concomitant medications were not reported. The reporter was a pharmacist asking if there was a contraindication for administering antibody therapy to a person after they had received the first dose of the covid vaccine. He reported that there was a patient that received the covid vaccine the week of 14Dec and subsequently tested positive for covid on the 23rd and 24th of December. The reporter was trying to determine the safety of administering antibody therapy for the patient even though the patient already got the first vaccine dose. The reporter reported this question had some urgency and needed the information within 48 hours. The patient underwent lab tests and procedures which included covid test: positive on 23Dec2020, positive on 24Dec2020. The outcome of the events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Based on the limited available information, the company considers that a causal relationship between the COVID test positive and vaccination with BNT162B2 cannot be excluded.,Linked Report(s) : US-PFIZER INC-2020516319 same reporter/ drug/ AE, different patient

tested positive; tested positive; This is a spontaneous report from a contactable nurse reported for herself. A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection) via an unspecified route of administration on 22Dec2020 at single dose for Covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient got the COVID vaccine on 22Dec2020 and tested positive (COVID) on 27Dec2020, she didn't expect to be immune. The outcome of the event tested positive was unknown. Follow-up activities are possible, information on the batch number has been requested.; Sender's Comments: Based on the information currently available, a lack of efficacy with BNT162B2 in this patient cannot be completely excluded. Further information like specific SARS-CoV-2 test and any symptom associated with SARS-CoV-2 test positive needed for full medical assessment

Received the first dose of the vaccine; Have now tested positive; Received the first dose of the vaccine; Have now tested positive; This is a spontaneous report from a pharmacist. It was reported that a patient of unspecified age and gender received bnt162b2 (BNT162B2) vaccine , via an unspecified route of administration on an unspecified date at single dose for covid-19 immunisation . The patient medical history and concomitant medications were not reported. The patient received the first dose of the vaccine; and have now tested positive. The patient underwent lab tests and procedures which included sars-cov-2 test: positive No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Sender's Comments: Based on the limited available information, the company

considers that a causal relationship between the reported events and vaccination with BNT162B2 cannot be excluded.

had a positive COVID test; had a positive COVID test; O2 Saturation of 80% / Hypoxia; shortness of breath; He has a CT scan which showed extensive infiltration in the lungs; muscle pain; chills; body aches; low grade fever; cough; This is a spontaneous report from a contactable physician (pulmonary medicine). This physician reported similar events for 2 patients. This is 1st of 2 reports. A 35-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 18Dec2020 at single dose for covid-19 immunization. There were no medical history and concomitant medications. Caller stated that his close friend who was ER physician (front line worker) and within 24 hours after receiving the COVID vaccine, developed COVID or symptoms of COVID. Patient received the COVID vaccine on 18Dec2020 and the same night patient started with a low grade fever, body aches, chills, muscle pain, shortness of breath, cough, O2 saturation of 80% (hypoxia) and was in the intensive care unit now. Patient swore this was related to the vaccine. This patient tested positive for COVID. He had a CT (computerised tomogram) scan which showed extensive infiltration in the lungs in Dec2020. Patient was admitted to the hospital on 24Dec2020 and then was moved to the ICU 2 days later, on 26Dec2020. Caller thought patient had a positive COVID test at another hospital. Caller did know that tested positive at the current hospital on 26Dec2020 which was done to confirm the previous positive test. Caller thought patient had his first positive COVID test either the same day or the next day after receiving the vaccine. Event of O2 Saturation of 80% / hypoxia was reported as hospitalization from 24Dec2020 and life threatening; infiltration in the lungs and shortness of breath caused hospitalization from 24Dec2020, muscle pain, chills and positive COVID test was reported as medically significant; and other events were reported as non-serious. Outcome of O2 saturation of 80% / hypoxia and shortness of breath was not recovered, outcome of cough was recovering; and outcome of other events were unknown. Information about lot/batch number has been requested. ; Sender's Comments: Based on the information currently available, a lack of efficacy with suspected vaccine BNT162B2 in this patient cannot be completely excluded.,Linked Report(s) : US-PFIZER INC-2020519020 same reporter/drug , different patient/AE.

Anaphylactic reaction requiring two doses of Epinephren to control. Still having issues; other vaccine same date product received; This is a spontaneous report from a contactable nurse (patient). A 54-year-old female patient received her first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), intramuscularly on right arm at 12:30 PM on 18Dec2020 at single dose for COVID-19 immunization, and first dose of other Pfizer vaccine same date product (other vaccine same date lot number: elt9899) on right deltoid on 18Dec2020 for unknown indication. Medical history reported as none. Concomitant medication included vitamin C and colecalciferol (VITAMIN D). The patient experienced anaphylactic reaction at 12:30 PM on 18Dec2020 requiring two doses of epinephren to control. still having issues, resulted in: Doctor or other healthcare professional office/clinic visit, Hospitalization in Dec2020. days hospitalization: 1. The patient received treatment: 2 doses of epinephrine, solumedrol, benadryl, IV and O2 for event anaphylactic reaction to vaccine. The outcome of anaphylactic reaction was not recovered. Lot/Batch and Expiration date has been requested.; Sender's Comments: The information available in this report is limited and anecdotal and does not allow a medically meaningful assessment of the case.

There is a plausible temporal association between vaccines administration and onset of the reported event. It is unclear what is the nature of the vaccine co-administered with BNT162b2. Currently no information is available on the co-administration of the Pfizer-BioNTech COVID-19 Vaccine with other vaccines.

patient received the first dose of COVID 19 vaccine on 16Dec2020. She got tested positive on 20Dec2020; patient received the first dose of COVID 19 vaccine on 16Dec2020. She got tested positive on 20Dec2020; This is a spontaneous report from a contactable nurse (patient). A female patient of an unspecified age received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 16Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient received the first dose of COVID 19 vaccine on 16Dec2020. She got tested positive on 20Dec2020. The patient wanted to know if it's safe for her to get the second dose of covid-19 vaccine scheduled for 07Jan2021. Outcome of the event was unknown. Information on the Batch/Lot number has been requested.; Sender's Comments: Based on the information currently available, a lack of efficacy with BNT162B2 in this patient might not be completely excluded.

anaphylactic shock/numb throat; high heart rate; light headed; anaphylactic shock/numb throat; This is a spontaneous report from a contactable consumer (patient himself). A male patient of an unspecified age (reported as 39: unknown unit) received bnt162b2 (BNT162B2 also reported as PFIZER-BIONTECH COVID-19 VACCINE, lot/batch number and expiry date were not reported), via an unspecified route of administration on 22Dec2020 at single dose, for covid-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient experienced anaphylactic shock, numb throat, high heart rate and light headed on an on 22Dec2020. The outcome of events was unknown. Information on the lot/batch number has been requested.

tested positive for COVID-19; tested positive for COVID-19; feeling sick; This is a spontaneous report from a consumer or other non hcp. A male patient of an unspecified age received bnt162b2 (BNT162B2) vaccine, via an unspecified route of administration on 22Dec2020 at single dose for covid-19 immunisation . The patient medical history and concomitant medications were not reported. On 24Dec2020 the patient was sick and was tested positive for covid-19, the outcome of the event was unknown. Information about Lot/Batch number has been requested.

Rhonchi, frothy sputum, low grade temp, elevated HR, 12/30 MD assessed 1:00PM and increased prednisone and added Cefdinir. Sent to hospital 12/30 at approximately 6:30PM with worsening symptoms

Redness and warmth with edema to right side of neck and under chin. Resident was on Hospice services and expired on 1.1.21

12/30/2020 07:02 AM Resident noted to have some redness in face and respiration were fast. Resident vital signs were abnormal except blood pressure. Temp at the time was 102.0 F taken temporal. Resident respirations were 22 labored at times. Pulse is 105 and pulse ox 94% on room air. Resident is made comfortable in bed. Notified triage of change in condition also made triage aware of resident

receiving Covid vaccination yesterday morning. Resident appetite and fluid consumption has been poor for few days. 12/30/2020 07:32 AM Received order from agency to administer Acetaminophen 650mg suppos rectally due to resident not wanting to swallow anything including fluids, medications and food. This writer administered medication as NP ordered. Will monitor for effectiveness and adverse effects if any. 12/30/2020 08:41 AM Received new orders to obtain Flu swab, obtain CBC and BMP, and Chest Xray all to be obtained today. Notified family of resident having temperature and vital signs excluding b/p that was abnormal. Family was thankful for call and inierated to nurse that family does not want resident sent to hospital. Did educate family on benefits of Hospice services, but family persistant on continued daily care provided by nursing staff. Requests visits if decline continues. Family assured if resident continues to decline, facility will accomandate resident family to be able to be at bedside when time comes to do so. NP ordered IVF and IV Levaquin on 12/31/20. Family chose at that time to sign for Hospice services and not have resident provided with IVF or IV Antibiotics

Numbness from Neck to face to head on the left side. Lasted a few days. 12-30-2020 to January 3rd, 2021.

Patient received her Vaccine on 12/16/2020. Afterwards she developed symptoms of fever, chills, diarrhea, nausea, vomiting and headache that became worse over time and on day os presentation to our hospital on 1/2/2021 she was having photophobia. Current headache at time of admission had been persistent for over a week. Patient has no immunocompromising risk factors and was diagnosed with confirmed CMV meningitis. She was also admitted with transaminitis.

"The resident received is vaccine around 11:00 am and tolerated it without any difficulty or immediate adverse effects. He was at therapy from 12:36 pm until 1:22 pm when he stated he was too tired and could not do anymore. The therapist took him back to his room at that time and he got into bed himself but stated his legs felt heavy. At 1:50 pm the CNA answered his call light and found he had taken himself to the bathroom. She stated that when he went to get back into the bed it was ""abnormal"" how he was getting into it so she assisted him. At that time he quit breathing and she called a RN into the room immediately. He was found without a pulse, respirations, or blood pressure at 1:54 pm. He was a DNR."

6-7 hours after the vaccine she developed arm pain, fever and chills. About an hour later she started to have abdominal pain which worsened over the course of the day to excruciating. She went to the Emergency Room where a CT scan revealed a perforation of her sigmoid colon and had a resection of the area of the colon and a diverting colostomy surgery done the evening of 1/3/2021.

starting to feel lethargic and weak. Had menses with increased blessed. Called physician to have blood work done to see if I was experiencing anemia. Blood work complete on 12/31/2020. On 1/3/2021, I woke up with blood blisters all over the inside of my mouth and petechia on my trunk and bilateral upper and lower extremities. I called my primary physician to report the symptoms. He suggested to go to the ER if my symptoms worsened. Later that evening I started with a nose bleed and did go to the ER. Upon arrival to the ER, my platelet count was 9. I was admitted to the hospital and diagnosed with ITP.

12/31/20 around 11am Numbness in right hand and right cheek, 5 minutes later, slurred speech. Episode lasted approximately 10 minutes. Treated in ER. Labs, MRI, all normal 1/3/21 Swollen lymph node to left axilla 1/4/21 Rash to injection site

Tachycardia, resident was sent out to the hospital for evaluation on 12/30/2020 and came back to the facility on 12/31/2020.

Anaphylactic Reaction, facial swelling, facial Redness, Face felt like it was burning, face flushing, throat swelling, heart palpitations, trouble swallowing , feet swelling, light headed, anxiety. Hospitalized from the 12/23/20 to 12/26/2020 . Medications now on Epinephrine, diphenhydramine, cetirizine, famotidine, prednisone, lorazepam, cephalexin. on 1/1/2021 was taken to E.R. by ambulance around 11:00 am left hand was tingle started to go numb traveled up my arm into left side of my face ,ear, tongue, and then down to the left side of my leg and into left foot, could not move left side of body for a good 7 to 8 mins then went away transferred to ambulance enroute to ER blood pressure was high and and started having right ear pain and right side frontal severe headache, arrived to ER and was given diphenhydramine ,ketorolac, metoclopramide HCl, lorazepam. MRI was ordered and Neurologist found two small lesions on right side of frontal brain, following up now with neurologist. added more meds naproxen

2 minutes after vaccine was administered, noticed swelling back of tongue, progressed to posterior 2/3 of tongue, tachycardia, elevated BP. Progressive angioedema involving larynx, cough, shortness of breath. No wheezing. Physical exam did do show any obvious swelling. O2 sat decreased to 80, 1st epinephrine IM administered, 50mg benadryl IV and Famotidine administered. some improvement in symptoms. In 30mins, reoccurrence of angioedema and second epinephrine vaccine administered. Monitored for 2 hours without reoccurrence of symptoms and discharged from ER.

palpitations, chest tightness/heaviness, scratchy throat/frequent throat clearing, head heaviness, blurred vision, elevated blood pressure. Evaluated in ED received solumedrol, benadryl. Discharged home and returned to hospital as direct admit due to continued symptoms. Pertinent labs reveled AKI, elevated LFTs. AKI and LFTs improved with IVFs.

Found deceased in her home, unknown cause, 6 days after vaccine.

Vaccine 12/30/2020 Screening PCR done 12/31/2020 Symptoms 1/1/2021 COVID test result came back positive 1/2/2021 Deceased 1/4/2021

Abdominal pain that proceeded to get worse into the next day. Connected with PCP, had labs drawn and ultrasound ordered. Ended up going to ER. Determined to have Appendicitis, needed and had appendectomy on 12/29/2020.

felt like she had a stroke; fell down; Pain in leg; itchiness in her head; left leg not functioning normally; This is a spontaneous report from a contactable nurse (reporting for herself). A 51-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot number: EH9899), via an unspecified route of administration in the left deltoid on 21Dec2020 at 10:00 (at the age

of 51-years-old) as a single dose for COVID-19 immunization. Medical history was none. There were no concomitant medications. There were no prior vaccinations within 4 weeks prior to the first administration of the suspect vaccine. On 21Dec2020, the patient experienced left leg not functioning normally, which was reported with the seriousness criteria of disability. On 21Dec2020, the patient had itchiness in her head. The patient felt like she had a stroke, fell down and pain in leg on 22Dec2020, which were all reported with the seriousness criteria of disability. The patient called the doctor office and spoke with the doctor on call and was told to use diphenhydramine hydrochloride (BENADRYL). No further details provided. The patient was sent home for 10 days and she was sent back to work. The patient underwent lab tests and procedures which included COVID: negative in Dec2020. The outcome of the events was not recovered. The reported assessed the events related to the suspect product, BNT162B2.; Sender's Comments: The reported events leg dragging, leg pain and fall and suspected stroke were possibly related to the use of first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), due to temporal relationship. However, stroke was not diagnosed. The case will be reassessed should additional information become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Had a rapid test for COVID, and it was positive; Had a rapid test for COVID, and it was positive; This is a spontaneous report from a contactable pharmacist. A male patient of an unspecified age started to receive BNT162B2 (lot number unknown), via an unspecified route of administration from an unspecified date to an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The pharmacist stated that they have vaccinated all their caregivers, and a physician (patient) who got the vaccine, called and reported to her that he had a rapid test for COVID, and it was positive. She is wondering if there was any data from the clinical trials where people tested positive after having the vaccine. The patient is now freaking out because he does not know if he needs to go to the hospital and get treatment for COVID. He works night shift and may have been exposed to COVID, but now she does not know how to guide him. The outcome of the events was unknown. The following information on the batch number has been requested.; Sender's Comments: The reported positive rapid test for COVID after COVID-19 immunization is considered related to the administration of BNT162B2.

"Systemic pruritis (itching) all over body; COVID test type: Nasal Swab and Rapid Antigen and were both positive; COVID test type: Nasal Swab and Rapid Antigen and were both positive; This is a spontaneous report from a contactable nurse (patient). A 26-year-old female patient started to receive BNT162B2 (lot number: EJ1685), intramuscular on 17Dec2020 16:30 at single dose in the left arm for COVID-19 immunization. Medical history included hypothyroidism from an unknown date. The patient was not pregnant at the time of vaccination. Concomitant medication included levothyroxine sodium (SYNTHROID) and spironolactone. The patient previously took cefprozil (CEFZIL) and tapazole and both experienced allergies. The patient experienced systemic pruritis (itching) all over body on 22Dec2020 10:00. The patient was not diagnosed with COVID-19 prior to vaccination and since the vaccination, the

patient has been tested for COVID-19. On 22Dec2020, the patient took COVID test type: Nasal Swab and Rapid Antigen and were both positive. No treatment received for the event ""Systemic pruritis (itching) all over body"". The outcome of the event ""Systemic pruritis (itching) all over body"" was not recovered. The outcome of the other events was unknown.; Sender's Comments: BNT162b2 provides protection against COVID-19 after 7 days from the second dose. This case does not match this codition"

result back w positive covid; positive COVID-19 test with symptoms; This is a spontaneous report from a contactable nurse reporting for herself. A 39-years-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration on 19Dec2020 11:00 (at age 39 years old) as a single dose (Dose 1) in the left arm for COVID-19 vaccination. The patient was not pregnant at the time of vaccination. The patient was not administered any other vaccine in the 4 weeks prior to COVID-19 vaccination. Medical history was none. There were no allergies to medication, food, or other products. The patient's concomitant medications were not reported; however the patient had not received any other medications in the last 2 weeks. The patient experienced a sore throat, voice loss on day 4, loss of smell on day 5, went to test, and the result came back with positive COVID. The events resulted in a Doctor's office visit. The patient was tested post vaccination on 22Dec2020 via NAAT-PCR (nasal swab), with a positive result. The patient had not been diagnosed with COVID-19 prior to vaccination. There was no treatment received for the event(s). The clinical outcome of the event positive COVID was unknown The event was reported as non-serious. The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up.; Sender's Comments: The association between the event drug ineffective (COVID-19 infection) with BNT162b2 can not be fully excluded.

tested positive for covid19/diagnosed with Covid; tested positive for covid19/diagnosed with Covid; she had SOB the day of her first vaccination; I am very sick; I feel bad; This is a spontaneous report from a contactable consumer (patient). A female patient of an unspecified age received 1st dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899), via an unspecified route of administration on 21Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient got the first dose of COVID-19 vaccine on Monday, 21Dec2020 and then was diagnosed with COVID-19 on 23Dec2020. Added that she was very sick and wondering if he'll get her second dose or not. The patient feel bad and is due for her second dose on 11Jan2021. The patient also reported that she had shortness of breath (SOB) the day of her first vaccination on 21Dec2020 and then tested positive for COVID-19 later. She posits she may have received the vaccine when she had an active COVID-19 infection. She is wondering if she can still get her second vaccination. Outcome of the events was unknown.

"tested positive for COVID-19; headache; cough; voice being hoarse; Drug ineffective; This is a spontaneous report from a Pfizer Sponsored Program Pfizer First Connect from a Contactable nurse reporting for herself. A 58-years-old female patient received bnt162b2 (BNT162B2; Lot # EK5730) vaccine , via an unspecified route of administration on 18Dec2020 10:30 at single dose for covid-19 immunisation . Medical history included hypertension from an unknown date and blood cholesterol increased. Concomitant medication included losartan (LOSARTAN), hctz (HCTZ), ezetimibe (ZETIA), famotidine (PEPCID). The patient started having a headache and cough on 25Dec2020 and these

symptoms worsened on 26Dec2020 in addition to her voice being hoarse. On 26Dec2020 she went to get tested at an urgent center and tested positive for Covid-19. The outcome of the event was not recovered.; Sender's Comments: The association between the event ""tested positive for COVID-19, headache, cough, and dysphonia"" with BNT162b2 can not be fully excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate."

It looks like one of the ingredients may have an animal cell lipid; Syncope; Dizziness; feeling faint; like going to pass out now and then; overall achiness, severe headaches, fever; overall achiness, severe headaches, fever; overall achiness, severe headaches, fever; This is a spontaneous report from a contactable nurse reporting for herself. This A 30-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (Lot # EH9899), intramuscular at single dose in the left arm on 22Dec2020 09:00 for covid-19 immunisation. Medical history included reaction to pork, porsine and/or if she ever was exposed to exposed to heparin. There were no concomitant medications. On 23Dec2020, the patient experienced syncope (medically significant), dizziness (medically significant), feeling faint; like going to pass out now and then (medically significant), overall achiness, severe headaches, fever. The outcome of the events syncope, dizziness, feeling faint; like going to pass out now was recovering and outcome of overall achiness, severe headaches, fever was recovered on 24Dec2020. The patient ask: are there any animal products, pork gelatin or a lipid form of that contain in the vaccine? The events were described as follows: She experienced a significant amount of syncope and dizziness, for greater than 4 or 5 days post-receiving the vaccination. Also feeling faint like she is going to pass out every now and then. Has a more important question, wondering along with the doctors if one of the ingredients may have an animal product, like pork gelatin or a lipid form of that. It looks like one of the ingredients may have an animal cell lipid and was wondering if she was having a reaction to that. Declines to provide primary care provider details. States she received this first dose at occupational health in her workplace. Received the vaccine on the 22Dec2020 at 9am. 24 hours post vaccination, 1 day after, the syncope, dizziness, feeling faint started. Also the other symptoms, overall achiness, severe headaches, and fever were also experienced, but they stopped after that 24 hours. Those were expected since it was listed as side effects that popped up, so she expected those and they stopped after 24 hours. The syncope, dizziness, and faint feeling are not any worse and are very slowly improving, but she still has it and had to call out of work today because of it. That's consistent. Mentions it takes her a while to get down the stairs when getting product details for the COVID-19 vaccine. Unable to provide the vaccine NDC or expiry, or dose. Did not have any other vaccines at time of this one and none 4 weeks prior. Had to call a (company withheld) doctor and has to go to occupational health tomorrow to be seen. Declines having COVID virus. No further details provided.; Sender's Comments: Based on the compatible time association, the events syncope and dizziness are possibly related to suspect BNT162B2 administration. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in

response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

positive COVID-19 antigen test with symptoms (ache, cough, fever); positive COVID-19 antigen test with symptoms (ache, cough, fever); This is a spontaneous report from a contactable physician (patient). A 51-year-old male patient received the first dose bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number EH9899), via an unspecified route of administration on 17Dec2020 at 10:30 at single dose in left arm for covid-19 immunization. Medical history included borderline diabetes, ongoing hypertension, ongoing hyperlipidemia, ongoing rhinitis allergic, and currently ill. Concomitant medication included ongoing fexofenadine hydrochloride (ALLEGRA, strength: 180 mg) at 180mg once daily by mouth for Rhinitis allergic taking for years, ongoing lisinopril (strength: 40 mg) at 40 mg once daily by mouth for hypertension taking for two or three years, ongoing atorvastatin (strength: 40 mg) at 40 mg once daily by mouth for hyperlipidemia taking for a year. The patient experienced positive covid-19 antigen test with symptoms (ache, cough, fever) from 19Dec2020. Event details: The patient received the COVID 19 Vaccine on 17Dec2020 10:30AM in the left arm. Tested for COVID 19 with the antigen test, on 20Dec2020 and his result was positive, he experienced ache and cough on 19Dec2020. Clarified he started having symptoms in the evening (19Dec2020) and then tested in the morning (20Dec2020). He experienced the low grade fever on 20Dec2020. His maximum temperature was 100.4 fahrenheit. He had only been treated with over the counter products. No further information provided for the over the counter products. He was not hospitalized. He will take the second dose of the COVID 19 vaccine on 07Jan2021. The patient didn't have SARS-CoV2 antibodies at diagnosis. The patient was not admitted to an Intensive Care Unit. The patient didn't display clinical signs at rest indicative of severe systemic illness. The patient didn't require supplemental oxygen (including high flow or ECMO) or receive mechanical ventilation. The patient didn't have any pre-existing diseases worsened during the SARS-CoV2 infection. The patient was not treated with immunomodulating or immunosuppressing medications or received any other vaccines around the time of COVID-19 vaccination. The outcome of all his symptoms was resolving.; Sender's Comments: The reported events drug ineffective and COVID-19 are likely intercurrent and are unrelated to suspect drug BNT162B2 based on short temporal relation between vaccination and onset of events.

positive COVID-19 rapid test with symptoms; positive COVID-19 rapid test with symptoms; headache; nasal congestion; This is a spontaneous report from a contactable physician. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, on an unspecified date at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced positive COVID-19 rapid test with symptoms, headache and nasal congestion on an unspecified date. The patient developed headache and nasal congestion by the third day after the vaccination. The patient underwent lab tests and procedures which included COVID-19 rapid test: positive on an unspecified date. The clinical outcome of positive COVID-19 rapid test with symptoms, headache and nasal congestion was unknown. The batch/lot number for the vaccine, BNT162B2, was not provided and has been requested during follow up.; Sender's Comments: The reported positive COVID-19 rapid test with symptoms after

COVID-19 immunization is considered ineffective of BNT162B2, and the Company cannot completely exclude the possible causality between the reported event and BNT162B2 administration.

positive COVID-19 test with symptoms; positive COVID-19 test with symptoms; This is a spontaneous report from a contactable nurse (patient). A 37-year-old female patient received their first dose of BNT162B2 (lot number: EL0140; expiry date unknown), intramuscular on 21Dec2020 at single dose for COVID-19 immunization. Medical history included congestion and dry cough (before vaccination), and not tasting anything from an unknown date. Concomitant medication included vitamins. The patient reported that they just have the concern about the vaccination last Monday that was 21Dec2020, on 25Dec2020, Christmas day they were diagnosed with Covid. They were thinking because the day before their vaccination they already had like some kind of congestion and also some kind of dry cough but they didn't really think that it was Covid but they were still able to get the vaccination on Monday. When they started to feel like they were not tasting anything, that's when they decided to get tested and it turns out to be positive. They were confirmed positive on the 25th but in their mind they were probably having Covid since the day before they got they vaccination. So their worry is, is there any effect where they got the vaccine where they already have the Covid in their body. So that is really their worry right now. The patient underwent lab tests and procedures which included SARS-CoV-2 test: positive on 25Dec2020. The outcome of the events was unknown.; Sender's Comments: The association between the event drug ineffective (COVID-19) with BNT162b2 can not be completely excluded.

developed rashes on the chest area, not spreading; This is a spontaneous report from a contactable nurse (patient). A 43-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot number EK5730), via an unspecified route of administration into the left deltoid on 18Dec2020 as the first single dose for covid-19 immunization. Medical history was reported as none. Concomitant medication included rosuvastatin calcium (CRESTOR). The patient developed rashes on the chest area, not spreading on 22Dec2020. The event as reported between not serious and medically significant by the reporter. Details were as follows: and patient was a nurse that had her vaccine through her workplace on 18Dec2020, so she was 10 days out, and noticed a rash on her chest on day 4, which was still present. It did not seem to be spreading, and she could not think of any reason for the reaction. She was scheduled to receive the second dose in three weeks. The outcome of developed rashes on the chest area, not spreading was not recovered. The relatedness of the event to the suspect drug was reported as unknown from the reporter.; Sender's Comments: Based on the information currently provided, the vaccination with BNT162B2 might play a contributory role in triggering the onset of rash. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

blurred vision; little spots on the inside of her eyelids; This is a spontaneous report from a contactable nurse (patient). A 53-year-old female patient received first dose of BNT162B2 (Pfizer-BioNTech COVID-19 mRNA vaccine; batch/lot number and expiry date were unknown), via an unspecified route of administration on 18Dec2020 at a single dose for COVID-19 immunization. Medical history included

eyeglasses wearer (reported as with her glasses). The patient's concomitant medications were not reported. The patient is experiencing symptoms from the COVID-19 vaccine received on 18Dec2020. She began to have blurred vision that night, and it worsened over the following weekend. She saw the eye doctor on 22Dec2020, and they stated her vision had changed even with her glasses. Now she has little spots on the inside of her eyelids that were also noticed on the eye examination in Dec2020. She has already reported these symptoms to the V-safe program. She mentioned that she is not the only nurse in the workplace that has experienced blurry vision. She asked if she should receive the second dose on 08Jan2021. It was still blurry, but it was better than it was a week ago. It still affected her reading and seeing at a distance. It scared her to get the second one because she doesn't want to go blind. She went to the eye doctor for visit on Tuesday. The outcome of the event blurred vision was recovering, while for the other event was unknown. The reporter considered blurred vision as serious due to being medically significant. Information about lot/batch number has been requested.; Sender's Comments: There is not a reasonable possibility that the reported event vision blurred and eyelid disorder related to the suspect product event most likely due to patient underlying contributory factors

positive COVID-19 test; positive COVID-19 test; This is a spontaneous report from a contactable pharmacist. A patient of unspecified age and gender received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, on an unspecified date at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced positive COVID-19 test on an unspecified date. The patient underwent lab tests and procedures which included COVID-19 test: positive on an unspecified date. The clinical outcome of positive COVID-19 test was unknown. The batch/lot number for the vaccine, BNT162B2, was not provided and has been requested during follow up.; Sender's Comments: The reported positive COVID-19 test after COVID-19 immunization is considered ineffective of BNT162B2, and the Company cannot completely exclude the possible causality between the reported event and BNT162B2 administration.

having symptoms/She tested positive to COVID-19; having symptoms/She tested positive to COVID-19; This is a spontaneous report from a contactable nurse (patient). A 30-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 16Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient started having symptoms on Thursday. On Friday, her supervisor had her get tested for COVID. She tested positive to COVID-19 in Dec2020. Outcome of the events was unknown. The patient wanted to know if she is symptom free, should/can she still get the 2nd dose as planned. Information on the lot/batch number has been requested.; Sender's Comments: Based on the information available, a possible contributory role of the suspect products cannot be excluded for the reported event of positive for corona virus infection for the lack of efficacy of the vaccine. However, based on the mechanism of action of the vaccine, it is unlikely the patient would have fully developed immunity for the vaccine to be effective, due to the single dose and short duration

single hive on abdomen (itchy)/full body hives and itching; single hive on abdomen (itchy)/full body hives and itching; This is a spontaneous report from a contactable Physician. A 36-year-old female

patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number EL0140, expiry date unknown) intramuscular at left arm on 24Dec2020 at single dose for Covid-19 immunization in a hospital facility. Medical history included Anxiety, Hypertension, and GERD (gastrooesophageal reflux disease). The patient was not diagnosed with Covid-19 prior to vaccination. Concomitant medications included diphtheria vaccine toxoid, pertussis vaccine acellular, tetanus vaccine toxoid (TDAP) on 08Dec2020 for immunization; bupropion hydrochloride (WELLBUTRIN), amlodipine, omeprazole; from unspecified date for unspecified indication. On 25Dec2020, the patient developed a single hive on abdomen (itchy), and on 26Dec2020 the patient developed full body hives and itching but spared the face and mucosal surfaces. The patient has no swelling, no respiratory symptoms. The patient has not been tested for Covid-19 since the vaccination. The patient received treatment of antihistamines (steroids if no improvement) on unspecified date. The hives responded to antihistamines temporarily. The outcome of the event single hive on abdomen (itchy)/full body hives and itching was not recovered. The reporter considered the events non-serious; did not results in death, was not life threatening, did not caused/prolonged hospitalization, was not disabling/incapacitating, not a congenital anomaly/birth defect.; Sender's Comments: Based on the information available, a possible contributory role of the suspect products cannot be excluded for the reported event hives and itching due to temporal association.

ended up testing positive for COVID virus after receiving the first dose of Pfizer-BioNTech COVID-19 Vaccine/ She had symptoms; ended up testing positive for COVID virus after receiving the first dose of Pfizer-BioNTech COVID-19 Vaccine/ She had symptoms; This is a spontaneous report from a contactable nurse. This nurse reported similar events for two patients. This is 1st of two reports. A female patient of an unspecified age received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899; expiry date unknown), via an unspecified route of administration, on an unspecified date, at 0.3 mL, single for COVID-19 vaccination. The patient's medical history and concomitant medications were not reported. The nurse reported on an unspecified date that the patient tested positive after the first dose. The reporter works in employee health at their hospital. The employee ended up testing positive for COVID virus after receiving the first dose of Pfizer-BioNTech COVID-19 Vaccine. She had symptoms the first 2-3 days after getting the vaccine and assumed it was a normal immune response, but after that she continued to have the symptoms. They went to see the provider and tested positive for COVID virus. They were asking how to handle their second doses. Outcome of the events was unknown.; Sender's Comments: Based on the information available, a possible contributory role of the suspect products cannot be excluded for the reported event of corona virus infection for the lack of efficacy of the vaccine. However, based on the mechanism of action of the vaccine, it is unlikely the patient would have fully developed immunity for the vaccine to be effective, due to the short duration of less than 5 days since the vaccine first dose is given.,Linked Report(s) : US-PFIZER INC-2020516628 same reporter, same drug, same event, different patient.

a patient received Pfizer COVID-19 vaccine, couple of days later the patient tested positive for COVID-19; a patient received Pfizer COVID-19 vaccine, couple of days later the patient tested positive for COVID-19; This is a spontaneous report from a contactable pharmacist. A patient of unspecified age and gender received the first dose of BNT162B2 (Pfizer-Biontech Covid-19 Vaccine) via an unspecified route of

administration on an unspecified date at a single dose as Pfizer COVID-19 vaccine. Medical history and concomitant medications were not reported. It was reported that on an unspecified date, a patient received Pfizer COVID-19 vaccine, couple of days later the patient tested positive for COVID-19, patient subsequently received monoclonal antibody treatment: a combination of Casirivimab and Imdevimab. It was inquired if the patient could receive the second dose of COVID-19 vaccine. The outcome of the events was unknown. Information about Lot/batch number has been requested.; Sender's Comments: Based on available information, a possible contributory role of BNT162B2 vaccine cannot be excluded for the reported events of LOE and COVID 19. There is very limited information provided in this report. This case will be reassessed upon receipt of follow-up information. Based on the information provided in the case, this individual report would not seem to modify the risk-benefit profile of the subject product.

I took the vaccine and two days after I tested positive/had lost my sense of smell and taste; I took the vaccine and two days after I tested positive/had lost my sense of smell and taste; Lost my sense of smell and taste; Lost my sense of smell and taste; This is a spontaneous report from a non-contactable consumer (patient). A patient of unspecified age and gender received BNT162B2 (Pfizer-BioNTech COVID-19 mRNA vaccine; lot/batch number and expiry date were unknown), via an unspecified route of administration on 23Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The consumer stated that he/she just got the vaccine on Wednesday (23Dec2020), and he/she started experiencing some symptoms on 24Dec2020 where he/she had lost his/her sense of smell and taste. On 25Dec2020, he/she went 'health' to get tested, and he/she tested positive. The consumer is asking whether this has been reported that one of the side effects of getting the vaccine. The consumer said he/she hasn't read anything about loss of taste and smell after taking the vaccine. He/she was wondering if this has been reported or this is one of those small side effects that the vaccine has. The consumer further stated that he/she took the vaccine and two days after, he/she tested positive. Now, his/her whole family is also positive but only his/herself had the vaccine, because he/she is the only one that works in healthcare (further clarification was unknown, hence reporter was captured as consumer). The outcome of the events was unknown. No follow-up attempts are possible; Information about lot/batch number could not be obtained. No further information is expected.; Sender's Comments: The association between the event lack of effect (COVID19, lost of taste and smell) with BNT162b2 can not completely excluded.

ended up testing positive for COVID virus after receiving the first dose of Pfizer-BioNTech COVID-19 Vaccine/had symptoms; ended up testing positive for COVID virus after receiving the first dose of Pfizer-BioNTech COVID-19 Vaccine/had symptoms; This is a spontaneous report from a contactable nurse. This nurse reported similar events for two patients. This is the 2nd of two reports. A patient of an unspecified age and gender received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, strength: 0.3 mL, lot number: EH9899; expiry date was unknown), via an unspecified route of administration on an unspecified date at 0.3 mL, single for COVID-19 vaccination. The patient's medical history and concomitant medications were not reported. The patient ended up testing positive for COVID virus after receiving the first dose of Pfizer-BioNTech COVID-19 Vaccine. The patient had symptoms the first 2-3 days after getting the vaccine and assumed it was a normal immune response, but after that the patient continued to have the symptoms. The patient went to see the provider and tested positive for COVID

virus. The patient was asking how to handle his/her second dose. The outcome of the event was unknown.; Sender's Comments: Based on the information currently provided, the company considers that a causal relationship between the COVID-19 and vaccination with BNT162B2 cannot be excluded.,Linked Report(s) : US-PFIZER INC-2020516297 same reporter, same event, different patient.

tested positive after receiving Covid-19 vaccine; tested positive after receiving Covid-19 vaccine; This is a spontaneous report from a contactable nurse. A 38-years-old female patient started received her first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date not reported), via an unspecified route of administration on 18Dec2020 at a single dose for prevention of Covid 19. The patient medical history and concomitant medications were not reported. The nurse reported that a staff member received the first dose of Covid-19 vaccine on 18Dec2020. Approximately 9 days later, on 27Dec2020, the patient developed/experienced tested positive after receiving Covid-19 vaccine. The seriousness criteria for this event was none. The nurse asked if the patient will be able to receive the second dose and what is the advice for the patient. The outcome of the event was unknown. The reporter considered the relationship of the event to treatment with BNT162B2 as not applicable. Information about lot/batch number was requested.; Sender's Comments: Based on the information available, a possible contributory role of the suspect BNT162B2 cannot be excluded for the reported event tested positive Covid-19 based on the known safety profile. However the short duration of 9 days since the vaccine first dose is given it is unlikely patient would have fully developed immunity.

had loss of sense of smell and tested positive for the virus; had loss of sense of smell and tested positive for the virus; This is a spontaneous report from a contactable healthcare professional (patient). A 42-years-old female patient received her first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date not reported), intramuscular on 17Dec2020 at a single dose on the left arm, for Covid-19 immunization. The patient has no medical history and no concomitant medications (no other vaccines in four weeks and no other medications in two weeks prior to vaccination). The patient has no known allergies to medications, food, or other products. The patient had loss of sense of smell, no other symptoms on 25Dec2020 and tested positive for the virus yesterday, on 27Dec2020. The patient has no Covid-19 prior to vaccination. The patient underwent Covid test (Nasal Swab) and result was positive on 27Dec2020. The patient did not receive any treatment for the event. Outcome of the event was unknown. The events were assessed as non-serious by the reporter. No follow-up attempts are possible, information about lot/batch number cannot be obtained.; Sender's Comments: A possible contributory role of BNT162B2 vaccine cannot be excluded for event based on available information.

PATIENT VACCINATED AROUND 9AM. SHE REPORTS SHE FELT WARM/FLUSHING, FAINT AND STOMACH SPASMS WITHIN ABOUT 4-5 MINS. SHE FELT BETTER AND GOT UP TO WALK ABOUT 30 MINS LATER. SYMPTOMS WORSENED AFTER WALKING ~9:45AM: FAINT AGAIN, SEVERE RETCHING, BP196/140 TO 199/164, TROUBLE SWALLOWING, SOB, WHEEZING. AT 9:58AM, EPI PEN 0.3MG ADMINISTERED AND EMS ACTIVATED. SYMPTOMS REPORTED IMPROVED FOLLOWING EPI. EMS ARRIVED 10:05AM. PATIENT REPORTED RECEIVING 2 BAGS OF PEPCID, STEROIDS, AND ZOFRAN AT HOSPITAL. WAS RELEASED BETWEEN 11:30AM-12PM ON 1/4/21, BP 140/90 AND ACUTE SYMPTOMS RESOLVED. FOLLOW UP WITH PATIENT 1/5/21: NO PRIOR HX OF HTN, BP 120/60, NO SOB/ BREATHING DIFFICULTY. C/O SEVERE HEADACHE, LOW TEMP, FATIGUE, MUSCLE ACHES, SORE THROAT.

Droopy left cheek.; This is a spontaneous report from a contactable nurse. A 52-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Lot number: EJ1685), intramuscularly in the left arm, on 17Dec2020 at 14:30 (at the age of 52-years-old) at a single dose for COVID-19 immunization. The patient had no medical history or concomitant medications. The patient had no other medications within two weeks of vaccination. The patient was not pregnant at the time of vaccination. Prior to the vaccination, the patient was not diagnosed with COVID-19. The patient previously took sulfamethoxazole, trimethoprim (SEPTRA) and experienced allergy. The patient did not receive any other vaccines within four weeks prior to the vaccination. The patient experienced droopy left cheek on 21Dec2020. No therapeutic measures were taken as a result of the event. The clinical outcome of droopy left cheek was recovered in Dec2020. It was also reported that since the vaccination, the patient had not been tested for COVID-19.; Sender's Comments: A possible causal association between administration of BNT162B2 and the onset of droopy left cheek might not be excluded considering the plausible temporal relationship. The patient had previous allergy reaction to antibiotic (sulfamethoxazole, trimethoprim) use. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

patient tested positive for COVID; patient tested positive for COVID; This is a spontaneous report from a contactable physician from a Pfizer-sponsored program Pfizer First Connect. A 29-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot Number: UNKNOWN), via an unspecified route of administration on 17Dec2020 as a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. On 27Dec2020, the patient tested positive for COVID. The clinical outcome of patient tested positive for COVID was unknown. The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up.; Sender's Comments: The efficacy of a drug varies from one patient to another and can be affected by different factors; however, a contributory role of the suspect drug BNT162B2 to the reported events Drug ineffective and COVID 19 cannot be ruled out.

"she was administered the first dose of Pfizer COVID-19 Vaccine and later got COVID-19; she was administered the first dose of Pfizer COVID-19 Vaccine and later got COVID-19; This is a spontaneous report from a Pfizer-sponsored program Pfizer First Connect. A contactable female physician (patient) of an unspecified age received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date not reported), via an unspecified route of administration from an unspecified date in 2020 at a single dose for Covid-19 immunization. The patient medical history and concomitant medications were not reported. On an unspecified date in 2020, the patient got the first shot of COVID vaccine and got COVID, she was wondering if she should still get the dose scheduled for 04Jan2021. The patient clarified that she is both a medical doctor/physician as well as the patient. She clarified that she was administered the first dose of Pfizer COVID-19 Vaccine and later got COVID-19. She called to ask if she should still get the second dose of COVID-19 Vaccine which is scheduled for 04Jan2021. She clarified that she does not think anything went wrong with the COVID-19 Vaccine. She does not think her

receiving the COVID-19 Vaccine and developing COVID-19 are related; there was no way she would have had time to develop any protection from the COVID-19 Vaccine at the time she was exposed to COVID-19 2 days later. She does not think she can provide any relevant medical information that would be helpful for this report and declined to continue report. The outcome of the event was unknown. Information on the lot/batch number has been requested.; Sender's Comments: The reported ""developing COVID-19"" after COVID-19 immunization is considered ineffective of BNT162B2, and the Company cannot completely exclude the possible causality between the reported event and BNT162B2 administration."

"She tested positive for COVID-19; She tested positive for COVID-19; This is a spontaneous report from a contactable healthcare professional (patient) via Pfizer sales representative. A 55-years-old female patient received her first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date not reported), via an unspecified route of administration on 22Dec2020 at a single dose for Covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient, who is a frontline medical worker, informed that she tested positive for COVID-19 today (28Dec2020). The patient stated that she was informed by her employee health division at (place) that she was exposed to a patient with COVID-19 prior to her vaccination. She asked to be contacted regarding the timing of her second dose in light of her current status. The outcome of the event was unknown. Information on the lot/batch number has been requested.; Sender's Comments: There is not a reasonable possibility that reported ""tested positive for COVID-19"" is related to BNT162B2 vaccine. The patient exposed to a patient with COVID-19 before vaccination."

Not feeling well; chills; muscle aches; headache; ears bothering; stuffy/runny nose; stuffy/runny nose; This is a spontaneous report from a non-contactable nurse (patient). A 43-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Lot number: EL0140), intramuscularly in the right arm, on 18Dec2020 at 06:00 (at the age of 43-years-old) at a single dose for COVID-19 immunization. Medical history included hypothyroid, breast cancer, and penicillin allergy. The patient was not pregnant at the time of vaccination. Prior to the vaccination, the patient was not diagnosed with COVID-19. Concomitant medications, taken within two weeks of vaccination, included levothyroxine (MANUFACTURER UNKNOWN) and tamoxifen (MANUFACTURER UNKNOWN). Other concomitant medications included unspecified multivitamin. The patient did not receive any other vaccines within four weeks prior to the vaccination. The patient experienced not feeling well, chills, muscle aches, headache, ears bothering, and stuffy/runny nose on 25Dec2020 at 20:00. The events were reported as non-serious. No therapeutic measures were taken as a result of the events. The clinical outcome of not feeling well, chills, muscle aches, headache, ears bothering, and stuffy/runny nose was unknown. It was also reported that since the vaccination, the patient had not been tested for COVID-19. No follow-up attempts are possible. No further information is expected.

tested positive for COVID-19; tested positive for COVID-19; This is a spontaneous report from a contactable nurse (patient). A 39-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 17Dec2020 at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient is a nurse anesthetist that got Covid vaccine on 17Dec2020 and tested positive for

COVID-19 after the vaccine on 26Dec2020. The patient was wondering if have seen this. Stated that she was signed up for the booster scheduled for 05Jan2021 and wanted to know if they had any information about taking this. The outcome of the events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: The efficacy of a drug varies from one patient to another and can be affected by different factors; however, a contributory role of the suspect drug bnt162b2 to the reported events drug ineffective and COVID-19 cannot be ruled out.

nauseous; weak; no appetite; numbness on the skin of my arms and legs; I was post Ictal for 2+ hours; seizures/having 2 non epileptic seizures; dizzy and lightheaded; This is a spontaneous report from a contactable nurse (patient). A 21-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE. Batch/lot number: EK5730), intramuscularly on 28Dec2020 07:45 AM at right arm, at single dose for covid-19 immunization. Medical history was none. There were no concomitant medications. The patient was not pregnant at the time of vaccination. The patient received vaccine around 7:45 AM. Within 2 minutes she felt extremely dizzy and lightheaded on 28Dec2020. She sat down and drank some Gatorade and took deep breaths. The feelings persisted 5 minutes later. She then woke up after having 2 non epileptic seizures while still in 15m waiting period, (This included posturing and color change) a rapid response was called and she was taken to the ER. She was post Ictal for 2+ hours. Dizzy and nauseous, weak and no appetite for the rest of the day. She had no history of epilepsy. She also have numbness on the skin of my arms and legs within 24 hours of the vaccine. Onset date of all events (except dizzy and lightheaded) was reported as 28Dec2020 08:00AM. Treatment fluids, Zofran was received for all events. All event resulted in emergency room. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The outcome of the events was recovered with sequel.; Sender's Comments: A possible contributory effect of suspect BNT162BW on reported seizures cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

"Patient had SVT; flushing; hives; heart rate increased to 160's (had been 180's earlier in the day); This is a spontaneous report from a contactable pharmacist. A 46-year-old female patient received the first dose of BNT162B2 (lot number: EK5730), via intramuscular, on 28Dec2020 at single dose for COVID-19 immunization. Facility where the most recent COVID-19 vaccine was administered was hospital. The patient was not pregnant at the time of vaccination. The patient was not diagnosed with COVID-19 prior to vaccination. Since the vaccination, it's unknown if the patient was tested for COVID-19. No other vaccines were received within 4 weeks prior to the COVID vaccine. The patient's medical history and concomitant medications were not reported. The patient had SVT, flushing, hives 20 min after receiving vaccine on 28Dec2020. Patient was taken to ED and evaluated. SVT resolved. Patient sent home on heart monitor. Later that night while in bed, heart rate increased to 160's (had been 180's earlier in the day) and patient was admitted to hospital. Patient is a NP. Treatment received for the adverse event included cold water to face, vagal massage. The outcome of the event""Patient had SVT"" was

recovered on 28Dec2020 and of other events was recovering.; Sender's Comments: A causal association between BNT162B2 and the reported events supraventricular tachycardia, flushing, hives, heart rate increased cannot be excluded based on the compatible temporal relation. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate."

"Hypertensive crisis; Numbness to my left ear; progressively it went down to my mandible, my face and my left shoulder numbness; Radial blood pressure cough; This is a spontaneous report from a contactable nurse reporting for himself. A 48-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899), via an unspecified route of administration on 28Dec2020 at single dose for covid-19 immunization. Medical history reported as none. There were no concomitant medications. During the administration the patient did experience some types of reaction where it wanted medical supervision. So, basically when he did got the injection he was waiting for his 15 minute prolapse. But within probably he would say 7 to 8 minutes he started to experiencing some numbness to his left ear and usually he thought it was secondary to the that he had (not clarified) but progressively it went down to his mandible, his face and his left shoulder numbness and he was experiencing some numbness that radiate towards his fingertips only to the left side. At that time he waived to the Nurse to supervise and at that time he wait again and a Physician came over. He checked his pulse and noted that he had normal rhythm during the pulse check and at that time and he had Emergency medical technician (EMT) come over. The EMT checked his blood pressure he thought multiple times through the left and to the right brachial. He was having what they would consider a hypertensive crisis where systolic were in 170's, 180's, diastolic numbers were between like 120's and 130's and his heart rate was in 70's. So, initially it was not anxiety induced. But he do not have no blood pressure. They wanted he to go to the hospital to treat the hypertensive crisis that was in. The patient opted not to. So he went home in a quieter environment he did have a radial blood pressure cough that he had been checking his blood pressure rigorously, tried different techniques and now he was back to normal state to 120-130 systolic and his diastolic was 70-80. This instance was weird that he did not see as a part of one of the side effects listed with Pfizer BioNTech Vaccine. No treatment received for the events, because he had no history of hypertension it was just more of decreasing the ambient around he. At that time he wanted to go to a quiet environment, took a shower and check his blood pressure. He did orthostatic while laying down sitting up, standing up and he was not hypertensive. For the causality, the nurse stated, ""I think it did. This is a fact I mean I was doing fine prior to administration and then this event is slowly subsiding."" The outcome of the events was recovering.; Sender's Comments: A possible contributory effect of suspect BNT162B2 on reported hypertensive crisis cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate."

huge welt on her arm; This is a spontaneous report from a contactable nurse (patient). A female patient of an unspecified age received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on an unspecified date at a single dose for covid-19 immunization. Medical history included covid-19 from end of Oct2020 to an unknown date. The patient's concomitant medications were not reported. The patient reported that she is an nurse in the ICU. She had received the 1st dose of the vaccine after she had covid the end of Oct2020. Her reaction to the vaccine was, she felt exactly how she did when she had covid. It lasted 3 days. She had a huge welt on her arm. Her pulmonologist suggested that she contact Pfizer for advice on if or when she should receive the 2nd dose, which is currently due 08Jan2021. Outcome of the event huge welt was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the reported event of giant urticaria due to temporal relationship. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Appendicitis / colic pain to her right midsection; This is a spontaneous report from a contactable Other-HCP (Nurse Practitioner). A female patient of an unspecified age received bnt162b2 (BNT162B2) at single dose on 20Dec2020 for covid-19 immunisation. The patient medical history and concomitant medications were not reported. In Dec2020 3 days after vaccination she experienced colic pain to her right midsection. She was diagnosed with appendicitis. The outcome of events was unknown. Information about lot/batch number has been requested.; Sender's Comments: The event appendicitis is most likely an intercurrent medical condition and is assessed as unrelated to BNT162B2.

Fever; feels weak; tired; lightheaded; pain at the injection site; back and hip pain; back and hip pain; This is a spontaneous report from a contactable other healthcare professional (patient). A 47-year-old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number: EK5730), via an unspecified route of administration on 29Dec2020 at a single dose for COVID-19 immunization. The patient's medical history included sick with coronavirus infection from 11Aug2020. There were no concomitant medications. The patient was experiencing the expected side effects fever, feels weak, tired, lightheaded, pain at the injection site in the right deltoid, hip and back joint pain on Dec2020. She does not know exactly when these events started but that she noticed them when she was trying to sleep last night. Outcome of the events was not recovered. The events were considered serious due to being medically significant.; Sender's Comments: Based on temporal association, the causal relationship between BNT162b2 and the events pyrexia, asthenia, fatigue, dizziness, vaccination site pain, back pain and arthralgia cannot be excluded.

a high fever; extreme fatigue; have allergies; This is spontaneous report from a non-contactable consumer. This consumer reported similar events for eight patients. This is the first of eight reports.

Only this report is serious. A patient of unspecified age and gender received bnt162b2 (BNT162B2 also reported as Pfizer version of the vaccine, lot/batch number and expiry date were not reported), via an unspecified route of administration on unknown date in Dec2020 at single dose, for Covid-19 immunisaton. The patient medical history and concomitant medications were not reported. The patient got the vaccine at a facility then had a high fever and extreme fatigue after getting the vaccine on Dec2020. The patient was admitted to the ICU. The patient had allergies, but it was unknown what the allergies are to. The outcome of events was unknown. No follow-up attempts are possible. Information on batch/Lot number can not be obtained. No further information is expected.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2020520700 same reporter/drug/AE, different patients;US-PFIZER INC-2020520703 same reporter/drug/AE, different patients;US-PFIZER INC-2020520699 same reporter/drug/AE, different patients;US-PFIZER INC-2020520704 same reporter/drug/AE, different patients;US-PFIZER INC-2020520705 same reporter/drug/AE, different patients;US-PFIZER INC-2020520701 same reporter/drug/AE, different patients;US-PFIZER INC-2020520702 same reporter/drug/AE, different patients;US-PFIZER INC-2020520700 same reporter, drug, events, and different patients;US-PFIZER INC-2020520701 same reporter, drug, events, and different patients

extremely lightheaded; This is a spontaneous report from a contactable physician (patient's husband). The physician reported same events for 2 patients. This is 2nd of 2 reports. A 74-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL0140), via an unspecified route of administration on 30Dec2020 at a single dose in deltoid left for Vaccination/COVID-19 vaccine. Medical history included COVID-19 in Jul2020, ongoing overweight. There were no concomitant medications. The patient experienced extremely lightheaded on 30Dec2020. Reporter seriousness for extremely lightheaded is medically significant. The reporter stated his wife (patient) was feeling about the same thing and believed his wife was feeling better. She got up and was walking around and is no longer beside him. No Emergency Room or Physician Office visited. The outcome of event was recovering.; Sender's Comments: Based on temporal association, the causal relationship between BNT162B2 and the event dizziness cannot be excluded. ,Linked Report(s) : US-PFIZER INC-2020520760 same reporter/drug/event, different patient

Pt received COVID Vaccine at 1055, 1120 pt began coughing severely and could not stop, unable to speak. 1120 25mg Benadryl liquid given, Pepcid 20 mg given PO, cough worsening. 1122 second dose of Benadryl given, called for MD. Brought pt to Private room via wheelchair. Upon arrival, audible stridor noted. Epinephrine 0.3 mg IM given at 1126. IV started, placed patient on monitor and O2 via 1L NC. MD at bedside along with RT and pharmacy. 1134 Solumedrol 125 mg IV given, 1 puff of Ventolin given. Lungs clear. 1140 Coughing stopped, pt able to speak now. Vital signs: 1130 SPO2 99% Pulse 142 1135 99% pulse 106 BP 168/102 1140 sats 100% HR 93 BP 157/105 1145 sats 100% HR 97 BP 159/93 1200 sats 99% HR 103 155/97 114

Pt vaccinated on 12/23. PCP notified that SOB and fatigue getting worse on 1/4. Unable to keep pre-op Dental work planned prior to mitral valve surgery on 1/14/2021. PCP referred her to our ED where she was diagnosed with COVID-19 and transferred to facility, which is where her surgery was planned.

Pt received vaccination and left after 15 min. observation symptom free. He drove a short distance away from the clinical site when he felt profuse sweating and had syncope (seconds) crashing into curb. He was aroused from impact and was able to stop car. He then developed profuse nausea and sudden urge to defecate. He went to restroom. Given these events he returned to the clinical site in another vehicle. Upon arrival he denied chest pain, shortness of breath or ongoing nausea or abdominal pain. He reported his AM blood sugar was 72 and does not take insulin. No history of coronary disease or syncope. EMS was activated and assumed care.

The resident who was known to have seizures, and under control for many yeas with Keppra 1000 mg twice a day, on the second day after vaccination developed recurrent seizures requiring hospitalization to an intensive care unit, with intubation and mechanical ventilation until 1/5/21 (to be extubated today). She is still at the hospital.

RECEIVED VACCINE ON 12/22; ON 12/24, STARTED FEELING WEAK AND HAVING GI ISSUES WITH DIARRHEA. ON 12/27, STARTED HAVING SHORTNESS OF BREATH AND WHEEZING MORETHAN HER NORMAL WITH HER ASTHMA ILLNESS AND CAME TO ER. WAS TESTED AND FOUND TO BE COVID POSITIVE.

Resident received Covid Vaccine, noted after 30 mins with labored breathing BP 161/77, HR 116, R 38, T 101.4,

22 year old patient with no known allergies or medical history admitted 12/21 with TTP and currently being worked up. Currently unclear if related or unrelated to COVID vaccination, but received Pfizer vaccine Thursday 12/17.

Contracted Covid after receiving the first vaccine; Contracted Covid after receiving the first vaccine; This is a spontaneous report from a contactable consumer (patient). A 51-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 21Dec2020 at single dose for covid-19 immunisation. Medical history included asthma, dry cough due to inhalation from fires over the years. The patient's concomitant medications were not reported. Contracted Covid after receiving the first vaccine was reported. The patient received the first dose of the Covid vaccine, then contracted Covid. He now had the option to receive antibodies through plasma. Since he had the vaccine, was that still an option? Or was that a no-no? He received the vaccine at work on 21Dec2020. He got sick on 22Dec2020 and he was at home. He didn't feel like eating, and can't lay down because it made it worse to cough. He didn't know what vitamins they were giving him. The patient probably should be in a hospital, but was not. The outcome of events was not recovered. Information on Lot/Batch number has been requested.

patient receive the first dose of the vaccine and has now tested positive for Covid; patient receive the first dose of the vaccine and has now tested positive for Covid; This is a spontaneous report from a Pfizer-sponsored program. A contactable pharmacist reported a patient of unspecified age and gender received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on an unspecified date at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The pharmacist reported that they had a

patient receive the first dose of the vaccine and has now tested positive for Covid. He stated the patient is a week out from receiving the second dose and asks what information Pfizer can provide on receiving the second dose for someone with Covid infection. Outcome of the event was unknown. Information on the Batch/Lot number has been requested.; Sender's Comments: Based on the information currently available, a lack of efficacy with BNT162B2 in this patient might not be completely excluded.

"lost my sense of smell and tested positive for Covid; lost my sense of smell and tested positive for Covid; This is a spontaneous report from a non-contactable consumer (patient) received via a Pfizer-sponsored program. A patient of unspecified age and gender received BNT162B2 via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. Medical history and concomitant medications were not reported. The content of a post was noted that on Dec2020, ""Got mine! And in a stroke of weird ironic awfulness, lost my sense of smell and tested positive for Covid later that day....If only a month sooner! Thank you for creating this vaccine. I know it had nothing to do with my diagnosis!"". The outcome of the events was unknown. No follow-up attempts are possible. Information about lot/batch number cannot be obtained. Sender's Comments: The events drug ineffective and COVID 19 are likely intercurrent and are unrelated to suspect drug BNT162B2 based on the short temporal relation between vaccination and onset of events."

"she is positive that she is positive"" and is having symptoms, although not yet been tested; she is positive that she is positive"" and is having symptoms, although not yet been tested; This is a spontaneous report from a contactable pharmacist (patient). A female patient of an unspecified age received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date not reported), via an unspecified route of administration on Dec2020 at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient reportedly asking if she should keep her appointment for the second dose of the vaccine as scheduled if she thinks she was positive for COVID and having symptoms. The patient had vaccine on Tuesday (Dec2020), and husband tested positive yesterday, ""she was positive that she was positive"" and was having symptoms, although not yet been tested. The 2nd dose was in 2 weeks. The outcome of the events was unknown. Information on the Lot/Batch number has been requested.; Sender's Comments: Based on the information currently provided, the company considers that a causal relationship between the suspected COVID-19 and vaccination with BNT162B2 cannot be excluded."

Tested positive for COVID-19; Tested positive for COVID-19; Sick; He got the chills and later came down with muscle aches and fatigue; He got the chills and later came down with muscle aches and fatigue; He got the chills and later came down with muscle aches and fatigue; His arm was sore for a day; This is a spontaneous report from a Pfizer-sponsored program Corporate (Pfizer) Social Media Platforms. A non-contactable consumer reported for a 45-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 18Dec2020 at single dose for covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced his arm was sore for a day on 18Dec2020 but he suffered no other side effects. Six days later on Christmas Eve (24Dec2020), after working a shift in the COVID-19 unit, the patient became sick. He got the chills and later came down with muscle aches and fatigue. The day after Christmas (26Dec2020), he went to a drive-up hospital testing site and tested positive for COVID-19. The patient

was feeling better since his symptoms peaked on Christmas Day but still felt fatigued. The outcome of event fatigue was not recovered, the outcome of the events sick, chills, muscle aches was recovering, the outcome of other events was unknown. No follow-up attempts are possible. Information about lot/batch number cannot be obtained.; Sender's Comments: The efficacy of a drug varies from one patient to another and can be affected by different factors; however, a contributory role of the suspect drug BNT162B2 to the reported events drug ineffective and COVID-19 cannot be ruled out.

"Severe allergic reaction; BP of 170/104; felt like his whole body was on fire; chest tightness; HR elevated at 110bpm; Severe allergic reaction with symptoms that include/ rash all over his body including his throat, chest, and inner legs.; Right side of neck was swollen and sore; Right side of neck was swollen and sore; his neck was stiff to turn; he feels ""really weak and tired""; he feels ""really weak and tired""; This is a spontaneous report from a contactable other healthcare professional. A 46-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number and expiry date unknown) via an unspecified route of administration, on 29Dec2020, at a single dose, for COVID-19. The patient's medical history and concomitant medications were not reported. Patient is a 46y/o male certified nursing assistant (CNA). He received his first dose of Pfizer-Biontech Covid19 vaccine, yesterday 29Dec2020. On an unspecified date in Dec2020, patient experienced severe allergic reaction with symptoms that include: felt like his whole body was on fire, chest tightness, BP of 170/104, HR elevated at 110 bpm, rash all over his body including his throat, chest, and inner legs. Right side of neck was swollen and sore. Both sides are swollen, today, and his neck was stiff to turn, he feels ""really weak and tired"". Patient was taken by ambulance to the emergency room. Patient then asked if he should get the second dose of the vaccine. Outcome of the events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: A possible causal association between administration of BNT162B2 and the onset of severe allergic reaction with multiple symptoms cannot be excluded, considering the plausible temporal relationship and the known adverse event profile of the suspect product. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate."

potential person infected with Sars-Cov-2 following the administration of the first dose of vaccine and was isolated during the timing of the second dose; potential person infected with Sars-Cov-2 following the administration of the first dose of vaccine and was isolated during the timing of the second dose; This is a spontaneous report from a contactable Pharmacist. A female patient of unspecified age received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The relevant medical history and concomitant medications were not reported. The pharmacist was questioning as to guidelines to the potential person infected with Sars-Cov-2 following the administration of the first dose of vaccine and was isolated during the timing of the second dose. The outcome of the event was unknown. Information on the Batch/Lot number has been requested.; Sender's Comments: The reported potential person infected with Sars-Cov-2 following the administration of the first dose of

vaccine is considered ineffective of BNT162B2, and the Company cannot completely exclude the possible causality between the reported event and BNT162B2 administration.

Migraines for several days, nausea on day three; nausea; This is a spontaneous report from a contactable other healthcare professional, the patient. A 51-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, Lot number: EL0140), via intramuscular route of administration in the left arm on 18Dec2020 at 09:00 (at the age of 51-years-old) as a single dose for COVID-19 vaccination. Medical history included fibromyalgia and history of migraines. The patient did not have any known allergies to medications, food, or other products. The patient was not pregnant at the time of vaccination. Prior to the vaccination, the patient was not diagnosed with COVID-19. The patient's concomitant medications were not reported; however, there were other medications the patient received within 2 weeks of the vaccination. The patient had not received any other vaccine within 4 weeks prior to the vaccine. On 21Dec2020 at 13:00 the patient experienced migraines for several days, nausea on day three. The patient did not receive any treatment for the events. The clinical outcome of the migraines for several days, nausea on day three was recovering. It was also reported that since the vaccination, the patient had not been tested for COVID-19.

Felt sore throat and tachycardia; Felt sore throat and tachycardia; COVID test came back positive; COVID test came back positive; This is a spontaneous report from a contactable physician, the patient. A male patient of an unspecified age received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), via an unspecified route of administration on 18Dec2020, as a single dose for COVID-19 immunization. The patient medical history and concomitant medications were not reported. It was unknown whether the patient received any other vaccine within 4 weeks prior to the vaccine. On 28Dec2020, the patient felt sore throat and tachycardia. The patient also reported that on an unspecified date, in Dec2020, the COVID test came back positive (the Sepheid test, not the rapid test). The events were reported as non-serious. The patient underwent lab tests, which included COVID-19 test: positive on an unspecified date in Dec2020. It was unknown if the patient received treatment for the COVID test came back positive, felt sore throat and tachycardia. The clinical outcome of the events the COVID test came back positive, felt sore throat and tachycardia was unknown. The batch/lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up.; Sender's Comments: Based on available information, a possible contributory role of subject vaccine cannot be excluded for the reported events of LOE, COVID 19, Oropharyngeal pain and tachycardia, based on temporal relationship. There is very limited information provided in this report. This case will be reassessed upon receipt of follow-up information.

positive for covid; positive for covid; positive for covid; This is a spontaneous report from a contactable nurse (patient). A 43-year-old female patient received 1st dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 18Dec2020 at a single dose for COVID-19 immunization. completely excluded. More information such as laboratory findings on nucleic acid /PCR test needed for meaningful medical assessment.The patient's medical history and concomitant medications were not reported. The patient tested positive for COVID on 20Dec2020. Outcome of the events was unknown. Information on the lot/batch number has been requested.; Sender's Comments:

Based on the information currently available, a lack of efficacy with the suspected vaccine BNT162B2 in this patient cannot be completely excluded. More information such as virus genome /nucleic acid detection needed for meaningful medical assessment

Swelling arm/ swelling down to their biceps after receiving the COVID-19 Vaccine; arm soreness/ soreness in their arms after receiving the COVID-19 Vaccine; light redness around the vaccine injection site; body felt cold; felt real tired right after; fell asleep quickly; This is a spontaneous report from a contactable consumer. A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 28Dec2020 13:00 at SINGLE DOSE for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. It was reported the patient got the COVID-19 Vaccine at the same time as her husband did, and she had some symptoms afterwards, but her symptoms went right away. It was reported both she and her husband had soreness in their arms after receiving the COVID-19 Vaccine. She said a micro needle was used when the COVID-19 Vaccine was administered to both her and her husband's left upper arms. It was also reported both her and her husband had swelling down to their biceps after receiving the COVID-19 Vaccine. She said the swelling went away on both of their left arms after 12-14 hours. It was also reported the husband and his wife continuously monitored each others vaccine injection sites. She said the husband used a LED light to look at her left upper arm, and saw a light redness around her vaccine injection site. The husband said the light redness around the vaccine injection site went away in 2 hours after receiving the COVID-19 Vaccine. It was reported her body felt cold after receiving the COVID-19 Vaccine on 28Dec2020, and that she felt real tired right after she noticed her body felt cold. The husband said his wife fell asleep quickly on 28Dec2020, which is not normal for her, and slept for awhile. The husband said after she woke up she was fine. It was reported their arm swelling and soreness didn't really effect either one of them right away. He said the vaccine injection site redness for his wife started about 45minutes to an hour after she received the COVID-19 Vaccine. He said they both started to feel the soreness in their left arms later. He said he could feel the soreness at the vaccine injection site when he moved his left arm. He said it was the same for his wife when she moved her left arm, clarifying it was a very subtle feeling of soreness. The outcome of the events was recovered. Lot/Batch has been requested.

51-year-old female with history of intermittent asthma presented to the ED with 1 week of intermittent fevers, myalgias, arthralgias and headache. Patient reports receiving first dose of moderna vaccine last week. She initially developed arm soreness followed by chills and body aches. Subsequently developed frontal headache, photophobia, back pain, nausea and vomiting. She was seen in the ER on 1/1/21, when her work-up including labs, CT spine, chest x-ray were negative therefore she was discharged home. She continued to have symptoms and also developed bilateral intermittent ear pain. She also developed rash in her extremities and torso. Rash is pruritic but not painful. reports ongoing history of neck pain for which she sees PT. Denies sore throat, cough, chest pain or shortness of breath.

Vaccine given on 12/29/20 by Pharmacy. On 1/1/21, resident became lethargic and sluggish and developed a rash on forearms. He was a Hospice recipient and doctor and Hospice ordered no treatment, just to continue to monitor. When no improvement of codition reported, doctor and Hospice ordered comfort meds (Morphine, Ativan, Levsin). Resident expired on 1/4/2021

DEATH ON 1/4/2021, RESIDENT RECIEVED VACCINE ON 1/2/20

Began experiencing increased temp of 101.4 on 1/4/2021 at 0701. Temp did not resolve with the use of Tylenol. HR increased to >100 and BP was decreasing below baseline. Increased weakness also noted. Temp increased to 102.9 on 1/4/2021 at 2220. Transferred from SNF to ER for evaluation.

Resident had body aches, a low O2 sat and had chills starting on 12/30/20. He had stated that they had slightly improved. On 1/1/21 he sustained a fall with a diagnosis of a displaced hip fracture. On 1/2/21 during the NOC shift his O2 sat dropped again. He later went unresponsive and passed away.

Administered first dose of COVID19 vaccine at 1:29pm on 1/4/21. At approximately 11:00pm resident exhibited acute respiratory decompensation with very limited air entry and hypoxemia. Patient received Benadryl, steroids, epinephrine, and Duoneb without improvement. Resident was referred to the emergency room and found to be COVID positive. No fever or rash were reported.

LTCF Pfizer Vaccine clinic conducted 12/29/2020 Vaccine lead received a call indicating that a staff member deceased somewhere between 1/3/2021 and 1/4/2021. Cause of death is unknown, and an autopsy is being performed.

Vaccine received at about 0900 on 01/04/2021 at her place of work, Medical Center, where she was employed as a housekeeper. About one hour after receiving the vaccine she experienced a hot flash, nausea, and feeling like she was going to pass out after she had bent down. Later at about 1500 hours she appeared tired and lethargic, then a short time later, at about 1600 hours, upon arrival to a friends home she complained of feeling hot and having difficulty breathing. She then collapsed, then when medics arrived, she was still breathing slowly then went into cardiac arrest and was unable to be revived.

tremors resident sent hospital facility.

Started out vague. Started with headache at the base of her head and then it felt like a web that covered her entire head. By 10:00 she did not feel good. Went to sleep instantly. Slept for about an hour. Began to have nausea. Sunday headache got worse. Started ringing , buzzing sound in her head. Took Zofran because of nausea. Sunday night chest discomfort. Monday had horrible chest pain, headache was horrible, then vomiting. went to ER, doctor felt it was a reaction to the vaccine. was give medicine for nausea and Decadron for the reaction. Gave fluids for dehydration. Got medicine for headache. Keep taking Zofran for nausea. Still has headache. Has appointment with pcp in the morning.

"Received COVID-19 Moderna vaccine on 12/28. Developed nausea, vomiting, diarrhea, fever, and hypoxia at facility the day follow vaccine administration (12/29). He was sent to the hospital on 12/29 and admitted for post vaccine fever where he had a chest x-ray that showed infiltrates but WBC count was normal and fever resolved upon admission to hospital. Provider documented ""expected reaction to vaccination in a patient with previous COVID exposure"". He returned to the facility on 12/30."

The resident was found deceased a little less than 12 hours following COVID vaccination, and he had had some changes over the last 2 days. He was 96 and had been on hospice care for a little while. Noone noticed any side effects from vaccine after it was given

Within 10 minutes of receiving the vaccine patient began to look sleepy and started to gasp for breath. She called for help and slouched over in a chair and was moved to lay on the floor. Her feet were elevated and 911 was called. Epinephrine was given, patient responded by being able to gasp for breath and her face returned to a more natural state. Within 5 min she began to struggle to breath and epi was given again. Some improvement did occur. EMS arrived and she was taken to the hospital.

Bell?s palsy

Anaphylactic reaction (swelling and redness of face and torso, shortness of breath, constriction of airway and dizziness)

Pt describes falling with onset of weakness below the hip level about 6 inches above the patella with missing clonus reflex. The pt cannot squat down with associated observable loss of strength, pt is not able to stand up. The pt has fallen 7 times since symptom onset around lunchtime between 1200 and 1300. Pt denies LOC.

After three days, couldn't sleep the whole night. The next day, went to work, came home felt jittery. Close to midnight bp 200/90. Took Clonidine 0.1 and went to ER, bp 180/90. waited for almost two hours bp came down to 141/80. Today, bp is back to normal. Took sleeping medication Zzzquil to go to sleep.

Aseptic meningitis, prolonged fever for more than a week, headache, elevated transaminase (ALT is 124). Lumbar tap showed elevated WBC of 23, 76% polys and 24% mononuclear, 25 RBC. Glucose and protein are normal. CSF PCR viral panel is negative. Patient was initially given Acyclovir and was stopped when HSV and VZV PCR were negative. He was given vancomycin IV for Gram positive bacteremia which was later stopped because it was deemed a contaminant.

Arm weakness increased each day by post vaccine day 4 arm weak and unable to raise arm, conduct ADLs, painful interrupting sleep. Unable to initiate movement in arm. Use other arm to help move arm. Went to ED on post vaccine day 4. Wbc 12. Crp 4. CT no abscess. Mri on 1/4 shows bursitis. DX SIRVA. Bursa aspirated. Pending cultures. PO MEDROL DOSEPAK.

3 Days after the covid vaccine. I Started to have these symptoms around 1am: fever, chills, body aches, cold sweats. I took ibuprofen fell asleep. Around 330am. Woke up with dizziness, headache, chills. Took tylenol. Fell asleep body was extremely cold esp hands and feet. Woke up around 7am. Still had severe body aches and was extremely dizzy, headache worsening. Took ibuprofen. Woke up around noon. Extremely dizzy with chills and body aches headache still severe. Took tylenol. I was not getting better. went to hospital . It was found I had extremely high wbc and had extremely low blood pressure. Diagnosed as septic shock.

Immediate warm rush to my head and body. Heart was beating out of my chest and difficultly breathing. Heart rate spiked to 150 (normal around 55). Hand, legs, and mouth started to go numb. Eventually settled down after about 1 hr. Have not felt normal since which has been 3 days.

Patient presented to receive COVID-19 vaccine, received vaccine at approximately 10 am. Patient waited 15 minutes for observation and left observation area without complaining of any sx. Patient returned a few minutes after reporting tongue tingling which eventually got to her lips. . No difficulty breathing or any other sx. No history of allergies. NP/RN administered PO Benadryl 25 mg. As of report of this iReport no additional symptoms or intervention needed. Last vitals: 131/83 75spo2. BP higher than usual per patient, sp02 normal.

red dotted rash only on my chest. the rash starts at my jaw line and goes behind my ears, around the front on my neck, then my entire chest in between each best down to bra strap line and stops.

Itching, pain, swelling, and redness at injection site; fevers, myalgia, fatigue, malaise.

Painful, swollen lymph node in arm of injection

Left side, neck near collar bone. Swollen bulge in neck (lymph nodes?) severely painful and swollen. No treatment.

Arm pain, extreme fatigue, body/muscle aches, fever, shortness of breath, sensitivity to light, unable to go to work or preform daily activities Onset 5 hours after vaccination

Itchy, red, swollen lump at injection site, 2-3 inches in diameter. Painful, swollen axillary lymph nodes on the same side (right).

I suffered a miscarriage on 12/31/2020. I was at 5 weeks gestation. This was my first pregnancy. I had uterine bleeding and abdominal cramps on 12/31/2020 and underwent evaluation by my Obstetrician and was diagnosed with a miscarriage after ultrasound.

Fever of 101 for the first 48 hrs, ibuprofen, fever went down Pain in the arm for first 24 hrs, ice, ibuprofen, pain went away

Ipsilateral axillary swelling and tenderness beginning 2 days after vaccine with notably increasing swelling and tenderness at 5 days post vaccine. Continuing to monitor at home.

Patient went to get in her car after completing time of wait after vaccination, felt cloudy, compared it to how she feels after having a glass of wine, denied vision changes but states perception of environment felt foggy. EMT assessed patient, HR normal at 71, O2 100%, Bp elevated at 182/100, patient did report anxiety, monitored for another 15-20min until patient felt better, cloudiness improved, Bp improved. Advised to consult with PCP re: Bp.

Significantly sore left shoulder (injection arm) with pain now radiating up into neck & downward around shoulder blade, severe headaches, nausea (no vomiting), sore throat, FATIGUE, chills/cold sweat, general body aches.

Pt states that she developed a rash on her chest along with chest and back pain around 1012pm on 4Jan2021

"19th received Covid Vaccine at noon 21st negative Covid surveillance test completed due to ED Cluster 22nd Bedtime approx. 2100 A very strange feeling of overwhelming fatigue ""spacey feeling""""" 23rd nausea dizzy general malaise 24th nausea dizzy general malaise 25th nausea dizzy general malaise Contacted Health Service 26th still nauseous dizzy general malaise and then chills Health Service Ordered Covid Test 26th negative Covid. 26th video appointment with PCP states no need for labs feels it's Vaccine related 27th minimal nausea no chills episodes of feeling ?spacey? and tired 28th Minimal nausea 29th Morning nausea and fatigue 30th Morning nausea and fatigue 31st increased nausea and fatigue all day easing as day progresses ""spacey"" with fatigue"

Approximately 10 minutes after injection tingling in right hand, red splotchy skin on palm of hands and forearms. Approximately 15-20 minutes after injection. Tingling in feet and lower extremities. Thirty minutes after injection slight itching at injection site. Approximately 1 1/2 hours after injection splotchy red skin inside both thighs and mild generalized itching. At 2:00 pm that day of injection tingling began in face with slight swelling in cheeks. Itching lasted 3 days. Currently intermittent itching since Monday 01/03/2021.

Shortness of breath Dizziness Nausea Soreness in arm of injection

Nausea vomiting chills headache fever

I was instructed to stay for 30min as i have been anaphylatic to cipro in past. at 30min was told i could leave. while driving home on rt 91 my cheekbones became numb. then slowly a few min later my cheeks became numb. a few min later my lips became numb. as i was driving off exit to rt 5 in longmeadow i developed a lump in my throat. i turned around at top of exit and went back to highway to go to ER. this was approx 1645-1650. i went to ER arrived approx 1655. i was shaking. my bp and pulse were elevated. no tingling or swelling in my face. nurse checked my pupils and my smile and were wnl. no history of bells palsy. i received iv fluids, solucortef 125mg ivp, pepcid 20mg ivp, and benedryl 25mg ivp approx 1840pm. approx 45 min after solucortef numbness better but not gone. it started to come back a little more before discharge, which i let md know. she discharged me with scripts for epi-pen, prednisone, and OTC pepcid and benedryl. follow up with my pcp's office in am 12/24 at 10am with his NP. total time with facial numbness/lip numbness 29 hours.

EE starting with migraine about 5 minutes after receiving vaccine. That night had rash to trunk and back with the chills. Took benadryl that night. Next am, had swollen eyes and hands. Within 24 hours,those sx resolved- but then had 48 hours of sx similar to past covid infection.

Severe chills and weakness. Ran 6 miles day of getting vaccinated (21st) unable to even reach the end of the street on the 22nd.

the top of her stomach felt swollen and gassy; Diarrhea/had diarrhea that was like liquid-y water; top of her stomach had a bad burning sensation; Vomiting; she got choked on some saline and sweat ran down

her face, and she had to concentrate on breathing; sore throat with a mild cough, like she needed to be clearing her throat; sore throat with a mild cough, like she needed to be clearing her throat; got a chill; food was not tasting right; arm was sore; could not raise her arm; her weight on 21Dec2020 when she got the vaccine, was 200.6, but her weight today, was 196.0 pounds; This is a spontaneous report from a contactable consumer (patient). A 52-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: unknown) via an unspecified route of administration on 21Dec2020 on left upper arm at a single dose for COVID-19 prevention. Current medical history included a lung disease called asthma and allergies, diagnosed in her late 20's; Diabetes Type 2, diagnosed about 10 years ago and High Blood pressure, diagnosed when she was in her 30's. Caller also wanted to include that she did have COVID before, she had COVID in Jul2020. Current concomitant medications included salbutamol (ALBUTEROL) at 2 Puffs via inhalation, twice daily for asthma; Unspecified Blood Pressure Medication One pill, once daily by mouth in the morning; Unspecified Nasal Spray 1 spray in each nare, once daily via nasal inhalation; montelukast sodium (SINGULAIR) at 1 pill via oral, once a day for allergies; metformin at 1 pill, daily, by mouth for Diabetes Type 2. The patient stated that her place of employment did not give her the card that has the lot number on it, they said they would give it to her with her second injection. The patient did not know the dose received, just that it was the first in the series. The patient had no other vaccines on the same day as the COVID vaccine. The patient reported that her weight on 21Dec2020 when she got the vaccine, was 200.6, but her weight today, was 196.0 pounds. The patient received the vaccine on 21Dec2020, and as soon as she got the shot, her arm was sore like a flu shot. When she got the shot, she could not raise her arm past her shoulder without pain, but now she can raise her arm again. On Thursday, 24Dec2020, patient got a chill, and later that same night, food was not tasting right. On 25Dec2020, the chill continued, and she had a little bit of a sore throat with a mild cough, like she needed to be clearing her throat. On 26Dec2020 morning, the patient experienced vomiting when she woke up, and the top of her stomach had a bad burning sensation, and she had diarrhea. The patient stated that while she was vomiting, she got choked on some saline and sweat ran down her face, and she had to concentrate on breathing. But the patient stated that she vomited, had diarrhea, and the burning sensation, the whole day on Saturday. The patient stated that on 27Dec2020, it calmed down, and she did not vomit at all. The patient stated that she felt like she needed to vomit, but she did not. The patient states that on Sunday, she still had the chills a little, and the top part of her stomach was still burning. The patient took some Pepto-Bismol and that helped calm down the caller's stomach. The patient stated that she could feel the Pepto-Bismol cooling her stomach off, like it had been hot, and patient stated that the top of her stomach felt swollen and gassy. The patient stated that later Sunday night, things calmed down, but she still has the burning sensation and she did not feel like she needed to vomit anymore. This morning, patient reported that she still has some burning sensation, but now, it is coming and going like labor pains. The patient stated that she did go to the bathroom once this morning and had diarrhea that was like liquid-y water. The patient stated that during all this over the last few days, each and every time that she tried to eat, she couldn't eat much because her stomach would burn more with eating. But yesterday, the patient had some fried fish and stated that the fried fish did not burn as much as the rest of the food she tried eating. The outcome of the events vomiting and the top of her stomach felt swollen and gassy was recovered on 27Dec2020, arm was sore and could not raise her arm was recovered on 26Dec2020, chills, top of her stomach had a bad burning sensation was recovering,

Diarrhea/had diarrhea that was like liquid-y water was not recovered and other events was unknown. Information about batch/lot number has been requested.; Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of events Vomiting and Foreign body aspiration cannot be totally excluded. The case will be reassessed if additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

I woke up with tingling in my right hand and arm, my right side, and down my right leg. I went to the ER at Hospital, and was confirmed to have had a stroke in my left thalmus.

Patient woke on 1/3/2021 weak having uncontroled bowels and off and on confusion.

12/22 Vaccination 12/24 sore throat, sniffles, diarrhea, malaise. Contacted PCP; Covid test; negative. Had symptoms to following Tues. Following week, felt better; 1/1/2021

Fever, RespDepression & COVID positive REMDESIVIR (EUA) 200 mg x1 then 100 mg daily

The patient received the vaccine indicated above. Immediately following vaccination the patient states that they began feeling lightheaded and dizzy.

Severe right lower quadrant pain, anorexia over 12 hours. Went to the emergency department. Lab results showed elevated WBC and CT scan showed acute appendicitis. Admitted for urgent surgery: laparoscopic appendectomy. Was hospitalized from 12/26/20-12/28/20.

Rapid heart rate, shakiness, headache, rash, scratchy throat, raspy voice, dizziness, extreme weakness

tested positive for the Covid 19; tested positive for the Covid 19; This is a spontaneous report from a Pfizer-sponsored program Pfizer First Connect from a contactable consumer. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), via an unspecified route of administration on 18Dec2020 as the first single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient tested positive for the COVID 19 on 27Dec2020. The patient underwent lab tests and procedures which included a test for Covid 19 virus, which was positive on 27Dec2020. The outcome of tested positive for the COVID 19 was unknown. The batch/lot number for the vaccine, BNT162B2, was not provided and will be requested during follow-up.; Sender's Comments: The information currently provided is too limited to make a meaningful medical assessment hence, the events are conservatively assessed as related to the suspect drug BNT162B2 until further information becomes available.

"drooping on one side of the face/ eye hurts to open and hurts to close it; Her eyes are droopy; ""my eye is hurting so bad"", it hurts to open and hurts to close it/pain in the eyes; Face is tender to the touch and hurts on that one side; Swelling of her left side of her face that hasn't gone down/swelling and drooping on one side of the face; This is a spontaneous report from a contactable nurse (patient). A 20-

year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot/batch number and expiry date were not provided), via an unspecified route of administration on 23Dec2020 at single dose for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. Caller asking if pain in the eyes and swelling and drooping on one side of the face a side effect of the vaccine. Patient received the Covid vaccine on 23Dec2020 and noticed the next day (24Dec2020) swelling of her left side of her face that hasn't gone down. Her face is tender to the touch and hurts on that one side. Her eyes are droopy, ""my eye is hurting so bad"", it hurts to open and hurts to close it. The outcome of the events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: A possible causal association between administration of BNT162B2 and the onset eye hurts to open and hurts to close/ eyes droopy cannot be excluded, considering the plausible temporal relationship. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate."

received the COVID-19 vaccine on 19Dec2020 and then contracted COVID-19/positive COVID-19 test after receiving COVID-19 vaccine; received the COVID-19 vaccine on 19Dec2020 and then contracted COVID-19/positive COVID-19 test after receiving COVID-19 vaccine; This is a spontaneous report from a Pfizer sponsored program Pfizer First Connect via a contactable consumer. A 22-year-old female patient receive bnt162b2 (BNT162B2, also reported as PFIZER-BIONTECH COVID-19 VACCINE, lot/batch number and expiry date were not reported), via an unspecified route of administration in left arm/deltoid on 19Dec2020 at 0.3 mL, single for Covid-19 immunisation (as protection). Medical history included ulcerative colitis. The patient's concomitant medications were not reported. On 28Dec2020, the patient was positive for COVID-19 test after receiving COVID-19 vaccine. She informed she contracted COVID-19 due to an exposure from a co-worker. The outcome of events was not recovered. Information about lot/batch number has been requested.

"received his first dose of the vaccine and tested positive for Covid yesterday; received his first dose of the vaccine and tested positive for Covid yesterday; This is a spontaneous report from a contactable healthcare professional. A male patient of an unspecified age received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date were not reported), via an unspecified route of administration on 17Dec2020 at single dose for COVID-19 immunisation. The patient medical history and concomitant medications were not reported. It was reported that the patient received his first dose of the vaccine on 17Dec2020 and tested positive for Covid yesterday (28Dec2020). He is scheduled to have his second dose in January. The outcome of the events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Based on available information, a possible contributory role BNT162B2 vaccine cannot be completely excluded for event ""tested positive for COVID""."

tested positive for COVID after the first dose; tested positive for COVID after the first dose; This is a spontaneous report from a contactable Pharmacist reported for herself. A female patient of an unspecified age received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for

injection, lot number and expiry date unknown) via an unspecified route of administration on 22Dec2020 at single dose for Covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient informed that she had the COVID-19 vaccine exactly a week ago (22Dec2020). However, she was tested positive for COVID (Dec2020) after the first dose. The outcome of the events tested positive for COVID after the first dose was unknown. The patient asked if she can take the second dose. Follow-up activities are possible, information on the batch number has been requested.; Sender's Comments: Based on the information currently available, a lack of efficacy with the suspected vaccine BNT162B2 in this patient cannot be completely excluded. Further information like confirmative virus genome /nucleic acid detection needed for meaningful medical assessment.

We have a patient that received the 1st vaccine, then 7days later they tested positive for COVID-19.; We have a patient that received the 1st vaccine, then 7days later they tested positive for COVID-19.; This is a spontaneous report from a contactable pharmacist (Pharmacy Intern) via Pizer-sponsored program: A patient of unspecified age and gender received first single dose of BNT162B2 (lot number, and exp date not reported), via an unspecified route of administration on an unspecified date for immunization. The patient's medical history and concomitant medications were not reported. The patient received the 1st vaccine, then 7days later tested positive for COVID-19 (date unspecified). It was asked if patient needed to wait 90 days to receive the 2nd Vaccine dose. The outcome of the event was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

tested positive for Covid; tested positive for Covid; This is a spontaneous report from a contactable consumer (patient). A female patient of an unspecified age received first single dose of BNT162B2 (Pfizer-Biontech Covid-19 Vaccine, lot number and exp date not reported), via an unspecified route of administration on 17Dec2020 for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. Patient received first Covid vaccine and on 26Dec2020, tested positive for Covid. Patient asked when if it was safe for her to get second dose. Asked if she get it on 21 days or if she had to wait. The outcome of the event was unknown. Information about Lot/Batch number has been requested.; Sender's Comments: Based on the information currently available, a lack of efficacy with the suspected vaccine BNT162B2 in this patient cannot be completely excluded. Further information like confirmative virus genome /nucleic acid detection is needed for meaningful medical assessment.

had covid and also received the Pfizer covid 19 vaccine.; had covid and also received the Pfizer covid 19 vaccine.; This is a spontaneous report from a contactable nurse. A patient of unspecified age and gender started received single dose of BNT162B2 (Solution for injection, batch/lot number and exp date not reported), via an unspecified route of administration on an unspecified date for immunization. The patient's medical history and concomitant medications were not reported. They have a patient that meets the criteria to receive product bamlanivimab. The patient had Covid and received the Pfizer covid 19 vaccine. The nurse asked if patient can still get the bamlanivimab after receiving vaccine. The outcome of the events was unknown. No follow-up attempts are possible; information about batch number cannot be obtained.; Sender's Comments: Based on the information currently available, it is unclear if Covid developed after BNT162B2 Pfizer covid 19 vaccine, pending further clarification, at this

moment, the Company would handle the reported COVID related to the suspect, BNT162B2, for reporting purpose.

flare of existing autoimmune disease (undifferentiated connective tissue disease (UCTD) with predominant features of systemic sclerosis); flare of existing autoimmune disease (undifferentiated connective tissue disease (UCTD) with predominant features of systemic sclerosis); flare of existing autoimmune disease (undifferentiated connective tissue disease (UCTD) with predominant features of systemic sclerosis); This is a spontaneous report from a contactable physician. A 35-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot EH9899) intramuscular on 22Dec2020 16:15 (04:15 PM) at a single dose on the left arm as COVID-19 vaccine. Medical history included autoimmune disease (undifferentiated connective tissue disease (UCTD) with predominant features of systemic sclerosis); secondary Raynaud's phenomenon with calcinosis; known allergies to sulfa drugs, pine nuts. Concomitant medications included mycophenolate mofetil (MMF) 1000mg bid (twice a day), hydroxychloroquine sulfate (PLAQUENIL) 300mg qd (once a day), and prednisone 15mg daily (received within 2 weeks of vaccination). The patient had an adverse event (AE) of flare of existing autoimmune disease (undifferentiated connective tissue disease (UCTD) with predominant features of systemic sclerosis) on 23Dec2020 09:00 PM (also reported as flare began about 36-48 hours after vaccine) which required increased daily dose of prednisone (higher dose) up to 80mg total daily dose (80mg daily x3d, then tapered down) (treatment received for AE) and lasted about 4-5 days. The patient was not pregnant at the time of vaccination. She had no other vaccine in four weeks (did not receive other vaccine within four weeks prior to the COVID vaccine). She was not diagnosed with COVID-19 prior to vaccination and did not have Covid tested post vaccination (had not been tested for COVID-19 since the vaccination). The patient was vaccinated in a hospital (facility where the most recent COVID-19 vaccine was administered). The outcome of the events was recovered on Dec2020.; Sender's Comments: The Company cannot completely exclude the possible causality between the reported flare of existing autoimmune disease (undifferentiated connective tissue disease (UCTD) with predominant features of systemic sclerosis) and the administration of BNT162B2, based on the plausible temporal association. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to agencys, as appropriate.

developed symptoms/mild/thought the symptoms were from the vaccine but turned out she did test positive for Covid; developed symptoms/mild/thought the symptoms were from the vaccine but turned out she did test positive for Covid; This is a spontaneous report from a contactable other healthcare professional (HCP) (patient). A 33-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 19Dec2020 at a single dose as vaccine. Medical history and concomitant medications were not reported. The patient received the vaccine on 19Dec2020 and 2 days later on 21Dec2020, she developed symptoms. Her symptoms had been mild. She thought the symptoms were from the vaccine but turned out she did test positive for Covid on Dec2020. She inquired what would happen if you get the vaccine and you test positive. She also inquired if her symptoms would be worse. The outcome of the events was unknown. Information on the

lot/batch number has been requested.; Sender's Comments: Based on the information currently available, a lack of efficacy with the suspected vaccine BNT162B2 in this patient cannot be completely excluded. Further information like confirmative virus genome /nucleic acid detection is needed for meaningful medical assessment.

positive for Covid/ symptoms of Covid; positive for Covid/ symptoms of Covid; This is a spontaneous report from a contactable nurse (reported for himself). A 33-year-old male patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot/batch number and expiration date not provided), via an unspecified route of administration on 17Dec2020 at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. Patient got the first dose of the vaccine on 17Dec2020 and then around Christmas he developed symptoms of Covid (Dec2020). On 27Dec2020, he came back positive for Covid and wanted to know if he skip the second dose. Patient questioned what percentage of persons obtained immunity after the first product dose. The outcome of the events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Based on the information currently available, a lack of efficacy with the suspected vaccine BNT162B2 in this patient cannot be completely excluded. Further information like confirmative virus genome /nucleic acid detection is needed for meaningful medical assessment.

tested positive for COVID-19 by PCR the following day and developed covid symptoms; tested positive for COVID-19 by PCR the following day and developed covid symptoms; This is a spontaneous report from a contactable physician (patient). A female patient of an unspecified age received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient received the first dose of the Pfizer-biontech covid-19 vaccine and tested positive for COVID-19 by PCR the following day and developed COVID symptoms. The outcome of the events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: The reported tested positive for COVID-19 by PCR after COVID-19 immunization is considered ineffective of BNT162B2, and the Company cannot completely exclude the possible causality between the reported event and BNT162B2 administration.

they suspect that I have rheumatoid arthritis; this is like abnormal I mean anybody with arthritis should not be a part of these trials; Never felt this kind of joint pain in my life/these are hitting my every joint in my hand, I can barely move; I have never been in as much pain in my life; I am really bad nauseous; soreness in your arm; This is a spontaneous report from a contactable consumer (patient) (Food service worker in the hospital). A 48-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: Unknown), via an unspecified route of administration on 28Dec2020 at single dose for COVID-19 immunisation. Medical history included Meniere's disease (reported 'Meniere's disease in my left ear'). The patient's concomitant medications were not reported. Consumer stated, ''I just took the COVID 19 vaccine I work at (institute name), (city name), I took it yesterday around 1 and all through the night; they suspect that I have rheumatoid arthritis I got an injection in one of my hips, my right hip and both my shoulders I can inject in cortisone injection and I have never felt this kind of joint pain in my life, I can barely move, I had been calling and I let my director know and anybody that has any kind of arthritis on these trials, I have never been in as much pain in my life and I

am really bad nauseous.'' When offered for the website consumer stated, ''I just wanted to report the side effects, I am really nauseous and I can barely move; this is like abnormal I mean anybody with arthritis should not be a part of these trials.'' When probed if vaccine was prescribed by Physician, Consumer stated, ''No it was voluntary, it was not mandatory it was given my hospital administration.'' Product details for vaccine (LOT#, Expiration date, NDC#, UPC#): Consumer stated, ''EH9894, I think for the last number.'' Treatment for adverse events: Consumer stated, ''I don't have anything for nausea, I did take, they told to me take Ibuprofen my doctor said that it would help with the soreness in your arm, I take my Ibuprofen every six hours because it is prescribed to me, but I could barely move my, I can barely move; these are hitting my every joint in my hand.'' Expiry Date of Ibuprofen: 16Jul2021. The outcome of the events was unknown. Information on the Batch/Lot number has been requested.

"Tested positive for COVID after receiving the vaccine/runny nose and felt achy/coughing/ dizzy and weak. It was affecting her legs and she had no taste; Tested positive for COVID after receiving the vaccine/runny nose and felt achy/coughing/ dizzy and weak. It was affecting her legs and she had no taste; This is a spontaneous report from a Pfizer-sponsored program IBCC (Inbound Call Center for HCPs). A contactable consumer (patient) reported a 53-year-old female received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: Unknown, did not see this information on the vaccination card), via an unspecified route of administration in the left arm on 20Dec2020 at single dose for covid-19 immunization (certified nurse assistant in healthcare). Other products, patient history and investigation assessment was No. There were no concomitant medications. The patient was vaccinated with the COVID Vaccine on 20Dec2020 but tested positive afterwards on 27Dec2020. The patent thought she had COVID in the vaccine and COVID in her body. She was scheduled for next dose on 10Jan2021 and would like to know if she should get the scheduled dose or if she needs to wait longer and re-schedule it. She was now a COVID patient and sick. She was waiting to get better. Before the vaccine she tested negative and felt great. Then she got the vaccine. She had a runny nose and felt achy. She asked her coworker, and her coworker felt the same. She thought if it continued that maybe it was a side effect. Caller confirmed her symptoms were runny nose, feeling achy, and coughing. She took Tylenol and the aches went away. They then came back, and she had more aching and she was wondering why. Caller clarified that these symptoms did not start the next day after receiving the vaccine. Achiness/body aches was started on 23Dec2020 when she was at work. It would wake her up at night. She did have aches right now, but her fever had lowered down. She was also dizzy and weak. It was affecting her legs and she had no taste. She was not eating but needs to eat. If she did, she eat something sweet. Runny nose was started on 24Dec2020. She went back to work on 26Dec2020 but told them she could not work because she had symptoms of COVID. She went to her second job where they do COVID testing and asked her boss for a test. She tested positive on 27Dec2020. Dose was unknown. She said she thought she got 1 vial. The whole thing. The outcome of events ""tested positive for COVID after receiving the vaccine"" was not recovered. Information on lot/batch number has been requested."

testing positive for COVID after getting the vaccine; testing positive for COVID after getting the vaccine; This is a spontaneous report from a contactable Other Health Professional reported for herself. A female patient of an unspecified age (reported as 42) received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for COVID-19

immunization. The patient's medical history and concomitant medications were not reported. The patient experienced testing positive for COVID after getting the vaccine in Dec2020 with outcome of unknown. The patient underwent lab tests and procedures which included COVID test in Dec2020: negative; positive. The reporter would like an explanation as to the rapidness of her testing positive for COVID after getting the vaccine. Can the vaccine cause false positive test results? Information on interpretation of SARS-CoV-2 test results. The patient tested negative on Monday, got the vaccine on Monday. However tested positive today, asymptomatic. Information about batch/lot number has been requested.; Sender's Comments: A possible contributory effect of suspect BNT162B2 on reported events cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

Had the vaccine eventually then I ended up getting the virus; I ended up going through a rapid test that turned positive; This is a spontaneous report from a contactable consumer reporting for himself. A 53-years-old male patient started to receive bnt162b2 (BNT162B2; Lot # EK5730) vaccine , intramuscular in the left arm on an unspecified date at single dose for Covid-19 immunisation . Medical history included hypothyroidism from an unknown date. Concomitant medication included levothyroxine sodium (SYNTHROID). The patient stated that he does get test for the virus twice weekly. He did end up getting the Pfizer, the first round of Pfizer vaccine a week ago. The patient had a test, a virus test before, a swab test afterwards, both were negative but by Christmas eve the patient started getting, what he thought was side effect of the vaccine and he ended up going through a rapid test and it turned out he was positive for the virus.

Tested positive for COVID /she received the first dose of the vaccine last 16Dec2020 but tested positive via Nasal Swab test on 24Dec2020; Tested positive for COVID/positive via Nasal Swab test/fever/body aches/headaches/She was very very weak, almost lethargic/felt really bad/fatigued; gas; bloated; the weight last week she was 167 and this week she was 180; This is a spontaneous report from a contactable nurse reporting for herself. A 48-year-old female patient received her first dose of BNT162B2 (Pfizer-Biontech Covid-19 Vaccine) Lot #EH9899, via an unspecified route of administration on 16Dec2020 at single dose by injection in the right deltoid for COVID-19 immunisation. Medical history included borderline hypertension from 2018 and ongoing. Concomitant medication included olmesartan medoxomil (BENICAR) from 2018 and ongoing for borderline hypertension. The nurse reported that she received the first dose of the vaccine last 16Dec2020 but tested positive via Nasal Swab test on 24Dec2020. She said this kinda weird. She received the COVID vaccine on 16Dec2020. She tested positive for COVID on 24Dec2020. Obviously she was exposed to COVID prior to the vaccine. She was scheduled to have the 2nd dose on 05Jan2021 but her hospital deferred it to 23Mar2021. She was asking if this was what's recommended.She said this was another weird thing, regarding the weight last week she was 167 and this week she was 180 (in Dec2020). She was very bloated in Dec2020, it was bizarre. He husband did not receive the vaccine and had symptoms on 24Dec2020. She had normal seasonal allergy symptoms. She did not think much of it. She took her Xyzal and her normal things.She

took her husband to get tested and he tested positive, so she got tested, and was positive. She worked at (address withheld), and all of her patients were immunocompromised. She was shocked. She did not think this had anything to do with the vaccine. If anything, it has helped her fight the virus.By Christmas day 25Dec2020 her fever was 102, she had body aches, she went into overdrive. She had headaches and lots of gas in Dec2020.She went into overdrive from partial recognition from the vaccine.She was very very weak, almost lethargic. Her O2 saturation have stayed good around 98% in Dec2020. She has done really well. Yesterday or the day before she felt really bad again. She did a virtual visit with (name withheld), and the doctor started her on steroids and gave her an inhaler just in case she needed it. She felt better on 30De2020. On 29De2020 she was so bad and bloated, she only had one dose of the steroids, but had unusual weight gain. Then 2 pounds were gone this morning on 30De2020.She had no pitting edema or edema period. She was very fatigued, but had more energy this morning, probably because of the steroids. She had the vaccine, even though day 7 post-injection, instead of day 10, which was about 50%, her body reacted more so than her husbands because her body recognized it. The outcome of the events was unknown. She was unsure of the outcome. It was up and down. She has felt worse and she has felt better. The reporter considered the event Tested positive for COVID was Not serious and unrelated to the BNT162B2.; Sender's Comments: While reporter causality is noted, a possible contributory effect of suspect BNT162B2 on reported events cannot be excluded.

Bell's palsy on the left side of his face; Headaches; Overall was not feeling well; This is a spontaneous report from contactable consumers (including the patient). A 64-year-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number EH9899), via an unspecified route of administration in right arm on 18Dec2020 04:00 at a single dose for covid-19 vaccination. There were no relevant medical history and concomitant medications. On, 19Dec2020, the patient had headaches and overall was not feeling well. On 28Dec2020, the patient experienced bell's palsy on the left side of his face. He said it was a little hard to talk as his mouth was not working at the moment. The provider he saw gave him steroids- Prednisone, and Valaciclovir. He was also told to get some eyedrops as one eye does not close very well. He laughed and said it was a little hard to drink his coffee. The outcome of the events headache and not feeling well was recovered on 21Dec2020 while the outcome of bell's palsy was not recovered. The information on the batch/lot number and expiration date has been requested.

positive COVID-19 test with symptoms; positive COVID-19 test with symptoms; This is a spontaneous report from a contactable physician reporting for a nurse (patient) from a Pfizer-sponsored program Pfizer First Connect. A 43-year-old female patient received first dose of BNT162B2 (Pfizer Covid-19 vaccine), via an unspecified route of administration on 22Dec2020 at single dose for covid-19 immunisation. There were no medical history and concomitant medications. The physician was reporting that a nurse received the vaccine and had a headache after receiving it. She also tested positive for Covid 6 days after getting the vaccine (on 28Dec2020). He was asking if there was any connection with getting the first shot and testing positive. She was very keen with social distancing and wearing a mask. The physician is a medical oncologist. He was reporting on one of the nurses that worked at the hospital. She also developed nasopharyngeal congestion 4-5 days later. The nurse was at work today. She was disappointed because she had to go home. The patient underwent lab tests and procedures which included SARS-CoV-2 test: positive on 28Dec2020. The outcome of the events was

unknown. Information on Lot/Batch number has been requested.; Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of events Drug ineffective and COVID-19 cannot be totally excluded. The case will be reassessed if additional information becomes available.

has tested positive shortly after; has tested positive shortly after; This is a spontaneous report from a contactable pharmacist. A patient of unknown age and gender received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on unknown date at single dose for COVID-19 immunization. Medical history and concomitant medications were not reported. The pharmacist asked for recommendation for the 2nd dose of the patient who had received the 1st dose but had tested positive shortly after. The outcome of the events was unknown. information on the LOT/Batch number has been requested.; Sender's Comments: A possible contributory effect of suspect BNT162B2 on reported event cannot be excluded.

"fatigue; arm soreness; chills; muscle pain/muscle aches; fever; vomiting; he was positive for COVID-19; he was positive for COVID-19; This is a spontaneous report from a contactable consumer and a nurse. A 45-year-old male patient started to receive BNT162B2, via an unspecified route of administration on 18Dec2020 at single dose for COVID-19 immunization. Medical history included bronchiolitis obliterans, and ulcerative colitis. Concomitant medications were not reported. Patient experienced arm soreness. Six days later, after working a shift in the COVID-19 unit, patient had chills, muscle pain and fatigue. A drive-up hospital test confirmed he was positive for COVID-19. Patient was tested positive after receiving vaccination on 18Dec2020. Patient experienced muscle aches, fever, chills, and vomiting. On 30Dec2020, patient was tested positive for Covid-19 after receiving Pfizer vaccination. Outcome of the events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: A possible contributory effect of suspect BNT162B2 on reported event ""he was positive for Covid-19"" cannot be excluded."

palpitations; Shortness of breath; Heart rate was 160s; This is a spontaneous report from a contactable Physician. This 29-Year-old female physician reported that she received 1st dose of BNT162B2 on 30Dec2020 08:30 AM at right arm for COVID-19 immunisation. Medical history included allergies: Citrus and cinnamon- perioral contact dermatitis. Concomitant therapy included birth control- Mylan. The patient reported within 5 mins of vaccine administration, she experienced palpitations and shortness of breath. Heart rate was 160s on 30Dec2020. No rash or fever. Event onset time was reported as 30Dec2020 8:30. She needed to be taken to the emergency room. Treatment was received as Steroids epinephrine Benadryl. The outcome of the event was recovering. The events were reported as non-serious. Lot/Batch and Expiration date has been requested.; Sender's Comments: A possible contributory effect of suspect BNT162B2 on reported events cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

tested positive; tested positive; This is a spontaneous report from a contactable Nurse. A female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 27Dec2020 (reported as about 3 days ago, as of 30Dec2020) at single dose for covid-19 immunisation. Medical history, concomitant medications or past drug history were not provided. She received the vaccine about 3 days ago and later tested positive in Dec2020 and asked if the patient needs to restart the 2 doses series. Outcome of the events were unknown. Lot/Batch and Expiration date has been requested.; Sender's Comments: The reported events drug ineffective and COVID-19 are likely intercurrent conditions and are unrelated to BNT162B2 based on the short temporal relation between vaccination and onset of event.

Caller stated that a patient tested positive for covid 19 after the first dose of the vaccine; Caller stated that a patient tested positive for covid 19 after the first dose of the vaccine; This is a spontaneous report from a contactable Pharmacist. A female patient of an unspecified age (age: 74; unit- unknown) received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient medical history was not reported. The patient's concomitant medications were not reported. The patient tested positive for COVID 19 after the first dose of the vaccine. Reporter wants to know if the patient can be treated with monoclonal antibodies after having received the vaccine. Reporter also wanted to know if the storage in the thermal shipper can be extended past the 30 days. Event outcome was unknown. Information on the lot/batch number has been requested.; Sender's Comments: The information currently provided is too limited to make a meaningful medical assessment hence, the events drug ineffective and COVID-19 are conservatively assessed as related to the suspect drug BNT162B2 until further information becomes available.

Patient who got the vaccine a week ago tested positive now for COVID; Patient who got the vaccine a week ago tested positive now for COVID; This is a spontaneous report from a contactable pharmacist. A patient of unspecified age and gender received first dose bnt162b2 (BNT162B2), via an unspecified route of administration on Dec2020 at single dose for covid-19 immunisation. The patient medical history was not reported. The patient's concomitant medications were not reported. The pharmacist reported the patient who got the vaccine a week ago tested positive now for covid on Dec2020 with outcome of unknown. The patient underwent lab tests and procedures which included covid: positive on Dec2020. the doctor is thinking of giving antibody. The event was reported at non-serious. Information on lot/batch number has been requested.; Sender's Comments: The information currently provided is too limited to make a meaningful medical assessment hence, the events are conservatively assessed as related to the suspect drug BNT162B2 until further information becomes available.

Moderate to severe Chills; body and head aches; head aches; Fever (99.6 F); This is a spontaneous report from a non-contactable other hcp. A 32-year-old male patient received BNT162b2 (COVID 19, Lot number: EK9231, dose number was 1), intramuscular at right arm on 28Dec2020 08:00 AM at single dose for COVID-19 immunization in hospital. Medical history was none. There was no known allergies to medications, food, or other products. The patient's concomitant medications were not reported. There was no other vaccine in four weeks. The patient experienced Moderate to severe Chills, body and head aches, and Fever (99.6 F) on 28Dec2020 20:30(08:30 P.M). There was no treatment. There was no COVID prior vaccination nor COVID tested post vaccination. Outcome was recovering. Events were assessed as

non-serious by the reporter. No follow-up attempts are possible. No further information is expected.; Sender's Comments: A causal association between BNT162B2 and the reported event chills cannot be excluded based on known safety profile of suspect drug and compatible temporal relation.

bell's palsy; This is a spontaneous report from a contactable physician. A female patient of an unspecified age (age: 37 unit: unknown), received BNT162B2(PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date were not reported), via an unspecified route of administration on 29Dec2020 at single dose for COVID-19 immunisation. The patient medical history and concomitant medications were not reported. The patient experienced bell's palsy on 30Dec2020. The outcome of the event was unknown. Information on the lot/batch number has been requested.; Sender's Comments: A possible causal association between administration of BNT162B2 and the onset of bell's palsy might not be excluded, considering the plausible temporal relationship. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

"heart rate (HR) was 180; tongue and lips tingled; walking for a short distance and felt ""off; This is a spontaneous report from a contactable Nurse reported for herself. This 34-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Lot number: EK9231), via an unspecified route of administration on 29Dec2020 15:15 at single dose on left arm for Covid-19 immunisation. Medical history included allergies to hepatitis B vaccine rhbsag (HEY B VACCINE) booster and poison ivy. Concomitant medication included biotin / calcium pantothenate / cyanocobalamin / folic acid / nicotinamide / pyridoxine hydrochloride / riboflavin / thiamine mononitrate (B COMPLEX), fexofenadine, ascorbic acid (VIT C) and Multivitamin. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. Immediately after shot (29Dec2020 15:15), her tongue and lips tingled but it went away quickly. She was walking for a short distance and felt ""off."" The patient checked her pulse and pulse ox and her heart rate (HR) was 180. Her HR had bounced around from 150-180 with minimal exertion and was in the 90s at rest. No treatment received for the events. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The outcome of not recovered. The events were non-serious.; Sender's Comments: A causal association between BNT162B2 and the event heart rate increased cannot be excluded based on a compatible temporal relation. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate."

dizzy; fever; elevated blood pressure; flushed feeling day of vaccine. The next day she continued to feel flushed; This is a spontaneous report from a contactable pharmacist. This pharmacist reported for a 60-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via intramuscular route on 29Dec2020 15:00 at single dose for COVID-19 immunization. Medical history included COVID-19, hypertension and depression. Concomitant medications included vitamins received

within 2 weeks of vaccination. The patient previously took duloxetine and experienced allergies. Facility that the most recent COVID-19 vaccine was administered in Workplace clinic. Prior to vaccination, the patient was diagnosed with COVID-19. Since the vaccination, the patient hasn't been tested for COVID-19. On 29Dec2020, the patient was dizzy, had fever, elevated blood pressure, and flushed feeling day of vaccine. The next day she continued to feel flushed that moved through her face and down her neck. It felt like she was on fire. The adverse events resulted in the following: Emergency room/department or urgent care. Outcome of the event feel flushed was recovered on 30Dec2020, outcome of other events was recovered in Dec2020. Treatment received for the adverse events included IV fluids, prednisone, diphenhydramine hydrochloride (BENADRYL). Events were reported as non-serious. Information on the lot/batch number has been requested.; Sender's Comments: A causal association between BNT162B2 and the events dizzy, fever, elevated blood pressure and flushed feeing cannot be excluded based on a compatible temporal relation. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

"swelling/cellulitis in her left arm/redness, inflammation, swelling that looked like cellulitis to the arm/deltoid area; redness; to the arm/deltoid area; inflammation; to the arm/deltoid area; swelling/cellulitis in her left arm/swelling; to the arm/deltoid area; This is a spontaneous report from a contactable nurse reported for herself. A 28-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number EK5730, expiry date unknown) intramuscular at left deltoid on 16Dec2020 16:45 at single dose for Covid-19 immunization at a hospital facility and not in a military facility. Medical history included ongoing acne. Concomitant medications included ongoing spironolactone for acne. The patient did not receive any other vaccines the day or 4 weeks prior Covid-19 vaccine. The patient informed that after 8 days of getting Covid vaccine she has swelling/cellulitis in her left arm. The patient got the COVID-19 vaccine and had kind of a delayed reaction. She got the vaccine on 16Dec2020 16:45 pm at her workplace. The patient informed that she had no reaction right after the vaccine. On 24Dec2020, the patient experienced redness, inflammation, swelling that looked like cellulitis to the arm/deltoid area. The patient got antibiotics and it has improved. The reporter informed that the events required visit to physician office. The outcome of the events swelling/cellulitis in her left arm/redness, inflammation, swelling that looked like cellulitis to the arm/deltoid area was recovering. The patient was queried regarding seriousness of the events and the patient stated ""it could have potentially dangerous."" The patient wanted to know if she should get second dose of the vaccine.; Sender's Comments: Based on temporal association, the causal relationship between BNT162B2 and the events vaccination site cellulitis, vaccination site erythema, vaccination site inflammation and vaccination site swelling cannot be excluded."

she had developed symptoms and tested positive to COVID-19; she had developed symptoms and tested positive to COVID-19; This is a spontaneous report from a contactable physician (patient). A female patient of unspecified age received BNT162B2 first dose on 20Dec2020 at single dose for COVID-19 immunization. Medical history and concomitant medications were not reported. She tested negative on

18Dec2020. She received the first dose of the COVID 19 vaccine on 20Dec2020. On the following Friday (25Dec2020), she had developed symptoms and tested positive to COVID-19. The outcome of the events was unknown. Information on the batch/lot number has been requested.; Sender's Comments: The causal relationship between BNT162B2 and the events drug ineffective and SARS-CoV-2 test positive cannot be excluded as the information available in this report is limited and does not allow a medically meaningful assessment. This case will be reassessed once additional information becomes available.

received the 1st dose of the COVID-19 vaccine on 21Dec2020, however, on 28Dec2020 she tested positive to COVID-19; received the 1st dose of the COVID-19 vaccine on 21Dec2020, however, on 28Dec2020 she tested positive to COVID-19; This is a spontaneous report from a contactable other healthcare professional (HCP) (patient) from a Pfizer-sponsored Program Pfizer First Connect. A 26-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EJ1685), intramuscularly on left deltoid on 21Dec2020 (between 2:15PM and 2:30PM) at single dose (reported as 225mcg/.45ml intramuscular suspension) for COVID-19 immunization. The relevant medical history included birth control. Concomitant medications included ongoing ethinylestradiol, ferrous fumarate, norethisterone acetate (TAYTULLA) for birth control. The patient received the 1st dose of the COVID-19 vaccine on 21Dec2020, however, on 28Dec2020 she tested positive to COVID-19. She wanted to know if the vaccine could have caused a positive test result, if the test assesses IgM or IgG (to the viral spike proteins), could a false positive result be caused by the vaccine. She hadn't been able to get up with her primary care on the phone. This was her first dose. The window to get the second vaccine is 07Jan2021 through 11Jan2021. The patient did not require a visit to emergency room or physician office. The outcome of the events was unknown.; Sender's Comments: The causal relationship between BNT162B2 and the events drug ineffective and SARS-CoV-2 test positive cannot be excluded as the information available in this report is limited and does not allow a medically meaningful assessment. This case will be reassessed once additional information becomes available.

acute pericarditis; This is a spontaneous report from a contactable physician. A male patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot/batch number not reported), via an unspecified route of administration on 23Dec2020 at a single dose for covid-19 immunization. The patient medical history and concomitant medications were not reported. It was unknown if other vaccines were given in four weeks and unknown if patient had Covid prior vaccination. The patient experienced acute pericarditis on 24Dec2020. Clinical course as follows: Doctor colleagues at the institution admitted (at Emergency room/department or urgent care) and treated a patient with acute pericarditis who received his first dose of Pfizer SARS-CoV-2 EUA vaccine on 23Dec2020. The physician (reporter) considered the event as non-serious. The outcome of the event was recovering. Information about batch/lot number has been requested.; Sender's Comments: The causal relationship between BNT162B2 and the event acute pericarditis cannot be excluded as the information available in this report is limited and does not allow a medically meaningful assessment. This case will be reassessed once additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as

well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate.

received the vaccine last week and tested positive for covid this week; received the vaccine last week and tested positive for covid this week; This is a spontaneous report from a contactable other Healthcare Professional (patient). A 30-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: Unknown), via an unspecified route of administration on 23Dec2020 at single dose by injection in the right arm for COVID-19 immunization (to be protected and to protect her family with other conditions like diabetes). The patient's medical history and concomitant medications were none. The patient got the first dose of the COVID vaccine last week on 23Dec2020 and then she tested positive for COVID on Monday on 28Dec2020. She was asking if it was safe to get the second dose. Patient was a pharmacy technician. The outcome of the events was not recovered. Information on the Lot/Batch number has been requested.; Sender's Comments: The causal relationship between BNT162B2 and the events drug ineffective and SARS-CoV-2 test positive cannot be excluded as the information available in this report is limited and does not allow a medically meaningful assessment. This case will be reassessed once additional information becomes available.

Headache; blurred vision; unable to read at time; Difficulty focusing; right hand numbness; This is a spontaneous report from a contactable Nurse (patient). A 35-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 28Dec2020 04:15 PM, Intramuscularly at single dose (Vaccine location: Left arm) for COVID-19 immunization. Medical history was reported none. Concomitant medications were not reported. Patient did not have any allergies. Patient did not receive other vaccine in four weeks. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. Patient experienced Headache, blurred vision and unable to read at time, Difficulty focusing and right hand numbness on 30Dec2020 12:00 AM. Patient did not receive any treatment. The outcome of the events was not recovered. This case was assessed non-serious by reporter. The events did not result in death, Life threatening, Caused/prolonged hospitalization, Disabling/Incapacitating, Congenital anomaly/birth defect. Information on the lot/ batch number has been requested.; Sender's Comments: The causal relationship between BNT162B2 and the events headache, vision blurred, cognitive disorder, disturbance in attention and hypoaesthesia cannot be excluded as the information available in this report is limited and does not allow a medically meaningful assessment. This case will be reassessed once additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate.

"mild supraglottic swelling of my aryepiglottic folds; feel difficulty swallowing (globus); allergic response; This is a spontaneous report from a contactable physician. A 41-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK5730), intramuscular on 23Dec2020 12:30 at single dose for COVID-19 immunisation. Medical history included allergies to medications, food, or other products: Penicillin. There were no concomitant medications. The patient previously took benzoyl peroxide and experienced allergies. The patient experienced stated that on

23Dec2020 12:31, ""I am an ENT surgeon. I received the first dose of the vaccine at 12:30pm. Within 1-2 minutes I started to feel difficulty swallowing (globus). I reported this to the nurse and she offered me ginger ale. My symptoms worsened and then stabilized after 10 minutes. I went upstairs and got the residents to perform a fiberoptic nasoendoscopy and this demonstrated mild supraglottic swelling of my aryepiglottic folds. I choose not to receive treatment as I did not want to dampen my allergic response and as an ENT surgeon manage airways on a daily basis. I stayed at the hospital for a further 6 hours and continued to work. My symptoms resolved after 9 hours"". The outcome of the events was recovered on 23Dec2020.; Sender's Comments: Based on temporal association, the causal relationship between BNT162B2 and the event laryngeal oedema cannot be excluded. This case will be reassessed once additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate."

chronic auto immune response; angioedema/tongue is swollen; urticaria/hives; This is a spontaneous report from a contactable other healthcare professional. A 35-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number and expiration date were not reported), intramuscular in the right arm on 28Dec2020 10:15 at a single dose for COVID-19 immunization. The patient's medical history was not reported. The patient was not pregnant. Concomitant medications included cetirizine hydrochloride (ZYRTEC), omeprazole (PROTONIX), naproxen sodium (ALEVE), and birth control. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient was not diagnosed with COVID-19 prior to vaccination and had not been tested for COVID-19 since the vaccination. On 30Dec2020 16:00, the patient have a chronic auto immune response in the form of urticaria and angioedema. The symptoms of hives as well as swollen tongue was maintained with antihistamines. Outcome of the events was not recovered. The events were considered non-serious. The following information on the batch number has been requested.; Sender's Comments: Based on the temporal relationship, the association between the events chronic autoimmune response in the form of urticaria and angioedema with BNT162b2 can not be completely excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

Tachycardia/her heart rate at 11:00PM last night was at around 100/ she checked her pulse it was 115; she was not feeling right, so she took the day off from work today; Lightheadedness; wobbly; she felt weak; This is a spontaneous report from a contactable nurse (patient). A 50-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Lot Number: EL1284, expiration date: Apr2021), via an unspecified route of administration at right deltoid on 29Dec2020 17:45 at a single dose for Covid-19 immunization. Medical history included asthma from 2003 and ongoing, tachycardia and major surgery. Concomitant medication included maintenance inhaler (unspecified) for asthma.

Patient was officially diagnosed with asthma in 2003. She said her asthma was controlled, and she takes a maintenance inhaler every day. She said she has been taking the same maintenance inhaler since she was first diagnosed with the asthma. She said she rarely uses a rescue inhaler. Reported she was prescribed the Metoprolol Tartrate 25mg for her tachycardia that she had after her major surgery, but she did not take the full 25mg dose during that time. She said she hasn't had taken the Metoprolol Tartrate 25mg in almost a year, clarifying it was last Jan2020 that she used the Metoprolol Tartrate. The patient previously received a flu shot in Oct2020, and felt rundown for a day afterwards, but that she always does after she receives a flu shot. She said she had no heart issues after receiving the flu shot in Oct2020. The patient who is a registered nurse reported she received the COVID-19 vaccine last night at work, on 29Dec2020, at 5:45PM, and had experienced some tachycardia after receiving the vaccine. Reported the COVID-19 Vaccine was offered through her employer. She said the COVID-19 vaccine was optional and offered to all employees if they work at the hospital. She experienced the tachycardia at 11:00 PM last night, 29Dec2020. She said her normal resting heart rate is between the high 60s to low 70s. She said her heart rate at 11:00PM last night was at around 100, clarifying she was not running a fever at that time. She stated after she received the COVID-19 vaccine, she was not feeling right, so she took the day off from work today, and slept in. She said when she woke up this morning (in Dec2020), she still didn't feel right, saying she felt weak and wobbly, and when she checked her pulse it was 115. She said she does have a past history of tachycardia. She said a year ago she had major surgery, and she had tachycardia after the major surgery. She said the tachycardia eventually went away, but she did have to see a cardiologist and take a beta blocker. She said she took a tiny dose of the beta blocker this morning, and called the cardiologist to let him know what was going on. She said she has not heard back from the cardiologist yet. She said the tachycardia went away once she took the beta blocker this morning. She said she took the beta blocker because her heart rate was going higher, and higher. She said she didn't want to end up like last year after her major surgery with a heart rate in the 170s. She said the tachycardia she was experiencing after receiving the COVID-19 Vaccine was not normal for her. She said once she got over the major surgery last year, her heart rate was fine. Reported her employer was making employees wait around for 15 minutes after the employees received the COVID-19 Vaccine to make sure no one had a major reaction to the COVID-19 Vaccine. She said after she received the COVID-19 Vaccine, she waited around longer than the 15 minutes. She said she felt weird after she received the COVID-19 Vaccine and thought maybe she was experiencing anxiety. She said she was lightheaded on 29Dec2020 after she received the COVID-19 Vaccine and completed a report right then on the website. She said the website is for reporting adverse events, and she was sent a website link to complete the adverse event reporting. She said she signed into the website link while she was still at the hospital. She said one of the website's first questions asked was how she was feeling. She said the question made her wonder if her lightheadedness was due to her heart rate being up because she becomes lightheaded when that happens. She clarified she reported only the lightheadedness on the website, and not the tachycardia. She said her lightheadedness got better and she was fine, and then at 11:00PM the tachycardia hit her like a switch. Reported this morning she felt fine, and then all of sudden she wasn't fine. Tachycardia Treatment: Reported she took a 8.5mg dose, or one quarter of a 25mg tablet (as provided by the reporter) of the beta blocker Metoprolol Tartrate 25mg tablet this morning and called her cardiologist to let him know. She said she split the Metoprolol Tartrate 25mg tablet this morning, and only took a quarter of the 25mg tablet (reported as a 8.5mg dose by the reporter).

Reported she believes 100% that her tachycardia was caused by the COVID-19 Vaccine, saying she has been fine up until receiving the COVID-19 Vaccine. She said she got the COVID-19 Vaccine because she was afraid of getting the COVID-19 Virus with her asthma. She said she has no other preexisting conditions besides the asthma. Reported she is not going to get the second COVID-19 Vaccine dose. She said it was scary when her heart rate shot up out of nowhere. She said the COVID-19 Vaccine is the only thing different she has done. She said before the COVID-19 Vaccine, she was completely fine. Patient asked if the Pfizer DSU agent had heard of anyone else who has experienced tachycardia after receiving the COVID-19 Vaccine. The outcome of the event tachycardia was recovered in Dec2020, event lightheadedness was recovering and unknown for the other events. The reporter assessed the event 'tachycardia' as Serious (Medically Significant).; Sender's Comments: Based on the close temporal relationship, the association between the event tachycardia with BNT162b2 can not be fully excluded. The medical history of tachycardia and asthma medication may be contributory as well. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

swelling and joint pain in the little finger on left arm; swelling and joint pain in the little finger on left arm; She got a bruise at the injection site; It bled a little bit when she put it in; This is a spontaneous report from a contactable nurse (patient). A 62-years-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number EK9231), via an unspecified route of administration on the left arm, on 28Dec2020 at 14:15 at a single dose for Covid-19 immunization. Medical history included environmental allergies, she has allergies and can have an asthmatic attack from cat dander and perfume, blood pressure (abnormal) and sleep (disorder). Concomitant medications included ongoing lisinopril for blood pressure, colecalciferol (VITAMIN D), acetylsalicylic acid (BABY ASPIRIN), paracetamol (TYLENOL). The patient previously took novocaine but was allergic. She got all this information when she got the vaccine on Monday at (place name) in (state name). It tells all the side effects from the first injection. She wanted to report that it is the same arm that she got the vaccine in. She has swelling and joint pain in the little finger on left arm. It says you can have joint pain, but nothing about swelling. She thought she better report it. This was her first shot. She is supposed to get the second one on 18Jan2021. She wanted to make sure she can take it. She received the vaccine on 28Dec2020. She laid around that day. Today is the first day she doesn't have arm pain and swelling at the injection site. It was the first time she has had arm pain. She has never had that with flu shot. The arm pain started within the 15 minutes she was observed. It hurt like hell until that day. She got a bruise at the injection site. It bled a little bit when she put it in. Swelling and joint pain in the little finger on left arm: she doesn't know if it was later that day. She can't remember. She really noticed it yesterday. She has never had joint pain or swelling. She doesn't have any problems with arthritis. Now her little finger is bigger than the rest of her fingers. It hurts because of the swelling. She doesn't want to take anything. It might be fluid. She has a high pain tolerance. She keeps bending it thinking it will get better. It isn't as bad, but its still swelled up. At first she thought it was better, but it is still pretty swollen. To her this is a reaction. She was thinking if she took paracetamol before, it wouldn't hurt as bad, but she can't remember if she took it that morning. She takes 500mg before bed for the heck of it at night. It helps

her sleep better. She has allergies and can have an asthmatic attack from cat dander and perfume. They think she was allergic to the preservative in the flu shot, but she has never had any trouble with the flu shot since. She has environmental allergies. They thought she was allergic to Novocaine once at the dentist office. Who knows, it only happened once. She's been to the dentist many times and who knows what they injected and why she reacted that way. She felt like she was going to pass out. They don't give it to her anymore. She doesn't know what was in it. She is worried since this vaccine is emergency authorization. She doesn't want to get the next one and have a worse reaction. She is not sure if she should be worried. The events of swelling and joint pain in the little finger on left arm were assessed as medically significant. Outcome of the event of 'swelling of fingers' was not recovered, the other events were unknown.; Sender's Comments: There is a reasonable possibility that the event joint pain was related to BNT162b2 based on known drug safety profile. Based on the temporal relationship, the association between the event swelling with BNT162b2 can not be fully excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

Covid 19 test: Nasal Swab Result: Positive; Covid 19 test: Nasal Swab Result: Positive; Severe joint swelling oral viral sores left lung fluid exhaustion; Severe joint swelling oral viral sores left lung fluid exhaustion; Severe joint swelling oral viral sores left lung fluid exhaustion; This is a spontaneous report from a contactable Other HCP (patient). A 56-year-old non-pregnant female patient received 1st dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), intramuscular in the left arm on 24Dec2020 12:00 at a single dose for COVID-19 immunization at the hospital. Medical history included juvenile idiopathic arthritis (JRA). The patient was not diagnosed with COVID-19 prior vaccination. Concomitant medications included imipramine, nebivolol hydrochloride (BYSTOLIC), and topiramate (TOPAMAX). The patient received other vaccine within 4 weeks prior to the COVID vaccine which is J&J cv trial. The patient experienced severe joint swelling, oral viral sores, and left lung fluid exhaustion on 25Dec2020 06:00; it was reported that no treatment was given for these. The patient tested for COVID-19 post vaccination. The COVID-19 test post vaccination was a Nasal Swab (Abbott Binax) on 27Dec2020. The COVID-19 test result was positive. Outcome of the events severe joint swelling, oral viral sores, and left lung fluid exhaustion was recovering; for the other events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: The association between the event lack of effect (COVID-19 test positive) with BNT162b2 can not be fully excluded. Based on the close temporal relationship, the association between the event left lung fluid exhaustion with BNT162b2 can not be fully excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

"blood pressure went up to 150/101; feeling like fainting; feeling really tired; Weakness; irregular heart beat; sob; feeling like flushing in the body; chills; This is a spontaneous report from a contactable

healthcare professional. A 39-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL1284), intramuscular on the left arm on 30Dec2020 07:15 at single dose for COVID-19 immunisation. Medical history included hypothyroidism, depression, cardiac murmur and pvc. The patient hadno known drug allergies and had not tested for COVID-19 prior and after vaccination. Concomitant medication included levothyroxine sodium (SYNTHROID), ergocalciferol (VITAMIN D), tocopherol (VITAMIN E) and sertraline hydrochloride (ZOLOFT). The patient experienced weakness, irregular heart beat, feeling like fainting, sob, blood pressure went up to 150/101, feeling like flushing in the body, chills, feeling really tired, all on 30Dec2020 07:15. The patient received treatment. The outcome of the events was recovering.; Sender's Comments: Based on the close temporal relationship, the association between the event ""blood pressure went up to 150/101"" with BNT162b2 can not fully excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate."

Got the first Pfizer COVID Vaccine and today I tested positive for COVID; Got the first Pfizer COVID Vaccine and today I tested positive for COVID; Congestion; Sore throat; This is a spontaneous report from a contactable consumer reporting for herself. A 26-years-old female patient received bnt162b2 (BNT162B2; Lot # EL0140) vaccine , via an unspecified route of administration on an unknown date in Dec2020 at single dose for Covid-19 immunisation . The patient medical history was not reported. There were no concomitant medications. The patient stated she got the first Pfizer Covid vaccine and on an unknown date in Dec2020 she tested positive for Covid 19, she also experienced nasal congestion and sore throat. The outcome of the events is unknown.

anaphylaxis; throat swelling; This is a spontaneous report from a contactable physician. A 50-year-old female patient (non-pregnant) received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 29Dec2020 at single dose for COVID-19 immunization. Medical history included hypertension, lipids (as reported) and asthma. The patient was known allergies: codeine, iodine, shellfish, latex, and cefatrizine propyleneglycolate (CEFTIN). Prior to vaccination, the patient was diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The most recent COVID-19 vaccine was administered in hospital. The patient experienced anaphylaxis and throat swelling on 22Dec2020 with outcome of recovered in Dec2020. The events were reported as non-serious. The events resulted in Emergency room/department or urgent care. Treatment of epinephrine, steroids, antihistamines, observation was received for the events. Information on lot/batch number has been requested.; Sender's Comments: A possible causal association between administration of BNT162B2 and the onset of anaphylaxis and throat swelling cannot be excluded, considering the plausible temporal relationship and the known adverse event profile of the suspect product. The underlying predisposing condition of allergies to multiple materials may put the patient at high risk of anaphylactic reactions. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of

aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

she got tunnel vision; almost passed out; Blood pressure dropped to 70/50; heart rate went up to 140; whole body got cold and tingly; whole body got cold and tingly; This is a spontaneous report from a contactable pharmacist (patient) reported for herself. A 25-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; brand: Pfizer Biotech; lot number: EL0142) via an unspecified route of administration at left arm on 30Dec2020 at 12:45 PM at a single dose (dose number: 1) for COVID-19 immunization. Facility where the most recent COVID-19 vaccine was administered was workplace clinic. Medical history included premature ventricular contractions (PVCs). No known allergies (no allergies to medications, food, or other products). The patient was not pregnant. No other vaccine in four weeks and no other medications in two weeks. The patient experienced adverse events included blood pressure dropped to 70/50, heart rate went up to 140, whole body got cold and tingly and she got tunnel vision and almost passed out. The events all started on 30Dec2020 at 12:45 PM. The events were reported as non-serious. No treatment received for events. The outcome of events was resolving. Prior to vaccination, the patient was not diagnosed with COVID-19, and since the vaccination, the patient had not been tested for COVID-19. No follow-up attempts are possible. No further information is expected.; Sender's Comments: Based on the close temporal relationship, the association between the event tunnel vision with BNT162b2 can not be fully excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

"The body aches started in his shoulder and now are all over his neck, back and whole body aches; The body aches started in his shoulder and now are all over his neck, back and whole body aches/ feeling like he has 1,000 pounds on his back; The body aches started in his shoulder and now are all over his neck, back and whole body aches; Body aches/The body aches started in his shoulder and now are all over his neck, back and whole body aches; Headache; Chills; Feel like crap; Low grade temperature; This is a spontaneous report from a contactable Nurse (patient). A 49-year-old male patient received BNT162B2 (Pfizer-BioNTech Covid-19 vaccine, lot number EL0142) intramuscularly at right shoulder approximately at 17:30 on 29Dec2020 for Covid-19 immunization. The patient's medical history included diagnosed allergies, compromised immune status, respiratory illness, genetic / chromosomal abnormalities, endocrine abnormalities (including diabetes) and obesity (a little over weight but he is fit). The patient had COVID in the end of Apr2020. The patient had no family medical history and had no prior vaccinations within four weeks. The patient had no concomitant medication. The second day of the vaccination, the patient called to report body aches, headache, chills, low grade temperature. As he reported, he just woke up and was walking around feeling like he had 1000 pounds on his back and felt like crap. The body aches started in his shoulder and currently all over his neck, back and whole body aches. Chills started last night (vaccination night). He was just trying to get to sleep and had to put an extra sweatshirt on last night. He did not check his temperature until he got up and it was 99.2 degrees

Fahrenheit. He was not able to provide a start date for the temperature. ""Body aches, headache between, chills between, low grade temperature (unspecified start date), feels like crap"" were considered developing between 24:00-01:00. He stated that they were all medically significant and he needs a day to recover hopefully. He just felt like he was hit by a truck. The patient had not visited physician or went to ER yet. The outcome of low grade temperature was unknown, chills was resolving and all other events did not resolve at the time of reporting.; Sender's Comments: There is a reasonable possibility that the events vaccination site pain, headache, chills, and pyrexia were related to BNT162b2 based on known drug safety profile. The association between the other reported events with BNT162b2 can not be completely excluded based on temporal relationship. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate."

"A nurse got Bell's Palsy after the vaccine; heart attack; This is a spontaneous report from a contactable consumer. A female patient (nurse) of an unspecified age received single dose of BNT162B2 (batch/lot number and exp date not reported), via an unspecified route of administration on an unspecified date for immunization. The patient's medical history and concomitant medications were not reported. The consumer asked if Pfizer have more information if so then what's the ingredients. States that ""injury lawyers know how many deaths because of the vaccine. Bell's palsy, a nurse got Bell Palsy after the vaccine, she is all distorted, and 30 days later, that's the 2nd one to have a heart attack."" The outcome of the events was unknown. Information on the Lot/Batch number has been requested."

2nd one to have a heart attack; This is a spontaneous report from a contactable consumer. A female patient of an unspecified age received BNT162B2 via an unspecified route of administration on an unspecified date at a single dose as Covid vaccine. Medical history and concomitant medications were not reported. After stating Pfizer has submitted a request for Emergency Use Authorization for potential COVID-19 vaccine and it was now in the FDA's hands, the reporter inquired if Pfizer had more information if so then what's the ingredients. It was then reported that the patient's the 2nd one to have a heart attack on an unspecified date. The outcome of the event was unknown. Information on the Batch/Lot number has been requested.; Sender's Comments: The association between the event heart attack with BNT162b2 can not be completely excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

"right mouth drop; right face numbness from eyebrow to below chin with right mouth drop; pins and needles feeling at injection site; then ears itching; This is a spontaneous report from a contactable nurse, the patient. A 63-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE Lot number: EK9231), via an unspecified route of administration, on 30Dec2020 at 03:45 AM (at the age of 63-years-old) as a single dose for COVID-19 vaccination. The facility where COVID-19 vaccine was administered was at a workplace clinic and anatomically located on

the right arm. Medical history included: History of Guillain Barre in 1970's with Swine Flu Vaccine. Concomitant medications included: clonidine (MANUFACTURER UNKNOWN), hydralazine ((MANUFACTURER UNKNOWN), spironolactone (MANUFACTURER UNKNOWN), pantoprazole (MANUFACTURER UNKNOWN); all for unknown indications from unknown dates and unknown if ongoing. The patient was not pregnant at the time of vaccination. Prior to the vaccination, the patient was not diagnosed with COVID-19. The patient did not receive any other vaccines within four weeks prior to the vaccination. The patient previously took unspecified medications (MANUFACTURER UNKNOWN), from unknown dates to unknown dates for unknown indications and experienced sensitivity to some medications, and unknown if ongoing. On 31Dec2020 04:15 PM, the patient reported ""'Within 30 minutes of vaccine, I had pins & needle feeling at injection site. Then ears itching followed by right face numbness from eyebrow to below chin with right mouth drop.'"" The patient did not receive any treatment for the events. The clinical outcome of the events pins & needle feeling at injection site, ears itching followed by right face numbness from eyebrow to below chin with right mouth drop, was not recovered. It was also reported that since the vaccination, the patient had not been tested for COVID-19.; Sender's Comments: A possible contributory role of the suspect products cannot be excluded for the reported events based on the temporal association."

Bell's Palsy; This is a spontaneous report from a contactable physician. A 37-year-old female patient (nurse) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot EK9231) via an unspecified route of administration on 29Dec2020 17:50 (5:50 pm) at a single dose as Covid vaccine. Medical history included hypertension and depression. Concomitant medications included venlafaxine hydrochloride (EFFEXOR); olmesartan medoxomil (BENICAR); and unspecified medications for depression and blood pressure medication (hypertension). It was reported that the reporter's nurse got her vaccine last night, about 6'o clock at night, and woke up with Bell's Palsy on Dec2020. She woke up in midnight to go to the bathroom and when she looked in the mirror, she noticed that there was discrepancy. The physician examined her this morning, so it was in several hours getting the vaccine that she noticed it. She got the vaccination last night at 5:50 pm. When she went to bed it wasn't a problem. She woke up at midnight and noticed it. The patient was started on Medrol dose pack but she hasn't taken it yet because she's at work so she would start it today (unknown if the treatment was already received); it's steroid, Methylprednisolone, at 24 mg on day one and then decreases 4 mg a day over the next five days until it's done. The doctor inquired what should the patient do about her second dose and also asked if she should not get her second dose. The outcome of the event was unknown.; Sender's Comments: Based on temporal association, the causal relationship between BNT162B2 and the event facial paralysis cannot be excluded. This case will be reassessed once additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate.

edema started in her feet and ankles and then moved 3 quarter way to her shin; 4+ pitting edema; This is a spontaneous report from a contactable nurse (patient). A 47-year-old female patient received the

first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 17Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient reported she received the Covid vaccine on 17Dec2020 and on 25Dec2020 she noticed her shoes were snug and on 26Dec2020 she noticed 4+ pitting edema lasting 3 days. She went and brought some compression stockings and this has helped the edema improve but was still mild. The edema started in her feet and ankles and then moved 3 quarter way to her shin. She would like to know if she should receive second dose of Pfizer vaccine. Outcome of the event was unknown. Information on the lot/batch number has been requested.; Sender's Comments: The reported information is limited. Based on the close temporal relationship and the description of the events, there is a reasonable possibility that the events are related to BNT162 vaccine. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

Having trouble clearing my throat, felt like it was closing up; Having trouble clearing my throat, felt like it was closing up; Uncontrollable rigors; High heart rate; Numb lips and hands; Numb lips and hands; Nausea; Shortness of breath, difficulty catching my breath; This is a spontaneous report from a contactable healthcare professional (reporting for herself). A 38-year-old female received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number EJ1685, expiry date 30Dec2020) intramuscular (Arm Left), on 30Dec2020 09:15, single dose, for COVID-19 immunization. Relevant medical history included bariatric surgery, had anterior vaginal repair and bladder sling, had gall bladder removed, and had tonsils removed. It was reported that the patient cannot take NSAIDS, patient was not allergic to them. No allergies to food or other products. Concomitant medications included rizatriptan and paracetamol (TYLENOL). On 30Dec2020, within about 10 minutes of the injection of the vaccine, the patient had trouble clearing her throat, felt like it was closing up, had uncontrollable rigors, high heart rate, numb lips and hands, and nausea. The patient was discharged from the ED, went home and took a nap. Later that evening, the patient began to have a rapid heart rate again, began to had shortness of breath, difficulty catching her breath, and was admitted to the ED again and given more IV medications. Therapeutic measures given in response to the event included administration of IV medications, epinephrine injection and breathing treatment. Prior to the COVID vaccine, the patient did not receive any other vaccines within 4 weeks, was not tested or diagnosed with COVID-19. Facility where the most recent COVID-19 vaccine was administered was in the workplace clinic. Outcome of the events was recovering at the time of the report.; Sender's Comments: Based on temporal association, the causal relationship between BNT162B2 and the events oropharyngeal discomfort, throat tightness, chills, heart rate increased, hypoaesthesia oral, hypoaesthesia, nausea and dyspnoea cannot be excluded. This case will be reassessed once additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate.

patient was noted to be flushed by residential home staff on 12/30/2020, approximately 2.5hrs after vaccination, fever present at that time. Prior to COVID19 vaccine administration, this patient did have exposure and was close contact with a known case of COVID19 in a residential care employee. Patient was taken to hospital for evaluation of febrile status, had positive COVID19 test at that time, and reported hypotension per residential care staff.

PATIENT SPOUSE REPORTS THAT PATIENT RECEIVED VACCINE ON 1/4/2021 AND ON 1/5/2021 PATIENT'S ARM BEGAN TO TURN RED AND SWELL AT THE INJECTION SITE. THE SWELLING AND REDNESS BEGAN TO GO DOWN HIS ARM AND HE BROKE OUT INTO A RASH. PATIENT THEN BECAME SHORT OF BREATH. EMS WAS CALLED AND PATIENT WAS TRANSPORTED TO HOSPITAL, WHERE HE WAS TREATED FOR ANAPHYLACTIC SHOCK TO THE COVID MODERNA VACCINE.

Anaphylaxis Narrative: 12/22 received COVID-19 vaccine at 1209 and developed SOB at 12:15. Took her own albuterol inhaler without relief. Transported to ED. PE: red hands with swelling, throat and lip swelling with difficulty swallowing. Later developed headache and dizziness then tachypnea and stridor. Meds given - See section 5 PLUS epinephrine IM and infusion @ 0.05 mcg/kg/min, Alb and ipratropium negs, racemic epi nebs. Admitted to the hospital on 12/22 and still hospitalized at the time of this report on 12/23. She remains on an epinephrine drip and was given methylprednisolone 125 mg IV x 2. No previous history of anaphylaxis. History of Reye's syndrome as a child when given aspirin.

Agitation, Sedation, Anaphylaxis, Rash & HYPOtension

"covid; covid; This is a spontaneous report from a contactable physician. A male patient of an unspecified age received single dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, batch/lot number and exp date not reported), via an unspecified route of administration on an unspecified date for immunization. The patient's medical history and concomitant medications were not reported. The physician inquired whether a person with previous history of COVID would experience more significant reaction to the COVID vaccine than a person without a previous diagnosis due to having already produced antibodies. Reporter's colleague (physician) had the vaccine 2 weeks ago, had a severe reaction (unspecified) wherein he got a shot of epi. Patient recovered and was okay. At the time of reporting, patient now had Covid or maybe he had Covid before, reporter was not sure. The outcome of the events was unknown. Information on the Batch/Lot number has been requested.; Sender's Comments: Based on available information, a possible contributory role of suspect BNT162B2 vaccine cannot be completely excluded for event ""Covid""."

positive COVID-19 test with symptoms; positive COVID-19 test with symptoms, tested for COVID (PCR); night sweats; Soreness at injection site; slight temp 99.5 degrees/her temperature was 101 degrees Fahrenheit/it was 102.5 degrees Fahrenheit/99 degrees Fahrenheit and then 98 degrees Fahrenheit; Tiredness she related to giving blood; This is a spontaneous report from a contactable nurse (patient). A 54-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL0140) via intramuscular on 19Dec2020 15:45 on left deltoid at a single dose for prevention as frontline health worker at hospital (COVID-19 immunisation). The patient donated blood on 18th and no antibodies were present then. The patient was a former smoker and quit 2 or 3 years

ago. Patient diagnosed Osteoporosis in 2015, benign heart arrhythmia in 2005. The patient took 70 mg alendronate sodium (FOSAMAX) once weekly and just a regular OTC daily multivitamin. Caller reported she was having the covid vaccine on 19Dec2020 and began having fever, night sweats, loss of taste and smell and then tested positive for covid. The patient received the Pfizer COVID 19 vaccine through work on 19Dec2020. She received it at 3:45 pm and should have taken temperature before, but she was afebrile the day before because she donated blood. At 7pm, she had slight temp 99.5 degrees Fahrenheit and by 10:30, her temperature was 101 degrees Fahrenheit and she still felt fine. She was surprised that it was that. She woke up at 2:30 am on 20Dec2020 and took her temperature and it was 102.5 degrees Fahrenheit. She took 2 Tylenol and went back to bed and felt fine. By morning it was 99 degrees Fahrenheit and then 98 degrees Fahrenheit a little later. She has been afebrile since then. She was a little tired because she gave blood and though it was related. She does not know if it was a side effect or not. It was not significant tiredness and was just not having energy in the evening of 19Dec2020. She also had soreness at injection site that night after 22:00 and the next day. It did not bother her until she woke up in the middle of night, and she noticed her left arm was sore. She received the vaccine at 3:45pm and started with low grade fever at 6:30 pm, earlier stated at 7:00 pm. There was no prescriber. She tested for COVID (PCR) on Saturday, 26Dec2020 at 14:50and it came back positive 28Dec2020 18:45. At 10pm on 19Dec2020, her temperature was 101 degrees Fahrenheit. If she had not been monitoring her temperature, she would not have known. She has been Afebrile since morning of 20Dec2020. Tiredness she related to giving blood and the holidays. She was a little stressed about the holidays and running around. It was very mild. Soreness at injection site was during the night after 10pm when she went to bed. On Wednesday, 23Dec2020, she woke up congested, sniffly, sneezy, with a runny nose. This persisted through Wednesday night. Her sense of taste was off. She had no problem with that on Tuesday. She had some horrible smell at work she recalled, so she knew her sense of smell was fine. On Thursday, 24Dec2020, she had no sense of taste or smell. She could not smell a pine candle. She was congested on Thursday and called employee health on 24Dec2020. This both improved and persisted. She is still congested but it has improved. She has never had a complete loss of sense of taste or smell before. Mild cough started yesterday morning. On the night of 20Dec2020, and 21Dec2020, she developed night sweats. She had not had any night sweats before this since menopause and she woke up really wet. The patient was not hospitalized and not admitted to an Intensive Care Unit. NO ER or physician's office required. She did not know if she was exposed on the day of the vaccine or if a couple of days later if the fever is from the vaccine. She stated what are the chances she goes 10 months and is super careful and then gets the vaccine and test positive. The patient did not display clinical signs at rest indicative of sever systemic illness. The patient did not require supplemental oxygen nor receive mechanical ventilation. No Multiorgan failure. The patient did not receive any additional therapies for COVID- 19. No initiation of new medication or other treatment or procedure. Not any preexisting diseases worsen during the SARS-CoV2 infection. She would like to know if there is a chance of false positive for this. It would just be her luck to be 10 months and not getting it. She has not gone anywhere without her N95 and then gets the vaccine and gets COVD. She wears mask and face shield at work always. She also wanted to know if she should get the second dose. The outcome of the event slight temperature was recovered on 20Dec2020 and the other event was recovering.; Sender's Comments: Based on the information currently available, a lack of efficacy with the suspected vaccine BNT162B2 in this patient cannot be completely excluded.

tested positive for Covid two days after getting vaccine; tested positive for Covid two days after getting vaccine/nasal swab/ NP PCR and result was positive; This is a spontaneous report from a contactable physician. A 39-years-old male patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number and expiration date not reported), intramuscular on the left arm on 24Dec2020 at 08:30 at a single dose for Covid-19 immunization. There were no medical history and no concomitant medications. The patient has no known allergies to medications, food, or other products. On 25Dec2020 at 09:00 am, also reported as 26Dec2020, the patient was tested positive for Covid two days after getting vaccine. He was wondering if he should get the booster dose in 3 weeks or not since he will have natural immunity. The patient did not receive any treatment for the events. The patient had a nasal swab/ NP PCR and result was positive on 26Dec2020. The outcome of the events was not recovering. The events were assessed as non-serious. Information on the lot/batch number has been requested.; Sender's Comments: No effect of the suspect vaccine could be reasonably achieved to protect from the targeted infection/disease due to the very short time lag. Instead, the COVID-19 PCR test positive represents the pre-existing infection prior to vaccine use. Further information like confirmative COVID 19 nucleic acid/ PCR test together with any associated symptoms are needed for full medical assessment.

positive COVID-19 test with symptoms; positive COVID-19 test with symptoms; This is a spontaneous report from a contactable unspecified HCP reporting for herself. This 61-year-old female patient received on 22Dec2020 BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) at single dose for COVID-19 vaccination. Medical history and concomitant medications were not reported. On 24Dec2020, the patient had a bad reaction, coughing, headache, no taste, tiredness and body aches. The patient thought originally, she was having a reaction to the vaccine, and took some ibuprofen (ADVIL). The patient was still congested and was sent for testing. She was tested positive on 28Dec2020. The test was a nasal swab. Outcome was unknown. The patient was wondering if this was part of the side of effect of the vaccine. Information on the batch number has been requested.; Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of events Drug ineffective and COVID-19 cannot be totally excluded. The case will be reassessed if additional information becomes available.

got the COVID-19 vaccine last week and six days later tested positive for COVID-19; got the COVID-19 vaccine last week and six days later tested positive for COVID-19; This is a spontaneous report from a contactable pharmacist. A patient of unspecified age and gender received bnt162b2 (BNT162B2 also reported as PFIZER-BIONTECH COVID-19 VACCINE, lot/batch number and expiry date were not reported), via an unspecified route of administration on unspecified date in Dec2020 at single dose, for covid-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient got the covid-19 vaccine last week and six days later (Dec2020) tested positive for Covid-19. The outcome of event was unknown. Information about Lot/Batch number has been requested.; Sender's Comments: The information currently provided is too limited to make a meaningful medical assessment hence, the events are conservatively assessed as related to the suspect drug BNT162B2 until further information becomes available.

anaphylaxis; ALOC/decreased level of consciousness; This is a spontaneous report from a contactable Pharmacist (patient). a 40-year-old female patient (no pregnant) received first dose BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number EL0140) via intramuscular at Left arm on 23Dec2020 at single dose for COVID-19 immunization. The patient's medical history included known allergies to egg, seafood, azithromycin, orange and seasonal allergies. The concomitant was reported as cetirizine hydrochloride (ALLERTEC) and PRN 1371. The patient with no known past medical history brought in by CODE Team to RUH ED with concern for ALOC after getting the COVID vaccination 30-40 minutes PTA. Patient was a nurse and experienced decreased level of consciousness following her COVID vaccination. Patient reports h/o anaphylaxis. She was given epinephrine PTA. Denies SOB, oral swelling, CP. Blood glucose (BGL) within normal limits. Patient denies any other complaints or symptoms at this time. Adverse event start date: 23Dec2020. Treatment was unknown for decreased level of consciousness. The outcome of the events was recovered in Dec2020.; Sender's Comments: A possible causal association between administration of BNT162B2 and the onset of anaphylaxis /decreased level of consciousness cannot be excluded, considering the plausible temporal relationship and the known adverse event profile of the suspect product. The underlying predisposing condition of allergies to multiple materials may put the patient at high risk of anaphylactic reactions. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

"caller couldn't hear properly; got the Covid vaccine last 18Dec2020/her second dose of COVID-19 Vaccine was scheduled on 06Jan2021; Caller got the Covid vaccine last 18Dec2020 and was tested positive, 29Dec2020; Caller got the Covid vaccine last 18Dec2020 and was tested positive, 29Dec2020; Nausea; Headache; Body aches; fatigue; Cold sweat; This is a spontaneous report from a contactable other health professional. A 51-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number reported as either EK5730, ER5730, or EX5730), via an unspecified route of administration on 18Dec2020 16:00 at single dose at left deltoid for COVID-19 immunisation. Medical history and concomitant medications were none. The patient previously had shingles shot in Sep2020, previous shingles shot either three months or six months prior to the one in Sep2020 (2020), both for immunization, and severe myalgia and fever that lasted for two days after the second shingles shot (adverse events followed prior vaccinations). It was reported that did a callback as caller couldn't hear properly. Caller got the Covid vaccine last 18Dec2020 and was tested positive, 29Dec2020. Want to know if it's safe for her to get the second dose. The patient received Pfizer COVID-19 Vaccine on 18Dec2020 at 16:00. Patient had a couple days worth of symptoms. Now patient had COVID. Patient believed most likely got COVID from her son who was home from college. She was in between dosages of COVID-19 Vaccine. Looked like from research her quarantine would be done on 05Jan2021 and her second dose of COVID-19 Vaccine was scheduled on 06Jan2021. Everything she had read stated if her symptoms were gone to go ahead and get the second COVID-19 Vaccine. Patient wanted to know if Pfizer was doing any studies regarding people who test positive for COVID after receiving the COVID-19 Vaccine. Not sure if Pfizer would be interested in doing antibody studies. Declined obtained COVID-19 Vaccine through work Clarified caller's days worth of symptoms as: Headache the same evening as

vaccination. Body Aches: began overnight on 18Dec2020. Fatigue that lasted all week, began overnight on 18Dec2020. Cold sweats: Lasted two days and began overnight on 18Dec2020. Nausea: began on 21Dec2020, not sure if it was related to COVID-19 Vaccine or not. The reporter considered the events weren't serious, but felt like she was having an immunological response. Diagnosed with COVID Seriousness: As of now, not serious. Is having a recurrence of all of those same symptoms as the COVID-19 Vaccine and then some. Lot number provided from patient card. Stated she was unable read it accurately. would take picture in case Pfizer wanted it. Stated lot number was either EK5730, ER5730, or EX5730. A sample of the product was not available to be returned. Vaccination facility type was Hospital, not administered at military site. No additional vaccines administered on same date of Pfizer suspect. No adverse events required a visit to. No prior vaccinations received within 4 weeks. The outcome of the event ""Cold sweat"" was recovered on 20Dec2020. The outcome of the other events was unknown. The reported considered the events Headache, Body aches, fatigue, Cold sweat, Nausea were related to the suspect drugs. Information on the lot/batch number has been requested.; Sender's Comments: The reported COVID test positive after COVID-19 immunization is considered ineffective of BNT162B2, and the Company cannot completely exclude the possible causality between the reported event and BNT162B2 administration."

had her shot of Covid vaccine last (22Dec2020) 7 days and was tested positive on Dec2020; had her shot of Covid vaccine last (22Dec2020) 7 days and was tested positive on Dec2020; This is a spontaneous report from a contactable consumer (patient). A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 22Dec2020 at a single dose as Covid vaccine. Medical history and concomitant medications were not reported. It was reported that the patient had her shot of Covid vaccine last (22Dec2020) 7 days and was tested positive on Dec2020. She wanted to know if this was normal to get false positive results after getting the vaccine. The outcome of the events was unknown. Information on the lot/batch number has been requested.

Positive for Covid after receiving the vaccine; Positive for Covid after receiving the vaccine; This is a spontaneous report from a Pfizer Sponsored Program. This consumer reported similar event for two patients. This is the 2nd of 2 reports. A female patient of an unspecified age received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number and expiration date not reported), via an unspecified route of administration on 22Dec2020 at a single dose for Covid-19 immunization. The patient medical history and concomitant medications were not reported. On an unspecified date, the patient was positive for Covid after receiving the vaccine. It was reported that patient was positive and they were all in the breakroom without a mask. The patient (person that is positive) got the vaccine and got worse, so co-workers are thinking that she (patient) had the virus before getting the vaccine and just didn't have any symptoms. Outcome of the events was unknown. Information on the batch/lot number has been requested.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2020518090 same reporter/drug, similar event, different patient

Asymptotic positive rapid COVID test 12 days post vaccination. Close contact testing/Nasal Swab positive; Asymptotic positive rapid COVID test 12 days post vaccination. Close contact testing/Nasal Swab positive; This is a spontaneous report from a contactable Other HCP (patient). A 52-year-old

female (not pregnant) patient received first dose bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EK5730), intramuscular in arm left on 17Dec2020 13:15 at single dose for COVID-19 immunisation. Medical history included seasonal allergies, depression and Allergies: Sulfa. Prior to vaccination, the patient was not diagnosed with COVID-19. Concomitant medications included sertraline hydrochloride (ZOLOFT), cefixime (FLEXERIL), fluticasone propionate, salmeterol xinafoate (ADVAIR), montelukast sodium (SINGULAIR), omeprazole (PRILOSEC). The patient previously took pethidine hydrochloride (DEMEROL) and experienced 'allergies: Demerol', codeine and experienced 'allergies: codeine'. The patient experienced asymptotic positive rapid COVID test 12 days post vaccination. Close contact testing on 29Dec2020. The patient underwent lab tests and procedures which included [{covid test type post vaccination= Nasal Swab, covid test date=29Dec2020, covid test result= Positive}]. Facility type vaccine was workplace clinic. No treatment received for the adverse event. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The outcome of the events was unknown.; Sender's Comments: Based on the information currently available, a lack of efficacy with the suspected vaccine BNT162B2 in this patient cannot be completely excluded.

"I got the Pfizer vaccine, the first shot; I tested positive for Covid; I got the Pfizer vaccine, the first shot; I tested positive for Covid; This is a spontaneous report from a contactable consumer (patient). A patient of unspecified age and gender received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EH9899), via an unspecified route of administration on 18Dec2020 at single dose for covid-19 immunization. The patient medical history and concomitant medications were not reported. Consumer stated, ""I had a question, I got the Pfizer vaccine, the first shot on the 18Dec but I tested positive for Covid on the 27Dec, so, my question is this and I asked my healthcare institution and they still haven't got back to me, so I just wanted to call you guys, what do I do about the second dose because I am scheduled to get the second dose net week?"" The outcome of event was unknown."

she received the COVID Vaccine on the evening of Christmas, and then she tested positive for COVID on Sunday; she received the COVID Vaccine on the evening of Christmas, and then she tested positive for COVID on Sunday; This is a spontaneous report from a contactable consumer, the patient. A 48-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE); in the left arm on 25Dec2020 as a single dose, for COVID-19 immunization. The patient had no known medical history. There were no concomitant medications. Caller confirmed the product was not specifically prescribed to her, but she received it via an options at her company and had received no other vaccines on the same day as the COVID vaccine. The patient received the COVID Vaccine on the evening of Christmas 25Dec2020, and then she tested positive for COVID on Sunday, 27Dec2020. The patient had a positive SARS-CoV-2 test on 27Dec2020. The clinical outcome of the event Drug ineffective and COVID-19 was unknown. Information regarding lot number has been requested.

tested positive for COVID; tested positive for COVID; This is a spontaneous report from a contactable consumer (patient). The consumer reported for self and husband. This is the first of two reports, and concerns the reporter (patient). A patient of an unspecified age and gender received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE) (lot number EJ1685/expiration date: 31Mar2021), via an unspecified route of administration, on 19Dec2020, as a single dose for COVID-19 immunization. Relevant medical history and concomitant medication were not provided. On an

unspecified date in Dec2020, the patient tested positive for COVID. The outcome of the event tested positive for COVID was unknown.

tested positive for COVID; tested positive for COVID; Flu; This is a spontaneous report from a contactable consumer. The consumer reported for self and husband. This is the second of two reports and concerns the reporter's husband. A male patient of an unspecified age received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE) (lot number EH9899/expiration date: not provided), via an unspecified route of administration, on 18Dec2020, as a single dose for COVID-19 immunization. Relevant medical history and concomitant medication were not provided. On an unspecified date in Dec2020, the patient experienced the flu after receiving the vaccine. On an unspecified date in Dec2020, the flu symptoms went away and the patient tested positive for COVID. The outcome of the event flu was recovered in Dec2020 and the outcome of tested positive for COVID was unknown.

Caller received COVID vaccine on the 18th then tested positive on the 24th; Caller received COVID vaccine on the 18th then tested positive on the 24th; This is a spontaneous report from a contactable healthcare professional. A female patient of an unspecified age received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiry date not reported), via an unspecified route of administration on 18Dec2020 at single dose for COVID-19 immunisation. Medical history and concomitant medications were not reported. It was reported that the patient received COVID 'vaccine on the 18th then tested positive on the 24th'. The reporter mentioned that a friend who works for Pfizer told her to call and report. Clinical outcome of the events was unknown. Information on batch/lot number was requested.; Sender's Comments: Based on the information available, a possible contributory role of the suspect products cannot be excluded for the reported event of positive for corona virus infection for the lack of efficacy of the vaccine. However, based on the mechanism of action of the vaccine, it is unlikely the patient would have fully developed immunity for the vaccine to be effective, due to the short duration of 6 days since the vaccine first dose is given.

Was diagnosed with the COVID-19 virus after receiving the COVID-19 Vaccine on 18Dec2020; Was diagnosed with the COVID-19 virus after receiving the COVID-19 Vaccine on 18Dec2020; This is a spontaneous report from a contactable Other Health Professional (patient) from a Pfizer-sponsored program IBCC (Inbound Call Center for HCPs). A 38 years old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 18Dec2020 at single dose in Deltoid Right for COVID-19 immunization. Medical history and concomitant medications were none. After receiving the COVID-19 Vaccine, the patient was diagnosed with the COVID-19 virus on 28Dec2020. she saw Dr. at the clinic where she works to seek treatment. She stated she is supposed to receive the 2nd dose of the COVID-19 Vaccine on 08Jan2021. She asked now that she is COVID-19 positive, should she get the 2nd COVID-19 Vaccine dose. Reported she had a rapid nasal swab COVID-19 test performed. Reported she is taking Hydroxychloroquine and a bunch of vitamins for treating COVID-19. Caller stated she did not have the COVID-19 Vaccine card with her to provide the Lot Number. The patient underwent lab tests and procedures, which included COVID-19 rapid POC test with positive result. Outcome of event was unknown. Information on the Batch/Lot number has been requested.; Sender's Comments: Based on the information available, a possible contributory role of the suspect

BNT162B2 cannot be excluded for the reported COVID-19 based on the known safety profile. However the short duration of 10 days since the vaccine first dose is given it is unlikely patient would have fully developed immunity.

"Lost sense of taste; Lost sense of smell; Whole body is sore; Rapid test came back positive for COVID; Rapid test came back positive for COVID; This is a spontaneous report from a Pfizer-sponsored program IBCC (Inbound Call Center for HCPs) via a contactable consumer (patient). A 21-year-old male patient received his first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number: EK5730, expiration date: 31Mar2021), via intramuscular on 29Dec2020 07:40 at 0.3 mL, single dose on his left deltoid for covid-19 immunization. Medical history included allergic to wasp stings. There were no concomitant medications. The patient had no additional vaccines administrated on the same date and no prior vaccinations were received within 4 weeks. Caller on the line calling about the COVID Vaccine he received on 29Dec2020. The day after receiving it he woke up and had a loss of sense of smell on 30Dec2020 12:00. That afternoon he went to get tested and the rapid test came back positive for COIVD on 30Dec2020. He was now waiting on the other one, clarified to be the PCR test, the lab test. The next day he also lost his sense of taste on 31Dec2020 11:00 and his whole body feels sore on 30Dec2020 around noon. Transfer agent stated the caller needs to be transferred to Medical Information as he was scheduled to get the next shot on 19Jan2021 and he was calling to ask if he should proceed with that. It was reported that the patient works in a hospital (not an HCP). No emergency room was visited and no physician office was visited. The outcome of the event ""rapid test came back positive for covid"" was unknown, the outcome of the other events ""lost sense of smell"", ""lost sense of taste"", ""whole body is sore"" were not recovered."

Went to the ER on the 31st, my face swelled and chest was covered in hives. Lips swelled. I would get nauseated and I felt like there was acid in my stomach. I also had a headache. I have been taking Zyrtec, Benadryl as needed.

The day after the vaccine I had fatigue and body aches. Then on 12-23 fevers of 101.4, chills, body aches, diarrhea, vomiting, productive cough, and profuse sweating. Jan 1st I was in the shower and was dizzy with a headache. Loss of consciousness almost happened and that is when i got out of the shower and laid down. Went to the ED and was diagnosed with bilateral pneumonia

I did let the nurse know right after I got the vaccine It did feel like a huge water balloon was sitting on my arm and very heavy at the site. I went to the waiting area and the last 5 minutes and I started feeling weird, kind of getting dizzy and my heart started racing really fast. Am I can tell I was getting really hot and my face was flushed and my heart was racing and my hands started shaking, trembling almost like I couldn't control it. I've never experienced something like this. The part that really scared me was my heart racing like it was going to come out of my chest. They called a code, put me in a wheel chair and took me to the ER (where I work). They took my blood pressure which was really high, they did EKG, blood work and urine test. They kept me there for about five hours, while watching me. And the last weird thing that happened at one point I felt like liquid was running thru my body and my feet were really cold for several hours, It felt like someone was pouring liquid over me. I kept asking the nurse if this is normal and no one knew what to tell me. After everything started slowing back down and it had

been a couple hours and the next day i felt like I had a slight head ache and felt out of it, kind of like I had a hangover and of course my arm was really sore. The Doctor in the ER did advise me not to get the second dose as it will be worse than the first one.

LEFT SIDED CHEST PAIN, SHORTNESS OF BREATH, FELT WARM AND FLUSHED

I got my shot on the 19th and that evening it was like a light switch and I was so tired I went to sleep at 730pm I had severe chills and fever and had to go to bed. The next day I still wasn't feeling well and I was called in to get covid tested and I went to the ER on the 21st and took a rapid covid test that was positive. I was stable and had good oxygenation and was discharged. I have fever nausea vomiting I also had problems with O2 stat i was in the 80s and realized I was having respiratory failure so I was admitted on the 27th and I've been here ever since. I had kinetic storm and infusions my O2 stats were bad and I was sent to the covid unit and put on high flow oxygen and negative for a PE, I'm still on the covid unit but I feel much better today

Patient was vaccinated Dec 30, 2020. Prime dose of Moderna vaccine. Observed for full 15 minutes post-injection. No complaints when asked during observation. Released. Subsequently, vaccine clinic staff learned from the patient's supervisor that on Jan 4, 2021 that the patient had expired on Jan 2, 2021. By report from the supervisor, the patient was found dead at his home. The patient's primary care provider was unaware of his death when contacted by this reporter today (Jan 6, 2021). Electronic Medical Record without any information since the vaccination.

5 MIN POST ADMINISTRATION: SOB, DIZZINESS, CHANGE IN VISION - GAVE BENADRYL 25 MG AND 1 VIAL ALBUTEROL VIA NEB 1 HOUR POST ADMINISTRATION: SWOLLEN LIPS, RASH ON CHEST AND ARMS - GAVE 1 DOSE OF EPI PEN AND IM SOLU-MEDROL, CALLED EMS, LEFT TO GO TO ER BP, HR, OXYGEN STABLE THROUGHOUT

after 20-30 minutes my throat started to get tight, I could not swallow properly, I felt dizzy & my heart was beating fast.

anaphylaxis, dyspnea

"Client received vaccine at approximately 3:50pm, waited in observational area x30min. Left with husband, stated that she got a few miles down the road and starting experiencing tightness in her chest and flushing. She took 50 mg of Benadryl, 30mg of prednisone and two puffs on her inhaler. She returned to the clinic, upon assessment from nursing she looked extremely flushed and anxious, she stated that she still felt tightness and that she had a history of anaphylaxis once before and had used an epi pen in the past. She had an epi pen with her and questioned whether or not she should give it to herself. BP was 190/68, pulse was normal, respirations normal, she continued to experience tightness and ""not able to catch my breath"", encouraged to use epi pen. She administered epi pen to right thigh at approximately 4:45PM, 911 called. Within a few minutes, she stated she was feeling better, less tightness in the chest, flushing was subsiding. BP at 190/70 at 4:52. EMS on scene at 5:03pm. Vitals normal , EKG normal. Client decided not to transport with EMS."

resident expired 1/1/2021

I started having intermittent chest pain moderate in intensity and palpitations.

Resident expired 1/3/21

Migraines, right side of face swollen, nausea, tingling

Patient tolerated the vaccine well with no apparent side effects. Ten days later awoke 12:30 AM with severe chest and upper back pain, presented to Med Center where he was found to have an Acute Coronary Syndrome. Transferred to Medical Center where he underwent successful PCI with two drug eluting stents for a 99% mid-LAD stenosis

Shortness of breath, fever, fatigue

At around 11:40am resident was observed to be unresponsive. resident noted with pulse and respiration. Not in any distress. lung sounds clear. Vital Signs BP162/82 P86 R18 T97.1 O2 Sat 96%, fingerstick is 133mg/dl .Resident received COVID 19 vaccine at 11:25am. O2 via 2l NC initiated. Nurse Stat call, 911 initiated, MD at Bedside. Resident awake and responsive. EMT responded and resident left with EMT to be transferred to hospital, remains awake and not in any respiratory distress.

Adult failure to thrive; Chronic hypoxemic respiratory failure; Generalized weakness

Patient did not display any obvious signs or symptoms; the vaccination was administered at approximately 10:00 AM and the patient continued throughout her day without any complaints or signs of adverse reaction. Patient was helped to bed by the nursing assistant estimated at around 9:00 PM. The facility received notification from the lab around 11:00 PM that the patient's COVID-19 specimen collection from Sunday, 1/3/21, detected COVID-19. When the nursing staff went to the room to check on the resident and prepare her to move to a COVID-19 care area the patient was found unresponsive, no movement, no chest rises, noted regurgitated small amount of food to mouth left side, lying on left side. Pupils non reactive.

coughing up blood, significant hemoptysis -- > cardiac arrest. started day after vaccine but likely related to ongoing progression of lung cancer

PATIENT REPORTING ITCHING AT 30 MINUTES POST INJECTION. AT 1.5 HOURS POST INJECTION PATIENT REPORTED ITCHY THROAT AND NUMBESS OF LEFT SIDE OF FACE. AT THAT TIME ADVISED TO GO TO EMERGENCY ROOM. NEXT DAY WHEN I FOLLOWED UP WITH PATIENT, SHE REPORTED HER AIRWAY STARTED TO CLOSE AND SHE RECEIVED EPINEPHRINE, AFTER 5 HOURS HER STARTED TO CLOSE AGAIN AND RECEIVED ANOTHER DOSE OF EPINEPHERINE, WAS RELEASED FROM HOSPITAL ROUGHLY 15-16 HOURS AFTER GOING TO ER.

At 10:12 am, Client c/o of sore throat, tightness in throat that relieve quickly, nausea, dry heaves, flushed, light headed and dizziness. Called for EMT. They arrive at 10:25 am and transported her to the

local hospital for observation. 01/06/21-Treatment in hospital blood draw, medications given Zofran, Decadron, Benadryl, and Pepcid, and IV fluids. Discharged home at 1244.

5 minutes after injection, my feet and palms itched and I was lightheaded but I tried to shake it off and it faded over the next 10 minutes. I did report it and stayed longer and was ok. Then i went straight home and layed down because i did not sleep well night before (was on call) i awoke 1 hour post injection dry heaving, very nauseated, mild headache, achy, itchy over different parts of my body and weak. Sat up and my face was getting itchier, lips started to swell, tongue started to swell and itch, throat felt like someone was strangling me, had trouble swallowing and trouble breathing. took 2 benadryls immediately and went out into cold air, thought about calling 911 but got better in 10-15 minutes. never have had a reaction like this in my life. have had hives though in the past. If I would have had an epi pen I would have used it (never have had an epi pen) I was frightened but the benadryl worked and I slept due to the benadryl for 5 hours, when I woke up the benadryl wore off and it started again. took more benadryl, and it improved. before bedtime, the benadryl wore off and I had a hard time swallowing my night time meds like my throat was swollen. Took 2 more benadryls, today I am weak and nauseated and ate very little and feel like my face is still red and itchy. I told my sister and she said she is allergic to PEG which i later noted was in the vaccine. i am very disappointed that I had this reaction- I have desparately wanted this vaccine as a medical worker with a lot of covid patients- I onlu hopr this one shot will protect me enough because it is clear to me that i cannot take this vaccine again.

Severe Hypotension, Redness, Warmth and sensitivity all over skin surfaces, lack of responsiveness, low oxygen saturation.

At approximately, 1855, I was alerted by caregiver, resident was not responding. Per caregiver, she was doing her rounds and found resident in bed, unresponsive, mouth open, observed gurgling noises and tongue hanging out of mouth. This primary caregiver observed resident at baseline and ambulating after dinner at approximately, 1800 less than an hour prior to incident. This PCG called 911 for EMS and gave report of incident. Resident was taken to Medical Center Emergency Department. At ER, CT scan and X-ray was performed. Per report from ER RN, CT scan and x-ray revealed an intracranial aneurysm and fluid in the lungs. Per RN, resident was still unresponsive and was admitted to Medical Center for observation and comfort measures. This primary caregiver reported to RN, resident recently received the first dose of COVID-19 vaccine on 1/2/21. Primary caregiver received a call from Castle RN at 0700, resident expired at 0615.

Three to four hours after vaccine had bruising, major loss of range of motion, severe sharp pain, elevated temp and chills due to reaction of injection site Treatment given 24 hrs later- strong antibiotics, anti inflammatory, exercise, and three days out of work Due to loss of function of left arm due to inflammation

Severe shortness of breath, administered inhaler, hydralazine with no improvement. Dr. notified. Sent to ER

COUGH, RIGORS, NAUSEA, VOMITING, URINARY URGENCY/FREQUENCY, DYSURIA - FOUND TO HAVE LLL PNEUMONIA, CONCERNING FOR POSSIBLE CYRPTOGENIC ORGANIZING PNEUMONIA

PATIENT DEVELOPED PROGRESSIVE NEW DYSPNEA, DIFFERENT FROM HER BASELINE. SHE HAS BEEN HOSPITALIZED TWICE FOR PERSISTENT DYSPNEA AND CENTRALIZED CHEST PAIN, WHICH HAS OTHERWISE HAD NEGATIVE WORK UP.

103.5 Fever that wouldn?t come down with Tylenol, chills, sharp headache, tachycardia, site pain, dizziness, body aches, nausea All symptoms started 11 hours after first dose of vaccine (3AM), went to hospital 15 hours after symptoms started and was treated for 9 hours until all symptoms abruptly stopped

positive COVID test; positive COVID test; fever; chills; sore throat; cough; nasal congestion; runny nose; little diarrhea; tiny bit of shortness of breath; Caller received the COVID-19 vaccine on 17Dec2020 and is scheduled to take the second dose on 5Jan2021.; Caller received the COVID-19 vaccine on 17Dec2020 and is scheduled to take the second dose on 5Jan2021.; sore arm; This is a spontaneous report from a Pfizer-sponsored program Pfizer First Connect via a contactable physician (patient himself). A 56-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Lot number: EH9899), via intramuscular route on 17Dec2020 at single dose (dose 1, left deltoid) for COVID-19 immunization. The patient medical history included non-smoker. Concomitant medications were reported as none. The patient was scheduled to take the second dose on 05Jan2021, also reported as 08Jan2021. The patient experienced sore arm for 24 hours afterwards on Dec2020. Patient experienced mild COVID symptoms such as fever, chills, sore throat, cough, nasal congestion, runny nose, little diarrhea, and tiny bit of shortness of breath on 24Dec2020, but stated he was better now. The patient was positive in the COVID test on 28Dec2020. He wanted to know if it was normal to get COVID after getting the vaccine and if he should get the booster shot if he gets better. He commented that testing positive for COVID was medically concerning. The patient did not require supplemental oxygen (including high flow ECMO) or receive a mechanical ventilation. Treatment included over the counter medication. No additional testing was done. The patient was not hospitalized. Outcome of the event sore arm was unknown; cough was not recovered; fever, chills, sore throat, nasal congestion, runny nose, little diarrhea, tiny bit of shortness of breath was recovering. No follow-up attempts are needed. Information about lot/batch number was already obtained. No further information is expected.; Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of events Drug ineffective and COVID-19 virus test positive cannot be totally excluded. The case will be reassessed if additional information becomes available.

2days after my 1st Covid vaccine I broke out into a rash with hives requiring me to go to the ER; 2days after my 1st Covid vaccine I broke out into a rash with hives requiring me to go to the ER; This is a spontaneous report from a contactable nurse (patient). A 58-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot/batch number: EH9899, expiry date was not provided) solution for injection, via an unspecified route of administration on left arm on 17Dec2020 08:00 at a single dose for Covid-19 immunization. Medical history included eczema, chronic kidney disease, thyroid disease. Patient had known allergies. The patient was not pregnant. Concomitant medications included apixaban (ELIQUIS), allopurinol (ALLOPURINOL), levothyroxine (LEVOTHYROXINE), iron (IRON), magnesium (MAGNESIUM). The patient reported that 2 days after her 1st Covid vaccine,

she broke out into a rash with hives requiring her to go to the ER on 19Dec2020 12:00. She also visited a physician. She was treated with steroids, Atarax, and Epi shot. The events were reported as non-serious. Outcome of the events was not recovered. No follow-up activities are needed. No further information is expected.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the reported events of urticaria and rash due to temporal relationship. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

tested positive within 2-4 days of the vaccine; tested positive within 2-4 days of the vaccine; This is a spontaneous report from a contactable nurse. This nurse reported similar events for two patients. This is the first of 2 reports. A patient of unspecified age and gender received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date not reported), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The nurse had questions about patients that received the first dose of the COVID 19 vaccine. One patient tested positive within 2-4 days of the vaccine and this patient had a known exposure to a COVID positive person. The nurse wanted to know if this patient should receive the second dose. The outcome of the events was unknown. Information about batch/lot number has been requested.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the reported events of SARS-CoV-2 test positive and LOE due to temporal relationship. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.,Linked Report(s) : US-PFIZER INC-2020520414 Same reporter, drug, and events; different patients

Tested positive for COVID; Tested positive for COVID; This is a spontaneous report from a contactable healthcare professional (patient). A 40-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899), via an unspecified route of administration on 18Dec2020 at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient received the first dose of the vaccine on 18Dec2020, and was tested positive for COVID yesterday, 29Dec2020. States that she knows she only has had the first dose and states her exposure level was high, states that she cannot believe she made it this far before testing positive. Second dose scheduled for 08Jan2021, wanting to know if she should get the second

dose since she was now positive. The outcome of the events was unknown.; Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of events Drug ineffective and COVID-19 virus test positive cannot be totally excluded. The case will be reassessed if additional information becomes available.

positive Covid results with symptoms; positive Covid results with symptoms; This is a spontaneous report from a contactable nurse (patient). A 56-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date not reported), via an unspecified route of administration on 20Dec2020 at single dose for COVID-19 immunization. Medical history included hypertension (diagnosed 3-4 years ago), hyperlipemia (diagnosed 3-4 years ago), supraventricular tachycardia since 2017, and asthma; all ongoing. Family history included hypertension. She has no history of adverse reactions or allergies to any vaccines received previously. The patient's concomitant medications were not reported. The patient explains that she got the COVID-19 vaccine on 20Dec2020. Afterward she had some coughing, so she went for a rapid test and found she tested positive after the vaccine. The patient was wondering if this has been reported previously, where someone tested positive after getting the vaccine. She has never tested positive before. She got the results on 28Dec2020 that she was positive. She was now in a hotel quarantining. She was looking trying to find information on this occurring. Since she was in the hotel, she would prefer to use email as communication for follow-up. The patient noticed the cough on 25Dec2020. She works nights so she stayed home on the 26Dec2020. Then on 27Dec2020 she had the test done and on 28Dec2020 the results were given to her and she was positive. Her second dose was due on 10Jan2020 and it was before the 14 days of quarantine will be up. She was checking to see is there anywhere else she can get the second dose. The patient explains that she has been researching and she wanted to get it because she was with elderly family members. She wanted to know how she was tested positive, what test was used as she had the rapid test. There were no treatments for the events. The caller patient was also experiencing a cough, sore throat, and nasal congestion. There was no shortness or anything else going on at this point. The outcome of the events was not recovered. Information on the lot/batch number has been requested.; Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of events Drug ineffective and COVID-19 virus test positive cannot be totally excluded. The case will be reassessed if additional information becomes available.

positive person for Covid after receiving the Covid vaccine; positive person for Covid after receiving the Covid vaccine; This is a spontaneous report from a contactable nurse. A patient of unspecified age and gender received bnt162b2 (BNT162B2 also reported as Pfizer-BioNTech COVID-19 Vaccine, lot/batch number and expiry date were unknown), via an unspecified route of administration on unknown date at single dose, for Covid-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient was a positive person for Covid after receiving the Covid vaccine on an unspecified date. The outcome of the event was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the

development of events Drug ineffective and COVID-19 cannot be totally excluded. The case will be reassessed if additional information becomes available.

"Her measured blood pressure at 7:35 am was 180/80 but came down to 146/62 at 9:37 am; arms had some pain; chills; headache; a stiff neck pain at the back of her neck; a stiff neck pain at the back of her neck; a trembling pain; This is a spontaneous report from a contactable consumer. This is the 1st of two reports. A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 29Dec2020 at single dose for COVID-19 immunisation. The patient medical history and concomitant medications were not reported. The patient stated on Dec2020, ""she reported that she herself felt fine but her arms had some pain. She was having chills, a headache, a stiff neck pain at the back of her neck, and a trembling pain. Her measured blood pressure at 7:35 am was 180/80 but came down to 146/62 at 9:37 am. Her pulse was at 62 bpm, Caller is asking for recommendations"". The outcome of ""her measured blood pressure at 7:35 am was 180/80 but came down to 146/62 at 9:37 am"" was recovering and other events was unknown. Information about Lot/batch no has been requested.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2020520380 same reporter/drug, different patient/event"

"extremely lightheaded; like he was about to fall down; This is a spontaneous report from a contactable physician. This physician reported similar events for 2 patients. This is the 1st of 2 reports. An 89-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number; EL0140), intramuscular on the right arm on 30Dec2020 10:10 at single dose for vaccination. Medical history included covid-19 on Jul2020 and had it fairly severe and almost died and he mentions he was overweight. There were no concomitant medications. The patient previously took flu shot (INFLUENZA VACCINE), a couple of months ago. He mentions he was in the military so he had a lots of shots in his life but he has never had a reaction like this. The patient stated that on 30Dec2020 10:30, ""he became extremely lightheaded, like he was about to fall down. He sat down and is currently sitting down. This lightheadedness started about 20 minutes after the injection. When probed for the outcome, the caller explains it might be improving a little. The lightheadedness is not still not gone, but it has not worsened. When probed for seriousness criteria, the caller explains he is just resting and sitting. He would say its not serious but it could be medically significant. He states he isn't sure if this is something that happens to just people who have had COVID before. He states none of his friends or relatives have this type of reaction. He lives in a retirement home and everybody is getting the injection. This is the second day of injections. He doesn't know if anybody had a reaction to the COVID-19 vaccine here"". The outcome of the events were recovering.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the reported events of lightheadedness and pre-syncope due to temporal relationship. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics

Committees and Investigators, as appropriate.,Linked Report(s) : US-PFIZER INC-2020520862 same reporter/drug, similar event, different patient."

Vomiting/threw up; Headache; muscles got rigid and tight in her neck; muscles got rigid and tight in her neck; sick; She doesn't know if she had the flu bug or not; She also had very high blood pressure. It was through the roof/Blood pressure was high and she was concerned she would have a stroke; Muscle soreness; Arm soreness; This is a spontaneous report from a contactable healthcare professional (physical therapist). A 57-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiry date not reported), intramuscular on the left arm on 21Dec2020 08:15 at a single dose for COVID-19 immunisation; and sumatriptan from 25Dec2020 to an unspecified date at unknown dose and frequency (standard unknown dose/ She only gets 9 pills a month) for migraine. Medical history included ongoing migraine, obesity (She would say she was kind of obese), coeliac disease (She had Celiac disease and cannot eat gluten which was diagnosed since she was 4), chronic back pain (this was diagnosed a couple of years before she took the COVID vaccine), spinal stenosis (this was diagnosed a couple of years before she took the COVID vaccine), and pain (she took hydrocodone for pain but did not take any that day). Concomitant medication included hydrocodone for pain. Prior Vaccinations (within 4 weeks) and events following prior vaccinations were none. The patient had the vaccine on 21Dec2020, and she got sick on Christmas day. She was vomiting at 14:00 and did not know if it was a side effect or not. She did have arm soreness muscle soreness at 15:00, that evening and the next day too. She normally gets a migraine once a month. She does not normally throw up with a headache though. The vomiting started when she threw up twice on 25Dec2020, then once on morning of 26Dec2020. She also had very high blood pressure. It was through the roof. She did not know if that was related to drug for migraine or vaccine. She also had the headache at 14:00 the whole time. She believed she threw up before she took Sumatriptan. The muscles got rigid and tight in her neck and she doesn't think she took it. She threw up and then she took it. She did not have a lot or expiration. There was no ER nor physician's office required. She would have it if her car was not buried in snow. Her blood pressure was high and she was concerned she would have a stroke. It was usually around 110/70 and was always very low usually. She did not know if it was accurate, but it was 165/124 at one point and she did know her pulse was accurate. She did not provide her pulse rate. She did not know if she was throwing up because her blood pressure was high and did not know if blood pressure was high because of Sumatriptan. She only gets 9 pills a month. She did not know if high blood pressure was one of the side effects. It was not a real safe medication to take once a day. She only took it once a month and only once that day. She had never thrown up with migraines before and was just concerned. She doesn't usually take her blood pressure and doesn't know if the Sumatriptan always makes it go up or not. She doesn't know if she had the flu bug or not. The action taken in response to the events for bnt162b2 was not applicable, while for sumatriptan was unknown. Clinical outcome of sickness and influenza was unknown, for headache was recovered on 27Dec2020, while for the other events was recovering. Information on the lot/batch number has been requested.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the elevated BP and other reported events due to temporal relationship. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics, counteractive treatment measures and concomitant medications. This case

will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

allergic reaction; This is a spontaneous report from a contactable other healthcare professional reported for herself. A 45-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number EK 5730, expiry date unknown) via unspecified route of administration at left arm on 30Dec2020 08:30 at single dose for Covid-19 immunization in a hospital facility. The patient was not diagnosed with Covid-19 prior vaccination. Medical history was none. Concomitant medications was not reported. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. On 30Dec2020 at 08:45, the patient experienced allergic reaction which resulted to patient visiting doctor or other healthcare professional office/clinic and emergency room/department or urgent care visit. The patient received treatment of epinephrine, decadron and Benadryl due to the event. The patient was not Covid tested post vaccination. The outcome of the event allergic reaction was recovering at this time of the report. The reporter considered the event non-serious; did not results in death, was not life threatening, did not cause/prolong hospitalization, was not disabling/incapacitating, and no congenital anomaly/birth defect.; Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of event Allergic reaction cannot be totally excluded. The case will be reassessed if additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

peripheral neuropathy type symptoms; tingling of the feet, legs, hands, arms; This is a spontaneous report from a contactable Other Health Professional (patient). A 34-year-old non-pregnant female patient received first dose of BNT162b2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration at Left arm on 22Dec2020 10:00 at single dose for covid-19 immunization. The COVID-19 vaccine was administered at Hospital. Medical history included hypothyroidism. The patient had no known allergies. Concomitant medication included levothyroxine and multivitamin. No other vaccine in four weeks. The patient was not sure if this was related to the vaccine or not. The patient didn't know if anyone else was having peripheral neuropathy type symptoms such as tingling of the feet, legs, hands, arms. The symptoms started a few days ago. The patient did not even sure if it related to the vaccine. Adverse event start date was 27Dec2020. Covid was not tested post vaccination. The outcome of the events was not recovered. No treatment received for the events. Information on the lot/batch number has been requested.; Sender's Comments: The temporal relationship between the onset of the event and administration of the vaccine does not support a causal relationship. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern

identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

tested positive for covid; tested positive for covid; fever; headache; runny nose; nasal congestion; This is a spontaneous report from a contactable consumer (patient). A 34-year-old female patient received the first single dose of BNT162B2 (Solution for injection, lot number: EK5730, exp date: Mar2021), intramuscular (injected in left upper arm) on 20Dec2020 12:30 to 20Dec2020 12:30 at 0.3 mL for immunisation. The vaccine was administered in a hospital and not in a military facility. Medical history included birth control. The patient had no other history. NO ER or physician's office required Prior Vaccinations (within 4 weeks). Patient had no relevant family history. Concomitant medication include unspecified birth control.There was no previous immunization. Patient, who was a Respiratory therapist, got the covid vaccine on 20Dec2020 (Sunday). She first stated she doesn't have any side effects and just had a question. Patient had COVID Symptoms on 26Dec2020 21:00 which was minimal like a runny nose. She further reports that on 26Dec2020 she started to have nasal congestion. On 27Dec2020 the nasal congestion worsened, and she started having a headache. She then experienced a 102.6 fever on 28Dec2020 (Monday). She has since tested positive for Covid on 28Dec2020 11:30. Patient asked if it was ok that she received the 2nd dose after testing positive for covid. Investigation assessment was not performed. There was no prescriber. She received at work because she was a front line healthcare worker. The patient does not have SARS-CoV2 antibodies at diagnosis but never tested for antibodies. The patient was not in the hospital, nor was admitted in ICU. The patient did not display clinical signs at rest indicative of severe systemic illness. The patient did not require supplemental oxygen (including high flow or ECMO) or receive mechanical ventilation. No Multiorgan failure. The patient did not receive any additional therapies for COVID-19. The patient did not require the initiation of new medication or other treatment or procedure. PCR on 28Dec2020 (Saturday) Results: just detected. No units available. No reference ranges provided. Standard range was not detected. It was just detected or not detected ranges. No other test or diagnostic imaging performed. The patient had not been treated with immune modulating or immunosuppressing medications or received any other vaccines around the time of COVID-19 vaccination. No pre-existing diseases worsened during the SARS-CoV2 infection. The patient was recovering from event positive for covid and runny nose; nasal congestion was not recovered and outcome of the other events was unknown.; Sender's Comments: Based on the information available, a possible contributory role of the suspect products cannot be excluded for the reported event of positive for corona virus infection for the lack of efficacy of the vaccine. However, based on the mechanism of action of the vaccine, it is unlikely the patient would have fully developed immunity for the vaccine to be effective, due to the number of days passed since the vaccine is given.

"had side effects of ""tongue feels swollen and globus sensation in my throat.""; had side effects of ""tongue feels swollen and globus sensation in my throat.""; she did not have a lot of injection site pain, it very minimal.; bruise or ecchymosis at the injection site; bruise or ecchymosis at the injection site; This is a spontaneous report from a contactable physician (patient) via a Pfizer sponsored program Pfizer First Connect. A 37-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot EH9899) via intramuscular on 19Dec2020 09:00 on left deltoid at a single dose for COVID-19 prophylaxis. The patient medical history, family history and relevant tests were reported

as none. Current concomitant medications included multivitamin took 2 chewable gummies sporadically for years as supplementation therapy. The patient previously took Flu shots she got a sore arm. It was not bad. Tetanus gives her a sore arm, but that was all. Caller wanted to know what she should do for preparation to safely get second dose of Covid vaccine and how to fix what she was feeling right now, making sure it doesn't get worse, considering she is still having symptoms. Caller stated that she had side effects of tongue felt swollen and globus sensation in her throat. The transferring agent stated that he has a caller on the line that was calling about the Covid-19 Vaccine and reported that the patient got the shot on the 19Dec2020 and was inquiring about to proceed with her weird side effects. Caller had not told her physician about her symptoms yet. Caller clarified that she said a half an hour after the dose on 19Dec2020 09:30 she said that she had a Globus sensation or like a lump in her throat. Caller also reported that the back of her tongue felt swollen. Caller said that the Globus sensation was intermittent and it was not as prominent now as it was. Caller said that it was medically significant, but she has not sought medical treatment yet. Caller said that she still had a bruise or ecchymosis at the injection site. She said that the injection was high but reported that she did not have a lot of injection site pain, it very minimal. No emergency room or physician office required. The outcome of the event tongue felt swollen and globus sensation in her throat was recovering and the outcome of the event a bruise or ecchymosis at the injection site was not recovered and the outcome of the event minimal injection site pain was unknown.; Sender's Comments: There is a plausible chronological association between vaccine administration and onset of the events. Causality cannot be completely excluded."

"had a reaction of bells palsy with mild symptoms 5 minutes of receiving covid vaccine; facial numbness right sided ear discomfort, difficulty closing right eye, only right side numbness and weakness of her face. It has gotten a lot better; facial numbness right sided ear discomfort, difficulty closing right eye, only right side numbness and weakness of her face. It has gotten a lot better; facial numbness right sided ear discomfort, difficulty closing right eye, only right side numbness and weakness of her face. It has gotten a lot better; This is a spontaneous report from a contactable Other Health Professional reported that a 35-year-old female patient receives first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot/Batch Number and Expiration Date unknown) via an unspecified route of administration on 21Dec2020 at single dose for covid-19 immunization. The patient's medical history and concomitant medications was not reported. The patient experienced a reaction of bells palsy with mild symptoms 5 minutes of receiving Covid vaccine. ""facial numbness right sided ear discomfort, difficulty closing right eye, only right side numbness and weakness of her face. It has gotten a lot better, patient was vaccinated 10 days ago on 21Dec2020. Patient was treated with 60mg of Prednisone for 5 days which was started today."" Question is regarding the 2nd dose of Covid vaccine, whether or not she should have it. The outcome of events was recovering. No follow-up attempts are possible; information about lot/batch number cannot be obtained. .; Sender's Comments: There is a positive chronological association between vaccine administration and onset of the events. Causality cannot be completely excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate."

now have a positive cov-19 test results; now have a positive cov-19 test results; This is a spontaneous report from a contactable nurse reporting for herself. A female patient of an unspecified age received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number and expiry date not reported) via an unspecified route of administration, on an unspecified date, single dose for COVID-19 immunization. Relevant medical history and concomitant medications were not reported. The patient took first round of cov-19 shot and due to take 2nd one Saturday but now have a positive cov-19 test result. Information on the lot/batch number has been requested.; Sender's Comments: Based on the information available, a possible contributory role of the suspect products cannot be excluded for the reported event of positive for corona virus infection for the lack of efficacy of the vaccine. However, based on the mechanism of action of the vaccine, it is unlikely the patient would have fully developed immunity for the vaccine to be effective, due to the number of days passed since the vaccine is given.

Contracted covid 19 virus after receiving first dose of vaccine; Contracted covid 19 virus after receiving first dose of vaccine; This is a spontaneous report from a contactable nurse. A 46-year-old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number Eh9899), intramuscular in left arm on 17Dec2020 18:00 at a single dose for covid-19 vaccination. Vaccine was administered in the hospital. There were no relevant medical history. The patient had no known allergies. Concomitant medication included levothyroxine sodium (SYNTHROID). On 27Dec2020 20:00, the patient contracted covid 19 virus after receiving first dose of vaccine. The outcome of the event was recovering. The patient did not received any treatment. The event resulted in a doctor or other healthcare professional office/clinic visit. The patient did not have COVID prior to vaccination. The patient was tested for COVID post vaccination. The patient had nasal swab on 31Dec2020 and had a positive result.; Sender's Comments: Based on the information available, a possible contributory role of the suspect products cannot be excluded for the reported event of positive for corona virus infection for the lack of efficacy of the vaccine. However, based on the mechanism of action of the vaccine, it is unlikely the patient would have fully developed immunity for the vaccine to be effective, due to the number of days passed since the vaccine is given.

tested positive following the first dose of vaccine; tested positive following the first dose of vaccine; This is a spontaneous report from a contactable healthcare professional. A female patient of an unspecified age received BNT162B2 (Pfizer-BioNTech COVID-19 mRNA vaccine; lot/batch number and expiry date were unknown), via an unspecified route of administration on unspecified date at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The reporter stated that she has a patient who tested positive following the first dose of vaccine and inquiring as to second dose recommendations. The outcome of the event was unknown. Information about lot/batch number has been requested.; Sender's Comments: There is scant information at this point. Case will be reevaluated based on additional information during the follow-up

"sore arm; aches and pains for a couple of days; a little headache; I received results yesterday and I am positive; I received results yesterday and I am positive; This is a spontaneous report from a non-contactable physician (patient). A male patient of an unspecified age started to receive bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), lot number and expiry date was unknown, via an unspecified route of administration on 19Dec2020 at single dose for COVID-19 immunization. The patient's medical

history and concomitant medications were not reported. The patient received his first covid vaccine dose on 19Dec2020, and due to get his second dose on 09Jan2021. The problem is he tested for the covid virus on Wednesday 26Dec2020 (was negative). He was tested again on the 30Dec2020, because his wife and son had tested positive on the 26Dec2020, he received the results yesterday and he is positive. He asked if he should proceed with the 2nd dose, another test on the 30th and tested positive. He reports that, other than initial side effects from the vaccine administration, sore arm, aches and pains for a couple of days, never had fever, a little headache for a day or two, he feels fine. The outcome of the events ""a little headache"" was recovered on an unspecified date while outcome of the other events was unknown. No follow-up attempts are possible. Information about lot/batch number cannot be obtained. No further information is expected.; Sender's Comments: Based on the information available, a possible contributory role of the suspect products cannot be excluded for the reported event of positive for corona virus infection for the lack of efficacy of the vaccine. However, based on the mechanism of action of the vaccine, it is unlikely the patient would have fully developed immunity for the vaccine to be effective, due to the number of days passed since the vaccine is given."

tested positive with COVID; tested positive with COVID; This is a spontaneous report from a contactable nurse. A male patient (Age:22 Units: unspecified) received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiry date were not reported), via an unspecified route of administration on 15Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient had the 1st dose last 15Dec2020 and tested positive with COVID on 25Dec2020. The outcome of the event was unknown. He will have the COVID result 04Jan2021 to check if he was still positive. Information on the Lot/Batch number has been requested.; Sender's Comments: Based on the information available, a possible contributory role of the suspect products cannot be excluded for the reported event of positive for corona virus infection for the lack of efficacy of the vaccine. However, based on the mechanism of action of the vaccine, it is unlikely the patient would have fully developed immunity for the vaccine to be effective, due to the number of days passed since the vaccine is given. Case will be reevaluated based on follow-up information

developing a left facial droop; Bell's palsy; This is a spontaneous report from a Pfizer-sponsored program IBCC (Inbound Call Center for HCPs). A contactable physician reported that a female patient of an unspecified age received the first dose of bnt162b2 (COVID-19 Vaccine) via an unspecified route of administration on an unspecified date in Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The physician reported that the patient received the COVID-19 vaccine roughly two weeks ago (Dec2020) and is developing a left facial droop, they are concerned if that is a sign of facial Bell's palsy. It's left side and it's a facial droop. The physician was concerned if patient is developing Bell's palsy and they are wondering if she should get the second dose or not. The physician further stated that her patient got the vaccine like about 2 weeks ago and developed Bell's palsy three days after the administration of the vaccine (Dec2020) and of course she won't be able to get to see because we are all booked up until yesterday and that is like about a week ago, after the onset of Bell's palsy. Outcome of the event was unknown. Information about lot and batch has been requested.; Sender's Comments: The event is considered possibly related to the suspect product based on the assumed positive temporal association. The information available in

this report is limited and does not allow a medically meaningful assessment of the case. In particular the following relevant information is not available: patient's medical history and concomitant medications, exact vaccination date, event outcome. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

nurse got Covid after getting the vaccine; nurse got Covid after getting the vaccine; This is a spontaneous report from a contactable nurse. A patient of unspecified age and gender received BNT162B2 (Pfizer-BioNTech COVID-19 mRNA vaccine; lot/batch number and expiry date were unknown), via an unspecified route of administration on unspecified date at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. It was reported that a nurse got Covid after getting the vaccine. The reporter wanted to know if the chills were common. She wanted to know if it is okay to feel chills every now and then. She wanted to know how people would know if they are positive when getting the vaccine. The outcome of the event was unknown. Information about the lot/batch number has been requested.; Sender's Comments: Based on the limited information available, a possible contributory role of the suspect products cannot be excluded for the reported event of positive for corona virus infection for the lack of efficacy of the vaccine. However, based on the mechanism of action of the vaccine, it is unlikely the patient would have fully developed immunity for the vaccine to be effective, due to the number of days passed since the vaccine is given. Case will be reevaluated based on follow-up information

a strong, whole body heat, and flushing; a strong, whole body heat; tachycardic; Palpitations; This is a spontaneous report from a contactable Nurse(patient). This Nurse reported for similar events for 6 patients. This is 1st of 6 reports. A 49-year-old female patient received BNT162B2(PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 28Dec2020 at the 49 years old at single dose for COVID-19 immunization. The medical history and concomitant medications were not reported. The registered nurse and 5 other registered nurses she worked with, had a serious reaction right after receiving the COVID-19 Vaccine. The patient had a weird reaction right after she was injected with the COVID-19 Vaccine. She had a strong, whole body heat, and flushing. She said she became tachycardic and had palpitations that lasted a few minutes. She said the tachycardia and palpitations then slowly resolved in less than 5 minutes. The patient said she had no other symptoms after receiving the COVID-19 Vaccine. The reporter said there were 5 other registered nurses that received the COVID-19 Vaccine at the same time and had the same exact symptoms she experienced. The reporter said stated the registered nurse who was monitoring the people who received the COVID-19 Vaccine indicated that the same feeling had occurred in many other workers who had received the COVID-19 vaccine. The reporter stated she did not know if the patient had received any other vaccines at the same time as the COVID-19 Vaccine, and if the patient had received any other vaccines within the last 4 weeks. The patient works at a hospital but didn't received any medical treatment. The patient just waited her symptoms out, and within 5 minutes her symptoms had gone away. The outcome of the events was recovered on 28Dec2020. Information on the lot/batch number has been requested.;

Sender's Comments: A possible contributory role of the suspect products cannot be excluded for the reported events based on the known safety profile and temporal association. Case will be reevaluated based on follow-up information ,Linked Report(s) : US-PFIZER INC-2021001363 same reporter/drug/event, different patient.;US-PFIZER INC-2021001364 same reporter/drug/event, different patient.;US-PFIZER INC-2021001195 same reporter/drug/event, different patient.;US-PFIZER INC-2021001204 same reporter/drug/event, different patient.;US-PFIZER INC-2021001329 same reporter/drug/event, different patient.

anaphylaxis; This is a spontaneous report from a contactable other healthcare professional (patient). A patient of unspecified age and gender received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for immunization. The patient's medical history and concomitant medications were not reported. Pfizer covid vaccine caused anaphylaxis on 30Dec2020 and landed patient in hospital. Patient was an anesthesiologist and had high IgG to thyroid with hashimotos. Patient thought he/she had IgG/neutrophil mediated anaphylaxis (not the typical IgE) as absolute neutrophil count elevated but everything else normal in labs. Had tachycardia into 140-150s and mild facial and throat edema. Still having sudden bouts of elevated heart rate in the morning of 31Dec2020. Heart tests all normal. Outcome of event elevated heart rate was not recovered, and outcome of other events was unknown. Information on the Lot/Batch number has been requested.; Sender's Comments: A possible contributory role of the suspect products cannot be excluded for the reported events based on the known safety profile and temporal association. Case will be reevaluated based on follow-up information

12/29/2020 2 hr after vaccination patient became hypotensive, decreased oxygen levels was transferred to Hospital currently inpatient at hospital - admitted for cardiac arrest

Deceased

Woke up Thursday am with hives on right lower abdomen and leg getting progressively worse throughout the day. By that afternoon had back pain in right back and continuing hives. Woke up Friday with numbness to right leg, hives, and back pain all on right side of body. Had numbness to foot, face but especially thigh, back and across upper buttocks. Saturday hives subsiding, numbness receding to face, upper thigh and foot only on right side of body. Sunday, back pain some improved, no hives or hives minimal, numbness persists upper thigh face and foot on right side of body. Monday, Tuesday and Wednesday the same. Woke up Thursday with shingles rash to upper thigh back, numbness to foot face and upper thigh persist only on right side of body. Darn!!!

I woke the next morning with flu like symptoms my arm was hurting, I was feelin tired and really couldn't get out of bed. As the day progressed I got chills, started running a fever, It went up to 104 and my heart rate went up and down from 120-165 so I went to the ER. They gave me fluids and ran a whole bunch of test, tested me for Covid and Sepsis and everything came back normal and negative for Covid. They monitored my heart rate and once it started getting back to normal, they ended up letting me go home, I was there from 8pm to about 3am. After that I felt tired and felt like when I had Covid back in

November. I started feeling better about Sunday, still a little tired but felt more back to normal. My heart rate is still getting back to normal so my Dr is following me on that.

PT was found deceased in his home on 1/5/2021

Expired 1/05/2021

"worry; frustration; regrets/wishing she would have never taken it; phlegm; can't talk; taking her voice, she felt like she was losing her voice; scary/""scaring"" her; coughing/cough; difficult for her to catch her breath/lost her breath, couldn't catch her breath/couldn't breath; allergic reaction to the vaccine; This is a spontaneous report from a contactable consumer (patient). A 61-year-old female patient received first dose BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number EL1284, expiry date 30Apr2021) intramuscular on 29Dec2020 09:16 at 0.3 mL, single for Covid-19 immunization in a hospital. Medical history included diabetic, allergy reactions, blood pressure (abnormal), cholesterol (abnormal); all ongoing, and reaction to dust. Concomitant medications included ongoing amlodipine;hydrochlorothiazide;valsartan for blood pressure, ongoing potassium for unspecified indication, BP pills (unspecified) and has cholesterol medications. The patient informed that yesterday (29Dec2020), she got the COVID vaccine shot at work, received it at 9:16 am and was monitored for 30 minutes post administration. The patient went to work and was holding the babies. The patient worked in transport in the NICU at a hospital. Few hours after the injection, while working in the NICU, she experienced coughing to the point where it was difficult for her to catch her breath. The patient started coughing so bad, she had no control. She mentioned trying to drink water and continued coughing more. The patient lost her breath, couldn't catch her breath, she had to call for the charge nurse (manager), as she couldn't breath and they took her to the ER and consulted at the ER of her facility. The patient informed that she kept coughing and couldn't catch her breath. They made her drink water. The patient has allergies, so she always has an epi pen with her. The patient felt like she had an allergic reaction to the vaccine. The doctor there explained that her symptoms were not related the Covid-19 vaccine she received earlier. The patient specified that the last time she had a similar reaction was at work and was due to dust. The patient explained that she was perfectly fine before receiving the vaccine, laughing, and so what can her symptoms be related to, if it was not the vaccine. The patient was coughing all night, can't get rid of the cough. She has called her doctor. The nurse said just to watch herself for now. The patient informed that she was supposed to go back to work tomorrow and she was afraid to go around the babies. The patient informed that today (30Dec2020), she gargled apple cider vinegar and salt water, and phlegm came out. The patient continued saying that she has still been coughing, can't talk and that it was scary. The patient informed that she was taking her voice, she felt like she was losing her voice. It was ""scaring"" her. She was unsure if it was the Pfizer vaccine. The patient attempted to reach her HCP and that she cannot be seeing at her clinic due to her cough. The patient mentioned that she won't have access to a respiratory clinic until Tuesday. The patient expressed her concerned about returning to work with babies and asked if she should return to work tomorrow. The patient pursued verbalizing her worry and frustration. The patient asked if she can decide not to get the second dose. The patient voiced her regrets on receiving the first dose of the COVID-19 vaccine. She stated wishing she would have never taken it and that all who have an EpiPen should not receive it. The outcome of the event cough was not recovered, Dyspnoea, Allergy to vaccine,

Productive cough, Speech disorder, Aphonia, Nervousness, Anxiety, Frustration tolerance, Depressed mood was unknown."

her face started to go numb/felt like a dental block you would get with Lidocaine; She got on her left side, a cold spike feeling up her shoulder and neck and up to her face; upper esophageal sphincter got tight and felt funny like she was going to throw up; her whole body was shaking- her head, hands, and legs; feeling giddy; blood pressure was up; being stressed; was going to throw up/transient nausea; felt a little funny; This is a spontaneous report from a contactable Nurse(patient). A 54-year-old female patient received BNT162B2 (lot number EL0140), via an unspecified route of administration at left deltoid on 30Dec2020 14:28 at the 54 years old at 0.3 mL single for where she works she was exposed to patients who need rehab that were exposed and getting COVID. The patient medical history included Primary Essential Tremors and ongoing (had these for about 10-11 years. Her mother and grandmother also had them. Normally they were very fine, small tremors that people didn't notice. She can hold and turn her head and hide it) and Sulfa drug allergy (would get shortness of breath). The concomitant product was none. The patient previously took flu vaccine and experienced preservative made neck twitch and joint sores. Yesterday the patient got the COVID Vaccine and had a pretty significant adverse event. She was calling to report it and to see if she should get the second dose of the vaccine. The patient was also a licensed speech pathologist. She received the vaccine yesterday at 2:28 PM. She was allergic to Sulfa drugs and would get shortness of breath, so they wanted her to wait 30 minutes for monitoring. She was feeling giddy on 30Dec2020, but she ran into a friend that she had not seen before quarantine, so they were talking. It was exciting. After her 30 minutes she went to her car and felt a little funny. She thought she was hungry so she ate half a banana and had some water. She had an appointment to get to so she started to drive off, and by the time she got to the interstate she was feeling funny. She got on her left side, a cold spike feeling up her shoulder and neck and up to her face on 30Dec2020. This was like the precursor. Then on 30Dec2020 her face started to go numb. It felt like a dental block you would get with Lidocaine. It went from her temple area, below her eye all the way to her lips. It was midline on the left side. She was breathing fine. She was trying to figure out if she should pull over or call(Number), but her airway did not close up. Her upper esophageal sphincter got tight and felt funny like she was going to throw up. She drove to the hospital close to her house which is affiliated with where she got the vaccine. She normally had primary tremors, small to where people do not notice. But her whole body was shaking- her head, hands, and legs on 30Dec2020. She looked like a bobble head. But she could still breath. They took her right in and they did an EKG to make sure it was not her heart. Her blood pressure was up on 30Dec2020, she assumes for being stressed. They monitored her. They gave her Pepcid and Benadryl. She did not want any nausea medications. She stayed for about 2 hours and slept some from the Benadryl. Her face slowly became less numb. The numbness went away started from her lips and outward to her check and temple area. Then it just felt funny. When she touched it, which she never lost sensation, it was like, whose face is this? It was strange. She is not numb anymore. It took a while for it to go away, and it still felt weird. When she woke up this morning it was completely gone. She had recovered completely from all of these things. The only thing she has now was some transient nausea. It was very mild. It comes and goes. It had improved. She had not taken anything for it. The events Feeling funny, her face started to go numb, upper esophageal sphincter got tight, a cold spike feeling up her shoulder and neck and up to her face, Her whole body was shaking- her

head, hands, and legs, were all assessed as Medically significant. The outcome of the event Nausea was recovering, the events Felt giddy, blood pressure was up, Stress was recovered on 31Dec2020, the other events were recovered on 30Dec2020. The reporter considered there was a reasonable possibility that the events Feeling funny, a cold spike feeling up her shoulder and neck and up to her face, Face started to go numb from her temple area, below her eye all the way to her lips, upper esophageal sphincter got tight , whole body was shaking- her head, hands, and legs, Nausea, were related to the product BNT162B2.; Sender's Comments: Based on the compatible temporal association, the vaccination with BNT162B2 might play a contributory role in triggering the onset of the events. The impacts of this report on the benefit/risk profile of the product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

"DVT; This is a spontaneous report from a contactable nurse. A patient of unspecified age and gender received BNT162B2, via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient medical history and concomitant medications were not reported. The nurse asked if there is any DVT cases reported following the administration of Pfizer-BioNTech COVID-19 Vaccine. E-transmitting duplicate AE caller already reported a DVT case post vaccination. Caller also asked ""Why is there's a statement indicating that individuals with a history of bleeding disorder or taking anti-coagulant should contact their vaccination provider? How did they prove 95 % efficacy? Why aren't antibodies produced after the 1st dose of Covid-19 vaccine?"" The outcome of the event DVT was unknown. Information on Lot/batch number has been requested.; Sender's Comments: Very limited information was provided for this individual patient, such as pre-existing medical history, suspect administration details, clinical course and relevant supportive lab data for the reported Deep vein thrombosis (DVT). Pending further details, the Company would handle this reported DVT related to the administration of BNT162B2, COVID-19 immunization, for reporting purpose. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RA, IEC, as appropriate."

throat swelling; Initially had headache; dizziness; irritability; Throat tingling; difficulty swallowing; This is a spontaneous report from a contactable other healthcare professional (HCP) (patient). A 49-year-old female patient received a single dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (Lot#: EJ1685) as the first dose via an unspecified route of administration in the left arm on 29Dec2020 06:00 for COVID-19 immunization. Medical history included fibromyalgia, asthma, prediabetes, and carpal tunnel syndrome. There were no concomitant medications. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. There were not any other medications the patient received within 2 weeks of vaccination. The patient was not diagnosed with COVID-19 prior to vaccination. The patient had not been tested for COVID-19 since the vaccination. The patient had no previous allergies to vaccines. The patient allergies to medications which included: doxycycline, medroxyprogesterone acetate (DEPO-PROVERA), metoclopramide (REGLAN), gluten. The patient initially

had headache, dizziness and irritability, throat tingling, throat swelling, and difficulty swallowing started around 12 hours after injection, event onset date reported as 29Dec2020 18:00. The events resulted in emergency room/ department or urgent care. The events were reported as non-serious by HCP. Treatment received for the events included diphenhydramine and hydroxyzine embonate (HYDROXYZINE PAMOATE). The outcome of the events was recovering.; Sender's Comments: The reported pharyngeal swelling together with other symptoms was likely related to the single dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) due to temporal relationship. The case will be reassessed should additional information become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics committees and Investigators, as appropriate.

Moderate to severe headache 24-48 hours post injection. Complete sensorineural hearing loss in left ear 1 week after injection; Moderate to severe headache 24-48 hours post injection. Complete sensorineural hearing loss in left ear 1 week after injection; This is a spontaneous report from a contactable physician (patient). A 37-year-old female non-pregnant patient received her first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 22Dec2020 17:15 at single dose on her left arm for covid-19 immunization. Medical history included known allergies to penicillin. The patient had no other medical history. There were no concomitant medications. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine and the patient was not received list of any other medications within 2 weeks of vaccination. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. The patient experienced moderate to severe headache 24-48 hours post injection. Complete sensorineural hearing loss in left ear 1 week after injection on 23Dec2020. These events resulted in doctor or other healthcare professional office/clinic visit, disability or permanent damage. The patient had received prednisone to treat the events. The outcome of the events was not recovered.; Sender's Comments: A possible contribution role of first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) to the onset of sensorineural hearing loss in left ear and headache cannot be excluded due to temporal relationship. The case will be reassessed should additional information become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics committees and Investigators, as appropriate.

jaw tightening; muscle spasms; entire face and around her mouth went numb; entire face and around her mouth went numb; heart palpitations; I had hives on my chest; a wave of heat rush up her back; This is a spontaneous report from a contactable nurse (patient). A 46-years-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899), via an unspecified route of administration in left arm on 22Dec2020 10:30 at first single dose for COVID-19 immunization. Medical history included ectopic pregnancy, hay fever. Concomitant medication received within 2 weeks

included: loratadine, colecalciferol (vitamin D), olly womens multivitamin. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. No known allergies. About 15 minutes after the vaccine the patient experienced jaw tightening and muscle spasms. The patient was given oral Benadryl 50 mg. About 5 minutes after taking the Benadryl, her entire face and around her mouth went numb. The patient began having heart palpitations and felt a wave of heat rush up her back. She had hives on her chest. The patient received 1 dose of epinephrine from an Epi-Pen and transported to the emergency room for further treatment. Adverse event start date: 22Dec2020 11:00 AM. Events were considered as non-serious. Events resulted in: Doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care. Treatment received for the adverse event included: Benadryl, Epinephrine, Solumedrol, Pepcid. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had been tested for COVID-19. Test Name: SARS-CoV-2 by PCR (Nasal Swab) on 30Dec2020: Negative. Outcome of the events was not recovered.; Sender's Comments: The temporal relationship is suggestive of an acute anaphylactic reaction. Based on the temporal relationship and the known pattern of response, the vaccination with BNT162B2 might play a contributory role in triggering the onset of the reported events. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

"Joint pain; loss of balance; increased drowsiness; Headaches induced by allergies; Limited neck mobility/lessened neck pain but still limited mobility; Scalp tenderness and sensitivity; Significant migraines/debilitating migraines (light & noise sensitivity, covers whole head, pulsating, sharp pain, loss of balance, increased drowsiness); Sharp pains in neck/Neck pain; Sharp pains in neck, ear, head pain (similar to an ear infection pain); head pain/sharp pains in lower head/covers whole head, pulsating, sharp pain/Increase in headaches but no longer centralized to back of head/ headaches induced by allergies; Nausea; Neck stiffness; This is a spontaneous report from a contactable Other Health Professional (patient). A 29-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) Solution for injection, lot number was unknown, via an unspecified route of administration in the right arm on 22Dec2020 07:30 at a single dose for COVID-19 immunization. Medical history was none. There were no concomitant medications. The patient was not pregnant. The patient had not receive any other vaccines within 4 weeks prior to the COVID vaccine. It was reported that the patient received vaccine in Tuesday (22Dec2020). The following Sunday (27Dec2020) at 12:00, she had nausea and neck stiffness. On Monday (28Dec2020), she had sharp pains in neck, ear, head pain (similar to an ear infection pain), and nausea. She used teledmed appt and got antibiotics (unspecified). On Tuesday (29Dec2020), she had significant migraines, limited neck mobility, sharp pains in neck and lower head, scalp tenderness and sensitivity which felt like whiplash when she moved her head w/ her head feeling ""swimmy"". She tried to see urgent care but was to go to ER. On Wednesday (30Dec2020), there was lessened neck pain but still limited mobility, increased in headaches but no longer centralized to back of head. She went to ER and they said that she had headaches induced by allergies. She mentioned that she never had migraines or allergies in her life. They also reported no ear infection. She did complete CT Scan with no concerning results on 30Dec2020. On Thursday (31Dec2020) & Friday, she

no longer has neck pain but with continued nausea, joint pain, debilitating migraines (light & noise sensitivity, covers whole head, pulsating, sharp pain, loss of balance, increased drowsiness). The events were reported as non-serious. The treatment received for the adverse events included fluids, pain & nausea meds. The patient was not diagnosed with Covid prior to vaccination. She was tested for covid post vaccination on 30Dec2020 through a nasal swab with negative result. The outcome of the events neck stiffness, ear pain, scalp tenderness and sensitivity, and 'Headaches induced by allergies' was unknown; while neck pain was recovered on 31Dec2020. The outcome of the events 'significant migraines/debilitating migraines', nausea, limited neck mobility, head pain/Headache, joint pain, loss of balance, and increased drowsiness was not recovered. Information on the lot/batch number has been requested.; Sender's Comments: A causal association between BNT162B2 and the event migraine cannot be excluded based on a compatible temporal relation between vaccination and onset of event. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate."

Miscarriage; patient was pregnant while taking BNT162B2; patient was pregnant while taking BNT162B2; This is a spontaneous report from a contactable Other Health Professional. A 34-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EL0140), intramuscularly on 22Dec2020 06:00 AM at single dose at Arm Right at Hospital for COVID. Medical history included ongoing sleep apnoea. There were no concomitant medications. There were no allergies to medications, food, or other products. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient did not receive any other medications the patient received within 2 weeks of vaccination. Prior to vaccination, the patient was not diagnosed with COVID-19. The patient experienced miscarriage on 29Dec2020 13:00. The patient was pregnant while taking BNT162B2. The patient was 4 Weeks pregnant at the onset of the event. Patient last menstrual period date was 24Nov2020. The Pregnancy due to deliver was on 07Sep2021. The pregnancy resulted in spontaneous abortion. Since the vaccination, the patient has been tested for COVID-19 on an unknown date with unknown results. Nasal Swab on 28Dec2020 was Negative. There was no treatment received for the adverse event. The outcome of event was recovering.; Sender's Comments: The information currently provided is too limited to make a meaningful medical assessment hence, the events are conservatively assessed as related to the suspect drug BNT162B2 until further information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to agency, Ethics Committees, and Investigators, as appropriate.

DVT left calf; This is a spontaneous report from a contactable Physician (patient). A 60-year-old male patient started to receive the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) Intramuscular on 20Dec2020 08:00 at single dose on right arm for COVID-19 immunization. Medical history included Gastric reflux. The patient had no known allergies. The patient had no covid prior vaccination. The patient had no covid tested post vaccination. Concomitant medications included

omeprazole (PRILOSEC) and ergocalciferol (VIT D). The patient had not received other vaccine in four weeks. The patient experienced deep vein thrombosis (DVT) left calf on 27Dec2020 09:00 which resulted emergency room visit. Treatment received for the event included Xarelto. The outcome of the event was not resolved. Information on the lot/batch number has been requested.; Sender's Comments: The information currently provided is too limited to make a meaningful medical assessment hence, the events are conservatively assessed as related to the suspect drug BNT162B2 until further information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

"reaction to excipient; kidneys tried to shut down; This is a spontaneous report from a contactable consumer from a Pfizer Sponsored Program. A female patient of an unspecified age received the bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), and potassium (MANUFACTURER UNKNOWN); both via an unspecified route of administration on an unspecified date at a single dose for COVID-19 immunisation. The patient's medical history included ongoing kidney issues from an unknown date, allergic to antibiotics and pain pills from an unknown date and unknown if ongoing. Concomitant medications were not reported. On an unspecified date, the patient experienced: kidneys tried to shut down and reaction to excipient; which were assessed as medically significant. The consumer stated, ""I looked at the ingredient list: potassium is listed. I have kidney issues and potassium is really bad, my kidneys tried to shut down on me. I'm allergic to ""antibiotics and pain pills."" The clinical outcome of the events, renal failure and reaction to excipient, was unknown. The batch/lot numbers for the vaccine, PFIZER-BIONTECH COVID-19 MRNA VACCINE, were not provided and will be requested during follow up."

Mild difficulty with thought/speech/concentration; strong wave of burning sensation growing inside the body; Lightheadedness; Blood pressure went up; Heart rate went up; Hands freezing; Mild difficulty with thought/speech/concentration; Mild difficulty with thought/speech/concentration; Weakness; Mildly shaky; Anxiety; Feeling that may pass out; This is a spontaneous report from a contactable other healthcare professional (HCP) (patient). A 61-year-old female patient received 1 dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EJ1686) via unspecified route on left arm single dose for COVID-19 immunization on 02Jan2021, 02:30 PM, at 61-year-old. Medical history: allergies to sulfa, paclitaxel (TAXOL); breast cancer in 2003 and 2007. Prior to vaccination, the patient did not be diagnosed with COVID-19. Concomitant medication in two weeks included: escitalopram oxalate (LEXAPRO, strength: 10m); omeprazole; multivitamin; ibuprofen. About 5 minutes after the vaccine (02Jan2021, 02:35 PM), the patient had a strong wave of burning sensation growing inside the body, lightheadedness, blood pressure went up, heart rate went up, hands freezing, mild difficulty with thought/speech/concentration, weakness, mildly shaky, anxiety, feeling that may pass out. Emergency room/department or urgent care visited. Treatment received for the adverse event included: heart rate H20 and BP monitor, water, observation. Since the vaccination, the patient did not have been tested for COVID-19. Action taken for BNT162B2 was not applicable. Outcome of the events was resolving. It was reported as non-serious per the reporter.; Sender's Comments: Based on the current available

information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of event Mental impairment cannot be totally excluded. The case will be reassessed if additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

"reported increased hand stiffness after vaccination; This is a spontaneous report from a contactable pharmacist via Pfizer sales representative. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for Covid-19 immunisation. Medical history included psoriasis and psoriatic arthritis. The patient's concomitant medications were not reported. The patient previously took adalimumab (HUMIRA) and non compliant with Humira. The patient had psoriasis and psoriatic arthritis, reported increased hand stiffness after vaccination on an unspecified date with outcome of unknown. Information on the lot/batch number has been requested.; Sender's Comments: The Company cannot completely exclude the possible causality between the reported ""psoriasis and psoriatic arthritis with increased hand stiffness after vaccination"" and the administration of BNT162B2, based on the reasonable temporal association. The patient's pre-existing medical condition of psoriasis and psoriatic arthritis might have provided alternative explanations. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RA, IEC, as appropriate."

"Confirmed DVT in the left leg; COVID test (PCR swab): positive on 26Dec2020; COVID test (PCR swab): positive on 26Dec2020; This is a spontaneous report from a contactable other healthcare professional. An 85-year-old female patient received 1st dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot# ELO140, expiration date: Mar2021), via an unspecified route of administration in arm (deltoid; unknown side) on 23Dec2020 at single dose for Covid-19 immunisation. Medical history included type 2 diabetes mellitus from 2017 and ongoing, high blood pressure from 2017 and ongoing, atrial fibrillation (A-Fib) from 2019 and ongoing. The patient's concomitant medications were not reported. The patient was administered first dose of the COVID vaccine on 23Dec2020 and then was swabbed for COVID on 26Dec2020, and then on 28Dec2020 her PCR swab was positive for COVID. She was asymptomatic until she started complaining of leg pain. She ordered an ultrasound for the patient on 30Dec2020, and it confirmed a deep vein thrombosis (DVT) in left leg. The patient was being treated with anticoagulant apixaban (ELIQUIS) currently. Caller stated that this could be that it (DVT) is from COVID, but her real question was, could it be from the vaccine? In Pfizer's information packet for patients, there is section on what to tell your provider prior to getting vaccinated. One of the things on there is if you have a bleeding disorder or are on an anticoagulant. There is no explanation as to why it was in the packet of information. Caller has looked everywhere and can not figure out why that is on the FAQ/packet information. The patient was due for the second dose on 13Jan2020, but she was worried and hesitant

to approve it. The patient underwent lab tests and procedures which included COVID test (PCR swab): positive on 26Dec2020, ultrasound of the left leg: confirmed DVT on 30Dec2020. The outcome of events was not recovered.; Sender's Comments: There is not a reasonable possibility that event ""COVID test (PCR swab): positive"" is related to BNT162B2 vaccine. The event occurred 3 days after vaccination, when vaccine was not expected to achieve the effect. The event DVT of legs is not considered related to BNT162B2 vaccine. The patient had underlying diabetes and cardiovascular disorders, which are considered as risk factors for DVT. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate."

Patient was poorly responsive to her inhalers that she used for asthma; Persistent shortness of breath and chest tightness starting within a few days after vaccine; Persistent shortness of breath and chest tightness starting within a few days after vaccine; This is a spontaneous report from a contactable physician (patient). A 40-year-old male patient received the first single dose of BNT162B2 (Solution for injection, lot number: EK5730, exp date not reported), via an unspecified route of administration (vaccine location: left arm) on 18Dec2020 04:15 for COVID-19 immunization. Medical history included allergy induced asthma, allergies to cats and dust, and occasional seasonal allergies. Concomitant medication included other vaccine/s received within 4 weeks prior to the COVID vaccine: first dose of diphtheria vaccine toxoid, pertussis vaccine acellular 3-component, tetanus vaccine toxoid (BOOSTRIX, GlaxoSmithKline) administered as single dose via unspecified route of administration (vaccine location: left arm) on 08Dec2020. There were no other medications the patient received within 2 weeks of vaccination. The patient experienced persistent shortness of breath and chest tightness starting within a few days after vaccine (24Dec2020). Patient was poorly responsive to her inhalers that she used for asthma (onset date not reported). She rarely needed the, used about once or twice a year). It was constant, but with periods of improvement followed regression. Will likely seek medical evaluation as it's been over a week now and rather concerning. The patient did not consider the events shortness of breath and chest tightness as serious. Treatment for the adverse events shortness of breath and chest tightness included fluticasone propionate, almeterol (ADVAIR), albuterol, and unspecified anti-allergy medications. Patient did not have covid prior vaccination. Patient was tested for COVID post vaccination wherein patient tested negative for COVID via Covid test rapid on 30Dec2020. The adverse event resulted in doctor or other healthcare professional office/clinic visit and emergency room/department or urgent care. The outcome of shortness of breath and chest tightness was not recovered and unknown for the other event.; Sender's Comments: Based on the time association, the possible contribution of BNT162B2 to the events shortness of breath , chest tightness and asthma aggravated cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

"diabetes was high; seeing double vision; Headache on the right side; This is a spontaneous report from a contactable nurse. A patient of an unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number/expiration date unknown) dose number 1, via an unspecified route of administration on 18Dec2020 at a single dose for COVID-19 immunization. Medical history and concomitant medications were not reported. The patient had the vaccine in a hospital on a Friday (18Dec2020). No side effect was noted over the weekend. On 21Dec2020, when the patient woke up, s/he was seeing double vision, so s/he went to the doctor; they ran some test (unknown result). Because the patient was having headache on the right side in Dec2020, s/he went back to the doctor on 23Dec2020; the patient was sent to the eye doctor and they ran all kind of test. On 24Dec2020, the only thing they could find was that the patient's diabetes was high, so they kind of felt that what that could have been was kind of coincidental. The outcome of the events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: The mentioned ""diabetes was high"" is likely an intercurrent disease, unlikely related to the administration of BNT162B2, the COVID-19 immunization. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RA, IEC, as appropriate."

joint pain; it doesn't seem to be feeling well; sweating; Fever; chills; night sweats, that he will randomly start sweating; headache; muscle pain/mild muscle aches; gastric upset; Fatigue; he had mild arm soreness right after he got the vaccine; This is a spontaneous report from a contactable Other-HCP (patient). This 45-year-old male Other-HCP received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EJ1685, NDC number: 59267-1000-1) on 22Dec2020 at single dose in his right arm for COVID-19 immunization. Medical history and concomitant drug were not reported. It was reported that patient experienced Fever on 27Dec2020 with outcome was recovered on 29Dec2020, chills and night sweats on 27Dec2020 with outcome was not recovered, Headache on 27Dec2020 with outcome was not recovered, muscle pain 27Dec2020 with outcome was not recovered, gastric upset on 27Dec2020 with outcome was Recovering, Fatigue on 27Dec2020 with outcome was unknown, arm soreness on 22Dec2020 with outcome was not recovered, joint pain with outcome was unknown, it doesn't seem to be feeling well with outcome was unknown, sweating with outcome was unknown. All events were serious (medical significant). Caller stated that he thought having a reaction to the vaccination, spoken with Occupational Health at his job and with a doctor, stated everyone is a bit stumped. Caller stated he has had for over a week now, fever, chills, night sweats, that he will randomly start sweating, headache, joint pain, gastric upset, and it doesn't seem to be feeling well. Stated the joint pain is actually more muscle pain. Stated he got the vaccination on Tuesday 22Dec2020, stated he has been having these symptoms for over 5 days now. Stated he does not think this is something infectious, that no one in his family is getting sick, his wife or child are not catching it from him. Stated he tried to do research online for data about delayed side effects, would like to know if we have any information on delayed side effects. Stated he considers these events medically significant because he cannot be cleared to go back to work. Stated he had mild arm soreness right after he got the vaccine, states he had mild muscle aches Wednesday and Thursday, then they went away and came back all on Saturday night and Sunday. Stated he is worried about getting a second vaccine. Stated he tested

negative for the COVID on 29Dec2020. Stated he has a CBC and other blood work scheduled for today, results unknown at this time. No follow-up attempts are possible. No further information is expected.; Sender's Comments: Based on the compatible temporal association and the drug's known safety profile, the vaccination with BNT162B2 might play a contributory role in triggering the onset of the events. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Tachycardia; Palpitations; had a strong, whole body heat, and flushing; had a strong, whole body heat, and flushing; This is a spontaneous report from a contactable nurse. This nurse reported similar events for 6 patients. This is the 4th of 6 reports. A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot/batch unknown) via an unspecified route of administration on 28Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The reporter said her friend is a registered nurse, and received the COVID-19 Vaccine on Monday, 28Dec2020. She said her friend stated she, and 5 other registered nurses she works with, had a serious reaction right after receiving the COVID-19 Vaccine. The patient had a strong, whole body heat, and flushing. The patient said she became tachycardic and had palpitations that lasted a few minutes. She said the tachycardia and palpitations then slowly resolved in less than 5 minutes. She had no other symptoms after receiving the COVID-19 Vaccine. There is unknown whether the patient received the treatment or not. The outcome of the events was recovered on 28Dec2020. Information on lot/batch number has been requested.; Sender's Comments: Based on the compatible temporal association, the vaccination with BNT162B2 might play a contributory role in triggering the onset of the events flushing, feeling hot, tachycardia and palpitations. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.,Linked Report(s) : US-PFIZER INC-2021001345 same reporter/drug/event, different patient.

It sounds like to be an allergic reaction; She passed out; Tachycardia; Nausea; Lightheadedness; This is a spontaneous report from a non-contactable physician. A 32-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) in Dec2020 at single dose to be vaccinated for her protection. Medical history was none. The patient's concomitant medications were not reported. Patient took the Pfizer COVID-19 vaccine and next day she had a very serious reaction. She did not know that if it was due to the vaccine. But she had tachycardia requiring her to go to the emergency room and she passed out and she had nausea and lightheadedness as well. It sounds like to be an allergic reaction. Given the seriousness of tachycardia and passing out as well as the lightheadedness and nausea it sounds too severe just to be a mild immune response. So, it was sort of rare immune response or it was unrelated it was unknown at this time. Outcome of event was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Sender's Comments: Based on the compatible time association, the contribution of suspect BNT162B2 to the events cannot be excluded. The impact of

this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

strong, whole body heat, and flushing; strong, whole body heat, and flushing; Tachycardia; Palpitations; This is a spontaneous report from a contactable Nurse. This Nurse reported for similar events for 6 patients. This is 2nd of 6 reports. A 49-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot/batch unknown), via an unspecified route of administration on 28Dec2020 at single dose for covid-19 immunization. The patient's medical history and concomitant medications were not reported. The reporter said her friend was a registered nurse, and received the COVID-19 Vaccine on Monday, 28Dec2020. She said her friend stated she, and 5 other registered nurses she works with, had a serious reaction right after receiving the COVID-19 Vaccine. The patient had a strong, whole body heat, and flushing. The patient said she became tachycardia and had palpitations that lasted a few minutes. She said the tachycardia and palpitations then slowly resolved in less than 5 minutes. She had no other symptoms after receiving the COVID-19 Vaccine. It was unknown whether the patient received the treatment or not. The outcome of the events was recovered on 28Dec2020. Information on lot/batch number has been requested.; Sender's Comments: The reported transient events of whole body heat, flushing, tachycardia and palpitations were likely related to BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) due to temporal relationship and clinic course. The case will be reassessed should additional information become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics committees and Investigators, as appropriate.,Linked Report(s) : US-PFIZER INC-2021001345 same reporter/drug/event, different patients.

Serious, weird reaction/had a strong, whole body heat, and flushing; Serious, weird reaction/had a strong, whole body heat, and flushing; Serious, weird reaction/tachycardic; Serious, weird reaction/had palpitations; This is a spontaneous report from a contactable nurse. This nurse reported similar events for 6 patients. This is 5th of 6 reports. A patient of unspecified gender and age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 28Dec2020 at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The reporter did not know if the patient had received any other vaccines at the same time as the COVID-19 Vaccine, and if the patient had received any other vaccines within the last 4 weeks. It was reporter that the reporter's friend texted her last night, on 30Dec2020, at around midnight. The reporter, and 5 other registered nurses she works with in a hospital, received the COVID-19 vaccine at the same time and had the same exact symptoms she experienced. They had a serious reaction right after receiving the COVID-19 Vaccine. The patient had a weird reaction right after being injected with the COVID-19 Vaccine. The patient had a strong, whole body heat, and flushing. The patient became tachycardic and had palpitations that lasted a few minutes. The tachycardia and palpitations then slowly resolved in less than 5 minutes. The patient had no other symptoms after

receiving the COVID-19 Vaccine. The registered nurse who was monitoring the people who received the COVID-19 Vaccine indicated that the same feeling had occurred in many other workers who had received the COVID-19 vaccine. For treatment information, the reporter didn't believe the patient received any medical attention. Reporter believed that the patient just waited symptoms out, and within 5 minutes the symptoms had gone away. The outcome of the events was recovered on 28Dec2020. Information on the lot/batch number has been requested.; Sender's Comments: Based on the compatible temporal association, the vaccination with BNT162B2 might play a contributory role in triggering the onset of the events flushing, feeling hot, tachycardia and palpitations. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.,Linked Report(s) : US-PFIZER INC-2021001345 same reporter/drug/event, different patient.

"Back of my right leg has a quarter size oblong shape lump it's little bit red but not warm to the touch; Back of my right leg has a quarter size oblong shape lump it's little bit red but not warm to the touch; Back of my right leg has a quarter size oblong shape lump it's little bit red but not warm to the touch, it may be a blood clot; This is a spontaneous report from a contactable consumer (patient). A patient of unspecified age and gender received single dose of BNT162B2 (Solution for injection, batch/lot number and exp date not reported), via an unspecified route of administration on 30Dec2020 18:30 SE for immunization. The patient's medical history and concomitant medications were not reported. Patient received the Pfizer Vaccine the day of reporting: 30Dec2020 at about 06:30 (tonight). Patient felt fine and still felt fine but when was going to rub some lotion on the back of right leg, has a quarter size oblong shaped lump (onset date not reported) which was little bit red but not warm to the touch. Patient didn't do anything to make it happen. Patient doesn't know if it may be a blood clot which was patient's question. ""The blood clot something may be concerned about."" Patient asked ""Is this a blood clot, it could go to my heart and I could die tomorrow? So I am going to call my family doctor but thank you."" The outcome of the events was unknown. Information about lot/batch number has been requested."

Fatigue and overall lethargic feeling/Sore throat; Dark colored urine despite pushing fluids; Frequent urination; Migraine; Swollen joints and could not move arm that received vaccine in; Swollen joints and could not move arm that received vaccine in; Stomach pains, nausea, diarrhea, swollen lymph nodes; Stomach pains, nausea, diarrhea, swollen lymph nodes; Stomach pains, nausea, diarrhea, swollen lymph nodes; Stomach pains, nausea, diarrhea, swollen lymph nodes; Chills, body aches, spiked fever of 102.; Chills, body aches, spiked fever of 102.; Chills, body aches, spiked fever of 102.; Fatigue and overall lethargic feeling; Fatigue and overall lethargic feeling; Sore throat; The initial case was missing the following minimum criteria: Invalid for no adverse effect. Upon receipt of follow-up information on (31Dec2020), this case now contains all required information to be considered valid. This is a spontaneous report from a contactable Nurse. A female patient of an unspecified age received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, batch/lot number EH9899, Expiry Date: Mar2021), intramuscular at Deltoid Left on 29Dec2020 07:20 at single dose for COVID-19 immunization. Medical

history included covid-19 from Nov2020 to an unknown date (had covid in the middle of November), surgeries from an unknown date and unknown if ongoing (She also had previous surgeries and has foreign objects in her body. Those areas were super hot. Those antibodies were like rejecting those foreign bodies because they were super hot.) There were no concomitant medications. Received call from RN calling about the Pfizer COVID vaccine. She got the vaccine on Tuesday and had a terrible reaction to it and she called a couple of different hotlines and spoke with the people who administered it. She confirmed that she did not report to Pfizer though. The people at her work that she spoke with told her to go to an Urgent care. They told her she should not get it within 90 days of having COVID. She had COVID in the middle of Nov2020. She went ahead and got it on Tuesday and had this terrible reaction. She would like to know if she should get the second dose or wait until 90 days after she had COVID and start again. There was no prescriber. She received it as part of the (hospital name withheld) front line health worker precaution. She thought that this was a normal reaction, but was told it was not. Fatigue and overall lethargic feeling happened exactly 12 hours after receiving. She works night shift and that is her base line. Pretty much everything hit after that within an hour. She was told low grade fever was normal, but not 102. She never spikes fevers, so it is medically significant. It persisted for 24 hours and is better today. She is on the 48 hour mark now. Stomach pains, nausea, diarrhea, lymph node swelling all over, including swelled armpits and groin area, Migraine, Frequent urination, were also listed as side effects. She was trying to push more fluids but her urine was dark color more than normal, despite pushing fluids. Swollen lymph nodes in her groin and armpits were concerning. Her head is lumpy. Meaning, she can feel swollen lymph nodes in back of neck area. Migraine was consistent through 24 hours and now has improved. Urine color remains dark and she will keep an eye on color. She had swollen joints, but really terrible swollen joints, and she could not move the arm that she got the vaccine in. She could not lift to above shoulder height. AE Details and time of onset: Sore Throat 12:00 on 29 Fatigue and overall lethargic feeling 20:00 Chills, body aches, spiked fever of 102: 21:00 Stomach pains, nausea, diarrhea, swollen lymph nodes- 21:00 Migraine- 21:00 Frequent Urination 23:00 Dark colored urine despite pushing fluids 23:00 Swollen joints and could not move arm that received vaccine in: 21:00. ER or physician's office required: Went to urgent care 36 hours after administration. No treatment given. She just wanted to make sure no additional infection was causing anything weird. All test were negative. Prior Vaccinations (within 4 weeks): none. Events Swollen joints and could not move arm that received vaccine in, Stomach pains, nausea, diarrhea, swollen lymph nodes, Chills, body aches, spiked fever of 102 were serious with criteria of medically significant, while the other events were non-serious. The outcome of the event Fatigue and overall lethargic feeling/Sore throat (Condition worsened) was unknown, the outcome of the events Swollen joints and could not move arm that received vaccine in, Chills, body aches, spiked fever of 102., Migraine, Dark colored urine despite pushing fluids, Frequent urination was recovering, while the outcome of the other events was not resolved.; Sender's Comments: Based on the information available, a possible contributory role of the suspect products cannot be excluded for the reported events due to temporal association. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators as appropriate.

anaphylactic reaction; neuropathy in fingers, toes, roof of mouth/lips; This is a spontaneous report from a contactable nurse (patient). This 48-year-old female patient (not pregnant at the time of vaccination) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot#: EL0140) at single dose on left arm on 30Dec2020 at 09:00 for COVID-19 immunization. Medical history included asthma (controlled); hypertension diagnosis 1 year ago; allergies to medications, food and environmental. Concomitant medications in two weeks included antihypertensives - amlodipine and losartan. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. On 30Dec2020 at 9:15 AM, the patient experienced anaphylactic reaction within 10 minutes of administration, neuropathy in fingers, toes, roof of mouth/lips. Neuropathy continued to date. The adverse events resulted in emergency room/department or urgent care. The patient received treatment Epinephrine IM (intramuscular) and IV (intravenous) steroids. The outcome of events was recovering.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the reported events of anaphylactic reaction and neuropathy peripheral due to temporal relationship. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics including serum tryptase and nerve conduction studies, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

"brain felt swollen; glands were also swollen; bad headache; minimal arm pain; fatigue; This is a spontaneous report from a contactable nurse (patient). A female patient of an unspecified age received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date not reported), via an unspecified route of administration on 30Dec2020 at single dose for COVID-19 immunization. Medical history included lupus-like history and chronic Lyme disease. The patient's concomitant medications were not reported. The patient stated she received the first vaccine dose on 30Dec2020 and had minimal arm pain, fatigue that went to a very bad headache on Thursday (31Dec2020). By Friday headache and fatigue were terrible until this morning. Her brain felt swollen and her glands were also swollen on 03Jan2021. The patient stated that she called healthcare professional (HCP) and was told that her body was ""having an auto immune response"", ""due to a lupus like history and a history of chronic Lyme disease and to hydrate well"". It was so hard to talk, she was so fatigued. Her doctor compared it to like an encephalopathy. The patient was feeling better today but was concerned about taking the second dose. She works in a facility with a lot of Covid-19 patients. The outcome of the events was recovering. Information on the lot/batch number has been requested.; Sender's Comments: Based on the current available information, a possible contributory role of the suspect product to the development of event brain felt swollen cannot be totally excluded. Medical history of lupus-like history and chronic Lyme disease may provide plausible alternative explanations for the event. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part

of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate."

numbness and weakness in left arm; numbness and weakness in left arm; had a brachial plexus pathology; her grip and fine motor are affected in her left arm/she could not do her job; This is a spontaneous report from a contactable physician (patient). A 35-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot# EH9899), via an unspecified route of administration in right arm on 21Dec2020 at single dose for Covid-19 immunisation. Medical history included ongoing birth control. No other medical history. Concomitant drug included other medication she took for birth control. On 29Dec2020, the patient experienced numbness and weakness in left arm, had a brachial plexus pathology, went to the emergency department on 30Dec2020 and was seen by one of the facility doctors and stated this doctor had her on steroids for treatment. She got the vaccine in her right arm, stated her grip and fine motor are affected in her left arm. States this was disabling since she could not do her job. She was following up with neurology on Monday (unspecified), that she had a CT scan of her neck and it was normal. Only other medication she was taking was for birth control, but she did not feel like it was relevant. The outcome of events numbness and weakness in left arm was recovering, while outcome of other events was unknown. This case was reported as serious, seriousness criteria was disabling.; Sender's Comments: Based on the information currently provided, the vaccination with BNT162B2 might play a contributory role in triggering the onset of the reported events. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

it hits a nerve; perceived it along the face still and the arm; Bell's Palsy; numbness in a small area of her tongue; right eye was irritated a little dry; right eye was irritated a little dry; right sided ear pain; fluid in the ear but no infection; This is a spontaneous report from a contactable health care professional (nurse practitioner). A 35-year-old female patient received her 1st dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) at single dose via an unknown route on the right side on 21Dec2020 for Covid-19 immunization. Medical history included intermittent hives. Concomitant drug included ongoing cetirizine hydrochloride (ZYRTEC) 5 mg for intermittent hives. The reporting nurse practitioner saw a patient on 31Dec2020 who was vaccinated on 21Dec2020 and had a Bell's Palsy reaction (reported as not serious). She did some research and saw no more incidents in the general population but she wanted to report this. She also wanted to get more information on if the patient should proceed with dose number 2 of the vaccine. The patient developed the Bell's Palsy within 5 minutes after getting the vaccine. She thought it was because she was anxious to get the vaccine, so she brushed it off. The Bell's Palsy was still occurring but per the patient it had improved. On exam she did not have any weakness, facial droop or dumbness with sharp or dull testing. The patient perceived it along the face still and the arm. The reporting nurse practitioner said that the arm was probably not Bell's Palsy, but more related to getting the vaccine in the arm and it hits a nerve. Patient stated that her smile was also unequal and it

was difficult for her to close her right eye, although now (as of 31Dec2020) she can. Her right eye was irritated a little dry. Regarding treatment, the patient was started on steroids on 31Dec2020. She did not start her on an anti-viral as she did not want it to impact her immunity to the vaccine. The patient also complained of right sided ear pain. She was unsure if that was related to the Bell's Palsy, but it was also on the right side. There was fluid in the ear but no infection. The pain was still ongoing. The patient also mentioned numbness in a small area of her tongue when she first got the vaccine. This was still ongoing. Outcome of Bell's Palsy was resolving. Outcome of the event numbness in a small area of her tongue, right sided ear pain was not resolved. Outcome of the other events was unknown. The reporting nurse practitioner stated that this was not serious as this was a mild case and was thankfully resolving. The reporting nurse practitioner comment that nothing of history was relevant besides for the last several months (as of 31Dec2020) the patient had been taking 5mg of cetirizine hydrochloride for intermittent hives. She wondered if she had not been taking it how she would have reacted or if the reaction would have been more severe. Information on the lot/Batch number has been requested.; Sender's Comments: A possible causal association between administration of BNT162B2 and the onset of Bell's Palsy cannot be excluded, considering the plausible temporal relationship. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Pitting edema/Edema: It was her feet, ankles, and 3/4 way up her shins.; This is a spontaneous report from a contactable nurse (patient). A 47-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number: EK5730, expiry date: Mar2021), intramuscular in the left deltoid on 17Dec2020 at 07:15 at single dose for COVID-19 immunization. Medical history included ongoing neuralgia since 2003 (has nerve pain in her face and neck. It has never caused swelling and that she has had it for a long time. Symptoms started 17 years ago, became apparent in 2009), ongoing hypothyroidism since 2003 (Diagnosed about 17 years ago. Nothing has changed medication wise). The patient's concomitant medications were not reported. The patient reported that she got the vaccine on 17Dec2020. On 25Dec2020, her shoes felt snug and by the next day she had 4 plus pitting edema. She could not fit in the shoes. She had the pitting edema for several days. She said that she went and bought compression stockings to help with the edema. It was her feet, ankles, and 3/4 way up her shins. It was more of the pedal area that was pitting. The patient further reported that she never had pitting edema before and the only thing new she had was the vaccine. Therapeutic measures were taken as a result of the event which included compression stockings. The patient was recovering from the event.; Sender's Comments: Based on temporal association, a possible contributory role of BNT162B2 cannot be excluded for reported event pitting edema. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

a strong, whole body heat, and flushing; a strong, whole body heat, and flushing; Tachycardia; Palpitations; This is a spontaneous report from a contactable Nurse. This Nurse reported similar event for 6 patients. This is 3rd of 6 reports. A 24-Year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 28Dec2020 at single dose for COVID-19 immunisation. Medical history and concomitant medications were not reported. Pfizer employee reporting on behalf of a friend, reported her friend texted her last night, 30Dec2020, at around midnight. The nurse and 5 other registered nurses she works with, had a serious reaction right after receiving the COVID-19 Vaccine. Caller said she had a strong, whole body heat, and flushing. She said she became tachycardic and had palpitations that lasted a few minutes. Caller said there were 5 other registered nurses that received the COVID-19 Vaccine at the same time and had the same exact symptoms she experienced. Outcome of events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Based on temporal association, a possible contributory role of BNT162B2 vaccine cannot be excluded for events flushing, feeling hot, tachycardia and palpitations. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate. ,Linked Report(s) : US-PFIZER INC-2021001345 same reporter/drug/event, different patient.

she had a strong, whole body heat, and flushing; she had a strong, whole body heat, and flushing; Tachycardia; Palpitations; This is a spontaneous report from a contactable nurse. This nurse reported similar events for 6 patients. This is the 6th of 6 reports. A 49-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot/batch unknown) via an unspecified route of administration on 28Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The reporter said her friend is a registered nurse, and received the COVID-19 Vaccine on Monday, 28Dec2020. She said her friend stated she, and 5 other registered nurses she works with, had a serious reaction right after receiving the COVID-19 Vaccine. The patient had a strong, whole body heat, and flushing. The patient said she became tachycardic and had palpitations that lasted a few minutes. She said the tachycardia and palpitations then slowly resolved in less than 5 minutes. She had no other symptoms after receiving the COVID-19 Vaccine. The registered nurse who was monitoring the people who received the COVID-19 Vaccine indicated that the same feeling had occurred in many other workers who had received the COVID-19 vaccine. The reporter did not know if the patient received any other vaccines at the same time as the COVID-19 Vaccine, and if had received any other vaccines within the last 4 weeks. The patient works at a hospital but doesn't believe that she received any medical attention. she believed just waited her symptoms out, and within 5 minutes her symptoms had gone away. The outcome of the events was recovered on 28Dec2020. Information on lot/batch number has been requested.; Sender's Comments: The Company cannot completely exclude the possible causality between the reported whole body heat, flushing, tachycardia and palpitations, and the administration of BNT162B2, based on the reasonable temporal association and lacking alternative explanations. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any

appropriate action in response, will be promptly notified to RA, IEC, as appropriate.,Linked Report(s) : US-PFIZER INC-2021001345 same reporter/drug/event, different patient.

Rash; Welts; she had a very sore arm; This is a spontaneous report from a contactable nurse (patient herself). A 65-year-old female patient received her first dose of bnt162b2 (BNT162B2 also reported as Pfizer Covid Vaccine, lot EH9099 or EH9899), via an unspecified route of administration in her left deltoid on 22Dec2020 09:32 at single dose for Covid-19 immunisation. Medical history included broken toe for 3 weeks. This was from her taekwondo and doesn't complain. No history of all previous immunization with the Pfizer vaccine considered as suspect drug. There were no additional vaccines administered on same date with Covid-19 vaccine. There were no concomitant medications. On 24Dec2020, she broke out in a rash on different parts of her body. She said the rash would come and go. She said she then had welts appear on different parts of her body and the welts would come and go. She said on the 3rd day, she had rash and welts together only on her trunk. She said on days 4, 5, and 6, she would have either a rash or welts come and go on different parts of her body. She clarified she had the rash and welts on her hands, wrists, ankles, and body. She reported that the rash and welts were serious-medically significant. On 22Dec2020, she had arm soreness and was just inconvenient and uncomfortable. She said she was not saying that what she was experiencing was related to receiving the COVID-19 Vaccine, but she doesn't know what else can be causing the rash and welts. She said she hasn't changed anything she has been eating or doing. She said she was worried about taking the 2nd COVID-19 Vaccine dose. She used Hydrocortisone 1% cream, Equate brand (reported to be expired) and took an oatmeal bath. She also took Benadryl and brand of Zyrtec called Wal-Zyr. Her height was 175cm, weight was 63kg. The rash and welts recovered on 30Dec2020; arm soreness recovered on 23Dec2020. Information about lot/batch number has been requested.; Sender's Comments: Based on temporal association, the causal relationship between BNT162B2 and the events rash and urticaria cannot be excluded. This case will be reassessed once additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate.

Saturation down to 84%; Temperature of 101.3; Rapid pulse having some difficulty; This is a spontaneous report from a contactable consumer. A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number and expiry date not reported) via an unspecified route of administration, on 30Dec2020, single dose for COVID-19 immunization. Relevant medical history and concomitant medications were not reported. The reporter is working in long term in Nursing care facility. It was reported that they have a resident who recovered from COVID. They are having some questions following the guidelines stuff, just kind of asking some more questions. Just one of their resident had temperature of 101.3, saturation down to 84%, 'frustration' at 24% and rapid pulse having some difficulty. The patient was put in her bed. The reporter contacted the doctor in house. 'The reporter wanted to see if any of the recommendation were for (incomplete sentence). The long term care facilities recovered COVID, the reporter wanted to know any of the lasting short term and any guideline for treating. They were all recovered COVID, all of two of the resident two weeks or more out

and we (Further clarification was unknown) just had the vaccine yesterday' (as reported, pending clarification). Outcome of the events was unknown. Information on the batch number has been requested.

Fainting; Red Palms; blotching; sweating profusely; heart palpitations; Chest pain; Elevated BP; This is a spontaneous report from a contactable consumer (patient). A 46-years-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 28Dec2020 09:15 at single dose on left arm (Lot number: ek9231) for COVID-19 immunisation. Medical history included asthma, bronchitis, mitral valve regurgitation, herpes, depression, ADHD. COVID prior vaccination: Yes. Known allergies: tramadol, milk products. No other vaccine in four weeks. Concomitant medication included amfetamine aspartate, amfetamine sulfate, dexamfetamine saccharate, dexamfetamine sulfate (ADDERALL), bupropion, and, losartan/hydrochlorothiazide. The patient experienced red palms/blotching, sweating profusely, heart palpitations, chest pain and fainting, elevated BP, all on 28Dec2020 09:15. All these events required Emergency room visit. Therapeutic measures were taken as a result of the events included 50 mg of Benadryl, 60 mg of Prednisone, omepresol. No COVID tested post vaccination. Outcome of events was recovered with sequelae.

I have a sleep problem almost eight hours; I was so tired; Headache; My arm was sore for 24 hours; so stiff; This is a spontaneous report from a contactable physician. A 69-year-old patient of an unspecified gender received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiry date were not reported), via an unspecified route of administration on an unspecified date at a single dose for COVD-19 immunization. The patient's medical history and concomitant medications were not reported. The patient had the first dose of the vaccine and had a pretty significant reaction, one say serious to moderate reaction. The patient's question was do they know yet if you take a second shot was your reaction get even worse because the patient had a sleep problem almost eight hours. The patient was so tired, had headache and so stiff, arm was sore for 24 hours. The patient was a little afraid to take a second shot. The outcome of the events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: A causal association between BNT162B2 and the reported events cannot be excluded based on a compatible temporal relation between vaccination and onset of events. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to agencys, Ethics Committees, and Investigators, as appropriate.

feeling close to loss of consciousness; intense chest pressure/tightness; shortness of breath; chills while driving home; This is a spontaneous report from a contactable healthcare professional (patient). A 50-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Lot number: EL0142), via an unspecified route of administration in the left arm, on 02Jan2021 at 11:30 (at the age of 50-years-old) as a single dose for COVID-19 immunization. The patient's medical history was not reported. The patient was not pregnant at the time of vaccination. Prior to the vaccination, the patient was not diagnosed with COVID-19. Concomitant medications, taken within two weeks of vaccination, included ibuprofen (MANUFACTURER UNKNOWN). The patient previously took amoxicillin (MANUFACTURER UNKNOWN) and experienced allergy. The patient did not receive any other vaccines

within four weeks prior to the vaccination. The patient experienced feeling close to loss of consciousness, intense chest pressure/tightness, shortness of breath, and chills while driving home on 02Jan2021 at 12:00. The patient did not receive any treatment for the events. The clinical outcome of feeling close to loss of consciousness, intense chest pressure/tightness, shortness of breath, and chills while driving home was recovering. It was also reported that since the vaccination, the patient had not been tested for COVID-19.; Sender's Comments: A possible causal association between administration of BNT162B2 and the onset of feeling close to loss of consciousness, intense chest pressure/tightness, shortness of breath cannot be excluded, considering the plausible temporal relationship. The underlying predisposing condition of penicillin allergy may put the patient at high risk of anaphylactic reactions. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Right sided facial & top lip Numbness & recurring pain; Right sided facial & top lip Numbness & recurring pain; Right sided facial & top lip Numbness & recurring pain; This is a spontaneous report from a contactable consumer reporting for herself. A 66-year-old female patient (not pregnant at the time of vaccination) received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number EK9231), via unspecified route of administration on 29Dec2020 13:30 on left arm at single dose for COVID-19 immunization. Facility where the most recent COVID-19 vaccine was administered in Hospital. Medical history included Hypertension, Reflux and low back pain. Concomitant medications included ibuprofen, dicycloverine hydrochloride (BENTYL), Valsartan and omeprazole. The patient previously took codeine, Bactrim, Zyrtec and experienced allergies. The patient experienced Right sided facial and top lip Numbness, recurring pain on 31Dec2020 16:00. All events resulted in emergency room visit and Hospitalization on 31Dec2020 for 1 day. The patient underwent lab tests and procedures, which included Cat scan, MRI, ultrasound of heart and labs on unspecified dates, Nasal Swab/Covid 19 test on 01Jan2021 with negative result. The outcome of the events were not resolved.

hives on her legs; a slight rash on abdomen (started morning on the next day when she woke up) and it spread to her legs (leg rash started 2 days later in the morning); This is a spontaneous report from a contactable nurse (patient). A 58-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) intramuscularly at left arm on 29Dec2020 10:30 at single dose for COVID-19 Immunization. No medical history. No family medical history. There were no concomitant medications. Patient received first dose last Tuesday, 29Dec2020, at the hospital. The next day, she had a slight rash on abdomen (started morning on the next day when she woke up) and it spread to her legs (leg rash started 2 days later in the morning). It was a pretty severe case of hives on her legs now (31Dec2020). Spread to legs and now has hives on legs was reported as worsened. Physician's office visit involved. She had a question. Her doctor prescribed a dosing pack of prednisone to get rid of the hives and her question was, will it affect the effectiveness of the vaccine if she takes it, also, is it ok to get 2nd dose in 2 weeks. She confirmed she had not taken the prednisone yet. There was no prescriber. She received it because she is a healthcare worker. Patient asked if there is any recommendation on getting pre medicated with ex: Benadryl before getting the vaccine. No previous history of all previous

immunization with the Pfizer vaccine considered as suspect. No additional vaccines administered on same date of the Pfizer suspect product. No medications prior vaccinations (within 4 weeks). No test done. This is a serious report. The slight rash on abdomen, spread to legs and now has hives on legs was considered medically significant per reporter. The outcome of the events was not recovered. Information about lot/batch number has been requested.; Sender's Comments: Based on temporal association, the causal relationship between BNT162B2 and the events rash and urticaria cannot be excluded. This case will be reassessed once additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate.

experienced eye puffiness; light headed ness; scratchy throat; This is a spontaneous report from a non-contactable consumer via Pfizer Sales Representative. A male patient (Health care worker) of an unspecified age and gender received BNT162B2(Pfizer BioNTech COVID-19 vaccine) via an unspecified route of administration in Dec2020 at single dose for COVID-19 immunization. The medical history and concomitant medications were not reported. The patient experienced eye puffiness, light headed ness and scratchy throat 10 minutes after vaccination in Dec2020. Reaction was not considered anaphylaxis. Patient received epinephrine, Pepcid and Benadryl in the ED, felt completely back to normal within an hour and was released. Event took place after use of product. The outcome of events was recovered in Dec2020. No follow-up attempts are possible; information about batch number cannot be obtained.

Felt sharp pain under jaw, then facial numbness. Then quickly developed facial swelling, left eye swelling and tongue swelling. Then felt like throat closing up within 7 minutes of receiving vaccine. Received vaccine in the clinic, was transported to Emergency Room. In ER received Epinephrine, steroids, Benadryl and Pepcid.

1 day after the vaccine he had a low grade fever... 1 week later he had a seizure and then multiple ones in the ER...

Developed shortness of breath, swelling of tongue, persistent cough within 5 minutes of vaccination. Was treated with EpiPen and kept in ER for observation overnight. Symptoms resolved.

Patient contacted provider 12/26 with following symptoms: Dry cough, diarrhea, fatigue for 7 days. Covid test ordered and positive. presented to ED on 12/31 and admitted into hospital. Still inpatient as of 1/7/2021.

Patient experienced an episode of SVT and then sinus tachycardia for approximately 6 hours after injection

"Pt last seen at 1200 by nurse for ID band check. No visible signs of distress noted. Pt states ""I just want to be left alone"". 1230 nurse was called to pt room. Pt was noted unresponsive, no pulse and respiration noted. CPR started immediately, at 1239 first shock given. 1245 EMT took over, at 1319 EMT called time of death"

Hemmoragic Stroke. Began with vision difficulty in the morning. Then I noticed she had left sided neglect. Went to ER. Treated with Andresxa (to counteract Elaquis). In SICU for 2 nights then telemetry unit for 3 nights. CUrrently in Rehab.

"Following vaccination the patient had progressively worsening abdominal pain over the next 24 hours. Presented to the ER and was initially thought to have appendicitis. However, it was then discovered during surgery that the appendix was surgically absent. The surgeon did not that the patient did have a ""Round, infarcted ligamentous tissue was wrapped around ascending colon. """

Patient developed hypoxia on 1/4/2021 and did not respond to maximal treatment and passed way on 1/5/2021

When vaccine was administered, seemed high on my arm. I had immediate soreness and shoulder discomfort, I was told this was normal. It continued to progress and I eventually had decreased ROM, weakness and sharp shooting pain in my shoulder. Working at OI, I consulted provider, xrays were obtained and I was evaluated. He strongly suggested an MRI be obtained as well. That was completed the same day as my evaluation on 12/31/2020 (1 week and 2 days after the vaccine was administered). The provider informed me that they have had patients with similar situations that were evaluated for frozen shoulder after having a vaccine d/t administration site and vaccine going into subacromial space. He does report that this was my case/situation, upon my exam, I had severe inflammation with this as well-he is now having me follow up for a surgical consultation for my shoulder to be repaired. Today's date is 1/7/2021, I have these same ongoing symptoms that have continued since day of administration, without diminishing in severity. He is unable to provide an injection d/t my upcoming second dose of the COVID vaccine this next week, 1/12/2021. He strongly suggests that my 2nd vaccine be administered elsewhere-advised NOT be administered in the same shoulder OR in opposite to cause these symptoms to flare. He advised in gluteus if possible to avoid any further issues if at all possible.

patient declined 12/30/2020 and was transferred to hospital where he did not respond to treatment and passed away 1/4/2020

Patient did not report any signs or symptoms of adverse reaction to vaccine. Patient suffered from several comorbidities (diabetes and renal insufficiency). Patient reported not feeling well 01/06/2021 and passed away that day.

Guillain Barre syndrome/AIDP event. Paresthesia and nerve pain developed in bilateral legs 4 hours after shot and progressed slowly for 4 days in intensity and area involved. Symptoms progressed distally to superior. On the 5th day symptoms progressed rapidly and involved bilateral legs up to the groin, left arm up to lateral shoulder, and right hand. I went to the hospital and was admitted to start IVIG treatment for Guillain Barre Syndrome/AIDP.

Vaccine Candidate received vaccine approxat 2:30pm, was monitored for 15 min no complications at the time, went home. Around 5:30pm while walking into her home she became unresponsive, was assisted in a siting position, became incoherent, mumbling and started to convulse to the right side of her r upper extremity. Foaming at the mouth and stopped breathing, CPR was initiated for 1-2 min, EMS

arrived was transported to Medical Center. She was admitted and is currently hospitalized. MD reports this event is highly unlikely related to the vaccine given her medical history but suggested to report being its a new vaccine. Current status: stable.

Person had a fever of 102.4, pulse rate of 118, he was non-responsive with edema of the right calf & ankle this morning when he was assessed.

Resident had the COVID vaccine 12/30/2020. 12/31/20, resident has been in bed all shift. Staff became concerned when resident was not easily aroused. Resident displayed signs of tremors, twitching, confusion, in and out of consciousness, low O2 sats, elevated pulse and fever, fatigue and weakness. Writer called NP. NP stated this is most likely a reaction d/t the COVID vaccine. She gave orders for Benadryl 25mg IM x1 now and Tylenol 1000 mg now. NP also stated resident will not be getting the second dose of vaccine. Will continue to monitor and update NP if worsening symptoms. After receiving Benadryl and Tylenol at 145pm, resident began to appear as though she was feeling better and was talking to talk, fever had gone down. Tonight resident is not easily aroused, lethargic, continues to have tremors and twitches, almost appearing as convulsions. When asked if she knows where she is or what day it is, resident can properly answer. Resident denies SOB but staff has noted loud squeals while breathing. NP was updated and gave new orders to give Benadryl 25 mg IM x1 if needed and Ok to send resident to ED. Resident currently refuses to go to the hospital. Will continue to monitor. BP 152/112, P 116, T 99.1, O2 87-91. Resident's O2 at 1205am was 80% on 3LPM. Resident unable to be aroused from sleep by writer. NAR called to assist. NAR could not arouse resident. Writer and NAR attempted to reposition resident and resident's breathing became more labored. Resident turned back to previous position and writer called on call MD at approx. 1220am. MD returned call approx. 1235am with orders to send resident to ED. 911 called and ambulance arrived about 1245am. History of present condition given to EMTs and they stated resident would be going to Hospital. Writer has attempted to contact Hospital ED x3 but have been unable to get through. An EMT did just call to clarify when vaccine was given, what symptoms have been present and when they started. She said she has everything she should need and she will let Hospital ED staff know to call if they need anything else. Writer will again attempt to contact them though. Resident's temp was 97.5 and BG 128. When EMTs arrived they got an O2 reading of 60%. Resident did open her eyes a couple times during transfer from bed to stretcher and while stretcher was going outside but no responses from resident were made.

had a vaccination on 12/31/2020 late morning passed away early morning 01/01/2020. This is a 93 year old with significant heart issues. EF of 20% among other comorbidities. He died suddenly approximately 0430, it is unlikely it was related to receiving the vaccine.

Immediate pain and loss of range of movement of left shoulder. Physical examination today demonstrates a healing injection site which is fairly superior on the left shoulder, and abduction of the left shoulder which is limited secondary to pain. Patient's physician's impression is that he has a subdeltoid bursitis which was temporally associated to the COVID-19 vaccination. (SIRVA)

RED CIRCULAR RASH AND LUMP UNDER SKIN. SKIN IS VERY ITCHY

Diffuse polyarthropathy starting the day after vaccination and continuing for 7+ days. Currently treating with abx for concern of possible cellulitis, and prednisone 60mg for polyarthropathy. Currently admitted.

woke up with fever and sore throat on 22nd; went to job and got tested and tested positive; on the 23rd developed right upper lobe pneumonia; on 27th was hospitalized with three lobe pneumonia; On 22nd received got zpack - azithromycin and sudafed; received at hospital doxicycleln IV ; ivermectin and went home with them, as well. Hospital

Day 2 (12/29/20): Fever (<100 degrees), Mild muscle aches, Fatigue Day 3 (12/30/20): Fatigue, Muscle aches Day 4 (12/31/20): Alternating chills and profuse sweating starting at 8am, Full body flushing, Grand Mal Seizure at 4:30pm

Patient was vaccinated at 11am and was found at the facility in his room deceased at approximately 3:00pm. Nurse did not have cause of death

Nausea, hives, anaphylactic shock, throat swelling, hypotension, headache, dizziness, weakness . The symptoms returned at 1:25pm the best day as well. I?ve now had two anaphylactic reactions

No adverse effects noted after vaccination. Patient with cardiac history was found unresponsive at 16:45 on 1/6/21. Abnormal breathing patterns, eyes partially closed SPO2 was 41%, pulseless with no cardiac sounds upon auscultation. CPR and pulse was regained and patient was breathing. Patient sent to Hospital ER were she remained in an unstable condition had multiple cardiac arrest and severe bradycardia and in the end the hospital was unable to bring her back.

Hives-like appearance on both arms within 10 minutes of administering vaccine. Resolved by itself in 30-40 minutes.

45 min later after receiving the vaccine I felt a lump in my throat. No other symptoms of an allergic reaction. Took benadryl with improvement of symptoms. Had intermittent difficulties swallowing seven hours afterwards. Went to the ED and was prescribed prednisone/ pepcid/benadryl. Symptoms improved but next day felt intermittent difficulty swallowing again. Returned to the ED and was given IV solumedrol and, IV pepdcid, IV benadryl.

Patient alerted pharmacist to feeling light headed at 12:10pm. Patient was instructed to sit down on the floor. She stated she felt hot and hadn't eaten all day. She was given a few bites of apple sauce and some Dr. Pepper to drink in case of low blood sugar. She was also given 25mg of diphenhydramine in case of an allergic reaction after the vaccine adminstration at 12:15pm. A few minutes later, she began shaking and stated she thought she was having an anxiety attack. At this time, the patient requested we call 911 because that would make her feel better and so we did.

Symptoms started during bedtime and woke me up. Began with severe full body chills and full body muscle shaking and weakness during the night of 1/5 and early morning of 1/6, around 1000 to 0200. Slight headache began during that time as well. Upon waking at 0900 on 1/6, chills and shaking decreased to mild severity, muscles still felt moderately weak and shaky, headache had increased in

severity to a severe throbbing pain that worsened upon standing and walking, and moderate visual photosensitivity began. The headache persisted until I took 2 tablets of ibuprofen 200 mg, which is when the severity decreased to moderate after a few hours and then mild by bedtime. The photosensitivity persisted through the day and did not decrease much by bedtime. Upon waking 1/7, there was only a mild headache and mild photosensitivity that faded completely within a few hours, no medication required. No more symptoms in the afternoon.

Moderna covid 19 vaccine EAU

2 hrs after vaccine felt sweating, clammy. Gas pains and cramps began. Loose stool once. 7 pm arm was sore and throbbing 6 of 10, injection site flushed and warm to the touch 9pm pain worsened to 8of 10. Unable to grab toothbrush with left arm sharp pain 10 of 10. Unable to sleep on left side due to pain and pressure . 6:00 am Thursday pain worse and unable to lift arm above the shoulder. Was unable to drive with left hand. All day today bad gas and abdominal cramps.by the end of the work day I was unable to hold anything in my left hand, body aches started, legs tight and achy. Frontal headache. Took Tylenol extra strength q 6 hrs, nsaid 800mg bid. And aleve, no relief

Had chills fever and body ache starting 01/07/21 Temperature went as high as 102.0 took ibuprofen and came down 97.9

On day 7, a red rash appeared just below the injection site and is indurated, hot, and tender. It spread in size within the next day.

Morning 8 days after injection, emergence of rash above injection site and redness and swelling at injection site. Morning 9 days after injection rash became a larger hive and doubled regular Zyrtec dosage. Morning 10 days after injection symptoms gone.

"Tire on day one-slept for 18 hours. Day 2: Woke up and was mildly achy, not wanting to do anything and red large swelling in my right deltoid. Very tender. Also, edema starting in my right axilla extending down my lateral chest about 7"". Day 3 to 7: Achiness is gone. Edema and swelling continue. Eventually the red swollen area became itchy. The edema under my arm (not a lymph node) was tender when my arm was close to my body. Woke me up during the night frequently. Very hard to sleep."

4 days later after the vaccine my left eye turned really red with crust and mucus coming out. I went to walk in clinic and was being treated for pink eye. I was started on an antibiotic eye drop. A day later my right eye started to have the same problem. I scheduled an appt with a eye specialist where he examined both eyes and said I had a major infection. I was started on steroid eye drops which I am still taking but seems my eyes are not getting better. I have a follow up with another specialist next week for further testing. I have been out of work due to this matter.

"Severe allergic reaction; anaphylactic reaction; A spontaneous report was received from a physician, who was also a male patient who received Moderna's COVID-19 Vaccine and developed a severe/anaphylactic allergic reaction. The patient's medical history, as provided by the reporter, included a shellfish allergy and elevated Immunoglobulin E. He reported no history of adverse events

following other immunizations, that all his immunizations were up to date, and that he gets the flu shot annually. Products known to have been used by the patient, within two weeks prior to the event, included pantoprazole, vitamin D, and vitamin B12. On 24 Dec 2020, minutes prior to the onset of the event, the patient received the first of two planned doses of mRNA-1273 intramuscularly for COVID-19 infection prophylaxis. Within minutes, the patient felt dizzy and his heart was racing. His throat felt swollen and he experienced shortness of breath (""heavy breathing"") with no wheezing or stridor, but with chest tightness that he felt was possibly related to anxiety about receiving the vaccine and the potential for allergic reaction. No supplemental oxygen was required. Vital signs showed a heart rate of 145, with normal blood pressure (BP) and oxygen saturation. After a few more minutes, he started to feel numbness and tingling in his mouth and tongue. He experienced diaphoresis (""drenched in a cold sweat""), skin pallor (""skin was severely pale""), felt faint, and reported that his blood pressure was undetectable by a monitor. He did not lose consciousness and denied any skin rash. The patient felt he was developing an allergic reaction and self-administered his personal epinephrine auto-injector. He felt better within five to six minutes after self-administration of epinephrine and was taken by stretcher to the Emergency Department for further evaluation and treatment of shortness of breath, dizziness, palpitations, and numbness. The patient was evaluated, treated, observed, and discharged four hours later. Treatment provided for the events while in the Emergency Department included diphenhydramine hydrochloride, intravenous (IV) fluids, IV steroids, and famotidine. On 25 Dec 2020, the patient felt fully recovered. On 26 Dec 2020, the patient felt dizzy and reported experiencing a ""rapid heart rate"" of 70-120 with a systolic BP that was abnormal for him at 150 mmHg. He also reported that he felt premature atrial contractions, for which he took his wife's propranolol. His heart rate came down, but he still felt flushing and dizziness for a few more hours. Action taken with mRNA-1273 in response to the event was not reported. The outcome of the event, severe/anaphylactic allergic reaction, was considered resolved on 26 Dec 2020. The reporter assessed the event of severe/anaphylactic allergic reaction as related to Moderna's COVID-19 Vaccine due to the temporal association and the similarity of symptoms previously experienced with severe/anaphylactic allergic reactions to shellfish.; Reporter's Comments: Company Comment: This case concerns a male patient with medical history of shellfish allergy , who experienced an unexpected events of severe allergic reaction; anaphylactic reaction, dizzy, faint, heart racing, tongue prickled and went numb, cold sweat, blood pressure plummeted, shortness of breath, numbness and skin was pale..The onset of event occurred 15 hrs the first dose of vaccine administration . The events are assessed as possibly related to vaccine."

throwing up; fever; body aches; her whole intestines hurt; it was horrible; thought she had contracted COVID-19; thought she had contracted COVID-19; tired; This is a spontaneous report from a contactable consumer. A 54-years-old female patient received her first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number EL0140), via an unspecified route of administration on left arm on 17Dec2020 at 19:15, at a single dose for vaccination. Medical history included ongoing ulcerative colitis, onset date was unknown, but when she was about 25 years of age. Concomitant medication included ongoing azathioprine for ulcerative colitis, started probably 5-10 years ago and taken daily since. In the past, she took different products for ulcerative colitis off and on when she had an episode. This patient reported she was administered her first Pfizer COVID-19 Vaccine injection on 17Dec2020 and was just kind of tired on 17Dec2020; but she had onset of serious reactions to the

COVID-19 Vaccine starting 18Dec2020 for 2 days straight and then as suddenly as the events started they suddenly stopped after 2 days with no lasting effects. She called to ask if there is any data about if the second dose of the COVID-19 Vaccine will be just like the first shot or if the events are just hit or miss; she is really hoping not to be that sick again with the second dose. Serious reactions to the COVID-19 Vaccine further described as sick for like 2 days straight. Afternoon of 18Dec2020 she was throwing up; had fever; body aches; thought she had contracted COVID-19 in between injection and onset of symptoms; she had no lung issues; her whole body hurt; she could not stop throwing up; her whole intestines hurt; it was horrible; she could not hold anything down for like 2 straight days and then just left on 20Dec2020. Scheduled date for second dose was on 06Jan2021, she has no plan to change dose schedule. The outcome of the event of tired recovered in Dec2020, while other events recovered on 20Dec2020.

positive COVID-19 test with symptoms; positive COVID-19 test; gastritis; diarrhea; This is a spontaneous report from a contactable other hcp (patient). A 50-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number: EJ1685; expiry date was not reported), via an unspecified route of administration on the upper right arm on 21Dec2020 at single dose for COVID-19 immunization. Medical history included blood pressure high, attention deficit hyperactivity disorder (ADHD), hypertension all from an unknown date and unknown if ongoing, and was a former smoker. Concomitant medication included lisinopril and methylphenidate. The patient reported that after he received the vaccine, he tested positive for Covid on 30Dec2020. The patient further reported that he ended up getting significant gastritis on Christmas Eve, which he didn't think about acquiring COVID, he had had the vaccine, he ate a bunch of holiday fare, so he thought he had got a stomach bug or something like that. He says he had considerable diarrhea on Christmas morning, but no fever or chills, then those symptoms resolved by Saturday, and he didn't think about it, he didn't have any issues. He says that he went to get tested, which they do frequently, and his temperature was checked frequently at the places he goes and he had no fever, and is still not febrile now. He says that he gets a weekly COVID test which allows for him to enter different facilities, and this was the first time in 9 months that he tested positive since this all came out. He says he has worked in some heavy duty places, but he wears his PPE, his respirator, his shield, and still did this stuff after he got the vaccine, he didn't let his guard down since it might take a while for immunity to kick in, but he still didn't think that it could be possible to have COVID on Christmas Eve, he was rather surprised he was positive. The patient confirms that he hasn't had the second dose of the vaccine yet. He says that his diarrhea improved on day or two starting after he had been having bloating on Christmas Eve and Christmas morning. He says his diarrhea resolved, he took no medication for it, and had no change in his heart rate or breathing, no problems anywhere else, he didn't feel that bad, except for the going to the bathroom. The patient underwent lab tests and procedures which included sars-cov-2 test: positive on 30Dec2020. The outcome of the events was unknown.; Sender's Comments: Based on the information currently available, a lack of efficacy with the suspected vaccine BNT162B2 in this subject cannot be completely excluded. Further information like confirmative virus genome /nucleic acid detection needed for meaningful medical assessment.

Reported to get the vaccine, and within a couple of hours or days, test positive for COVID; Reported to get the vaccine, and within a couple of hours or days, test positive for COVID; This is a spontaneous

report from a contactable other HCP received from a Pfizer-sponsored program IBCC (Inbound Call Center for HCPs). A patient of unspecified age and gender received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiry date were not reported), via an unspecified route of administration on an unspecified date at a single dose for covid-19 vaccination. The patient's medical history and concomitant medications were not reported. The patient reported to get the vaccine, and within a couple of hours or days, test positive for covid. The outcome of the event was unknown Information on the lot/batch number has been requested.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the reported events of SARS-CoV-2 test positive and LOE due to temporal relationship. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.,Linked Report(s) : US-PFIZER INC-2020520145 different patients, same drug and event

Cough; Fever; body aches; Tested positive for COVID after the first dose of the vaccine/tested positive for COVID-19; Tested positive for COVID after the first dose of the vaccine/tested positive for COVID-19; This is a spontaneous report from a contactable physician reporting for himself from a Pfizer sponsored program, IBCC (Inbound Call Center for HCPs). A 31-year-old male received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number EK5730) intramuscular Deltoid Left, on 17Dec2020 9:00, single dose for COVID-19 immunisation. Relevant medical history included seasonal allergies and asthma. Concomitant medications were reported as none. The patient took the first dose of the COVID-19 Vaccine and he is schedule on 07Jan2021 for his second dose. After the first dose he tested positive for COVID on 30Dec2020. The patient got tested for COVID-19 around 10:30 a.m. The patient hasn't seen a physician and he doesn't don't plan on it. The patient had a cough on an unspecified. Early on he had a fever and body aches but that passed after the first day. Caller clarifies the fever and body aches started Sunday and were gone by Tuesday morning. The cough started on Monday and is still ongoing and persisting. The patient was not hospitalized in response to the events. Outcome of the event cough was not recovered, the events fever and body aches recovered on an unspecified date, while it was unknown for tested positive for COVID after the first dose of the vaccine.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the SARS-CoV-2 test positive, LOE and other reported events due to temporal relationship. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Test positive for COVID after the first vaccine dose; Test positive for COVID after the first vaccine dose; This is a spontaneous report from a contactable Physician. This Physician reported similar events for 2 patients. This is the 2nd of 2 reports. A female patient of unspecified age received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiry date were not reported), via an unspecified route of administration on an unspecified date at a single dose for COVID-19 vaccination. The patient's relevant medical history and concomitant medications was not reported. The patient was tested positive after the first dose of the vaccine. The outcome of the event was unknown. Information on the lot/batch number has been requested; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the reported events of COVID-19 virus test positive and LOE due to temporal relationship. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.,Linked Report(s) : US-PFIZER INC-2020520651 same reporter/product/event, different patient

Test positive for COVID after the first vaccine dose; Test positive for COVID after the first vaccine dose; This is a spontaneous report from a contactable Physician. This Physician reported similar events for 2 patients. This is the 1st of 2 reports. A 42-year-old female patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number EH9899), via an unspecified route of administration in left deltoid on 16Dec2020 at a single dose for COVID-19 vaccination. There were no relevant medical history and concomitant medications. The patient was test positive for covid after the first vaccine dose on 27Dec2020 with outcome of not recovered.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the reported events of COVID 19 test positive and LOE due to temporal relationship. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.,Linked Report(s) : US-PFIZER INC-2020520645 same reporter/product/event, different patient

positive for COVID-19 after 1st dose; positive for COVID-19 after 1st dose; This is a spontaneous report from a contactable nurse. A female patient of an unspecified age received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on an unspecified date at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The nurse was inquiring about receiving the second dose of vaccine

after testing positive for COVID-19 after 1st dose. Outcome of the event was unknown. Information on Lot/batch number has been requested.; Sender's Comments: Based on the information currently available, a lack of efficacy with the suspected vaccine BNT162B2 in this patient cannot be completely excluded. Further information like confirmative virus genome /nucleic acid detection needed for meaningful medical assessment.

came out positive for Covid-19; came out positive for Covid-19; This is a spontaneous report from a contactable pharmacist. A male patient of an unspecified age received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration in 29Dec2020 at a single dose for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient came out positive for covid-19 on 30Dec2020 and inquired if he should still get the 2nd dose. Information on the lot/batch number has been requested.

"testing positive for covid/ they have had a patient have a positive COVID test after vaccine was given; testing positive for covid/ they have had a patient have a positive COVID test after vaccine was given; This is a spontaneous report from a contactable pharmacist via medical information team and a Pfizer-sponsored program IBCC (Inbound Call Center for HCPs). A 43-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (lot number EK5730, expiration date 31Mar2021), via an unspecified route of administration on 18Dec2020 at single dose for COVID-19 immunization. The patient's medical history included ongoing asthma. The reporter was not aware of any allergies, adverse reactions to previous vaccines, significant medical history or any relevant family medical history of the patients. Concomitant medications were reported as none. It was reported that that they had a patient who had a positive COVID test after vaccine was given. The patient who received the vaccine on 18Dec2020 now testing positive for COVID. The patient received the first vaccine dose on 18Dec2020. She tested positive 30Dec2020. They wanted to give her monoclonal antibodies (Bamlanivimab) but they don't know how that would interact with the vaccine. Also, they didn't know how the product and the positive test would play into her already having the first dose and getting the second dose. The second shot would be due on 08Jan2020. The patient was not at the facility at the point of reporting, they had been talking to her by phone. The type of test done was unknown. No treatments known. The outcome of the event ""positive COVID test after vaccine was given"" was not recovered. The event was assessed as medically significant, and unrelated to vaccine by reporter. The seriousness assessment option was made due to her history of asthma.; Sender's Comments: Based on available information, a possible contributory role of suspect BNT162B2 cannot be completely excluded for reported ""positive COVID test after vaccine was given""."

Contracted Covid; Contracted Covid; This is a spontaneous report from a contactable Other Health Professional (patient). A 59-year-old female patient received the first dose of BNT162b2 (Lot/batch number and Expiration date were not provided), via an unspecified route of administration at left arm on 21Dec2020 18:00 at single dose for COVID-19 immunization. Medical history included chronic obstructive pulmonary disease (COPD). The patient received the unspecified concomitant medications within 2 weeks of vaccination; patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient was contracted COVID on 29Dec2020 20:00. The event resulted in Doctor or other healthcare professional office/clinic visit. Patient received the treatment Monochrome antibiotic

for event. The patient received the COVID test post vaccination on 29Dec2020. The COVID test type post vaccination was Nasal Swab, COVID test name post vaccination was RNA, COVID test result was Positive. The patient was not COVID prior vaccination. The patient was not pregnant at the time of vaccination. The outcome of the events was not recovered. Information on the Lot/batch number has been requested.; Sender's Comments: Based on the information currently available, a lack of efficacy with the vaccination with BNT162B2 in this patient cannot be completely excluded.

He lost the sense of smell on 28Dec2020 and later tested positive; He lost the sense of smell on 28Dec2020 and later tested positive; He lost the sense of smell on 28Dec2020 and later tested positive; This is a spontaneous report from a contactable other healthcare professional (HCP). A male patient (respiratory therapist) of an unspecified age received a single dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) as the first dose via an unspecified route of administration on 16Dec2020 for COVID-19 immunization. The patient medical history and concomitant medications were not reported. He lost the sense of smell on 28Dec2020 and later tested positive in Dec2020. The outcome of the events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Based on the information currently available, a lack of efficacy with the suspected vaccine BNT162B2 in this patient cannot be completely excluded. Further information like confirmative virus genome /nucleic acid detection is needed for meaningful medical assessment.

"I came down with a COVID infection; I came down with a COVID infection; This is a spontaneous report from a contactable healthcare professional (HCP) reporting for herself. A female patient of an unspecified age received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (lot number not reported) via an unspecified route of administration on 18Dec2020 at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient came down with a COVID infection on 23Dec2020 with outcome of unknown. Information on the lot/batch number has been requested.; Sender's Comments: Based on the information available, a possible contributory role of the suspect BNT162B2 cannot be excluded for the reported event ""came down with a COVID infection"" based on the known safety profile. However the short duration of 5 days since the vaccine first dose is given it is unlikely patient would have fully developed immunity."

Anaphylactic reaction; hives in the first 10 minutes of the vaccine; This is a spontaneous report from a contactable Other Health Professional (Physician Assistant). A 29-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 29Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The reporter stated that she is treating a patient in ICU that got the COVID-19 vaccine on 29Dec2020. The patient developed hives in the first 10 minutes of the vaccine and had an anaphylactic reaction 1 hour later. Seriousness of events was reported to be hospitalization. Outcome of the events was unknown. The reporter also mentioned that it was not a mild reaction and patient was still in the ICU, 48 hours later. Information about lot/batch number has been requested.; Sender's Comments: A possible causal association between administration of BNT162B2 and the onset of anaphylactic reaction and hives cannot be excluded, considering the plausible temporal relationship and the known adverse event profile of the suspect product. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation,

including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

"She tested positive PCR; She tested positive PCR; This is a spontaneous report from a contactable Nurse. A female patient of unspecified age received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 17Dec2020 at single dose for COVID-19 immunization. The relevant medical history and concomitant medications were not reported. Resident inoculated on 17Dec. She tested positive PCR on 29Dec2020. Currently in quarantine and asymptomatic. She was scheduled for dose 2 on 06Jan2021. This still fell in quarantine period. The nurse wanted to know if the patient could get the second dose on 06Jan, if not when should she get second dose. The outcome of the events was unknown. Information about lot/batch number has been requested.; Sender's Comments: Based on available information, a possible contributory role of suspect BNT162B2 vaccine cannot be completely excluded for reported event ""test positive PCR""."

I tested positive for COVID 9 days after receiving the vaccine; I tested positive for COVID 9 days after receiving the vaccine; Rhinorrhea; aches; fatigue; cough; This is a spontaneous report from a contactable physician. This physician reported similar events for two patients. This is the first of the two reports. A 68-years-old female patient (not pregnant) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number and expiry date not reported), via an unspecified route of administration on the left arm on 21Dec2020 at 09:30 at a single dose for COVID-19 immunization. Medical history included hypertension. The patient had no known allergies. Concomitant medications included losartan (LOSARTAN), amlodipine (AMLODIPINE), and atorvastatin (ATORVASTATIN). On 28Dec2020, the patient had rhinorrhea, aches, fatigue, and cough. The patient had no COVID prior vaccination, and when tested post vaccination showed a positive result. It was reported that the patient was tested via nasal swab (PCR SARS) and showed positive for COVID on 30Dec2020, 9 days after receiving the vaccine. The patient had no other vaccines in four weeks. No treatment was administered for the events. The events had not resolved. Information on the lot/ batch number has been requested.; Sender's Comments: A causal association between BNT162B2 and the events drug ineffective and SARS-COV-2 test positive cannot be excluded based on a compatible temporal relation. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.,Linked Report(s) : US-PFIZER INC-2021001246 Same reporter, same drug, similar events, different patients.

She also complained of all the COVID signs and symptoms; She also complained of all the COVID signs and symptoms; left cervical, axillary, clavicular and periscapular lymphadenopathy; left arm and shoulder pain; left arm and shoulder pain; This is a spontaneous report from a contactable physician. An adult female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) Solution for injection, lot number was unknown, intramuscular in the left arm on 28Dec2020 at a single dose for COVID-19 immunization. Medical history included covid-19 from an unknown date and unknown if ongoing. The patient's concomitant medications were not reported. The patient is not pregnant. It was

unknown if the patient received any other vaccines within 4 weeks prior to the COVID vaccine. It was reported that after receiving the Pfizer COVID-19 vaccine in the left deltoid, the patient experienced left cervical, axillary, clavicular and periscapular lymphadenopathy in Dec2020 with outcome of not recovered. She also complained of left arm and shoulder pain and all the COVID signs and symptoms in Dec2020 with outcome of not recovered. The onset was within a day of immunization. She has a history of COVID-19, she had Covid prior vaccination. It was unknown if the patient tested for Covid post vaccination. The onset date of the events was reported as Dec2020. The events was reported as non-serious and it was unknown if the patient received treatment for the events. Information on the lot/batch number has been requested.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the suspected LOE, COVID 19 and other reported events due to temporal relationship. Of note, it is reported that the patient had a history of COVID-19, and she was diagnosed with COVID 19 infection prior to the vaccination. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics , counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

tested positive for Covid test; tested positive for Covid test; difficulty breathing; chills; fluctuating fever; nausea; weakness; weakness/extreme fatigue; loss of taste and smell; loss of taste and smell; muscle pain; cough; sore throat; nasal drip; dizziness; fast heartbeat; injection site pain; anxiety; crying; This is a spontaneous report from a contactable healthcare professional. This 21-year-old female patient reported for herself that she received BNT162B2 1st dose on 31Dec2020 10:00 AM intramuscular at left arm for COVID-19 immunisation. Medical history included known allergies: Penicillin and Covid-19. Concomitant therapy included BC as reported. The patient experienced difficulty breathing, chills, fluctuating fever, nausea, dizziness, weakness, fast heartbeat, tiredness, loss of taste and smell, muscle pain, injection site pain, anxiety, cough, sore throat, nasal drip, crying, extreme fatigue, Etc on 31Dec2020 at 06:00 PM. The events resulted in doctor or other healthcare professional office/clinic visit, emergency. The patient was hospitalized for 1 day and received treatment included blood thinner rivaroxaban (XARELTO) and had 2 weeks quarantine. The patient had Covid prior to vaccination and tested positive for Covid test post vaccination on 01Jan2021. The outcome of the events was not resolved. Information on Lot/batch number has been requested.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the suspected LOE, SARS-CoV-2 test positive and the other reported events due to temporal relationship. Of note, it is reported that the patient had history of COVID 19 infection prior to the vaccination. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part

of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

polyneuropathy; facet joint diagnosis/new left forefoot paresthesia; This is a spontaneous report from a contactable physician (patient). A 45-years-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (lot EJ1685) at the first dose in left arm on 17Dec2020 12:45 at single dose for COVID-19 immunisation. Facility where the most recent COVID-19 vaccine was administered at Doctor's office/urgent care. Medical history included ongoing back pain (thinking it was due to running/physical therapy overuse injury). No allergies to medications, food, or other products. There were no concomitant medications. Patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. No any other medications the patient received within 2 weeks of vaccination. It was reported that 20Dec2020 morning: new left forefoot paresthesia. no weakness. Patient thought this might be due to the back pain he had been watching for 3 months, thinking it was due to running/physical therapy overuse injury. On 21Dec2020 sports medicine physician evaluation. numbness was gone, facet joint diagnosis, MRI lumbar ordered (still pending). On 24Dec2020 9 pm, paresthesia both hands and feet, no weakness nor other symptoms those continued and were slightly worse on 27Dec2020 morning, including face/teeth. no other symptoms; 27Dec2020 afternoon: internal medicine physician evaluation, working diagnosis polyneuropathy. Neurologist appointment will be 07Jan2021, 2 hours before 2nd shot was scheduled. The patient had been tested for COVID-19 test type post vaccination: negative on 22Dec2020. No treatment for event. Prior to vaccination, the patient was not diagnosed with COVID-19. Outcome of events was not resolved.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the reported events of polyneuropathy and facet joint diagnosis/new left forefoot paresthesia due to temporal relationship. However, the reported events may possibly represent intercurrent medical conditions in this patient. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics including nerve conduction tests, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

got COVID-19 from his son and tested positive; got COVID-19 from his son and tested positive; This is a spontaneous report from a contactable physician. A 51-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 18Dec2020 at single dose for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient got COVID-19 from his son and he tested positive 31Dec2020. The patient's son got the COVID-19 virus on 20Dec202020. The patient is due to have 2nd vaccine on 07Jan2021. Outcome of the events was unknown. Information on batch number has been requested.;

Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of events Drug ineffective and COVID-19 virus test positive cannot be totally excluded. The case will be reassessed if additional information becomes available.

was diagnosis with COVID-19 through nasopharyngeal swab today, 02Jan2021; was diagnosis with COVID-19 through nasopharyngeal swab today, 02Jan2021; This is a spontaneous report from a contactable pharmacist (patient himself). A 34-year-old male patient received his first dose of bnt162b2 (BNT162B2 also reported as COVID 19 brand Pfizer, lot EJ1685, expiry date not reported), via an unspecified route of administration in his right arm on 23Dec2020 15:30 at single dose, for Covid-19 vaccination. The patient's medical history was not reported. Prior to vaccination the patient was not diagnosed with COVID-19. He did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Concomitant medication included bupropion. The patient informed that he was diagnosed with Covid-19 through nasopharyngeal swab (COVID-19 Nucleic Acid Amplification test) on 02Jan2021 01:00 and Influenza virus test was unknown results (02Jan2021). It was unknown if there was a treatment used. The outcome of event was not recovered.; Sender's Comments: Based on the information available, a possible contributory role of the suspect products cannot be excluded for the reported event of positive for corona virus infection for the lack of efficacy of the vaccine. However, based on the mechanism of action of the vaccine, it is unlikely the patient would have fully developed immunity for the vaccine to be effective, due to the number of days passed since the vaccine is given. Case will be reevaluated based on follow-up information

she received the Pfizer vaccine on 29Dec2020. She tested positive for coronavirus on 01Jan2021. Is the efficacy of the vaccine after the second dose?; tested positive for coronavirus; This is a spontaneous report from a contactable nurse reported for herself. A female patient of an unspecified age received first dose of BNT162B2 (Pfizer-BioNTech COVID-19 mRNA vaccine; lot/batch number and expiry date were unknown), via an unspecified route of administration on 29Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. VA nurse calling stating that she received the Pfizer vaccine on 29Dec2020. She tested positive for coronavirus on 01Jan2021. She wanted to know how to proceed with getting her second vaccine, and if the efficacy of the vaccine is after the second dose. The outcome of the event was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of events Drug ineffective and Coronavirus test positive cannot be totally excluded. The case will be reassessed if additional information becomes available.

received vaccine on 17Dec2020, then tested positive for coronavirus on 25Dec2020; received vaccine on 17Dec2020, then tested positive for coronavirus on 25Dec2020; This is a spontaneous report from a contactable nurse (patient). A female patient of an unspecified age received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 17Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient received vaccine on 17Dec2020, then tested positive for coronavirus on 25Dec2020. The patient was calling to inquire if she can get second vaccine. Outcome of the event was

unknown. Information on the lot/batch number has been requested.; Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of events Drug ineffective and COVID-19 cannot be totally excluded. The case will be reassessed if additional information becomes available.

became positive for covid 19; became positive for covid 19; This is a spontaneous report from a contactable other healthcare professional (patient). A female patient of an unspecified age received the first dose of bnt162b2 (Pfizer-Biontech Covid-19 Vaccine) via an unspecified route of administration on 22Dec2020 at a single dose for covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient she received covid vaccine on 22Dec2020 and on 30Dec2020 became positive for covid 19. The patient wanted to know when she can schedule her 2nd dose. Outcome of the event was unknown. Information about Batch/Lot number has been requested.; Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of events Drug ineffective and COVID-19 cannot be totally excluded. The case will be reassessed if additional information becomes available.

slight cough; diarrhea; shortness of breath; no sense of smell; positive for covid 19 virus; positive for covid 19 virus; feel tired; sore arm; This is a spontaneous report from a non-contactable consumer (patient). A 44-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) first dose on 20Dec2020 at single dose for COVID-19 immunization. Medical history and concomitant medications were not reported. Patient was Diagnosed with covid 19 virus on the 31Dec2020, she was set to have the second vaccine on the 10Jan2021. She wanted to know if she can get the second dose and if so, when. Also asked if she should get tested before taking the 2nd dose of the covid 19 vaccine. Her Adverse effects are sore arm on vaccination day (20Dec2020), and she began to feel tired on 27Dec2020 and thought that was normal. She went to a Christmas eve party 24Dec2020 and no one was masked, friend had several people from work tested positive. was tested and was positive for covid 19 virus on 31Dec2020. She also was experiencing slight cough, diarrhea (which is normal for her), shortness of breath is improving and she had no sense of smell but she was able to taste. The outcome of event shortness of breath is recovering. The outcome of other events was unknown. No follow-up attempts are possible. information about lot/batch number cannot be obtained.

Tested Positive for COVID-19/nausea, occasional dry cough, neck and lower back soreness, and sore throat; Tested Positive for COVID-19/nausea, occasional dry cough, neck and lower back soreness, and sore throat; Weakness/generalized weakness; This is a spontaneous report from a contactable nurse (patient). A 62-year-old female patient received first dose of BNT162b2 (Pfizer, Lot number: 5730), via an unspecified route of administration at right arm at 22Dec2020 21:00 at single dose for covid-19 immunization. Medical history included Mayonaise allergies. The patient's concomitant medications were not reported. The patient previously took codeine and experienced allergies. At 31Dec2020 06:00, the patient experienced Weakness, nausea, occasional dry cough, generalized weakness, neck and lower back soreness, and sore throat which has now dissipated. Tested Positive for COVID-19 on 02Jan2021 (also reported as 01Jan2021, pending clarification). The covid test type post vaccination was Nasal Swab, Covid test name post vaccination was COVID-19 PCR ROCHE c6800(NTX), RNA SARS CoV2 TGT1, PAN

SARS RNA TGT2. No treatment received for events. The events result in Emergency room/department or urgent care. The patient was not pregnant. The outcome of the events were nor recovered.; Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of events Drug ineffective and COVID-19 cannot be totally excluded. The case will be reassessed if additional information becomes available.

Took the COVID vaccine; Rapid Antigen Test turned out positive, PCR test came out negative; Took the COVID vaccine; Rapid Antigen Test turned out positive, PCR test came out negative; This is a spontaneous report from a non-contactable consumer. A patient of unspecified age and gender received BNT162b2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on an unspecified date at single dose for covid-19 immunization. The patient medical history and concomitant medications were not reported. The patient took the COVID vaccine, and a few days later they took the Rapid Antigen Test, the COVID test. And it turned out positive. The person took other tests as well, PCR test which came out negative. The reporter didn't know if there was any research or data if that was done maybe during clinical trials of whether it is possible to come out positive on an antigen test which tests for bio-protein. The reporter believe that was what in the vaccine. The reporter guess the vaccine causes the reaction in the body to make that protein in the body. The reporter wonder if it was possible it could be false positive on one of those tests because of the vaccine, because of the way that rapid test works. The outcome of the events was unknown. No follow-up attempts are possible. Information about lot/batch number cannot be obtained. No further information is expected.

"Got tested positive; Got tested positive; This is a spontaneous report from a contactable nurse from a Pfizer-sponsored program Pfizer First Connect. A male patient of an unspecified age received first dose bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EJ1685, Expiry Date: 31Mar2021), via an unspecified route of administration on 17Dec2020 at single dose for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. Transferring agent stated, ""I have a nurse (reporter) on the other line. She is currently on hold. She is reporting an adverse event about COVID Vaccine because she is saying that their doctor (Incomplete sentence). I mean, the nurse on the other line is working at the vaccine clinic. One of their doctors in the clinic had COVID Vaccine on 17Dec2020. I mean, the Doctor got positive or tested positive on 23Dec2020. Should that mean that the COVID Vaccine or the first dose of COVID Vaccine did not take effect for the Doctor itself because the Doctor got positive? They would like to know if they should still need to take second dose of COVID Vaccine."" When paraphrased the concern, reporter stated, ""Correct. And the question is would he need to get his second dose. It is said that it's two doses."" The outcome of the events was unknown.; Sender's Comments: Based on the information available, a possible contributory role of the suspect BNT162B2 cannot be excluded for the reported event test positive based on the known safety profile. However the short duration of 6 days since the vaccine first dose is given it is unlikely patient would have fully developed immunity."

Anaphylactic reaction; This is a spontaneous report from a contactable nurse. A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899), via an unspecified route of administration on deltoid (unknown which) on 31Dec2020 at 0.3 mL, single for

COVID-19 immunization. There were no medical history and concomitant medications. The patient experienced anaphylactic reaction on 31Dec2020. The event required emergency room visit for observation and treatment.; Sender's Comments: A possible causal association between administration of BNT162B2 and the onset of anaphylactic reaction cannot be excluded, considering the plausible temporal relationship and the known adverse event profile of the suspect product. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

"Tested positive for COVID after having received the vaccine; Tested positive for COVID after having received the vaccine; This is a spontaneous report from a contactable nurse. This nurse reported similar events for 2 patients. This is second of 2 reports. A 7-decade-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (lot number EJ1685, expiration date Mar2021), via an unspecified route of administration on 19Dec2020 at 0.3 mL, single in the left deltoid for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. It was reported that on 30Dec2020, the patient tested positive for COVID after having received the vaccine. The reporter said that they had been vaccinating people at their work. The reporter had vaccinated two people now who within about a week after, they tested positive for COVID. The patient was exposed to COVID outside of work. This patient was a healthcare worker (Doctor) in his 60's, weight within normal limits. He seemed healthy. He was fit. He showed up for work everyday. He was vaccinated on 19Dec2020, then tested positive for COVID yesterday, on 30Dec2020. The reporter was wondering if the patient should still get the second dose in 3 weeks, or wait 90 days after tested positive. The reporter needed to know whether to stick with the 21 day time period for the second dose, or wait 90 days. They had been telling people who were already positive, or who had COVID in the past, to wait 90 days to get the vaccine. The reporter had read all of the literature and looked online and could not find any information on this. The outcome of the event ""tested positive for COVID after having received the vaccine"" was not recovered. The event was assessed as non-serious, and unrelated to vaccine by reporter. She did not think, with either of these patients that them getting COVID had anything to do with the vaccine. She thought it was a coincidence and they were obviously exposed prior to receiving the vaccine.; Sender's Comments: Based on the information currently available, the reported event ""tested positive for COVID"" which was further reported as getting COVID by the nurse, was likely related to patient's exposure to SARS-CoV-2 virus prior to vaccination, and unlikely causally related to BNT162B2 vaccine. Further information like confirmative virus genome /nucleic acid detection needed for more meaningful medical assessment.,Linked Report(s) : US-PFIZER INC-2021001215 Same drug and events, different patient"

"Got the vaccine and developed COVID; Got the vaccine and developed COVID; This is a spontaneous report from a Pfizer-sponsored program IBCC (Inbound Call Center for HCPs) from a contactable physician. This pharmacist reported similar events for two patients. This is the second of two reports for Infection Control Nurse's daughter. A female patient of an unspecified age received her first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date not reported), via an

unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient got the vaccine and 10 days later, got COVID, so, she got swabbed on unknown date. The patient was wondering if she needed to start over or if she was okay to get the second dose. The outcome of events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Based on the information available, a possible contributory role of the suspect BNT162B2 cannot be excluded for the reported ""got COVID"", based on the known safety profile. However the short duration of 10 days since the vaccine first dose is given it is unlikely patient would have fully developed immunity.,Linked Report(s) : US-PFIZER INC-2021001217 same reporter/product, similar events, different patients."

"Tested positive for COVID after having received the vaccine; Tested positive for COVID after having received the vaccine; This is a spontaneous report from a contactable nurse. This nurse reported similar events for 2 patients. This is 1st of 2 reports. A 7-decade-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, batch/lot number: EJ1685, expiration date: Mar2021), via an unspecified route of administration on 18Dec2020 at left deltoid, at 0.3 mL, single for covid-19 immunization. Medical history included ongoing diabetic. Concomitant medication included insulin for diabetic; pioglitazone hydrochloride (ACTOS) for diabetic and all ongoing. The patient received the vaccine on 18Dec2020 and then less than a week later, on 23Dec2020 was positive for COVID. The reporter said that they had been vaccinating people at their work. The reporter had vaccinated two people now who within about a week after, they tested positive for COVID. The patient was exposed to COVID outside of work. This patient was a healthcare worker (Doctor) in his 60's, weight within normal limits. The reported stated that obviously this person was exposed prior to getting the vaccine and was not symptomatic. But she needed to know, should she stick with the 21 day time period for the second dose or wait 90 days. The patient described COVID as the flu with an attitude. He was staying home and resting. The reporter did not think, with either of these patients that them getting COVID had anything to do with the vaccine. She thought it was a coincidence and they were obviously exposed prior to receiving the vaccine. The event was assessed as non-serious, and unrelated to vaccine by reporter. The outcome of the events was not recovered.; Sender's Comments: There is not a reasonable possibility that event ""tested positive for COVID"" is related to BNT162B2 vaccine. Patient most likely was exposed to SARS-CoV-2 virus prior vaccination.,Linked Report(s) : US-PFIZER INC-2021001199 Same drug and events, different patient"

Patient got the vaccine and 10 days later got Covid; Patient got the vaccine and 10 days later got Covid; Sinus drainage; This is a spontaneous report from a Pfizer-sponsored program IBCC (Inbound Call Center for HCPs) from a contactable physician. This pharmacist reported similar events for two patients. This is the first of two reports for Infection Control Nurse. A female patient of an unspecified age received her first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date not reported), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient got the vaccine and 10 days later, got COVID. So, the patient got swabbed because of the sinus draining but she was not ill. The patient was not sick she got some sinus drainage. The outcome of event was unknown. The patients were wondering if they need to start over or if they were okay to get the

second dose. Information on the lot/batch number has been requested.; Sender's Comments: Based on the information currently available, a lack of efficacy with the suspected vaccine BNT162B2 in this patient cannot be completely excluded. However, the duration of 10 days since the vaccine first dose is short, and it is unlikely patient would have fully developed immunity. Further information like confirmative virus genome /nucleic acid detection needed for meaningful medical assessment.,Linked Report(s) : US-PFIZER INC-2021001212 same reporter/product, similar events, different patients.

patient tested positive for COVID 1 week after vaccination; patient tested positive for COVID 1 week after vaccination; This is a spontaneous report from a contactable physician (patient's wife). This physician reported similar events for two patients. This is the second of two reports. A male patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number and expiry date not reported) via an unspecified route of administration, on 21Dec2020, single dose, for COVID-19 immunization. Relevant medical history and concomitant medications were not reported. The patient tested positive for COVID on 28Dec2020 (1 week after vaccination). Outcome of the events was unknown. Information about lot/batch number has been requested.; Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of events Drug ineffective and COVID-19 virus test positive cannot be totally excluded. The case will be reassessed if additional information becomes available.

chills and not feeling very good; chills and not feeling very good; rapid COVID test positive; rapid COVID test positive; This is a spontaneous report from a contactable consumer. This consumer reported similar events for two patients. This is the first of two reports. This case is serious, the other one is non-serious. A 22-year-old female patient received first dose of BNT162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/Lot Number: EH9899) intramuscular at left deltoid on 22Dec2020 19:00 at single dose for covid-19 immunization. The patient medical history and concomitant medications were not reported. No other vaccines given at the same time. The patient received a flu shot back between 27th or 28th Nov2020 in her left deltoid. Caller reported getting the COVID vaccine on the 22Dec2020 and feeling fine before that. On the 28Dec2020 she started feeling chills and not feeling very good and that hasn't gone away. The patient went and got a rapid COVID test and it came back positive, not sure if it was because of the vaccine having antigens in it or she came into contact with it or if she just weakened immune system from the shot. The patient wanted to know if that was true. Then stated she and her mom got the COVID vaccine and her mom received it on the 23Dec. On the 29Dec her whole family started to get sick and experiencing the same things she experienced. The patient was not feeling well at the time of the call. The outcome of the events was not recovered.; Sender's Comments: Linked Report(s) : 2021001266 same reporter/ drug, different patient/event

PCR was positive last night; PCR was positive last night; This is a spontaneous report from a contactable Other Health Professional (Patient) reported that a 39-year-old female patient receives first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot/Batch Number: EH9899 and Expiration Date unknown) via an unspecified route of administration on 18Dec2020 at single dose for covid-19 immunization. The patient's medical history was unknown. The concomitant medications were reported as none. The patient experienced received the Pfizer's COVID Vaccine on 18Dec2020 (later clarified) at

work, at (Institution name) and she just wanted to report that on 23Dec2020, her husband developed symptoms, he was positive on the 26Dec2020 and then she was just converted and her PCR was positive last night on 30Dec2020 (later clarified). Patient think her husband exposed then she was exposed. Treatment included Advair is twice a day and albuterol is three times a day. The outcome of events was unknown.; Sender's Comments: Based on the information available, a possible contributory role of the suspect BNT162B2 cannot be excluded for the reported COVID-19 PCR test positive based on the known safety profile. However the short duration of 12 days since the vaccine first dose is given it is unlikely patient would have fully developed immunity. Of note, the patient was exposure to COVID-19 (her husband developed COVID-19).

tested positive for the Covid antigen with no signs or symptoms; tested positive for the Covid antigen with no signs or symptoms; This is a spontaneous report from a contactable consumer(an administrator of skilled nursing facility). A patient of unspecified age and gender received BNT162B2 (Covid vaccine) , via an unspecified route of administration on an unspecified date at single dose for covid-19 immunisation. The patient medical history and concomitant medications were not reported. The reporter stated the pharmacy did a Pfizer vaccine clinic at his facility, stated that after looking at the FAQs he would like to know if they should not expect a positive antigen test after the vaccine, states the reason he was asking was because the patient they tested today(31Dec2020) that got the vaccine tested positive for the Covid antigen with no signs or symptoms. Outcome of event was unknown. Information on the lot/batch number has been requested.

given the Covid 19 vaccine and subsequently tested positive for SARS CoV2 a day or so later; given the Covid 19 vaccine and subsequently tested positive for SARS CoV2 a day or so later; This is a spontaneous report from a non-contactable healthcare professional via Pfizer sales representative. A patient of an unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number and expiry date not reported) via an unspecified route of administration, from an unspecified date, single dose for COVID-19 immunization. Relevant medical history and concomitant medications were not reported. The patient was given the COVID 19 vaccine and subsequently tested + for SARS CoV2 a day or so later on an unspecified date. Outcome of the events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Sender's Comments: Based on the information available, a possible contributory role of the suspect products cannot be excluded for the reported event of positive for corona virus infection for the lack of efficacy of the vaccine. However, based on the mechanism of action of the vaccine, it is unlikely the patient would have fully developed immunity for the vaccine to be effective, due to the number of days passed since the vaccine is given. Case will be reevaluated based on follow-up information

Allergic reaction; Hives on back; Flushed; Chills; Swollen tongue; Burning tongue; This is a spontaneous report from a contactable consumer (patient). This 47-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 29Dec2020 07:00 at single dose on left arm for COVID-19 vaccination. There were no medical history and concomitant medications. The patient previously took flu shot. Vaccination Facility Type was hospital. Patient did not receive any other vaccines at time COVID-19 vaccine given and no vaccines given 4 weeks prior. Patient got the Pfizer COVID-19 vaccine on 29Dec2020 and had an allergic reaction

to it. Had hives on her back, was flushed, had chills, and swollen tongue on 29Dec2020. There was swelling on either side of tongue not in the center. Swelling seemed to bounce around sides of tongue. Patient mentioned she also had burning sensation of tongue first on 29Dec2020 and then the swelling was after that. Adverse events hives, flushed, chills, burning sensation of tongue and swelling of tongue required a visit to emergency room. Patient was seen in the emergency room and given diphenhydramine hydrochloride (BENADRYL) and an Epi-pen to take home. This all happened after receiving the vaccine on 29Dec2020. Patient wasn't getting any better/feeling better and went back to the emergency room on 30Dec2020. Patient was treated with dexamethasone and told her to take diphenhydramine hydrochloride every 4 hours, her last dose was at 2pm 31Dec2020. Patient said all events still persisting, but there maybe a little more swelling of the tongue, but not much. Patient had had a flu shot before, but never had anything to happen like this. Outcome of allergic reaction, hives, flushed, chills and burning tongue was not recovered, outcome of swollen tongue was unknown. Information on the lot/batch number has been requested.

tested positive for Covid; tested positive for Covid; This is a spontaneous report from a contactable Nurse reported for self. This 42-year-old patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on an 22Dec2020 08:00 on Left arm at single dose (Lot # EH9899) for covid-19 immunisation. Medical history, concomitant medications were none. The patient tested positive for Covid in 25Dec2020. The patient was scheduled to receive the second dose in 08Jan2021 so should the patient get it. (Further clarified the dates and years). Outcome of the events were unknown.; Sender's Comments: A possible contributory effect of suspect BNT162B2 on reported event cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

"Left axillary, supraclavicual, and cervical chain lymphadenopathy > 1-week post-injection.; since the vaccination, has the patient been tested for COVID-19?: Yes; since the vaccination, has the patient been tested for COVID-19?: Yes; This is a spontaneous report from a contactable healthcare professional. A 26-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899), intramuscular on the left arm on 21Dec2020 20:00 at single dose for COVID-19 immunisation. The patient medical history was not reported. The patient's concomitant medications were not reported. The patient experienced left axillary, supraclavicual, and cervical chain lymphadenopathy > 1-week post-injection on 22Dec2020 16:00. in which the patient received no treatment. It was also reported on Dec2020, ""since the vaccination, has the patient been tested for COVID-19?: Yes"". The patient has other pending test. The outcome of left axillary, supraclavicual, and cervical chain lymphadenopathy > 1-week post-injection was not recovered and other events was unknown.; Sender's Comments: Based on the information provided, the COVID-19 test positive are possibly related to drug ineffective of BNT162B2 vaccine."

One of my partners was the same way, tested positive after getting the vaccine; One of my partners was the same way, tested positive after getting the vaccine; This is a spontaneous report from a contactable nurse. This nurse reported similar events for 2 patient. This is the second of 2 reports. A patient of

unspecified age and gender received bnt162b2 (BNT162B2, Pfizer biontech Covid-19 Vaccine, solution for injection, lot number and expiation date unknown), via an unspecified route of administration on an unspecified date at a single dose for covid-19 immunization. The patient's medical history and concomitant medications were not reported. On an unknown date, the patient was tested positive after getting the vaccine. The outcome of the event was unknown. Information on Lot/batch number has been requested.; Sender's Comments: The association between the event lack of effect (SARS CoV2 test positive) with BNT162b2 can not be fully excluded.,Linked Report(s) : US-PFIZER INC-2020510419 same reporter/ drug/similar events, different patient

positive COVID-19 test with symptoms; her arm ached; positive COVID-19 test with symptoms; This is a spontaneous report from a non-contactable nurse (patient) and two consumers. A 45-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number and expiry date not reported), via an unspecified route of administration on Dec2020 at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient who is a nurse got the disease after getting coronavirus vaccine. This nurse reported that her arm ached after the vaccination and that she did not experience any other side effects. This nurse who worked in the coronavirus unit after the vaccine, fell ill 6 days after the vaccine. Stating that she was cold, the nurse later reported that she was experiencing muscle pain and feeling weak. The nurse, who applied to the hospital after becoming increasingly sluggish, performed a coronavirus test. The nurse's corona test was positive on an unspecified date in Dec2020. The patient underwent lab tests and procedures which included sars-cov-2 test: positive on Dec2020. The outcome of the events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.; Sender's Comments: The association between lack of effect (SARS CoV test positive) with BNT162b2 can not be fully excluded based on the temporal relationship. Occupational exposure may have played a contributory role as well.

she woke up sick and was having the same symptoms as her husband so she was positive; she woke up sick and was having the same symptoms as her husband so she was positive; This is a spontaneous report from a contactable pharmacist reported for herself. A 31-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration in Dec2020 at single dose for COVID-19 immunization. The patient medical history was not reported. The patient's concomitant medications were not reported. Caller stated that she was a pharmacist and on Tuesday last week that she received the Pfizer BioNTech Vaccine. Stated that her husband tested positive yesterday (on 29Dec2020). Stated that she was positive that she was positive because that was her husband. Stated that she woke up sick and was having the same symptoms as her husband so she was positive. Stated that she was due for second dose in 2 weeks. Stated that she received the vaccine last week and was negative. The patient underwent lab tests and procedures which included covid test: negative in Dec2020. The outcome of the events was unknown. Information about Batch/Lot number has been requested.; Sender's Comments: The information currently provided is too limited to make a meaningful medical assessment hence, the events are conservatively assessed as related to the suspect drug BNT162B2 until further information becomes available.

symptomatic of Covid; symptomatic of Covid; inoculated on 15Dec2020; patient was scheduled on 04Jan2021 for 2nd dose; inoculated on 15Dec2020; patient was scheduled on 04Jan2021 for 2nd dose; This is a spontaneous report from a contactable nurse. A patient of unspecified age and gender received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number and expiry date unknown) via an unspecified route of administration on 15Dec2020 at single dose for Covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient was inoculated on 15Dec2020 and currently on 28Dec2020 the patient was symptomatic of Covid. The patient was scheduled on 04Jan2021 for 2nd dose. The outcome of the events symptomatic of Covid was unknown. Follow-up activities are possible, information on the batch number has been requested.; Sender's Comments: The information currently provided is too limited to make a meaningful medical assessment hence, the events are conservatively assessed as related to the suspect drug BNT162B2 until further information becomes available.

got the vaccine within the past 24 hours and resulted positive for the test; got the vaccine within the past 24 hours and resulted positive for the test; This is a spontaneous report from a contactable consumer (patient). A 24-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL1284), via an unspecified route of administration on an unspecified date in 2020 at a single dose for COVID-19 immunization. There were no medical history or concomitant medications. The patient got the vaccine within the past 24 hours and resulted positive for the test, the patient took 48 hours ago like was that going to some adverse reaction like patient had the positive results before knowing the result patient got the vaccine so at present patient was just kind of anxious about what going to happen. Next shot will be due on 20Jan2021. The outcome of events was unknown.

tested positive for Covid a week after receiving the vaccine; tested positive for Covid a week after receiving the vaccine; patient stated that she was pregnant; patient stated that she was pregnant; patient stated that she was pregnant; This is a spontaneous report from a contactable nurse (patient) from a Pfizer sponsored program. A 37-year-old female patient received 1st dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot# EH9899), via an unspecified route of administration on 18Dec2020 at left deltoid for Covid-19 immunisation. The patient medical history was not reported. There were no concomitant medications. The patient experienced tested positive for Covid a week after receiving the vaccine on 28Dec2020 (as reported), the patient stated that she was pregnant. The patient underwent lab tests and procedures which included Covid test: positive on 28Dec2020. The outcome of events was unknown.; Sender's Comments: Based on the information currently available, a lack of efficacy with the suspected vaccine BNT162B2 in this patient cannot be completely excluded. Further information like confirmative virus genome /nucleic acid detection is needed for meaningful medical assessment.

had the vaccine and later tested positive for COVID-19; had the vaccine and later tested positive for COVID-19; This is a spontaneous report from a non-contactable consumer. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on Dec2020 at single dose for COVID-19 immunisation. Medical history included that the patient previously was positive from the virus COVID-19. The patient's concomitant medications were not reported. The patient that had the vaccine and later tested positive for COVID-19. The outcome of

the events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

Severe anaphylaxis; This is a spontaneous report from a non-contactable consumer. This consumer reported similar events for six patients. This is the second of six reports. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date not reported), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced severe anaphylaxis on an unspecified date. The outcome of the event was unknown. No follow up attempts are possible; information about lot/batch number cannot be obtained.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021003207 same drug/event; different patient

severe anaphylaxis; This is a spontaneous report from a non-contactable consumer. This consumer reported similar events for 6 patients. This is 5th of 6th reports. A patient of unspecified age and gender received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number and expiration date were not reported), via an unspecified route of administration on an unspecified date at a single dose for vaccination. The patient's medical history and concomitant medications were not reported. The patient experienced severe anaphylaxis on an unspecified date. Outcome of the event was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021003207 same drug/event and different patients

severe anaphylaxis; This is a spontaneous report from a non-contactable Consumer. This Consumer reported similar event for six patient. This is 6th of sixth reports. A patient of unspecified age and gender received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date not reported), via an unspecified route of administration on an unspecified date a single dose for covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced severe anaphylaxis on an unspecified date with outcome of unknown. No follow-up attempts are possible. Information about batch number cannot be obtained.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021003207 same drug/event and different patients

tested positive for COVID after receiving the COVID Vaccine; tested positive for COVID after receiving the COVID Vaccine; This is a spontaneous report from a contactable other HCP from a Pfizer-sponsored Program Pfizer First Connect. A female patient (sister) of an unspecified age received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot/batch number and expiry date were not provided), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. Caller stated that her sister tested positive for COVID after receiving the COVID Vaccine. Caller stated that her sister is a respiratory therapist and she has it (COVID) at the same time as the caller. Caller's sister tested positive at the same time as the caller on 01Jan2021. Caller's sister received the COVID Vaccine from a different facility from the caller. The outcome of the events was unknown. Information on the Batch/Lot number has been requested.; Sender's Comments: Based on the information currently available, a lack of efficacy with the

suspected vaccine BNT162B2 in this patient cannot be completely excluded. Further information like confirmative virus genome /nucleic acid detection is needed for meaningful medical assessment.

He received his first dose on 22Dec2020, then on 29Dec2020, he tested positive COVID.; He received his first dose on 22Dec2020, then on 29Dec2020, he tested positive COVID.; This is a spontaneous report from a Pfizer-sponsored program IBCC (Inbound Call Center for HCPs). A contactable healthcare professional (patient) reported for himself that a 30-year-old male patient received his first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EH9899), via an unspecified route of administration on 22Dec2020, at single dose for COVID-19 immunization. Medical history and concomitant medications were not reported. The healthcare professional is physician assistant. He received his first dose on 22Dec2020, then on 29Dec2020, his COVID 19 test revealed positive. He is supposed to get a second dose on 14Jan2021. He wondered if he is going to be able to take second dose or not. He doesn't have a prescribing doctor. He got it (vaccine) at work/at the hospital he works at. Outcome of the events was not recovered.; Sender's Comments: Based on the information currently available, a lack of efficacy with the suspected vaccine BNT162B2 in this patient cannot be completely excluded. Further information like confirmative virus genome /nucleic acid detection is needed for meaningful medical assessment.

Abdominal pain, chills, n/v, dark urine, elevated LFT's, Bilirubin in urine. Patient currently admitted to hospital

Received Moderna vaccine on 12/29/2020. 12/30/2020 fever of 100.4 Tylenol given and monitored and fever went down. 12/31/2020 Chest x-ray completed and sent to the hospital and admitted with pneumonia. 1/3/2021 reported by the hospital that Covid-19 results were positive. He had had Covid-19 positive results back on 11/4/2020 prior to vaccine.

"Pt experiencing and c/o left nasal burning, left upper lip tingling progressing to numbness with slight swelling noted, scattered patchy hives to upper front chest, sharp HA above right eye, denies SOB, no acute respiratory distress noted or reported, slurring of words shortly after onset of other symptoms. Pt repeating ""something ain't right"". Pt received Moderna COVID vaccine at 4:35pm with no reactions or side effect noted within the post 15 and 30 minutes. EMS notified at 5:49pm. MD notifed and ordered Benadryl 50mg IM (given at 5:53pm), EpiPen and DepoMedrol 40mg IM if needed. No respiratory distess noted, pt denies SOB. EMS arrived and transported pt to ER."

Developed SOB and fatigue 1 day after vaccine, went to urgent care and tested positive for COVID at urgent care. Returned to our ED after going to urgent care again on 1/7/21, had o2 sat of 84% on room air, impoved to 98 on 3 liters. Was transferred to another facility for admission.

vomiting later on 01/05/21. Lethargy and hypoxia in pm of 01/06/21. Hypotension am of 01/07/21. Hospitalized, intubated, cardiac arrest, died 01/07/21.

Swollen lips/tongue, shortness of breath, cough, hives, nausea, headache Epi shot, Benadryl, Pepcid, prednisone

Less than 5 minutes after vaccine, nose drained, weird taste in mouth, tingle in nose and on tongue. Throat and tongue swelled, couldn?t speak. Dizzy and slurring speech. Was taken to ambulance outside, BP was 191/101. Given beta blockade. Confused and dizzy for next 2 hours in ER. Evaluated for stroke and given a 12-lead ECG. Given benedryl and prednisone. Felt better after 3 1/2 hours. Continued steroids for 5 days and had to take benedryl every 4 hours for 3 days or swelling/itching/bad taste in mouth would return. Sore arm on day 3.

symptoms:chest and stomach pain Has markedly elevated liver function tests that were normal 2 weeks prior to immunization Is being admitted the hospital to monitor liver function test.

headache, sore throat, runny nose, arm pain that migrated to the axilla and down the side of the body, joint pain (hands, wrist, feet, hips, knees, spine, neck), insomnia, general malaise, fatigue, and lower grade fever. Most symptoms lasted about 7 -10 days. However, it is now day 20 after the initial vaccine and I still have joint pain that has not gone away. esp in hands, wrists, and feet. When I sleep I still wake up with all my joints hurting it gets better as I start moving but the wrist, hands, and feet pain has not gone away. This pain will wake me in the night when I change positions. I called my doctor today to inquire if it is a good idea if I should take the second dose because the first dose made me so dibiliated. Awaiting for a response. I am due to take the second vaccine on 2/9/21.

Fever, coughing, drowsiness, generalized weakness. Was found to be hypercalcemic (corrected calcium 14) and admitted 1/2-4. No prior history of hypercalcemia.

Congestion Shortness of breath Tachycardia Transferred out 911. Per hospital, patient had a myocardial infarction, is unresponsive, and on hospice services.

Anaphylactic reaction, Severe edema and raised red rash entire body, Severe itching ,Soft tissue edema of throat. Swelling of, eyes, lips, face. Multiple trips to ER, treated with steroids, Benadryl, prevacid. , CURRENTLY IN ICU ON EPINEPHRINE DRIP, STEROIDS, MULTIPLE MEDS

Resident passed away in her sleep

Patient c/o fatigue and cough on 1.4.2021 and was encouraged to be tested for COVID. We were notified that the patient was hospitalized on 1.7.2021 with COVID symptoms and positive test results. She is currently on a ventilator and dialysis.

On December 25th I had mild chest pain and then on January 1st, 2021 I had severe chest pain that persisted and on January 3rd I was admitted into the hospital. My Ddimer was elevated and my Troponin levels were elevated. An angiogram was performed and Dr. injected nitro into my arteries because they were constricted from Coronary Spasms.

Sxs started 3-5 minutes post vax. Dizziness, hypotension, throat fullness, CODE called, given IM Epi at vax site. Taken to ED from vax site. Started on epi drip. Admitted to SHC.

Nausea/ dizzy, Syncope 12 hours later.

Patient felt warm with palpitations 5 minutes after vaccine administered. was monitored for 30 mins & then returned to work. on 12/30/2020 patient was at work in Presurgical testing dept & experienced near syncope, dizziness & elevated BP. reported to ED & was admitted to telemetry unit.

Dr. called this morning and reported that an employee that works in billing had her vaccine on Wednesday and developed and anaphylactic reaction to Moderna. This was 24 hours later with rash, SVT heart rate above 140, low grade fever, redness at site. Admitted and treated with steroids and Benadryl.

Came to ER on 12/20/20 with chills, heart palpitations, body aches and increased SOB. Had ST elevation on EKG in ER, taken to Cath Lab- no intervention done. D/C home 12/22/20. Previous Hx of COVID per patient

Initial event was soreness at site which resolved on its own within a few days. 2 days after receiving vaccine, I began having an allergy reaction to the same brand N95 that I had been utilizing since the beginning of the pandemic. Symptoms are swollen cheeks and welts , sudden itchiness at the site of my mask placement. The reason for this report is a sudden onset of excruciating and debilitating pain throughout my body specifically pain of my right shoulder radiating down my sprightly arm. I have been receiving testing and treatment for ongoing neuropathy due to Longhauler syndrome, however This recent pain is so debilitating, I spend most of my time in bed. I have been experiencing chills then profuse sweating. I also so fatigued, I sleep much of the day. I have been having episodes of tachycardia with chest tightness which has increased since after having the vaccine. I also become short winded on exertion. I?ve been waking up in a panic and sweating.

Patient received first dose of Pfizer COVID-19 vaccine on December 26. On the next day, December 27, patient started having pressure in her head and sinuses, weakness. Then she developed nonproductive cough and progressive shortness of breath. She was seen at urgent care and tested positive for COVID-19 on December 29. She had low oxygen saturation on home oximeter and severe shortness of breath. Patient's husband is also ill with COVID-19 at home. Patient was sent to the ED and admitted to the hospital.

Patient had been diagnosed with COVID-19 on Dec. 11th, 2020. Symptoms were thought to have started on 12/5/2020. Received Moderna vaccine on 12/23. Unexpected death on 1/8/2021. Resuscitation attempts unsuccessful

infection of SARS-COV-2; infection of SARS-COV-2; This is a spontaneous report from a contactable healthcare professional. A 31-year-old male patient started to receive received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot number EL0140), intramuscular into the left arm on 18Dec2020, at 10:30 as single dose for covid-19 immunization. There was no medical history and no concomitant medications. The patient experienced infection of SARS-COV-2 on 25Dec2020. Details were as follows: The patient received the first dose of the two dose series. On 20Dec2020, he was exposed to COVID-19. Official positive diagnosis of COVID-19 was made on 25Dec2020. Patient had symptoms of fatigue, joint pain and a small fever on an unspecified date, and had been exposed to SARS-COV-2 on 20Dec2020, and the infection on 25Dec2020. The patient underwent lab tests and procedures which

included sars-cov-2 test which was positive on 25Dec2020. The patient was scheduled to receive second dose of the vaccine; he will be out of quarantine around five to six days before that dose. The outcome of infection of SARS-COV-2 was recovering.; Sender's Comments: The efficacy of a drug varies from one patient to another and can be affected by different factors; however, a contributory role of the suspect drug BNT162B2 to the reported events drug ineffective and COVID-19 cannot be ruled out.

recipient of the covid 19 vaccine received a positive antigen test within 10 days of getting the vaccine; recipient of the covid 19 vaccine received a positive antigen test within 10 days of getting the vaccine; This is a spontaneous report from a contactable nurse. This nurse reported similar events for two patients. This is the second of 2 reports. A female patient of an unspecified age (Age: 30, Unit: Unknown) received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number and expiration date were not reported), via an unspecified route of administration on an unspecified date at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient received a positive antigen test within 10 days of the vaccine and wanted to know if the vaccine could cause a positive antigen test. There was no mention of exposure to a positive person. Outcome of the events was unknown. Information on lot/batch number has been requested.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the reported events of COVID-19 antigen test positive and LOE due to temporal relationship. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.,Linked Report(s) : US-PFIZER INC-2020519946 same reporter, drug, and events; different patients

"neuropathy/ started acutely in feet bilaterally / persist intermittently in left extremities; One-time episode of upper extremity (UE) numbness; This is a spontaneous report from a contactable health care professional (patient). A 40-year-old female patient (not pregnant) received her 1st dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, batch/lot unknown) at single dose via an unknown route at left arm on 26Dec2020 for Covid-19 immunization. COVID-19 vaccine was administered in Pharmacy or Drug Store. Medical history was reported as ""none"". Patient had no COVID prior vaccination, further reported as patient was not diagnosed with COVID-19 prior to vaccination. No known medications, food, or other products allergies. Concomitant drugs (Other-medications-in-two weeks) included levocabastine hydrochloride (ZYRTEC), diphenhydramine hydrochloride (BENADRYL) as needed, ibuprofen (MOTRIN), and multivitamin. No other-vaccine-in-four weeks received. Patient experienced adverse-event of neuropathy, which started acutely in feet bilaterally and now (as of 02Jan2021) persist intermittently in left extremities (LEs). One-time episode of upper extremity (UE) numbness. No weakness. Patient inquired if 2nd dose should be held. Adverse-event-start-date was 26Dec2020. The adverse event result in doctor or other healthcare professional office/clinic visit. No treatment received.

The event was reported as non-serious. Since the vaccination, patient had not been tested for COVID-19. Outcome of the event was not resolved. Information about lot/batch number has been requested.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the reported events of peripheral neuropathy and upper extremity (UE) numbness due to temporal relationship. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics including head CT/MRI and nerve conduction tests, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate."

Became extremely flushed; tingling in hands and feet; disorientation; This is a spontaneous report from a non-contactable nurse (patient). A 34-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE) (lot number: EL0140/expiration date unknown), via intramuscular route of administration, on 28Dec2020 (at the age of 34 years old) as a single dose in the left arm for COVID-19 immunization at hospital facility. Relevant medical history included Gastrooesophageal reflux disease (GERD), Attention deficit hyperactivity disorder (ADD), Generalised anxiety disorder (GAD). The patient did not have any known allergies to medications, food, or other products. Prior to the vaccination, the patient was not diagnosed with COVID-19. Concomitant medications included esomeprazole sodium (NEXIUM), venlafaxine hydrochloride (EFFEXOR), amfetamine aspartate, amfetamine sulfate, dexamfetamine saccharate, dexamfetamine sulfate (ADDERALL). The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. On 28Dec2020, at 09:00 PM, the patient became extremely flushed, tingling in hands and feet, disorientation. Treatment was received for the events became extremely flushed, tingling in hands and feet, disorientation included Diphenhydramine 50mg @2200 and again at 0200. The outcome of the events became extremely flushed, tingling in hands and feet, disorientation was recovered on unknown date. Since the vaccination, the patient had not been tested for COVID-19.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the reported events of extremely flushed, tingling in hands and feet and disorientation due to temporal relationship. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics including chemistry panel and Head CT/MRI, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Around 10:30pm I felt like my throat was closing and I was choking; Around 10:30pm I felt like my throat was closing and I was choking; I had chest pain, chest tightness; I had chest pain, chest tightness; Very

SOB at rest; Throughout the day I was cough and my face started flushing so I tool Benadryl/severe facial flushing; On 23Dec I got nerve blocks for my migraines.; Throughout the day I was cough and my face started flushing so I tool Benadryl.; This is a spontaneous report from a contactable nurse who reported for herself. A 36-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot: EK5730) dose number 1, via an unspecified route of administration on 19Dec2020 11:30 at single dose for COVID-19 immunization. Medical history included von willebrand's disease, narcolepsy with cataplexy, IIH (Idiopathic intracranial hypertension), HTN (hypertension), GERD (gastrooesophageal reflux disease), migraines. Patient also had known allergies: PCN (penicillin), shellfish, IV contrast, cefdinir and bees. On 23Dec2020, patient got nerve blocks for her migraines. Throughout the day patient was cough and her face started flushing so she tooled diphenhydramine hydrochloride (BENADRYL). Around 22:30, patient felt like her throat was closing and she was choking. She had chest pain, chest tightness. EMS (emergency medical services) was called and patient was brought to the hospital. On 25Dec2020, patient felt like her throat was closing, like someone was sitting on her chest and chest tightness still with chest pain. Very SOB (shortness of breath) at rest. Patient went to the ER (emergency room) and received IV dexamethasone (DECADRON) and diphenhydramine hydrochloride. On 26Dec2020, patient had the same symptoms but with severe facial flushing and patient went back to the ER and was given IV dexamethasone. Patient was sent home on a maximum amount of medications. I had seen her primary care, ENT (ear nose throat centre), Allergy, ID (infectious disease), and pulmonology. Her CT (computerised tomogram) of chest on 25Dec2020 was negative along with her COVID test. Patient SOB on rest and exertion still. Onset date of the adverse events was reported as 23Dec2020, 22:30. Patient received treatment for the events included multiple medications and high dose prednisone. Lab data on 25Dec2020 included CT of chest: negative, influenza type A/B combo: negative, Covid 19: negative and nasal swab: negative. Action taken in response to the events for bnt162b2 was not applicable. Outcome of the events was not resolved.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the reported events due to temporal relationship. The clinical presentation of the events is suggestive of possible allergic reactions. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

I tested positive for COVID today; I tested positive for COVID today; This is a spontaneous report from a contactable other Health Care Professional (HCP). A female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, lot number and expiration date unknown) via an unspecified route of administration on 24Dec2020 (at an unknown age) at an unknown dose for COVID-19 vaccination. The patient's medical history was not reported. The patient's concomitant medications were not reported. The patient tested positive for COVID on 01Jan2021. The patient was inquiring as to if she can still get the second dose since she has tested positive in between. The patient underwent lab

tests and procedures which included SARS-COV-2 test: positive on 01Jan2021. The clinical outcome of COVID-19 virus test positive was unknown. The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up.; Sender's Comments: The information currently provided is too limited to make a meaningful medical assessment hence, the events are conservatively assessed as related to the suspect drug BNT162B2 until further information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

experienced loss of smell, taste and a headache/she came down with signs and symptoms/she got tested and got the results on Thursday that she was positive for covid 19 virus; experienced loss of smell, taste and a headache/she came down with signs and symptoms/she got tested and got the results on Thursday that she was positive for covid 19 virus; This is a spontaneous report from a contactable Other Health Professional (patient). A 45-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) Solution for injection, lot number, via an unspecified route of administration from 14Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient had the first dose of COVID vaccine on 14Dec2020. Eleven days following first dose, she experienced loss of smell, taste and a headache. She stated that she came down with signs and symptoms on 25Dec2020 and she got tested and got the results on Thursday that she was positive for Covid 19 virus. She was due for the 2nd dose of the COVID vaccine on the 6th of January. She asked what she should do about the second dose. She mentioned that her symptoms and positive test results were reported where she works in (State name). She wanted to know information as to whether she should get the second dose. Her second dose's scheduled was 6Jan2021. The event outcome was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the reported events of suspected LOE and COVID 19 infection due to temporal relationship. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

had a positive covid test results; had a positive covid test results; This is a spontaneous report from a contactable physician. A male patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 17Dec2020 at a single dose for COVID-19 immunization.On 22Dec2020 he started to experience COVID like symptoms. On 26Dec2020, he had a positive COVID test results. On 28Dec2020, he received the Regeneron antibody infusion. Patient wants to know more about receiving the 2nd dose based on his positive diagnosis/antibody

treatment. Outcome of the event was unknown. Information on batch number has been requested.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the reported events of SARS-CoV-2 test positive and suspected LOE due to temporal relationship. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

diarrhea; headache; lower back pain; Fatigue; arrhythmia; Tachycardia; High Blood pressure; Redness on chest; Chest tightness; Lightheaded; possible tongue swelling; possible tongue swelling (felt heavy after vaccine); dry mouth; sore throat; This is a spontaneous report from a contactable nurse (patient) who reported for herself that a 31-year-old female patient received her first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899) via an unspecified route of administration, on 20Dec2020 14:15 at left arm/arm right (pending clarification), single dose for COVID-19 immunization. Medical history included factor II, history of melanoma. She has no known allergies. She was not pregnant at the time of the vaccination. Concomitant medications included bupropion hydrochloride (WELLBUTRIN), ibuprofen (MOTRIN), multivitamin. Nurse reported administering COVID-19 vaccine at hospital, experiencing tachycardia, high blood pressure, redness on chest, chest tightness, lightheaded, possible tongue swelling (felt heavy after vaccine), arrhythmia, dry mouth, sore throat (after leaving emergency department) at 14:30 on 20Dec2020; After one day, she experienced diarrhea, headache, lower back pain and fatigue since 21Dec2020. Fatigue lasting for several days. Adverse events resulted in emergency room/department or urgent care (pending clarification). Nurse received intravenous diphenhydramine hydrochloride (BENADRYL) and fluids as treatments. Nurse assessed the events as non-serious. Nurse also reported that, prior to vaccination, she was not diagnosed with COVID-19; since the vaccination, she has not been tested for COVID-19. She did not receive other vaccine in four weeks. Outcome of fatigue was not recovered, outcome of the rest of the events was recovered.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the tachycardia, high blood pressure, arrhythmia and the other reported events due to temporal relationship. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics including EKG at baseline and during subject drug therapy, echocardiogram, cardiac enzymes, electrolytes, chemistry panel and serum toxicology screen, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

"Chills; Soreness at the injection site; generalized body aches/Body aches; Shortness of breath; Asthma attack; Difficulty sleeping; Light headed and dizzy; Nausea; high BP 140's; HR 110's to 120s; Nasal congestion; Swelling of the face; Sore throat; This is a spontaneous report from a contactable nurse. A 42-years-old female patient received her first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number EK5730, expiration date not reported), intramuscular on the right arm on 31Dec2020 at 10:15 AM, at a single dose for Covid-19 immunization. Medical history included asthma, allergy, hypothyroidism, and some fish allergy. There were no concomitant medications (no other vaccine in four weeks and no other medications in two weeks). Patient previously took ibuprofen and experienced allergy. The patient is not pregnant. On 31Dec2020, after ten-15 minutes (10:30 AM) of receiving the vaccine, she was light headed and dizzy with some nausea. Monitored in the emergency room (ER) with high BP 140's and heart rate (HR) 110s to 120s. After an hour of saline bolus, she was better but she got nasal congestion and swelling of the face with sore throat. On 01Jan2021, after 24 hours, she got some soreness at the injection site with generalized body aches. Also she got some shortness of breath which lead to her asthma attack and difficulty sleeping. On 02Jan2021, after 48hours, she was feeling still light headed with some sore throat, chills, body aches and severe headache which lead her to go to the ER and got herself tested for flu, covid and strep, which came back all negative but her signs and symptoms (s/sx)still after discharge was getting worst especially the headache and generalized body aches. As well as congestion and sore throat. The patient had given ""Ivf"" for the events. The patient was not diagnosed with Covid prior to vaccination and was not Covid tested post vaccination. The outcome of the events was not recovered. The reporter assessed the events as non-serious.; Sender's Comments: A causal association between BNT162B2 and the reported events cannot be excluded based on a compatible temporal relation between vaccination and onset of events. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate."

becoming incoherent and talking nonsense; This is a spontaneous report from a contactable physician (patient). A female patient of an unspecified age received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiry date not reported), via an unspecified route of administration on 23Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. Physician calling about whether or not she should receive the second dose of vaccine. She received dose on 23Dec2020. On 26Dec2020 she started experiencing several side effects including becoming incoherent and talking nonsense. Her daughter who is an EMT suggested that she go to the ER. While in the ER she received TPA but it was later decided she did not have a stroke. Her EKG, bloodwork and other testing came back negative. She otherwise healthy and has no comorbidities. She already spoke with agency. She has also already spoken with an infectious disease doctor and her neurologist. The outcome of the event was unknown. Information on the lot/batch number has been requested.; Sender's Comments: The information currently provided is too limited to make a meaningful medical assessment hence, the event incoherent is conservatively assessed as related to the suspect drug BNT162B2 until further information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety

evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to agencys, Ethics Committees, and Investigators, as appropriate.

tingly feeling to my lips; some lip swelling; tightness in my throat.; This is a spontaneous report from a contactable Other HCP. A 35-years-old female patient started to receive BNT162B2, via an unspecified route of administration from 30Dec2020 12:00 to 30Dec2020 12:00 at SINGLE DOSE for covid-19 immunisation. Medical history included hypersensitivity from an unknown date and unknown if ongoing, gastritis from an unknown date and unknown if ongoing, anxiety from an unknown date and unknown if ongoing, depression from an unknown date and unknown if ongoing. Concomitant medication included lorazepam (ATIVAN), ivermectin (IVERMECTIN), escitalopram oxalate (LEXAPRO), esomeprazole magnesium (NEXIUM [ESOMEPRAZOLE MAGNESIUM]), levocetirizine dihydrochloride (XYZAL). The patient previously took tamiflu and experienced drug hypersensitivity. The patient experienced tingly feeling to my lips (paraesthesia oral) (non-serious) on 30Dec2020 15:30 with outcome of recovered, some lip swelling (lip swelling) (non-serious) on 30Dec2020 15:30 with outcome of recovered, tightness in my throat. (throat tightness) (non-serious) on 30Dec2020 15:30 with outcome of recovered. The action taken in response to the event(s) for BNT162B2 was not applicable. Therapeutic measures were taken as a result of tingly feeling to my lips (paraesthesia oral), some lip swelling (lip swelling), tightness in my throat. (throat tightness). This is a spontaneous report from a contactable other HCP. This 35-year-old female other HCP reported that: Report about covid vaccine: Yes Reporter type: Patient Age group: Adult (18-64 Years) Is pregnant: No Race: (race provided) Ethnicity: (ethnicity provided) Patient occupation: Other Health Professional Covid vaccine details: product-COVID 19, Lot number-EL1284, Lot unknown-False, Administration date-30Dec2020, Administration time-12:00 PM, Vaccine location-Left arm, Dose number-1 Facility type vaccine: Hospital If other vaccine in four weeks: Yes Other vaccine 4weeks details: other vaccine 4weeks product -Allergy Immunotherapy injections , Other vaccine 4weeks vaccine date -07Dec2020, Other vaccine 4weeks dose number -2 , Other vaccine 4weeks vaccine location-Left and right arm. Other medications in two weeks: Nexium, xyzal, Ativan, Lexapro, Ivermectin Adverse event: At about almost 4 hrs after receiving the injection I started to experience a tingly feeling to my lips, some lip swelling and tightness in my throat. I had my epi pen on hand incase I needed it but I ended up taking 25mg of Benadryl, then 50 mg of Benadryl 5 hrs later. The following morning my lips where feeling tingly again so I took 25mg of Benadryl again and continued for the next 48 hrs at the advice of my doctor. Adverse event start date: 30Dec2020 Adverse event start time: 3:30PM AE resulted in: None of the above If patient recovered: Recovered If treatment AE: Yes AE treatment: Benadryl for 48 hrs If covid prior vaccination: No If covid tested post vaccination: No Known allergies: Tamiflu Other medical history: Chronic allergies, gastritis, anxiety, Depression Identification of the case safety report Serious: No Seriousness criteria-Results in death: No Seriousness criteria-Life threatening: No Seriousness criteria-Caused/prolonged hospitalization: No Seriousness criteria-Disabling/Incapacitating: No Seriousness criteria-Congenital anomaly/birth defect: No VAERS Primary Reporter Addl Qualification: Patient Relevant medical history and concurrent conditions: Structured information (Patient episode name): Chronic allergies, gastritis, anxiety, depression Reaction(s)/Event(s): Reaction/event as reported by primary source: At about almost 4 hrs after receiving the injection I started to experience a tingly feeling to my lips, some lip swelling and tightness in my throat. I had my epi pen on hand incase I

needed it but I Reaction/event in terminology (LLT) : At about almost 4 hrs after receiving the injection I started to experience a tingly feeling to my lips, some lip swelling and tightness in my throat. I had my epi pen on hand incase I needed it but I ended up taking 25mg of Benadryl, then 50 mg of B Date of start of reaction/event: 30Dec2020 Outcome of reaction/event at the time of last observation: RECOVERED/RESOLVED Drug(s) Information: Characterization of drug role: Suspect Batch/lot number: EL1284 Date of start of drug:30Dec2020 Anatomical location: Arm left Dose number:1 Active drug substance information: Active drug substances name: COVID 19 Drug(s) Information: Characterization of drug role: CONCOMITANT Proprietary medicinal product name: Allergy Immunotherapy injections Date of start of drug:07Dec2020 Dose number:2 Narrative case summary and further information: Case narrative Age at vaccination: 35 Pregnant at the time of vaccination?: No Start Date/Time:30Dec2020 12:00 PM Facility where the most recent COVID-19 vaccine was administered: Hospital Did the patient receive any other vaccines within 4 weeks prior to the COVID vaccine: Yes List of any other medications the patient received within 2 weeks of vaccination: Nexium, xyzal, Ativan, Lexapro, Ivermectin Reported Event: At about almost 4 hrs after receiving the injection I started to experience a tingly feeling to my lips, some lip swelling and tightness in my throat. I had my epi pen on hand incase I needed it but I ended up taking 25mg of Benadryl, then 50 mg of Benadryl 5 hrs later. The following morning my lips where feeling tingly again so I took 25mg of Benadryl again and continued for the next 48 hrs at the advice of my doctor. Was treatment received for the adverse event?: Yes: Benadryl for 48 hrs Prior to vaccination, was the patient diagnosed with COVID-19?:No Since the vaccination, has the patient been tested for COVID-19?:No Allergies to medications, food, or other products: Tamiflu Vaccine Facility information available. Ethnicity information is available. Race information is available. Location of injection information is available for other vaccines within 4 weeks PRIOR.; Sender's Comments: A causal association between BNT162B2 and the reported events cannot be excluded based on a compatible temporal relation between vaccination and onset of events. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

About 15 minutes after receiving the vaccine she felt palpitations. She was monitored for another 15 minutes and while she was walking to her car se started noticing sore throat associated with inability to talk, unable to swallow secretions, and swelling the lips. Patient presented to the emergency room where she received EpiPen dose. Received diphenhydramine, famotidine, and prednisone. Lip swelling and sore throat began improving in ED.

I was given a vaccine on Dec17th, on Dec21st I tested positive for Covid; I was given a vaccine on Dec17th, on Dec21st I tested positive for Covid; This is a spontaneous report from a contactable nurse. A 46-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number EK5730), via an unspecified route of administration on 17Dec2020 at a single dose for COVID-19 immunization. There was no relevant medical history. The patient's concomitant medications were not reported. The patient was given a vaccine on 17Dec2020, the on 21Dec2020, the patient tested positive for COVID. The outcome of the event was unknown.; Sender's Comments: Based on the information

available, a possible contributory role of the suspect products cannot be excluded for the reported event of positive for corona virus infection for the lack of efficacy of the vaccine. However, based on the mechanism of action of the vaccine, it is unlikely the patient would have fully developed immunity for the vaccine to be effective, due to the number of days passed since the vaccine is given. Case will be reevaluated based on follow-up information

TSH level has been borderline hypothyroidism; Almost feel like somebody is gently holding my throat, so I could still breathe, talk, eat but I had the feeling that my throat was being kind of squished; This is a spontaneous report from a contactable nurse. A 64-year-old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number EK5730), via an unspecified route of administration in right deltoid on an unspecified date at a single dose for covid-19 immunization. Medical history included hypertension and high cholesterol. Concomitant medication included evolocumab (REPATHA) for high cholesterol and two unspecified medications for hypertension. The got the first dose of Pfizer Vaccine for COVID, and for about 3 or 4 almost 5 days afterwards, she felt like somebody, it almost feel like somebody was gently holding her throat, so she could still breathe, talk, eat but had the feeling that throat was being kind of squished. The patient had her lipid panel liver and TSH level done because of the Repatha and TSH level has been borderline hypothyroidism, so she haven't really been on medicine for it but it might be. The patient added that the events had certainly correlated with the vaccine. She didn't have the events until she got the vaccine, so she feel like it was and then her concern was it wouldn't be safe to take the second one. The patient did not visit emergency room and physician office because of the issue 'feel like somebody was gently holding her throat' and all she did was take Benadryl at night. The outcome of the events was unknown.; Sender's Comments: The causal relationship between bnt162b2 and the event hypothyroidism cannot be excluded as the information available in this report is limited and does not allow a medically meaningful assessment. This case will be reassessed once additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate.

test positive for COVID-19/fever, chills, body aches, joint pain; test positive for COVID-19/fever, chills, body aches, joint pain; This is a spontaneous report from a contactable other HCP. A 35-year-old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK5703), via an unspecified route of administration in left arm on 15Dec2020 17:30 at a single dose for covid-19 immunization. Administration was done in the hospital. Medical history included seronegative rheumatoid arthritis and allergies to latex and actemra. Concomitant medication included tofacitinib citrate (XELJANZ), and ibuprofen. Eight days after vaccination, on 23Dec2020 at 13:30, the patient came down with fever, chills, body aches, joint pain. The patient was initially tested negative for COVID (nasal swab) and influenza on 27Dec2020 but did test positive for COVID-19 on 29Dec2020 (nasal swab). The patient stated that she knew that the vaccine did not cause COVID however as she was on immunosuppressants (Xeljanz), she wanted to record this information. There was no treatment included for the events. The outcome of the events was recovering. Prior to vaccination, the patient was not

diagnosed with COVID-19.; Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of events Drug ineffective and COVID-19 cannot be totally excluded. The case will be reassessed if additional information becomes available.

COVID-19 rapid POC test positive; COVID-19 rapid POC test positive; the amount of vaccine given as 1 cc; This is a spontaneous report from a Pfizer-sponsored program, IBCC (Inbound Call Center for HCPs). A contactable nurse (patient) reported that a 52-year-old female patient received first dose of BNT162B2 (Pfizer-BioNTech COVID-19 mRNA vaccine; lot number: EH9899), via an unspecified route of administration on 17Dec2020 at 1 mL, single dose for COVID-19 immunization. Medical history included ongoing hypertension diagnosed when she was 33 years old. There were no concomitant medications. The patient got the vaccine on 17Dec2020. The patient stated that the amount of vaccine given was 1 cc. She took a COVID-19 rapid POC test on the 28Dec2020 and tested positive. She wanted to know if she should have the second dose of the vaccine. The outcome of the events was unknown.; Sender's Comments: The information currently provided is too limited to make a meaningful medical assessment hence, the events are conservatively assessed as related to the suspect drug BNT162B2 until further information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

"When she went back to work on 25Dec2020 it was positive/On the weekend she had to come back to do a PCR test on28Dec2020 and it was positive.; When she went back to work on 25Dec2020 it was positive/On the weekend she had to come back to do a PCR test on28Dec2020 and it was positive.; This is a spontaneous report from a contactable nurse. A 43-year-old female patient receive bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EH9899), via an unspecified route of administration given in the left arm on 22Dec2020 at a single dose for covid-19 immunization. The patient medical history included ""patient's a blood donor"" reported as, she donated blood on 12Sep2020 and it was negative for covid. The patient's concomitant medications were not reported. The patient experienced ""when she went back to work on 25Dec2020 it was positive/on the weekend she had to come back to do a pcr test on28dec2020 and it was positive"" on 25Dec2020 with an unknown outcome. It was further reported that the patient was a registered nurse that works night shift. She clarified that the rapid test was taken each time she goes to work. When she went to work on the night of 21Dec2020 the rapid test was negative.Then she got the Covid vaccine in the morning of 22Dec2020. When she went back to work the night of 22Dec2020 the rapid test was negative. When she went back to work on 25Dec2020 it was positive. On the weekend she had to come back to do a PCR test on28Dec2020 and it was positive. Caller clarifies that the rapid tests were Nasal Swabs. The patient's latest test was on 28Dec2020, she was told that when she comes back, they do not have to do the rapid test daily anymore, it will now be every 90 days. The patient did not have a test before the vaccine. She has had no issues with Vaccines in the past.; Sender's Comments: Based on the information available, a possible contributory role of the suspect BNT162B2 cannot be excluded for the reported event positive

for corona virus infection based on the known safety profile. However given the short duration of 3 days since the vaccine first dose, it is unlikely patient would have fully developed immunity."

positive COVID-19 test with symptoms/had like a head cold and cold like symptoms/he tested positive for COVID.; positive COVID-19 test with symptoms/had like a head cold and cold like symptoms/he tested positive for COVID.; This is a spontaneous report from a contactable nurse. A 67-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EJ1685), intramuscular on left deltoid on 18Dec2020 at single dose for COVID prevention. The patient had no medical history. There were no concomitant medications. The patient got his first dose of the COVID Vaccine on 18Dec2020, and he states that he did fine and had no problems. But on 28Dec2020, when he was going to work, he noticed that he had like a head cold and cold like symptoms. He was swabbed and tested for COVID PCR on that day, and he tested positive for COVID. After his positive COVID test, he was tested for monoclonal antibodies, and at first, he was told that test came back positive, but then about 12 hours later, he was told that the staff had misread it, and he was actually negative for monoclonal antibodies, so the caller was given monoclonal antibody therapy and he did fine with that, and he is recovered now. He is scheduled to go back to work this Thursday, and he is supposed to receive the second dose of the vaccine, on Friday. He checked the schedule for getting the second dose, and he was not on the list, so he called the infection control nurse, and she told the caller that because he received the monoclonal antibody therapy, he now has to wait 90 days to receive the second dose of the vaccine. Caller states that he looked for that information, and he did not see that anywhere, so he is wondering if that is correct, because it almost seems to him that if he waits 90 days, he would have to start the series again. The outcome of the event was recovered on an unspecified date.; Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of events Drug ineffective and COVID-19 cannot be totally excluded. The case will be reassessed if additional information becomes available.

low grade fever/low grade fever of 103; chills; dry cough; lethargy; This is a spontaneous report from a contactable nurse. A 62-year-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number EJ1685 with expiry date Mar2021), via an unspecified route of administration in left deltoid on 30Dec2020 14:30 at a single dose for COVID-19 immunization. The administration was one in a local pharmacy. There were no relevant medical history and concomitant medications. On Saturday night, 02Jan2021, the patient started getting a low grade fever of 103, had chills, lethargy and an intermittent dry cough. The outcome of the events was not recovered. The events were considered medically significant events.; Sender's Comments: A possible contributory effect of suspect BNT162B2 on reported events cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

a left sided nystagmus; urgent MRI showing multiple brain lesions consistent with Acute disseminated encephalomyelitis; Patient developed paresthesias on entire right side of body / The paresthesias continued, not progressing; a brief headache; episode of dizziness / developed severe dizziness; This is a

spontaneous report from a contactable physician (patient). A 34-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK5730) intramuscularly at right arm on 21Dec2020 07:00 at single dose for COVID-19 immunization. Medical history included known allergies to sulfa meds. The patient's concomitant medications included multivitamins [vitamins nos] within 2 weeks of vaccination. Patient developed paresthesias on entire right side of body after a brief headache and episode of dizziness, all since 29Dec2020 15: 00. The paresthesias continued, not progressing, but patient was advised to obtain an MRI Brain and C spine as an outpatient. On 02Jan2021, the patient developed severe dizziness and a left sided nystagmus. She went to the ER and underwent urgent MRI showing multiple brain lesions consistent with acute disseminated encephalomyelitis. Lumbar puncture (LP) was performed, awaiting final results. Patient was admitted and was receiving IV steroids (solumedrol). Duration of hospitalization was 5 days since Dec2020. Patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. The patient underwent lab tests and procedures, which included Nasal Swab and Rapid covid swab, both on 02Jan2020 with result of negative. The outcome of the events was recovering.; Sender's Comments: Based on temporal association and lack of other provided etiology, a possible contributory role of suspect BNT162B2 vaccine cannot be excluded for reported acute disseminated encephalomyelitis, paraesthesia, headache, dizziness and nystagmus. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

hives; face swelling; itching; rash; This is a spontaneous report from a contactable nurse (patient). A 71-year-old female patient received 1st dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot# EH9899), intramuscular in left arm on 22Dec2020 11:08 at single dose for COVID-19 vaccination. Medical history included ongoing blood pressure high, ongoing cholesterol, ongoing depression. Concomitant medication included atenolol (tablet, strength 50 mg) from an unknown date and ongoing for blood pressure high, simvastatin (tablet, strength 20 mg) from an unknown date and ongoing for cholesterol, paroxetine hydrochloride (PAXIL, tablet, strength 40 mg) from an unknown date and ongoing for depression. The patient experienced hives, face swelling, itching and rash on 27Dec2020. No additional vaccines administered on same date of the Pfizer suspect. Prior vaccination within 4 weeks was none. She got the first Covid 19 dose on 22Dec2020 and was fine, then on 27Dec2020 she had hives, itching, and face swelling for several days. Caller stated her lungs were clear and she was okay other than the extreme itching. The face swelling was what worried her. The hives and itching went away within about 36 hours. The face swelling kind of got worse for a couple of days before it went away. Caller verifies she recovered from the hives/rash/itching within 36 hours. She got a steroid shot and things like that and it went away pretty quickly. The face swelling was completely gone but did last for a good 5 days. She didn't know if this reaction was related to the vaccine. She wanted to call and let Pfizer know and see if there was any reports of anything else like that or similar to that type of reaction. She was not sure if that really matters or not except she was not sure about taking the booster. She was kind of leaning towards taking the second vaccine. She didn't have any breathing issues. She asked as far as the second

dose after those side affects, was it recommended? Her doctor said she could get the second one and prescribed her an Epi pen and would give a dose of Benadryl at the time of the second vaccine. She may take some Benadryl before getting the second vaccine and have her EpiPen with her just in case. She hadn't seen her doctor about this experience with the COVID-19 vaccine. She only went to an urgent care. The caller stated she went to urgent care twice. She received a steroid shot but doesn't have any name, NDC/UPC, Lot number or expiration date for any of the medication she received. She probably threw that paperwork out. She knew she wasn't given anything the second time she went to the urgent care. The second time she went back was because the face swelling was getting worse. She was prescribed an EpiPen and was told to take Zyrtec which did help. Everything had gone away. She would consider these events to be medically significant because of the face swelling, it kind of scared her. She made the comment she was taking high blood pressure medicine and cholesterol medicine, but other than that she was very healthy. She was not really an allergic person. She had not had any testing done since she received the vaccine. She did have bloodwork done prior but not since the vaccine. The patient underwent lab tests and procedures which included blood work prior vaccine with unknown result. The outcome of hives, rash and itching was recovered on an unspecified date of Dec2020 (within about 36 hours); face swelling was recovered on 01Jan2021.; Sender's Comments: Based on the time gap between the vaccine and the events there is not a reasonable possibility that the reported events were related to the suspect product, events are most likely due to patient underlying contributory factors The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators as appropriate.

drop in blood pressure resulting in fainting; drop in blood pressure resulting in fainting; Severe headache; fever; This is a spontaneous report from a contactable other healthcare professional (patient). A 26-year-old female patient (non-pregnant) received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number EK9231), via an unspecified route of administration on 03Jan2021 at single dose at left arm for immunization. Medical history included allergies to Penicillins. The patient's concomitant medications within 2 weeks of vaccination included birth control pill, prenatal vitamin. Patient didn't receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, patient was diagnosed with COVID-19. Since the vaccination, patient has not been tested for COVID-19. The patient experienced severe headache, fever, and drop in blood pressure resulting in fainting the morning following receiving the vaccine on 04Jan2021 with outcome of recovering. Patient didn't receive treatment for events. Adverse events resulted in doctor or other healthcare professional office/clinic visit. This report is considered non-serious. No follow-up attempts are possible. Information about Batch number cannot be obtained. No further information is expected.; Sender's Comments: Based on the close temporal relationship, the association between the event fainting with BNT162b2 can not be completely excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

Test positive for COVID-19/have symptoms on 26, 27 and 28Dec2020; Test positive for COVID-19/have symptoms on 26, 27 and 28Dec2020; This is a spontaneous report from a contactable physician (patient). A 59-year-old male patient started to receive first dose of BNT162B2 (Batch/lot number: EH9899) intramuscular into left deltoid on 15Dec2020 at single dose for covid-19 immunisation. Medical history included hypertension and the patient was on blood pressure (BP) medications. The patient received no other vaccines on the same day as the COVID Vaccine. The patient received first dose on 15Dec2020 and was exposed to someone with COVID on 24Dec2020 and tested positive for COVID 28Dec2020. The patient stated that he was wondering what the recommendations are for receiving the second dose of the product, if someone contracted COVID-19 after receiving the first dose. He tested Positive for COVID-19 on 28Dec2020 and he does not know if it is ongoing or not, as he does not re-test for COVID-19 until Wednesday (30Dec2020), but he currently has no symptoms. The patient stated that he did have symptoms on 26, 27 and 28Dec2020. The lab tests and included COVID-19 PCR test: positive on 28Dec2020. The outcome of events was unknown.; Sender's Comments: The association between the event lack of effect (COVID-19) with BNT162b2 can not be completely excluded.

Patient fainted in the ICU setting.; dizziness; hypotension; This is a spontaneous report from a contactable Other HCP. A 25-year-old male patient received BNT162B2 (Lot number: eh9899) via an unspecified route of administration on 24Dec2020 13:00 at single dose for covid-19 immunisation. The patient did not have any known allergies or medical history. Prior to vaccination, the patient was not diagnosed with COVID-19. There were no concomitant medications. On 24Dec2020, patient experienced dizziness and hypotension. Patient's blood pressure (BP) was 50/30 and heart rate (HR) 45. Patient fainted in the intensive care unit (ICU) setting. This happened during work hours while treating a patient. Patient was treated in the emergency department (ED). The adverse events resulted in emergency room/department or urgent care. It was unknown if treatment was received for the adverse event. Since the vaccination, the patient has not been tested for COVID-19. The outcome of events was recovered.; Sender's Comments: A possible contributory effect of suspect BNT162B2 on reported events cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

temperature of 101 ¦F; body aches; headache; nausea; chills; This is a spontaneous report from a contactable Other HCP (patient). A 26-year-old female patient started to receive BNT162B2 (Batch/lot number: EK9231) at right deltoid via an unspecified route of administration on 03Jan2021 12:20 at single dose for covid-19 immunisation. Medical history was none. The patient's concomitant medications were not reported. The patient experienced temperature of 101 ¦F, chills, body aches, headache and nausea on 04Jan2021 02:00. Patient stated for the second one, she was hoping for the best, but she got the vaccine yesterday (03Jan2021), at 12:20, and today (04Jan2021), at 2 AM, she had a temperature of 101, and chills, body aches, headaches, and nausea. She was out of it today, she was not feeling good, and was told to do this. Caller got the vaccine at Employee Health. After 4 hours of Tylenol (expiry is May2021, lot is P115252), her temperature went right back up. It was about 99 when she had Tylenol.

Chills started late this morning (04Jan2021) and were ongoing when she was not on Tylenol, but her body aches were ongoing. 9AM was when her headache started, and she was intermittently on Tylenol, but if past the 4 hour mark, they were as bad as they were this morning, but with Tylenol they were better. Nausea was mostly this morning, and had gotten better. Patient stated that due to her current symptoms her employer had required her to be tested for COVID-19. She had not yet received the results of that test. Seriousness for events temperature of 101 ¦F, chills, body aches, headache and nausea was Medically significant. Lab data included COVID test on 23Dec2020 was negative. The outcome of temperature of 101 ¦F, headache and nausea was recovering; of body aches was not recovered; of chills was unknown. Primary Source Reporter (Method of assessment was Global Introspection) considered the events were related to BNT162B2.; Sender's Comments: There is a reasonable possibility that the events reported were related to BNT162b2 based on known drug safety profile and close temporal relationship. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

"Itching and redness over whole body/I turned all red and was itching all over my body by about 10:30-10:45 am/I still have mild itching; Itching and redness over whole body/I turned all red and was itching all over my body by about 10:30- 10:45 am/I still have mild itching; Elevated heart rate and blood pressure; Elevated heart rate and blood pressure; Had an allergic reaction; This is a spontaneous report from a contactable nurse (patient). A 43-year-old female patient received the first dose of bnt162b2 (BNT162B2) lot no: EK9231, via an unspecified route of administration in left arm on 30Dec2020 09:00 at a single dose for COVID-19 immunization. Medical history HTN and exercise-induced asthma, both from an unspecified date and unknown if ongoing. The patient was not pregnant at the time of vaccination. The patient had no covid prior to vaccination and was not covid tested post vaccination. Concomitant medication included colecalciferol (VITAMIN D), montelukast sodium (SINGULAIR), and biotin. No other vaccines were administered in four weeks. Known allergies include tapendalol (NUCYNTA) and trimethoprim/sulfamethoxazole (BACTRIM). On 30Dec2020 09:30, the patient experienced itching and redness over whole body, elevated heart rate, and blood pressure. The patient was given IV diphenhydramine (BENADRYL) 50 mg, IV famotidine (PEPCID), IV methylprednisolone (SOLU MEDROL), ""flui"" as treatment for AEs. The patient further clarified that she received the COVID 19 vaccine on 30Dec2020 at 9:00 and she had an allergic reaction. She turned all red and was itching all over her body by about 10:30- 10:45 am and was at the ER by about 11am. She started on prednisone 40mg for 3 days and diphenhydramine every 6 hours, as needed on 30Dec2020. On Sunday (03Jan2021), she was still severely itching and turning red so prednisone was continued for an additional 3 days and was switched to cetirizine (ZYRTEC) because she can't function on diphenhydramine. Cetirizine was not helping so she had to take diphenhydramine yesterday morning (04Jan2021). Last night (04Jan2021), she was ok without any diphenhydramine but this morning (05Jan2021), she still have mild itching, and no redness. The redness comes and goes; it is on the face, chest, arms, legs. When it first started, it was whole body redness. Then it moved to different areas on different days; she don't have a rash or hives, just redness. She had a 4 inch band of redness on both arms one day. The events were reported as non-serious. The

patient had not recovered from the events.; Sender's Comments: A possible causal association between administration of BNT162B2 and the onset of allergic reactions cannot be excluded, considering the plausible temporal relationship and the known adverse event profile of the suspect product. The underlying predisposing condition of drug allergies to multiple materials may put the patient at high risk of allergic reactions. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate"

contracted Sars-Cov-2 in between her two doses; contracted Sars-Cov-2 in between her two doses; This is a spontaneous report from a Contactable Other HCP. A female patient of an unspecified age started to receive the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on unknown date at single dose for covid-19 immunisation. The patient medical history was not reported. The patient's concomitant medications were not reported. Patient was due for her 2nd dose of Pfizer-Biontech Covid19 vaccine on 06Jan2020. She contracted Sars-Cov-2 in between her two doses, want to know if she should receive her second dose as scheduled. Patient had COVID-19 test with unknown result. Outcome of events was unknown. Information about lot/batch number has been requested.; Sender's Comments: The association between the event lack of effect (contracted SARS CoV 2) with BNT162b2 cannot be completely excluded.

tested positive for COVID-19 more than a week after receiving our COVID-19 vaccine; tested positive for COVID-19 more than a week after receiving our COVID-19 vaccine; This is a spontaneous report from a non-contactable consumer. A 45-years-old patient of an unspecified gender started received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number and expiration date not reported), via an unspecified route of administration from an unspecified date at a single dose for Covid-19 immunization. The patient medical history and concomitant medications were not reported. The patient tested positive for COVID-19 more than a week after receiving COVID-19 vaccine. Outcome of the event was unknown. No follow up attempts are possible. Information on lot/batch number cannot be obtained.; Sender's Comments: Based on the information available, a possible contributory role of the suspect products cannot be excluded for the reported event of positive for corona virus infection for the lack of efficacy of the vaccine. However, based on the mechanism of action of the vaccine, it is unlikely the patient would have fully developed immunity for the vaccine to be effective, due to the number of days passed since the vaccine is given. Case will be reevaluated based on follow-up information

"I was pretty sick, I felt palsy; I was pretty sick, I felt palsy; I developed the fever for all about 30 hours after the vaccination; Headache; This is a spontaneous report from a contactable physician. This physician reported for himself that a 67-years-old male patient received BNT162B2 (BioNTech Covid 19 vaccine; Batch/lot number: EL1284), via an unspecified route of administration on 30Dec2020 at SINGLE DOSE for ""Because I am a physician, a healthcare provider"" (covid-19 immunization). Medical history included had Covid back on the 4th of December. There were no concomitant medications. Physician stated he was wondering he just took your Pfizer Covid vaccination, the first one. He took it couple of

days ago. He took it on the 30th of this month, two days ago. Physician further stated he developed the fever for all about 30 hours after the vaccination. Just because he developed the fever with the first one, it was like a 101.7 that was about 36 hours. So the question was just because he developed the fever with the first one, he was pretty sick, he meant he felt palsy, you know headache and all that it was like probably developed the same with the second one? Patient weight was maybe 125 pounds. When probed if vaccine was prescribed by any Physician, Physician stated he went himself. Causality by physician stated as ""he think so"". Lab work reported as He did not have the results yet. He just look a Covid screening test because he had Covid back on the 04Dec. So, he just took a Covid screening test. Treatment received included aspirin. The outcome of all events was unknown.; Sender's Comments: The causal relationship between BNT162B2 and the event palsy cannot be excluded as the information available in this report is limited and does not allow a medically meaningful assessment. This case will be reassessed once additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate."

had the COVID-19 vaccine on 28Dec2020 and was tested positive today (04Jan2021) for COVID-19; had the COVID-19 vaccine on 28Dec2020 and was tested positive today (04Jan2021) for COVID-19; This is a spontaneous report from a contactable other hcp via the Pfizer-sponsored program. A male patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 28Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient had the COVID-19 vaccine on 28Dec2020 and was tested positive today (04Jan2021) for COVID-19. Outcome of the events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: The reported positive with Covid 19 test after COVID-19 immunization is considered ineffective of BNT162B2, and the Company cannot completely exclude the possible causality between the reported event and BNT162B2 administration.

blurriness on the right eye with consistent optic neuritis; read up on transverse myelitis that may be related to her condition; blurriness on the right eye with consistent optic neuritis; This is a spontaneous report from a contactable physician. This physician (patient) reported for self that the 31-year-old female patient received bnt162b2 (BNT162B2, PFIZER-BIONTECH COVID-19 VACCINE, lot: EK5730), via an unspecified route of administration on Deltoid, Left on 20Dec2020 13:00 at single dose for covid-19 immunisation. Medical history and concomitant medications were none. Reported she has a flu vaccine in Sep2020, and had no reaction to the flu vaccine. She clarified she has never had a reaction to a vaccination before. The patient received the vaccine last 20Dec2020 and has reported to have blurriness on the right eye with consistent optic neuritis since 24Dec2020. She has already consulted with an ophthalmologist who said her case was interesting and referred her to Pfizer. She is scheduled to have her second dose on 10Jan2021 and is asking if she should still take it. She also mentioned that she read up on transverse myelitis that may be related to her condition and is asking for any information we may have on this. Doctor reporting she is having a possible adverse event to the COVID-19 Vaccine. The

patient clarified she received the COVID-19 Vaccine on Sunday, 20Dec2020 at approximately 1:00PM. Reported the COVID-19 Vaccine was administered at her employer. Doctor reported she is experiencing blurry vision in her right eye only, consistent with optic neuritis in Dec2020 (Medically significant). She said her right eye blurry vision gets worse after working out or showering. She said she has read some medical information that states some kind of autoimmune reaction, like transfer myelitis, may occur after receiving the COVID-19 Vaccine. The patient asked if she should get the second COVID-19 Vaccine, clarifying she is scheduled to receive her second dose on 10Jan2021. Clarified she started experiencing the right eye blurry vision on either 24Dec2020 or 25Dec2020. Treatment: Reported she saw an ophthalmologist, and the ophthalmologist said he didn't see anything concerning or not normal. She said the ophthalmologist referred her to see a neurologist, and to get a MRI of her head. She clarified her MRI appointment is on 19Jan2021. She clarified her ophthalmologist called her back 2 hours after she left her appointment. She said the ophthalmologist told her he found what she was experiencing to be interesting, as to when she received the COVID-19 Vaccine, and the start of her right eye blurry vision, and that he wanted her to get further evaluation. She said the ophthalmologist performed visual field testing, and took a fancy picture of her retina. No further details provided. Vaccination Facility Type was hospital. No Vaccine Administered at Military Facility. History of all previous immunization with the Pfizer vaccine considered as suspect (or patient age at first and subsequent immunizations if dates of birth or immunizations are not available) was none. Additional Vaccines Administered on Same Date of the Pfizer Suspect was none. No AE(s) required a visit to Emergency Room but AE(s) required a visit to Physician Office. Prior Vaccinations (within 4 weeks) was none. Patient's Medical History(including any illness at time of vaccination) was none. Family Medical History Relevant to AE(s) was not provided. Relevant Tests included Visual field test, and picture of her retina. The outcome of the events was not recovered.; Sender's Comments: Based on temporal association, the causal relationship between bnt162b2 and the events optic neuritis, vision blurred and myelitis transverse cannot be excluded. The information available in this report is limited and does not allow a medically meaningful assessment. This case will be reassessed once additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate.

tested positive for Covid-19; tested positive for Covid-19; This is a spontaneous report from a contactable healthcare professional (reporting for herself). A female patient of an unspecified age received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number and expiry date not reported) via an unspecified route of administration, on 24Dec2020, single dose for COVID-19 immunization. Relevant medical history and concomitant medications were not reported. The patient tested negative for Covid-19 on 22Dec2020, received her first vaccine dose on 24Dec2020 and then tested positive for Covid-19 on 26Dec2020. Outcome of the events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: The efficacy of a drug varies from patient to patient and can be affected by different factors; however, a contributory role of the suspect product bnt162b2 to the reported drug ineffective and SARS-CoV-2 test positive cannot be ruled out.

Cp initially that resolved in seconds. Then severe muscle aches, fatigue, temp 1 week,excruciating joint pain continues now. Malaise.

full body rash; heart palpitations; reaction to drug excipient; This is a spontaneous report from a contactable nurse, the patient. A female patient of an unspecified age received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot Number: UNKNOWN), via an unspecified route of administration on 26Dec2020 as a single dose for COVID-19 immunization. Medical history included several outdoor allergies, but no known food allergies. The patient's concomitant medications were not reported. On 28Dec2020, the patient experienced full body rash and heart palpitations. The clinical course was as follows: the patient developed a full body rash and heart palpitations on 28Dec2020 and went to the emergency room. The patient had a full work-up which included electrocardiogram, troponin levels, and electrolytes, and all were normal. She was instructed to take diphenhydramine hydrochloride (BENADRYL). She thought it may have been due to the polyethylene glycol; however, she did mention that she previously took macrogol 3350 (MIRALAX) on unknown dates for an unknown indication and was fine. The clinical outcomes of the full body rash, heart palpitations, and reaction to polyethylene glycol, were unknown. The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up.; Sender's Comments: The Company cannot completely exclude the possible causality between the reported full body rash and the administration of the suspect, BNT162B2, based on the reasonable temporal association. While the possibility of allergic to polyethylene glycol (drug excipient) might have provided alternative explanations. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RA, IEC, as appropriate.

neuropathy; This is a spontaneous report from a contactable Nurse. A male patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient medical history was not reported. The patient's concomitant medications were not reported. Reporter called about Covid vaccine and has a question connected to the AE he has reported. Wants to know if neuropathy is a side effect of the vaccine. Event outcome was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Very limited information was provided in this case, pending further details such as medical history, clinical course, specified event description, at this moment, the mentioned neuropathy is considered related to BNT162B2 for reporting purpose. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RA, IEC, as appropriate.

Development of microemboli on distal, fourth right phalange on the ventral surface. Just past the DIP. Small blue hue below skin surface with mild tenderness on deep palpation.; This is a spontaneous report from a non-contactable Physician (patient). This adult female patient (not pregnant at the time of vaccination) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number:

EH9899), intramuscular on 23Dec2020 09:30 at single dose on right arm for COVID-19 immunisation. Medical history included migraine with aura. Concomitant medication included propranolol, loratadine (CLARITINE) and multivitamin. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient previously took cefprozil (CEFZIL) and experienced allergies. The patient experienced development of microemboli on distal, fourth right phalange on the ventral surface. Just past the DIP. Small blue hue below skin surface with mild tenderness on deep palpation on 24Dec2020 12:00. The event was considered as non-serious. Treatment for the events was unknown. The outcome of the event was unknown. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, the patient had not been tested for COVID-19. No follow up attempts are possible. No further information is expected.; Sender's Comments: Based on the close temporal relationship, the association between the event microemboli on distal phalange with BNT162b2 can not be fully excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

Went to ER left side of face sagging. They did MRI it showed he had stroke. happened before 4pm that same day as vaccine. Happened between 2-4 pm; Went to ER left side of face sagging. They did MRI it showed he had stroke. happened before 4pm that same day as vaccine. Happened between 2-4 pm; This is a spontaneous report from a contactable consumer (patient). A 78-year-old male patient receive BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (lot number: EK5730), on 31Dec2020 11:00 AM via unknown route of administration at single dose for COVID-19 immunization. Medical history included high blood pressure, but went up and down and had to readjust. His BP was high and not sure how long it was that way. Concomitant medications included unspecified blood pressure medications. There were no known allergies. Patient went to ER left side of face sagging. They did MRI it showed he had stroke. It Happened before 4pm that same day as vaccine on 31Dec2020 02:00 PM. And it Happened between 2-4 pm. Patient received treatment. Patient had ER test blood, cat scan, MRI. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient did not have been tested for COVID-19. The outcome of the events was recovering. This case was assessed non-serious by reporter. And the events did not result in death, Life threatening, Caused/prolonged hospitalization, Disabling/Incapacitating, Congenital anomaly/birth defect.

occipital neuralgia; left-side Bells Palsy; bilateral headache; This is a spontaneous report from a contactable physician (patient). A 65-year-old male patient received BNT162b2 (Lot/batch number and Expiration date were not provided), via an unspecified route of administration at right deltoid on 21Dec2020 19:00 at single dose for covid-19 immunization. The patient's medical history included low high density lipoprotein (HDL). There were no concomitant medications. The patient previously took influenza vaccine (longer than 4 weeks ago, and he did not have any reaction), pravastatin for low HDL. Reported 2 days ago (02Jan2021) he developed a bilateral headache. He stated he was asymptomatic until then. He said he now has Bells Palsy on 02Jan2021, clarified he has left-side Bells Palsy. He said it is

unknown to him if the bilateral headache and Bells Palsy are related to taking the COVID-19 Vaccine. He stated he started wearing a N95 mask for the past 2 weeks. He said the N95 mask is very tight on the back of his head. He said he believes he is experiencing occipital neuralgia caused by wearing the N95 mask. He said studies show that the N95 mask can cause Bells Palsy, and the N95 mask maybe a confounding factor. He stated he doesn't have any further information on the N95 mask he was using. Initially he had a severe headache and administered to himself a sphenopalatine block of Lidocaine 1% in his nose. He stated being an ER doctor, he knows how to administer the sphenopalatine block to a patient. He went to the ER on 03Jan2021 to make sure he did not have a tumor or a stroke. He said the hospital performed a CT of his head, a MRA, labs, and a COVID-19 test (clarified as a PCR COVID-19 test) with a full viral count. He said all the tests were negative. His wife noticed his Bells Palsy yesterday, 03Jan2021. He said he thinks the Bells Palsy started the night before on 02Jan2021. He said he noticed on the night of 02Jan2021 when he was brushing his teeth, he hit a tooth on that side (clarified as left side) of his mouth with his tooth brush. He hasn't started taking steroids yet, but will be starting steroids real soon. He clarified his doctor prescribed a Medrol dose pack and Valtrex for the Bells Palsy. He stated he has not started the Medrol dose pack and Valtrex. He is ordering Lidocaine 1% viscous for himself, so he can do an internasal sphenopalatine block on himself. He does not know if the bilateral headache and Bells Palsy were caused by taking the COVID-19 Vaccine. The events required Emergency Room visit. The outcome of the event Bell's palsy was not recovered, Headache was recovering, Occipital neuralgia was unknown. Information on the Lot/Batch number has been requested.; Sender's Comments: A possible causal association between administration of BNT162b2 and the onset of Bell's palsy/Headache might not be excluded, considering the plausible temporal relationship. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Headache; Fever: She said that she started with kind of chills and shakes; Fever: She said that she started with kind of chills and shakes; she was not feeling too good; real high heart rate that were in the 110's that last for lasted for hours; Fever; This is a spontaneous report from a contactable nurse reported for herself. A 59-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, batch/lot number: EK9231 and expiration date unknown), via intramuscular on left deltoid on 03Jan2021 09:13 at single dose for COVID-19 prophylaxis. The patient medical history and concomitant medications reported as none. The reporter is a registered nurse that reported that she had the first Covid-19 vaccine yesterday morning on 03Jan2021 and she had side effects. She reported that she had a fever, headache, and a real high heart rate that was in the 110's that last for lasted for hours. She said that she started with kind of chills and shakes 11 hours and 40 minutes after receiving the vaccine. One minute she was fine and the next minute she was feeling chilled. By the time she got home from her mother's house, which is a hours drive, she was not feeling too good. Her fever broke today 04Jan2021 at around 04:00 and when she checked her temperature it was 98.7 degrees. She said that 100.2 degrees was the highest temperature she recorded. The patient said that it was a mild fever. Her headache started about 22:00 03Jan2021. The patient said that she still has the headache a little bit and she has been treating it with Tylenol and it has gotten better. She said that she wears a fit bit that tracks

her heart rate and she can hear her heartbeat in her ears and she could hear it going fast. Caller said that her heart rate was down to 98 beats per minute at 06:30 this morning. She said that her current heart rate was Body temperature. Caller said that her high heart rate had her very concerned. She said that it is not normal. She is supposed to go back on 30Jan2021 to get her 2nd injection. Should she still plan on getting the second part of the vaccine? The reporter assessed event real high heart rate that were in the 110's that last for lasted for hours as serious with medically significant. Other events were assessed as non serious. The outcome of the events fever and real high heart rate that were in the 110's that last for lasted for hours was recovered on 04Jan2020, outcome of the event headache was recovering, outcome of the other events was unknown.; Sender's Comments: Based on the close temporal relationship, the association between the event high heart rate with BNT162b2 can not be completely excluded.

I was having trouble clearing my throat, felt like it was closing up; high heart rate/rapid heart rate agai; uncontrollable rigors; numb lips and hands; numb lips and hands; nausea; shortness of breath, difficulty catching my breath; This is a spontaneous report from a contactable Other Health Professional (patient). A 38-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) lot number: EJ1685, intramuscular in the left arm, on 30Dec2020 09:15 at a single dose for COVID-19 immunization. Medical history included bariatric surgery, had anterior vaginal repair and bladder sling, had her gall bladder and tonsils removed. Concomitant medication included rizatriptan and paracetamol (TYLENOL). The patient had no known allergies but mentioned that she cannot take the NSAIDs eventhough she was not allergic to them. She had no allergies to food or to other products. It was reported that within about 10 minutes of the injection of the vaccine, she had trouble clearing her throat, felt like it was closing up, had uncontrollable rigors, high heart rate, numb lips and hands, and nausea on 30Dec2020 at 09:30 AM. She was discharged from the ED (emergency department), went home and took a nap. Later that evening, she began to have a rapid heart rate again, began to had shortness of breath, difficulty catching her breath and she was admitted to the emergency department again and given more IV medications. The onset of the events was reported to be 30Dec2020 at 09:30 AM with outcome of recovering. As a result of the events, the patient visited that Emergency room/department or urgent care. Treatment received with IV medications (unspecified), breathing treatment, and epinephrine injection. The patient had no covid prior vaccination. She had not had Covid test post vaccination.; Sender's Comments: Based on temporal association, the causal relationship between BNT162B2 and the events throat tightness, heart rate increased, chills, hypoaesthesia oral, hypoaesthesia, nausea and dyspnoea cannot be excluded. The information available in this report is limited and does not allow a medically meaningful assessment. This case will be reassessed once additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate.

fibromyalgia and neuropathy on the lower cervical/pain has exacerbated; fibromyalgia and neuropathy on the lower cervical/pain has exacerbated; headache; channeled body pain; fever at 100.7F; This is a

spontaneous report from a contactable consumer (patient). A male patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, on an unspecified date (reported as 31Jan2020) as a single dose for COVID-19 immunization. Medical history included fibromyalgia and neuropathy on the lower cervical. The patient's concomitant medications were not reported. The patient experienced fibromyalgia and neuropathy on the lower cervical/pain has exacerbated, headache, channeled body pain, and fever at 100.7 F on an unspecified date. It was reported that headache, channeled body pain, and fever at 100.7 F occurred 1 hour after vaccination. The patient underwent lab tests and procedure, which included: body temperature: 100.7 Fahrenheit on an unspecified date. The patient has been taking unspecified medications for the condition, in addition to acetaminophen (TYLENOL FOR ARTHRITIS). Therapeutic measures were taken as a result of all of the events as aforementioned. The clinical outcome of fibromyalgia and neuropathy on the lower cervical/pain has exacerbated, headache, channeled body pain, and fever at 100.7 F was unknown.

Fainting; This is a spontaneous report from a non-contactable consumer (patient). This consumer reported similar events for 02 patient. This is the 1st of 2 reports. A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 23Dec2020 at single dose for COVID-19 immunization. The patient medical history was not reported. The patient's concomitant medications were not reported. The patient experienced fainting on 31Dec2020. The patient went to the emergency department in regards to fainting and was told the fainting couldn't be related to the COVID-19 Vaccine. Then she heard about someone else fainting. Outcome of the event was unknown. No follow-up attempts are possible, information about lot/batch cannot be obtained. No further information is expected; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021006463 same reporter/drug/event, different patient

difficulty breathing/swallowing; difficulty breathing/swallowing; Hives/hives all over including in her mouth; This is a spontaneous report from a contactable consumer (spouse). A 46-year-old female patient (wife) received BNT162B2 (Pfizer-Biontech Covid-19 Vaccine, lot number: EH9899) via unspecified route of administration at arm right on 29Dec2020 at single dose for Covid-19 vaccine. Medical history included ongoing anxiety diagnosed 22 years ago. Concomitant medications were not none. Patient received the vaccine and was one big hive (01Jan2021). She went to the ER on sat and will have to go back. Caller is asking where she should go. patient went through the VAERS report 3 times. She did not have any sides effects. patient is a frontline worker. On 29Dec2020 she got the Covid vaccine. On Sat 02Jan2021 she went the ER with hives all over including in her mouth, stated she had difficulty breathing/swallowing, was given medication to take home and discharged. She was readmitted yesterday 05Jan2020 with worsening symptoms and needed to be given a prednisone nebulizer. they had two ER visits. No Investigation Assessment. patient was not recovered from the event hives/hives all over including in her mouth, the final outcome of other events was unknown.

"What I believe may have triggered this reaction is that in October I had a carpal and ulnar tunnel release in the same extremity/affected the nerves; my entire upper arm began aching-pain from my trapezius down to my elbow; my index and middle finger began tingling; I am noting pain in each of the major joints of my arm-shoulder, elbow and wrist; I am noting pain in each of the major joints of my

arm-shoulder, elbow and wrist.; I am noting pain in each of the major joints of my arm-shoulder, elbow and wrist.; This is a spontaneous report from a contactable nurse (patient). A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), via an unspecified route of administration on the arm on 19Dec2020 as single dose for covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced the following: "" my entire upper arm began aching-pain from my trapezius down to my elbow "" in Dec2020 with outcome of unknown; ""my index and middle finger began tingling "" in Dec2020 with outcome of unknown; "" I am noting pain in each of the major joints of my arm-shoulder, elbow and wrist "" in Dec2020 with outcome of unknown; "" what I believe may have triggered this reaction is that in October I had a carpal and ulnar tunnel release in the same extremity "" in Dec2020 with outcome of unknown. Therapeutic measures were taken as a result of the events. Details were as follows: The injection itself was without any issues. However, 6-7 hours later, the patient described the following: patients entire upper arm began aching-pain from trapezius down to the elbow. This continued throughout the weekend and then Monday, patients index and middle finger began tingling (as if asleep). This symptom never subsided. The patient noted pain in each of the major joints of the arm shoulder, elbow and wrist. The patient tried trigger injections in the trapezius, ibuprofen, muscle relaxers, heat, exercises, and a steroid burst-all without relief of symptoms. Patient was able to move arm and had strength in the extremity. Patient saw a specialist in physical medicine and rehabilitation. The patient believed that what triggered this reaction is that in October the patient had a carpal and ulnar tunnel release in the same extremity. The patient wondered whether the medication affected the nerves that had been manipulated during surgery. The events outcome was unknown. The batch/lot number for the vaccine, BNT162B2, was not provided and will be requested during follow-up .; Sender's Comments: Based on the time association, the possible contribution of suspect BNT 162B2 injection to the event Neuropathy peripheral cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate."

"Rash; Itching at different spot at different time; Hives; This is a spontaneous report from a contactable consumer. A 58-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL3246), via an unspecified route of administration on 02Jan2021 at single dose as reported for ""Indication: Consumer stated, ""Because I work in Covid testing, in healthcare."" Medical history included hypertension and allergy. Concomitant medication included amlodipine, lisinopril, metoprolol, hydrochlorothiazide (HYDROCHLORZIDE), desloratadine and montelukast. The patient stated, ""had the first dose of the Pfizer vaccine yesterday for the Covid 19, 2 hours after I started itching and it has been different places all over my body. I do not know has it anything to do with the way that it goes through the body, I do not know. I have had to take a lots of Benadryl. I have had to take some steroids that I had here at the house I never had started and I thought it was okay. Last night my husband put hydrocortisone cream (later clarified as treatment) on areas I was itching and had hives. I slept all night I did not have any problem since I got up this morning I started itching in other place. So, I have done the whole thing again. I am going to has to go. I did not want to go ER because I am not

having trouble on breathing or anything like that but I have got various places it is like different places every time it starts. So, I need to I am going to go and have a probably a strong steroid shot and have strong steroid given to me, not for oral but I just want to let you know if that is a side effect and I do not know whether I am going to take the second one or not?"" I have taken Benadryl and I have taken Methylprednisolone and I have used on the Cortisone Cream, the topical cream"". The outcome of the events was unknown.; Sender's Comments: A causal association between BNT162B2 and the events rash, pruritus and urticaria cannot be excluded based on a compatible temporal relation between vaccination and onset of events. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate."

"Coughing so hard; coughed during COVID but not like this; Hard to stand up; Pain/body wrecking pains; Fever; Started heaving; Dizzy; Nauseous; Throwing up; Chills; Draining; This is a spontaneous report from a contactable consumer. An adult female patient (consumer's daughter) received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for covid-19 immunization. Medical history included covid-19 from Nov2020. The patient had COVID in the middle of Nov2020 and her father and reporter had it two weeks before and then about two weeks later, she got it. She took her 14 days quarantine, she coughed and had some tummy issues. She had fever, the aches and pains with Covid, a little bit of dry cough. She did not feel good for probably about 5 days, after that she started working again. She had COVID and did not have to be hospitalized, any IV drip or anything before vaccination. 6 weeks later, she got the vaccine shot. The patient's concomitant medications were not reported. The vaccine came out on Wednesday (30Dec2020), the patient signed up at work to take it. Within about 12 hours (unknown onset date), she did start to feel 'oily', and had started having aches, pains and very shortly after that she started running a fever, all of a sudden the cough came out of the blue, she started heaving, dizzy, nauseous and it's three days later, she was coughing so hard. She coughed during COVID but not like this, this was like COVID ten times over, same symptoms though, throwing up, throwing up, hard to stand up, aches, pains, fever, chills, body wrecking pains. The patient can hardly talk because she kept coughing and draining. The reporter asked that ""Should her daughter be given vaccine? Does her antibodies, daughter was asked - Did you have any severe case, and she told - No, I was able to stay home and just stay in bed, they said - Okay we'll give it to you. Should she have gotten so close to the signs that she had COVID? Why her daughter be asked that question? What is going on regarding the symptoms. What should we do about it?"" Consumer tried to get daughter to go to a COVID Clinic today (02Jan2021), and know she didn't have COVID, that's not how it worked, but normal doctors didn't want to see her daughter. Consumer called the COVID Clinic and they said ""Yes, we could probably see her"". The outcome of events was unknown. Information about lot/batch number has been requested; Sender's Comments: A causal association between BNT162B2 and the reported events cough and difficulty standing cannot be excluded based on temporal relation of vaccination and onset of events. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety

concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate."

3:07 pm lung sounds diminished oxygen sats 68%, oxygen applied Oxygen sats remained low for next 36 hours (patient on Hospice care) expired 6:22 am 1-8-21

1/6/21 Pt received vaccine and complained of difficulty swallowing and rapid heart rate. Pt received methylprednisolone 125mg IVP, diphenhydramine 25mg IVP, & famotidine 20mg IVP. Pt reported improvement and was discharged. Sent home on diphenhydramine and oral prednisone. 1/7/21 Pt unable to swallow her own secretions and experienced eyelid swelling. Pt vomitted. Pt received epinephrine and Benadryl X 1 dose each. Pt then transported to hospital via ambulance. Reason for admission - acute respiratory failure secondary to anaphylactic reaction. Decision was made to emergently intubate the patient for airway protection despite aggressive intervention. Pt successfully extubated 1/8/21. Plan to discharge home and start Medrol Dose Pack 1/9/21.

Sudden onset of tinnitus followed by complete hearing loss in Right ear upon awaking from sleep (7 hours)

Swelling of lips & tongue, tightening of throat. Quivering of arms & legs. Tightening of chest. Dizzyness lightheaded.

tested positive for COVID-19; tested positive for COVID-19; Headache; feeling unwell; muscle pain; This is a spontaneous report from a contactable nurse reporting on himself. A 61-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE) (lot number/expiration date: not provided), via an unspecified route of administration, on 28Dec2020 at 08:15 AM (at the age of 61 years old) as a single dose in the left arm for COVID-19 vaccination. Relevant medical history and concomitant medication were not provided. The patient did not have any known allergies to medications, food, or other products. Prior to the vaccination, the patient was not diagnosed with COVID-19. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. On 01Jan2021, the patient experienced mild side effects consisting of headache with feeling unwell and muscle pain. The patient reported this happened on 01Jan2021, and 02Jan2021 and on 03Jan2021 and later, the patient did not experience any side effect. Since the vaccination, the patient was tested for COVID-19 on 02Jan2021 with a Nasal Swab Rapid Test and tested positive for COVID-19. The adverse events resulted in Emergency room/department or urgent care visit. The patient did not receive any treatment for these events. The outcome of the events headache with feeling unwell and muscle pain and tested positive for COVID-19 was recovering. The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow-up.; Sender's Comments: The information currently provided is too limited to make a meaningful medical assessment hence, the events are conservatively assessed as related to the suspect drug BNT162B2 until further information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

felt the need to have a COVID test, which turned out positive; felt the need to have a COVID test, which turned out positive; felt the need to have a COVID test, which turned out positive; Chills; Fever; This is a spontaneous report from a contactable Other HCP. A 55-year-old female patient received frist dose of BNT162B2 (Batch/lot number: EK5730) via an unspecified route of administration on 21Dec2020 at single dose for covid-19 immunisation. The patient medical history was not reported. There were no concomitant medications. The patient explained receiving the COVID-19 vaccine on the 21Dec2020 and experienced fever and some chills. She pursed explaining that she was fine afterwards but felt the need to have a COVID test, which turned out positive of the 31Dec2020. The patient stated that she only had chills and fever the evening of 29Dec2020 and had been fine every since. Her fever that night did not hit 100 degrees. She thought that it would be better if she did not go to work on that Wednesday since she had had a fever the night before. She called her doctor who told her to come into the office on 31Dec2020 to have a rapid COVID test done and it came back positive. She only had fever and chills that one night and has not had any other symptoms. She received no treatment and did not take anything for the fever. This all happened during the night. She felt fine when she got up the next morning. Because she had received the first dose of the COVID vaccine, she thinks that this helped her. She thinks if she had not had the vaccine, then the virus would have been a lot worse. She stated that her second dose of the vaccine is scheduled on the 11Jan2021, and asked if it is safe to get the second dose of the COVID-19 vaccine. The outcome of events chills and fever was recovered; of other events was unknown.; Sender's Comments: The association between lack of effect (suspected COVID-19, SARS CoV2 test positive) with BNT162b2 can not be completely excluded.

Caller tested positive for COVID after the first dose; Caller tested positive for COVID after the first dose; This is a spontaneous report from an other Health Care Professional (HCP). A male patient of an unspecified age received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE lot number and expiration date unknown) via an unspecified route of administration on an unspecified date (at an unknown age) at an unspecified dose for COVID-19 vaccination. The patient's medical history was not reported. The patient's concomitant medications were not reported. The patient tested positive for COVID after the first dose. The patient underwent lab tests and procedures which included sars-cov-2 test: positive on an unspecified date. The clinical outcome was unknown. The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up.; Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of events Drug ineffective and COVID-19 cannot be totally excluded. The case will be reassessed if additional information becomes available.

got the 1st dose of the vaccine then tested positive after; got the 1st dose of the vaccine then tested positive after; This is a spontaneous report from a contactable nurse (patient). A female patient of an unspecified age received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on an unspecified date at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient got the 1st dose of the vaccine then tested positive after. She was asking if she can get the 2nd dose even if she is tested positive. She asked if it can cause to have a false positive result if she received the vaccine.

Outcome of the event was unknown. Information about lot/batch number has been requested.; Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of events Drug ineffective and COVID-19 cannot be totally excluded. The case will be reassessed if additional information becomes available.

his regular COVID test came back positive; his regular COVID test came back positive; This is a spontaneous report from a contactable nurse (reporting for himself) from a Pfizer-sponsored program. A 48-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number and expiry date not reported) via an unspecified route of administration, on 23Dec2020, single dose for COVID-19 immunization. Relevant medical history and concomitant medications were not reported. On 23Dec2020, the patient received the COVID vaccine. On 28Dec2020, he had a negative rapid COVID test, and then on 01Jan2021 his regular COVID test came back positive. The patient would like to see if he should still get the second dose of the vaccine. Outcome of the events was unknown. Information on the Batch/Lot number has been requested.; Sender's Comments: Based on the information available, a possible contributory role of the suspect BNT162B2 cannot be excluded for the reported event SARS-CoV-2 test positive based on the known safety profile. However given the short duration of 9 days since the vaccine first dose, it is unlikely patient would have fully developed immunity.

"tested positive for covid ""yesterday""/asymptomatic; tested positive for covid ""yesterday""/asymptomatic; This is a spontaneous report from a contactable nurse (patient). A female patient of an unspecified age received 1st dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 21Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient received the first dose of the vaccine on 21Dec2020 and was scheduled for the second on 11Jan2021. The patient tested positive for COVID yesterday, 03Jan2021 and wanted to know what to do about her second dose. The patient added that she was asymptomatic at this point and not taking any medications. Outcome of the events was unknown. The events was assessed as non-serious. Information on the lot/batch number has been requested.; Sender's Comments: The reported positive test with Covid-19 after COVID-19 immunization is considered ineffective of BNT162B2, and the Company cannot completely exclude the possible causality between the reported event and BNT162B2 administration."

severe anaphylaxis; This is a spontaneous report from a non-contactable consumer. This consumer reported similar events for 6 patients. This is the first of 6 reports. A patient of unspecified age and gender received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date not reported), via an unspecified route of administration from an unspecified date at a single dose for vaccination. The patient's medical history and concomitant medications were not reported. The patient experienced severe anaphylaxis, on an unspecified date. Outcome of the event was unknown. No follow up attempts are possible; information about lot/batch number cannot be obtained.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021003208 different patient/same drug/event;US-PFIZER INC-2021003209 different patient/same drug/event;US-PFIZER INC-2021003210 different patient/same

drug/event;US-PFIZER INC-2021003211 different patient/same drug/event;US-PFIZER INC-2021003212 different patient/same drug/event

This is a spontaneous report from a non-contactable consumer. This consumer reported similar events for six patients. This is third of six reports. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date not reported) via an unspecified route of administration on an unspecified date at a single dose as vaccination. Medical history and concomitant medications were not reported. The patient experienced severe anaphylaxis with vaccination on an unspecified date. The outcome of the event was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021003207 same drug/event and different patients

severe anaphylaxis; This is a spontaneous report from a non-contactable consumer. This consumer reported similar events for 6 patients. This is 4th of six reports. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date not reported), via an unspecified route of administration on an unspecified date at a single dose for vaccination. The patient's medical history and concomitant medications were not reported. The patient experienced severe anaphylaxis with vaccination on an unspecified date. Outcome of the event was unknown. No follow up attempts are possible; information about lot/batch number cannot be obtained.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021003207 same drug/event and different patients

"diagnosed with COVID-19; diagnosed with COVID-19; This is a spontaneous report from a contactable nurse. A female patient of an unspecified age received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date were not reported), via an unspecified route of administration on 19Dec2020 at single dose for COVID-19 immunisation. The patient medical history and concomitant medications were not reported. The patient stated, ""I received the first dose of the COVID-19 vaccine last 19Dec2020 and unfortunately was exposed to COVID-19 in the evening. I was diagnosed with COVID-19 on 22Dec2020 or 23Dec2020. Should I have my second dose as scheduled tomorrow considering that I have the COVID-19?"". The outcome of the event was unknown. Information on lot number has been requested.; Sender's Comments: The efficacy of a drug varies from patient to patient and can be affected by different factors; however, a contributory role of the suspect product bnt162b2 to the reported drug ineffective and COVID-19 cannot be ruled out."

"Received the first COVID vaccine and then tested positive for COVID; Received the first COVID vaccine and then tested positive for COVID; This is a spontaneous report from Pfizer sponsored program Pfizer First Connect. A contactable nurse (patient) reported that a 22-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date not reported), via an unspecified route of administration on 15Dec2020 at single dose for COVID-19 immunization. There were no medical history and concomitant medications. The patient received the first COVID vaccine on 15Dec2020 and then tested positive for COVID on the 25Dec2020. He was not sure on the time frame, but he wanted to call in for an adverse event, just in case (incomplete sentence) and then he was scheduled to get the second dose within the next week or so. He forgot what date it was but, he wants

to see if it was safe for him to get the second dose. The patient stated that he has a lot of lab work like blood cultures, basic metabolic panel, lactic acid, CBC; results were unknown. The outcome of the event was unknown. Information on the lot number/batch number has been requested.; Reporter's Comments: :; Sender's Comments: Based on available information, a possible contributory role of BNT162B2 vaccine cannot be completely excluded for reported ""tested positive for COVID""."

Tested positive for covid a week later after his first shot; Tested positive for covid a week later after his first shot; This is a spontaneous report from a contactable consumer. A 68-year-old male patient received the first dose of BNT162B2 (Pfizer-BIONTECH Covid-19 Vaccine), via an unspecified route of administration in the left arm on 28Dec2020 at 12:00 PM in a hospital at a single dose as a COVID vaccine. The patient's medical history and concomitant medications were not reported. The patient had no known allergies but had other medical history (unspecified). The patient did not receive any other vaccine within four weeks prior to the COVID vaccine, had other medications in two weeks (unspecified), and was not diagnosed with COVID-19 prior to the vaccination. The patient tested positive for COVID a week later after his first shot. The test used was via nasal swab on 04Jan2021. The patient did not receive any treatment for the events. Outcome of the events was reported as recovering. The case was reported as non-serious (did not result in death, was not life-threatening, did not cause/prolong hospitalization, was not disabling/incapacitating, and did not result to any congenital anomaly/birth defect). Information on the lot/batch number has been requested.

Patient received Positive Covid 19 test result on 02Jan2021; Patient received Positive Covid 19 test result on 02Jan2021; This is a spontaneous report from contactable consumers. An adult male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: IL0140), via an unspecified route of administration on 28Dec2020 at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient received positive COVID 19 test result on 02Jan2021. The patient had unknown test with positive result on 31Dec2020. The case was identified as non-serious by reporter. Facility where the most recent COVID-19 vaccine was administered was in hospital. It was unknown that the patient received any other vaccines within 4 weeks prior to the COVID vaccine. It was unknown that the treatment received for the adverse event. Prior to vaccination, patient was not diagnosed with COVID-19. Since the vaccination, the patient had been tested for COVID-19. The outcome of event was recovering.

"developed active Covid within 24 hours of receiving vaccine; developed active Covid within 24 hours of receiving vaccine; This is a spontaneous report from a contactable physician received via a Pfizer sales Representative. A female patient (physician) of an unspecified age received first dose of BNT162B2 via an unspecified route of administration on an unspecified date at a single dose as vaccine. Medical history included exposed to COVID-19 a few days prior to receiving the COVID-19 vaccine (works within a hospital and had been exposed to COVID-19 active infected patients). Concomitant medications were not reported. A physician reported that a female physician developed active Covid within 24 hours of receiving vaccine (also reported as received the vaccine and within 24 hours developed active symptoms of Covid) on an unspecified date. Requested information on whether to receive the second vaccine at this point. Unsure of the need or complications that could potentially rise from receiving a second vaccine in the series. The events took place after use of product. The outcome of the events was

unknown. Information about Lot/Batch number has been requested.; Sender's Comments: There is not a reasonable possibility that reported ""active Covid"" is related to BNT162B2 vaccine. Event occurred within 24 hours of receiving vaccination, when the vaccine is not expected to achieve the effect. The event is most likely intercurrent medical condition."

"developed Covid infection after being vaccinated with COVID-19 vaccine; developed Covid infection after being vaccinated with COVID-19 vaccine; This is a spontaneous report from a contactable physician (patient) received via a Pfizer sales representative. A female patient of an unspecified age received BNT162B2 via an unspecified route of administration on an unspecified date at a single dose as COVID-19 vaccine. Medical history included exposed several days prior to patients with Covid (exposed prior to receiving the vaccine to individuals who had an active Covid infection). Concomitant medications were not reported. It was reported that on an unspecified date, the female physician developed Covid infection after being vaccinated with COVID-19 vaccine (also reported as she received the COVID-19 vaccine and developed active Covid a few days later). The events took place after use of product. The outcome of the events was unknown. Information on the Lot/Batch number has been requested.; Sender's Comments: There is not a reasonable possibility that reported ""Covid infection"" is related to BNT162B2 per current available information. The patient exposed to individuals who had an active Covid infection prior to receive the vaccine."

received a covid positive diagnosis; received a covid positive diagnosis; This is a spontaneous report from a contactable nurse (patient). A 35-year-old non-pregnant female patient received 1st dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), intramuscular in the left arm on 21Dec2020 09:45 at a single dose for COVID-19 immunization at the hospital. The patient has no medical history. The patient has no known allergies. The patient's concomitant medications were not reported. The patient did not received any other vaccines within 4 weeks prior to the COVID vaccine and did not received other medications within 2 weeks of vaccination. The patient received a COVID positive diagnosis on 29Dec2020, 8 days later. The events led to a doctor or other healthcare professional office/clinic visit. The patient underwent COVID tests post vaccination on 29Dec2020 - Nasal Swab (NAA nasal swab) and Rapid COVID test, both showed positive test results. The patient was not diagnosed with COVID-19 prior to vaccination. Outcome of the events was recovering. No treatment was given for the events. The events were assessed as non-serious. Information on the lot/batch number has been requested.; Sender's Comments: The efficacy of a drug varies from patient to patient and can be affected by different factors; however, a contributory role of the suspect product BNT162B2 to the reported drug ineffective and COVID-19 cannot be ruled out.

tested positive after taking the first dose of the vaccine; exposed to a family member with the virus/tested positive after taking the first dose of the vaccine; tested positive after taking the first dose of the vaccine; This is a spontaneous report from a Pfizer-sponsored program Pfizer First Connect. A contactable nurse reported for a 60-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 28Dec2020 at single dose for covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient who tested and was positive for the virus after being exposed to a family member with the virus after taking the first dose of the vaccine. Patient was asymptomatic. The Nurse asking if

we have any recommendations for the 2nd dose. The outcome of the events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: The association between the events lack of effect (suspected COVID-19, tested and was positive) with BNT162b2 can not be completely excluded.

contracted covid after getting the vaccine; contracted covid after getting the vaccine; This is a spontaneous report from a Pfizer-sponsored program. A contactable physician reported similar events for 4 patients. This is 1st of 4 reports. A 46-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: Unknown, does not have lot number to provide) via an unspecified route of administration on 24Dec2020 at single dose for covid-19 immunization. The patient medical history and concomitant medications were not reported. The patient contracted COVID after getting the vaccine on 01Jan2021. The outcome of the events was unknown. Information on the Lot/Batch number has been requested; Sender's Comments: The association between the event lack of effect (contracted COVID) with BNT162b2 can not be completely excluded.,Linked Report(s) : US-PFIZER INC-2021003894 same reporter/drug/event, different patient;US-PFIZER INC-2021003893 same reporter/drug/event, different patient;US-PFIZER INC-2021003895 same reporter/drug/event, different patient

Contracted covid after getting the vaccine; Contracted covid after getting the vaccine; This is a spontaneous report from a Pfizer Sponsored Program. A contactable physician reported similar events for 4 patients. This is 2nd of 4 reports. A patient of unspecified age and gender received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot/batch number and expiration date not provided), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced contracted covid after getting the vaccine on an unspecified date. The report was non-serious per the reporter. The outcome of the events was unknown. Information on Lot/Batch number has been requested.; Sender's Comments: The association between the event lack of effect (contracted COVID) with BNT162b2 can not be completely excluded.,Linked Report(s) : US-PFIZER INC-2021003873 same reporter/drug/event, different patient

contracted covid after getting the vaccine; contracted covid after getting the vaccine; This is a spontaneous report from a Pfizer-sponsored program. A contactable Physician reported similar events for 4 patients. This is 3rd of 4 reports. A patient of an unknown age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: Unknown) via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient medical history and concomitant medications were not reported. The patient contracted COVID after getting the vaccine. The outcome of the events was unknown. Information on the Lot/Batch number has been requested.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021003873 same reporter/drug/event, different patient

contracted covid after getting the vaccine; contracted covid after getting the vaccine; This is a spontaneous report from a Pfizer-sponsored program IBCC (Inbound Call Center for HCPs). A contactable physician reported similar events for 4 patients. This is 4th of 4 reports. A patient of unspecified age and

gender received bnt162b2 (lot/batch number and expiration date not provided), via an unspecified route of administration, on an unspecified date, at single dose, for Covid-19 immunization. The patient medical history and concomitant medications were not reported. The patient contracted COVID after getting the vaccine. The outcome of the events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: The association between the event lack of effect (contracted COVID) with BNT162b2 can not be fully excluded.,Linked Report(s) : US-PFIZER INC-2021003873 same reporter/drug/event, different patient

"Headache; Body aches; This is a spontaneous report from a contactable nurse (patient). A 55-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (lot number EH9899), intramuscular (hope it was IM, but did not know for sure because she was not watching) at right arm deltoid on 29Dec2020 08:40 at single dose for COVID-19 immunization, at the hospital where she works. The vaccine was not administered at military facility. The patient's second dose was scheduled to be 19Jan2021. The patient's medical history included potassium low, hypertension, pericarditis, asthma, herniated disc in back, pain, gastrointestinal infection (GI), Vitamin D low, wheezing, exposed to someone who was positive with COVID at a wedding on 28Dec2020, ""diuretic"", ""cardiac/heart"" and ""Cholesterol"". Concomitant medication included ranolazine (RANEXA) for heart, isosorbide for cardiac, potassium chloride for potassium Low, furosemide for diuretic, atorvastatin (LIPITOR) for cholesterol, acetylsalicylic acid (ASPIRIN) for cardiac, montelukast sodium (SINGULAIR) for asthma, pregabalin (LYRICA) for herniated disc in back take for pain, nebivolol hydrochloride (BYSTOLIC) for blood pressure, pantoprazole sodium sesquihydrate (PROTONIX) for GI, celecoxib (CELEBREX) for pain, spironolactone for diuretic, vitamin D for Vitamin D low, nitroglycerin for angina, salbutamol (ALBUTEROL) for wheezing, and oxycodone for pain; all ongoing. History of all previous immunizations with the Pfizer vaccine considered as suspect was reported as none. No additional vaccines administered on same date of the Pfizer Suspect. No prior vaccinations within 4 weeks. The patient reported events on the Pfizer COVID Vaccine. She reported after getting the vaccine she had body ache and headaches. On 30Dec2020 16:00, the patient experienced headache and body aches. The event headache was reported as serious medically significant. She received the COVID vaccine on 29Dec2020 and had significant body aches, but she still had a headache that had not gone away since she got the vaccine. The patient explained the body aches were mild to non-existent/resolved, later confirmed as still ongoing, but better. Her main issue was the headaches that had not gone away. The events headache and body aches started around 16:00. She worked nightshift and she woke up with it. The events did not require a visit to the emergency room or physician office. The day after she received the COVID Vaccine she was tested for COVID. She found out she was exposed the day before she received the COVID vaccine, 28Dec2020 to someone who was positive with COVID at a wedding. She later found out her COVID test on 30Dec2020 was negative. The reporter assessed both events headache and body aches as related to the suspect vaccine. She believed the body ache and headache were related to the COVID Vaccine itself. She added, she felt it's related because these events are not part of her typical health problems. She added they're not going away even with medications (oxycodone, Celebrex, and ibuprofen). Oxycodone was located in an orange pharmacy filled bottle and she was unable to provide a lot/exp/NDC. Celebrex was located in an orange pharmacy filled bottle and unable to provide a lot/exp/NDC. She saw a use by date of 10Mar2021. Ibuprofen (Lot number: OCE2824A and expiration

date: Dec2021). The outcome of the event headache was not recovered, for the event body aches was recovering.; Sender's Comments: There is a reasonable possibility that the event headache was related to BNT162b2 based on known drug safety profile and close temporal relationship. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate."

covid 19 test result came up positive; covid 19 test result came up positive; severe left arm pain; This is a spontaneous report from a contactable unspecified Healthcare professional reporting for himself. This 52-year-old male patient received on 20Dec2020 02:30 PM first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot EK5730) at single dose intramuscular in the left arm for COVID-19 immunization. No allergies to medications, food, or other products. Medical history was not reported. Prior to vaccination, the patient was not diagnosed with COVID 19. Concomitant medications (all started on an unknown date and received within 2 weeks of vaccination) included buspirone hydrochloride (BUSPIRON), atorvastatin (manufacturer unknown) and acetylsalicylic acid (BABY ASPIRIN). On 21Dec2020, 10 hours after getting vaccine the patient had body aches, cold and severe left arm pain. 4 days after getting vaccine again the patient had cold, body aches and sore throat for couple of days. On 28Dec2020, covid 19 test (nasal swab) result came up positive. The patient went to Emergency room. Outcome was recovered on an unknown date. It was unknown if a treatment was performed.; Sender's Comments: The association between the event lack of effect (COVID 19 nasal swab test result came up positive) with BNT162b2 can not be fully excluded.

Anaphylactic reaction 6 days post vaccine 24Dec2020; I had severe chest tightness; SOB; throat soreness; hoarse voice; mouth swelling; This is a spontaneous report from a contactable physician, the patient. A 34-year-old non-pregnant female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot Number: EL0140), via an unspecified route of administration in the left arm on 18Dec2020 at 15:30 (at the age of 34-years-old) as a single dose for COVID-19 immunization. Medical history included severe dust mite allergy (based on skin test). Prior to the vaccination, the patient was not diagnosed with COVID-19. Concomitant medications included cetirizine hydrochloride (MANUFACTURER UNKNOWN), hydrocodone bitartrate/paracetamol (NORCO), ibuprofen (MANUFACTURER UNKNOWN), and ondansetron (ZOFRAN); all for unspecified indications from unknown dates and unknown if ongoing. The patient did not receive any other vaccines within four weeks prior to the vaccination. On 24Dec2020 at 10:00, 6 days post vaccination, the patient experienced anaphylactic reaction, severe chest tightness, shortness of breath, throat soreness, hoarse voice, and mouth swelling; all reported as life threatening. The events led to an emergency room visit and she was given epinephrine (EPI-PEN), methylprednisolone (SOLUMEDROL), and diphenhydramine hydrochloride (BENADRYL) as treatment. The patient stated that she developed the reactions 45 minutes after she took premedications for a dilatation and curettage procedure. The premedications included ibuprofen, hydrocodone bitartrate/paracetamol, ondansetron. She stated she had taken these medications several times before and this was the first time she had this reaction. Since the vaccination, the patient had not been tested for COVID-19. The clinical outcomes of the anaphylactic reaction, severe chest tightness,

shortness of breath, throat soreness, hoarse voice, and mouth swelling were recovered on unknown dates.; Sender's Comments: Anaphylactic reactions presented as chest tightness, shortness of breath, throat soreness, hoarse voice, and mouth swelling, developed 45 minutes after premedications including included ibuprofen, hydrocodone bitartrate/paracetamol, ondansetron for a dilatation and curettage procedure and 6 days post vaccination with BNT162B2, the event therefore is most likely attributed to these premedications unrelated to the vaccine use. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

"Tested positive for covid; Received first Pfizer covid vaccine on 23Dec, tested positive for covid; This is a spontaneous report from a contactable pharmacist. A 75-year-old patient of an unspecified gender started to receive bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 23Dec2020 at SINGLE DOSE for COVID-19 immunization. The patient medical history and concomitant medications were not reported. The reporter stated ""75 year old patient with some comorbidities who received first Pfizer covid vaccine on 23Dec, tested positive for covid on 28Dec. Patient has been treated at home and is doing well. What is the protocol for their second dose of Pfizer covid vaccine due on 13Jan?"" The outcome of the events was unknown. Information about lot/batch number has been requested."

Covid positive/ testing positive for the virus/ asymptomatic; Covid positive/ testing positive for the virus/ asymptomatic; This is a spontaneous report from a contactable consumer who reported for herself. A 30-year-old female consumer received her first single dose of BNT162B2 (Pfizer/ BioNTech Covid-19 vaccine, Lot number: EH9899) on 17Dec2020 per works recommendation (COVID-19 immunization). The patient had a history of back pain and had no concomitant medications. The patient got the vaccine and tested for Covid as a preventative to make sure she was safe to travel for a wedding. Her Covid test was pending and she found out that she was Covid positive the day after receiving her first dose of the Pfizer Covid vaccine. Her primary care informed her to get the booster despite testing positive for the virus. She was told since she was asymptomatic that she could get the vaccine. She received the second dose on 04Jan2021. The outcome of the event Covid positive was not reported.

COVID; COVID; This is a spontaneous report from a Pfizer-sponsored program Pfizer First Connect from a non-contactable consumer (patient). A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on Tuesday 29Dec2020 at single dose for COVID-19 immunization. The patient medical history and concomitant medications were not reported. The patient was diagnosed with COVID on Saturday 02Jan2021. The outcome of the event was unknown. No follow up attempts are possible; information about lot/batch number cannot be obtained.

Tested positive for COVID; Tested positive for COVID; This is a spontaneous report from a contactable other HCP via a Pfizer-sponsored program IBCC (Inbound Call Center for HCPs). A patient of unspecified age and gender started to receive BNT162B2, via an unspecified route of administration from

23Dec2020 to 23Dec2020 at first single dose for COIVD-19 immunization. The patient medical history was not reported. The patient's concomitant medications were not reported. Pharmacy student on the line who had patient who received the first dose of the COVID vaccine shot on 23Dec2020. Then the patient went home on Christmas break and later tested positive for COVID on 29Dec2020. She was calling to see how to proceed with the second dosage. Outcome of the event was unknown. information on the lot/batch number has been requested.; Sender's Comments: Based on the information available, a possible contributory role of the suspect BNT162B2 cannot be excluded for the reported event positive for corona virus infection based on the known safety profile. However given the short duration of 6 days since the vaccine first dose, it is unlikely patient would have fully developed immunity.

I tested positive for COVID-19; I tested positive for COVID-19; This is a spontaneous report from a contactable nurse. A 29-year-old female patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899), intramuscular in left arm on 17Dec2020 19:45 at single dose for covid-19 immunisation. Medical history was not reported. There were no concomitant medications. The patient tested positive for COVID-19 on 03Jan2021. Outcome of event was recovering. Patient has not been diagnosed with COVID-19 prior to vaccination.

Patient tested positive for COVID-19 about 2 weeks after receiving the 1st dose of COVID vaccine; Patient tested positive for COVID-19 about 2 weeks after receiving the 1st dose of COVID vaccine; This is a spontaneous report from a contactable consumer reported that a male patient of unspecified age received his first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on an unspecified date, at single dose for COVID-19 immunization. Medical history and concomitant medications were not reported. Patient is a health care worker who works with COVID patients as part of his daily work duties. He tested positive for COVID-19 about 2 weeks after receiving the 1st dose of BNT162B2. Outcome of the events was unknown. No follow up attempts are possible; information about lot/batch number cannot be obtained.

Tested positive; Tested positive; This is a spontaneous report from a contactable nurse via Pfizer sales representative. A 35-year-old female patient received BNT162B2 (lot: EKS730), via an unspecified route of administration on 17Dec2020 at single dose for COVID-19 immunization. Medical history and concomitant medications were not reported. Patient received 1st COVID vaccine dose on 17Dec2020 and tested positive on 23Dec2020. Patient was exposed to COVID. She was curious if and when she should get a second dose having tested positive after her first dose. Outcome of the events was unknown.; Sender's Comments: Based on the information available, a possible contributory role of the suspect BNT162B2 cannot be excluded for the reported event SARS-CoV-2 test positive based on the known safety profile. However given the short duration of 6 days since the vaccine first dose, it is unlikely patient would have fully developed immunity.

C/o shortness of breath routine oxygen increased cannula changed to mask oxygen sats at 88%

started to feel a little sick; had COVID-19 test and results came back positive; had COVID-19 test and results came back positive; This is a spontaneous report from a contactable healthcare professional. A 27-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for

injection, lot number EH9899/expiration date unknown) via an unspecified route of administration on 27Dec2020 at a single dose for COVID-19 immunization. The patient had no relevant medical history. Concomitant medications were not reported. The patient stated that he got the vaccination on the 27th and then that same night he started to feel a little sick. He was assuming that it has just to be the side effect of the vaccine (unspecified vaccine). On 28Dec2020, he was feeling pretty sick; he did not go to the work. He had COVID-19 test (Dec2020) and results came back positive. He added that he didn't know if it was the COVID because he was reading up on the vaccines and it said that one could not get COVID from the vaccine. The outcome of the events was unknown.; Sender's Comments: The reported positive with COVID-19 test after COVID-19 immunization is considered ineffective of BNT162B2, and the Company cannot completely exclude the possible causality between the reported event and BNT162B2 administration.

Labored breathing with oxygen running at 4l/min, muscle weakness

Fever to 103.7F, respiratory rate 36. Was transferred from facility to hospital. Since then has been found to have gram-negative rod bacteremia, although urinalysis was negative, urine culture pending. Patient has since defervesced after receiving 1 dose of cefepime. Overall the most likely cause of fever seems to be urosepsis w/ bacteremia, pending confirmation with urine & blood cultures.

The patient was found deceased at home about 24 hours after immunization. Date of Death:: 12/29/2020; estimated time of death 6:00pm

Patient received vaccine on 1/4/2021. He was in Hospice for CHF and renal failure, but was able to get up in his wheelchair and eat and take medications and talk. On 1/5/2021 am, he was noted to be very lethargic an could only mumble, could not swallow. No localizing neurologic findings. He was too lethargic to get up in chair.

initial; swelling of tongue, tingling and numbness in legs, syncope. later; HA

Resident displayed with confusion/shaking at 1400, condition worsens at time went. Resident unable to state where he is, knows his name. can tell you he does not feel right. Temp 97.3, p 88, O2 91%, Bp 214/116 Transferred to ED with fever, temp of 103, and shortness of breath, admitted to ICU Positive COVID-19 test at hospital. Diagnoses include acute COVID-19 pneumonia and hypoxia. PO had confusion, fatigue, weakness, hypoxia, increased BP

Swelling of throat and tongue, anaphylaxis, hives, redness, swelling

shoulder joint pain, injection was given in joint.... I am now on prednisone, physical therapy, if this doesnt help will need a MRI .

She began with an earache and dizziness. Pain got so severe that she could no longer take it. Went to the doctor which she was put on pain medications. Went to ER on 1/6 and on 1/7 went to her PCP. Still in severe pain.

Patient experiencing Chest pain and elevated troponin. Patient taken to the cath lab and treated for suspected stress induced cardiomyopathy.

ITP Plt 2

Notified today that he passed away. No other details known at this time.

Hospital on 1/2 - then again on 1/5, transferred and admitted to hospital, discharged 1/6 Abnormal reflex/weakness back pain paresthesia and weakness of legs abdominal pain evaluation for possible GBS post covid 19 vaccine

29-year-old previously healthy female presenting today with difficulty sleeping, sore throat, and nausea after receiving the second Pfizer COVID-19 vaccine around 10 AM. Patient says that after her first dose of the vaccine she had mild sore throat and hoarse voice that resolved spontaneously. She had her vaccine around 10, several hours later before coming to the emergency department between 2--230 she had the sudden onset of difficulty speaking with associated sore throat and nausea. She has had dry heaving but no large amounts of vomiting. She has not had stridor, wheezing, shortness of breath, syncope, or the development of a rash or hives. She has not had a reaction to her prior vaccines she does not have any other allergies in general. She has otherwise been well recently without infectious symptoms including fevers, chills, cough, and has not been exposed to Covid to her knowledge. Medications administered in ED included diphenhydramine 50 mg IV once, dexamethasone 10 mg IV once, famotidine 40 mg IV once, ondansetron 4 mg IV once. Had brief episode of shaking and R arm rigidity in the ED. Patient denies LOC during the episode, did not have a post ictal state, no tongue biting or episodes of incontinence. Given single event without LOC, less concern about episode being a seizure. Patient has had no further episodes of shaking since admission. CT brain was wnl, no FNDs noted on exam.

I am breastfeeding. My daughter had seizure like episodes starting on Saturday 1/2, Sunday 1/3, Monday, 1/4 and 2 times on Tuesday 1/5.

Patient received first dose of vaccine on 12/28, developed COVID-19 infection shortly thereafter and expired on 1/6/2021.

Patient received first dose of vaccine on 12/28, developed COVID-19 infection shortly thereafter and expired on 1/4/2021

Cardiac event, 2 days after vaccination, patient expired.

Fever, shortness of breath and chest pain that resulted in a heart attack a few hours after vaccination

Acute allergic reaction Tongue swelling Facial swelling Throat swelling Rash on throat and chest Redness in throat Diaphoresis Momentary loss of consciousness

Altered Mental Status began the middle of the night of 01/06/21 and 01/07/21 with worsening overall status- definitive symptoms unknown to this reporter, this person was admitted to the local hospital at

approximately 1800 01/07/2021. This reporter was not told the admitting diagnosis or any defining symptoms, only that the person was admitted.

Medical docter state patient has a acute cardiac attack

Initial itching at injection site, observed and returned to work. Came back ~30-40 minutes later with itchiness in throat and hives to arm. Given Benadryl PO and observed for extended period of time. Symptoms not resolving. Patient transferred to Emergency Department for further care. At that point observed to have full body rash, SOB. Given Epi while in ED. Developed tachycardia, hypotension. Treatment continued.

After about 15 min: hr went to over 170bpm , flushed sensation, brain fog, was driving at the time and my brain wouldn?t figure out how to call 911 , eventually I figured it out but it took extreme mental effort. Paramedics came and my pulse was From 100 - 170 changing rapidly, bp 150-175/x changing rapidly, symptoms would come and go about 8 times on way to hospital. In ER same thing then about 2 hrs go by and then all started again. Pulse remained at 90- 100bpm at least until 2am. (My resting hr is between 40 and 50, my normal bp is usually sub 120/80) I later realized my hands were swollen, mostly on my left side. Lingering symptoms include brain fog, tiredness, and headache. Maybe an exasperating issue was I had low potassium levels likely making symptoms worse - I worked out heavily early in the morning, probably had low intake of potassium that day and day before, and maybe slightly dehydrated from my workout - I do Functional lifting, run, and other types of exercise regularly.

Developed hypercapnic respiratory failure, CHF exacerbation - readmitted to Hospital. In ICU with BIPAP

patient begin to feel bad that night was admitted into hospital sometime in the next couple of days for dehydration, patient discharged home and then readmitted to hospital for positive covid testing after feeling very ill.

At 1431, pt received the first dose of the Moderna COVID-19 vaccine. Hx of anaphylactic reactions to penicillin as a child. At 1445, pt started complaining of tongue swelling, which proceeded to increase in severity. At 1449, Epi-Pen administered (0.3 mg) in R deltoid. At 1450, 50 mg diphenhydramine IM administered in L deltoid, followed by an additional dose at 1452 in R deltoid. 911 was called between 1445 - 1450. Pt was moved to another exam room where she could lay down because she was hypotensive, lightheaded, and pale. O2 sats remained between 95-98%, BP 81/53-190/100, P 94-136, RR 16-24 throughout. Tongue swelling improved slightly after receiving Epi-Pen. EMS arrived and were able to start an IV before transporting her to the local hospital at 1502.

Patient presented to the emergency department with sensory loss and loss of reflexes, evaluated by neurology and diagnosed with Guillain- Barre Syndrome thought to be secondary to the Pfizer Covid Vaccine

Death

I had a myocardial infarction on December 27, 2020. I had received my first vaccination for COVID-19 on December 22, 2020. Not sure if these are related but I felt I should report it.

Low grade Fever, headache needing admission Intracranial hemorrhage with hypertension Medical management for hypertensive emergency Received surgical evacuation admitted in Intensive care,

1/4/21: Headache, Dizziness & Fatigue 1/7/21: Left Sided Facial Droop

Shortness of breath, cough, rash on face and neck, arthralgia

Patient received COVID vaccination around 12:15pm. Patient was monitored for the appropriate amount of time by nursing staff. Patient passed away at 2:15pm.

Diarrhea followed by death 24 hrs after vaccination

Patient is a 32 yo G2P1001 with EDD 5/2/2021 by 7w US. She had the first dose of the Pfizer Covid 19 vaccination on 12/17/2020 at the Health Clinic and the second dose on 1/7/2021 at 1115 am. She began having abdominal pain and vaginal bleeding at 315 sm on 1/8/2021 progressing to a previable (22w2d) preterm birth at 739pm on 1/8/2021.

Pt experienced extreme fatigue and sleepiness the day following her second vaccination for Covid 19 and was found by her family after collapsing on 1/6/21 at 05:30. Upon arousal, she experienced headache, vomiting, weakness, difficulty speaking and difficulty walking with lower extremity weakness. She was taken to urgent care and subsequently admitted for evaluation at hospital and found to have a normal chemistry, blood count, normal lumbar puncture and normal imaging of her neck and brain. Discharge summary notes 3/5 strength and hyporeflexia throughout. Pt had televisit consult with psychiatry and neurology. She is subsequently to be discharged to a Facility without explanation for her sudden onset of progressive lower extremity and vocal weakness. She is noted to have a history of shellfish allergy. She experienced mild symptoms after the first vaccination, but no neurologic or vascular symptoms at that time.

I am a physician and I got dose 2 at 1:30pm on Jan 4. Next afternoon, Jan 5, I got severe myalgias, fever up to 100, severe fatigue, went home after work and slept til the next morning, went to work, took ibuprofen, and the myalgias improved and felt better. But around 3 pm, Jan 6, I got mild vertigo. By about 7pm Jan 6, I noticed my L ear didn't hear well. I changed the battery in my hearing aide and cleaned it but It made no difference. I woke up on Jan 7 with severe vertigo and hearing loss. I did Epley's maneuvers with no effect. I have had similar episodes. I went to work, but gave up when I could not hear patients talking to me. I went to the Emergency Dept and got admitted. I was too unsteady on my feet. Audiogram showed profound hearing loss both ears and almost complete loss of discrmination in R ear. I was put on high dose steroids. Also having tinnitus (mostly whooshing sound of my own pulse). MRI negative. Blood work negative. Some mild improvement now, after 1 dose steroids.

Fever up to 102.9, chills, headache, hypertension, tachycardia, dyspnea.

"Myocardial Infarction: patient began to complain of severe chest pain 3 hours after the vaccine was given .. Vaccine NDC # 59267-1000-1. 0.3 ml given by RN. Patient called his PCP: ""... I had very bad chest and shoulder pains, neck pains and slight fever from 9 pm until early this morning (Jan 8). My blood pressure was 155/95 mmHg. Should I see you today? Still feel sore all upper body. Above message

received at 0720 am (Jan 8) and the patient was called back at 0757 am (Jan 8): patient was told that many of the side effects above were related to the vaccine but the chest pain was worrisome and the provider requested the patient go to the emergency room. Patient understood the importance to seek medical attention..... Emergency Room notes: seen by MD on Jan 9. Note at 0749: patient complained of chest pain on/off since received COVID vaccine on Jan 7. Pain was substernal and radiated to the left shoulder, assoc with some SOB. EKG obtained and revealed ST segment elevation and a ""cardiac alert"" was called."

At around 11:45pm tingling started in my left eyebrow. I thought there was something in my eyebrow and after time of wiping it a few times I went to look into the mirror and realized that nothing was there. about and hour later I got a drink and a snack to eat and I realized I had a numb sensation in the left corner of my lip. As a nurse I went though the signs of a stroke with 2 other nurses I called. Everything was normal other than that sensation. Thinking I was just overly tired I went to bed. When I woke up the next day I felt okay until I went to drink some coffee and the numb sensation in my corner lip was still there. Now I was concerned and called employee health and was instructed to go to the ER to role out a stoke. I followed employee health's instructions and went to the ER. I was diagnosed with facial paresthesia and discharged with instructions to come back if symptoms got worse. Symptoms persisted all day and around 7 I called my mom on video chat to show a visual facial twitch on the left side of my face. right after I got off the phone with her the left side of my face drooped and my fiance immediately drove me to the closest ER. I was seen immediately and they decided to admit me. The did labs and head CT. They admitted me to labor and delivery because there were no other rooms. The next day I was seen by a neurologist and many doctors.

Patient was unresponsive in her room during the night, had gotten the vaccine this morning, 911 called. Had right arm pain and loss of consciousness. EMS got 180/104 BP and blood glucose was 122. Was transported to hospital. Returned to the facility the next day with no complications, was just fatigued.

8 hours after vaccine I experienced stomach pain and nausea. I then became very ill and extremely weak. I was laying on floor. Very difficult to talk and very dizzy. Unable to walk. Called 911 and went to ER. Had chest pressure and cardia work up was done. Dx wi ST elevation.

7 day after site itching, hot swelling. Unsure if related 9 day after suffered CVA and have hyper coagulation

sudden sensorineural hearing loss in the right ear, audiology and ENT assessment, currently being treated with steroid medication

after receiving vaccine patient immediately felt warm, dizzy and started dry heaving. we dosed Zofran 4mg, gave one dose epi-pen, and 50mg Benadryl. patient still complained of chest pain and was dry heaving. she was then transported by ems to the hospital at 4pm.

Received vaccine 12/19/2020 at hospital around lunch time. Severe abd pain started 10 hours after vaccine administration with vomiting. I went to emergency room next morning Emergency appendectomy 12/20/2020. Had bleeding after surgery. Second surgery 12/21/2020

Anaphylaxis

After the vaccine was administered I walked away maybe 50' and I started to feel dizzy I felt light headed and as if I was drunk my legs feel real week they took me outside so I could catch some fridge fresh air and they set me down on a chair I was very dizzy my legs and my knees felt like I couldn't stand up and they were very weak I kept seeing a the rails double vision and I started to have a tightness in the back of my neck I felt they warrant come over my head and my forehead got very very cold And then I felt as I was gonna blackout and pass out and I was gasping for air and suddenly my tongue went into a spasm and it went to the top of my the roof of my Roof of my mouth and I couldn't breathe and I was able to send a message for someone to come and help me as I was sitting there by myself they rushed over by now looking at my text message it was for 02 which was within 15 minutes of the vaccine when I had my 1st episode and then minutes after that 3 more came with the same oh unable to swallow I lost the ability to swallow and my tongue fell like I had no control it was just automatically stuck to the roof of my mouth.. Upon the arrival of Ems I was told there was no treatment and there was nothing they could do told me to wait 24 to 48 hours in the symptoms should subside it's been over 72 hours in the symptoms are still occurring. I continue to feel dizzy light headed and now have high blood pressure which was not present before visit ER prescriptions for steroids with issued, I Told to go home and rest. Followed up with family doctor in the morning and was told it was not an allergic anaphylactic reaction probably more so neurologically ransom blood tests waiting for results continue to have loss of control over tounge spasms unable to eat Accompanied by fatigue dizziness and high blood pressure

On 01/07/2021 I woke up at 0300am with chills, headache, body aches, joint pain, fever of 101.2 and swollen left axillary lymph nodes. I took Tylenol and Benadryl and it relieved the fever/headache/body aches/joint pain, however the lymph nodes in my left axillary remained swollen. I continue to take Tylenol for the fever/body aches/pains without relief for the swollen and painful axillary lymph nodes. Warm compresses do help to relieve the pain temporarily but they remain painfully swollen. On 01/08/21 I called my doctors office to ask if it was normal to experience such painfully swollen axillary lymph nodes to which they stated ?we don?t know, it is too soon for us to tell what?s normal and what isn?t normal right now.? They did not offer any suggestions to relieve the pain or swelling. The morning of 01/09/2021 , I called Employee Health at my hospital (my place of work and also where I received the vaccine) and they also stated they didn?t know if this was a normal reaction due to the newness of the vaccine. A couple hours later, employee health emailed me a link to the VAERS reporting website and asked me to file a report.

I am currently breastfeeding my 5-month-old son. I received my first vaccine on 12/28/2020 and directly breastfed within 4 hours of receiving the vaccine. Two days after my vaccine my son was at daycare and had two large diarrhea blowouts and two large emeses followed by a 1-minute episode where he was limp with entire body cyanosis and in-and-out of consciousness. He also had a maculopapular rash on his torso. EMS was called. He was observed in the emergency department for a few hours then recovered well without intervention and did not require hospitalization. EKG was normal. He has continued to be well and back to baseline since the event.

"Dizziness started within 30 minutes after injection on 01/08/21 and felt ""off"". On 01/09/21 approx. 0800 Patient began feeling body aches, fevers, injection site pain, increased dizziness, and nausea. At approximately 1pm patient began vomiting and having diarrhea. Symptoms worsened over the next couple hours to where patient was unable to walk without stumbling. Wife witnessed patient becoming very pale and almost pass out at approx. 5:30pm. Patient states he feels like he's in slow motion. Patient is unable to maintain balance when walking and reports increasing fatigue and weakness."

Started severe belly pain and went to Emergency room and diagnosed with mesenteric vein thrombosis after the CT scan of the abdomen, treated with heparin drip, antibiotic and discharged with anticoagulant pills(Eliquis). I am not sure that it is because of the vaccine my doctors are also not sure about it, but I am sure that I am a healthy person without any health issues . I am working as registered nurse, our unit is for covid-19 patient's since march 2020 and I had covid -19 on August month and recovered after 3 weeks.

Pfizer-BioNTech COVID-19 Vaccine EUA Miscarriage - (date of vaccination 1/6/21, miscarriage symptoms (cramping) started 1/8/21, confirmed 1/10/21; estimated date of delivery 8/30/21)

Patient came into the emergency department on 1/8/21 with an acute ischemic stroke with complete occlusion of her left MCA. She had acute and complete flaccid paresis of her right face, arm, and leg, complete aphasia, and neglect of the right side of her body. NIHSS of 27. Onset of deficit was between 6:30pm-7:10pm. She recieved her 1st COVID-19 vaccine dose that morning at 10:31am.

I was injected high on my shoulder, significantly higher than I?ve ever been injected in my life. I believe I have SIRVA. The pain has become so severe that I cannot use my left arm. The pain is intolerable. I take four Advil every six hours, ice my arm regularly, and keep my arm in a sling. The pain has gotten significantly worse with time (not better). I?ve never experienced pain like this from a vaccine in my life. No history of bursitis or shoulder injury. Again, the pain gets worse with time. I?m almost 48 hours post injection

1/7-21 - Received second dose of pfizer covid-19 vaccine 1/8/21 - Fever, dizziness, headache 1/10/21 0250 was found not breathing. EMS performed CPR and patient deceased

The patient presented with left eye peripheral visual loss, left upper and lower extremity and facial numbness sensation and weakness. This started 1 hour after receiving COVID-19 vaccine at her place of employment. Pt was brought to CRMC via EMS.

Facial (cheek) numbness and swelling with slight face droop Swelling continued on 1/7/2021 On 1/8/2021, lip swelling and numbness and tongue numbness By 1/9/2021 4pm, swelling and numbness resolved but chills and muscle aches began

Patient received the Moderna Vaccine 1/2/21 at his VA Clinic. He received the vaccine that morning and by the evening he was not feeling well. He developed cough, weakness and fever and now is unable to ambulate. He has since been hospitalized and has tested positive for COVID-19.

Headache, Myalgia, Arthralgia, Fever, CoughWheeze & Syncope

NauseaVomiting History of vasovagal episodes; c/o warm feeling and nausea without vomiting. Recovered Narrative: 10 minutes after vaccine admin. c/o/ warmth and nausea. Triaged by the ER nurse and observed for 45 minutes. Discharged in stable condition 133/84, 104, 18

I am not sure if related on not. This event was 13 days after my COVID-19 1/2 immunization. Otherwise, I am a very healthy physician, normal BMI, I have also been tested 5-6 times negative for COVID. I do get exposed in my job, but wear proper PPE. Viral infection in FEB that was like COVID-19 sx, I did AB test as soon as it was available, and negative. ---The Event: Monday morning (1/4/21), after getting out of shower, I was talking to my husband (who is MD)and started having BROCA's aphasia sx (could not get words out coherently), then fell into bed and started right wrist and right foot posturing. This lasted 10 min. I have non-memory of it, but my MD husband witnessed it. After 10 minutes, I was back to normal, except shaky and some word finding difficulties. After 30 min, totally back to normal.

pt received Moderna vaccine. next day he had high fevers up to 103, confusion. admitted to hospital. infectious work up negative. improved off antibiotics.

Resident appeared to be jaundice with yellow skin and eyes. Resident also complained of not feeling well. Urine was dark yellow. Resident short of breath. Resident was admitted to hospital and diagnosed with post-covid pneumonia.

Throat closing Pruritic throat and tongue Tingling lips and tongue Throat clearing Hoarse voice

Acute ischemic stroke, basilar occlusion

SOB

Nausea/vomiting and diarrhea loss of appetite tachicardia sent to er for hydration.

I immediately felt dizzy, and there was ringing in my ears, I felt faint. I also felt shakey. I have had these symptoms for 12 days, unchanged. I cannot work because of these symptoms. I have been to urgent care and have had lab work and an EKG

RECIEVED VACCINE 1/8/21 EXPIRED UNEXPECTED 1/10/21, NO ADVERSE REACTIONS NOTED

Two days following the first COVID vaccination he developed epigastric pain and was evaluated in the ER and was admitted for gallbladder surgery. He has a 6 year history of gallbladder disease but was not experiencing symptoms until after the COVID vaccination.

The patient had an apparent cardiac arrest on 12/23/20 and was admitted to the ICU. He was taken off of life support on 12/30/20. He had known cardiac disease.

Severe thrombocytopenia (plts 3k/uL), oral mucosal bleeding, bruising

Sudden, severe worst headache of her life, coupled with onset of oral herpetic lesions and inflammation to unrelated body part (belly button piercing) occurred one week after vaccination received. She presented to ED 12/28 noted to have hypokalemia and head CT showed mild occipital encephalitis,

admitted overnight for obs subsequent brain MRI was normal. She was seen in my clinic 2 days later (1/4/21) and was started on 3 day course of Decadron, topical acyclovir for herpetic lesion. As she is a nurse, I kept her off work until resolution of symptoms. Seen again on 1/8/21, headache resolved. She did discuss CT and MRI results with neurologist. He was not convinced this was vaccine related. She is having 2nd dose of vaccine on 1/11/21.

Patient died, I have a copy of his vaccination card

Moderna vaccine dose #1 received in right shoulder on 12/31/20 at 2:15PM. Injection was uneventful other than sensation of pressure. I did notice at the time, but could not fully see, that the injection appeared to be much higher on the shoulder than normal. I immediately came home afterwards and relaxed. Approximately 2hrs later, I began experiencing extreme pain in my right shoulder. As the night progressed, the pain worsened to 10/10 with inability to move my arm. Later that night after requiring assistance to take off my shirt, I noticed that the bandaid overlying the injection site was very high, immediately below and bordering the acromion process. This was concerning but I was hopeful the pain would go away over the next few days. I took tylenol that night. I woke up multiple times during the night because the pain was so severe. When I woke up, the pain and inability to move my arm were still present. I began taking 800mg ibuprofen and 1000mg tylenol alternating Q4 throughout the next few days. The pain and disability remained so severe that I required assistance performing ADLs for the next 4 days. On day four, with the pain not resolved and still severe despite consistent advil and tylenol use, I began having concern for shoulder injury related to vaccine administration. The next day I decided to seek an evaluation by an orthopedist. I am a physician and was unable to perform basic tasks and ADLs. I happened to have a few days off after the injection but would not have been able to work had I not. After an evaluation by the an orthopedic PA, I obtained an MRI of my right shoulder with results shown below - as I expected evidence of rotator cuff tendinopathy and subdeltoid bursitis consistent with SIRVA. As of now, I still have limited range of motion and shoulder pain on the right which has improved slightly but is far from resolved. I still have difficulty with certain ADLs including putting clothes on and off, lifting items, and tasks that require raising my right arm above my head. I am concerned with the possibility of long term and/or permanent damage after reviewing the literature. I am also concerned about how many other healthcare workers the person who gave me my vaccine may be injuring and/or causing permanent harm to.

Pain at site of injection, eyes, throat, face swelling. Unclear thinking, hoarse speech, headache, hives, swelling. Intervention taken immediately. Ongoing 11 days: SOB, headaches, nose bleeds, coughing, blood sugars triple, hair falling out, major swelling, dizziness.

feeling flushed elevated HR dizzy nausea evaluated by EMS, VSS and wnl except HR 100 bpm lungs cta at 5:36 patient reported to be feeling better - drank water - declined transport to ER - felt able/safe to drive home

Headache, Muscle aches and chills

"Chills; Fever; Loss of consciousness x 2; GI upset; Diarrhea; Difficulty sleeping; Pallor; Stomach flu; A spontaneous report was received from a nurse concerning a 31-year-old, male patient, who received

Moderna's COVID-19 vaccine (mRNA-1273) and experienced loss of consciousness (LOC) x 2, gastrointestinal (GI) upset, diarrhea, difficulty sleeping, pallor, stomach flu, chills and fever. The patient's medical history, as provided by the reporter, included allergy to cefaclor and hereditary hemorrhagic telangiectasia. Concomitant medications reported included desvenlafaxine succinate, gabapentin and dexlansoprazole. On 23 Dec 2020 at 11:30 am, approximately six hours prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (Lot number: 025J20A) intramuscularly in the left arm for prophylaxis of COVID-19 infection. On the morning of 23 Dec 2020, prior to receiving mRNA-1273, the patient felt ""achy"". At 5:30 pm, the patient experienced chills, fever to 102, GI upset and diarrhea. At 11:00 pm, the patient reported difficulty sleeping, GI upset, LOC x 2 and pallor. The patient was transported to the emergency room via ambulance. A COVID-19 polymerase chain reaction test and routine labs were collected; however, results were not provided. Treatment for the events included paracetamol, unspecified intravenous (IV) medications, ondansetron and ketorolac tromethamine. The emergency room discharge diagnosis was stomach flu. Action taken with mRNA-1273 in response to the events was not reported. The events, loss of consciousness (LOC) x 2, GI upset, diarrhea, difficulty sleeping, pallor, stomach flu, chills and fever, were considered resolved on 24 Dec 2020.; Reporter's Comments: This case concerns a 31-year-old, male subject with a medical history of hereditary hemorrhagic telangiectasia, who experienced the unexpected events of loss of consciousness (LOC) x 2, gastrointestinal (GI) upset, diarrhea, difficulty sleeping, pallor, and stomach flu, and the expected events of chills and fever. The events of chills, fever occurred approximately 6 hrs. and the events of GI upset, loss of consciousness, difficulty sleeping occurred after 12 hrs. after the first dose of Moderna COVID-19 Vaccine. The time to onset for the events of GI upset and diarrhea were unknown. The reporter did not provide the causality assessment for the events. Due to the temporal association between the LOC and the administration of the vaccine, a causal relationship cannot be excluded, however, the subject's medical history of hereditary hemorrhagic telangiectasia and other concurrent conditions of GI upset, diarrhea, and stomach flu remain as confounders."

Sharp shooting pain up my arm, upper chest, the shoulder, above my brest; Trouble swallowing, slurred speech, red across the chest and hoarse/raspy voice; A report was received from a consumer concerning a patient who was participating in the mRNA-1273 Emergency Use Program and who experienced sharp shooting pain up my arm, upper chest, the shoulder, above my brest, trouble swallowing - could not swallow my saliva, slurry speech, red across my chest, and hoarse/raspy voice. The patient's medical history included diphenhydramine hydrochloride allergy, shellfish allergy, and latex allergy. Concomitant medications included salbutamol sulfate. The patient received their first dose of mRNA-1273 intramuscularly for prophylaxis of COVID-19 infection in their right arm on 26 Dec 2020. Five minutes following administration of the vaccine, the patient felt sharp shooting pains up her arm, upper chest, the shoulder, above the breast. Five to 10 minutes after, the patient had trouble swallowing and began to have slurred speech. The patient was administered epinephrine in her right thigh. Following this, she began to experience redness across the chest and was administered another dose of epinephrine. She also experienced hoarse/raspy voice. The patient was then transported to the emergency room in an ambulance, where she received intravenous fluids and solumedrol after which she began feeling better. The patient was observed in the hospital for several hours and discharged on the same day. Action taken with mRNA-1273 in response to the event was not reported. The outcome of the event, sharp shooting

pain up my arm, upper chest, the shoulder, above my brest, was unknown. The event, trouble swallowing - could not swallow my saliva, was considered resolved on 26 Dec 2020. The outcome of the event, slurry speech, was unknown. The outcome of the event, red across my chest, was unknown. The outcome of the event, hoarse/raspy voice, was unknown. The reporter did not provide an assessment for the events, sharp shooting pain up my arm, upper chest, the shoulder, above my brest, trouble swallowing - could not swallow my saliva, slurry speech, red across my chest, or hoarse/raspy voice.; Reporter's Comments: This case concerns a female patient with a medical history of diphenhydramine hydrochloride allergy, shellfish allergy, and latex allergy who experienced the events of pains up her arm, upper chest, the shoulder, hypersensitivity reaction with symptoms of trouble swallowing, slurred speech, erythema of the chest and hoarse/raspy voice, occurring between five and ten minutes following administration of the first dose of mRNA-1273 vaccine. The patient was treated with 2 shots of epinephrine, was transported to the hospital and received and IV solumedrol, after which symptoms improved. Based on the information provided and temporal association, the event is assessed as possibly related to mRNA-1273. The patient's medical history of multiple allergies could have contributed to the event. Further information has been requested.

generalized itchiness; woke up with headache; feeling fatigued; anaphylactic reaction; right arm started going numb; right arm was tingling; A spontaneous report was received from a 26-year-old, female consumer who received Moderna's COVID-19 vaccine and experienced anaphylactic reaction, right arm numbness and tingling, headache, fatigue, and generalized itchiness. The patient's medical history was not provided. No relevant concomitant medications were reported. On 23 Dec 2020 prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (Lot number: OU520A/011520A) intramuscularly in the left arm for prophylaxis of COVID-19 infection. On 23 Dec 2020, within minutes of receiving the vaccine, the patient experienced an anaphylactic reaction and was rushed to the emergency room (ER). When transported to the ER she began to experience throat swelling, redness of arms and chest, trouble breathing with lower chest pain shooting into lungs, and numbness with tingling in her right arm. Treatment for the event included epinephrine, steroids, and diphenhydramine. She was released from the ER on 23 Dec 2020. On 24 Dec 2020 patient awoke with a headache, fatigue, and generalized itchiness. Treatment for the event included ibuprofen and diphenhydramine. Action taken with the second dose of mRNA-1273 in response to the event was not reported. The outcome for the events, anaphylactic reaction, right arm numbness and tingling, were reported as resolved on 23 December 2020. The events of headache, fatigue, and generalized itchiness were considered resolving.; Reporter's Comments: This case concerns a 26-year-old female patient who received their first of two planned doses of mRNA-1273 (Lot OU520A/011520A), and who experienced the unlisted events of anaphylactic reaction, right arm numbness and tingling, and generalized itchiness, and the listed events of headache and fatigue. The events were considered to be possibly related to the vaccine due to the temporal relationship with onset on the day of vaccination.

Anaphylactic reaction; Chest pressure; Rash (on neck,belly and arm); Metallic taste in mouth; Hot flashes; Headaches; A spontaneous report was received from a 49-year-old female nurse, who was also a patient, who received Moderna's COVID-19 vaccine and experienced anaphylactic reaction, chest pressure, rash (on neck, belly and arm), metallic taste in mouth, hot flashes and headaches. The

patient's medical history was not provided. No relevant concomitant medications were reported. On 22 Dec 2020, at 7:00 pm, approximately 15 minutes prior to the onset of the events, the patient received her first of two planned doses of mRNA-1273 intramuscularly, for prophylaxis of COVID-19 infection. On 22 Dec 2020, approximately 15 minutes after the mRNA-1273 vaccination, the patient experienced anaphylactic reaction, chest pressure, rash (on neck, belly and arm), metallic taste in mouth, hot flashes and headaches. She was taken immediately to the emergency room. Laboratory values included a negative troponin level and low potassium at 3.3. All other laboratory results were normal. Treatment included prednisone for five days, diphenhydramine hydrochloride, famotidine and paracetamol. Action taken with mRNA-1273 in response to the events was not reported. The outcome for the events, anaphylactic reaction, chest pressure, rash (on neck, belly and arm), metallic taste in mouth, hot flashes and headaches was not reported The causality assessment for the events, anaphylactic reaction, chest pressure, rash (on neck, belly and arm), metallic taste in mouth, hot flashes and headache was not reported.; Reporter's Comments: This case concerns a 49-year-old, female patient who received their first of two planned doses of mRNA-1273 (Lot-# and expiration date -unknown), reporting an unexpected event of anaphylactic reaction, chest pressure, rash, metallic taste in mouth, hot flush and an expected event of headache. The events occurred the same day, 15 minutes after vaccine administration. The reporter did not provide the causality assessment for the events. Due to the temporal association between the events and administration of the vaccine, a causal relationship cannot be excluded, and the events are assessed as possibly related to vaccine.

Anaphylactic type of reaction; A spontaneous report was received from a female consumer who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced an anaphylactic type of reaction. The patient's medical history was not provided. Concomitant product use was not provided by the reporter. On an unknown date, the patient received their first of two planned doses of mRNA-1273 intramuscularly for prophylaxis of COVID-19 infection. On an unknown date, after receiving the Moderna vaccine, patient reported that she had some adverse side effects and believed she needed an Epi-pen before getting a second dose due to the anaphylactic type of reaction she had. Treatment information was not provided. Action taken with mRNA-1273 in response to the event was not provided. The outcome of the event, anaphylactic type of reaction, was not reported.; Reporter's Comments: This case concerns a female patient of unreported age. The patient's medical history is not provided. The patient experienced an unexpected event of anaphylactic type of reaction. The event occurred on an unknown date and unknown duration after receiving the first dose of mRNA-1273. Very limited information regarding this event has been provided at this time. Based on temporal association between the use of the product and the event, a causal relationship cannot be excluded. Additional information about the event details are required for further assessment.

"I developed symptoms on 29Dec2020 and test obtained on 30Dec2020. My results are back today and I'm positive.; I developed symptoms on 29Dec2020 and test obtained on 30Dec2020. My results are back today and I'm positive.; This is a spontaneous report from a contactable other HCP (healthcare professional) who reported for himself. A male patient of unspecified age received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE) via an unspecified route of administration on 16Dec2020 (at an unspecified age) as a single dose for COVID-19 immunization. Medical history and

concomitant medications were not reported. The patient tested positive for coronavirus on 30Dec2020. It was reported that the patient obtained his first Pfizer vaccine dose on 16Dec2020. The patient reported that he was a physician assistant and worked in a dedicated COVID patient care area. The patient developed symptoms on 29Dec2020, and a test was obtained on 30Dec2020. The patient's results were back ""today"" and he was positive. The patient was scheduled for his second dose of the vaccine on 06Jan2021. He reported that he would cancel that because he would still be in his 10-day isolation period. Given those circumstances, the patient inquired as to ""when would be the most ideal time to obtain my second dose of the vaccine? When should I take my second dose of the vaccine if I contracted COVID after receiving the first dose?"" The clinical outcome of the event ""I developed symptoms on 29Dec2020, and test obtained on 30Dec2020. My results are back today and I'm positive"" was unknown. The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up.; Sender's Comments: Based on a compatible temporal asociation, a causal relationship between event ""patient developed symptoms on 29Dec2020 and test obtained on 30Dec2020. was positive"" (coded to Drug ineffective / COVID-19) and BNT162B2 vaccine cannot be completely excluded."

person then became symptomatic and tested positive within 7 days of receiving the vaccine; person then became symptomatic and tested positive within 7 days of receiving the vaccine; This is a spontaneous report from a contactable pharmacist. A patient of unspecified age and gender received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE lot number and expiration date unknown) via an unspecified route of administration on an unspecified date (at an unknown age) at an unknown dose for COVID-19 vaccination. The patient's medical history was not reported. The patient's concomitant medications were not reported. The patient became symptomatic and tested positive within seven (7) days of receiving the COVID-19 vaccine. The patient underwent lab tests and procedures which included sars-cov-2 test: positive on an unspecified date. The clinical outcome was unknown. The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up.; Sender's Comments: Based on the information available, a possible contributory role of the suspect products cannot be excluded for the reported event of positive for corona virus infection for the lack of efficacy of the vaccine. However, based on the mechanism of action of the vaccine, it is unlikely the patient would have fully developed immunity for the vaccine to be effective, due to the number of days passed since the vaccine is given. Case will be reevaluated based on follow-up information

Complete loss of smell and taste; Complete loss of smell and taste; This is a spontaneous report from a contactable physician reported for herself. A 37-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; brand: PfizerbioNtech, lot number: EH9888) intramuscularly at left arm on 17Dec2020 at 03:00 PM at a single dose (dose number: 1) for COVID-19 immunization. Medical history was reported as none. No known allergies (no allergies to medications, food, or other products). The patient was not pregnant. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. No other medications the patient received within 2 weeks of vaccination. Facility where the most recent COVID-19 vaccine was administered was at hospital. The patient experienced adverse event complete loss of smell and taste on 19Dec2020 at 07:00 AM. The event was considered as serious due to resulted in disability or permanent damage. No treatment received for the event. The outcome of

event was not resolved. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19.; Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of events complete loss of smell and taste cannot be totally excluded. The case will be reassessed if additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

ball palsy, facial dropping; painful shingles; This is spontaneous report from a contactable consumer reported for herself. A 47-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; batch/lot number: EK5730; dosage form: injection) via an unspecified route of administration as injection to left arm on 24Dec2020 at 7:30 am at a single dose for COVID-19 immunization. Relevant medical history and concurrent conditions included slight hypertension from Jul2020 and ongoing. Concomitant medications included lisinopril from Jul2020 and ongoing for slight hypertension. The patient developed ball palsy, facial dropping which did not lasted long but she still had the painful shingles on 27Dec2020, after the first dose. She wanted to know the recommendations for taking the second dose which is due in 10 days. The patient wanted to know if she should receive the shingles vaccine. This caller was a lab tech who works in the healthcare industry and manages a medical office; but clarified she did not call on behalf of a healthcare professional. She was the patient who received her first dose of Pfizer SARS-CoV-2 Vaccine on 24Dec2020. She reported onset of what the Urgent Care Physician believed was Shingles on 27Dec2020. She called to ask if she should or should not receive the second dose of Pfizer SARS-CoV-2 Vaccine on 14Jan2021 as scheduled due to the Shingles. The Urgent Care Physician advised her to still get the second dose, as there was about a 1:10,000 chance of developing shingles with the vaccine. She reported shingles as a reaction subsequent to the Pfizer SARS-CoV-2 Vaccine. Initially on 27Dec2020 she developed sites of what she thought were canker sores or fever blisters in her mouth which had gotten pretty large and stopped her from being able to eat on 29Dec2020. Then on 30Dec2020 she developed sites on her face which have gotten scarily large; and was causing some deep nerve pain going to her eye and down her chin; the sites felt like lesions on her face with roots. The sites in her mouth were now completely gone; but the sites on her face are ongoing. Now it has kind of taken over her face. She saw the Urgent Care Physician regarding this who believed the sites to be shingles. She had never had fever blisters or shingles before this event. She was still kind of reeling. The report was reported as non-serious. The outcome of event ball palsy/facial dropping was resolved and of shingles was unknown.

received the Covid 19 vaccine/then tested positive for the virus/symptomatic; received the Covid 19 vaccine/then tested positive for the virus/symptomatic; This is a spontaneous report from a contactable nurse (patient). A female patient of an unspecified age received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 17Dec2020 at a single dose as Covid 19 vaccine. Medical history and concomitant medications were not reported. It was reported that the patient received the Covid 19 vaccine on 17Dec2020 and then tested positive for the virus on an

unspecified date. She was scheduled to have the second vaccine on 07Jan2021, but she was not able to go to work because she's still symptomatic. She would like to know if there's an extension to the 21 days since she has the virus now. The outcome of the events was unknown. Information about Lot/Batch number is requested.; Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of events Drug ineffective and COVID-19 cannot be totally excluded. The case will be reassessed if additional information becomes available.

developed UTI very quickly; Puffy face and eyes; Puffy face and eyes; Burning inside digestive tract; Diarrhea; Dehydrated; arm pain; Headache; At bedtime neck stiffness began and worsened; This is a spontaneous report from a contactable healthcare professional. A 39-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number EL3246/expiration date unknown), dose number 1, via an unspecified route of administration on 02Jan2021 10:30 at a single dose on the left arm for COVID-19 immunization. The patient had no relevant medical history. Concomitant medications included alprazolam (XANAX). The patient experienced arm pain and headache 4 hours post injection requiring Excedrin. At bedtime, neck stiffness began and worsened. She was treated with lidocaine patches and Aleve. She developed diarrhea 33 hours post injection. She went ER because she was dehydrated. She developed UTI very quickly by hour 35 post injection. She had puffy face and eyes, and burning inside her digestive tract. She was treated with Benedryl at home for allergic reaction, Toradol for pain, IV fluids for dehydration and Keflex for infection. The patient was not diagnosed with COVID-19 prior vaccination and was not tested for COVID-19 since vaccination. The outcome of the events was recovering.; Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of event Dehydration cannot be totally excluded. The case will be reassessed if additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

"vomited; diarrhea; a severe headache; severe muscle pain; severe fatigue like being ""beat up in a bar""; This is a spontaneous report from a contactable nurse (patient). A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot and expiry not reported), via an unspecified route of administration on 28Dec2020 at single dose for covid-19 immunisation. The patient's medical history and concomitant medications were not reported. On 29Dec2020, patient experienced a severe headache, severe muscle pain and severe fatigue; further reported as like being ""beat up in a bar"" for over 1 week. It was also reported that the patient vomited and experienced diarrhea on an unspecified date. The patient was also inquiring if there is difference between the symptoms in dose 1 and 2. Outcome of events was unknown. Information of lot and batch number has been requested.; Sender's Comments: Based on the available information and known BNT162B2 vaccine safety profile, a causal relationship between events severe headache, severe muscle pain and severe fatigue and BNT162B2 vaccine cannot be excluded. The impact of this report on the benefit/risk profile

of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate."

Bell's Palsy; This is a spontaneous report from a contactable physician (patient). A 62-years-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), intramuscular on left arm on 19Dec2020 19:00 at single dose for COVID-19 immunisation. Known allergies: No. Other medical history: None. No other vaccine in four weeks. No other medications in two weeks. The patient experienced bell's palsy on 03Jan2021 21:00 and required visit to physician office. Covid test type post vaccination: Nasal Swab (PCR) on 29Dec202: Negative. Therapeutic measures were taken as a result of bell's palsy included Prednisone, Valtrex. Outcome of event was not recovered. Information on the lot/batch number has been requested.; Sender's Comments: Based on a compatible association, causality between event Bell's palsy and BNT162B2 vaccine cannot be completely excluded. The case will be reevaluated should additional information become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

"Tested positive with covid 19 with symptoms; Tested positive with covid 19 with symptoms; This is a spontaneous report from a contactable healthcare professional. A male patient of an unspecified age received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date were not reported), via an unspecified route of administration on 22Dec2020 at single dose for COVID-19 immunisation. The patient medical history and concomitant medications were not reported. The patient stated, ""I received the covid 19 vaccine on 22Dec; was supposed to have 2nd dose on 12Jan2021. Tested positive with covid 19 on 01Jan2021 with symptoms. I want to know how long I need to wait to get the second dose"".The outcome of the events was unknown. Information on the lot number has been requested.; Sender's Comments: Although, BNT162B2 vaccine immunogenicity is not in full effect after short time (10 days in this case) of first dose administration, a causal relationship between event ""Tested positive with covid 19 with symptoms"" (coded to Drug ineffective / COVID-19) and BNT162B2 vaccine cannot be completely excluded."

"received covid vaccine then contracted covid-19, 9 days after getting the vaccine; received covid vaccine then contracted covid-19, 9 days after getting the vaccine; This is a spontaneous report from a contactable physician. A male patient of an unspecified age received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date were not reported), via an unspecified route of administration on Dec2021 at single dose for COVID-19 immunisation. The patient medical history and concomitant medications were not reported. It was stated, ""received covid vaccine then contracted covid-19, 9 days after getting the vaccine, should he get his 2nd dose which is on Friday? Tested positive on the 30th, received monoclonal antibody infusion on the 31st. Any information regarding this?"". The outcome of the event was unknown. Information on the lot number has been requested.; Sender's Comments: Although, BNT162B2 vaccine immunogenicity is not in full effect after

short time (9 days in this case) after first dose administration, a causal relationship between event ""received covid vaccine then contracted covid-19"" (coded to Drug ineffective / SARS-CoV-2 test positive) and BNT162B2 vaccine cannot be completely excluded."

"Bell's palsy/Face was turning side ways; This is a spontaneous report from a contactable nurse. A female patient of unspecified age received BNT162B2 (reported as ""Covid-19 Vaccine, manufacturer: Unspecified"", Batch/lot number: not provided) via unspecified route of administration on unspecified date at single dose for COVID-19 immunization. Medical history and concomitant medication were not reported. A woman received a Covid vaccine. She did not know which one. The woman experienced Bell's Palsy. The woman was crying and her face was turning sideways. Outcome of the event was unknown. Pfizer is a marketing authorization holder of Covid-19 Vaccine in the country of incident or the country where the product was purchased (if different). This may be a duplicate report if another marketing authorization holder of Covid-19 Vaccine has submitted the same report to the regulatory authorities. Information on the Batch/Lot number has been requested.; Sender's Comments: Based on a compatible temporal relationship, causality between reported event Bell's Palsy and BNT162B2 vaccine cannot be completely excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate."

memory care patients received Pfizer-BioNTech covid vaccine, and then were diagnosed with COVID, all three had COVID symptoms; memory care patients received Pfizer-BioNTech covid vaccine, and then were diagnosed; This is a spontaneous report from a contactable other health professional. This reporter reported same events for three patients. This is first of three reports. A patient of unspecified age and gender received BNT162B2 (Pfizer BioNTech COVID vaccine), via an unspecified route of administration on an unspecified date at single dose for Covid-19 immunization. The patient's medical history and concomitant medications were not reported. The memory care patient received Pfizer-Biontech Covid vaccine, and then was diagnosed with Covid and had Covid symptoms on an unspecified date, the patient was scheduled to receive monoclonal antibody. Event took place after use of product. The outcome of events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Sender's Comments: Based on the information available, a possible contributory role of the suspect products cannot be excluded for the reported event of positive for corona virus infection for the lack of efficacy of the vaccine. However, based on the mechanism of action of the vaccine, it is unlikely the patient would have fully developed immunity for the vaccine to be effective, due to possibly short number of days passed since the vaccine is given. Case will be reevaluated based on follow-up information,Linked Report(s) : US-PFIZER INC-2021004747 same reporter/product/event, different patient;US-PFIZER INC-2021004748 same reporter/product/event, different patient

Diagnosed with COVID; Diagnosed with COVID; This is a spontaneous report from a contactable other health professional. This reporter reported same events for three patients. This is second of three reports. A patient of unspecified age and gender received BNT162B2 (Pfizer BioNTech COVID vaccine),

via an unspecified route of administration on an unspecified date at single dose for Covid-19 immunization. The patient's medical history and concomitant medications were not reported. The memory care patient received Pfizer-Biontech Covid vaccine, and then was diagnosed with Covid and had Covid symptoms on an unspecified date, the patient was scheduled to receive monoclonal antibody. Event took place after use of product. The outcome of events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Sender's Comments: Based on the information available, a possible contributory role of the suspect products cannot be excluded for the reported event of positive for corona virus infection for the lack of efficacy of the vaccine. However, based on the mechanism of action of the vaccine, it is unlikely the patient would have fully developed immunity for the vaccine to be effective, due to possibly short number of days passed since the vaccine is given. Case will be reevaluated based on follow-up information,Linked Report(s) : US-PFIZER INC-2021004746 same reporter/product/event, different patient;US-PFIZER INC-2021004748 same reporter/product/event, different patient

Diagnosed with COVID; Diagnosed with COVID; This is a spontaneous report from a contactable other health professional. This reporter reported same events for three patients. This is 3rd of three reports. A patient of unspecified age and gender received BNT162B2 (Pfizer BioNTech COVID vaccine), via an unspecified route of administration on an unspecified date at single dose for Covid-19 immunization. The patient's medical history and concomitant medications were not reported. The memory care patient received Pfizer-Biontech Covid vaccine, and then was diagnosed with Covid and had Covid symptoms on an unspecified date, the patient was scheduled to receive monoclonal antibody. Event took place after use of product. The outcome of events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Sender's Comments: There is limited information reported, it is possible patient would have taken only single dose, a possible contributory role of the suspect products cannot be excluded for the reported event of positive for corona virus infection for the lack of efficacy of the vaccine. However, based on the mechanism of action of the vaccine, it is unlikely the patient would have fully developed immunity for the vaccine to be effective, due to the number of days passed since the vaccine is given. Case will be reevaluated based on follow-up information,Linked Report(s) : US-PFIZER INC-2021004746 same reporter/product/event, different patient;US-PFIZER INC-2021004747 same reporter/product/event, different patient

had a positive test for COVID; had a positive test for COVID; This is a spontaneous report from a Pfizer-sponsored program Pfizer First Connect from a contactable physician who reported for himself. A male patient of an unspecified age received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 19Dec2020 at single dose for COVID-19 immunisation. The patient medical history and concomitant medications were not reported. Patient had a PCR COVID-19 swab performed on 23Dec2020 which returned positive on 26Dec2020. The action taken in response to the event for bnt162b2 was not applicable. Outcome of the event was unknown. Information for lot number has been requested in follow up activity.; Sender's Comments: Based on the information available, a possible contributory role of the suspect products cannot be excluded for the reported event of positive for corona virus infection for the lack of efficacy of the vaccine. However, based on the mechanism of action of the vaccine, it is unlikely the patient would have fully developed immunity for

the vaccine to be effective, due to the number of days passed since the vaccine is given. Case will be reevaluated based on follow-up information

positive COVID-19 test with symptoms; positive COVID-19 test with symptoms; This is a spontaneous report from a non-contactable pharmacist via Pfizer Sales Representative. A 25-year-old male patient (nurse) received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot/batch number and expiration date unknown as did not have this information), via an unspecified route of administration in Dec2020 (reported as received either 17Dec2020 or 18Dec2020) at single dose for COVID-19 immunization in hospital. The patient's medical history and concomitant medications were not reported. One of the reporter's employees (patient) got the COVID-19 Vaccine. Ended up testing positive for COVID probably due to patient care. Patient was taking care of two to three people who were not positive for COVID while in the hospital, but tests came up as positive. Patient developed symptoms in Dec2020 and tested positive for COVID on 24Dec2020. Patient received COVID-19 Vaccine either 17Dec2020 or 18Dec2020. Began coughing three to four days after vaccination in Dec2020. Rapid test was negative in Dec2020. On 24Dec2020, the M20 test came back as positive for COVID. Only other symptom patient experienced was loss of taste and smell in Dec2020. Had been a stressful situation for the patient. The outcome of the events was unknown. Information on the Lot/ Batch number has been requested.; Sender's Comments: Based on the information available, a possible contributory role of the suspect products cannot be excluded for the reported event of positive for corona virus infection for the lack of efficacy of the vaccine. However, based on the mechanism of action of the vaccine, it is unlikely the patient would have fully developed immunity for the vaccine to be effective, due to the number of days passed since the vaccine is given. Case will be reevaluated based on follow-up information

encephalitis; This is a spontaneous report from a contactable consumer. A patient of unspecified age and gender received BNT162B2(PFIZER-BIONTECH COVID-19 VACCINE) , via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient was allergic to UTI(urinary tract infection) infection medication (i.e. sulfamethoxazole, trimethoprim etc.). Concomitant medications were not reported. The patient got encephalitis and was put in the ICU(intensive care unit) after getting vaccinated, led to hospitalization. Outcome of event was unknown. Information about lot/batch number has been requested.

Anaphylactic reaction

Pronounced dead 1/9/2021 at 12:42. Received first dose of vaccine 1/8/2021

"Staff member checked on her at 3am and patient stated that she felt like she couldn't breathe. 911 was called and taken to the hospital. While in the ambulance, patient coded. Patient was given CPR and ""brought back"". Once at the hospital, patient was placed on a ventilator and efforts were made to contact the guardian for end of life decisions. Two EEGs were given to determine that patient had no brain activity. Guardian, made the decision to end all life saving measures. Patient was taken off the ventilator on 1/9/2021 and passed away at 1:30am on 1/10/2021. The initial indication from the ICU doctor was the patient had a mucus plug that she couldn't clear."

Aprox 5 minutes after vaccine was given, patient stated he was not feeling well, asked for water and stated he was having trouble breathing. Was then assisted to clinic treatment room, vitals were taken: 08:45 B/P 171/110, HR 84, R 28 O2 97. EMS was activated. At 0900 158/94 HR 84 R 24 O2 97. Patient then voice he was having tightness in his throat. Epi Pen 0.3mg administered at 0900. At 0904 EMS arrived and patient taken to the nearest hospital.

Numbness and tingling bil upper extremities, seizure, temporary paralysis R arm. Started day after vaccine given, was observed overnight in hospital.

"Manager was notified that the employee had suffered a stoke-like ""serious medical event"" hours after the end of her shift, while at home."

Patient had vaccine in Left arm. That same night patient had temp of 100.1 and the right neck at base of head to shoulder began to hurt patient was unable to swallow without pain in the next few days. Patient went to ER and was hospitalized for 2 days treated with IV steroids and 2 antibiotics (clindamycin and acyclovir). Patients symptoms resolved and patient was discharged without additional issues. The admitting physician was unable to identify the cause of these symptoms, but the vaccine could not be ruled out.

"1-2-2021 10:30 PM Complained Right arm/back hurt - took Tylenol 1-3-2021 Complained Right arm hurt, dizzy 1-4-2021 Felt better - did laundry, daughter found her deceased at 3:30 pm. Dr. at hospital said it was ""cardiac event"" according to death certificate."

Upon assessment resident noted to have increased respirations, lungs CTA. Resident c/o increased fatigue and muscle aches. VS 202/180, 118, 22, 97.1, 96%.

Sever thrombocytopenia (platelet count 2,000) 8 days following Moderna COVID vaccine. Clinically suspicious for ITP.

Received vaccine on 1/5, began having swelling in bilateral hands and lower extremities on 1/7, along with fatigue. On 1/8 she reports new swelling started in her face (eyes and cheeks). Swelling has not improved today and fatigue has worsened.

Found on floor by CNA at 6 am. On assessment by charge nurse, VS: 99.6-94-16 212/105 manual. Noted increased confusion. Temp. 99.6 FBS 114. Resident had been provided tylenol just prior in shift for general discomfort (sore muscles) and low grade temp. On call for Dr notified of all and received order to send to ER.

Staff reported that patient was found Friday morning (Jan 8) sitting at a table with his head tilted forward and unresponsive to verbal or physical stimuli. Staff lowered patient to floor and started CPR. EMS was called and continued CPR at scene, however they were not able to revive patient. Patient was pronounced dead at the scene. Staff written statements following the death of patient show that he had a fall about 1 hr. prior. It is unknown if this fall contributed to patient's death. An autopsy has been requested.

Acute anterior MI with death

Approximately 15 minutes after receiving the vaccine, client started c/o itching to face and lips. Transported to triage area. Where she started c/o burning lips also. vital signs monitored, Benadryl 50mg po given. In a few minutes she reported chest tightness, labored breathing. 1:44pm Epinephrine was given IM. client was on 02 increased to 15 Liters. She admits to decreased chest tightness and itching of face improving. She was taken by ambulance to hospital, where she was admitted overnight for observation. She was given Benadryl and epi X2 more time, once in ambulance and once at the hospital. She denies any problems since then. She did say that approx 3 weeks ago she was a contact to a case of covi

Patient is a 41 y.o. female who presented to the ED with complaints of a reaction after she took the COVID vaccine. Patient is an RN here and had earlier received COVID-19 vaccination (Moderna) around 0130 this afternoon. Soon after she experienced rash which was burning and itchy on her arms thighs and back. She reported to Occ health and was directed to the ED. While in the ED she experienced throat tightness and nausea. She had one episode of diarrhea. No tongue, lip swelling, SOB or difficulty swallowing. Denies any chest pain, palpitations, pre-syncope/syncope. No vomiting abdominal pain. H/o of allergy to fish mix and dust mite.

01/06/21 at 6 pm, body aches, and chills 01/07/21 at 12am T102.2, SPO2 62% on room air. Was sent to ER and returned. 01/08/21 at SPO@ less then 60% on room air, non responsive to verbal tactile stimuli. Responsive to sternal rub only. Was sent to ER and admitted to ICU.

The resident resides in an independent living facility/apartment. The reporter at the center was informed by his daughter he was not feeling well on 1/1/2021 (specific symptoms could not be ascertained). He reportedly went to be COVID tested on 1/1/2020 and observed to be deceased in his apartment on 1/2/2020. I do not have confirmation of his COVID results, although the reporter indicates his daughter reports his test was positive.

Patient went to bed around 11pm on Saturday PM and sometime between then and 1:30am on Sunday morning got up and went into the living room without waking up her husband (which is normal). At 1:30am, the husband got up to use the restroom and she was out of bed then, but the husband did not know if she was having any problems at this time. When he got up at 7:45am, she was in the recliner and did not move or anything, which is normal for her. At 8:45am, the husband went back into the living room and tried to wake his wife and that is when he noticed there was no pulse and he called 9-1-1 at this time. EMS got on scene and did CPR for 30 mins and she was pronounced dead at 9:21am.

Approximately 10 minutes after receiving the vaccine she started experiencing numbness and inability to move all 4 extremities. No difficulty breathing or swallowing. Benedryl 25 mg was administered with no relief. EMS was called, she was transported to the ED and admitted to the hospital for evaluation. She was given Ativan 0.5 mg IV with some mild improvement in symptoms. She has had gradual improvement in her symptoms, now able to move her arms normally. She has persistent weakness and discomfort in both lower extremities and is unable to ambulate without assistance.

1/8/2021 tachycardia Pulse 140, Fever T99.4 then 100.2 Lethargy, Somewhat Altered Mental status

"Her voice became raspy, she could hardly talk, she could barely talk; her hand and whole arm swelled up; her hand and whole arm swelled up; Trouble breathing; This is a spontaneous report from a contactable healthcare professional (patient). A 57-year-old female patient received the 1st dose of bnt162b2 (BNT162B2, Manufacturer Pfizer-BioNTech) (lot# EK9231, exp date Apr2021), via an unspecified route of administration in the right arm, on 29Dec2020, at single dose, for COVID-19 immunization and diphenhydramine hydrochloride (BENADRYL), via an unspecified route of administration, at unknown posology, on 29Dec2020 (20 minutes prior to taking bnt162b2), for anaphylactic reaction. Medical history included ongoing thyroid disorder. Concomitant medications included apixaban (ELIQUIS), diltiazem (unknown trade name), losartan (unknown manufacturer), rosuvastatin calcium (CRESTOR), levothyroxine (unknown trade name), ongoing levothyroxine sodium (SYNTHROID) for thyroid disorder and metformin (unknown trade name). Previously the patient received unspecified influenza vaccine (reported as flu shot) for immunisation, on unspecified date, and experienced anaphylactic reaction treated with Benadryl. On 29Dec2020, an hour after getting the vaccine, the patient experienced her voice became raspy, she could hardly talk, she could barely talk with outcome of unknown, her hand and whole arm swelled up with outcome of unknown, trouble breathing with outcome of unknown. The reporter stated that her voice and everything reacted and made her go to the emergency room on 29Dec2020. She reported that had adverse effect more than normal. The event ""Her voice became raspy, she could hardly talk, she could barely talk"" caused patient's hospitalization on unknown date. The action taken as a result of the events with diphenhydramine hydrochloride was post-therapy. Therapeutic measures were taken at the emergency room as a result of the events and included treatment with Topcid and Benadryl every 6 hours, 2x 40 mg of steroid. The information on the lot/batch number has been requested. Follow-up (02Jan2021): New information received from the same contactable healthcare professional reporting for herself includes: patient's details, medical history, events updated, vaccine lot# and exp date, concomitant, seriousness of event ""Her voice became raspy, she could hardly talk, she could barely talk"" added as hospitalization, historical vaccine, suspect Benadryl details, therapeutic measures updated.; Sender's Comments: A causal association between BNT162B2 and the reported events cannot be excluded based on a compatible temporal relation between vaccination and onset of events. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate."

Resident died suddenly and expectantly on 01/05/2021

Patient received COVID-19 (Moderna) vaccine from the Health Department on afternoon of January 8, 2021 and went to sleep approximately 2300 that night. Was found unresponsive in bed the following morning and pronounced dead at 1336 on January 9, 2021

Chills Hip pain

Resident had seizure like activity followed by a vagel response with large bowel movement. Resident then began to show signs of blood clot to left lower extremity. No pedal pulse, area on leg warm to touch. Left lower leg now cold to touch, stiff, purple and white in color. No other signs of modeling, body warm to touch, no fever noted. Respirations and pulse increased with low oxygen levels. Resident not responding to stimuli.

38-year-old female who is healthcare worker and received first dose of COVID vaccine (Pfizer). Immediately after receiving the vaccine, patient developed lightheadedness, flushing, hives, wheezing and throat swelling. Patient was treated in an emergency department with epinephrine, gradually improved and was able to be sent home with an EpiPen, prednisone, hydroxyzine, and famotidine. The next day, patient again developed shortness of breath and her husband administered the EpiPen. EMS arrived and gave another dose of IM epinephrine and IV diphenhydramine. On arrival to the emergency department, the patient was altered, diaphoretic, tachypneic, tachycardic, and stridulous. Patient was given multiple doses of IM epinephrine and started on epinephrine drip. Stridor continued and was unresponsive to nebulized albuterol. Patient was then intubated and placed on mechanical ventilation. Other treatments included solumedrol, pepcid, magnesium sulfate, nebulized epinephrine, and IV fluids. admitted to the intensive care unit, weaned off epinephrine drip, and extubated the next day. Patient was monitored on hospital floor for one additional day and was then discharged with no residual symptoms.

Patient had a rash prior to COVID vaccine. Prednisone 10mg started on 1/5/21 (only one dose administered) 1/6/21, 1am - Rash worsened with increase redness, warmth and extending of body surface, Temp 100.4, 1/6/21, 1:20am Benadryl 25mg administered, (Keflex was ordered at this time, however never administered). 1/6/21, 3am rash improved, temp 99.1 1/6/21, 6:50am Right facial droop and right sided weakness, sent to ER 1/6/21 transferred to hospital, continues to be hospitalized 1/11/2021

Patient expressed: Pain in the left side of the face and migraine on 25Dec2020, and came to emergency room where apparently they diagnosed facial paralysis; Patient expressed: Pain in the left side of the face and migraine on 25Dec2020, and came to emergency room where apparently they diagnosed facial paralysis; This is a spontaneous report from a contactable nurse. A 42-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number EK5730) intramuscular, on 17Dec2020 04:15, single dose arm left for COVID-19 immunization. Relevant medical history included hypothyroidism, hypertension, hyperlipidemia, obesity, and penicillin allergy. Concomitant medications included levothyroxine sodium (SYNTHROID), butalbital, caffeine, paracetamol (FIORICET 50-40- 325mg), dexamethasone 4mg Inj., diclofenac (VOLTAREN 1% Gel), Magnesium, valsartan (VASOFLEX) (pending confirmation), cyanocobalamin (VITAMIN B12), losartan potassium. The patient was not pregnant and did not received any vaccine in four weeks. The patient previously took cephalosporin and experienced allergy. On 24Dec2020, the patient experienced pain left side of the face and migraine, and came to emergency room where apparently they diagnosed facial paralysis. The events resulted in emergency room visit/ urgent care where the patient was administered dexamethasone 4mg Inj, Medrol dose pack, Vit B12 500mcg, and Fioricet 50-325-40. Facility where the most recent COVID-19 vaccine was administered was in the doctor's office/urgent care. It was unknown if the patient was diagnosed with

COVID-19 prior or since the vaccination. The events were assessed by the nurse as non-serious. Outcome of the events was recovering at the time of the report.; Sender's Comments: A causal association between BNT162B2 and the reported events cannot be excluded based on a compatible temporal relation between vaccination and onset of events. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

HPI narrative: Patient was fine until 2 days ago. Patient does have chronic dementia but got Covid vaccine 11:00 2 days ago and that night seem to be confused and not able to walk since then. Patient poor appetite since yesterday. Patient had diarrhea 3 x 2 days ago. No vomiting no fever no cough does not appear to be short of breath. Patient also with left hip pain for few days with no injury.All history obtained from caretaker at bedside.

Started as a red raised rash under my arms and my waistline; rash turned to hot to touch; raised red large hives all over my body including my face/head; numbness to my hands/feet/chest area; the SOB started; This is a spontaneous report from a contactable nurse, the patient. A 53-year-old non-pregnant female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot Number: EU9231), via an unspecified route of administration in the left arm on 30Dec2020 at 08:30 as a single dose for COVID-19 immunization. Medical history included hypothyroidism and chronic low back pain. Prior to the vaccination, the patient was not diagnosed with COVID-19. Concomitant medications included levothyroxine (MANUFACTURER UNKNOWN), baclofen (MANUFACTURER UNKNOWN), and etodolac (MANUFACTURER UNKNOWN). The patient did not receive any other vaccines within four weeks prior to the vaccination. The patient previously took miconazole nitrate (MONISTAT) on unknown dates for an unknown indication and experienced drug allergy. On 31Dec2020 at 10:00, the patient started with a red raised rash under her arms and waistline and as the day progressed the rash turned hot to touch with raised red large hives all over her body including her face/head. By 23:00 on 31Dec2020, the patient had already taken 3 doses of diphenhydramine (BENADRYL) which was not effective. Then, later on 31Dec2020, shortness of breath started with numbness in the hands/feet/chest area. Her daughter took her to the emergency room. She was started on intravenous diphenhydramine, dexamethasone, and famotidine (PEPCID). The medications took time to work but they did resolve her shortness of breath and the hives subsided to mild redness. She was sent home and given the following medications to take: diphenhydramine 50 mg every 4 hours, methylprednisolone (MEDROL DOSE PAK), cetirizine (ZYRTEC) daily, and famotidine (PEPCID) daily. Since the vaccination, the patient had not been tested for COVID-19. The clinical outcomes of the red rash, rash was hot to touch, shortness of breath, and numbness, were reported as recovered with lasting effects; while that of the hives was recovering as they still flared up if she did not take the medications every 4 hours. The reporter assessed all the events as non-serious.; Sender's Comments: The reported shortness of breath together with red rash was probably related to the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE together with rash was probably related to the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), due to temporal relationship and clinical course. The impact of this report on the

benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory authorities, Ethics committees and Investigators, as appropriate.

Rectal bleeding; Stomach ache; Diarrhea; sick; This is a spontaneous report from a contactable consumer (patient) from a Pfizer sponsored program Pfizer First Connect. A 41-year-old female patient received the first dose of the bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot Number: EK5730 and Expiration Date: 31Mar2021), via an unspecified route of administration in the right arm on 20Dec2020 at a single dose for COVID-19 immunization. The patient's medical history was reported as none. There were no concomitant medications. On 01Jan2021, the patient experienced: rectal bleeding, stomachache, diarrhea, sick; all assessed as medically significant. The clinical course was reported as follows: The patient received the first dose of the COVID-19 vaccine on 20Dec2020; as she was at high risk due to working with COVID patients in the hospital. The patient became sick on 01Jan2021. The patient experienced a stomach-ache, diarrhea, and rectal bleeding. When these events occurred, the patient went to the emergency room (ER). A doctor there prescribed the patient the antibiotics metronidazole 500 mg and cefdinir 300 mg. The patient was also scheduled to follow up with a gastrointestinal (GI) doctor. The patient called asking if she should get the second dose since she was taking antibiotics. The patient was scheduled for the second dose on 08Jan2020.The patient reported she had improved. The symptoms, at the time of the report, were not that bad. Therapeutic measures were taken as a result of rectal bleeding, stomachache, diarrhea, and sick. The clinical outcome of the events was recovering.

Numbness lips,mouth; Was feeling bad; leg numbness/numbness in head, face; pain in head; increased BP; blood pressure was up and down; This is a spontaneous report from a contactable consumer (patient). A 55-year-old female patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EL0140) via an unspecified route of administration in left arm on 29Dec2020 6 am at single dose for covid-19 immunisation. Co-suspected drug amoxicillin;clavulanic acid (AUGMENTIN, Batch/lot number: KN4291, Expiry Date: Mar2022) by mouth from Dec2020 to 28Dec2020 at 875mg, 1 tablet twice daily for pain or infection; MOXIFLOXACIN HYDROCHLORIDE (AVELOX, strength:400mg) by mouth from 29Dec2020 and ongoing at 400mg, 1 tablet once daily for infection; fluconazole (DIFLUCAN, strength:200mg) orally (by mouth) from unknown date and ongoing at 200mg, 1 tablet once daily for Infection.The patient's medical history was reported as ongoing high blood pressure, ongoing pains in her fingers and toes and they thought she had an infection from 02Dec2020, white count went down on 09Dec2020, ongoing pain was up and down. No other vaccines given at that time and none given 4 weeks prior. Had a Flu shot back in Oct2020, but no problems. None diagnosed allergies and family medical history relevant to adverse event. The concomitant medications included unspecified blood pressure medication by mouth daily for high blood pressure. She had also started 2 antibiotics around the same time that she received the vaccine. No further details provided Was on antibiotics at the time she was given the Pfizer COVID-19 vaccine. Patient experienced increased BP/ high blood pressure, pain in head, and leg numbness; all started 2 days (on 31Dec2020) after receiving the vaccine and persisted for 48 hours. First her blood pressure was up and they had to get it

stable and had numbness in her head, face, and mouth for 48 hours. Her blood pressure was up and down and she has history of blood pressure and takes medicine. Was taken off work for a few hours and went to the emergency department on Fri night about 2am. Her blood pressure was 170/92 on 01Jan2021. Not sure if this was related to the vaccine, but the numbness in her head started from her upper neck to face to the right side of her check and she also had leg numbness. Wanting to know if this was related because she was worried about getting the second dose. Had a hard time for 48 hours. Weight was between 150-155 pounds. Stated everything improved after 48 hours. Her lip was also just a little bit numb, but it is feeling better. Patient was feeling bad from 01Jan2021, all Fri and Sat and much better by Sun. Events of increased BP/ blood pressure up and down, leg numbness, numbness in lips, head, face, mouth with emergency room visiting. Wanted to know if she should have the second dose. The action taken in response to Augmentin was permanently discontinued on 28Dec2020, for Avelox and Diflucan was dose not changed. The outcome of events was recovering.

eventually inability to move arm; pain; joint pain; tenderness at injection site; loss of strength; This is a spontaneous report from a contactable nurse. A 36-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, Batch/lot number: EJ1685) intramuscular at arm left, on 19Dec2020 06:45 at single dose for covid-19 immunisation. Medical history included ongoing acne. Patient had no known allergies. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Concomitant medication included isotretinoin (ACCUTANE). On 19Dec2020 11:30, approximate 5 hours after vaccine, the patient experienced pain, joint pain and tenderness at injection site, progressively loss of strength and eventually inability to move arm. Since the vaccination, the patient hasn't been tested for COVID-19. The outcome of events was recovered.; Sender's Comments: Based on the compatible temporal association, the vaccination with BNT162B2 might play a contributory role in triggering the onset of the reported events. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

she is positive for blood in her stool; left hip/back/kidney pain; left hip/back/kidney pain; left hip/back/kidney pain; This is a spontaneous report from a contactable consumer reporting for herself. A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (lot number and expiration date unknown) via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient received the vaccine on 28Dec2020 (reported on 05Jan2021 as 'a week ago Monday'). After getting the vaccine (2-3 days after getting the vaccine) she started to have some events happen that she was not sure were side effects from the vaccine. She mentioned she started to experience blood in her stool - following a test at her doctor's she was positive for blood in her stool. Also, the left side of her lower back and hip started hurting. She was experiencing left hip/back/kidney pain, as reported. She took hydrochlorothiazide. The outcome of the events was unknown. She wanted to know if this had anything to do with the vaccine and if this could be a side effect. These events did

not start happening until after she got the vaccine. Information on the lot/Batch number has been requested.

difficulty of breathing; chest pain; nearly passing out/fainting; This is a spontaneous report from a contactable consumer. A 50-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number and expiry date unknown) via unspecified route of administration on unspecified date at single dose for Covid-19 immunization. The patient's medical history and concomitant medications were not reported. The reporter called in behalf of her friend that has been experiencing serious adverse event. The patient experienced difficulty of breathing, chest pain, nearly passing out/fainting on unspecified date. They felt that the vaccination provider did not provide enough support about the adverse event that happened. Follow-up activities are possible, information on the batch number has been requested.

believed it was injected incorrectly because she didn't have pain in her deltoid but she did have all the pain inside her shoulder, like in the bursa; received the first dose 17DEC2020 / received the second dose 4JAN2021; anterior medial shoulder joint/shoulder pain/pain in shoulder after second dose of COVID 19 vaccine; can't actively use shoulder / can't move her arm; weakness in her hand; bone pain; This is a spontaneous report from a contactable healthcare professional (HCP) reporting for herself. A 40-year-old female patient received the first single dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (lot number EJ1685, expiry date not provided) via an unspecified route of administration in the left arm on 17Dec2020 13:30, and the second dose (lot number EK9231, expiry date not provided)via an unspecified route of administration in the left arm on 04Jan2021 13:30, for COVID-19 immunization. There was no relevant medical history. The patient's concomitant medications were not reported. The patient experienced anterior medial shoulder joint/shoulder pain/pain in shoulder after second dose of the vaccine on 04Jan2021, and couldn't actively use shoulder. She believed it was injected incorrectly because she didn't have pain in her deltoid but she did have all the pain inside her shoulder, like in the bursa, and she couldn't move her arm and felt weakness in her hand. She noticed the pain and all other symptoms immediately when they were injecting it. She told the nurse who said she was tensing up. The events were considered medically significant by the patient. She also reported experiencing bone pain, unable to put in sutures at work. She was taking 600mg Ibuprofen and 1000mg paracetamol (TYLENOL) every 6-8 hours. The events were not resolved. The pain had gotten worse. The other symptoms were persisting.; Sender's Comments: Based on the compatible temporal association, the vaccination with BNT162B2 might play a contributory role in triggering the onset of the events. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

SEVERE ABDOMINAL PAIN

"tongue not swollen but felt sluggish/tongue felt strange, it was sluggish to swallow; tongue felt strange like hard to swallow/tongue felt strange, it was sluggish to swallow/Her tongue felt strange; tongue felt strange like hard to swallow/tongue felt strange, it was sluggish to swallow/felt hard to swallow; hot

flash; flush feeling all over her face/flush all over her face/she felt flush; arm was sore; arm was sore and heavy; drowsiness; pain and redness at injection site; pain and redness at injection site; This is a spontaneous report from a contactable nurse reporting for herself. A 36-year-old female patient received the first single dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (lot number EL1284, expiry date not provided) on 23Dec2020 09:15 intramuscularly in the left arm for COVID-19 immunisation (reported as preventive). There was no relevant medical history and no concomitant medications. The nurse (patient) received her first dose of the vaccine on 23Dec2020 at the hospital that she worked at. She was kept there for 15 min for monitoring and she felt fine. About 30 minutes post vaccination she got a hot flash, a flush over her face, she does not know if she was red but she felt flush. Her tongue felt strange, nothing swelled that she could tell, it felt hard to swallow, to make the motion to swallow it felt kind of sluggish. She felt weird swallowing which lasted for only a few minutes. She never struggled to breathe. She went back to park in the hospital parking lot since she was not sure if she was experiencing a anaphylactic reaction and then after a few minutes it went away. Her arm was sore and heavy feeling for that day. She had drowsiness for a couple of hours and pain and redness at the injection site for a couple of days that was not bothersome, it was mild. No relevant test. She wanted to know if she should get the second dose of the vaccine due to the symptoms she had after the first dose. The pain and redness at injection site was resolved on an unspecified date in Dec2020, while the other events were resolved on 23Dec2020. The reporting nurse considered the events hot flash, flush all over her face, arm was sore and heavy, drowsiness, pain and redness at injection site were non-serious, while the events ""tongue felt strange, it was sluggish to swallow"" were serious that she drove back to the hospital (no emergency room/phycian office visit). She considered the events were related to the vaccine.; Sender's Comments: A possible contributory effect of suspect BNT162Bw on the reported events cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate."

Sudden and rapid onset of generalized Urticaria accompanied by dyspnea; sudden and rapid onset of generalized uritcaria accompanied by dyspnea; This is a spontaneous report from a contactable nurse (patient). A 34-year-old female patient (non-pregnant) received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EH9899), intramuscular on 30Dec2020 11:00 at single dose at right arm for covid-19 immunization. Medical history included Grave's dse, psoriasis, bronchial asthma. Concomitant medication in two weeks included propranolol, methimazole, fluticasone furoate, vilanterol trifenatate (BREO ELLIPTA), colecalciferol (VITAMIN D). Patient didn't receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient previously took adalimumab and experienced drug allergies. The patient was not diagnosed with COVID-19 prior to vaccination. Since the vaccination, patient has not been tested for COVID-19. 9hrs post-vaccine, patient developed sudden and rapid onset of generalized uritcaria accompanied by dyspnea on 30Dec2020 20:00 with outcome of recovered with sequelae. Adverse events resulted in emergency room/department or urgent care. Patient received intramuscular epinephrine, intravenous solumedrol & benadryl, and oral prednisone x5 for events. This report is considered as non-serious.; Sender's Comments: Based on temporal

association, the causal relationship between bnt162b2 and the events urticaria and dyspnoea cannot be excluded. The information available in this report is limited and does not allow a medically meaningful assessment. This case will be reassessed once additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate.

Facial paralysis; stress; This is a spontaneous report from a contactable Nurse. A 42-year-old female patient received first dose of BNT162B2(PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The reporter felt worried about the patient(partner) that had facial paralysis and asked if they could administer the second dose of the vaccine of covid-19 from Pfizer. The paralysis it was previous from the fist dose of the vaccine, a consequences of the stress, the partner had 42 years. The reporter considered that the event was non-serious. The outcome of the event was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Based on temporal association, the causal relationship between BNT162B2and the event facial paralysis cannot be excluded. The information available in this report is limited and does not allow a medically meaningful assessment. This case will be reassessed once additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate.

"experienced symptoms of TIA; Severe aphasia; blurred vision; confusion; short term memory loss; elevated blood pressure; This is a spontaneous report from a contactable Other-HCP(Patient). A 57-year-old female patient received first dose of BNT162B2(PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration at right arm, on 22Dec2020 08:15 at single dose for COVID-19 immunization. The patient was not pregnant. Medical history included herpes simplex on lips, post menopause, elevated cholesterol w/lifestyle changes. Known allergies reported as no. Concomitant medication included varicella zoster vaccine rge (cho) (SHINGRIX) for immunization. On 04Jan2021 08:30, the patient experienced symptoms of transient ischaemic attack(TIA), severe aphasia, blurred vision, confusion, short term memory loss, elevated blood pressure. The patient admitted to (Hospital name) (still here, hospitalization days reported as 2). Symptoms resolved except very mild aphasia. The patient had very few risk factors for TIA but did have family history of cardiovascular(CV) disease at young age, low density lipoprotein(LDL) was 192. The patient did not have diabetes, HTN, or known heart disease. She did not have severe anxiety. She did not smoke or use any substances. She walked about five miles 4x a week. Weigh reported as 157. Events reported as serious due to hospitalization. The patient had no Covid prior vaccination. Covid(nasal swab) was tested post vaccination on 04Jan2021, Covid test result was Negative. The event resulted in emergency room/department or urgent care. Treatment received for the adverse event included clopidogrel bisulfate(PLAVIX),

acetylsalicylic acid (ASPIRIN), statin; potassium, CT, MRI, ""telemet"". The outcome of the events was recovering. Information on the lot/batch number has been requested.; Sender's Comments: The Company cannot completely exclude the possible causality between the reported symptoms of transient ischaemic attack(TIA), severe aphasia, blurred vision, confusion, short term memory loss, elevated blood pressure and the administration of BNT162B2, based on the reasonable temporal association. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RA, Agency, as appropriate."

"two skin procedures performed in his surgeons office the day before- one on his nose and one on his arm; nose was still slightly bleeding; This is a spontaneous report from a contactable consumer(patient). áA 72-year-old male patient received first dose of BNT162B2(PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 30Dec2020 at single dose for COVID-19 immunization. Medical history included phlebotomy in Sep2020 because his blood was ""too thick"" and he had no history of a clotting problem until the time of the report. The patient's concomitant medications were not reported. He reported having two skin procedures performed in his surgeons office the day before- one on his nose and one on his arm. The surgeon nicked a vein on his arm and it began bleeding again last night. The arm was addressed in the emergency deportment(ED) and was fine at time of the report. His nose was still slightly bleeding. This morning his blood was drawn for a CT scan and it took a little while to get the bleeding to stop. He had a ""phlebotomy"" in Sep2020 because his blood was ""too thick"" and he had no history of a clotting problem until the time of the report. The patient asked if the Covid vaccine act as an anticoagulant. He had not spoken to this HCP yet. He was not on a blood thinner. The reporter considered that the event was non-serious. The outcome of the event arm bleeding/bleeding was recovered, of event ""nose was still slightly bleeding"" was not recovered. á Information about lot/batch number has been requested."

soreness around the injection site; Had severe arm pain; Had a fever on the night of the 31Dec2020 of 101.3; I have painful lymph nodes/the swollen lymph nodes under her right arm, the armpit area had swollen and painful lymph nodes; I have painful lymph nodes/the swollen lymph nodes under her right arm, the armpit area had swollen and painful lymph nodes; had joint pains/knees and hip joint pain; severe fatigue; muscle pain; This is spontaneous report from a contactable nurse (patient). A 59-years-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK9231), via an unspecified route of administration in right arm on 30Dec2020 14:15 at first single dose (0.3 cc, but really uncertain of dose) for covid-19 immunization. Medical history included COVID virus from Nov2020 to 2020 (The patient was not hospitalized. It was a mild case and lasted about 10 days. she had any positive antibodies at that time. Was off work for about 12 days and was very lucky to have had a very light case with fever, cough, cold, and super fatigue). The patient's concomitant medications were not reported. The patient did not receive any other vaccines at the same time or 4 weeks prior. No problems with vaccinations in past or events. Caller reported she had the first injection of the Pfizer BioNTech COVID-19 vaccine on the 30Dec2020 and having some side effect symptoms and her supervisor recommended for her to report these things, they are not life threatening, obviously, but things were

still lingering. Side effect of severe fatigue started on the 31Dec2020 and lasted for 72 hours. It was so severe, now it is mild. The patient reported soreness around the injection site. Had a fever on the night of the 31Dec2020 of 101.3 and had that for 6 hours then it dissipated and was gone. Had never had a fever after injections before. Had severe arm pain that usually goes along with an injection. It started also that night of 31Dec2020. She had rolled over in the middle of the night and it hurt. That lasted for about 48 hours, but it has improved. Had some muscle aches since 31Dec2020 but that had improved and had joint pains since 31Dec2020. What was worrisome was the swollen lymph nodes under her right arm, the armpit area had swollen and painful lymph nodes, since 31Dec2020. The patient was still having that and that is why she was so concerned because shouldn't that have gone away after a week. Had knee and hip joint pain, but that had improved. Again, mentioned she had never had that before with an injection. The patient received vaccine at her workplace. Some of her coworkers got it the same day and no one else has this. Mentioned she did have COVID virus back in Nov2020 and wonders if this correlates with her getting the vaccine. Was not hospitalized or notified she had any positive antibodies at that time. Was off work for about 12 days and was very lucky to have had a very light case with fever, cough, cold, and super fatigue. This is the same way she felt back when she had the virus back in November. The patient was concerned about having these side effects would it be okay for her to get the next injection in 3 weeks. AEs did not require a visit to emergency room and physician office. No further details provided. Outcome of the events Fever was recovered, of event swollen and painful lymph nodes was not recovered, of events knees and hip joint pain, fatigue, muscle pain, severe arm pain was recovering, of event soreness around the injection site was unknown. The reporter considered the events severe fatigue, fever, swollen lymph nodes and pain under right arm, knees and hip joint pain as serious (medically significant). The reporter considered the events severe fatigue, fever, severe arm pain, muscle ache, swollen lymph nodes and pain under right arm, knees and hip joint pain as related to BNT162B2.; Sender's Comments: Based on the compatible temporal association, the vaccination with BNT162B2 might play a contributory role in triggering the onset of the reported events. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

chest pressure; tightness /pressure in throat; Face red; BP 186/90; within 2 min. of injection had near syncope that would come in waves every 2-3 minutes; Headache; rapid HR; Chills; mild cough; Dizziness; fatigue; This is a spontaneous report from a non-contactable health care professional nurse, the patient. A 53-years-old non-pregnant female patient (nurse) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot Number: EJ1685), in the right arm on 28DEC2020 08:15 as a single dose, for COVID-19 vaccination. Facility where the most recent COVID-19 vaccine was administered was a Hospital. Medical history included asthma and gastroesophageal reflux disease from an unknown date and unknown if ongoing. Known allergies include Tape, Walnuts, and Cat hair. Concomitant medication received within 2 weeks of vaccination included acyclovir [aciclovir] (ACYCLOVIR [ACICLOVIR]), ferrous gluconate, herbal nos, vitamins nos (FLORADIX), lansoprazole (PREVACID), cholecalciferol (VITAMIN D [COLECALCIFEROL]). No other vaccines were given within 4 weeks. Prior to vaccination, the patient was not diagnosed with COVID-19. On 28DEC2020 08:15 within

2 min. of injection had near syncope that would come in waves every 2-3 minutes, face red, chest pressure, tightness /pressure in throat, headache, BP 186/90, rapid HR. The patient Spent 1 hour in ER. Later in day 28Dec2020, continued to have dizziness, chest pressure, chills, headache, fatigue. This continued for 4 days and had mild cough. The adverse events resulted in an emergency room (ER) visit. and Physician Office Visit. Treatment included Xyzal which relieved majority of symptoms. Laboratory test and procedures on 28Dec2020 include Electrocardiogram (EKG) with normal results, Blood Pressure Measurement 186/90 and Heart Rate Rapid. Treatment was given for chest tightness, throat tightness and red face and No treatment was given for chills, cough, dizziness, fatigue, headache, heart rate increase, blood pressure high and near syncope. The clinical outcome of near syncope that would come in waves every 2-3 minutes, face red, chest pressure, tightness /pressure in throat, headache, BP 186/90, rapid HR, dizziness, chest pressure, chills, headache, fatigue, mild cough was recovered. No follow-up attempts are possible. No further information is expected.; Sender's Comments: The Company cannot completely exclude the possible causality between the reported face red, chest pressure, tightness /pressure in throat, blood pressure increased (BP 186/90), near syncope and the administration of BNT162B2, based on the reasonable temporal association. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RA, IEC, as appropriate.

DVT; have pain in same site where DVT is; This is a spontaneous report from a contactable consumer. A 28-years-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number EK9291), via an unspecified route of administration in left deltoid on 24Dec2020 10:00 at first single dose for COVID-19 immunization. Medical history was none. There were no concomitant medications. Caller was calling to report a possible adverse reaction to the Pfizer Covid-19 vaccine. The patient was currently at hospital, she was admitted for deep vein thrombosis (DVT) of left iliac vein, the patient had no past history as to why this would happen, that she is only 28 years old. Received the vaccine on 24Dec2020, the following day she did have pain in same site where DVT was. Took ibuprofen for the pain. The patient was admitted yesterday 04Jan2020 for the DVT, they were currently treating her with Lovenox injections and prescribing dose for discharge is Eliquis. CT scans and three shots of Lovenox for it, doing a doppler of bilateral legs and echocardiogram (echo) of her heart to make sure there is nothing else. The AEs require a visit to emergency room. The patient was asking if she can still get the 2nd dose based off the adverse event she experienced. Outcome of DVT was not recovered, of pain was unknown.

Chills; Headache; Coughing; Tiredness; Nasal congested; Feels like her sinus were blocked; Body ache; feeling sick; Sneezing; This is a spontaneous report from a contactable nurse (patient, front line health care worker). A 51-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (Lot#: EH9899) via an unspecified route of administration in the left arm on 28Dec2020 (at 10:30 or 11:00 AM) at single dose for COVID-19 immunization. Medical history included hypertension, diabetes, and stroke, all reported as family history (her parent). There were no concomitant medications. There was no history of all previous immunization with the Pfizer vaccine considered as suspect. There was no additional vaccines administered on same date of the Pfizer

suspect. The patient did not have prior vaccinations within 4 weeks. The patient had body ache (reported as medically significant) on 01Jan2021 with outcome of recovering, had been sick for a week/ very ill on 28Dec2020 with outcome of unknown, sneezing on 28Dec2020 with outcome of not recovered, chills on 01Jan2021 with outcome of unknown, headache on 01Jan2021 with outcome of recovering, coughing on 01Jan2021 with outcome of not recovered, tiredness on 01Jan2021 with outcome of unknown, nasal congested on 01Jan2021 with outcome of not recovered, feels like her sinus were blocked on 01Jan2021 with outcome of unknown. Treatment was received for the events. Reported she had a lot of sickness, by evening that day (28Dec2020) she got sneezing and feeling sick. Then the next day was the same, then the third day. She became very ill with chills, body ache, headache, coughing, and tiredness on 01Jan2021 (also reported as 3 days later vaccination). And she had no fever, but stated she had been sick for a week. Added the headache and body ache were a little better but still she felt so congested. Clarified she had nasal congested that feels like her sinus were blocked. She treated herself with acetaminophen, once daily 500 mg by mouth starting 01Jan2021. Added the body ache pain was still on the back of her chest but her legs and arms were better. She used steam inhalation for the congestion. She was not scheduled for the next dose yet, she was just waiting. The patient was wondering if she should do a test for COVID 19. Mentioned she had been healthy all through this year and digging in the COVID 19 all the time but then after the vaccine she got so sick. This was the first day she could get up and did anything. Advised caller to consult her HCP.; Sender's Comments: Based on the information currently provided, the vaccination with BNT162B2 might play a contributory role in triggering the onset of the body ache. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

TB test; This is a spontaneous report from a contactable consumer. This female consumer (patient) reported that received received bnt162b2 (BNT162B2, PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 30Dec2020 at single dose for covid-19 immunisation. Medical history and concomitant medications were unknown. Certified Nursing Assistant got the first dose of the covid vaccine on January 2nd and also she needs to get her TB test. She was told to wait 2weeks between the application and the TB test but the 2 weeks period ends on January 15th and she needs to have the test before that day, so she was wondering if she could get the test done a couple of days early. The outcome of the event was unknown. Information about lot/batch number has been requested.

"miscarriage at 5 weeks of gestation; pregnant patient received the vaccine; pregnant patient received the vaccine; This is a spontaneous report from a contactable physician (patient herself) from a Pfizer Sponsored program. This physician only reported information for the mother (herself). This is the maternal case. A pregnant female patient of an unspecified age received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Lot number: EK5730), via an unspecified route of administration, on 17Dec2020 as a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The pregnant patient received the vaccine on 17Dec2020

and experienced miscarriage at 5 weeks of gestation on 31Dec2020. The clinical outcome of pregnant patient received the vaccine and miscarriage at 5 weeks of gestation was unknown.; Sender's Comments: The association between the event ""miscarriage"" with BNT162b2 can not be fully excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate."

2 week migraine; headache; flushed/Got flushed; persistent extreme dizziness; This is a spontaneous report from a contactable nurse (patient). A 37-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) Batch/lot number: EK5730, Intramuscular at single dose on 17Dec2020 19:00 on right arm for precaution as front line health care worker. Medical history included Hemiplegic migraine. Her mother also had migraines. Concomitant medication included ranitidine hydrochloride (ZANTAC) and H1 and H2 blocker. The patient called to report AE of flushed, persistent extreme dizziness, and a headache that has evolved into a 2 week migraine. She has a history of hemiplegic migraines and was taking and h1 and h2 blocker when she received the vaccine. She was calling on guidance whether or not to receive the second vaccine. She was scheduled for second dose on Thursday, but wanted to speak with someone before she got it to see if it was OK. About 15 minutes after receiving the first dose, she got flushed and extremely dizzy. She had a mild headache when she woke up on 18Dec2020 06:00, which then developed into a severe migraine on 22Dec2020 08:00 that she has had for 2 weeks and dizziness continues. She received it at work and there was no prescriber. She called and left a message with Pfizer but has not heard back from anyone yet about this. She would say the flushed and dizziness would be medically serious because she had allergies and had medication on board. She takes daily allergy medication and Zantac and not sure she would not have had a worse reaction if she hadn't had that on board. She took it every night. She had an H1 and H2 blocker on board. Flushed has improved but the dizziness has stayed constant. She had been treated twice for headache and now they have put her on a Prednisone taper. She got it on her right arm so she could work her arm out. On 22Dec2020, she saw a Neurologist for the Migraine. They gave her Toradol 30 mg and Zofran 4mg injection in office. They were given IM. Then, she had another office visit for urgent care on 02Jan2021, and that was for the exacerbation of the migraine. They prescribed 1 liter of fluids and then another Toradol injection, Zofran injection and Decadron injection. The dose of the Toradol was 30 mg, Decadron was 6 mg, and Zofran was 4mg. These were given IV in urgent care. The patient had no prior vaccinations within 4 weeks. The outcome of flushed/Got flushed was resolving. The outcome of other events was not resolved.; Sender's Comments: Based on the compatible temporal association, the vaccination with BNT162B2 might play a contributory role in triggering the onset of the events flushing, dizziness, headache and migraine. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

syncope; diaphoresis; varying HR; blurred vision; This is a spontaneous report from a contactable physician (patient). A male patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), via an unspecified route of administration on 05Jan2021 as single dose for COVID - 19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced syncope, diaphoresis, varying HR (heart rate) and blurred vision in Jan2021. The patient underwent lab tests and procedures which included heart rate: varying in Jan2021. Details were as follows: Patient received the vaccine in the morning. He reported diaphoresis, syncope, varying HR, and blurred vision within 10 minutes of receiving the vaccine. He was taken to the emergency room and therapeutic measures were taken as a result of the events; he was given fluids. The patient generally tolerated vaccines and has recovered from the episode. The events, syncope, diaphoresis, varying HR (heart rate) and blurred vision recovered in Jan2021. The batch/lot number for the vaccine, BNT162B2, was not provided and will be requested during follow-up .; Sender's Comments: Based on the information available, a possible contributory role of the suspect products cannot be excluded for the reported event due to temporal association. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators as appropriate.

one of those biopsies was bleeding pretty heavy/looked at the incision/The one on his nose is still dripping blood and its coming up on 24 hours now; This is a spontaneous report from a contactable consumer (patient). A 72-year-old male patient received his first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (Batch/lot number: E70124), Intramuscular in arm on 30Dec2020 at single dose for COVID-19 vaccination. Medical history included ongoing blood pressure high and he had been treated for that for a number of years, diabetes from 2009 and ongoing, COPD (chronic obstructive pulmonary disease) issues from 2020 and ongoing and his issues began within the last year, ongoing kidney failure and this started occurring within the last 2 or 3 years, had a urostomy done, had bladder cancer and he had had phlebotomy performed around 3-4 months ago in 2020 and he knew his blood was thick at the time. There were no concomitant medications. The patient received the first vaccine on Wednesday, 30Dec2020. He had noticed something. He had a couple of things happen that basically involved a couple of skin biopsies. He had some lab work drawn for a CT scan, and he didn't clot right away on 05Jan2021. Last night 04Jan2021, he went to the emergency room because one of those biopsies was bleeding pretty heavy. He wanted to know if there is any known connection with the COVID vaccine and anti-clogging. He was going to follow up with the surgeon that did the biopsies. He stated its weird. He had had phlebotomy performed around 3-4 months ago in 2020 and he knew his blood was thick at the time. There had been 2 or 3 incidents where he was not clogging up. He clarified they were skin cancer biopsies, which was something diagnosed prior to receiving the vaccine. It was a follow-up because they didn't get it all the first time and they had to go back in. His skin biopsies were done yesterday, 04Jan2021. He verified when he went to the emergency room last night 04Jan2021 he was not admitted into the hospital. It was outpatient and they looked at the incision and put a little clotting tape (or whatever it is) on him and wrapped it up. He hadn't been bleeding. He knew the doctor nicked a vein. There were 2 biopsies done- one was on his nose. The one on his nose was still dripping blood and its

coming up on 24 hours now. The blood drawn for the CT scan was drawn early this morning 05Jan2021 around 7:30 AM. The outcome of the event was not resolved.

Followed by neurological symptoms staring day 4; parasthesias of both upper extremity; progression to muscle weakness of all four extremities/Currently with significant muscle weakness, Left hand weakness leading to dropping of objects and left foot drop; progression to muscle weakness of all four extremities/Currently with significant muscle weakness, Left hand weakness leading to dropping of objects and left foot drop; Flu like symptoms first 3 days; This is a spontaneous report from a contactable physician (patient). A 39-year-old male patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number: ek5730) at left arm, via an unspecified route of administration on 16Dec2020 at single dose for covid-19 immunisation. Medical history included hypertension, diabetes, migraines, Eosinophilic granulomatosis with polyangiitis (EGPA) remission. Prior to vaccination, the patient was not diagnosed with COVID-19. The patient did not have any allergies to medications, food, or other products. The patient's concomitant medications were not reported. On 21Dec2020, the patient experienced flu like symptoms first 3 days. Followed by neurological symptoms staring day 4, parasthesias of both upper extremity with progression to muscle weakness of all four extremities. Leading to 2 ER visits and hospital admission. Evaluation by internal medicine, neurology and rheumatology. Currently with significant muscle weakness, Left hand weakness leading to dropping of objects and left foot drop. The events resulted in Doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care, Hospitalization, Disability or permanent damage. The treatment for events included High dose steroid. Covid test included Nasal Swab: negative on 19Dec2020. The outcome of events was not recovered.; Sender's Comments: Based on temporal association, the causal relationship between bnt162b2 and the events influenza like illness, neurological symptom, paraesthesia, muscular weakness and peroneal nerve palsy cannot be excluded. The information available in this report is limited. This case will be reassessed once additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate.

tired; no energy; low back pain; her fingers are hurting; passed out on toilet; Nauseated; hit head on wall, head just hurts; hit head on wall, head just hurts; Chills; she was very cold; could not sleep good; site of vaccine was sore; Muscle pain; Joint pain; This is a spontaneous report from a contactable consumer. A 58-year-old female patient started to receive first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, Batch/lot number: EK9231) by injection once to left arm, via an unspecified route of administration on 04Jan2021 12:30 at single dose for covid-19 immunisation. Medical history included thyroid disorder. Concomitant medication included levothyroxine sodium (SYNTHROID) for thyroid disorder; patient started it after she had her son, and her son is 18 years old. The patient had her vaccine yesterday (04Jan2021) at 12:30, and at nighttime, around 22:00, she started having chills, she was very cold, so she went to bed, she could not sleep good, she kept waking up, and the site of vaccine was sore, she had muscle pain, joint pain, she didn't have fever, but she got up late

today (05Jan2021), around 11:00, and had breakfast and felt nauseated, so she stopped eating, and she went to the bathroom and passed out on the toilet, when she woke up, she had her nightgown inside the toilet, it was all wet, she felt better, so she stood up and then she woke up again, and was inside the tub, her legs were inside the basin, she was lying down with her back inside the tub, she thinks she hit her head on the wall, and it just hurts, it didn't bleed or nothing. The patient stated she had the paper she was given. Again stated she can not even function. Patient still feels Chills a little bit, not as bad as last night. She is awake now, but she feels very very tired, like she has no energy, she is laying down on couch right now. She kept waking up and noticed this morning, she had low back pain, in the muscles, even her fingers are hurting. Regarding hitting her head on the wall, states she has a terrible headache, not a little pain, she thinks it is because she hurt her head. The patient is supposed to get second vaccination on 25Jan2021. The outcome of events Chills, Joint pain and nauseated was recovering; of events site of vaccine was sore and muscle pain was not recovered; of other events was unknown.

Fainting; This is a spontaneous report from a non-contactable consumer. This consumer reported similar events for 2 patients. This is 2nd of 2 reports. A patient of unspecified age and gender received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for covid-19 immunisation. The patient medical history and concomitant medications were not reported. The patient experienced fainting on an unspecified date with outcome of unknown. The action taken in response to the event for bnt162b2 was not applicable. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021006219 same reporter/drug/event, different patient

Auditory & visual hallucinations; Auditory & visual hallucinations; tachycardia; extreme panic; confusion; felt like skin was on fire/pulsating; felt like skin was on fire/pulsating; severe pain especially at knees/hips/base of head and neck; severe pain especially at knees/hips/base of head and neck; severe pain especially at knees/hips/base of head and neck; uncontrollable vomiting; bad chills and fever; bad chills and fever; insomnia; felt as if she had been given drugs; This is Spontaneous report from a contactable Other Healthcare Professional reported for herself. This 40-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, lot number: EK9231), via an unspecified route of administration on 04Jan2021 14:30 at single dose on right arm for COVID-19 immunization. Medical history included COVID prior vaccination and latex allergy. There were no concomitant medications. No other vaccine in four weeks. The patient previously had allergic to diazepam (VALIUM), clonazepam (KLONOPIN), ondansetron (ZOFRAN) and lorazepam (ATIVAN). The patient experienced auditory & visual hallucinations, tachycardia, extreme panic, confusion, felt like skin was on fire/pulsating, severe pain especially at knees/hips/base of head and neck, uncontrollable vomiting, bad chills and fever, insomnia. She felt as if she had been given drugs. All of the events happened on 05Jan2021 01:30 and resulted in Doctor or other healthcare Recovering professional office/clinic visit. No treatment received for the events. No COVID tested post vaccination. The outcome of the events was recovering.; Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of events Auditory hallucinations and Visual hallucinations cannot be totally excluded. The case will be reassessed if additional information becomes available. The impact of

this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

rash; All over rash with some itching; This is a spontaneous report from a contactable Nurse reported for self. This 34-year-old female patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 05Jan 2021 12:50 on right arm at single dose (Lot # EK4176, Expiration Date: Mar2021) for covid-19 immunisation. Medical history was not provided. Concomitant medications were none. Past drug history included the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 15Dec2020 16:00 at age of 34 year old at single dose (Lot # EH9899) for covid-19 immunisation. About 30 minutes after being administered (05Jan2021 13:20) that second dose she developed all over rash with some itching. She took Benadryl and Pepcid in response. Today the all over rash with some itching came back at the same persistent level. She wants to know what kind of timeframe she can expect with the continued allergic reaction of all over rash with some itching. She was made to check into the emergency room for observation, but did not have any testing/lab work/investigations done and was not admitted to the hospital. Outcome of the events was not recovered. Reporter seriousness for All over rash with some itching was Medically significant. Drug result was related.; Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of events Rash and Itching cannot be totally excluded. The case will be reassessed if additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Chills with no fever; Cramping in legs; super tired with no energy; Body aches; tiredness/Feeling super tired with no energy; This is a spontaneous report from a contactable consumer. This consumer (patient) reported for self that the 45-year-old female patient who receive first dose of bnt162b2 (BNT162B2, PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EH9899), via an unspecified route of administration on Saturday (02Jan2021) at single dose (once by injection in the right arm) for covid-19 immunisation. Medical history included ongoing Hypothyroidism from 2008. Concomitant medications included levothyroxine at 75 ug ongoing from 2008 for Hypothyroidism. Medical Professional and told by her work that she could get it because contact with COVID patients. The consumer calls for information about if the side effects she is experiencing after the administration of the COVID-19 vaccine will last for more days. The consumer reported tiredness and other side effects to DSU. A Consumer calls for information about if it would be appropriate the second dose of the COVID-19 vaccine is not administered considering that she had adverse reactions. Consumer calls for information about if the second dose of the COVID-19 vaccine would cause her more side effects than the first one. Received the vaccine on Saturday, 02Jan2021. The day she got it she did not feel anything at all. She was completely fine. She did not even have pain at the injection site. The next day, on Sunday she started

feeling super tired with no energy, had body aches, and cramping in legs from 03Jan2021. She has had these for the past 3 days now. She also had chills with no fever from 03Jan2021 to 05Jan2021. She took Tylenol for the first 2 days, but it did not help her at all. She is feeling a little better today, but not much. Her question is, how long will these side effects last? Tylenol: She says it did help a little bit. She think she would just sleep because she was uncomfortable. The Tylenol just did not make her symptoms go away completely. LOT/Batch: AA46487, EXP: Apr2022 UPC: The consumer says the number under the barcode is: 5187536. Feeling super tired and body aches: Has improved about 20%. She says these are all medically significant as she is not able to do what she was able to do before getting the vaccine. She is super tired with no energy and she is confined to her bed most of the time. The consumer confirms this is her first dose of the COVID Vaccine. She thinks she got the standard dose. Vaccine card does not have the expiration date or NDC written on it. Unknown causality. She said that she could be positive for COVID. She is unsure. The outcome of the event Chills with no fever was recovered. The outcome of the event Cramping in legs was not recovered. The outcome of the other events was recovering.; Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of reported events cannot be totally excluded. The case will be reassessed if additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

I was in a low disease state of SLE, 2 days after injection i had a severe flare of lupus requiring steroids; This is a spontaneous report from a contactable other Hcp (patient). This 36-years-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (lot number: EH9899), intramuscularly on 16Dec2020 13:30 at single dose in Arm left for COVID-19 immunisation. Facility where the most recent COVID-19 vaccine was administered was Hospital. Medical history included systemic lupus erythematosus (SLE) and in remission. No Pregnant at the time of vaccination. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient did not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19.Concomitant medication received within 2 weeks of vaccination included hydroxychloroquine, topiramate (TROKENDI), prucalopride succinate (MOTEGRITY). The patient was in a low disease state of SLE, 2 days after injection and had a severe flare of lupus requiring steroids on 18Dec2020. The adverse event result in Doctor or other healthcare professional office/clinic visit. Steroids received as treatment. The outcome was recovering. The events were assessed as non-serious; Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of event Systemic lupus erythematosus syndrome aggravated cannot be totally excluded. The case will be reassessed if additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this

review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

experiencing an allergic reaction; Hives all over her face and neck/hives on face and neck; This is a spontaneous report from a contactable Physician (patient). A 30-years-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (lot number: EL0140, Expiry Date: 31Mar2021) via an unspecified route of administration in left upper arm on 31Dec2020 13:25 at single dose for COVID-19 immunisation. Medical history included crohn's disease from Jul2005 and ongoing, ongoing psoriasis, gastrooesophageal reflux disease (GERD), hand tremor. Concomitant medication included ongoing infliximab (REMICADE) for Crohn's, ongoing esomeprazole sodium (NEXIUM) for GERD, ongoing propranolol for hand tremor, copatsol topical steroid for Psoriasis, ongoing Multivitamin, ongoing vitamin B complex (B COMPLEX), ongoing biotin, ongoing iron, ongoing Calcium/Vitamin D, ongoing curcuma longa (TURMERIC). The patient had an allergic reaction after getting the COVID vaccine. She had an allergic reaction after getting the vaccine. She had hives all over her face and neck. She already had a Medrol Dose Pack at home and some Benadryl. She contacted her doctor who prescribed an Epi Pen for her, but she did not have to use the Epi Pen. She stated she used the Benadryl for three days. She started to get hives all over her face and neck the same date she got the vaccine. It started 2 hours after she got the vaccine (31Dec2020 15:25). She confirmed this was the first dose of the COVID Vaccine. She asked that if it is safe to take the second dose after experiencing an allergic reaction to the first dose. Symptoms include hives on face and neck. Patient had no trouble breathing. Took steroids and Benadryl for 3 days or until symptoms have been managed. No any of the events require a visit to emergency room. Reporter seriousness for hives all over her face and neck was reported as medically significant. Events outcome was recovered on 03Jan2021.; Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of events Allergic reaction and Hives cannot be totally excluded. The case will be reassessed if additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

blasting headaches; chills all night; dry heaving all night; Nausea; no fever but her skin felt hot; sore left arm; This is a spontaneous report from a contactable nurse for herself. This 64-year-old female patient started to receive BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), intramuscular on 18Dec2020 at single dose on left upper arm (lot: EKS730), via an unspecified route of administration on 05Jan2021 14:30 at single dose (lot: EL1284 or EKI284) for COVID-19 immunisation. Medical history and concomitant medications were none. The patient did not have anything with the first shot except a sore left arm on 18Dec2020. She stated that if she lays on left side it is sore. The patient had the sore left arm both times that she got the vaccine. She got second dose of vaccine on 05Jan2021 at 2:30pm and had a blasting headache and just had chills that went away about hour ago on 05Jan2021. She did not have a fever but her skin felt hot on 05Jan2021. She stated that she had dry heaves on 05Jan2021. The patient started that she had a blasting headache within a few hours of the vaccine and it gradually got worst by

the time she went to bed. Stated that the chills and dry heaves started then and throughout the night. The chills stopped an hour before she got up. Stated that she went to check her temperature and did not have a fever despite having chills and her skin feeling hot. Stated that nausea started about 10 at night on 05Jan2021. Seriousness for blasting headache, chills and dry heaves was disabling, for nausea was medically significant, for other events was non-serious. The patient took Ibuprofen for the headache. Stated that she was going to try to drink something. The outcome of sore left arm was not recovered; of chills was recovered on 06Jan2021. The outcome of other events was recovering. The causality for blasting headache, chills, dry heaves, nausea and skin felt hot was related (Source of assessment: Primary Source Reporter, Method of assessment: Agency Information on the batch number has been requested.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the headache, chills, dry heaves and other reported events due to temporal relationship. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

severe muscle pain, diagnosis of polymyalgia rheumatica; This is a spontaneous report from a contactable other HCP (patient). A 53-year-old female patient received the first dose of BNT162b2 (Lot/batch number and Expiration date were not provided), at the age of 53-year-old, via an unspecified route of administration at right arm on 18Dec2020 08:30 at single dose for covid-19 immunization. Medical history included hypertension (htn), allergies: penicillin. Concomitant medication included cefatrizine propyleneglycolate (CEFTIN), lisinopril, levothyroxine sodium (SYNTHROID). The patient experienced severe muscle pain, diagnosis of polymyalgia rheumatica on an unspecified date. The patient was not pregnant at the time of vaccination. The patient underwent lab tests and procedures which included COVID test rapid (Nasal Swab): negative on 06Jan2021. The outcome of the event was unknown. Information on the lot/batch number has been requested.; Sender's Comments: A possible contributory effect of suspect drug BNT162B2 on reported event cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

shaking; weak; cough; shortness of breath; very ill/ sick; horrible chills; I had a 103 degree fever for 4 days, horrible chills that were just debilitating; ached everywhere/ severe aches; site soreness; This is a spontaneous report from a contactable nurse (patient). A 62-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EH9899) via an unspecified route of administration at left upper arm on 18Dec2020 at single dose for COVID-19 immunization. Medical history included auto immune problems, diabetes, thyroid condition, all ongoing since age 28;

pemphigusvulgarism since Sep2020 and ongoing. No concomitant medications. Patient is a frontline worker. She received the vaccine on 18Dec2020 at (Name) where she works. 9 days later she got very ill. she didn't know if it's unrelated. She wanted to know if there is anything she need to be watching out for in order to get her second vaccine on Friday. She was so sick and she did have some autoimmune problems. She was really healthy. On 26Dec2020, she had a 103 degree fever for 4 days, horrible chills that were just debilitating. She was just shaking. She ached everywhere, she had severe aches since 26Dec2020. She got tested for Covid and it was negative on 28Dec2020, she had no cough and no vomit. She stayed in bed and drank lots of fluids and toughed it out. By New Year's Day (reported as 30Dec2020) her fever broke but she was so weak and didn't work. She was back at work now. Also, she experienced site soreness from the injection since 19Dec2020. She did have a cough or any shortness of breath. She felt awful. She had recovered. She was just a little nervous because everything she read said the reaction was more severe with second injection. She planned on getting the second shot. She would have a repeat Covid test on 07Jan2020. Reporter seriousness for fever 103: Medically significant. Reporter seriousness for severe aches: Medically significant. Reporter considered the causality of the event site soreness was related with bnt162b2, of the events fever 103 and severe aches was unknown. The outcome of the event fever was recovered on 30Dec2020, of event ache was recovered on 31Dec2020, of event chills was recovering, of event vaccination site pain was recovered on an unspecified date in Dec2020, of events cough and shortness of breath was recovered on an unspecified date.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the fever, pain and other reported events due to temporal relationship. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

(doctor) was not sure whether or not he might get a staph infection, a viral infection; (doctor) was not sure whether or not he might get a staph infection, a viral infection; thought he had a mosquito bite; area on the opposite side of his body, on the left hand side, he noticed that there were several small pustules; the area was raised, it was red, it was warm; Pain; extremely uncomfortable; It was very, very itchy and the area felt like it got itself swollen; It was very, very itchy and the area felt like it got itself swollen; irritation; Initially an area under his left arm which was very swollen it appeared to be filled with fluid of some type/thought it was edema/now had it under his right arm, it's probably impacting lymph system; This is a spontaneous report from a contactable consumer (patient wife). A male patient of an unspecified age started to receive bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number: EH9899, expiration date not reported), via an unspecified route of administration on 03Jan2020 16:00, at a single dose for Covid-19 immunization. Medical history included heart bypass 15 years ago and some orthopedic problems. The patient's concomitant medications were not reported. The patient previously took codeine and epinephrine experienced sensitivity. On 03Jan2020, the patient

had an injection the Pfizer vaccine in county (not clarified further) (place name withheld) which is the (place name withheld) area on Sunday at approximately 4:00 PM EST. He has no significant medical problems other than the prior history of, he had heart bypass 15 years ago and some orthopedic problems, but nothing else other than that. She had never had any adverse reactions to any medications although he has, he shouldn't say, he does have a sensitivity to Codeine which he reported and Epinephrine which he had a sensitivity to also. He got the vaccine after waiting three and half hours in line and they went off, last night that would be Sunday night, several hours later he noticed an odd sensation and did not really take a look at it, he thought he had a mosquito bite perhaps as they live in (place name withheld) and they live in the land that has lots of mosquito, so he didn't pay too much attention to it. Approximately four hours after the injection, he was going to go to bed and removed his shirt and found that the area on the opposite side of his body, on the left hand side he noticed that there were several small pustules, the area was raised it was red it was warm, it was on the opposite side under his arm on his chest he was extremely uncomfortable. It was very, very itchy and the area felt like it got itself swollen and he shared with his wife, the wife suggested that he contact the physician of course he didn't contact, his primary physician said he can see a dermatologist and sent images and yesterday he went to see a dermatologist, so prophylactically he took the 25 mg of diphenhydramine hydrochloride (BENADRYL) and also 2 acetaminophen (EXTRA STRENGTH TYLENOL) and he treated the pain and itching with ice. He slept with an ice bag and woke up just in morning and in New Year they were able to see a dermatologist, he thought it was dermatological. He was concerned but not overly concerned with the area pretty swollen. He saw a dermatologist yesterday, and gave him a topical treatment, the dermatologist gave him three different, naproxene (NAPROSYN), the other one is Triamcinolone Acetonide cream now the irritation he got the MUPIROCIN ointment now as the dermatoligist told him to do, continue what he was doing as he was comfortable, The dermatologist took some specimens from the pustules and send them to lab and she (doctor) is not sure whether or not he might get a staph infection, a viral infection he was not sure. Initially there was an area under his left arm which is very swollen it appeared to be filled with fluid of some type, he was not sure what was it. He thought it was edema but when he popped it, it felt very much like fluid not like blood but it is some type of fluid filled area most likely his wife said the size are greater and less that it was yesterday and that seems to go down over the last night but not all the way it's decreased by what 20%, 30%, 40% he can't tell, alright 50% but now he has it under under right arm, it's probably impacting his lymph system and he put a call into his cardiologist. So he was asking now what does he do. The outcome of the events were unknown.

Her arm is a little sore; the tissue paper is red after wiping her anal area/ reddish looking poop/ there are pieces of blood or something is different; This is a spontaneous report from a contactable other Health Professional (patient). A 75-year-old female patient receive BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EL0142), via an unspecified route of administration on 05Jan2021 at single dose for covid-19 immunization, also reported as for work. Medical history included ulcer (15 to 20 years before 06Jan2021). Concomitant medication included prasugrel from Apr2020 and ongoing as blood thinner, acetylsalicylic acid, ascorbic acid (ASPIRIN) from Apr2020 and ongoing as blood thinner. The patient went to the bathroom in the morning 06Jan2021, she had to poop. When she wiped, it was reddish looking. The patient stated her stool color was normal, but the tissue paper is red after wiping

her anal area. At first she thought hm oh well. Then she had been to the bathroom a couple of times 06Jan2021, and that the same thing happened. She had never experienced that before. It seems to her that there were pieces of blood or something was different. She wasn't hurting or anything. She was not weak or anything at this time. Her arm was a little sore, but she expected that. She was concerned about the color. She worked in the mammography department. She didn't have a prescribing doctor. She got it at work. She had noticed a difference of color in her poop. It had been the same all day. The outcome of the reddish poop was not recovered, of sore arm was unknown. The patient asked would the vaccine cause rectal blood upon wiping after defecation?; Sender's Comments: Reported blood in stool is considered intercurrent and unrelated to BNT162B2. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

The subject experienced acute pericarditis on 27Dec2020; Other vaccine same date vaccine date= 23Dec2020; This is a spontaneous report from a contactable consumer. A 50-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 23Dec2020 at single dose for covid-19 immunization. The facility type vaccine was hospital. None medical history. The patient's concomitant medications were not reported. Other vaccine same date vaccine date on 23Dec2020. The patient experienced acute pericarditis on 27dec2020 with outcome of recovered. The adverse event resulted in Doctor or other healthcare professional office/clinic visit. It's unknown if treatment was received for the adverse event. The event was reported as non-serious. Pfizer is a marketing authorization holder of [BNT162B2] in the country of incidence or the country where the product was purchased (if different). This may be a duplicate report if another marketing authorization holder of [BNT162B2] has submitted the same report to the regulatory authorities. Information on the lot/batch number has been requested.

Joint pain /felt like it was worsening joint pain; just severe pain to where she couldn't walk; This is a spontaneous report from a contactable Other HCP. A 70-year-old female patient received BNT162B2(Lot Number: ET1685), via an unspecified route of administration at Deltoid Left on 23Dec2020 08:00 at the 70 years old at single dose for COVID-19 immunization. The medical history included rheumatoid arthritis. The concomitant medications were none. The patient received the shot on 23Dec2020 and experienced Joint pain afterward on 02Jan2021. The patient did have rheumatoid arthritis so there was that. The patient felt like it was worsening joint pain on 02Jan2021. She has had no fever, just severe pain to where she couldn't walk on 02Jan2021. The joint pain has gotten worse and it has gotten to where she is going to advise her not to take the second shot. The Reporter assessed the seriousness for the events was Disabling. The events did not require a visit to Emergency Room but required a Physician Office visit on 06Jan2021. The patient received a steroid injection on 06Jan2021. There was none History of all previous immunization with the Pfizer vaccine considered as suspect. There was none Additional Vaccines Administered on Same Date of the Pfizer Suspect. There was no Prior Vaccinations within 4 weeks. The patient underwent lab tests and procedures, which included x-rays on 06Jan2021: unknown results (they were awaiting the X-rays). The outcome of the events was not recovered. The information

on the batch number has been requested.; Sender's Comments: Based on the available information the events worsening joint pain and walking difficulty are attributed to underlying Rheumatoid arthritis; however, based on a compatible temporal association, contributory role of BNT162B2 vaccine to events occurrence cannot be completely excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

it was debilitating for her at work; It even hurts to move the right eye in one direction and hurts to speak, the pain was so bad.; pain in right leg and bottom sole of right foot; hurts to speak; numbness right upper side of lip; pins and needle feeling right upper quadrant of face; pain and dull aching right upper side of face; right hand numbness, wasn't able to feel anything; generalized headache; generalized muscle weakness and pain; generalized muscle weakness and pain; This is a spontaneous report from a contactable other hcp (patient). A 31-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 03Jan2021 at single dose in deltoid right for covid-19 immunization. There were no medical history or concomitant medications. The patient received the vaccine on 03Jan2021 and within 15 minutes had a generalized headache. Later that night she had generalized muscle weakness and pain, but really didn't think too much about it. The next day at work (04Jan2021), she had numbness on the right upper side of her lip and a pins and needle feeling in the right upper quadrant of the face. Had a lot of pain in the area as well on the right upper side of the face as well as a dull aching pain that lasted for hours. Later that day when using the computer and she was trying to reach for her mouse she noticed her right hand wasn't able to feel anything and that lasted about 20-25 minutes. Kept slapping the mouse with her hand, but could not feel anything, her hand went numb. Yesterday (05Jan2021), she had the same pins and needle feeling in the same area of the face and that dull achy feeling and it occurred for hours and it was very kind of debilitating for her at work. Later that night she had pain in her right leg and felt the same way, that very severe achiness, which was the pins and needles feeling up and down the leg and underneath the right foot. All these symptoms tend to be on her right side and it definitely lasted for hours. It started about 1 and didn't end until 6-7pm. It even hurts to move the right eye in one direction and hurts to speak, the pain was so bad. This morning (06Jan2021) she had to call out of work because at 3am the generalized headache, pain was unbearable. She was still experiencing the pain in right leg and bottom sole of right foot. She did not receive any vaccines the same day or 4 weeks prior. No problems with vaccines in past. She had made an appointment with a neurologist and will have a MRI done on Friday, 08Jan2021. No further details provided. All events required a visit to physician office. All events were reported as serious per medically significant. The outcome of all events was not resolved. The reporter considered all events were related to the vaccine. Information about Lot/Batch number has been requested.; Sender's Comments: Based on a compatible temporal relationship, causality between reported events and BNT162B2 vaccine cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as

well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

soreness/The pain radiates down to her left elbow and also goes up the neck; The pain radiates down to her left elbow and also goes up the neck; The pain radiates down to her left elbow and also goes up the neck; This is a spontaneous report from contactable other HCP (patient' husband). A 43-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number EK9231), via an unspecified route of administration on 31Dec2020 at single dose for COVID-19 immunization. Medical history reported as none. No concomitant medications. The patient had a whole lot of soreness on 01Jan2021 and it was not getting any better. His wife had called her health care provider. She had an appointment in several days. The pain radiates down to her left elbow and also goes up the neck in Jan2021. The reporter seriousness for soreness: Medically significant. The outcome of event pain was not recovered. The outcome of rest events was unknown.; Sender's Comments: Based on a compatible temporal relationship, causality between event pain and BNT162B2 vaccine cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

She is having an allergic reaction; Itching was reported as worsened/Swelling was reported as worsened/loss of appetite was reported as worsened; From the time she got the vaccine to now, she has lost 20 lbs; shake/shaking; swelling in the lips, throat, and eye lids; swelling in the lips, throat, and eye lids; swelling in the lips, throat, and eye lids; She has been sick since Wednesday; itching all over from head to toe; loss of appetite; This is a spontaneous report from a contactable consumer (patient). A 59-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration at left arm on 30Dec2020 at single dose for COVID-19 immunization. Medical history included hypertension and allergic to ace inhibitors. There were no concomitant medications. Patient was calling about the Covid Vaccine. She was having an allergic reaction. She did not know what to do to stop it. She went to the ER yesterday (04Jan2021). She had been sick since Wednesday (30Dec2020), she was itching all over from head to toe since 30Dec2020, she got a prescription for Prednisone, she took 2 doses yesterday, 1 dose today, and would take another this evening. She took Benadryl, an hour ago and had an episode, and so she had to jump in the shower and let the cold water run to stop itching, the itching did not stop but it has minimized. She put Benadryl gel and she was still itching, she had taken enough Benadryl. Patient asked what is the best way and if she needed an IV of something, she went to ER on Sunday, she was not seen by doctor, it was a nurse practitioner, she didn't do anything but just listen to her and she only looked at ankles to check for swelling. Patient stated that she had been drinking water and urinating, she had no appetite and lost 20 lbs. Patient confirmed that she got her first dose of the Covid vaccine on 30Dec2020 at 1 o clock, the itching started the same day at 5 o clock, the itching was from head to toe. She experienced swelling in the lips, throat, and eye lids, which started 02Jan2021. She began losing her appetite on 30Dec2020. From the time she got the vaccine to now (05Jan2021), she has lost 20 lbs. An hour ago (05Jan2020) she had an episode, which made her shake, and she did not have the shakes before, this was the first date

she started shaking. Itching was reported as worsened/Swelling was reported as worsened/loss of appetite was reported as worsened. Her 2nd dose was scheduled in 21 Days. However, she may not get the second dose, patient stated that she could not get through this no more. She had no positive test for Covid prior to vaccine. She had no antibody test prior to the vaccine. She had not any issues with vaccines in the past. Patient stated that if she was still feeling this way, she would go to a different hospital. When she went to the ER, she was not hospitalized, they sent her back home the same day. Patient would like to know if there was anything that can remove the vaccine from the body. The outcome of the events itching all over from head to toe, loss of appetite, swelling in the lips, throat, and eye lids was not recovered, of the other events was unknown. Information about lot/batch number has been requested.

Acute demyelinating encephalomyelitis; Slurring his speech; Stroke; This is a spontaneous report from a contactable physician. A 35-year-old male patient received first dose bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), intramuscular in deltoid (unknown if right or left) on 17Dec2020 at 30 ug, single for 'Preventative'. Medical history included hypertension. There were no concomitant medications.(Physician) He is calling about the Pfizer Covid 19 vaccine. States what is going on with the patient may be associated as a side effect. The patient got the vaccine two to three weeks ago, he clarifies the patient received the vaccine on 17Dec2020 and the patient ended up acutely developing (states it is a presumptive diagnosis) Acute demyelinating encephalomyelitis, states it looks like a radiologic diagnosis. The patient is an employee at hospital. When querying seriousness states it is medically significant but could be disabling but he thinks the patient will recover. Reporter seriousness for acute demyelinating encephalomyelitis: Medically significant, Hospitalization. Patient was hospitalized on Sunday and he is still admitted at this time. Dates when patient was in hospital for acute demyelinating encephalomyelitis was from 03Jan2021 to ongoing. Caller thinks the patient was flown to (Place) yesterday. The patient's mother asked the caller if the caller thought the acute demyelinating encephalomyelitis was from the vaccine and the caller responded that he did not think it was from the vaccine. He confirms the patient is still admitted in the hospital and the patient's attending neurologist is doctor. The caller heard about the patient from doctor. When querying covid vaccine dose, the caller states the standard dose is 30 mcg. This was clarified and documented as provided. The patient has not received his second dose yet. He asks if the patient should receive the second dose. He asks a general question if a pregnant patient can be given the Pfizer covid vaccine. He heard the patient had a stroke then the CFO tried to talk to him and the patient was slurring his speech. Caller spoke to the patient's mother this morning and caller told the mother that he would try to find out what is going on with the patient. He asked that the patient get an HIV test even though he does not think the patient is at risk. Vaccination facility type was Hospital. Vaccine administered at military facility was No. None additional vaccines administered on same date of the PFIZER suspect. AE acute demyelinating encephalomyelitis require a visit to Emergency Room, not visit to physician office. Prior Vaccinations (within 4 weeks) was none. He has heard of acute demyelinating encephalomyelitis being associated with vaccines in the past and states that it is rare and usually in kids. States he saw patients that may have had acute demyelinating encephalomyelitis back in the 80s and 90s. Therapeutic measures were taken as a result of acute demyelinating encephalomyelitis (Patient will get steroids tonight pending the review of the x-ray). The outcome of the events was unknown. Information on the lot/batch number has been

requested.; Sender's Comments: The reported stroke with speech slurred, and the presumptive diagnosis of acute demyelinating encephalomyelitis (looks like a radiologic diagnosis by the reporting physician), was most likely an intercurrent disease, and unlikely causally related to the first dose bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE). The case will be reassessed should additional information become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

"her nerve was bad; Getting all sick, cold, sick and experiencing terrible side effects; Getting all sick, cold, sick and experiencing terrible side effects; Fatigue; Muscle ache; Nauseous; Felt awful; Can't eat all the day, no appetite; phobic something to drinking water; This is a spontaneous report from a contactable consumer (patient). A 49-year-old female patient received bnt162b2 (lot/batch number and expiration date not provided), via an unspecified route of administration, on an unspecified date, at single dose, for COVID-19 immunization. No relevant medical history. The patient's concomitant medications were not reported. The patient experienced getting all sick, cold, sick and experiencing terrible side effects, fatigue, muscle ache, nauseous, cannot do anything, felt awful, cannot eat all the day, no appetite, phobic something to drinking water. The patient has been sick for three days now. The patient was a ""senior"" (not clarified) care giver at the nursing home. Everybody at nursing home at the nursing home got the shot and now everybody has cold and sick. She has only one day of work and she has to come into her job to take care of elderly people. As since current everybody is experiencing the terrible adverse, terrible side effects, everything. Fatigue, muscle ache everything. The bosses at her nursing home cannot give them three days or even seven days off of work after receiving a contract to give them shot. It was confirmed that the patient received the COVID vaccine. The patient also stated that they are off of that side effects. They are not interrupted not just the ""arm"" (not clarified) been there. The patient said she getting everything. She was getting all the side effects. So when they had this Pfizer drug shot ""they didn't get seven days off of"" (not clarified) work. If a person gets a shot, they are feeling fatigue, nauseous (incomprehensible voice). They can't do anything. They should be allowed to stay home from work. Right now everybody in the nursing home is feeling the adverse effect. The entire building. So, she was telling Pfizer to report the report is that all of sudden that the nursing home ""seniors"" (not clarified) and nurses they got the shot, they can't even get to work. The effects are so bad that they can't do anything. The patient also stated that fatigue, she had fatigue all day. The first day she got the shot her nerve was bad but the second day was everything fatigue. She felt awful, she could not eat, she had no appetite. She was phobic something to drinking water, she cannot eat all the day. ""Fruit or something 5 I can eat"" (incomprehensible voice)."" When probed for the LOT#, the reporter stated, ""No they did not give me anything. All they did is I think 037 I think it looks like a 'K' 20A. (further not clarified) like it says (further not clarified) 037K20A that's (further not clarified)."" The outcome of the events was unknown. Information on lot number/batch number was requested."

aware of 6 cases of Bell's Palsy by the companies making these vaccines; This is a spontaneous report from contactable Other HCP. This Other HCP reported same events for 6 patients. This report is for 2nd

of 6 patients. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for covid-19 immunization. The patient medical history and concomitant medications were not reported. The other HCP was aware of 6 cases of Bell's Palsy by the companies making these vaccines since an unknown date. The event was reported as non-serious. The event outcome was unknown. Information about lot/batch number has been requested.; Sender's Comments: Based on a compatible temporal relationship, causality between event Bell's Palsy and BNT162B2 vaccine cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.,Linked Report(s) : US-PFIZER INC-2021007605 same reporter, same drug, same event, different patients.

aware of 6 cases of Bell's Palsy by the companies making these vaccines; This is a spontaneous report from a contactable other HCP. This Other HCP reported similar events for 6 patients. This report is for 3rd of 6 patient. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at SINGLE DOSE for covid-19 immunization. The patient medical history and concomitant medications were not reported. The reporter reported since the use of modified RNA in covid vaccines, he/she had aware of 6 cases of Bell's Palsy by the companies making these vaccines since an unknown date. The outcome of the event was unknown. Information about batch/lot number has been requested.; Sender's Comments: Based on a compatible temporal relationship, causality between event Bell's Palsy and BNT162B2 vaccine cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.,Linked Report(s) : US-PFIZER INC-2021007605 Different patient, same drug/event.

aware of 6 cases of Bell's Palsy by the companies making these vaccines; This is Spontaneous report from a contactable Other HCP. This Other HCP reported similar events for 6 patients. This is 4th of six reports. A patient of unspecified age and gender received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot/batch number and expiration date not provided), via an unspecified route of administration on an unspecified date at single dose for covid-19 immunization. The patient medical history and concomitant medications were not reported. The reporter reported since the use of modified RNA in covid vaccines, he/she had aware of 6 cases of Bell's Palsy by the companies making these vaccines since an unknown date. The outcome of the event was unknown. Information on the Lot/batch number has been requested.; Sender's Comments: Based on a compatible temporal relationship, causality between event Bell's Palsy and BNT162B2 vaccine cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly

notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.,Linked Report(s) : US-PFIZER INC-2021007605 same reporter, same drug, same event, different patient

aware of 6 cases of Bell's Palsy by the companies making these vaccines; This is a spontaneous report from a contactable other health professional (HCP). This other HCP reported similar events for 6 patients. This is the 5th of 6 patient. A patient of unspecified age and gender received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot/batch number and expiration date not provided), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The reporter reported since the use of modified RNA in covid vaccines, he/she had aware of 6 cases of Bell's Palsy by the companies making these vaccines since an unknown date. The outcome of the event was unknown. Information about batch/lot number has been requested.; Sender's Comments: Based on temporal association, the causal relationship between bnt162b2 and the event facial paralysis cannot be excluded. The information available in this report is limited and does not allow a medically meaningful assessment. This case will be reassessed once additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate.,Linked Report(s) : US-PFIZER INC-2021007605 Different patient, same drug/event.

"Looked like an encephalopathy; Face was all swollen; Head swelled; Glands swelled; Fatigue; Headache/ So much pain in my head; Couldn't talk; Complete brain fog; nausea; This is a spontaneous report from a contactable nurse. This 60-year-old female nurse (Patient) reported that received bnt162b2 (BNT162B2, Pfizer COVID-19 vaccine), via an unspecified route of administration on 30Dec2020 at single dose for covid-19 immunisation. Medical history included Atrial fibrillation, Chronic Lyme, Lupus and Autoimmune. Concomitant medications included Metoprolol at 12.5 mg for Atrial fibrillation and acetylsalicylic acid (BABY ASPIRIN). No diabetes, no hypertension. None of the usual common diseases. Registered Nurse stated, ""I received vaccine this past Wednesday. I was just talking to a couple of my colleagues and honestly I received the vac. at work. I did not really read through the paperwork and was 'weird' sharing reactions to the vaccine which for me was pretty bad reaction and thought like I need to go through your paperwork and report it. So I thought I should call and just give some information. The usual fatigue which I go to after being normal, my arm was not sore. However, as the week progressed into Friday I had a constant headache but it was manageable and then by Friday night my glands swelled, my nerves behind my ears, my neck and I was extremely fatigued, bad headache and went to bed and I had not gone out and finally I got out today I spoke with my Physician yesterday. What happened it looked like an encephalopathy but my head swelled, my face was all swollen, complete brain fog, fatigue and I couldn't talk. I was in so much pain in my head resulting in (incomplete sentence)."" Lab work included the only thing is the PCR swabbing. No blood test. Registered Nurse further stated, ""I don't know if that is important. But I will tell you and if it is you can send me the questions. I do have a history of Autoimmune. So my Physician thought that this was just like an enhancement of like my bodies reaction I have Chronic Lyme and I have lupus like my ANA has

always been stressful. But we think that it is a family thing. No treatment for the Lyme. I did a lot of antibiotic and a lot of naturopathic stuff but that is in the past. But anyhow for anything else what I did was when I got the injection they said try and just take Tylenol not Ibuprofen but there was no way I was going to make it through with just that . So I took Ibuprofen. I called my Physician yesterday morning because I was not sure about what was is happening and I thought it might be secondary sinus infection or something else going on and it reassured me that it is definitely due to the vaccine. He said it is just your body's reaction, take the Ibuprofen, hydrate. Had me take what I had in my house Tigan for nausea. So I was extremely nauseous from the severity of the headache."" Registered Nurse stated, ""I just wanted to let you know what happened and the intensity of what it was because normally I would expect a headache. But this was a 'go dated'. Registered Nurse stated, ""I guess the only question that I have is so do my work has this question and I was going to call my doctor tomorrow may be might know it better. I know that I have to take the second dose. But I understand the second round can be worse than the first. Is there anything that they are recommending that I can do may be prior to ease the reaction?"" The outcome of the events was unknown. Information on the Lot/Batch number has been requested.; Sender's Comments: The reported clinical manifestations including swelling face and head swelled, which was suspected as encephalopathy by the reporting nurse, was probably related to the bnt162b2 (BNT162B2, Pfizer COVID-19 vaccine), due to temporal relationship. The subject's underlying Chronic Lyme, Lupus and Autoimmune were likely the risk factors to the onset of the events. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory authorities, Ethics committees and Investigators, as appropriate."

"Swollen lymph nodes; blood pressure was 90/50; Chills; body aches; Fatigue; Joint pain; Bone pain; Headache; Swelling, pain, redness and soreness at the injection site; Swelling, pain, redness and soreness at the injection site; Swelling, pain, redness and soreness at the injection site; Tachycardia / heart rate was 144-152; painful to breath and she was grunting; also said that the injection site itched a little bit.; Fever; First dose on 17Dec2020, second does on 04Jan2021; This is a spontaneous report from a contactable nurse reporting for herself. A 35-year-old female patient received the first single dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) ((lot number was unknown) intramuscularly on 17Dec2020 at 0.3ml, and the second single dose (lot number EJ1685) intramuscularly on 04Jan2021 07:45 at 0.3ml, for COVID-19 prophylaxis. Medical history included ongoing diabetes. Her diabetes was diagnosed about 6 months ago (reported on 06Jan2021) and was well controlled. Her glucose was at 140 at the ER (emergency room) even after drinking a drink that had sugar in it. The patient's concomitant medications were not reported. The patient received the second dose on 04Jan2021 at 07:45 and experienced a severe reaction hours after she received it, and she ended up having to go the ER and that they were baffled about what happened. She reported her symptoms were: fatigue, joint pain mainly in her knees, bone pain that did not feel like muscle pain, headache, swollen lymph nodes in the left axilla, and swelling, redness, pain, and soreness in the left arm at the injection site and also said that the injection site itched a little bit. Her symptoms started about 9-10 at night on 04Jan2021. She said that she felt like with the second dose she noticed the soreness and pain and redness at injection site after about 2 hours after receiving the second dose, which was sooner than with the first injection.

The fever started with the chills and body aches. The chills and body aches started at 22:00 on 04Jan2021. She took acetaminophen and melatonin to try and sleep it off. Fever was after that at around midnight 04Jan2021 and she was burning in fever and her temperature was 104. She stated she started taking layers off and got out from under her covers. She had a sweater on when she took her temperature and her axillary temperature was 105. She said that she got into a hot shower because that was the only thing that provided comfort to her chills. She had not had any chills in about the last 12 hours though (as reported on 06Jan2021). She said that the body aches were so severe that she just sat in her bed and cried. She had tachycardia and she was grunting in pain. She was rotating ibuprofen and acetaminophen and then her fever was not as high. She stated that if her fever came back it was lower each time, and if she did not take the medications though, the bone pain was excruciating. She said that with the bone pain it was like no-one can hold her hand or hug her. Fatigue started at around midnight 04Jan2021. Her headache was at midnight. She felt like she had a headband on and was radiating down the back of her neck. She noticed the lymph nodes were swollen after she went to the ER at around 07:00-08:00 05Jan2021. She was walking with pillow under her arm, and if she moved or lifted her arm it hurt. She went to the ER at 01:00 05Jan2021. Her blood pressure was 90/50, her heart rate was 144-152 at rest, temperature was 102.8, O2 saturation was 95-96. She said that it was painful to breath and she was grunting, but did not have any breathing issues. The nurse thought she was septic and notified the doctor. The nurse and the doctor did not think it was the vaccine and thought that she was COVID-19 positive. But after they tested her, she was negative for flu and COVID and they were baffled. They were unclear on what happened and did not think it was from the vaccine. They bolused her 1 liter of Normal Saline and gave her a dose of Fentanyl that minimally helped with the bone pain. She was also given 30mg of ketorolac (TORADOL) IV (intravenous) and that significantly improved her pain. She was there a total of 3 hours. She was admitted to the back area of the ER. She said that they drew labs and everything was within normal limits. Her CRP (C-reactive protein) was 30 and her lactate was at 1.5. She said that they told her that she was most likely having an immune response to the vaccine. Her heart rate and blood pressure came to a more normal range and everything returned to baseline. Her heart rate was 109. She was told to rotate paracetamol (TYLENOL) and ibuprofen for at least the next 24 hours and hydrate. The events fever, chills, fatigue, joint pain, bone pain, headache, swollen lymph nodes, and swelling, pain, redness and soreness at the injection site were serious due to hospitalization from 05Jan2021 to 05Jan2021. The patient was recovering from fever, chills, joint pain, headache, heart rate and blood pressure, not recovered from fatigue, bone pain, swollen lymph nodes and swelling, pain, redness and soreness at the injection site. The event swollen lymph nodes worsened. The outcome of ""injection site itched a little bit"" was unknown. The reporter considered the events fever, chills, fatigue, joint pain, bone pain, headache, swollen lymph nodes, and swelling, pain, redness and soreness at the injection site were all related to the vaccine; Sender's Comments: Based on temporal association, the causal relationship between BNT162B2 and the events pyrexia, chills, fatigue, pain, arthralgia, bone pain, headache, lymphadenopathy, vaccination site erythema, vaccination site swelling, vaccination site pain, blood pressure decreased, tachycardia, grunting and vaccination site pruritus cannot be excluded. The information available in this report is limited and does not allow a medically meaningful assessment. This case will be reassessed once additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern

identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate."

Death; This is a spontaneous report from a contactable Physician. An elderly male patient received BNT162B2 (COVID vaccine), via an unspecified route of administration on an unspecified date in Dec2020 at single dose for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient experienced death in Jan2021. It was unknown if an autopsy was performed. It was unknown if any treatment was received for the event. It was unknown if the patient was diagnosed with COVID prior vaccination or if the patient had been tested for COVID post vaccination. Seriousness criteria for the event was reported as death and hospitalization. Pfizer is a marketing authorization holder of [COVID vaccine] in the country of incidence or the country where the product was purchased (if different). This may be a duplicate report if another marketing authorization holder of [COVID vaccine] has submitted the same report to the regulatory authorities. Information about lot/batch number has been requested.; Sender's Comments: Current information is very limited for full assessment. Further information such medical history, concomitant medications, concurrent illness and event term details especially death cause and autopsy results are needed for meaningful evaluation. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.; Reported Cause(s) of Death: Death

"The lip starting ripping and the face started itching; The lip starting ripping and the face started itching; It started spreading from the ear to the neck, it started itching bad and getting hive in that area; having trouble in breathing because it was swelling up; having trouble in breathing because it was swelling up; The lip was swelled to red and then it started to going up the jaw; The lip was swelled to red and then it started to going up the jaw; This is a spontaneous report from a contactable consumer (patient). A 64-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (Lot#: EJ1686, expiration date: Mar2021) via an unspecified route of administration on the arm right in Dec2020 at single dose for COVID-19 immunisation. Medical history included ongoing blood pressure high. Concomitant medication included lisinopril taken for blood pressure high. The patient had the BNT162B2 on Thursday morning (Dec2020) and Thursday evening the patient had a reaction to that, the lip was swelled to red and then it started to going up the jaw. So the next day it was in the jaw and in the lip and then the lip starting ripping and the face started itching and that's didn't go away and then yesterday it started spreading from the ear to the neck, it started itching bad and getting hive in that area. The patient went to the emergency room, consumer stated that she had nurse practitioner that called her on a steroid (treatment). The consumer stated, ""the thing she called her also in an Epi Pen in case she has started having trouble in breathing because it was swelling up. The patient didn't have to end up using that but she just has to use in case she has"". Treatment was received for the events. The outcome of the events was unknown."

COVID-19; COVID-19; Pneumonia; respiratory failure; This is a spontaneous report from a contactable consumer. An 80-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19

VACCINE) via an unspecified route of administration on 02Jan2021 for COVID-19 immunization. Medical history included Alzheimer's and others. No known allergies. Concomitant medications included unspecified medications. The reporter's mother in law was tested for COVID-19 at a nursing facility on 25Dec2020 and she was negative. On 02Jan2021, she received the first dose of Pfizer vaccine. On 04Jan2020, she developed a high fever, needed oxygen and was positive for COVID-19. Date of death was 04Jan2021. The cause of her death was listed as pneumonia, respiratory failure and COVID-19. No autopsy performed. No treatment received. No one knew if the vaccination contributed to her death. It was hard to know if her death was due to the administration of the vaccine or it exacerbated the COVID19 symptoms which led to her death. Since this was unknown, it could have been a possibility. The reporter wanted to give us this information because we might want to consider having high risk population, patients with underlying conditions, older population tested for COVID-19 prior to the vaccination, as this is not currently a recommendation or a requirement. All is very new and they are all learning so the reporter wanted to share this information with us. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. There are medications the patient received within 2 weeks of vaccination. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has been tested for COVID-19. The outcome of the events was fatal. Information about Lot/Batch has been requested.; Sender's Comments: The association between the fatal event lack of effect (pneumonia, respiratory failure and COVID-19) with BNT162b2 can not be fully excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.; Reported Cause(s) of Death: Pneumonia, respiratory failure and COVID-19; Pneumonia, respiratory failure and COVID-19; Pneumonia, respiratory failure and COVID-19; Pneumonia, respiratory failure and COVID-19

he passed away; not responsive; mind just seemed like it was racing; body was hyper dried; Restless; not feeling well; ate a bit but not much; kind of pale; Agitated; Vomiting; trouble in breathing; This is a spontaneous report from a contactable consumer (brother of the patient). A 54-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, on 04Jan2021 (at the age of 54-years-old) as a single dose for COVID-19 immunization. Medical history included diabetes and high blood pressure. Concomitant medications included metformin (MANUFACTURER UNKNOWN) taken for diabetes, glimepiride (MANUFACTURER UNKNOWN) taken for diabetes, lisinopril (MANUFACTURER UNKNOWN), and amlodipine (MANUFACTURER UNKNOWN). The patient experienced not feeling well, ate a bit but not much, kind of pale, vomiting, trouble in breathing, and agitated on 04Jan2021; body was hyper dried and restless on 05Jan2021; mind just seemed like it was racing on 06Jan2021; and not responsive and he passed away on 06Jan2021 at 10:15 (reported as: around 10:15 AM). The clinical course was reported as follows: The patient received the vaccine on 04Jan2021, after which he started not feeling well. He went right home and went to bed. He woke up and ate a bit but not much and then was kind of pale. The patient then started to vomit, which continued throughout the night. He was having trouble in breathing. Emergency services were called, and they took his vitals and said that everything was okay, but he was very agitated; reported as not like

this prior to the vaccine. The patient was taken to urgent care where they gave him an unspecified steroid shot and unspecified medication for vomiting. The patient was told he was probably having a reaction to the vaccine, but he was just dried up. The patient continued to vomit throughout the day and then he was very agitated again and would fall asleep for may be 15-20 minutes. When the patient woke up, he was very restless (reported as: his body was just amped up and could not calm down). The patient calmed down just a little bit in the evening. When the patient was awoken at 6:00 AM in the morning, he was still agitated. The patient stated that he couldn't breathe, and his mind was racing. The patient's other brother went to him and he was not responsive, and he passed away on 06Jan2021 around 10:15 AM. It was reported that none of the symptoms occurred until the patient received the vaccine. Therapeutic measures were taken as a result of vomiting as aforementioned. The clinical outcome of all of the events was unknown; not responsive was not recovered, the patient died on 06Jan2021. The cause of death was unknown (reported as: not known by reporter). An autopsy was not performed. The batch/lot number for the vaccine, BNT162B2, was not provided and has been requested during follow up.; Reported Cause(s) of Death: not responsive and he passed away

Acute appendicitis; Severe acute abdominal pain; Chills; Fever; This is a spontaneous report from a contactable Nurse (patient). A 42-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (expiration date Mar2021, incomplete lot number L0140, not sure the first letter it is C or E), via an unspecified route of administration on 23Dec2020 at single dose for covid-19 immunization. None medical history. Concomitant medication included escitalopram oxalate (LEXAPRO). The patient experienced a little bit chills and fever she felt coming exactly on the 26th but she expected that and that was all fine but patient ended up in (Incomplete sentence). She went to work on 30th December and had some onset of severe acute abdominal pain and she ended up in an emergency appendectomy by 6 O'clock that evening. So she had an acute appendicitis and she did some research and it says that she can be listed in to the severe complications that the number in the vaccinated group was double back to the procedural group. The 26th it resided and patient felt better until the 30th when she have acute severe abdominal pain onset. She left work went for emergency room and she was in surgery within four hours. The outcome of events chills and fever was recovering, the other events was unknown. Because of the research that is on the website patient cannot help and think that it is related. Patient believed the relatedness of drug to events was related. Information about lot/batch number has been requested.; Sender's Comments: A possible contributory effect of suspect BNT162B2 on reported events cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate

26-year-old lady came in after she noticed she had bruises on her left hand after a CPR procedure at hospital. Patient was apparently in well health, she had received COVID-19 mRNA vaccine on January 7 at 3 PM, she has taken 2 pills with ibuprofen and tylenol for pain in right deltoid following vaccination. She was doing the CPR at 1:00 this afternoon, and she noticed that her left dorsum had some bruises. She took day off and went home and noticed that she also had bruises in both medial thighs, above the

knee and some bruises in scalp. Patient presented to the Emergency Room 1/9/2021 ~6PM and platelet count was found to be 2x10^3/uL. Patient required transfusion of 7 units of platelets, steroids, and IVIG.

SOB, Sleeplessness,

Scratchy throat, dizziness and eventually feeling like her throat is closing in

Patient was reported to be deceased at home by law enforcement on 1/7/21

"Patient presents with abdominal pain that started in the middle of the night. Had first COVID vaccine the previous day. Patient states the pain is intermittent ""comes and goes"" ""cramping"" ""pressure and bloating"" feeling. Patient states her normal bowel movements are 12 times per day. The last time she went was this morning. She is concerned about an ""obstruction"" Patient states she has ""some nausea"" She states she has ate and drank normally today. Patient has a history of ulcerative colitis and a complete colectomy with a ileal rectal pouch. She has had abdominal pain since this morning which is crampy, associated with nausea and recurrent vomiting. She normally has 6-12 bowel movements a day, but none since this morning. She does feel her abdomen is distended as well. The last time she had anything like this was when she developed pouch itis last spring, but that was much less painful than this. Her appendix is gone, but she believes she still has her gallbladder."

Went into the ED for bilateral hand and feet tingling. Worked up for possible Guillain Barre.

"Patient reported stroke-like symptoms as he was driving to work: started ""feeling funny"" with dizziness; progressed to feeling weakness in left side of face with facial drooping; tingling in left hand progressed to numbness and weakness in left arm and leg; difficultly coordinating motor movement in right arm; difficulty/ diminished speech ""tongue felt fat."" Symptoms resolved within appx 1+ hour from onset. Per patient, he was given an injection at the hospital (unsure for what?) and was discharged with a prescription for chlorthalidone 25mg daily, blood pressure was elevated."

There were no adverse reactions. Resident Died, she had a history of issues with her health prior to the vaccine.

Patient was found unresponsive at home with SpO2 20% 1/2/2021

1/6/21 8pm started with Nasuea, vomiting, diarrhea and fever. 1/7/21 started having intermittent chest pain in the morning. Then in the evening it became constant. Went to ER that evening due to chest pain. EKG showed t wave abnormality. 1st Trop was negative went from 0.08 to 2.3 Had 2 Echo's done and they were normal. Platelets were 85. Was discharged without chest pain. Troponin on discharge was 0.67 and platelets 61. Was admitted due to Chest pain and troponin. Attending provider diagnosed as myocarditis and thrombocytopenia R/T vaccine.

right after vaccine was given i got a head to toe hot flush. i thought it was just anxiety. within 2 minutes i had expolsive diarrhea, felt dizzy. looked in the mirror and saw my neck and chest covered in red rash and hives. felt hot flush again. dr came in noticed hives all over both my arms as well. felt sob and if someone was holding my neck with their hand. given benadryl and epi taken to local er.

Patient received the 1st dose of Moderna and was found deceased in her home the next day.

In the first 2 days (probably a couple of hours after the shot) I felt achiness, and it got worse body pains, joint pains and fatigue. Almost a week after I started getting sick, aches, shore throat, headache and fever (101.5F) that is when I went to the ED and it lasted about 2 days and then it went away. At the ED they did COVID and strep tests both negative. This was with my first dose and my second one the same thing happened.

Pfizer COVID-19 Vaccine A couple hours after the vaccination the patient experienced pain in the vaccine arm, headache, and feeling ache. Day 1 post vaccination patient experienced sore arm, headache, low grade fever, feeling ache, and GI symptoms with diarrhea. Day 2 post vaccination patient experienced sore arm, Migraine, and diarrhea. Day 3 post vaccine patient woke up with chest pain that radiated into her left arm and some weakness. Patient's blood sugar was >500 and was admitted to hospital for DKA.

My mother was given Pfizer vaccine on Thursday and she died 3 days later yesterday on Sunday!!!

Extremely tired went to bed at 8:30. At 11:00, tossed and turned until 12:16 a.m. Did not think she could stand up. Walked in the bathroom had pain in stomach, was very hot and freezing at the same time, was shaking. Head hurt was hurting so bad. Tried standing up from toilet, was passed out. Eye, half of face is bruised and swollen , eye shut for two days. More than forty minutes passed before she could call her husband. Does not remember anything because she was passed out. Husband came in and grabbed her, to get her back into bed. she could not stand. Went to ER at Hospital. Had CT scan, blood work , EKG, chest xray. Was still kind of out of it but was able to communicate with nurses. Face is still black and blue. Last night got up at 4:00 a.m. something was wrong with her throat. Felt like a walnut was in her throat. Went to doctor this morning. They said it was a reaction from the shot. Got an EpiPen, prednisone. Call them in 2 days to let them know how she's doing and also wear a heart monitor because they do not know how to take care of her, Has had vision blurriness in both eyes. Has not felt well at all.

Difficulty breathing, death.

Noted left lymph nodes left neck. On January 7, 10 days post injection had acute appendicitis requiring emergency appendectomy.

Metallic taste in the back of throat between 15-20 minutes post vaccination, noticeable swallowing and throat irritation at 20-25 minutes post vaccination, tongue and lip numbness and throat tightness at 25-30 minutes, dry hacking cough at 30 minutes. Treated in the ED approximately 1 hour post vaccination, at time of arrival in respiratory distress with subcostal retractions, coughing, speaking 1-2 word sentences, with tachycardia and tachypnea. Treated with IM epinephrine, IV solumedrol and IV Benadryl and IV Benadryl with marked improvement in symptoms.

Woke up 1/4/21 with right sided facial weakness consistent with Bell's Palsy. Started high dose Prednisone and Valtex. Received IVIG infusion on 1/6/21 and 1/7/21. Mild improvement 1/11/21.

About 15 minutes after vaccine, hr 155, fever 102, covered in hives, sick to her stomach and a pounding headache. Has had headache since then and been extremely fatigue.

Anaphylaxis within 5 minutes of dose given. Tachycardia 130-140s, hot body temperature, trouble swallowing, lightheaded/dizzy, ekg changes, feeling like I was going to pass out even when in bed. IV fluids, benedryl, soul-medrol, famotadine and IM epi given.

Trouble swallowing, tingling around the mouth within 5 minutes of vaccine administration. IV started with 25mg Benadryl within 5 minutes of symptom onset. Transfer to ER at 1430. Symptoms unresolved, hr - 120, bp 140/100, O2 sats 100, resp: 21 Additional 25mg Benadryl, 125mg solumedrol, 1ml Ativan given IV at 1435. Symptoms began to resolve, patient discharged at 1600 to home with instructions to return if needed. Patient returned to ER Sunday January 10 at 1300 complaining of throat tightness. Patient was seen by doctor, no acute distress and airway issues seen. Patient elected to stay for 50mg benadryl and 40mg prednisone PO. Patient was discharged to home with script for 40mg prednisone q day for 3 days. Patient feels any remaining allergic symptoms have resolved.

RESIDENT 1ST DOSE OF MODERNA VACCINE ADMINISTERED ON 01/04/2021 AT 8:30PM, RESIDENT FOUND UNRESPONSIVE ON 01/05/2021.

Herpatic infection left eye causing a herpatic dendrite

One week after administration, I had sudden onset inability to move left arm. I was transported to ER immediately. Treated, scanned with CT of brain, MRI of brain, c-spine and brachioplexus. In hospital for 2 days and no answers. Still no answers to left arm paresthesia and proprioreceptor deficits. Spreading into left leg and mild systemic symptoms. I have been to the ER, seen by primary physician, Physiatrist and Neurology and Occupational Therapy. I am scheduled for many more appointments and trying to find and answer.

COVID-19/Caller received the first dose of the vaccine and she tested positive with Covid; COVID-19/Caller received the first dose of the vaccine and she tested positive with Covid; arm pain; she felt like crap the night; chills; This is a spontaneous report from a contactable pharmacist (patient). A 51-year-old female patient received her first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number: EH9899, expiration date Mar2021), intramuscular on left arm, on 18Dec2020 at 0.3 mL, a single dose for vaccination. The patient medical history and concomitant medications were not reported. The patient received the first dose of the vaccine and she tested positive with Covid. She received the Pfizer Covid vaccine on 18Dec2020. She was exposed to the virus through close personal contact right around this same time-frame and did develop the virus herself. She wanted to know if there were any recommendations regarding her needing to get the second dose in series. She stated that her husband, who was not vaccinated, had the virus and developed more serious symptoms than she did. She is concerned about worsening side effects with the second dose and stated that she felt like crap the night after her first dose with chills and arm pain. The patient tested positive for COVID-19 on 26Dec2020. Specific test name was unknown, but she knows it was not a rapid test. She is scheduled to get the second dose of the Pfizer COVID-19 Vaccine on 08Jan2021. She called to ask if she should or should not get the second dose relative to the COVID-19 diagnosis. She has not been able to find the

information she is asking about. The outcome of the event of Covid-19 was recovering while other events was unknown. The Covid-19 was assessed as unrelated to the suspect drug.; Sender's Comments: No effect of the suspect vaccine could be reasonably achieved to protect from the targeted infection/disease due to the very short time lag. Instead, the positive COVID represents the pre-existing infection prior to vaccine use. Further information like confirmative COVID 19 Nucleic acid/ PCR test together with any associated symptoms are needed for full medical assessment. COVID-19 antigen test positive.

tested positive for Covid-19 after receiving 1st dose; COVID-19 PCR test: positive on 31Dec2020, Covid-19 rapid test: positive on 31Dec2020; smell was gone/no sense of smell; no sense of taste; This is a spontaneous report from a contactable nurse (patient). A 59-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number EH9899, expiry date unknown) via unspecified route of administration in the left arm on 26Dec2020 at single dose for Covid-19 immunization. Medical history included cholesterol, blood pressure (controlled blood pressure), hypothyroidism. Concomitant medications included TELMISARTAN (MICARDIS) for blood pressure and ATORVASTATIN (LIPITOR) for cholesterol; both on unspecified date. The patient was asking if she was able to get the 2nd dose of vaccine, since she was tested positive for Covid-19 (31Dec2020) after receiving 1st dose. The patient was asking information about missing 2nd dose and when can she get it and wanted to know if it was still okay to get the second dose. The patient asked if she needed to have a test negative for covid-19 prior to receiving 2nd dose. The patient experienced no sense of taste and actually realized it on 29Dec2020 that her food was not tasting good. The patient didn't notice her smell was gone until she was cooking the chicken curry, she even tested it out by spraying some perfume, she has no sense of smell on 30Dec2020. The patient informed that both her taste and smell returned 02Jan2021 but was not recovered completely. The patient underwent lab tests and procedures which included A1C: 6.4 on 12Dec2020, COVID-19 PCR test: positive on 31Dec2020, Covid-19 rapid test: positive on 31Dec2020. The patient informed that she had no positive test before the Covid-19 vaccine, she took Covid-19 antibody test in Apr2020 and it was negative. The outcome of the events tested positive for Covid-19 after receiving 1st dose was unknown, no sense of taste and smell was gone/no sense of smell was recovered with sequel on 02Jan2021.; Sender's Comments: No effect of the suspect vaccine could be reasonably achieved to protect from the targeted infection/disease due to the very short time lag. Instead, the positive COVID represents the pre-existing infection prior to vaccine use.

congestion; positive for Covid-19; positive for Covid-19; This is a spontaneous report from a contactable healthcare professional (patient). A 61-years-old female patient received her first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number EH9899, expiration date not reported), via an unspecified route of administration on left arm on 31Dec2020 at 08:15 at a single dose for Covid-19 immunization/precaution because she works with hospice patients. Medical history included blood pressure (abnormal), diabetes, cholesterol (abnormal), and acid reflux, all are ongoing. The patient has no family medical history. Concomitant medications included amlodipine besilate, benazepril hydrochloride for blood pressure taking about 4-5 years, metformin for diabetes taking about 5 years, rosuvastatin for cholesterol Taking about 5 years, pantoprazole for acid reflux taking 5 years, and vitamin D as supplement taking for 3 years. No previous immunization nor vaccines administered on

same date of the suspect drug. The patient was calling about the COVID vaccination, which she received on Thursday, 31Dec2020. Her husband tested positive on Thursday, so she took the test on Thursday after she took the vaccination and they just told her today, 04Jan2021, that she is positive for Covid-19. She wanted to know if that was going to mess up her vaccination in any way and if there are recommendations for second dose. She is a CNA. There was no prescriber. She received it because she works with hospice patients. Test was administered on 31Dec2020. COVID Test resulted on 10:00 04Jan2020 as positive. ER or physician's office required: She just went to get a COVID test when her husband tested and they gave her a azithromycin (Z-PACK) 250 mg because she had congestion. Take two tabs first day and then one daily for 4 more days. She is taking last one today (04Jan2021). Outcome of the events was unknown.; Sender's Comments: A causal association between reported events and BNT162B2 cannot be excluded.

slight sore arm; slight chest congestion; positive COVID-19 test after first dose of vaccine; positive COVID-19 test after first dose of vaccine; Fever; cold like symptoms; stuffy head; horrible headache; Cough; This is a spontaneous report from a contactable healthcare professional (patient) from a Pfizer-sponsored program, Pfizer First Connect. A 44-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, on 16Dec2020 as a single dose (reported as 0.3 mL) (at the age of 44-years-old) for COVID-19 immunization. Medical history included ongoing hypothyroidism, one thyroid gland removed due to a nodule on an unspecified date (years ago), ongoing acid reflux, ongoing hypercholesteremia, ongoing fluid retention, and ongoing history of headaches. Concomitant medications included levothyroxine sodium (SYNTHROID) taken for hypothyroidism and for one thyroid gland removed due to a nodule from an unspecified date and ongoing, dexlansoprazole (DEXILANT) taken for acid reflux from an unspecified date and ongoing, atorvastatin (LIPITOR) taken for hypercholesterolemia from an unspecified date to an unspecified date, and hydrochlorothiazide (MANUFACTURER UNKNOWN) taken for fluid retention from an unspecified date and ongoing. Additional concomitant medications included unspecified vitamins. The patient had a positive COVID-19 test after first dose of vaccine on 01Jan2021; cold like symptoms, stuffy head, horrible headache, cough, and fever on 31Dec2020; slight chest congestion on 02Jan2021; and slight sore arm on an unspecified date. The events, stuffy head and horrible headache, were reported as medically significant. The events, cough, fever, and slight chest congestion, were reported as non-serious. The clinical course was reported as follows: It was reported that the patient was vaccinated on 16Dec2020, became symptomatic on 31Dec2020, and tested positive for COVID-19 on 01Jan2021. The patient stated that she became symptomatic one day prior to testing positive for COVID-19, on 31Dec2020. She initially had cold-like symptoms with a stuffy head, cough and a horrible headache; the worst headache she had ever had. These symptoms occurred earlier in the day on the 31Dec2020. Then later that night about 10:00 PM, she had a fever with a body temperature of 102 degrees Fahrenheit. Her body temperature had been normal at 98 degrees all day that day until that night. She also had slight chest congestion and then was fever free for over 48 hours. The patient stated that she had a history of headaches and can tolerate a headache. The headache started 31Dec2020 and was significant. It was reported that after the vaccine, she had no other symptoms other than a slight sore arm, which lasted a day; maybe 24 hours after she received the vaccine. The patient stated that she does not think any of the other symptoms, other than the sore arm, have anything to do with the

vaccine. The clinical outcome of positive COVID-19 test after first dose of vaccine and slight sore arm was unknown; cold like symptoms, horrible headache, and cough was recovering; fever was recovered on 02Jan2021; and stuffy head and slight chest congestion was not recovered. The reporter assessed the causality assessment between the events, positive COVID-19 test after first dose of vaccine, cold symptoms, stuffy head, cough, horrible headache, fever, and slight chest congestion, as unrelated. The batch/lot number for the vaccine, BNT162B2, was not provided and has been requested during follow up.; Sender's Comments: The efficacy of a drug varies from one patient to another and can be affected by different factors; however, a contributory role of the suspect drug BNT162B2 to the reported events cannot be ruled out. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

suspected COVID-19; suspected COVID-19; Fatigue; Body aches; Headache; chills; The initial case was missing the following minimum criteria: no adverse event. Upon receipt of follow-up information on 04Jan2021, this case now contains all required information to be considered valid. This is a spontaneous report from a contactable healthcare professional, the patient, from a Pfizer sponsored program IBCC (Inbound Call Center for HCPs). A 32-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot Number: EK5730), intramuscular in the left deltoid on 15Dec2020 at 21:00 (at the age of 32-years-old) as a single dose for COVID-19 immunization. Medical history included ongoing hypertension from 2009 and COVID-19 from 10Jun2020 to an unknown date in 2020. Ongoing concomitant medications included fosinopril (MANUFACTURER UNKNOWN) taken for hypertension from 2017. The patient did not receive any other vaccines on the same day as the BNT162B2 vaccine. On 19Dec2020, shy of about 96 hours of getting the vaccine, the patient experienced fatigue, body aches, headache and chills. He did not have any fever. The patient stated that he recovered from the fatigue, body aches, headache and chills by 19Dec2020. The patient was fine from 19Dec2020 until 01Jan2021. On 28Dec2020, the patient had a COVID-19 PCR test that came back negative. On 01Jan2021, the patient suspected that he had COVID-19. He had a fever of 103.1 degrees Fahrenheit, body aches, chills like he was freezing to death, fatigue, diarrhea; however, he did not have nausea or loss of taste or smell. He had swollen lymph nodes, but no sore throat and his oxygen saturation was okay in Jan2021. He was also having chest pain but it was more like intercoastal pain. He stated that these current symptoms were significantly worse than the ones he had just after getting the vaccine and felt more like the symptoms he had when he had COVID-19 before on 10Jun2020 (positive IgG for COVID-19-tested in 2020). The patient had a COVID nasal swab (PCR) done at an urgent care (physician's office) on 02Jan2020 or 03Jan2020 and was awaiting the results. The clinical outcome of the suspected COVID-19 was not recovered.; Sender's Comments: A causal association between reported suspected COVID-19 cannot be excluded.

Patient complained of itching starting on her legs, which went upwards; Redness on her arms, neck, face; Redness on her arms, neck, face; Redness on her arms, neck, face; Itching up to her scalp; Dry cough; Rash; This is a spontaneous report from a contactable nurse (patient). A 44-year-old non-

pregnant female patient received the first dose of BNT162B2 (Pfizer-Biontech Covid-19 Vaccine) at single dose, in the left arm, on 26Dec2020, at 09:00 AM, for COVID-19 immunisation. COVID-19 vaccine was administered at hospital. The patient had not received any other vaccines within 4 weeks prior to the BNT162B2 vaccine. Relevant medical history included asthma, hypertension, hypothyroidism, penicillin allergy, food allergy (melon and pineapple) and latex allergy. Concomitant medications, received within 2 weeks of vaccination, included omalizumab (XOLAIR), levothyroxine sodium (LEVOXYL), levocetirizine dihydrochloride (XYZAL), losartan and formoterol fumarate, mometasone furoate (DULERA). After covid vaccination, the patient was advised to stay 30 minutes for observation. On 26Dec2020 at 09:15, less than 15 minutes later, the patient complained of itching starting on her legs, which went upwards. The patient took 25 mg oral diphenhydramine hydrochloride (BENADRYL). She noted to have redness on her arms, neck, face, itching up to her scalp. By then she started to have a dry cough, removed her mask, nurse who was with her called for a rapid response team. Patient's epi pen was used, they then started IV and pushed emergency meds and transported to ED. Emergency room/department or urgent care was required. Another dose of epinephrine IM and additional meds were given. Placed on oxygen via non-rebreather with albuterol. Epinephrine drip started. Stabilized after 3 hours, stayed in observation for 12 hours then discharged to home. Around the clock 50 mg diphenhydramine hydrochloride (BENADRYL) at home x 2 days, then levocetirizine (ZYXAL) thrice daily x 7 days to control itching and redness/rash. Other treatment included steroids, pepcid. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, the patient has been tested for COVID-19 (PCR, Nasal Swab) on 26Dec2020 and the result was negative. Clinical outcome of the adverse events was recovering at time of this report. Information on the lot/batch number has been requested.; Sender's Comments: Based on a close temporal association, a causal relationship between reported events and BNT162B2 vaccine cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

anaphylaxis; This is a spontaneous report from a contactable consumer. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), on an unspecified date as single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced anaphylaxis on an unspecified date. The outcome of anaphylaxis was unknown.

tested positive for COVID-19; tested positive for COVID-19; loss of taste and smell; loss of taste and smell; excruciating headache; runny nose; congestion; shortness of breath when she started talking; having aches and pains; lightheaded, experienced dizziness; tied; This is a spontaneous report from a contactable consumer(patient). The 58-year-old female patient received first dose BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EJ1685, intramuscular injection), intramuscularly in left arm on 23Dec2020 at single dose for COVID-19 vaccination in nursing home. Medical history included she had a right knee injury so she had some inflammation, She had stomach issues in the past-Barrett's syndrome, H. pylori(Helicobacter infection), GERD(Gastrooesophageal reflux disease), so,

Pantoprazole is just a maintenance medicine, she was stable right now. She had a Vitamin D deficiency at one point. Ongoing concomitant medication included meloxicam for inflammation, thyroid for thyroid(Thyroid disorder), pantoprazole for stomach issues, colecalciferol (VITAMIN D 3) for supplementation therapy. There was no vaccination within 4 weeks. She received her first vaccine on 23Dec2020. There no other vaccine received in the same day. By 26Dec2020, she started with symptoms and then she tested positive for COVID-19 on 29Dec2020. She felt horrible with an excruciating headache and was wondering if she was going to die now. She can really feel for the residents she works with who get it. Right now, she was hopefully going back to work next week, but she was wondering about the second vaccine. People are saying she got COVID-19 because of receiving the first vaccine and she was hoping it was not the case. Is it going to be an issue getting the second vaccine after testing positive? The caller declines to include her healthcare professional for this report, stating she has been talking with her doctors over the week. Her symptoms included runny nose, congestion, and what seemed like shortness of breath when she started talking. She started having aches and pains over the weekend. By Monday, 28Dec2020, there was loss of taste and smell, it was totally gone. She also was lightheaded, experienced dizziness, was tied. She went through a lot of symptoms which was shocking to her. She clarified these symptoms first began the morning of the 26Dec2020. Christmas she was fine, and then she to go out to get snow off of her car and do some running around on 26Dec2020 and she noticed she started having symptoms. When probed for outcome, the caller state she was most definitely feeling better. She was having some excruciating headaches and she has worked with her doctor on what they needed to do. She is still working with the doctor on her lightheadedness. She has set up a follow-up appointment, but she was feeling better. There was no emergency room nor physician office. Relevant test was none. It was also reported lot number was either EJ1685 or EJ1085, she can't tell. Outcome of loss of taste and smell was recovered, of dizziness was not recovered, of other events was recovering.

tested positive for COVID virus; tested positive for COVID virus; cold all day; tiny cough; chills; sweating/ woke up sweating wet; arm pain/Very sore arms; body aches; fever; some muscle aches; This is a spontaneous report from a contactable consumer(Patient's Wife). A 67-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration in left arm on 02Jan2021 13:30 at single dose for COVID-19 vaccination. There were no concomitant medications nor medical history. He did not receive any other vaccines that day or 4 weeks prior. No history of any other vaccines or events. He got his vaccine on Saturday(02Jan2021) at 1:30pm(13:30) and by 5:30pm(17:30) had very sore arms/arm pain, at 7:30pm(19:30) he had chills off and on and was sweating. He woke up soaking wet and did that on Sunday, but was feeling a little better today. He also experienced body aches and fever in Jan2021. Today is testing day at his work and he tested positive for COVID virus on 05Jan2021. Not sure if it's a coincidence. Again, he got the shot and then started having all these symptoms at 5:30 and 7:30. Now they are both on quarantine for the 10-14 days. He wanted to see if it's possible to test positive for the virus after getting the shot or is it just a coincidence. He also had some muscle aches in Jan2021. Last night (04Jan2021), he woke up again sweating, but not like on Saturday, but he got really warm and started to sweat a little, and on Sunday(03Jan2021) he was cold all day and had a tiny cough, but it wasn't significant. Ever so often she would hear him cough. All of a sudden patient would wake up sweating. Again, Saturday he soaked everything. There was no

Emergency Room nor Physician Office. Outcome of Very sore arms, sweating was recovering, of pain and fever was unknown, of other events was not recovered. Information on Lot/Batch has been requested.

a little bit of a cough.; headache; runny nose; Aside from her taste and smell still being gone; Aside from her taste and smell still being gone/loss of taste; fogginess; Patient had since tested positive; Patient had since tested positive; patient likely had exposure on 22Dec2020; This is a spontaneous report from a contactable physician. A female patient of an unspecified age received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 21Dec2020 at single dose for covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient likely had exposure on 22Dec2020. She showed the first covid symptoms on 31Dec2020. Patient experienced loss of taste, headache, fogginess, runny nose, and a little bit of a cough on unspecified date. Patient received her first covid dose on 21Dec2020. The first dose likely helped her, she has rapidly gotten better and was feeling much better today. Aside from her taste and smell still being gone. The patient was scheduled to receive her second dose on 11Jan2021. Patient had since tested positive. Caller clarified that the patient didn't get a test until 03Jan2021. Outcome of events taste and smell still being gone was not recovered, and outcome of other events was unknown. Information on batch/lot number was requested.; Sender's Comments: No effect of the suspect vaccine could be reasonably achieved to protect from the targeted infection/disease due to the very short time lag. Instead, the positive COVID likely represents the pre-existing infection prior to vaccine use. Further information like confirmative COVID 19 Nucleic acid/ PCR test together with any associated symptoms are needed for full medical assessment.

tested positive; tested positive; runny nose; headache; This is a spontaneous report from a Pfizer-sponsored program Pfizer First Connect. A contactable consumer reported that a 51-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced tested positive, runny nose, headache after getting the vaccine on an unspecified date with outcome of unknown. This report is considered as non-serious.

"tested positive for COVID-19; tested positive for COVID-19; This is a spontaneous report from a contactable nurse (patient) from a Pfizer-sponsored program Pfizer First Connect. A 55-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EK5730), via an unspecified route of administration in the right arm on 18Dec2020 at single dose for covid 19 immunisation as healthcare professional and husband was high risk. Medical history included hypertension from 2019 and ongoing. Concomitant medication included amlodipine besilate (NORVASC, 5 mg) from 2019 and ongoing for high blood pressure. The patient experienced tested positive for covid-19 on 03Jan2021 with outcome of not recovered, congestion and headache in Jan2021 with outcome of unknown. The patient underwent lab tests and procedures which included COVID test on 03Jan2021 and the results came back positive on 04Jan2021. The patient was scheduled to receive her second injection on 08Jan2021. Since her first injection she had tested positive for COVID-19. The second dose had to be given a certain amount of days after the first. She would be outside that window. She would like to

know if there is any guidance regarding the if/when she should get the second dose. The reporter would like to know if she waits longer than the recommended 21 days to receive her second dose of the COVID-19 vaccine would she need to restart the vaccination series. The reporter said this was not serious as she only had congestion and headache with treatment: using over the counter stuff. Event relatedness with COVID vaccine was unknown.; Sender's Comments: Based on available information, a possible contributory role of suspect BNT162B2 vaccine cannot be completely excluded for reported ""tested positive for COVID-19""."

it was like having Covid again; it was like having Covid again; body aches; dry mouth; generalized weakness; temp was 38.1 Celsius; head feels weird; can't sleep; decreased appetite; pain at the injection site; This is a spontaneous report from a contactable Nurse (patient). A 36-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 04Jan2021 at single dose for COVID-19 immunization. Medical history included COVID-19 from Mar2020 to an unknown date. The patient's concomitant medications were not reported. The patient experienced body aches, dry mouth, can't sleep, generalized weakness, decreased appetite, and pain at the injection site, temp was 38.1 Celsius, head feels weird in Jan2021. The patient got her first dose and was looking online to see the symptoms. She said that she saw that during the trials, people were experiencing the symptoms she was experiencing after the second dose and she was concerned. She said that she wanted to make sure her symptoms are ok and to make sure that the symptoms are not just caused from the booster, but also from the first dose. The caller said that her mom told her that someone died from the Pfizer vaccine. No further details provided. The patient was having body aches, could not sleep, her mouth is really dry, her temp was 38.1 Celsius, her head feels weird, she has generalized weakness, pain at the injection site, and decreased appetite. She said that it was like having Covid again. She said that she had Covid back in Mar2020. The patient underwent lab tests and procedures which included body temperature: 38.1 centigrade. The outcome of all the events was unknown. The events were reported as non-serious. Information on the lot/batch number has been requested.; Sender's Comments: No effect of the suspect vaccine could be reasonably achieved to protect from the targeted infection/disease due to the very short time lag. Instead, the suspected COVID likely represents a pre-existing infection prior to vaccine use. Further information like confirmative COVID 19 Nucleic acid/ PCR test is needed for full medical assessment.

she is pregnant as well; she reported to be diagnosed positive for COVID last 01Jan2021 after showing symptoms on 31Dec2020; she reported to be diagnosed positive for COVID last 01Jan2021 after showing symptoms on 31Dec2020/tested positive for COVID-19; This is spontaneous report from a contactable Other Health Professional (patient) via a Pfizer Sponsored Program. A 29-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot# EJ1685), intramuscularly in right deltoid on 23Dec2020 14:30 at single dose for COVID-19 vaccination while pregnant. Medical history was none. Concomitant medication included ongoing ascorbic acid, betacarotene, calcium carbonate, colecalciferol, docosahexaenoic acid, ferrous fumarate, folic acid, nicotinamide, pyridoxine hydrochloride, riboflavin, thiamine mononitrate, tocopheryl acetate, vitamin b12 nos, zinc oxide (PRENATAL MULTIVITAMIN + DHA, Prenatal Multi + DHA), one soft gel, every morning as prenatal medication. The reporter was asking for recommendations for her in taking the second dose as she

reported to be diagnosed positive for COVID last 01Jan2021 after showing symptoms on 31Dec2020. She received the first dose of the vaccine last 23Dec2020. She is asking if she should wait 90 days before taking the 2nd dose. Agent has a physical therapist on the phone. She had her first dose of the COVID vaccine on 23Dec2020. She started to show symptoms of COVID on 31Dec2020. She tested positive on 01Jan2020. Caller wants to know does she need to wait 90 days for the second dose. Caller wanted to add she is pregnant as well. She declined to include a healthcare professional for the report. The caller states she started to feel symptoms towards the end of the day on 31Dec2020. She clarifies she felt like she was having a cold coming on. She had some congestion. When probed for outcome, caller stated it had improved quite a bit. She had been improved but today, its kind of like she had a cold again, but that had improved. Vaccination Facility Type: Hospital. Vaccine Administered at Military Facility: No. Prior Vaccinations (within 4 weeks): None within 4 weeks. Additional Vaccines Administered on Same Date of the Pfizer Suspect: None. Relevant Tests: None. Investigation Assessment: Yes. Is a sample of the product available to be returned, if requested (Y/N): Vaccine was administered in hospital. No AE required a visit to emergency room and physician office. The reporter stated her symptoms have been pretty mild. The patient underwent lab tests and procedures which included COVID Fast-acting (rapid) test: positive on 01Jan2021. Outcome of events was recovering.; Sender's Comments: Based on available information, a possible contributory role of suspect BNT162B2 cannot be completely excluded

She did a rapid antigen test and was positive; She did a rapid antigen test and was positive; her arm hurt after vaccination; she lost taste; This is a spontaneous report from a contactable Consumer. An adult female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 04Jan2021 at single dose for COVID-19 immunization. The patient medical history was not reported. The patient's concomitant medications were not reported. Friend shared that the patient's arm hurt after vaccination and the following day she lost taste. She did a rapid antigen test and was positive. Adverse event start date was 04Jan2021. No treatment was received for the adverse event. AE resulted in doctor or other healthcare professional office/clinic visit. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had been tested for COVID-19. Test name: antigen (positive). Outcome of the events was not recovered. Information on the lot/batch number has been requested.

"Received the Pfizer COVID-19 on 21Dec2020. I got Covid from a family member, sore throat, felt like a flu or bad cold,headache, body aches and sinus issue. She now has congestion and cough; Received the Pfizer COVID-19 on 21Dec2020. I got Covid from a family member, sore throat, felt like a flu or bad cold,headache, body aches and sinus issue. She now has congestion and cough; This is a spontaneous report from a contactable health care professional nurse, the patient. A female patient (nurse) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE) on 21Dec2020 as a single dose for COVID-19 vaccination. The patient had no known medical history. The patients concomitant medications were not reported. On an unspecified date the patient experienced I got Covid from a family member. She reported being symptomatic on 1Jan2021 started with a sore throat, felt like a flu or bad cold. She reported sore throat, headache, body aches and sinus issue. She now has congestion and cough. She had no issue when she got the vaccine. The patient will be getting the second dose 11Jan2021 and she would like to know if she is eligible to receive the second dose Pfizer Covid-19

Vaccine. The clinical outcome of the event was unknown . Information on the Lot number has been requested.; Sender's Comments: The reported ""got COVID from a family member"" after COVID-19 immunization is considered ineffective of BNT162B2, and the Company cannot completely exclude the possible causality between the reported event and BNT162B2 administration."

received the vaccine on December 17th and tested positive for Covid on December 27th/COVID PCR (polymerase chain reaction) test: positive on 28Dec2020; received the vaccine on December 17th and tested positive for Covid on December 27th/COVID PCR (polymerase chain reaction) test: positive on 28Dec2020; This is a spontaneous report from a Pfizer sponsored program Pfizer First Connect. A contactable nurse (patient) reported that a 65-year-old female patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EK5730), via an unspecified route of administration on 17Dec2020 11:00 in left deltoid at single dose for covid-19 immunization. Medical history included thyroid cancer from an unknown date and unknown if ongoing, bilateral thyroidectomy in 2014. Family Medical History: Father died of lung cancer. Mother died of cardiac arrest in 1972. Concomitant medication included levothyroxine sodium (SYNTHROID) for bilateral thyroidectomy. The patient received the vaccine on 17Dec2020 and tested positive for covid on 27Dec2020. The adverse events resulted in emergency room visit. The patient underwent lab tests and procedures which included tested positive for COVID on 27Dec2020, COVID PCR (polymerase chain reaction) test: positive on 28Dec2020. Vaccination facility type was hospital. No additional vaccines administered on same date of Pfizer suspect. Received COVID Vaccine on 17Dec2020. Tested positive for COVID in emergency room on 27Dec2020. Tested positive on a COVID PCR test on 28Dec2020. Prior vaccinations within 4 weeks was none. Caller received the first dose of the COVID Vaccine. Tested positive for COVID on 27Dec2020. Is about to get the second dose of COVID Vaccine and would like to know if she should proceed or wait. Since quarantine, she has had no fever. Is slightly short of breath and has a headache. Works in COVID units in a hospital. Wants to make sure she can receive the second dose. Stated she had no adverse reaction to the COVID Vaccine unless an adverse reaction can occur two weeks after. Is attributing the shortness of breath and headache to testing positive for COVID. Shortness of breath and headache only occurred after testing positive for COVID. Reason she went to the hospital is because she lost her sense of smell. She got tested and was positive for COVID. Lost sense of smell, went to Emergency Room, and notified doctor of positive test the following day, 28Dec2020. Clarified she just went to the emergency department to get tested for COVID and then went home. Was called with positive results in an hour. Caller wanted to know when she should proceed with getting her second dose of Covid vaccine. She is supposed to receive her second dose tomorrow. She thought she was going to take second dose when I completely recovered. Caller asked if she waited until the 13th to receive second dose of Covid vaccine, would it be effective. She would feel more comfortable doing that. The outcome of events was unknown.; Sender's Comments: Based on the information available, a possible contributory role of the suspect BNT162B2 cannot be excluded for the reported COVID-19 based on the known safety profile. However the short duration of 9 days since the vaccine first dose is given it is unlikely patient would have fully developed immunity.

"Felt like he couldn't breath; He still has his sense of taste, but it is dulled; Recently got the vaccine and also came down with covid; Recently got the vaccine and also came down with covid; Exhaustion/feeling

tired; Loss of smell; Mild congestion/The congestion went into full nasal drainage; This is a spontaneous report from a contactable pharmacist (patient). A 30-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EL0140, Expiry Date: 31Mar2021), via an unspecified route of administration on 31Dec2020 13:00 at single dose for Covid-19 immunization. The patient had no relevant medical history and concomitant drug. The patient experienced recently got the vaccine and also came down with covid on 04Jan2021 00:30, mild congestion/the congestion went into full nasal drainage on 31Dec2020, loss of smell on 02Jan2021, exhaustion/feeling tired on 03Jan2021, felt like he couldn't breathe, he still has his sense of taste, but it is dulled on an unspecified date. He was a pharmacist. He received his first dose of the COVID vaccine on Thursday 31Dec2020 1pm. Shortly thereafter, he got the typical side effects of the vaccine that are posted. Then 2.5 days letter he no longer had a sense of smell. Everything he read said that he probably came in contact with COVID prior to administration. His questions was since he test positive for COVID, should he still get the second shot. He got it at a clinic. He did experience mild congestion which started by 6 o'clock. He started to notice slight congestion that kind of went away. Then, on Friday, about 24 hours later, he really noticed he had congestion. He took pseudoephedrine hydrochloride (SUDAFED) and paracetamol (TYLENOL). Then his sense of smell diminished with the congestion and felt like he couldn't breathe. On Saturday, he decided to not take medication. That was when he noticed he could not smell anything. He had full blown congestion. It probably took two days when he started to lose his sense of smell. He received the shot on Thursday. On Saturday, he lost his sense of smell. He still has his sense of taste, but it was dulled. Sunday, he was just exhausted and feeling tired. These were all listed as typical side effects except for the loss of smell. Saturday was the worst. The congestion went into full nasal drainage. On Sunday he had no sinus issues. He still hasn't gained his sense of smell back. The exhaustion set in Sunday 03Jan2020. He doesn't feel like any of the side effects are serious. The exhaustion has started to let up some so it is improving. He was pretty much back to normal. He just couldn't figure out why he had a loss of smell. He had a COVID rapid test on 04Jan2021 at 8:30 am (as reported). He received an alert and hour later that it was positive. He was wondering whether the loss of smell could be from the vaccine. The patient underwent lab tests and procedures which included COVID-19 rapid POC test: positive on 04Jan2021. The outcome of events for mild congestion/the congestion went into full nasal drainage was resolved on 03Jan2021, for loss of smell was not resolved, for exhaustion/feeling tired was resolving, for other events was unknown. The events were reported as non-serious.; Sender's Comments: Reported event ""recently got the vaccine and also came down with covid"" is considered possibly related to suspect BNT162B2 based on temporal association and known drug safety profile."

"Doctor had the 1st dose last 16Dec2020 then tested positive for COVID 17Dec2020; Doctor had the 1st dose last 16Dec2020 then tested positive for COVID 17Dec2020; This is a spontaneous report from a Pfizer-sponsored program Pfizer First Connect, received from a contactable physician (patient). A male patient of an unspecified age started to the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), unspecified route of administration on 16Dec2020 as a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The physician inquired ""is it recommended to receive the 2nd dose despite having antibodies and recovered from COVID?"" The doctor had the 1st dose on 16Dec2020 then tested positive for COVID

17Dec2020. He will receive the 2nd dose tomorrow 06Jan2021 and he was recovering. The patient underwent lab tests and procedures which included COVID test: result positive on 17Dec2020. Outcome of the event doctor had the 1st dose last 16Dec2020 then tested positive for COVID 17Dec2020 was recovering. Information on the lot/batch number has been requested.; Sender's Comments: The reported tested positive for COVID after COVID-19 immunization is considered ineffective of BNT162B2, and the Company cannot completely exclude the possible causality between the reported event and BNT162B2 administration."

"he received his first dose of the vaccine on 22Dec2020 and tested positive for Covid yesterday (04Jan2021).; he received his first dose of the vaccine on 22Dec2020 and tested positive for Covid yesterday (04Jan2021).; This is a spontaneous report from a contactable other healthcare professional (patient). A male patient of an unspecified age started to the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), unspecified route of administration on 22Dec2020 as a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. He received his first dose of the vaccine on 22Dec2020 and tested positive for COVID yesterday (04Jan2021). He stated his ""symptoms were general at first, then weakness after 10 days, chilly and muscle strain"". The other HCP reported ""do I need to take the second dose on 11Jan2021?"" The patient underwent lab tests and procedures which included COVID test: result positive on 04Jan2021. Outcome of the event he received his first dose of the vaccine on 22Dec2020 and tested positive for COVID yesterday (04Jan2021) was unknown. Information on the lot/batch number has been requested.; Sender's Comments: The reported positive test for Covid after COVID-19 immunization is considered ineffective of BNT162B2, and the Company cannot completely exclude the possible causality between the reported event and BNT162B2 administration."

she had COVID symptoms; she had COVID symptoms; chills; low grade fever; muscle joint pain; muscle joint pain; exhausted with a headache/ She doesn't want to get up she is tired; exhausted with a headache/slight headache; muscle joint pain which is a stabbing pain all over her body; feeling unwell; This is a spontaneous report from a contactable nurse (patient). A 47-year-old female patient receive first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EH9899, manufacturer: Pfizer), via an unspecified route of administration on 04Jan2021 14:00 at single dose for Covid-19 immunization. Medical history included ongoing childhood asthma, COVID 19 positive from 07Dec2020 to an unknown date. There were no concomitant medications. The patient felt like she had covid symptoms, chills, low grade fever, muscle joint pain, exhausted with a headache/ she doesn't want to get up she was tired, muscle joint pain, which was a stabbing pain all over her body, feeling unwell, all on 05Jan2021 05:00. The events were reported as non-serious. Caller had Sars-COV-2 infection diagnosed 07Dec2020. Received first dose of vaccine 04Jan2021 at 14:00. She was experiencing chills, low grade fever, muscle joint pain, exhausted with a headache. Asking for information on efficacy of second dose. She didn't have any side effects or anything initially. Then, 12 hours later at 5- 6 am she felt like she had COVID symptoms. She already had COVID so she known what it feels like. She was wondering how long would last. It was almost like having real COVID. She didn't have a prescribing doctor. She had COVID 07Dec2020. She was currently experiencing Chills, fever low grade, muscle joint pain which was a stabbing pain all over her body, and she was feeling unwell. She didn't want to get up

she was tired. She has a slight headache. This all started at 5 am on 05Jan2021. Even with medication. She has been taking paracetamol (TYLENOL) and excedrin. She cannot work if she wanted to, but these effects are not serious. Her fever has went down. The chills have stayed the same. She was diagnosed with childhood asthma. Caller asked about interval information between the SARS-COV-2 infection diagnosed 07Dec2020 and her first dose of vaccine 04Jan2021 at 14:00. The outcome of events for felt like she had covid symptoms was unknown, for low grade fever was resolving, for other events was not resolved.; Sender's Comments: There is not a reasonable possibility that event suspected COVID-19 is related to BNT162B2. There is no test done to confirm whether patient got COVID-19 or not. And symptoms that were suspected by reporter as due to COVID-19 occurred one after the vaccination, when vaccine was not expected to achieve the effect.

he tested positive for COVID; he tested positive for COVID; This is a spontaneous report from a Pfizer-sponsored program IBCC (Inbound Call Center for HCPs) from a contactable physician (patient). A 73-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on the right deltoid on 28Dec2020 09:30 at single dose for COVID-19 immunization. Medical history included diabetic (he is a diabetic, but he is not on medication for it) from Nov2018 and ongoing, hepatitis (not ongoing) (He had hepatitis virus for 15 to 20 years. It resolved 5 or 6 years ago. It corrected on it's own), supplement, hypertension and carcinoma of the lung. Everyone in his family has hypertension. His sister had carcinoma of the lung. There was no history of all previous immunization with the Pfizer vaccine considered as suspect. The patient did not have additional vaccines administered on same date of the Pfizer suspect. There were no prior vaccinations within 4 weeks. There were no adverse events following prior vaccinations. Concomitant medication included doxazosin mesilate (CARDURA), bisoprolol fumarate, hydrochlorothiazide (ZIAC), nystatin (STATIN) taken for lipids, colecalciferol (VITAMIN D) taken for supplement, fish oil, acetylsalicylic acid (BABY ASPIRIN), vitamin C [ascorbic acid]. The patient also received multivitamin. He has been on all concomitant medications for at least three to four years. The patient was scheduled for the next dose on 18Jan2021. On 05Jan2021 he tested positive for COVID. The event was reported as serious as medically significant. The patient was given the antibody infusion and steroid injection. It was outpatient. He was not admitted. Treatment was received for the events. The outcome of the events was unknown. Information on lot number/batch number has been requested.; Sender's Comments: Based on the information currently available, a lack of efficacy with the suspected vaccine BNT162B2 in this patient cannot be completely excluded. However individuals may not be protected until at least 7 days after their second dose of the vaccine.

she previously had a SARS-Cov-2 infection; she previously had a SARS-Cov-2 infection; This is a spontaneous report from a Pfizer-sponsored program Pfizer First Connect. A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunisation. Caller just had wisdom teeth extracted and was currently on antibiotics. She stated she previously had a SARS-Cov-2 infection on an unspecified date. Outcome of SARS-Cov-2 infection were unknown. Information on the lot/batch number has been requested.

following the receipt of the first dose of the COVID-19 vaccine; testing positive to COVID; This is a spontaneous report from a non-contactable other Healthcare Professional reported for herself. A female

patient of an unspecified age (Age: 47, Unit: Unknown) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 20Dec2020 at single dose for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient explained testing positive to COVID on the 29Dec2020, following the receipt of the first dose of the COVID-19 vaccine on the 20Dec2020. She stated that minor symptoms remain, and asked if she could receive the second dose of the vaccine due on the 10Jan2021. The outcome of the events was not reported. No follow-up attempts are possible; information about lot/ batch number cannot be obtained.; Sender's Comments: The reported testing positive to COVID after COVID-19 immunization is considered ineffective of BNT162B2, and the Company cannot completely exclude the possible causality between the reported event and BNT162B2 administration.

"Flu-like symptoms; Cold symptoms; tested positive for SARS-COV-2 infection; tested positive for SARS-COV-2 infection; muscle and body aches; muscle and body aches; loss sense of taste; Congestion nasal; Sore throat; Loss of smell; Sinus pressure; Headache; general fatigue; This is a spontaneous report from a contactable consumer (patient). A 28-year-old female patient received BNT162B2(PFIZER-BIONTECH COVID-19 VACCINE) Batch/lot number: EJ1685, via an unspecified route of administration on 17Dec2020 16:00 at single dose for COVID-19 immunisation. Medical history was none. There were no concomitant medications. The patient got the COVID Vaccine and the day after, was exposed to the virus, got sick right away and tested positive for the virus. The patient stated that she got vaccinated around 4pm, 17Dec2020. She was exposed to the virus by the same coworker twice on 18Dec2020 and then the next week, she believed, on 22Dec2020, the coworker tested positive for COVID. Patient stated that her symptoms started 24Dec2020. She did not think she had a fever as she did not feel feverish. She had flu like symptoms from an unspecified date with muscle and body aches from 25Dec2020. She lost her sense of taste and smell from 25Dec2020. She had cold-like symptoms from an unspecified date with congestion nasal and sore throat from 25Dec2020, sinus pressure and headaches from 24Dec2020. She had general fatigue from 24Dec2020 for a while. Patient had not had another COVID test since the one she had 28Dec2020, when she tested positive for COVID. She became symptoms-free on 03Jan2021. Patient was asking should she still get the 2nd dose of the COVID Vaccine. She was also concerned about the reaction her body was going to have to the vaccine after being sick. The patient had recovered from Flu-like symptoms and Cold symptoms on an unspecified date, recovered from muscle and body aches on 29Dec2020, recovered from loss sense of taste and loss of smell on 31Dec2020, recovered from congestion nasal, sinus pressure and headache on 03Jan2021, recovered from Sore throat on 01Jan2021, recovered from general fatigue on 02Jan2021. And outcome of ""tested positive for COVID after receiving the COVID Vaccine"" was unknown."

He received the 1st dose of the vaccine on Friday 18DEC2020. He developed COVID the following Thursday.; He received the 1st dose of the vaccine on Friday 18DEC2020. He developed COVID the following Thursday.; This is a spontaneous report from a contactable Physician (patient's wife). A 55-year-old male patient received the 1st dose of bnt162b2 (BNT162B2) on 18Dec2020 at single dose for Covid-19 immunisation. The patient medical history and concomitant medications were not reported. The patient experienced developed Covid on 24Dec2020 (reported as the following Thursday). The patient underwent lab tests and procedures which included Sars-Cov-2 test: developed Covid. He was

fairly symptomatic for 7 days but he was doing well now. The outcome of events was recovering. The reporter quereide whether he should receive the 2nd dose, which is due on 08Jan2021 or should it be deferred. Information on Lot/Batch number requested.; Sender's Comments: The Company cannot completely exclude the possible causality between the reported positive Sars-Cov-2 test, which is considered ineffective of BNT162B2, and the administration of BNT162B2.

began having Covid symptoms on 24Dec and tested positive for Covid on Christmas; began having Covid symptoms on 24Dec and tested positive for Covid on Christmas; Arm was sore; This is a spontaneous report from a contactable physician reported for herself. A 55-year-old female patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK5730), via an unspecified route of administration on 17Dec2020 at single dose for COVID-19 vaccination. Medical history was not reported. There were no concomitant medications. Patient had arm sore on 18Dec2020. She started having COVID symptoms on 24Dec2020. She tested positive on Christmas, 25Dec2020. She was asking if she should get the second vaccine. When she got the vaccine she didn't pay attention to the paperwork. She was busy. Her arm was a little sore for a day that was the only reaction she had. She was hoping when she developed COVID symptoms that she was not sick. She was not hospitalized, and she is wondering if maybe the vaccine helped her not get as sick, and not end up in the hospital. It was the first dose she received. She has no other medical conditions. All the previous agent did was read off information to her. It sounds to her like she should go ahead and get the second dose. Outcome of event Arm was sore was recovered in 19Dec2020, of others was unknown.; Sender's Comments: Based on available information, a possible contributory role of BNT162B2 vaccine cannot be completely excluded for reported events.

developed covid like symptoms a few days later/ tested positive on the 26th; developed covid like symptoms a few days later/tested positive on the 26th; This is a spontaneous report from a contactable physician. A patient of unspecified age and gender received the first dose bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 18Dec2020 at single dose for covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient received the vaccine on 18Dec2020 and developed covid like symptoms a few days later in Dec2020 and believed the patient was likely exposed. The patient was tested positive on 26Dec2020. The outcome of the events was unknown. Information about Lot/Batch number has been requested.; Sender's Comments: The reported covid like symptoms a few days with tested positive after COVID-19 immunization is considered ineffective of BNT162B2, and the Company cannot completely exclude the possible causality between the reported event and BNT162B2 administration.

tested positive for the COVID-19 virus; tested positive for the COVID-19 virus; This is a spontaneous report from a contactable nurse. A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient medical history and concomitant medications were not reported. The patient was tested positive for the COVID-19 virus on an unspecified date after being administered with the vaccine. The outcome of the event was unknown. Information on Lot/Batch number has been requested.; Sender's Comments: Based on the information currently available, a lack of efficacy with the suspected vaccine BNT162B2 in this patient cannot be completely excluded. Further

information like confirmative virus genome /nucleic acid detection is needed for meaningful medical assessment. ,Linked Report(s) : US-PFIZER INC-2021005630 same reporter and drug, different patient and event

"was tested and diagnosed positive for the SARS-CoV-2 infection; was tested and diagnosed positive for the SARS-CoV-2 infection; developed symptoms after being exposed at work on 27Dec2020; This is a spontaneous report from a contactable nurse. A male patient (reporter's husband) of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) as the first dose via an unspecified route of administration on 22Dec2020 at single dose for COVID-19 immunization. The patient medical history and concomitant medications were not reported. The patient got exposed as a first line nurse working in the emergency room. The nurse reports that her husband developed symptoms after being exposed at work on 27Dec2020 five days after being administered with the first dose of BNT162B2 and he was tested and diagnosed positive for the SARS-CoV-2 infection on 27Dec2020. The outcome of the events was unknown. Information about Lot/batch number has been requested.; Sender's Comments: There is not a reasonable possibility that reported ""tested and diagnosed positive for the SARS-CoV-2 infection"" is related to BNT162B2. Event occurred only 5 days after receiving first vaccine and patient was exposed to virus at work."

positive COVID test result; positive COVID test result; cough; This is a spontaneous report from a contactable consumer reporting for herself. A 49-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE) (lot number/expiration date: not provided), via an unspecified route of administration, on 16Dec2020 (at the age of 49 years old) as a single dose for COVID-19 vaccination. Relevant medical history and concomitant medication were not provided. On 21Dec2020, the patient experienced a strange cough. The patient reported that she received the first dose of COVID vaccine on 16Dec2020 and that she was then exposed to her husband who tested positive on 17Dec2020. Due to a strange cough, she was tested on 21Dec2020, which resulted in a positive COVID test result. The outcome of the events strange cough and positive COVID test was unknown. The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow-up.

Developed covid symptoms 21Dec, tested positive 26Dec; Developed covid symptoms 21Dec, tested positive 26Dec; This is a spontaneous report from a contactable physician reporting for a patient. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration on 18Dec2020 as a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient developed COVID symptoms 21Dec2020, tested positive 26Dec2020. The outcome of the event was unknown. The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up.; Sender's Comments: Based on the information currently available, a lack of efficacy with the suspected vaccine BNT162B2 in this patient cannot be completely excluded. However individuals may not be protected until at least 7 days after their second dose of the vaccine.

received the first dose of the Pfizer COVID vaccine on 28Dec2020 and tested positive for COVID 03Jan2021 (nasal swab) & symptomatic; received the first dose of the Pfizer COVID vaccine on

28Dec2020 and tested positive for COVID 03Jan2021 (nasal swab) & symptomatic; This is a spontaneous report from a contactable Nurse (patient). A female patient of unspecified age received BNT162B2 (Pfizer, lot number: EL0140) first dose on 28Dec2020 at single dose for COVID-19 immunization. Medical history and concomitant medications were not reported. Patient was tested positive for COVID 03Jan2021 (nasal swab) & symptomatic, her second dose of the vaccine is scheduled 18Jan2021. She was wondering if she still get the second dose. The outcome of the events was unknown.; Sender's Comments: The reported tested positive for COVID (nasal swab) & symptomatic after COVID-19 immunization is considered ineffective of BNT162B2, and the Company cannot completely exclude the possible causality between the reported event and BNT162B2 administration.

within 6 hours experienced severe chills and covid-like symptoms, she also tested positive for COVID-19; within 6 hours experienced severe chills and covid-like symptoms, she also tested positive for COVID-19; This is a spontaneous report from a contactable nurse. A 30-year-old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiry date were not reported), via an unspecified route of administration in left arm on 04Jan2021 11:30 at a single dose for COVID-19 vaccination. Medical history included allergies to Sulfa diagnosed in 2008, Allergies to Strawberries diagnosed when she was very young, Diamox allergy diagnosed in 2008, dyslexic, and Obesity but never been treated. Concomitant medication included levothyroxine (LEVOTHYROXINE), ascorbic acid, betacarotene, calcium sulfate, colecalciferol, cyanocobalamin, ferrous fumarate, folic acid, nicotinamide, pyridoxine hydrochloride, retinol acetate, riboflavin, thiamine mononitrate, tocopheryl acetate, zinc oxide (PRENATAL VITAMINS), zinc (ZINC), nd cetirizine hydrochloride (ZYRTEC). The patient previously took diamox [acetazolamide] and experienced drug hypersensitivity. Patient received first dose Monday, 04Jan2021, then she experienced severe chills and Covid like symptoms. Apparently, she tested positive for COVID 19. She ws not sure if it was a false positive or if she actually has COVID, but was concerned because her husband has cancer and was immunocompromised. Literally, she got the vaccine because her OB/GYN told her she needs to get it as soon as possible. She did blood work and she tested negative for pregnancy. There was no prescriber as it was given as part of her work. Fifteen minutes after receiving the vaccine, she had the worst headache she has ever had in her life. Six hours after that, she had such bad chills. That night, it worsened and it got better every hour when she took something. She said her congestion was still present. She stated she took Tylenol and hour later and it subsided. The outcome of the events was not recovered. The patient underwent laboratory date including negative antibodies on an unknown date, blood work on Mar2020 with unknown result, then on 05Jan2020 tested positive to COVID 19 by saliva test at 09:15 and nasal test at 11:30 Information about Lot/batch number has been requested.; Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of events Drug ineffective and COVID-19 cannot be totally excluded. The case will be reassessed if additional information becomes available

patient got the first dose of the COVID vaccine on 18Dec2020/was positive via COVID PCR test on 26Dec2020; patient got the first dose of the COVID vaccine on 18Dec2020/was positive via COVID PCR test on 26Dec2020; had a COVID exposure on 23Dec2020; This is a spontaneous report from a contactable physician. A patient of unspecified age and gender received the first dose of bnt162b2

(PFIZER-BIONTECH COVID-19 VACCINE; lot number and expiration date not provided), via an unspecified route of administration on 18Dec2020 at single dose for COVID-19 immunization. Patient's medical history was not reported. Concomitant medication included chemotherapy. It was reported that patient got the first dose of the COVID vaccine on 18Dec2020 and then had a COVID exposure on 23Dec2020 and was positive via COVID PCR test on 26Dec2020. It was mentioned that patient is a chemotherapy patient. The patient was given the antibodies for COVID on 28Dec2020 and the patient is currently doing well. Reporter's question was that the patient was scheduled to get the second dose of the vaccine on 08Jan2021 and the reporter is wondering if given this patient's situation, is it safe for the patient to receive the second dose or if there are any recommendations on when the patient should receive the second dose. Outcome of the events was recovering. Information on the lot/batch number has been requested.; Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of events Drug ineffective and SARS-CoV-2 test positive cannot be totally excluded. The case will be reassessed if additional information becomes available.

tested positive for covid; tested positive for covid; This is a spontaneous report from a contactable consumer. A 35-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration at the left upper arm on 18Dec2020 15:30 at a single dose for COVID-19 immunisation. Medical history included high blood pressure and had electrocardiogram (EKG) unknown result a week before vaccination in Dec2020. Concomitant medication included acetylsalicylic acid (ASPIRIN), lisinopril, and guaifenesin (MUCINEX). It was reported that patient tested positive for COVID on 31Dec2020. She has not gotten her second dose but it was scheduled for 08Jan2021 for which will still be in quarantine then and requested guidance on when/if she should get the second dose. Patient explained her parents have COVID and that the rapid test for the COVID test was how she found out she had COVID. The patient has not recovered from the events.

Developing symptoms of covid/ symptoms of Covid after having the vaccine; Developing symptoms of covid/ symptoms of Covid after having the vaccine; This is a spontaneous report from a contactable consumer (patient) via a Pfizer-sponsored program. A 31-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection) lot number: EJ1688, via an unspecified route of administration in the left arm, on 21Dec2020 at a single dose for covid-19 immunisation as she works with disabled people and for general community health. Patient's medical history was none. Family history included her kids/children had covid (unknown if ongoing). There were no concomitant medications. It was reported that the patient had symptoms of covid after having the vaccine with outcome of recovering. The patient received the first dose of covid vaccine on 21Dec2020 and on the 02Jan2021 she started developing symptoms of covid. She mentioned that her children have virus and she had the covid test done. She wanted to know if she can get the second dose of the vaccine. She queried for her co-worker who has the Covid and was told to not take the vaccine yet and how long they need to wait. She was tested this morning. She has not gotten the results. Her kids had Covid and she felt certain she had it because she has symptoms. It comes and goes. It was better during the day and worse at night. She received the vaccine because she works with disabled people where

there are extremely high numbers of the virus. She also got it for general community health. The Covid test was done on 06Jan2021 with unknown result.

had a positive Covid test after receiving the vaccine; had a positive Covid test after receiving the vaccine; This is a spontaneous report from a contactable nurse (patient) via a Pfizer Sponsored program, Pfizer First Connect. A 30-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection) lot number: EH9899, intramuscular in the left arm, on 18Dec2020 at 0.3 mL, single dose for COVID-19 immunization. Medical history included was none. There were no concomitant medications. The patient had a positive Covid test after receiving the vaccine with outcome of unknown. It was reported that the patient got the first dose of the vaccine on 18Dec2020, and tested positive on 28Dec2020 due to some exposure. She asked for any recommendations on the second dose whether or not she could get it. She is scheduled to get it this weekend. The reporter considered the event as non-serious and unrelated to the use of the vaccine.; Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of events Drug ineffective and COVID-19 virus test positive cannot be totally excluded. The case will be reassessed if additional information becomes available.

He tested positive last Tuesday for SARS-Cov-2; He tested positive last Tuesday for SARS-Cov-2; This is a spontaneous report from a Pfizer Sponsored Program, Pfizer First Connect via a contactable other health professional (HCP) (patient). A male patient of an unspecified age received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 18Dec2020 at single dose for covid-19 immunization. The patient medical history and concomitant medications were not reported. The patient tested positive last Tuesday (05Jan2021) for SARS-Cov-2 and the patient wanted to know if he could receive his second dose of vaccine. The outcome of the event was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Based on the information currently available, a lack of efficacy with the suspected vaccine BNT162B2 in this patient cannot be completely excluded. Further information like confirmative virus genome /nucleic acid detection is needed for meaningful medical assessment.

she received the COVID-19 vaccine and the next day she tested positive for the viral infection; she received the COVID-19 vaccine and the next day she tested positive for the viral infection; This is a spontaneous report from a contactable consumer (patient) from a Pfizer sponsored program Pfizer First Connect. A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 05Jan2021 at single dose for COVID-19 immunisation. The patient medical history and the concomitant medications were not reported. The patient was tested on 02Jan2021, and did not get the results till 06Jan2021 and tested positive. The patient wanted to know if she could have any side effects if she received the COVID-19 vaccine and the next day she tested positive for the viral infection. She is unsure of when she contracted the infection. The outcome was unknown. Information on the lot/batch number has been requested.

chest tightness; palpitations; elevated heart rate; fatigue; This is a spontaneous report from a contactable Other HCP. A 37-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19

VACCINE), via an unspecified route of administration on 31Dec2020 at single dose for covid-19 immunisation. Medical history included Dermatographia. The patient is allergic to Penicillin, lactose, Cephalosporins and Beepen-VK. There were no concomitant medications. Seventy two hours after the vaccine was given the patient had an elevated heart rate, chest tightness and fatigue. Are this consistent with the vaccine. She does not have a history of elevated heart rate or palpitations. She checked her heart rate with her Apple watch and sent in a strip to the doctor. The doctor is concerned and is asking if this is related. She went to the ER to make sure she was ok but was not admitted. Outcome of event heart rate increased as recovered on 05Jan2021, of fatigue was not recovered, of others was recovering. Information about Lot/batch number has been requested.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the reported events of elevated heart rate, chest tightness, palpitations and fatigue due to temporal relationship. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics including 12-lead EKG , counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

if a patient experienced an allergic reaction to the first dose is there anything prophylactically needing to be done when administering the second dose of the Covid vaccine; delayed hyper sensitive reaction; Angioedema; Urticarial rash; This is a spontaneous report from a contactable other hcp. A 47-years-old male patient received first dose of bnt162b2 (BNT162B2), unknown on 18Dec2020 (lot number: EK5730) at SINGLE DOSE for COVID-19 immunisation. The patient medical history and concomitant medications were not reported. Caller is a Physician Assistant. Caller states that she is calling about the Covid Vaccine. She had a patient received his first dose of the vaccine on Friday 18Dec2020, 3 days later on 21Dec2020 he had an urticarial rash that persisted, The urticarial rash was treated with prednisone and resolved by 27Dec2020, it has not reoccurred. The allergist said it was a delayed hyper sensitive reaction that was Prompted by the immune simulation from the vaccine. The Patient was treated for the urticaria. Caller would like to know if a patient experienced an allergic reaction to the first dose is there anything prophylactically needing to be done when administering the second dose of the Covid vaccine? Caller is very upset and frustrated and stating she wants to speak to someone that is a clinician with the clinical trial team who can give her recommendations for a specific patient. Caller asks if they should do Prophylaxis with antihistamines for the second dose. He did not have anaphylaxis but he had angioedema. Caller states that she did a Vaers report on 22Dec2020, but no one contacted her. He started taking Zyrtec and Vistaril. The Allergist said it was fine and he will still need the 2nd Booster Dose. The Angioedema started on 22Dec2020, it was also treated with prednisone, in addition to being administered Benadryl IM, and Vistaril. The outcome of the event urticarial rash was recovered on 27Dec2020 and Angioedema was recovered on 22Dec2020. No follow-up attempts are needed; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the angioedema and the other reported events due to

temporal relationship. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics including serum tryptase level and complement panel, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Angioedema; Tongue numb observer notified about 10 minutes after vaccine, then tongue and Lower lips numb; tachycardia with throat tightness; tachycardia with throat tightness.; This is a spontaneous report from a contactable nurse (patient). The 37-years-old female patient received first dose of bnt162b2 (BNT162B2, Lot number: EK9231), unknown on 05Jan2021 07:45 at SINGLE DOSE on left arm for COVID-19 immunisation. The patient is not pregnant. No covid tested post vaccination. Medical history included Idiopathic angioedema, HTN, PCOS, Allergies to medications, food, or other products: Latex, penicillin, coconut. Prior to vaccination, the patient was diagnosed with COVID-19. Concomitant medication included spironolactone (ALDACTONE), fexofenadine hydrochloride (ALLEGRA), hydrochlorothiazide, amlodipine besilate (NORVASC). The patient did not take other vaccine in four weeks. The patient experienced Angioedema event occurred approximately 18 hrs later with repeat of treatment in ER on 06Jan2021, tongue numb observer notified about 10 minutes after vaccine, then tongue and lower lips numb on 05Jan2021 08:00, taken to ER became tachycardia with throat tightness on 05Jan2021 08:00. EPIPEN administered, benadryl and prednisone (steroids), and famotidine administered along with a saline bolus. The outcome of the events was recovered. No follow-up attempts are needed.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the angioedema and other reported events due to temporal relationship. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics including complement levels, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

"extremely bad dry mouth; lips were going numb; facial numbness; rash from his neck to his nipple line; BP was 180/110 / BP stayed around 160/100; felt an ""amped"" feeling; felt flush; uncomfortable; This is a spontaneous report from a contactable healthcare professional. A 44-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number/expiration date unknown), dose number 1, intramuscularly on 21Dec2020 14:00 at a single dose on the right arm for COVID-19 immunization. Medical history included gluten allergy with causes dermatitis herpetiformis, osteoporosis, and fibromyalgia. The patient previously took Benadryl and experienced allergies. Concomitant medications were not reported. The patient reported that immediately after receiving

vaccine on 21Dec2020, he felt an ""amped"" feeling and felt flush. It was uncomfortable but not alarming at first. About ten minutes after shot, he started to have extremely bad dry mouth. He went back to work, but he went back downstairs after feeling like he was getting seriously ill and his lips were going numb. His BP was 180/110. The facial numbness went away but his BP stayed around 160/100. He was asked to go to ER, but he refused because he would have to pay for it and he was feeling better. He also noticed after going back upstairs that he had a rash from his neck to his nipple line. The doctor asked for Benadryl, but he was not given due to possible Benadryl allergy. He went home and his BP returned to normal 2 hours later. The patient was not diagnosed with COVID-19 prior to vaccination, and was not tested for COVID-19 since the vaccination. The outcome of the events was recovered in 21Dec2020 for blood pressure increased and facial numbness, and recovered on an unspecified date for the other events. Information on the lot/batch number has been requested.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the BP increased and other reported events due to temporal relationship. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics including EKG and chemistry panel, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate."

crystals in her urine; muscle pain; joint pain; flu like symptoms/feeling like she has the flu; having no energy; feeling tired/Tiredness; kidney stone; pain in her back; did not feel good; This is a spontaneous report from a contactable consumer (patient). A 54-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot EL0140) intramuscular on 31Dec2020 16:00 at a single dose on left arm for Covid-19 prophylaxis. Medical history included rheumatoid arthritis. There were no concomitant medications. The patient wanted to know if she could receive the second dose of the COVID-19 vaccine if she presented the following side effects with the first shot: feeling tired/tiredness on 02Jan2021; having no energy on 03Jan2021; muscle pain, joint pain, and flu like symptoms/feeling like she has the flu, on 04Jan2021. She went to work on Monday and has taken the last couple of days off because she did not feel good on Jan2021. She did have rheumatoid arthritis, but it was different and has not been like this. She went to the doctor on Monday after she got off of work and thought at first maybe she had a UTI; treated herself with AZO, but had a urinalysis that was negative on an unspecified date. She was told some of the pain in her back might have been a kidney stone on Jan2021 because they found crystals in her urine on 04Jan2021, but she did not know about that. She noticed having no energy on Sunday. She wanted to know if it was recommended that she get the second vaccine since she was having side effects. The events required a visit to physician office and did not require a visit to Emergency Room. Prior vaccinations within 4 weeks was noted as none. Family medical history relevant to the events (AE) was noted as none.The outcome of the events of feeling tired/tiredness was not recovered; of having no energy, muscle pain, joint pain, flu like symptoms/feeling like she has the flu was recovering; of the rest of events was unknown.

Left Bell's palsy/left side of face, inability to raise left eyebrow; numbness and paresthesia of tongue; numbness and paresthesia of tongue; pain in left upper arm between elbow and shoulder; tachycardia; elevated blood pressure; This is a spontaneous report from a contactable physician. A 35-year-old female patient (not pregnant at the time of vaccination) received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EH9899), intramuscular at arm left on 31Dec2020 at single dose for covid-19 immunization. The vaccine was administered at other (as reported). Medical history included asthma (Allergy induced asthma). Concomitant medication within 2 weeks of vaccination included cetirizine hydrochloride (ZYRTEC) from Dec2020 at 10mg daily. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. On 31Dec2020, the patient experienced Left Bell's palsy, numbness and paresthesia of tongue, left side of face, inability to raise left eyebrow, pain in left upper arm between elbow and shoulder, tachycardia, elevated blood pressure. The adverse events result in emergency room/department or urgent care. The patient received treatment for the adverse events which included Prednisone 20mg daily, Valacyclovir 1000mg twice a day. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, the patient was not been tested for COVID-19. The outcome of events was not recovered.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the Bell's palsy and other reported events due to temporal relationship. However, the Bell's palsy may possibly represent a concurrent medical condition. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics including viral serologies, and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Shortness of breath, stridor, migraine for 5 days and 10 days later cellulitis at injection site.; Shortness of breath, stridor, migraine for 5 days and 10 days later cellulitis at injection site.; Shortness of breath, stridor, migraine for 5 days and 10 days later cellulitis at injection site.; Shortness of breath, stridor, migraine for 5 days and 10 days later cellulitis at injection site.; This is a spontaneous report from a contactable Nurse (patient). A 51-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (lot number EH9899), intramuscularly on 28Dec2020 14:30 at single dose for covid-19 immunization. Vaccine location was left arm and it was the first dose. The facility type vaccine was hospital. Medical history included migraine from an unknown date. Concomitant medication included erenumab aooe (AIMOVIG), estradiol, diphenhydramine hydrochloride (BENADRYL), trazodone hydrochloride (TRAZODON). No known allergies. Patient was not diagnosed with COVID-19 prior to vaccination nor tested for COVID-19 since the vaccination. The patient didn't receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient experienced shortness of breath, stridor, migraine for 5 days and 10 days later cellulitis at injection site on 28Dec2020 15:00. Patient received Antibiotics, steroids epi as treatment for the adverse events. The adverse events resulted in Doctor or other healthcare professional office/clinic visit. The outcome of event migraine was recovered in Jan2021, other events was recovered on an unknown date. The events were reported as non-serious.;

Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the reported events of Vaccination site cellulitis, shortness of breath, stridor and migraine, due to temporal relationship. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics, and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

to get Botox injection for her Dystonia; got her 1st dose of Covid vaccine last 04Jan and was scheduled to have her 2nd dose on 22Jan; This is a spontaneous report from a Pfizer-sponsored program. A contactable consumer(patient) reported that a 62-year-old female received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 04Jan2021 at single dose for covid-19 immunization. The patient medical history and concomitant medications were not reported. The patient got her 1st dose of Covid vaccine last 04Jan2021 and was scheduled to have her 2nd dose on 22Jan2021, but she had an appointment 2 days prior this to get botulinum toxin type a (BOTOX) injection for her Dystonia. The patient wanted to know if it's ok for her to get 2nd dose of Covid vaccine after getting botulinum toxin type A. Outcome of the events was unknown.

she tested positive 5 days after taking the first COVID19 Vaccine dose; she tested positive 5 days after taking the first COVID19 Vaccine dose; This is a spontaneous report from a contactable nurse (patient). A female patient of an unspecified age received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number and expiration date were not reported), via an unspecified route of administration on an unspecified date at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. On an unspecified date, the patient tested positive 5 days after taking the first COVID-19 vaccine dose. Outcome of the events was unknown. Information about lot/batch number has been requested.

received first dose of covid vaccine on 19Dec2020 tested positive on 31Dec2020; received first dose of covid vaccine on 19Dec2020 tested positive on 31Dec2020; This is a spontaneous report from a contactable other HCP (patient). A male patient of an unspecified age received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) , via an unspecified route of administration on 19Dec2020 at the first single dose for covid-19 immunisation. The patient medical history was not reported. The patient's concomitant medications were not reported. The patient received first dose of covid vaccine on 19Dec2020 tested positive on 31Dec2020. The outcome of events was unknown. Information about Lot/Batch has been requested.; Sender's Comments: A causal association between reported event and BNT162B2 cannot be excluded.

tested positive for covid19; tested positive for covid19; This is a spontaneous report from a contactable nurse (patient). A 22-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 21Dec2020 at single dose for COVID-19

immunization. The patient medical history and concomitant medications were not reported. The patient received vaccine 1st dose on 21Dec2020 and on 29Dec2020 she tested positive for covid19. She is coming up on 2nd dose on Friday (will be out of quarantine on the same day), she asked if she should get the vaccine. Her primary care physician advised her not to receive, within 30 days because there had been reports of people having reactions (ie: high fevers) to the vaccine. If she has a high fever she can't go to school. She asked if waiting 90 days make the vaccine not as effective and if she need to restart the series. The outcome of the events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Test positive for covid19 found 7 day following the vaccination, no adequate effect of the suspect vaccine thus could be reasonably achieved to protect from the targeted infection/disease due to the very short time lag

collapse/rapid progression of symptoms; hypotension/rapid progression of symptoms; respiratory distress with stridor; respiratory distress with stridor; dizziness/rapid progression of symptoms; not limited to abdominal pain/rapid progression of symptoms; blood pressure abnormality/rapid progression of symptoms; chest pain/rapid progression of symptoms; drooling/rapid progression of symptoms; increased swelling/rapid progression of symptoms; wheezing; dyspnea and increased work of breathing; skin changes; tongue swelling and vomiting; tongue swelling and vomiting; This is a spontaneous report from a non-contactable other health professional. A 35-year-old female patient (Age at vaccination: 35) received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK9231), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. During her 15 minute waiting period after the injection, the patient began to experience dizziness. Monitored patient for severe reaction symptoms, including but not limited to abdominal pain, blood pressure abnormality, chest pain, collapse, drooling, hypotension, increased swelling, rapid progression of symptoms, respiratory distress with stridor, wheezing, dyspnea and increased work of breathing, skin changes, tongue swelling and vomiting. Treatment included: no therapy. The outcome of the events was unknown. No follow up attempts are possible. No further information is expected.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the collapse, hypotension, respiratory distress and other reported events due to temporal relationship. There is very limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics including BP measurements, chest x-ray, EKG and chemistry panel, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Escherichia Coli infection; This is a spontaneous report from a non-contactable consumer (daughter) from a Pfizer sponsored program Pfizer First Connect. A female patient of unspecified age received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. Medical history and

concomitant medications were not reported. The reporter's mother has Escherichia Coli infection and is taking Nitrofurantoin antibiotic (Macrodantin). Asked if it is safe to take the second dose of the vaccine while on antibiotic. Caller asking if we could update info regarding antibiotic as even her doctor does not have info on this. Saying that even her doctor is unsure as Pfizer should know information regarding this more than her doctor. Treatment for event was Nitrofurantoin antibiotic (Macrodantin). Outcome of event was unknown. No follow up attempts are possible; Information about lot/batch number cannot be obtained.

"tested positive for Covid; tested positive for Covid; This is a spontaneous report from a contactable physician (patient). A female patient of an unspecified age received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 20Dec2020 at single dose for COVID-19 immunization. The patient medical history and concomitant medications were not reported. The patient tested positive for Covid on 22Dec2020. She wanted to know if there is any more information on receiving the second dose after testing positive. The outcome of the event was unknown. Information on the Lot/batch number has been requested.; Sender's Comments: Based on the mechanism of action of BNT162B2 vaccine, it is unlikely the patient would have fully developed immunity for the vaccine to be effective, due to the number of days passed since the vaccine was given (in this case 2 days). However, a causal relationship between event ""tested positive with Covid "" (coded to Drug ineffective / SARS-CoV-2 test positive) and BNT162B2 vaccine cannot be completely excluded."

she received the Pfizer-BioNTech Covid-19 Vaccine .She said she tested positive for Covid-19 after being exposed to someone infected with the virus last Christmas; she received the Pfizer-BioNTech Covid-19 Vaccine .She said she tested positive for Covid-19 after being exposed to someone infected with the virus last Christmas; after being exposed to someone infected with the virus; This is a spontaneous report from a contactable Physician (patient). A female patient of an unspecified age receive the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) , via an unspecified route of administration on 18Dec2020 at single dose for covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient she received the Pfizer-BioNTech Covid-19 Vaccine on 18Dec2020. She said she tested positive for Covid-19 after being exposed to someone infected with the virus last Christmas (25Dec2020). Now, she wanted to know if she can still take the 2nd dose. The outcome of the events was unknown. Information on the Lot/Batch number has been requested.; Sender's Comments: A causal association between reported event and BNT162B2 cannot be excluded.

tested positive for covid; tested positive for covid; This is a spontaneous report from a contactable consumer received from a Pfizer-sponsored program Pfizer First Connect. A 64-years-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number EH9899, expiry date Mar2021, NDC 59267-1000-1), intramuscular in right arm on 18Dec2020 11:45 at a single dose as prevention. The vaccine was administered in the hospital. Medical history included ongoing cardiomyopathy diagnosed about 32 years ago and had pacemaker defibrillator Placed about 12 years ago. There were no concomitant medications. She was supposed to get the second dose of the Covid vaccine but she was positive for Covid. She found out she was positive for covid on Monday 04Jan2021 after she had a nasal swab test on 02Jan2020. The outcome of the event was unknown.

Bell's Palsy; developed flu like symptoms; This is a spontaneous report from a contactable pharmacist. A female patient of an unspecified age (reported as 32-40) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date in 2020 at single dose for COVID-19 immunization. The patient medical history and concomitant medications were not reported. The patient developed side effects side effects from first vaccine, Bell's palsy 4 days after vaccination (Dec2020) which lasted for 2 weeks and flu like symptoms (Dec2020) which also lasted 2 weeks. The events outcome was unknown. The patient was receiving 2nd dose on 06Jan2021, the reporter asked any information regarding this? Information on the lot/batch number has been requested.; Sender's Comments: Based on a compatible temporal relationship, causality between event Bell's palsy and BNT162B2 vaccine cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Fatigue; tested positive after receiving Covid-19 vaccine; tested positive after receiving Covid-19 vaccine; severely congested; This is a spontaneous report from a Pfizer-sponsored program IBCC (Inbound Call Center for HCPs). A contactable consumer (patient) reported that a 47-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EJ1685, Expiry Date: Mar2021) via an unspecified route of administration at right deltoid on 20Dec2020 at single dose for COVID-19 immunization. Medical history included ongoing severe asthmatic diagnosed as a child. There were no concomitant medications. Patient (a front line worker) is Grief Counselor. She tested positive after receiving BNT162B2 on 29Dec2020. She was supposed to get the second dose on 10Jan2021. She was having fatigue since 01Jan2021 and was severely congested since 26Dec2020. She was asking if she should get the second dose. The outcome of the events severely congested and fatigue was recovering, of the other events was unknown.

recently got vaccinated unwillingly knowing she had Covid; recently got vaccinated unwillingly knowing she had Covid; This is a spontaneous report from a contactable Other healthcare professional (HCP) reporting for herself. A female patient of an unspecified age received her first dose BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient recently got vaccinated unwillingly knowing she had covid on an unspecified date. The patient wanted to known if she should get her second dose still and in the same timely manner. The outcome of the events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Based on available information, a possible contributory role of suspect BNT162B2 cannot be completely excluded for reported event.

she received the first dose of the vaccine on the 22nd of December and tested positive on the 28th; she received the first dose of the vaccine on the 22nd of December and tested positive on the 28th; This is a spontaneous report from a Pfizer-sponsored program Pfizer First Connect. A contactable consumer(patient) reported that a female patient of an unspecified age received first dose BNT162B2, via an unspecified route of administration on 22Dec2020 at single dose for COVID-19 immunization. The

medical history and concomitant medications were not reported. The patient received the first dose of the vaccine on the 22nd of December and tested positive on the 28Dec2020, she was scheduled to get the 2nd dose on Jan 12th. The reporter wanted to know if it was safe for her to take the 2nd dose. The outcome of the events was unknown. Information about lot/batch number has been requested.

testing positive for COVID on nasal swab after first dose of COVID vaccine; testing positive for COVID on nasal swab after first dose of COVID vaccine; This is a spontaneous report from a non-contactable pharmacist. A patient of unspecified age and gender received 1st dose of BNT162B2 (reported as COVID vaccine), via an unspecified route of administration on an unspecified date at single dose for Covid-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient experienced testing positive for Covid on nasal swab after first dose of Covid vaccine on an unspecified date with outcome of unknown. No follow-up attempts are possible. Information about lot/batch number cannot be obtained. Pfizer is a marketing authorization holder of COVID vaccine in the country of incidence or the country where the product was purchased (if different). This may be a duplicate report if another marketing authorization holder of COVID vaccine has submitted the same report to the regulatory authorities.; Sender's Comments: The reported testing positive for Covid on nasal swab after COVID-19 immunization is considered ineffective of BNT162B2, and the Company cannot completely exclude the possible causality between the reported event and BNT162B2 administration.

She thinks there has been more anaphylactic reactions than usual and said that a physician female friend had experienced one; This is a spontaneous report from a non-contactable Other Health Professional via Pfizer sales representative. A female patient of unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunisation. Medical history and concomitant medications were not reported. During a conference call, (Name) mentioned that she thinks there has been more anaphylactic reactions than usual and said that a physician female friend had experienced one. It was unclear whether it was after a Pfizer or Moderna vaccine. She did mention that her friend recovered without any issues. Outcome of event was recovered on an unspecified date. No follow-up attempts are possible. Information about lot/batch number cannot be obtained.; Sender's Comments: A possible causal association between administration of BNT162B2 and the onset of anaphylaxis cannot be excluded, considering the plausible temporal relationship and the known adverse event profile of the suspect product. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Tested positive for COVID; Tested positive for COVID; This is a spontaneous report from a Pfizer-sponsored program from a contactable consumer (patient). A 68-year-old female patient received first dose of bnt162b2 (Pfizer BioNTech COVID vaccine), via an unspecified route of administration on an unspecified date at a single dose in left arm for COVID-19 immunization. Medical history included ongoing rheumatoid arthritis, open heart surgery had this done a year ago, knee replacement, and hip

replacement. Concomitant medications included patient took a lot of different medications, but no additional details provided. The test done on Saturday 02Jan2021 and on Sunday 03Jan2021, she got the results that she was positive for COVID. Clinical details: She received the first dose of her COVID vaccine, and she will be due for her second dose on Saturday. However, she tested positive for COVID after getting her first dose. The doctor informed her she should have a COVID infusion. She took the COVID infusion and now after getting the infusion she is told she is not able to get her second dose of the COVID vaccine for 60-90 days. She is not sure what to do. She cannot remember the date she got the COVID vaccine, she knew she is due for her second one on Saturday. She received the COVID infusion this morning, originally she was told she would be able to have a second shot even after getting the COVID infusion. Now they are saying she cannot have the next dose on Saturday. She was told later she would have to wait two weeks. Then she was told she would have to possibly wait 90 days. She was thankful for the vaccine because even though she tested positive it probably kept her from dropping dead. Information on the lot/batch number has been requested.

"got Covid/She tested positive for SARS-Cov-2 04JAN2021; got Covid; This is a spontaneous report from a contactable other healthcare professional (patient). A female patient of an unspecified age received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 21Dec2020 at single dose for covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient indicated she received her first dose of vaccine 21Dec2020. She tested positive for SARS-Cov-2 04Jan2021. She was asking how she ""got Covid"" and if she should receive the second dose. The outcome of the event was unknown. Information on Lot/Batch number has been requested.; Sender's Comments: The reported tested positive for SARS-Cov-2 after COVID-19 immunization is considered ineffective of BNT162B2, and the Company cannot completely exclude the possible causality between the reported event and BNT162B2 administration."

The day after vaccine administration, pt was still experiencing vertigo, spinning and headache.; The day after vaccine administration, pt was still experiencing vertigo, spinning and headache.; This is a spontaneous report from a non-contactable other healthcare professional (hcp). A 27-year-old female patient receive first dose of bnt162b2 (Pfizer BioNTech COVID vaccine, lot number: EL0140), intramuscularly on 30Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. There is unknown if any other vaccine received in four weeks. The patient experienced the day after vaccine administration, patient was still experiencing vertigo, spinning and headache, all on 31Dec2020 the day after vaccine administration. The outcome of events was unknown. This is a non-serious report. It's unknown if patient was diagnosed with COVID-19 or tested for COVID-19 since the vaccination. The adverse did not result in 'doctor or other HCP visit or emergency room or urgent care, hospitalization or prolongation, life threatening illness, disability or death or congential anomaly'. No follow-up attempts are possible. Information about Lot/Batch cannot be obtained.

anaphylaxis; throat tightening; throat tightening/tingling; throat tightening/tingling/soreness; dry wheezy cough a little dizziness; dizziness; tachycardia; Itching; chills; numb R foot; Low grade temp; h/a today; This is a spontaneous report from a contactable Nurse (patient). A 51-years-old female patient (no pregnant) started to receive bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number el3248),

via an unspecified route of administration on 06Jan2021 11:00 at the first single dose at left arm for covid-19 immunisation. Medical history included supraventricular tachycardia, adrenal insufficiency, hypothyroidism, attention deficit hyperactivity disorder, hypermobility syndrome, developmental hip. Concomitant medication included hydrocortisone, trazodone, levothyroxine sodium (LEVOTHROID), bupropion hydrochloride (WELLBUTRIN). The patient previously took erythromycin, morphine and experienced drug hypersensitivity. The patient experienced anaphylaxis, throat tightening/tingling/soreness, dry wheezy cough a little dizziness and tachycardia. Itching, numb R foot, Low grade temp and chills and headache on 06Jan2021 11:15. Seriousness criteria reported as life threatening. Taken to ER had IV benadryl, solumedrol, pepcid for anaphylaxis. Placed on O2 and given albuterol nebulizer. Had IV fluid bolus. Now on benadryl and 5 days of prednisone. The patient felt completely fine prior to vaccine. The patient underwent lab tests and procedures which included sars-cov-2 test: negative on 06Jan2021. The outcome of events was recovering. No other vaccine in four weeks; No covid prior vaccination.; Sender's Comments: A possible causal association between administration of BNT162B2 and the onset of anaphylaxis presented as throat tightening/tingling/soreness, dry wheezy cough a little dizziness and tachycardia. Itching, numb R foot, Low grade temp and chills and headache cannot be excluded, considering the plausible temporal relationship and the known adverse event profile of the suspect product. The underlying predisposing condition of drug allergies may put the patient at high risk of anaphylactic reactions. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Soreness at injection site started at 1600 Body aches, headache, and low grade fever woke me up around 0100

Patient with Covid between their first and second doses of the Covid vaccine; Patient with Covid between their first and second doses of the Covid vaccine; This is a spontaneous report from a Pfizer-sponsored program from a contactable Pharmacist reported similar events for 2 patients. This is the 2nd of 2 reports. A patient of an unspecified age and gender received the first dose of BNT162B2 (Pfizer/BioNTech Covid-19 vaccine) on an unspecified date for Covid-19 immunization. The patient's medical history and concomitant medications were not reported. On an unspecified date, the patient got Covid between first and second doses of the Covid vaccine. The outcome of the event was unknown. Information on the lot/batch number has been requested.; Sender's Comments: The association between the event lack of effect (got COVID between first and second doses) with BNT162b2 can not be fully excluded.,Linked Report(s) : US-PFIZER INC-2021011515 same reporter/drug/AE, different patient

patient with covid between their first and second doses of the covid vaccine; patient with covid between their first and second doses of the covid vaccine; This is a spontaneous report from a Pfizer sponsored program IBCC (Inbound Call Center for HCPs). A contactable pharmacist reported similar events for two patients. This is the first case out of 2 cases. A patient of unspecified age and gender received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK9231, expiration date: Apr2021, NDC#59267-1000-1), via an unspecified route of administration on an unspecified date at

single dose for covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient with Covid between the first and second doses of the Covid vaccine on an unspecified date. The reporting pharmacist wanted to know if the patients with covid between their first and second doses of the covid vaccine what their risk would be, Reportedly 2 different patient. The outcome of the events was unknown.; Sender's Comments: The association between the event lack of effect (COVID between first and second dose) with BNT162b2 can not be fully excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.,Linked Report(s) : US-PFIZER INC-2021011471 same reporter/drug/event, different patient..

tested positive and also received the vaccine from COVID-19; tested positive and also received the vaccine from COVID-19; This is a spontaneous report from a Pfizer sponsored program. This contactable physician reported similar events for the physician herself and a patient. This is the second report, the patient report of 2 reports. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for covid-19 immunization. The patient medical history and concomitant medications were not reported. The physician reported there was another person in her clinic that tested positive and also received the COVID vaccine on an unspecified date with outcome of unknown. The information on the batch number has been requested.; Sender's Comments: Based on the information currently available, a lack of efficacy with the suspected vaccine BNT162B2 in this patient cannot be completely excluded. Further information like confirmative virus genome /nucleic acid detection needed for meaningful medical assessment.,Linked Report(s) : US-PFIZER INC-2021000799 Same reporter, same drug, different patients

"did develop COVID that week probably symptoms in general by 25Dec/probably infected whenever got the vaccine; did develop COVID that week probably symptoms in general by 25Dec/probably infected whenever got the vaccine/I don't feel very well right now; This is a spontaneous report from a contactable consumer (patient). A patient of unspecified age and gender received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EJ1685), via an unspecified route of administration on 21Dec2020 at single dose for covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient received 1st vaccine on 21Dec2020. The patient did develop COVID that week probably symptoms in general by 25Dec2020. She was probably infected whenever she got the vaccine and the patient was scheduled to have second vaccine on 11Jan2021 which was next Monday and the patient was still sick, should the patient delayed that. The patient also did not feel very well on an unknown date (""right now""). The outcome of the events was not recovered."

"had covid after his first dose; had covid after his first dose; headaches; This is a spontaneous report from a Pfizer-sponsored program Pfizer First Connect from a contactable Physician. A male patient of an unspecified age received his first single dose of BNT162B2 (Pfizer/ BioNTech Covid-19 vaccine) on an unspecified date in Dec2020 for Covid-19 immunization. The patient previously had Covid in Apr2020.

Concomitant medications were not reported. After his first dose of vaccine, in Dec2020, the patient had Covid and headaches. The outcome of the events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: The reported ""had Covid"" after COVID-19 immunization is considered ineffective of BNT162B2, and the Company cannot completely exclude the possible causality between the reported event and BNT162B2 administration."

Got the first dose of the vaccine on 23Dec2020, this week the patient was tested positive for COVID; Got the first dose of the vaccine on 23Dec2020, this week the patient was tested positive for COVID; This is a spontaneous report from a Pfizer-sponsored program Pfizer First Connect from a contactable other healthcare professional (HCP) (patient). A female patient of an unspecified age received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 23Dec2020 at single dose for COVID-19 immunisation. The patient medical history and concomitant medications were not reported. The patient got the first dose of the vaccine on 23Dec2020, this week the patient was tested positive for COVID in Jan2021. The outcome of the events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: The reported tested positive for COVID after COVID-19 immunization is considered ineffective of BNT162B2, and the Company cannot completely exclude the possible causality between the reported event and BNT162B2 administration.

she tested positive in the middle; she tested positive in the middle; This is a spontaneous report from a contactable female consumer (patient) via a Pfizer-sponsored program . A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 16Dec2020 at first single dose for COVID-19 immunization. The patient medical history was not reported. The patient's concomitant medications were not reported. Caller was asking if it was safe for her to get the second dose, she had the 1st dose on the 16Dec2020 and scheduled for the second dose today (reported on 06Jan2021), however she tested positive in the middle. Outcome of the event was unknown. information on the lot/batch number has been requested.

tested positive for Covid-19; tested positive for Covid-19; This is a spontaneous report from a contactable healthcare professional (HCP) reporting for himself via a Pfizer-sponsored program Pfizer First Connect. A male patient of an unspecified age received the first single dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (lot number and expiry date not reported) via an unspecified route of administration on 21Dec2020 for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient was tested positive for COVID-19 on 28Dec2020 and he was wondering if he was still able to receive the second dose of the vaccine. The outcome of the event was unknown. Information on the lot/ batch number has been requested.; Sender's Comments: The reported tested positive for COVID-19 after COVID-19 immunization is considered ineffective of BNT162B2, and the Company cannot completely exclude the possible causality between the reported event and BNT162B2 administration.

Anaphylactic reaction; Flushed; Diaphoretic; redness and rash; hives on chest; Tachycardia; shortness of breath; Chest tightness; Dizziness; Headache; This is a spontaneous report from a contactable nurse, the patient. A 47-year-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-

19 mRNA VACCINE; Lot Number: EL1283), via an unspecified route of administration on 08Jan2021 at 08:49 (at the age of 47-years-old) as a single dose for COVID-19 immunization. There were no known medical history or concomitant medications. The patient previously received the first dose of BNT162B2 on 18Dec2020 (Lot Number: EK5730) for COVID-19 immunization and experienced nausea, headache, and fatigue. On 08Jan2021, about 5-10 minutes after the second dose, the patient experienced anaphylactic reaction, flushed, diaphoretic, redness and rash, hives on chest, tachycardia, shortness of breath, and chest tightness, reported as life-threatening. She reported that these events occurred within less than 10 minutes of receiving the vaccine. She went to the emergency room and was treated with methylprednisolone (SOLUMEDROL), diphenhydramine hydrochloride (BENADRYL), famotidine (PEPCID), and epinephrine (MANUFACTURER UNKNOWN). She was sent home and prescribed methylprednisolone and epinephrine (EPI-PEN). Later on 08Jan2021, she experienced dizziness and headache, which were consistent. She stated she would most likely take ibuprofen (MOTRIN) as treatment (not specified if taken). The clinical outcomes of the flushed, diaphoretic, redness and rash, hives on chest, tachycardia, shortness of breath, and chest tightness were recovered on 08Jan2021; while the outcomes of the dizziness and headache were not recovered and that of the anaphylaxis was reported as recovering.; Sender's Comments: The reported information is limited. Based on the close temporal relationship and the description of the events, there is a reasonable possibility that the events are related to BNT162 vaccine. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

Approx 10-15 post vaccine, employee said she felt lightheaded and like her heart was racing. Within 10 minutes she said she felt difficulty breathing, She then vomited. The observation nurse at the clinic administered Epi Pen and called a Code. The employee was transported to the Emergency Dep't and then to intensive care. She was placed on an Epi drip.

loss of consciousness Narrative: Patient received COVID-19 vaccine dose #1 on 1/6/21 w/o complications. Per 1/6/21- 1/9/21 nursing notes, patient did not experience any injection site reactions, denied pain or tenderness at injection site, no dizziness, no n/v, remained afebrile. Around 1/9/21 @1810, patient became acutely nonresponsive after being helped to the edge of bed. Per nurses, he was previously awake/alert, talking and asymptomatic. Patient is DNR/DNI but facility rapid response emergency team called d/t patient's sudden change of condition. Emergency team helped patient into lying position. Per 1/9/21 ICU emergency team note, patient appeared comfortable w/ no palpable radial pulse and had minimal shallow agonal breathing. Pulse ox 94%, HR in 60s per machine. BP unmeasurably low by BP cuffx3. Resident passed at 18:20 pm.

Approximately 1 - 2 hours after receiving I had numbess and soreness to my neck. A few days later started experiencing tingling, buzzing, weakness and heaviness to my right arm and leg. I reported this to my MS doctor who ordered an MRI of the brain and told me to report to you

Patient received the vaccine on 12/22/20 without complication. It was reported today that the patient was found unresponsive and subsequently expired at home on 1/11/21.

Increased weakness leading to a fall and fever of 101.3

Patient began experiencing fevers, body aches, back pain, fatigue, chills the night she received the vaccine. Symptoms progressed for the following four days when she was ultimately seen in PCP office. Laboratory evaluation demonstrated atypical pneumonia and elevated WBC count. Patient was diagnosed with Acute Myeloid Leukemia via bone marrow biopsy and is receiving treatment at the hospital.

LEFT FACIAL AND TONGUE NUMBNESS - WORK UP CVA NEG Narrative: Developed left facial and tongue numbness 4 hours after vaccine - went to ER and admitted for 2 days, negative workup for CVA or other acute etiology. Symptoms resolved prior to discharge from hospital

Reported feeling faint and nauseated during observation period. Placed on cart in trendelenberg

Within 24 hrs, developed headaches, burning sensation down spine and neck. fullness in head intensified next day. balance was off, numbness and tingling throughout body. Went to ER. Diagnosed Paresthesia

The facility had positive cases of COVID when we were able to begin vaccinating residents. Within about a week of vaccination, patient was tested positive for COVID. He was 91 years old and his immune system did not have the time to allow the vaccine to begin working before exposure. His age was a major contributing factor to his death.

The facility had positive cases for COVID 19 when the vaccine was received and administered to patient. With her advanced age and chronic conditions, she did not have time to build immunity between the time of vaccination and her testing positive.

The facility had a number of positive COVID 19 cases prior to patients vaccination. Due to her advanced age, chronic condition, and exposure, patient did not have the time to build immunity after exposure before becoming positive.

Within approximately 30 minutes after vaccine (Thursday), patient presented with red rash to upper chest, severe headache, dizziness and nausea. Was treated with Benadryl and Tylenol per anesthesia onsite. Symptoms remained throughout the day with minimal improvement. The following morning (Friday) only headache remained. patient began having abdominal pain, and was admitted to hospital the next day (Saturday). It is now Tuesday and patient is still hospitalized. Unclear if this entire event is vaccine related.

Pt expired due to possible cardiac arrest. Unsure if this was vaccine related.

Resident was found deceased at approximately 6pm in her apartment

Pt experienced the following morning: fever (100 F) chills, malaise, nausea, and numbness in hands at 0624 and 0836. Pt went to hospital at 1000, tx with IV fluids.

"In the early morning of Monday, January 11th the patient developed a significant headache with neck pain. She also reported parathesia and tingling in bilateral upper extremities with weakness of the right upper extremity. She reported feeling very anxious and ""wound up"". Patient presented to the Emergency Department 3 hours later. CT of the head/brain, EKG, CBC,CMP, Magnesium and Cardiac profile were performed with no significant findings. Ativan 0.5mg was administered orally. Patient was admitted to the facility for observation. Symptoms gradually resolved with no additional treatment."

Large red area surrounding injection site.

unsure if related to vaccine, but was notified by her next of kin that she died on 1/4/2021. No reports of side effects or hospitalization were reported to the facility prior to the notification of death.

patient reported expired 1/7/2021

On 12/31/2020, at approximately 00:15, pt developed a fever of 102.9 F and tachycardia with rate of 120. He was treated with acetaminophen. Later in the morning, he complained of nausea, generalized muscle aches, intermittent increase in confusion. At approximately 14:00, he had a fall out of bed and at that time noted to be short of breath, tachypneic. He was taken via ambulance to Emergency Department. From there he was transferred to Hospital for admission with acute respiratory distress, suspected sepsis with lactic acid 7.4 and Bilateral Pulmonary Emboli. He was started on heparin and broad spectrum antibiotics and transitioned to ELIQUIS on 1/3/2021. Infectious etiology of sepsis was unclear. He continued broad spectrum antibiotics with clinical improvement. Abdominal CT scan was obtained due to intermittent nausea, vomiting, abdominal pain, loose stools. His heart rhythm flipped to Atrial Fibrillation with RVR on 1/2 and his rate improved with titration of metoprolol. He was also treated with prednisone for suspected underlying undiagnosed COPD. It is noted in his hospital summary that PEs presumed provoked in the setting of his recent COVID 19 infection. He was discharged from the hospital on 1/8/2021 and readmitted to the Veterans Home. He has been stable.

Received Moderna vaccine on 1/5. Had a single episode of vomiting approximately 1 hour after vaccine. Hx of Asthma, started to develop SOB approximately 2 days later. She reached out to PCP and used inhaler with little relief. SOB worsened and she was admitted to the hospital on 1/8/21. Eval was negative for COVID (3 tests completed), flu and pneumonia. She has elevated WBCs and was given steroids and supplemental oxygen. She is improving but remains inpatient.

Patient was sent to the ED due to significant hematuria. He was afebrile.

Patient presented with myalgias, fevers, and chest pain on 1/10/21 and was found to have diffuse ST elevation and elevation troponin. He was evaluated by cardiology and diagnosed with acute myopericarditis. He was treated with NSAIDs and colchicine. He improved with this treatment and was discharged on 1/12/21 with ibuprofen and colchicine and outpatient cardiology follow up.

Rash on neck; gall bladder attack; This is a spontaneous report from a contactable nurse (patient). A 34-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK5730), via an unspecified route of administration at the left arm on 18Dec2020 10:30 at a single dose for COVID-19 immunization in the hospital, and morphine sulfate (manufacturer unknown), via an unspecified route of administration from an unspecified date at unspecified dose and frequency for an unspecified indication. Medical history included S/P rouxen-y gastric bypass, sleep apnea, cholelithiasis, HSV-2, obesity, and Hashimoto hypothyroid disease. The patient was not pregnant at the time of vaccination. Concomitant medications included ursodiol, valacyclovir, levothyroxine sodium (LEVOTH) and vitamins. The patient previously took morphine and experienced allergies. The patient did not receive any other vaccine within 4 weeks prior to the vaccine. Prior to the vaccination, the patient was not diagnosed with COVID-19. The patient experienced Rash on neck, morphine reaction and May or may not be related - gall bladder attack on 18Dec2020 14:30. The events resulted in Doctor or other healthcare professional office/clinic visit and Emergency room/department or urgent care. The patient was administered with NS bolus, diphenhydramine (BENADRYL) and also morphine in response to the events. Since the vaccination, the patient had been tested for COVID-19 via Nasal Swab/COVID-19 rapid ABBT which was negative on 18Dec2020. The action taken in response to the events for morphine sulfate was unknown. The outcome of the events was recovered with sequel. The patient assessed the events as non-serious. Pfizer is a marketing authorization holder of morphine sulfate in the country of incidence or the country where the product was purchased (if different). This may be a duplicate report if another marketing authorization holder of morphine sulfate has submitted the same report to the regulatory authorities.; Sender's Comments: The information currently provided is too limited to make a meaningful medical assessment hence, the events are conservatively assessed as related to the suspect drug BNT162B2 until further information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

mild elevation of his sed rate and leukocytosis; mild elevation of his sed rate and leukocytosis; myalgia (was reported as worsened); Arthralgia; Ten days later and still having pain/started in neck and migrated to his back, the buttocks and gluteal and quadriceps area; Ten days later and still having pain/started in neck and migrated to his back, the buttocks and gluteal and quadriceps area; Ten days later and still having pain/started in neck and migrated to his back, the buttocks and gluteal and quadriceps area; Ten days later and still having pain/started in neck and migrated to his back, the buttocks and gluteal and quadriceps area; This is a spontaneous report from a contactable physician (patient). A 76-years-old male patient received bnt162b2 (Pfizer-Biontech Covid-19 Vaccine), via an unspecified route of administration on 23Dec2020 at single dose on deltoid Right for covid-19 immunisation. Medical history included ongoing type 2 diabetes mellitus (diagnosed about 8 years ago). There were no concomitant medications. Patient developed myalgia on 27Dec2020 and arthralgia on 28Dec2020. Patient also experience ten days later and still having pain/ started in neck and migrated to his back, the buttocks and gluteal and quadriceps area in Dec2020. He had labs a few days ago. He had a mild elevation of his sed rate and leukocytosis. Events myalgia and arthralgia considered serious due to medically significant.

Outcome of events myalgia (was reported as worsened) and arthralgia was not recovered. Information about batch/lot number has been requested.; Sender's Comments: Based on the time association, the events myalgia and arthralgia are possibly related to suspect bnt162b2 administration. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

blood pressure increased and her pulse; blood pressure increased and her pulse; Chest pain; Numb fingers and later numb face; Mind fog; This is a spontaneous report from a contactable other HCP. This 37-year-old female other HCP (patient) reported that she received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: 1685), via intramuscular at left arm on 02Jan2021 08:15 AM at single dose for COVID-19 immunization. Facility type of vaccine was pharmacy or drug store. Medical history included panic disorder (last attack 2 years prior) and known allergies: latex, Iodine dye. Concomitant medications were not reported. No other vaccine in four weeks. No covid prior vaccination. No covid tested post vaccination. On 02Jan2021 08:15 AM, within a few minutes while still under observation at pharmacy, her blood pressure increased and her pulse. Numb fingers and later numb face. Chest pain presented. She went to ER (emergency room) 3hours later with ongoing symptoms that never resolved until 6 or 7 that evening while still in ER waiting room. Mind fog (02Jan2021 08:15 AM) was currently ongoing. The treatment for events included lorazepam (ADIVAN), diphenhydramine (BENADRYL), ibuprofen. Outcome of event mind fog was not recovered, and the rest of events was recovered/resolved with sequel.; Sender's Comments: Based on the compatible temporal association, the vaccination with BNT162B2 might play a contributory role in triggering the onset of the reported events. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

lost the sense of smell and taste; lost the sense of smell and taste; nasal congestion/stuffy nose; runny nose; tiredness/felt tired; eye pain; pain in the muscles; chills; sore pain in the arm; This is a spontaneous report from a contactable Other HCP (Dentist) reporting for herself. A 43-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) at single dose on 31Dec2020 at 10:00AM in the left arm for COVID-19 immunization. Lot number was EJ1685. Medical history and concomitant medications were none. On 01Jan2021 in the morning, she had a sore pain in her arm, and by nighttime she had chills. On 02Jan2021 and on 03Jan2021, Saturday and Sunday she had pain in her muscles, felt tired, and had some pain around her eye every time she moved her eyes. On 04Jan2021, Monday everything went away but she had stuffy nose and runny nose. Her stuffy and runny nose was better but she still had some congestion, but she could not blow anything out of her nose. On 05Jan2021, Tuesday she noticed she could not smell and she still could not smell. On 06Jan2021, she had no smell and no taste either. Stated everything was good at the time of report but she still could not smell or taste anything. She treated herself with Tylenol for the muscle aches. She

took one 500mg Tylenol by mouth on 02Jan2021 at bedtime and then one Tylenol 500mg by mouth again on 03Jan2021. She was scheduled for the next dose 19Jan2021. Mention she was planning to get a COVID 19 test to see if she had the disease. The patient recovered from fatigue, eye pain, pain in muscles on 03Jan2021, the patient recovered from chills on 02Jan2021, the patient recovered from sore pain in the arm on 01Jan2021, the patient was recovering from nasal congestion/stuffy nose, the patient did not recover from runny nose and loss the sense of smell and taste. Information on the lot/batch number has been requested.; Sender's Comments: The Company cannot completely exclude the possible causality between the reported pain in her muscles, felt tired,had some pain around her eye every time she moved her eyes, had no smell and no taste, and the administration of the COVID-19 vaccine, BNT162B2, based on the reasonable temporal association. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RA, IEC, as appropriate.

aware of 6 cases of Bell's Palsy by the companies making these vaccines; This is a spontaneous report from a contactable Other HCP. This Other HCP reported similar events for 6 patients. This is 1st of 6 reports. A patient of unspecified age and gender received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for covid-19 immunisation. The patient medical history was not reported. The patient's concomitant medications were not reported. The reporter reported since the use of modified RNA in covid vaccines,he/she had aware of 6 cases of Bell's Palsy by the companies making these vaccines since an unknown date. The event outcome was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Bell's Palsy is not uncommon in general population. The information provided in this case is limited and does not allow a full medically meaningful assessment. The case will be reassessed should additional information become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics committees and Investigators, as appropriate.,Linked Report(s) : US-PFIZER INC-2021009409 Different patient, same drug/event.;US-PFIZER INC-2021009412 Different patient, same drug/event.;US-PFIZER INC-2021009410 Different patient, same drug/event.;US-PFIZER INC-2021009411 Different patient, same drug/event.;US-PFIZER INC-2021009408 Different patient, same drug/event.

joint pain and muscle; joint pain and muscle; Vertigo; an itchy rash bilaterally on her arms; developing swollen, tender, and hard lymph nodes under the Left subclavian area/ swollen left subclavian lymph nodes; developing swollen, tender, and hard lymph nodes under the Left subclavian area; extreme fatigue; Runny nose; Headache; This is a spontaneous report from a contactable nurse (RN) reporting for herself. A 42-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) first dose on 23Dec2020 h 09:00 intramuscularly in left deltoid (left arm) lot number: EK5730 at single dose for COVID-19 immunization. Concomitant medications were not provided. Patient stated that she has had double mastectomy, and missing a lot of lymph nodes, states she got the first dose of Pfizer Covid

vaccine on 23Dec2020, states it made her left subclavian lymph nodes swollen and hard. States that when she gets the flu vaccine at her hospital every year, she gets swollen lymph nodes ever since she had a double mastectomy and chemotherapy. She originally was wondering if she could get the vaccine in another large muscle group. States she even went as far as to cross reference flu shot ingredients with the Pfizer Covid ingredients to see if something in the vaccines were causing the swollen lymph nodes but was unable to come to any conclusion, the only think in common is the Sodium Chloride and she does not feel like that would cause any issue. States the swollen lymph nodes occurred after the Sanofi brand flu vaccine (no other information known or provided). Patient is on day 15 post vaccination and they are still swollen and hard, she is wondering if there is any data on how long this side effect can last. She made an appointment with her oncologist, she knows that the swollen lymph had the first dose, lymph nodes are still swollen and hard, knows it can cause swollen lymph nodes but wants to know what is the typically length of the event. Patient also experienced other side effects, on 30Dec2020 (last week), she developed vertigo that lasted through the weekend intermittently, states she at first thought she was having a stroke. States it seems to have subsided as of 05Jan2021 (yesterday). Patient also reported she had an itchy rash twice as part of her side effects reported from the COVID 19 vaccine. She noticed an itchy rash and it went away but she is unsure exactly the day or time. Stated she definitely remembered the rash on 28Dec2020 as she took pictures. It was gone in about three hours on the same day. She did not treat the rash because it was gone and not itching. The rash came and went and had not come back. It was mostly on the bends of the arms, bilateral arms. Patient reported developing swollen, tender, and hard lymph nodes under the Left subclavian area the day after the injection, on 24Dec2020. They were not as tender at the time of the report but were continuing and this was 15 days from her vaccination. Patient also experienced an itchy rash bilaterally on her arms that occurred twice and only lasted a few hours each time, onset date reported as 25Dec2020. She was advised to take diphenhydramine hydrochloride (BENADRYL) for it however she did not take it. On 23Dec2020 patient experienced headache. On 24Dec2020 patient experienced extreme fatigue, swollen left subclavian lymph nodes and runny nose. On 30Dec2020 patient experienced joint pain and muscle and vertigo. The events headache, experienced extreme fatigue, swollen left subclavian lymph nodes, runny nose, joint pain and muscle and an itchy rash bilaterally on her arms were considered serious as medically significant events. Patient had not recovered from swollen left subclavian lymph nodes, joint pain and muscle, extreme fatigue and swollen, tender, and hard lymph nodes under the Left subclavian area, she was recovering from headache, runny nose and vertigo and recovered completely from an itchy rash bilaterally on her arms on 28Dec2020.; Sender's Comments: The Causality between the events, headache, experienced extreme fatigue, swollen left subclavian lymph nodes, runny nose, joint pain and muscle and an itchy rash bilaterally on her arms, and the administration of the COVID 19 vaccine cannot be denied based on the reasonable temporal association. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RA, IEC, as appropriate.

Seizure; This is a spontaneous report from a contactable physician (patient). A female patient of an unspecified age received BNT162B2 (Pfizer-Biontech Covid-19 Vaccine) on an unspecified date, at single

dose, for COVID-19 immunisation. Relevant medical history and concomitant medications were unknown. On an unspecified date, after the vaccination, the patient had a seizure. Clinical outcome of the adverse event was unknown at time of this report. The information on the lot number has been requested.; Sender's Comments: A possible causal relationship between seizure and BNT162B2 cannot be completely ruled out considering the temporal relationship. However, more information would allow for a full medically meaningful assessment, especially medical history, concomitant medications, concurrent illness and event details description including time lag between the onset of the event and vaccination date of BNT162B2. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

"Her INR was 5.8 (normal range 1 to 2)/increasing INR; Scratched arm; Scratched arm and bled through 3 shirts, it kept bleeding; This is a spontaneous report from a contactable nurse (patient). A 64-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (lot number EC1284), via an unspecified route of administration administered to left arm/deltoid on 29Dec2020 13:15 at single dose for COVID-19 immunization at a research medical facility; and received warfarin sodium (COUMADIN, strength 2 mg), oral (by mouth) from an unspecified date in 2017 and ongoing at ""3 1/2 tablets once daily in the evening at 5:30pm (total 7mg)"" for metal heart valve. The patient's medical history included had the surgery (for her metal heart valve), about 01Mar in 2017 (about 4 years ago) and so she thought she had been on Coumadin for about 4 years, had been on the 7mg dose for over a year; and has a history of metal heart valve and takes Coumadin for the metal heart valve. Denied illness. Denied family medical history relevant to event. There were no concomitant medications. The patient previously received Shingrix vaccine in past and remenbered she had the usual side effects from it, had mild symptoms. History of all previous immunization with the Pfizer vaccine considered as suspect was none. The patient did not receive any other vaccines the same date of the Pfizer Suspect or 4 weeks prior. On Jan2021, the patient experienced scratched arm and bled through 3 shirts, it kept bleeding. On 04Jan2021, her international normalised ratio (INR) was 5.8 (normal range 1 to 2). The events did not lead to emergency room visit, however led to physician office visit. The events were reported as serious medically significant. The nurse got the first Pfizer COVID-19 shot on 29Dec2020 because she is a healthcare provider. She wanted information on increasing INR. The nurse has a history of metal heart valve and takes Coumadin. Her INR was typically 1.7 to 2.3. She reported her last INR, before the covid-19 vaccine was given, was ""some time ago"" but it had not varied much over the years. Normally she got her INR run and it was about 2. She had to be scheduled for her INR on the 04Jan2021 and it was 5.8 (normal range 1 to 2) and they asked about anything that may have changed and the only thing was that she got her first shot. The nurse reported not having any changes in her medications, food, or life style to account for the change, other than receiving the COVID-19 vaccine. The patient stated that it could be a serious problem if she had an accident or fell and started bleeding. A normal person's lab result is between 1 and 2, but they like to keep people with the metal heart valves between 2 and 3. She had been bleeding. She had barely scratched her arm the other day and went through 3 shirts because she kept bleeding. This is more than unusual for her, it's kind of unusual.

Getting the vaccine is the only variant she has had since getting her last INR. The patient underwent lab tests and procedures which included INR (normal range 1 to 2): typically 1.7 to 2.3 on an unspecified date; it's about 2 on an unspecified date: and 5.8 on 04Jan2021. The action taken in response to the events for warfarin sodium was dose not changed. The outcome of the event INR was 5.8 was not recovered, for the other events was unknown. The nurse (patient) assessed the event ""INR was 5.8; it's normally about 2"" as related to the COVID-19 vaccine.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the reported events of International normalised ratio increased and wound hemorrhage due to temporal relationship. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics coagulation panel, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate."

Dizziness; palpitations; resting tachycardia that persisted for 3 days; muscles aches; Chills; Restlessness; feeling unwell; arm pain; This is a spontaneous report from a contactable physician reported for herself. This 37-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: Ek5730) via intramuscular on 23Dec2020 09:30 AM on left arm at single dose for COVID-19 immunisation. Medical history included chronic kidney disease, HTN (hypertension), persistent proteinuria. No known allergies. Concomitant medication included losartan. The patient did not have other vaccine in four weeks and did not diagnosed with COVID-19 prior to vaccination. The patient was not pregnant at the time of vaccination. On 24Dec2020, the patient experienced dizziness, palpitations, resting tachycardia that persisted for 3 days, muscles aches, chills, restlessness, feeling unwell and arm pain, and resulted in Emergency room/department or urgent care. Treatment included paracetamol (TYLENOL). The patient had COVID tested on 28Dec2020 post vaccination, covid test type post vaccination=Nasal Swab, covid test name post vaccination=PCR, covid test result=Negative. Outcome of events was recovered.; Sender's Comments: The reported events dizziness, palpitations, resting tachycardia that persisted for 3 days, muscles aches, chills, restlessness, feeling unwell and arm pain, were likely related to the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) due to temporal relationship and clinical course. The case will be reassessed should additional information become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics committees and Investigators, as appropriate.

Hellucinogenic visions of monsters and violent events; This is a spontaneous report from a contactable consumer (patient). A 68-year-old female patient (not pregnant) received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EK5730), via an unspecified route of

administration on 05Jan2021 at 14:30 on Right arm at single dose for COVID-19 immunization in hospital. The patient medical history included Hypertension, Hypothyroid. Prior to vaccination, patient was not diagnosed with COVID-19. Concomitant medications included levothyroxine sodium (LEVOXYL); Olmesartan; aluminium hydroxide gel, dried, magnesium carbonate (PEPCID); bifidobacterium bifidum, bifidobacterium lactis, bifidobacterium longum, lactobacillus acidophilus, lactobacillus rhamnosus (PROBIOTIC); ascorbic acid, biotin, folic acid, iodine, pantothenic acid, pyridoxine hydrochloride, retinol, vitamin b12 nos, vitamin d nos, vitamin e nos, zinc (CENTRUM MULTIGUMMIES). Patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient previously took and had known allergies with bacitracin zinc;neomycin sulfate;polymyxin b sulfate (NEOSPORIN) and bacitracin zinc;neomycin sulfate;polymyxin b sulfate (POLYSPORIN). The patient experienced hellucinogenic visions of monsters and violent events on 06Jan2021 at 02:00 AM. Since the vaccination, patient had not been tested for COVID-19. No treatment was received for the event. The outcome of the event was recovering. The report was reported as non-serious, with seriousness criteria-Results in death: No; Life threatening: No; Caused/prolonged hospitalization: No; Disabling/Incapacitating: No; Congenital anomaly/birth defect: No.

severe ITP; This is a spontaneous report from a contactable physician. A 22-years-old male patient received his first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 17Dec2020 at single dose for COVID-19 immunization. The patient medical history and concomitant medications were not reported. The patient developed severe ITP (Idiopathic thrombocytopenic purpura) on 20Dec2020, 3 days after first dose of the vaccine on 17Dec2020. He was hospitalized for 3 days and now the patient was healthy with a normal platelet count on an unspecified date. The physician wanted to know if this patient can get the second dose. The outcome of the event was recovered on an unspecified date. Information on the lot/batch number has been requested.; Sender's Comments: A possible contributory effect of suspect BNT162B2 on reported ITP cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

"immune deficiencies; She said the joint pain felt like ""flu"" joint pain; She said she was really sweaty, so much so, that she had sweat under her eyes; thyroid problems; feels shaky inside; Numbness facial; Exhaustion; Foggy feeling in head/feeling rundown; felt exasperated; sweating like crazy and then gets chills; felt yucky/she didn't feel good at all; Joint pain; Nausea; Chills; after receiving the COVID-19 Vaccine on (Dated), she had left upper shoulder pain.; She clarified she had some injection site pain; and the injection site was a little itchy; This is a spontaneous report from a contactable consumer (patient). A 58-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot EL3246), via an unspecified route of administration on 02Jan2021 14:30 at single dose in the left upper arm for COVID-19 immunization. Medical history included Pernicious anaemia from 2006 and ongoing, Hashimoto's disease ongoing, stated she was diagnosed with Hashimoto's disease in either 1994 or 1995. Psoriatic arthritis from Nov2020 and ongoing. Potassium low ongoing, reported she has

had low potassium off and on for years. She said she can't remember when she didn't have low potassium. She said she normally finds out her potassium is low when she has blood work done. She stated she has had low potassium most of her adult life. IgA deficiency from Feb2019 and ongoing, Psoriasis ongoing, paralysis in her left trapezius muscle. Concomitant medication included B-12 for pernicious anemia. She said she had the typical reactions that one might get with a vaccine. She clarified she had some injection site pain and the injection site was a little itchy on 02Jan2021. She stated on the second day (03Jan2021) she had joint pain, felt yucky, had nausea, and chills. She said the next day (04Jan2021) she felt a little better, but still had chills. She said yesterday (05Jan2021) she thought she was feeling better, but by yesterday, clarified as late afternoon and evening, she crashed. She said she has a lot of autoimmune issues and immune deficiencies, saying she has pernicious anemia and Hashimoto's disease. She said yesterday evening she experienced extreme body temperature issues. She said she was really sweaty, so much so, that she had sweat under her eyes. She said she would get really hot and had chills. She said she was feeling really bad and was feeling shaky inside. She said she thought it was important that she report what she was experiencing to Pfizer. She stated she has psoriatic arthritis, too. Reported after receiving the COVID-19 Vaccine on 02Jan2021, she had left upper shoulder pain. She clarified that she had a previous history of paralysis in her left trapezius muscle and had surgery in 1998 on her left shoulder. She said she had a weird feeling that went around where her scar was from the surgery on the back of her left shoulder. She said maybe the left shoulder pain had to do with how she held her left shoulder. She said on Monday, 04Jan2021, she had a little bit of pain in her left shoulder and by yesterday night, 05Jan2021, there was not much pain at all. Clarified her joint pain was in her ankles, wrists, hips, neck, back, and knees. She said the joint pain felt like ""flu"" joint pain. She stated she normally has joint pain with the other issues she has, but this joint pain felt different. She said the joint pain she experienced after taking the COVID-19 Vaccine was all over her body. She said yesterday (05Jan2021) her joint pain felt so much better, but later in the afternoon she didn't feel right. She said she has pernicious anemia, and thought maybe she needs her B-12 shot. She said yesterday (05Jan2021) she experienced a lot more symptoms. She said she had numbness in her face, felt extremely exhausted, had a foggy feeling, and felt exasperated. She said the symptoms didn't start until late in the afternoon into the evening of 05Jan2021. She said she did not feel well and went to bed at 8:45PM, which is early for her. She said she did give herself a B-12 1mcg/ml shot intramuscularly yesterday. She provided the B-12 1mcg/ml NDC Number: 7006900510, Lot Number: C0495, and Expiration Date: Aug2022. She said the name (company name) was listed on the B-12 1mcg/ml packaging. She said she gives herself a B-12 shot every 10 days. She said she still has some joint pain, but the joint pain is not like it was on 03Jan2021. She said she still has a tiny bit of heaviness in her joints with a constant throbbing pain, which is a different joint pain from her normal. Reported last night (05Jan2021) she didn't feel good at all. She said she felt horrible, and had to go to bed. She said she felt shaky inside all night, and still feels that way now. She said she was sweating like crazy, and then would get chills. She clarified she is used to being hot and cold in her normal life because of her thyroid problems, but stated what she experienced last night was beyond that. She said her hot and cold issue was bumped up several levels last night. She said she was chilled or sweating all the time last night, but did not have a temperature. She clarified her normal body temperature is 96.7, and when she checked her temperature at one point, her temperature was 98 degrees. Reported the hot and cold with sweating and chills, and nausea come and go. She said if she has nausea, it is a mild feeling of nausea.

Clarified if Sunday, 03Jan2021. was a work day, she would have called out sick. She said Monday (04Jan2021) and Tuesday (05Jan2021) she did go to work. Reported she has low potassium and made herself an electrolyte cocktail. Reported if her system feels off, she said her electrolytes maybe off. She said her heart felt like it may be shaky, so she ate a banana to get potassium in her system. She said she does her little routine before she would call her doctor to get blood work done. She said she had her blood work done not too long ago. She said she wasn't feeling this way before she had the COVID-19 Vaccine, and is feeling rundown now. She said she was feeling good before she had the COVID-19 Vaccine. She said she feels like something is going on with her body now. Reported her last blood work was done on 04Dec2020 and everything was kind of normal. She clarified her thyroid was a little off, and her doctor adjusted her medication. She said her potassium was a little down. Reported she was told when she got the COVID-19 Vaccine shot she has to be a little more careful, and she might not be as protected as some people. She said she was told there have not been enough studies on the COVID-19 Vaccine. She clarified she was told that information by a person at the site where she received the COVID-19 Vaccination, saying the person was helping her with the COVID-19 Vaccination authorization form. Reported she thought she was doing OK after she received the COVID-19 Vaccine, until after last night and yesterday afternoon. She said if she continues feeling the way she is, she will see her doctor. She said her system seems off. She said she normally tries everything she knows first, like drinking a lot of water, and drinking electrolytes, and will take potassium to see if that is the issue. She said those are her own things that she does before she calls her doctor. Clarified sometimes she has numbness in her face due to not having her B-12. She said she still has a little numbness in face. She said on 05Jan2021, the numbness went across her face from the bridge of her nose down through to her mouth. She said the numbness was nothing like paralysis in her face, but her face was really hot at the same time she had the numbness. Reported she took Tylenol (clarified as (company) brand Tylenol, stating she doesn't have the UPC, Lot and Expiration Date). She said the Tylenol wasn't kicking in, so she took Ibuprofen (clarified as (company)brand Ibuprofen, and she doesn't have the Ibuprofen NDC, Lot and Expiration date). She said she took her normal medications. Outcome of events ""She clarified she had some injection site pain"" ""and the injection site was a little itchy"" and Shoulder pain were recovered on an unspecified date, ""Chills"" and ""feels shaky inside"" were not recovered, ""Joint pain"" ""Nausea"" ""Numbness facial"" were recovering, while outcome of other events was unknown."

Bell's Palsy; This is spontaneous report from a contactable Other Health Professional. This reporter reported similar events for 6 patients. This is a 6th of 6 reports. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced bell's palsy on an unspecified date with outcome of unknown. Since the use of modified RNA in COVID vaccines, the reporter aware of 6 cases of Bell's Palsy by the companies making these vaccines. Information about lot/batch number has been requested.; Sender's Comments: Based on temporal association, the causal relationship between BNT162B2 and the event facial paralysis cannot be excluded. The information available in this report is limited and does not allow a medically meaningful assessment. This case will be reassessed once additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and

analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate.,Linked Report(s) : US-PFIZER INC-2021007605 Different patient, same drug/event.

The numbness began to intensify and I could not feel myself blinking or smiling on the left side of my face; pain and numbness to my left ear and left jaw that began to spread down my left jaw and upward across my left cheek, left eye, and left temple, and above my left eyebrow; pain and numbness to my left ear and left jaw that began to spread down my left jaw and upward across my left cheek, left eye, and left temple, and above my left eyebrow; pain and numbness to my left ear and left jaw that began to spread down my left jaw and upward across my left cheek, left eye, and left temple, and above my left eyebrow; pain and numbness to my left ear and left jaw that began to spread down my left jaw and upward across my left cheek, left eye, and left temple, and above my left eyebrow; pain and numbness to my left ear and left jaw that began to spread down my left jaw and upward across my left cheek, left eye, and left temple, and above my left eyebrow; This is a spontaneous report from a contactable nurse reported for herself. A 39-years-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (lot number EL0142) via an unspecified route of administration on 07Jan2021 07:00 at single dose for covid-19 immunization. Vaccine location was left deltoid. The facility type vaccine was Workplace Clinic. Medical history included food allergy at shrimp. Concomitant medications were not reported. The patient did not received any other vaccines within 4 weeks prior to the COVID vaccine. On 07Jan2021 at 07:15 AM the patient notice pain and numbness to her left ear and left jaw that began to spread down left jaw and upward across left cheek, left eye, and left temple, and above left eyebrow. The numbness began to intensify and patient could not feel herself blinking or smiling on the left side of my face. The numbness slowly began improving over the next hour in the same order that it began, but she still have mild left ear and jaw pain and mild numbness. Events outcome are recovering. No treatment was received. The action taken was not applicable.; Sender's Comments: Based on the compatible time association, the facial palsy is possibly related to suspect BNT162B2 administration. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Burst blood vessel in left eye 24 hours after vaccine was given.; This is a spontaneous report from a contactable other-HCP. A 45-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) lot number not available, via an unspecified route of administration on 21Dec2020 07:45 AM at single dose for covid-19 immunization. Vaccine location was left deltoid. The patient did not received any other vaccines within 4 weeks prior to the COVID vaccine. Medical history included morbid obesity and blood pressure high. No known allergies. Patient didn't do relevant test. Concomitant medication included amlodipine (AMLODIPINE) at 5mg daily. The patient experienced burst blood vessel in left eye 24 hours after vaccine was given (eye haemorrhage) on 22Dec2020 08:30 with outcome of recovered. No treatment received. The action taken in response to the event for BNT162B2 was not applicable. Information on the lot/batch number has been requested.; Sender's Comments: Based on the available

information, the company considers that a causal relationship between the eye haemorrhage and vaccination with BNT162B2 cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer drug is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Had ruptured blood vessels x 2 spontaneously in eyes; This is a spontaneous report from a contactable nurse reported for herself. A 54-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (lot number EK5730), via an unspecified route of administration on 17Dec2020 03:00 P.M at single dose for covid-19 immunization. The facility type vaccine was: workplace clinic. Medical history included manifesting carrier BMD (Becker's muscular dystrophy). Allergies to medication: allergies rash on Sulfa. The patient did not received any other vaccines within 4 weeks prior to the COVID vaccine. Concomitant medication included pregabalin (LYRICA), duloxetine hydrochloride (DULOXETINE [DULOXETINE HYDROCHLORIDE]). The patient experienced ruptured blood vessels x 2 spontaneously in eyes (eye haemorrhage) on 18Dec2020 with outcome of recovered. No treatment received. The action taken in response to the event for BNT162B2 was not applicable.; Sender's Comments: Based on the available information, the company considers that a causal relationship between the eye haemorrhage and vaccination with BNT162B2 cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer drug is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

some congestion that just came on; her arm was really aching after the injection; she started coughing; voice was hoarse; light wheeze; soles of her feet were hurting; pressure in bilateral groin; aching all over; very tired; balance issues; This is a spontaneous report from a contactable nurse (patient). A 62-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EK9231) intramuscularly in left upper arm on 05Jan2021 at single dose for covid-19 immunisation. The patient got her Covid vaccine yesterday (05Jan2021) around 11 or 11:30 am in her left upper arm. She had bilateral breast cancer and had lymph nodes removed in each arm but more removed from her Right, so she got the vaccine in the left arm. She also had some skin cancers removed, one would not heal properly on her left arm and formed a blister, and her dermatologist popped it and put a band aid on it. The vaccine was given 3 inches above it. The patient's concomitant medications were not reported. The patient experienced pressure in bilateral groin, aching all over, very tired and balance issues on 05Jan2021; light wheeze on 06Jan2021. Seriousness for these events was medically significant. The patient stated she had some congestion that just came on. She felt fine yesterday (05Jan2021) right after getting the vaccine, that at work she did notice that there was something different feeling in the left side of her groin. She was not in direct patient care. She noticed on her left side in the groin, something felt different, then yesterday evening (05Jan2021) after work she was really tired in the evening, aching all over last night, even the soles of her feet were hurting, woke up like her balance was off, she would walk one way and go another, states it is not like an orthostatic issue, that

she knows what that feels like. She stated that in her inguinal area she could feel pressure, bilaterally. Her arm was really aching after the injection. Her breathing, heard a light wheezing, was clearing her voice, and then she started coughing, voice was hoarse. The outcome of events pressure in bilateral groin, very tired and light wheeze was not recovered; of events aching all over and balance issues was recovering; of other events was unknown.; Sender's Comments: The reported events bilateral groin, aching all over, very tired, balance issues and light wheeze were possibly related to the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), due to temporal relationship. The case will be reassessed should additional information become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics committees and Investigators, as appropriate.

Severe respiratory distress; This is a spontaneous report from a contactable pharmacist. A 51-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection),Lot# lot number: EL1284, intramuscular at right arm on 07Jan2021 12:00 PM, at SINGLE DOSE for COVID-19 immunization. No known allergy , no other medical history.No COVID prior vaccination. Facility where the most recent COVID-19 vaccine was administered was Nursing Home/Senior Living Facility .No any other vaccines within 4 weeks prior to the COVID vaccine. No Concomitant medications (received within 2 weeks of vaccination) . On 07Jan2021 the patient experienced Severe respiratory distress that resulted in Emergency room/department or urgent care.It was unknown if treatment was received for the event. The patient had not been tested for COVID post vaccination. The outcome of the event was unknown.; Sender's Comments: A possible causal relationship between Severe respiratory distress and BNT162B2 cannot be completely ruled out considering the temporal relationship. However, more information would allow for a full medically meaningful assessment, especially medical history, concomitant medications, concurrent illness and event details. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

she was transferred to the hospital with tachycardia, congestion, shortness of breath, and is now unresponsive; she was transferred to the hospital with tachycardia, congestion, shortness of breath, and is now unresponsive; she was transferred to the hospital with tachycardia, congestion, shortness of breath, and is now unresponsive; she was transferred to the hospital with tachycardia, congestion, shortness of breath, and is now unresponsive; This is a spontaneous report from a contactable nurse. A 95-year-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), Lot# EH9899 Exipration on 06Jan2021 at 15:00 at SINGLE DOSE at deltoid for COVID-19 immunization. The patient received first dose of the same vaccine BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), Lot# EH9899 Exipration date : 31Mar20221, on 16Dec2020. Medical history included : cardiac failure congestive, hypertension, cardiac murmur .There were no concomitant medications. The patient previously took cymbalta , vasotec and

zocor and experienced drug hypersensitivity. The patient didn't receive any other vaccines within 4 weeks prior to the COVID vaccine.This nurse,worker at a skilled nursing facility, reported that this patient with a history of heart failure, received her second dose of the Pfizer-BioNTech Covid-19 vaccine yesterday, 06Jan2021, at 3pm. At 7am on 07Jan2021 she was transferred to the hospital with tachycardia, congestion, shortness of breath, and is now unresponsive. Patient was stable prior to vaccination, but will now be transferred to hospice care. The nurse added the patient had the second COVID vaccine on 06Jan2021 yesterday and has now been transport to hospital due to a drastic decline after the shot. It was explained that this morning around 7 am she was transferred to the hospital. She was experiencing tachycardia, shortness of breath, and congestion. The events started this morning around 6-6:30am. The patient was admitted to the hospital. The shot was given at the facility. She received it at 3pm on 06Jan2021, First dose was on 16Dec2020.The caller relays she didn't know how aggressive the hospital will be for the patient. She was a full code when left and now a DNR and is unresponsive. The patient will be going on hospice care. The causality was reported as related. The outcome of the events was not recovered.; Sender's Comments: The Company cannot completely exclude the possible causality between the reported tachycardia, shortness of breath, congestion, unresponsive, and the administration of the COVID 19 vaccine, BNT162B2, based on the reasonable temporal association. The patient's pre-existing medical condition of cardiac failure congestive, hypertension, cardiac murmur are confounding factors. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RA, IEC, as appropriate.

patient developed acute onset of right-sided facial palsy and pain; patient developed acute onset of right-sided facial palsy and pain; Brain MRI done showing T2 hyperintensity in the brainstem and basal ganglia, suspicious for inflammation; This is a spontaneous report from a contactable physician. A 46-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), on 18Dec2020 at SINGLE DOSE for COVID-19 immunization. Medical history included psoriasis. No COVID prior vaccination. It was unknown if the patient received any other vaccines within 4 weeks prior to the COVID vaccine.No known allergies. Concomitant medications (received within 2 weeks of vaccination) included fluoxetine. days following vaccination,on 23Dec2020,the patient developed acute onset of right-sided facial palsy and pain. Brain MRI done showing T2 hyperintensity in the brainstem and basal ganglia, suspicious for inflammation. Work-up is ongoing. AE Resulted in: Doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care, Disability or permanent damage].It was unknown if the event was treated. The event was assessed as serious for Disabling/Incapacitating. The patient had been tested for COVID post vaccination (covid test result-Negative). The outcome of the events werenot recovered Information about lot/batch number has been requested.; Sender's Comments: A possible causal relationship between acute onset of right-sided facial palsy and pain with MRI findings suspicious for brain inflammation and BNT162B2 cannot be completely ruled out considering the temporal relationship. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as

well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

myositis; This is a spontaneous report from a contactable physician. A 43-year-old male patient received first dose BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number/expiration date unknown) on an unspecified date in Dec2020 reported as around the end of December, at single dose for COVID-19 immunization. Relevant medical history and concomitant medications were not reported. On an unspecified date after he received the vaccine he had right arm pain and swelling (states it was in his bicep brachial radialis in the muscle) which is the opposite arm of the injection site. He had an MRI done on an unknown date that showed myositis. He thinks could be due to the vaccine since it started two days after he received the vaccine. His pain peaked at about a week and a half and now the pain was improving and the swelling was down. He still had function in the right arm but when he strained it would hurt. His concern was that the reaction may be an autoimmune reaction and the first response was muted. He was worried the second dose may elicit a larger response. At the time of the reporting the patient was recovering from the events. Information on Lot/Batch number has been requested.; Sender's Comments: Based on the available information, the company considers that a causal relationship between the myositis and vaccination with BNT162B2 cannot be excluded. Additional information regarding onset latency, relevant medical history, concomitant medications and detailed clinical course around the event onset will aid in comprehensive assessment of the case. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics committees and Investigators, as appropriate.

Atrial fibrillation; Was not feeling well; Warm sensation in chest; This is a spontaneous report from a contactable nurse (patient). This 62-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot EJ 1685), intramuscular, on 21Dec2020 at 09:30 PM at single dose for COVID-19 immunisation. Vaccine location was left arm. The patient was vaccinated at hospital, age at vaccination was 62-years-old. The patient received also varicella zoster vaccine RGE (CHO) (SHINGRIX) on 19Nov2020. Medical history included gastrooesophageal reflux disease (GERD) and high cholesterol. Concomitant medications included omeprazole, colestyramine (QUESTRAN), and vitamins. On 22Dec2020, the patient was not feeling well intermittently starting the day after the injection with warm sensation in chest that would go away until 31Dec2020 when the warm sensation of chest would not go away. The patient was sent for EKG that showed atrial fibrillation that she is now being treated for. The events resulted in doctor or other healthcare professional office/clinic visit. The events were reported as non-serious. Outcome of the events was unknown.; Sender's Comments: The Company cannot completely exclude the possible causality between the reported atrial fibrillation and the administration of COVID 19 vaccine, BNT162B2. More information regarding the clinical course, the patient's underlying concurrent medical condition are required for the Company to make a more meaningful causality assessment. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for

adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RA, Agency, as appropriate.

blood in the stool; fevers; night sweats; chills; aches; This is a spontaneous report from a contactable Physician reporting for herself. A 30-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 30Dec2020 at single dose for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. She experienced chills and aches after 24 hours (on 31Dec2020) and experienced significant fevers that wouldn't break and cycles of chills and fevers that would last for 2 hours each cycle over the next 24 hours. She also experienced night sweats and blood in the stool and mentioned it was the first time that happened to a healthy 30 year old like her. She is asking for reports of these side effects, especially blood in the stool and for recommendations regarding taking the 2nd dose as she is still not sure on whether to take it due to hearing that the 2nd dose side effects were worse. The outcome of the events was unknown. Information on the Lot/Batch number has been requested.; Sender's Comments: Based on the information currently provided, the vaccination with BNT162B2 might play a contributory role in triggering the onset of blood in the stool. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Tested positive for COVID-19; CT showed increased infiltrates 10-15%; Dehydration/Dehydrated; Chills; Tested positive for COVID-19; Hypotensive; Achy; Severe achy cramps/Severe cramps all over body; This is a spontaneous report from a contactable nephrologist (patient himself). This 78-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number EK5730), via an unknown route, on 17Dec2020 at single dose for COVID-19 immunisation. Age at vaccination was 78-year-old. The patient was diabetic and hypertensive. Additional medical history included hyperlipidaemia. No relevant concomitant medications were provided. On 18Dec2020, the patient developed severe achy cramps/severe cramps all over body. On 19Dec2020, the patient developed achy. On 20Dec2020, the patient was dehydrated and hypotensive, he had also chills. On unknown date, blood pressure was down to 76/50. His symptoms for COVID were severe achy cramps, hypotension, and dehydration. On 20Dec2020, COVID-19 test was positive. On 21Dec2020, the patient was given monoclonal antibodies. A computerized tomogram (CT) of the lungs was performed on 21Dec2020 and it was ok. A week later (Dec2020), he had a repeat CT which showed increased infiltrates of 10 to 15%. He then started on dexamethasone, apixaban (ELIQUIS) and the rest of the things. He had a repeat CT on 05Jan2021 which showed resolution of the infiltrates; most of the lesions went gone. CT results had improved significantly. The patient underwent a second COVID test a week ago which was still positive. He had a third COVID on 06Jan2021, but results were not available yet. The patient queried if he can proceed with second dose planned on 07Jan2021 or if he should wait. The clinical outcome was recovered for the event 'severe achy cramps/severe cramps all over body' on 19Dec2020, for 'dehydration/dehydrated' on 20Dec2020, for 'chills' on unknown date in Dec2020, for 'achy' on 30Dec2020, for 'hypotensive' on 20Dec2020; the outcome of the event 'CT showed increased infiltrates

10-15%' was recovering; the outcome for 'Tested positive for COVID-19' was unknown. The reporter considered the events 'achy' and 'severe achy cramps/severe cramps all over body' serious because causing disability; the events 'tested positive for COVID-19', 'dehydration/dehydrated', 'chills' and 'hypotensive' were considered medically significant. The reporter considered the events 'Tested positive for COVID-19', 'CT showed increased infiltrates 10-15%' and 'dehydrated/dehydration' unrelated to BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE).; Sender's Comments: A possible contributory effect of suspect BNT162B2 on reported events cannot be excluded. Case will be reassessed when new information is received. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

Possible cellulitis; slight redness in left upper within 24 hours; severe redness and swelling and warmth of entire upper left arm and half of lower arm; severe redness and swelling and warmth of entire upper left arm and half of lower arm; Some pain; This is a spontaneous report from a contactable Physician. A 94-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number: EL0140) on 30Dec2020 at 12.00 pm at single dose Intramuscular on left arm for COVID-19 immunization. Relevant medical history included COVID 19 infection, on 19Jul2020, post COVID left femoral DVT oral anticoagulation, Alzheimer dementia, Osteoarthritis, Spinal Stenosis, Gait Dysfunction and Constipation. Known allergies included acetazolamide, penicillin and sulfa. Concomitant medications included apixban (ELIQUIS) 5 mg twice a day, colecalciferol (VIT D3) 1000u once a day. On 31Dec2020 at 12:00 pm patient experienced slight redness in left upper within 24 hours. The patient also experienced possible cellulitis, severe redness and swelling and warmth of entire upper left arm and half of lower arm. Some pain. No fever. It was also informed that patient underwent nasal Swab test for Coronavirus (Abbott BinaxNOW) on 05Jan2021 and on 07Jan2021 and resulted negative, for both. Treatment received for cellulitis included Cefuroxime. Outcome for the event possible cellulitis was unknown. Outcome of other reported events was recovering.; Sender's Comments: Based on the information available, a possible contributory role of the suspect products cannot be excluded for the reported events due to temporal association. However patient old age and other underlying conditions cannot be excluded for a contributory role The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators as appropriate.

Facial paralysis; This is a spontaneous report from a contactable Pharmacist. A 70-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number EH9899, Expiration Date 30Mar2021), via intramuscular, on 17Dec2020 (at 15:35), at single dose of 0.3 mL for COVID-19 immunisation. The patient was vaccinated at hospital, age at vaccination was 70-year-old. Vaccine location was deltoid but unsure which deltoid. The patient did not have a relevant medical history and concomitant medications. Pharmacist said that after vaccination, she waited to be

monitored the standard 15 minutes at hospital and then when she got in the car and was on the way home like 20 minutes later she had brief episode of what the patient described as facial paralysis. It was like the side of her face in one area felt funny, it felt numb and it was not anywhere else on her face. It lasted the 20 minutes and then went away. The patient had recovered from the events on 17Dec2020. The pharmacist queried if the patient can proceed with the 2nd dose of the vaccine. The reporting pharmacist considered the event 'facial paralysis' as non-serious.; Sender's Comments: A possible causal relationship between acute onset of facial paralysis and BNT162B2 cannot be completely ruled out considering the temporal relationship and the known adverse event profile of the suspect vaccine. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

got home from the shot at 1145a. Fell asleep until 930pm. During sleep was told by family that i was angry, cursing and yelling in my sleep. I don't remember any of it , i felt delirious and out of co; got home from the shot at 1145a. Fell asleep until 930pm. During sleep was told by family that i was angry, cursing and yelling in my sleep. I don't remember any of it , i felt delirious and out of co; got home from the shot at 1145a. Fell asleep until 930pm. During sleep was told by family that i was angry, cursing and yelling in my sleep. I don't remember any of it , i felt delirious and out of co; got home from the shot at 1145a. Fell asleep until 930pm. During sleep was told by family that i was angry, cursing and yelling in my sleep. I don't remember any of it , i felt delirious and out of co; Left arm was extremely painful; This is a spontaneous report from a contactable Other-HCP. A 51-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number # EL1284) on 02Jan2021 at 10:00 AM at single dose via intramuscular on left arm for COVID-19 immunization. Medical history included allergy to codeine hypertension and asymptomatic HIV infection. Concomitant medications were not reported. Patient got home from the shot on 02Jan2021 at 11: 45 am. Fell asleep until 930p:m. During sleep was told by family that He was angry, cursing and yelling in his sleep. He didn't remember any of it, He felt delirious and out of control. Left arm was extremely painful. At the time of the reporting had recovered from the events without any treatment.; Sender's Comments: A possible contributory effect of suspect BNT162B2 on reported event delirious cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

"lymph node swelling and lymphedema in the right forearm side and the right upper arm; lymph node swelling and lymphedema in the right forearm side and the right upper arm; cold blister on lip; significant swelling on the right side of the base of her neck near her clavicles; slightly itchy scalp; redness, swelling, tenderness at injection site; redness, swelling, tenderness at injection site; redness, swelling, tenderness at injection site; This is a spontaneous report from a contactable Registered nurse reporting for herself. A 58-years-old female patient received the first dose of BNT162B2 Pfizer-BioNTech COVID-19 Vaccine (Batch/lot number: EL0140), in Hospital, by intramuscular route in right upper arm on

23Dec2020 at 08:30, at 58-year-old of age, at single dose for COVID-19 immunization. The patient had no relevant medical history. She didn't receive any prior vaccinations within 4 weeks. There were no concomitant medications. The patient reported that it has been 2 weeks since she received the COVID-19 Vaccine now and she still has a considerable amount of lymph node swelling and lymphedema in the right forearm side and the right upper arm. The nodes on the right side of her neck around the clavicle have been quite swollen for about 2 weeks. She has the list of side effects so she was not concerned, as this was listed but now she's not sure. When she got the vaccine she had the expected redness, swelling and tenderness at injection site (onset reported as 23Dec2020). On the evening of the 24Dec2020 she had an itchy scalp but she didn't see any rash and that only lasted a short time. On 29Dec2020 the patient had a significant swelling on the right side of the base of her neck near her clavicles that wrapped around to the posterior of her neck and was assessed as medically significant. She treated it by putting ice on it in the evening. On 30Dec2020 the swelling seemed to be slightly decreased but it is still a visible lump, the nodes are firm and there is swelling around those and it has not improved since the 30Dec2020. On 30Dec2020 she noticed a little cold blister or hive on the center of her lower lip and that was resolved by 03Jan2021, she did not have fever and did not feel sick, but her main problem is the swollen lymph nodes around base of neck around clavicle and it is considerably swollen there. The patient reported that last night (06Jan2021) it looked like her right arm was swollen, she thinks she is having lymphedema on the right arm, her right forearm is half an inch circumference larger than her left arm and was measured at her work. The patient reported she is seeing her new primary care doctor on 26Jan2021 and will follow up with the doctor. The patient wanted to know if she should get the second dose scheduled for the next week or should wait until the swelling resolves. Moreover the patient asked how long do the side effects usually last (specifically systemic side effects). The events ""redness, swelling and tenderness at injection site"" and ""slightly itchy scalp"" resolved on 25Dec2020, the event ""Cold blister on lip"" resolved on 03Jan2021. The event ""Swelling on the right side of the base of her neck near her clavicles"" had not resolved yet at the time of the report. All the reported events were assessed as related to the COVID-19 Vaccine by the Primary Source Reporter (Method of assessment:Agency).; Sender's Comments: Based on temporal association, the causal relationship between BNT162B2 and the events swelling and lymphadenopathy cannot be excluded. The information available in this report is limited and does not allow a medically meaningful assessment. This case will be reassessed once additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate."

kidney infection; urine turning a different color/urine was an orange color/urine was a tea color; This is a spontaneous report from a contactable Nurse reporting for herself. A 24-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 06Jan2021 at single dose for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient stated earlier this afternoon (07Jan2021) urine turning a different color, her urine was an orange color, and this afternoon her urine was a tea color. She had no other symptoms as if she had a kidney infection. The outcome of the events was

unknown. Information on the lot/ batch number has been requested.; Sender's Comments: The causal relationship between BNT162B2 and the event kidney infection cannot be excluded as the information available in this report is limited and does not allow a medically meaningful assessment. This case will be reassessed once additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate.

Nausea; Diarrhea; Jitteriness; foggy head or brain; she can't concentrate /she didn't pay it any attention; sleeping a lot; sick; Headache; body aches; This is a spontaneous report from a contactable nurse. A 62-years-old female patient started to receive BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot# EK5730), via an unspecified route of administration on 05Jan2021 08:15 at single dose for COVID-19 immunisation. Anatomical location of administration of vaccine was right deltoid. Medical history was not reported. The patient previously took omeprazole (PRILOSEC) and experienced drug hypersensitivity and lip swelling. Concomitant medication included atorvastatin (LIPITOR). The patient experienced headache on Jan2021, body aches on Jan2021, nausea on 06Jan2021, diarrhea on Jan2021, jitteriness on Jan2021, foggy head or brain on Jan2021, sleeping a lot on Jan2021, sick on Jan2021, she can't concentrate /she didn't pay it any attention on Jan2021. The outcome of headache and she can't concentrate /she didn't pay it any attention was recovering, of pain, jitteriness, foggy head or brain was not recovered, of sleeping a lot and sick was unknown. Nausea, and diarrhea recovered on 07Jan2021.; Sender's Comments: Based on temporal association, the causal relationship between BNT162B2 and the events headache, pain, nausea, diarrhea, feeling jittery, feeling abnormal, disturbance in attention and hypersomnia cannot be excluded. The information available in this report is limited and does not allow a medically meaningful assessment. This case will be reassessed once additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate.

High fever; Vomiting; Severe fatigue; Weakness; This is a spontaneous report from a contactable physician (patient himself). This 61-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number EL1442), via intramuscular, on 05Jan2021 at single dose for COVID-19 immunisation. Age at vaccination was 61-year-old. Vaccine location was deltoid left. The subject did not have a relevant medical history and concomitant medications. On 06Jan2021, the patient developed high fever, vomiting, severe fatigue and weakness. He did not experience anaphylaxis. The events were considered serious as medically significant. The patient stated that side effects mentioned lasted 3 hours and he felt much better now. However, the final clinical outcome was unknown. The patient is not sure if he should get the shot again in 3 weeks since he was really sick. The reporting physician considered the events 'high fever', 'vomiting', 'severe fatigue' and 'weakness' related to BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE).; Sender's Comments: Based on temporal association, the causal

relationship between BNT162B2 and the events pyrexia, vomiting, fatigue and asthenia cannot be excluded. The information available in this report is limited and does not allow a medically meaningful assessment. This case will be reassessed once additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate.

feeling of fullness in her ear; it felt like fluid in her right ear; Hearing loss in right ear; Soreness in the left arm; This is a spontaneous report from a contactable Other-HCP. A 34-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number # EH9899) 16Dec2020 at 07:40AM in the left arm at single dose via intramuscular for COVID-19 immunization. Medical history included seasonal allergy. Concomitant medications included fluticasone propionate for seasonal allergy. The day after vaccination she noticed soreness of the left arm. Then two days later she noticed hearing loss secondary to a feeling of fullness in her ear; it felt like fluid in her right ear which has improved and she states it was not serious after the first dose. Patient received the second dose of vaccine on 04Jan2021 at 08:00AM in the left arm. That night she experienced myalgia, fever, chills, back pain, and started with a constant ringing in her right ear and the hearing loss that worsened from before (reported under AER 2021012152. All of these effects have resolved except the hearing loss and ringing in her ear. Additionally she went to see an ENT doctor and get a hearing test. The Hearing test showed moderate hearing loss and speech clarity of 96% in her left ear compared to 52% in the right ear. They don't know if it is permanent. She was currently being treated with 80mg of Prednisone daily by mouth and getting Dexamethasone injections to her middle eardrum. Patient informed that on 17Dec2020 she was tested for COVID 19 with the PCR test due to an exposure at work. The result was negative. The patient recovered from soreness in the left arm on 19Dec2020. The patient had not yet recovered from deafness.; Sender's Comments: Based on temporal association, the causal relationship between BNT162B2 and the events ear congestion and hearing loss unilateral cannot be excluded. The information available in this report is limited and does not allow a medically meaningful assessment. This case will be reassessed once additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate.

constant ringing in right ear; Myalgia; Fever; Chills; back pain; Inappropriate schedule of vaccine administered; hearing loss that worsened from before; hearing loss that worsened from before; This is a spontaneous report from a contactable physician (patient). This 34-year-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot EH9899), via an unspecified route of administration, on 04Jan2021 at 08:00AM at single dose for COVID-19 immunisation. The first dose was received on 16Dec2020 at 7:40 AM at single dose. Vaccine location was in the left arm. The patient was vaccinated at hospital, age at vaccination was 34-years-old. No other vaccine was received in four weeks. Medical history was none. Concomitant medications included ongoing fluticasone proprionate

(FLONASE) for seasonal allergy taking for two years. On 17Dec2020, COVID-19 PCR test was negative. On 04Jan2021 at night, she experienced myalgia, fever, chills, back pain and started with a constant ringing in her right ear and the hearing loss that worsened from before (started on 18Dec2020 after first dose, see AER # 2021012126). Start date of constant ringing in right ear was 05Jan2021. The events resulted in Physician Office visit. Hearing loss in right ear worsened and constant ringing in right ear were reported serious as medically significant while the other events were reported as non-serious. She went to see an ENT doctor and get a hearing test. The hearing test showed moderate hearing loss and speech clarity of 96% in her left ear compared to 52% in the right ear. They don't know if it is permanent. She is currently being treated with 80mg of Prednisone daily by mouth and getting dexamethasone injections to her middle eardrum. All of these effects have resolved except the hearing loss and ringing in her ear. All the events were considered related to the vaccine per reporter.; Sender's Comments: A causal association between BNT162B2 and the reported events cannot be excluded based on a compatible temporal relation between vaccination and onset of events. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

fever of 103.7; Cough; body aches; Joint pain; chills; This is a spontaneous report from a contactable Nurse reporting for herself. A 54-year-old female patient received first dose of intramuscular BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 06Jan2021 at single dose in left deltoid for COVID-19 immunisation at the age of 54-year-old. Lot number was EL1284. Medical history included Asthma since 1991 and ongoing, high blood pressure since 2020 (6 months before the report) and ongoing. Concomitant medications were unknown. On 07Jan2021, the patient experienced fever of 103.7 at 1:30PM, chills at 9:00AM, body aches at 11:00AM, Joint pain at 09:00AM, cough at 1:00PM; the events were considered medically significant. The patient was not treated for the events. On 13Nov2020, test showed she had COVID-19. On 07Jan2021, body temperature was 103.7 Fahrenheit. The patient did not recover from the events. The nurse considered the events were related to suspect vaccine.; Sender's Comments: A causal association between BNT162B2 and the reported events cannot be excluded based on a compatible temporal relation between vaccination and onset of events. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

"Hypokalemia; Hypomagnesemia; Hypocalcemia; Hemoglobin dropped little bit; Tetany; Muscle cramps; This is a spontaneous report from a contactable healthcare professional, a physician assistant. A 50-year-old female patient received the first dose of the BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot Number: UNKNOWN), via an unspecified route of administration on 18Dec2020 (at the age of 50-years-old) as a single dose for COVID-19 immunization. Medical history included tachycardia, tension headache, and glucose tolerance impaired. Concomitant medications included rosuvastatin calcium (CRESTOR), gabapentin (MANUFACTURER UNKNOWN), and metoprolol (MANUFACTURER

UNKNOWN). On 18Dec2020, the patient experienced hypokalemia, hypomagnesemia, hypocalcemia, tetany, muscle cramps, and hemoglobin dropped little bit. The clinical course was as follows: The patient received the vaccine and about 30 minutes later she started to ""feel bad"". She went to the urgent care and about an hour after they took her to the emergency room (also reported as hospital). She had a complete blood count, complete metabolic panel, and magnesium level done on the 18th, 21th, 23rd, 26th, 28th, 30th of Dec2020 and then again on 04Jan2021. On 18Dec2020, her initial lab test showed potassium: 2.6, hemoglobin: 10.2, magnesium: 1.2, and calcium: 5.7. The physician assistant reported that a potassium of 2.6 was critically low and a hemoglobin was 10.2 was about normal for the patient. She received oral medications of potassium 20 mEq twice a day and calcium and magnesium supplements once a day. On 04Jan2021, lab data showed: potassium: 4.2, magnesium: 2.1, calcium: 9.5 and hemoglobin: 14.5. Per the reporting physician assistant, the above levels went back to normal but stated she had to be supplemented to get back to that point. The clinical outcomes of the hypokalemia, hypomagnesemia, hypocalcemia, and hemoglobin dropped little bit were recovered on 04Jan2021; while that of the tetany and muscle cramps, were unknown. The physician assistant assessed the events as related to the suspect vaccine. The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up.; Sender's Comments: A possible contributory effect of suspect BNT162B2 on reported events cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate."

patient felt tingling in their neck, arms and hand and then few days later it went to their feet; This is a spontaneous report from a contactable consumer (patient). A patient of unspecified age and gender received the bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot Number and Expiration Date: unknown), via an unspecified route of administration on an unspecified date at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. On an unspecified date, the patient felt tingling in their neck, arms and hand and then few days later it went to their feet (medically significant). The clinical outcome of the event was unknown. The batch/lot numbers for the vaccine, PFIZER-BIONTECH COVID-19 MRNA VACCINE, were not provided and will be requested during follow up.; Sender's Comments: A causal association between BNT162B2 and the reported events cannot be excluded based on a compatible temporal relation between vaccination and onset of events. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

Bell's palsy; Flu like symptoms; This is a spontaneous report from a non-contactable consumer reported that a female patient of an unspecified age received bnt162b2, via an unspecified route of administration on an unspecified date at a single dose for COVID-19 vaccination. The patient's medical history and concomitant medications were not reported. It was reported that the patient got Bell's palsy four days after the vaccine and had flu-like symptoms for two weeks. Added that patient is completely

symptom free at the time of report. The outcome of the events was recovered. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

"Got very hot and clammy but at the same time had the goosebumps; Got very hot and clammy but at the same time had the goosebumps; Got very hot and clammy but at the same time had the goosebumps; My whole body was as if I was sun burnt; My heart started to race; This is a spontaneous report from a contactable consumer (patient). A 45-year-old female patient received BNT162B2, (Pfizer COVID Vaccine, lot number: EK9231, expiry date: Apr2021) intramuscular on an unspecified date at single dose on right arm for COVID-19 immunisation. Medical history included migraine from an unknown date and unknown if ongoing. Concomitant medication included nortriptyline for migraine, botulinum toxin type a (BOTOX) for migraine and birth control medication. The patient stated that, ""I was wondering if this was a reaction to the vaccination I had today. So I ended up 3 hours after I received the vaccine, I got very hot and clammy but at the same time had the goosebumps and then my whole body was as if I was sun burnt and my heart started to race. And then my whole body was red as if I had a sunburn. Actually I went to the ER today and they just did lab work because of the way I was feeling. All they gave me in the emergency room is IV fluids."" Therapeutic measures taken as a result of the events included IV fluids. The outcome of the events was unknown."

died; This is a spontaneous report from a non-contactable consumer via a Pfizer-sponsored program. A patient of unspecified age and gender received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, via an unspecified route of administration on an unspecified date at single dose for covid-19 immunisation. The patient medical history and concomitant medications were not reported. It was reported the patient was a doctor, died after the vaccine with no apparent disease. It was not reported if an autopsy was performed. No follow-up attempts are possible. Information about lot/batch number cannot be obtained.; Reported Cause(s) of Death: Unknown cause of death

COVID-19 positive and admitted to hospital 6 days post-vaccination

Received first dose Moderna COVID vaccine on 12/28/2020; on that same day 12/28 he noticed a dry cough; on 1/1/2021 he reported fever, chills, body aches, Headache, sinus congestion. On 1/1/2021 he tested positive for COVID-19, he reported being with a family member on Christmas who had COVID symptoms. On 1/11/2021 he required hospitalization for COVID-19 pneumonia

on 1/8/2021 17:30 patient taken to ER, cerebellar hemorrhage, stroke, aneurysm

Following the first COVID vaccine dose on Dec/18/2020, I had headaches that started on the third day and ended on the tenth day. The headaches were usually light, unilateral, and alternating from one side to the other. I was usually functional except on the fourth and seventh days where the headaches were moderate to severe, and I took naps to help with the headaches for those two days. I have never had an issue with headaches before, and these symptoms were a new experience for me. I did not take any medications as treatment for the headaches. Following the second COVID vaccine dose on January/7/2021, I felt fatigue and generalized muscle aches within six to twelve hours, and these symptoms lasted for two days. On January/10/2021, when I woke up that morning I again felt light, unilateral, and alternating headaches. In addition, I noticed that I was unable to move the left side of my

face. I felt moderate tingling sensations associated with the distribution of the paralysis. When I looked in the mirror, I could quite noticeably see asymmetry in my face. I immediately went to the emergency department at the hospital where my primary care doctor is located. I was kept in the hospital into the next day for observation. After evaluation by a neurology team and an MRI, I was provided with the diagnosis of Bells Palsy. I have never previously been diagnosed with Bells Palsy, and I have never previously had a hospital stay before. The doctors prescribed medications which I am currently taking. As of today January/12/2021, the symptoms have had some improvement, but the symptoms still continue.

Beginning at 6:30 am on 1/8, two days following vaccination, the individual was driving to work and began to experience nausea while at a traffic light. He pulled over and threw up. Once he got to work he vomited again. He drove to another facility for work and then threw up 3 or 4 more times. He began experiencing hot flashes at this time. He went to the hospital and was seen in the emergency room. He threw up several more times in the ER and stated that his heart was racing and that he had diarrhea. The emergency room gave him medications for the nausea and he stayed there for 2 or 3 hours. He began to feel better and was discharged to home.

Immediately developed intense burning that progressed over the next 30 minutes and continued to burn for 3 days. The next day progressive extreme fatigue last 4 days. felt like it was going to pass out. full on body pain, dizzy and lightheaded. need assistance to get to the walk, intense headache.

Very large, reddened, tender area at injection site (like the size of an angry red egg), and fever of 103.2.

GIVEN ON 12/23. SORENESS FELT ON LEFT ARM SITE THE NEXT DAY, WITH DECREASED MOBILITY AND STRENGTH DUE TO SEVERE SORENESS AND PAIN. PAIN PROGRESSIVELY LESSENED BUT THE SORENESS STILL VERY APPARENT. ON 1/5, SPOKE TO PRIMARY MD, XRAY ON LEFT SHOULDER DONE ON 1/6. ON 1/7, STIFFNESS WITH SEVERE PAIN UPON MOVEMENT NOTED ESP IN THE MORNING. ULTRASOUND WAS DONE ON 1/8, NOTED BICEPS TENOSYNOVITIS. ORTHOPEDIC SURGEON SEEN ON 1/11, W DX OF ADHESIVE CAPSULITIS, SUGGESTED FOR PT FOR NOW, AND OFF WORK, AND TO BE FOLLOWED UP ON 2/1 BY SAME ORTHO SURGEON. WILL NOT OFFER CORTISONE SHOT FOR NOW AS IT MAY COMPROMISED OR WEAKEN IMMUNE RESPONSE, IN WHICH MY SECOND COVID SHOT DUE ON THE 15TH OF JANUARY. FIRST APPT FOR PT ON 1/15

Sudden hearing loss right ear accompanied by tinnitus

Sudden hearing loss right arm accompanied by tinnitus

Patient presented on the morning of 1/10/2021 with swollen lips and hives. Vaccination took place on Wednesday January 6th, 2021.

Patient had mild bilateral knee and hip pain 1 month ago, then she received her 1st dose of COVID vaccine on 12/14/20. Her joint pain worsened then on 1/4/21 she received her 2nd dose of COIVD vaccine on 1/4/21 and then her pain increased in spread up to her shoulders. She was seen at immediate care on 1/11/21 because her joint pain had worsened throughout and her shoulder pain was

making it difficult to raise her arms above the level of her shoulders. Her pain was made worse w/ movement.

Woke up on 1/6/2021 with hot flashes, palpitations, dizziness and heart racing. Went to urgent care and they did an EKG which showed A-Fib, so I was sent to the ER and from there, I was transferred to an ICU at a different facility . I stayed until 1/8/2021. No cause was found and no history of A-Fib or family history.

immediate tingling of lips, followed by fullness of posterior oropharynx, hoarseness and pruritus

"Fever (103-104 oF) and 4""x1"" red, swelling area around site of injection. Pt states she received an IV."

Acute approximate respiratory failure secondary to acute COPD

first day after shot, nausea, body aches, 2nd day Sunday headache, Monday 5 am woke up itching, then 9 am hives everywhere, trouble breathing, anaphylaxis, went to ER, got epi X 2, solumedrol, benadryl, pepcid, then still with hives, tachycardia, dyspnea, iv fluids were influsing and epi drip started, went to ICU

Back pain, bilateral PE and DVT

"Patient states that she received her second vaccination and in the hours after she had flu-like symptoms. Then over the next few days, she started to notice tingling and a ""prickly"" sensation in various areas. This progressed to symmetric BLE weakness which started in her feet and had reached to just above her knees bilaterally time and she arrived. The weakness had progressed to her hips. She also noticed weakness in her arms and they are easily fatigued. She is able to walk but it takes much effort."

coughing, flushing, cyanosis, diaphoresis

Within 3 minutes of receiving vaccine felt flush and throat swelling, responded to Epi Pen and Benadryl p.o. EMS took him to ED where he remained several hours receiving 1 liter NS 125 mg solumedrol IV, discharge with 4 days of prednisone 40 mg daily and a prescription for an Epi Pen. As of 1.12 he is totally okay with no after effects.

First Day after the injection I had a headache and nausea the entire day into the next day. The second day I still had the headache and the nausea. I work overnights. When I awoke in the afternoon, my throat was closing up. It was hard to swallow and I struggled to breath. I immediately drank liquid Benadryl and called my doctor in the morning.

Patient presents to the Emergency Department who was doing well up until she received COVID-19 vaccine at 1150. 15 minutes later patient started to experience throat tightening and tongue swelling. She was administered Epipen at 1217 by staff at vaccination clinic. EMS was called and prior to arrival at ER tongue swelling had subsided.

-0715 vaccine administered. -0735 started to feel dizzy/off and right side of tongue felt like it was mildly swelling and itchy. -0735 asked to have blood pressure taken as know when I am having anaphylaxis my

blood pressure escalates. -0740 took blood pressure and it was 141/86 in right arm. Normal is 110s/60s-70s. No anxiety feelings. -0740 throat started to have increased mucous production. Had the tickle and tightness in throat. Asked and received 25mg Benadryl with cup of water. -0742 started clearing throat frequently and slight cough. Knew it was anaphylaxis and told the team I need to go to the ER. Asked for additional 25mg Benadryl. Also took 20mg Famotidine and 2 puffs Albuterol inhaler--this is my prescribed anaphylaxis routine. Had Epipens on standby. -0743 put on O2 saturation monitor and watched O2 drop into 90-92 range. Asked for epipen on standby as I know when I need to start it. Didn't want to take that when I knew I was about to get it in the ER and knowing self hadn't progressed that far. Felt chest tightness and shortness of breath. Voice started becoming hoarse. -0800 EMS arrived (delay as team didn't know if they were supposed to call 911 or a Code--they chose EMS even though in hospital). Then staff at COVID vaccine clinic kept emphasizing need to go in ambulance while EMS and self fought to go through hospital (much quicker route). Finally cleared to go through hospital to ER. To get some air via breathing in had to sit up leaning forward. Voice completely hoarse by this time. -About 0817 arrived to ER bay. At this time, frequently coughing and cough started to sound stridorous. Difficulty getting breaths in. Had chest pain near heart. Greeted by MD, 2 RNS, and technician. -0819 received IM epinephrine. Attached to 5 lead EKG monitoring and O2 monitoring. Blood pressure done again. Higher than previous. -About 0821 had working IV (previous two attempts failed as veins were constricting). Given IV Solumderol. Started bolus of 1L Normal Saline. -Not sure how long after by cough subsided, increased mucous production subsided, as well as hoarseness decreased. -Held for observation for 2hours (would be longer if not resolved). - Discharged around 1015. At this time, hoarseness almost all gone. Minimal throat clearing. Cough resolved. -Prescribed epipen inhalers (mine expired) and Prednisone. Prednisone is PRN for mild breathing difficulties if it starts again tomorrow 1/13/21. -At 1400 took 50mg Benadryl and 20mg Famotidine as previously prescribed for anaphylaxis maintenance. Will continue this as previously prescribed every 6hours until symptoms stay resolved. - Made follow up appointment with Primary Care Physician per protocol

Immediately after she felt faint, heart rate 121, felt faint again bp 62/33. Was taken to the ER, within a half hour, she fully recovered. Vitals went back to normal.

Hospice Resident received first Covid 19 vaccine dose on 1/6/21. 1/7/21 resident had decreased appetite noted in am but ate 100% of meal at dinner. 1/9/21 resident had decreased appetite with emesis x 2, loose BM x 2. Call placed to hospice. 1/10/21 5:44 am resident able to take HS meds, ingest 2 cups of shake. No emesis or loose stool noted. 12PM nurse noted resident not eating meals but ingesting milkshake and medications without any problems. Hospice contacted for change in condition. 1:00 pm hospice ordered Phenergan 12.5 mg Q 6 hrs PRN. Labs to be drawn 1/11/21. Hospice notified POA. 1/11/21 12:24am Resident had blood in stool. Resident denies any pain, on 2L of O2 for comfort.

Severely dizzy, left hand totally numb but painful, cold to touch. Felt better before she got to ER.

Patient vaccinated on 12/28. Approximately one day later, develops cough and on azithromycin x 1 week. On 1/3, patient develops left-sided weakness and aphasia. Taken to the hospital, tested COVID+, required intubation -- acute hypoxic respiratory failure secondary to COVID - on H&P. Patient died on 1/4/21 at 7:20am.

Attempting to confirm which COVID 19 vaccine was given (Moderna or Pfizer). They did not send the record when they sent the patient to General ER the next am. Did not answer the phone.

Started to feel lightheaded, weak, faint like I was going to pass out, heart rate increased, confusion, trouble speaking, brought to the ED, throat started to swell and started having thick spit and clearing my throat excessively. Diagnosed as anaphylaxis.

within 1 hr post-vaccine on 1/7 I had a mild headache that resolved with Tylenol. At about 12 hours post-vaccine I developed nausea, fever (100.4) and chills and secondary to this had poor sleep. The next day I took scheduled alternating Tylenol & ibuprofen during the day and then overnight 1 episode of chills that woke me up. no events Saturday or Sunday. Then Monday 1/11 in the early morning I started to develop a rash on my b/l elbow and right foot 3rd toe. I applied mometasone topical cream to these locations. while at work the rash extended down both forearms then by 5pm it was on both hips and extending along both legs. I applied Benadryl cream to the most irritated sites and took PO Benadryl 50mg at bedtime and again at 1am when the itching woke me up. I repeated Benadryl 25mg at 8am. The rash seems to be getting better on the arms but then by noon I had a new breakout on my neck and face. I took Benadryl 50mg at 1pm. The rash continued to have a rapid progression over the next hour and resulted in angioedema with my throat swelling, lips puffed and numb and eye swelling. I was injected with an epi pen and sent to the ED where I received PO prednisone, famotidine, and Benadryl. The face/neck rash then greatly improved and I was sent home on prednisone 40mg daily for 3 days.

Blurred vision, difficulty breathing (pale skin/blue lips), profuse sweating, muscle fatigue, headache. This lasted about 15 minutes. Until severity went down. Followed by 20 minutes of profuse sweating and headache. I thought I was going to die

Sudden cardiac death

"COVID-19 PCR test/he was positive per the PCR test; COVID-19 PCR test/he was positive per the PCR test; Sweating; Fever; running to bathroom with urination every 15 minutes with a large amount of urine; running to bathroom with urination every 15 minutes with a large amount of urine; Heart pounding; tired and fatigue; Weight loss; Chills; pain all over the body; Sluggishness; This is a spontaneous report from a contactable consumer. A 63-years-old male patient received his first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number EH9899, expiry date was unknown), via an unspecified route of administration on the left arm on 21Dec2020 14:40, at a single dose for Covid 19. The patient's medical history and concomitant medications were not reported. The patient has no prior vaccinations -within 4 weeks. The patient is an EEG technician. On 22Dec2020, the patient reported the next day he started to feel sluggish, chills, tired/fatigue, pain all over his body, patient mentioned he has lost weight everyday since he got the shot from 153 pounds to 142 pounds; then on Wednesday evening 23Dec2020, it was a nightmare, he got sweating; fever with a high of 101.4 Fahrenheit; he was running to bathroom with urination every 15 minutes with a large amount of urine; and he was so tired and fatigued. Added when he was getting up all that night he was having night sweats up to five times a night and chills; and his heart was pounding. The urination, heart pounding resolved the next day. All of these events have improved at the time of report (now) or gone away but

he is still sweating once at night for the last two days and he is tired and fatigued. He stated that he is scheduled for the second dose on 11Jan2021 and he is concerned if he should take the vaccine. He mentioned that he was tested for COVID 19 on 18Dec2020 and the result was inconclusive. He went again 23Dec2020 they called him on 25Dec2020 and informed he was positive per the PCR test. He treated himself with 500mg acetaminophen (UPC 0904672059; lot OBE2896 and expiration Oct2021) and azithromycin Z-Pack (NDC 65862-641-69; Lot ZYSA20012-A; and expiration date Mar2022). The sample of the product is not available to be returned. Predisposing factor was that the patient's wife was at home and was sick too at the same time. She was tested Sunday with no results yet. The outcome of the events of fever recovered on 28Dec2020, sluggishness recovered on 29Dec2020, pain all over the body was recovered on 02Jan2021; running to the bathroom with urination every 15 minutes with a large amount of urine and heart pounding were recovered on 24Dec2020, weight loss was not recovered, and for other events was recovering.; Sender's Comments: Based on the mechanism of action of BNT162B2 vaccine, it is unlikely the patient would have fully developed immunity for the vaccine to be effective, due to the number of days passed since the vaccine was given (4 days in this case). However, a causal relationship between event ""COVID-19 PCR test/he was positive per the PCR test"" (coded to Drug ineffective / SARS-CoV-2 test positive) and BNT162B2 vaccine cannot be completely excluded"

Tested positive to COVID; Tested positive to COVID; This is a spontaneous report from a contactable nurse, the patient. A 41-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration on 23Dec2020 as a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. On 02Jan2021, the patient tested positive to Covid. The outcome of the event, tested positive to Covid, was unknown. The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up.

neuropathy; pain; nausea; fatigue; bone, muscle, stomach pain; bone, muscle, stomach pain; bone, muscle, stomach pain; flare; increase in joint pain from his baseline; This is a spontaneous report from a Pfizer sponsored program Accredo Xeljanz Program. A contactable nurse and contactable consumer (patient) reported that a 56-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration on 18Dec2020 at a single dose for COVID-19 immunization and tofacitinib citrate (XELJANZ XR), orally from 02Oct2020 at 11 mg, daily for rheumatoid arthritis. The patient's medical history and concomitant medications were not reported. On 19Dec2020, the patient experienced neuropathy, pain, nausea, fatigue, bone, muscle, stomach pain and flare. In Dec2020, the patient experienced increase in joint pain from his baseline. The physician was aware. The patient was placed on unspecified steroids for the events, neuropathy, pain, nausea, fatigue, bone, muscle, stomach pain and flare which minimized symptoms. While weaning off steroids, the severity of symptoms returned. The patient was instructed by the doctor to stop taking tofacitinib citrate which was stopped on 29Dec2020. The action taken in response to the events for BNT162B2 was not applicable and for tofacitinib citrate was permanently withdrawn on 29Dec2020. The patient reported slight improvement after stopping tofacitinib citrate. The outcome of neuropathy, pain, nausea, fatigue, bone, muscle, stomach pain and flare was recovering and of increase in joint pain from his baseline was

unknown. The batch/lot number for the vaccine, BNT162B2, was not provided and will be requested during follow-up.; Sender's Comments: Based on the information available, the reported events are most likely due to patient underlying contributory factors and unlikely that it is related to the suspect product. However due to temporal association with the vaccine, a possible contributory role of vaccine cannot be ruled out. Case will be reevaluated based on additional information during the follow-up. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators as appropriate.

I developed Covid -19 (positive PCR) on 02Jan2021 after respecting quarantine, mask wearing, and was not onsite at work; I developed Covid -19 (positive PCR) on 02Jan2021 after respecting quarantine, mask wearing, and was not onsite at work; This is a spontaneous report from a contactable pharmacist. A 25-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE) lot number: EK5130, via an unspecified route of administration at left arm from 23Dec2020 16:30 to 23Dec2020 16:30 at a single dose for COVID-19 immunization. Medical history and concomitant medications were not reported. The patient developed Covid-19 (positive polymerase chain reaction (PRC)) on 02Jan2021, after respecting quarantine, mask wearing, and was not onsite at work. The patient did not received treatment for the adverse events. The outcome of the events was recovering.; Sender's Comments: A causal association between reported event and suspect BNT162B2 cannot be excluded.

she received her first dose of COVID vaccine on 18Dec and a week later contracted COVID; she received her first dose of COVID vaccine on 18Dec and a week later contracted COVID; This is a spontaneous report from a Pfizer-sponsored program IBCC (Inbound Call Center for HCPs) from a contactable registered nurse (patient). This 67-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) at single dose on 18Dec2020 for COVID-19 immunization. Medical history and concomitant medication were not reported. Patient stated she received her first dose of COVID vaccine on 18Dec and a week later contracted COVID (in Dec2020) after receiving COVID vaccine. She just wanted to find out the answer to some medical questions. She had questions about antibodies and whether or not she should take the second dose. She stated her second dose was scheduled in two days, on Friday. She said after being positive on 28Dec2020 for COVID-19 virus test, she received the medication Bamlanivumab 700 mg intravenous passive antibodies therapy to lessen the COVID symptoms and to keep her out of the hospital, which it did. The outcome of events was unknown. Information about lot and batch number was requested.; Sender's Comments: Based on the information currently available, a lack of efficacy with the suspected vaccine BNT162B2 cannot be completely excluded. However, it is unlikely that the patient would have fully developed immunity due to the very short time lag between the first vaccine dose and the event onset.

COVID Rapid Test and COVID-19 PCR test positive/ symptomatic/ fever/ not feeling well; COVID Rapid Test and COVID-19 PCR test positive/ symptomatic/ fever/ not feeling well; This is a spontaneous report from a Pfizer-sponsored Program Pfizer First Connect. A contactable nurse reported for a male patient (husband) with unspecified age received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK5730) via IM injection left deltoid on 19Dec2020 at single dose for COVID Prevention.

Medical history and concomitant medications were none. The patient did not receive any other vaccines on the same day as the COVID vaccine. The patient was a healthcare professional. The vaccine was not specifically prescribed to the patient, but rather was given to him via his workplace policy, although it was not mandatory. The patient received 1st dose on 19Dec2020, and he had exposure to the virus at work, and on 01Jan2021 he woke up with a fever and was not feeling well and tested positive for COVID-19. Currently he is still symptomatic. The reporter is inquiring about how to follow up with the second dose for the patient, as the patient is due for his second dose on 09Jan2021. It was reported that it had mostly been a low grade fever. The patient had both COVID Rapid Test and COVID-19 PCR test performed on 01Jan2021, and both were positive. The outcome of event was unknown. The reporter was unsure of seriousness for the patient's positive COVID tests, so far it had not been terrible, but he was still symptomatic, so it was hard to say seriousness at this time. Relatedness of vaccine to event fever and positive COVID test both rapid and PCR from the reporter was unrelated.; Sender's Comments: Based on the information currently available, a lack of efficacy with the suspected vaccine BNT162B2 cannot be completely excluded. However, it is unlikely that the patient would have fully developed immunity due to the very short time lag between the first vaccine dose and the event onset.

"got the covid 19 vaccine on 29Dec2020 and tested positive for covid on 05Jan2021; got the covid 19 vaccine on 29Dec2020 and tested positive for covid on 05Jan2021; This is a spontaneous report from a contactable nurse (patient). A female patient of an unspecified age (reported as ""Age-48, Unit-Unknown"") received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 29Dec2020 at single dose for COVID-19 immunization. The patient medical history and concomitant medications were not reported. The patient stated she got the covid 19 vaccine on 29Dec2020 and tested positive for covid on 05Jan2021. She wanted to know what to do about the second dose of the vaccine. Information about Lot/batch number has been requested."

"I ended up testing positive on Monday 04Jan2021; I ended up testing positive on Monday 04Jan2021; This is a spontaneous report from a contactable Other Health Professional (patient). A male patient of an unspecified age received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection) lot number was not reported, via an unspecified route of administration on 30Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. Family history included patient was ""99.9% sure that his daughter at day care had direct contact (COVID-19)"". It was reported that the patient received first dose on 30Dec2020, and that same Wednesday morning 99.9% sure that his daughter at day care had direct contact (COVID-19). He ended up testing positive on Monday 04Jan2021 with outcome of unknown, and was scheduled for second dose on 04Jan2021. He asked for specific recommendation for his weird situation. Information on Lot/Batch has been requested.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the reported events of suspected LOE and SARS-CoV-2 test positive due to temporal relationship. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available."

anaphylactic reaction; arm was really sore; tiredness; dizzy; This is a spontaneous report from a contactable other health professional (patient). A 53-year-old female patient received bnt162b2 (Pfizer-biontech covid-19 vaccine), via an unspecified route of administration on 31Dec2020 at single dose for covid-19 immunization. Medical history included shellfish allergy. The patient's concomitant medications were not reported. The patient experienced anaphylactic reaction on an unspecified date, dizzy on 31Dec2020, arm was really sore on an unspecified date, tiredness on an unspecified date. Event details: She was dizzy that day especially with changing positions, she didn't need to go to the doctor or anything. It wasn't severe. She was just a little dizzy. It's probably just the vaccine and it did go away. Her arm was really sore and went away after a few days. the tiredness, it wasn't a big deal. She did feel better about. it wasn't a serious anaphylactic reaction. It didn't happen right away. She had arm soreness. it wasn't immediate. She usually didn't have. It was really weird. She thought she was well hydrated. The outcome of event was really sore was resolved, outcome of other events was unknown. Information on the Lot/Batch number has been requested.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the anaphylactic reaction and other reported events due to temporal relationship. There is very limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

she tested positive for COVID-19 after receiving the first dose of the Pfizer-Biontech COVID-19 vaccine.; she tested positive for COVID-19 after receiving the first dose of the Pfizer-Biontech COVID-19 vaccine.; This is a spontaneous report from a contactable physician. A 41-year-old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number EH9899) intramuscular in left arm on 26Dec2020 14:30 at a single dose for COVID-19 immunization.The patient's medical history and concomitant medications were not reported. The physician received her first dose of the COVID vaccine on 26Dec2020 and on 02Jan2021, tested positive for COVID. She actually tested negative 2 days before testing positive (26Dec2020). The outcome of the event was recovered on an unknown date. According to the physician, the event was unrelated to the vaccine as her nanny and her son was also tested positive.; Sender's Comments: The Company cannot completely exclude the possible causality between the reported tested positive for COVID, which is considered ineffective of BNT162B2, and the administration of BNT162B2.

Tested positive for COVID; Tested positive for COVID; This is a spontaneous report received from a contactable Registered Nurse (patient) via a Pfizer sponsored program IBCC (Inbound Call Center for HCPs). A female patient of an unspecified age received BNT162B2, via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient experienced tested positive for COVID on an unspecified date with outcome of unknown. The patient just received the COVID vaccine,

and also tested positive for COVID. The patient underwent lab tests and procedures which included COVID test: positive. Information on the lot/batch number has been requested.

has COVID now and was pretty ill and in their ICU, positive COVID-19 test; has COVID now and was pretty ill and in their ICU, positive COVID-19 test; This is a spontaneous report from a contactable pharmacist. A 55-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), on unspecified date in Dec2020 at SINGLE DOSE for COVID-19 immunization. The patient developed positive COVID-19 test with symptoms on unknown date. The clinical course was as follows: the patient received the first dose of the vaccine 2 weeks ago and has COVID now and was pretty ill and in their ICU. Laboratory data included: SARS-CoV-2 test (unknown date): positive. The pharmacist was wondering if the participants in the trials received their second dose if they tested positive before the second dose and if there is any data on when to give the second dose of the vaccine for patients that test positive before the second dose. The outcome of the events was unknown. Information on lot/batch number has been requested.; Sender's Comments: No effect of the suspect vaccine could be reasonably achieved to protect from the targeted infection/disease due to the very short time lag. Instead, the positive COVID likely represents a pre-existing infection prior to vaccine use. Further information is needed for full medical assessment.

"Anaphylactic reaction; Tongue was swelling; Difficulty breathing; This is a spontaneous report from a contactable Pharmacist. A 55-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), at SINGLE DOSE for COVID-19 immunization. The patient experienced ""Tongue was swelling, Difficulty breathing, and an Anaphylactic reaction"".No other details provided. The outcome of the events was unknown Information on lot/batch number has been requested.; Sender's Comments: A possible causal relationship between acute onset of Anaphylactic reactions presented as Tongue swelling/Difficulty breathing and BNT162B2 cannot be completely ruled out considering the temporal relationship and the known adverse event profile of the suspect vaccine. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate."

Positive COVID-19 rapid test; Positive COVID-19 rapid test; Positive COVID-19 rapid test; Patient got sick; 2 weeks of on and off fever and unproductive cough; Patient got sick; 2 weeks of on and off fever and unproductive cough; Patient got sick; 2 weeks of on and off fever and unproductive cough; Lost sense of taste and smell; Lost sense of taste and smell; sore throat; This is a spontaneous report from a contactable nurse (patient). A 50-year-old male patient received the 1st dose of bnt162b2 (BNT162B2), via an unspecified route of administration, on 16Dec2020, at single dose, for COVID-19 immunisation. Medical history and concomitant medications were none. On 17Dec2020 patient got sick; 2 weeks of on and off fever and unproductive cough. In Dec2020 the patient also experienced lost sense of taste and smell. On 20Dec2020 the patient underwent COVID-19 rapid POC test and was found positive. The events required emergency room visit. Therapeutic measures were taken as a result of the events and included treatment with Tylenol 650 every 4 hours. The events recovered on unspecified date except unproductive cough and sore throat that were recovering. The information on the lot/batch number has

been requested.; Sender's Comments: The association between the event lack of effect (COVID-19 rapid POC test) with BNT162b2 can not be completely excluded.

Covid; Covid; This is a spontaneous report from a contactable Other Healthcare Professional (HCP). A female patient of unknown age received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, on an unknown date at single dose for COVID-19 immunisation. Medical history and concomitant medications were unknown. The patient was scheduled for her second dose of vaccine tomorrow (08Jan2021) but she was diagnosed with Covid on 07Jan2021. Outcome was unknown. Information on the lot/ batch number has been requested.; Sender's Comments: Based on the information available, a possible contributory role of the suspect products cannot be excluded for the reported event of positive for corona virus infection for the lack of efficacy of the vaccine. However, based on the mechanism of action of the vaccine, it is unlikely the patient would have fully developed immunity for the vaccine to be effective, due to the number of days passed since the vaccine is given. Case will be reevaluated based on follow-up information

Drug ineffective; tested positive for COVID-19; This is a spontaneous report from a contactable pharmacist reporting for his/her mother-in-law. A 99-years-old female patient in good health received the first dose of BNT162B2 Pfizer-BioNTech COVID-19 Vaccine, via an unspecified route of administration on an unspecified date (presumably on 02Jan2021 - to be confirmed) at single dose for COVID-19 immunization. The patient's medical history was not reported. Concomitant medication included monoclonal antibody bamlanivimab on an unknown date. On 06Jan2021 the patient experienced tested positive for COVID-19. It was reported that the patient is scheduled to have her 2nd dose on 23Jan2021. The reporter asked if the patient should wait 90 days before taking the second dose. Information on the lot/batch number has been requested.; Sender's Comments: A causal association between event and suspect BNT162B2 cannot be excluded

"positive with covid; positive with covid; sinus strainagned at the back of the throat.; sinus strainagned at the back of the throat.; This is a spontaneous report from a contactable nurse. A female patient of an unspecified age started to receive BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot# unknown), via an unspecified route of administration on an unspecified date single dose for COVID-19 immunisation. The patient medical history was not reported. The patient's concomitant medications were not reported. The patient experienced positive with COVID on an unspecified date, sinus strainagned at the back of the throat on an unspecified date. The outcome of the events was unknown. Information on the Batch/Lot number has been requested.; Sender's Comments: A causal association between reported ""positive with covid"" and suspect BNT162B2 cannot be excluded."

received her 1st COVID vaccine shot 22Dec2020, however she got diagnosed with COVID; received her 1st COVID vaccine shot 22Dec2020, however she got diagnosed with COVID / pneumonia; rash; This is a spontaneous report from a contactable consumer (patient). This 77-years-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, on 22Dec2020 at single dose for COVID-19 immunisation. Medical history and concomitant medications were unknown. After the first dose, the patient got diagnosed with COVID. She does not want to waste a second dose if it will not be useful. Everyone on her department has had

COVID, and have been told to wait 3 months before getting their second dose. Caller had a 'rash' after her 1st dose of the COVID vaccine. The patient is now recuperating from the pneumonia. Outcome of pneumonia was recovering while outcome of the other events was unknown. Information on the Lot/Batch Number has been requested.

headaches on both sides of his head; This is a spontaneous report from a contactable Physician reporting for himself. A 53-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) at 0.3ml single dose on 30Dec2020 in the left deltoid for COVID-19 immunisation at the age of 53-year-old. Lot number was EK9231, expiration date 30Apr2021. Medical history and concomitant medications were unknown. On 31Dec2020, headaches on both sides of his head; the event was considered medically significant. The patient received TYLENOL for the event. The patient did not recover from the event. The physician considered the event was related to suspect vaccine. Information on the lot/batch number has been requested.; Sender's Comments: A causal association between BNT162B2 and the reported events cannot be excluded based on a compatible temporal relation between vaccination and onset of events. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

Received the first dose of Pfizer COVID Vaccine and then tested positive after receiving it; Received the first dose of Pfizer COVID Vaccine and then tested positive after receiving it; This is a spontaneous report from a Pfizer-sponsored program. A contactable consumer (patient) reported that a male patient of an unspecified age received the first dose of bnt162b2 (lot no. and expiry date were unknown), via an unspecified route of administration on an unspecified date at single dose for Covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient received the first dose of Pfizer COVID Vaccine and then tested positive after receiving it. He says it has been 14 days after he tested positive and he is wondering about getting his second dose. The outcome of the event was unknown. Information on the Lot/batch number has been requested.

increased respiratory infection; Allergic reaction; Yeast infection; Non-diagnosed allergic conjunctivitis; seasonal allergies; This is a spontaneous report from a Pfizer-sponsored program, IBCC (Inbound Call Center for HCPs), from a contactable nurse (patient) reported for herself. A female patient of an unspecified age received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 22Dec2020 at a single dose for COVID-19 immunization. Medical history and concomitant medications were not reported. The patient was having an allergic reaction and had a yeast infection. She was supposed to get the next dose soon (on 12Jan2021) but she was worried about getting the second dose. The patient stated so she had some increased (incomplete sentence).The patient stated she had a non-diagnosed allergic conjunctivitis followed by a yeast infection, followed by increased respiratory infection and she did make a report of the seasonal allergies that I did not used to get at this time of year. So, she did not report the conjunctivitis because it was not diagnosed and did not report the yeast infection because she handled it herself. The outcome of events was unknown. Information about Lot/Batch number is requested.; Sender's Comments: Based solely on a compatible

temporal association causality between reported events and BNT162B2 vaccine cannot be excluded. The case will be reevaluated should additional information become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

On 1/5/2020, I, the patient woke up at 3:30 with sharp boring epigastric pain. Progressed to include nausea. On evaluation in the ED was diagnosed with acute pancreatitis. Prior hx includes 2 episodes with hospitalization for gallstone pancreatitis in 2016. Subsequently had laparoscopic cholecystectomy in 2016. Last alcoholic beverage prior to 2020 ED presentation was 3 weeks prior. No tobacco or drug use.

The patient presented to hospital on 1/6/2021 with a primary complaint of Fatigue (pt had covid vaccine yesterday. Now displaying increased weakness, blood in urine, increased confusion and urinated on herself today. Fever of 101.9) 79-year-old female presents to the emergency room with fatigue. The patient states yesterday she had the Moderna COVID-19 The patient states today she had a temperature 101.8¦ prior to arrival. Her son noted that she was having episodes of urinary frequency and also that she was profoundly weak and fatigued. They denied falling or hitting her head. The patient also states she been having nausea vomiting with diarrhea.

Vaccine was given on 12/23/20 on 01/07.21 went to get a routine physical and received an emergency call that my pallet blood count was around 10K instead of 150k. Was instructed to go to the ER asap. However didn't received the message until the next morning at 6:30am. Was checked into the E.R. , given sterioids, pallets, hemogolibin. Stayed overnight in the hospital was able to leaved the next day around 1pm with pallets at 47k.

swelling at the injection site, pain, headache, feeling like numb, change in the taste, fever the 1st day x2, body ache, lower back pain.

Three hours after receiving COVID 19 vaccination, Patient oxygen level decreased to a critical level and went into cardiac arrest. Staff performed full code but was unable to bring back patient from cardiac arrest.

2230 feeling of unease, body aches, site arm tingling, general mild aches 0220 awoke from sleep choking, having difficulty breathing, felt very SOB, worse with exertion or trying to speak, great difficulty swallowing and speaking even in brief words. Took 50mg of Benadryl PO and went to the ED, about a 15 minute car ride. Had tingling and numbness of the tongue and back of throat by arrival but still able to breath with focus. Exertion of just walking into the ED greatly increased the SOB. Was triaged, Benadryl starting to help, was able to speak a little better, 3-4 words without too much SOB caused. Was walked to a room, SOB milder with that exertion. Seen by Dr. Given IV Sol-u-Medrol and 50mg Benadryl. Was observed on cardiac monitor/Q15VS for a few hours and discharged home around 5:30. Given Rx of Prednisone 20mg -3tabs x2 days, 2tabs x5 days all once a days and told to take 50mg of Benadryl Q4H for the next 24 hours at least and to return prn. I did need to stay on Benadryl, as the Sol-u-Medrol wore off some of the swelling in thr throat did return but not severe, Benadryl did help, along with taking my

Asthmnex I already had. I also continued my normal HS antihistamines. I had SOB on exertion, progressively better from the 6th-10th with it mostly resolved to yesterday. Body aches have continued but also progressively better. Yeasterday1/12/21 the Rx of prednisone was completed and I did have some mild swelling /tingling in the throat/face/mouth return in the evening, took Benadryl 50mg again and inhaler used. I have an appointment today to seek further care at my primary doctor's office. Asthmnax used again this morning as well, only mild tightness in the throat currently with mild body aches this whole time.

Systemic: Fever-Severe, Systemic: hypotension, dyspnea-Severe; symptoms lasted 1 day

Patient day after vaccination had fever, chills, headache and malaise but recovered the next day. starting four days after vaccination started to have left neck swelling . Of note day prior vaccination had left wisdom teeth removal and maxillary root canal. 1 week after vaccination and 8 days after oral procedures worsening left neck swelling, trouble swallowing's and change voice found resulting left neck 3x2cm necrotic neck abscess and significant neck inflammation. Patient was seen by ENT and started on IV Unysan and admitted for airway monitoring due to swelling with improvement over next 48 hours.

12/23/2020-RECEIVED VACCINE AT 9:52 AM. REPORTS NOT FEELING WELL IN THE AFTERNOON, LIGHTHEADED AND DIZZY, THROBBING HEADACHE. CRAMPING/ACHING IN BACK OF CALVES. 12/24/2020 CONTINUED WITH DIZZINESS, THROBBING HEADACHE, BLOOD PRESSURE ELEVATED, CHEST PRESSURE 8:00 PM REPORTED FEELING THAT SHE WAS GOING TO DIE, WENT TO LAKE CITY MEDICAL CENTER- BLOOD PRESSURE ON ARRIVAL 184/101 HR. 117. GIVEN NITRO AND MEDICATIONS. ADMITTED, DISCHARGED 48 HOURS LATER ON 12/26/2020. DISCHARGED ON BLOOD PRESSURE MEDICATION 12/27/2020-LESS THAN 24 HOURS AFTER BEING DISCHARGED SHE WAS READMITTED TO MEDICAL CENTER WITH SAME SYMPTOMS. 36 HOURS AFTER ADMISSION, TRANSFERRED TO MEDICAL CENTER. FOR CARDIC WORKUP AND HIGHER LEVEL OF CARE.

Became dizzy, headache, felt like she was going to faint, rigors and a temperature of 101.5. Next morning she had upset stomach, feeling dizzy, thought she was going to faint and a headache.

Had Covid Vaccine AM of 1.8.2021. Woke up with Nausea, Vomiting X 4, Chills the following AM. Presented to ED. Found to be hypotensive during ER. Nausea Vomiting resolved. Tx with fluid replacement and dismissed home instructed to monitor BP. B/P dropped again at home returned and admitted to hospital.

Site: Pain at Injection Site-Medium, Systemic: Generalized Body Aches -Severe, Systemic: Headache-Severe, Systemic: Severe drop in blood pressure, pulse, and o-sat-Severe

Patient reported symptoms started ~15 mins s/p dose. Symptoms reported LUE and LLE numbness/tingling, and notable tachycardia

NauseaVomiting, HYPERtension, Tachycardia, throat swelling Narrative: Went home after vaccine and starting vomiting, throat swelling. HR and BP elevated Went to ER was given beta blockers, in hospital for observation.

"Patient received vaccine on 1/8/2021. On 1/9/2021 I checked on patient via phone for symptoms or problems and he reported none but mild soreness at injection site. On 1/10/2021 family friend called me to tell me that patient had expired at about 8:00 pm. Patient reportedly complained of ""pain"" unspecific and collapsed at home. Hospital reportedly told family that it appeared to be a ""heart attack""."

I was being monitored for 15 mins since I was allergic to tree nuts stayed 20 mins. I started feeling dizzy and exp nausea lasted 20 sec. After about 12 hrs later I woke up had difficult swallowing felt like something in my throat. I went to ER received a dose pack, Benadryl and steroid injection.

Jan 1st, patient had a seizure after breakfast. Temperature was 98.5 Pulse 95. B.P. 160/70 Two hours later another seizure at the home, with emesis, Sent to hospital at 2pm. Focal Status elepticus. Seizure activity along with continuous persistent activity with emesis throughout the 12 hour time in the ED. Seizure during the CT scan.

severe stabbing-shooting lower back pain; severe stabbing-shooting lower back pain that radiated to both legs; Pricking, pins and needles sensations in the hands and feet; numbness; weakness to both legs but mostly the right leg; Coordination problems, unsteadiness; Coordination problems, unsteadiness; This is a spontaneous report from a contactable nurse (patient). A 39-year-old male patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EL0140), intramuscular on 20Dec2020 08:00 at single dose at left arm for covid-19 immunization. Medical history included hypertension from an unknown date and unknown if ongoing. The patient's concomitant medications in two weeks included multivitamins. Patient didn't receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient was not diagnosed with COVID-19 prior to vaccination. No known allergies to medications, food, or other products. On 22Dec2020 at approximately 19:15, the patient experienced sudden onset of severe stabbing-shooting lower back pain that radiated to both legs. Pricking, pins and needles sensations in the hands and feet. Coordination problems, unsteadiness, numbness, and weakness to both legs but mostly the right leg. The patient underwent lab tests and procedures post-vaccination which included nasal swab for covid test: negative on 30Dec2020 (Antigen Test). Adverse events resulted in doctor or other healthcare professional office/clinic visit, emergency room/department or urgent care, disability or permanent damage. Patient received pain medication, steroid dose pack, MRI (pending), and physical therapy (pending) as treatment. Outcome of all events was not recovered.; Sender's Comments: Based on the compatible temporal association, a contributory role of vaccination with BNT162B2 in the onset of the events cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

high blood pressure within 15 min post vaccination. BP 180/94/BP rose to 202/110; This is a spontaneous report from a contactable nurse. An adult female (age:18-64 Years) patient (pregnant: No) received first dose of BNT162B2 (Pfizer), intramuscularly in left arm on 05Jan2021 10:30 at single dose for COVID-19 immunization. The patient's medical history was not reported. The patient was received

other concomitant drugs. The patient experienced high blood pressure within 15 min post vaccination. BP (blood pressure) 180/94 rose to 202/110 on 05Jan2021 10:45. The event resulted in doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care. The events were reported as non-serious. Recipient experienced high blood pressure within 15 min post vaccination. Went to hospital where her pressure was 202/110, vaccine given on 05Jan2021 at 10:30 am, by 10:45 am BP was 180/94, recipient refused hospitalization. Sister took her home but made her go to the hospital where her BP rose to 202/110. IV (intravenous) steroids given. The outcome of event was resolved in Jan2021. The patient didn't receive any other vaccines within 4 weeks prior to the COVID vaccine. The medications the patient received within 2 weeks of vaccination: Protein drink. Unknown whether was the patient diagnosed with COVID-19 prior to vaccination. Unknown whether the patient been tested for COVID-19 Since the vaccination. Unknown allergies to medications, food, or other products. Information on the lot/batch number has been requested.; Sender's Comments: Based on temporal association, a possible contributory role of BNT162B2 cannot be excluded for reported event hypertension. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

First dose on 16Dec2020, second dose on 05Jan2021; Tinnitus; constant ringing in ears; louder this time; This is a spontaneous report from a contactable nurse (patient). A 51-year-old female patient (no pregnancy) received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), with first dose (lot number: EH9899) on 16Dec2020 via intramuscular route, with second dose (lot number: EK4176) on 05Jan2021 via an unspecified route of administration, both at single dose for covid-19 immunization. Medical history included allergies: penicillin. Concomitant medication included famotidine, ibuprofen (DUEXIS), iron (IRON) and multivitamins, all received within two weeks of vaccination. On 17Dec2020, the patient experienced tinnitus, constant ringing in ears that started 24 hours after first vaccine, lasted about 2-3 days and went away. Ringing in ears started again and is louder this time on 06Jan2021. Facility where the most recent COVID-19 vaccine was administered was in hospital. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. No treatment received for the adverse event. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. The event was identified as serious and resulted in disability or permanent damage. The outcome of event tinnitus was not recovered. The outcome of the other event was unknown.; Sender's Comments: Based on the compatible temporal association with positive rechallenge result, the Company considers the event tinnitus is possibly related to vaccination with BNT162B2. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Injection site was red and a little swollen the next day and has become increasingly larger. Today (3 days later) the injection site is red, warm, swollen, and about the size of a grapefruit.; Injection site was red and a little swollen the next day and has become increasingly larger. Today (3 days later) the injection site is red, warm, swollen, and about the size of a grapefruit.; Injection site was red and a little swollen the next day and has become increasingly larger. Today (3 days later) the injection site is red, warm, swollen, and about the size of a grapefruit.; This is a spontaneous report from a contactable other HCP. A 39-yearsold female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number EL1284), intramuscular in left arm on 04Jan2021 14:00 at a single dose for COVID-19 immunization. Medical history included COVID-19 prior to vaccination. Concomitant medication included desvenlafaxine succinate (PRISTIQ), fluoxetine (FLUOXETINE), bupropion hydrochloride, naltrexone hydrochloride (CONTRAVE), hydrochlorothiazide (HYDROCHLOROTHIAZIDE), etonogestrel (NEXPLANON) , ergocalciferol (VITAMIN D [ERGOCALCIFEROL]), cyanocobalamin (VIT B12), and iron. On 05Jan2021, the patient experienced injection site was red and a little swollen and has become increasingly larger. 3 days later, on 08Jan2021, the injection site was red, warm, swollen, and about the size of a grapefruit. The outcome of the event was not recovered. Treatment included over the counter medications and ice. The patient was not tested for COVID-19 post vaccination.; Sender's Comments: Based on the information currently provided, the vaccination with BNT162B2 might play a contributory role in triggering the onset of the reported injection site reactions. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

"dizzy; felt like I was going to pass out; shaky; ringing in ears; This is a spontaneous report from a contactable nurse (patient herself). A 63-year-old non-pregnant female patient received her first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: unknown), via intramuscular route of administration on the left arm on 30Dec2020 17:00 at a single dose for COVID-19 immunization at hospital facility. The patient had no relevant medical history and no known allergies. The patient's concomitant medications were not reported. The patient did not receive any other vaccines within 4 weeks, or any other medications within 2 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. The patient reported ""almost immediately, dizzy, felt like I was going to pass out, shaky, and ringing in ears"" on 30Dec2020 17:00. Events were reported as non-serious but resulted in visit to the Emergency room/department or urgent care. Ondansetron (ZOFRAN) was given as treatment for nausea and meclizine. The outcome of the events was not recovered. Since the vaccination, the patient had not been tested for COVID-19. Information on the lot/batch number has been requested.; Sender's Comments: The Company cannot completely exclude the possible causality between the reported ""dizzy, felt like I was going to pass out, shaky, and ringing in ears"" and the administration of COVID 19 vaccine, BNT162B2, based on the plausible temporal association. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RA, IEC, as appropriate."

felt flushed; BP elevated 226/97; dull occipital headache/dull headache; This is a spontaneous report from a contactable other HCP (patient). A 64-year-old female patient received second dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number: EL1284; expiration date not provided) via an unspecified route of administration (vaccination location: left arm) on 06Jan2021 09:30 at SINGLE DOSE for COVID-19 immunisation. Medical history was reported as 'none'. It was also reported that patient didn't receive any other vaccines within 4 weeks prior to the COVID vaccine, and prior to vaccination, the patient was not diagnosed with COVID. The patient has no allergies to medications, food, or other products (no known allergies). The patient's concomitant medications were not reported. The patient previously took bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number: EH9899; expiration date not provided), via an unspecified route of administration (vaccination location: left arm) on 18Dec2020 18:00 at SINGLE DOSE for COVID-19 immunisation. It was reported that patient received second dose of Pfizer Covid vaccine on 06Jan2021 at 09:30 am. One hour after the 2nd dose (10:30 am), patient experienced dull occipital headache. Patient took paracetamol (TYLENOL). At 10:45 am, patient felt flushed. The nurse took patient's vital signs and noted no fever, normal heart rate and respiratory rate. BP elevated 226/97 (reported at 10:30, no unit provided; normal BP: 130's/80's). At 12:45, patient was taken to ED. CT scan and lab work were reported as all normal. BP continues to be elevated. Amlodipine (NORVASC) 10 mg was given at 17:00. BP slowly came down. Twenty-four hours later, BP was normal at 137/72 (no unit provided). No additional medication taken. It was reported that patient continues to have dull headache. No arm soreness or other symptoms. It was also reported that since the vaccination, the patient has not been tested for COVID-19. Outcome of the events 'BP elevated 226/97' and 'felt flushed' was recovering, outcome of the event 'dull occipital headache/dull headache' was not recovered.; Sender's Comments: Based on the compatible temporal association and in absence of strong confounding factors, the Company considers the reported event blood pressure increased is possibly related to vaccination with BNT162B2. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

"rash/getting this rash on my face and everywhere/rash and it is breaking out her face and now it is all over; a lot of muscle pain; could not sleep; This is a spontaneous report from a contactable consumer (patient). A 27-year-old female patient received first dose bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), intramuscular in left deltoid on 24Dec2020 09:30 at single dose for preventative. Medical history included none. There were no concomitant medications. The patient previously took influenza vaccine (FLU) for immunization and experienced sick (Flu shot if it contains egg she gets really sick). Patient reported experiencing a rash 2 weeks on 06Jan2021 after getting her first dose of the vaccine. Caller stated ''I'm concerned because I'm getting this rash on my face and everywhere and I'm due for my booster on 13Jan2021.'" Caller questioned if others had reported this. She had a lot of muscle pain on 24Dec2020 and could not sleep from the pain in Dec2020. Reports the pain is gone now and lasted till 28Dec2020. She has a rash and it is breaking out her face and now it is all over. States nothing has changed and the vaccine was the only new thing. States the rash started two weeks since she got the vaccine. Vaccination facility type was Hospital. Vaccine administered at military facility was No.

Additional Vaccines Administered on Same Date of the Pfizer Suspect was none. AE not require a visit to emergency room. Therapeutic measures were taken as a result of rash/getting this rash on my face and everywhere/rash and it is breaking out her face and now it is all over (Doctor ordered steroids for her today she is a CNA). The outcome of the event a lot of muscle pain was recovered on 28Dec2020. The outcome of the event rash/getting this rash on my face and everywhere/rash and it is breaking out her face and now it is all over was not recovered. The outcome of the event could not sleep was unknown. Information about lot/batch has been requested."

"passed out; blood pressure was lowered; blood sugar high; weakened; feeling tired and her legs are heavy; feeling tired and her legs are heavy; This is a spontaneous report from a contactable consumer (Patient's Mother). A 23-years-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 04Jan2021 Monday at single dose for COVID-19 immunisation. The patient medical history and concomitant medications were not reported. The patient experienced passed out 12 hours post injection (Jan2021). She specified that her daughter was therefore brought to hospital by ambulance. She continued explaining that her blood pressure was lowered, her blood sugar high and that she was weakened (Jan2021). On 08Jan2021, ""day 4"", she said that her daughter had been feeling tired and her legs are heavy (Jan2021). The event outcome was unknown. She then asked if those side effects were experienced after the vaccine. It was not reported as serious. Information on the batch number has been requested."

left side will blur; Left side of face was sagging/ water leaking out of mouth/Progressive weakness on left side of face/ Swelling on lower left mandible/ diagnosed with Bell's Palsy.; Eye tearing; This is a spontaneous report from a contactable nurse who reported for himself. A 61-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Batch/lot number: EK5780) in left arm on 26Dec2020 at 08:30 at single dose for covid-19 immunisation (worked in surgical ICU and was over 61 years old). Medical history included Pre-diabetic. Family history included: mother died; mother's side had colon cancer and grandparents and uncles had cardiovascular diseases.Concomitant medication included exenatide (BYDUREON), amlodipine besilate (NORVASC), omeprazole (PROTONIX), hydrochlorothiazide, lisinopril and pneumococcal vaccine on 08Dec2020 and tetanus vaccine on 08Dec2020. It was reported that on 31Dec2020 at 07:30, the patient had eye tearing and water leaking out of mouth, left side of face was sagging, swelling on lower left mandible (eye tearing was first, as reported); on 31Dec2020 he also experienced progressive weakness on left side of face; on 02Jan2021 the patient was diagnosed with Bell's Palsy. Then on an unknown date, left side will blur occurred. All events required emergency room visit and physician office visit. Diagnosis of Bell's Palsy and event eye tearing were serious per disability; left side will blur was non serious. Patient described the events as follows: on 31Dec2020 he was brushing teeth and noticed the water was going everywhere. Left side of face was sagging, noticed some swelling and thought it was from a bug bite. He wasn't sure if it was a stroke or not. In the morning of 01Jan2021 noticed it was progressively causing a problem. Days before noticed tearing of left eye (as reported). On 31Dec2020 before midnight, something felt wrong. He saw four cases on clinical trial with similar side effects (he clarified he had no patient information for the four patients mentioned with similar side effects from Pfizer Clinical trial. He saw this information from a article; stated four from Pfizer and Moderna). In the morning of 02Jan202, he went to Emergency Room

(ER) and was diagnosed with Bells Palsy. He was given prednisone 20mg to take 3 times by mouth every day for 5 days, tetracycline 100mg, at 1 capsule by mouth twice a day for 10 days and methylprednisolone (SOLU MEDROL; Lot: 9945776;Exp: Nov2021) 4mg dose pack, started with 6 tablets first day. It was told by doctor it might cause tick problems. He was waiting for results. On 04Jan2021 went to family doctor and more blood work was taken. Because he was taking prednisone, noticed his sugar was up a little bit (date unspecified). It was prescribed Glitizide extended release, 2.5mg one tablet twice a day with breakfast. Patient was checking sugar every 6 hours. It was also prescribed Acyclovir 400mg one tablet orally five times per day for 10 days. 08Jan2021 is last day of prednisone 5 day dose and will follow up with methylprednisolone tablets. Patient had an appointment with a neurologist on 13Jan2021. Patient was still having symptoms. It was really hard for him. Not hard to swallow. Face was still drooping. Eyes were still tearing. Could not work with eyes tearing all of the time. Needed to be alert. When driving, had to focus on the right side because his left side will blur. He had to chew only on the right side because food will be left behind in between his cheeks and gums. If he drank through a straw, he had to cover the left side of his lips so he was able to suck out fluids. He thought symptoms were progressively getting worse, he didn't see much improvement. He clarified swelling was on lower part of mandible on left side. It was slightly bigger than right. When looking at face, the lines on his forehead on the left side were down. If he smiled he cannot raise his left eye brow, when before the COVID-19 vaccine he could. Noticed left side of nose was lower than the right. Cannot raise left side of lips. Outcome of the event Eyes tearing and Bell's Palsy was not recovered; outcome of the other event was unknown. Information on the batch number has been requested.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the reported events of Bell's palsy, Lacrimation increased and vision blurred due to temporal relationship. However, the Bell's palsy may likely possibly represent concurrent medical condition in this patient. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics including head CT/MRI and viral serologies, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Bell's Palsy; This is a spontaneous report from a contactable nurse. A 33-year-old male patient received his first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for covid-19 immunization. The patient medical history and concomitant medications were not reported. The reporter reported a patient developed Bell's Palsy after receiving the first dose of the vaccine. This patient was a physician, the reporter stated that the patient was scheduled to receive the second dose on Monday (unspecified date) and questioned if he should or should not get the second dose. The outcome of the event was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Based on temporal association, the causal relationship between bnt162b2 and the event facial paralysis cannot be excluded. The information available in this report is limited and does not allow a medically meaningful

assessment. This case will be reassessed once additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate.

hearing loss; ringing and pulsating in her ears; Chills; Headache; This is a spontaneous report from a contactable consumer (patient). A 36-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EK9231), via an unspecified route of administration in in the left arm on 04Jan2021 at single dose for covid-19 immunization. Medical history included ongoing acid reflux. The patient had no concomitant medications. The patient previous received the flu shot. The patient experienced hearing loss, ringing and pulsating in her ears on 05Jan2021, headache on 04Jan2021, chills on 05Jan2021. Treatment was none. She had the vaccine on Monday at work and some of the symptoms that she has had have not resolved. She was having ringing in her ears and hearing loss. Went to see them and had her ears looked at. Everything was normal. Got the vaccine on 04Jan2021. Ringing in ears and hearing loss: Had been very consistent with no improvement. If anything, it had worsened. She was going to re-contact her doctor. She was also going to ask, should she go on Prednisone or something. She was worried she was going to lose her hearing. Her doctor said that a hearing test may need to be done. History: Takes one medication that she has been taking for years. She has never had an adverse event to any vaccine before. She got the flu shot every year. She was expecting the chills and headache, but they resolved fast. The next vaccine was 25Jan2021, the patient was asked whether she should get the second dose. The outcome of events for hearing loss, ringing and pulsating in her ears was not resolved, for headache and chills was resolved on 06Jan2021.

she was dying as her blood pressure dropped to 70/40 and to come for a last visit; This is a spontaneous report from a contactable consumer. A 100-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 02Jan2021 at single dose for COVID-19 immunization. Medical history included COVID in Dec2020, urinary tract infection (UTI), dehydration and Covid sickness (vomiting) (was treated earlier in month for UTI and dehydration from the Covid sickness (vomiting)). Known allergies: no. The patient's concomitant medications were not reported. After testing positive in mid December to COVID and being declared Covid free on 30Dec by the nursing staff and in good health, with normal vitals and oxygen levels, the patient was given a vaccination on 02Jan2021. In the early evening the patient's blood pressure dropped to 70/40 and the reporter was told to come for a last visit. The patient was sleeping comfortably. She did not wake up when spoke with her. No one expected her to make it through the night. The next morning she work up, ate breakfast, watched TV, got IVs and oxygen and her vitals improved significantly. Lab tests and procedures included blood pressure: 70/40 on 02Jan2021, oxygen levels: normal, COVID test: positive in Dec2020 (testing positive in mid December to COVID and being declare Covid free on 30Dec), vitals: normal; improved significantly. Facility where the most recent COVID-19 vaccine was administered: Nursing Home/Senior Living Facility. If the patient received any other vaccines within 4 weeks prior to the COVID vaccine: No. Prior to vaccination, was the patient diagnosed with COVID-19: Yes. Since the vaccination, has the patient been tested for COVID-19: No. AE resulted in: Life threatening illness

(immediate risk of death from the event). Serious: Yes. Seriousness criteria-Results in death: No. Seriousness criteria-Life threatening: Yes. Seriousness criteria-Caused/prolonged hospitalization: No. Seriousness criteria-Disabling/Incapacitating: No. Seriousness criteria-Congenital anomaly/birth defect: No. Information about lot/batch number has been requested.

dizzy; itchy throat; coughing; swollen throat; This is a spontaneous report from a contactable pharmacist. A 21-year-old female patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EL0142, NDC number: 59267-1000-1; Expiry Date: Mar2021), via an unspecified route of administration on 07Jan2021 11:20 at 0.3 mL, single at left arm for vaccination. Medical history included Cushing's disease (recovering), bipolar disorder from an unknown date and unknown if ongoing. Concomitant medication included lamotrigine (LAMICTAL) for bipolar disorder. On 07Jan2021, looked like after receiving the vaccine about 30 minutes later patient was standing and felt like dizzy. About 15 or 20 more minutes, or 45-50 minutes after received injection, she felt like itchy throat, then itchy throat triggered coughing, then she felt like swollen throat. For the treatment on scene patient was administered 50mg of diphenhydramine hydrochloride (BENADRYL) and when she complained of swollen throat was administered epinephrine (EPI-PEN) 0.3mg injection to right thigh. Then they called EMS who transported her to the hospital where she was admitted to the hospital. Outcome of events was unknown. This report was considered as serious per caused/prolonged hospitalization. Causality: Cannot jump to that conclusion.; Sender's Comments: Based on temporal association, the causal relationship between bnt162b2 and the events dizziness, throat irritation, cough and pharyngeal swelling cannot be excluded. The information available in this report is limited and does not allow a medically meaningful assessment. This case will be reassessed once additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate.

horrible body aches; Nausea; head fogginess; felt like a lump and couldn't move; not wanting to eat; This is a spontaneous report from a contactable nurse (patient). A 63-year-old female patient received BNT162B2 (Batch/lot number: E10140) first dose on 28Dec2020 11:15AM in the right arm at single dose since she is front line health care worker. Medical history included pain. Medical history included tramadol for pain. No Prior Vaccinations (within 4 weeks). Family Medical History Relevant to AE was none. She received the vaccine 28Dec2020 and it flattened her for two days. Her primary care provided has advised her not to take the next dose. Within 45 minutes she noticed nausea. She was eating lunch and she felt like everything was coming up and she forced herself not to vomit. The she noticed horrible body aches; head was foggy; she felt like a lump and couldn't move;. The body aches hurt in her arms, legs, hips, and back. Adds she was out of work for two days. She could feel it working as the symptoms would peak and then drop. She did go back to work but shouldn't have as she continued to feel nauseous and not wanting to eat. All of these symptoms have now resolved. Vaccination Facility Type was nursing home. No Vaccine Administered at Military Facility. Facility Name: Nursing Home. History of all previous immunization with the Pfizer vaccine considered as suspect was none. Additional Vaccines

Administered on Same Date of the Pfizer Suspect was none. Event not resulted in Physician office or ER. The outcome of the event nausea was recovered on 02Jan2021. The outcome of event not wanting to eat recovered on 03Jan2021. The outcome of other events was recovered on 01Jan2021. The seriousness criteria for event horrible body aches was reported as medical significant.; Sender's Comments: The patient had medical history included pain. A possible contribution role of the first dose of BNT162B2 to the horrible body aches cannot be excluded. The case will be reassessed should additional information become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

patient passed away after receiving the Covid vaccine; This is a spontaneous report from a contactable nurse. An 81-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), intramuscular into the right arm on 07Jan2021 at 0.3 mL, single for covid-19 immunization. There was no medical history and no concomitant medications. On 08Jan2021, the patient passed away after receiving the COVID vaccine. The patient died on 08Jan2021. An autopsy was not performed. Investigations indicate that unspecified labs were done, but nothing two weeks prior; no further details were provided. The patient received the first dose the day prior. The reporting nurse discussed it with the medical director, and he thought that he potentially passed away from the COVID vaccine. The relatedness of the event to the suspect vaccine was reported as related by the reporting nurse per The Agency. The batch/lot number for the vaccine, BNT162B2, was not provided and will be requested during follow-up .; Sender's Comments: Based on the limited information available, it is medically not possible to make meaningful causality assessment, it is unlikely the vaccine could have contributed to the death of the patient based on the known safety profile. However case will be reevaluated when additional information is received during the follow-up The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.; Reported Cause(s) of Death: Stated that the patient passed away after receiving the Covid vaccine

Patient received her vaccination on 1/12/21 administered by pharmacy*+. She expired on 1/12/21 an approximately 7:30pm. Resident did not have any adverse reactions and was a hospice patient.

"Patient was found ""acting abnormal"" on 1/9/2021 at 1215. VS HR 20-30's. EMS activated. EMS arrived and patient was found pulseless in PEA/ asystole, CPR and ACLS initiated and then transported to the MC. Unsuccessful resuscitation and expired on 1/09/2021 at 1348. Clinical impression Cardiopulmonary arrest."

"5 days after administration- heavy uterine bleeding; constipation; severe knee/shoulder joint pain; light sensitivity; dizziness/ light headedness; thigh numbness; pain when prodded on either sides of thighs; harsh headache; This is a spontaneous report from a contactable Other healthcare professional

(patient). A 21-year-old female patient received BNT162B2 first dose on 31Dec2020 03:15 PM intramuscularly on left arm at single dose for COVID-19 immunization. Medical history included Depression, Anxiety, Factor V Leiden, Known allergies to Penicillin and Onion sensitivity. Patient is not pregnant. No other vaccine in four weeks. Concomitant medications in two weeks included unspecified medications. ""5 days after administration"" (also reported as 01Jan2021)- heavy uterine bleeding (resulting with trip to ER), constipation, severe knee/ shoulder joint pain, light sensitivity, dizziness/ light headedness, thigh numbness, pain when prodded on either sides of thighs, harsh headache. No treatment received for the events. Events resulted in ER and physician office visit. No covid prior vaccination. No covid tested post vaccination. The outcome of the events was not recovered. The seriousness was reported as no. Information on the lot/batch number has been requested.; Sender's Comments: A possible contributory effect of suspect BNT162B2 on reported uterine bleeding cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate."

thrombopenia; pulmonary embolism; neutropenia fever; This is a spontaneous report from a Pfizer-sponsored program . A contactable consumer reported for a patient that received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration on an unspecified date at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced thrombopenia, pulmonary embolism and neutropenia fever on an unspecified date. The clinical outcome of thrombopenia, pulmonary embolism and neutropenia fever was fatal. The patient died on an unspecified date. It was unknown if an autopsy was performed. The batch/lot number for the vaccine, BNT162B2, was not provided and will be requested during follow-up.; Reported Cause(s) of Death: thrombopenia; pulmonary embolism; neutropenia fever

"Began to start having bulbar reaction with clearing of throat and tightness of chest; Began to start having bulbar reaction with clearing of throat and tightness of chest; Numb bottom lip progressed to both lips with swelling, then tip of tongue and progressed to tongue with numbing /swelling sensation; Numb bottom lip progressed to both lips with swelling, then tip of tongue and progressed to tongue with numbing /swelling sensation; Numb bottom lip progressed to both lips with swelling, then tip of tongue and progressed to tongue with numbing /swelling sensation; This is a spontaneous report from a contactable Other-HCP (patient herself). This 48-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number EL0142), via an unknown route, on 07Jan2021 at 14:15 at single dose for COVID-19 immunisation. Vaccine location was left arm. The patient was vaccinated at hospital, age at vaccination was 48-year-old. The patient was not pregnant. No other vaccine was received in four weeks.Relevant medical history included COVID 19 complications (prior to vaccination). The patient has allergy to contrast dye, sulfa and molds. Relevant concomitant medications included nebivolol hydrochloride (BYSTOLIC), topiramate (TOPAMAX), atorvastatin (LIPITOR), ascorbic acid, betacarotene, biotin, calcium, chromium, copper, folic acid, iodine, iron, lycopene, magnesium, manganese, nicotinamide, pantothenic acid, phytomenadione, pyridoxine hydrochloride, retinol,

riboflavin, selenium, vitamin b1 nos, vitamin b12 nos, vitamin d nos, vitamin e nos, xantofyl, zinc (CENTRUM WOMEN), and acetylsalicylic acid (ASA). After vaccination, within 5 min she started with numb bottom lip progressed to both lips with swelling, then tip of tongue and progressed to tongue with numbing /swelling sensation. Began to start having bulbar reaction with clearing of throat and tightness of chest. She was given diphenhydramine hydrochloride (BENADRYL) total 50 mg, famotidine (PEPCID) 20 mg, dexamethasone (DECADRON) 4 mg and racemic epinephrine. The events required visit at emergency room/department and urgent care. However, the events were reported as non-serious by the reporter. Post-vaccination COVID test was not performed. The patient had not recovered from the events.; Sender's Comments: The reported ""numb bottom lip progressed to both lips with swelling, then tip of tongue and progressed to tongue with numbing /swelling sensation"", ""bulbar reaction with clearing of throat and tightness of chest"" developed within 5 min administration of BNT162B2, is likely an allergic reaction to BNT162B2, and considered related. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RA, IEC, as appropriate."

My b/p shot up as well 180/107; My heart started racing....noted at 133/I had strong heart palpitations; Feeling of lightheadedness; This is a spontaneous report from a contactable nurse reporting for herself. A 50-years-old female patient received the first dose of BNT162B2 Pfizer-BioNTech COVID-19 Vaccine, via an unspecified route of administration in the right arm on 29Dec2020 at 12:15 pm, at 50-years of age, at single dose for COVID-19 immunization. The patient received the vaccine in Hospital and didn't receive any other vaccine in the previous four weeks. Medical history included hypertension from an unknown date (controlled) and no known allergy. Concomitant medication included amlodipine besilate 10 mg (NORVASC). The patient reported that, on 29Dec2020, within 6 minutes after receiving the vaccine dose, her heart started racing, it was noted at 133, her blood pressure shot up as well to 180/107, she had strong heart palpitations with feeling of lightheadedness. Prior to the vaccine the patient was at work, feeling well and taking care of her patients. Emergency Room visit and Physician Office visit were required, moreover fluids and potassium were administered to the patient as a result of the events. She reported she spent 8 hours in the ER. The events were reported as non-serious but they were assessed as important medical events by the Company. At the time of the report the reported events were resolving. Information about Lot/Batch number has been requested.; Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of events Hypertensive crisis, Palpitations, and Lightheadedness cannot be excluded. The case will be reassessed if additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

"Heart attack; This is a spontaneous report from a contactable consumer. An 82-year-old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot Number: and Expiration Date: Unknown), via an unspecified route of administration in the left arm on 05Jan2021 at 13:00 at a single dose for COVID-19 immunization; administered in doctor's office/urgent care. The patient's medical history and concomitant medications were not reported. It was unknown if the patient received any other vaccines within four weeks prior to the COVID vaccine. Prior to the vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. On 05Jan2021, the patient experienced heart attack; which resulted in death and was assessed as medically significant. The patient also experienced the associated symptoms of cold sweats, chest pain, shortness of breath. Therapeutic measures were taken as a result of heart attack, which included ""life saving measures"" by the paramedics performed upon arrival with no success. The clinical outcome of the event, heart attack, was fatal. The patient died on 05Jan2021 due to heart attack; as ruled by the paramedics. It was unknown if an autopsy was performed. The batch/lot numbers for the vaccine, PFIZER-BIONTECH COVID-19 MRNA VACCINE, were not provided and will be requested during follow up.; Reported Cause(s) of Death: Heart attack"

"Cardiac Arrest; Patient was found pulseless and breathless 20 minutes following the vaccine administration.; Patient was found pulseless and breathless 20 minutes following the vaccine administration.; This is a spontaneous report from a contactable other healthcare professional (HCP). A 66-year-old female patient (pregnant at the time of vaccination: no) received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL1284) via intramuscular at left arm on 11Jan2021 12:15 PM at single dose for COVID-19 immunization. Medical history included diastolic CHF, spinal stenosis, morbid obesity, epilepsy, pulmonary hypertension and COVID-19 (Prior to vaccination, the patient was diagnosed with COVID-19). The patient received medication within 2 weeks of vaccination included amiodarone, melatonin, venlafaxine hydrochloride (EFFEXOR), ibuprofen, aripiprazole (ABILIFY), lisinopril, cranberry capsules, diltiazem, paracetamol (TYLENOL), famotidine, furosemide (LASIX [FUROSEMIDE]), ipratropium bromide, salbutamol sulfate (IPRATROPIUM/ALBUTEROL), buspirone, senna alexandrina leaf (SENNA [SENNA ALEXANDRINA LEAF]), polyethylene glycol 3350 and morphine. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Patient used took Penicillin, propranolol, quetiapine, topiramate, Lamictal and had allergy to them. Patient used took the first dose of BNT162B2 (lot number: EJ1685) via intramuscular at right arm on 21Dec2020 12:00 PM at single dose for COVID-19 immunization. Since the vaccination, the patient been tested for COVID-19 (Sars-cov-2 PCR) via nasal swab on 06Jan2021, covid test result was negative. Patient was found pulseless and breathless 20 minutes following the vaccine administration (11Jan2021 12:30 AM). MD found no signs of anaphylaxis. Patient died on 11Jan2021 12:30 AM because of cardiac arrest. No treatment received for the events. Outcome of pulseless and breathless was unknown. the autopsy was performed, and autopsy remarks was unknown. Autopsy-determined cause of death was unknown. It was reported as non-serious, not results in death, Life threatening, caused/prolonged hospitalization, disabling/Incapacitating nor congenital anomaly/birth defect.; Sender's Comments: Based on the available information this patient had multiple underlying medical conditions including morbid obesity, diastolic CHF, epilepsy, pulmonary hypertension and COVID-19 diagnosed prior to vaccination. All these conditions more likely contributed to patients cardiac

arrest resulting in death. However, based on a close temporal association (""Patient was found pulseless and breathless 20 minutes following the second dose of BNT162B2 vaccine administration, contributory role of BNT162B2 vaccine to the onset of reported events cannot be completely excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.; Reported Cause(s) of Death: Cardiac arrest; Autopsy-determined Cause(s) of Death: autopsy remarks was unknown. Autopsy-determined cause of death was unknown"

Patient admitted for a fib; This is a spontaneous report from a contactable consumer. A female patient in her 70s received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection) lot number was unknown, via an unspecified route of administration on 05Jan2021 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. It was reported that the patient received vaccine on Tuesday, 05Jan2021. On Thursday, 07Jan2021, patient did not feel good-pulse and blood pressure. It was mentioned that the patient admitted for a fib. Two days after receiving Pfizer-BioNTech Covid 19 vaccine, the woman patient in her 70s was admitted for a fib. Information about lot/batch number has been requested.

Vaccine administered at 08:16--08:25 patient c/o feeling unwell and dizzy 87, 143/84, 18, 100%; 08:28: Pt c/o dizzy & chest tightness, appeared pale, monitoring; 08:34: Pt c/o increased chest tightness 130, 144/81, 22, 100% monitoring 08:36: Epinephrine .3mg given IM to R thigh, pt. reported flushing, pounding heart, 911 called; 08:40: Pt flushed.

5 days after Moderna vaccine, developed severe abd pain, mid epigastrium. No Nausea or vomiting. No fever. Mild diarrhea. after 48 hrs with no improvement went to ED

At first I has some injection site pain and soreness nothing too bad. But around 01:30 I awoke with a really high fever. My fever was 102.8 when I first woke up. I was very nauseous and my fever felt worse. My thermometer would not read any more until my temp came down. I can only guess how high it got but at least 103 degrees. I took Advil Liquid Gells and then my fever broke. I was actually scare for my life. In March I actually caught coronavirus and developed anti bodies for Covid. I can only guess my body was fighting for it's life.

positive COVID-19 test with symptoms; positive COVID-19 test with symptoms; After the shot i have headache, sorethroat, cough and cold till this date; After the shot i have headache, sorethroat, cough and cold till this date; After the shot i have headache, sorethroat, cough and cold till this date; After the shot i have headache, sorethroat, cough and cold till this date; A 48-years-old non-pregnant female patient, receivedBNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), via an unspecified route of administration, in left arm, on 18Dec2020 (at the age of 41 years-old) as a single dose for COVID-19 immunization. The vaccination was administered at a pharmacy/drug store. Medical history was not reported. Concomitant medication included sertraline hydrochloride (SERTRALINE HYDROCHLORIDE). The patient had not received any other vaccines within four weeks prior to the vaccination nor received

any other medications withing 2 weeks prior. It was reported that the patient had been tested for COVID-19 prior to vaccination and was negative. On 18Dec2020, the patient experienced itchy sore eyes one hour after vaccination, sore and itchy arm for 5 days, headache, swollen sore throat, tiredness all 5 days after. The patient was not hospitalized nor received treatment for the events. The clinical outcome of the events of Itchy, sore eyes 1 hour after, sore and itchy arm for 5 days, headache, swollen sore throat, tiredness all 5 days after, was not recovered., the outcome of the COVID-19 positive was unknown. It was reported that the patient tested positive for COVID-19 via nasal swab, post vaccination on 31Dec2020. No follow-up attempts possible. No further information expected. Lot/batch number was not provided and unable to obtain

tested positive for Covid; tested positive for Covid; This is a spontaneous report from a contactable consumer. A 7-decade-old female patient (in her 60s) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 23Dec2020 at a single dose for COVID-19 immunisation. Medical history and concomitant medications were not reported. A pharmacy student received this drug information question in which a female patient in her 60s received the first Covid vaccine on 23Dec2020 and tested positive for Covid on 04Jan2021. Could the patient receive antibody treatment? Could she get the second vaccine and when? The outcome of the events was unknown. Information about Lot/Batch number has been requested.

Caller is a respiratory therapist who reports that he tested positive for covid after receiving the first dose of the vaccine on 17Dec; Caller is a respiratory therapist who reports that he tested positive for covid after receiving the first dose of the vaccine on 17Dec; This is a spontaneous report from a contactable consumer (patient) reported that a 32-year-old male patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EH9899), via an unspecified route of administration from on 17Dec2020 at single dose (once by injection in the right arm/bicep) for COVID-19 immunization (Healthcare worker). There were no medical history and concomitant medications reported. The patient/caller is a respiratory therapist who reported that he tested positive for covid after receiving the first dose of the vaccine on 17Dec2020. He called to ask if he can get the second dose. He also wanted to ask if people experienced side effects or what side effects people experience after the second dose. He tested positive for Covid-19 on 21Dec2020, after receiving the first dose of the vaccine. He said it had been 14 days since he tested positive for COVID and he is if he can get the second dose. He says he is actually on his way to get the second dose right now, and thought he should call. The outcome of the event was unknown.

hypertension like 190/90; I had tachycardia to 165; Flushing; This is a spontaneous report from a contactable consumer (patient). A 22-year-old female patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) lot number: EK9231, intramuscular on 06Jan2021 at single dose for COVID-19 immunization. Medical history included migraine. Concomitant medication included cyproheptadine for migraine, unspecified multivitamins; and diphenhydramine (BENADRYL) and famotidine as pre-medications. The patient previously received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 17Dec2020 for COVID-19 immunization, and experienced dizziness, palpitations, tingling in face and legs, myalgia, nausea, headache, fatigue. It was reported that patient got the second dose and had tachycardia to 165 and hypertension like 190/90 and had some flushing

(event onset: 06Jan2021). Patient was no longer tachycardiac or hypertensive; lasted for about 30-40 minutes. Outcome of the events tachycardia and hypertension was recovered on 06Jan2021. Outcome of the event flushing was unknown.

Actual event and cause of death were unknown; This is a spontaneous report from a non-contactable consumer. A 90-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 06Jan2021 at single dose for COVID Prevention. The relevant medical history included aortic valve replacement from Nov2019. Concomitant medications were not reported. The consumer stated that she was taking the reporting responsibilities to report that a friend of hers, informed that the patient passed away on Friday, and had received the COVID vaccine on Wednesday. The consumer stated that it was unknown to her at this time, if the friend had called to complete a report herself, regarding the incident. Their conversation was very brief. The patient was 90 years old, and it was her friend's mother that was the patient. Actual event and cause of death were unknown. The patient had her vaccine on Wednesday 06Jan2021, and then the patient collapsed in front of the reporter at Friday night on 08Jan2021 and passed away that same day. The autopsy was unknown. The outcome of the event was fatal. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Reported Cause(s) of Death: Actual event and cause of death were unknown

episodes of severe dyspnea and lightheadedness over the past couple of weeks; episodes of severe dyspnea and lightheadedness over the past couple of weeks; ventricular tachycardia with a rate of 270; severe right ventricular dilatation and dysfunction with inflammation and fibrosis throughout the RV and septum, but minimal LV involvement.; severe right ventricular dilatation and dysfunction with inflammation and fibrosis throughout the RV and septum, but minimal LV involvement.; severe right ventricular dilatation and dysfunction with inflammation and fibrosis throughout the RV and septum, but minimal LV involvement.; This is a spontaneous report from a contactable physician (patient). A 4-decade-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via unspecified route of administration on 18Dec2020 at single dose for COVID-19 immunization. Patient medical history and concomitant medications were not reported. Patient reported that on 18Dec2020, she received the first dose of Pfizer / BioNTech vaccine. On 30Dec2020 (Wednesday), she was diagnosed of ventricular tachycardia with a rate of 270, severe right ventricular dilatation and dysfunction with inflammation and fibrosis throughout the RV and septum, but minimal LV involvement. On 30Dec2020, EKG showing RBBB with PR 234 (in presence of normal EKG and ECHO from Dec2016), and positive troponin 0.07 that has remained stable in the following week. On unspecified date in Jan2021, the patient had been having episodes of severe dyspnea and lightheadedness over the past couple of weeks, but it had been sporadic - it became significantly worse in the last 2 weeks, which is why patient sought out an electrophysiologist (and purchased at-home EKG monitor on which she saw the VT). Patient do not know the cause at all. She was tested for SARS-CoV-2 antibody yesterday (unspecified date in Jan2021), which was negative. Patient was also trying to determine if she should get the second dose or not. She will have cardiac PET scan next week, which hopefully further elucidate causes. Outcome of the events dyspnea and lightheadedness was not recovered; while outcome of other events was unknown. Information on the Lot/Batch number has been requested.; Sender's Comments: Based on the available

information, a causal relationship between reported events and BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) cannot be completely excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

My right leg from the knee down was purple and they thought I have a blood clot; My right leg from the knee down was purple and they thought I have a blood clot; This is a spontaneous report from a non-contactable consumer (patient). A patient of unspecified age and gender received bnt162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient medical history and concomitant medications were not reported. Three days after vaccination the patient felt very sick and he/she was so bad that he/she thought he/she might die with outcome of recovered after one week. The patient reported also that on unknown date his/her right leg from the knee down was purple and they thought he/she have a blood clot, due to which the patient was hospitalized for 14 days. The patient ended in the hospital because his/her right leg from the knee down was purple and they thought he/she have a blood clot but they did an ultrasound that was not the case but they put he/she on antibiotic. The patient was still taking them but his/her leg has got better. No follow-up attempts are possible. Information about lot/batch number cannot be obtained. No further information is expected.

Covid symptoms began 2-3 days after shot. Presented to ER day 11 day after positive with extreme dyspnea O2 Sat at 88% Chest xray opacities throughout the bilateral hemithoracies would suggest multifocal infiltrate Admitted on high flow oxygen reduced to 6 liters currently D-dimer is >35.20

Patient is a 99yr old female who got a covid vaccine in the afternoon of 1/10/21 and woke up in the morning of 1/11/21 with altered mental status, weakness, and dysarthria. She was taken from her assisted living facility to the hospital and MRI showed a small stroke in the right medial thalamus. She was also found to have new onset atrial fibrillation. She was treated appropriately for both conditions and discharged to a skilled nursing facility on 1/13/21.

Pt was accompanied by daughter, who drove pt to clinic. Pt was correctly identified, screened, given vaccine, monitored for appropriate time. Pt left clinic as passenger of vehicle and was being driven by daughter. Pt started complainingg of Shortness of breath and not feeling right.. Daughter brought pt to local emergency room, Pt was later transferred to higher care hospital. Information regarding symptoms and further medical care was relayed to clinic by family member.

Patient received vaccine in afternoon of 12/28. She works in ER as housekeeper 7pm-7am. The day she received the vaccine she became ill with fever chills and nausea and left work at 2am. On 12/31 she developed hemianopia. She went to ER and they did CT scan. She was told it was complex migraine. She left and came Home. On 1/1/21 her vision was back to normal. On 1/3 she suffered bilateral cerebellum ischemic stroke. She is currently in medical center. In Trauma.

Patient experienced a syncopal episode post vaccination, accompanied by feeling hot and tachycardic. Prior to the syncope, she reported hyperventilating. She remained unresponsive for about 10 minutes and was brought to the ED. There she became responsive, and reported chest pain and had sinus tachycardia episodes. She also had lower extremity weakness. This has improved per the latest neurology notes. She also had a negative EEG. Unsure if this is an allergic reaction or if the syncope was due to hyperventilation. Patient is currently on day 3 of hospitalization.

Systemic: Headache, Systemic: Eyes dilated and difficulty remembering information; symptoms lasted 2 days

I was short of breath and went to emergency room on 1/5/2021. I was diagnosed with bilateral pulmonary embolisms. I was Covid negative and had no other symptoms.

2 Hours after the injection, my arm hurt so bad I could not raise it laterally. This continued for 3 days. After that I felt tired and achy until Jan 4th, I had chills and whole body aches. I came home from work, took the next day off. Feeling better, I worked 3 more days and developed the worst headache of my life. I consulted my PCP and went to the emergency room. I was diagnosed with viral meningitis and admitted to the hospital for 3 days. .

Staff walked into resident's room around 10:00am and noted resident's left side of his face was flaccid. Nurse was called and upon assessment resident noted to have an unequal hand grasp with left worse. He was able to talk but was mumbled and hard to understand. Physician, hospice, and family were notified. Resident had a stroke at 10:06 am on 1/8/2020. He lost all ability to use his left side. Resident passed away on 1/11/2020.

Patient received COVID-19 Vaccine at 0956 and reported symptoms of itchy face and chest pressure at approximately 1008 during observation period. Pt vital signs were 133/86, HR 130 and oxygen saturation 100% on room air. Pt reported worsening symptoms of chest pressure and itchiness to face. Provider instructed Epi Pen be given and pt to be transported to ED for further evaluation. EKG obtained and showed sinus tachycardia. Nonrebreather oxygen mask applied with 2L/min and oxygen saturation remained at 100%. Pt was transported via ambulance to at 1038 and pt reported feeling improved symptoms prior to leaving the clinic at approximately 1034. Pt stable at time of transfer.

Employee was awaken at 5:30 am on 1/13/2021 by chills and a feverish feeling. She then became nauseous and faint. She passed out and was noted by her mother who is a RN to have a seizure. She remained out for several minutes and then aroused. She has remained groggy the rest of today but has improved. She has a history of non-epileptic seizures since she was 14 and has been on medications for this. Employee stated she has not has any seizure activity in over a year. She did not see medical attention due to recovering quickly from this.

The patient passed away today, 1/13/2021. She was a hospice patient. She showed no adverse effects after receiving the vaccine on 1/12/2021. This morning she woke up as normal and during her morning shower she had a bowel movement, went limp and was non-responsive. The patient passed away at 7:45 am.

The morning following COVID-19 vaccination, patient's right shoulder had swelling, generalized weakness and myalgia. Hospitalized for 2 days, received intravenous fluids and bedrest, and acetaminophen. He was prostrate for 2 days.

numbness to forearm then to lower leg that then took on a dermatomal pattern, brain fog w word finding issues that progressively worsened, LLE weakness. ct brain neg. MRI/MRA head and neck neg. labs neg. MRI of c spine t spine l spine s spine neg. emg and eeg neg. discharged from hospital. symptoms fluctuating. slowly improving.

Presented to MD'S office on 01/05/2021 with cough, HA, fever 101.9, chills, and fatigue. Returned on 01/07/2021 with no improvement. Returned on 01/11/2021 with fatigue, elevated temp 101.2, SOB, 02 Sat at 90%, Rocephin 1G IM administered, CXR revealed pneumonia. MD received call from patients husband stating worsening 02 Sat levels at 81-82%. Was transferred to hospital and admitted with pneumonia..

This person was found to be deceased on routine rounds during the night, 3am. No symptoms of reaction noted post vaccine. No injection site reaction. No reports of any allergic reaction.

Resident began having fever on 1/11/21 @0600. VS= T-102 B/P- 100/57 P- 112 RR- 24 O2 Sat 92% on RA. MD called. Rapid COVID Test was negative. CBC,CMP, U/A were ordered as well as CXR. Resident's condition declined. At 3:00pm resident started having respiratory distress and hypoxia O2 Sat 89%. Supplemental O2/mask @ 5LPM. Neb TX, EKG, and Rocephin 1 GM ordered. Condition worsened. Resident sent to nearest ER for evaluation. Later in the evening the staff AT Medical Center called to inform staff that resident had expired @ 2230 as a result of Respiratory Failure and Sepsis.

about 14 hours after vaccination I experienced what appeared to be a severe case of Cytokine storm. I had a moderate case of COVID in May 2020 and had positive IgG AB in August. The symptoms started with heavy shaking chills, lasting 1 1/2 hours , fever and most concerning sustained tachycardia with heart rate of 180' to 200' over hours, which then destabilized into runs of Vtach and complex ventricular dysrythmia, low BP, profound weaklness, head aches and joint and muscle pains (similar to the experienced COVID symptoms)

"Patient received vaccine at 0939. 30 minute wait period related to history of previous anaphylactic reaction. 10:05 patient walked from observation area to vaccinator and reported that her ""chest was burning"" and ""feels like it is getting tighter to breathe. Pt had change in voice. Patient moved to chair and started on oxygen 1.5 L/m per nasal cannula. MD came to room to assess patient. ED arrived and checked patient B/P. Patient transferred by cart to ED."

Patient began having cramping of her upper extremities and subsequent swelling of her face and neck and also shortness of breath, chest pressure and flushed appearance. She denies any tongue or throat swelling. She is also complaining of bilateral arm pain. The initial reaction treatment was started in the conference room and then the patient was transferred to the emergency room. She continued to has arm and chest pain in the emergency room. She had muscle tension/rigidity in the upper extremity which caused significant pain. She also developed a nonspecific rash on the chest and abdomen that

persisted for through out he hospital stay. Treatment was started with epinephrine 0.5 mg IM x2 and diphenhydramine 50 mg IM x1, prior to transfer to emergency room. In the emergency room treatment was dexamethasone 10mg IV x 1, famotidine 20mg IV x1, Ketorolac 30mg IV x 1, lorazepam, 1mg IV x 2, morphine 4mg IV x 2, 1000ml Saline Solution. As an inpatient the treatment included scheduled acetaminophen 500mg TID, as need morphine for pain after treatment with fentanyl, scheduled diphenhydramine 25mg IV q8 and compazine 5mg IV for nausea, cyclobenzapine 10mg as need for muscle spasms, dexamethasone as a scheduled dose started at 4 mg BID and tapered to 2 mg BID, Naproxen 500mg BID and Norco 7.5/325 as need for pain. with famotidine 20mg BID .

Note: I am currently breastfeeding. Had body aches; chills; fever of 102.6; headache; nausea; cough; shortness of breath - I went to ER and that is where I received COVID positive test and positive tests for COVID Pneumonia and Microplasm Pneumonia as well. Stayed overnight in ER observation - 2 am to 8 am . Went home next morning and was quarantined approximately 8 days. Body aches and a cough had started two days prior to injection. IV antibiotics at the hospital and oral antibiotics at home. Received nebulizer breathing treatments. Pain meds and anti-inflammatory medication.

Onset of tachycardia was 8:30pm on 1/12/21 with a noted HR of 164 and SR. Went to ER and had HR of 171 upon arriving to triage window. EKG said Sinus Tachycardia. Admitted to observation station with telemetry to monitor HR. HR normalized around 100 when up and walking at 10:45am on 1/13/21.

I received my covid vaccine on 12/29/2020 at 4:42pm. In 10 minutes after the shot, I went into anaphylactic shock, I broke out in hives, and my throat was closing

Pt reported chest tightness and throat tightness following vaccination. Time course following vaccination unknown.

little bit of a reaction light headed after 5 minutes. vitals were low, so observed for 30 minutes after being light headed. Patient was found unresponsive and pronounced dead later that day.

Death occurred 3 days after vaccine receipt; attributed to complications of her chronic advanced dementia with aspiration at age 87. No evidence of acute vaccine reaction.

No adverse effects from vaccination seen on 1/2/21. On 1/6/21 resident was seen by Dr and her baclofen pump was refilled with 20 ml Baclofen 4,000mcg/ml. ITB Rate increased by 6% to 455.5 mcg/day simple continuous rate over 3 days. On 1/8/21 at 0615 resident was shaking, lower extremities mottled, Sa02 70%, pulse 45. Oxygen started at 2 L/m per NC. At 0715 her primary physician was notified as well as her daughter. Oxygen increased to 4 L/min, sats at 83%. SOA noted, reported all over pain. At 0850 when they attempted to reposition the resident, she was not responsive. Licensed nurse assessed her and no heartbeat heard or pulse found.

I had a mild headache the evening of the shot, I had a headache the next two days that was relieved by Advil. I had a very sore arm at the injection site Friday and Saturday after the shot was given. The arm pain was gone Sunday morning. I was very tired on Saturday especially and slept through the morning and early afternoon on and off until about 3:00 pm. On Friday during the day, I noticed my right ear

starting to feel unusual and uncomfortable. On Saturday, the ear issue continued, I felt like I had some hearing loss and a constant buzzing and ear fullness feeling. On Sunday, the ear issued continued with the hearing loss, buzzing and fullness and has through today and hasn't stopped. I tried some nasal decongestant on Sunday afternoon, but it didn't have any effect. I made an appointment with the ENT doctor on Monday morning for Tuesday. I had a hearing test on Tuesday and saw the ENT doctor on Wednesday. He prescribed prednisone and ordered an MRI. I will be starting the prednisone later today (Wednesday) when the pharmacy has the prescription ready.

54 y/o M with PMH of HTN, HLD, Alcoholic Cirrhosis, Aortic Valve Stenosis, and angina BIBA as a Medical Alert for cardiac arrest noted PTA. Per EMS, the patient called because he was having constant, diffuse abdominal pain x 1 day that radiated to his chest. On scene, the patient had a witnessed arrest with EMS starting CPR. He was given 3 rounds of epi without ROSC. Pt had no associated shockable rhythm. Of note, pt's wife, had noted pt had received covid vaccine the prior day.

A few minutes after the vaccine, she had mild tongue swelling. It only lasted a few minutes, and then she felt fine. However, her BP went up. I'm not sure how high. she then has a short run of asymptomatic V tach. Taken to hospital observed overnight. No further events or problems.

She got the vaccine on Dec 23, and then on Jan 4 she had a mild stroke with left sided arm and face weakness. She did recover fully. She already has known CAD and risk factors for CVD. It is possible, but by no means certain, that the vaccine was an indirect cause of the event. Since the vaccine provoked an immune response, as it was supposed to, it is possible that this inflammation may have set up a metabolic predisposition that may have contributed to the event, which was 12 days later.

New onset altered mental status after fall. Per son, she was found in bed, unresponsive at around 12:15 AM on 1/10 by her husband. Brought to the emergency room and admitted, Began treatment for UTI w/ CTX. Discharged 1/11/21 with f/u appointments

Resident received 1st dose on 1/4/2021. On 1/6/2021 resident having SOB, increased weakness with O2 sats at 91% RA. On 8th resident sustained a fall, O2 sats 88-92, dizzy, weakness. Rapid COVID test performed with negative results. Evening of 8th resident was lethargic and diaphoretic with fever of 99.9. Resident transferred to ER, on 5lt of oxygen. Resident returned from the ER on 1/9/2021 with new diagnosis of Leukemia and orders for hospice. Continued with fever, crackles and N/V and loss of appetite from the 9th and 10th of January. Resident expired at 820am on 1/11/2021.

I had a headache at the top of my head, and a tingling sensation down my left leg from my buttocks to my calf. The tingling lasted until the next morning then went away. On 1/3/2021 I experienced a strong headache followed by facial numbness and tingling. This lasted for an hour or so and slowly subsided. The headache lingered for 3 days.

Headache; migraine; tenderness at injection site; Ten hours after injection he had shaking, sweats, hot and cold flashes, and augmentation of myalgias; Ten hours after injection he had shaking, sweats, hot and cold flashes, and augmentation of myalgias; Ten hours after injection he had shaking, sweats, hot and cold flashes, and augmentation of myalgias; Ten hours after injection he had shaking, sweats, hot

and cold flashes, and augmentation of myalgias; Ten hours after injection he had shaking, sweats, hot and cold flashes, and augmentation of myalgias; Fatigue; This is a spontaneous report from a contactable physician (patient). A 53-year-old male patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK9231), via an unspecified route of administration on right deltoid on 05Jan2021 07:45 at single dose for covid-19 immunization. Family history included migraine (other family members). Medical history included mild blood pressure and kidney stones, reactive airway disease. Concomitant medication included colecalciferol (VITAMIN D), potassium, allopurinol and hydrochlorothiazide/valsartan for mild blood pressure and kidney stones, fluticasone propionate, salmeterol xinafoate (ADVAIR) for reactive airway disease, atorvastatin, and multivitamins. The patient previously took fluticasone propionate, salmeterol xinafoate (ADVAIR) and experienced dry mouth and lost sense of taste. The patient also previously took Tdap booster on Aug2020, Shingrix on 10Aug2020, and influenza on 12Oct2020; all for immunization; and tetanus injections for immunization and experienced localized tenderness. The patient had the first dose of BNT162B2 (lot number: EH9899) for COVID-19 immunization on 15Dec2020 and experienced localized tenderness at injection point. The received his second dose of COVID vaccine on 05Jan2021. With the first dose he had increased localized tenderness at injection site on 15Dec2020, and he rated it mild to moderate. He would say it was 80% resolved in 24 hours. It had completely resolved in 36 hours. He would say that he has recovered completely form the localized tenderness with the first dose. Then he noted his second dose was yesterday, in the context of not having much sleep the night before. The actual injection was uncommonly eerily painless. The other folks in his department had similar experience. Maybe it was the nurse who gave the injection. Maybe it was because it was the same area and sensitivity was decreased. They had to check the Band-Aid to make sure blood was there. The administration was painless. He was relieved when the arm started getting sore to know he actually received it. He had increased arm tenderness at injection site which he rated as moderate which has now resolved. It got to moderate where lifting the arm up was sore. He definitely knew that he had been vaccinated. He got the vaccine at 7:45AM and now it is 16 to 17 hours later and he would say the pain is mild now. It did persist. The first vaccine hurt a little more. He expects this to go away. Ten hours after injection he had shaking, sweats, hot and cold flashes, and augmentation of myalgias. He had unrelenting headache over night that was moderate to severe. He said it kept him awake. It was exacerbated by lying down. Sitting up helped him. It became a migraine which is something he doesn't often experience. Migraines are pretty rare for him. He took 800mg of Advil at 6AM that helped for headache and migraine. The weight of the patient was 250 to 255 pounds. Shaking, sweats, hot and cold flashes, and augmentation of myalgias have resolved. Everything has resolved except for a little headache. In the background he literally had one or two hours of sleep. He thinks that likely precipitated a migraine was increased. Last night he slept literally an hour. He took 800mg of Advil and fell asleep. He is operating on 2 hours of sleep in 48 hours. Most of the stuff is gone except a little headache and expected fatigue. Headache Seriousness Criteria: he would say that it was relatively disabling. He would not have been able to carry on. He wouldn't have been able to operate last night. It would have interfered. It was dissimilar to others. He gets rare migraines. Everything was amplified with a migraine. He certainly felt that. It was fair to say the vaccine precipitated the migraine that was mild or severe. He doesn't want to falsely attribute these things to the vaccine. Causality Headache: precipitated by the vaccine. In the context that he had not slept the night before. He had a nasopharyngeal COVID test and it was negative. He has been in a COVID study

where they are looking at combination. They developed a saliva test at (Name). There is a combination of saliva oropharyngeal and immunoglobins. He has been negative multiple times. The outcome of the events headache and fatigue was not recovered and recovered for the rest of the events.; Sender's Comments: A causal association between BNT162B2 and the reported event headache cannot be excluded based on a compatible temporal relation between vaccination and onset of events. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

A PCR test was done and received results Monday (4th) as positive; A PCR test was done and received results Monday (4th) as positive; Had some scratchy throat late friday night; Saturday called out sick to work as the cough started; Saturday called out sick to work as the cough started.; Lost taste and smell monday; Lost taste and smell monday; Running fever; fatigue; This is a spontaneous report from a contactable Pharmacist (the patient). A 52-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, lot number EJ1686, expiration date unknown) via an unspecified route of administration on 28Dec2020 at 12:00 PM (at the age of 52-years-old) via an unspecified route of administration at an unspecified dose in the right arm for COVID-19 vaccination. Medical history included hypertension, high blood cholesterol from unknown dates. Allergy information was not provided. Prior to the vaccination, the patient was not diagnosed with COVID-19. The patient was administered the vaccine at a Nursing Home/Senior Living Facility. Concomitant medication included hydrochlorothiazide, valsartan (VALSARTAN/HYDROCHLOROTHIAZIDE), atorvastatin (LIPITOR), fenofibric acid (FENOFIBRIC ACID), amlodipine besilate (NORVASC). The patient did not receive any other vaccines within four weeks prior to the vaccination. The patient received the vaccine on Monday 28Dec2020. A PCR test for COVID was done on Tuesday and a rapid test on Wednesday both of which were negative. The patient experienced some scratchy throat late Friday night on Saturday, 02Jan2021 the patient called out sick to work as a cough had started. A PCR test was done on 02Jan2021 and he received results Monday (4th) as positive. The patient continued to say that the cough had subsided, as he took Delsym. He lost taste and smell on Monday. He reports running a fever that varies from 99-101.5. He took Tylenol and Motrin to control the fever. In addition he has experienced fatigue. It was also reported, in contradiction of the above reported chronology of events, that the onset date of events was 25Dec2020 (CONFIRMATION PENDING for onset date of events relative to vaccine administration). The patient experiences of COVID 19 positive test, scratchy throat, sickness, cough, loss of test and smell, fever and fatigue resulted in a physician office visit (date not specified). The patient underwent lab tests that includes a PCR test on 29Dec2020 which was negative, a rapid test on 30Dec2020 which was negative and a PCR test on 02Jan2021 which was positive. Treatment for the events was reported as Motrin and Tylenol for fever and Delsym. for cough. The clinical outcome of COVID 19 positive test, scratchy throat, sickness, cough, loss of test and smell, fever and fatigue was reported as not recovered.; Sender's Comments: The patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE) on 28Dec2020, and COVID-19 PCR test positive on 02Jan2021. No effect of the suspect vaccine could be reasonably achieved to protect from the targeted

infection/disease due to the very short time lag. Instead, the positive COVID likely represents the pre-existing infection prior to vaccine use. Further information is needed for full medical assessment.

"he tested positive for COVID-19 / (probably infected by a family member); runny nose; dry cough; flu-like symptoms; he tested positive for COVID-19 / (probably infected by a family member); he tested positive for COVID-19 / (probably infected by a family member); This is a spontaneous report from a contactable consumer (patient). A 40-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 17Dec2020 at single dose for COVID-19 immunisation. The relevant medical history and concomitant medications were not reported. The patient stated that the next dose is scheduled for the time of the report, however he tested positive for COVID-19 on 05Jan2021 (probably infected by a family member). Representatives at the administration site are not sure if he should get the second dose. The patient reported minor symptoms ""flu-like symptoms, runny nose, dry cough, no major symptoms"". The outcome of the events was unknown. Information on the lot/batch number has been requested."

diagnosed with covid 30Dec2020; diagnosed with covid 30dec2020; This is a spontaneous report from a contactable nurse (patient). A 27-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number EK5730), via an unspecified route of administration in right deltoid on 21Dec2020 13:45 at single dose for Vaccination. There were no medical history and concomitant medications. The patient was diagnosed with covid on 30Dec2020 with outcome of recovering. The patient underwent lab tests and procedures which included COVID test: positive on 30Dec2020. The patient received the first dose of the covid vaccine on 21Dec2020, and was diagnosed with covid on 30Dec2020. The patient had COVID test on 30Dec2020 and received positive result of COVID test on 31Dec2020. He was scheduled for the second dose between 08Jan2021 and 11Jan2021. He asked if he should continue to get the second dose as scheduled in relation to the diagnosis of COVID. COVID: the patient still had chest congestion, but no fever without medication, no cough anymore. He was having cough, fever, loss of taste and smell, fatigue and malaise. Reporter seriousness for COVID: Not serious. Relatedness of drug to reaction/event: Reaction assessed: COVID, Source of assessment: Primary Source Reporter, Method of assessment: Global Introspection, Drug result: Unrelated. Verbatim event relatedness: Pfizer COVID-19 Vaccine: COVID-Unrelated.; Sender's Comments: The patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE) on 21Dec2020, and was diagnosed with COVID-19 on 30Dec2020. No effect of the suspect vaccine could be reasonably achieved to protect from the targeted infection/disease due to the very short time lag. Instead, the diagnosed COVID-19 likely represents the pre-existing infection prior to vaccine use, and unrelated to BNT162B2.

she got Covid; she got Covid; This is a spontaneous report from a contactable physician. A female patient (Patient Age: 18; Unit: Unspecified) received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiry date were not reported), via an unspecified route of administration on an unspecified date t a single dose for covid-19 immunization. The patient's medical history and concomitant medications were not reported. The nurse that her first Pfizer Covid 19 vaccine and a couple of days later developed symptoms of Covid and tested positive. Stated that she recovered and had no symptoms. Information on Lot/Batch number has been requested.; Sender's Comments: The

reported symptoms of Covid with tested positive after COVID-19 immunization is considered ineffective of BNT162B2, and the Company cannot completely exclude the possible causality between the reported event and BNT162B2 administration.

covid test result=Positive; covid test result=Positive; This is a spontaneous report from a contactable other healthcare professional (other HCP reporting for himself). A 39-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE Solution for injection, batch/lot no. and expiry date unknown), via an unspecified route of administration on 16Dec2020 12:45 (1st dose) at a single dose on his left arm for COVID-19 immunization. The patient medical history was not reported. Concomitant medication included hydrochlorothiazide, losartan potassium (HYZAAR), omeprazole, and ibuprofen; all on unspecified dates for unspecified indications. The patient previously took amoxicillin and experienced allergies. Patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine, he was also not diagnosed with COVID-19 prior to vaccination. However, since the medication, the patient has been tested positive for COVID-19. Patient had his nasal swab on 22Dec2020, and it turned out positive (COVID test result=positive). Outcome of the event drug ineffective and COVID-19 virus test positive was unknown. Facility where the most recent COVID-19 vaccine was administered at the hospital. Information on the lot/batch number has been requested.; Sender's Comments: Based on the information currently available, a lack of efficacy with the suspected vaccine BNT162B2 cannot be completely excluded. However, it is unlikely that the patient would have fully developed immunity due to the very short time lag between the first vaccine dose and the event onset.

covid test result=Positive; covid test result=Positive; nasal congestion; sneezing runny nose; sneezing runny nose; sinus pressure; dry cough; This is a spontaneous report from a contactable Nurse (patient herself). This 37-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number EL0140), via an unknown route, on 19Dec2020 at 16:15 at single dose for COVID-19 immunisation. Vaccine location was arm left. The patient was not pregnant. The patient was vaccinated at hospital, age at vaccination was 37-year-old. No other vaccine was received in four weeks. No relevant medical history was provided. Relevant concomitant medications included amoxicillin sodium, clavulanate potassium (AUGMENTIN, formulation: tablet) at dose of 875 mg twice daily from an unknown. Pre-vaccination COVID test was not performed. On 25Dec2020 at 20:00, the patient complained of nasal congestion, sneezing runny nose, sinus pressure, and cough. On 28Dec2020, COVID test Nasal Swab (SOFIA SARS ANTIGEN FIA/QUIDEL) was performed and resulted positive. She was given oral azithromycin 500 mg 1 tab Daily and oral benzonatate (TESSALON PERLES) 1 Capsule three times a day (TID). The symptoms of nasal congestion, sneezing runny nose, sinus pressure, and cough were improving. The outcome of 'COVID test result=Positive' was unknown.; Sender's Comments: The efficacy of a drug varies from patient to patient and can be affected by different factors; however, a contributory role of the suspect product BNT162B2 to the reported drug ineffective and SARS-CoV-2 test positive cannot be ruled out.

two staff members who tested positive for covid after receiving the first dose.; two staff members who tested positive for covid after receiving the first dose.; This is a spontaneous report from a Pfizer-sponsored program from a contactable pharmacist reported similar events for 2 patients. This is a first of two reports. A staff member of unknown age and gender received the first dose of BNT162B2 Pfizer-

BioNTech COVID-19 Vaccine, via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medication were unknown. The reporter stated that have a staff member took the first shot and afterward got a positive COVID test. He is asking about the recommendation regarding taking the second shot. The reporter explained he is the immunizer and 2.5 weeks ago he gave the employ at the facility the first does of the vaccine. He has very little information to provide on this event. He called to go over the procedure for administering the second dose and that is when in was inform. Information on the lot/batch number has been requested.; Sender's Comments: The efficacy of a drug varies from patient to patient and can be affected by different factors; however, a contributory role of the suspect product BNT162B2 to the reported drug ineffective and SARS-CoV-2 test positive cannot be ruled out.,Linked Report(s) : US-PFIZER INC-2021011912 Same reporter/ drug/ event for different patients.

received first dose of the vaccine on 19Dec and tested positive on 30Dec; received first dose of the vaccine on 19Dec and tested positive on 30Dec; This is a spontaneous report from a contactable nurse reported for herself. A female patient on unknown age received the first dose of BNT162B2 Pfizer-BioNTech COVID-19 Vaccine, via an unspecified route of administration on 19Dec2020 at single dose for COVID-19 immunization. The patient's medical history and concomitant medication were not provided. On 30Dec2020 the patient experienced tested positive for COVID-19. It was reported that the patient is scheduled to have her 2nd dose on 09Jan2021however she's been getting roundabout information on what to do in her case. Information on the lot/batch number has been requested.; Sender's Comments: The efficacy of a drug varies from patient to patient and can be affected by different factors; however, a contributory role of the suspect product BNT162B2 to the reported drug ineffective and SARS-CoV-2 test positive cannot be ruled out.

She tested positive to COVID on 29DEC2020; She tested positive to COVID on 29DEC2020; This is a spontaneous report from a contactable nurse (patient). A female patient of an unspecified age received first dose of bnt162b2 (BNT162B2, lot no. and expiry date were unknown), via an unspecified route of administration on 21Dec2020 at single dose for Covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient was tested positive to COVID on 29Dec2020. She received the 1st dose of the vaccine on 21Dec2020. She is due for the 2nd dose on 11Jan2020. They asked if she should still receive the 2nd dose. The outcome of the event was unknown. Information on the lot/batch number has been requested.; Sender's Comments: No effect of the suspect vaccine could be reasonably achieved to protect from the targeted infection/disease due to the very short time lag. Instead, the positive COVID likely represents the pre-existing infection prior to vaccine use. Further information like confirmative COVID 19 Nucleic acid/ PCR test together with any associated symptoms are needed for full medical assessment.

"got the covid 19 vaccine on 21Dec2020 and tested positive for covid on 24Dec2020; got the covid 19 vaccine on 21Dec2020 and tested positive for covid on 24Dec2020; This is a spontaneous report from a contactable Nurse (patient) from a Pfizer-sponsored program Pfizer First Connect. A 36-year-old female patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, batch/lot number: EK5730), via intramuscular in left deltoid on 21Dec2020 10:00 at 0.3 ml, single for precaution as front line healthcare worker in hospital which is not a military facility. Medical history included nonsmoker.

She did not provide causality but stated that she probably already had COVID when she got the vaccine. It was unknown if the patient had SARS-CoV2 antibodies at diagnosis as she had never been tested. Other history was none. The patient did not have a history of hypertension, diabetes, heart disease, lung disease, liver disease, kidney disease, cancer, immunosuppressive disorder, obesity. There was not any pre-existing diseases worsened during the SARS-CoV2 infection. The patient hadn't been treated with immunomodulating or immunosuppressing medications or received any other vaccines around the time of COVID-19 vaccination. Concomitant medication included bupropion hydrochloride (WELLBUTRIN SR), sertraline hydrochloride (ZOLOFT), amfetamine aspartate, amfetamine sulfate, dexamfetamine saccharate, dexamfetamine sulfate (ADDERALL). Prior Vaccinations (within 4 weeks) were none. AE following prior vaccinations were none. There was no additional vaccines administered on Same Date (21Dec2020) of the Pfizer bnt162b2. The patient got the covid 19 vaccine on 21Dec2020 and tested positive for covid on 24Dec2020. The patient wanted guidance on receiving the 2nd dose of the vaccine. The reporter considered event was non-serious. The patient received the first dose of the vaccine on 21Dec2020, and after that on 24Dec2020, she tested positive for COVID . She was supposed to be revaccinated on 07Jan2021. She would like to know if she should she get this or does she need to be revaccinated. There is no prescriber. She received it through her work. She received the first dose on 21Dec2020, and assumed she was positive when she got it. She just had cough and muscle aches and a headache. Her dad was hospitalized. Hers was not that serious. She had not completely recovered yet. Her smell had not come back yet and she was just tired still. She said the headache was prior to getting vaccine. She did not provide causality but stated that she probably already had COVID when she got the vaccine. The cough occurred on 25Dec2020, muscle aches on 22Dec2020 at 08:00. There was no emergency room of or physician's office required for the events. The patient was not hospitalized or admitted to an ICU. Nasal swab test done. Imaging for COVID-Pneumonia, other radiological investigations, hematology, clinical chemistry, inflammatory markers, urinalysis, evidence of hypoxemia, other relevant test were none. The patient did not display clinical signs at rest indicative of severe systemic illness. The patient did not require supplemental oxygen (including high flow or ECMO) or receive mechanical ventilation. The patient did not receive any additional therapies for COVID-19. The event did not require the initiation of new medication or other treatment or procedure. She did start taking extra vitamins on her own. The patient was recovered with some lasting effects such as not being able to smell and is tired still.; Sender's Comments: The Company cannot completely exclude the possible causality between the reported COVID with symptoms and the administration of COVID 19 vaccine, bnt162b2. However, as the reporter claimed ""she probably already had COVID when she got the vaccine"", this may provide an alternative explanation."

had the first dose of the COVID-19 vaccine last 24Dec2020 and the second dose is scheduled on 14Jan2021/tested positive for COVID-19; had the first dose of the COVID-19 vaccine last 24Dec2020 and the second dose is scheduled on 14Jan2021/tested positive for COVID-19; This is a spontaneous report from a contactable Nurse (patient). A male patient of an unspecified age received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number and expiry date: unknown), via an unspecified route of administration on 24Dec2020 at single dose for COVID-19 immunization. The patient medical history and concomitant medications were not reported. The patient had the first dose of the COVID-19 vaccine last 24Dec2020 and the second dose is scheduled on 14Jan2021. However, last 04Jan2021, the patient

tested positive for COVID-19. The patient was looking for recommendations on when he/she can take the COVID-19 vaccine. The patient underwent lab tests and procedures which included COVID-19 test: positive on 04Jan2021. The outcome of the event was unknown. Information on the Batch/Lot number has been requested.

Received the vaccine on 23Dec2020. She tested positive for COVID on 31Dec2020.; Received the vaccine on 23Dec2020. She tested positive for COVID on 31Dec2020.; This is a spontaneous report from a Pfizer-sponsored program Pfizer First Connect. A contactable other healthcare professional (patient herself) reported that a 37-year-old female patient received bnt162b2 (BNT162B2 also reported as PFIZER-BIONTECH COVID-19 VACCINE, lot EH9899), via an unspecified route of administration in the left arm 23Dec2020 at single dose, for Covid-19 immunization. Medical history included migraine (takes a migraine medication). Her height was 168cm, weight of 72.5kg. There were no concomitant medications. Received the vaccine on 23Dec2020. She tested positive for COVID on 31Dec2020. Then she had another test and was negative for COVID on 03Jan2021 and was also negative for another test on 05Jan2021. She was wondering if this was like a super vaccine and knocked it out or if there was an error with the test. She acknowledged that there was a lag time for the second dose of 21 days. She was wondering if there was a grace period for that since she cannot be cleared for work. She was also wondering what to do before her second dose of the vaccine. The outcome of event was unknown.; Sender's Comments: The Company cannot completely exclude the possible causality between the reported positive Sars-Cov-2 test, which is considered ineffective of BNT162B2, and the administration of BNT162B2.

she tested positive for the Covid-19; she tested positive for the Covid-19; This is a spontaneous report from a contactable nurse (patient). A female patient of an unspecified age received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot no. and expiry date were unknown), via an unspecified route of administration on 17Dec2020 at single dose for Covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient received the Covid-19 vaccine on 17Dec2020. She said that she tested positive for the Covid-19 after that (unspecified date) and she is due to get her second dose of the vaccine today 07Jan2021. She said that she is wondering if she needs to get the second dose. The outcome of the event was unknown. Information about Batch/Lot number has been requested.; Sender's Comments: Based on available information, a possible contributory role of BNT162B2 cannot be completely excluded for reported event.

tested positive for COVID; tested positive for COVID; This is a spontaneous report from a non-contactable nurse (patient) and a contactable consumer. A 43-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 23Dec2020 at single dose for COVID Prevention because of occupation. The patient's medical history and concomitant medications were not reported. The patient experienced tested positive for COVID on 02Jan2021 with outcome of unknown. The patient underwent lab tests and procedures which included COVID test: positive on 02Jan2021. The patient got the first dose of the COVID vaccine, and then tested positive for COVID afterward. The patient was inquiring about if there are any recommendations for getting the second dose, if the person tested positive for COVID after getting the first dose. The patient

did not provide prescriber information. The patient should come off of quarantine on 15Jan2021. It was unknow if the patient received any other vaccines on the same day as the COVID vaccine and if there were any concomitant medications, history or investigations other than the COVID test. The type of COVID test the patient received was unknown, just that she got the positive result on 02Jan2021. Information on the lot/batch number has been requested.; Sender's Comments: The information currently provided is too limited to make a meaningful medical assessment hence, the events are conservatively assessed as related to the suspect drug BNT162B2 until further information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

He is losing some taste/but reduced by 30-40%; received first dose of vaccine 21DEC2020 and SARS-Cov-2 positive/Nasal swab COVID positive; received first dose of vaccine 21DEC2020 and SARS-Cov-2 positive/Nasal swab COVID positive; Sniffles; This is a spontaneous report received from Pfizer sponsored program Pfizer First Connect via a contactable other HCP (parent) reported for the patient (son). A 22-years-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (lot: EK5730) intramuscularly in left arm on 21Dec2020 (15:00-16:00) at single dose for COVID-19 immunisation. There was no medical history. There were no concomitant medications. The patient received first dose of vaccine 21Dec2020 and SARS-Cov-2 positive 06Jan2021 13:00. The patient got COVID vaccine 21Dec2020, and was scheduled to get second dose on 11Jan2021. He had a sniffle the other day on 05Jan2021 night time and tested positive for COVID on 06Jan2021, so reporter wanted to know if he should still get second dose. His symptoms are stable. He is quarantining. He is on his way to do a PCR now. Reporter read somewhere people could have false positive in nasal. He is losing some taste from 07Jan2021 (01:00 - 02:00). Most things he can taste. Some he cannot. It is not completely gone but reduced by 30-40%. He did a mouthwash with a sting and is not feeling that sting anymore. He said last night, same thing. He did a mouth wash and did not really taste much. It is not as prevalent as it was before. The patient underwent lab tests and procedures which included SARS-CoV-2 test: positive on 06Jan2021, positive COVID test 06Jan2021, 13:00, Nasal swab COVID. Event outcome of sniffles was recovering, while for other events was unknown.; Sender's Comments: The efficacy of a drug varies from one patient to another and can be affected by different factors; however, a contributory role of the suspect drug BNT162B2 to the reported event ___ cannot be ruled out. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

woke up in the middle of the night; lower legs felt kind of numb and tingly; weak; nausea; anaphylactic reaction; hot flash started on my head, went over my body; dizzy/lightheaded; blurred vision; chest became very tight/chest tightness; throat felt like there was a lump in it; coughing; irritated throat; heart rate was in the 140s; sinus tachycardia; lower legs felt kind of numb and tingly; chills; fever; body aches; diarrhea; This is a spontaneous report from a contactable nurse. A 26-year-old female patient

started to receive BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot# EH9899) via an unspecified route of administration on 29Dec2020 07:30 at single dose for COVID-19 immunisation. The patient medical history was not reported. The patient's concomitant medications were not reported. The patient experienced anaphylactic reaction, hot flash started on my head, went over my body, dizzy, lightheaded, blurred vision, chest became very tight/chest tightness, throat felt like there was a lump in it, coughing, irritated throat, heart rate was in the 140s, sinus tachycardia, fever, chills, body aches, diarrhea, lower legs felt kind of numb and tingly, weak, all on 29Dec2020 and , woke up in the middle of the night on an unspecified date. She reported severe reaction to Pfizer COVID-19 Vaccine onset 8 minutes after being administered that first dose. She asked for information regarding her severe reaction related to the product. This event started with a hot flash that started in her head and went all the way through her body; became really lightheaded; dizzy; her chest became really tight; felt like there was a lump in her throat closing her throat up. They took her to the emergency room where she was treated and kept for a couple of hours, but was not admitted to the hospital in response to this event. While in the hospital she received IV fluids; steroids clarified as Prednisone; Benadryl; Pepcid; and was sent home. On 30Dec2020 afternoon she ended up with the same type of severe reaction: her chest felt tight, she felt her throat closing and itching; she started coughing. She went back to the emergency room in response to the severe reaction. The emergency room thinks it was the same thing again as on 29Dec2020; she again was not admitted to the hospital in response to this event, but was treated and kept for a couple of hours; while in emergency room they again gave her IV fluids; steroids clarified as Prednisone; Benadryl, and because her heart rate was like in the 140s also gave her Ativan to help bring her heart rate down. The anaphylactic aspect of the severe reaction is not ongoing any longer. She then developed fever; body aches; nausea; diarrhea; all the kind of what you would call normal side effects. She reported that on 03Jan2021 morning she woke super dizzy, lightheaded and her vision was blurred. In response to those events she went to her Primary Care Physician on 04Jan2021. The Primary Care Physician told patient to just ride it out for a little bit to see what happens; so that is what the patient has been doing. The dizziness and blurred vision have improved over the last couple of days; but last night she was up all night because she felt a numbness in her lower legs; she can still walk, it is not painful; it's just a weird numbness, tingling kind of feeling. Severe reaction events reported as improved, but ongoing. The patient underwent lab tests and procedures which included electrocardiogram: sinus tachycardia on 30Dec2020, heart rate: was in the 140s on 29Dec2020. The outcome of anaphylactic reaction was recovering, of hot flash started on my head, went over my body, dizzy/lightheaded, blurred vision, chest became very tight/chest tightness, throat felt like there was a lump in it, coughing, irritated throat, heart rate was in the 140s, sinus tachycardia, fever, chills, body aches, diarrhea, woke up in the middle of the night, lower legs felt kind of numb and tingly, weak was unknown. Caller explained she will not receive the second dose.; Sender's Comments: A possible causal association between administration of BNT162B2 and the onset anaphylactic reactions cannot be excluded, considering the plausible temporal relationship and the known adverse event profile of the suspect product. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

an employee who received the first dose of the Covid 19 vaccine, has tested positive for Covid 19 today; an employee who received the first dose of the Covid 19 vaccine, has tested positive for Covid 19 today; This is a spontaneous report from a contactable other HCP and a nurse. A female patient of an unspecified age received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiry date were not reported), via an unspecified route of administration on an unspecified date at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient employee who received the first dose of the COVID 19 vaccine, has tested positive for COVID 19 today, 07Jan2021. The outcome of the event was unknown. The reporter would like to know if the patient can get the second COVID-19 vaccine. Information on the lot/batch number has been requested.; Sender's Comments: Based on available information, a possible contributory role of BNT162B2 cannot be completely excluded for reported event.

Tested positive for COVID after receiving the first dose of the vaccine; Tested positive for COVID after receiving the first dose of the vaccine; This is a spontaneous report from a contactable other healthcare professional (patient). A 26-year-old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number: EJ-685, expiration date: Mar2021), via an unspecified route of administration in the right arm on 21Dec2020 at a single dose for COVID-19 immunization. There were no medical history and concomitant medications. The patient tested positive for COVID on 26Dec2020. Now, she is wanting to know if she should still get the second dose. Outcome of the events was unknown.; Sender's Comments: The patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE) on 21Dec2020, and COVID-19 test positive on 26Dec2020. No effect of the suspect vaccine could be reasonably achieved to protect from the targeted infection/disease due to the very short time lag. Instead, the positive COVID likely represents the pre-existing infection prior to vaccine use. Further information is needed for full medical assessment.

tested positive/had the COVID infection/cough; tested positive/had the COVID infection/cough; PFIZER-BIONTECH COVID-19 VACCINE at 1.3 mL; This is a spontaneous report from a contactable nurse (patient). A 39-year-old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number and expiration date were not reported), via an unspecified route of administration on 19Dec2020 at 1.3 mL, single for COVID-19 immunization. There were no medical history and concomitant medications. She received the first COVID-19 vaccine dose on 19Dec2020 then she tested positive on 22Dec2020. She got the first dose of the COVID vaccine and now she had the COVID infection. She was wondering if she should continue to get the second dose. She was also wondering if it will affect whether or not she gets the second dose. She couldn't find information online about what to do. Before she got the vaccine, she did take a test on an unspecified date to make sure she was negative, and she was. She had a cough at the end of the call. Outcome of the events was unknown. Information on lot/batch number has been requested.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the reported events of COVID-19 and suspected LOE due to temporal relationship. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this

report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Idiopathic trigeminal neuralgia; This is a spontaneous report from a contactable nurse (patient). A 34-year-old female patient started to receive BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number EL0140), intramuscular (right deltoid) first dose on 21Dec2020 at single dose for Covid-19 immunization. The patient's medical history included multiple sclerosis from 2015 (Diagnosed 5 year) and ear infection from 03Dec2020 prior to vaccination, she was seen in urgent care with an ear infection, states it was super painful and lasted about 7-10 days treated it with drops.. There were no concomitant medications. The patient requested guidance on whether or not she should get the second dose of the covid vaccine after being diagnosed with Trigeminal Neuralgia following the first dose. The patient stated that she received the first done on 21Dec2020 and on 27Dec2020 was diagnosed with Idiopathic trigeminal neuralgia. The patient was unclear if the vaccine played a part in the diagnosis and wonders if there is any data available about this as an adverse event as she read that Bells Palsy was reported and this was similar. The patient need guidance on whether to get second dose of the Covid vaccine scheduled for on Monday. Wondering if getting the second dose would be risking it flaring up, states she was now on anticonvulsant medication and gabapentin and they have increased the anticonvulsant medication. The patient experienced idiopathic trigeminal neuralgia (trigeminal neuralgia) (non-serious) on 27Dec2020 with outcome of not recovered. The action taken in response to the event(s) for bnt162b2 was not applicable. The outcome of the event was not recovered.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the reported event of Trigeminal Neuralgia due to temporal relationship. However, the event may possibly represent concurrent medical condition in this patient with medical history of multiple sclerosis. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics including head CT/MRI and viral serologies, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

rash developed on 50% of her body; vomiting; nausea; headache; severe muscle aches; This is a spontaneous report from a contactable nurse reported for herself. This 39-year-old female patient received the 1st dose of BNT162B2 (Pfizer-BioNTech COVID-19 vaccine) via Intramuscular at left arm on 16Dec2020 at 01:00 PM at single dose (lot number: EK5730) for COVID-19 immunisation. Medical history was unknown. Concomitant medications included bupropion hydrochloride (WELLBUTRIN), zolpidem tartrate (AMBIEN) and vitamins. The patient previously took dicycloverine hydrochloride (BENTYL), amlodipine and azithromycin (ZITHROMAX), all experiencing allergies. The patient experienced rash developed on 50% of her body, vomiting, nausea, headache, severe muscle aches 24

hours post vaccination on 17Dec2020 10:45 AM. The patient was treated with Benadryl, Tylenol, IM Solumedrol. The patient had Covid test post vaccination by Nasal Swab on 28Dec2020 and on 04Jan2021, both with negative results. The patient was not pregnant at the time of vaccination. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Outcome of all events was recovered.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the rash and other reported events due to temporal relationship. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

COVID-19 virus test positive; COVID-19 virus test positive; Headache; Sinus congestion; This is a spontaneous report from a contactable consumer reported for himself. A 61-year-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EN9899 and expiration date unknown), via intramuscular on left arm on 22Dec2020 at single dose for COVID-19 prophylaxis. The patient medical history reported as none. Concomitant medications reported as none. The patient is a radiology technician that reported that he got the Pfizer vaccine on the 22Dec2020. He said that he got a positive Covid test on 04Jan2021. The patient had the Covid symptoms as of last Monday night on 04Jan2021. He stated that he developed a headaches and sinus congestion on the 04Jan2021. Stated that he has not had a fever. He said that there was no adverse reaction from the vaccine itself. He said that he was due for the second dose on the 11Jan2021 and he is currently quarantined so he will not be getting the second dose. The outcome of the events was unknown.

two staff members who tested positive for covid after receiving the first dose.; two staff members who tested positive for covid after receiving the first dose.; This is a spontaneous report from the Pfizer Sponsored Program called 'Pfizer First Connect' received by a contactable pharmacist. This pharmacist reported similar events for 2 staff members. This is 2nd of 2 reports. A patient (demographics unknown) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unknown route, in Dec2020 at single dose for COVID-19 immunisation. No relevant medical history and concomitant medications were provided. On unknown date, after first shot of vaccine, COVID test resulted positive. The reporting pharmacist is asking about the recommendation regarding taking the second shot. The outcome of the event was unknown. Information about Batch/Lot number has been requested.; Sender's Comments: A causal association between reported event and suspect BNT162B2 cannot be excluded. ,Linked Report(s) : US-PFIZER INC-2021010495 Same reporter/ drug/ event for different patients.

positive COVID-19 test with symptoms; positive COVID-19 test with symptoms; The patient had MS and was immune compromised; The patient had MS and was immune compromised; This is a spontaneous

report from a contactable consumer (patient). This female consumer of unspecified age received the first single dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 04Jan2021, for COVID-19 immunization. She had MS and was immune compromised. Concomitant medications were not reported. On 07Jan2021 the patient woke up with headache, runny nose, groggy and muscle aches. She went to pharmacy and got a rapid COVID test that resulted positive. She was asking if the 1st dose could have caused her to be positive on the test. Events outcome was unknown. Information on the batch/lot number has been requested.; Sender's Comments: Based on the information available, a possible contributory role of the suspect products cannot be excluded for the reported event of positive for corona virus infection for the lack of efficacy of the vaccine. However, based on the mechanism of action of the vaccine, it is unlikely the patient would have fully developed immunity for the vaccine to be effective, due to the number of days passed since the vaccine is given. Case will be reevaluated based on follow-up information

tested COVID Positive; tested COVID Positive; This is a spontaneous report from a contactable nurse. A female patient of an unspecified age received 1st dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 22Dec2020 at single dose for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient experienced tested COVID positive on 01Jan2021. She still has a few symptoms and is scheduled for the 2nd dose on 12Jan2020 or 13Jan2020. She was asking if there were any recommendations on the scheduling of the vaccine for her. The outcome of event was unknown. information on the lot/batch number has been requested.; Sender's Comments: Based on the information currently available, a lack of efficacy with BNT162B2 in this patient cannot be completely excluded.

severe angioedema, hives, tachycardia, hypertension, pruritus, chest tightness and shortness of breath.; severe angioedema, hives, tachycardia, hypertension, pruritus, chest tightness and shortness of breath.; severe angioedema, hives, tachycardia, hypertension, pruritus, chest tightness and shortness of breath.; severe angioedema, hives, tachycardia, hypertension, pruritus, chest tightness and shortness of breath.; severe angioedema, hives, tachycardia, hypertension, pruritus, chest tightness and shortness of breath.; severe angioedema, hives, tachycardia, hypertension, pruritus, chest tightness and shortness of breath; severe angioedema, hives, tachycardia, hypertension, pruritus, chest tightness and shortness of breath; This is a spontaneous report from a contactable nurse (reporting for herself). A 41-year-old non-pregnant female patient received two doses of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), both via an unspecified route of administration in the left arm, the first dose on 16Dec2020 09:00 (lot number: EH9899) and the second dose on 08Jan2021 07:15 (lot number: EL0140), both at a single dose for COVID-19 immunization. Medical history included ongoing anxiety, from an unspecified date. The patient had no known allergies. Concomitant medication included escitalopram oxalate (LEXAPRO), acetaminophen (MANUFACTURER UNKNOWN), naproxen sodium (MANUFACTURER UNKNOWN), ibuprofen (MANUFACTURER UNKNOWN). The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, has not been tested for COVID-19. On 09Jan2021 at 01:30 AM, the patient experienced severe angioedema, hives, tachycardia, hypertension, pruritus, chest tightness and shortness of breath, all of which were reported as being life-threatening. The patient went to the

Emergency room due to the events. Therapeutic measures were taken as a result of the events and included: methylprednisolone sodium succinate (SOLUMEDROL) 125 mg, famotidine (MANUFACTURER UNKNOWN) 20 mg and diphenhydramine hydrochloride (BENADRYL) 50 mg. The clinical outcome of severe angioedema, hives, tachycardia, hypertension, pruritus, chest tightness and shortness of breath was recovering.; Sender's Comments: A possible causal association between administration of BNT162B2 and the onset severe angioedema, hives, tachycardia, hypertension, pruritus, chest tightness and shortness of breath cannot be excluded, considering the plausible temporal relationship and the known adverse event profile of the suspect product. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

the person who took the 1st dose of the vaccine and still tested positive; the person who took the 1st dose of the vaccine and still tested positive; This is a spontaneous report from a Pfizer sponsored program Pfizer First Connect. A non-contactable consumer reported that a patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via unspecified route of administration on unspecified date at single dose for COVID-19 immunization. Patient medical history and concomitant medications were not reported. ~The patient took the 1st dose of the vaccine and still tested positive on unspecified date. They would like to know if the patient still needs to take the 2nd dose of the vaccine or not. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

Received 2nd vaccination in series on 11 JAN 21. By next morning started to experience some muscle and joint symptoms. By afternoon of 12 JAN 21 experienced sudden onset loss of bladder control for first time in his life, followed a few hours later by blurry vision, vertigo, motion sickness, emesis and cold sweats that drenched his clothes. Taken to ER by paramedics, and admitted for further observation and evaluation for underlying neurologic vs. cardiogenic problems. Given positional treatments by PT for possible otoliths. Feels much improved on afternoon of 13 JAN 21, but symptoms not fully resolved. Will likely be discharged from hospital on 14 JAN 21 if problems continue to resolve.

Admission Note: ? Weakness - Generalized á á Patient reports feeling weak prior to dialysis, but demanded clinic to perform dialysis. Had full tx done and brought to ER. Reports still feels weak after dialysis. á 84 year old male comes in today after completing dialysis for evaluation of generalized weakness x 5 days. He has also lost his voice. He tells me he received his COVID vaccine yesterday, but he is concerned he may have COVID. He denies any fevers, cough, sore throat, NVD, abd pain. Transfer Note: HOSPITAL COURSE: Patient is a 84 y.o. male who presented with shaking chills and was found to have Gram-negative rods in the blood. The source of infection was unclear. Initially it was thought that it could possibly be cholecystitis but imaging was negative for that. There was concern that it could be UTI but the patient is on dialysis and is an uric and therefore no urinalysis could be got. Early this morning when I saw the patient the patient did have significant pain and tenderness in the right knee and is not able to put weight on that. I.e. Consulted Dr. Today with per lumbar from Orthopedics who said that it would be in the best interest of the patient for him to be transferred to hospital where he could decide on aspiration and or washout of the right knee. á Transfer center has been called and we are trying to

finalize a transfer of the patient hospital at this point of time á Please see problem list listed below. á REASON FOR ADMISSION/ ADMISSION DIAGNOSES á Sepsis cause unclear

History of Present Illness: á Patient is a 80 y.o. male who presents with chest pain. Patient reported that he 1st had the chest pain approximately 2 weeks ago when he woke from sleep. At that time patient pain lasted about 5 minutes or so and resolved when he got out of bed. He did well for the rest of the day up until yesterday. Patient reported that yesterday morning he woke up with the pain at the lasted about 30 minutes or so. Patient also had associated burping felt that it is likely GI in nature. The pain was located mainly in the left side of the chest without any radiation. No diaphoresis. No shortness of breath or palpitation. No radiation for the pain. Since yesterday morning he had another 3 episodes of pain the last after dinner tonight. Patient reported that this pain was located more on the left side of the chest, likely lasted about 10 minutes or so. There was no exertional component to the pain. No known history of heart disease. Due to rather recurrent nature of the pain patient was brought to the hospital by his son who is a cardiologist to be evaluated. No fever or chills. No cough . Patient reported that he got vaccination for COVID 2 days ago-of a concern that this may be a side effect of the vaccine. No dizziness lightheadedness. Patient with history of GI bleed in the past at that time patient was on NSAIDs. Patient with burping associated with the pain

Chief Complaint Patient presents with ? Generalized Body Aches á á Pt presents via EMS c/o DOE, dry non-productive cough, subjective fevers Tmax 101.9, decreased appetite, aches since testing + for COVID on 1/5. á Patient is a 50 year old male with PMH of Crohns/MS on fingolimod presenting to the Hospital for fevers, shortness of breath and weakness. Patient received COVID vaccine on 12/29. Patient had initial left arm discomfort though has had worsening weakness, cough, shortness of breath and fevers since that time. Patient tested positive for COVID19 on Patient has shortness of breath with exertion that is relieved by rest. Patient denies N/V/D. Patient has taken tylenol at home to attempt to alleviate symptoms.

Chief Complaint Patient presents with ? Vomiting á á pt reports dry heaving and nausea that started an hour ago á Patient is an 68 y.o. year old male with PMHx significant for HTN, BPH, who presents to the ED today with nausea and dry heaving for one hour PTA. States that he was at work as a courier when he had onset of sensation of room spinning, nausea, and dry heaving. Also having tinnitus which he thinks is b/l. This happened once about two weeks ago and resolved spontaneously overnight when he was asleep. No preceding illnesses, medication changes, or other associated symptoms. Vertigo has no clear exacerbating or relieving factors. Has not yet taken anything for symptoms. á The patient denies fevers, chills, headaches, syncope, chest pain, shortness of breath, rhinorrhea, sore throat, cough, abdominal pain, changes in usual bowel movements, changes with urination, back pain, pain anywhere else in body. The patient has no sick contacts, recent travel history.

HOSPITAL COURSE: Patient is a 50 y.o. female with a history of anxiety and migraine headaches who presented to hospital with cough and diarrhea. The patient had felt the symptoms on 12/31/2020 and eventually went to have a COVID test on 1/1/2021. She was subsequently positive but due to dehydration and diarrhea she came to the emergency department where she was admitted for

remdesivir and dexamethasone. She was able to be weaned off any supplemental oxygen. Her diarrhea resolved. She is feeling well and will be discharged home in good condition.

None stated.

Peripheral neuropathy

Pt experienced 103.7 fever and muscle spasms. Hospitalized.

Numbness tingling in feet, toes progressed to waist. ER Sunday hosp, pt was admitted inpatient, diagnosis transverse myelitis.

Systemic: Dizzy, hyperventolation-Medium

Began with tingling/itching to tongue and roof of mouth approx 15 minutes after administration, progressed to tingling of lips, was sent to the ED for observation. Within 20-30 minutes developed cough, throat tightness, difficulty swallowing, breathing, vomiting, shortness of breath. Noted to have uvular swelling and wheezing on examination. Given Benadryl, Pepcid, Solumedrol, Zofran, Albuterol MDI, Epi IM. within a few minutes symptoms returned and were worse where I felt like I could not breathe, throat was closing, could not talk. Noted to be pale, HR in 140?s. Given second dose of epi IM and symptoms improved. Was transferred to Obs Unit., within 2 hours (approx 6 hours after administration), developed SOB, throat tightness, cough, vomiting, difficulty breathing. Again noted to have swelling of uvula, wheezing on exam. Given Solumedrol, Benadryl, SQ epi, Albuterol, Racemic Epi nebulizer. Was transferred to ICU, all meds held except Pepcid. Day #2 ~10 am (25 hours from administration) developed throat tightness, diffuse red rash to arms, difficulty breathing, vomiting. Again noted to have uvular swelling and wheezing. Given Solumedrol, Benadryl, Pepcid, Albuterol MDI, Racemic Epi neb. Solumedrol started q12hour dosing. Strange feeling/fullness in throat continued all day, got additional racemic Epi neb that night with improvement of symptoms. Following morning (day#2 after vaccine) noted to have diffuse red rash to chest and face, spread to arms, then began coughing. Given Solumedrol, Pepcid, Benadryl, Advair, Racemic Epi nebulizer. Solumedrol changed to q8 dosing. Approx 4 hrs later nurse noted rash worse on face, associated with itching, throat tightness. Given additional Benadryl, Racemic Epi neb with improvement. Rash continued that night with throat tightness, got additional Benadryl and Racemic Neb that night (total of 3 Racemic nebulizer on Day#2 post vaccine). Transferred to telemetry floor. Day#3 post vaccine rash improved, but still present to chest and face. Throat fullness present, especially after drinking. Am still hospitalized while writing this report

Initial pain in back of head and extreme headache. Some vomiting. At emergency, went into coma and was intubated. Hole drilled in skull to relieve pressure. MRI taken. Lot of bleeding in brain - anuerism lead to death approximately 14 hours after initial symptoms.

Systemic: Anaphylaxis-Medium; symptoms lasted 1 day

Unprovoked seizure (clonic tonic) 13 days later, requiring hospitalization and testing

Pt collapsed at home approx 5:30 pm and died

On day due for 2nd dose, Patient was found unresponsive at work in the hospital. Patient pupils were fixed and dilated. Full ACLS was initiated for 55 minutes with multiple rounds of bicarb, calcium chloride, magnesium, and epinephrine. Patient was intubated. Patient continued into V. Fib arrest and was shocked multiple times.

Systemic: reported by staff patient expired under suspicious circumstnces after receiving vaccine. Patient was on hospice, reported not expected to pass this soon; symptoms lasted 0 days

Extreme lockjaw unable to barely talk or chew

Day 7 post vaccine, woke with vertigo, nausea and double vision prior to my alarm going off at 5:30am, told my husband that I did not feel right and it felt like something was wrong with me. I asked him to send a message to work that I was not feeling well and would not be in. I was not able to see my phone clearly as I had double vision. I went back to sleep to try to get relief, woke up and called out to husband for help and he said I was just making groaning noises but I know in my head I was saying please help me as I could not move my right side and I was not sleeping or having a dream. At approximately 9:30am my husband kept telling me someone was trying to text me and needed a response. I tried to get up and still could not move my right side. He helped me sit up and I could not use my right arm and hand. He helped me get some clothes on and took me to the ED. When we arrived I still could not use my right hand and my arm still felt weak. The weakness resolved within a couple of hours and I got the strength back in my hand. I did have some concern that my TIA type symptoms could possibly be related to vaccine but it was just a thought until I received my second dose. 3 hours post vaccine my face became numb and tingly. It remained that way until I went to sleep. This is why I am reporting this incident.

Per patient report on follow-up: admitted to hospital following initial vaccine on 12/29 with N/V and severe HA. Patient placed on Morphine for pain, now resolved. Admission occurred outside of hospital system providing initial vaccine.

Patient reports no symptoms until 1/8/21 at which time a rash developed along with fatigue and fevers. Patient was seen in ED 1/8 and 1/11/21. Was admitted 1/11/21 with Concern for STevens Johnson and sepsis. Patient subsequently developed full body macular rash and mucosal lesions. Fevers to 102-104.

Reported redness, swelling and pain at injection site, diarrhea and light headedness1/5/21. Evaluated in ED and hospitalized for neurological symptoms that started 1/8/21.

vaccinated at Hospital on 1/12/2021. According to patients father she developed stomach pains, constant vomiting, sweating which started at approx. 4am. She arrived at Medical center at approx. 7:20 stating she had been vomiting since 4am. Attempted PO fluids while in ED. Uncontrolled nausea persisted despite medication. Admitted to Hospital for observation for uncontrolled nausea. IV fluids given

Developed pulmonary embolism in right lung one week after vaccination. Sharp pain on right side when breathing. Treated with IV Apixaban while inpatient for 2 days, oral Apixaban 5 mg, 2 tabs twice daily 1/5/21-1/11/21, then one 5 mg tab twice a day. Pain has subsided as of 1/14/21.

No adverse reactions observed after administration of medication. Patient starting complaining of shortness of breath around 0500 the following morning. SP02 checked in the 80s. Patient expired 01/09/2021;

altered mental status, hypoxic, fever 39.3, agitated

a positive Covid test after receiving their first dose; a positive Covid test after receiving their first dose; The initial case was missing the following minimum criteria: No adverse effect. Upon receipt of follow-up information on 06Jan2021, this case now contains all required information to be considered valid. This is a spontaneous report from a Pfizer-sponsored program IBCC (Inbound Call Center for HCPs). A contactable other healthcare professional (student pharmacist) and a contactable pharmacist reported that a patient of unspecified age and gender received BNT162B2 (PFIZER BIONTECH COVID-19 VACCINE, lot number unknown), via an unspecified route of administration, on an unspecified date, at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. Reporter that works at a hospital pharmacy called about a patient that received their first dosage of COVID-19 vaccine who had a positive COVID test on an unspecified date after receiving their first dose of the vaccine. They wanted to know hoe to proceed and if they needed the second dose. The outcome of the event was unknown. Information on the lot/batch number has been requested.

covid a week after the1st dose of the vaccine. When to get the 2nd dose?/tested positive for COVID; covid a week after the1st dose of the vaccine. When to get the 2nd dose?/tested positive for COVID; body aches; fever; Headache; This is a spontaneous report from a contactable physician. A 31-year-old female patient (healthcare worker) received the 1st dose of bnt162b2 (BNT162B2) at single dose in Dec2020 (9 days before 07Jan2021) for Covid-19 immunisation. The patient medical history and concomitant medications were not reported. The patient received the 1st dose of the COVID vaccine 9 days before 07Jan2021 and got a headache afterward in Dec2020. After 6 days, in Jan2021 the patient had a worse headache, body aches, and fever. She was swabbed for COVID on 06Jan2021 and tested positive. The reporter wanted to know what to do about the 2nd dose. The outcome of events was unknown. A product complaint was filed. information about lot and batch number was requested.

tested positive for covid/headache, ever, cough, diarrhea; tested positive for covid/headache, ever, cough, diarrhea; This is a spontaneous report from a contactable consumer (patient) via a Pfizer Sponsored Program IBCC (Inbound Call Center for HCPs). A 47-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EK5730, expiration date: 20Mar2021), via an unspecified route of administration on 19Dec2020 16:15 at left arm, at single dose for covid-19 immunization. Medical history included hysterectomy in 2010, pulmonary Embolism in 2010, gallbladder removed on an unknown date. There were no concomitant medications. The patient received 1st dose 19Dec2020, she was supposed to get her second dose, but tested positive for covid. She thought she had side effects after vaccine, she began with a headache, fever a week later and

thought they were from the vaccine, but then her sister-in-law was positive for COVID, her sister-in-law passed away from covid virus. Then the patient, her mom, and husband tested positive for COVID. She tested positive for COVID on 27Dec2020. She developed symptoms of COVID on 27Dec2020. It was exactly one week after receiving the first dose. It was also reported that she got tested on the 30th (as reported) and received results on 31Dec2020 that she was positive. After she got sick she has taken Mucinex. Day eleven, she is doing ok, but has a little cough. No more fever. Sometimes she has diarrhea but today no diarrhea. The patient asked if she can get her second dose of the covid vaccine on day 24. The outcome of the events was recovering.

arm is red, warm, and itchy; arm is red, warm, and itchy; arm is red, warm, and itchy; Chest tightness; bitter taste in her mouth; funny feeling; arm was hurting; swelling; patient thinks the vaccine was given to her subcutaneously instead of intramuscularly; This is a spontaneous report from a contactable nurse (reporting for herself). A 43-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot number: EK9231), subcutaneously in the left arm on 05Jan2021 15:00 at 0.3 mL, single for COVID-19 immunization. The patient's medical history was not reported. Concomitant medication included an unspecified multivitamin, taken at one tablet daily by mouth for supplementation therapy. The patient previously took the flu vaccine (MANUFACTURER UNKNOWN) in 2016 for immunization and experienced chest tightness, which she took diphenhydramine hydrochloride (BENADRYL). The patient experienced arm is red, warm, and itchy on 05Jan2021, which was reported as being medically significant. On 05Jan2021, the patient experienced chest tightness, bitter taste in her mouth, funny feeling, arm was hurting, swelling and patient thinks the vaccine was given to her subcutaneously instead of intramuscularly. On 06Jan2021, the patient experienced arm is red, warm, and itchy was reported as worsened. The outcome of arm is red, warm, and itchy, chest tightness and arm is red, warm, and itchy was reported as worsened was not recovered and of bitter taste in her mouth, funny feeling, arm was hurting, swelling and patient thinks the vaccine was given to her subcutaneously instead of intramuscularly was unknown. The reporter assessed the relatedness to the event, arm is red, warm, and itchy to the Covid-19 Vaccine as related; Sender's Comments: Based on the time association, the possible contribution of suspect BNT162B2 to the events pruritus, erythema and feeling hot cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

The patient had an ongoing medical history of Crohn's disease/Concomitant medication included vedolizumab (ENTYVIO) for Crohn's disease; shortness of breath; difficulty swallowing; fever; headache; nausea; she was feeling as if her throat was closing; Chest tightness; This is a spontaneous report from a contactable physician reporting for a patient. A 34-year-old female patient received the first dose of BNT162B2 (COIVD-19 Vaccine) , via an unspecified route of administration on 03Jan2021 at single dose for covid-19 immunisation. Medical history included Crohn's disease from an unknown date and unknown if ongoing, COVID-19 in 2020 to an unknown date and unknown if ongoing. Concomitant medication included vedolizumab (ENTYVIO) for Crohn's disease. The reporter is a physician who is

reporting and AE for a patient who received the vaccine and subsequently developed symptoms including short of breath, fever, headache, nausea, difficulty swallowing with seriousness criteria of Medically significant on 03Jan2021. The patient self-medicated with benadryl and symptoms resolved briefly but then went to urgent care with re-occurring symptoms and was prescribed prednisone. Caller states the patient's symptoms have resolved. She is calling to get more information to determine if the patient should receive the second dose. The reporter further stated that she has a patient who received her first shot, clarified as the COVID-19 Vaccine. About an hour and 45 minutes later, the patient had shortness of breath and then later had a fever, headache and nausea. It was later that night when the patient had a fever. The patient had difficulty swallowing which worsen; she was feeling as if her throat was closing. The patient is a nurse, so she self medicated with Benadryl. After taking the Benadryl, the patient was better in the early morning. When the doctor's office opened, the patient called and was having similar symptoms, clarified as all the symptoms mentioned above. The patient went to the urgent care where she received more Benadryl and was started on prednisone. Caller did not know the dose of prednisone the patient had received. After that, the patient started feeling better. The patient's second dose of the COVID19 Vaccine is due around 24 to 26Jan2021. The patient has not called the doctor/caller back. The caller assumes that the patient has recovered but could not be certain. Caller added that the patient also experienced chest tightness when she was having shortness of breath. The patient's fever was 101 on 03Jan2021. The patient was not drooling with her difficulty swallowing. Caller stated that the patient had a positive COVID test earlier, she thinks it was maybe 3 to 4 months ago (in 2020). The patient has not received another COVID test since she received the first dose of the COVID-19 vaccine to the caller's knowledge. Reporting physician is an internal medicine physician. Therapeutic measures were taken as a result of the events. The outcome of the events was unknown. Information on the Batch/Lot number has been requested.; Sender's Comments: The Company cannot completely exclude the possible causality between the reported short of breath, fever, headache, nausea, difficulty swallowing, throat closing, chest tightness, and the administration of COVID 19 vaccine, BNT162B2, based on the plausible temporal association. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RA, IEC, as appropriate.

headache; injection site is itchy and swelled up; injection site is itchy and swelled up; But this one turned red; can't lift her arm it's heavy and painful; can't lift her arm it's heavy and painful; shortness of breath; palpitation; Dizziness, lightheaded/ feeling dizzy; Uneasiness; hands are so cold; nauseous; This is spontaneous report from a contactable nurse reported for herself. This 42-year-old female patient (No pregnant) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via Intramuscular on Left arm on 29Dec2020 17:00 PM on left arm at single dose (Lot # EL1284) for COVID-19 immunisation. Medical history included None. No Allergies to medications, food, or other products. Concomitant medications included ascorbic acid, bioflavonoids nos, hesperidin, malpighia glabra, rosa canina, rutoside (VITAMIN C), collagen, colecalciferol (VITAMIN D), cynara cardunculus, malus spp. vinegar extract, taraxacum officinale (APPLE CIDER). No other vaccine in four weeks. The patient experienced Dizziness, lightheaded, palpitation, uneasyness, shortness of breath on 29Dec2020 17:15 pm. Then when the patient drove home, she felt so uneasy and hands are so cold, nauseous and feeling

dizzy on 29Dec2020 17:15 pm. Felt the same way in the house for a good 2 hours after the vaccination. Drank water and didn't sleep right away. Tried to monitor herself. After that day the patient felt better but with bouts of headache and dizziness every now and then. The injection site was itchy and swelled up. But it went down if didn't scratch it. The patient didn't have allergies to any medications. But this one turned red. And the next day after the vaccination (30Dec2020) the patient can't lift her arm it's heavy and painful. Then pain went away. But now it was the itchiness in the site that bothered her. But the patient didn't scratch it. So it didn't swell up as much. Prior to vaccination, was the patient did not diagnose with COVID-19. Lab data on 07Jan2021 Nasal Swab post vaccination for Covid 19: result was pending. No treatments received for the events. Outcome of the events Dizziness, lightheaded/ feeling dizzy, palpitation, Uneasiness, shortness of breath, hands are so cold, nauseous was recovering. Outcome of the event pain in arm was recovered. Outcome of other events was unknown.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the dizziness, lightheaded, palpitation, shortness of breath and other reported events due to temporal relationship. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics including chest x-ray, EKG and chemistry panel, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

trouble breathing; She had bad pain in her chest; Her oxygen saturation dropped to 92 and it is usually 98 or 100; not been feeling well; A fast heartbeat 5-10 minutes after initial dose; This is a spontaneous report from a contactable healthcare professional (dental assistant) reporting for self. This female patient with unspecified age received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 22Dec2020 at single dose for COVID-19 immunisation. Medical history and concomitant medications were not reported. The patient previously had reactions with the flu shot in the past for immunisation and she only was able to take the vegan version of the flu shot due to the egg content in the regular version of the flu shot. She also stated not being able to take the flu shot in the arm, leg, hip etc. Patient stated she was scheduled to take her second dose of vaccine tomorrow. She received the first dose on 22Dec2020. She stated she was in the ER on Monday for 5 hours because she was unable to see her primary care physician because his office was filled with patients with Covid and they could not provide her with guidance. She stated after receiving the first dose of vaccine she had not been feeling well ever since. Stated she had had trouble breathing and this took her by surprise. She had bad pain in her chest and a fast heartbeat 5-10 minutes after initial dose (on 22Dec2020). Her oxygen saturation dropped to 92 and it was usually 98 or 100. She stated something inhibited her ability to breathe and this scared her because she was healthy prior to the vaccine and never been in hospital and wasn't born in the hospital. She stated the condition she was diagnosed with will take 6-12 months for her to recover from and go back to normal. She stated during her ER room visit there were a lot of tests done. She would like to know if she should receive the second dose of the vaccine. The outcome of events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Based on available

information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the dyspnea, chest pain, oxygen saturation decreased and other reported events due to temporal relationship. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics including chest x-ray, arterial blood gas and pulmonary function tests, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

On 1/12/20 resident woke up and was not able to stand in the E-Z stand. E-Z lift was needed. In addition he needed assistance with eating. At that time VS were stable, equal hand grasp noted, and no further concerns. Around 3pm resident became flaccid on the left side of his face and speech became mumbled. Hand grasp was equal at that time and VS were stable, but B/P was elevated compared to previous recordings earlier in the day. Family did not want him sent to the hospital and asked for comfort cares. Hospice referral obtained and he will be admitted to hospice in the near future. Resident's left side of face has improved within the last 48 hours. He remains total assist with all cares.

develops symptomatic covid; develops symptomatic covid; This is a spontaneous report from a contactable physician received via a Pfizer sales representative. This physician reported similar events for two patients. This is the first of two reports. A patient of unspecified age and gender received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot/batch number and expiry date were not provided) solution for injection, via an unspecified route of administration on an unspecified date at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient developed symptomatic Covid on an unspecified date. The patient received dose #1 of a Covid-19 vaccine and contracted Covid-19 prior to dose #2. The patient underwent lab test which included Covid-19 test in which he/she developed a symptomatic Covid-19 on an unknown date. Outcome of the event was unknown. Information about batch/lot number has been requested.; Sender's Comments: A causal association between BNT162B2 and the reported events cannot be excluded based on a compatible temporal relation between vaccination and onset of events. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate. ,Linked Report(s) : US-PFIZER INC-2021014755 Same reporter/drug/event, different patient

"flushed; hives; tongue felt ""thick""; the lump in my throat feels bigger; This is a spontaneous report received from a contactable pharmacist. A 23-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, lot number EL0142), via an unspecified route of administration in the left arm on 22Dec2020 (at the age of 23-years-old) as a single dose for COVID-19 immunization. The patient's medical history included: allergies to medications, food, or other products (unspecified). It was unknown if the patient was pregnant at the time of vaccination. The patient's

concomitant medications were not reported. It was unknown if the patient received any other vaccine within 4 weeks prior to the vaccine. On 22Dec2020, approximately 8 minutes after vaccine administration, the patient began feeling flushed. She reported to the observation area, and the registered nurse noted hives on her left neck (22Dec2020). The patient was brought back for closer monitoring. The doctor evaluated the patient. Vital signs were monitored every 5 minutes (22Dec2020). The patient was given 50 mg diphenhydramine (BENADRYL) orally. Some improvement was noted in hives; however, the patient began to state her tongue felt ""thick"" and ""the lump in my throat feels bigger"" (both on 22Dec2020). Per doctor, 0.3 mg epinephrine (MANUFACTURER UNKNOWN) given intramuscularly with rapid improvement in hives. The patient reported feeling some improvement as well. The patient was taken to the emergency department for ongoing observation. The patient was released from emergency department after observation. The clinical outcome of flushed, hives, tongue felt ""thick"", and ""the lump in my throat feels bigger"" was recovered on an unspecified date.; Sender's Comments: Based on the compatible time association, the events flushing, urticaria, tong disorder, sensation of foreign body are possibly related to suspect BNT162B2 administration. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate."

Egg sized lymphadenopathy under right arm 36 hours after 2D injection; flu symptoms; joint aches; muscle and joint aches; arm pain; arm pain and swelling; 1st dose of BNT162B2 on 17Dec2020 15:45/ 2nd dose on 06Jan2021 14:30; 1st dose of BNT162B2 on 17Dec2020 15:45/ 2nd dose on 06Jan2021 14:30; This is a spontaneous report from a contactable nurse (patient). A 55-year-old female patient received 2nd dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration in right arm on 06Jan2021 14:30 at single dose for COVID-19 immunisation. Medical history included mild hypertension and arthritis. The patient was not pregnant. No Covid prior vaccination, no Covid tested post vaccination. No known allergies. Concomitant medication included estradiol, norethisterone acetate (COMBIPATCH), meloxicam, propanol. The patient previously received 1st dose of BNT162B2 in left arm on 17Dec2020 15:45 for COVID-19 immunisation. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient experienced egg sized lymphadenopathy under right arm 36 hours after 2D injection (08Jan2021 03:00), after flu symptoms of muscle and joint aches, arm pain and swelling at 20 hours (07Jan2021 12:00). No treatment received for the events. The outcome of events was not recovered. This case was reported as non-serious. Information on the lot/batch number has been requested.; Sender's Comments: Based on the compatible temporal association and the drug's known safety profile, the vaccination with BNT162B2 might play a contributory role in triggering the onset of lymphadenopathy. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

She was wiped out the next day with aches and pains still.; tired; brain fog; started to get cold; shake/her hands were shaking so hard; they took her temperature and it was 100/her fever went to 101/temperature had gone to 102.6; heart rate was elevated at 100/heart rate was 110/heart rate went to the high 120s; headache; backache; nauseated; chest was hurting; The initial case was missing the following minimum criteria: Invalid for unspecified adverse event. Upon receipt of follow-up information on 08Jan2021, this case now contains all required information to be considered valid. This is a spontaneous report from a contactable nurse (patient). A 54-year-old female patient received 1st dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot# EK5730), via an unspecified route of administration in deltoid left on 29Dec2020 07:30 at single dose for COVID-19 immunisation. Medical history included ongoing sleep apnoea (diagnosed about 3-4 years ago, wear her CPAP religiously), Hashimoto's hypothyroid, and chronic low vitamin d (lack of sunlight). Concomitant medication included levothyroxine sodium (SYNTHROID) from 2016 and ongoing for Hashimoto's hypothyroid, ergocalciferol (VIT D) from 2018 for chronic low vitamin d; lack of sunlight (She did not take it religiously, but was supposed to take it everyday). At 10:30 AM (29Dec2020), she started to get cold and shake. She thought that this was insane and it was in her head. It became so severe she could not use her computer her hands were shaking so hard. She went back up to where they were giving vaccines, they took her temperature and it was 100. It had been normal the morning before she got the vaccine. Her heart rate was elevated at 100. They put a blanket on her and said they wanted to watch her for 15 minutes. In that time her fever went to 101 and her heart rate was 110. They took her to the ER. She was there for 5 hours. Her heart rate went to the high 120s. They did a 12 lead EKG. Her temperature had gone to 102.6, which was the highest. They gave her a liter of Normal Saline. She also had a headache, backache, and felt nauseated. The liter of fluid helped, no doubt. She was not admitted. She was wiped out the next day (30Dec2020) with aches and pains still. Their concern was they said they did not give her epinephrine because her heart was too high. She had no breathing issues. Just extreme cold. At one point she had woke up in the ER (29 or 30Dec2020) and her chest was hurting, she knows from her heart rate being too fast. She was so cold. She had on 6 blankets. The next day (30Dec2020) she still had the aches and pains, she was tired, and had brain fog. It all went away on 30Dec2020. She had nothing after that. What scared her was the heart rhythm. The ER doctor says its not great, but felt that getting the second dose was better than her having COVID. The Electrophysiologist she saw, said she was unsure if she should get the second dose. The hospital said that for this next dose, they would give her the injection, wait 15 minutes, then send her home, expecting that she would have the same thing happen. When after the first dose, she was in the ER on a 12 lead EKG with an intravenous (IV). She had no arm pain the whole time. The reporter assessed all events related. She felt fine prior, walking in to get the vaccine. But she was much better the next day and recovered completely. She was just worried about the second dose. The outcome of events was recovered on 30Dec2020.; Sender's Comments: Based on the compatible temporal association and the drug's known safety profile, the vaccination with BNT162B2 might play a contributory role in triggering the onset of the reported events. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Myocardial Infarction; This is a spontaneous report from a contactable Other healthcare professional (patient). A 64-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, Batch/lot number: 20201216-1), via an unspecified route of administration on 16Dec2020 08:15 at single dose for COVID-19 immunization, vaccine location provided as Left arm. Medical history included arthritis and sulfa allergy. Prior to vaccination, the patient was not diagnosed with COVID-19. The patient's concomitant medications were not reported. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient experienced myocardial infarction on 19Dec2020 23:00. The patient was hospitalized for myocardial infarction for 3 days. The patient underwent lab test which included Covid test via Nasal Swab post vaccination on 20Dec2020 with test result Negative. Therapeutic measure Cardiac cath procedure was taken as a result of myocardial infarction. The outcome of the event was recovering. This case was reported as Serious with seriousness criteria hospitalization.; Sender's Comments: The Company cannot completely exclude the possible causality between the reported myocardial infarction and the administration of COVID-19 vaccine, BNT162B2, based on the reasonable temporal association. However, more information is required, such as the complete medical history, clinical course, for the Company to make a more meaningful causality assessment. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RA, IEC, as appropriate.

Rash over all over body, started at neck.; itching; This is a spontaneous report from a contactable Nurse. A 25-year-old female patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number: EL3246, expiry date: unknown), intramuscular on 06Jan2021 15:15 at single dose (Left arm) for COVID-19 immunization. The patient medical history and concomitant medications were not reported. Facility type vaccine was Clinic/Facility. The patient experienced rash over all over body, started at neck and also complained of itching on 06Jan2021 15:30. Patient denied breathing difficulties. EMTs arrived and gave client oxygen and Benadryl. AE resulted in Emergency room/department or urgent care. It was unknown if patient had COVID prior vaccination. The patient was not tested for COVID post vaccination. Therapeutic measures were taken as a result of rash over all over body, started at neck and itching. The outcome of the events was recovering.; Sender's Comments: Based on the close temporal association, the Company considers the events rash and pruritus are possibly related to vaccination with BNT162B2. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

took a rapid test and it came up positive; took a rapid test and it came up positive; fever 100.8; coughing; This is a spontaneous report from a contactable consumer (patient herself). A 41-year-old female patient (non-pregnant) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, reported as Pfizer covid19 el1284), via an unspecified route of administration on 30Dec2020 14:30 in left arm at single dose for covid-19 immunisation. Medical history included asthma and

arthritis. Concomitant medication included ibuprofen and paracetamol (TYLENOL). The most recent COVID-19 vaccine was administered in public health clinic/ veterans administration facility. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had been tested for COVID-19. Patient got the vaccine on Wednesday 30Dec2020, and by Saturday (02Jan2021 22:30) she started with a little coughing that increase on Monday (04Jan2021), Monday afternoon she had fever 100.8. She thought she was experiencing side effects and reported to her supervisor and didn't work the 2 next days. She when back to work on Thursday (07Jan2021), she was sent to a covid clinic and took a rapid test and it came up positive. The patient underwent lab tests and procedures which included nasal swab (rapid antigen testing - SARS-CoV-2): positive on 07Jan2021. The events were reported as non-serious. No treatment was received for the events. Outcome of events were recovering. Information on the lot/batch number has been requested.

diebities; overweight; This is a spontaneous report from a contactable consumer. A 53-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiry date were not reported), via an unspecified route of administration on an unspecified date t a single dose for COVID-19 immunization. Medical history included 'dibeities'. The patient's concomitant medications were not reported. The patient experienced 'diebities' and was overweight on an unspecified date with outcome of unknown. The patient was not tested for COVID-19 post vaccination. Information on the Lot/batch number has been requested.

Received the first dose of the COVID Vaccine on 29Dec2020 and tested positive for COVID on 08Jan2021; Received the first dose of the COVID Vaccine on 29Dec2020 and tested positive for COVID on 08Jan2021; This is a spontaneous report from a non-contactable consumer. A 45-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK5730), via an unspecified route of administration on 29Dec2020 at single dose for COVID-19 immunisation. The patient medical history and concomitant medications were not reported. The patient received the first dose of the COVID Vaccine on 29Dec2020 and tested positive for COVID (Nasal Swab) on 08Jan2021. The outcome of the event was not recovered. No follow-up attempts are possible. No further information is expected.

12/31-mild facial weakness left forehead, left cheek/smile asymmetry.; 12/30-headache, left ear pain, left face pain/continued numbness tingling; 12/30-headache, left ear pain, left face pain/continued numbness tingling; 12/30-headache, left ear pain, left face pain/continued numbness tingling; 12/30-headache, left ear pain, left face pain/continued numbness tingling; 12/29-+fatigue, SOB, left sided lowback pain - severe; 12/29-+fatigue, SOB, left sided lowback pain - severe; 12/29-+fatigue, SOB, left sided lowback pain - severe; 19:00- chills, myalgias, cold sensation of b/l feet; 19:00- chills; 19:00- chills, myalgias; At 16:00- palpitations; At 16:00- palpitations, chest tightness; At 12:00 (within 4 hrs) began experiencing L sided facial and Left foot numbness/tingling and left hand.; Reported to health care provider, began steroids for early onset bell's palsy; This is a spontaneous report from a contactable other health professional (patient). An adult female patient (not pregnant) received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) lot number EL1284 via intramuscular in left arm on 28Dec2020 08:30 at single dose for COVID-19 immunization. Medical history included Crohns, asthma,

migraine, GERD (gastrooesophageal reflux disease), Known Allergies: pyridium. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient did not have COVID tested post vaccination and did not have COVID prior vaccination. Concomitant medication included mesalazine (PENTASA), famotidine (PEPCID), paracetamol (TYLENOL), calcium phosphate, colecalciferol (VITAFUSION CALCIUM), ascorbic acid, biotin, calcium, choline bitartrate, chromium, copper, folic acid, inositol, iodine, iron, magnesium, manganese, molybdenum, nicotinamide, pantothenic acid, phosphorus, potassium, pyridoxine, retinol, riboflavin, selenium, thiamine, tocopherol, vitamin b12 nos, vitamin d nos, zinc (MULTIVITAMIN) , biotin, colecalciferol (VITAMIN D). Reported Event: on 28Dec2020 at 12:00 (within 4 hrs) began experiencing L sided facial and Left foot numbness/tingling and left hand. At 16:00- palpitations, chest tightness. 19:00- chills, myalgias, cold sensation of b/l feet. 12/29-+fatigue, SOB, left sided low back pain - severe. 12/30-headache, left ear pain, left face pain/continued numbness tingling. 12/31-mild facial weakness left forehead, left cheek/smile asymmetry. Reported to health care provider, began steroids for early onset bell's palsy. On 08Jan2021 continue to have paresthesia of my left face, left hand, left foot, headache, mild left facial weakness/altered sensation. The events resulted in Doctor or other healthcare professional office/clinic visit. The patient received treatment received for the adverse events on 01Jan2021. The outcome of the events was recovering.; Sender's Comments: A possible causal association between administration of BNT162B2 and the onset of bell's palsy /facial paresis cannot be fully excluded, considering the plausible temporal relationship and the known adverse event profile of the suspect product. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate

Bell's palsy; Loss of taste; Can not close one eye, no muscle movement on one side of the face.; This is a spontaneous report from a contactable nurse. An adult female (not pregnant) patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), intramuscular in left arm on 05Jan2021 15:30 at single dose for COVID-19 immunization. There were no medical history or concomitant medications. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient did not have COVID tested post vaccination and did not have COVID prior vaccination. The patient had no known allergies. The patient experienced Half face paralysis, Bell's palsy. Loss of taste. Can not close one eye, no muscle movement on one side of the face. All on 08Jan2021 14:30 with outcome of unknown. No treatment was received.; Sender's Comments: A possible causal association between administration of BNT162B2 and the onset of Half face paralysis/Bell's palsy cannot be fully excluded, considering the plausible temporal relationship and the known adverse event profile of the suspect product. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate

He collapsed with left sided hemiparesis; Stroke; Rt basal ganglia hemorrhage w/ edema and mass effect.; Rt basal ganglia hemorrhage w/ edema and mass effect.; Low platelets, 114; His bp as high as

200s/100; Hand weakness; Myalgia; Fever; Severe fatigue; This is a spontaneous report from a contactable physician. A 58-year-old male patient received first dose of bnt162b2 (Pfizer BioNTech COVID vaccine), intramuscularly on 16Dec2020 at a single dose for COVID-19 immunization. Medical history included hypertension with reported med noncompliance in the last few months due to stress. Concomitant medication included hypertension medications in two weeks. The patient was presumed neg covid status prior to vaccine. He worked as a Pulm/critical care physician. He reported fever, myalgia, fatigue on 16Dec2020. Next day (17Dec2020), he took off from work due to his symptoms. The following day (18Dec2020), he came to work. He c/o ongoing severe fatigue & hand weakness in am. Staff noted him to be evaluating his hands during clinic. At 12:15, he collapsed with left sided hemiparesis. The reporter had suspicion for stroke. He was transported to the Emergency Room (ER), head CT showed Rt basal ganglia hemorrhage w/ edema and mass effect. Labs notable for Low platelets, 114 (unknown baseline) on 18Dec2020, normal coags on an unspecified date. BP recorded as 179/101, but it was noted in trauma room his bp as high as 200s/100. He had a history of hypertension with reported med noncompliance in the last few months due to stress. Patient was transferred for further care. Full course was unknown but had rebleed there with low plts. Adverse event (he collapsed with left sided hemiparesis) resulted in hospitalization (22 days), life threatening illness (immediate risk of death from the event), disability/incapacitating or permanent damage. Treatment was received for adverse events. Results of tests and procedures for investigation of the patient: on 18Dec2020, Nasal Swab test: negative. The outcome of events was not recovered. Unknown if any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient was not tested for COVID-19. Information on the lot/batch number has been requested.; Sender's Comments: Collapsed with left sided hemiparesis/suspicion for stroke are as consequences of basal ganglia hemorrhage with edema, which is caused by worsening of hypertension. Low platelet also contributes to brain hemorrhage. All these serious events are unrelated to the vaccine use. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

"Sore throat, severe chest tightness and pressure, very hard to breathe in, more than 30 minutes after covid vaccine, dizziness, headache, lightheadedness; severe chest tightness and pressure; very hard to breathe in, more than 30 minutes after covid vaccine; Dizziness /lightheadedness; headache; This is a spontaneous report from a contactable consumer (patient). A 35-year-old female (not pregnant at the time of vaccination) patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (lot number EL0142), via an unspecified route of administration at left arm on 09Jan2021 10:30 at single dose for COVID-19 immunization at a hospital. The patient's medical history included migraines, asthma, diabetes, sleep apnea, low immune system, post-traumatic stress disorder (PTSD), depression, panic attacks, insomnia, borderline personality disorder, and known allergies to medications, food, or other product (10 total). Concomitant medications included adult tetanus vaccine on 04Jan2021 received at right arm, for immunization (within 4 weeks prior to the COVID vaccine); first dose of botulinum toxin type a (BOTOX) on 06Jan2021 at single (31 shots in 7 muscle groups) for migraines (within 4 weeks prior

to the COVID vaccine); and clindamycin antibiotic for infection in finger (took within in two weeks). The patient was not diagnosed with COVID-19 prior to vaccination, and had not been tested for COVID-19 since the vaccination. On 09Jan2021 11:00, the patient experienced sore throat, severe chest tightness and pressure, very hard to breathe in, more than 30 minutes after COVID vaccine, ""dizziness/lightheadedness"", and headache. The above mentioned events resulted in emergency room/department or urgent care visit, and patient received breathing treatment, oxygen for over an hour for these events. The outcome of the events was unknown. The reporter considered the events as non-serious."

complete hearing loss at the right ear, 5 hours post injection, continued till now 3 days past injection, not resolved yet prior to report; This is a spontaneous report from a contactable physician. A 72-years-old male patient started to receive bnt162b2 (BNT162B2) Lot number# ek9231 intramuscularly on 06Jan2021 12:00 at single dose for covid-19 immunisation. Anatomical Location: Arm Right. Facility where the most recent COVID-19 vaccine was administered: Hospital. Medical history included diabetes mellitus, hypertension. The patient did not received any other vaccines within 4 weeks prior to the COVID vaccine. Concomitant medication included alprazolam (AZOR [ALPRAZOLAM]), metformin hydrochloride, sitagliptin phosphate monohydrate (JANUMET [METFORMIN HYDROCHLORIDE;SITAGLIPTIN PHOSPHATE MONOHYDRATE]), atorvastatin calcium (LIPITOR [ATORVASTATIN CALCIUM]). The patient on 06Jan2021 18:00 reported complete hearing loss at the right ear, 5 hours post injection, continued till now 3 days past injection, not resolved yet prior to report. The action taken was not applicable.; Sender's Comments: A possible contributory effect of suspect BNT162B2 on reported hearing loss cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

Allergic reaction to vaccine; tingling to upper lip and face; tingling to upper lip and face; red rash on bilateral forearms; Patient developed Bell's Palsy 2-3 days later; This is a spontaneous report from a contactable consumer. A 45-year-old non-pregnant female patient received the first dose bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EL1284), via an unspecified route of administration on 23Dec2020 at 14:30 at single dose in left arm for covid-19 immunization. Medical history included mitral valve prolapse from an unknown date, and allergies: Cephalosporins and nut (peanut derived). Concomitant medication included epinephrine (EPIPEN) 0.3MG/0.3ML, fluticasone propionate 50MCG/ACT nasal spray. On 23Dec2020 at 14:45, the patient experienced allergic reaction to vaccine, tingling to upper lip and face, red rash on bilateral forearms. Reactions resolved with no treatment. The patient developed Bell's Palsy 2-3 days later in Dec2020. Currently being treated with high dose steroids and acyclovir. All events required emergency room visit and physician office visit. All events were reported as non-serious by reporter. The outcome of event Bell's Palsy was not resolved, outcome of other events was resolved on an unspecified date. The patient was not diagnosed with COVID-19 prior to vaccination, and it was unknown if the patient has been tested for COVID-19 since the vaccination.

fever and chills; fever and chills; blood pressure was low, about 90/50; did not feel well; syncope episode; unconscious; This is a spontaneous report from a contactable other health professional. A 27-year-old non-pregnant female patient received the first dose of the bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot Number: EH9899), via an unspecified route of administration in the left arm on 08Jan2021 at 12:00 at a single dose for COVID-19 immunization; received at a nursing home/senior living facility. The patient did not receive any other vaccines within four weeks prior to the COVID vaccine. Medical history included COVID-19 from an unknown date and unknown if ongoing. No known allergies. Concomitant medications included unspecified birth control taken for an unspecified indication from an unknown date to an unknown date; within two weeks of vaccination. The patient experienced the following events and outcomes: syncope episode in Jan2021 with outcome of unknown, unconscious in Jan2021 with outcome of unknown, fever and chills on 09Jan2021 with outcome of unknown, blood pressure was low, about 90/50 on 09Jan2021 with outcome of unknown, did not feel well in Jan2021 with outcome of unknown; all of which were assessed as medically significant. The clinical course was reported as follows: the fever and chills began about one hour after vaccination (as reported). About 18 hours after the vaccination, the patient was getting up to take more paracetamol (TYLENOL) and did not feel well. The patient had a syncope episode in the bathroom (no issues as she sat on the floor before hand). The patient was unconscious for about 1-2 minutes. The patient's blood pressure several minutes later was low, about 90/50; however, the patient took the blood pressure measurement herself, so it may not have been exactly accurate. The patient underwent lab tests and procedures which included blood pressure measurement: low, about 90/50 on 09Jan2021. Therapeutic measures were taken as a result of fever. Prior to vaccination, the patient was diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19.; Sender's Comments: A possible causal association between administration of BNT162B2 and the onset of all reported serious events cannot be excluded, considering the plausible temporal relationship and the known adverse event profile of the suspect product. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

"Heart rate shot up to 170 with numbness of feet.; Heart rate shot up to 170 with numbness of feet.; Chest pain; feeling like I was going to vomit and faint; feeling like I was going to vomit and faint; This is a spontaneous report from a contactable other hcp (patient). A 25-year-old non-pregnant female patient received the first dose bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 06Jan2021 at 11:45 at single dose in left arm for covid-19 immunization. There was no medical history. Concomitant medication included valaciclovir hydrochloride (VALTREX), topiramate (TOPAMAX), lamotrigine (LAMICTAL), duloxetine hydrochloride (CYMBALTA), ziprasidone hydrochloride (GEODON). On 06Jan2021 at 12:30, The patient experienced heart rate shot up to 170 with numbness of feet, started to feel chest pain, and feeling like she was going to vomit and faint. The events required emergency room visit and were reported as serious per hospitalization. Heart rate at the hospital was 135-140 where two EKG were done and fluids were given. An x-ray of the heart was done and blood work was completed. The patient didn't receive treatment for the events. The patient didn't receive any

other vaccines within 4 weeks prior to the COVID vaccine. The patient was not diagnosed with COVID-19 prior to vaccination, and has not been tested for COVID-19 since the vaccination. The outcome of the events was resolved in Jan2021. Information on batch/lot number has been requested.; Sender's Comments: There is a reasonable possibility that the event ""feeling like she was going to vomit"" was related to BNT162b2 based on known drug safety profile. Based on the temporal relationship, the association between the other reported serious events with BNT 162b2 can not be completely excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate."

resident coded on 09Jan at 8am and expired; This is a spontaneous report from a contactable Other Health Professional. A 70-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EL0140), intramuscularly in left arm on 05Jan2021 15:15 at single dose for COVID-19 immunization. Medical history included DM2(Type two diabetes mellitus), CHF(congestive heart failure), open wound, wound infection, heart failure. Allergies to medications, food, or other products: none. Concomitant medications included unspecified products (List of any other medications the patient received within 2 weeks of vaccination: yes). If the patient received any other vaccines within 4 weeks prior to the COVID vaccine: Unknown. Facility where the most recent COVID-19 vaccine was administered: Nursing Home/Senior Living Facility. The resident coded on 09Jan2021 at 8 AM and expired. The patient died on 09Jan2021. An autopsy was not performed. AE resulted in: patient died. Death cause: unknown at this time. Was treatment received for the adverse event: Unknown. Prior to vaccination, was the patient diagnosed with COVID-19: No. Since the vaccination, has the patient been tested for COVID-19: No. Serious: Yes. Seriousness criteria-Results in death: Yes. Seriousness criteria-Life threatening: No. Seriousness criteria-Caused/prolonged hospitalization: No. Seriousness criteria-Disabling/Incapacitating: No. Seriousness criteria-Congenital anomaly/birth defect: No.; Sender's Comments: The old patient had diabetes mellitus, congestive heart failure, open wound complicated by infection, all these pre-existing medical conditions contribute to the patient death. More information including complete medical history, concomitant medications and event term details especially death cause and autopsy results are needed for a full assessment of the case. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate; Reported Cause(s) of Death: resident coded on 09Jan at 8am and expired

Saturday had. Sweating. Chills. Headache. Nausea.; Saturday had. Sweating. Chills. Headache. Nausea.; Saturday had. Sweating. Chills. Headache. Nausea.; Saturday had. Sweating. Chills. Headache. Nausea.; Sunday had emergency appendectomy for actuate appendicitis.; Friday at 3pm, the patient had numbness and tingling to left hand, lips and throat; Friday at 3pm, the patient had numbness and tingling to left hand, lips and throat; Friday at 3pm, the patient had numbness and tingling to left hand, lips and throat; Friday at 3pm, the patient had numbness and tingling to left hand, lips and throat; Friday

at 3pm, the patient had numbness and tingling to left hand, lips and throat; Friday at 3pm, the patient had numbness and tingling to left hand, lips and throat; Post surgery had allergic reaction unknown reason with head to toe rash; Post surgery had allergic reaction unknown reason with head to toe rash; This is a spontaneous report from a contactable nurse (patient). A 34-year-old female patient (pregnant: No) received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via intramuscular (lot number: EL1283) on left arm on 08Jan2021 at 6:30 AM at single dose for covid-19 immunisation. The relevant medical history included celiac, anemia, known allergies: Sulfa and Gluten. Concomitant medications were not reported. The patient received first dose of BNT162B2 via intramuscular (lot number: Ek5730) on left leg on 18Dec2020 at 11:00 AM at single dose for covid-19 immunisation. The patient previously took Codeine, fish oil and experienced allergies. Friday at 3pm, the patient had numbness and tingling to left hand, lips and throat. On Saturday the patient had sweating, chills, headache, nausea. On Sunday had emergency appendectomy for actuate appendicitis. Post surgery had allergic reaction unknown reason with head to toe rash. It was also reported that the adverse event started on 08Jan2021 at 03: 15 PM (as reported). The patient had 1-day hospitalization. The patient received treatment for the events. The adverse events resulted in Emergency room/department or urgent care. The events were reported as serious due to life threatening and hospitalization. The most recent COVID-19 vaccine was administered at hospital. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The outcome of the events was recovering.; Sender's Comments: A causal association between BNT162B2 and the reported events cannot be excluded based on a compatible temporal relation between vaccination and onset of events. Medications administered during appendectomy may confound reactions experienced post-surgery. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

passing out sensation; heart palpitations; sweating; diarrhea; This is a spontaneous report from a contactable consumer (patient's boyfriend). A female patient of an unspecified age received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for covid-19 immunization. The patient's medical history and concomitant medications were not reported. The reporter reported that symptoms were related to the use of Covid 19 vaccine. The patient received the first dose on 15Jan (as reported) and the day after developed sweating, passing out sensation, heart palpitations and this morning on 11Jan2021 when she woke up she had the same symptoms plus diarrhea. The outcome of the events was unknown. Information on the lot number/batch number was requested.

severe hypertension (190/100); flushing tachycardia; flushing tachycardia; blurred vision in the left eye; This is a spontaneous report from a contactable healthcare professional reporting for self. This 65-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via unspecified route of administration on unspecified date at single dose for COVID-19 immunisation. Medical history included ongoing underlying HTN (hypertension). Concomitant medications were not reported. The patient experienced AE following administration of first dose of vaccine of including:

severe hypertension (190/100), flushing tachycardia, and blurred vision in the left eye. These symptoms started 20minutes after administration. The patient stated her PCP thought that she had underlying hypertension and had since started her on medications. She was looking for guidance with regard to receiving the second dose. The outcome of events was unknown. Information about Batch/Lot number has been requested.; Sender's Comments: The administration of BNT162B2 might have played a contributory role in triggering the onset of serious event hypertension worsened, considering the plausible temporal relationship. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate

"he was in AFIB for about 3 hours after receiving his first dose of the COVID19 Vaccine; he noticed the rest of the day, right up to going to bed that he felt cold; This is a spontaneous report from a contactable consumer. A 66-year-old male patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot Number: EL1284) at arm, left upper, via an unspecified route of administration on 29Dec2020 06:15 at single dose for covid-19 immunisation. Medical history included atrial fibrillation (Afib) formally diagnosed around Jan2020. There were no concomitant medications. The patient reported he got the COVID-19 Vaccine at 06:15 on 29Dec2020 and had to sit for 15 minutes afterwards before he could leave. He said everything was fine, and he walked out to the hospital lobby, and was speaking with a work associate for 10 minutes before he headed to his car. When he got ready to leave, he got in his car, and started his car. He started driving home, and realized he was in AFIB. He did have an AFIB issue. His AFIB has been pretty well controlled for a year now, as long as, he didn't do something stupid. He had a moderately aggressive run of AFIB. He said his ""smart"" watch told him his heart rate was 117. His normal heart rate is around 60-70. He was in AFIB for about 3 hours. His typical runs of AFIB are considerably shorter. He only had a total of 2 episodes of AFIB in the last year. His prior AFIB episodes would have been about 4-5 minutes. The last time he had AFIB that lasted any length of time was when he was hospitalized for AFIB around Jan2020. He said at that time, he was hospitalized overnight for observation. He received medication during the hospitalization and his AFIB broke. He didn't remember what medications were given to him during the hospitalization. He said he had flutters before that hospitalization, but the flutters were always gone after a few minutes, so he never sought treatment because there would be nothing to treat. The patient reported he noticed the rest of the day on 29Dec2020, right up to going to bed that he felt cold. His house wasn't cold, and he didn't have a fever. He said the cold feeling went away during the night while he was sleeping. He said the cold feeling easily lasted for a 12 hours. He said the cold feeling could have been something else. The outcome of ""he was in afib for about 3 hours after receiving his first dose of the covid19 vaccine"" was recovered on 29Dec2020; of ""he noticed the rest of the day, right up to going to bed that he felt cold"" was recovered on 30Dec2020."

she was diagnosed with bilateral deep vein thrombosis (DVT) and pulmonary embolism (PE); she was diagnosed with bilateral deep vein thrombosis (DVT) and pulmonary embolism (PE); This is a spontaneous report from a contactable nurse (patient). A 22-year-old female patient received 2nd dose

of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot# EK9231), via an unspecified route of administration in left arm on 06Jan2021 13:45 at single dose for COVID-19 immunisation. Medical history included allergy to all fish, and clots. The patient was not pregnant. There were no concomitant medications. The patient previously received 1st dose of BNT162B2 (lot numer: EH9899) in left arm on 16Dec2020 13:45 for COVID-19 immunisation and experienced left sided lower back pain on 20Dec2020. No other vaccine received in four weeks. It was reported that the patient had the first covid vaccine on 16Dec2020 and on 20Dec2020 started with left sided lower back pain and then received the second on 06Jan2021 and then on 09Jan2021 11:00 her legs became blue and swollen and she was diagnosed with bilateral deep vein thrombosis (DVT) and pulmonary embolism (PE). The patient otherwise healthy and had never had covid. Other than the clots, she had no other health issues. The patient underwent lab tests and procedures which included nasal swab: negative on 09Jan2021. Events resulted in doctor or other healthcare professional office/clinic visit, emergency room/department or urgent care, hospitalization, and life threatening illness (immediate risk of death from the event), hospitalized for 2 days (in Jan2021). Adverse event treatment: heparin drip and xarelto at home. Recovered with lasting effects on an unspecified date of Jan2020. This case was reported as serious, serious criteria was life threatening, caused/prolonged hospitalization.; Sender's Comments: The underlying risk factors/predisposing condition of thrombotic diathesis have been assessed to have played a contributory role toward the events.

Resident expired on 12/30/20, dx cardiac arrest.

Resident expired on 1/2/21.

Per pt, sx onset began at 1520 with pruritus/hives of the scalp. She was in the post vaccine observation area at this time. At 1530, EE returned to vaccination room to alert staff of her reaction. Upon hearing her new onset cough, an assessment was performed immediately. Reported tingling and swelling of her lips, cough, minor difficulty breathing with mask on, facial flushing and feeling hot, and severe pruritus, especially on the scalp. 50 mg IM Benadryl administered and was taken to ED via wheelchair which is 7 minutes away. Epi Pen administered in ED and admitted overnight for observation d/t irregular HR and ST depression on monitor.

felt kind of tired; Tested positive for COVID after receiving the first dose of the COVID Vaccine; Tested positive for COVID after receiving the first dose of the COVID Vaccine; slight fever; body aches; headache; This is a spontaneous report from a Pfizer-sponsored program. A contactable nurse (the patient) reported that a 39-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EK5730) via unspecified route of administration on the left arm/shoulder on 22Dec2020 at single dose for COVID-19 immunisation. Medical history included gained weight since the pandemic started. The patient's concomitant medications were not reported. Patient received first dose of the vaccine. She had symptoms right after she got the vaccine the next day, on 23Dec2020. She had a slight fever, body aches, and a headache, which she never gets. She had these for about 2-3 days, they lingered around, and kicked back up around 26Dec2020/27Dec2020. She also felt kind of tired. She got covid 19 infection tested on 02Jan2021 and the results came back positive on 03Jan2021. Patient was calling to report this and see what to do about the second dose. She was

supposed to get her second dose next Tuesday. The outcome of events was unknown.; Sender's Comments: Based on the information currently available, a lack of efficacy with the suspected vaccine BNT162B2 cannot be completely excluded. However, individuals may not be protected until at least 7 days after their second dose of the vaccine. It is unlikely that the patient would have fully developed immunity due to the very short time lag between the first vaccine dose and the event onset.

received the first dose of the vaccine on 21Dec2020 and tested positive for Covid-19; received the first dose of the vaccine on 21Dec2020 and tested positive for Covid-19; This is a spontaneous report from a contactable consumer. A patient of unspecified age and gender received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number and expiration date was not provided) via an unspecified route of administration on 21Dec2020 at single dose for covid-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient received the first dose of the vaccine on 21Dec2020 and tested positive for covid-19 on 07Jan2021. The patient was isolated for 10 days. Outcome of event was unknown. Information on the lot/batch number has been requested.

COVID virus/on 29Dec2020 tested positive/symptoms of cough, chills, lost of taste and smell; COVID virus/on 29Dec2020 tested positive/symptoms of cough, chills, lost of taste and smell; This is a spontaneous report from a contactable other health professional (patient). A 57-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number EJ1685, expiration date: 31Mar2021), intramuscularly on 20Dec2020 17:43 at left deltoid, at single dose for vaccination. Medical history included asthma and diabetes. There were no concomitant medications. The patient received the first dose of vaccine on 20Dec2020. On 22Dec2020 she was exposed to Covid, on 28Dec2020 developed symptoms of cough, chills, lost of taste and smell, she had onset of COVID virus symptoms on 28Dec2020 with positive COVID result from COVID nasal swab test performed on 29Dec2020. She has already completed her Bamlanivimab infusion therapy to treat COVID virus on 31Dec2020. Her 2nd dose is due on 10Jan2020 and she wanted information on the use of antibody therapy with the Covid-19 vaccine. She asked if she should still get the second dose of Pfizer-BioNTech COVID-19 Vaccine as scheduled on 10Jan2021 relative to these events. She reported she still has COVID symptoms which have improved, but the symptoms she can't taste or smell are ongoing and persistent. Seriousness criteria: she thought it was serious but she was not injured or anything with it; she thought event was offset it by taking some medication and the Bamlanivimab infusion. In addition to Bamlanivimab infusion for treatment of the COVID virus she was also prescribed Azithromycin for 5 days started on 29Dec2020 which she completed; and Prednisone for 7 days started on 29Dec2020 which she stopped after 5 days of therapy because she did not like how it made her feel. The outcome of the event was recovering. Event relatedness between Pfizer-BioNTech COVID-19 Vaccine and COVID virus was unrelated.; Sender's Comments: Based on the information currently available, lack of efficacy of the suspected vaccine BNT162B2 cannot be completely excluded. However, individuals may not be protected until at least 7 days after their second dose of the vaccine. It is unlikely that the patient would have fully developed immunity due to the very short time lag between the first vaccine dose and the event onset.

positive COVID-19 test; positive COVID-19 test; positive COVID-19 test; This is a spontaneous report from a contactable pharmacist. A around 50-year-old male patient received bnt162b2 (PFIZER-

BIONTECH COVID-19 VACCINE, lot/batch number and expiration date not provided), via an unspecified route of administration on 22Dec2020 at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The physician reported that he knew the patient got the vaccine on 22Dec2020. On 02Jan2021, he tested positive to COVID-19. The outcome of the events was unknown. Information on the Lot/batch number has been requested.; Sender's Comments: The association between the event lack of effect (tested positive for COVID-19) with BNT162b2 can not be completely excluded.

Tufts of my hair came out by the handful - first time in my life I have experienced ANY hair loss! It is still ongoing and I am worried it will result in permanent baldness.

Cardiac arrest within 1 hour Patient had the second vaccine approximately 2 pm on Tuesday Jan 12th He works at the extended care community and was in good health that morning with no complaints. He waited 10-15 minutes at the vaccine admin site and then told them he felt fine and was ready to get back to work. He then was found unresponsive at 3 pm within an hour of the 2nd vaccine. EMS called immediately worked on him 30 minutes in field then 30 minutes at ER was able to put him on life support yet deemed Brain dead 1-14-21 and pronounced dead an hour or so later

He died nine hours later.

Patient died on 1/21-2021

1/7/2021 @ 5:00 a.m. patient woke up and couldn't move her right side (neck, arm and leg). Sister helped dress her and drove her to the hospital. During the ride the hospital the patient had 2 seizures and a 3rd seizure in the ER at the hospital. Patient states she has never had multiple, back to back seizures before. States she hasn't had a seizure for 2 years. EEG was done. Was released from the hospital on 1/9/2021 and to have outpatient MRI of head, shoulder, c-spine. Does not have full range of motion of right neck, and arm, hand and fingers and is painful. 1/14/2021 - full release back to work on 1/14/2021.

Resident had been monitored and had shown no signs or symptoms of any kind until 2 pm on 1/14/2021. Resident was found in the floor of her room. She had fallen and was having a seizure, temperature was 99.7F and Oxygen saturation was 82%.

Resident found unresponsive and without pulse at 05:45am.

on 1/14/21 patients HR 155 at 0800 per patient's home pulse ox device. arrived at ER, HR 148 at 1130. Continued to stay up even after 2 doses of 10mg iv push Cardizem and one dose of 30mg Cardizem. Cardizem drip started, heparin drip started, patient admitted to hospital

"12/23/2020: 2 hr after injection, patient noted swollen lymph nodes, nausea, room spinning (motion sickness-like) sx. Stayed home from work that day and slept. 12/24/2020: ""typical injection site pain"" 12/30/2020: injection site hot, itchy, welts 12/31/2020: area of welts doubled in size to entire upper left arm; throat starting to close up"

Patient presented herself to LPN slurring words and 'not herself'. Upon evaluation, patient denied drinking alcohol, knew she was not able to speak correctly and visibly frustrated . With great difficulty she was able to communicate that she had a headache and was slightly dizzy. Failed FAST and does have a history of CVAs. EMS called and patient was taken to ER where they admitted her for observation post Stroke. Per the hosp nurse, patient received tPA treatment and will be moved to step-down unit when a bed is available.

On 1/11/21 noted with headache, nausea/vomiting, severe melaise. On 1/12/21 resident expired.

Vaccination given 1314 and sent to waiting room for monitoring. Began to have itching at 1325. PO benadryl administered. Then with throat swelling. Epinephrine administered by EMS/Fire at 1:32pm: 0.5mg IM right arm. 1342 improving 1350 itching/throat swelling returning while EMS/Fire on phone with medical director. 1352 second dose of epinephrine administered by De Pere EMS/Fire: 0.5mg IM left arm Medical Director on site for evaluation. Client given option to transport to hospital or stay for monitoring with EMS/Dr. Condition improving, chose to stay for monitoring. Client improved and up walking halls 1513 Client cleared to be released home via private transport

EXTREME LETHERGY, NAUSEA, REFUSING TO EAT OR DRINK, ELEVATED HEARTRATE, FATIGUE, ELEVATED TEMP

Day after vaccine : mild shortness of breath, sensation of swelling in my throat/neck area. Took Benadryl 50mg before bedtime. 2 days after vaccine: woke up with voice changes, coughing/choking with speaking. Used epipen once, felt full relief for about 1-2 hours. Trouble speaking again. Then went to ER, had epipen again twice, over two hours, Benadryl 50IV and Pepcid and steroids. Sitting in the ER now debating admission. Likely being admitted., home epipen are too expensive to treat q2h by myself.

Generalized myalagias, weakness, vertigo, nausea with emesis, one episode of urinary incontinence. Admitted for observation. Patient improved without intervention with some residual dizziness on day two of symptoms.

Dec 24 felt light headed and loss of appetite, Dec 25, fever 103 and chills, Dec 26 Team member Covid hub had me do a Covid test, negative result, continue high fever, no appetite, chills and body ache, Health Hub contacted me daily with app to review symptoms, Dec 27-29 continued symptoms, unable to eat and little bit of water intake, Dec 29 appointment made with Health Urgent Care, received text from Urgent Care cancelling appointment and instructed to take sips of water and Tylenol that I was having an immune reaction to vaccine. Dec 29 virtual appointment with PCP continued symptoms, Dec 31 repeat of COVID swab along with Flu swab both negative, Jan 2-3 hospital admission for abnormal labs, jaundice, dehydration, Sodium/Potassium and Magnesium boluses given, and work up for infectious process was negative. Discharged to home Jan 3 with low grade fever, dry mouth, dry eyes, nausea, body ache and continued loss of appetite. Jan 4-7 continued worsening jaundice and appetite with low grade fever, GI Clinic consulted at Health Clinic, PCP in daily contact, repeat liver function labs on Jan 8 showed worsening labs. Jan 9-12 afebrile, started Ursodiol, low appetite better energy, continue dry mouth, GI appointment Jan 12 with plan to repeat liver functions on Jan 15, jaundice improved and able to eat liquids. No Tylenol or antipyretic taken since Jan 3 due to liver function tests.

Developed chest pressure 8.5 hours after vaccine, unrelieved after 3 hours, went to ED, elevated troponin, EKG changes. Admitted to hospital low grade fever next day

I developed severe abdominal pain 3 days after injection that turned out to be pancreatitis

71yo female resident who died after receiving Pfizer BioNTech vaccine. On 1/14/2021, VS taken at 10am, B/P 99/60, O2 sats, 95% (trach w/O2). At 11:30am, Patient showed no s/sx of distress, A&Ox3. At 11:50am, a nurse went to perform a COVID test and assessment (the facility is experiencing an outbreak), and found the patient unresponsive on the bathroom floor. CPR was immediately started; no shock advised per AED; 12:15pm EMS arrived and took over. At 12:38pm, EMT called time of death.

Has underlying dementia and often with difficulty eating. 1 week after immunization she developed a stroke with left sided weakness and difficulty swallowing. Comfort measures instituted. Not sure if this is related to the vaccine, but thought I should report

"83yo female resident who died after receiving Pfizer BioNTech vaccine. On 1/14/2021, the patient reportedly got up in the middle of the night with c/o feeling ""blah"", restlessness, and nausea. VS normal, no other s/sx. At 4:15am, the patient was asked to go back to bed, assisted by a nurse and GNA. At 6am, GNA was going to do morning VS and found the patient unresponsive, no pulse, no respirations. GNA notified the nurse. At 6:03am, CPR started and EMS called. At 6:15am, EMS arrived and took over. At or around 6:30am, EMT called time of death"

I had fatigue, headache, pain, weakness and I was so miserable decided to go to ER on (12/24/20) and then was transferred to hospital admitted (12/25/20) one day - discharged on 12/26/20 at night

Staff reported that he wasn't being himself. He was leaning more towards the right. Had symptoms similar to Bell's Palsy, some right sided facial droop, right eyelid drooping. On CT right maxillary sinusitis, ventriculomegaly.

Shortness of breath Chest pain Ongoing since

Fever to 100.4 on day 1 after vaccine, to 101.9 on day 3 after vaccine. Acute kidney injury (creatinine rose from 1.73 to 2.43) requiring hospitalization.

After first vaccine i experienced fatigue, body aches, headache and nausea for 2 days and injection site pain for two weeks. After second Vaccine given at 9:55am. tingling of feet for about 20 mins, 30 mins after the vaccine. Two hours later fatigue, body aches, headache and nausea began. At 0030 1/12/2021 I woke up with severe chills and left chest pain, temp was 101.6 and heart rate was 160. I began to see black and chest pain was severe feeling like i was having a heart atack and was going to pass out so i called 911. I then began to get short of breath and got numbess on my legs, left arm and left side of neck. Chest pressure/pain radiated to left arm and neck. I was taken by the ambulance to hospital. Arrived around 0130. My heart rate sustained at 140s in the ER so I was admitted at 0530 am. My D Dimer was a bit elevated as well as my lactic so I was given a bolus of fluids plus maintenance. I had a CXR done, CTA chest(negative for PE), UA, Labs, entire cardiac workup including an ECHO during my admission. I also began to have loose stools and wrist joint pain. MY heart rate sustained at 125-147 for

about 30 hours. Fevers on and off. After everthing was negative we determined this was secondary to the covid 19 vaccine. I was discharged 1/13/2021 at around 1:30 pm. My heart rate is still not at baseline which is 87-90. I'm 100-130 and still get very fatigued with a simple slow walking. Still having tachycardia, fevers, body aches, joint wrist pain, chest discomfort and headaches. My potassium was 3.0 at discharge so will be needing labs in a week. Also bruised a little different than I usually do with lab draws so keeping an eye on them and will be checking my platelets again in a week. Ive been taking tylenol for my fever and pain and ativan for any anxiety when my heart rate goes up. (treatment during hospital stay was normal saline bolus, nomal saline maintenance fluids at 150 cc/hr, tylenol, ativan, ice packs, rest)

Fever, joint pain, weakness. Pain at the injection site.

No reactions immediately after vaccine was given. Resident has dementia, has had multiple hospitalizations related to a renal stone recently. Had a tooth that was bothering her, went to see her dentist and it was extracted on 1/6/21. On 1/10 they noted feet and ankles are dark purple with white splotches appears to be mottling. Minimally responsive to voice and touch. Not eating. Compassionate visit with family. Family did not want hospice, did not feel it was needed, said, what more could they do for her than you're already doing? On 1/11 at 1950 was determined to be deceased.

Anaphylaxis- throat tightness , nausea , rash , pruritis , chest tightness, wheezing . 9-11 called epinephrine x 2 , decade on , IV Benadryl , duo-nebs, famotidine, admission to icu high dose prednisone , nebulizers , zofran , duo-neb nebulizers

Had no immediate issues with the vaccine. He had returned from the hospital on 12/21 and had some concerns about his weight which were shared with his physician on 1/4/21. On 1/5/21 had a visit with his cardiologist for a pacemaker check. On 1/8/21 staff were called to his room, he was on the floor, bluish skin color. No vital signs found, no heart rhythm heard at 2200.

Had COVID infection 10 days after the getting the vaccine; Had COVID infection 10 days after the getting the vaccine; This is a spontaneous report from a contactable physician. A 48-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number: EK5730), intramuscular in right arm on 24Dec2020 09:00 at a single dose for Covid-19 immunization. Medical history was reported as none. The patient's concomitant medications were not reported. The patient was not pregnant at the time of vaccination. Patient did not receive any other vaccines within 4 weeks prior to Covid vaccine. The patient was not diagnosed with Covid-19 prior to vaccination. Patient has no allergies to medications, food, or other products. Physician would like to know if her patient can receive second dose of vaccine. Patient received vaccine 10 days ago. On 05Jan2021, the patient had Covid infection 10 days after the getting the vaccine. No treatment was received for the event. Patient tested positive for Covid after receiving vaccine. The patient underwent lab test which included nasal swab: positive on 04Jan2021. The outcome of the event was recovering.; Sender's Comments: Based on the information available, a possible contributory role of the suspect BNT162B2 cannot be excluded for the reported COVID 19 infection based on the known safety profile. However the short duration of 10 days since the vaccine first dose is given it is unlikely patient would have fully developed immunity.

Caller received the first dose of covid 19 vaccine and tested positive for covid.; Caller received the first dose of covid 19 vaccine and tested positive for covid.; Caller received the first dose of covid 19 vaccine and tested positive for covid.; This is a spontaneous report from a Pfizer-sponsored program Pfizer First Connect. A contactable other health professional (patient) reported that a female (age: 22; unit: not reported) patient of an unspecified age received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient received the first dose of COVID 19 vaccine and tested positive for COVID on an unspecified date. She was under quarantine and wanted to know when and if she should get the second dose. Due date for second dose is 11Jan2021. The patient underwent lab tests and procedures which included Covid-19: positive on an unspecified date. The outcome of event was unknown. Information on the lot/ batch number has been requested.; Sender's Comments: The association between the event lack of effect (Covid-19 test positive) with BNT162b2 can not be completely excluded.

had her 1st dose of Covid vaccine yesterday and started experiencing all expected side effects today including lost of smell and taste/ Rapid PCR Test which came back positive; had her 1st dose of Covid vaccine yesterday and started experiencing all expected side effects today including lost of smell and taste/ Rapid PCR Test which came back positive; This is a spontaneous report from a contactable nurse (patient). A female patient of an unspecified age received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date not provided), via an unspecified route of administration on 07Jan2021 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient had her 1st dose of COVID vaccine yesterday, 07Jan2021 and started experiencing all expected side effects today (08Jan2021) including loss of smell and taste. She also had a Rapid PCR test done today which came back positive. She wanted to know if this could be a false positive result from the vaccine. The outcome of the events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of events Drug ineffective and COVID-19 cannot be totally excluded. The case will be reassessed if additional information becomes available.

It felt like a viral meningitis; arm soreness; feel some tension; migraine headache; body started shaking; chills/Rigors; temperature 104; I had sensitivity that I never had; headache; photophobia; Sinophobia; paresthesia/tingling sensation along my upper extremity; I felt like I was freezing; I didn't feel comfortable; vertigo; nausea; hard time to focus; This is a spontaneous report from a contactable other health professional (patient himself). A male patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration in Jan2021 at single dose for covid-19 immunization. The patient's medical history and concomitant medications were not reported. He didn't have any allergies. He was in good health, no underlying issue. He never had a surgery. In Jan2021, patient got the vaccine last night around. It started with arm soreness. Around 10:00 am he started to feel some tension, migraine headache. Around 11:00 he felt his body started shaking. He had chills, rigors and temperature 104. For 5-6 hours he had sensitivity that he never had. Patient had a headache, photophobia, sinophobia, paresthesia and tingling sensation along his upper extremity. he

felt like he was freezing. He didn't feel comfortable. It resolved afterwards, he felt no weakness, no facial paralysis. It felt like a viral meningitis. He also had vertigo, nausea and hard time to focus. Outcome of events were unknown. Information about lot/batch number has been requested.; Sender's Comments: Based on the temporal relationship, the association between the event viral meningitis with BNT162b2 can not be fully excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

"I have latent TB and am diagnosed with herpes 1 and 2; I have latent TB and am diagnosed with herpes 1 and 2; This is a spontaneous report from a contactable other health professional. A female patient of an unspecified age received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 11Jan2021 at single dose for covid-19 immunization. Patient had the first dose of the vaccine on 11Jan2021 and she/he had pre-existing conditions. A long time ago, she/he had 2 tachycardia episodes and was sensitive to epinephrine. Patient had latent TB and was diagnosed with herpes 1 and 2 in Jan2021. Outcome of events were unknown. Information about lot/batch number has been requested.; Sender's Comments: The association between the events ""latent PTB and Herpes 1 and 2"" with BNT162b2 can not be completely excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate."

difficulty breathing and stridor; difficulty breathing and stridor; noises on inspiration; dizziness; headache; sore throat; Anaphylaxis developed within 2 hours of injection; This is a spontaneous report from a contactable other health professional (patient). A 57-year-old female patient (not pregnant) received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (lot number EL0142), via an unspecified route of administration in arm left on 08Jan2021 09:00 at single dose for covid-19 immunisation. Medical history included Idiopathic Angioedema, Hypothyroidism. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient did not have COVID tested post vaccination and did not have COVID prior vaccination. The patient's concomitant medications were not reported. Reported Event: Anaphylaxis developed within 2 hours of injection. 9:00 am injection; 9:05 am Developed sore throat, 9:20 am Developed dizziness and headache, 10:00 am developed noises on inspiration, 10:20 am Presented to Emergency Services, 10:40 am IV (intravenous) diphenhydramine (BENADRYL) and dexamethasone (DECADRON), 10:45 am difficulty breathing and stridor, 11:00 am intramuscular Epinephrine, 11:10 am Racemic Epi Nebulizer, 11:20 am Breathing improved, 14:00 Discharged home. The adverse events result in Emergency room/department or urgent care. The outcome of all the events was recovering.; Sender's Comments: A possible causal association between administration of BNT162B2 and the onset of anaphylaxis reactions considering the plausible temporal relationship and the known adverse event profile of the suspect product. The underlying predisposing condition included Idiopathic Angioedema. The impact of this report on the benefit/risk profile of the

Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Receives dose #1 of the covid vaccine and contracts covid prior to dose #2; Receives dose #1 of the covid vaccine and contracts covid prior to dose #2; This is a spontaneous report from a contactable physician via Pfizer sales representative. This physician reported similar events for two patients. This is 2nd of two reports. A patient of unspecified age and gender received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot/batch number and expiry date were not provided) solution for injection, via an unspecified route of administration on an unspecified date at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. It was reported that patient received dose #1 of the COVID vaccine and contracts COVID prior to dose #2 on an unspecified date. The patient underwent lab test which included Covid-19 test in which he/she tested positive on an unknown date. Outcome of the events was unknown. Information about batch/lot number has been requested.; Sender's Comments: A causal association between BNT162B2 and the reported events cannot be excluded based on a compatible temporal relation between vaccination and onset of events. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate. ,Linked Report(s) : US-PFIZER INC-2021012928 Same reporter/drug/event, different patient

"My heart rate, I was like in AFib; very high fever of 103; dizzy, light headed; arms sore; exhausted like an extreme fatigue; palpitations; This is a spontaneous report from a contactable consumer (patient). A 38-year-old female patient received the bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot Number: EH9899), via an unspecified route of administration on 30Dec2020 at 38-years-old at a single dose for COVID-19 immunization. Medical history included blood clotting disorder from an unknown date and unknown if ongoing. The patient experienced the following events and outcomes: my heart rate, I was like in AFib (medically significant) on 31Dec2020 with outcome of recovering, very high fever of 103 (non-serious) on 31Dec2020 with outcome of unknown, dizzy, light headed (non-serious) on 31Dec2020 with outcome of unknown, arms sore (non-serious) on 31Dec2020 with outcome of unknown, exhausted like an extreme fatigue (non-serious) on 31Dec2020 with outcome of not recovered, palpitations (non-serious) on 31Dec2020 with outcome of not recovered. The clinical course was reported as follows: The patient stated, ""the day after the shot I got a very high fever of 103. I was dizzy, lightheaded. My heart rate I was like in AFib, it was going from 60s to 50s all over the place. And this was the next day after the vaccination. That evening nothing my arms was just sore. But the next day all of these side effects just started in and even still today I just feel so exhausted like an extreme fatigue and I am still getting like palpitations."" The patient stated, ""So I went to urgent care and they check my vitals and stuff and when they wanted me to send me to the hospital. But I told them I will get a ride and I go by myself just because I didn't want, capable of an ambulance ride and I ended up just going home because I couldn't get a hold up anybody. So, I came home and took my blood thinner

medication because I do have blood clotting disorder."" In regard to the outcomes of the events, the patient stated, ""I am not experiencing all of them still definitely my heart is much better. I am still getting palpitations but nothing near how it was that first day. I am experiencing extreme fatigue."""

received the vaccine on 17Dec2020 the next dose is today but during this time she was positive for covid; received the vaccine on 17Dec2020 the next dose is today but during this time she was positive for covid; This is a spontaneous report from a Pfizer-sponsored program, Pfizer First Connect. A contactable nurse reported for herself, a female patient of an unspecified age who received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date unknown), via an unspecified route of administration on 17Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. It was reported that patient received the vaccine on 17Dec2020, the next dose is today (07Jan2021) but during this time she was positive for covid since an unspecified date. She was asking if she would take the second vaccine or if she needed to be revaccinated with the first dose. She was also asking what should she do. The outcome of the events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: The association between the event lack of effect (positive for COVID) with BNT162b2 can not be fully excluded.

"received first dose of bnt162b2/ symptoms started on the 26th (26Dec2020) but did not test positive until the 29th (29Dec2020); received first dose of bnt162b2/ symptoms started on the 26th (26Dec2020) but did not test positive until the 29th (29Dec2020); This is a spontaneous report from a Pfizer-sponsored program via a contactable nurse (patient). A 61-year-old female patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE; lot/batch number: VAC0002881; expiration date not provided), via an unspecified route of administration on 17Dec2020 at SINGLE DOSE for COVID-19 immunisation. Patient's medical history included hypothyroidism and osteoporosis from unknown dates, both ongoing. Concomitant medications included levothyroxine for hypothyroidism and alendronate sodium (FOSAMAX) for osteoporosis. Patient reported that her symptoms started on the 26th (26Dec2020) but did not test positive until the 29th (29Dec2020). Patient further stated ""She received the first dose of Pfizer vaccine last 17Dec (17Dec2020) and 26Dec she was positive with COVID (later clarified of tested positive on 29Dec2020) because of someone else, it seems that it has been transferred, the virus has been transferred to her and then after a few days she got fully recovered, no symptoms, just fully recovered. She is just asking if she really need the second dose of vaccine if she is fully recovered right now."" It was reported that patient did not receive treatment for the event. Laboratory test included COVID-19 virus test on 29Dec2020 with positive result. Outcome of the event was recovered.; Sender's Comments: Based on the information currently available, lack of efficacy of the suspected vaccine BNT162B2 cannot be completely excluded. However, individuals may not be protected until at least 7 days after their second dose of the vaccine. It is unlikely that the patient would have fully developed immunity due to the very short time lag between the first vaccine dose and the event onset."

Tested positive for Covid, 10 days after receiving the vaccine; Tested positive for Covid, 10 days after receiving the vaccine; This is a spontaneous report from a contactable consumer. A patient of unspecified age and gender started to receive bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE; Solution

for injection, lot number and expiry date were not reported), via an unspecified route of administration on an unspecified date at a single dose for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient tested positive for COVID on an unspecified date 10 days after receiving the vaccine. The patient underwent lab tests and procedures which included Covid test: positive on an unspecified date. The outcome of the events was unknown. The information on the batch/lot number has been requested.

coughs once in a while, may be a nervous cough every 40 min; voice hoarse; tested positive for Covid-19; tested positive for Covid-19; didn't feel well at all; bad headache; dry cough; This is a spontaneous report from a contactable consumer who reported for himself, a 70-year-old male patient who received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, lot number and expiration date unknown), via an unspecified route of administration on 06Jan2021 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient stated that he received the first dose of the Pfizer-BioNtech Covid-19 vaccine on Wednesday, 06Jan2021, and on that day he had no problem. On Thursday, 07Jan2021, he started experiencing dry cough. On Friday, 08Jan2021, he didn't feel well at all and had a bad headache. On Saturday, 09Jan2021, he felt better but he tested positive for Covid-19. Today, 11Jan2021, he stated he feels good, he coughs once in a while, may be a nervous cough every 40 min. He had not experienced fever or chills, he breathes well, he can hold his breath for 5-10 seconds, no chest pain or congestion, but his voice was hoarse. Patient wanted to know if this has been reported before, and wanted to know how long should he test himself again for Covid-19. The events were reported as non-serious. The outcome of the events was unknown. Information about lot/batch number is requested.

I was exposed to Covid-19 4 days after and tested + 9 days after dose #1; I was exposed to Covid-19 4 days after and tested + 9 days after dose #1; I was exposed to Covid-19 4 days after and tested + 9 days after dose #1; This is a spontaneous report from a contactable female nurse (patient) via Pfizer sponsored program. A female patient of an unspecified age received bnt162b2 (BNT162B2) on 26Dec2020 at single dose for Covid-19 immunisation. The patient medical history and concomitant medications were not reported. The patient was exposed to Covid-19 4 days after on 30Dec2020 and tested + 9 days after dose #1 on 04Jan2021. The outcome of events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Based on the information available, a possible contributory role of the suspect products cannot be excluded for the reported event of positive for corona virus infection for the lack of efficacy of the vaccine. However, based on the mechanism of action of the vaccine, it is unlikely the patient would have fully developed immunity for the vaccine to be effective, due to the number of days passed since the vaccine is given. Case will be reevaluated based on follow-up information

positive for covid19; positive for covid19; got or felt sick; This is a spontaneous report from a contactable physician reported for self and consumer. This 51-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on Dec2020 at single dose for covid-19 immunisation. As soon as patient got vaccine she got or felt sick in Dec2020 and had the test and finds out she was positive, so she stays home two weeks and doesn't have no symptom at all and wants to know when has to take a test. The day after the patient developed symptoms thought it was the

vaccine, but the symptoms continued for 2-3 days, the 3rd day the patient got herself tested. The patient was positive for covid19 at the time had the shot/ as soon as she got vaccinated she became positive. The patient hasn't had any symptoms for the past 2 weeks. The patient was scheduled to get retested. The patient was scheduled for 2nd dose of vaccine. The patient asked if there are any risks since developed covid the day after getting the vaccine. What if miss today. The patient wanted to know time after having no symptoms past two weeks, when she has to take a test. Outcome of the events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Test positive for covid19 found as soon as following the vaccination, no adequate effect of the suspect vaccine thus could be reasonably achieved to protect from the targeted infection/disease due to the very short time lag.

I've got the 1st dose of vaccine and then unfortunately, in the interim, I started feeling sick and tested positive for Covid.; I've got the 1st dose of vaccine and then unfortunately, in the interim, I started feeling sick and tested positive for Covid.; This is a spontaneous report from a Pfizer-sponsored program, received from a contactable consumer (patient). A male patient of an unspecified age received his first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot/batch number and expiry date were not provided) solution for injection, via an unspecified route of administration on an unspecified date at a single dose for Covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient reported he got the 1st dose of the vaccine and then unfortunately, in the interim, he started feeling sick and tested positive for Covid. The patient underwent Covid test and resulted positive on an unknown date. Outcome of the event was unknown. No follow-up activities are needed. No further information is expected.

13 people, who were applied the vaccine previously, were corona positive after a week; 13 people, who were applied the vaccine previously, were corona positive after a week; This is a spontaneous report from a non-contactable consumer. This consumer reported similar events for 13 patients. This is 12th of 13 reports. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Solution for injection; lot number and expiration date: not known), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. It was reported that 13 people, who were applied the vaccine previously, were corona positive after a week on an unspecified date. The outcome of the events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021018407 same reporter, similar suspect drug and event; different patient

Positive COVID-19 test with symptoms; Positive COVID-19 test with symptoms; This is a spontaneous report from a Pfizer-sponsored program, from a contactable nurse (patient). A 35-year-old female patient (weight 55.79 kg, height 160 cm) received the first dose of BNT162B2 (Pfizer-Biontech Covid-19 Vaccine, Lot. EK5730) intramuscularly, in the left deltoid, at single dose, on 23Dec2020 at 12:30, for COVID-19 immunisation. The patient had not received any other vaccines within 4 weeks prior to the BNT162B2 vaccine. Relevant medical history and concomitant medications were none. On 25Dec2020, the patient felt extremely tired (fatigue). On 28Dec2020, the patient had headache and minor cough noticed. On 29Dec2020, the patient experienced back pain and she said that it felt like sunburn soreness

more than anything else. She said that she literally slept 3 days in a row (29Dec2020, 30Dec2020, and 31Dec2020). On 31Dec2020, the patient lost her sense of smell and developed dizziness. On 01Jan2021, the patient experienced nausea and lost her sense of taste. COVID-19 virus test was found positive on 01Jan2021.The patient recovered from back pain, sunburn and sleepy on 31Dec2020, recovered from tiredness on 01Jan2021, recovered from nausea and dizziness on 06Jan2021. Clinical outcome of the events, smell loss, cough, headache, and loss of taste was recovering. Final clinical outcome of positive COVID-19 test with symptoms was unknown at time of this report. The case was assessed as serious (medically significant). She is scheduled to get 2nd dose of BNT162B2 (Pfizer-Biontech Covid-19 Vaccine) on 13Jan2021 and is wanting to know if she is supposed to get it.; Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of events Drug ineffective and COVID-19 cannot be totally excluded. The case will be reassessed if additional information becomes available.

Received Covid vaccine and tested positive for Covid 10 days after; Received Covid vaccine and tested positive for Covid 10 days after; This is a spontaneous report from a contactable consumer. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number and expiry date were not reported), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient received COVID vaccine and tested positive for COVID, 10 days after on an unspecified date. The patient underwent lab tests and procedures which included sars-cov-2 test: positive on an unspecified date. The outcome of the events was unknown. Information on the lot/batch number has been requested.

started with left sided lower back pain; This is a spontaneous report from a contactable Nurse (patient). A 22-year-old female patient received the first dose of BNT162B2 (lot number: EH9899), via an unspecified route of administration at left arm on 16Dec2020 13:45 at single dose for covid-19 immunization. Medical history included allergies for All fish. The patient's concomitant medications were not reported. The patient had the first covid vaccine on 16Dec2020 and on 20Dec2020 started with left sided lower back pain. The event resulted in Doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care, Hospitalization (2 days), Life threatening illness (immediate risk of death from the event). The patient received the Heparin drip and xarelto at home for the event. The patient was not pregnant. The patient received the covid test post vaccination on 09Jan2021. Test type was Nasal Swab. The result was negative. The outcome of the event was recovered with sequel on unspecified date.; Sender's Comments: From the information provided it is unclear what is the nature of the reported event and what are the reasons that have put the subject at immediate risk of death. The event is considered possibly related to the suspect product based on the positive temporal association.

throat closing up; struggled the breath; This is a spontaneous report from a contactable consumer (patient). A 44-year-old female patient (non-pregnant) received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: Pfizer EL 3302), via an unspecified route of administration on 09Jan2021 07:30 am at single dose at left arm for covid-19 immunization. Medical history included diabetes, high blood pressure, allergies. The patient's concomitant medications were

not reported. Patient didn't receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient was not diagnosed with COVID-19 prior to vaccination. Since the vaccination, patient has not been tested for COVID-19. On 10Jan2021 14:30, patient woke up with throat closing up and struggled the breath. Patient immediately drank a dose of diphenhydramine hydrochloride (BENADRYL). Patient did that two more time in the evening of 10Jan2021. Patient called the doctor in the morning. Events were considered serious per life-threatening. The adverse events resulted in doctor or other healthcare professional office/clinic visit, life threatening illness (immediate risk of death from the event). Patient received treatment liquid diphenhydramine hydrochloride, epinephrine (EPI-PEN) for events. Outcome of events was recovered in Jan2021.

chills; body aches; fever; flu like symptoms; headache; was drenched in sweat; This is a spontaneous report from a contactable nurse (patient). A 46-year-old female patient received the second dose of BNT162b2 (lot: EL1283), via an unspecified route of administration in left deltoid on 09Jan2021 15:30 at single dose for covid-19 immunization. Medical history included asthma from Dec2019 and ongoing, insomnia, hypertension. Concomitant medication included ongoing hydrochlorothiazide, metoprolol tartrate (LOPRESSOR HCT) for Hypertension. The patient previously took lopressor and experienced edema. The patient previously received the first dose of BNT162b2 (Lot number: EK5730), intramuscularly in right deltoid at single dose on 19Dec2020 for covid-19 immunization. The patient experienced fever, chills, flu like symptoms, headache all day long on 10Jan2021. The above events were reported as serious as medical significant. No nausea or diarrhea. She had chills and was drenched in sweat on 10Jan2021. She woke up at 10:30 am with chills, body aches on 10Jan2021. Last night at 10 pm she finally fell asleep. She woke up this morning (11Jan2021) and felt fine. The outcome of the event sweating was unknown, other events was recovered on 11Jan2021.; Sender's Comments: Based on a close temporal relationship there is a reasonable possibility of an association between the events and the product. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

Moderna COVID-19 Vaccine At 2 PM I went blind in my left eye. Went to emergency room at Hospital Was told I have Blood clot in my eye causing the blindness and Ophthamologist says it will probably be permanent

At approximately 10:30pm on 1/14/2021, resident was noted to have a rash on her face, hands, arms, and chest. VS:100.2, 113, 20,108/59, 84% room air. applied nasal cannula at 4-L, telephoned Physician orders 6mg Decadron one time order, a second set of Vitals , reads 99.3, 110, 20, 106/60, 90% on 4-L N/C. On coming shift advised. At approximately 2:00am on 1/15/2021, resident congested and coughing. BP 151/70, pulse 124, temp 98.1 forehead, resp 20 and pulse oc 79% on 3L. At approximately 2:30am PRN cough syrup and breathing tx. Resident's condition began to worsen with breathing tx. This LPN updated at 0248 doctor on resident's condition. Doctor gave permission for resident to go to hospital. At 4:19am the Er called to say resident passed away.

THAT EVENING BETWEEN 10-11 PM HAD A GRAND MAL SEIZURE AND WAS UNRESPONSIVE. TAKEN TO ER WHERE BLOOD WORK WAS DONE AND CT SCAN. SENT HOME AROUND 6:30 AM ON JAN 1ST. (I DO NOT REMEMBER MUCH JUST WHAT MY FAMILY HAD TOLD ME) . I DO REMEMBER BEING SEVERLY SICK WITH VOMITING IN THE ER. CURRENTLY FOLLOWING UP WITH MY FAMILY MD AND HAVE MRI AND EEG TESTS SCHECULED WITHIN THE NEXT COUPLE OF WEEKS.

51 year old M with h/o O2 dependent COPD, Severe pulmonary fibrosis became increasingly hypoxic around 1800hours 1/7/2021. He was transported to hospital for acute on chronic hypoxia respiratory failure. On 1/12/2021 he decompensated further, and after discussing with family and palliative care, He was changed to comfort care. He expired on 1/12/2021@2325 at medical center.

Maybe 1 minute after receiving the vaccine I began to have a syncopal episode, the nurse practitioner thought that since I was heavy I began to have a vasovagal reaction. From there they asked me to sit with the others waiting 15 minutes to make sure they were ok to leave. As I sat the symptoms would come and go, as if in a pattern, and then return. The longer I sat there the more the symptoms began to grow, after sitting for an hour they decided to send me to the ER. At this time I was experiencing nausea, vomiting, sweating, I was itchy, I could not stop coughing, it was difficult to breath, and I had the worse headache. When I got to the ER they gave me drugs to reverse the allergic reaction and told me they would watch me for a while. In the next 4 hours all of the symptoms started again and I had to get another round of the reaction drugs, I ended up going through this process 4 times before I was safe enough to go home the next day. The provider that saw me and admitted me did not do any blood work or labs, they simply provided me with the reaction drugs when needed and my home medications.

Increased lethargy on 1/14/21 at 9pm, Vital signs-106/66, Heart rate-112, temp 98.2; Sent to ER for eval admitted with fever.

On 1/8 she took her 2nd dose of Pfizer vaccine around 3 PM. She went home in the evening and started sweating. She passed out. Her daughter was at home and she took her to the nearest hospital. Her BP was 60/34 and she had a temp of 100.3F on 1/8 during hospital admission. Her K was low. She received lot of fluids. She called our office on 1/10 and during the f/u she was still in the hospital. On 1/10 she has a temp of 98.4F and BP of 109/61. But she still has dizziness, nausea, anorexia and mild cough (Former smoker). COVID-19 test was done on 1/9, its negative. Dx was dehydration. Discharged from the hospital on 1/11, feels better but is tired. Will follow up with PCP on 1/16/21.

anaphylaxis by lethargy, nausea, vomiting, palpitations, funny feeling in chest, swollen lips

"Patient received Pfizer COVID-19 vaccine without any immediate complication on 1/14/21approx 1455, was then escorted to observation area for a 30 minute observation time. Pt had previously had a known reaction to contrast media. Approximately 5 -8 minutes into observation, pt had one audible cough. Nurse asked patient if this was a new onset cough. The patient stated she would try to ""manage"" cough. Pt escorted to bay for monitoring. Pt developed shortness of breath and wheezing rapidly. Rapid response team called and local 9-11 also called. Pt received albuterol nebulizer treatment, placed on O2 at 8L. O2 sat 99%, HR 115-120. Respiratory therapy assisted and Rapid Response Team monitored pt while waiting for EMS. Physician order to give Epinephrine 0.3 mg IM in right deltoid, given as directed

at approx 1515. Second epinephrine 0.3 mg IM given approx 1530-1535. HR 144, O2 sat 99%. Patient transported to local ER, pt intubated approx 1927."

Received the 2nd vaccine at 10am on 1/11/21 intramuscular in the right arm. At 3pm on the same day, I had a painful swolle lymph node on left side of neck. That same evening I developed pain, swelling, in my right armpit radiating to the right upper breast and down my right arm with a swollen lymph node under the right arm pit. The pain was about a number 7 on a scale of 1 to 10. The pain and swelling still persist today on 1/15/2021 Still painful, especially to touch. Still radiating down the arm. Lymph node still swollen The pain is about a 2 on a scale of 1 to 10

Rash, swollen tongue and 2 seizures. Admitted to hospital with diagnosis of seizure and allergic reaction.,

7:00PM fatigued, burning up fever 100., ibuprofen/tylenol dose; Sunday afternoon nausea, loss control of body, anxious, feeling of fainting, unable to move-paralyzed, pressed button for medical help, ambulance arrived, pt transported to ER -- 102. temp ambulance, RN at hosp temp 98., pt was shaky, 8:30PM erratic heartbeat per admitting doctor - pt admitted. Pt PCP/Cardiologist contacted, kept on heart monitor, pt discharged Monday afternoon. 1/14/21 chest pain, nausea, 102. fever. symptoms

#Right parietal/temporal subarachnoid hemorrhage and right intra-axial hemorrhage CT brain (1/12/21): Right parietal intra-axial hemorrhage toward the convexity measuring 2.3 x 1.1 x 1.7 cm with decompression into the subarachnoid space, mild right predominantly temporal and parietal subarachnoid hemorrhage is seen with minimal associated hemorrhage along the tentorium. Mild diffuse right cerebral sulcal effacement with minimal leftward midline shift measuring 2.5 mm. #Dural sinus thrombosis CTA head (1/11/21): Increased density within the superior sagittal sinus, inferior sagittal sinus, and transverse sinuses on noncontrasted images with no flow seen on postcontrast sequences consistent with venous sinus thrombosis #Left sided weakness 2/2 above #Recent jaw alignment procedure

Patient developed headache and nausea on 1-11-2021. She was hospitalized on 1-14-2021 at Hospital. Found to have dural sinus thrombosis of the superior sagittal and right transverse/sigmoid sinus on MRV brain. Currently admitted to ICU at Hospital, getting injectable blood thinners. Neurology and hematology have been consulted.

Hospital Course: á Patient is a 43 y.o. female patient who originally presented to the hospital on 1/3/2021 due to Left lower extremity pain and swelling. Patient found to have extensive DVT of left lower extremity and started on heparin drip. Vascular was consulted and recommended thrombolysis. Patient was also seen by IR who took patient for thrombectomy and left iliac stent placement on 01/05/2021. Patient tolerated procedure well. Patient was transitioned from heparin drip to Eliquis upon discharge. Patient given vascular follow-up as well as Hematology follow-up.

Sudden death 18 hours post vaccine .

Onset of shortness of breath and cough on 1/3 that progressively got worse. Clinical diagnosis of pneumonia without fever was made, patient started azithromycin on 1/5 and albuterol treatments every 4-6 hrs. Initially he improved, but then worsened. chest xray on 1/6 was negative for pneumonia, PCR covid test was negative, albuterol treatment did not bring much relief. He started respiratory distress on 1/10 and was taken by car to the local ER where another covid test was negative and chest CT revealed multiple bilateral pulmonary emboli. The leg US revealed blood clots in both of his legs. He had an emergency catheter-delivered thrombolysis and was discharged home from the ICU on 1/12 on oral anticoagulants. He is gradually improving, but very weak. He tires easily and gets a drop in oxygen to 90- 93%, as well as an increase in the heart rate to 120 when walking less than half a mile. He runs out of breath with exertion.

Patient developed a hoarsenss of voice and tightness of throat and flushed feeling immediately following vaccination. Epi Pen was administered and 50 mg Benadryl given p.o., EMS transport to ED after administration of solumedrol 125 mg - received Pepcid and Zofran and NS IV in the ED. Discharged from ED with prednisone 40 mg daily x 4 day with Epi Pen prescription.

Resident received Moderna vaccine on 12/23/2020 around 5 pm. At approximately 3:35 am on 12/25/2020, resident had a CVA and died on 1/1/2021 at 3:00 am.

"it hard to inject; some came out and squirted down her arm; some came out and squirted down her arm; he did not get the full 0.3mL dose; This is a spontaneous report from a contactable nurse (patient). A 74-year-old-female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot EK9231) via Intramuscular on 05Jan2021 13:00 at single dose in the left arm for COVID-19 immunisation. Medical history included COPD and high cholesterol. Concomitant medications included Symbicort for COPD. Patient took COVID vaccine (Verbatim) since precaution as frontline healthcare worker. On Tuesday, she received the first dose of the Pfizer COVID Vaccine. The nurse who was injecting found it hard to inject, and at the end of the injection, it came back and squirted down her arm. It was a decent amount. She is unable to say if she got 0.1ml, 0.2ml, but she certainly did not get full 0.3ml. The hospital said they are just going to go ahead and give her the second dose, but she wanted to call and find out what would be the safest thing. Would it be best to receive another dose or go ahead with the second dose or get a third dose. She is due in 2 1/2 weeks to get second dose. She also has COPD and is a little more concerned than if she were 25 years old. There was no prescriber provided. When asked about other medications, she stated she has a list of medications, but did not think they were relevant. She was diagnosed with COPD last year and had a series of test. Reporter seriousness for ""it came back and squirted down her arm"" is medically significant. Outcome of events was unknown.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the reported events due to temporal relationship. There is limited information provided in this report. This case will be reassessed once additional information is available."

positive COVID-19 test with symptoms; positive COVID-19 test with symptoms; This is a spontaneous report from a contactable nurse (patient). A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number and expiry date were not reported), via an

unspecified route of administration on 23Dec2020 at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient received her first dose on 23Dec2020 and was subsequently exposed at work to the virus and became symptomatic and tested positive on 31Dec2020. Her next scheduled dose is on Sunday, they may have to reschedule. The patient queried on how long should they delay the next dose. The patient underwent lab tests and procedures which included sars-cov-2 test: positive on 31Dec2020. The outcome of the events was unknown. Information about Lot/Batch number is requested.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the reported events of suspected Covid-19 infection and suspected LOE due to temporal relationship. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

fainting spell; almost passed out; dizzy spells; weak; This is a spontaneous report from a contactable consumer (patient herself). A 22-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot: EL3246), via an unspecified route of administration on 07Jan2021 in right upper arm shoulder area at single dose for prevent covid. Medical history included ongoing acne. Concomitant medication included doxycycline from 2020 (taking it 6 months ago) and ongoing for acne. Patient stated that she got the Covid vaccine yesterday 07Jan2021 and almost passed out in her kitchen after a couple hours. Patient stated got in shower had dizzy spells and was weak 07Jan2021, she felt better now. Patient stated that she was a small girl of 105 pounds and the dose could have made her sick. She wanted to make sure she did not need to go and be seen. Patent had another spell in shower this morning and stated that the fainting spell and feeling weak started at 9:00 yesterday evening on 07Jan2021. Outcome of dizzy spells was recovering, and outcome of other events were unknown.

Body chills; fever that went up to 100.4 degrees F.; fatigue; excess mucus; bone pain 10/10; muscle pain 8/10; other vaccine same date vaccine date 05Jan2021; This is a spontaneous report from a contactable other health professional (patient). A 66-year-old female patient (not pregnant at the time of vaccination) received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot/batch number and expiration date not provided), via an unspecified route of administration on 05Jan2021 at single dose for COVID-19 immunization. Medical history included DM type 2, hypertension (HTN), fibromyalgia, chronic asthma, Covid prior vaccination, No Allergies to medications, food, or other products. Concomitant medications received within 2 weeks of vaccination. Facility where the most recent COVID-19 vaccine was administered at Nursing Home/Senior Living Facility. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Other vaccine same date included other vaccine same date product was Pfizer, other vaccine same date vaccine date 05Jan2021. On 06Jan2021, the patient experienced Body chills, fever that went up to 100.4 degrees F., bone pain 10/10, muscle pain 8/10,

fatigue and excess mucus. No treatment received for the adverse events Body chills, fever that went up to 100.4 degrees F., bone pain 10/10, muscle pain 8/10, fatigue and excess mucus. The events were non-serious per the reporter. Prior to vaccination, the patient was diagnosed with COVID-19. Since the vaccination, the patient hadn't been tested for COVID-19. The outcome of the events Body chills, fever that went up to 100.4 degrees F., bone pain 10/10, muscle pain 8/10, fatigue and excess mucus was recovering. No follow-up attempts are possible. Information about Lot/Batch cannot be obtained.; Sender's Comments: A possible causal association between administration of BNT162B2 and the onset of bone and muscle pain cannot be excluded, considering the plausible temporal relationship and the known adverse event profile of the suspect product. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

burning of the tongue; Difficulty in breathing; headaches; Pressure in the chest area; nausea; dizziness; fast heartbeat; tiredness; Had a hard time swallowing at night from the dryness; bitter taste; her mouth went completely dry; patient received 0.45 mL, single dose (225mcg) of PFIZER-BIONTECH COVID-19 VACCINE; This is a spontaneous report from a contactable nurse (patient). A 64-year-old female patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EJ1685), via an unspecified route of administration on 23Dec2020 15:00 at 0.45 mL, single dose (225mcg) at left arm to prevent COVID. Medical history included a bout of dry mouth about 7 years ago, no other relevant medical history (including any illness at time of vaccination). The patient's concomitant medications were not reported. There's no adverse events following prior vaccinations. Patient didn't receive any other vaccines within 4 weeks prior to the COVID vaccine. From the time she got the vaccine her mouth went completely dry on 23Dec2020 and she kept thinking it would go away and she still had it. Event was reported as serious per medically significant. Had a hard time swallowing at night from the dryness. Patient had the bitter taste was also on 23Dec2020, but it went away. It lasted about 5-6 hours. Then after that the dry mouth started right after. It is tolerable but she still had it. Mentioned she had a bout of dry mouth about 7 years ago and it did go away, but she never got a diagnosis for it. Patient thought that something underlying may have triggered it again. Patient also experienced burning of the tongue, tiredness, headaches, pressure in the chest area similar to difficulty in breathing, nausea, dizziness, and a fast heartbeat on unspecified date. Outcome of event dry mouth was not recovered, outcome of event bitter taste was recovered on unspecified date in Dec2020, outcome of other events was unknown. No family medical history relevant to adverse events. No relevant tests. No history of all previous immunization with the Pfizer vaccine considered as suspect. No additional vaccines administered on same date of the Pfizer suspect. The adverse events resulted in neither doctor or other healthcare professional office/clinic visit, nor emergency room/department or urgent care. Relatedness of Pfizer BioNTech Covid-19 vaccine with dry mouth and bitter taste per primary source reporter with method of assessment of global Introspection was related. Reporter seriousness for event bitter taste was not serious.; Sender's Comments: A possible causal association between administration of BNT162B2 and the onset of dry mouth cannot be excluded, considering the plausible temporal relationship. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures

for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

throat tightness; This is a spontaneous report from a non-contactable other healthcare professional (HCP). An 18-year-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot EK9231) via an unspecified route of administration on Jan2021 at a single dose in the left deltoid muscle for COVID 19 vaccination. Medical history and concomitant medications were not reported. The patient denied any history of previous adverse reactions to vaccines and denied reaction to her first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) for COVID 19 vaccination on an unspecified date. The patient was seen at a COVID vaccine clinic today for her second dose of the COVID 19 vaccination. She was given the Pfizer vaccination in the left deltoid muscle. During her 15-minute waiting period after the injection, the patient began to experience throat tightness on Jan2021. Treatment included: Benadryl 25mg po (orally) and Solumedrol 125mg IM. The event did not result in death, not life threatening, did not caused/prolonged hospitalization, not disabling/incapacitating, did not cause congenital anomaly/birth defect. The outcome of the event was unknown. No follow-up attempts are possible. Information about lot/batch has been obtained. No further information is expected.; Sender's Comments: A possible causal association between administration of BNT162B2 and the onset of throat tightness cannot be excluded, considering the plausible temporal relationship. Sever allergic reaction is the known risk for the product. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

blood pressure skyrocketed, it was 175/110/Very high blood pressure; almost falling down; Severe fatigue; Dizzy/dizziness; Bad headache/severe headache; Neck pain; This is a spontaneous report from a contactable nurse (reporting for herself). An adult female patient (over the age for 60) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration in an unspecified deltoid on 28Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced dizzy/dizziness, bad headache/severe headache, neck pain on 28Dec2020 and almost falling down, blood pressure skyrocketed (175/110)/very high blood pressure and severe fatigue on 29Dec2020 10:00. Clinical details were reported as follows: After the vaccine the patient was there waiting for 20 minutes and when she got in her car, after about an hour after the patient was really dizzy and was driving and was going to get in the next lane and thank God did not get in an accident. The patient parked and called her family to come pick her up. She had a bad headache, neck pain and dizziness that lasted for an hour. Finally, they came in and took me home. The patient slept for 7 hours. 9 hours after, the headache, neck pain, and dizziness were gone. The next day at 10:00 at work the patient almost fell down and one of the coworkers held her. The patients blood pressure skyrocketed, it was 175/110 and the patient was very dizzy again had severe fatigue. Her blood pressure was high for about 2 hours and slowly came down, but the fatigue lasted for almost a week and it slowly got better. The patient underwent lab tests

and procedures which included blood pressure measurement: 175/110 on 29Dec2020 skyrocketed/very high. The outcome of the events was recovered on an unspecified date. The batch/lot number for the vaccine, BNT162B2, was not provided and will be requested during follow-up.; Sender's Comments: Based on the time association, the possible contribution of suspect BNT162B2 to the event blood pressure increased cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

exposed to my sister/she did not know she had Covid/I tested positive with Covid test; exposed to my sister/she did not know she had Covid/I tested positive with Covid test; This is a spontaneous report from a contactable other HCP (patient). This female patient of unspecified age reported for herself that she received dose one of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number and Expiration date were not reported) on 21Dec2020 00:00 (at unspecified age) as single dose, unspecified route, for COVID-19 immunisation. Medical history and concomitant medications were not reported. The Patient received the vaccine on 21Dec2020 and was exposed to her sister on 22Dec2020 she did not know she had Covid. Patient tested positive with Covid test on 26Dec2020. Patient is scheduled to get second dose 11Jan2021. Lab data included a positive Covid test on 26Dec2020. The outcome of exposed to my sister/she did not know she had Covid/I tested positive with Covid test was unknown. The lot number for the vaccine BNT162B2 was not provided and will be requested during follow up.; Sender's Comments: The information currently provided is too limited to make a meaningful medical assessment hence, the events are conservatively assessed as related to the suspect drug BNT162B2 until further information becomes available. Efficacy of suspect drug however, is documented 7 days after second dose. Patient has received only the 1st dose.

"old scar that I forgot that I have there, it just swelled up really bad; The injection site looked like ""a small pox vaccine,"" in which appear red and scabby with a blue dot in the middle; The injection site looked like ""a small pox vaccine,"" in which appear red and scabby with a blue dot in the middle; The injection site looked like ""a small pox vaccine,"" in which appear red and scabby with a blue dot in the middle; The injection site looked like ""a small pox vaccine,"" in which appear red and scabby with a blue dot in the middle; Injection site began to itch; Injection site soreness; This is a spontaneous report from a contactable nurse (patient). A 50-year-old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL0142 (also reported as EL0140, pending clarification), expiry date: 03Mar2021 (also reported as 31Mar2021, pending clarification), intramuscular on the right arm on 08Jan2021 06:30 at a single dose for covid-19 immunisation. Medical history included heartburn, hot flashes, Grave's disease (father also has Grave's disease), had a thyroidectomy in Dec2015, menopause, weight loss, and appetite control, allergies, compromised immune status (brother and father side with autoimmune), respiratory illness, genetic/chromosomal abnormalities, endocrine abnormalities (including diabetes) and obesity, and diabetes type 2 diagnosed in 2019 (both parents and brother also with diabetes). Concomitant medications included levothyroxine sodium (SYNTHROID) in Dec2015 for Grave's disease and had a thyroidectomy, esomeprazole sodium (NEXIUM

[ESOMEPRAZOLE SODIUM]) on 02Jan2021 for heartburn, phentermine for weight loss and appetite control, estradiol on 02Jan2021 for hot flashes and menopause, medroxyprogesterone acetate (PROVERA) on 02Jan2021 for hot flashes and menopause, prednisone for unexplained whelps (pending clarification), and cimicifuga racemosa (also reported as black cohosh) for hot flashes. The patient previously took metformin and experienced GI upset (she quit taking metformin/it was causing GI upset because they increased dose/current dose is 1,000mg twice daily increased from 500 mg twice daily) and generic levothyroxine sodium and experienced feels like crap. The patient had no previous history of immunization with the Pfizer vaccine. No additional vaccines administered on same date of the bnt162b2. No prior vaccinations within four weeks. The patient wanted to know if she can receive the second dose of the Covid vaccine after experiencing adverse events. On 08Jan2021, the patient experienced some injection site soreness, in which she took TYLENOL for. Around 14:30, she noticed that the injection site began to itch. Around 16:00, the injection site looked like ""a small pox vaccine,"" in which appear red and scabby with a blue dot in the middle. The patient also reported, ""scar that I have on my arm, it is not a reaction, it is an old scar that I forgot that I have there, it just swelled up really bad."" Event injection site looked like a smallpox vaccine was assessed as serious-other medically important condition. No emergency room or physician's office required. Therapeutic measure was taken as a result of injection site soreness. Outcome of the event injection site looked like a smallpox vaccine was not recovered. Outcome of the events injection site soreness, injection site began to itch, vaccination site erythema, vaccination site scab, vaccination site discoloration, and old scar that I forgot that I have there, it just swelled up really bad was unknown.; Sender's Comments: Based on the time association, the possible contribution of suspect BNT162B2 to the event vaccination site discomfort cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate."

Dizzy; headaches; flu feeling; side effects she had were like the COVID symptoms she had, like the chills and everything; lethargic feeling; weak; Nausea; the whole left side of her body went numb including even her vagina; left side of her body was so numb and weird and tingly feeling/left leg went numb; whole left side of face swelled up; left eye turned red; pressure in head; felt like someone squeezing her eyeball out; eye went black/left eye looked bruised/blackness around the eyes; whole face went numb/left side of face slightly numb; bells palsy; allergic reaction; This is a spontaneous report from a contactable consumer (patient). A 44-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration in arm left on 05Jan2021 at single dose for COVID-19 immunization. Medical history included cutaneous t-cell lymphoma from 2017 and ongoing, ongoing cholesterol, ongoing thyroid, covid-19 from Nov2020 to an unknown date not ongoing (lasted about 1-1.5 months; she did not have any breathing problems) and blood cancer. Concomitant medication included bexarotene ongoing for cutaneous T-cell lymphoma, rosuvastatin ongoing for cholesterol, levothyroxine ongoing for thyriod. The patient underwent lab tests and procedures which included COVID 19: positive in Nov2020, found out tested positive around holiday. Clinical course: onset about 26 hours after administered the first dose; onset as soon as she got back to

work next day: 06Jan2021. The side effects were at their worst for at least 24-48 hours. Further described as all side effects occurred only on left side of her body: whole left side of face swelled up on 06Jan2021; left eye turned red on 06Jan2021; whole face went numb/left side of face slightly numb on 05Jan2021; eye went black/left eye looked bruised on 05Jan2021; pressure in head on 06Jan2021; felt like someone squeezing her eyeball out on 06Jan2021, within the first 24-48 hours, her 'left leg went numb'. She called to talk to physician and nurse who advised her to take Benadryl; which she did take and the Benadryl stopped the side effects; but she could not take a lot of Benadryl or anything because she was at work. She stayed at work because at least there were healthcare professionals, adults in case she passed out; at home she has 7 young children and is also raising her grandchild. The side effects did not completely go away. The arm thing was normal; The next day she was at work and had the swelling on left side of face; blackness around the eyes; arriving home she had headaches on 07Jan2021 and then her leg went numb for like 20 mins; the whole left side of her body went numb including even her vagina; left side of her body was so numb and weird and tingly feeling that she started panicking because she was driving on 06Jan2021. She calmed herself down thinking it's only the left side; you can drive with your right side to get home and be fine. It was more like left side of her body was asleep, tingling, she has never had that happen before. Everything else like the headache, flu feeling was about 48 hours later (on 07Jan2021). She had COVID already back in Nov2020 for about 1-1.5 months; the next side effects she had were like the COVID symptoms she had, like the chills and everything on 06Jan2021. She had the lethargic feeling again, her head was hurting, she felt extremely weak on 06Jan2021. Patient also felt nausea on 06Jan2021, Dizzy on 08Jan2021. Another doctor said it sounded like the side effects she experienced with the vaccine sounded like allergic reaction or Bell's palsy. Patient was asking the doctor if she could get like an Epi-pen or prescription Benadryl or something because she is afraid to get the second dose of Pfizer COVID-19 Vaccine and not have something to respond to side effects with. The outcome of event whole face went numb/left side of face slightly numb was recovered on 07Jan2021, for headaches was recovering, chills and nausea was recovered on 08Jan2021. Outcome of other events was unknown. Information about lot/batch number has been requested.

"felt like she had Covid; felt like she had Covid; stomach cramps; chills; aches; not feeling good; temp was around 101- 101.6/fever 102; Icy hot sensation; lethargy; arm was red and swollen; arm was red and swollen; This is a spontaneous report from a non-contactable nurse (patient). A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for covid-19 immunization. Medical history included covid-19 from Jul2020. The patient's concomitant medications were not reported. The patient got her injection on Tuesday (specified date unknown) at 3pm. Felt good but then woke up with stomach cramps. She went to work and at around 1pm she started having chills, aches and not feeling good at 4:30 pm her temp was around 101- 101.6 so she took Tylenol went to bed. She woke up with fever 102 and felt like she had Covid all over again reporting that she had covid in Jul. Having what she has heard described as ""Icy hot sensation"" and lethargy and not feeling good with chills aches. Then on Thursday her arm was red and swollen with the redness expanding swelling and her fever was going back up. The outcome of the events was unknown. No follow-up attempts are possible. Information about lot/batch number cannot be obtained. No further information is expected.; Sender's Comments: Based on the information currently available, the local reactions and flu like symptoms following

vaccination with BNT162B2 are more likely attributed to the vaccine use. Further information like diagnostic detection of virus genetic material or virus protein antigen needed for meaningful medical assessment on protective effects with the vaccine."

"convulsive chills, fever- (high); convulsive chills; fever- (high); all of my muscles and joints were flaring in extreme pain; all of my muscles and joints were flaring in extreme pain; I could NOT move my vaccine arm more than 3 inches and my whole body hurt; my vision was extremely blurry; When I tried to walk, it was slow; achy/whole body hurt; tired, and took a nap; This is a spontaneous report from a contactable consumer (patient). A 54-year-old female patient (no pregnant) received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EL0142) via an unspecified route of administration on the left arm on 05Jan2021 11:00 AM at single dose for COVID-19 immunisation. Medical history included having Covid the 3rd week in Mar2020, Positive for Antibodies in early May2020. Fairly sick but not emergency situation ""Long haulers"" covid symptoms that continued through Nov2020. Patient still had skin pain. Other medical history included hashimoto's. Past drug event included known allergy to codeine. The patient's concomitant medications included 25 mg of Levothyroxine in two weeks. No other vaccine in four weeks. On 05Jan2021 at 12:30, patient felt achy, tired, and took a nap. By 2:00ish. The patient's vision was extremely blurry and continued for 2 days. At 05Jan2021 8 pm- 6 hours later of convulsive chills, fever- (high) and all of her muscles and joints were flaring in extreme pain. Patient could not move vaccine arm more than 3 inches and whole body hurt as if she had been hit by a train. When patient tried to walk, it was slow. Patient groped walls for support. Patient had a televisit with a doctor friend who said this was not a normal side effect and go to emergency room (ER). Doctor or other healthcare professional office/clinic visit. Covid test post vaccination included nasal swab, Covid -19 diagnostic on 08Jan2021 with pending result. No treatment received for events. The outcome of convulsive chills fever was unknown. The outcome of other events was recovered in Jan2021."

tunnel vision; experienced a sudden onset of vertigo; presyncope; My hands became cold and numb; My hands became cold and numb; fatigue; sore arm, leg/thigh aching; sniffles; sore throat; brief dry cough; slight headache; neck ache; This is a spontaneous report from a contactable Nurse (patient). A 34-year-old non-pregnant female patient received the first dose bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), intramuscular on 05Jan2021 at 12:30 at single dose in left arm for covid-19 immunization. Medical history included Mild ADHD/ADD. The patient's concomitant medications were not reported. Approximately 5 minutes after receiving vaccination, she was standing in the observation room (where they had all of them stay for at least 15 minutes to ensure no severe reactions) and experienced a sudden onset of vertigo, tunnel vision and pre-syncope. Her hands became cold and numb and she was trying to talk to another staff member who was arranging/scheduling her second vaccination dose at the same time when this event occurred, but it subsided quickly and she started to feel normal again. All these events occurred at 12:45 on 05Jan2021. She reported this event right away and they had her stay in the room longer. She was stable at that point but experienced these symptoms again but very mildly twice more while she walked back to her car to go home. Other side effects on 05Jan2021 that started in the evening and for the following 2-3 days included fatigue, sore arm, leg/thigh aching, sniffles/sore throat, brief dry cough and slight headache/neck ache. Very mild and tolerable symptoms. All events

were reported as non-serious by reporter. The patient did not receive treatment for the events. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient was not diagnosed with COVID-19 prior to vaccination, and the patient has not been tested for COVID-19 since the vaccination. The outcome of all events was resolved in Jan2021. Information on the lot/batch number has been requested.; Sender's Comments: Based on temporal association, a possible contributory role of BNT162B2 cannot be excluded for reported events. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Experienced vasovagal syncope after standing, resulting in fall; Experienced vasovagal syncope after standing, resulting in fall; Awoke with severe chills; nausea; body/muscle aches; body/muscle aches; left arm pain; extreme thirst; fatigue; This is a spontaneous report from a contactable consumer. A 44-year-old female patient (non-pregnant) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot: EK9231), via an unspecified route of administration on 08Jan2021 14:30 in left arm at single dose for covid-19 immunization. There was no medical history and concomitant medications. Allergies to medications, food, or other products was no. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The most recent COVID-19 vaccine was administered was in hospital. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. On 09Jan2021 01:30 am, patient woke with severe chills, nausea, body/muscle aches, left arm pain, nausea, extreme thirst. Patient experienced vasovagal syncope after standing, resulting in fall. Worst symptoms were lasted about 30 minutes, muscle aches and fatigue continue about 16 hours later. All events were reported as non-serious. No treatment was received for these events. Outcome of all events were recovering.

foggy minded; on first vaccine it made him feel a little sluggish; tired; This is a spontaneous report from a contactable pharmacist. A 36-year-old male patient started to receive BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK5730), intramuscular from 18Dec2020 to 18Dec2020 at SINGLE DOSE for COVID-19 immunisation. Medical history included ADHD. Concomitant medication included amfetamine aspartate, amfetamine sulfate, dexamfetamine saccharate, dexamfetamine sulfate (ADDERALL) and escitalopram oxalate (LEXAPRO). On an unspecified date, the patient stated that on first vaccine, it made him feel a little sluggish, tired and foggy minded. Outcome of the events was unknown.; Sender's Comments: Based on temporal association, a possible contributory role of suspect BNT162B2 cannot be excluded for event mental dullness. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

partial complex seizure; I lost muscle tone and collapsed; severe LUE weakness; severe pain; aura; I lost muscle tone and collapsed; This is a spontaneous report from a contactable other health care professional (HCP) reporting for herself. A 40-year-old female not pregnant patient received first dose of

BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration in the Left arm on 30Dec2020 h 05:00 PM at single dose for COVID-19 immunisation, lot number: EH9899. Patient did not receive any other vaccines within four weeks prior to the vaccination. Prior to the vaccination, the patient was not diagnosed with COVID-19. Medical history included epilepsy (well controlled with medications) and she was allergic to phenytoin (DILANTIN). Concomitant medications in two weeks prior to the vaccination included carbamazepine, lamotrigine (LAMICTAL) and fluoxetine. It was reported that on 31Dec2020 h 14:00 (also reported as approximately 22 hours after vaccine) patient experienced severe left upper extremity (LUE) weakness and severe pain. She then experienced an aura and had a partial complex seizure. Patient lost muscle tone and collapsed. The episode lasted approximately 1.5 minutes, no treatment was given. Patient was tested for Covid post vaccination, she underwent Covid-19 PCR Test (Nasal Swab) on 04Jan2021 and on 07Jan2021, both with negative results. She also underwent a Covid-19 PCR Test on unknown unknown date in Jan2021 with unknown results. Patient recovered on 31Dec2020 from the events.; Sender's Comments: There is not a reasonable possibility that the reported events were related to the suspect product event most likely due to patient underlying contributory factors. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators as appropriate.

spontaneous rupture of membranes at 36-0 weeks; Pregnant at the time of vaccination?: Yes; This is a spontaneous report from a contactable physician. This physician reported information for both mother and fetus/baby. This is the maternal report. A 29-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), intramuscular (left arm) on 18Dec2020 and 08Jan2021 at a single dose for COVID-19 immunization. Medical history included cold sores, no active cold sore at time of labor. On an unspecified date, it was reported that a healthy 29-year-old G1P0 with good prenatal care and no pregnancy complications who had spontaneous rupture of membranes at 36-0 weeks, one day after her second Pfizer CoVid vaccine (09Jan2021). She felt well after her vaccine and had no symptoms today. The mother reported she became pregnant while taking BNT162B2. The patient takes prenatal vitamins. The mother was 33 Weeks pregnant at the onset of the event. The mother was due to deliver on 06Feb2021. Therapeutic measures were taken as a result of premature rupture of membranes. The outcome of the event was recovering. Information about Batch/Lot number has been requested.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the reported event of spontaneous rupture of membranes due to temporal relationship. However, the reported event may possibly represent intercurrent medical condition in this patient. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any

appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Within 15 minutes, I began feeling dry throat; Within 15 minutes, I began feeling dry throat, then itching, then it felt like I had a lump inside my throat.; it felt like I had a lump inside my throat.; Then I began to have difficulty swallowing my saliva.; difficulty breathing; very groggy; This is a spontaneous report from a contactable pharmacist. A 47-year-old female patient received the first dose bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number EL0140), intramuscular in left arm on 20Dec2020 at a single dose for COVID-19 immunization. Vaccination was administered in a hospital. Prior to vaccination, the patient was not diagnosed with COVID-19. Medical history included hypertension, overweight, and known allergies to bee stings and hair dye. The patient's concomitant medication included multivitamins. On 20Dec2020, within 15 minutes, the patient began feeling dry throat, then itching, then it felt like she had a lump inside her throat. Then she began to have difficulty swallowing her saliva. And then the lump inside her throat started to feel larger and larger. By this time, the doctor had already injected the patient with Epipen and the pharmacist injected her with Solumedrol and she still felt as if she was having difficulty breathing and then she was taken to ER and she really can't remember too much after that. The patient was very groggy and then was discharged from ED about 9:30 pm. The outcome of the events was recovered on an unknown date. Treatment for the events included epinephrine, methylprednisolone, diphenhydramine. Since the vaccination, the patient has not been tested for COVID-19.; Sender's Comments: A possible causal association between administration of BNT162B2 and the onset of feeling dry throat, itching, felt like having lump inside her throat, having difficulty swallowing saliva, difficulty breathing and very groggy cannot be excluded, considering the plausible temporal relationship and the known adverse event profile of the suspect product. Severe allergic reaction is the known risk for the product. The underlying predisposing condition of allergies to multiple materials may put the patient at high risk of anaphylactic reactions. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

significant swelling to lymph nodes under armpit of injection side (L arm); This is a spontaneous report from a contactable consumer. A 26-year-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK9231), via an unspecified route of administration at the left arm on 09Jan2021 08:00 at SINGLE DOSE for COVID-19 immunization at a hospital. Medical history included asthma, food allergy with peanuts and pine nuts. No known medication allergy. The concomitant medications included albuterol and unspecified multivitamin. The patient previously took the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899) at the left arm on 19Dec2020 08:00. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient was not diagnosed with COVID-19 prior to vaccination and was not tested for it since the vaccination. The patient was not pregnant. On 10Jan2021 16:00, the patient noted significant swelling to lymph nodes under armpit of injection side, swelling in the left armpit lymph nodes began approximately 32 hours after injection. Swelling measuring approximately size of a ping pong ball. At

time of this reporting (approximately 40 hours post-injection) lymph node swelling still persists, with no change in size. The patient did not receive any treatment for the events. The patient has not recovered from the events. No follow-up attempts are needed. No further information expected.

Patient was tested for Covid post vaccination/ Covid test on 28Dec2020 and resulted positive; Patient was tested for Covid post vaccination/ Covid test on 28Dec2020 and resulted positive; This is a spontaneous report from a contactable healthcare professional (patient). A 40-year-old female patient received her first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK7530) solution for injection, intramuscular on left arm on 16Dec2020 12:00 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient was not pregnant. It was reported that patient was tested for Covid post vaccination. Nasal swab for Covid test was done on 28Dec2020 and resulted positive. Outcome of the event was unknown. No follow up attempts are possible. No further information is expected.; Sender's Comments: Based on the information currently available, a lack of efficacy with BNT162B2 in this patient cannot be completely excluded.

had a metallic taste; turned to swollen tongue; hives around chest and neck; difficult to breathe; tachycardia; This is a spontaneous report from a contactable other HCP (Patient). A 33-year-old non-pregnant female received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number=EL 3248), via an unspecified route of administration at right arm on 07Jan2021 16:15 at single dose for covid-19 immunization. Vaccine was administered at hospital. Known allergies included cyclobenzaprine and dairy latex. Concomitant medication included amfetamine aspartate, amfetamine sulfate, dexamfetamine saccharate, dexamfetamine sulfate (ADDERALL) 10 mg, gabapentin 300 mg, venlafaxine 150 mg. No other vaccine in four weeks. Three minutes after vaccination the patient had a metallic taste, turned to swollen tongue, hives around chest and neck, difficult to breathe, and tachycardia on 07Jan2021 16:18. The events resulted in Emergency room/department or urgent care. Treatment received included Epinephrine, methylprednisolone sodium succinate (SOLU-ME dork) and famotidine (PEPCID) also diphenhydramine HCl (BENADRYL). The outcome of the events was unknown.; Sender's Comments: Based on temporal association, a possible contributory role of suspect BNT162B2 cannot be excluded for events metallic taste, swollen tongue, hives, difficulty breathing and tachycardia. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

tested (COVID-19 virus test) positive after receiving first dose of vaccine; tested (COVID-19 virus test) positive after receiving first dose of vaccine; This is a spontaneous report from a contactable pharmacist. A patient of unspecified age and gender received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number and expiration date not provided) via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunisation. Patient's medical history and concomitant medications were not reported. It was reported that patient tested (COVID-19 virus test) positive after receiving first dose of vaccine. It was also reported that they are looking for administration recommendations following receipt of monoclonal antibodies and interval information. Outcome of the

events was unknown. Information of the lot number/batch number was requested.; Sender's Comments: A causal association between reported event and suspect BNT162B2 cannot be excluded.

really extreme high blood pressure (202/104); feeling very sick; This is a spontaneous report from a contactable consumer (patient). A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration, on 04Jan2021 at a single dose for COVID-19 immunization. Medical history included strokes and bleeding disorder (gene that makes blood clot). The patient's concomitant medications were not reported. The patient experienced really extreme high blood pressure (202/104) and feeling very sick on an unspecified date. The clinical course was reported as: The patient received the vaccine on 04Jan2021 and experienced a lot of side effects, the most concerning of which was really extreme high blood pressure. The patient went to the emergency room (ER) on an unspecified date and her blood pressure was 202/104 on an unspecified date. The patient stated that she had been very sick and in bed for days. The patient had a follow-up appointment with her doctor on the day of the report. The clinical outcome of really extreme high blood pressure (202/104) and feeling very sick was unknown. The batch/lot number for the vaccine, BNT162B2, was not provided and has been requested during follow up.

tested positive for COVID; tested positive for COVID; This is a spontaneous report from a contactable nurse (patient). A 64-year-old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK5730, expiration date: 31Mar2021), via intramuscular on 21Dec2020 at 0.3 mL single in left deltoid for preventative. Medical history included she only had one kidney from 25Feb2020. There were no concomitant medications. It was reported that the patient was supposed (was scheduled) to get her second dose today (11Jan2021) but this past weekend she tested positive for COVID on 09Jan2021. The patient wanted to know if it would affect getting the second dose of the vaccine. The patient supposed to be quarantining right now and she was not symptomatic. On 09Jan2021 she found out she was positive for covid. The outcome of the event was unknown.; Sender's Comments: A causal association between reported event and suspect BNT162B2 cannot be excluded.

he is infected with COVID-19; he is infected with COVID-19; This is a spontaneous report from a contactable nurse (patient). A male patient of an unspecified age received 1st dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient called to find out if there should be a delay in the second dose because he was infected with COVID-19 on an unspecified date. His second dose was scheduled on 13Jan2021 and he was wondering if he should continue in 2 days. Outcome of the events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Based on the information currently available, a lack of efficacy with BNT162B2 in this patient cannot be completely excluded.

she had a little bleed in the blood vessel of her left eye; This is a spontaneous report from a contactable other healthcare professional (patient). A female patient of unspecified age received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot/batch number and expiration date not provided), via an unspecified route of administration on 21Dec2020 at single dose for COVID-19 immunization. The

patient's medical history and concomitant medications were not reported. The patient asking if bleeding of the eye was an adverse reaction to bnt162b2. Patient received the Covid vaccine on 21Dec2020 and on the 27Dec2020, she had a little bleed in the blood vessel of her left eye. She was supposed to get the second vaccine today (11Jan2021) at 12:30. The outcome of the event was unknown. Information on the lot/batch number has been requested.; Sender's Comments: A possible contributory effect of suspect BNT162B2 on reported event cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

"got the first dose of the vaccine and on 25Dec2020, he started getting symptoms of possible covid; got the first dose of the vaccine and on 25Dec2020, he started getting symptoms of possible covid; This is a spontaneous report from a contactable pharmacist. A 7-decade-old (65 years or 66 years) male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 25Dec2020 at single dose for COVID-19 immunisation. The patient medical history and concomitant medications were not reported. The stated, ""my uncle got the first dose of the vaccine and on 25Dec2020, he started getting symptoms of possible Covid. He got tested for covid today (11Jan2021). He's supposed to get the second dose on 15Jan2021. If he is positive for covid, what does that mean for his second dose? If he is positive, and waits for quarantine, then he wouldn't be able to get the second dose until day 36."" The outcome of the events was unknown. Information on the Lot/Batch Number has been requested.; Sender's Comments: A causal association between reported event and suspect BNT162B2 cannot be excluded."

On (Dated) tested positive for Covid; On (Dated) tested positive for Covid; On (Dated) tested positive for Covid; Felt run down; This is a spontaneous report from a contactable other health professional (HCP). A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 28Dec2020 at a single dose (first dose) for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient got her first dose on 28Dec2020 and on 07Jan2021, she felt run down so she decided to get tested for COVID. On 09Jan2021, she tested positive for COVID. Her second dose is due 18Jan2021 and she needed to know if it is ok for her to get her second dose. The patient underwent lab tests and procedures which included sars-cov-2 test: positive on 09Jan2021. The outcome of the events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: The association between the event lack of effect (tested positive for COVID) with BNT162b2 can not be completely excluded.

Caller tested positive on 05Jan2021.; Caller tested positive on 05Jan2021.; Caller tested positive on 05Jan2021.; This is a spontaneous report from a contactable physician (patient). A male patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 29Dec2020 at a single dose for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. Patient received the first dose of the COVID 19 vaccine on 29Dec2020, second dose is due on 20Jan2021. Patient tested positive on 05Jan2021. Patient wanted

to know if he should get the second shot and if he chooses to wait the 90 days, would he need to start over. The patient underwent lab tests and procedures which included sars-cov-2 test: positive on 05Jan2021. The outcome of the events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: The association between the event lack of effect (tested positive) with BNT162b2 can not be completely excluded.

13 people, who were applied the vaccine previously, were corona positive after a week; 13 people, who were applied the vaccine previously, were corona positive after a week; This is a spontaneous report from a non-contactable consumer. This consumer reported similar events for 13 patients. This is second of 13 reports. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Solution for injection; lot number and expiration date: not known), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. It was reported that 13 people, who were applied the vaccine previously, were corona positive after a week on an unspecified date. The outcome of the events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021018407 same reporter, similar suspect drug and event; different patient

13 people, who were applied the vaccine previously, were corona positive after a week; 13 people, who were applied the vaccine previously, were corona positive after a week; This is a spontaneous report from a non-contactable consumer. This consumer reported similar events for 13 patients. This is third of 13 reports. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Solution for injection; lot number and expiration date: not known), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. It was reported that 13 people, who were applied the vaccine previously, were corona positive after a week on an unspecified date. The outcome of the events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021018407 same reporter, similar suspect drug and event; different patient

13 people, who were applied the vaccine previously, were corona positive after a week; 13 people, who were applied the vaccine previously, were corona positive after a week; This is a spontaneous report from a non-contactable consumer. This consumer reported similar events for 13 patients. This is fourth of 13 reports. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Solution for injection; lot number and expiration date: not known), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. It was reported that 13 people, who were applied the vaccine previously, were corona positive after a week on an unspecified date. The outcome of the events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021018407 same reporter, similar suspect drug and event; different patient.

13 people, who were applied the vaccine previously, were corona positive after a week; 13 people, who were applied the vaccine previously, were corona positive after a week; This is a spontaneous report from a non-contactable consumer. This consumer reported similar events for 13 patients. This is fifth of 13 reports. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Solution for injection; lot number and expiration date: not known), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. It was reported that 13 people, who were applied the vaccine previously, were corona positive after a week on an unspecified date. The outcome of the events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021018407 same reporter, similar suspect drug and event; different patient.

13 People, who were applied the vaccine previously, were corona positive after a week; 13 People, who were applied the vaccine previously, were corona positive after a week; This is a spontaneous report from a non-contactable consumer. This consumer reported similar events for 13 patients. This is 6th of 13 reports. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Solution for injection; lot number and expiration date: not known), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. It was reported that 13 people, who were applied the vaccine previously, were corona positive after a week on an unspecified date. The outcome of the events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021018407 same reporter, similar suspect drug and event; different patient.

13 people, who were applied the vaccine previously, were corona positive after a week; 13 people, who were applied the vaccine previously, were corona positive after a week; This is a spontaneous report from a non-contactable consumer. This consumer reported similar events for 13 patients. This is 7th of 13 reports. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Solution for injection; lot number and expiration date: not known), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. It was reported that 13 people, who were applied the vaccine previously, were corona positive after a week on an unspecified date. The outcome of the events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021018407

13 people, who were applied the vaccine previously, were corona positive after a week; 13 people, who were applied the vaccine previously, were corona positive after a week; This is a spontaneous report from a non-contactable consumer. This consumer reported similar events for 13 patients. This is 8th of 13 reports. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Solution for injection; lot number and expiration date: not known), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. It was reported that 13 people, who were applied the vaccine previously, were corona positive after a week on an unspecified date. The outcome

of the events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021018407

13 people, who were applied the vaccine previously, were corona positive after a week; 13 people, who were applied the vaccine previously, were corona positive after a week; This is a spontaneous report from a non-contactable consumer. This consumer reported similar events for 13 patients. This is 9th of 13 reports. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Solution for injection; lot number and expiration date: not known), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. It was reported that 13 people, who were applied the vaccine previously, were corona positive after a week on an unspecified date. The outcome of the events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021018407 : same reporter, similar suspect drug and event; different patient.

13 people, who were applied the vaccine previously, were corona positive after a week; 13 people, who were applied the vaccine previously, were corona positive after a week; This is a spontaneous report from a non-contactable consumer. This consumer reported similar events for 13 patients. This is tenth of 13 reports. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Solution for injection; lot number and expiration date: not known), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. It was reported that 13 people, who were applied the vaccine previously, were corona positive after a week on an unspecified date. The outcome of the events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021018407 same reporter, similar suspect drug and event; different patient

13 people, who were applied the vaccine previously, were corona positive after a week; 13 people, who were applied the vaccine previously, were corona positive after a week; This is a spontaneous report from a non-contactable consumer. This consumer reported similar events for 13 patients. This is 11th of 13 reports. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Solution for injection; lot number and expiration date: not known), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. It was reported that 13 people, who were applied the vaccine previously, were corona positive after a week on an unspecified date. The outcome of the events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021018407 same reporter, similar suspect drug and event; different patient

13 people, who were applied the vaccine previously, were corona positive after a week; 13 people, who were applied the vaccine previously, were corona positive after a week; This is a spontaneous report from a non-contactable consumer. This consumer reported similar events for 13 patient. This is the 13th of 13 report. A patient of unspecified age and gender received bnt162b2 (PFIZER-BIONTECH COVID-19

VACCINE; Solution for injection, batch/lot number unknown), via an unspecified route of administration on an unspecified date at a single dose for covid-19 immunisation. The patient's medical history and concomitant medications were not reported. It was reported that 13 people, who were applied the vaccine previously, were corona positive after a week. on an unspecified date. The outcome of the events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021018407 same reporter, similar suspect drug and event; different patient

She tested positive for Covid-19 a week later after receiving the first dose of the vaccine; She tested positive for Covid-19 a week later after receiving the first dose of the vaccine; This is a spontaneous report from a Pfizer-sponsored program IBCC (Inbound Call Center for HCPs) received from a contactable consumer (patient). A female patient of an unspecified age received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot/batch number unknown), via an unspecified route of administration on 29Dec2020 at a single dose for covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient took the first dose of Covid-19 vaccine on 29Dec2020. She tested positive for Covid-19 a week later after receiving the first dose of the vaccine. She is scheduled to get the second dose on 19Jan2021 and she was asking what to do. The outcome of the event was unknown. Information about lot/batch number has been requested.

tested positive for COVID; tested positive for COVID/fatigue, headache, body aches again; allergies were flaring up; Coughing; congestion; body aches; This is a spontaneous report from a Pfizer-sponsored program IBCC (Inbound Call Center for HCPs). A contactable nurse (female) reported that a female patient of an unspecified age received first dose of bnt162b2, via an unspecified route of administration on 21Dec2020 at single dose for covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced tested positive for covid on 31Dec2020, coughing, congestion, body aches on 24Dec2020, fatigue, headache, allergies were flaring up on 28Dec2020. The caller got her first COVID-19 injection on 21Dec2020. She didn't have symptoms until 2 days after the vaccine. She then experienced coughing, congestion, body aches, but no fever. Then the next day, she felt fine. On 28Dec2020, she thought her allergies were flaring up. She started to feel fatigue, headache, body aches again. She went and got tested for the virus. She tested positive on 31Dec2020. Caller was due for a second vaccine on 11Jan2021. She was to remain in quarantine until 10Jan2021. Caller wanted to know should she get her second shot on 11Jan2021 or should she wait. The patient underwent lab tests and procedures which included Covid-19: positive on 31Dec2020. The outcome of events for tested positive for covid, fatigue, headache and allergies were flaring up was unknown, for other events was resolving. No further information was obtained. Information on lot/batch number has been requested.; Sender's Comments: A causal association between BNT162B2 and the events drug ineffective and COVID-19 cannot be excluded based on a compatible temporal relation between vaccination and onset of events.

short of breath; aching so bad again; was still short of breath, getting worse, aching so bad again; choking; got as cold as ice; throat was real swollen; started itching terribly; This is a spontaneous report from a contactable consumer (patient). A 73-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number EK4176), via an unspecified route of administration

on 06Jan2021 single for COVID-19 immunization. Medical history included hypertension and had 4 heart attacks. The patient's concomitant medications were not reported. The patient just had the Covid 19 Vaccine first shot. After the shot he went to the dining room to get some lunch. He was reading since 'calculative'. He started itching terribly. Onset date for started itching terribly was reported as 06Jan2021. He got as cold as ice. He started getting real short of breath, he was choking but he managed to get them out of his throat. His throat was real swollen and choked. He went back to the clinic and the Nurse took him straight to the emergency room. He was there in his wheelchair freeze in and crawling himself, struggling to breathe for almost 25 minutes before the Nurse finally came in and helped him get him on the stretcher. She took his time, she got the IV started and gave him a steroid a shot and Benadryl. He did not know the dosage and some capsules. He did not know why the capsules and he was still struggling for a while but he found day tough for about an hour. When he came too he was still short of breath, getting worse, aching so bad again. He was struggling to breathe, he was still having some breathing problem, some choking and aching. The events was still short of breath, getting worse, aching so bad again were serious as hospitalization. Laboratory work: Work was normal. The COVID Test was negative. The outcome of events short of breath and started itching terribly was not recovered while for other events were unknown.

dehydration; This is a spontaneous report from a contactable Nurse. A patient of unknown age and gender received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, on an unknown date at single dose for COVID-19 immunisation. Medical history and concomitant medications were unknown. After vaccination on an unknown date, the patient went to ER and was diagnosed with dehydration. Patient was hydrated and recovered. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Sender's Comments: The information currently provided is too limited to make a meaningful medical assessment hence, the events are conservatively assessed as related to the suspect drug BNT162B2 until further information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

died two days after receiving the vaccine; Fever; This is a spontaneous report from a contactable consumer (patient's stepchild). A 66-year-old male patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration, on 07Jan2021 (at the age of 66-years-old) as a single dose for COVID-19 immunization. The patient's medical history was not reported. Concomitant medications included an unspecified statin. The patient experienced fever on 08Jan2021. The patient died two days after receiving the vaccine on 09Jan2021, which was reported as fatal. The clinical course was reported as follows: The patient had a fever the day after getting the vaccine and then he just died in the middle of night. It was reported that it was not clear what exactly happened, but they are looking into this. The clinical outcome of fever was unknown and of died two days after receiving the vaccine was fatal. The patient died on 09Jan2021. The cause of death was not reported. An autopsy was not performed (was reported to be taking place soon). The batch/lot

number for the vaccine, BNT162B2, was not provided and has been requested during follow up.; Reported Cause(s) of Death: died two days after receiving the vaccine

Pt. with dizziness, then Afib with RVR, then massive cerebral hemorrhage Pt. non oriented & unable to give history - History provided by S.O and daughter

Accelerated decline in condition with decreased input, decreased responsiveness, somnolence, and death

Received vaccine in left deltoid within minute felt throat tighten self administered personal epi pen.

I had no side effects after my vaccine on 12/24/20 until 1/8/21. On Friday, 1/8/21 at 830pm I began with severe abdominal pain, low grade fever, nausea and loss of appetite. My abdominal pain persisted and worsened over the next 24-36hours. I presented to the ER on Sunday, January 10, 2021 at 8am with severe right lower quadrant pain, pelvic pain, nausea and low grade fever. I was promptly diagnosed with appendicitis and taken to the OR at approximately 2pm on the same day. In the OR my appendix was gangrenous, there was pus in the pelvic area nd fluid in my peritoneum. My appendix was not ruptured. My appendix was removed as well as part of the omentum. I remained in the hospital on IV Metronidazole and Ciprofloxacin for 2 days and was discharged on 1/13/21 at 9pm. I am continuing to recvoer at home on the same 2 antibiotics in oral form. I have a JP drain that is still in place. Of note I had two negative COVID 19 tests on 1/9/21 and 1/10/21. Both were PCR tests.

Tingling and throat swelling to Moderna COVID-19 Vaccine EUA

Patient had no immediate effects from the vaccine, but died approximately 8 hours after receiving first dose of vaccine.

positive for Covid; positive for Covid; This is a spontaneous report from a contactable healthcare professional (patient). A 48-years-old female patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number EH9899, expiration date unknown), via an unspecified route of administration in right deltoid, on 18Dec2020 07:15 at a single dose for Covid-19 immunization. Medical history included ongoing hypothyroidism and hysterectomy. Concomitant medications included estradiol (taking after hysterectomy) and levothyroxine for hypothyroidism, both ongoing. The patient has no any other vaccinations within four weeks prior to the first administration date of the suspect vaccine. The patient stated that she received the Covid vaccine mid- Dec2020. She stated she was supposed to receive the 2nd dose 2 days ago, 06Jan2021. On 03Jan2021, she started feeling bad the day before testing positive, went to urgent care to be tested, thought she had the flu. She tested positive for Covid on Monday 04Jan2021, so she has been in quarantine. She was unable to receive her 2nd dose because she was in quarantine. She wanted to know if it's ok to delay the second dose or if she needs to re-start the series. The reporter assessed the event relatedness was unknown, patient stated that she doesn't know the causality, she has not been in contact with anyone that was known to be positive, but she is a healthcare worker who sees multiple patients a day, so one of them could have been asymptomatic. Outcome of the events was not recovered.; Sender's Comments: The information currently provided is too limited to make a meaningful medical assessment hence, the

events are conservatively assessed as related to the suspect drug BNT162B2 until further information becomes available.

received first dose of bnt162b2/by the 3rd (03Jan2021), he was diagnosed as covid positive; received first dose of bnt162b2/by the 3rd (03Jan2021), he was diagnosed as covid positive; patient lost his sense of smell and taste; patient lost his sense of smell and taste; This is a spontaneous report from a contactable nurse (patient). A male patient of an unspecified age received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number and expiration date not provided), via an unspecified route of administration on 17Dec2020 at SINGLE DOSE for COVID-19 immunisation. Patient's medical history and concomitant medications were not reported. The patient reported he needs advice on the second dose of the vaccine. Patient stated he is an ER nurse and received the first dose of the vaccine on 17Dec2020. On 31Dec2020, patient lost his sense of smell and taste and by the 3rd (03Jan2021), he was diagnosed as covid positive. The patient underwent lab tests and procedures which included Covid test: positive on 03Jan2021. The patient is asking how safe it is to get the second dose now and if there's a time period that he should wait so that he can get the second dose. Outcome of the events was unknown. Information about lot/batch number has been requested.; Sender's Comments: Based on the information currently available, a lack of efficacy with BNT162B2 in this patient cannot be completely excluded. Further information like diagnostic detection of virus genetic material or virus protein antigen needed for meaningful medical assessment.

"she tested positive for COVID-19 on Monday 27Dec2020; she tested positive for COVID-19 on Monday 27Dec2020; This is a spontaneous report from a contactable nurse (patient herself). A female patient of an unspecified age received her first dose of bnt162b2 (BNT162B2 also reported as Pfizer-Biontech Covid-19 Vaccine, lot/batch number and expiry date not reported), via an unspecified route of administration on 19Dec2020 at single dose, for Covid-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient was scheduled for her second dose today 09Jan2021. However, she tested positive for COVID-19 on Monday, 27Dec2020. She stated that she has still some of the symptoms of COVID-19 even though she has been declared fit to work. She was asking if she could take the second dose today. Information about batch/lot number has been requested.; Sender's Comments: Based on available information, a possible contributory role of BNT162B2 cannot be excluded for reported event ""she tested positive for COVID-19""."

Resident was found without a pulse and not breathing 20 minutes after vaccine administration. Upon MD review, no signs of anaphylaxis were noted.

About 10 minutes after getting my vaccine I noticed the roof of my mouth itching as well as my tongue and back of my throat. I waited to see if it would go away and then a couple minutes later noticed my lips started itching and swelling and from there it just got worse. I told the nurse practitioner that I think I was having a reaction, she had me take a seat told her my entire mouth throat & lips felt swollen and itching and she looked and said it was full blown anaphylaxis reaction. Administered EpiPen, benadryl and called ambulance where they took me to medial emergency department.

Patient had just recovered from COVID and ended quarantine on 1/1/21. On 1/4/21, she received the first COVID vaccination. While driving home on 1/6/21, she experienced an MI diagnosed in the emergency room 30 minutes later. She was admitted to the hospital and underwent a heart catheterization and received a STENT. She had previous cardiogenic shock in 2003.

Pfizer-BioNTech COVID- 19 Vaccine EUA Received communication that patient experienced a stroke and received alteplase at a non-facility (Medical Center) 5 days after receiving COVID-19 vaccination.

increase weakness and fatigue, weakness in extremities, incontinent, jerky arm movements, within first 24 hours, continue to decline sent to hospital returned weaker, within 24 hrs hours BP dropped, low pulse oximeter reading, diaphoretic, lung sounds diminished, loss consciousness and passed away. 01-12-2021

01/11/2021- Found lying on bed in apartment, incontinent, lethargic, unable to respond to questions, unable to do hand grasps. sent to hospital. 01/14/2021- remains in hospital- confusion and disorientation continues, poor verbal skills, limited ability to feed self, out of bed to sit in chair. uncertain of return to facility status.

Abdominal pain, Headaches, chest pain, loss of appetite, confusion, elevated liver enzymes 1/8-1/15/21

01-09-2021 Very confused, nauseous, sweating profusely. sent to hospital- admitted with encephalitis, severe cognition decline. 01-13-2021 still in hospital, cognition Improved.

Death Chest pain; irreg heart rhythm; evening of vaccine; death on toilet on 1/13/21

Initially headache and body aches. Within 24 hours developed chest pain, dyspnea on exertion and shortness of breath. Patient still currently hospitalized.

Patient reportedly expired the day following receipt of the vaccine.

Observed in her room having seizure activity and unresponsive to stimuli. BP of 200/120, oxygen level dropped to 86%, HR was 116. She was transferred from Hospital A and later transferred to Hospital B and placed on a ventilator. This remains her current status

We (myself and 2 other pharmacists) were conducting a COVID-19 vaccine clinic. The patient is on staff at the clinic and came in for her 1st dose of the Pfizer/BioNTech COVID vaccine. 10 minutes post-vaccination, patient started experiencing SOB, tingling fingers and face, and swelling of her lips and tongue. She moved herself outside to cooler air and then sent someone back inside to ask us for help. I ran outside with an EpiPen and immediately noted her pulse of 158 on her watch and she appeared to be experiencing an anaphylactic reaction. Patient stated she did not want to use the EpiPen but wanted to try chewing Benadryl instead first. I asked the staff for a blood pressure monitor and pulse oximeter. The 1st readings, approximately 12 minutes after vaccination, were HR 158, BP 155/105, and pulse ox 97%. Patient stated the Benadryl was working and her swelling was decreasing. The patient was not having trouble breathing at the time. I continued monitoring vitals and talking with the patient and approximately 20 minutes post-vaccination, she was improving (BP down to 134/80 and HR 120) but

agreed we should call 911. She decided she wanted to move inside and lie down. I escorted her with support to a bed. Her vitals then increased again to BP 152/95 and HR 133 and her lips and tongue started swelling again. The patient appeared to be more labored in breathing then but still refused the EpiPen. Roughly 5 minutes after lying down, the medics showed up and took over and I went back to the vaccination area. I learned later that the patient refused to go to the hospital and after more observation was eventually allowed to leave with a friend/coworker driving her home.

Patient was at work on 1/15/21 after having received the vaccine on 1/12/21. She complained of being diaphoretic and her heart rate was 156. She was taken to Hospital. She is being admitted to hospital and has reported that her heart rate is 122 and she has a temperature of 99.4 and elevated lactic acid levels.

1/5/2021 0718 Pt received 2nd COVID vaccine 1/4/21. Oral temp 100.6, near syncope, muscle aches and head aches. Per EMS NSR, denies SOB, and chest pain. 500 ml bolus received in route. In ED, Pt c/o nausea. Pt anxious, sweating and uncomfortable. 0855 Pt resting comfortably, reports decease in pain/body aches 4/10. 1043 Discharge disposition: home. Accompanied By: self. Mode: walk. --Hospital

Expired on 1/12/2021; unknown cause of death

We got a call from a home health nurse Brandu Talamo, stating that the patient passed away.

5-6 HOURS AFTER VACCINATION. CONVULSIONS/SEIZURE, HIGH BLOOD PRESSURE, INCREASED HEART RATE,

Severe pain at injection site with some swelling, lethargy, and fever to 101.6 degrees F the day after the injection. He was given acetaminophen, which reduced fever to normal. Low grade fever (99-100 degrees F) two days after vaccine. On the third day after vaccine, on 12/31, he became confused and anxious. Temperature was 104.8 degrees F. He was given acetaminophen and oral hydration overnight. He continued to have a fever to 102 on the following day and was taken to the ED. He was COVID-positive and admitted to the hospital for treatment of COVID-19.

Initially started as shortness of breath followed by fevers, aches, muscle cramps. Ultimately ended up in the hospital with hypoxemia, pleural effusions. Laboratory values showed evidence of acute renal insufficiency, eosinophilia. Physical exam consistent with pulmonary edema and lower extremity macular rash. Entire presentation concerning for DRESS syndrome

Resident had lunch on 01/14/21 and after lunch around 2:00pm, he vomited and stopped breathing. We coded the resident and 911 paramedics came. They pronounced him dead at 2:18pm.

Around 00:50am on 01/15/21, C.N.A. reported that the resident looked different and not responding. Initiated Code Blue and started CPR. 911 arrived and pronounced resident dead at 1:01 am.

"The patient stated "" I just feel Blah"". vital signs obtained. 156/75 p-84 spo2 94% via NC 2L. T-96.7, c/o feeling restless, c/o nausea with no vomiting. Patient observed at 0600 nonresponsive, CPR initiated, and EMS notified Patient expired"

Received Pfizer vaccine, first dose on Wed. 01/13/21 between 12 and 1 P.M. Thurs. 01/14/21 in the afternoon he began to note that he had difficultly walking. Went to bed when he woke up at 5:48 A.M. he reported he had ataxia. Patient reported having to walk in tiny steps to stay upright. He went to the emergency room. Had CT scan of head and found blood clots. MRI performed. Stroke found in right PCA territory, but no loss in strength in left lower extremity. Sensation and vision intact. Strength in all four extremities is 5 out of 5.

At 6 days after my second COVID-19 Pfizer vaccine (first dose given 12/17/20), I had acute onset of chest pain and shortness of breath prompting a trip to the Emergency Department. A chest CT Angio to rule out pulmonary embolus was done and negative for pulmonary embolus. My EKG showed some mild ST changes and a troponin I level was elevated at 0.08 (normal 0.04). Subsequent troponin levels 90 minutes apart showed a rising troponin at 0.18 and 0.38. An echocardiogram was performed which showed regional wall motion abnormalities consistent with Takotsubo cardiomyopathy and an ejection fraction of 45%. I was then taken to cardiac catheterization lab for coronary angiograms which were normal. My LV angiogram was consistent with Takotsubo cardiomyopathy and my LVEDP was elevated. I was started on a beta blocker and sent home the following day.

This patient has been under hospice care for over 2 years at the nursing home. She has had a steady decline with gradual weight loss. She was totally dependent in her care needs. She received the vaccine on 1/2/2021 as part of the facility vaccination campaign. No adverse events noted initially. On 1/3/2021 at 6:06 pm, she was noted on vital sign checks (done every 4 hours for first 72 hours after vaccination) with BP 64/52 but otherwise asymptomatic. Subsequent BP improved. On 1/4/2021 at 4:45 am, pt found with respiratory rate of 30 with otherwise normal vital signs. Tachypnea persisted, so she received liquid morphine 2.5 mg without improvement. Supplemental oxygen was applied. Tachypnea persisted. She had poor oral intake after that point had persistent tachypnea and worsening hypoxemia despite clear lungs on exam. She remained under hospice care and comfort measures were continued. No blood testing or imaging tests were done. She required increasing amounts of oxygen, became hypotensive, and died peacefully on 1/8/2021 at 7:45 pm.

Veteran was found by family slumped over and unresponsive at the breakfast table on 1/13/21, had expired

Anaphylaxis

Pt had 3 vessel CABG on 1/14/21 after presenting to ED with chest pain on 1/9/21. Pt is critically ill following OR after cardiogenic shock, bleeding. Requiring inotropes and Impella.

vertigo nausea / vomiting diarrhea low-grade fever pain at injection site

Bells Palsy 1st injection on 12/20/21 symptoms started 1/7/21, 2nd dose on 1/10/21 immediate numbness in mouth and tightness in throat which triggered bells palsy symptoms immediately

Patient information was reviewed. Patient was asked if they ever had any form of severe reaction to anything they had had in the past. Patient did not state yes to anything other than having a reaction that

was managed at home to shellfish as a child. They stated their throat had swollen as a child during the event. Patient was told that it was an anaphylactic reaction and shouldn't have been managed at home as a child by nurse and should have been taken to the hospital. Patient was told they would be monitored for 30 minutes after receiving the vaccine. Within 2-3 minutes after receiving the vaccine the patient reported tingling or burning around the site of injections. Within 5 minutes they stated to be feeling tired and that their arm had felt numb. After this the patient began starring into the distance and was unresponsive. Called for help and advice by turning around as patient had syncoped. Got nurses and other team members attention and had an epi-pen ready just in case it was needed. Patient began having notable distress with respiration and administed an epi-pen. Advised for a nurse to call EMS for patient and crash cart/oxygen was also obtaine dby the facility. Oxygen was required. Patient was not responsive after the first dose and was given a second as they remained un-alert with notable distress. The patient became alert a while after receiving the second shot and not long after that the EMS arrived to the event.

Resident reported loose stool, not feeling well, resident complaint of lost taste. Hospitalization on 01/14/2020.

Vomiting

"Per husband, was in usual state of health on the AM of 1/10/20, AOx3 able to perform all I/ADLs. At around 2:30pm that day was complaining of chills and generalized malaise. Then at ~9:30pm when husband returned home from work found patient diaphoretic, confused (stating things like ""not now, I want to go to lake""), and complaining of chills and weakness. Unable to provide any additional hx regarding other sx. Initially presented to ED, where mental status had deteriorated to AOx0, unable to respond to verbal commands. Initial vitals notable for T102.6F (unclear other vitals). Patient is now AOx0 most concerning for encephalopathy."

Patient 101 years old, nursing home resident, received vaccine 1/11, on 1/13 found on floor without obvious trauma, unresponsive. Brought to ED and was bradycardic, hypotensive, hypothermic and refractory to aggressive medical management. No obvious cause of death found on exam or labs, cxr. Unknown if event could be related to vaccine or not. Medical Examiner accepted case although initially unknown that patient had recently received vaccine. ME updated with that information today as soon as discovered.

Throbbing head ache, difficulty breathing, lips numbness, chest discomfort, upper back, lower legs, fingers tingling/numbness, high blood pressure 148/83, underarm sweating, feels weak

Nausea with emesis, headache, upper abdominal pain.

Patient suffered a cardiac arrest and was unable to give details about her symptoms. Per husband, patient did not complain of any symptoms after vaccine administration. She began seizing without warning which was complicated by cardiac arrest of uncertain etiology

Right arm weakness 2 hrs after vaccine and then right leg weakness later that evening

"On 1/15/2021 at 1800, resident noted to be lethargic and shaking, stating ""I don't care."" repeatedly. C/O head and neck pain. T100.6. Given Tylenol with no relief of pain. Order received for Aleve and administered.. Assisted to bed as usual in evening. Monitored during night shift and noted to be resting comfortably/sleeping.. Noted agonal breathing at 4:10 AM 1/16/2021 , T 99.4, Absence of vital signs at 4:15AM 1/16/21 and death pronounced at 4:40AM 1/16/21."

"""Moderna COVID-19 Vaccine EUA"" It has been reported to me that pt. had gone into hospital for a heart catheterization on 1/12/2021. It was found during this procedure that pt. had suffered a MI. She was release to home the following day and passed away at her residence on 1/15/2021."

anaphalactic shock reaction, epi injection by hospital emergency staff at vaccine site, emergency room admission . We were very lucky vaccine site was Hospital was concerned that this might happen as patient had a previous anaphalactic shock by antibiotic injection few years ago

Right thumb joint pain. I can't hold unto things in my right hand that requires me using pressure from my thumb. Pain is a 9/10 when holding, grabbing, or using the thumb in any way. When not using the thumb there is no pain at all. I work out everyday and I am no longer to lift weights using my right hand because of the excruciating pain when I try to.

Patient had COVID-19 infection April 2020, ataxia and myoclonus developed, treated with IVIG and steroids at that time. June 2020 had full recovery after PT. Pt received Pfizer COVID-19 dose 1 on 12/22/20 and developed similar symptoms to above on 1/7/2021. Ataxia and tremor on examination, no myoclonus at this time.

Appendectomy Narrative: Developed abdominal pain with nausea on 12/24/2020, went to ER and noted to have appendicitis, resulting in an appendectomy

Swollen tongue and sob with decreased swallow

Vaccinated at 8:55am, Per Nurse Practitioner note patient started experiencing itching upper chest, medicated with Benadryl P.O., started with throat itching, medicated with Benadryl IM, EPI IM, EMS called, placed on O2, diminished breath sounds bases, slight stridor, EPI IM, Solumedrol IM, EMS transported to local ED. Patient called NP later in day and said she was admitted to the hospital.

Pt had witnessed arrest by wife. Pt wife started CPR and called EMS. CPR started at 15:12. Continued by EMS. Pt arrived to medical center asystole with CRP in progress and ventilated via igel device. He was in refractory ventricular fibrillation and continued CPR for a total of 1 hour. At that point, we checked a bedside ultrasound which showed his heart at a standstill. He was unresponsive to verbal and tactile stimulus and had fixed unreactive pupils. He was pronounced at 16:13.

Tachypnea, Angina, Tachycardia, Sore Muscles Narrative: Started feeling ill on the 28th. Drove himself to get checked out at the hospital. Hospital sent him home. Called EMS at 12/30/2020 @ 0200 and was hospitalized for 1 day. He is more stable now but still has these symptoms at a moderate level.

ADVERSE REACTION REPORTED AS TEMPERATURE OF 100.0, CONFUSION, AND VERTIGO. PATIENT WAS TAKEN TO HOSPITAL, UNAWARE OF CURRENT STATUS, TREATMENTS, OR OUTCOME.

After vaccination on 1.8.21 felt fatigue, metallic taste, and intermittent tingling. on 1.15.21 at approximately 8 am developed occipital headache (4/10 pain) inability to move right upper or lower extremities and slurred speech. No evidence of intracranial hemorrhage on CT. Patient administered Alteplase and transferred to higher level of care

Day 1-3 after the dose flu like symptoms Day 3-7 swelling in lymph nodes on left side of body (baseball sized) took ibuprofen and Tylenol Day 8 angioedema, anaphylaxis. Received epi subq, IVP 50mg Benadryl, Pepcid 20mg IVP, liter of NS Day 9 raised red rash all over body and face still going on Day 16-present: severe joint pain and fever, unable to obtain any relief

Muscle Spas; Weakness in both limbs. Pressured speech

Pounding headache, heart racing to over 145 bps, chest burning and tightness and hard to breath. I was taken to the Emergency Room at Hospital immediately. Reaction occurred within 30 minutes of the injection. An EKG was administered. I was prescribed prednisone and Benadryl. I was diagnosed with Anaphylaxis.

Patient had slow progression of kidney disease but since vaccine had unexpected acute kidney failure. He had to have dialysis and may need biopsy of kidney to confirm if he needs lifelong dialysis. He is still being hospitalized.

Numbness and tingling sensations in both hands and sometimes radiating up my forearms, more severe in right hand and right thumb; these symptoms still didn?t go away since 1/11

Death

After 2nd dose in the afternoon at 2:30pm pt collapse in the unit V/S was high blood sugar was high. Pt was held over at work for 16 hours. Shot was given at 6:45am. Paramedics was called. Sent to ER.

Remarkable Myalgia of extremities and back, interfering with rolling or sitting. Spasmodic twitching of upper extremities, These resulted in Hospitalization.

Resident expired

On 1/9/2021 started to have Postural Orthostatic Tachycardia Syndrome and PVCs associated with SOB and chest tightness and not recovered yet.

Headache after dose was given at 10:00 a.m Died at after 7:30 pm the same night the dose was given.

On January 14, 2021, I noticed generalized petechiae all over my body. I went to seek medical care and was found to have platelet count of 2. I was hospitalized for idiopathic thrombocytopenic purapura. I was given platelets which increased my platelets to 4. Next day, given IVIG dose. Also receiving 4 doses of decadron. Day after IVIG, platelets to 20. I am still in the hospital getting treatment today.

Moderna COVID-19 Vaccine EUA. Patient has tested positive for Covid 19 as of 1/10/2021, when he was hospitalized. Patient's wife had been rushed to the ER previously, and they discovered she was Covid positive when she was admitted. Patient immediately notified public health and was being restricted and followed up with. During his quarantine, he started developing symptoms (08Jan2021). On 10 Jan, he was rushed to the ER and diagnosed with pneumonia due to Covid. He was also experiencing painful stomach cramps, low oxygen saturations and fluctuations in blood pressure. He spent 3 days inpatient in the Covid wing then was discharged to resume resting at home. Our provider immediately reached out to the member and checked in with them. At this time, the patient's only real complaint is lack of energy or getting winded when doing projects around the house. Patient will isolate at home and monitor his symptoms. Public health and the provider will follow up with the member and her family periodically to ensure recovery.

PATIENT GOT HER FIRST COVID PFIZER VACCINE AT 12/31 IN THE AM. HAD GOTTEN FLU LIKE SYMPTOMS AND HAD BEEN SICK FOR A COUPLE OF DAYS. HAD NAUSEA AND VOMITTING DURING THIS TIME AS WELL. ON 1/3 THE CARE GIVER WENT TO CHECK ON HER PT AT HER LTC FACILITY WHERE SHE LIVES AND SHE WASN'T ACTING RIGHT. SHE WAS UNABLE TO DO A STROKE EXAM. PT HAD NO MOVEMNET IN ARMS OR LEGS AND WAS UNABLE TO SPEAK. PT WAS VITALLY STABLE AT THE TIME. EMS RECORDED THAT THEY THOUGHT DIAGNOSIS WOULD BE STROKE, PNEUMONIA OR SEPSIS. AFTER ARRIVAL AT THE HOSPITIAL DETERMED THAT SHE HAD A STORKE, ACUTE KIDNEY INJURY, ABNORMAL LFTS.

allergic reaction- skin rash , throat itching. patient visited the ER and was given episode and steroids but returned because symptoms were not improving. She was hospitalized on 1/11 for this reason

12/29/2020 Vaccination 12-13 minutes later started left arm was tight and sore. Wasn't feeling right; hot, hives, rash at injection site up neck and face; tightness in throat; tachychardic, BP increase. I took benadryl and Pepcid . Sat for another 30-45 min. Palpitations, heaviness. Transported to ER. IV and medications. Stayed till 1:30, went home, and then came that evening. 5:00 that same night, hives, chest pressure, burning sensation, 'didn't feel right', anxious. Benadryl. Tachychardic; admitted to hospital that evening. Stayed in house admission till the 12/31/2020. Went back to admission in house, 1/3/2021 - 1/4/2021. Two hospital admissions.

Approximately 28 hours after vaccine, I began to feel tingling in my right eye Approximately 12 hours after that, my face started drooping and was numb so I went to ER. Today is Sunday, and the numbness and drooping was called Bells Palsy at the hospital.

Injection given without unusual pain, but appeared to be at higher site than usual for other vaccinations patient has received. No immediate reactions. No redness or swelling at injection site. Approximately 3 hours later with restriction of abduction of left arm, which became worse over 24 hours. No numbnness, pain 4-5/10 diffusely over deltoid and in acromium, posterior suprascapular area.. Able to passively move arm, treated with topical Voltaren gel, Naproxyn 500 x 1 dose. D2 with increased ROM, but still restricted.

New onset leukopenia/neutropenia with fever, unclear if related to vaccination, but temporally occurred the day after receiving 1st dose. No labs immediately prior to vaccination, so leukopenia may have

preceded vaccine. No other new medications to explain neutropenia. Off chemotherapy since 8/2020. Possible relapsed disease though no other evidence in support of this as remainder of CBC stable.

Shortness of breath, Congestive heart failure, Afib

RespDepression found to have low potassium Narrative: Patient reports experiencing shortness of breath 24 hours after the vaccine was administered, went to ER and admitted for one night. Informed her supervisor she had low potassium.

Patient presented with diffuse petechiae, easy bruising and oral bruises. She has a history of stable ITP with her last required infusion of IVIG 12 years prior during pregnancy and monitors her CBC every 6 months. Her baseline platelet count is ~50-60k. She received treatment with dexamethasone 40 mg IVPB x 3 doses and IVIG 95 grams (1 gram/kg) IVPB x 2 doses.

3 days after receiving the first dose of the vaccine on 12/21/2020, experienced flu-like symptoms that lasted 24 hours. About 17 hours after receiving the second does on 1/11/2021, flu-like symptoms reoccurred. The following day (1/13/2021) severe chills, and difficulty breathing occurred. Patient was admitted to Medical Center, where blood work, EKG, and oxygen were given and ordered. After overnight observation, the patient was discharged and informed that he had a severe reaction due to the Pfizer vaccine for Covid-19. As of 1/17/2021, patient still recovering and feeling generally weak and tired without much appetite.

Vaccine was administered on 1/12/21 at Memory Care. On 1/15/21 at 12:30 he developed slurred speech at his facility and slumped to his left side. Out of concern for stroke he was sent by ambulance to Hospital. There he was found to have no evidence of stroke on MRI or CT angiogram. He was admitted to the hospital due to fever and elevated inflammatory markers (ferritin, CRP) and transaminases. He was found to have a positive SARS-CoV-2 PCR and IgG. His symptoms resolved the following morning and may have represented a TIA. He had many markers consistent with COVID-19 and his CT pulmonary angiogram did show ground glass opacities but no pulmonary embolism. It was difficult to assess if this was a reinfection with COVID-19, persistent PCR positivity from November, or an adverse event to the vaccine.

I received the dose at 1:45 pm on 1/13/2021 at Medical Center. Almost 1 hour post vaccine I started to feel a lump in my throat, as the minutes passed my throat started to feel tighter and fight and flight mode kicked in. It was hard to swallow, my tongue was swelling and I called EMS at 2:40 pm 1/13/2021. EMS noticed hives on my chest and left arm where I got the first dose of Moderna. I received epinephrine IM and IV benadryl in the ambulance. I was sinus tachycardic with heart rate in the 140s oxygen was 99% room air, lungs clear.. I was taken to ER where I was on observation for 2 hours. I was discharged around 5:10 pm on 1/13/2021. On my car ride home around 5:40pm I again started to feel my throat tighten, tongue swell, and heart race. I called EMS again, and was treated with IV benadryl, and epinephrine IM. I was taken to Medical Center where I was given IV solu-medrol and got blood taken and a pregnancy test done. My potassium was 3.1 and I took 2 potassium tablets to supplement. My EKG was normal sinus tach, oxygen 100% room air, blood pressure 140s/90s and got down to

120/80s. I was transported to another Medical Center for overnight observation because first Medical Center was full.

"Narrative: Patient with severe aphasia and only able to say ""hey, hey, hey"" or ""uh huh"" or shake his head no as a way to communicate. Patient previously able to ambulate with significant limp and hyperextension of right knee, but mostly wheelchair bound over last several years as he had had a slow and steady decline in overall health and mobility. Patient developed aggressive behavior of shouting ""hey"" and grabbing of groin in 2016. This was worked up with CT scans, labs, referral to urology, neurology, and referrals to psychiatry. The exact etiology of this action was never able to be affirmed, but thought to be more psychiatrically related. It improved significantly with addition of antipsychotics, worsened when antipsychotics were reduced, and improved again with addition of injectable antipsychotic on 12-10-2020.Patient suffered from falls on occasion given his significantly impaired physical mobility. His last documented fall was 8-31-2019. Patient began utilizing wheelchair most of time following that fall. No significant injuries noted in documentation of the falls. In the last 3 months, patient would often refuse medications. He would sometimes indicate that they would cause dizziness, and other times he would simply refuse. We attempted to hide medications in his food/fluid (with wife's blessing) and when he detected this he would occasionally refuse to eat. Patient previously on DOAC. After pharmacy review in 12/2020 it was recommended to discontinue this as no clear indication to continue use. He was high fall risk and would often refuse this medication as well since 10/2020. Noted to be in NSR on EKGs and decision made to discontinue the DOAC. Patient had no evidence of adverse effects noted after vaccination on December 28th. Patient seen by provider on the morning of his death (1/4/2021) with no noticeable significant change in health condition. Temperature 36.8Con January 4th at 19:45. During routine bedtime cares, patient suddenly collapsed and death was pronounced January 4, 2021 at 20:05. Autopsy was requested from next of kin and no autopsy was granted. Symptoms: & DEATH Treatment:"

Narrative: Symptoms: Palpitations & Syncope Treatment: EPINEPHRINE 1 MG ONCE ,EPINEPHRINE 1 MG ONCE ,SODIUM BICARBONATE 50 ML ONCE

Ventricular fibrillation- Code blue

Severe Right sided chest pain, right sided muscle spasms and difficulty breathing two weeks after vaccine was administered Diagnosis of bilateral pulmonary embolism was made on presentation to ER. No personal or family history of clots in arteries or deep veins or any risk factors in patient. Received heparin drip, pain medications, muscle relaxants inpatient. Pain progressively improved over days. Was discharged after 6 days on admission. Was discharged on oral anticoagulant (Rivaroxaban aka xarelto)

Developed dizziness and nausea within 90minutes of vaccine; then developed tingling, and flushing of my skin. Then rapid heart rate and chest tightness by 2.5hrs post vaccine. I went to urgent Care and they thought it was an allergic reaction (BP 182/90, HR 82) and gave me 125mg solumedrol and Benadryl intramuscularly which caused worsened dizziness and a racing heart which caused me to collapse and they gave me a epi pen and called 911. I was transferred to ER and they completed EKG which was

normal and monitored vitals for a few hours and I was released. I continue to remain extremely dizzy and nauseated 2days after the vaccine.

"2.5 hours after receiving vaccine, I started getting dizzy and vomiting. I vomited 6 or 7 times. I was so dizzy I couldn't open my eyes without getting sick. We called ER and explained that we thought I was having a reaction to the vaccine, and their response was they had never heard of that type of reaction. I was sick all night, called my primary Dr in the am and they told me to go to ER. We had to call ambulance to take me there because I was so sick and couldn't open my eyes without having to vomit. Room spun in circles. My arrival at ER, they did MRI, EKG, blood work. My blood pressure was very high, so they connected me to a heart monitor. I had low Magnesium due to vomiting so much. I was treated with Valium and anti-vert medication and fluids. I stayed overnight in hospital- had PT Jan 13th for DX of Vertigo. Then referred to Outpatient PT for Vertigo. Dr's felt it was a ""coincident"" that I got Vertigo shortly after vaccine, and strongly felt it was not related. . Today is Jan 17th, and I am still dizzy, but feeling better. I have an appointment with my primary Jan 18th and not sure if I should take the 2nd dose. That is the question."

Acute Appendicitis

Heart attack death medical test

Resident expired 1/17/21

29yo female patient reports feeling her throat tingling and closing sensation in her throat with a metallic taste and diaphoretic approximately 3 minutes after receiving vaccine. She did not report these sensations until about 15min after injection. EMS assist was immediately called and pt was brought into one of the patient rooms. She was given Epipen injection approx. 20min after injection and EMS arrived to transport patient down to ER within 1-2 minutes after Epipen administered. Patient was monitored in ER and recovered well

rash on the arm and side of my body where the injection was given. i took some Benadryl on 01/14/2021 the rash came back and the injection spot became really warm and harden. i took Benadryl again it went away. the rash came back 01/16/2021 and i took more Benadryl and the itcing stop. isaw a few red spots on my arm today bot no itching.

lymphadenopathy on left side (starting in axillary and progressing to supraclavicular and eventually neck as well. swollen and extremely tender) in addition to normal side effects of chills, fatigue. also was having irregular heart rhythm (reason for hospitalization) do not know if the heart rhythms are related to the vaccine or not, onset was a few days after vaccination (ER 12/30/2020, then another hospital 1/1-1/2). but the hospitalization below is referring to the heart rhythm not the lymphadenopathy.

The patient received her first Moderna COVID-19 vaccination on 12/29/2020. However the patient was diagnosed with a positive COVID-19 test on January 4, 2021. Patient complained of nausea, vomiting, back pain, and sharp chest pain. On January 13, the patient presented to the emergency department again with shortness of breath and sharp, stabbing left-sided chest pain radiating to her back and right

side. Initial work up ruled out cardiac etiologies. CTA chest demonstrated COVID-19 pneumonia. The patient complained of bilateral lower extremity weakness which had been progressing since her COVID-19 vaccination, per patient report. However, during her hospitalization the patient's bilateral lower extremity weakness began to accelerate. On the 13th, the patient was able to ambulate to and from the bathroom herself. Then on January 14 the patient required maximum assistance. Neurology was consulted and work up initiated for suspected possible Guillain-BarrT syndrome (GBS) secondary to recent COVID-19 infection. On January 15, 2021, the patient became obtunded and unable to protect airway. She was emergently intubated for acute hypercapnic respiratory failure secondary to GBS. Neurology started GBS treatment with IVIG. Patient also developed NSTEMI and Takotsubo cardiomyopathy. Patient remains critically ill requiring mechanical ventilation.

The day after receiving the second vaccination, I began to have mild intermittent abdominal pain2-3/10. The pain gradually increased, became more intense, and more constant. Mild fever and chills started happening, and I took Ibuprofen. By about 4 days after the vaccine, the abdominal pain was severe enough that I had some difficulty walking and I couldn?t sleep at night. Pain was 6-8/10. I went to the ER, and CT scan with IV contrast showed 18 mm appendicitis. I underwent laparoscopic surgery and it was found to be perforated. It was removed. I am currently recovering in the hospital. I received the vaccine as a health care provider at my hospital, specifically I am a practicing pediatrician physician for over 10 years.

I felt quite sick, like I had the flu; became very lightheaded and dizzy; passed out; felt quite sick; This is a spontaneous report from a contactable consumer (patient). A 69-year-old non-pregnant female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 08Jan2021 at 12:30 at single dose in left arm for covid-19 immunization. Medical history included R.A.D., osteopenia, migraine with aura, the patient had previously suffered episodes of vasal vagal syncopy when she got the flu or other severe illnesses, and the patient was diagnosed with COVID-19 prior to vaccination. Concomitant medication included atenolol, atorvastatin, azelastine, and fluticasone. The patient previously took gramicidin, neomycin sulfate, polymyxin b sulfate (NEOSPORIN) and experienced allergies. The morning after receiving the vaccine, she felt quite sick, like she had the flu. When she got up from bed and went to the bathroom to urinate, she became very lightheaded and dizzy. She attempted to return to bed, but passed out on the bedroom floor before she could get to the bed, and seized while she was unconscious. Once she came to, she was helped to bed and, after about 90 minutes, felt much better, and got up, and ate food and had coffee. All events occurred at 07:30 AM on 09Jan2021. All events were reported as non-serious by reporter. The patient did not receive treatment for the events. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient has not been tested for COVID-19 since the vaccination. The outcome of the events was resolved in Jan2021. Information on the lot/batch number has been requested.

Blacked out; Fainted; Felt very unwell; Nauseous; Chills; Fell; Knocked out, hit her nose, started to bleed; Humongous scar on her nose; In her hand there's a rash with different dots/red; She has petechiae/rash on the forearm; hit her face; knocked out, hit her nose; This is a spontaneous report from a contactable physician. This physician reported that a 30-year-old female patient (daughter) received second dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on

08Jan2021 at single dose for covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced blacked out, fainted, felt very unwell, nauseous, chills, fell, knocked out, hit her nose, started to bleed, humongous scar on her nose, in her hand there's a rash with different dots/red, she has petechiae/rash on the forearm, all on an unspecified date in Jan2021. The Caller wanted information on side effects specifically looking at platelet or clotting or bleeding issues. Her daughter, (female, age 29 date of birth) received the 2nd dose of Pfizer vaccine, received it at the (State name), last night. She felt very unwell, nauseous, chills, and then blacked out, fell, knocked out, hit her nose, started to bleed; fainted and hit her face, didn't stop bleeding for 2 hours. There's a humongous scar on her nose. It took 2 hours to stop bleeding. She's going to urgent care today. Her daughter was healthy, yesterday was 2nd dose. In her hand, there's a rash with different dots/red. She has petechiae/rash on the forearm. Thankfully it (bleeding) did stop. The outcome of events for 'knocked out, hit her nose, started to bleed' was resolved on an unspecified date, for other events was unknown. The case was reported as non-serious. Information on the Batch/Lot number has been requested.; Sender's Comments: Based solely on a chronological association a causal relationship between events blacked out and fainted and BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), cannot be completely excluded. The case will be reevaluated should additional information become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

fist dose on 21Dec2020, second dose on 07Jan2021; pain and stiffness radiating from injection site all the way down arm,into breast, and middle of back; pain and stiffness radiating from injection site all the way down arm,into breast, and middle of back; pain and stiffness radiating from injection site all the way down arm,into breast, and middle of back; Started having chills; Severe headache; collapsed on the way back to bathroom and was unable to get up for about 20 minutes; tachycardia; extremely fatigued entire day; This is a spontaneous report from a contactable Pharmacist who reported for herself. A 30-year-old female patient received her second dose of BNT162B2 (Pfizer/ BioNTech Covid-19 vaccine, lot number Ej1685) at a single dose at 09:45 AM 07Jan2021 at left arm for Covid-19 immunization in a hospital. The patient had her first dose of Pifzer Covid-19 vaccine on 21Dec2020 at 12:00 PM at left arm, and experienced very mild reactions which included mild pain at injection site and runny nose/sneezing day after vaccine. The paitent had a medical hisotry of rash to penicillin as a child. Concomitant medications were not reported. The patient did not receive any other vaccines within 4 weeks prior to her first dose of Pfizer COVID vaccine. In the evening of second vaccine (around 17:00), pain and stiffness radiated from injection site all the way down arm, into breast, and middle of back. She started having chills. Around 10 hours after dose chills became somewhat violent despite being under 4 blankets. Severe headache also started. In the middle of the night to go to bathroom, she collapsed on the way back and was unable to get up for about 20 minutes. She also suffered from tachycardia overnight. her baseline heart rate runs in 60s- 70s, but was in 110s-120s (based on Apple Watch monitoring). Day after vaccine, she was extremely fatigue entire day and spent all but a few hours in bed. Arm pain mostly gone. Headache was very strong and persistent through the day. On second night chills not as bad but still occurred overnight. HR still elevated in 80s overnight. Morning of day 2 still had

headache and fatigue. The patient did not receive any treatment for the events. The outcome of collapse and unable to get up for 20minutes, pain and stiffness radiating from injection site all the way down arm,into breast, and middle of back was resolved, chills and tachycardia was resolving, headache, fatigue was not resolved. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. The reporter considered that the events was non-serious.; Sender's Comments: Based on a chronological temporal association and known BNT162B2 vaccine safety profile, causality between events fainting, violent chills and severe headache and BNT162B2 ((Pfizer/ BioNTech Covid-19 vaccine) cannot be completely excluded. The case will be reevaluated should additional information become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

anaphylactic reaction/anaphylaxis; This is a spontaneous report from a Pfizer Sponsored Program from a contactable pharmacist. A female patient of an unspecified age received first dose of bnt162b2 (Pfizer BioNTech COVID vaccine, lot number: EK4176), via an unspecified route of administration on 09Jan2021 at 0.3 mL, single (standard like 0.3ml by injection once to deltoid, side unknown) to prevent from getting COVID. The patient's medical history and concomitant medications were not reported. The patient experienced anaphylactic reaction/anaphylaxis on 09Jan2021. Clinical course: The patient got the vaccine while waiting to go into the watch room, to be watched for a few minutes, and she experienced anaphylactic reaction/anaphylaxis, she went down, they gave her an Epinephrine, she didn't respond to the first dose, a second dose was given in the arm where the vaccine was given, then she was picked up by an ambulance. Agent stated the caller has been on hold for almost an hour. Caller clarifies dose was given in the arm, it occurred on Saturday with the same lot. Saturday and it went away on Saturday, the patient was worried about it coming back, thus why she asked about Epinephrine pen, the patient was taken to the hospital, and given Epinephrine a couple more times, and it resolved eventually, the patient was not admitted, she went to the Emergency Department. It could have required hospitalization but would most likely say life threatening had she not been treated. Reporter seriousness for anaphylaxis is life threatening. The outcome of event was recovered on 09Jan2021. Relatedness of bnt162b2 to reaction anaphylaxis is related for primary source.; Sender's Comments: A possible causal association between administration of BNT162B2 and the onset anaphylactic reaction/anaphylaxis cannot be excluded, considering the plausible temporal relationship and the known adverse event profile of the suspect product. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

developed symptoms for Covid/tested positive after receiving the vaccine; developed symptoms for Covid/tested positive after receiving the vaccine; developed symptoms for Covid/tested positive after receiving the vaccine; This is a spontaneous report from a contactable physician (patient) and a

consumer (patient's spouse). A 67-year-old male patient received first dose BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Solution for injection; lot number: EH9899; expiration date: not known), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The physician had a question. As a patient, he received the first dose of Pfizer BioNTech vaccine and on an unspecified date, two days later, he developed symptoms for Covid and tested positive after receiving the vaccine. He stated this had nothing to do with vaccine but had to do with the timing. He wanted to know if should take or delay vaccine. He is doing fine now. His second dose is coming up next week. The outcome of the events was recovered on an unspecified date.; Sender's Comments: The association between the event lack of effect (he developed symptoms for COVID and tested positive) with BNT162b2 can not be completely excluded.

got the first vaccine and then tested positive for the virus; got the first vaccine and then tested positive for the virus/fairly sick; This is a spontaneous report from Pfizer-sponsored Program IBCC (Inbound Call Center for HCPs). A contactable physician reported similar events for two patients. This is the first of two reports. A patient of unspecified age and gender received first dose BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Solution for injection; lot number and expiration date: not known), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The reporter is a cardiologist. He is inquiring about the COVID-19 vaccine. He had several patients (pending clarification) who got the first vaccine and then tested positive for the virus. He is asking when can they get the second dose after testing positive. He had two patients that are fairly sick now. He has had patients who have monochromal antibodies (pending clarification). He is asking when they can get the vaccine after that treatment. The outcome of the events was unknown. Information about lot/batch number has been requested.; Sender's Comments: A causal association between BNT162B2 and the reported events cannot be excluded based on a compatible temporal relation between vaccination and onset of events.,Linked Report(s) : US-PFIZER INC-2021022171 same reporter, similar suspect drug and event; different patient

got the first vaccine and then tested positive for the virus; got the first vaccine and then tested positive for the virus/fairly sick now; This is a spontaneous report from Pfizer-sponsored Program. A contactable physician reported similar events for two patients. This is the second of two reports. A patient of unspecified age and gender received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Solution for injection; lot number and expiration date: not known), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The reporter is a cardiologist. He is inquiring about the COVID-19 vaccine. He had several patients (pending clarification) who got the first vaccine and then tested positive for the virus. He is asking when can they get the second dose after testing positive. He had two patients that are fairly sick now. He has had patients who have monochromal antibodies (pending clarification). He is asking when they can get the vaccine after that treatment. The outcome of the events was unknown. Information about lot/batch number has been requested.; Sender's Comments: A causal association between BNT162B2 and the reported events cannot be excluded based

on a compatible temporal relation between vaccination and onset of events.,Linked Report(s) : US-PFIZER INC-2021022153 same reporter, similar suspect drug and event; different patient

The day following vaccination, the patient experienced nausea/vomiting, shortness of breath, followed by extremity paresthesia, and increased heart rate. The patient went to the emergency room and was assigned an overnight admission for a potential post-vaccination adverse event. Patient was discharged the following day.

The day of vaccination, the patient presented to the emergency room with a complaint of dizziness and syncope. Reported that she became dizzy, presyncopal feelings, and had a witnessed syncopal event. The patient stated she does have vasovagal syncopal events after blood draws in the past. The patient was assigned an overnight admission for a potential post-vaccination adverse event, new onset atrial fibrillation, dehydration, and syncope. Patient was discharged the following day.

Myalgia Narrative:

Patient became sick 3 hours after the vaccine and was found deceased 1 day after his vaccination. He passed away in his sleep.

nausea and vomiting possible cause of diabetic ketoacidosis and svt

0900 IM Covid 19 vaccine 0905 Sore throat 0920 Dizzy episode followed by headache 0945 Stridor upon deep breath 1000 Facial tingling, top lip and eye swelling 1015 Present to Emergency Services 1040 IV benadryl - Tingling throughout body, stridor worsening, , visible facial swelling 1045 IV Decadron - Throat swelling worsening, chest heaviness, wheezing 1050 IM Epinephrine 1055 Racemic Epi nebulizer treatment 1100 Facial and throat Swelling reducing, breathing easier, 1105 Breathing back to normal 1430 Discharged from Emergency Services with prescription for Dexamethasone 4Mg for 3 days, 2 allegra 2x daily, famotidine 2 x daily

Jan 11-vaccination day. On Jan 14, in afternoon had tinnitus and muffled hearing that went away. The next morning Jan15, complete sudden hearing loss on left ear. Tinnitus and muffled hearing that has not went away.

Patient experienced abdominal pain on January 12th. She reported having a headache and joint pain as well. Her temperature was 103.5. On January 14th the patient was admitted for acute appendicitis with perforation, localized peritonitis, and gangrene. Patient was discharged on January 16th post appendectomy.

Patient received Moderna Covid vaccine on Friday evening 1/8/21. She awoke Saturday am around 2AM with a severe headache. She also developed a fever during the day. She did not seek treatment until Sunday and went to Hospital ED. She was treated and released same day. She went back to hospital on Monday as she felt worse and she was admitted at that time and treated for a bloodstream infection and meningitis. We are not sure it was caused by the vaccine. She consulted her PCP and her PCP feels it may be more coincidental given her medical HX.

A few days after the vaccine I began to have a cough about mid morning which changed to SOB. Covid test on 12/27 which was neg. I went to work on 12/28 but woke up 12/29 with a low grade fever and felt like my throat was on fire. so on the 29th I went and got a Strep and flu test which were negative. I was feeling so bad so on the 6th of Jan do I went to the stand alone ER and got a chest xray and CT scan which revealed I did have pnemonia. I went back home but was feeling worse and was taken to and admitted in hospital for 2 days. Initially I was admitted into the COVID unit but never was diagnosed COVID positive so I was moved off the COVID unit. I was given albuterol pills to try to help with the symptoms but didnt work causing me to have to be admitted and was given several doses of steorid and other antibioics and had to use O2 at night because my stats kept falling.

Patient reported to the emergency room from fever and shortness of breath the day after receiving the COVID-19 vaccine. Patient was found to have a UTI and possible sepsis. Unknown if truly related to COVID vaccine.

Severe fatigue, Headache frontal and temporal, dizziness/vertigo, tinnitus,

"Pt is 33 yo female with h/o multiple drug allergies , including allergy to benadryl. She has received first dose of COVID vaccine made by Phfizer at 3:45. She reports about 10 minutes after the vaccination she started feeling tingling in her lips, throat and prickly sensation on her chest and feeling ""off"". Felt dizzy, developed small hives on her chest. She was attended to immediately at the vaccine site and our team was called to white code. Pt was sitting on the floor, alert , breathing comfortably. Her BP was 151/84, HR 90, O2 Sats 100%. Her lungs were clear the whole time, no wheezing, no difficulty swallowing or talking. Patient received 125 mg of IV solumedrol and 20 mg of pepcid in vaccination room, she felt the same, still breathing comfotably, speaking full sentences, hives faiding away. She was transported to Urgent Care clinic on wheelchair. Pt kept her EpiPen by her site the whole time but refused to used it, states she is afraid to use it and wants to hold off or get it in ER if necessary. About 16:30 patient reported her tingling, prickly sensation In her chest is getting worse, developed sensation of lump in her throat, able to swallow and breath without problems, lungs exam clear. Again recommended to give Epipen but patient again refused as she feels very anxious about getting new medicine. She was able to speak full sentences and breathing well, O2 Sats 100% the whole time, she repetitively refused EpiPen. EMS called and patient transported to ER, ER notified. Pt left in stable condition."

On 01/13/2021 at about 11pm I began having pain in both arms and across my chest. Also nausea and vomiting. At midnight I went to the Emergency room and was diagnosed with a heart attack, underwent emergency catheterization and stent placement. I had complete occlusion of the right coronary artery

Patient is 39-year-old male with no significant past medical history who works at long-term care facility. He received COVID-19 vaccine on 1/13/2021 and immediately developed numbness and tingling in the area of injection which was the left shoulder. Over the next 15 to 30 minutes numbness and tingling expanded to the left side of his body including face arm and leg and the left side of his trunk. He began to feel foggy and had some slurred speech. He presented to the Emergency Room and tests were performed to rule out a stroke. The patient denies any other symptoms such as fever chills myalgias. He

did not have any weakness of the extremities. He did not have any speech disturbances or visual disturbances. This morning on examination he states his symptoms are much better. He still has some residual numbness in his leg and arm. Facial numbness is almost all gone. As of 1/18/2021, residual numbness and tingling is only in his left ring and pinky finger.

"Patient with PMH of depression and GERD who presented 1/8 with constipation, abdominal discomfort and worsening dyspnea. Symptoms began around 12/29. COVID vaccine 12/19. Previously quite active, marathon runner, gained some weight over last couple years but was still in good enough shape to complete 10K in New Orleans in early February. In late February, had a flu-like illness, as did one of his friends from church. 2020 was hard on him - weight gain, decreased activity, stress, overall deconditioning. No issues apart from sore arm after COVID vaccine 12/19 but then starting getting abdominal fullness/discomfort around 12/29, which steadily worsened, also develop worsening dyspnea on slight exertion. No known sick contacts.. Work-up notable for pericardial effusion, pleural effusions. Echo with severe diffuse LV hypokinesis, concern raised for myocarditis. COVID PCR negative, serology negative. RVP negative. . Concern raised that COVID vaccine may have played a role in myocarditis. He was found to have the following conditions Acute heart failure with reduced EF NYHA FC II, non-ischemic cardiomyopathy. Myocarditis appears subacute per MRI hypertension obesity small pericardial effusion-asysmptomatic no pericarditis suspected obstructive sleep apnea. .Started on the following medications. Continue Carvedilol 12.5mg BID, Farxiga 5mg daily, Digoxin 0.125mg daily, Entresto 97-103mg BID, and Spironolactone 25mg daily. Per MD note. While it remains uncertain, team is doubtful COVID vaccine played a role in his cardiac issues. Given the MRI findings are not acute, more likely that the cardiac insult occurred weeks to months ago - potentially in the setting of the February 2020 illness. Perhaps his ""deconditioning"" in 2020 was related to worsening cardiac function. Nevertheless, will hold on 2nd COVID vaccine dose given absence of a clear explanation for his myocarditis. conversation with team will continue to determine if candidate for second covid vaccine. If consensus is that myocarditis pre-dated vaccine, might be able to proceed with dose 2 of vaccine."

"PATIENT RECEIVED VACCINE 1/7/21 AT 1000. THE NEXT DAY, PATIENT PRESENTS TO ER ON 1/13/21 WITH COMPLAINTS OF PALPITATIONS AND DIZZINESS OCCURING SINCE HER FIRST DOSE OF VACCINE. ""The patient states she has had these episodes for the last 6 days and they started when she got her COVID vaccine. The patient states she has had numerous episodes over the last 6 days of this that lasts between 2 and 4 hours. The patient can feel her heart fluttering and she gets a little dizzy with it. The patient has not had any nausea, shortness of breath or chest pain with these episodes however. The patient has not had any prior episodes of this. The patient takes no regular medications apart from vitamins."" PATIENT WAS DIAGNOSED WITH NEW FOUND A. FIB WITH RVR. ADMITTED TO HOSPITAL FOR OBSERVATION. PATIENT RETURNED TO NORMAL SINUS RHYTHM THE NEXT DAY AFTER INITIATING DILTIAZEM AND ELIQUIS."

EDD July 4, 2021 January 15th baby no longer had a heartbeat after two previous visits confirming heartbeat and EDD.

DVT in right leg 4 days after injection, severe pain in thigh/calf, difficulty walking Placed on Xarelto 15mg 2X daily for 21 days and then 20mg daily for 9 days. Next Doctor visit is 1/26/2021 at 9:00am Next scheduled Covid 19 vaccine is scheduled for 2/5/2021 at 7:15am

After I received the vaccine went home rested temp went up one time 99.0. The next day woke up heart was pounding check my BP 150/80 laid back down. I woke up around 5pm my BP had elevated to 160 (don't remember diastolic reading) pulse rate normal limits. I informed my spouse of what was happening called 911. At the hospital checked vitals, EKG, CT Scan, Chest X-ray, Blood work and Potassium was low took 2 Potassium pills. I went back home on 12/31 returned to work did fine that day. On New Years day everything started back again discomfort went back to ER. I felt like force in my chest the doctor collected my information and I was placed on a low dose BP medication until I return to my PCP, cardiologist(stress test). I followed up with PCP via Telehealth about my BP concerns, my dosage was increased to 25 mg and due to my symptoms I was placed on leave from work 2 wks. I also have a appointment scheduled with Neurologist.

Daughter call in for VAERS report to file for father whom committed suicide 1/16/2021 in the AM after reportable ae of COVID 19 vaccine administered 1/14/2021. Patient sought care twice at ER; first visit by ambulance around 5PM and Friday 1/15/2021 Medical Center: Emergency Room. 1st Discharge summary diagnosis: adverse reaction to COVID shot; 2nd Discharge summary diagnosis: adverse reaction to COVID shot, fever, Panic Disorder-- ER. Medical Center Discharge summary diagnosis: Adverse reaction to the vaccine, acute anxiety. Reportable patient symptoms at, 1st visit : fever, shaking stomach cramps, breathing issues. Medical Center -- No fever, confusion and dementia type, patient would not stay in patient bed; patient would get up and sit down again repeatedly, agitated and anxious. Attempted to urinated hospital bed. Patient committed suicide in home.

Anaphylaxis (urticaria, tongue swelling, subjective difficulty breathing) starting approx. 24hrs first moderna dose. No prior episodes of anaphylaxis/allergic rxn. Treated with Benadryl 100mg PO (prior to arrival, pt administered), famotidine 20mg IV, Epinepherine 0.3mg IM. Monitored in ED, complete resolution of symptoms, discharged home.

Weakness, Low O2, death. Positive for COVID on 1/12/21, dies on 1/16/21

Patient presented to ED with complaint of chest pain, radiating down left arm, not relieved with Tums. Symptoms started at 0530 1/12/2020. Patient presented to ED b/c of strong family history of CAD, with father having MI in his 50s.

On 1/17/2021 at 4:35 am resident found apneic and pulseless, at 4:40am death confirmed

I was vaccinated at 3:30pm . At 5:27pm while driving home i felt a cold sensation in the back of my neck and back of my throat which began spreading to the back of my head . My heart felt as if I was startled by something. I looked at my smart watch and my heart rate was 145. I began trembling and having abdominal cramping . The back of my head felt like I had swelling or collection of fluid. I opened my windows and began taking slow deep breaths to bring down my heart rate . It took quite a while to get it below 100. I felt as if I was going to pass out. After deep breathing for what felt like atleasr 15 to 20

minutes , my pulse came down and I closed my windows . As soon as my body warmed back up in the car , the symptoms returned and my heart rate went back up to 130s , 140s . I had to keep my windows down and deep breathe the entire way home which took an hour . My body was trembling. When I got home I felt as if I was too week to get out of the car . I still felt that startled feeling in my heart and was afraid of what could happen next . My lips and face were swollen. My lips were also slightly itchy. I called 911 for help . By the time they arrived my vital signs had stabilized but I still had swelling in my face and lips . My EKG , vital signs and oxygen levels checked out normal so I did not go to the ER. That night I took benadryl and Tylenol. Day 2 post vaccine the collection of fluid or swelling in the back of my head had now spread to the top . That night I had the feeling that my throat was swelling do I took benadryl and Tylenol and my face and lips were still slightly swollen . Day 3 post vaccine I woke up with slightly blurry vision. The swelling in my head now feels like it has encompassed my entire head and have a slight headache. I went to the urgent care requesting an MRI of the head and an epi pen . I was given Medrol dose pack , an RX for epi pen for emergencies and advised to continue benadryl and Tylenol. Day 4 post vaccine, slight headache continues. Slightly blurry vision

12/29/2020 Vaccination. Within minutes blurry vision, dizzy, tx to stretcher. EXTREME HA, coughing, sensitivity to light. EPI pen in ER. I fell asleep. Woke up, don't remember much. Admitted to hospital. Chest pains started within 2 hours, SOB, HA. Admitted for 2 nights, 3 days. Discharged home. Still having SOB and referred to Pulmonologist. Waiting on appt. *did NOT have problems before this vaccine. I was fine. Now i am completely different person, I have to monitor my walking, etc.

"80YO male who htn, cva, epilepsy, ckd, cerebral avm s/p repair, cad s/p cab, cva (left sided hemiplegia) , hx of prostate cancer recent admission for pna on abx presents to ED on 1/11 with dizziness, hypoxia. CT with Bilateral PE ""Large bilateral pulmonary artery emboli in the right and left main pulmonary artery extending into the right and left main pulmonary artery branches bilaterally. Findings are associated with right-sided heart strain."" ""Patchy alveolar airspace disease within the lungs highly suspicious for COVID pneumonia"" Covid negative. Patients wife recovered from Covid-19 infection within last month. Patent thus far has tested negative. Doppler lower extremity revealed Acute occlusive vein thrombosis of the entire course of the gastrocnemius vein and soleal vein. Patient received covid vaccine on 1/4/21. Patient has several risk factors for clot - age, previous CVA, hx of prostate cancer. Also had positive covid exposure though tested negative"

Resident was seen by MD on 1/11/2021 due to increasing in edema and shortness of breath. Lasix 40 mg STAT given. New orders to get a STAT CBC, CMP, and BNP. Resident has been dependent on Oxygen since his diagnosis of COVID-19 on 11/23/2020. Labs were abnormal. Continued on the lasix 40 mgs. Resident remained short of breath with exertion and on oxygen. He was assisted to the toilet on 1/15/2021 in the morning where he subsequently passed away.

hives on her face; This is a spontaneous report from a contactable healthcare professional (physician assistant). A 42-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot number: EK5730), via an unspecified route of administration, on 24Dec2020 as a single dose (reported as 0.3) for COVID-19 immunization. The patient had no medical history or concomitant medications. The patient experienced hives on her face in Dec2020, which was reported as

medically significant. It was reported that within 24 hours of vaccination, the patient had hives for 48 hours. The event was reported as a moderate systemic reaction. The clinical outcome of hives on her face was recovered in Dec2020.; Sender's Comments: Based on the compatible time association, the event hives on her face is possibly related to suspect BNT162B2 administration. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

"a low grade fever; cough; doesn't feel very well; feeling yucky; soreness in the arm where vaccine was given; This is a spontaneous report from a contactable Nurse (reporting for herself). A 29-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE solution for injection, bacth/lot no: EK9231 while expiry date was unknown), intramuscular on left deltoid on 07Jan2021 16:45 at a single dose for covid-19 immunization. There were no medical history and concomitant medications reported. Patient has no prior vaccination within 4 weeks.The patient got her first dose of the COVID 19 vaccine yesterday (07Jan2021) from her employer. She started ""feeling yucky"" today (08Jan2021) around noon with a low grade fever,and developed a cough that was not persistent. Patient has soreness in the arm where vaccine was given. She was asking what should she do about it? Outcome of the events low grade fever, cough, feeling unwell, feeling abnormal were not recovered while vaccination site pain was unknown. The events low grade fever, cough, feeling unwell were considered serious medically significant and related to vaccine.; Sender's Comments: Based on the time association, the events fever, cough and malaise are possibly related to suspect BNT162B2 administration. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate."

generalized weakness; flushing; my BP is high; dose 1 start date 19Dec2020; dose 2 start date 8Jan2021; This is a spontaneous report from a contactable pharmacist. A 34-year-old female patient received the second dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number EL3246), intramuscular in left arm on 08Jan2021 at a single dose for COVID-19 immunization. Medical history included chronic HTN and allergies to baclofen and statins. The patient's concomitant medications were unspecified medications taken for hypertension. The patient previously received the first dose of bnt162b2 on 19Dec2020 via intramuscular in left arm, lot EL0140. On 08Jan2021, the patient was brought into ER as code MET. Patient was receiving her second vaccine for COVID-19 when she experienced generalized weakness and flushing. She stated that she knew her BP was high. Endorses hx chronic HTN, reports she took all three medications this AM. The patient denied any headache, new visual change, CP, SOB, or focal weakness. The events recovered on an unknown date in Jan2021. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. No treatment was received for the events.; Sender's Comments: Based on the time association, the events asthenia, flushing and hypertension are possibly related to suspect BNT162B2 administration. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer

procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Profuse watery vaginal bleeding 12 hrs after injection. Bleeding lasted approximately six hours. After first injection and vaginal bleeding, gynecology exam completed for abnormalities; This is a spontaneous report from a contactable physician (patient). A 55-year-old female patient received the first dose of BNT162B2 (Pfizer-BIONTECH Covid-19 Vaccine), intramuscular in the left arm on 22Dec2020 at 16:00 at a single dose; and the second dose via intramuscular in the left arm on 08Jan2021 at 08:00 at a single dose as COVID-19 vaccine. Medical history included a known latex allergy and previous spontaneous cerebral artery dissection x 3 (nonspecific connective tissue disease). The patient was not pregnant at the time of vaccination and did not receive any other vaccine within 4 weeks prior to the COVID vaccine. The patient was not diagnosed with COVID-19 prior to the vaccination and was not tested for COVID-19 post vaccination. Concomitant medications (reported as other medications within two weeks of vaccination) included estrogens conjugated (PREMARIN), micronized progesterone, colecalciferol (Vitamin D), folic acid (FOLATE), and diphenhydramine hydrochloride (BENADRYL). On 23Dec2020, the patient experienced profuse watery vaginal bleeding 12 hours after the injection. The bleeding lasted approximately six hours. After the first injection and vaginal bleeding, a gynecology exam was completed for abnormalities. Previously diagnosed uterine fibroids present and some free fluid in the pelvis by ultrasound. Bleeding resolved by the end of post-vaccine day 1. After the second vaccine, heavy vaginal bleeding started 10 hours after a injection. It was reported that the adverse event result in a doctor or other healthcare professional office/clinic visit. Treatment for the event involved removal of the IUD. Outcome of the event was recovering. The case was reported as non-serious (did not result in death, was not life-threatening, did not cause/prolong hospitalization, was not disabling/incapacitating, and did not result to any congenital anomaly/birth defect). Information about the lot/batch number has been requested.; Sender's Comments: There is reasonable possibility that the event vaginal hemorrhage is related to suspect drug BNT162B2 based on a compatible temporal relation between vaccination and the onset of events. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

few enlarged and abnormal lymph nodes believed to be reactive in nature; patient was pregnant at the time of vaccination; large mass appeared in right axilla; mass was painful to touch; large mass appeared in right axilla; mass was painful to touch; This is a spontaneous report from a contactable healthcare professional (patient). A 36-year-old female patient received the first dose of bnt162b2 (COVID 19, brand: Pfizer) lot no: EJ1685, via an unspecified route of administration in right arm on 23Dec2020 07:15 at a single dose for COVID-19 immunization in a hospital. The patient had no relevant medical history and no known allergies. The patient was pregnant at the time of vaccination, last menstrual date was on 05Oct2020, delivery date will be on 12Jun2021, gestation period: 11. Concomitant medication includes daily multivitamin. The patient did not receive other vaccines within 4 weeks prior to the COVID vaccine.

The patient was not diagnosed with COVID-19 prior to vaccination and was not tested for COVID-19 since the vaccination. On 30Dec2020 04:00 am, 7 days after vaccine (as reported), a large mass appeared in right axilla. The mass was painful to touch. Overnight mass more than doubled in size on 31Dec2020 the mass took up her entire arm pit, went to immediate care and was given antibiotics. The mass decreased in size but has not gone away. She followed up with primary care. She had bloodwork and ultrasound of axilla and right breast. Blood work was normal. Ultrasound showed a few enlarged and abnormal lymph nodes believed to be reactive in nature. Largest lymph node as of 08Dec2020 2.5 x 0.9 x 2.2 cm. The events were reported as non-serious. The events resulted in doctor or other healthcare professional office/clinic visit and emergency room/department or urgent care. Outcome of the events was unknown.; Sender's Comments: A causal association between BNT162B2 and the reported events cannot be excluded based on a compatible temporal relation between vaccination and onset of events. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

Syncopal event; Nausea; Vomiting; This is a spontaneous report from a contactable nurse. A 29-year-old female received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number:EL1284), via an unspecified route of administration on the right arm on 08Jan2021 12:15 at single dose for COVID-19 immunisation. The patient medical history was not reported. Concomitant medication included influenza vaccine (INFLUENZA VACCINE) on 13Dec2020. The patient previously took first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899) on 18Dec2021 12:15. The patient experienced syncopal event, nausea and vomiting on 09Jan2021 05:00. The patient received no treatment. The outcome of the events was recovering. No follow-up attempts are possible. No further information is expected.; Sender's Comments: Based on the compatible time association, the event syncope is possibly related to suspect drug BNT162B2 administration. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

allergic reaction; large red itchy rash on her neck / chest area; trembling; This is a spontaneous report from a contactable pharmacist. A 33-year-old female patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via unspecified route of administration (lot number: EL1283) in the arm right on 07Jan2021 09:00; at single doses for COVID-19 immunization. Medical history included known allergies: latex. Concomitant medications included magnesium oxide (MAG OXIDE) at 200 mg, daily (every day) and cetirizine hydrochloride (ZYRTEC) at 10 mg, daily (every day); and toprolol at 25 mg, every day (pending clarification for the drug). The patient previously received first dose of BNT162B2 on 17Dec2020 (lot number: EK5730) for COVID-19 immunization. Patient was not diagnosed with COVID-19 prior to vaccination; and has not been tested for COVID-19 since vaccination. Within the 15-minute observation period on 07Jan2021, the patient developed a large red itchy rash on her neck and chest area; she stated she felt fine but was observed trembling. She was transported to ED

(emergency department, 5 min transport). She was treated with diphenhydramine hydrochloride (BENADRYL) at 25mg IV X1 (intravenous), and methylprednisolone (SOLUMEDROL) at 60mg IV X1 and famotidine 20mg IV X 1. Patient diagnosis was allergic reaction on 07Jan2021. Patient improved after treatment and was discharged (after being in Emergency room/department or urgent care) as she was observed from 09:11 until 10:33. Final outcome of the events was all recovered on unspecified date.; Sender's Comments: Based on the time association, the allergic reaction, rash erythematous and trembling are possibly related to suspect BNT62B2 administration.The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

couldn't differentiate the tingling in hands and feet from shot or from that; sharp pain jolt behind eyes/eyes hurt; icreamed; Her hand eye coordination was off as well and she wasn't able to be accurate on keyboard and her cursive was off; Whole body still weak; sharp pain jolt behind eyes, left one in particular so bad she screamed and the nerves went all the way to finger tips; Twitching of face when do certain movements; brain zaps and brain buzzing began; numbness to right side of face to neck/made its way to left side; Horrible headache; fatigue; felt pressure behind her right eye; felt in a fog; forgetful mid conversation; This is a spontaneous report from a contactable other health professional (patient). A 42-year-old female patient (not pregnant at the time of vaccination) received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, EL0140), intramuscular on 23Dec2020 08:00 at single dose at right arm for COVID-19 immunization; prednisone via an unspecified route of administration from an unspecified date to an unspecified date (for 4 days) at 50 mg for an unspecified indication. Medical history included Known allergis: latex, contrast dye. Concomitant medication included the first dose of influenza vaccine (FLU) on 30Nov2020 at single dose at right arm for immunization. Facility where the most recent COVID-19 vaccine was administered at Hospital. The patient received other vaccines within 4 weeks prior to the COVID vaccine. It was reported that Day 1: on 23Dec2020 08:15, the patient felt pressure behind her right eye after shot, felt in a fog, forgetful mid conversation. Day 2. (24Dec2020) Horrible headache started, fatigue. Day 3 (25Dec2020) brain zaps and brain buzzing began, headache, fatigue, numbness to right side of face to neck. By day 5 (27Dec2020) made its way to left side. Twitching of face when do certain movements. Her Dr gave her Prednisone and she took 50 mg for 4 days and stopped because she couldn't differentiate the tingling in hands and feet from shot or from that. Still brain zaps, newest issue sharp pain jolt behind eyes, left one in particular so bad she screamed and the nerves went all the way to finger tips. Her hand eye coordination was off as well and she wasn't able to be accurate on keyboard and her cursive was off. Whole body still weak, eyes hurt. Head a lot better than a day ago but still having buzzing and twitching. Today was day 18. She was awaiting an MRI with contrast on Friday hoping it got moved sooner as she was scared to what was going on. The adverse events result in Doctor or other healthcare professional office/clinic visit and Emergency room/department or urgent care. Treatment received for the adverse events included CT/MRI/Optic Nerve Scan/Pain Shot/Meds for Zaps. The events were non-serious per the reporter. Prior to vaccination, the patient wasn't diagnosed with COVID-19. Since the vaccination, the patient had been tested for COVID-19. The patient underwent lab tests and procedures which

included Nasal Swab: negative on 28Dec2020. The action taken in response to the events for prednisone was permanently withdrawn on an unspecified date. The outcome of the events reported as not recovered.; Sender's Comments: A possible causal association between administration of BNT162B2 and the onset of all these reported serious events might not be fully excluded, considering the plausible temporal relationship. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

"Heart fluttering; chest pressure; This is a spontaneous report from a contactable nurse (patient). A 55-year-old female patient received first dose BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Solution for injection; lot number: EK5730; expiration date: not known), via an unspecified route of administration in the left arm at hospital on 31Dec2020 10:00 at at single dose for COVID-19 immunization. Medical history included known allergies with sulfa. The patient is not pregnant. The patient's concomitant medications were not reported. The patient previously took clarithromycin (BIAXIN), metronidazole benzoate (FLAGYL), and sulfamethoxazole, trimethoprim (BACTRIM), and all but experienced allergies (reported as ""known allergies: Biaxin, Flagyl, sulfa, Bactrim""). No COVID prior to vaccination and no COVID tested post vaccination. The patient experienced heart fluttering and chest pressure on 04Jan2021. There was no treatment received for the reported events. The outcome of the events was not recovered.; Sender's Comments: A causal relationship between the reported heart fluttering and the use of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) cannot be completely excluded due to temporal relationship. The case will be reassessed should additional information become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate."

Tachycardia up to 150 resting; Nausea; Vomiting; Diarrhea; Headache; Migraine; Body aches; Chills; Fever up to 102; This is a spontaneous report from a contactable nurse (patient). This 26-year-old female patient (pregnant: no) received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, lot number: EL3248), intramuscular on 08Jan2021 at 07:45 AM at single dose on right arm for COVID-19 immunisation. Medical history included anxiety and depression. No known allergies. Concomitant medication included fluoxetine hydrochloride (PROZAC), bupropion hydrochloride (WELLBUTRIN), diphenhydramine hydrochloride (ZZZQUIL). No other-vaccine-in-four weeks. The patient previously received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, lot number: EK5730), intramuscular on 22Dec2020 at 08:00 PM on right arm for COVID-19 immunisation. The patient experienced tachycardia up to 150 resting, nausea, vomiting, diarrhea, headache, migraine, body aches, chills and fever up to 102. Symptom onset around 7PM on 08Jan2021 and stopped around 12PM 09Jan2021 except for headache which was still persisting as of 9PM 09Jan2021. No treatment was received for the events. The outcome of headache was not recovered. The outcome of other events was

recovered on 09Jan2021 at 12PM. The patient did not have COVID-prior-vaccination. The patient did not have COVID tested post vaccination.; Sender's Comments: The reported tachycardia was probably related to the use of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE) due to temporal relationship. The case will be reassessed should additional information become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Bell's palsy onset within 48 hours of second vaccine, R side of face; First dose of vaccine on 20Dec2020 and second dose received on 06Jan2021; First dose of vaccine on 20Dec2020 and second dose received on 06Jan2021; This is a spontaneous report from a contactable healthcare professional reporting for himself from a Pfizer sponsored program. A 24-year-old male patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection; lot number EJ1686) via an unspecified route of administration, on 06Jan2021 at 11:30am on left arm, single dose for COVID-19 immunization. Relevant medical history and concomitant medications were reported as none. The patient had no known allergies. The patient had no other vaccine in four weeks and no other medications in two weeks. The patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number EL0140) at right arm on 20Dec2020 10:30am for COVID-19 immunization. On 08Jan2021 at 12:00pm, the patient experienced facial droop 2 days after taking the 2nd dose of the vaccine. The patient went to the hospital for doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care and were advised to take Valtrex and Prednisone and told its Bell's palsy. Bell's palsy onset within 48 hours of second vaccine, R side of face. Wanted to confirm if there will be a problem once they take these drugs since the paient have just received the vaccine recently or wanted to know if the new medications prescribed will affect the vaccine's effectivity. The patient was not diagnosed with COVID prior vaccination and was not tested for COVID post vaccination. Outcome of the event Bell's palsy was not recovered.; Sender's Comments: Facial droop/ Bell's palsy occurred 2 days after taking the 2nd dose of the BNT162B2 vaccine, a possible causal association between administration of BNT162B2 and the event onset thus might not be fully excluded, considering the plausible temporal relationship. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

7 days later diagnosed with pneumonia; 3 days after developed hives on my stomach and arm; felt tired; confused; unwell; This is a spontaneous report from a contactable healthcare professional (patient). A 37-year-old female patient received her first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: Ek5730), via an unspecified route of administration on the left arm on 28Dec2020 12:00PM at a single dose for COVID-19 immunization at hospital facility. Medical history included Hashimotos disease. The patient had no known allergies and has not had COVID prior to vaccination. The patient's concomitant medications were not reported. The patient reported that she felt tired and confused and unwell on day of injection, 28Dec2020. After three days (31Dec2020), she developed hives on her

stomach and arm and seven days later (04Jan2021), she was diagnosed with pneumonia and continued to have hives all over her legs and arms to this day. The patient was treated with antibiotics for pneumonia. She underwent Covid test/ Nasal swab post vaccination on 09Jan2021, pending result. The outcome of the events was not recovered.; Sender's Comments: The reported pneumonia was more likely an intercurrent disease, and unlikely causally related to the use of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE). The case will be reassessed should additional information become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

difficult breathing; Pain on the chest; Not being able to move my upper neither lower body; itchiness all over my body; unconscious; Headaches; major anxiety; depression; very light-headed; weak; almost faint; This is a spontaneous report from a contactable Other HCP (patient). A 28-years-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 08Jan2021 12:00 at single dose on Left arm for COVID-19 immunisation. Facility type vaccine was Hospital. Medical history was none. The patient's concomitant medications were not reported. No other vaccine in four weeks. The patient experienced Not being able to move my upper neither lower body, Headaches, major anxiety, and depression, unconscious, very light-headed, weak, almost faint, Pain on the chest, difficult breathing, itchiness all over my body on 08Jan2021. AEs resulted in Emergency room/department or urgent care, Hospitalization. Received injected fluids as treatment. The outcome was Not Recovered. No COVID prior vaccination. No COVID tested post vaccination. Information on the lot/ batch number has been requested.; Sender's Comments: Based on a close temporal association, a causal relationship between reported events and BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

I had a very early miscarriage at five weeks; I had a very early miscarriage at five weeks; I had a very early miscarriage at five weeks; This is a spontaneous report from a contactable Physician (patient). A 31-year-old female patient received BNT162B2 first dose of (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EJI685) intramuscular at arm right on 19Dec2020 06:30 at single dose for covid-19 immunization. Facility type vaccine was hospital. Medical history was none. The patient had no known allergies or other medical history. There were no concomitant medications. No other vaccine in four weeks and no other medications in two weeks. The patient experienced a very early miscarriage at five weeks on 01Jan2021. The event result in doctor or other healthcare professional office/clinic visit. No treatment received. The outcome of the event miscarriage was recovered in Jan2021. No covid prior vaccination and no covid tested post vaccination.; Sender's Comments: All pregnancies have a risk of birth defect, loss, or other adverse outcomes. The data on BNT162B2 administered to pregnant women is insufficient to make a meaningful medical assessment hence, the events are conservatively assessed as related to the suspect drug BNT162B2 until further information becomes available. The impact of this

report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

almost pass out; Chills; nausea; diarrhea; abdominal pain; clammy; elevated heart rate; dizzy; This is a spontaneous report from a contactable consumer (patient's parent). A 24-year-old female patient (pregnant: No) received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK9231) via an unspecified route of administration on left arm on an unspecified date in Dec2020 at single dose for COVID-19 immunization. The relevant medical history included asthma, migraines and anxiety all from an unspecified date. Concomitant medications included ethinylestradiol, etonogestrel (NUVARING), topiramate (TOPAMAX), verapamil and sertraline hydrochloride (ZOLOFT). The patient experienced chills, nausea, diarrhea, abdominal pain, clammy, elevated heart rate, almost pass out, dizzy, all on 05Jan2021. The patient had no treatment for the events. No covid prior vaccination. The patient underwent lab test included heart rate showed elevated on 05Jan2021, Nasal Swab showed negative on 06Jan2021. The outcome of the events was not recovered.

Rash on lower legs similar to that seen with Thrombocytopenia.; Rash on lower legs similar to that seen with Thrombocytopenia.; This is a spontaneous report from a contactable Other HCP (patient). A 21-year-old female patient (not pregnant) received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, Lot number= EJ1686), via an unspecified route of administration at Left arm on 05Jan2021 10:00 AM at single dose for covid-19 immunization. The COVID-19 vaccine was administered at Hospital. The patient's medical history and concomitant medications were unknown. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient experienced rash on lower legs similar to that seen with thrombocytopenia on 09Jan2021 at time of 12:00 PM. No treatment received for the events. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, the patient was not been tested for COVID-19. The outcome of the events was not recovered.; Sender's Comments: A possible contributory effect of suspect drug on reported thrombocytopenia cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

Fatigued; Sore in her throat; Lost her voice (hoarse); Reddish nose; Intermittent coughs; she went to work to a COVID unit which she usually didn't do; described her symptoms as a chest cold; Feeling strange like coming down; swelling and soreness in the injection site for a day or two; swelling and soreness in the injection site for a day or two; This is a spontaneous report from a contactable nurse reported for self. This 41-year-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number unknown) via unspecified route of administration on 07Jan2021 13:30 PM at single dose for COVID-19 immunization. The patient medical history and concomitant medications were not provided. The patient previously received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number unknown) for COVID-19 immunization on an

unspecified date. On 07Jan2021 after second dose vaccination, the patient started experiencing swelling and soreness in the injection site for a day or two. On 08Jan2021 the next day, she went to work to a COVID unit which she usually didn't do. On 08Jan2021 the next day after her shift at 15:00 PM, she started feeling strange like coming down. On 09Jan2021, she felt totally fatigued. The symptom that bothered her the most is the sore in her throat which has gone 10Jan2021, she said she lost her voice (hoarse). She was also experiencing a reddish nose and intermittent coughs. She described her symptoms as a chest cold. The patient also stated she didn't have fever or chills. She's afraid she might be sick. The outcome of event the sore in her throat was resolved on 10Jan2021. The outcome of other events was unknown. Information about lot/batch number has been requested.; Sender's Comments: A possible contributory effect of suspect BNT162B2 on reported chest cold cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

"tingling sensation in right eye and mid cheek area,Unable to wink, or scrunch right eye; muscles on the right side of my face were noticeably weaker; This is a spontaneous report from a contactable nurse (patient). This 48-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot # EH9899), via an unspecified route of administration, on 23Dec2020 at 04:00 PM at single dose for COVID-19 immunisation. Vaccine location was right arm. The patient was vaccinated at Public Health Clinic/Veterans Administration facility, age at vaccination was 48-years-old. No other vaccine was received in four weeks. Medical history included gastrooesophageal reflux disease (GERD). Known allergies included levofloxacin (LEVOFLOXACIN), pethidine hydrochloride (DEMEROL), phenobarbital, cefalexin monohydrate (KEFLEX), charithromycin (BIAXIN). Concomitant medications included dexlansoprazole (DEXILANT), estradiol, phentermine, ergocalciferol (VIT D), calcium. The patient was not tested for covid prior or post vaccination. On 23Dec2020 at 04:45 PM, after leaving the clinic, the patient felt tingling sensation in right eye and mid cheek area. Within 1.5 hours, muscles on the right side of her face were noticeably weaker. Unable to wink, or scrunch right eye. The events resulted in doctor or other healthcare professional office/clinic visit, and emergency room/department or urgent care. The patient was treated with prednisone. Outcome was recovering.; Sender's Comments: Based on a close temporal relationship causality between events ""tingling sensation in right eye and mid cheek area"" and ""muscles on the right side of her face were noticeably weaker"" and BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate."

She is still freezing to death; Sick as a dog; Fever; Chills; cannot eat and have no appetite; nauseous; This is a spontaneous report from a contactable nurse (patient). A 79-year-old female patient received first dose of bnt162b2 (also reported as Pfizer Covid vaccine, lot number: EK4176), intramuscular into left arm on 05Jan2021 16:00 at single dose indicated as presentation because she is a nurse/Covid-19

immunization. Medical history included Type 2 Diabetes, about 2 years ago in 2019 in which she takes metformin 1,000mg twice daily. Concomitant medication included metformin on unspecified date at 1,000mg twice daily for Type 2 Diabetes. There was no history of all previous immunization with the Pfizer vaccine nor there were additional vaccines administered on same date of the Pfizer Covid vaccine. The patient received the Pfizer COVID vaccine last Tuesday and since 06Jan2021 at 06:00, she has been sick as a dog. She is running a fever, has chills, can't eat and has no appetite because she is nauseous; all on 06Jan2021 at 06:00. This is the third day of it. She would like to know what she can she do. She said that it all started Wednesday morning when she got up. It just gets worse every day. It looks like it would get better by now, but it hasn't. She never runs a temperature, but she has now (unspecified date). She is still freezing to death on unspecified date. She usually has a good appetite. Even the thought of food makes her sick. She further reported that she has had nothing but chills, fever, and nausea and states it will not go away. She is treating it with ibuprofen. She confirms she already talked to a nurse in this department to report this and she was transferred to see what she could do and states they never answered. This is her first dose and she does not know if she should get the second dose. The patient can't calm down since she has been sick since last Wednesday. She stated that she needed some help because she is so sick. She was suggested to call again calling Pfizer medical information department. She stated that she had called back three times, but there is no such number. The events sick as a dog, fever, chills, can't eat and has no appetite, and nauseous were considered serious (Other medically important condition). The outcome of the events sick as a dog, fever, chills, can't eat and has no appetite, and nauseous was not recovered, and the outcome of the remaining event was unknown.; Sender's Comments: A causal association between BNT162B2 and the reported events cannot be completed based on known safety profile and a compatible temporal relation between vaccination and onset of events. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

palms of my hands were bright red; very warm flush feeling; nausea; swelling of the throat; rash on my arms and abdomen; This is a spontaneous report from a contactable nurse (patient). A 49-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899 and expiration date not provided), intramuscular in the left arm on 06Jan2021 16:00 (at the age of 49 years old) at a single dose for COVID-19 immunization. Medical history included psoriasis, microscopic colitis, allergies to shellfish, and coconut. The patient's concomitant medications were not reported. The patient previously took estrogen patch, etanercept (ENBREL) and sulfamethoxazole, trimethoprim (BACTRIM) and experienced allergies to all. The patient was not pregnant at the time of vaccination. The patient did not receive any other vaccine within 4 weeks prior to the COVID vaccine and did not take any other medications with 2 weeks of vaccination. Prior to the vaccination, the patient was not diagnosed with COVID-19. On 06Jan2021 16:15, the patient experienced a very warm flush feeling, nausea started and by 15 minutes, she had swelling of the throat and rash on her arms and abdomen and the palms of her hands were bright red. The events resulted in Emergency room/department or urgent care visit. The patient was treated with diphenhydramine hcl (BENADRYL), steroids (unspecified), famotidine (PEPCID) and ondansetron (ZOFRAN) in response to the events. The patient assessed the events as non-serious.

The outcome of the events was recovered with sequel on an unspecified date in Jan2021. The patient has not been tested for COVID-19 since the vaccination.; Sender's Comments: A possible contributory effect of suspect BNT162B2 on reported events cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

glaucoma; This is spontaneous report from a contactable consumer (patient). A female patient of an unspecified age received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number and expiry date unknown) via unspecified route of administration on unspecified date at single dose for Covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient received the first shot and was scheduled to receive the second dose on 27Jan2021 however, she has an eye surgery for glaucoma scheduled on 22Jan2021 and 25Jan2021. The patient wanted to know if she re-schedule the eye surgery. The outcome of the event glaucoma was unknown. Follow-up activities are possible, information on the batch number has been requested.

"Stevens Johnson Syndrome; rash was starting to peel; developed a rash all over her neck/ the rash has spread to face eyes, cheek; developed a rash all over her neck, ""looks like its peeling and taut""; developed a rash all over her neck, ""looks like its peeling and taut""; This is a spontaneous report from a contactable nurse (patient). A female patient of an unspecified age (Age: 48, Unit unknown) received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 10Jan2021 at single dose for covid-19 immunization. Medical history included she had an allergic reaction to sulfa and developed Stevens Johnson syndrome from an unknown date and unknown if ongoing. The patient's concomitant medications were not reported. The patient experienced Stevens Johnson Syndrome, developed a rash all over her neck/ the rash has spread to face eyes, cheek; ""looks like its peeling and taut""; and the rash was starting to peel, all in Jan2021. The patient received 1st dose of vaccine on 10Jan2021, developed a rash all over her neck, ""looks like its peeling and taut"". She had an allergic reaction to sulfa and developed Stevens Johnson syndrome, this looks similar to that (Experience of Stevens Johnson Syndrome). The patient was asking if she did take the steroid dose pack from her dermatologist for the skin rash will it prohibit her from taking the second dose of the vaccine. She called yesterday and reported a rash after receiving the first dose of the COVID-19 vaccine. She stated that she went to her Dermatologist this morning because the rash has spread to face eyes, cheek and the rash was starting to peel. She stated that the dermatologist wanted to know if it was safe to treat her with a prednisone dose pack after receiving the vaccine. Her rash was worsening so she went to her dermatologist for treatment. She was asking if she should get the second dose. The outcome of events for developed a rash all over her neck/ the rash has spread to face eyes, cheek was not resolved, for other events was unknown. Information about lot/batch number has been requested.; Sender's Comments: A possible causal association between administration of BNT162B2 and the onset of suspect Stevens Johnson Syndrome presented as skin reactions cannot be excluded, considering the plausible temporal relationship. Severe allergic reaction is the known risk for the vaccine. The underlying

predisposing condition of an allergic reaction to sulfa developed Stevens Johnson syndrome may put the patient at high risk of the similar occurrence. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate"

following day around 7pm lip swelling; tongue tingling; body hives; chills; After first dose of Covid vaccine face flushing; increased HR about 45 mins. went away on its own; hours later left eye swollen; This is a spontaneous report from a contactable Nurse (patient). A 31-years-old female patient received first dose of bnt162b2 (BNT162B2, Lot number: EK9231), via an unspecified route of administration on 06Jan2021 15:00 at single dose on Left arm for covid-19 immunisation. Medical history included Known allergies: Shellfish, IV contrast dye, Penicillin. There were no concomitant medications. No other vaccine in four weeks. No other medications in two weeks. The patient experienced after first dose of covid vaccine face flushing; increased hr about 45 mins. went away on its own since 06Jan2021 16:00; hours later left eye swollen on 06Jan2021; following day around 7pm lip swelling, tongue tingling, body hives, chills on 07Jan2021 19:00. The patient underwent lab tests and procedures which included heart rate: increased on Jan2021. Ae resulted in: Doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care. Ae treatment: Steroids, IV fluids, Benadryl. No COVID prior vaccination. No COVID tested post vaccinate. This report was reported non-serious. The event outcome of increased hr about 45 mins. went away on its own was recovered on 06Jan2021 16:45, outcome of other events were not recovered.; Sender's Comments: Based on the compatible time association, the serious events are possibly related to suspect BNT162B2 administration. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

kidneys weren't acting/kidney issues; not having the feeling to urinate; Light-headed; This is a spontaneous report from a contactable consumer (reported for herself). A 91-year-old female patient received first dose BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Solution for injection; lot number: EL3248; expiration date: not known), via an unspecified route of administration in the left arm on 07Jan2021 at single dose for COVID-19 immunization. Medical history included high blood pressure and blood thinner. Concomitant medication included apixaban (ELIQUIS) for blood thinner. The patient is asking if there were any reports of adverse events with kidneys and the vaccine. She received the 1st shot last Thursday (07Jan2021) and told that yesterday (10Jan2021), she had an episode where kidneys weren't acting. She also mentioned that she is on a blood thinner, ELIQUIS. She is due to receive the 2nd shot on 28Jan2021. She said that she wouldn't want to receive the 2nd dose if this was related to her adverse reaction. The issue with the kidney started after on 10Jan2021, yesterday she was really having problems, she went to church then came home by that time she would have to go to the bathroom, but she did not go, she ended up cooking dinner which was 3 hours later, she was noticing that she was not urinating. She drank some Gatorade and that made it little better, she is wondering if it's a side effect.

On 10Jan2021, when she noticed the kidney issues, she did not know for certain if it started before that, she didn't pay attention. Also, yesterday (10Jan2021), she got sick in which she had to grab the counter, she felt bad, she wasn't dizzy, but felt light-headed. The symptom of not having the feeling to urinate had improved a little today but she is concerned and wanted to know if this was a side effect. Her being light-headed only occurred on 10Jan2021, it was a onetime occurrence yesterday. However, she was also just sitting around, laying around, after that yesterday. The outcome of the event 'light-headed' was unknown; while outcome of other events was recovering.

difficulty thinking; Extreme fatigue; dizziness; This is a spontaneous report from a contactable nurse (patient). A 42-year-old female patient received her second dose of BNT162B2(PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 10Jan2021 11:15 at single dose at Arm Right for COVID-19 immunisation. Medical history included hypothyroidism, thyroid cancer, hypertension from an unknown date and ongoing, Known allergies: Latex, aluminium, nickel.The patient was not pregnant. Concomitant medication included gabapentin, propranolol, levothyroxine sodium (SYNTHROID), and pantoprazole. The patient has previously received her first dose of BNT162B2 on 20Dec2020 08:45 PM for COVID-19 immunisation at Arm left. There was no any other vaccines within 4 weeks prior to the COVID vaccine.The patient experienced difficulty thinking, extreme fatigue and dizziness resulted in Doctor or other healthcare professional office/clinic visit. All the events occurred on 11Jan2021 09:00 with outcome of recovering. No treatment was received. Prior to vaccination the patient was not diagnosed with COVID-19 and since the vaccination, the patient has not been tested for COVID-19.The events were considered as non-serious. Information about lot/batch number has been requested.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the mental impairment and other reported events due to temporal relationship. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

concern for injection to the subcutaneous tissue/concerned about improper administration/patient has a mark where you can see the vaccine and it's higher up where you expect it to be; induration at the injection site; felt induration was moving down his/her arm/can feel it migrated down her arm, 7 inches below injection site; This is a spontaneous report from a contactable pharmacist. A patient of unspecified age and gender received the second dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number: EK4176), subcutaneous (reported as injection to the subcutaneous tissue to deltoid) on 09Jan2021 at 0.3 mL, single to prevent from getting COVID. The patient's medical history and concomitant medications were not reported. The patient previously took the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) on Dec2020 for COVID-19 immunization. On 09Jan2021, within a couple hours after, the patient experienced induration at the

injection site. The patient felt induration was moving down his/her arm with concern for injection to the subcutaneous tissue. The patient can feel it migrated down his/her arm, 7 inches below injection site. The reporter assessed that the causality was yes for the suspect drug and the patient was concerned about improper administration. The reporter was unsure if it is administration or vaccine, the patient has a mark where you can see the vaccine and it's higher up where you expect it to be. Outcome of the vaccination site induration and induration was not recovered. The events were considered medically significant by the reporter.; Sender's Comments: Based on the available information a causal relationship between reported events induration at the injection site / induration and incorrect route (subcutaneous) of BNT162B2 vaccine administration cannot be excluded. The case will be reevaluated should additional information become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Slight left sided facial weakness/droop 4 days post vaccination; Slight left sided facial weakness/droop 4 days post vaccination; Tingling in injected arm and facial tingling in cheeks/lips same day of vaccination/Tingling to lower extremities; Tingling in injected arm and facial tingling in cheeks/lips same day of vaccination; Tingling in injected arm and facial tingling in cheeks/lips same day of vaccination; This is a spontaneous report from a contactable consumer (patient herself). A 36-year-old female patient received her first dose of bnt162b2 (BNT162B2 also reported as COVID 19 brand Pfizer, lot EK9231), via an unspecified route of administration in the left arm on 04Jan2021 13:00 at single dose, for Covid-19 immunisation. The vaccine was given in a Nursing Home/Senior Living Facility. Medical history was none. No known drug allergies. No other vaccine in four weeks. No Covid-19 prior vaccination. Concomitant medication included naproxen sodium (ALEVE). The patient experienced tingling in injected arm and facial tingling in cheeks/lips same day of vaccination (04Jan2021). Tingling to lower extremities the day after vaccination (still continuing). Slight left sided facial weakness/droop 4 days post vaccination (04Jan2021). Tingling to left arm continuing on and off. No treatment reported. On 04Jan2021, she was negative to PCR covid test post vaccination. She went to the Emergency room/department or urgent care. The outcome of events was not recovered.

"slurring speech; rash around his neck and upper chest; his earlobes were bright red, as was his nose; mouth was dry; nose was dry; dry throat; almost ""drunk""; Only abnormal finding was BP 159/94; This is a spontaneous report from contactable pharmacist. A 36-year-old male patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number=EL1283 and Expiration Date unknown) via Intramuscular on 08Jan2021 11:25 at single dose for COVID-19 immunisation. The patient's medical history was reported toradol made him feel lightheaded and foggy (similar to his first Pfizer BioNTech covid vaccine), Attention deficit hyperactivity disorder (ADHD). History vaccine included first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number =EK5730 and Expiration Date unknown) via Intramuscular on 18Dec2020 at single dose for COVID-19 immunisation. Patient did report that on first vaccine it made him feel a little sluggish, tired and foggy minded. The concomitant medications were reported as amfetamine aspartate, amfetamine sulfate, dexamfetamine saccharate,

dexamfetamine sulfate (Adderall XR) at 25mg twice a day (BID) and escitalopram oxalate (LEXAPRO) oral (PO) at 10mg every day. No other vaccine in four weeks. Patient was vaccinated at 11:25. Patient was observed for 30 minutes. Pharmacist checked on patient at 17 minutes after vaccination - he was fine able to communicate and showed no signs of distress. Pharmacist came back and checked on patient at 25 minutes after vaccination (11:50) and patient was slurring speech, had developed rash around his neck and upper chest, his earlobes were bright red, as was his nose - mouth was dry, reported dry throat - no visible swelling of the lips or tongue. Patient was transported to ED (2 min) Home meds: Adderall XR 25mg BID [Twice a day], Lexapro 10mg Q [every]PM. Only abnormal finding was BP 159/94 - after initial workup patient was noted to be almost ""drunk"" as reported by Emergency Room (ER Doc). Patient was offered diphenhydramine declined several times but eventually agreed. Approx 30 min after diphenhydramine patient fully recovered and stated ""I'm back"". The second dose reaction was much more exaggerated and lasted much longer. No COVID prior vaccination and no COVID tested post vaccination. The adverse event result in Emergency room/department or urgent care. The outcome of events was recovered in Jan2021 after treatment was given.; Sender's Comments: Based on the time association, all events are possibly related to suspect BNT162B2 administration. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate."

SOB; leukocytosis; acute onset of fever (101.2); CXR = bilateral vascular congestion; This is a spontaneous report from a contactable consumer. An elderly NH resident patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on an unspecified date, at single dose, for COVID-19 immunization. Medical history and concomitant medications were not reported. On an unspecified date the patient experienced shortness of breath (SOB), leukocytosis (17,800), acute onset of fever (101.2), bilateral vascular congestion. The patient was admitted with acute onset of fever (101.2), leukocytosis (17,800, no eosinophilia) and SOB, all beginning 3-4 hours after BNT162B2 administration. CXR showed bilateral vascular congestion. No facial or SQ edema. No evidence of myocardial damage or CHF based on BNP and troponin, respectively. The patient was treated with brief (3 days) pulse of methylprednisolone sodium succinate (SOLUMEDROL) with improvement. Chalking it up to acute capillary leak syndrome 2^2 vaccine. The final events outcome was unknown. Information on lot/batch number has been requested.

Blood in stool; Fever; Night sweats; Chills; Ache; This is a spontaneous report from a contactable physician reporting for herself. An adult (reported as 30-something year old) female patient received the 1st dose of bnt162b2 (BNT162B2), via an unspecified route of administration, on 30Dec2020, at single dose, for COVID-19 immunisation. The patient's medical history was none. Concomitant medications were not reported. The patient experienced blood in stool in Jan2021 with outcome of unknown, chills on 31Dec2020 with outcome of unknown, ache on 31Dec2020 with outcome of unknown, fever in Jan2021 with outcome of unknown, night sweats in Jan2021 with outcome of unknown. The patient reported that 24 hours after vaccination she experienced chills and aches, and after the 24 hours experienced some significant fevers that wouldn't break and chills. Then, after about 2 hours, the fever

would break and come back and it was like a cycle. Also had night sweats and blood in her stools after that. The information on the lot/batch number has been requested.; Sender's Comments: The female patient received the 1st dose of bnt162b2 (BNT162B2) on 30Dec2020, and experienced blood in stool in Jan2021 with outcome of unknown. The information available is limited, and case will be reassessed should additional information become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Patient presented to our Emergency Department via EMS in full code status; asystole. Patient expired. Per nursing, husband stated patient awoke this AM and reported pain in back between shoulders and in bilateral shoulders. Patient then went unresponsive and husband called EMS.

1/11/21 at 8:57 Resident with fever and at 11 am saturation down to 83 O2 to 10 liters. Resident continued to decline until CTB on 1/14/2021 at 1325

I was diagnosed with COVID-19 on 12/7/2020. My course of symptoms lasted 16 days, meaning I started feeling healthy again on 12/23/20. I am a pharmacist with a healthcare system and they have been offering the Pfizer/Biontech COVID-19 vaccine for essential associates. I received by first dose of vaccine on 12/31/20. On 1/1/20 I woke up with very noticeable muscle aches and fairly profound lethargy, which last 18-20 hours. I was not able to do much on 1/1/21 because of the way I was feeling. I'm not sure if this reaction is normal for patients who receive their COVID-19 vaccine close to their illness/infection with COVID-19, which is why I'm reporting this to the FDA.

Heart rate slowed significantly down to 32bpm Tightness in chest, trouble breathing Elevated blood pressure

injection site became red & swollen, the size of a softball. Employee started having seizure like symptoms on 1/14/21 and was admitted to hospital. DC from hospital on 1/16/21 and on 1/17/21 started having seizures again and readmitted back to hospital. Employee has no history of seizures.

I received the Pfizer vaccine on 12/21/20 without adverse events other than soreness in deltoid. On 12/31/20 I began to notice pain, redness and swelling in second toe on R foot from base of toe to base of nail. I initially thought it was gout and self medicated with ibuprofen 400 mg BID x 1 day on 01/01/21 with some improvement. I did not take anything on 01/02/21 and woke up on 01/03/21 with return of swelling, redness and pain. I took another 400 mg of ibuprofen and it felt better but after examining the toe, I questioned whether I had developed pernio (COVID toe).

patient began with vomiting and diarrhea the day after administration, leading to bowel and urine incontinence. patient was hospitalized on 01/16/20 with sepsis. no origin discovered yet. still waiting on blood/urine/stool cultures.

Patient was living in a nursing home with positive cases when administered. His age and chronic condition was such that he did not have time after the vaccination to avoid exposure or develop immunity.

Resident had seizure like activity that was about 30 minutes in duration where her upper/lower extremities were shaking uncontrollably. Resident had to be admitted into hospital for observation.

blistering rash - bullous pemphigoid, steroids, admitted to hospital pending further evaluation.

1day after vaccine,developed severe headache & later blister in head officially Shingle . Then decreased platelet count fatally to 29(ITP).now hospitalized getting treatment.

Was feeling anxious right after vaccine given. Laid in cot for a short time, then stated her throat felt like it was closing.

Severe rash. Platelets drop to almost needing transfusion

1252 Resident rang with complaints of chest pain and shortness of breath. BP 126/70, Temp 97.5, pulse 72, resp. 20, O2 sats on room air 90%. While awaiting transport complained of increasing shortness of breath. Resident transported to Community Hospital via Ambulance with 3L O2 . Resident placed on ventilator and transported to Medical Center

severe body aches; severe chills; night sweats; Fatigue; This is a spontaneous report from a contactable Physician (patient). A 55-year-old male patient received the second dose bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 06Jan2021 at 12:00 at single dose in left arm for covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient previously received the first dose bnt162b2 in Dec2020 three weeks ago at 12:00 noon in the left arm for covid-19 immunization and experienced mild pain at the injection site which lasted two days and then was gone. The patient experienced severe body aches, severe chills, night sweats, and fatigue on 07Jan2021. Event details: The patient reported that he received the first dose of the Pfizer COVID 19 vaccine three weeks ago at 12:00 noon in the left arm. He did not know the exact date. After the first dose there was mild pain at the injection site which lasted two days and then was gone. He received the second dose of the Pfizer COVID 19 vaccine on 06Jan2021 at 12:00 noon in the left arm. He noticed 12 hours later severe body aches, severe chills, and night sweats. He also felt fatigue. Everything had mostly resolved except for the night sweats and they were still pretty severe. All events were reported as serious by reporter per medically significant. The outcome of event night sweats was not resolved, outcome of other events was resolved on 10Jan2021. Information about lot/batch number has been requested.; Sender's Comments: The Company cannot completely exclude the possible causality between the reported severe body aches, severe chills, fatigue and night sweats, and the administration of the COVID 19 vaccine, bnt162b2, based on the reasonable temporal association. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RA, IEC, as appropriate.

eosinophil count is 12.2%; Congestion; rhinitis; Cough; This is a spontaneous report from a contactable consumer. A 68-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot/batch number unknown), via an unspecified route of administration on 21Dec2020 at a single dose for Covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient who is an MD received the COVID vaccine on 21Dec2020. She quickly developed rhinitis, cough, and congestion which have persisted. Her eosinophil count is 12.2%. She received a Medrol pack, but it did not relieve her symptoms. She has delayed her second injection for now. The outcome of the events was unknown. Information about lot/batch number has been requested.

resident expired; This is a spontaneous report from a contactable healthcare professional. An 82-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot number: EL0140), intramuscular in the left arm on 05Jan2021 15:00 at a single dose for COVID-19 immunization. Medical history included metabolic encephalopathy from, failure to thrive (FTT), diabetes mellitus (DM) 2 , chronic obstructive pulmonary disease (COPD), arthritis, weakness, hyperlipidemia, chronic kidney disease (CKD), dementia. Known allergies was none. The patient took unspecified concomitant medication. On 11Jan2021, the resident expired. The patient underwent lab tests and procedures which included nasal swab: negative on 09Jan2021. There was no treatment given for the event. The patient died on 11Jan2021. An autopsy was not performed.; Sender's Comments: Lacking information on the cause of patient's demise, the Company cannot completely exclude a causal relationship between COVID 19 vaccine, BNT162B2, and patient's death of unknown cause, as a cautionary measure and for reporting purposes. The patient's pre-existing medical condition of metabolic encephalopathy from, failure to thrive (FTT), diabetes mellitus (DM) 2 , chronic obstructive pulmonary disease (COPD), arthritis, weakness, hyperlipidemia, chronic kidney disease (CKD), dementia may have provided the contribution to the event in this 82-year-old male patient. The impacts of this report on the benefit/risk profile of the product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.; Reported Cause(s) of Death: resident expired

Facial paralysis; This is a spontaneous report from a contactable consumer (patient herself). A 36-year-old female patient received bnt162b2 (COVID-19 Vaccine by Pfizer, lot EK9231, expiry date was not reported), via an unspecified route of administration on 08Jan2021 at SINGLE DOSE for Covid-19 immunisation (to prevent the COVID). Medical history was none. There were no concomitant medications. The patient experienced facial paralysis on the left side of her face upon waking up on 09Jan2021. The outcome of event was not recovered.

"Congestion in my lungs; I am coughing up junk; This is a spontaneous report from a contactable consumer (patient). A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number and expiry date was not reported) via an unspecified route of administration on an unspecified date at single dose for covid-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient experienced congestion in lungs and was reportedly coughing up ""junk"" on an unspecified date. It was also reported that the patient

woke up this morning with a pretty bad side effect. Outcome of events was unknown. Information on the lot/batch number has been requested."

"Started to have symptoms and fainted; Hit her nose and has a scar now; She blacked out; hit her nose, got the scar in the nose, àshe was bleeding from that scar; hit her nose, got the scar in the nose, àshe was bleeding from that scar; She started to feel unwell; Chills; Nausea; Rash in her arm; She had little red in her bumps; This is a spontaneous report from a contactable physician. A 29-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE Solution for injection, batch/lot no. and expiry date: unknown), via an unspecified route of administration on arm on unspecified date at a single dose (2nd dose) for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. Physician stated, ""she had no medical conditions, she was in very good you know very like standing with herself."" Patient had her 1st dose of Covid vaccine on unspecified date for COVID-19 immunization. Physician (reporter) stated, ""I am the parent of someone who got the COVID dose, the second dose yesterday. I am very concerned because my daughter yesterday (08Jan2021) started to have symptoms and fainted at 4:00 in the morning and hit her nose and has a scar now. She had her second dose yesterday (pending clarification), after the second dose last night she started to feel unwell, getting chills, nausea and when she got up to go to the bathroom, she fainted, she blacked out. She lives alone, she is an adult, she hit her nose, got the scar in the nose, and the bleeding wouldn't stop, she was bleeding from that scar. She told me it took two hours for bleeding to stop from that scar."" When asked when the events started, Physician stated, ""Last night (08Jan2021), at 4:00 am she took the shot during the day while she was at work. She said, she started to getting chills and then she was nauseated."" When asked if patient was still experiencing the event, the parent reported no as patient was just resting. Also stated, ""She didn't take any treatment but she said she took Tylenol."" Physician further added, ""I am concerned, we are going to be taking her to the urgent care now but I am concerned about what is going on with platelets and all of that because of what had happened, last night the bleeding wouldn't stop for two hours and she was alone at the night and weekends. She said, she had to lay down and then her dad is there now because he is closer, he is going to be taking care of the urgent care but I want Pfizer to know what my daughter has gone through last night after she took this second dose."" Physician further added, ""she is having a rash in her arm, she had little red in her bumps as well. I want her to go get checked up as soon as possible in urgent care."" Patient was taking some Ibuprofen (later clarified that patient took Tylenol as treatment). She was not taking any other medication. Outcome of the events was unknown. Information Requested on Lot/ Batch number.; Sender's Comments: The reported faint was most likely due to an accident, and less likely causally related to the use of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE). The case will be reassessed should additional information become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate."

1) Skin rash over 80% of my body including, face and lips; started to change my voice sound and started to compromise my airways. 2) Uncontrollable shakes, but not sure if this was related to Covid-19 itself.

Was given steroids via injection into my blood stream, within minutes the shakes stopped and within 2 hours the rash was gone.

12/22 Vaccine 12/23 ER. Admitted to hospital for 7 days. Dr stated was due to fluid. Radiology stated no fluid present. Couldn't breath. Pulmonologist put on 2nd inhaler. Coughing a lot. Not able to walk more then 6 steps without stopping to catch breath. *Has had 2nd vaccination on 1/13/2020

1/12 vaccination 1/13 swelling and pain at injection site. Admitted for 4 days.

patient suddenly developed pneumonia 7 days after vaccination and died the evening of developing pneumonia

Couple hours after the vaccine, experienced elevated temperature, difficulty taking full deep breathes (attributed to fatigue). Temperature improved but fatigue and shortness of breathe continued until 1/16/21. a bilater arm rash occurred and employee went to the Emergency Department for an assessment. At this time, she was having chest tightness, shortness of breathe. Lab - troponins elevated. Other labs - within normal limits. Admitted to hospital for observation and discharged next day. Today, during cardiac follow-up appt, was having decreased oxygen saturation levels, increased pulse rate. Admitted again today for obsevation with cncern of acute endocarditis.

Death

1 hour post injection patient returned with redness and borderline hives in her left arm, chest, neck and face. She complained of feeling very hot and with mental confusion. We administered 50 mg of diphenhydramine, and 15 minutes later sent her to the ED. At the ED they diagnosed her with a minor anaphylaxis reaction, gave her methylprednisolone and epinephrine.

"Individual felt fine except a sore arm until 1/5/2021 legs became weak and dizziness and light headed and did t"" feel well"" and passed out. had general muscle weakness and went to ER. She was given fluid for possible dehydration and went home and weakness increase and went back to ER and was admitted to hospital for testing."

Individual had no side effect except sore arm for 5 days then on 1/5/2021 became weak and dizzy and passed out. had not felt well in am. she had continued weakness and extreme leg weakness and taken to ER for evaluation. She states got IV fluids and sent home but weakness increase and went back to ER on 1/5/2021 and admitted to hospital.

patient started to decline 1/10/2021, patient seen at facility by medical professional - patient deceased 1/13/2021

REPORTING ONLY AS RESIDENT EXPIRED ON 1/17/2021 3 DAYS AFTER. S/S HYPOXIA/CONGESTED LUNG SOUNDS

ventricular fibrillation cardiac arrest. Witnessed collapse. Bystander CPR performed. Paramedics performed ACLS with defibrillation x 6 before ROSC

PVCs with compensatory pauses, postural orthostatic hypotension associated with chest tightness, shortness of breath, dizziness and blurry vision

The day following the vaccine, the patient complained of throat issues and anxiety. This was not new... however . That evening he reported difficulty breathing and was placed on oxygen; a COVID test was performed and was negative. On 12/30/2020, patient complained of sternal pressure and was transferred to the hospital. The patient died 12/31/2020 and records obtained from the hospital indicated the patient died from a massive myocardial infarction.

Seizure

WITHIN 30 SECONDS OF RECEIVING VACCINE PATIENT STATED THAT SHE DID NOT FEEL WELL. HER FACE BECAME FLUSHED. HER LIPS BECAME NUMB AND HER TONGUE AND THROAT STARTED SWELLING. AN EPIPEN WAS ADMINISTERED AND 911 CALLED. AFTER THE EPIPEN SYMPTOMS BEGAN TO RESOLVE. EMS CHECKED HER OUT AND SHE REFUSED TRANSPORT.

8 hours after vaccine severe injection site pain/swelling, severe body aches, 101.0 temp. 16 hours after vaccine woke up from sleeping with flushed skin, facial swelling, and throat swelling. I immediately took 100mg of Benadryl and went to hospital emergency room. Approximately 30-40 minutes later symptoms started to lessen. Once at the ER, at the same time symptoms began to resolve, I was given PO Solumedrol and Pepcid. I was monitored and then discharged with RX for prednisone, and EPIPEN (to use if needed). No other issues with allergic reaction. Mild injection site soreness, mild body aches, 99.3 temp persist at 36 hours post injection.

Received Moderna COVID vaccine 12/31/20, 3 days later noticed generalized joint pain all over. Day 4 noticed both knees were red and tender and could palpate pockets of fluid. Had bilateral ankle and foot pain, right ankle swollen. Overnight 1/5-1/6/21 was in severe pain and unable to sleep, very difficult to walk on ankles and feet, stairs were very painful. Motrin relieved symptoms to where able to walk more comfortably but generalized achiness and tenderness to ankles and knees remain.

Anaphylaxis after Covid 19 vaccine #1. Pfizer Lot # EH9899

71 year old woman at rehabilitation center for physical therapy with history of cirrhosis of the liver, asthma, and heart condition was tested for COVID-19 on 01/07/21, received 1st dose of Pfizer COVID-19 vaccine on 01/08/21, positive test result for COVID-19 received on 01/09/21. She was sent to the hospital and admitted on 01/12/21 after O2 was 70% and was in a confused state. Patient passed away on 01/17/21.

Received shot Wednesday night, developed arm soreness and mild flu like symptoms on left side of my body and facial paresthesias on the left side of my face. Twelve hours later, after waking up those same symptoms were only on the right side of my body. Friday morning, mostly normal physically just with some overall fatigue. Friday afternoon I started to get hives on my chest and overnight into Saturday they were on my lower back, sides, and legs. I took 50 mg of Benadryl every 6-12 hours until Monday mid-day when Benadryl was not helping reduce the hives and so I had full body hives. I did try an

drugstore cortisone cream which did not help. Sought treatment at an urgent care as I was feeling anxious and could not control the itching. I and was diagnosed with likely allergic reaction to the covid-19 vaccine.

She woke up soaking wet. She had sweats kind of.; Tested positive for COVID; Tested positive for COVID; This is a spontaneous report from a Pfizer-sponsored program Pfizer First Connect. A contactable nurse (patient herself) reported that a 64-year-old female patient received her first dose of bnt162b2 (BNT162B2 also reported as PFIZER-BIONTECH COVID-19 VACCINE, lot EK5730, expiry date not reported), via an unspecified route of administration in the upper left arm on 21Dec2020 17:00 at SINGLE DOSE for Covid-19 immunisation. Medical history included ongoing hypertension (blood pressure high). She was a former smoker, a teenage smoker. She has not smoked since the age of 19 years old. Concomitant medication included amlodipine for high blood pressure. The patient informed that she was vaccinated on 21Dec2020. On 05Jan2021, she had a positive COVID Test and she was wondering when she should have the second dose of the COVID Vaccine. She thought initially she just had a cold. She took the COVID test as a precaution. It started out with a stuffy nose. She had a congested cough, upper airway cough, nothing deep in the lungs. She had a low grade fever. It was like 99.9. It was possible it was higher, but she had taken Ibuprofen at night. She woke up soaking wet. She had sweats kind of. Her temperature however never registered a true fever if a fever was considered 100.4. She was not really having body aches any more unusual than one would have for a 64 year old. She has a very mild sore throat. Her stuffy nose had improved, it's still there slightly, but not like it was the first few days. The outcome of events was unknown.; Sender's Comments: Test positive for covid19 found 14 day following the first dose of COVID-19 vaccination, bnt162b2, no adequate effect of the suspect vaccine thus could be reasonably achieved to protect from the targeted infection/disease due to the very short time lag.

"received the first dose of vaccine in a hospital on 18Dec2020/tested positive for COVID on 01Jan2021; received the first dose of vaccine in a hospital on 18Dec2020/tested positive for COVID on 01Jan2021; This is a spontaneous report from a contactable nurse (patient) via Pfizer-sponsored program, Pfizer First Connect. A 43-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Solution for injection, Lot number: EK5730, expiration 31Mar2021) , via an unspecified route of administration in left arm, on 18Dec2020 at 15:00, at 0.3 mL, single, for COVID-19 immunization. Medical history and concomitant medications were reported as none. The patient received the first dose of vaccine in a hospital on 18Dec2020 at 15:00 as she works in emergency room and tested positive for COVID on 01Jan2021. The patient stated that the second dose is scheduled this afternoon (08Jan2021) and wants to know if she should proceed with the vaccine. The patient is looking for guidance on whether or not to get the second dose or wait. The patient has been directed to receive second COVID vaccine. No additional vaccines administered on the same date. The event required a visit to urgent care. The patient did not have prior vaccinations within 4 weeks. No events prior to vaccination. The patient underwent lab tests and procedures which included COVID 19: positive on 01Jan2021. Outcome of the events was unknown. The event was assessed as serious (medically significant). The event ""Tested positive for COVID"" was assessed as unrelated to COVID vaccine as her husband was COVID positive before her.; Sender's Comments: The information currently provided is too

limited to make a meaningful medical assessment hence, the events are conservatively assessed as related to the suspect drug BNT162B2 until further information becomes available."

She reported being exposed to her husband, who tested positive for COVID, and that she tested positive following her first vaccine dose; She reported being exposed to her husband, who tested positive for COVID, and that she tested positive following her first vaccine dose; She reported being exposed to her husband, who tested positive for COVID, and that she tested positive following her first vaccine dose; This is a spontaneous report from a contactable female nurse (patient). A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE Solution for injection, batch/lot no. and expiry date unspecified) via an unspecified route of administration on 23Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient was asking if it is safe to get the second dose of the vaccine after being exposed to or having COVID? She reported being exposed to her husband (on an unspecified date), who tested positive for COVID, and that she tested positive following her first vaccine dose. She got her Covid-19 vaccine on the 23Dec2020 and tested positive for Covid-19 on the 28Dec2020. She was scheduled to get the next dose on Wednesday and wants to know if she should still get it. Outcome of the events drug ineffective, COVID-19 and Exposure to COVID-19 was unknown. Information on the lot/batch number has been requested.; Sender's Comments: The patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE) on 23Dec2020, and COVID-19 test positive on 28Dec2020. No effect of the suspect vaccine could be reasonably achieved to protect from the targeted infection/disease due to the very short time lag. Instead, the positive COVID test was likely associated with being exposed to her husband, who had COVID-19. Further information is needed for full medical assessment.

She had sniffles and post nasal drip; Got first dose then went to (Entertainment complex name) and contracted COVID/tested positive after getting the 1st dose; Tested positive after getting the 1st dose; She returned home with sniffles, fatigue, and no taste/She had sniffles and post nasal drip; This is a spontaneous report from a contactable nurse (patient) via Pfizer-sponsored program: IBCC (Inbound Call Center for HCPs). A 53-year-old female patient received first single dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK5730, exp date not reported), via an unspecified route of administration on 19Dec2020 for given since patient works with COVID patients (COVID-19 immunisation). The patient had no relevant medical history. There were no concomitant medications. Nurse called asking if she can get the 2nd dose of the vaccine 6 days after the 21st day. She tested positive on 05Jan2021 after getting the 1st dose and was still in quarantine. The nurse works at a hospital. She received her first dose of the COVID-19 Vaccine on 19Dec2020, and afterwards donated blood on the same day. She got the vaccine through her place of work. She said when she donated blood on 19Dec2020, her blood was tested for the COVID-19 Virus antibodies, and her blood was negative for the virus antibodies. She lives about 30 mins from work, so she thought she would get both done in the same day. She gave blood right before she got the vaccine. She gave the blood then went and got the Vaccine. She said on 26Dec2020 she went to Entertainment complex as it was her vacation. Her and her family went for 4 days. On 30Dec2020 she returned home with sniffles, fatigue, and no taste. She said she tested positive for the COVID-19 Virus on 05Jan2021. On 30Dec2020 they got back,

and on 02Jan2021 she had sniffles and post nasal drip. On 03Jan2021 she did not wanna get out of bed. She was profoundly fatigued. She also lost her smell. She had to go back to work on 07Jan2021, but did not want to go back in unless she was sure she was okay because she works with babies. She had no other symptoms after 03Jan2021, except no smell and no taste. She got tested for COVID and was positive on 05Jan2021 (also reported as 06Jan2021 [pending clarification]). Her and her husband were both positive, but her kids were not. The weird thing was she also on 06Jan2021 got her results back from giving blood and she was negative for COVID on 19Dec2020 prior to getting the vaccine. Caller clarifies that her COVID test was a nasal swab. Patient thought her age may have contributed to her feelings of fatigue. She had indicated she worked in either a hospital NICU or nursery, and that is why she had to quarantine for 14 days. She probably would not have even gotten tested for COVID if she was not a nurse and did not know that losing taste and smell were a sign. She feels fine. She said she was scheduled for her second dose of the COVID-19 Vaccine on 12Jan2021. She said she was now in quarantine for 14 days due to testing positive for the COVID-19 Virus, and her quarantine period ends on 14Jan2021. Since now she is in quarantine, she will miss her second dose which was supposed to be on 12Jan2021. She said she rescheduled her second dose of the COVID-19 Vaccine to 18Jan2021, which was 6 days later than when she was supposed to receive the 2nd COVID-19 Vaccine dose. She asked if getting the dose 6 days late was okay. The events were considered as non-serious by the reporter. The outcome of the events was unknown.; Sender's Comments: The information currently provided is too limited to make a meaningful medical assessment hence, the events are conservatively assessed as related to the suspect drug BNT162B2 until further information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

tested positive for COVID; tested positive for COVID; achiness; Chills; not feeling well; This is a spontaneous report from a Pfizer-sponsored program Pfizer First Connect. A contactable consumer (patient's wife) reported similar events for four patients. This is the first of four reports. A 48-year-old male patient received his first dose of bnt162b2 (BNT162B2 also reported as Pfizer-Biontech Covid-19 Vaccine, lot/batch number and expiry date were not reported), via an unspecified route of administration on 17Dec2020 at single dose, for Covid-19 immunisation. Medical history was none. There were no concomitant medications. The patient received the vaccine last 17Dec2020. The following day, 18Dec2020, he was not feeling well. Clarified those side effects as achiness and chills. He had been working so hard and thought initially were getting side effects from the COVID Vaccine. He was tested positive for COVID on 22Dec2020. He was in bed basically until 31Dec2020. His wife wants to know if he should get the second dose. The outcome of events was recovered. Information on the Lot/Batch number has been requested.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021019513 same drug, similar events, different patient;US-PFIZER INC-2021019535 same drug, similar events, different patient;US-PFIZER INC-2021019534 same drug, similar events, different patient

"tested positive for SARS-COV-2; tested positive for SARS-COV-2; This is a spontaneous report from a Pfizer-sponsored program Pfizer First Connect, received from a contactable nurse (patient). A 31-year-

old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot/batch number and expiry date were not reported), via an unspecified route of administration on 18Dec2020 at a single dose for an unspecified indication. The patient's medical history and concomitant medications were not reported. The patient received first dose of vaccine on 18Dec2020 and tested positive for SARS-COV-2 20Dec2020. She reported ""las major symptom"" on 27Dec2020 and asked if it was okay to take the second dose. Outcome of the events was unknown. Information about lot/batch number has been requested.; Sender's Comments: Positive SARS-COV-2 came back 2 days following the vaccine use is compatible with COVID 19 infection. No adequate effect of the suspect vaccine could be reasonably achieved to protect from the targeted infection/disease due to the very short time lag."

Fevers; Chills; he is suspecting that he got infected with the Covid-19 though he already received the 1st dose; he is suspecting that he got infected with the Covid-19 though he already received the 1st dose; Body aches; Patient suspected that he has gotten infected also from his spouse; This is a spontaneous report from a contactable physician (patient). A 48-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 05Jan2021 (Tuesday) at single dose for covid-19 immunization. The patient medical history and concomitant medications were not reported. Patient reported body aches developing the evening of receiving the vaccine, and it has persisted for three days. Patient started to get the chills on Wednesday (06Jan2021). Patient said his wife has been tested positive after he took the 1st dose and he is suspecting that he got infected with the Covid-19 though he already received the 1st dose. Patient thought that he may have been infected by his spouse. He got the vaccine on Tuesday and on Wednesday had fever and chills and still has them. Stated that his spouse lost her sense of smell and taste and tested positive for Covid on Wednesday. Patient stated that this was the day after he received his vaccine. Patient suspected that he has gotten infected also from his spouse and was not aware when he got the vaccine. Stated that now that he is having expected side effects of fever and chills. The outcome events was not recovered. This case was reported as non-serious. Information on the lot/batch number has been requested.; Sender's Comments: The subject received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE) on 05Jan2021, and suspected got COVID-19 infection via exposure to COVID-19 living with his wife, who lost her sense of smell and taste and tested positive for COVID on 06Jan2021. No effect of the suspect vaccine could be reasonably achieved to protect from the targeted infection/disease due to the very short time lag. Further information is needed for full medical assessment.

exposed to her 6 month old grand daughter who was positive; tested and received a positive test result, without symptoms.; tested and received a positive test result, without symptoms.; This is a spontaneous report from a contactable consumer. A 59-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EJ1685), via an unspecified route of administration at the right arm on 30Dec2020 at a single dose for COVID-19 immunization. Medical history included high blood pressure from 2001 and ongoing. There were no concomitant medications. Patient had the flu, shingles and pneumonia vaccines and a booster for MMR in the past 6 months. Patient was exposed to COVID-19 on 01Jan2021. Patient was tested on 07Jan2021 and received a positive test result on

08Jan2021. Patient does not have any symptoms. She was exposed to her 6 month old grand daughter who was positive. The doctor said he thinks it was a false positive. Outcome of the events was unknown.

Tested positive for the Covid virus; Tested positive for the Covid virus; This is a spontaneous report from a contactable nurse. A male patient of an unspecified age received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 29Dec2020 at single dose for COVID-19 immunisation. The patient medical history and concomitant medications were not reported. The patient received the first dose of the vaccine on 29Dec2020 and four days ago, he tested positive for the Covid virus (02Jan2021). The outcome of the event was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Test positive for the Covid virus found 4 day following the vaccination, no adequate effect of the suspect vaccine thus could be reasonably achieved to protect from the targeted infection/disease due to the very short time lag.

"the symptoms as ""having Covid all over again""; the symptoms as ""having Covid all over again""; headache; nausea; severe joint and body pain; body pain; coughing; fever; This is a spontaneous report from a contactable other healthcare professional (HCP) reporting for herself. A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for covid-19 immunization. Medical history included covid-19 from an unknown date. The patient's concomitant medications were not reported. The patient just got the Covid vaccine and was experiencing side effects. She described the symptoms as ""having Covid all over again"", mentioned headache, nausea, severe joint and body pain, coughing and fever on an unknown date. Want to see how long these side effects last. The outcome of the events was unknown. Information regarding lot/batch number has been requested.; Sender's Comments: Based on the information currently available, a lack of efficacy with the suspected vaccine BNT162B2 in this patient cannot be completely excluded. Further information like confirmative virus genome /nucleic acid detection is needed for meaningful medical assessment."

caller was rushed to the emergency room and was tested positive for COVID-19; caller was rushed to the emergency room and was tested positive for COVID-19; caller became symptomatic and experienced headaches; This is a spontaneous report from a contactable physician. A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 18Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. It was reported that the patient received the first dose on 18Dec2020 and is scheduled for the second dose today, 09Jan2021. However, on 24Dec2020, she became symptomatic and experienced headaches. On Saturday, she was rushed to the emergency room and was tested positive for COVID-19. Her physician told her that she could get the COVID-19 vaccine if she has no symptoms anymore. She wanted to know the guidance per Pfizer. The patient underwent lab tests and procedures which included SARS-COV-2 test: positive on 09Jan2021. The outcome of the events was unknown. Information about lot/batch number has been requested.; Sender's Comments: Based on the information currently available, a lack of efficacy with BNT162B2 in this patient cannot be completely excluded.

got a positive test on 31Dec2020. Her 2nd dose is due on Wed and she is currently symptomatic.; got a positive test on 31Dec2020. Her 2nd dose is due on Wed and she is currently symptomatic.; This is a spontaneous report from a contactable consumer via Pfizer-sponsored program . A female patient of an unspecified age received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, batch/lot and expiration date unknown), via an unspecified route of administration on an unspecified date at a single dose for covid-19 immunization. The patient's medical history and concomitant medications were not reported. On 31Dec2020, the patient got a positive test. Her 2nd dose was due on wed and she was currently symptomatic. Patent would to know if she should get second dose on her scheduled date even though she still was feeling unwell. The outcome of the events was unknown. Information about batch/lot number has been requested.

COVID test result as positive; COVID test result as positive; Chills; Body aches; Headache; Weakness; This is a spontaneous report from a contactable nurse (patient). A 46-year-old female patient received first dose BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Solution for injection, Lot number: 49899, unknown expiration), intramuscular in right arm, in Dec2020 at 09:00 AM, at single dose, for COVID-19 immunization. Medical history included asthma, hypothyroid, and interstitial cystitis. The patient has no known allergies. Concomitant medication included influenza vaccine in right arm (lot number: US47SAA) on 08Dec2020 for immunization. Patient also received other unspecified medication within two weeks of vaccination. COVID-19 vaccine was administered in a hospital. On 23Dec2020 at 01:30 AM, the patient woke up with chills, body aches, headache and weakness. On 31Dec2020, the patient had nasal swab for COVID with COVID test result as positive post vaccination. Patient is not pregnant at the time of vaccination. The patient did not have COVID prior to vaccination. The patient received ibuprofen for the events chills, body aches, headache and weakness. The patient recovered from the events chills, body aches, headache and weakness on unspecified date; while unknown outcome for the remaining events.; Sender's Comments: The patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE) on 23Dec2020, and nasal swab for COVID-19 test positive on 31Dec2020. No effect of the suspect vaccine could be reasonably achieved to protect from the targeted infection/disease due to the very short time lag. Instead, the positive COVID likely represents the pre-existing infection prior to vaccine use. Further information is needed for full medical assessment.

maybe she could have COVID too; maybe she could have COVID too; a rash on her leg; some shortness of breath; This is a spontaneous report from a contactable consumer. A 72-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number and expiry date were not reported), via an unspecified route of administration on 06Jan2021 at a single dose for Covid-19 immunization. The patient's medical history and concomitant medications were not reported. It was reported that the patient received her first dose of COVID-19 vaccine on Wednesday, 06Jan2021 and today, on 09Jan2021, the patient started having a rash on her leg, some shortness of breath. She used an asthma inhaler. She experienced some of the symptoms before Wednesday. The reporter was concerned that maybe the patient could have COVID, too. The reporter heard that with COVID, sometimes rashes and/or shortness of breath can come, too. The outcome of the events was unknown. Information on the lot/batch number has been requested.

severe headache behind the eyes; Initially extreme fatigue; started to have shortness of breath; muscle aches; cough; second dose on 05Jan2021 08:30; This is a spontaneous report from a contactable physician (patient). A 39-year-old female patient received second dose of BNT162B2 (Lot number: EL3246), intramuscularly on 05Jan2021 08:30 in left arm at single dose for COVID-19 immunization. Medical history included known allergies: latex and asthma. Patient did not have COVID prior vaccination. Concomitant medications included sertraline hydrochloride (ZOLOFT), drospirenone/ethinylestradiol (YASMIN), melatonin, and ibuprofen (MOTRIN). Patient previously took montelukast sodium (SINGULAIR) and experienced allergy. Patient received first dose of BNT162B2 (Lot number: EK5730), intramuscularly on 18Dec2020 09:00 in left arm at single dose for COVID-19 immunization. Patient experienced initially extreme fatigue, then muscle ached all within 12-24 hours, severe headache behind the eyes. Then when thought was getting better, she started to have shortness of breath, worsening fatigue, and cough; all on 05Jan2021 12:00. These events were resulted in emergency room/department or urgent care. COVID was tested post vaccination. COVID test type post vaccination was nasal swab. COVID test name post vaccination was COVID 19 nasopharyngeal swan. COVID test date was on 08Jan2021. Test result was pending. Treatment received included nebulizer treatment, and steroid course. Patient was not recovered from these events.; Sender's Comments: Based on a compatible temporal relationship and known product safety profile, causality between events severe headache and extreme fatigue and BNT162B2 vaccine cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Hospitalized for stroke on 31Dec two days after vaccine.; sudden loss of hearing to right ear; dizzy and lightheaded/severe dizziness/felt like fainting; difficulty breathing; vomiting; This is a spontaneous report from a contactable nurse (patient). This 43-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), (Lot number: EL1285) via intramuscular route on 29Dec2020 14:30 at single dose on the left arm for COVID-19 immunization. Medical history included anxiety. No known allergies. Concomitant medications were not reported. Patient was not pregnant. Facility type vaccine was Nursing Home/Senior Living Facility. No other vaccine received in four weeks. Patient hospitalized for stroke on 31Dec2020 two days after vaccine (Days of hospitalization: 4). Day of vaccine-6 hours after patient had dizzy and lightheaded for about 45 min then went away. On 31Dec2020 at 19:15 had sudden loss of hearing to right ear and severe dizziness, difficulty breathing, vomiting, and felt like fainting. Paramedics were called-sent to ER, had CTA which showed partial blockage and received TPA. Treatment included TPA, fluids, medications, hospital stay, outpatient follow ups, physical therapy. Patient was not diagnosed with COVID prior to vaccination. Patient has been tested for COVID post vaccination. The patient underwent lab tests and procedures which included Nasal Swab: Negative and Pixel: Negative on 08Jan2021. Outcome of the events was recovering.; Sender's Comments: The Company cannot completely exclude the possible causality between the reported events including stroke, dizzy/lightheaded/felt like fainting, difficulty breathing, vomiting, and sudden loss of hearing to right, and the administration of the COVID-19 vaccine, BNT162B2. More

information regarding the patient's underlying medical conditions, relevant lab tests would be helpful for the Company to make a more meaningful causality assessment.

fever 102 F; headache; chills; body aches; This is a spontaneous report from a contactable Nurse reported for herself. A 63-years-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) at single dose on 22Dec2020 14:30 and the second dose single dose (lot number=EK9231) on 09Jan2021 19:15 for COVID-19 immunization. Vaccine location=Left arm, dose number 1 and dose number 2. Facility-type-vaccine: Hospital. Medical history included asthma. The patient's concomitant medications were not reported. On 10Jan2021 at 14:00 the patient experienced headache with outcome of not recovered, fever 102 ¦F with outcome of not recovered, chills with outcome of not recovered and body aches with outcome of not recovered. The action taken was not applicable. Tylenol was received as therapeutic measures for fever.; Sender's Comments: Based on a compatible temporal association and known product safety profile, a causal relationship between reported events and BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Developed chest tightness around right side of chest into back and SOB 50.5 hours after vaccination. Went to local ER and found to have a right lower lobe pulmonary embolism. Treated with Xarelto and sent home with outpatient follow up.

Temperature spike to 104.6; received first dose of bnt162b2 on 20Dec2020 and second dose on 08Jan2021 13:15; This is a spontaneous report from a contactable consumer. A 38-year-old male patient received the second dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiry date were not reported), via an unspecified route of administration, on the left arm on 08Jan2021 13:15 at a single dose for COVID-19 immunization. Medical history included prediabetic kidney disease. Concomitant medications included salmo salar oil (OMEGA-3 [SALMO SALAR OIL]), lisinopril, furosemide, escitalopram, and rosuvastatin calcium (CRESTOR). The patient is reported to have received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) on 20Dec2020 15:45, on the left arm, for COVID-19 immunization. The patient had no prior Covid vaccination. The patient was not tested for Covid post vaccination. The patient had no known allergies. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. It was reported that the patient received first dose of bnt162b2 on 20Dec2020 and second dose on 08Jan2021 13:15. On 09Jan2021 at 04:30, the patient experienced temperature spike to 104.6, brought down with TYLENOL to hover around 101.0 to 102.0 for 24 hours, normal after that. The patient called a nurse who instructed to go the emergency room/physician office visit. Outcome of the event Temperature spike to 104.6 was recovered on unspecified date in Jan2021. Information about lot/batch number has been requested.

tested positive for COVID; tested positive for COVID; This is a spontaneous report from a non-contactable consumer. A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH

COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunisation. The patient medical history and concomitant medications were not reported. The patient who is a nurse visited last weekend in the reporter's home for a few hours was advised that she tested positive for COVID today (unspecified date) and her family as well. She was vaccinated recently with the Pfizer vaccine. The outcome of the events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

I tested positive for COVID 8 days after my first dose.; I tested positive for COVID 8 days after my first dose.; This is a spontaneous report from a contactable consumer (patient). A 55-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number and expiration date were not reported), via an unspecified route of administration on an unspecified date in Dec2020 at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient got his first dose of Pfizer COVID 19 vaccine 21 days ago in Dec2020. He mentioned that he tested positive for COVID 8 days after his first dose in Dec2020. He stated that he got the second dose yesterday (unspecified date) and queried if should he not have gotten it. The outcome of the events was unknown. Information about Lot/batch number has been requested.

9th: cold (?fever?), restless, body aches (especially headache, neck pain, bilateral knee pain), nausea, vomiting 10th: profound fatigue, hives, intermittent vertigo 11-17th: vertigo, mild headache and neck pain, nausea, vomiting 18th-current: vertigo, nausea, vomiting *Hospitalized from 17-18th, diagnosed with vestibular neuritis secondary to the vaccine

positive COVID-19 test with symptoms; positive COVID-19 test with symptoms; This is a spontaneous report from a Pfizer-sponsored program, Pfizer First Connect. A contactable 39-year-old male healthcare professional reported to have received the first single dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 02Jan2021, for COVID-19 immunization. Medical history and concomitant medications were not reported. On an unspecified date in Jan2021, after the first dose of vaccine, the patient felt sick at some point, so he took a rapid test which came back positive. He stated that the test if testing the antigens (as reported). Antibody testing was not currently recommended to assess for immunity to COVID-19 following Pfizer-BioNTech COVID-19 vaccination. Events outcome was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Based on the information currently available, a lack of efficacy with BNT162B2 in this patient cannot be completely excluded.

13 people, who were applied the vaccine previously, were corona positive after a week; 13 people, who were applied the vaccine previously, were corona positive after a week; This is a spontaneous report from a non-contactable consumer. This consumer reported similar events for 13 patients. This is first of 13 reports. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Solution for injection; lot number and expiration date: not known), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. It was reported that 13 people, who were applied the vaccine previously, were corona positive after a week on an unspecified date. The outcome of the events was unknown. No follow-up attempts are possible; information about lot/batch number

cannot be obtained.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021018408 same reporter, similar suspect drug and event; different patient;US-PFIZER INC-2021018409 same reporter, similar suspect drug and event; different patient;US-PFIZER INC-2021018410 same reporter, similar suspect drug and event; different patient;US-PFIZER INC-2021018411 same reporter, similar suspect drug and event; different patient;US-PFIZER INC-2021018412 same reporter, similar suspect drug and event; different patient;US-PFIZER INC-2021018413 same reporter, similar suspect drug and event; different patient;US-PFIZER INC-2021018414 same reporter, similar suspect drug and event; different patient;US-PFIZER INC-2021018415 same reporter, similar suspect drug and event; different patient;US-PFIZER INC-2021018416 same reporter, similar suspect drug and event; different patient;US-PFIZER INC-2021018417 same reporter, similar suspect drug and event; different patient;US-PFIZER INC-2021018418 same reporter, similar suspect drug and event; different patient;US-PFIZER INC-2021018419 same reporter, similar suspect drug and event; different patient;US-PFIZER INC-2021018410 same reporter, similar suspect drug and event; different patient.;US-PFIZER INC-2021018412 same reporter, similar suspect drug and event; different patient.

After getting the first shot and the patient test positive for Corona virus; After getting the first shot and the patient test positive/perhaps positive; This is a spontaneous report from a Pfizer-sponsored program IBCC (Inbound Call Center for HCPs). A contactable pharmacist reported that a patient of unspecified age and gender started to receive BNT162B2 (PFIZER BIONTECH COVID-19 VACCINE), via an unspecified route of administration, first dose on an unspecified date at single dose for COVID-19 vaccination. The patient's medical history and concomitant medications were not reported. A pharmacist in a hospital wanted to know if after getting the first shot and the patient test positive for Corona virus, how long do they have to wait to get the second? A colleague is perhaps positive. He doesn't know if they got tested. Outcome of the events was unknown. Information on the lot/ batch number has been requested.; Sender's Comments: A causal association between reported event and BNT162B2 cannot be excluded.

Tested positive for COVID; Tested positive for COVID; Phlegm in throat; Cough; Runny nose; cold; Sneezing; Body aches; Nausea; Chills; Headache; This is a spontaneous report from a contactable consumer (patient). A 51-year-old female patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 29Dec2020 14:50 at single dose at right arm for covid-19 immunization. No additional vaccines administered on the same date. Patient didn't receive any other vaccines within 4 weeks prior to the COVID vaccine. Medical history included ongoing migraine. Concomitant medication included acetylsalicylic acid, caffeine, paracetamol (EXCEDRIN EXTRA STRENGTH) for migraine, patient had been alternating this with paracetamol (TYLENOL) while she has been recovering. She clarified the symptoms she experienced as the same day she got the vaccine that evening she had a headache on 29Dec2020. It eventually became a migraine and she left work early. On 30Dec2020 she had body aches, little nausea, and chills. On 31Dec2020, she had more chills, a runny nose, she felt like she was coming down with a cold. She was sneezing, had more chills, more body aches. On 01Jan2021 she felt like she noticed she had phlegm in her throat, but she did not have any pain. The phlegm was causing her to cough more. She had a runny nose the next morning as well. She did the rapid test for COVID on 02Jan2021 evening, and it was positive. She had a headache almost every day. The body aches had pretty much worn off. Runny nose and sneezing

resolved in Jan2021. Phlegm in throat confirmed with no pain. This also resolved, as well as coughing. Outcome of event tested positive for COVID was unknown, outcome of event headache was not recovered. outcome of event nausea was recovered on 07Jan2021, event chills was recovered on 08Jan2021, outcome of other events was recovered on unspecified date in Jan2021. The adverse events resulted in neither doctor or other healthcare professional office/clinic visit, nor emergency room/department or urgent care. Information of lot/batch number has been requested.

Positive COVID test; Positive COVID test; This is a spontaneous report from a contactable consumer (patient's wife). This consumer reported similar events for 2 patients. This is the 2nd of 2 reports. A male patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date not reported), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient was an Odontist and received COVID vaccine on Monday. He was scheduled to have a cath done on Thursday, but that was not happening now. The patient has positive COVID test. The outcome of the events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021013678 same reporter/drug, similar event, different patient

Her stomach is still weirded out/sour stomach; feeling sick; arm pain; She was sick to her stomach; kidneys were hurting; body aches; tested positive; tested positive; The arm wasn't swollen it was just burning.; This is a spontaneous report from a contactable consumer (patient). A 51-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number EL1284) via an unspecified route of administration on 29Dec2020 at single dose for COVID-19 immunization. Medical history was none. The patient's concomitant medications were not reported. At first, she thought she was having a reaction, but then she started feeling sick so she got tested. She was positive so she wasn't having a reaction. She was scared from the pain of COVID. She experienced sickness. Her stomach was still weirded out. She did experience arm pain from the vaccine. Her doctor told her it was fine that it needed to air out. She left the bandage on too long. She didn't have a prescribing doctor. She received the vaccine on the 29Dec2020. She tested positive 02Jan2020. The arm wasn't swollen it was just burning. She was sick to her stomach when she got the stomach. The sick to the stomach lasted maybe two days, but then she got COVID. The burning was around the arm. It wasn't that bad. It lasted for a day. It started the day she got the shot (on the 29Dec2020). On 07Jan2021, she went to the hospital because her kidneys were hurting. The doctor said her kidneys were good. They did labs which were good. She was still going through body aches. She was told she was currently in the worst part of the virus. She still had a sour stomach going on from the virus as well. The outcome of the body aches and sour stomach was not recovered, for other events was unknown.

tested positive after receiving the vaccine; tested positive after receiving the vaccine; she did not think symptoms were related to COVID like leg pain. She noticed that it was a lot worst; she did not think symptoms were related to COVID like leg pain. She noticed that it was a lot worst; This is a spontaneous report from a contactable consumer (patient herself). A 27-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE Solution for injection, batch/lot no. EH9899 and expiry date Mar2021), via an unspecified route of administration on 05Jan2021 on her left arm at a single dose

for covid-19 immunization. Medical history included leg pain. There was no reported concomitant medications. On an unspecified date, patient received COVID vaccine. She stated that she was symptomatic during the vaccine and somewhere after confirmed that she was COVID-positive. She wanted to know if there are any health concerns with getting the vaccine while COVID positive. She added that this was her first dose. she did not think symptoms were related to COVID like leg pain. She noticed that it was a lot worst but did not think that it was a symptom. She stated that she does not recall the first time ever that she had leg pain but stated that the leg pain was really bad the night before the vaccine. She added that she was isolated until 14Jan2021. Outcome of the events drug ineffective, COVID-19 virus test positive and leg pain were unknown.; Sender's Comments: Leg pain is considered intercurrent and unrelated to suspect BNT162B2.

COVID-19 or flu-like symptoms following COVID-19 vaccination/COVID-19 results were to be positive; COVID-19 or flu-like symptoms following COVID-19 vaccination/COVID-19 results were to be positive; COVID-19 or flu-like symptoms following COVID-19 vaccination; This is a spontaneous report from a contactable Other-HCP. A 61-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via unspecified route of administration on unspecified date at single dose for COVID-19 immunization. Patient medical history and concomitant medications were not reported. On unspecified date, COVID-19 or flu-like symptoms following COVID-19 vaccination was reported for the patient. COVID-19 results were to be positive on unspecified date. Changing diet to vegan was reported. Outcome of the events was unknown. Information on the lot/batch number has been requested.

contracted COVID two days after receiving vaccine; contracted COVID two days after receiving vaccine; This is a spontaneous report from a non-contactable nurse. A patient of unspecified age and gender received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number and expiry date were not reported), via an unspecified route of administration on an unspecified date at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. It was reported that the patient got their first dose of the COVID vaccination. The patient contracted COVID on an unspecified date two days after receiving the vaccine. The outcome of the events was unknown. No follow-up attempts are possible. Information about lot/batch could not be obtained. No further information is expected.; Sender's Comments: A causal association between reported event and suspect BNT162B2 cannot be excluded.

tested positive for covid; tested positive for covid; This is a spontaneous report from a contactable consumer (patient) via a Pfizer sponsored program Pfizer Connect. A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number and expiry date not reported), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient works for a hospital. Said had 1st dose of vaccine. Had tested positive for covid on an unspecified date and is under quarantine. The patient would like to know when she should get 2nd dose. The patient underwent lab tests and procedures which included sars-cov-2 test: positive on an unspecified date. The outcome of the events was unknown. Information on the lot/Batch number has been requested.

got sick and tested positive with COVID; got sick and tested positive with COVID; This is a spontaneous report from a contactable consumer via Pfizer Sponsored Pfizer First Connect. A contactable consumer reported similar events for four patients. This is second of four reports. A patient of unspecified age and gender received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, batch/lot and expiration date unknown), via an unspecified route of administration on an unspecified date at a single dose for covid-19 immunisation. The patient's medical history and concomitant medications were not reported. It was reported that the patient got sick and tested positive with covid on an unspecified date. It was further reported that patient who received the COVID vaccine, tested positive for COVID, and experienced side effects afterwards. The outcome of the events was unknown. Information about batch/lot number has been requested.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021013589 same drug, similar events, different patient

got sick and tested positive with COVID; got sick and tested positive with COVID; This is a spontaneous report from a contactable consumer via Pfizer Sponsored Pfizer First Connect. A contactable consumer reported similar events for four patients. This is fourth of four reports. A patient of unspecified age and gender received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, batch/lot and expiration date unknown), via an unspecified route of administration on an unspecified date at a single dose for covid-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient got sick and tested positive with covid on an unspecified date and experienced side effects afterwards. The outcome of the events was unknown. Information about batch/lot number has been requested.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021013589 same drug, similar events, different patient

got sick and tested positive with COVID after getting the first dose of the COVID vaccine; got sick and tested positive with COVID after getting the first dose of the COVID vaccine; This is a spontaneous report from a contactable consumer received from Pfizer-sponsored program Pfizer First Connect. This consumer reported similar events for four patients. This is 3rd of four reports. A patient of unspecified age and gender received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiry date were not reported), via an unspecified route of administration on an unspecified date at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient got sick and tested positive with COVID after getting the first dose of the COVID vaccine. The outcome of the events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021013589 same reporter, same product, similar events, different patient.

caller tested positive on covid a week after taking the 1st dose of vaccine; caller tested positive on covid a week after taking the 1st dose of vaccine; This is a spontaneous report from a contactable consumer (patient) via Pfizer-sponsored program Pfizer First Connect. A female patient of an unspecified age received the 1st dose of bnt162b2 (BNT162B2) at single dose on an unspecified date for Covid-19 immunisation. The patient medical history was and concomitant medications were not reported. The patient was tested positive for Covid a week after taking the 1st dose of vaccine on an unspecified date. The outcome of events was unknown. Patient wanted to know if she can get the second dose. Information on the lot/batch number has been requested.

"COVID-19 virus test positive; COVID-19 virus test positive; This is a spontaneous report from a Pfizer-sponsored program ""Pfizer First Connect"" from a contactable consumer reporting for himself. A male patient of an unspecified age received the 1st dose of bnt162b2 (BNT162B2), via an unspecified route of administration, on 22Dec2020, at single dose, for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient experienced COVID-19 virus test positive on an unspecified date with outcome of unknown. It was reported that the patient was scheduled to get his second dose on 12Jan2021, however between 22Dec2020 and 12Jan2021 the patient experienced the adverse event. The information on the lot/batch number has been requested."

Got the first dose and was contracted with COVID; Got the first dose and was contracted with COVID; This is a spontaneous report from a contactable consumer (patient) from a Pfizer-sponsored program IBCC (Inbound Call Center for HCPs). A female patient of an unspecified age received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 20Dec2020 at single dose for COVID-19 immunisation. The patient medical history and concomitant medications were not reported. The patient was contracted with covid on an unspecified date in Dec2020 (27Dec2020 or 28Dec2020) with outcome of unknown. Information about lot/batch number has been requested.

throat swelling; headache; Pain; little bit of chills; GI upset; This is a spontaneous report from a contactable nurse. A 48-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot: EK9231, expiry: 30Apr2021), via an unspecified route of administration on an unspecified date at 0.3 mL, single dose for covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient received her first dose of bnt162b2 on an unknown date for covid-19 immunization and experienced pain at the injection site. On an unspecified date, the patient experienced head ache, throat swelling, gastrointestinal (GI) upset, pain, and little bit of chills (don't believe to have had fever). It was clarified that the event took place after use of product. The outcome of the events was unknown.; Sender's Comments: The information in this report is limited, and does not allow a full medically meaningful assessment of the case. Considering temporal relationship, a causal relationship between the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) and the reported events including throat swelling cannot be excluded. The case will be reassessed should additional information become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

five employees in a nursing home have gotten the first dose of the vaccine, and then tested positive for COVID; five employees in a nursing home have gotten the first dose of the vaccine, and then tested positive for COVID; This is a spontaneous report from a contactable nurse. This nurse reported similar events for five patients. This is the first of five reports. A patient of unspecified age and gender received first dose BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection; lot number and expiry date not reported) via an unspecified route of administration, on an unspecified date, single dose for COVID-19 immunization. Relevant medical history and concomitant medications were not reported.

It was reported that five employees in a nursing home have gotten the first dose of the vaccine, and then tested positive for COVID on an unspecified date. They would like to know if they still get the second dose. Outcome of the events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the reported events of Covid-19 virus test positive and suspected LOE due to temporal relationship. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.,Linked Report(s) : US-PFIZER INC-2021021909 Same reporter/ drug/ event for different patients.;US-PFIZER INC-2021021910 Same reporter/ drug/ event for different patients.;US-PFIZER INC-2021021911 Same reporter/ drug/ event for different patients.;US-PFIZER INC-2021021912 Same reporter/ drug/ event for different patients.

five employees in a nursing home have gotten the first dose of the vaccine, and then tested positive for COVID; five employees in a nursing home have gotten the first dose of the vaccine, and then tested positive for COVID; This is a spontaneous report from contactable nurse. This nurse reported similar events for 5 patients. This is the second of five reports. A patient of unspecified age and gender received first dose BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection; lot number and expiry date not reported) via an unspecified route of administration, on an unspecified date, single dose for COVID-19 immunization. Relevant medical history and concomitant medications were not reported. It was reported that five employees in a nursing home have gotten the first dose of the vaccine, and then tested positive for COVID on an unspecified date. They would like to know if they still get the second dose. Outcome of the events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: The information currently provided is too limited to make a meaningful medical assessment hence, the events are conservatively assessed as related to the suspect drug BNT162B2 until further information becomes available.,Linked Report(s) : US-PFIZER INC-2021021881 Same reporter/ drug/ event for different patients

five employees in a nursing home have gotten the first dose of the vaccine, and then tested positive for COVID; five employees in a nursing home have gotten the first dose of the vaccine, and then tested positive for COVID; This is a spontaneous report from a contactable nurse. This nurse reported similar events for five patients. This is the third of five reports. A patient of unspecified age and gender received first dose BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection; lot number and expiry date: not reported), via an unspecified route of administration, on an unspecified date at single dose for COVID-19 immunisation. Relevant medical history and concomitant medications were not reported. It was reported that five employees in a nursing home have gotten the first dose of the vaccine, and then tested positive for COVID on an unspecified date. They would like to know if they still get the second dose. Outcome of the events was unknown. Information on the Lot/Batch number has

been requested.; Sender's Comments: The information currently provided is too limited to make a meaningful medical assessment hence, the events are conservatively assessed as related to the suspect drug BNT162B2 until further information becomes available.,Linked Report(s) : US-PFIZER INC-2021021881 Same reporter/ drug/ event for different patients.

five employees in a nursing home have gotten the first dose of the vaccine, and then tested positive for COVID; five employees in a nursing home have gotten the first dose of the vaccine, and then tested positive for COVID; This is a spontaneous report from a contactable nurse. This nurse reported similar events for five patients. This is the fourth of five reports. A patient of unspecified age and gender received first dose BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection; lot number and expiry date not reported) via an unspecified route of administration, on an unspecified date, single dose for COVID-19 immunization. Relevant medical history and concomitant medications were not reported. It was reported that five employees in a nursing home have gotten the first dose of the vaccine, and then tested positive for COVID on an unspecified date. They would like to know if they still get the second dose. Outcome of the events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: The information currently provided is too limited to make a meaningful medical assessment hence, the events are conservatively assessed as related to the suspect drug BNT162B2 until further information becomes available.,Linked Report(s) : US-PFIZER INC-2021021881 Same reporter/ drug/ event for different patients

five employees in a nursing home have gotten the first dose of the vaccine, and then tested positive for COVID; five employees in a nursing home have gotten the first dose of the vaccine, and then tested positive for COVID; she had felt weird; This is a spontaneous report from a contactable nurse. This nurse reported similar events for five patients. This is the fifth of five reports. A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; batch/lot number and expiration date unknown), via an unspecified route of administration on an unspecified date at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The nurse reported on behalf of her sister (patient). It was reported that the patient called right before Christmas and she had gotten the Pfizer COVID Vaccine. She reported that she had felt weird and had side effects to the vaccine. The patient works in a nursing home type thing, and she said she has had people who have gotten the first dose of the vaccine, and then tested positive for COVID. The patient called to ask the reporter if they should still get the second dose. The only other details that her sister (patient) provided her was that this has happened with several people; 5 employees and several or 9 patients. She is unsure if she said several patients or 9 patients, but there were 5 employees. The outcome of the events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: The information currently provided is too limited to make a meaningful medical assessment hence, the events are conservatively assessed as related to the suspect drug BNT162B2 until further information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics

Committees, and Investigators, as appropriate.,Linked Report(s) : US-PFIZER INC-2021021881 Same reporter/ drug/ event for different patients.

Diarrhea; nausea and vomiting; nausea and vomiting; rash on her right arm, like a hive or whelp; Fever; Headache; really sore right arm; right arm felt numb; This is a spontaneous report from a contactable nurse (patient). A 44-year-old female patient received the first dose of BNT162B2 (Pfizer COVD 19 vaccine), lot number: EL0142, via an unspecified route of administration on 07Jan2021 17:00 at single dose in right arm for COVID-19 immunisation. Medical history included blood pressure abnormal, had a cough from having COVID 19 on 16Dec2020, cough was ongoing and unknown for COVID-19. Concomitant medication included amlodipine from an unspecified date (taking for 2 years) and ongoing at 10mg once daily by mouth for blood pressure abnormal. No other vaccines were administered on same date and no prior vaccinations (within 4 weeks). Registered nurse (patient) was calling regarding Pfizer COVID 19 vaccine. Reported she received the first dose last Wednesday 07Jan2021 17:00 in the right arm. Reported she noticed the next day (08Jan2021) fever and a headache. On 08Jan2021, Friday she had a really sore right arm and her right arm felt numb. On 09Jan2021, Saturday, she experienced nausea and vomiting and also noticed a rash on her right arm, like a hive or whelp. On 10Jan2021 Sunday, again with the fever, nausea, vomiting and she had diarrhea. Today she stated she woke up a new woman. She feels felt with no fever and her arm was better. She still had a cough from having COVID 19 on 16Dec2020. Stated she was used to coughing. Added she treated the fever with Tylenol 1000mg. Stated she didn't remember exactly but she took a little everyday starting on Thursday the day after the vaccine. Stated she was unsure if she would have the next dose. The events didn't require a visit to physician office or emergency room. The outcome of fever was recovered on 10Jan2021, of Headache, sore arm, rash on right arm, nausea and vomiting was recovered on 11Jan2021, of arm numb was recovered on 09Jan2021, of diarrhea was recovering. Serious criteria for fever was reported as yes, medical significant, for Headache, sore arm, arm numb and Diarrhea was non-serious, for rash on right arm, nausea and vomiting was unspecified.; Sender's Comments: Based on the compatible time association, the event fever is possibly related to suspect BNT162B2 administration. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

COVID-19 confirmed by positive COVID-19 test; COVID-19 confirmed by positive COVID-19 test; This is a spontaneous report from a contactable consumer (patient). A patient of unspecified age and gender received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration in Dec2020 at single dose for COVID-19 immunisation. The patient medical history and concomitant medications were not reported. The patient develop Covid-19 diagnosed by PCR about may be six or seven days after received the vaccine. The patient recovered from the event. Information on the lot/batch number has been requested.

after the patient got vaccinated his relative tested positive; after the patient got vaccinated his relative tested positive; This is a spontaneous report from a Pfizer-sponsored program . A contactable nurse (relative of the patient) reported for a patient of unspecified age and gender received the first dose of

bnt162b2 (also reported as Pfizer Covid-19 Vaccine, lot no. and expiry date was not reported), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The nurse called in because his relative got the 1st dose of vaccine but after the patient got vaccinated his relative tested positive on unspecified date. The nurse called in if the patient can take the 2nd dose of vaccine. The outcome of the event was unknown. Information on the Lot/Batch number has been requested.; Sender's Comments: The patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE) but after the patient got vaccinated his relative tested positive on unspecified date. The case will be reassessed should additional information become available.

Tested positive for COVID; Tested positive for COVID; This is a spontaneous report from a contactable nurse (patient). A male patient of an unspecified age received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date not provided), via an unspecified route of administration on 22Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and patient's concomitant medications were not reported. The patient received his first dose on 22Dec2020 then, nine days later, on 31Dec2020, he tested positive for COVID. He is scheduled for his second dose on 12Jan2021. However, he is still out of work. He called to see if he could get his second dose a couple of days later or does it have to be exactly 3 weeks from the first shot and if it is okay to go a little longer. During the call, he stated he just wanted his question answered about the second shot, if can he wait a little longer. The outcome of the events was unknown. Follow-up attempts are completed. The following information on the batch number has been requested.; Sender's Comments: A causal association between reported event and suspect BNT162B2 cannot be excluded.

Got my Covid vaccine on the 20th and then I came back positive for Covid last week; Got my Covid vaccine on the 20th and then I came back positive for Covid last week; This is a spontaneous report from a contactable consumer. A patient of unspecified age and gender started to receive BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number/expiration date unknown), via an unspecified route of administration on 20Dec2020 at a single dose for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. It was reported that the patient got the COVID vaccine on the 20th (20Dec2020) and then came back positive for COVID on an unspecified in Jan2021 (reported as last week), then tested negative on 08Jan2021 and was due for vaccine on 09Jan2021. It was asked if the patient will be able to get the vaccine. The outcome of the events was recovered on 08Jan2021. Information on the lot/batch number has been requested.

"diagnosed with Covid; diagnosed with Covid; This is a spontaneous report from contactable other healthcare professional via a Pfizer sales representative. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number and expiry date was not reported) via an unspecified route of administration on 04Jan2021 at single dose for covid-19 immunisation. The patient's medical history and concomitant medications were not reported. It was reported that the patient received the vaccine on 04Jan2021 and was diagnosed with COVID on 07Jan2021. Outcome of the event was unknown. Information about Lot/Batch number has been requested.; Sender's Comments: Although, BNT162B2 vaccine immunogenicity is not in full effect after short time (3 days in this case) from the first dose administration, a causal relationship between event

""diagnosed with COVID"" (coded to Drug ineffective / COVID-19) and BNT162B2 vaccine cannot be completely excluded."

Patient received 1st dose on 28Dec and presented symptoms on 05Jan; Patient received 1st dose on 28Dec and presented symptoms on 05Jan; This is a spontaneous report from a contactable pharmacist reporting for self via Pfizer field representative (Field Medical Director). A patient of unspecified age and gender received the first single dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (lot number and expiry date not reported) on 28Dec2020 via an unspecified route of administration for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient presented COVID-19 symptoms on 05Jan2021. No lab tests reported. The outcome of the event was unknown. Information about lot/batch number has been requested.; Sender's Comments: The patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE) on 28Dec2020, and patient presented COVID-19 symptoms on 05Jan2021. No effect of the suspect vaccine could be reasonably achieved to protect from the targeted infection/disease due to the very short time lag. Instead, patient's COVID-19 symptoms on 05Jan2021 likely represents a pre-existing infection prior to vaccine use. Further information is needed for full medical assessment.

This morning he is diabetic. His sugar it was elevated, it was up to 300 which is he said much higher than normal; This is a spontaneous report from a contactable consumer (patient) from a Pfizer-sponsored program Pfizer First Connect. A male patient of unspecified age received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 09Jan2021 at single dose for COVID-19 immunisation. Medical history and concomitant medications were not reported. He has his first dose of the COVID Vaccine yesterday and this morning he is diabetic. When he woke up this morning to test his sugar it was elevated, it was up to 300 which is he said much higher than normal and wants to know if that would be a symptom. Outcome of event was unknown. Information on the lot/batch number has been requested.

1/16/21, Covid vaccine injection at 12:09 PM Minute 1: dizzy and light headed (like drinking a beer on an empty stomach) Minute 10: Nausea Minutes 23-25: Neck tightness (like doing unsupported crunches and holding my head up) Minute 27: Inability to swallow and inability to speak EMS on site administered EpiPen auto-injection to left thigh, immediate improvement in symptoms Transport to hospital via ambulance Hospital monitored me for several hours and discharged same day

itching, hives, short of breath, numbness and tingling to lips with hives to bottom. headache.

On 1/13/2021, resident had sudden emesis. Immediately following emesis he was noted without a pulse and pronounced deceased. No acute symptoms noted prior to this episode. Resident does have a significant cardiac history.

Started with severe chills, body aches and feverish. The. Slight leg pain which worsened with time , swelling on the right leg calf, warm to touch and difficulty breathing. Got hospitalized on 1/16 21 with multiple clots in my right leg and clot in the lung. Still in the hospital now.

She had the first dose of Pfizer vaccine at the Campus on Friday 1/15 at 4:30 pm. After the vaccine, she had no new symptoms or signs of vaccine reaction and MD friend reports that he checked her pulse which was not elevated from baseline. On 1/16, she awakened and continued to feel at her recent baseline. However, in the early afternoon, she complained of headache, nausea/epigastric pain, and chest heaviness. These apparently were not unusual symptoms for her to feel intermittently. Per her niece, who has a home O2 sat device, her 02 sat that morning was 97 with a HR of 87 irregularly irregular. She was afebrile. (continue on page 2)

Aphasia, ,right-sided weakness and garbled speech

"Had severe body aches m, fever, headache, progressed into dizziness and ""foggy memory"", started to have some chest pain. Felt as if I was intoxicated, lasted the whole day. Woke up the next morning and still felt ""out of it"" and weak but thought it would get better, went to work (im a nurse). Started having continous vomiting, shortness of breath and chest pain at work. As well as severe tremors. I was taken to the hospital, given fluids and my QT was prolonged with my heart which i have never had before . Was given iv magnesium and waited for my heart rhythm to improve. Was told not to take anymore of my prescribed medications or nausea medications and follow up with my pcp the next day. Im still feeling horrible, nausea, body aches, low grade fever and I am 72 hours out. Now I have huge hospital bill to pay, can't work currently because I still feel bad and my heart has a weird rhythm. Hoping this helps as if this was what I was expecting I would have never got it."

Pt complained at ED of Headache, Nausea, SOB, felt like had been running. Pt in AFIB started on cardizem admitted to hospital 1/15 discharged 1/17

Patient tested positive for COVID 19 on Jan 5th 2021 Patient was admitted to the hospital January 9th for pneumonia due to COVID

Acute liver injury requiring transplant evaluation and acute kidney injury

Anaphylaxis after Covid 19 vaccine #1. Pfizer Lot # EH9899

Two days after her shot, she was sitting down working on her computer paying bills. She became nauseas and dizzy and then fainted. She hit the tile floor.

Lot number for the first dose was EK5730. After receiving the 2nd dose on the 01/11/2021 went to lunch and in the evening started feeling nausea and was throwing and abdominal pain. Went to work sick Tuesday and Wednesday low grade fever, nausea and abdominal pain, wasn't eating was to sick to eat. Thursday early morning hours the pain was unbearable so she went to the ER and the cat scan. It was determined that she had appendicitis and they removed my appendix same day. Feels so much better now.

"After receiving Moderna vaccine, pt became increasingly tired, withdrawn, and confused, refusing to walk at home. He has begun to have mild memory changes after suspected COVID illness (covid testing negative) in November, but daughter of patient, with whom he lives, states that his memory and orientation now significantly changed- he seems to have forgotten the last ""3 years"" of memory.

Presented to ER 1/16/21 as she checked his O2 and found him to be hypoxic in 60s. He is being treated for possible CAP with underlying perviously undiagnosed ILD vs post-covid lung changes (per pulmonology), and his energy and ability to walk have returned but memory is significantly impaired, confabulating and oriented only to self despite good oxygenation on 5L O2 by NC."

About 22 hours after the shot, I had a mini stroke that required going to the emergency room by ambulance. I was transported that evening to the stroke division that same evening for further evaluation, tests and care. I have never had a mini stroke before this.The doctors said it may have been from the vaccination, or it may not have been precipitated by it. They said they don't have enough information on the Moderna vaccine to make that call.

Patient was vaccinated in right arm. Within 5 to 10 seconds after vaccination, patient started clinching his hands tightly and became unresponsive. Patient was lowered to the floor and did not exhibit a pulse. CPR was initiated and 911 was called. An AED was used and healthcare professionals onsite continued compressions until the paramedics arrived.

Death

Received vaccination on 12/30/2020, had positive Covid test result on 1/6/2021, was hospitalized with respiratory issues on 1/11/2021, and discharged home from the hospital on 1/18/2021

12:52 PM resident rang her call bell with complaints of chest pain and shortnes of breath. BP 126/70, Temp 97.5, Pulse 72, Resp. 20, O@ stats on room air 90%. resident requesting transport to ER. EMS called at their arrival resident had increasing SOB o2 on at 3L Nasal Canula. Transported to hospital. Resident placed on ventilator and tranported to different hospital.

"Felt tachycardia immediately, thought she was anxious. After 35-45 minutes she felt like she was having a hard time swallowing which progressed to tongue swelling, all taste buds popped up and sore, hives on face & neck, reddened face. Itchy neck and face. Took double dose of Atarax and went to bed. Felt extremely fatigued unsure if double dose of Atarax. Woke with swelling all over body. Woke up feeling heaviness as if she had ""sumo wrestler"" on her body. 24 hours post vaccine heaviness started to lift but felt as if she had a vise on her lungs. Continuing to take Atarax every 6 hours per MD order."

Resident received vaccination on January 15, 2021. She was found unresponsive with shallow respirations on the morning of January 16, 2021 and was sent to ER via ambulance. The resident was admitted to medical center ICU where she passed away later that day.

resident had a pressure ulcer to RT hip, was getting treatment on. Was scheduled to have wound debrided and wound vac applied on 1-19-2021. Appetite was poor, not wanting to get out of bed, and decline in alertness. Passed away on 1-16-2021

patient received vaccine 12/29. Unexpected death 1/5.

Patient had received second Pfizer vaccination after no reported issues with the first dose. Patient was observed post vaccination without incident and released. Patient developed wheezing and attempted to

treat with her albuterol inhaler but did not improve. patient presented to the ED approximately 2 hours after vaccination and was admitted for respiratory failure and placed on BiPAP for a brief period of time. patient has known history of Asthma Exacerbation requiring hospitalization and intubations. D/C diagnosis Asthma Exacerbation

Systemic: Anaphylaxis-Severe; symptoms lasted 1 day

Systemic: Anaphylaxis-Severe, Systemic: Seizure-Severe

Temp of 104.5, hospitalization

COVID 19 Vaccination administered by pharmacy staff. No adverse effect at the present time. Staff will continue to observe adverse reaction. Will continue to monitor. Patient at start of shift awake in the bed. Pt at 3am was on the commode leaned to the side. Patient body still warm to touch no pulse. Called for assistance Asap. Cpr started promptly. Cpr given patient on floor 911 arrived at the scene at 3:10am Cpr rotated Between Nursing and EMT on Scene. Cpr was given to patient for over 45 minutes. Patient was pronounced at the scene at 3:50am. Call placed to Pt family by supervisor on shift. MD to be notified. AT 3:00am, I was notified by the nurse that resident is unresponsive. Upon entering room, resident was sitting on the commode unresponsive with absent respiration and pulse. Resident lowered down on the floor with 4 person assist. CPR initiated, AED pads placed on chest with no shock indicated. 911 called and EMT and paramedics arrived around 3:10am. ACLS performed until code stopped and pronounced death at 3:48am. I called and notified family member of his demise and awaiting for family to call us back for funeral arrangements.

One week after the shot (1-14-2021) Patient (19 y.o.)reported side pain and appeared constipated, Laxatives given along with Tylenol, on further assessment Patient was noted to have left leg redness and abdominal fullness. Dr. was updated and we had orders for close monitoring, the next day when she got up, her leg appeared better, and she had passed a small BM, but by lunch she had developed significant pain and edema in her left leg, and the color of her leg was reddened again. She was sent to the emergency room with her symptoms. She was admitted back to our facility yesterday, her diagnoses included Acute provoked left external illiac, femoral, popliteal, and peroneal DVT. Elevated Factor II levels, Elevated APC resistant, May-Thurner Syndrome, history of developmental disabilities, fecal impaction and urinary retention - suspected related to her fecal impaction. Vascular surgery was consulted, and pt. was started on a heparin drip, and mechanical thrombectomy was needed for both legs due to multiple clots. She was started on Eliquis and Plavix, and thigh high compression stockings were ordered, ace wraps being used until these are supplied. Her Fecal impaction was addressed also and the urinary retention resolved.

Death

Hx Covid infection Had Covid vaccine #1 - no problems Within 1 hr after Covid vaccine #2 progressed to SOB, pruritis throat tickle TxT-ed self with Benadrl but symptoms persisted Went to ED txt with Bendryl, prednisone, zyrtec.

"right sided weakness with numbness from her face down her entire body; right sided weakness with numbness from her face down her entire body; right sided weakness with numbness from her face down her entire body; bad headache; pain at the injection site; This is a spontaneous report from a contactable consumer (patient). A female patient of an unspecified age (reported as 41 unknown unit) received the first dose of bnt162b2 (BNT162B2) via an unspecified route of administration on an unspecified date at a single dose for covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient wanted to know how long side effects last after receiving the first dose of the Covid vaccine. The patient received first dose of Covid vaccine on Thursday (unspecified date) and reported side effects. She reported side effects of right sided weakness with numbness from her face down her entire body. She describes the feeling as if she's been ""shot up with novocaine on the right side of her body."" She was also experiencing a really bad headache and pain at the injection site. She reported that the side effects do not seem to be wearing off. She wanted to know if this has been reported as a common side effect. Outcome of the events was unknown. Information on the lot/batch number has been requested."

Severe headache from 12-36h post administration impairing ability to perform ADLs with inability to turn head from side to side or to change positions without lancing temporal pain and a/w photophobia; Severe headache from 12-36h post administration impairing ability to perform ADLs with inability to turn head from side to side or to change positions without lancing temporal pain and a/w photophobia; Severe malaise; Severe headache from 12-36h post administration impairing ability to perform ADLs with inability to turn head from side to side or to change positions without lancing temporal pain and a/w photophobia; loss of appetite; Transient dysgeusia; Mild nausea; Pleuritic chest pain; This is a spontaneous report from a non-contactable physician. This 27-year-old female physician (patient) reported that she received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number=E15249), via unspecified route at left arm on 08Jan2021 07:30 AM at single dose for COVID-19 immunization. Medical history was none. Concomitant medication was not reported. The historical vaccine included the first dose of BNT162B2 for COVID-19 immunization. Facility type of vaccine was hospital. No other vaccine in four weeks. No Covid prior vaccination. No covid tested post vaccination. On 08Jan2021 06:00 PM, patient experienced severe headache from 12-36h post administration (as reported), impairing ability to perform ADLs with inability to turn head from side to side or to change positions without lancing temporal pain and a/w photophobia (nearly meningeal signs); mild nausea; pleuritic chest pain; severe malaise; transient dysgeusia; loss of appetite. Treatment for events included initially NSAIDs until had difficulty tolerating was received. Outcome of events was recovering. No follow-up attempts are possible. No further information is expected.; Sender's Comments: Based on the time association, the possible contribution of suspect BNT162B2 to the events cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

tachycardia; shortness of breath; elevated blood pressure 165/90; tired; stomach upset; felt unwell; This is a spontaneous report from a contactable other health professional (patient). A 25-year-old female

patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 31Dec2020 at single dose for COVID-19 immunization. The patient medical history and concomitant medications were not reported. The patient experienced on 04Jan2021 felt unwell, tired, stomach upset (it continued all week) and on 07Jan2021 tachycardia and shortness of breath. Clinical course: she was feeling very like short of breath and her heart racing, had elevated blood pressure 165/90, usually it was normal. The patient was sent to the emergency room (ER) and got worked up, she had a complete blood panel, everything came back normal; she had a chest X-Ray and 2 bags of fluid, then the patient was discharged. The patient outcome of the events was recovered. The information on the batch number has been requested.; Sender's Comments: A causal association between BNT162B2 and the reported events cannot be excluded based on a compatible temporal relation between vaccination and onset of events. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

started having a lot of left eye pain/he diagnosed her with Scleritis; This is a spontaneous report from a contactable other healthcare professional (HCP) a Nurse Practitioner, who reported for herself. A 35-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Batch/lot number: EJ1685 also reported as ES1685), intramuscular in left deltoid on 24Dec2020 at single dose for COVID-19 immunization. Medical history included ongoing anxiety diagnosed years ago, maybe when she was 23. Concomitant medication included ongoing celecoxib (CELEXA) for anxiety started about a year, or year and a half ago. She did not take other vaccines on the same day as the COVID vaccine. She had no recent labs. On 02Jan2021 the patient experienced scleritis. Event was described as follows: patient got her first COVID vaccine on 24Dec2020 and on 02Jan2021 she started having a lot of left eye pain. She went to her Ophthalmologist and he diagnosed her with Scleritis. She had no history of anything with her eyes or any vascular or autoimmune issues; no eye disorder history or rheumatology history. Patient is due to get her second dose of the vaccine on 14Jan2021, and she spoke with her primary care doctor and her ophthalmologist, and neither of them have any answer on if she should get the second dose or not, they did not have much guidance for her as this was such a new product. Patient reported that scleritis was persisting, but it has improved and she was on Prednisone eye drops. Event scleritis was considered serious as Medically significant because of what it is and what it can do, but this was not a severe case (as reported). Final outcome of scleritis was recovering.; Sender's Comments: The reported scleritis was more likely an intercurrent disease, and less likely causally related to the use of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE). The case will be reassessed should additional information become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics committees and Investigators, as appropriate.

Appendicitis; Vomiting; Nausea; Chills; This is a spontaneous report from a contactable consumer. A consumer reported that her 65-year-old mother received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot number Unknown), into the arm at single dose on 31Dec2020 for COVID-19 immunization. The patient did not have any medical history and did not receive any concomitant products. On 31Dec2020 the same evening of vaccination, the patient experienced vomiting, nausea and chills that were considered flu like. On 03Jan2021 or 04Jan2021 her appendix ruptured. She entered emergency room on 07Jan2021 and was diagnosed with appendicitis. She was admitted to hospital on 07Jan2021. She has been given hospital care for past four days. She will have surgery in 6 weeks to repair and right now they are cleaning ruptured area. Her care team is wondering if she should get second dosage. The patient is currently hospitalized. The patient recovered from the event vomiting on 31Dec2020, recovered from the events Nausea and Chills on 07Jan2021 and was Recovering from the appendicitis. Information on the lot/batch number has been requested.

"Bell's Palsy; This is a spontaneous report from a contactable consumer. A 63-years-old female patient received the first dose of BNT162B2 Pfizer-BioNTech COVID-19 Vaccine, Batch/lot number: ELD14D, via an unspecified route of administration, in left side of arm, on 04Jan2021 at single dose for COVID-19 immunization. Medical history included early breast cancer from 2017 and ongoing. Concomitant medication included tamoxifen citrate 20 mg tablet by mouth once daily from 2017 and ongoing for breast cancer (cancer pill, she has to be on it for 5 years). The patient received the vaccine as she is ""with fire department, thought she needed to take it, she had early breast cancer, is around lots of people"". On 09Jan2021 the patient was diagnosed with Bell's palsy, assessed as medically significant and in Jan2021 she experienced earache (she thought it was an earache, but it was more than that, but it made her ear hurt, and she has no infection), her mouth was drawled a little, further detailed as numbness and ""the eye, it is messing with it, when she is trying to see out of it, she can see, but it's blurry like"" and, ""where the ear thing is"", on the back of the lymph node was real sore and her face was kind of puffy, which is the reason she went to the doctor. The patient had to go to her doctor, he told her she had a reaction to the shot, he called it Bell's Palsy, and said to let Pfizer know. Her doctor gave her something to take for mouth drawled/numbness, which is supposed to help, and she has to go back in a week. The event Bell's palsy outcome was unknown at the time of the report."

Doesn't feel like eating; Fever; Chills/ Chilled; Nausea; Severe Headache/Dull headache/Frontal headache; Fatigue; Body aches; This is a spontaneous report from a contactable Nurse (patient). This 61-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number EJ1686), via intramuscular, on 06Jan2021 (at 14:30) at single dose at left deltoid for COVID-19 immunisation, administered at hospital. Age at vaccination is 61-year-old. Historical vaccine included Diphtheria and Tetanus vaccine (intramuscular, at single dose) on 15Dec2020 for immunization; and Shingles vaccine (intramuscular, at single dose) on 15Dec2020 for varicella immunization. Relevant medical history included usual tenderness. No relevant concomitant medications were provided. On 07Jan2021, she woke up at 2:00 in the morning, she had a high temperature, she was chilled, she had a severe headache, nausea, fatigue, and body aches. She got up and took ibuprofen (ADVIL). She was basically in bed, she had to cancel all her appointments in the morning, she just laid in bed and the following afternoon her fever broke at about 4:30 in the afternoon then she just had a low grade

temperature and a dull headache, nausea through the next day, Friday the 08Jan2021. She still has a very dull headache and just not right, kind of like a flu bug. She had no fever; she had not had any fever after Friday afternoon or Saturday. Fever started at 2 in the morning 07Jan2021 and she experienced the chills until after fever broke. Fever went above 102 degrees. She still had a little of the nausea, she just didn't feel like eating. She still had the dull headache. The nausea and headache have improved when compared to how it was on the 07Jan2021. She was back to work now she just has a dull frontal headache. The reporting nurse assessed all the events, except of 'Doesn't feel like eating', serious for disability. She stated she may have had usual tenderness but nothing like this. The patient had recovered from the event fever on 08Jan2021 and from the event 'chills/chilled' on 07Jan2021; the patient was recovering from 'nausea' and 'severe Headache/Dull headache/Frontal headache', while the outcome of the remaining events was unknown.; Sender's Comments: A possible contribution role of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) to the onset of the reported events cannot be excluded due to temporal relationship. It is worth noting that patient had other vaccines not far ago, including Diphtheria and Tetanus vaccine and Shingles vaccine on 15Dec2020 for immunization. The case will be reassessed should additional information become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics committees and Investigators, as appropriate.

throat and tongue started to feel weird and tight/throat got to the point of so swollen and itchy I couldn't swallow; throat and tongue started to feel weird and tight/throat got to the point of so swollen and itchy I couldn't swallow; throat and tongue started to feel weird and tight/throat got to the point of so swollen and itchy I couldn't swallow; throat and tongue started to feel weird and tight/throat got to the point of so swollen and itchy I couldn't swallow; This is a spontaneous report from a non-contactable consumer (patient) via a Pfizer-sponsored program Corporate (Pfizer) Social Media Platforms. This patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration at single dose on an unspecified date for covid-19 immunisation. The patient medical history and concomitant medications were not reported. On an unspecified date, the patient experienced throat and tongue started to feel weird and tight/throat got to the point of so swollen and itchy I couldn't swallow. The patient condition was life threatening. The patient described the events as follows: 40 min after injection my throat and tongue started to feel weird and tight. Pharmacy at my work hospital gave me 25 mg Benadryl and 650mg Tylenol. At about 1 hr 45 min after injection my throat got to the point of so swollen and itchy I couldn't swallow. I went to nearest emergency room hospital they administered Decadron orally, Pepcid P.O. (orally), and Toradol via IM (Intramuscular). The outcome of the events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

"Have a cut in my leg which is very unusual; Saw a big cut in my feet; I was bleeding from somewhere; It was quite a lot of blood drawing out of my body; This is a spontaneous report from a contactable consumer (patient). A 62-year-old male patient started to receive single dose of BNT162B2 (Solution for injection, batch/lot number and exp date not reported), via an unspecified route of administration on

23Dec2020 09:00 for COVID-19 immunization; and adalimumab (HUMIRA), via an unspecified route of administration from an unspecified date at unspecified dose (injection every other month) for arthritis. Medical history included arthritis, blood pressure (abnormal), and blood cholesterol (abnormal). Concomitant medication included rosuvastatin for blood cholesterol, olmesartan medoxomil, metoprolol succinate (TOPROL XL), and vitamins: ascorbic acid, ergocalciferol, nicotinamide, retinol, riboflavin, thiamine hydrochloride. Patient stated, ""The reason I am calling, I have just a concern that something happened to me. I did not pay much attention but now I have read the news one doctor died after getting this COVID Vaccine (Further details were not available over the call) I have a small incident happened to me the day after I received my first dose of the COVID Vaccine. I just wanted to get some information. You know what happened the next day night, in the evening I was taking a shower and all of sudden I was bleeding from somewhere. Lot of blood was coming out while I was toweling my body out. I couldn't find out where the blood is coming from. I checked, it's not from my urine, not from my rectum but it was quite a lot of blood drawing out of my body. Immediately, I called my wife into bathroom, then I squeezed my body then the bleeding stops. It was on 24Dec2020. You know my kids were at home. I don't want them to find it. The bleeding stopped and everything went away. Then I thought maybe it is something related to my GI. I went to my GI doctor yesterday to have a checkup, they don't know anything either but I am due for my second dose for next week Wednesday. Now I had this news about thrombocytopenia on this doctor died (Clarification unknown). So I am just afraid if there is anything related this. Do you have any explanation on how I bleed and where it bleed? It was lot of bleeding even my towel was full of blood."" Patient wanted to see if anybody else had similar experience or if he get the second dose and he get the complication again. Patient was a medical technologist. He was doing ultrasounds. He was working in a pediatric hospital. Patient was not prescribed/recommended vaccination. ""Nobody recommended it. During my hospital. I am healthcare professional. So everybody in my hospital. I just went there and get it. I didn't ask my doctor."" Patient added, ""You know everything I read about this case and then you know, I have a cut in my leg which is very unusual. I have never seen that. I don't know how it happened. You know all of sudden oneday I wake up and I saw a big cut in my feet also. So, I am just afraid (onset date not reported)."" The action taken in response to the events for adalimumab was unknown. The outcome of the events was unknown. Information about Lot/Batch number is requested."

Possible Bells Palsy; Arm/neck soreness; Arm/neck soreness/ neck are painful; travel up neck to side of face/around temple/ Side of head/face/cheeks/jaw; travel up neck to side of face/around temple/ Side of head/face/cheeks/jaw; travel up neck to side of face/around temple/ Side of head/face/cheeks/jaw; Feel numb; Sore-all on same side as injection; This is a spontaneous report from a contactable consumer (patient). A 52-year-old female patient received first dose of bnt162b2 (Pfizer COVID 19 vaccine, lot number: EL3246) , via an unspecified route of administration on 13Jan2021 17:00 at single dose on left arm for covid-19 immunisation . The patient medical history was not reported. Concomitant medication included fluticasone propionate (FLONASE), pantoprazole. The patient experienced arm/neck soreness, travel up neck to side of face/around temple; side of head/face/cheeks/jaw, neck are painful, feel numb, and sore-all on same side as injection; and possible Bells Palsy on 14Jan2021 02:00. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19.

No allergies to medications, food, or other products. No treatment was received for the events. The outcome of the events was not recovered.

his platelet levels dropped and he had a hemorrhagic stroke; his platelet levels dropped and he had a hemorrhagic stroke; This is a spontaneous report from a contactable consumer. A male patient of unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The relevant medical history and concomitant medications were not reported. The patient died 2 weeks after his COVID shot because his platelet levels dropped and he had a hemorrhagic stroke. No further information provided. The autopsy was unknown. The outcome of the events was fatal. Information on the lot/ batch number has been requested.; Reported Cause(s) of Death: his platelet levels dropped and he had a hemorrhagic stroke; his platelet levels dropped and he had a hemorrhagic stroke

expired before receiving the second dose; This is a spontaneous report from a contactable nurse. This nurse reported similar death events for 8 patients. This report is for 5th of 8 patients. A patient of unspecified age and gender received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 22Dec2020 at single dose for COVID-19 immunisation. The patient medical history and concomitant medications were not reported. The patient expired before receiving the second dose on an unspecified date. The patient died on an unspecified date. It was unknown if an autopsy was performed. Information on the lot/batch number has been requested.; Sender's Comments: The limited information provided in this report does not allow a full assessment of the case. The event death with unknown cause is assessed as related to the suspect drug per company guidance. This case will be reassessed when additional information, particularly the clinical course before death, complete medical history and concomitant medication and autopsy report, becomes available.,Linked Report(s) : US-PFIZER INC-2021034595 same drug, reporter and event but different patient; Reported Cause(s) of Death: expired before receiving the second dose

passed unexpectedly; This is a spontaneous report from a contactable nurse communicated to a Pfizer colleague. This nurse reported similar death events for 8 patients. This report is for 8th of 8 patients. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 22Dec2020 at single dose for COVID-19 immunisation. The patient medical history and concomitant medications were not reported. The patient passed unexpectedly on an unspecified date. The patient died on an unspecified date. It was unknown if an autopsy was performed. Information on the lot/batch number has been requested.; Sender's Comments: The limited information provided in this report does not allow a full assessment of the case. The event death with unknown cause is assessed as related to the suspect drug per company guidance. This case will be reassessed when additional information, particularly the clinical course before death, complete medical history and concomitant medication and autopsy report, becomes available. The case will be reassessed if additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.,Linked Report(s) : US-PFIZER INC-

2021034595 same drug, reporter and event but different patient; Reported Cause(s) of Death: passed unexpectedly

allergy; Short of breath; Tachycardia/my heartrate was like 140 - 150; Blood pressure was like 165 over 114/my blood pressure just like skyrocketed; Upset stomach; Tired; Started to feel not very good/not feeling like wonderful/overall sickness; Muscle ache; This is a spontaneous report from a contactable consumer (patient). A 25-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), lot number: EL014 (can't really tell), via an unspecified route of administration on 31Dec2020 at single dose for COVID-19 immunization. Medical history included allergy and heartburn. Concomitant medication included omeprazole for heartburn, cetirizine hydrochloride (off-brand for Zyrtec) as allergy medicine and a birth control medicine. Consumer stated, she just was calling this number because she didn't necessarily know if she had an adverse reaction or a symptom. She just wanted to report it and see if maybe you had any insight if this has happened to anybody else. Consumer further stated, she had an adverse reaction where she had to go to the emergency room. So, she didn't know if it was from the Vaccine or not because her reaction was very delayed. She got her vaccine on 31Dec2020, New Year's Eve and then starting on Monday after the vaccine on 04Jan2021. She started to feel not very good, it was mostly just like overall sickness, just as muscle aches, tired, having upset stomach so that was after 4 days. Patient had allergy from an unspecified date. And then on 07Jan2021, a week after she got the vaccine, she had signs of tachycardia and her blood pressure just like skyrocketed, her blood pressure was like 165 over a 114 and her heartrate was like 140 - 150. And she worked in healthcare, which was why she was one of the first ones to get the vaccine and she went to the ER and got worked up and they couldn't find, nothing was abnormal with her labs or blood work. She even had a chest X-ray and they couldn't find anything and they just gave her fluids and sent her home. And she was home now and still not feeling like wonderful, she felt better though but she just wanted to report that and see if there was any correlation. She didn't really know because it was so delayed, a week later. So she just wanted to report it. Consumer further stated, she forget to tell one thing, she was also short of breath on 07Jan2021. So that was why they had sent her to ER because of Tachycardia, shortness of breath and her blood pressure was really high. They didn't give her any medicine they just gave two big bags of fluid and then they discharged her. Consumer stated, she was scheduled to have her second one, she thought it was 14Jan2021. She wanted to know if she should get the second one. Consumer stated, when she went into the ER she had a lot of lab work. She didn't even know what all they did but a lot like, blood panels, she checked everything was there, that was on Thursday, last week, 07Jan2021. Consumer stated no treatment was received for the events. Outcome of the events was unknown.; Sender's Comments: A causal association between BNT162B2 and the reported events cannot be excluded based on a compatible temporal relation between vaccination and onset of events. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

Approximately 3 days after my injection I began experience severe tremors Ib bilateral arms, bilateral legs, head, and vocal cord tremors as well as blurry vision and memory impairment. Unfortunately, the symptoms don't seem to be improving. My MD prescribed metoprolol, which I will begin today.

a couple hours after the vaccine, I experienced a bit of rapid heart rate, which resolved after a few minutes. The following day around 3 pm I began to have chills and felt like I had the raid heart rate again. By 5 pm I was beginning to feel really bad, I was freezing, chills and my heart rate was now extremely fast, I was having trouble speaking complete sentences, my husband drove me to the emergency department. I had a very high heart rate and high fever, I was admitted and in the hospital until Sunday afternoon. The diagnosis was pneumonia, I don't really believe this, as I felt fine and had no symptoms prior to the onset of the fever.

Patient died 1 week after vaccination. According to family was having very rapid decline in status in recent weeks and they did not think related to vaccination.

Anaphylaxis less than two hours after vaccination. I had no symptoms immediately after vaccine however did develop symptoms within one minute of completing a run. Developed b/l hand swelling and tingling, diffuse hives and itching, tachycardia, elevated blood pressure, lips tingling and swelling which required emergency room visit and EpiPen, IV fluids, Benadryl and IV steroids. This is similar to previous reactions I have had to running previously. Symptoms resolved within one hour after treatment in ED.

Severe headaches, vomiting, dehydration, shortness of breath ... led to trip to Emergency Room at Hospital on 1/16/21 at 10:45 am; diagnosis for treatment was Diabetic Ketoacidosis (DKA); patient was admitted to ICU to address critical fluid and electrolyte imbalances , headaches, body aches, dehydration, nausea, shortness of breath. DKA is medical emergency.

Pt brought to the ER with SVT. He was given 2 doses of adenosine by EMT's. Pt was found to have hypomagnesemia and hypophosphatemia in the ER. He was admitted for observation and evaluated by Cardiology. He remained stable with NSR during admission. Pt has a follow up appt with Cardiology EP clinic on 2/18/21.

Fatigue, wheezing, soreness, palpitations

38 year old female - healthy with no significant past medical history. Morning of 1/15/21, pt woke up with difficulty speaking (would be talking and then unable to articulate words which were replaced by grunting sounds) and tingling to her face. No changes to breathing, no numbness/tingling to extremities, equal facial symmetry. Slow onset of symptoms. Pt went to the ED, where she received a CT, MRI (inconclusive reading), lab work reported as normal per pt, EKG and chest x-ray. Symptoms self resolved while in the ED, however MD staff wanted to admit patient for 24 hours of observation and to complete an echocardiogram. Pt left AMA the evening of 1/15/21 due to resolution of symptoms and wanting to follow up with her cardiologist for the echocardiogram. Pt told by MD staff symptoms were likely caused by either TIA, possible reaction to vaccine or migraine presentation (no report of headaches/auras). Plan

was to have patient on blood thinners x 30 days then baby Aspirin thereafter. Pt still needing to follow up with PCP and cardiologist for further work up.

Received vaccine on 1/16/21, on 1/17/21 started with coughing, white phlegm, SOB and on 1/18/21 developed fever to 101 and increased need for oxygen. Home requirement increased from 3L O2 to 6L O2. On 1/18/21 presented to hospital. Quickly defervesced with steroids and cefepime. Possible post-obstructive pneumonia vs immune response to vaccination.

Patient could not open and close hand after the first day of vaccination. On the third day his arm turned purple and could not be moved and was numb. A week and a half after vaccine, arm hurt and was numb. Patient was hospitalized.

Systemic: Pt monitored by nursing for 30min after inj,pt was stable/no reaction.At ~1hr post inj pt was unresponsive.Pt was a hospice/dnr per director

9 to 36 hours. Lymphnode swelling , pain left axilla. Fever, chills ,muscle aches, brain fog. 1 week post Facial paralysis, fatigue, vocal cord weakness, feeling of unwell.

12/28/2020: generalized weakness and fell twice at home, cough, nausea,1/04/2021: cough, nausea, fever and chronic pain when she fell from being weak. admitted to hospital with Covid pneumonia, shortness of breath, covid postive, 1/09/2021: pt on bipap, 1/15/2021: pt was intubated, on TPN, pt DNR, 1/18/2021: was extubated and put on comfort measures and passed away

Patient was vaccinated for SARS-CoV-2 on 6-Jan-21 at his site of employment, a Nursing Home. Patient presented to Urgent Care on 15-Jan-21 complaining of left sided chest pain that started the evening before with an associated slight cough. Pt was afebrile with a heart rate of 88 and an O2 sat on room air of 98% in triage. His EKG showed a sinus tachycardia of 114 with a slightly prolonged QTc of 463 ms. Physical exam was significant for bibasilar crackles and X-ray showed bibasilar infiltrates consistent with COVID pneumonia but bacterial pneumonia could not be excluded. The patients BP was documented as 97/64. He was treated with Zofran for nausea and tylenol. He was prescribed a five day course of Azithromycin, an Albuterol inhaler, guaifenessin with codeine cough syrup, and Zofran. Labs were drawn and he was discharged. His lab results were reported after his departure and were significant for a white blood cell count of 1.33, platelet count of 73, 2% myelocytes, 1% metamyelocytes, an absolute neutrophil count of 0.75 K/ul, a creatinine of 1.83, total bilirubin of 1.3, with direct bilirubin of 0.8, alkaline phosphatase of 294 and AST of 112 with ALT noted to be within normal limit. His COVID nasopharyngeal swab from the visit was reported as negative and a swab performed at his employment on 13-Jan-21 was also reported to be negative. Patient could not be reached by phone after discharge from Urgent Care about these labs. On the evening of 16-Jan-21, Police Department received a 911 call about an adult at the patient's address who was found unresponsive. Upon arrival on scene, the patient was found to be deceased and a decision was made not to attempt to resuscitate. The death was deemed to be non-suspicious and the patient's body was transported to a funeral home. On 19-Jan-21, I contacted the State Medical Examiner's Office. They have decided to perform an autopsy and have recovered the CBC and chemistry specimens obtained for further testing.

27-year-old female with past medical history of anxiety, allergic to shellfish, presented for COVID-19 vaccination, developed shortness of breath after COVID-19 Moderna injection, felt lightheadedness and noted with cyanosis as per nursing, received epinephrine injection and transferred to ED. In ED she received solumedrol, benadryl and pepcid. Vitals in the ER Revealed tachycardia HR 95-105 , Sat 96% on room air not in distress. Patient was admitted for further observation

1. Shaking 2. Whole body tingling 3. Left arm tense (injection was provided in right arm) 4. Felt clammy Walked over to hospital attached to the facility and was discharged the same day. All symptoms resolved.

"Patient called this nurse stating she had an allergic reaction to COVID vaccination given on Friday 1/15/21. States she felt fine for the 15 minutes post immunization, was on her way home and started feeling dizzy, short of breath, chest heavy, throat felt full ""like a ball in it"". She came back to clinic which was closed but sat in the parking lot for a while. While in parking lot trying to figure out what to do, her symptoms lessened. She got home safely but started to feel jittery/shaky and her BP was very high (couldnt remember exact number). She then went to urgent care where they told her she was having an allergic reaction and given a pill of something and steroid for 6 days. Went home from urgent care and BP still high but got better at bedtime. Saturday she had a ""really bad headache and just layed around all day. I was not able to function at all."" Sunday she still had a headache and added muscle aches. Monday she started feeling ""a lot better"" until 8 PM when she was walking around doing her nightly routine and started to feel a wave of dizziness, throat felt funny so she sat down and took her BP with result of 207/131. Says this reaction felt worse than Friday's reaction so she went to ER where she was again told she was having an allergic reaction and the steroid given to her at Urgent Care was not helping and to stop taking them. Given Benadryl in the waiting room, had labs and EKG which came back ""normal"", and given a different med Vistaril to take with any future symptoms. Was also told to NOT take the second dose of COVID vaccination. Says she has not had to take the Vistaril yet and has not had any sign of reaction today so far. Said she did report the initial headache on the V-safe app."

Anaphylactic

At approximately 4pm on Jan 11, 2021, I began to have hard chills and fever that reached 104.9. I was admitted to ICU at the Hospital. My blood pressure dropped to dangerous levels. I was diagnosed with sepsis and the doctors determined it was caused by the vaccine.

Pulmonary Edema, fever, nausea, vomiting

Moderna COVID- 19 Vaccine. Vaccine recipient reported on 1/19/2021 that they received the Moderna Vaccine on 1/8/2021. The following week on 1/15/2021, they reported while driving, their area around their right eye became numb and they began to have blurry vision. The numbness spread to around their face/mouth. They pulled over and their spouse drove him to the hospital. Roughly 20 minutes after the initial symptoms, they developed chest pain and patient reported that the ED noted an abnormality on their EKG. The patient had to be admitted overnight for observation. The patient reported that on 1/18/2021, they still had mild chest pain and facial numbness remains around the right eye, left mouth/cheek area, and tongue. They did develop fever and a headache. The patient reported that on

1/19/2021, they are waiting on results, additional testing, and further follow-up appointment with their provider.

Visited Provider appx 500 pm 1.14.2021 DVT - left calf - 2 clots via ultrasound on Eliquis now

Lacunar infarct (CVA) of right thalamus

Patient developed symptoms of Guillain-Barre syndrome on January 15, 2021 and was admitted the Hospital. She was diagnosed and eventually required ICU level care and has been treated with plasmapheresis. She is currently still in the ICU but is stable.

Family was told that Patient expired in his sleep during the early morning hours of 1/15. I spoke with him the evening before (on 1/14), which was a day after he had received the Covid vaccine. He was not having any symptoms of allergy or reaction then. He did say that he felt tired, but he often complained of feeling tired over time.

Hypoglycemia(40mg/dL) and required ICU admission.

Resident was noted unresponsive, no respiration, no blood pressure, no pulse, code blue called according to facility protocol, resident is full code, CPR started, 911 called, arrived and took over from staff. Resident was pronounced dead at 1:16pm 1/18/21

"""Patient states that he received the Covid vaccine today on left arm. Immediately after receiving it, felt his left arm went numb, then felt his lips on the left side going numb. Sensation progressed to his whole face, and down his neck, and back down to the whole left arm. He states that he even felt his truncal area, kidney, and part of his right foot going numb. States that he went to the ER for further evaluation, and while waiting there for about an hour, the sensation resolved. He denies any tingling or painful sensation. Does not think he was weak at the time."""

Resident was found deceased in his bed at 7:15 am.

Tachycardia, Shortness of breath, headache, dizzyness, weakness, chills, nausea, fever

Dizziness, Headache, Myalgia, Tachypnea, CoughWheeze, NauseaVomiting, Palpitations & Tachycardia & Narrative: Patient stated that after receiving injection on 01/06/2021, tasted metal in her mouth. No reaction noted in clinic after vaccine administered. Patient states that after returning home, she began to have chills, headache, and muscle aches. Could not sleep. On 01/07/2021. Patient continued to experience above symptoms. Approx. 13:50 on 01/07/2021. Patient presented with respiratory difficult, tachypnea stridor, and stated she felt as if her airway was closing. Patient was vomiting and was tachycardic. Epi-pen administered via left lateral thigh. Patient administered 50mg of PO Benadryl, and 2 puffs of albuterol inhaler. Continuous V/S initiated. Patient began to experience relief of symptoms. HR and blood pressure remained elevated, but this was expected side effect of epi. SpO2 stabilized around 99% on room air. Patient was monitored for 60 minutes. Transportation home was arranged and family was present to observe overnight.

mi Narrative: patient with asymptomatic covid 19, covid positive 12/10/2020.

dose given 1/13/21, patient hospitalized with high blood sugar, hyperkalemia, hypernatremia on 1/15/21 after being lethargic with shallow breathing. Patient still hospitalized as of 1/19/21 and diagnosed with Diabetes

Severe dissociative event (psychotic break) beginning <72hr after administration of vaccine, and continuing another 48 hours before resolution. Patient has no prior adverse psychiatric history. Transported to local ER on Monday 11th upon worsening of condition. Administered Haldol in the ER as a sedative after becoming combative during dissociative state. Patient woke up Tuesday the 12th with recurrent, but significantly diminished, dissociation, which had largely resolved by late Tuesday. Patient transported to Mental Health on a 5150. Released Friday the 15th around noon. No recurrent symptoms since.

Resident reported she didn't feel well. She started running a fever of 103. Resident complained her stomach and genitals were burning and pain in her legs. Resident has been vomiting today and diarrhea. EMS was called and resident transported to Hospital today 1/19/21

COVID 19 vaccine, unknown which company Chronically ill in a skilled nursing facility found diaphoretic, hypotensive, hypoxia to 85% arrived to Emergency dept in cardiac arrest Died within 65 minutes of nursing finding patient in distress Wife felt it may have been related to vaccine date of vaccination 1/6/20 hx covid 19 PNA in April 2020

hypoxia, secretions,cough, dyspnea Narrative: ALS patient on hospice with ongoing history of aspiration pna, receiving tube feeds. Developed incr in secretions, hypoxeia, temp and with recently noted clogged feeding tube.

pneumonia Narrative: On 11/9/20, Patient had a presumptive positive COVID (COBAS) screen as part of routine CLC screening and then on 11/13/20, he had a repeat COVID (CEPHID) that was negative. Then on 12/22/20, he received his first COVID vaccine. On 12/26/20, he began to have c/o hurting all over. Noted history of aspiration and COPD. On 12/29/20, he began to have coughing, increased shortness of breath and runny nose with course breath sounds in his bilateral lower lobes. A chest xray was done and he was initiated on oral azithromycin and cefepime for a bilateral pneumonia. On 1/3/21, he continued to decline with increasing shortness of breath and was subsequently transferred to acute care medicine. All COVID tests have been negative since the presumptive positive on 11/9/20. He did have a CTA that ruled out PE but did show bilateral pneumonia. His antibiotics have been changed to meropenem, vancomycin and IV azithromycin. He remains on acute care at time and has not required ICU care.

COVID positive Narrative: Patient is a resident and received his first COVID vaccine on 12/28/20. On 1/4/21, he had a COVID routine screen done that returned positive on 1/6/21. Per notes, he was asymptomatic at the time; however for isolation purposes, he was transferred to acute care medicine services. On 1/7/21, he was noted to have a slight increase in BUN/creatinine ratio thought to be due to volume depletion and has been ordered IV fluids. He still remains free of any respiratory symptoms at this time.

The patient had severe shortness of breath resulting in cardiac arrest on the 5th day after the vaccine. Shortness of breath started 12 hours after injection. On the 5th day, the patient was discovered to also have a rash throughout his body, but it is unknown when this rash started.

Diarrhea & NauseaVomiting Narrative:

Pt is 39 y/o female. Pt is casual RN for ED. Pt received COVID-19 vaccination here on the 23rd of December. Pt began feeling weak on the 17th of January. On the 18, Pt began experiencing numbness and tingling in hands and feet. Pt has been seen at facility and her PCP prior to coming to ED. Pt PCP called me and told me she is concerned that the Pt might have Guillain Barre syndrome and referred her here. Pt now c/o numbness and tingling from feet to mid abdomen and numbness/tingling up entire arm. IV was established and labs drawn, CT Head normal. Pt to IR for LP for definitive Dx of Guillain Berre. Pt admitted to room 202. Director of ED notified.

COVID-19 Vaccine

Sudden death without warning symptoms 4 days after vaccine. Many medical problems which most likely explain the outcome but spouse feels it is related and it is a new vaccine. Monitor for pattern?

Excruciating abdominal pain, left arm pain, chest pain. Gangrenous appendicitis requiring emergency surgery and followed by admission for complicated acute abdomen.

"Resident experienced chest pain the evening he received the vaccine and requested to go to the hospital as he stated his ""chest is pounding""."

Resident received 1st on 1/11/21 at 12:10am (1/12/21) resident was found unresponsive. Code Blue, 911 called at 12:11am. FD and EMS arrived, resident pronounced at 12:51am.

24 hours after the vaccine administration, patient began experiencing respiratory (asthma) symptoms. She was treated with nubulizer treatment and albuterol HFA inhaler.

Hypotension, Prolonged seizure with bowel incontinence, cough, weakness and delirium, resulting in 911 transport and admission to hospital for intubation and mechanical ventilation for acute respiratory hypoxia.

Appendicitis

received first dose of COVID vaccine on 18Dec2020 and tested positive on 30Dec2020; received first dose of COVID vaccine on 18Dec2020 and tested positive on 30Dec2020; she had a 5 day migraine after the first dose; This is a spontaneous report from a contactable other healthcare professional (patient). A female patient of an unspecified age started to receive BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) Solution for injection (lot number and expiry date were unknown), via an unspecified route of administration on 18Dec2020 at first single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient received first dose of COVID vaccine on 18Dec2020 and tested positive on 30Dec2020. The patient stated her isolation will be over

the day that she was to receive her second dose. The patient stated that she had a 5-day migraine after the first dose. Outcome of the events was unknown. Information on the lot/batch number has been requested. Follow-up (06Jan2021): New information received in response to query via mail includes confirmation of the primary reporter's last name. Information on the lot/batch number has been requested.; Sender's Comments: Based on the information currently available, a lack of efficacy with the suspected vaccine BNT162B2 in this patient cannot be completely excluded. Further information like confirmative virus genome /nucleic acid detection needed for meaningful medical assessment.

Pregnant at the time of vaccination; Pregnant at the time of vaccination; Miscarriage (symptoms started 08Jan2021, confirmed 10Jan2021); This is a spontaneous report from a contactable physician (patient herself). A 37-year-old female patient received her first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiry date were unknown), via an unspecified route of administration on the right arm on 06Jan2021 12:30 at a single dose for COVID-19 immunization at the hospital facility. The patient had no relevant medical history and no known allergies. Concomitant medication included azelastine;fluticasone nasal sprays, prenatal. The patient did not have any other vaccine in four weeks. She did not have COVID prior to vaccination. The patient was 6 weeks pregnant at the onset of the event. Last menstrual date was on 11Nov2020 and Gestational period was 7. The patient was due to deliver on 26Aug2021. The patient reported miscarriage (symptoms started 08Jan2021 06:00 PM, confirmed 10Jan2021). The event resulted in doctor or other healthcare professional office/clinic visit, Congenital anomaly or birth defect. Treatment and event outcome were unknown. The patient had not been COVID tested post vaccination. Information on the lot/batch number has been requested.; Sender's Comments: Based on a close compatible temporal association, contributory role of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) to patient's miscarriage cannot be completely excluded. The case will be reevaluated should additional information become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

tested positive after 1st dose; tested positive after 1st dose; This is a spontaneous report from a contactable nurse reporting for herself. This nurse reported similar events for 2 patients: this is the first of two reports. This 39-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 28Dec2020 for COVID-19 immunization. Medical history and concomitant medications were not reported. On an unknown date, the patient tested positive after first dose. Outcome was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Based on the information currently available, a lack of efficacy with the suspected vaccine BNT162B2 cannot be completely excluded. However, it is unlikely that the patient would have fully developed immunity due to the very short time lag between the first vaccine dose and the event onset.,Linked Report(s) : US-PFIZER INC-2021021888 same reporter/drug/AE, different patient.

"Between then and now I tested positive; Between then and now I tested positive; This is a spontaneous report from a contactable consumer (patient). A male patient of an unspecified age received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot/batch number unknown), via an

unspecified route of administration on 28Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient stated, ""I have taken the vaccine (1st dose) on 28Dec2020 at the hospital. Between then and now I tested positive on the 04Jan2021, the hospital sent me home for 2 weeks. The 2nd part of the vaccine is coming up, it isn't until the 18Jan2021."" The outcome of the events was unknown. Information about lot/batch number has been requested."

"Hypertensive Emergency (BP 219/114) with no previous blood pressure issues; Radiating chest pain, left arm pain; jaw pain; This is a spontaneous report from a contactable other Health Professional (patient). A 40-year-old non-pregnant female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EX5170), via an unspecified route of administration on 16Dec2020 15:00 at single dose in left arm for covid-19 immunization. Medical history included symptomatic PVC's (Premature ventricular contractions), tachycardia, bradycardia, CVA (cerebrovascular accident) from 2018 to an unknown date, asthma and rhythm. Concomitant medication included flecainide, spironolactone, metoprolol for rhythm. The patient had known allergies included hydrocodone bitartrate, paracetamol (VICODIN), eletriptan and adhesive. Prior vaccination, the patient had no covid. On 22Dec2020 18:00, the patient experienced hypertensive Emergency (BP 219/114) with no previous blood pressure issues. Radiating chest pain, left arm pain, and jaw pain. Admitted to the hospital where an echocardiogram and angiogram was performed showing clear coronary arteries and no hypertensive remodeling of the heart. Issue has been ongoing since, despite interventions. The events result in emergency room/department or urgent care and hospitalization from an unspecified date for 1 day. The patient received the treatment for the events included frequent nitroglycerin, hydralazine and metoprolol. The patient underwent curative-SARS-Cov-2 Assay RT-PCR on 01Jan2021 with negative result. The outcome of the events was not recovered.; Sender's Comments: Based on the information available, contributory role of BNT162B2 ((PFIZER-BIONTECH COVID-19 VACCINE,) to event ""hypertensive emergency (BP 219/114) with no previous blood pressure issues"" cannot be excluded. The events chest pain and pain in jaw are attributed to underlying medical conditions and assessed unrelated. BNT162B2 ((PFIZER-BIONTECH COVID-19 VACCINE,). The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate."

having symptoms, tested covid+(positive); having symptoms, tested covid+(positive); This is a spontaneous report from a contactable consumer (patient). This 57-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unknown route, on 17Dec2020 at single dose for COVID-19 immunization. No relevant medical history and concomitant medications were provided. The patient started having symptoms on 23Dec2020 and she was tested for COVID 19 on 27Dec2020 and resulted positive. The outcome of the event was unknown. Information on the batch/lot number has been requested.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021015240 Same patient/reporter, 2nd dose of drug, different AE

tested + 9 days after dose #1; tested + 9 days after dose #1; exposed to Covid-19 four days after vaccination; This is a spontaneous report from a contactable patient. A patient of unknown age and gender received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, on 26Dec2020 at single dose for COVID-19 immunisation. Medical history and concomitant medications were unknown. The patient was exposed to Covid-19 four days after vaccination and tested positive (+) nine days after dose 1 on 04Jan2021. The patient would like the advice for receiving the second dose. Outcome was unknown. Information about batch/lot number has been requested.

"I still have uncomfortable feeling in my arm/I was finally able to raise it above my head, my left arm, after two days but it was not comfortable to do it, it was painful; I have severe pain in my arm/it started hurting and then it continued to get worse and worse and it was severe; It was the worst pain I have ever had and I could not move my arm; It continued to get worse and that night I went to bed and I cannot sleep, it hurts so bad/I could not sleep on the right side or on a left side; This is a spontaneous report from a contactable consumer (patient). An 82-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date was not provided), via an unspecified route of administration (left arm) first dose on 30Dec2020 10:30 at single dose for covid-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient stated that I had the vaccine back a week and half ago on 30Dec2020 and was due to get the booster this month and wanted to report severe pain arm for two days. The patient stated that he had many vaccine (Unspecified Vaccine) over the years and have never had anything that hurts so bad after about six hours. The patient just wanted to know that was that normal. Consumer further stated, ""I took the vaccine about 10:30 in the morning and about four hours later, it started getting sore but that thing was normal you know some vaccines (Unspecified Vaccine) do that but along with that it started hurting about four hours after the vaccine and it continued to get worse and that night I went to bed and I cannot sleep, it hurts so bad. The patient even have thoughts about getting up and go in to the emergency room. It was the worst pain I have ever had and I could not move my arm. I could not sleep on the right side or on a left side and all I did was take Tylenol as prescribed and that helped a little bit but not much but I did not go to the emergency room, I am not going to do that but I felt like it because it hurts so bad but I made it through the night and next day it continued to hurt really bad. I just keep taking Tylenol every four hours and that continued for two days and then finally I was able to raise my arm up above my head without little pain, it was discomfort, but it was not hurting so bad."" The patient stated that the event started about two hours later it started, it started hurting and then it continued to get worse and worse and it was severe, that is the reason why I am calling that it was severe. I wanted a shot or morphine to relieve myself that how bad it was."" (no clarified further). The patient stated that the vaccine was given in my left arm only about one inch below the top of my shoulder which I think that might have been the problem, I don't know if you can answer that or not but I have never received the vaccine or shot anywhere near that area, it is always three or four inches down in my muscle, on my arm either on left or right, this was given in my left arm but this was given almost in my joint I am wondering if that would cause pain."" The patient stated it was given only one inch below the tip above shoulder may be that is causing so much pain."" The patient just wanted to report the severe pain, that was for two whole days and then it was subsided and it lasted for four days and I still have

uncomfortable feeling in my arm. I was finally able to raise it above my head, my left arm, after two days but it was not comfortable to do it, it was painful."" The outcome of the events was unknown. Information on the lot/batch number has been requested."

"Spot on arm where I got the vaccine probably 4 days ago is continuing to increase in size and is red, swollen and hard; it's huge and it's purple and red and it feels like bee sting, it feels like an allergic reaction; purple and red; continuing to increase in size and it is red and swollen and hard now; Made me really, really sick like bedridden for 2 days; Spot on arm where I got the vaccine probably 4 days ago is continuing to increase in size and is red, swollen and hard; This is a spontaneous report from a contactable Other HCP (patient). An unknown age and gender patient received BNT162B2 (lot# unknown) on Jan2021 at single dose for COVID-19 immunization. Medical history and concomitant drug were not reported. Patient stated, ""I just have a question, my Pfizer COVID Vaccine made me really, really sick like bedridden for 2 days which I am finding out is probably normal. But the spot on my arm where I got the vaccine, it was probably 4 days ago that I got it and it's continuing to increase in size and it is red and swollen and hard now. Like I am a Nurse Practitioner, this is not like a normal injection site reaction, it's huge and it's purple and red and it feels like bee sting, it feels like an allergic reaction, should I be concerned, do I need to go to the hospital?"" Outcome of the event was unknown. Information on the lot/ batch number has been requested.; Sender's Comments: A causal association between BNT162B2 and the reported events cannot be excluded based on a compatible temporal relation between vaccination and onset of events. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate."

"Tested positive for Covid/had the (Covid) infection; Tested positive for Covid/had the (Covid) infection; Swollen lymph nodes under my right arm; This is a spontaneous report from a contactable nurse. This 42-year-old female nurse (patient) reported for herself that she received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot#: nurse stated she thought she had a lot# it looked like EK5703), via unspecified route at right deltoid on 21Dec2020 at single dose for COVID-19 immunization. Medical history included blood pressure (patient had taken blood pressure medicine but hadn't taking currently because her blood pressure was being controlled). Concomitant medications included unspecified vitamins. Patient was tested positive for Covid on the 29Dec2020. She stated she didn't know about causality, she was saying no but she did have swollen lymph nodes under the right arm before getting sick (Dec2020), now she thought that might get from her vaccination but in her understanding she could get it from Covid so, she couldn't answer that, she tested positive, she didn't think it's from vaccination but her concern was because she had got the vaccination the first one then had the (Covid) infection and right now she should get the second one or not. Regarding treatment, patient stated she was taking methylprednisolone sodium succinate (SOLU-MEDROL) and salbutamol (ALBUTEROL) inhaler, taking over the counter Vitamin D3, Zinc and Vitamin C and acetylsalicylic acid (ASPIRIN). Patient reported she did go to the physician office/ emergency room. Outcome of events was unknown.; Sender's Comments: Based on the mechanism of action of BNT162B2 vaccine, it is unlikely

the patient would have fully developed immunity for the vaccine to be effective, due to the number of days passed since the vaccine was given (8 days in this case). However, a causal relationship between events ""Tested positive for Covid/had the (Covid) infection"" (coded to Drug ineffective / COVID-19) and swollen lymph nodes and BNT162B2 vaccine cannot be completely excluded.The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate."

I am a registered nurse at hospital. On 12/25, seven days after receiving the shot I started to get right lower leg pain and I kept complaining about it till New Years Day. I had no symptoms of a DVT. I triaged on 1/1/21 and the doctors ordered labs/imaging and the results were as followed: D-Dimer biomarker (+) , Ultrasound of the Rt lower leg (-) , CTA showed a PE (segmental right upper lobe pulmonary artery consistent with pulmonary embolus). I was discharged on Xarelto and advised to follow up with a hematologist. On 1/5/2021, I went to hematology and they did a whole bunch of labs. I was sent to get a ultrasound of the leg because the pain persist and they found a clot hidden by my soleus. The plan is to continue on the Xarelto for 6 months. Come back in 3 weeks to scan my leg again and get my lab results. On 1/12/2021, I received the 2nd shot of the Pfizer vaccination.

"Client was administer 2nd dose of Moderna COVID-19 vaccine at 1:32pm. Client reported has ""sore arm from first dose"", but denied any other issues from 1st dose. At 1:44pm, client reported was feeling flushed and slightly dizzy/light headed. Client appeared flushed, clammy and was slightly confused. Client was sitting in chair and was assisted to the floor and clinical assist code was called. VS were: BP: 149/84 and pulse ox was 97% on RA. Initially, HR was in the low 30's, but after lying down, came up to 86 and stayed in the 80-90's during assist. Client began to report chest tightness and feeling foggy and remained slightly confused and at times speech was garbled. Client denies sensation of throat closing and denied shortness of breath. Client was assisted to a cot and transported by ER staff and MD to the ER for evaluation."

Presented to Urgent Care for weakness and confusion, transferred to ED, patient had a cardiac arrest and was unable to be resuscitated

"""I received the Pfizer Covid vaccine Wed afternoon around 4pm. Thursday morning around 9:30 I started with severe pain in my left leg. The pain worsened through the day and my leg began swelling. No other symptoms at all. This morning my leg was twice the size of my right leg so I went to the ER. I live in so I'm at ED. I have a massive blood clot running the the length of my leg - from my thigh to my ankle. I'm very lucky I got here so fast! I?m a very healthy 49 year old with no history of DVT or blood clots so they dug further to find out why. A cat scan showed I have a congenital condition called May Thurner Syndrome. I?m so relieved to have an answer and it?s fixable! The vascular doctors are not 100% convinced that?s not all that was going on as I was born with the syndrome and I?ve gone this long without a clot. So they are doing lots of labs to see if anything else shows up. This is where we are at. I?m being admitted to take care of the clot."""

Pt woke up with tongue swelling morning following her vaccine. Was admitted for angioedema.

Rapid heart Rate that began about 12 hours after the injection. Heart rate of 123 all night and went to ER next morning after calling Nurse on Call system. I was admitted and the Dr ordered bag after bag of fluids to and kept me in the unit overnight for observation. Did may hear tests (EKG, ECHO STRESS,CTA chest) and results all came back good. I was released on 1/19/21 at 2pm and my hear rate is back to normal (82 bpm).

Extreme fatigue since getting shot - effecting ability to work

Started with cough, mild shortness of breath and feeling terrible in evening of 1/19.

Death 3 days after receiving 2nd dose of COVID vaccine, unknown if related to vaccine administration.

Approximately after 20 minutes after vaccine administration, my throat felt numb and i could not swallow my saliva, no acute breathing difficulty , I could not swallow water , I was very anxious and went back to facility I got vaccine , The attending doctor administered Benadryl I 50 mg IM , and then EPI 0.3 mg . EMT was called , and ED at Hospital i was attended , and Solumedrol 1.25 mg was administered IV and Pepsid for GERD , i also had, I was observed for a few HRs and skript for Prednisone and Benadryl was issued. I was then feeling better,

My arm was a little sore after the vaccination but no other symptoms. And on 12/30 I woke up with a sever fever, vomiting and diarreah. Went to the ER and was diagnosed with CHF because my feet were so swollen and was given lasix and released. I continued to feel bad so on that Sunday 1/3 I went back to the hospital and was admitted and tested positive for COVID-19. I spent from Sun-Wed in the hospital

Patient has end stage renal disease and rapidly worsening dementia, family could no longer care for him at home, and he was admitted for 14-day quarantine prior to admission to inpatient hospice. Received vaccine on 1/12 without apparent adverse reactions. Patient started refusing oral intake on 1/16, and CMP on 1/17 showed hypernatremia 165 (new issue). His BUN 138 CREAT 6.93 K 5.2 were his baseline. He was found to be deceased on 1/18 at 11:18 pm.

Pt found unresponsive at home, respiratory distress. Had reported nausea and vointing for two days prior to admit which started 1/15. Acute metabolic encephalopathy and acute renal failure Currently at time of this report still in critical care

Myalgia Narrative:

Shaking and then became unresponsive

Headache and stoke

Stroke-like symptoms approximately 2-3 hours after receiving shot (aphasia), BP bottomed out, was transported by EMS and is currently on a ventilator in hospital. CT scan clear; MRI pending.

The next morning I felt chills, really cold, my arm never hurt at all. I was freezing. I had no energy. Very lethargic, with a blanket around me. Never had a fever. All of a sudden, around 2:30PM all dissipated, it was all gone and I was fine. A week later I called my PCP because the symptoms came back - the lethargy. He suggested me to go to the ER. I went and could barely write my name on the sign in sheet at the hospital. They did 5 COVID tests and 4 of them were negative. I was at the ER for 3 days and finally was admitted and stayed for 11 days. I was sent home with oxygen and my levels are finally getting back to 92/93. I can't walk at this time. I lost 17 lbs and if I try to walk my lungs shut down. (I went to the ER n 01/07 and was discharged on the 17th - I was also at the ER the week before when they tested me and it kept coming back negative) My pulmonary MD

death by suicide Narrative: death by suicide; 12/26/20, self inflicted gun shot wound; found deceased by family member

Started with HA/fever/fatigue and body aches on date of vaccine on 1/5/21. Also had shakes,and had numbness loss of feeling to leg leg. Was admitted to Hospital for 5days. Had intermittnet seizure type episodes. Has had labs and imaging tests that have been neg Under the care of the A Neuro Group. MRI scheduled for 1/20/21. As of 1/20/21 feeling better but still weak.

Fainting, dizziness and weakness, trembling, BP 168/129. HR 145

Patient received Vaccine and during observation period began starring forward and not responding to staff. Patient was taken to the emergency room and evaluated and noted to have a flat affect and general weakness. Patient did not loos consciousness or have any signs of distress. Was admitted to the hospital and noted that she had been in out of country for a week (possibly had cosmetic surgery)

Around 10pm on Tuesday I started to have severe neck pain, headache, fatigue. I ended up going to the emergency room after my shift but due to the physicians recommendations I deferred the lumbar puncture while there. Later Thursday night, the neck pain continued, and I started having fevers with a max of 102.1 so I returned to the ER the following day for the lumbar puncture. I was admitted to the hospital for aseptic meningitis.

severe temporary paralysis from the neck down.

Resident was noted to have increase weakness on 1/15/2021. Resident was warm to touch with low grade fever of 99.3 F. Resident was up propelling self in w/c on 1/16/2021 he was pleasant, accepted medications and ate lunch. He was found slumped over in his w/c not responding and vital signs absent.

Pt was 18 weeks pregnant at the time of the vaccine. Second pregnancy. Pt is a physician. Pregnancy was entirely normal up to that time. On 1/18/2021, she began to have heavy vaginal bleeding probably due to a placental abruption and subsequently delivered at 18 weeks. Baby was stillborn. Ultrasound done 1/15/2021 normal. Lethal event for the fetus. The patient did well.

sinus arrhythmia; Night sweats; Heart rate low; Dyskinesia; This is a spontaneous report from a contactable nurse (patient). This 36-year-old female patient the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), intramuscular at single dose in the left arm on 07Jan2021 10:00 for

covid-19 immunisation. Medical history included hypotension, rheumatoid arthritis, asthma. Concomitant medication included clonazepam, methylprednisolone. On 07Jan2021 21:00, the patient experienced sinus arrhythmia, night sweats, heart rate low, dyskinesia, all with outcome of recovered with sequelae. Therapeutic measures were taken as a result of the events included Inderal 10mg. The events were assessed as congenital anomaly. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient was not diagnosed with COVID-19 prior to vaccination. The patient had not been tested for COVID-19 since the vaccination. The patient was not pregnant at the time of vaccination. Information on the lot/batch number has been requested.; Sender's Comments: A possible contributory effect of suspect BNT162B2 on reported events cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

postural dizziness; dyspnea; paresthesia; This is a spontaneous report from a contactable Physician. This Physician reported for a 28-year-old male patient received 2nd dose of BNT162B2 Intramuscular on 10Jan2021 07:30 on Left arm for covid-19 immunization. Medical history and concomitant drug were not reported. No other-vaccine-in-four weeks. No other-medications-in-two weeks. Historical Vaccine was first dose of BNT162B2 on an unspecific date. Patient experienced Moderate reaction: postural dizziness, dyspnea, and paresthesia on 10Jan2021 09:00 AM that resolved with H1 and H2 antagonists and IV hydration. AE-resulted-in Emergency room/department or urgent care. Outcome of the event was recovered. No covid-prior-vaccination. No covid-tested-post-vaccination. Information on the lot/batch number has been requested.; Sender's Comments: A causal association between BNT162B2 and the reported events cannot be excluded based on a compatible temporal relation between vaccination and onset of events. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

passed out; dizzy; hit the ground; nausea; pain at injection site; fever; chills; tired; severe headache; vomiting x 2; cold; experienced orthostatic hypotension; This is a spontaneous report from a contactable other HCP. A 65-years-old female patient started to receive bnt162b2 (BNT162B2; Lot # EK9231) vaccine , intramuscular in the left arm on 07Jan2021 11:00 at single dose for Covid-19 immunisation . Medical history included rubber sensitivity (Latex). The patient's concomitant medications were not reported. On 09Jan2021 12:00 the patient experienced orthostatic hypotension , passed out with outcome of recovered , dizzy with outcome of recovered , hit the ground with outcome of recovered. These events were considered serious because medically significant. On 09Jan2021 12:00 the patient also experienced the following non serious events: nausea with outcome of recovered , pain at injection site with outcome of recovered , fever with outcome of recovered , chills with outcome of recovered , tired with outcome of recovered , severe headache on with outcome of recovered , vomiting twice with outcome of recovered , cold with outcome of recovered. The reporter stated the patient attempted to get out of

bed and she passed and hit the floor. Caller states she think she may have experienced orthostatic hypotension. Caller stated if she had stayed in bed she probably would not have fallen. Her husband found her laying in vomit The patient underwent lab tests and procedures which included body temperature: 99.6 fahrenheit on unknown date.; Sender's Comments: Based on a chronological temporal association a causal relationship between events orthostatic hypotension , passed out dizzy and falling down and BNT162B2 vaccine cannot be completely excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Several back operations of stimulator in the back and in pain management; This is a spontaneous report from a contactable Consumer. This adult female Consumer(patient) reported that: An adult female patient received bnt162b2 (BNT162B2) at single dose on an unspecified date for Covid-19 immunisation. Medical history was none. No known allergies. The patient's concomitant medications were not reported. Patient was not pregnant a time of vaccination. The patient had not received any other vaccines within 4 weeks prior to the BNT162B2 vaccine. The patient had not experienced Covid-19 prior to vaccination. The patient experienced several back operations of stimulator in the back and in pain management on an unspecified date, resulted in disability or permanent damage. Post the vaccination, the patient has not been tested for COVID-19. The outcome of events was unknown. Information on the lot/batch number has been requested.

"I began to pass out and yelled for my husband, he said when he came in I was sitting on the toilet with my head back, eyes rolling back not responsive.; I had my 2nd vaccine at work early Sat the 9th and felt increasingly worse all day; I woke up at midnight and felt extreme malaise; I was covered in sweat; vomited; I checked my temp and it was 99.7¦F; sore; I think I had either a seizure or a vasovagal response.; This is a spontaneous report from a contactable nurse (patient). This 58-year-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (Lot EJ1685 or FJ1685), intramuscular at single dose in the left arm on 09Jan2021 06:00 for Covid-19 immunisation. Medical history included atrial fibrillation on unknown date (1 episode), allergic to Keflex. There were no concomitant medications. The patient previously received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (Lot EJ1685 or FJ1685), intramuscular in the left arm on 22Dec2020 for Covid-19 immunisation. On 10Jan2021 01:00 AM, the patient experienced: I began to pass out and yelled for my husband, he said when he came in i was sitting on the toilet with my head back, eyes rolling back not responsive (loss of consciousness) (medically significant), I had my 2nd vaccine at work early sat the 9th and felt increasingly worse all day (feeling abnormal), Iwoke up at midnight and felt extreme malaise (malaise), I was covered in sweat (hyperhidrosis), vomited (vomiting), I checked my temp and it was 99.7¦F (pyrexia), sore (pain), I think I had either a seizure or a vasovagal response (seizure). No treatment required. The outcome of the events was recovered. The events were described as follows: I am healthy RN with no active medical problems. I had my 2nd vaccine at work early Sat the 9th and felt increasingly worse all day, I expected this so was not alarmed and went to bed around 10pm. I woke up at midnight and felt extreme malaise and went to the bathroom in case I might vomit, etc. and I tried to

have a BM. I began to pass out and yelled for my husband, he said when he came in I was sitting on the toilet with my head back, eyes rolling back not responsive. He yelled at me for about 10 seconds and I came to, I was covered in sweat. I asked him to walk me back to the bedroom where I again passed out, fell to the floor and hit the bed, then was unresponsive again for about 10 seconds then came to again and vomited. After this I felt completely relieved of my malaise. I checked my temp and it was 99.7¦F. After this I was sore but otherwise completely okay, the next day I had a temp of 99.5¦F. Today I am back to normal. I think I had either a seizure or a vasovagal response. The vaccine was administered at Hospital Facility. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient was not diagnosed with COVID-19 prior to vaccination. The patient had not been tested for COVID-19 since the vaccination. The patient was not pregnant at the time of vaccination.; Sender's Comments: Based on the close temporal relationship, the association between the event ""began to pass out"" with BNT162b2 can not be fully excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate."

"suddenly lost mobility of left arm; Continue paresthesia and proprioreceptive deficits of left arm; Continue paresthesia and proprioreceptive deficits of left arm; This is a spontaneous report from a contactable nurse (patient). This 46-year-old female patient received the first single dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot EK5730) intramuscular, in right arm, on 16Dec2020 at 14:00, for COVID-19 immunization. No other vaccine was given in 4 weeks. Medical history included hypothyroidism, migraine headaches, IBS and COVID-19 (on an unspecified date prior to vaccination). Past drug history included allergy to morphine. Concomitant medication included levothyroxine sodium (SYNTHROID). On 23Dec2020 at 09:30 the patient experienced suddenly lost mobility of left arm, continue paresthesia and proprioreceptive deficits of left arm. She was transported to the ER and was admitted to hospital for 2 days. CT of brain X3, MRI of brain X2, MRI of C-spine and Brachioplexus were performed with unknown results. The patient was not tested for COVID19 after vaccination. The events resulted in: Doctor or other healthcare professional office/clinic visit, emergency room/department or urgent care, hospitalization, disability or permanent damage. No treatment was administered. The events had not yet resolved.; Sender's Comments: Based on the temporal relationship, the association between the events "" lost mobility of left arm, continue paresthesia and proprioceptive deficits of left arm"" with BNT162b2 can not be fully excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate."

thrombocytopenia; This is a spontaneous report from a contactable other health professional (patient). A 59-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration in arm left on 04Jan2021 13:30 at single dose for COVID-19 immunization. Medical history was none. The patient's concomitant medications were not reported. The

patient did not have COVID tested post vaccination and did not have COVID prior vaccination. The patient experienced thrombocytopenia on an unspecified date with outcome of unknown. It was reported he had thrombocytopenia but did not experience any side effects. Information about lot/batch number has been requested.; Sender's Comments: A possible contributory effect of suspect BNT162B2 on reported thrombocytopenia cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

on 1/12 started body aches and chills, took Tylenol and felt better, Wednesday felt short beat and irregular and heart beat not regular. checked pulse and it was irregular, that night 9-9:30 I went to ER close to house and pulse and heart rate abnormal after 2 hours went home and advised to contact cardiologist, he said to come in Thursday and the irregular beats were off and on atrial flutter, on Friday I came home and went back to hospital and got the shot cardio version or ablation to revert the rhythm and because the rhythm was back and forth I was observed until released on 1/19/21. Surgery was in 2017 and never had problems and they stated heart was compromised and maybe this is your reaction to the vaccine.

The patient was seen in my office on 1/19/21 with complaint of heavy vaginal bleeding. A CBC was obtained which revealed an H/H of 12.2/36.1 and a platelet count of 1 (not 1K, but 1 platelet!) and this was confirmed on smear review. She was immediately sent to the Hospital ED and repeat CBC confirmed the critically low platelet count. She is currently hospitalized and she has received platelet transfusions but her platelet count is still critically low. She is also receiving steroids and immunoglobulin and is under the care of MD (Heme/Onc)

Resident became lethargic, general weakness outside baseline, unable to walk, bumbled speech. Elevated HR and Temp of 105.2F

Death on 1/15/2020

Patient developed right facial numbness and facial droop on 1/7/21. She came to the TMH ED and was admitted. She was afebrile; neurologic exam was consistent with a peripheral facial palsy on the right.

Sudden Death within 24 hours of vaccine

Hemorrhagic Stroke, Right Basal Ganglion

12:00 noon my arm was super sore and swollen and I could barely raise it. By the evening on the 24th I was super tired. Christmas , the 25th,I was really fatigued. 26th, I was very fatigued and no energy - like I almost had the flu. 27th - the same - couldn't get out of bed. 28th - started getting a dry, hacky cough and then it went away. 29th - tried to go to work and I didn't feel good at all and I just wasn't feeling myself. Had brain fog. Went to work - things that I know that Know wasn't there because of brain fog. Felt really like flu symptoms that night. 30th - body aches; headache and eyes felt like pressure behind

them. Sent me to COVID and it was positive - was out 2 weeks from work. Went to back to work last week - but I still had shortness of breath, brain fog and fatigue and cough on Moday the11th; super tired still and I kept pushing myself to try to work and by Friday, 15th, I was just done. Exhausted. 16th - still having fatigue and 17th I thought I felt better when I woke up but still had my shortness of breath, cough and brain fog. At 2:00 pm I started feeling dizzy and faint like. I ate and within 20-30 min after food started throwing up, pounding headache. Every time I started trying to drink I would throw up. Monday, 18th, I went to work and I noticed whenever I moved around I was dizzy and short of breath and I couldn't eat or I would throw up. So slept the rest of the day. About 4:pm on Monday I thought I was going to pass out. 02 level at 86. Heartrate - Palpitations at 130. It was bouncing. Hving chest pressure, dizzy, pounding heart - 02 86 and Heartrate145. ER at 5:00 pm at Medical Ctr. Nausea medicine: Phenergan and Zofran. Did IV to hydrate me as I was dehydrated. Gave me Pepsid. I was a direct admit. They kept giving me hydration and nausea med and med for headaches and cardio workup - cardio came back normal. Severe lung inflammation. Was in the hospital until evening of 19th.

Patient woke apx 0200 complaining of nausea to group home staff. Vitals were checked at that time and WNL. Patient went back to bed. When staff went to wake patient apx 0530, he was unresponsive and had no pulse. Chest compressions were started and EMS called.

Patient got her 2nd dose of Pfizer covid vaccine on 1/8. On 1/11 she had intermittent chest pain that lasted a few days and started to notice small purpura rash on left breast. She didn't think much of it but noticed the same type of rash on her pant line and then right thigh. On 1/15 she called Occupational Health who advised her to go straight to the ED.

On 1/9/2021 observed with elevated respirations of 38-42 per minute, BP manually 72/50. pulse is jumping rapidly between 110-16 bpm. oxygen sat 76% RA, resident refusing oxygen at first attempt, allowed oxygen to be placed, is now 84% on 4L. resident shaking head yes that he is hurting, and yes that he would take medication for pain. Dr. notified, branch block. Received order for morphine 2mg per hr as needed for elevated respirations and pain. Dr. also gave orders to D/C Tamsulosin and finasteride. Resident continue with decreased O2 sats and elevated respirations. Absence of vital signs on 1/10/21 at 826PM.

Jan 4, 2021 received shot at work in morning around 11:00 am- felt fine at work all day. Around 7:00 that night began to have back pain, fever reached up to 102 around 2:00 am and took Tylenol. Felt very weak, headache, difficulty walking and decreased balance. On Jan 5, 2021 still had back ache and headache. On Jan 6, 2021 I felt better and began to have abdominal pain after eating dinner. I assumed it may be because of eating more then I had in past few days and did not attribute to much but the pain gradually increased to a strange burning/pressure across my upper abdomen that night. Very nauseous and ran low grade fever (99.45). Next morning I had less diffuse pain and could localize it to right lower quadrant.

Tinnitus started in right ear within hour after receiving first vaccination but resolved within a couple of day. Within 24 hours of receiving second vaccination had muffled hearing, Jan 3, 2021. Symptoms were ignored thinking they would resolve. When symptoms persisted and evaluated patient was noted to

have a severe right sided low frequency hearing loss with poor word recognition score. Patient was started on high dose steroids with partial recovery of symptoms.

Idiopathic intracranial HTN - IIH

Unknown as to any correlation with vaccine as this was a hospice patient that was already experiencing decline. Patient became Jaundice for approximately one week prior to expiring.

Unrelenting headache, chills, nausea, body aches, fever of 101.3F. Onset 14 hours after vaccine. Fever 20 hours after. Relieved with Tylenol and Motrin, ice packs.

Patient received COVID 19 vaccine 01/14/2021. Patient died in his sleep 01/16/2021.

Patient received COVID-19 vaccination on 1/14/2021. On 1/17/2021, patient was transferred to Hospital s/p multiple cardiac arrests. Patient was hyperkalemic and in acute renal failure at time of transfer. Hyperkalemia was treated, but the patient suffered PEA vs VFib. At the time of transfer, patient was on vasopressin, norepinephrine, and epinephrine. The patient had an EF of 40-45% and elevated troponins. Patient was made DNR and placed on comfort care. Patient passed away on 1/18/2021. Ultimately we suspect that the patients condition was a direct result of his underlying disease states, but wanted to make sure reporting was made available.

Thursday 1/6/21 body aches, fever, chills Fri, Sat, Sun- Vomiting and diarrhea. Low blood pressure (average 70/40 Went to ER Sunday for hydration and low BP Wednesday 1/20/21 diarrhea x 25 episodes while at work, Sent home at 3:30pm. Body aches, chills, sever abdominal pain.

Patient died 4 days after immunization. Probably unrelated to immunization, as patient has been in poor health and was receiving hospice services. I have no details related to his illness or symptoms. Daughter is the HIPAA/emergency contact and will have all the information needed.

Sudden Sensorineural Hearing Loss in left ear. Symptoms began Friday evening Jan. 8, 2021. Sounded like muffled sound in my ear, water running, ringing. Then on Saturday Jan.9, 2021 my left ear felt like it had to pop and I felt my hearing was impaired. By Sunday evening Jan. 10, 2021, I could barely hear out of my left ear. I called MD immediately Monday morning, Jan. 11, 2021 and was seen that afternoon. I was examined and had a hearing test. I was diagnosed with SSHL and started treatment of a series of steroid injections directly into my eardrum to save my hearing immediately. I have had 2 injections and hearing test since then. The doctors feel this was a side effect of the COVID vaccine due to my compromised immune system, but not an allergic reaction, but a side effect. I had the same condition about 15 years ago from a virus.

Pt passed away the day after the vaccine was given.

12 hours after vaccination began experiencing fever, chills, body aches, slight head ache - lasted around 12 hours Had slight pain above eye prior to getting vaccination Saw PCP on 01/08/2021 due to eye pain - had CT scan for possible aneurysm, found 2 spots on brain, thought patient had shingles On 01/10/2021 shingles rash appeared

I was having episodes of dyspnea and non productive cough starting from 1/1/2021. On 1/13/2021 I experienced severe dyspnea and had loss of consciousness for 5 seconds and was found down. I was rushed to the hospital and diagnosed with multiple pulmonary embolus (about 9) which was treated with direct TPA via catheterization. I then recovered in the ICU and transitioned to oral anticoagulation and discharged home on 1/15/2021.

Anaphylaxis Allergic reaction COVID-19 vaccine: dizziness, vomiting and shortness of breath. Received vaccine and about 5/10 minutes later developed symptoms of chest tightness shortness of breath wheezing. Arrived to ED at 1156 and discharged at 1507. Given epi IM Solu-Medrol, Pepcid, Benadryl, albuterol.

1/4/21- Patient stated she had tenderness on the back of her left lower leg with redness then 1/8/21 started to have shortness of breath and made a doctor's appointment for 1/13/21. Seen by provider on 1/13/21 and was sent to ED and admitted to the hospital [ICU] with NSTEMI, acute deep, occlusive venous thrombosis left femoral vein and saddle embolus of pulmonary artery. Transferred to another acute care hospital for removal of thrombosis. Patient started on Eliqus and no intervention for removal of the thrombosis.

Patient received her first dose of the Moderna COVID-19 Vaccination on Saturday January 16th 2021 at approximately 12pm. She completed all necessary screening forms and was deemed to be at low risk for serious allergic reactions. She tolerated the vaccination well, and no complications or immediate adverse events occurred. She was observed for a full 15 mins per CDPHE/CDC guidelines and left the Clinic in stable condition after her observation period was complete. On the morning of Tuesday, January 19th, 2021, the patient was found unconscious and unresponsive by her husband. She was transferred by Ambulance to Hospital shortly thereafter. She was diagnosed with a brain bleed that was determined to be inoperable. She was transferred to other Hospital for higher level care. She was seen by neurosurgery and diagnosed with a ruptured aneurysm. She was treated in the ICU for 24 hours, at which point her team determined that the severity of her brain bleed would not respond to treatment. Supportive cares were withdrawn on Wednesday Jan 20th, and she passed away shortly thereafter.

Resident has increase weakness and lethargy with abnormal labs. He was transferred to the ER. He was admitted to the hospital and treated for worsening AKI and hypotension.

Appendicitis, presenting as periumbilical tenderness at onset (26 hrs after vaccine admin) migrating to RLQ approx 20hrs later (46hrs after vaccine admin) accompanied by fever, chills, sweats, and nausea. Presented to ER that evening and CT confirmed appendicitis (52hrs after vaccine admin). Surgery following day laparoscopic appendectomy (69hrs after vaccine admin). Recovery and clinical improvement over next 8hrs (77hrs after vaccine admin). Discharged following day (96hrs after vaccine admin)

3 days post = tremors; 4 days post= pneumonia; 6 days post= hospitalized

Patient unresponsive post vaccine. Taken to hospital. Please contact facility for full Report.

Per Nursing Staff- patient died within 24 hours of receiving the vaccine. patient has hospice. Please contact director of nursing for more details.

Started itching within (left arm) 15 minutes. THey said I was fine and to go back to work. About an hour later, I started breaking out in hives and whole body itching. I went back in and they gave me to full strength Benadryl and it was not helping and my BP was 190/140 (stroke level) and they tried to bring that down. About 10:15 my face was starting to swell and I was short of breath and 10:30 they took me to ER - and gave me Cortisol shot. And IV fluids. And I was in ER for two hours. They wrote me a prescription for six days for 2 prednisone for every day for one week. The PA saw me at the ER and he prescribed. I went home but couldn't drive home because I couldn't see straight so got a ride home. They tested my O2 levels before they left me. Oxygen was 96. My blood pressure was down to 140/95 - so it was down but still elevated. I still had facial swelling for 3 days. But after three or four days it resolved the face swelling. Had a weakness from the shot and still itching but nothing like it was that day still after the four days. Dr. told me I couldn't get second dose. It was an anaphalactic reaction. Dr - prescribed me an EpiPen in case I have another bad reaction to anything.

per staff at facility patient died 24 hours post vaccination. Please contact Director of Nursing for further details.

Swelling all over her body, ear popping all the time, hands and feet are numb, torso swollen and numb, face swollen and red. Taking steroids for four days. Went to hospital. Then went to other facility.

short of breath Narrative: patient complained of shortness of breath prior to getting covid vaccine, patient and wife stating it was his norm. After vaccine he complained of increasing shortness of breath, and hypoxic with bluish nail beds, lips, and greyish in color. Applied O2 via mask, and nail beds, lips, and facial color returned, sent patient to local ER for treatment and evaluation.

"Narrative: Patient seen in ED 1-17-21 with c/c of ""bloated with epigastric pain"". Patient with complicated medical history including stage 1B pancreatic cancer (was currently on chemotherapy mFOLFIRINOX), and a leadless permanent pacemaker implantation on 1-11-21 for long episodes of SR with complete heart block following symptoms of syncope (other cardiac history: CAD s/p CABG 2009, PAF, and HTN). Regarding ER visit for epigastric pain, nothing notable was found on workup and patient was to discharge home to rest. There were available doses of COVID-19 Vaccine following a vaccine clinic that same day, and patient was offered and agreed to a dose of vaccine. Patient was monitored for 15 minutes post vaccine with no notable issues. The following day, Monday 1-18-21, patient's caregiver called facility at 22:30 to report he had a fever of 102.8 degrees and that he had been ""feeling kind of bad all day"". Patient was advise to seek urgent medical care and reported back to ED on 1-19-21 at 00:55. Patient wasd admitted for SIRS (tachycardia and febrile) -- patient also reported diffuse myalgia. WBC WNL, CXR unremarkable for infection, UA neg for bacteria, LFTs WNL, blood cultures negative. Procalcitonin elevated at 17.8 -- suggesting inflammatory response. Patient initially reported feeling better on the morning of 1-19-21, but around 13:00 began rapidly declining (confusion, unable to walk) and started experiencing EKG changes (9 beats of SVT). Patient then coded and resuscitation was

attempted for approximately 30 minutes. Patient did not survive the code. Coroner has been notified and family is considering autopsy at time of this report."

Vaccine was administered very high, presumably in the joint space, rather than the deltoid. Patient experienced intense pain in the entire shoulder area for 24 hours following administration. After initial 24 hours, pain remained more localized in the joint itself. Pain is intensified when moving out of the neutral position.

significant facial/lip angioedema first noted ~20 hours post vaccination, leading to intubation in ED due to concern for airway protection. extubated and discharged in 2 days

Admitted in Hospital for Anaphylaxis.

Noticed small area of burning sensation at right side of wrist and the vein there was very enlarged and sticking out.

Began itching and wheezing approximately 5 minutes after the injection. Gave first epi dose. Throat started tightening, and nausea presented. Gave second epi 5 min after the first. Gave third epi 5 min after the second. EMS arrived, gave 4th epi in ambulance. ER treated with breathing treatment, IV steroids, IV Benadryl, IV Pepcid and IV zofran. Was observed for 6.5 hours.

Patient came to ED at 1600 with right upper lip swelling and finger swelling after getting covid vaccine earlier. Angioedema of lips, initial encounter; History of allergic reaction; Lip swelling; Vaccination side effects, initial encounter. Pt has history of rheumatoid arthritis. Was treated & discharged home on 1/12/21

Slurred speech started morning of 1/8 and patient went to ED after dialysis appointment. Admitted for TIA (transient ischemic attack). Discharged home on 1/10 with follow up appts with Neurology.

Presented to ED 1/12 with primary complaint of Fatigue starting that AM. Being treated for Stage IV Sacral Decubitus Ulcer w/ possible osteomyelitis, Still admitted

Pt reported difficulty in swallowing and wife noticed left-sided facial droop morning of 1/10. Patient admitted for concerns of TIA. Symptoms resolved prior to hospitalization. Patient had MRI brain without contrast of the find evidence of acute infarct. Neurology recommended treatment patient has TIA and having dual anti-platelet therapy for 21 days followed by monotherapy of Plavix for stroke prevention. Patient was stable discharge to home 1/12/21

Patient was receiving dialysis and had low grade fevers on the morning on 1/15/2021. Patient was sent to the hospital's emergency room and was found to have a temperature of 103. The patient also had mental status changes. It is unsure what caused the mental status changes and fevers.

Pt presented to ED with Left facial numbness and concern for stroke. Observed over night. MRI brain negative for acute process. Stable at baseline neuro status 1/10/21, discharged home.

Pt Rec'd Covid vaccine and injection in Lt eye for macular degeneration. Monday 1/11 slurring speech/jumbled words since dinner, went to bed, wife states improved from last night but still difficult clearly communicating. Also reports difficulty writing. Came to ED and admitted for stroke evaluation. Stable for discharge home 1/13 with neurology follow up visits.

Pt presented to ED 1/12 complaining of shortness of breath and nonproductive cough which onset approximately 8 days ago. Tested positive for COVID. Remains admitted for management of COVID.

Stated since Xmas he has not feeling well after a family gathering. His wife in hospital for Covid-19 pneumonia. He reports for about 1 week, his SOB worsen, not eating well at all for the past 3 days. Which prompt him to visit the ED. Admitted to Hopital for Dehydration; Dyspnea; Pneumonia due to COVID-19 virus; COVID+ 1/10/21; still admitted

expired before receiving the second dose; This is a spontaneous report from a contactable nurse. This nurse reported similar death events for 8 patients. This report is for 1st of 8 patient. A patient of unspecified age and gender received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 22Dec2020 at single dose for covid-19 immunisation. The patient medical history was and concomitant medications were not reported. The patient expired before receiving the second dose on an unspecified date. It was not reported if an autopsy was performed. Information about Lot/Batch number is requested.; Sender's Comments: Current information is very limited for full assessment. The patient died following the vaccine use; further information such as patient demographics, complete medical history, concomitant medications, concurrent illness and event term details especially death cause and autopsy results are needed for meaningful evaluation. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.,Linked Report(s) : US-PFIZER INC-2021034597 same drug, reporter and event but different patient;US-PFIZER INC-2021034598 same drug, reporter and event but different patient;US-PFIZER INC-2021034599 same drug, reporter and event but different patient;US-PFIZER INC-2021034600 same drug, reporter and event but different patient;US-PFIZER INC-2021034601 same drug, reporter and event but different patient;US-PFIZER INC-2021034603 same drug, reporter and event but different patient;US-PFIZER INC-2021034596 same drug, reporter and event but different patient.; Reported Cause(s) of Death: expired before receiving the second dose

expired before receiving the second dose; This is a spontaneous report from a contactable nurse. This nurse reported similar events for 8 patients. This report is for 2nd of 8 patients. A patient of unspecified age and gender received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 22Dec2020 at single dose for covid-19 immunisation. The patient medical history and concomitant medications were not reported. The patient expired before receiving the second dose on an unspecified date. It was not reported if an autopsy was performed. Information about Lot/Batch number is requested.; Sender's Comments: Current information is very limited for full assessment. The patient died following the vaccine use; further information such as patient

demographics, complete medical history, concomitant medications, concurrent illness and event term details especially death cause and autopsy results are needed for meaningful evaluation. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.; Reported Cause(s) of Death: expired before receiving the second dose

expired before receiving the second dose; This is a spontaneous report from a contactable nurse. This nurse reported similar events for 8 patients. This report is for 3rd of 8 patients. A patient of unspecified age and gender received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 22Dec2020 at single dose for covid-19 immunisation. The patient medical history and concomitant medications were not reported. The patient expired before receiving the second dose on an unspecified date. It was not reported if an autopsy was performed. Information about Lot/Batch number is requested.; Sender's Comments: Based on the reasonable temporal association, the Company cannot completely exclude the possible causality between the reported death and the administration of COVID 19 vaccine, bnt162b2. However, more information on the patient's underlying medical condition, concomitant medications, patient's age group, clinical course and relevant lab tests would be helpful for the Company to make a more meaningful causality assessment. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RA, IEC, as appropriate.; Reported Cause(s) of Death: expired before receiving the second dose

expired before receiving the second dose; This is a spontaneous report from a contactable nurse. This nurse reported similar events for 8 patients. This report is for 4th of 8 patient. A patient of unspecified age and gender received the first dose bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 22Dec2020 at single dose for covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient expired before receiving the second dose on an unspecified date. The patient died on an unspecified date. It was not reported if an autopsy was performed. Information about Lot/Batch number has been requested.; Sender's Comments: Current information is very limited for full assessment. The patient died following the vaccine use; further information such as patient demographics, complete medical history, concomitant medications, concurrent illness and event term details especially death cause and autopsy results are needed for meaningful evaluation. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.,Linked Report(s) : US-PFIZER INC-2021034595 same drug, reporter and event but different patient; Reported Cause(s) of Death: expired before receiving the second dose

7 residents expired before receiving the second dose; This is a spontaneous report from a contactable nurse. This nurse reported similar events for 8 patients. This report is for 6th of 8 patients. A patient of unspecified age and gender received first dose bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at SINGLE DOSE for covid-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient expired before receiving the second dose on an unspecified date. It was not reported if an autopsy was performed. Information on the lot/batch number has been requested.; Sender's Comments: The event death is assessed as related to BNT162b2 vaccine and documented as such in the global safety database until sufficient information is available to allow an unrelated causality assessment. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.,Linked Report(s) : US-PFIZER INC-2021034595 same drug, reporter and event but different patient; Reported Cause(s) of Death: 7 residents expired before receiving the second dose

expired before receiving the second dose; This is a spontaneous report from a contactable nurse. This nurse reported similar death events for 8 patients. This report is for 7th of 8 patient. A patient of unspecified age and gender received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 22Dec2020 at single dose for covid-19 immunisation. The patient medical history was and concomitant medications were not reported. The patient expired before receiving the second dose on an unspecified date. It was not reported if an autopsy was performed. Information about Lot/Batch number is requested.; Sender's Comments: Current information is very limited for full assessment. The patient died following the vaccine use; further information such as patient demographics, complete medical history, concomitant medications, concurrent illness and event term details especially death cause and autopsy results are needed for meaningful evaluation. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.,Linked Report(s) : US-PFIZER INC-2021034595 same drug, reporter and event but different patient; Reported Cause(s) of Death: expired before receiving the second dose

platelets dropped so low/thrombocytopenia; Hemorrhagic stroke/brain hemorrhage; This is a spontaneous report from a contactable nurse. A 56-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 18Dec2020 at single dose for covid-19 immunisation. Medical history and concomitant medications were unknown. The reporter read about the doctor that died that developed thrombocytopenia after taking the vaccine, stated it was in the news yesterday. The patient received the Pfizer Covid vaccine on 18Dec2020, and he died 16 days later from a brain hemorrhage. Autopsy stated that said he had a hemorrhagic stroke on 03Jan2021. His platelets dropped so low that he had specialists that tried to get his platelet count back up again and they could not get his platelets back up again and he ended up having the hemorrhagic stroke. The

reporter already had thrombocytopenia and she was debating what she should do about getting vaccine. Outcome of the events was fatal. Information on the lot/batch number has been requested.; Sender's Comments: Very limited information is currently available. Lacking patient's underlying medical conditions, clinical course, relevant lab data, the Company cannot make a meaningful causality assessment. The reported hemorrhagic stroke following low platelet count are managed as related to the suspect, BNT162B2, for reporting purpose only. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RA, IEC, as appropriate.; Reported Cause(s) of Death: Hemorrhagic stroke/brain hemorrhage; platelets dropped so low/thrombocytopenia

"died; tested positive for COVID; tested positive for COVID; This is a spontaneous report from a contactable consumer from a Pfizer-sponsored program, Pfizer First Connect. A 97-year-old male patient received the first dose of the bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration on 30Dec2020 at 97-years-old at a single dose for COVID-19 immunization; administered by the nursing home. Medical history included glaucoma from an unknown date and unknown if ongoing. Concomitant medications included: ""used a sav for skin tears"", and ""eye drops for glaucoma"" from an unknown date to an unknown date. On 07Jan2021, the patient experienced: tested positive for COVID (medically significant). The patient died (death, medically significant) on 17Jan2021. The clinical course was reported as follows: The reporter stated that in regard to the patient's height and weight: ""was probably getting down to about five foot eight. Shrinking."" The reporter stated that If she remembered correctly, they were trying to maintain the patient's weight 135 to 136 pounds. The reporter stated that her father was in a nursing home. The patient received his first dose of the COVID vaccine on 30Dec2020. The patient died on 17Jan2021. The reporter stated that she ""wanted Pfizer to know that the little old people in the nursing might not be strong enough for the vaccine."" The reporter stated that she was ""not calling to complaining."" The reporter stated that there was nothing wrong with her dad. He was elderly with no health issues. ""He was literally on no medications. The only reason he was in the nursing home was because he was afraid to walk."" The reporter stated that she received a call about giving the patient the vaccine and she said yes because she wanted him to have the vaccine. One week after the vaccine, the patient tested positive for COVID ""like all the other people"" (no further details provided). The reporter stated that her dad had no symptoms of COVID. The director of nursing said the patient was doing so well. The patient ate his lunch, he laid down for nap, and at 14:30 he was gone. The patient ""went peacefully in his sleep."" The reporter then again stated that the patient literally had nothing wrong with him. ""They were shocked. They fed him and he took a nap. He was sleeping, but it was eternally."" The reporter stated that, ""it might not have been the Pfizer vaccine, maybe his heart wore out."" In regard to an autopsy: the reporter stated that they would get it done if needed. The patient underwent lab tests and procedures which included COVID-19 virus test: positive on 07Jan2021. History of all previous immunization with the Pfizer vaccine considered as suspect: none. It was unknown if there were additional vaccines administered on the same date of the Pfizer suspect, but the reporter doubted it. There were no prior vaccinations within 4 weeks. There were no adverse events following the prior vaccinations. The clinical

outcome of the event, died, was fatal. The clinical outcome of the event, tested positive for COVID, was unknown. The patient died on 17Jan2021 due to an unknown cause of death. An autopsy was not performed. The batch/lot numbers for the vaccine, PFIZER-BIONTECH COVID-19 MRNA VACCINE, were not provided and will be requested during follow up.; Reported Cause(s) of Death: died"

At approximately 930am I arrived at Memory Care. I met with the director of the facility and she directed me to where my team would be setting up. My team consisted of (technician), (nurse) and I. As we were setting up, the director asked how she can help. I explained to her that we would need a designated area for patients to be monitored after vaccination for 15 minutes and maybe even longer . I also explained that we would need one of her staff monitoring while we vaccinate. She agreed, and proceeded to designate her staff and the cafeteria area, facing the vaccination station,the monitoring station. Throughout the day, nurse and I were both vaccinating,while the staff of the facility would monitor the vaccinated patients. I would also stop occasionally to mix the vaccine and check the temperature of the aero safe. At approximately 12:50pm, the director rushed in and stated that a patient is not responding, and that she had been vaccinated. At that point, I grabbed epipens and a thermometer and I also instructed nurse to grab an Epipen and come with me. We followed the director to pt's room. Once we got to the room, the patient was in bed and there were 4 staff members standing bedside and one of them turned and stated the patient has passed. At that point I asked the staff how long ago did the patient get the vaccine, they stated about 30 minutes ago. They also stated that the patient was a hospice patient and that the patient had declined, and was rapidly detiorating and had not eaten or drank anything all day . They also stated that the patient had been monitored for 15 minutes post vaccination. I then left the room and grabbed the patients COVID Vaccine intake consent form. I looked at the answered questionaire and all the responses were circled NO. Patient had a temp of 96.5 at the time of vaccination.The vaccine administration information for Immunizer Section was filled out by Nurse. I then proceeded to ask the director once again if there were staff that was monitoring her for 15 minutes, the director stated they had staff monitoring her. She also stated the Hospice nurse has to announce her death, so they waited for the Hospice Nurse to come. I then called Corporate and explained the situation. After speaking to corporate, I also asked nurse, if she remembered the patient. She stated that she did and at the time of the vaccination the patient was not alert, there were two staff members with the patient. She was non oriented and she kept closing her eyes. At that point, Nurse stated that she asked the two staff members with her if this is how she usually is and if its ok to vaccinate her. Both Staff members stated that it its ok,this is how she is. The Nurse then proceeded to vaccinate. At approximately 3:10pm, as I was leaving I spoke to the director, and one of her Staff members. Staff that the patient has actually not eaten/ or drank anything for the past several days, including today(01/18/21). Staff also stated that on Friday, Jan 15th,2021, they had informed the family that the patient was rapidly detiorating. Staff also stated that the family knowingly gave the consent to vaccinate her. She also stated that the hospice Nurse believes that the death was primarily caused by her detiorating state. She also stated that the hospice Nurse informed that the death was not due to the Vaccine. Per Lead Pharmacist at the clinic.

Extreme Fatigue

Patient developed 104.4 temp approximately 48 hours after being given the vaccine. I treated him with antibiotics, IV fluids, cooling methods. CXR does show a new right perihilar infiltrate. However, his fever came down within the next 24-48 hours. Unfortunately, he suffered a cardiac arrest on 1/21/21 in the early morning and expired.

Resident returned to the memory support unit at 1500. Resident was than toileted and transferred in to bed per his request. At 1515 resident was observed face down beside bed, resident sustained a 1inX1in eccyhmotic/hematoma to the forehead. Neuro Checks with in normal limes Vital signs: 100/52, 100, 97.2, 28. Resident sent to ED for further medical evaluation via EMS.

possibly got it at clinic, possibly who administered shot. Pts. daughter said the pts boyfriend denied any symptoms the whole day but that in the middle of the night the pt passed away.

This is a 94-year-old male who is brought in by ambulance after being found on the floor with unknown downtime. He was in asystole upon EMS arrival. He remains in asystole. No advanced airway is in place. The patient is getting compressions from Lucas device upon arrival. It was reported that he was last talked to by family at 2 PM. The patient got his SARS-CoV-2 vaccination this morning. The patient is evaluated emergently. CPR was ongoing with 3 rounds of epinephrine given. The patient remains in asystole. He has rigor mortis. The patient's pupils are fixed and dilated. The patient has compressions paused and ultrasound is used to evaluate for cardiac activity. None is detected. The patient has no electrical activity on monitor. The patient's time of death is 2113.

approximately 3 hours prior to expiring the patient was experiencing forceful emesis. later was found to have expired, patient was comfort care only.

Theápatientáreceivedáhisávaccineáináthe.ámorningáofá1/20/2021,áwhileágettingáintoácarátoágoáseeáhisápulmonologist,áaboutá2áhoursáafter,ácollapsed,áunresponsiveáwitháasystolicácardiacáarrest.ááNoásymptomsáprioráotheráthanáchronicádyspnea.ááNoáallergicátypeásymptomsáreportedábyáfamily.ááAsystoleáwitháEMS,ánoáresponseátoáACLS,ápresentedátoáED,áDOA.

1/13/2021 12:00 PM: Patient received COVID-19 Vaccine. 1/14/2021 21:00: Nurse performed routine rounds and the patient appeared okay. 1/14/2021 22:00: CNA discovered patient unresponsive in bed, began CPR, and called 911. 1/14/2021 23:08: Pronounced deceased.

Narrative:

"Narrative: Was pt previously covid positive?- Yes. Initial- 10/27/2020, 11/29/2020, 12/22/2020 Are there any predisposing factors for patient experiencing adverse drug event?- Yes, patient had multiple co-morbidities including GI bleed, hepatitis congestion due to cardiac issues, treatment for PE, NSTEMI, or antibiotics for PNA, also on concurrent medications APAP, Atorvastatin, Mirtazapine and Duloxetine. Pt with 2 doses of covid-19 vaccine, second one on 01/08/2021, 2 days pre-death Any occurrence of an ADR at time of administration? Did not specify injection site issues, per RN admin note- Vaccine ""administered without complications."" Did patient recover from event? Not s/p dose on 01/08/2021. First dose given on 12/21/2021, LFTS increased ~01/01/2021, peaked on 01/03/2021 and were

decreasing on 01/07/2021 Was there an ADR between observation period and date of death? No Did patient recover from event? No (01/08/2021 event, died 01/10/2021) Was patient hospitalized prior to vaccination? Yes, in between inpatient and nursing home Was patient hospitalized prior to death--was hospitalization attributable to ADE? Yes re-admitted to inpatient on 12/31/2020. GI bleed Is there an alternative cause of death? Yes, as noted above. Quite a complicated case with many comorbidities/concurrent medications as noted above. Primary Diagnosis: Upper GI Bleed in the death note from 01/10/2021"

tired; legs felt heavy; stopped breathing; This is a spontaneous report from a Pfizer-sponsored program a non-contactable consumer. A 93-year-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 04Jan2021 11:00 at single dose for covid-19 immunisation. The patient medical history and concomitant medications were not reported. Patient received vaccine around 11:00 a.m. About two hours later, he said he was tired and couldn't continue with the physical therapy he was doing. He was taken back to his room, where he said his legs felt heavy. Soon after, he stopped breathing. A nurse declared a do-not-resuscitate order. The patient died on 04Jan2021. It was not reported if an autopsy was performed. Outcome of stopped breathing was fatal. Outcome of tired and legs felt heavy was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Reported Cause(s) of Death: stopped breathing

died; This is a spontaneous report from a Pfizer-sponsored program. A contactable consumer reported that an 83-year-old female patient (reporter mother) received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection), via an unspecified route of administration on an unspecified date at single dose for covid-19 immunization. Medical history included hospice care and dementia. The patient's concomitant medications were not reported. The patient died one day after getting vaccine. She was reportedly in good health the day before receiving vaccine. She was on hospice, frail, but in good condition and checked by a hospice nurse the day before which she reported her in good health considering. She was with dementia but stable in her health. The reporter read investigating 23 deaths of people receiving vaccine in similar conditions. The patient died on an unspecified date. It was not reported if an autopsy was performed.; Reported Cause(s) of Death: died

"Called to schedule second vaccine and daughter reports that he died on01/19/2021 with ""COVID"""

"Patient's wife called this morning stating that her husband has passed away last night. After receiving first dose of Pfizer COVID-19 vaccine at around 0830, patient remained in the Immunizations Department for the 15-minute monitoring period. Per wife, patient's only complaint was pain at the injection site. At 1300, wife states that patient complaint of dizziness which ""dissipated after a few minutes"" followed by a headache which ""dissipated after a few minutes"" as well. Then patient complained of nausea, no vomiting and ""couldn't relax."" Per wife, from around 1400/1500, patient stayed on his recliner while still having a conversation with her--""he didn't get up to eat."" Last conversation they had was around 2000/2100. Per wife, at around 2100/2200, patient was quiet and when she checked on him, ""he wasn't responding anymore."" Wife then called 911, ""but they couldn't revive him."""

Admitted to hospital after vaccination with Acute hypoxemic respiratory failure, Septic shock; Aneurysm of arteriovenous dialysis fistula; expired 1/16/2021

We do not believe that the patient's death was an adverse event from the vaccine. Patient received COVID vaccine from Pfizer Dose #1 12/19/2020 (lot # EK5730) and Dose #2 1/7/2021 (lot # EL1284). No side effects or adverse events noted; lived in 24/7 care facility and monitored twice daily for reaction. Patient died 1/10/2021 from chronic respiratory failure and congestive heart failure after recent aspiration pneumonia requiring hospitalization. Death was anticipated and not sudden. We were told to report his death to VAERS even though his death was anticipated and not related to his vaccination.

Patient deceased

Patient did not have any adverse reaction to the COVID vaccine, but we were asked by our health dept to submit a VAERS report since the patient died between his first and second dose. Received Pfizer Dose #1 12/17/2020. No side effects or adverse events noted; lived in 24/7 care facility and monitored twice daily for reaction. Date of death 12/23/2020 from aspiration pneumonia complicated by end-stage heart failure and ischemic cardiomyopathy. Death was anticipated and not sudden.

patient expired 1/15/2021; had been treated as outpatient for pneumonia, likely COVID-19 but no positive test result in December 2020. PMH diabetes

Admitted 1/14/21: Patient is an elderly 93-year-old female with multiple medical problems including chronic combined CHF, P 80, diabetes mellitus, HTN, hyperlipidemia, CKD stage 3, has been complaining of generalized weakness, fatigue, decreased appetite for the past few days. She had an outpatient COVID-19 vaccine earlier today. Within 2 hr of admitting the patient to the hospital, condition clinically deteriorated. Patient elected to be DNR/DNI while in the ED. Patient was pronounced dead at 10:30 p.m. earlier today. Preliminary cause of death: Hypoglycemia induced lactic acidosis.

Pt received second dose of COVID vaccine on 01/20/2021 at 1430. At 1600 Pt developed a wet productive cough with coarse crackles. Pt ate dinner at 5 pm cough persisted. At 18:30 the nurse went to Pt's room to give him his medications. Pt still had a cough, denied shortness of breath. Pt was in a good mood and joking with staff. Pt asked to be shaved. At 19:45 Pt was sitting in the lounge and a CNA noticed that Pt was pale/white in color and clammy. 02 Sat was 85%. Respirations were labored. Pt was placed on 4 L of 02. Increased to 5 L via face mask and 02 sat was 89-90%. Ambulance was called at unknown time. Pt arrived at Medical Center at 2120 and was pronounced dead at 2127.

On Saturday, 1/16/2021, Patient went to the grocery store. Upon her return, she indicated she was experiencing N/V and some throat swelling. Patient subsequently collapsed and expired before she could be brought to an emergency room. During investigation by Coroners Office, it has been reported that Patient may have gotten some takeout food while she was out. Labs are pending and the Coroners investigation is ongoing. Spouse believes that her death was caused by the vaccine.

No immediate reaction. Patient-reported deceased four days later on Jan. 19, 2021. As of this date cause of death is unknown to our clinic.

unknown. Event occurred after leaving vaccination site

presented to ED 1/9/21 with abdominal pain, progressive worsening weakness and fatigue and new onset A fib with RVR likely due to hypertensive urgency . Patient progressed clinically with severe hypoxia and transferred to ICU and started on BiPAP; progressive decline with decreased urinary output with uremia likely secondary to sepsis. Concern with patient worsening clinical decline, palliative care had been consulted on end of life care. Patient expired 1/17/21

Narrative:

Fever, Tachypnea, HYPERtension, Tachycardia & HYPERglycemia Narrative: Was inpatient overnight in a telemetry until. DC with diagnosis of DM and CHF

1/11 asymptomatic COVID Positive test Narrative:

Narrative: Symptoms: & Cardiac Arrest; Death Treatment: EPINEPHRINE

shaking, altered consciousness Narrative: One day after pt received his first covid vaccine, pt experienced upper extremity shaking leading to ED visit and subsequent hospitalization with concern for seizure. Examination and labs were not consistent with seizure. He had features of lewy body disease and parkinsonism. Labs were significant for leukocytosis, but pt had no other signs/symptoms of infection or findings to indicate a source of infection. Pt referred to Neurology.

Patient diagnosed with COVID on January 9, 2021 after being exposed to family member that was under quarantine in the same household. Admitted to the hospital and was discharged on January 14, 2021 with home hospice. Patient passed away on January 18, 2021

Patient passed away on 01/18/2021

Patient died unexpectedly 5 days after receiving vaccine (1/10/2021).

Patient deceased on 01/17/2021

Death; This is a spontaneous report from four non-contactable consumers via a Pfizer-sponsored program Corporate (Pfizer) Social Media Platforms. A 78-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration, on 28Dec2020 at a single dose for COVID-19 immunization. Ongoing medical history included Alzheimer's Disease, encephalopathy, hypertension, acute kidney failure, urinary retention and recent urinary tract infection (UTI), all from an unspecified date. Concomitant medication included acetaminophen (MANUFACTURER UNKNOWN), bisacodyl (MANUFACTURER UNKNOWN), bupropion (MANUFACTURER UNKNOWN), escitalopram (MANUFACTURER UNKNOWN), hydrocodone bitartrate, paracetamol (HYDROCODONE/ACETAMINOPHEN), loperamide (MANUFACTURER UNKNOWN), ondansetron (MANUFACTURER UNKNOWN), senna alexandrina (SENNA PLUS), vitamin d3 (MANUFACTURER UNKNOWN). The patient had no known drug allergies. The patient experienced death on 30Dec2020. The vaccine was given on 28Dec2020 with no adverse events and no issues on 29Dec2020. The patient

died on 30Dec2020, at approximately 2:00 AM. It was unknown if an autopsy was performed. It was unknown if the event was related to the suspect drug, the administrator marked as natural causes. No follow-up attempts are possible; information about batch/lot number cannot be obtained.; Reported Cause(s) of Death: Death

Pt died 4 days after vaccine, no known reaction to the vaccination

Death, which I believe is unrelated to vaccination

Narrative:

Death - Hospice patient with metastatic CA admitted to facility and received vaccine during stay. No adverse sequelae noted from vaccine administration, but reporting as required because pt died 7 days later. Narrative: Reporting this event because patient died 7 days after receiving vaccine in the facility where he was in hospice care for metastatic cancer. Vaccine was administered by protocol without complications. The patient had been asked and denied any prior severe reaction to this vaccine or its components and gave permission to receive it. No vaccine adverse sequelae were documented after the immunization as monitored for 15 minutes nor in facility notes for 7 days after the immunization. The patient's death was felt to be due to underlying terminal illness.

Pt on hospice in facility for severe cardiomyopathy unable to perform interventions received vaccine without adverse sequelae died 5 days later. Reporting as required. Narrative: Reporting as required patient death 5 days after immunization with Pfizer vaccine. However, no adverse sequelae were noted to the vaccine in the 15minute observation period, nor in the days following the immunization related to the vaccine. The patient denied any prior severe reaction to this vaccine or its components, and the patient gave verbal consent to receive the vaccine. Patient had been in the facility on hospice since 11/18/20 for severe decompensated HF and newly diagnosed cardiomyopathy, unable to perform interventions, also LE ischemic wounds with very poor potential to heal due to advanced PVD.

Narrative: Temporary restriction on driving until further evaluation due to symptoms of seizures.

loss of consciousness; respiratory distress Narrative: Patient tolerated his 1st dose of the COVID-19 vaccine well, on 12/16/2020, and received his 2nd dose on 1/6/2021. Patient had some mild clinical decline the past few days prior to 2nd vaccination, with a decreased appetite and some increased fatigue per nursing report, but no significant changes. He experienced nausea on the evening of 1/6/21, which was effectively managed, but by early morning he spiked a fever of 102.9 with a sat of 86.1%. He continued to deteriorate from that point on and died 1/7/21 @13:20. Clinically, the presentation was most consistent with an aspiration pneumonia.

Death on 1-5-21

Death 1-15-21

Note: Submitting a report to VAERS does not mean that healthcare personnel or the vaccine caused or contributed to the adverse event (possible side effect).

Some measures are hidden, use Quick or More Options above to restore them.

VAERS ID

Results are sorted in by-variable order

Adverse Event Description Click to sort by Adverse Event Description ascending Click to sort by Adverse Event Description descending

C/O Headache

felt warm, hot and face and ears were red and flushed.

within 15 minutes progressive light-headedness leading to near-syncope and diaphoresis. After 20 minutes symptoms subsided.

Pt felt wave come over body @ 1218 starting in head and going down. Bad taste in mouth, tingling in body , legs, back , across stomach, BP 150/100 P 120@ 1219, EMS activated. BP 120/80, P 80 Pt alert and oriented, Pt declined transport and Benadryl. Symptoms come and go, pt feels better but then bad taste in mouth starts, shaking of hands, tingling starts again in stomach and back. @ 1300 pt requests Benadryl, 25 mg administered. Pt notified family by phone of circumstances and family in transit.@1324 BP 120/80, P 84, tongue tingling and pt reports smelling chemical smell. @1345 Pt complained of mouth itching, EMS activated and will transport to Medical Center. Pt oriented and transported at @13

"rPfizer-BionNTech COVID-19 Vaccine EUA 5-7 minutes after the vaccine Associate stated she did not feel right, mentioned chest pain. ""My chest feels funny. It feels like when you have really bad heartburn coming on"". ""I feel flushed like when you get contrast for a CT"". Pulse 90 BP 160/90 checked later 130/90"

Headache, body ache

Within a few minutes of receiving the COVID 19 vaccination, patient developed lightheadedness, shortness of breath, headache, and some nausea. She did get some redness to her neck and upper chest. No recent illness. Had elevated BPs ranged from 158/103 to 207/126 . HR ranged from 82-106. O2 sats always > 96%. Temp 37.1 C. Received Tylenol 1000 mg PO, Dexamethasone 10 mg IV, diphenhydramine 50 mg IV, famotidine 20 mg IV, ketorolac 30 mg IV, ondansetron 4 mg IV, and 1 L NS. Patient prescribed EpiPen and prednisone and discharged.

About 25 minutes after receiving vaccine complained of dizziness and being hot and nauseated. No difficulty breathing. No chest pain. B/P was 130/90 and was monitored. It went down to 124/80 after he started feeling better. He was wearing sweater over shirt and it was warm in building. Took sweater off. Cool wet cloth applied to back of neck. States he had only had a donut and cup of hot chocolate before receiving vaccine. Sprite and peanut butter crackers given. Became nauseated after eating peanut butter crackers Blood pressure monitored monitored. He laid on exam table for about 15 minutes. He felt

better. Stood up and walked to conference room for another 15 minutes. Stated he felt much better and was ready to leave. Coworker drove him back. Received email from him letting us know he had made it back and they had stopped and eaten pizza on the way. Received text from coworker that he was dizzy and seeing spots and that his blood pressure had been 120/80 and then spiked to 160/100. Coworkers taking him to ER at Hospital for evaluation.

At 12:55 pm 10 minutes following vaccine being given states feeling lightheaded and flush. Was sitting in the chair. Encouraged him to lay down on the floor which he did on his own. Feet elevated. BP 174/70 pulse 82. Denies any other complaints. Laid on floor for 15 minutes then sat in chair. Denies complaints. 1:15 pm was allowed to leave. BP 120/80 and states feeling fine.

Patient felt facial flushing, pounding in chest, burning and hot ears and blood pressure went up. Tingly in right arm and chest and hands. Symptoms resolved, after a few minutes but then returned. Patient sat with nurse during this reaction.

She claims she experienced tightness in the right side of throat and her tongue started tingling. Took her the Emergency Department, She decided to go and buy Benadryl

System was not populating immunization record, member denied having immunizations within last 14 days. Vaccine given, record populated and patient had anthrax on 12/10/20

Tingling of upper lip and cheeks, warmth in face, and itchy eyes Treatment: diphenhydramine 50 mg PO x1 Outcome: symptom onset within 15 minutes of vaccine administration. Symptoms resolved within 20-30 minutes of diphenhydramine administration.

I am a immunization nurse at this location. I gave 2 of the first 4 Covid vaccinations given at our location. Then I received dose # 5. It was easy. I did a couple of things and then returned to my desk. As I sat down, my arm started feeling very heavy. I was unable to send a text. I told staff that I was feeling funny and that I was going to the other room to lay down. Staff followed me and took my Pulse 100 and BP 164/ 82 (high for me!) . I felt shaky, but my hands were not shaking. Put a wet cloth on my head and laid there a few minutes, telling staff stories and laughing at my BP. When I sat up, my BP was 126/74 and pulse was 80. I stood up for a minute or two, then my legs got heavy and I sat down for a few more minutes. I went to the bathroom and came back to my desk, but was weak and tired. I ate and drank some fluids. Because it was snowing and I live 25 miles away, I accepted a ride home from a co-worker. I walked across the parking lot without problems and talked all the way home. At home, I was tired, but had a sandwich and talked on the phone. I would still describe myself as tired, but functioning.

1750- IM injection ot R Deltoid. She was sitting, and felt short of breath without wheeze or tightness in the chest or throat. She stood up, and then felt tunneling. Assisted to chair and floor. Pulse weak, skin flushed, sweating on torso. Face and Neck remained flushed and red. She refused epi at first. So we gave her benedryll 25 mg po with apple juice. She said she just had a big meal 30 min prior, but we checked her blood sugar- it was 85. 10 min after the first SOB feeling, it returned. BP was recorded as 160/100.

Pfizer-BioNTech COVID-19 Vaccine EUA Developed chills, nausea and vomiting beginning at 2 AM the night after receiving the vaccine. Potential fever as well (I don't have a thermometer to check). Symptoms have lasted over 3 hours thus far, still continuing.

Pain in deltoid muscle upon pressure at night. Hard to lay on the side of the vaccine due to pain in the arm

I received the vaccine @ 3:40 pm 12-15-20 and felt fine until around 9:00 pm 12-15-20 when I noted headache, nausea, no energy, overall not feeling well, and injection site pain. I did not have a fever. Symptoms still present @ 6:00 am 12-16-20.

Right sided facial/lip swelling. Started about 0200 on 12/16/20. Patient sometimes gets angioedema, so unsure if this is related but wanted to report

Patient received shot around 1pm later that night he started to experience chills, hot/cold, nausea, headache, extreme fatigue, low grade temp (99.1) Associate vomited several times the early the next morning. By the next day, day patient was vomiting less and was able to keep food down. Patient is feeling better the second day, experiencing some nausea.

diffuse rash at anterior and right lateral neck associated with feeling of warmth

Patient received shot and sat for 15 minutes, left and came back and reported she felt woozy. She felt dizzy. Patient stated she felt dizzy off and on while she was in clinic getting shot, patient left.

chills - 0730 body ache, headache - 1000 headache significantly worse - 1110

sore throat, headache, lightheadedness

"Pt. became lightheaded, and clammy. noted heart rate to be 51, oxygen saturation 100%. after sitting for a few minutes, she felt better, but then became dizzy and had some chest tightness and bilateral hand tingling. Pt. noted to have respiratory rate 22-26 with deep breath, but other vital signs were stable. (Blood pressures 108-138/70's to 80's) Heart rate remained stable in the 70-90's range, lungs remained clear to auscultation through out. No rash or swelling noted anywhere. No itching, no throat tightness. Pt. repeatedly stated ""I think I am having a panic attack"". Due to the continued complaint of chest tightness, pt. sent to the emergency department for evaluation."

redness around the injection spot, fever chills, Stomach Ache, Body Ache, Short of breath (walking up stairs), Headaches no appetite, Dry heating .

After patient received vaccine had localized reaction in left deltoid. Redness and firm to touch. Patient observed for additional time frame and redness lessened. Patient released home.

About 12 hours after the injection woke up and body was hurting all over, chills, body aches, felt feverish, temperature was 100.3F and really tired and hurting all over. Took Tylenol and returned to sleep. Woke up some hours later and took an Ibuprofen. rested for the rest of the day and now the only

side effects is a little soreness on her injection mark. No other symptoms. Only the first 24 hours after the shot.

Immediately after the vaccine, I got severely nauseaed, got a yucky metal taste in my mouth and got super lightheaded and hadnt even gotten up. The agent helped walk me to a chair and I felt really loopy in the head. After the 15 minutes, I got up and immediately felt the whole room was spinning causing me to have to sit back down another 15 minutes. Closing my eyes made the dizziness much worse. I was given juice, my sugar was checked at was 115. After about 30 minutes I stood and felt alot better. I went back to my assigned duties but was feeling super bad and my supervisor sent me home because they states I didnt look good. On the drive home I threw up and my PCP called in Zopran to help with the nausea.

"After patient received vaccine had complaints of being ""lightheaded and slightly dizzy"". Monitored vital signs and patient symptoms. Resolved after 20 minutes and patient was released to go home."

Left arm swelling of forearm, old L wrist tattoo because raised and lifted out of skin approx 3 mm, whole arm was itching with several red dots; reaction resolved within 8 hours without intervention body wide itching persisting now

Patient had sudden onset of nausea . Patient was laid flat on the floor and given and alcohol. Symptoms resolved and patient was released home.

Patient has a prior anaphylaxis reaction to Doxycycline. 10minutes after immunization, she developed sweaty palms and lightheadedness. No throat swelling or difficulty breathing. Placed supine, BP 160/100, HR 60-70, O2 97% RA. After a period of monitoring the symptoms improved. No intervention given.

Pain; This is a spontaneous report from a non-contactable physician. A 39-year-old male patient received BNT162B2 (Pfizer-BioNTech COVID-19 mRNA vaccine), via an unspecified route of administration on 14Dec2020 at 12:00 (at the age of 39-years-old) as a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. On an unknown date in Dec2020, the patient experienced pain. The clinical outcome of the pain was unknown. No follow-up attempts are possible; information about lot number cannot be obtained.

Bp of 85/44, nauseous, body aches, chills

I worked overnight after getting the vaccine. I felt really tired and came home and slept until 3 pm. When I woke up I had a dull headache and felt crummy. Decided to sleep the remainder of the day but no fever just was fatigued and had a headache. My arm was hurting at the injection site but the pain has sense left and the headache is gone also.

NORMAL ARM PAIN HOWEVER THE FOLLOWING WAS FELT REAL TIRED BARELY ABLE TO STAY AWAKE

I experienced a sore arm and could not lift my arm.

Swelling on arm. Placement lower than deltoid, 4 cm. treated with corticosteroids, antihistamines

Pt started to have a metallic taste in her mouth immediately after administration of the Covid-19 vaccine. She started to feel nauseous and myalgias. The patient was seated, given Zofran 4mg once and Benadryl 25 mg once. After 10 min patient was eating juice + crackers. Reports she feels better. A co-worker verbalized he would drive her home, patient agreed.

12/15/2020 5:00 PM Nauseas(worst) 5:30 Pm Headache 6:00 Pm Stomach Pain

PAIN AND EDEMA AT SITE OF INJECTION LEFT ARM WITH DECREASED RANGE OF MOTION LEFT ARM RIB CAGE PAIN ON INSPIRATION MUSCLE PAIN RIGHT AND LEFT THIGHS, WORSENING UPON AMBULATION MUSCLE PAIN AND TINGLING RIGHT UPPER EXTREMITY AND BACK

Following first dose, patient became hypotensive, pale, and diaphoretic. Denies syncope. Patient went to nearby emergency department at Hospital. Was monitored for several hours and was discharged in stable condition.

Chills, Body Ache, Fever

The employee experienced headaches the evening after receiving the vaccine. The next morning he experienced improvements in the headaches but developed chills, fatigue, and fever, all of which have improved somewhat by the afternoon when he reported these adverse effects to our employee health service. As he is recently recovered from COVID, a repeat COVID test may not be helpful. He was advised to call our employee health service and followup with his own doctor if these symptoms do not improve or resolve after 3 days.

Headache, onset ~45 minutes after injection

I got it about 10 am I went home I attempted to work from home for about an hour and had a headache, took a 3 hour nap and felt much better after waking up, I felt like I couldn't concentrate. I felt fine this morning 12/16/2020 and I went to work just fine. I don't have a headache and don't feel like I need a nap, my arm still hurts but that is usual. I called my provider and asked if I could take Tylenol, but they were unsure so I did not take medication

"@ ~5 min felt cotton mouth. Got up to ask if he could go early. Then at 10 min post injection, felt eyes feeling weird and he felt ""high"". As in lightheaded. @ 10 min, skin surrounding the eyes are puffy. Given 25 mf benedryl. No immediate SOB or wheeze. No lip or mouth or throat swelling. Taken to ED. Given IM epi 1:1000 0.3ml. Pepcid and more benedryll PO."

Fever , chills, Body Ache all over body, Joint Pain (worse in hips) Injection site swollen The PT cannot life her arm

Burning and itching at injection site

Soreness and swelling at injection site

.5 inch bruise at injection site, slight swelling, sore muscle, ibuprofen, ice bag,

Vaccinator Nurse noted upon vaccination there was bleeding from site and immediate bruising. Extended post vaccination monitoring to 30 minutes and asked patient to not leave before being reevaluated. Visual monitoring in post vaccination space by this RN. á Upon reassessment @ 1352 pt stated she felt the need to use her inhaler and chest tightness. Pt denies SOB and able to transfer independently to wheelchair. Pt began to cough and was immediately transferred to ED per FNP. á á Upon ED arrival, pt was transferred to back hall 9, report given to RN and assessed by physician. Vital signs 98% on RA, t- 98.2, HR 78.

Nausea, tremors, and decrease in HR. Patient taken to ED. No epinephrine injection administered.

Patient started to develop maculopapular rash and itching starting ~15 minutes after the vaccine administration. The patient did not report shortness of breath or other respiratory symptoms. The patient was given IV diphenhydramine 50 mg, famotidine 20 mg IV, and methylprednisolone 125 mg IV. The patient's symptoms resolved and was sent home with a Medrol dose pack and antihistamine.

redness, itching to face, armpit, and neck

Swelling and numbness at injection side. Increased blood pressure 199/99. Immediate headache. Workplace clinic called hospital ER, clinic administered Benadryl. Symptoms resolved.

The patient got a rash on the upper chest and neck approximately 3 hours after vaccination. The rash was self limiting and no treatment currently needed.

Pt presents to the ED for c/o L anterior chest wall pain after receiving covid19 vaccination today around 1030. Pt reports she received the first dose in the L bicep. Pt reports after she received that shot she started having L anterior chest wall pain. Pt states she doesn't have any chest tightness but does have stabbing pain to the L anterior chest wall. Pt denies any difficulty breathing or hives or any allergic reaction. Pt was hooked up to cardiac/sp02 and BP monitoring equipment. Medication: Ibuprofen Route: PO Dose:800 mg Patient tolerated medication well; no adverse reaction noted. Medication: Tylenol Route: PO Dose:975 mg Patient tolerated medication well; no adverse reaction noted.

Received Pfizer Covid Vaccine - Had fever of 102 and flu like symptoms. Took Tylenol and temp resolved to 99.

11 minutes after first dose of Covid Pfizer vaccine, patient became unresponsive, pale, diaphoretic with possible seizure activity. Patient dropped all belongings, leaned to the left side, with eyes rolling back in her head. Episode lasted about a minute. Patient could not remember what had happened. Vitals were BP 110/60, HR 64, RR 22. Patient was advised to go to ED for further evaluation but she refused. Patient was given a snack and an RN stayed with her for about 20 more minutes to monitor.

":1039: Responded to notification of potential adverse reaction after receiving COVID-19 vaccination. Pt had been escorted from observation area to emergency area with PA with c/o tightness in throat. On my arrival, pt was eupneic, p/w/d, ambulatory, NAD. á Vitals @ 1039: P72, 100% pulse ox on RA Vitals @

1056: P72, 98% pulse ox on RA, 112/78 seated. á Administered 25mg diphenhydramine po per PA @ 1050, pt swallowed with water. á Called 911 for EMS response @ 1103 per instruction from provider. á Vitals @ 1103: 98% pulse ox on RA, P74, denies shortness of breath or pain. á Off phone with EMS @ 1108, en route. á EMS on site @ 1115, report given to medic. á Pt left with EMS en route to ED @ 1116. á Report called to ED Charge Nurse @ 1121. Patient presented to vaccination clinic. Patient received her vaccination at approximately 1021. Patient reports symptoms onset at approximately 1038 with tightness of the throat and difficulty swolowing. She described it as a swelling of the throat sensation. She states she had a sensation moving from her head to her toes as in a ""wave "". Patient denied shortness of breath, chest pain denies nausea. Patient denies hives or rashes or pruitis. á á Patient was assessed and moved to the emergency area. á Her symptoms continued with some improvement. At this point time 25 mg of Benadryl was administered orally. Approximately 10 to 15 minutes after administration the patient developed numbness tingling around the upper lip, the right upper extremity. She denied shortness of breath or chest pain. She denied increasing severity of the throat sensations. á Pertinent past medical history: Reactions bee stings currently carries EpiPen. á She is not had any previous reactions to vaccinations. á á áAllergic reaction. á The patient symptoms seem to continue with the numbness tingling around the lips after administration of the Benadryl. Hand tingling of the right upper extremity also continued although it was decreasing. á Her symptoms of the tightness of the throat remain the same. She did not develop shortness or breath or chest tightness or pain. á At this time I feel be prudent to evacuate the patient to higher level care. á Patient was evacuated at 11:16 by ambulance service. á á á"

1-2 minutes later patient felt nausea, palpitations, and lightheaded

My symptoms started about 15 minutes after shot. Initially I felt slight dizziness begin in my head. Then I felt slight uncomfortable feeling in my lungs, throat, and tongue. They were very slight so I left the vaccine center about 25 minutes after injection. On drive home my lips started to feel numb as well as my tongue & throat. Arriving home very tired. BP 135/ 80 P70 R20 T97.6 Blood sugar 101. Slept for about 4 hours. Called in sick for 7PM shift. Too weak & tired.

""""Pfizer-BioNTech COVID-19 Vaccine EUA"": Acute onset of tongue swelling, throat tightness, and diffuse erythema approximately 5 minutes after receiving COVID-19 vaccine. Patient transferred to emergency department. Patient treated with Epinephrine 0.3 mg IM X1 dose, Dexamethasone 10 mg IV x1 dose, Diphenhydramine 25 mg IV x1 dose. Patient discharged same day with resolution of symptoms."

"When injecting the vaccine fluid, the vaccine administrator noted about 4 drops of liquid that leaked from the area of the syringe tip / needle hub connection. This particular dose was administered by a pharmacist who has experience administering vaccines. In speaking with a few other nurses who administered COVID-19 Pfizer vaccinations at the same clinic (this was the first clinic day), the consensus was that they all did not like the syringes/needles provided by Pfizer. It was a shared opinion that they felt ""cheap"" and ""flimsy"". Going forward, our site is not going to use the Pfizer supplied syringes/needles but will be using our own syringes and needles for vaccine administration."

I inserted my NuvaRing birth control on 12/14/2020. I have the Covid19 vaccine on 12/15/2020 at about 8:30am. The injection site was mildly sore and that continued into the next day. I woke up on 12/16/2020 feeling a little off and it progressed throughout the day. I felt a headache that I knew was turning into a migraine, threw up a few times (this is normal for me when I get migraines), and started having hot flashes. My temperature never went above 98. After sleeping a few hours and taking some Excedrin migraine I was feeling much better, though still a little sickly, by 4pm. I really think this is due to my migraines (which I get roughly once a month) even though it was a day later than normal.

Patient marked that he had received the flu vaccine 7 days ago. This was missed on screening procedure and patient received the vaccine today. Contacted the CDC and instructed to enter a VAERS report.

Patient was feeling nauseated in the morning prior to coming to work and prior to receiving vaccine. He had a banana thinking he would feel better. He then received the vaccine and felt progressively worse experiencing diarrhea, weakness, and malaise.

Patient complained of feeling dizzy, anxious, shortness of breath. Did have some pain with injection. Did have mask on while waiting standard 15 minutes.

Associate received vaccine at 12:15 pm and was monitored for 15 minutes. After 15 minutes, associate went to check out table. While at check out table, associate fell to ground and was experiencing seizure like activity. Supportive treatment was administerd and associate was transferred to ED.

Dizziness that lasted for about an hour. Weakness, extreme fatigue lasted the rest of the day.

Feeling flush and wheezing when walking.

Patient was in observation area after admistration of covid vaccine. At 15 Minute mark patient stated throat felt tight and like it was closing up. Assesment of patient showed tongue PWD, vital signs as follows. 97.6, 118/72, 66 pulse and 100% pulse oxygenation. Observed patient for 15 minutes more, gave patient water and monitored for full 30 minutes. Breathing normal at this time. States feeling better. Discharged and advised to monitor throughout night and if worse go to emergency room. Patient agreed and stated understanding.

Fatigue, nausea, muscle aches

Redness at injection site

Headache, body aches, low grade fever (99.3 F)

Severe muscle aches Diarrhea Headaches Feverish Nauseous Left arm super sore Sore throat

I developed a new rash on my torso and have had three bouts of diarrhea.

Redness to injection site

myalgia, joint pain, local site pain

Within and hour and a half of receiving developed tinnitus in both ears lasting 6 hours. The night after receiving vaccine also developed orthostatic hypotension and started to pass out but caught myself with an assisted fall. Fever(102 F with temporal and oral thermometer) body aches/sweats/general malaise lasting close to 24 hours after receiving vaccine. Fever/aches treated with acetaminophen.

Immediately after injection of vaccination her left deltoid started swelling. Complains of pain at injection site. No other complaints. Applied ice. She took Tylenol and Benedryl. Stayed 30 minutes after vaccination without further complaint.

Patient received covid-19 vaccine. 20+ minutes later patient states she began feeling flushed and nauseous. Patient states she look at her injection site, and it was hot and red. Local reaction approx. 2 inches x 2 inches. Dr. ordered 25 mg oral Benadryl. Vitals stable at 1840 133/88, 66 for pulse and regular, SPO2 99% on room air, respirations 20. Patient continued having complaints of light headedness and nausea. 1850 119/79, 74, 99% RA. Dr. states patient may depart from clinic if able to sit up and walk out, patient given instructions go to ED in symptoms progress. 1857 120/82, 70, 99.4. Patient's face becomes flushed and hot on left side, patient states she is shaky, and does not feel well at all. 1905 patient transferred to ED on 2L O2 for further evaluation and workup. Narrative ER Medical decision making narrative: Accu-Chek was obtained noting a glucose to be at 80. She received IV fluids as well as Solu-Medrol Benadryl and IV Pepcid. She also received IV Tylenol as she developed a headache while in the emergency department. Headache resolved and she was able to ambulate without assistance. Requested to go home states she felt much improved near normal. Clinical Impression: Adverse reaction to drug Patient Education: Anaphylaxis (ED)

Patient feeling very anxious before and after vaccination. Described having difficulty swallowing water shortly (~15 min) post vaccination. Patient was tearful but breathing normally. Walked under her own power from the pharmacy down to the Emergency Room for anxiety over anaphylaxis. Given dose of Vistaril in ER.

Local pain and swelling of the injection site

Local Pain and swelling of the injection site

Started with onset of fatigue and disorientation shortly after receiving the vaccine. Several hours after the disorientation got worse, a headache came on and my whole body aches fatigue is bad. I feel like the flu just hit me.

"Allergic reaction with facial swelling, eye tearing, ""itchy"" throat"

Systemic rash, dry cough (causing cough); 650mg Tylenol every 6; 50mg Benadryl to start then 25 mg every 6, Pepcid 20mg every 12 hours; rash is slowly resolving; throat still very dry with dry cough

Nausea started about 8 hours after getting vaccine and progressively got worse over 12 hours

Day 0 of injection that evening , experienced fevers, chills, rigors, malaise. Day 1 morning experienced nausea

60 minutes after receiving the vaccine the patient became very dizzy and was unable to walk. After a couple of hours dizziness lessened and patient was able to ambulate.

"Patient presented with feeling of ""headrush"" dizziness, tachycardia to 130's, itching to neck, visible hives to face and neck."

Hives within 3 hours lasted 12 hours. Left Arm edema and erythema 24 hours

Extreme fatigue, felt very warm all over body for 14 - 16 hours, exceptional pruritus on head and back, all joints are exceptionally achey

Patient left the vaccine clinic after waiting 15 minutes. While driving home, she began to feel clammy with a tightness in her chest and throat. She reports that it felt harder for her to breathe. She describes the onset as 20-30 minutes after vaccine was administered. She returned to the vaccine clinic where she was given diphenhydramine 25 mg PO, and her blood pressure was ~130/100 mmHg. She reports that she is usually normotensive. Patient was observed for 30-45 minutes, and she reports feeling better.

NAUSEA, CHILLS, MUSCLE PAIN, WEAKNESS

02:45 PM walking , dizzy, rapid heart rate, mild chest pain. Directed to ER in hospital, CT Chest -- normal, EKG -- normal, Lab test-- normal. Xray Chest results -- basilar atelectasis, Hyperinflation of lungs. Blood pressure 171/109. No treatment given in ER -- f/u with PCP 12/18/20. 08:00PM nausea, headache, vomit 1x. 10:00PM fever 104.00; Tylenol extra strength dose. 12/17/20 6:00am temp 99.00, Tylenol dose extra strength; body aches, fatigue, mild headache.

caller reported Flushing, redness around face and nauseous. Advised that Number for IMT (Incident management Team)will be activated. Caller declined. Advised to return to observation room where shot was given. Caller stated she would. Called her 5 minutes and left a message to call back if symptoms also persist or worsens

Injection site swelling and pain

Stomach crump & vomiting

DIZZY, SLIGHTLY EVEVATED BLOOD PRESSURE

left arm soreness/pain tender to touch/palpation

"After receiving the injection the patient stated ""my throat feels funny, similar to how it has felt in the past when I have had a reaction."" Pt. transferred from the vaccine clinic location to ED."

Patient reports of itching immediately after vaccine, dizzy, feeling of flush. Medical directive given for itching that include OTC antihistamine (Claritin). Incident Management team activated for dizziness and feeling of flush.

Pfizer-BioNTech COVID-19 Vaccine EUA Fever, chills, severe body aches. Fever resolved with ibuprofen

0749 - tingling in body, scratchy throat for 10 minutes, flushing

Patient was given to co vid injection- developed numbness and tingling inside bicep- speech- slurred speech- tongue speech- tongue not swollen- feels like novican. Takes lisinopril, novolog jardiance, lansoprazole, and mirena.

0752- numbness and redness left arm (inj site)

throat dryness and scratchiness, numbness. hoarse coughing

Headache, Left arm and shoulder pain

Headache, fatigue, muscle aches, nausea, sweating

shortly after patient received vaccine became flushed, bottom lip went numb, vitals were in normal limits. 911 was called emergency staff came and patient went to ER to be monitored.

immediate burning upon injection, VS stable

Swelling of hands follwed by angioedema

Papular, pustular rash on back occurring approximately 6-10 hours after injection of vaccine.

"While waiting the 15 minute after vaccination the Patient noticed a ""tingling"" feeling in throat about 5 minutes after vaccine was given. Time: 0930 - Oxygen Saturation was 98% Pulse Rate 100. Patient stated that the feeling went away and then came back. Time: 0938 - Again vital signs were taken BP 156/88 Oxygen Saturation 100% Pulse Rate 83. Time: 0942 - 50 mg of Benadryl PO were given with water at this time. Patient was taken to ER for evaluation."

Dizziness, headache, chills

Pfizer-BioNTech COVID-19 Vaccine EUA. Injection site pain, headache, tiredness, muscle pain, chills and fever. Took acetaminophen, no longer have fever after 12 hrs.

Patient stated she started to feel a burning sensation in her chest about 7 minutes after receiving injection. Lasted about 5 minutes, then left.

Medication error - reached the patient no harm, additional monitoring to preclude harm. A nurse (RN) diluted new vial of vaccine at 10:41 am. In the midst of adding diluent to vaccine vial, a patient arrived at our vaccine station. After drawing up and administering the 0.3 ml vaccine the RN looked at the vial again and noted that it was almost empty. She became concerned because she had just mixed a new vial and the amount of fluid remaining was not at the expected level. We immediately stopped and reported this to an employee who contacted pharmacy. We notified the patient that there was a discrepancy and had him wait for > 30 minutes to watch for any reaction. (APRN) called him at 1:30p to check on him and apprise him of the possibility of receiving higher than recommended concentration of vaccine. He stated he felt fine and felt no unusual symptoms.

I was tired and took a two hour nap

Headache, fatigue, temperature of 100.3. Lasted about 8 hours.

fever, cough,chills,body aches, weakness, loss of smell

rash - treatment: acetaminophen and diphenhydramine

fatigue, soreness, headache occurred the night after receiving vaccine (approx. 8 hours later) lasting into the following day. I did not take any medications for this .

pt developed chills, nausea and vomiting. Reports > 10 episodes of vomiting total. Went to lunch and continued to have chills and vomiting. Also developed chest pain - described as burning and heaviness. Denies any shortness of breath. CT negative for any changes. Chest X ray normal.

SWEATY, NAUSEA, DIZZY, EYES GLAZED OVER, NOT TRACKING RIGHT, STARTED MORNING AFTER SHOT

Morning after injection: mild fatigue, arm soreness; later in the morning-headache then chills, muscle aches, joint pain and low grade fever (99) and nausea/loss of appetite. These persisted for approximately 12 hours then cleared completely.

12/15/2020 615 received vaccine 2pm belly pains, relief 'not like normal bowel movement', 'urge to go' 5 belly pain, relief self'not like normal bowel movement', 'urge to go' 8-10 pm body chills, covered with 3+ blankets 10 pm body chills subsided 12/16/2020 fatigue; not exercise; 5miles per day (only able to walk 2 miles) Flu vaccine; 'pretty sure it was 09/2020'; Unknown brand

Patient received the vaccine. During the 15 minute observation period she developed chest heaviness, arm tingling, and throat tingling. BP elevated at 169/79. The patient was sent to the ED and evaluated. Diagnosed with more anxiety type symptoms. Discharge from ED stable.

17 minutes after vaccine, suddenly had a , crushing squeezing chest pain, very severe lasted 45 seconds. after 45 seconds continue to have moderate chest pain, light headiness, diaphoretic, very hot. NO fever, elevated BP. Mild to moderate chest and light headiness for about 3-4 hours and it self solved.

She had received a shingles vaccine on 12/10/2020.

I had a headache, body aches and fatigue.

Patient complained of vision disturbance confusion dizziness, chills, clammy, no trouble breathing. Nausea, Patient stated she did not have any breakfast. gave patient diphenhydramine 25 mg and EMS arrived to take her to the hospital.

After receiving vaccine patient started complain of vision disturbance, confusion, nurses started he was slow to respond. Nurses also documented that he was acting the same way the day before due to UTI. No SOB . no signs of allergic reaction

started feeling nauseated, had her sit until feelings resolved.

Patient reported to CNA that they felt like they soiled their pants. CNA confirmed that patient did not soil themself and transferred patient to the restroom. While the patient was on the toilet attempting to have a bowel movement the CNA reported patient had 10 seconds of tonic clonic behavior and then went unresponsive and then back to tonic clonic behavior. This happened 3 times prior to getting patient put back into his bed. Patient went unconscious after last episode while on bed for a more extended period of time while a STAT page was called. Physical Therapist and Aid sternal rubbed him and he had gasp and woke up. Prior to and immediately following the episode his vitals were within normal limits. Neuro exam was unremarkable after patient came to. When he woke up he knew his name, date, and day of the week. He was only confused to where he was. Patient was agreeable to be transported out. EMS was called and transported the patient to Hospital. Patient displayed no seizure activity or neurological deficits in ER. Patient had a CT scan, which came back normal. Virals remained within normal limits and laboratory values were noncontributory. He was diagnosed with a UTI due to the presence of hematuria associated with a syncopal episode. Patient had a Foley catheter upon admission to the nursing home. Patient was administered Ceftriaxone at the hospital and discharged back to Nursing Home on Omnicef the same day. Patient is back at nursing home facility and has not displayed any additional signs of seizure. He is stable and Foley catheter has been removed. Facility spoke to wife who reported that patient did not have a seizure history.

Fatigue, migraine, muscle fatigue on site, diarrhea.

Approximately 11 minutes after receiving the vaccine, the patient complained of shortness of breath, tingling in arms and hands, numbness and tingling in legs and feet, and was observably shaking, with no complaints of swelling in throat or other signs of anaphylaxis. Patient was brought to ER in same facility via stretcher and was examined by staff there. ER report states the patient presented with shortness of breath and what appeared to be a panic attack, with fast breathing, slight flushing, and shaking. Per ER report, the patient was treated for an acute anaphylactic reaction, with clear lungs and given an EpiPen shot in the right thigh. IV was initiated and given a fluid bolus, solu medrol, famotidine, and lorazepam. Labs and a chest x-ray done and reviewed. After treatment, patient found to be stable and was discharged home at 4:42 pm with orders for famotidine, albuterol inhaler, and epinephrine pen.

The nurse was tapping the syringe to get all the air out and the needle popped out of the vaccine vial and stuck to the sticker that was on the vial. 0.3ml of the vaccine was discarded with the syringe into the sharps box.

I woke up at 6:15am had a terrible headache, low fever 100.1. I took Tylenol for the headache and fever. Throughout the day exp muscle aches and joint pain. I also exp hot/cold flashes and fatigue. Around 6:00pm on 12/16 started to l feel better and was able to return to work on 12/17.

I took tylenol for fever and headache and rested, left side lymph nodes were swollen on 12/16/20 which was the worst day, and has gotten better today 12/17/2020. Did not go to the doctor.

Caller stated at 11:30 a.m caller had right arm pain at injection site and headache. 12/17/20 headache and arm paid has subsided.

Fever (37.8 ¦C) and muscle pain.

Headache, right retroocular pain, exacerbation of rosacea Tx. acetaminophen Duration: 3 hours

12/15/2020 Around 7:30pm, I started to itch on neck and face. Progressed to scalp, stomach, back and whole body; ears, top of head to bottom of toes. Called critical care healthcare staff; 1 25mg benadryl Had nausea, fatigue, hip and joint pain 12/16/2020 Still itchy not as severe as 12/15/2020. Still joint pain and achiness. Nausea was a 8/10. 12/17/2020 feel better. About 80% . Mild itchiness. 'letting it run its course' and haven't taken any other benadryl since 12/15/2020. Joint and nausea has subsided. Flu shot 09/2020 Second dose of Pfizer shot is scheduled for 01/05/2021

~30 minutes after vaccination, patient reported lightheadedness, difficulty swallowing, SOB, feeling flushed, pallor, bilateral arm tingling, brief chest pain and tremors. Symptoms lasted approximately 30 minutes and then resolved. Benadryl given after resolution of acute symptoms. Reported a metallic taste in her mouth immediately after receiving the COVID vaccine (dose #1). Had uneventful 15 minute recovery period immediately after vaccination.

2 hours later pain in arm approximately 4-5 inches. Was not able to utilize left arm on yesterday. last night experienced muscle aches and chills. Taken Tylenol and rested. This morning experienced a really bad headache.

"Individual received vaccine on 12/17/20 at 0815. Began with feeling faint and ""spinning"" at approx. 11:00 am, reported resolution of symptoms at approx. 11:11 am on 12/17/20."

"Stayed for 15 minutes after the vaccine given and no reaction was noted and she left. States she got into her car about 20 minutes after the vaccine and started to ""itch"" all over and noted ""red bumps"" on the back of her neck. She had a flushed face by the time she arrived home but remained afebrile. Her itchiness is better but only concentrated on the back of her neck on 12/17/20 when she reported the reaction to Employee Health Services. She denied any further issues today."

I have a sore arm and I am experiencing severe back pain, nausea and a headache that comes and goes.

arm felt hot to the touch, felt arm heavy very difficult to move the arm, felt feverish, took temperature but no fever, but hot to the touch, lots of chills, nausea, body aches. Took some tylenol and at night it started getting a little better. This morning the injection site is red and is sore but I can move my arm again.

chills, headache, weakness, fatigue

stated her lips started to feel numb, like she was at the dentist. lips did not appear cyanotic.

about 1 1/2 hour after receiving it I felt a pain and numbness down left arm into pinky and ring finger. That only last about 2 minutes. Then the pain radiated to left side of neck and head and headache is still there at 1pm.

Caller had vaccine and at 12:30 at night caller had extreme paid in left arm and had to take Tylenol. Next day caller stated pain had subsided.

Employee states that there was confusion at the time of vaccine injection, and that she was possibly given a second injection right after the first. approximately 45 minutes later she experienced headache and dizziness and had an observed syncopal episode. She was taken to the ER, evaluated for MI. Was found to be stable and was discharged.

I WOKE UP WITH DIARRHEA AND A CONSTANT HEADACHE THAT HASNT LEFT

Headache at base of skull near spinal cord 3 hours after dose given

12/15/2020 I felt terrible with muscle aches, shivering, chills, fever was 102.8,I took tylenol and ibuprofen (alternated) 24 hours after initial fever I ceased meds and fever was still 101.5, this morning I was 98.6. The course of the fever was 36 hours total

Around 630pm I began to have a really bad had a bad headache, feverish and body aching. Tenderness in the injection site area which eventually turned into full body aches and was tired. No vomiting or nausea. No redness at the site or injection site issues

Muscle ache, fatigue, drowsiness, brief confusion, bilateral headache, onset 11 AM, duration 2-3 hours

Persistant cough, dyspnea, sweats, myalgias, mental staus changes and diarrhea, still resoving

"1145: Patient complained of minor left eye swelling. Vital signs 99%, 83, 141/80. 1155: Vitals rechecked 1155 100%, 79, 112/80. Patient has new complaints of itchy ears, facial ""heat"", and slight tingling in fingers. 1200: 25 mg of oral Benadryl given. 1211: per RN, patient states symptoms are resolving. 1230: Patient still feels slight eye discomfort, all other symptoms have resolved. Patient states she feels comfortable leaving vaccination clinic, her son will be taking her home."

Headache , dizziness, neck pain, left flank pain, fever 100.2 , chills,fatigue and muscle aches.

I noticed the injection site was sore, swollen and warm. As the day progressed headache, fatigue, joint, legs aching and feeling heavy tires. Also had a fever of 101.2.Around 9:30 pm on 12/16 started to feel better fever was down.

12/15/2020My arm was really sore at first, and then my arm was worse the next day on 12/16/2020 as the morning went on my temperature felt like it was going up and down I felt body aches and felt really tired I had covid in June and it wasn't as bad as when I had it in June but it was still pretty bad, I also had a headache, I took tylenol and my fever broke but after a few hours my headache was worse and I started to take tylenol and ibuprofen. 12/17/2020 Under my left arm my lymph nodes are swollen but I feel much better and will go to work today 12/17/2020

40 min after shot experienced dizziness, feeling like was going to pass out, not coherent, BP high, fast heart rate, light headed. Got chills, freezing cold, shivering, and later in the day my ears were ringing. Extremely fatigued.

Approximately 10 minutes after receiving the vaccine in the left arm, the patient began feeling lightheaded and had some chest heaviness. They became diaphoretic and at this point blood pressure and heart rate were checked. HR was elevated to 90 bpm from patient's baseline of approximately 60-65 bpm. Blood pressure was elevated at 150/100 mmHg. Pt was provided water and symptoms resolved. Patient was monitored an additional 30 minutes and did not have any recurrence of symptoms. Blood pressure and heart rate returned to baseline.

Patient felt flushed, heart racing. Had irregular rhythm. Transported to Emergency Department. Treated with epinephrine. EKG performed, having pre-ventricular contractions. Checked in to ED for further evaluation.

Fever, severe body aches, severe chills, still have symptoms this morning although less severe.

Patient came to workplace clinic 12/17 @ 1215 saying she had a reaction to the COVID vaccination. She stated she took ibuprofen in the morning for the headache, however, rash was still present. N/V on 12/16 at night. Patient reported no throat swelling or SOB. Rash on injection site (left) arm and chest. Patient received Benadryl 50 mg po x 1 dose and Tylenol 500 mg po x 1 dose. After Benadryl and Tylenol, patient felt better and was able to go back to work. recommended to go home and rest.

12/16/2020 episode of abdominal cramps I had a BM episode of loose stools and soon after that within seconds I started profusely sweating on my forehead and felt lightheaded and very weak, My wife noticed how much i was sweating my body was cool and clammy, episode lasted at least 5 mins if not more so I just laid down until I started feeling better. Once symptoms subsided I took 1000 mg of tylenol, Heavy head throughout the day.

Myalgias, headache, neck pain

Injection site soreness started about 3 hrs post-injection. By that evening I was experiencing body aches & chills. I took Advil 400mg with dinner and felt okay for about 4 hours. As soon as the Advil wore off, body aches & chills returned. I did not take anymore Advil that night. My sleep was restless with body aches, chills, & pain at the injection site. I took my temperature during the night and was afebrile. I woke feeling tired with a mild headache. I took Advil after breakfast and currently feel okay.

About 5 minutes after the vaccine developed chest tightness, increased work of breathing, palpitations and severe dizzyness. Transferred to the ED where i received oxygen, IV benadryl, IV fluids and monitoring. Released after about 4 hours and continue to take benadryl 50 mg PO q 4 hours. Also developed red facial rash (unknown time) Pain at injection site began the morning after the injection.

tachycardia, flushed,low grade fever

My left arm was very sore and very painful to move and ached.

Throat swelling, raspy voice, tachycardia, itching, anxiety, rash

patient felt jaw pain, a strange taste (unable to describe), and numbness in her right arm patient was monitered and symptoms resolved within 30 minutes of vaccine administration

Nausea, fatigue, body aches, joint pain, malaise

40 year female received Pfizer-BioNTech COVID-19 Vaccine today Patient reported prior h/o severe allergic reaction to influenza vaccine with eggs preservative. She has received flu vaccine w/o egg w/o problem. Due to her prior history of severe allergic reaction/ anaphylaxis to another vaccine, in this case flu vaccine with eggs, we should proceed with caution. She was told we could defer vaccination until more information becomes available. She opted to proceed with receiving Pfizer-BioNTech COVID-19 Vaccine and be observed for 30 minute observation period. Patient developed throat tightening approximately 20 minutes after vaccination. She received EpiPen within 1 minute of symptoms and was sent to ER immediately in wheelchair by nursing staff. Patient was evaluated in ED and was hemodynamically stable. She was given IV benadryl and was stable throughout observation

"1204 Patient became flushed and started saying she was having a difficult time ""catching her breath"". She then became tachycardic (upper 90's- low 100's). 1205 Benadryl given (25mg). Physician called down to clinic. Vital signs obtained and showed increased BP (145/90) and pulse. 1214 Patient verbalized she was feeling a little better. Monitoring continued until 1245, vital signs were improving and patient no longer had symptoms. She was released at 1252 but encouraged to seek medical attention if she developed new symptoms or had symptoms reoccur."

At 24 minutes after vaccination, pt experienced chest tightness, shortness of breath, cough, flushing, and rash on chest and neck.

woke up the next day and felt nauseated, could not stand up, my heart started racing, I had to lay down, felt cramping, extreme fatigue, felt overall sick, and the pain at the injection site. No fever. Just lasted that day. Feel better today.

during the administration of vaccine patient developed a wheal at the site on injection. Pressure and message reduced the wheal.

Today I have really bad stomach cramps and diarrhea. Yesterday I had a temp 101.2 with tylenol, chills, joint pain and really bad headache

Caller stated after injection at bout 9pm caller had severe headache with nausea and pain at injection site . Caller stated this morning she felt a bit better.

Pt showed for Covid Vasc #1, received the immunization in left deltoid. minutes later, felt numbness, in arm, the a lump in the throat. Denied SOB, or Dyspnea. Patient the stated weakness in the legs. Assisted to the restroom, x 1. no difficulty. after 30 minutes and no relief from symptoms, patient was wheelchaired over to urgent care, and treated there. Patient was able to leave urgent care on her own, with no problems Patient transferred to urgent care for evaluation. Left from urgent care on her own

Employee had tingling sensation in Right upper extremity, and heaviness in bilateral lower extremities 5 minutes after receiving vaccine. These symptoms resolved approximately 2 hours after they began

Patient states she got a headache 30 minutes after taking the vaccine. Checked on patient 4 hours later, still complaining of a headache.

Pain at the injection site and the whole arm felt sore. Felt like a pressure behind my eyes, very tired, extreme fatigue.

1215 pm on 12/16/2020: pfizer covid vac in left arm Poor nights sleep with left arm pain at injection site 500am on 12/17/2020: stood up to get ready and immediately started to dizzy. Then immediately threw up and had darker green diarrhea. Once that finished I had the sweats and felt cold with a subjective fever until around 9 am with continued nausea. Symptoms resolved 11:40 AM.

"Patient state, one hour after vaccination, ""I got the warm feeling, I got hot"" Temp taken at 2 hour, no temp. Temp taken 4 hours later, no temp."

Chills, Body Ache, Hard around the injection

12/15/2020 I was tired, body chills, pain in left arm but was all very light until 12/16/2020 headache was more severe

Immediately after the injection the tips of my finger began to go numb my hand started itching my throat started to go numb and itch and I got 25mg of Benedryl symptoms got worse so they had to give me in IV injection of benedryl which made the symptoms a litter better. I was released and when I got home I went to sleep. When I woke up my body felt like I had been run over by a big truck. I took my temp and it was 99.8. I laid back down and decided to sleep it off and woke up this morning not feeling any worse but not any better. My hands got red from the rash and is still a little red.

After receiving the injection, patient felt flushed and lightheaded. Began to feel like heart was racing and chest tightness. The patient's heart rate was checked, the patient was provided with Tylenol and water, and observed for an additional 15 minutes. Symptoms resolved during this time.

At 11:15am, patient received first dose of SARS-CoV-2 vaccine. At 12:00pm, patient began to develop a rash and had mild edema noted in the uvula. She did not have difficulty breathing/swallowing/speaking. She was given prednisone 50mg x 1 and diphenhydramine 50mg x 1 in the ED.

Headache

1450 COVID19 vaccine given. 1503 Patient verbalized a racing heartbeat. 1504 Vital signs obtained, BP & HR were elevated. 1507 Physician paged. 1509 Patient reports feeling much better. 1511 Physician arrived to evaluate. 1516 Patient no longer had symptoms. Vital signs improving. Verbalized understanding to seek medical attention if symptoms reoccur or new symptoms begin. Patient left.

Dr.; the following day 12/16/2020, I woke up feeling more fatigue then usual with a migraine. Severe with nausea and light sensitivity. AE occurred about 4 hours. Resolved with Advil and Zofran. Missed work 12/16/2020. 12/17/2020 feel back to normal

Sensation of swelling around the mouth and throat felt funny

Allergic reaction to vaccine +1 more Dx Referred by MD Reason for Visit Progress Notes PA-C (Physician Assistant) ? ? Physician Assistant Cosign Needed á Patient was seen at COVID Vaccine Clinic today for her first dose of the COVID 19 vaccination. She denied any history of previous adverse reactions to vaccines. á She was given the Pfizer-Biontech (lot: EH9899) vaccination in the left deltoid muscle. á During her 15 minute waiting period after the injection, the patient began to experience oral tingling (upper lip and then into the lower lib) It then progressed to the tongue and she reported tingling to the tip of the tongue and further back to the middle of tongue. She thought there might be some mild swelling to the tip of the tongue. She denied rash, hives, welts, difficulty breathing, difficulty swallowing, wheezing, throat tightness, hoarseness, stridor, itching, lightheadedness, dizziness, facial swelling and lip swelling. á This Staff member was notified of patient reaction and she was then assessed in the emergency bay area. á PMH: Hx hypertension but did not take her medication today. Patient had recovered from the COVID-19 virus about 2 weeks ago. á Vitals Time 1130 BP 170/90 HR 86 s/r RR 14 nl O2 97 % á Physical Exam Constitutional: She is oriented to person, place, and time. She appears well-developed and well-nourished. No distress. HENT: Head: Normocephalic and atraumatic. Right Ear: Hearing and external ear normal. Left Ear: Hearing and external ear normal. Eyes: Conjunctivae are normal. Right eye exhibits no discharge. Left eye exhibits no discharge. No scleral icterus. Neck: Normal range of motion. Cardiovascular: Normal rate, regular rhythm and normal heart sounds. Pulmonary/Chest: Effort normal and breath sounds normal. No stridor. No respiratory distress. She has no wheezes. She has no rales. Musculoskeletal: Normal range of motion. Neurological: She is alert and oriented to person, place, and time. No sensory deficit. Gait normal. Skin: Skin is warm and dry. She is not diaphoretic. Psychiatric: She has a normal mood and affect. Her behavior is normal. Judgment and thought content normal. Cognition and memory are normal. Vitals reviewed. á á Treatment included antihistamines. Patient was given 50 mg of benadryl at 1138. á Vitals Time 1147 BP 160/100 HR 90 S/R RR 14 nl O2 98% á Response to care: Patient states the upper lip resolved but the lower lip and tongue sensations remained but did not worsen. Patient was recommended to go to the hospital given her sudden response with concern of tongue swelling. Patient did agree to this. COVID staff was made aware that the patient would be leaving her SUV in the parking lot. á Patient was transfer by Response team to the hospital at 11:53 AM. á á

Pt underwent 15 minutes observation and felt fine during that time, while walking back to work on the way to work unit noticed tingling on the L side of her lower lip and a few inches back along jaw. It persisted so she returned to the vaccine clinic for evaluation. She was evaluated by a physician and had a normal cranial nerve and motor exam other than diminished sensation CN5- no change in appearance of lip. There was no other reaction at vaccination site or change in symptoms during a further 30 minute observation period. She was released back to work. Checkin after a few hours the tingling had improved.

On the night 12/15 exp body aches typically how you feel when having a virus, no fever, no gi symptoms. The following day I had fatigue and one point had chills, body aches. Then took Motrin on night of 12/16 and felt better on 12/17.

Began to feel weak, felt as though going to faint, became cool and clammy, BP 100/70 P 46, O2 Sat 100% on room air, no loss of consciousness. Taken to ED - noted patient did not eat prior to getting the vaccine

Light headed, felt faint. Vitals remained stable. Did need to lay down for approximately 30 min. then sent to ED for evaluation

I had pain at the injection site, swollen, body aches, and headache. It eventually just went away on its own. Did not take anything for it. Arm feels better after using it. Now I am just tired.

On day after vaccination: Left arm soreness, chills, headaches

sudden onset of rinorrhea 5 minutes after receiving vaccine. then itching near ears, 5 minutes later had diffuse itching a rash, was sent to ED. There was evaluated for mild shortness of breath and hives on wrists. Did NOT et epi but did get benedryl and steroids, discharge home

Two minutes after vaccination, she reported itching at the site. Upon assessment, red hives started to develop. Dr. came and assessed patient. Benadryl 50 mg. PO and 2 puffs Albuterol administered by Rapid Response Team RN. Tightness in chest, lightheaded, lungs clear throughout, itchiness in left arm. Resolved within 15 minutes.

Muscle aches , Joint aches, cold sweats, chills, Stomach Pain, Diarrhea

tingling in arm at the time of admin down into fingers which faded over 15 mins and then soreness in arm

Last night I was slightly nauseous, tired and full body aches and today I am just tired and still suffering from the full body aches.

tingling in lips no treatment

headache, red raised area at injection site, 100.6 fever, fatigue, muscle aches

Itching all over the body

12/15/2020 little bit of a headache at night and took an ibuprofen, intermittent nausea the next day, around 530 pm 12/16/2020 fatigue joint pain chills, I had a fever but I did not take my temp, nausea at 9pm I took ibuprofen and this morning 12/17/2020 I woke up fine.

Immediately after the injection, site turned red, I got hot and began sweating profusely. This lasted about 10 minutes and resolved.

Within about an hour headache and mild pain at the injection site, around 4:30/5PM all other symptoms hit: chills, fever, fatigue, runny nose and diarrhea, joint and muscle pain, very sweaty and clammy skin

Paresthesias of lateral tongue and throat, subjective swelling of tongue and throat, subjective shortness of breath

Caller stated that headaches occurred at 12 in the afternoon and fatigue set in through out the day. Caller took Tylenol and Advil with no relief. Caller stated 12/17/20 headache and fatigue went away.

Patient may have received undiluted Pfizer COVID-19 vaccine 0.3 ml= ~120 mcg

Headache , fever 100.8, chills, Fatigue, body ache . Nausea

Swollen tongue, scratchy throat, rash, tachycardia, and raspy voice

Morning after he got the shot....Wave of severe fatigue, had to lay down as he thought he would fall over. Temperature went up a 1/2 degree celius. Went back down later that day. 12/17/2020 2:34 am he woke up with rigors and chills, went away in 3-4 min. Had abdominal pain later during the day.N

2 1/2 hours after the shot, I felt pressure building in my head, my eyes felt bulging, my throat felt tight, and I started having an asthma attack

Symptoms- light headedness, dizziness while in the 30 minute observation window, EE reports she drank water and immediately felt better. EE also endorses mild HA shortly after. EE endorses symptoms completely resolved by 1:30 pm. Called vaccine support line at approximately 3:43 pm to notify us for our records.

During COVID vaccine administration being held at Medical Center, vaccine was administered by Health Department staff on 12/17/2. At 1:30 pm, during observation, patient stated he was having mild chest pain that was not there prior to vaccine. Client walked to observation room, blood pressure taken 169/89. Patient rated chest pain 1/10, described it as random sharp pain. In ER observation room, client was offered EKG which was declined. Patient was then offered to check in through ER for monitoring, patient also declined. Continued to monitor patient until 2:00 pm, at which point patient stated chest pain had subsided and he requested to go home to relax. Encouraged to return to ER if chest pain returns.

Severe dizzy spell about 5-10 following injection, helped to the floor, this lasted approximately 30-40 minutes after start of symptom. Hot flashes and visual disturbance lasting into following day.

12-16 I was nauseous, I received the vaccine and walked to my department, I ate a graham cracker and didn't subside the rest of my shift at 130pm and went home and ate lunch took Tylenol laid down, at that time my arm started to hurt at the injection site. And when I woke up later that night around 5pm and was feeling better kind of tired but good. Coworkers could tell I didn't feel good. I felt like I needed to have a Bowl movement and urinate more than usual

woke up at 3am with diarrhea and nausea . Woke at 6 am with fever of 101.7, joint pain, Headache and fatigue any myalgia

Fatigue and headaches 12/14/2020 about 12pm , Caller took Tylenol and advil with no relief and next day pain had subsided.

I had headache, muscle fatigue, nausea, stomach pain, severe joint pain in the shoulder where I received the injection. I got Covid tested yesterday afternoon to be safe and I'm waiting on the results.

Chills nausea sweats headache

Patient reported feeling fine for the first 15 minutes after the vaccination was given then reported itching of her face excluding her forehead. Patient was given 25mg IM diphenhydramine. Pulse ox was taken and read within normal limits. Within 5-10 minutes after the diphenhydramine was given patient reported itching involving her arms, facial flushing but no shortness of breath. An extra dose of 25mg IM diphenhydramine was given and an IM EpiPen.

Facial swelling, slurred speech, taste in mouth (medicine like), heart palpitations, rash to chest and face.

Joint Ache , Dizzy, tickly throat, Tiredness,

"Patient complains of ""tingling sensation down arm radiating to the hand"" Patient given 25 mg PO Benadryl."

COVID vaccine administered to patient. She began to have lightheadedness and dizziness. She disclosed she had not yet eaten for the day, except for a glass of milk. Writer brought her to an exam table and had her lay down. After 5-10 minutes, she was given a banana and two small apple juice boxes. She then laid back down. After another 5 minutes, she complained of headache and slight phlegm development in her throat. Dr. was called to evaluate- after an assessment, she asked for a BP. Writer completed the vitals and found her BP was 113/77. 5 more minutes passed. Dr. advised that since her situation was not improving and headache and phlegm appeared to be getting worse, patient should receive epi and go to the hospital. Writer administered 0.3mg/0.3mL of epi and drove patient to the Emergency Department of Hospital. She was there for about two hours before being discharged. Symptoms largely resolved by the evening.

Patient reports chest heaviness, muscle aches, loss of energy. No fever or chills noted.

Pain in right arm , Pain in shot site

Patient with tachycardia and elevated BP about 20 min following vaccination; O2 sat okay; sat down for 15 min and symptoms resolved without treatment

Patient is suspected to have received 0.3mL of undiluted vaccine (150mcg vs 30mcg). Patient reported having a dull headache 3/10 pain scale since yesterday afternoon post vaccination. Patient also reported soreness in her right arm down to her elbow. She did not experience any other symptoms.

12/16 It's hard to know because I have a fever but I work on the COVID unit and there has been an outbreak, chills, fatigue, and the thought of moving to take a shower I feel in pain

"Heart rate increase, flushed for about 20 minutes. She has an internal monitor/defibrillator. States ""it feels like when they do a dvice check."""

about 15 minutes after shot, pt had itching. After another 15 minutes the itching resolved and patient left facility

12/16/2020 Pain in the left deltoid uncomfortable to elevate and abduct my arm, it feels better today but it hurt yesterday to even elevate my arm to the steering wheel of my car

Pfizer-BioNTech COVID-19 Vaccine EUA within the first hour of dose, facial numbness on right side of face that migrated to lips. Within 2 hours of dose, nausea.

Patient experiences palpitations, dizziness, and hypertension within 10 minutes of receiving the vaccine.

Patient reports it started as a tingling, pain and burning in the elbow and travelled up the shoulder and up the chest and to the heart. Pain felt like a cardio thump . Grabbed the epi. Sitting forward. Talked Dr. Doctor stated to sit back and uncross legs. Initiated slow breathing. Pain subsided to a tolerable amount. Not short of breath but tachycardic. Still dizzy. Stayed an hour sitting position, after injection. Felt there was an irritating sensation around the heart. Left and walked back to clinic. 10 minutes after arriving to the clinic, dizziness, flushing , came back and irritation around the heart was still noticed but tolerable. 2 minutes after, voice started cracking and drank some water. Intensity of dizziness increased and overall symptoms also intensified. Returned to COVID immunization clinic 15 minutes later. Patient was moved to direct observation in a chair. Given oral benadryl. Instructed to stay and would evaluate if new interventions would be deemed necessary. Benadryl helped. Symptoms were relieved in 15 mins. Patient has been in the clinic under direct observation for about 3.5 hours.

I got the injection on left deltoid and went to sit doe town. seafood allergy started to get hot, flush nasal passage way got really dry and got headache, face and mouth tingling. The headache felt like a rubber band around my head and continued to get hot 20 mins. When I got up to walk out felt light headed. Then went to the clinic dint feel right couldn't focus, temp was 100.Also exp gi problems had loose stool. I took Tylenol and Motrin for headache/fever and also on 12/17. Had to leave work early on 12/16 and was able to return on 12/17.

Headache and, limited motion to the Injected arm

Fever 102, nausea, headaches, muscle pain, lightheaded, chills

Right ankle swollen within an hour of injection. Felt like sprain. Still swollen but pain better today. Took naproxen.

elevated heart rate 102, flushed, cold, tingly fingertips

Pharmacist was diluting doses of vaccine for vaccination clinic in hospital. After dilution of 3 vials, the compounding pharmacist passed off to the on coming pharmacist. The on coming pharmacist grabbed one of the empty vials of vaccine and added diluent to the empty vial. 6 doses were drawn up and delivered to the vaccine clinic with only diluent in the syringe. The pharmacist in the clinic noted the number of syringe doses exceeded the number possible from the amount of vials used and sequestered all vaccine doses in clinic. It is possible some of the patients in the first hour received diluent instead of vaccine but is not known for certain. The pharmacist at the clinic kept the record of all the patients in the morning clinic. Would you recommend any actions prior to the second dose for these patients? Is there any utility in antibody testing the identified patients prior to administering the second dose? Have parameters been established for titter? Please provide direction.

I work night shift so when I got home 12h after my injection and at approximately 11:00 (am) my back hurt but not terribly. When I woke after sleeping today at 4:00 (pm) I experienced joint pain in my bilateral elbows, bilateral shoulders, neck, lumbar spine & bilateral knees. It's mild pain and I will not be going in for an MD appt. It does hurt a little more if I bump into something.

"1658 Patient reports feeling lightheaded after receiving COVID vaccine. VS obtained, BP & HR are elevated. 1700 PA called 1702 PA arrived Patient remains lightheaded with some palpitations but denies any trouble breathing. 1711 VS are improving 1716 Patient states she starts feeling better but then gets a new wave of lightheadedness with ""fogginess"". Monitoring continued. 1741 Patient starting to feel ""extra lightheaded"" 1742 Benadryl given per PA 1748 Patient verbalized a headache 1818 Medic called because BP & HR have not improved after 1 hour of monitoring. 1825 Medic team transported patient to the ER"

Immediate swelling at injection site, approximately 1.5cm diameter and raised about 1 cm

PAIN AND REDNESS ON INJECTION SITE.

Patient developed hives, facial swelling, throat swelling/itching, and nausea approximately 13min after vaccination while in observation. Patient immediately taken to Emergency Department where epinephrine was given IM in the left thigh followed by 125mg IV solumedrol, 50mg IV benadryl, 1000mL NS, and 20mg IV famotidine. Hemodynamically stable throughout ED course.

I had arm pain. Yesterday I had a hot flash with throwing up and diarrhea.

Approximately 5 minutes after receiving vaccine I noted an intense flushing and burning sensation from my waist up followed by tachycardia with heart rate in 150s elevated BP 150/100. These symptoms subsided after approximately 10 minutes but were then followed by a ?cloudy? feeling in my head as well as tingling in bilateral hands that lasted the rest of the day but had resolved by the next morning. The next morning I felt very well until 2 pm when I had a short period (approximately 2 minutes) of elevated heart rate (120s) that then resolved.

End of monitoring period, when staff asked how he was feeling he said he was having palpations. Nursing checked his HR and associates HR was 100-120BPM. But denied chest pain and SOB.

Soreness to arm , Couldn't lift arm above shoulder

Fever of Tmax 100.5, chills and headache 24 hours after receiving the covid vaccine

Left arm pain. Painful enough it awoke from sleep when I would roll on it. It is tender to touch. However no limit to range of motion or use

Within 10min patient first experienced feeling hot and tightening of throat. Patient visibly sweating on forehead. Patient expressed feeling extremely flushed. No meds given per patient request. 30 min post-vaccination, patient now feeling very cold, throat feels better but still a little tight, and a little dizzy. No nausea.

After vaccination in the medical office building adjacent to the hospital, the hospital employee felt palpitations (within 30 minutes of shot). Employee went to the ED at the hospital and was evaluated by medical personnel. Employee was SOB but did not have difficulty breathing. No other untoward reactions were observed. All other ROS was unremarkable. Sinus tachycardia of 140bpm observed in the ED, repeated ECG was sinus tachycardia of 119bpm, no other abnormalities. IVF, 50mg IV diphenhydramine, 40mg IV famotidine, and 125mg IV methylprednisolone given. Symptoms of palpitations and SOB resolved. Discharged with instruction to return to the ED if any symptoms returned.

Elevated temperature, muscle pain, tiredness

TINGLING AROUND LIPS, MONITORED FOR ADDITIONAL 15 MINS. (TOTAL OF 30MINS), PATIENT STATES TINGLING RESOLVED. REPORTED HEADACHE BUT STATES SHE HAD IT ALL DAY.

Approximately 10 minutes after vaccine administration, patient reported wheezing and coughing. Patient received epinephrine IM, IV Benadryl, IV solumedrol and racemic epinephrine SVN. Patient never developed a rash, hypotension, swelling of the lips, mouth or tongue, other GI side effects . Per ER attending and admitting physician, this reaction seems to be a clear exacerbation of the patient's tracheomalacia. The patient was more responsive to racemic epi SVN as opposed to IM epi. Patient admits that psychological stress may have been a component of her symptoms. The admitting physician does not consider this to be an anaphylactic reaction to the vaccination.

I received the vaccination on 12/14 no problems 3-4 later sore arm. After went home next day on 12/15 had a sore arm went to work as normal. At work left early felt tired went to bed early around 8pm. The next day on 12/16 overslept important morning meeting reported to V-safe was feeling tired, mild headache and had severe fatigue. On 12/17 felt much better not as tired returned to normal and no headache.

Joint Pain , tiredness, Body Ache . Injection site pain, fever

5 minutes after I received the injection, I experienced a mild headache and metallic taste in my mouth, with very slight dizziness for a couple seconds. I reported the mild headache and taste disturbance to the RN in the Covid vaccine room before I left for her information. I stayed 15 minutes , then walked to

my car. I sat in my car, then began to feel cold, dizzy, and my heart began to race. I walked back to the Neurology clinic where I work as an NP, and sat in the Neurologist's office, who observed me to be pale and sweating. I continued to feel dizzy with tachycardia for about 7 minutes until this resolved. The only symptom remaining after this was a headache and metallic taste.

Around 4:15PM, employee's arm felt very hot and extremely itchy. Light pink rash on left upper arm around injection site. No respiratory symptoms. She received diphenhydramine 25mg IM; 15 minutes later she stated her symptoms and rash were improved.

1. Left arm very sore, could not abduct more than 40 degrees, hard time sleeping, lasted for about 26 hours 2. Elevated temp to 100.2 F with chills and myalgia, lasted about 8 hours on second day 3. Diarrhea and indigestion for 2 days

About 20 minutes after the injection, the arm i received the injection in became very cold, changed color like I was not perfusion to the limb. This was gone in about two hours. Woke up eye lid continually twitching.

numbness to right ear and in front of ear. Also right ear feels plugged/underwater sound, Very sore left arm injection site.

Loss of taste

After an hour I got vaccinated, I started to feel nauseated and started throwing up. Theres pain and heaviness on the injection site. I had a headache as well.

Patient reported she was pregnant at time of screening. Patient confirmed that her and her OB/GYN discussed the COVID19 vaccine and determined it was the right decision for her to receive the vaccine. Upon receipt of the vaccine, she stated she was feeling flushed, nauseated and felt she was going to pass out. The vaccine clinic team took her to the ED for evaluation and monitoring.

Palpitations, shortness of breath, lump in throat

Racing heart, itching throat. Heart racing resolved in 45 minutes, Itching throat never worsened and resolved after taking Benadryl and sleeping. Woke up 12/17 feeling fine, but also has a golf ball size knot and redness at injection site.

6 minutes after receiving the vaccine I became lightheaded. I was the worst for about 1-2 hours after the vaccine but then symptoms improved some. 11 hours later I am still mildly lightheaded.

Headache, fever, malaise, body ache

I developed moderate to severe pain in my deltoid (of injection) that lasted 48 hours. I would describe the pain as 8/10 and moderately affected my ability to use my right arm on 12/16/20. I reported the side effect to VSafe, who called me and asked me to submit a VAERS.

Soreness injection site Headache Prickly sensation of skin Weakness/fatigue Stomach pain/nausea/ loss of appetite

Noticed Arm pain at bedtime on the day of the injection. Soreness lasted approximately two days.

Warm flushing feeling within about 10-15 seconds of injection, as well as metallic taste in mouth. Repeated on an off for the next hour. Taken to ED of hospital. Noted right arm mild rash distal to injection site and on chest, mild to moderate nausea.. IV Bendadryl 50mg given, IV Solumedrol 125mg, IV Pepcid, IV Zofran. Discharged home with PO prednisone x 4 days. PO Pepcid and Benadryl PRN

10:00 am received vaccine @ medical center right side of mouth felt strange on the way home. 13:00 pm right side of mouth continued to feel strange. Looked in mirror and noticed uneven smile, right side of mouth drooping. 13:35 pm messaged my primary care MD. And called Nurse triage. 14:00 pm Nurse triage advised me to go the emergency room ASAP. 15:00 pm @ Emergency room. Stroke code called, labs, CT, MRI completed. Diagnosis Bell's palsy. Went home with steroid and anti-viral. Symptoms are improving.

tachycardia, HR up to 130s 1 hour after vaccination. Tachycardia while sitting down. Lightheadedness. Tachycardia improved but still100-118 while at rest for hours

SOB, tingling

Nausea, myalgia, injection site pain, malaise, diarrhea, chills, joint pain, headache, nasal congestion,

40 min after injection my throat and tongue started to feel weird and tight, pharmacy at my work hospital gave me 25 mg Benadryl and 650mg Tylenol. At about 1 hr 45 min after injection my throat got to the point of so swollen and itchy I couldn?t swallow. I went to nearest emergency room hospital they administered decadron orally, Pepcid P.O., and Toradol via IM.

I received 1st dose of the vaccine at 4:30pm on the 15th, felt well and at my baseline. The morning of the 16th (~1030), I woke up with my face and cheeks swollen and mildly red. I then took 50mg Benadryl and 10mg zyrtec, and iced my face (1 zyrtec in the morning, another at night). I began to see improvement in my swelling. The morning of the 17th I took another 50mg of Benadryl and my face is back to it's baseline.

Headache - centralized at front of head, from temples to forehead; no treatment taken; resolved after a nap; lasted about 4 hours

Patient reported that she started to feel unwell immediately after the vaccine with some nausea. She presented to the Emergency Department where she was treated by myself approximately 17 hours vaccine administration. She was having vomiting, diarrhea, diffuse rash, and throat discomfort. She was successfully treated for anaphylaxis and was able to discharge to home.

Fever and chills that started approximately 24 hours after injection lasting for approximately 8 hours.

hot flushing feeling, light headed, legs heavy gave patient a chair to sit and candy symptoms resolved by 11:36

Seizure approximately 24 hours after vaccination

vasovagal response - dizziness and nausea which lasted about one hour after injection - resolved with supine position and dry cereal

Immediately after administration felt a strange sensation on nostrils and mouth that dissipated after the initial 15 minutes. Then I started with mild itching in the next arm and neck. About 30 minutes after administration my eyelids became swollen. No shortness of breath or tachycardia. I received Benadryl and solumedrol at ER. Stay at the ED for about 2 hours and left home. After that I felt strange for a while and could not sleep at all. The next morning everything was fine except for mild left arm side of injection pain.

Headache. Aleeve X2 taken Thursday 12.17 at 2p. went away after several hours. Have another headache this morning

Hives at the injection site 2-2.5 hours later extremely itchy and bumpy, self limited to the upper arm, resolved 3 hours later only intervention was ice as uncertain if Benadryl or steroids would have blunted an immune response

COMPLAINS OF NUMBNESS TO TIP OF LIP WITHIN MINUTES OF ADMINISTRATION. DENIES HISTORY OF ANAPHYLAXSIS. TRANSFERRED IMMEDIATELY TO HOSPITAL ED

5-10 minutes after vaccination, vasovagal syncope: pallor, diaphoresis, dizziness, tunnel vision, nausea, weakness, tingling in arms/legs, BP 103/69

undiluted dose given

soreness in right hand...seems to go away as i start to move my arm

undiluted dose given

Event happened outside of the ER at a clinic and not witnessed by any hospital staff. Patient reported dizziness, shortness of breath, headache, chest pain, sore throat, hoarse voice and tightening in the throat and chest minutes after vaccine administration. Treated with IM epi on scene by EMS. In the ED abtou 30-45 minutes after event, given IV normal saline, solumedrol, benadryl, and famotidine. Given PO potassium after labs for mild hypokalemia. She was monitored for about 4-5 hours total in the ED with complete resolve of symptoms.

severe, acute hearing loss and tinnitus in R ear.

Right arm soreness, headache, hot flashes.

Received the vaccine at 2:30 PM. Approximately at 2:50 I started feeling paresthesia of my left leg, approximately 1 to 2 hours later a progressed to my left arm. Around 8:00 PM it progressed to my right

leg, right arm, torso and face. I subsequently took Aleve. No significant shortness of breath, or weakness noted. This morning paresthesia continues but less apparent. It feels more apparent in my left side. I can no longer feel it on my torso or face.

Fever with max of 101.9, headache, chills, heartburn, cough, fatigue.

Breastfeeding toddler developed rash to torso, back, and cheek

Metallic Taste in the mouth; lasted for a few hours.

Chest pain and tighness, generalized with stabbing pain intermittently elevated blood pressure 180/95

She became diaphoretic, her throat felt dry and as if it was beginning to close. Rapid response was called and she was transported to the ER. She was tachycardic, experienced chest tightness, and shortness of breath.

Pfizer-BioNTech COVID-19 Vaccine EUA - Sore and sensitive right arm

fever, fatigue, injection site slightly red and raised

31 hours after the vaccination I woke up at 11:00 p.m. and had two and a half hours of alternating sweats and chills that went away with 1000 mg of acetaminophen and 600 mg of ibuprofen. I did not have a fever, my temperature was 98.8, and I did not have diffuse muscle lakes. this was similar to but much shorter lived in milder than my reaction with shingrix earlier in the year.

Fever of 100.2, joint pain and fatigue

Dizzy,Hives on neck and chest, body aches

Monitored 30 minutes in clinic, woke up at 930pm itchy hands/arms, then spread. No respiratory issues, but called to ED. Spread to thighs, and back of legs rash. 10:30 ED medicated with IV Solumedrol, Pepcid and Benadryl. Sent home with Prednisone, Pepcid and taper. Dr. spoke with this am and plan to pre-medicate prior to 2nd dose, but does approve. Monitor another 30 minutes . Rash resolved minimal on forearms.

pruritis of upper extremities. Erythema of bilateral palms and dorsal wrists

Severe headache, fatigue, muscle aches

Metallic Taste in the mouth lasting for several hours post vaccination

body aches, chills, right arm pain and some swelling which is migrating to right axilla and right breast

Headache, fatigue sudden onset at 10 am, resolved after acetaminophen

hives all over body. with swelling.. Red eyes.

Patient received two Pfizer-bioNTech vaccinacation on the same day by accident. Received both doses in a time span of 5 minutes apart. (Received both doses in left arm). Patient kept in observation room for 30 minutes after time of vaccination to monitor for any adverse events. Patient will contact nursing supervisor if any severe adverse events occur within the week.

About 5-10 minutes the vaccine I began to get tingling and a itchiness in the back of my throat , notified personnel and vitals were checked and stable. The tingling and numbing sensationent away and came back and benedryl was given. The symptoms came in waves of about ever 2-3 minutes so I was transported to ER and somumedrol was given was monitor for 1-1.5 hrs and the numbness and tingling sensation continued for about an 1-2 hours and finally subsided and was released to go home

Bleeding and significant swelling (marble size) at site immediately after administration.

Swelling, redness, warmth at the injection site starting approx 15 min after injection was given. Then severe itching starting in right arm, right side of head approx 25 min after injection. Then itching progressed through the entire body including toes Claritin 10mg taken approx approx 2 hours prior to inj Allegra 1 tab Diclofenac 50mg Tylenol 1000mg Pepcid 1 tab Solumrdrol 40mg IM All given at approx 8:30am Itching continued. Inj site reaction started to improve. At approx 9:20am Benadryl 50mg taken at 10:00am Benadryl and Pepcid repeated at 6pm due to return of itching Facial flushing and temp of 100.1 orally noted at 6am the next morning

Dry, Scaly hands - Bilateral

Pt with dizziness, bilateral arm tingling and hand sweating. Hands extremely cold. Vital signs wnl

Ear pressure followed by bilateral under arm soreness. Later in the day both arms warm to touch and felt swollen. Face flushed and overall body aches and inability to stay awake. 600mg ibuprofen and rest. Felt myself in morning except as expected left arm pain at injection site and a little left arm tiredness or weakness.

Sore at the site of injection, and sore.

Urticaria, pruritis, headache

PATIENT REPORTED FEELING TINGLY ALL OVER AND NOT RIGHT, placed in supine position, HR 120's, BP 186/96, RR 24, not diaphoretic, patient was transported to ER where she was given Zofran and IV Benadryl. She reports that the Benadryl helped immediately. She took an oral dose of Benadryl after being discharged home.

Rash - noted all over body - mostly trunk, neck, upper arms bilaterally - mostly macular with slight papular component. Significant itch.

Approximately 90 minutes following first dose of vaccine, developed severe headache, chills, joint pain and full body muscle aches. Continued throughout the night and were improved by next morning, but not fully resolved by the time of this submission.

None stated.

Gradually improving.

None stated.

Hypothermia with body temp of 95.0 F. Treated with heating blanket and covers.

"5 minutes after the Pfizer Covid-19 vaccine administration, the patient developed flushing, hives, felt warm and eventually short of breath. She started to wheeze and was wheeled into ER c/o ""I can't breathe while holding throat and thrashing with facial flushness noted. PT took 2 Benadryls and had several Epi shots. She was then discharged from the ER and later on that day, started to feel short of breath again. In the ED today she was audibly gasping for air, however had no wheezing, had a normal saturation and a normal blood pressure. She had taken another dose of her EpiPen IM and diphenhydramine 50 mg by mouth prior to coming. She was then admitted to the hospital for further observation. While on the floor, she started to feel short of breath again (about 9 am on 12/18/2020), which required an RRT . Patient received another dose of diphenhydramine IV, methylprednisolone 125 mg IV and several doses of IM epinephrine. She also required oxygen. She was then transferred to an ICU for further care."

None stated.

My symptoms started with bodyaches and fatigue. Quckly followed by a fever that reached 102.4. Later that night I had congestion, cough and headache. Woke up the next mornign with moderate/sever bodyaches, chills, cough and headache. Moderate fatigue as well. Had to miss work.

Entire left side of body muscle aches and joint aches. Started about 2 hours after getting injection and worse the next day

After I received the vaccine about 1 1/2 hours later I started experiencing a metallic taste in my mouth. I am also experiencing no appetite. Throughout the night I had to force myself to eat. I'm still experiencing no appetite and this is very unusual. The metallic taste is still present, but it is getting better

Treatment dugs:

Patient with a h/o syncope to vaccines, felt light headed and laid down on floor roughly 3-5 minutes after vaccination in the observation area. Patient pale, pulse regular in mid-60's, A&O x3, conversant. Medical assistance team called, bp 94/60, lightheaded after attempt at standing for 90 seconds. Transported to ED for observation.

Initial symptoms started in less than 5 minutes were tingling in the lips and tongue. Thickness feeling to the tongue. Progressed to hoarseness to voice that worsened. Received 50mg Benadryl chewable tablets. Symptoms continued to worsen. Epi pen injection in left thigh. 5 minutes later still no improvement and another Epi pen injection in right thigh. Monitored for 5 to 10 min and no

improvement and was taken to the ER. In the ED, received IV fluids, IV Benadryl, IV Decadron and IV Pepcid. Monitored for 3 1/2 to 4 hour and discharged home with 3 days of Prednisone 60 mg and Benadryl po every 6 hours as long as allergic like symptoms persisted. 12/18 morning still with lip tingling and Asthma like symptoms. Voice is still in and out of hoarseness

Slight tingling down left arm into left fingertips

None stated.

On 12/16/2020, approximately two hours after administration of Pfizer BioNTech Covid-19 vaccine, patient developed SOB and chest pain. Patient reported to ED where she was given fluids, diphenhydramine, ipratropium/albuterol nebulizer treatment, magnesium, famotidine, and epinephrine. Of note, patient has anaphylactic reaction to corticosteroids. On 12/17/2020, around 3:00 pm the patient reports to the ED at a different facility (one closer to her home) with difficulty breathing and sensation of her airway closing. Patient again was given epinephrine, fluids, ipratropium/albuterol nebulizer, diphenhydramine, famotidine, and was also given a dose of lorazepam. The patient now has stated that she had an anaphylactic reaction to a prior flu vaccine, however this was not listed as an allergy prior to administration of the Pfizer BioNTech Covid-19 Vaccine.

Patient experienced mild alllergic reaction starting at 4:19pm. The ER staff came to tend to the patient. The patient reported dizziness and weakness. Her vitals are as follows: BP 142/80, O2-99% on room air, Pulse-98, Resp Rate-18, Temp-97.3F. The patient was taken to the ER and received Benadryl 50mg IV and an Epipen. The patient's pain was 0/10. The patient was reported stable at 4:27pm.

Patient began experiencing itching and tingling in lower back and down right leg after leaving the facility (had waited the required 15 minutes). Drove around building and parked and came back in. No rash noted. Vital signs BP 157/73, HR 69, Resp.- 16, O2Sat- 98, Temp- 97. No obvious distress, Alert and Oriented X3. Grips equal and strong, no facial weakness and ambulating without difficulty. After 20 more minutes C/O tingling of lips. Consented to call 911. Assessed by EMS. Vital signs remained stable and patient refused to go to hospital. Called wife to pick him up. Patient required no treatment and left facility at 5:30 pm.

Employee presented to the Emergency Department for dizziness. Patient received COVID-19 vaccination today. About an hour and half later he started experiencing dizziness and lightheadedness. Patient was normotensive with regular heart rate at the time. Patient reports when he would get up to go patient room he would start to feel unsteady. Patient has history of orthostatic hypotension intermittently in the past. Patient reports he had some tingling to his bilateral hands.

12/16/2020-6:00 pm Fever 101.6 body aches 12/17/2020 1:00 pm Sick stomach, light headed 12/17/2020-5:00 pm Stomach cramps, diarrhea Light headed Cold sweats 12/17/2020-7:00 pm Extreme intestinal cramps, diarrhea Loose bloody stool Lack of appetite Light headed Cold sweats 12/18/2020 - 4:00 am Extreme intestinal cramps Loose bloody stool Nautious Lack of appetite Unable to sleep Light headed Cold sweats 12/18/2020 Intestinal cramps/pain Lack of appetite Nautious Light headed

NAUSEA AND VOMITING

Approximately 10 minutes s/p vaccination, employee became sweaty, c/o tingly hands, low BP, c/o nausea. Medical assistance team called, patient transported to ED.

Fever, chills, body aches, headache, injection site pain and swelling

Nurse call line recommended ER visit. Employee opted not to, drank salt water and gradually feeling better, although aches persist.

1 hour after administration of vaccine 0.3ml the staff member began to have a systemic blotching on skin and dry, severe cough.

around 2 a.m. patient woke up noticed weird smell in her nose, and tingling in her fingers and hands on left side and has headache

Pfizer-BioNTech COVID-19 Vaccine EUA Pin and needle feeling throughout body with flushing and hives. Mouth and throat felt tight with numbness sensation in mouth. Voice became very raspy and breathing felt somewhat difficult. Tachycardiac and Hypertensive Reported to the ED, received 50 mg IV Benadryl, 125mg Solu-medrol and 40 mg Pepcid, symptoms began to suside after about 5-10 minutes. Had report throat tightness at approximately 1700 and self medicated with Benadryl 2 times throughout the evening.

Patient began experiencing itching all over body 15 minutes after IM injection. Patient was given benadryl 25mg at 09:22. Benadryl 25 mg dose given again and pepcid 20 mg at 09:53. Patient symptoms are resolving at this time. Notified patient to inform primary physician of itching reaction.

After receiving the vaccine approx. 1 hour he notice redness ant itching at the top/middle of chest. Area approx. 3 X 3. Area was red and warm not hot and not much warmer than surrounding area. Denied SOB or swelling in mouth or chest. Denied itching elsewhere in body.

Pfizer-BioNTech COVID-19 Vaccine EUA. Patient felt dizzy and had elevated blood pressure. Pulse normal.

Patient was seen at COVID Vaccine Clinic today for her first dose of the COVID 19 vaccination. She denied any history of previous adverse reactions to vaccines. She reports that she also had a shingles and pneumonia vaccination on Monday 12/14/2020. She confirmed with both her PCP and transplant specialist that okay to receive all vaccinations. á She was given the Pfizer vaccination in the right deltoid muscle. á During her 15 minute waiting period after the injection, the patient began to experience tongue tingling and swelling specific to the left side of her tongue. She denied rash, difficulty breathing, difficulty swallowing, wheezing, throat tightness, dizziness and lip swelling. She reports similar reactions after receiving other vaccinations. States that those symptoms always resolved with time and never required any treatment. á This APP was notified of patient reaction and she was then assessed in the emergency bay area. á Vitals Vitals: á 12/17/20 1545 12/17/20 1555 12/17/20 1620 BP: 128/85 116/72 126/73 BP Location: Left arm Left arm Left arm Patient Position: Sitting Sitting Sitting Pulse: (!) 109 100

99 Resp: 12 12 12 SpO2: 99% 97% 98% Physical Exam Constitutional: She is oriented to person, place, and time. She appears well-developed and well-nourished. No distress. HENT: Nose: Nose normal. Mouth/Throat: Oropharynx is clear and moist. Neck: No tracheal deviation present. Cardiovascular: Normal rate, regular rhythm and normal heart sounds. Pulmonary/Chest: Effort normal and breath sounds normal. No stridor. No respiratory distress. She has no wheezes. She has no rales. Musculoskeletal: General: No edema. Neurological: She is alert and oriented to person, place, and time. Skin: Skin is warm and dry. No rash noted. She is not diaphoretic. No erythema. Psychiatric: She has a normal mood and affect. Her behavior is normal. Thought content normal. á Patient's health history, medications and allergies were reviewed. She denied any further symptoms and the tongue numbness/swelling resolved in 30 minutes. She specifically denied any difficulty swallowing or breathing. No treatment was required. Pharmacy responded and did advise that current recommendations include no other vaccinations within two weeks of COVID. Discussed with patient. She is advised to notify staff of this reaction when receiving her 2nd dose. Patient release after 45 minutes of observation. á

Felt lightheaded about to faint @0920 which resolved @930

Itchy throat and back of tongue, received IM epi, pt complaints unchanged <5 min after epi inj, received diphenhydramine, famotidine, prednisone (1 hr later), patient comfortable, throat symptoms improving (2.5 hrs later)

Within minutes of receiving the vaccine I experienced a metallic taste in the back of my throat (while I had mint gum in my mouth), dizziness, increased heart rate, labored breathing, and a floating feeling. These symptoms lasted no more than 10 minutes except the floating feeling lasted about an hour.

itching all over the body after 7 hours of administration of the vaccine lasted for a couple of hours headache, body aches, chills, sweating after 12 hours of vaccine administration lasted for 24 hours

She received her covid vaccine around 1700. She had a reaction that we monitored in the observation room for approximately 40 minutes. She was not feeling better so we took her to the ED for monitoring. She was discharged from the ED after an hour and a half. No intervention was needed. Her symptoms were feeling flushed/ anxious/ shaky, injection arm felt hot (was cool to the touch), HR was 117, BP was 143/96, which is high for her. We are recommending she reach out to her PCP prior to scheduling her second dose.

Treatment dugs:

Pfizer-BioNTech COVID-19 Vaccine EUA. 5 minutes after vaccination patient felt warm, light headed, left arm pain, and blurred vision. Lasted about 3 minutes and gradually was gone by 5 minutes.

Patient experienced generalized itching in face area 1 hour after injection. Itching spread to neck and chest area soon after. Patient was given benadryl 25 mg at 09:25. Given another benadryl 25 mg and pepcid 20 mg at 10:00 due to start of itching again. Itching has mostly resolved as of 10:15. Patient

advised to contact primary physician to notify them of vaccination and to monitor for any more adverse events after leaving hospital.

Headache, neck pain, vomiting

Dizziness within 10 minutes that lasted 30 minutes or longer. Waves of nausea for over 24 hours

Felt unable to answer questions possibly hypoglycemic event, felt something in back of throat, symptoms resolved after providing apple juice

patient called in to work today at 7:15 a.m. with fever and body aches

local soreness, muscle pain in both thighs, fatigue, runny nose

Eye redness, pain, swollen Face swelling Bilateral arms and hands swelling Rash SOB

started to feel tingling in arm received shot.

Patient developed flushing, red warm itchy rash on arms and trunk area. Happened approximately an hour after receiving vaccine. Was given 50mg IM of benadryl and symptoms improved after about an hour after they appeared.

Pt reported a lump in her throat 10 min after the injections. Pt thought she needed a drink of water. Pt reported to feeling fine and returned to work. Pt then reported to the ER with dizziness and lump in her throat at 2:18pm. Pt was admitted to hospital for observation overnight.

12/16- received vaccine at 6:44pm, 12-17- 0400am woke up with nausea/ vomiting and fever, had to call off work 12/18- continued to have nausea/ vomiting and fever until 10 am at which time symptoms and fever resolved

PAIN AND SWELLING OF LEFT SUPRECLAVICULAR AREA, LEFT LEG PAIN.

Felt a lump in her throat 5 minutes after vaccination. BP and HR elevated slightly, no swelling in lips or tongue, denies lightheaded or dizziness, Alert/oriented x3. Vaccination site WNL. Listened to lungs and heart (WNL). Lungs clear throughout and able to move air without difficulty. Within 15 minutes slight improvements in Vital Signs, decreased feeling of lump in her throat, no swelling in lips or tongue, site WNL, alert/oriented x 3. Listened to lungs and heart (WNL). Lungs clear throughout and able to move air without difficulty. 30minutes later 50% improvement of feeling of lump in her throat, cont. improvements in VS, no swelling in lips or tongue, Listened to lungs and heart (WNL). Lungs clear throughout and able to move air without difficulty. 75 minutes post vaccination back to normal, Vital signs back to WNL, Alert/oriented x3, no swelling in lips or tongue. Listened to lungs and heart (WNL). Lungs clear throughout and able to move air without difficulty. Resolved on own without medications

Initial within 10 minutes, redness and burning pain at site. Ice was applied and this went away, then about 25 minutes, itchy throat, trouble swallowing, mild confusion. Oral benadryl 50mh and solumedrol IM. Once again this dissapated after 30 minutes. 3 hours later, trouble swallowing, felt as if something

was in my throat, redness and flushing all over.fluid bolus, epinephrine I'm, iv benadryl, pepcid oral, and claritin oral, fluid bolus. 12 hours after getting the vaccine blurry vision, ringing ears, headache, benadryl, steroid, claritin all oral

"lightheaded; ""funny feeling"" in throat; systolic BP in the 80's; given famotidine and loratadine @ 12/16 (2 hrs later); pressure and heart rate improved greatly (3.5 hrs later)"

10 minutes after the vaccine I had sudden cold hands (the kind of inside cold like Propofol gives you), with palpitations and dizziness. Self limited in a few minutes. BP was 150/90 which is high for me. Similar episode but shorter and less intense within next half an hour. There was also a sensation of chest awareness (not pain, but a bit of tension, which I have experienced before with anxiety and put it on anxiety). After a while decided to go home and while walking I noticed a clear sensation of chest warmth. I decided to stick around the hospital a bit more, pondering about going into the ER. DRank 2 bottles of orange juice and headed home. Then on the way home I had 2 presyncopal episodes. The fact that I had not eaten all day and wasn't well hydrated might have contributed. However, that was scary enough that I called 911. By the time they arrived I was fine. DEcided not to go to the ER. I ate some, drank some, and took Benadryl 25 mg. The chest tightness got better. I still continued to experience waves of chest warmth/heat/burning sensation and chest awareness/ tension, coming on in waves and going away in a couple of minutes. I was obviously anxious by this time but I do not believe the warmth was anxiety related. I have had anxiety before but never with this manifestation. I was tired, slept like a baby and this morning I feel at baseline. Some soreness at injection site but none of that chest warmth.

Numbness and heavy feeling on the tongue and lower lip

ITCHING AND REDNESS ON INJECTION SITE, NEXT DAY GENERALIZED ITCHING. DIARRHEA.

Lightheaded, flushed

At 8pm I developed extreme itching throughout my entire body, inside my ears,throat eyes. No rash or hives no sob or swelling. Headache also noted. I took tylenol 1000 mg and at 9pm I took benadryl 50 mg. I woke up 12-18-2020 with less intense itchiness but it was still present, not my throat or inside my ears. I took allegra 180 mg. At 1100 I developed a headache and took tylenol 1000 mg.

Patient was seen at COVID Vaccine Clinic today for her first dose of the COVID 19 vaccination. She denied any history of previous adverse reactions to vaccines. She does report a history of similar reaction that occurs fairly regularly after drinking beverages containing alcohol. á She was given the Pfizer vaccination in the right deltoid muscle. á During her 15 minute waiting period after the injection, the patient began to experience flushed, warm face and ears. She denied rash, difficulty breathing, difficulty swallowing, wheezing, throat tightness, lightheadedness, lip swelling and tongue swelling. á This APP was notified of patient reaction and she was then assessed in the emergency bay area. á Vitals Vitals: á 12/17/20 1450 12/17/20 1500 12/17/20 1515 BP: (!) 153/73 120/60 138/70 BP Location: Right arm Right arm Right arm Patient Position: Sitting Semi-fowlers Sitting Pulse: 84 79 78 Resp: 14 14 14 SpO2: 100% 98% 98% Physical Exam Constitutional: She is oriented to person, place, and time. She appears well-developed and well-nourished. No distress. HENT: Nose: Nose normal. Mouth/Throat:

Oropharynx is clear and moist. Neck: No tracheal deviation present. Cardiovascular: Normal rate, regular rhythm and normal heart sounds. Pulmonary/Chest: Effort normal and breath sounds normal. No stridor. No respiratory distress. She has no wheezes. She has no rales. Musculoskeletal: General: No edema. Neurological: She is alert and oriented to person, place, and time. Skin: Skin is warm and dry. No rash noted. She is not diaphoretic. No erythema. Psychiatric: She has a normal mood and affect. Her behavior is normal. Thought content normal. á Patient was observed x 35 minutes after receiving vaccination. All symptoms resolved within 20 minutes. No treatment was required. She reports some mild history of anxiety and questions if perhaps she was having a panic attack. She has medication to treat this at home if needed. She was observed x 35 minutes and then released. á

Lightheadedness, shortness of breath, chest tightness Needed to take Ventolin inhaler 2 puffs, Duoneb nebulizer, liquid benadryl Symptoms improved with medications. Felt very tired rest of day. Symtoms to relief was probably 1 to 1.5 hours

Fever, Chills, weakness, Headache. Fatigue. Onset symptoms 12/17/2020 to 12/18/2020. Highest fever 101.8.

"5-7 min after injection she felt flushed face and ""as if they were checking my pacer"" ""so my heart rate revved up a little"" She sat down and the feeling resolved within 15 min"

Dizziness, light headed, fatigue, easily winded, headache.

"Vaccine received 15:00 while at work at Medical Center; Around 19:00 started having intermittent ""hot flash"" feeling and general fatigued feeling. Got home from work (RN in ED) at 19:40. Took a shower and felt nauseous when I sat down to eat dinner. Declined to eat dinner and opted to lie down in bed instead, at 20:50. Awoke at 22:00 to urinate. Felt dizzy standing up, with cold-sweats and body aches. Checked temperature, 97.9 F. Went to the bathroom, drank some water, took 400mg ibuprofen and 325mg tylenol, and went back to bed. Awoke back up at 01:30am with abdominal cramping and nausea. 2 episodes of dry heaving, but no vomit. Awoke back up at 06:55am, GI symptoms resolved but bodyaches persist, as well as overwhelming fatigue. Checked temp at 07:25, 98.3 F. Employer notified."

Chills, body aches, headache

Had COVID-19 November

patient presented with a (L) hand numbness + coldness (ipsilated to vaccine) right after her vaccination symptoms resolved after a warm shower

Swelling locally in arm began within 12hrs. No systemic symptoms, started on dose pack (Medrol) antihistamines, Ice bag.

Right arm soreness, mild swelling, subjective fever, chills, bodyaches, headaches, loose stools x 2, 6 hours of duration, Treatment Tylenol

4:30pm pt noticed tingling & hot flash of face and neck- stiffness of jaw took 50mg of Benadryl. 530-6pm pt noticed the addition of numbness and tingling arms. Pt slept. Pt woke at 11:30pm and noticed that tingling was gone. Pt woke this morning and reports to feeling fine.

I have consistently had a positive ANA (anti-nuclear antibodies) test. Not positive for positive for lupus or rheumatoid arthrits. I wanted to let you know that. But after 15 min I started feeling some wooziness, and about 30 min later a headache, feeling like i was mildly drunk, shoulder (injection site) sore, chills, no fever, mild body aches.

Right eye fullness and blurry vision

I experienced after 40 or 50 minutes I felt funny. I felt fatigue, sleep and after that I felt a sharp pain from my neck to my upper back.

Within 10-15 min of injection, she was walking in the POD, waiting around to leave, but felt dizzy. Was instructed to sit down. People around her noticed a flushed face, she felt her HR increase (as a sensation, not measured) she rested and stay seated for about 10 min. While she was seated, her (she checked her own pulse) noticed it went from 55- 70.

FATIGUE, MUSCLE ACHES, JOINT PAIN, LOW GRADE FEVER 99.8

The patient began to feel itchy throughout the body, particularly both arms and the back. This happened 30 minutes after injecting her with the COVID-19 vaccine

Issues were similar to what I have experienced with the flu vaccine but a bit more pronounced including soreness at the injection site (moderate), tiredness (moderate), joint pain (moderate), headache (mild). The worst of the symptoms started on the first day post-vaccine and subsided about 36 hours later.

(1145) Left eyelid swelling 15 minutes after vaccination. (1155) b/l superior periorbital edema and erythema, b/l ear erythema and burning, and b/l hand tingling. (1200) Oral Benadryl 25 mg was given. (1230) symptoms improved and I was able to leave. While riding in the car on the way home started to have chills w/ goosebumps and nausea in short waves. Took an nap b/c my chills worsened and slept until 1630. Work up b/c of worsening chills, shivering, chest tightness, nausea, b/l hand numbness and tingling, right foot burning and stinging, and constant throat clearing b/c throat felt thick. Called the nurse on-call number provided in vaccine packet and was transferred to virtual care and report was given. Medical team advised me to go to the ED. (1900) Arrived at ED and temp was 101 and the chills, numbness, foot burning, and chest heaviness were worse and my eyes were burning and heavy. I was given oral Pepcid and an IV was started. After an IVP of Benadryl and Solu-Medrol I experienced severe burning starting in my head, neck, chest, and stomach. Then it felt like my veins were on fire all the way to my fingers and toes. This was followed by strong nausea w/o vomiting. I was then given IVP of Zofran and Ativan and NS drip. (1940-2020) Chills, burning around eyes, and vertigo continued other symptoms were improving .(2020) Provider returned and reported that labs were normal and I was probably having a reaction to the vaccine. (2035) Discharged from ED. Experienced chills, hand and foot numbness and tinging after discharge but was able to go to sleep.

Became hot and felt itching minutes after receiving vaccine. No swelling of lip or tongue or throat. No rash. No shortness of breath. ER doctor on site evaluated and determined this was not likely to be an allergic reaction.

sore arm at injection site, fever and chills, headache and felt stuffiness

extreme fatigue. Pt called in sick the next day for work.

"PATIENT FAINTED AT WORK THE DAY FOLLOWING HER VACCINE. BLOOD SUGAR AND VITALS WE'RE CHECKED FOLLOWING THE FAINTING SPELL AND WERE IN NORMAL RANGE. SHE WAS PASSED OUT FOR ""A FEW MINUTES"" PER WITNESSES AND WRITTEN REPORT. SHE SLEPT WELL THE NIGHT BEFORE. SHE WAS UNINJURED AS A COWORKER CAUGHT HER. AFTER HER VITALS WE'RE CHECKED SHE FELT WELL AND RETURNED TO WORK AND WORKED THE ENTIRE REST OF HER SHIFT WITHOUT INCEIDENT OR COMPLAINT."

CIRCUMORAL TINGLING

12/17/2020 patient reports an intense head ache with intermittent shooting pains that are debilitating. Patient also reports fever of 103.4 that is unchanged with use of antipyretics.

Vaccine recipient was administered the vaccine at 11:30 am and then around 1:30 pm started to feel dizzy with hives and itching to his arms. The vaccine recipient was sent to the emergency department for further evaluation. There was an erythematous macular/papular rash on bilateral arms. He was administered diphenhydramine 12.5 mg IV, famotidine 20 mg IV, and methylprednisolone 125 mg IV. After reexamining, the patient felt much better, no dizziness, no itching, and no rash. He was discharge to home at 4:57 pm same day.

chills, aching, fever, extremely cold feet

At 6pm patient's tongue was numb and the left side of their face was tingling. Patient felt like she had burnt her tongue and was trying to taste with it still. Around 11pm the numbness started to go away and she could taste things better. Today everything is pretty much normal.

The pain around the injection site progress to full body ache, head stuffed ness breathing though mouth and slight fever 100.1 took Ibuprofen. The next day sore all over, hard to walk and took Ibuprofen for 6 hrs. On 12/16 lost taste/smell, diarrhea, nausea .Then 12/17 continued aches and fever pt went to get a Covid test was results positive. This morning exp body aches and slightly gaining taste .Pt has been not able to work for 10 days since testing positive.

nausea, lightheadedness, and palpitations that occurred ~10 minute post injection with decreased blood pressures c/w vasovagal response, improved over a few minutes

Chills, low grade fever, body aches, injection site muscle spasm, burning sensation in the chest

Day 1 of shot: headache 10 hours after Day 2: headache, fatigue, joint pain Day 3: headache. Fatigue, joint pain Day 4: headache, fatigue, joint pain and low grade fever, diaphoresis Day 5: worsening headache, fatigue, joint pain Tylenol was obtained per bottle recommendation for pain on all days.

After injecting vaccine the patient began to fell heavy tongue, dizziness and nausea. Vital signs: BP:205/161 mmHg, R:21, 97% oxygen saturation

Approximately 20 minutes after vaccination patient c/o feeling lightheaded, hands tingling and feeling as if there was something in her throat.

Left arm and quad soreness, nausea, headache, light headedness, light sensitivity, dizziness, body aches. No fever nor respiratory symptoms.

Patient experienced heart palpitations. Pulse was 135 SpO2 99. Calmed patient to pulse 70. BP 132/84. Patient reported to feel better after 10 min. No other intervention needed.

weakness and body aches

After receiving injection 14-15 minutes after I started to get chest tightness. I took two puffs of inhaler and walked to triage room to be monitored for another twenty minutes. I took two more puffs of inhaler and chest tightness went away a few minutes after. No other reactions occurred and was cleared to leave after twenty minutes.

about 12 minutes after receiving the vaccine had a sudden onset of sharp headache while seated. When she stood up became lightheaded and dizzy and nauseous. She also had elevated Blood pressure p to 168/108. After 35 minutes her positional symptoms persisted with BP still elevated 159/102. No respiratory or skin symptoms. She was transported to the ED and had a head Ct which was normal, discharged with pain medications.

Additional to the symptoms previously reported I woke up with headache and thighs feeling heavy. Those are the remaining symptoms, the previous ones reported have subsided

on 12/16 i was given the vaccine at noon and finished my day as usual, I had a beer before bed and fell asleep at 9pm, at about 1am on 12/17/2020 I woke up with severe chest pain like something was crushing me, like a car being crush it felt like. I went to the ER at 3am and I was told I had a severe reaction to the vaccine. I had a weird taste in my mouth, cough, watery eyes, pain in all limbs, jaw pain and neck pain. I am going to get tested today 12/18/2020 for covid

"Pt was ambulating through hospital cafeteria at approx 13:50 when she developed sudden difficulty walking, gait ataxia witnessed by nursing staff. States, ""It felt like the floor was rolling and I couldn't stay balanced."" Pt diaphoretic, hypertensive. No other focal deficits. On arrival to ED, pt continues to have gait ataxia, but no ataxia on NIHHS assessment. Denies headache. Received COVID vaccine at approx 1 pm today."

PATIENT REPORTS BLURRED VISION LASTING 1 HOUR APPROX. 2 HOURS AFTER INJECTION. INJECTION SITE SORENESS ON 12/16/20 AND CONTINUES TO PERSIST; NO SIGNS OF CELLULITIS. GENERALIZED MALAISE STARTED 12/19/20 AT 1000.

First day right after the vaccine the left arm was extremely sore, the next day I felt like I had the flu. body aches , headache, knees aching , abdominal pain, could not eat, lots of chill, breaking out in sweats .

Diarrhea the day I got the vaccine and 1 time the day after

Metallic taste, chest pain, coughing or throat clearing, bilateral arm numbness

Metallic smell. Started about 10 minutes after vaccine administration and occurred intermittently for about 30 seconds at a time every 10 minutes for almost an hour. Adverse effect subsided after about an hour.

Injection site reaction. Mild localized redness and swelling. Reaction occurred on 12/15, the day after receiving 1st dose of Pfizer covid vaccine. Day 4 12/18 injection site is circular redness, approx 2.5 inches in diameter. Mild discomfort, not painful not itchy. Have been applying over the counter 1% hydrocortisone cream with some relief.

After the patient received Covid vaccine, she started experiencing itching. The nurse monitoring the patient noticed she was scratching. The patient continued to itch during the 15 minute observations period but no other adverse effects were noticed. The observation period was extended to 30 minutes and then the patient was released. An hour after she left the vaccination site she experienced an episode of vomiting which resolved. Her husband noticed her to be pale upon returning home. Later that night the patient was visibly shaking and had another episode of vomiting. All symptoms have since resolved.

Symptoms began 30 min after vaccinated was tired then HAd fatigue. Took Tylenol/Advil. Fatigue persists > 24 hours Sore @ vaccine site. No induration . nl appetite. Increased fluid intake. takes Allegra + Flonase regularly. Recent sinus surgery in Oct.

AT 0600 WOKE UP NAUSEA THEN DRY HEAVES THEN VOMITING, VOMITED NUMEROUS TIMES THEN HAD EXPLOSIVE DIARRHEA, TOOK 25 MG BENADRYL ABOUT 1 HOUR AFTER TO MAKE SURE I COULD HOLD IT DOWN AND NOT VOMIT

I experienced a fever of 100.7 with it getting as high as 101, I have joint pains and body aches and pain at the injection site. Kinda the same as when I had Covid. I was only sick one day.

Patient stated that within 3-4 hours of receiving the covid-19 vaccine he began to lose his sense of taste and smell. Patient presented to ER (12-17) with his arm was hurting, headache, weakness, back hurting, and blood pressure was up. B/P was 204/112; pulse 84;resp 19; temp 102.4; Covid-19 test- negative. He had no sob or cough. Meds given:Tylenol tabs 650mg x1, Toradol 30mg iv x 1; NS 0.9% 1000ml iv, Tusssionex 5ml x1; Lopressor 50mg po x1, Patient released at 10:23am

within 5 min, pt reported feeling dizzy and lightheaded. No loss of consciousness. Pt also reports having eaten M and Ms as only food today. Pt happened to have a pulse ox on self (is an RT). SaO2 96% on room air, pulse 94. Pt given some trail mix and water and began to feel better. Upon standing pt reported not feeling well again and returned to seated. Pt then began with jerky muscular movements of upper extremities and stuttered speech. Pt states that this is how her PNES presents. No loss of mentation or consciousness. EMT team called for transfer to ER. Pt alert and oriented on transfer

Cough Muscle Ache Fatigue Lethargy Run Down feeling Chills

Itchy, Chest pressure on a scale of 1-10 rated a 3 down to a 2 after 2 minutes. Nausea and lightheaded Requested EMS to evaluate so EMS was called and Allergist presented. Remained stable throughout entire event. Allergist recommended triptophase lab be drawn to ensure that this was an actual allergic reaction. This was particularly to prepare for 2nd dose. Because of this patient was transported to ED and discharge within a few hours.

I began getting a headache about 1hr after injection. I also got very fatigued for a few hours. I took Ibuprofen to help with the headache and I took a nap to help with the fatigure.

Site injection reaction: light swelling with raised bump to injection site arm, with tenderness to light touch. Hurt to move arm.

After I woke up next morning, experienced dry cough.

30 minutes after injection, pt experienced tiredness. About 5 hours after injection, patient experienced severe nausea. Woken up out of sleep at 01:30 AM with body cramps (legs, arms). Severe soreness at injection site as well. Pt also experienced headache and nausea today (12/18) after taking Zofran, with no effect.

The employee was vaccinated yesterday and today has a severe headache with vomiting

my symptoms were chills, fever, muscle pain, my skin hurt, fatigue, only treatment was tylenol and I went to bed

Immediately after injection I felt a tiny pinch in what felt like my heart. I happened 2 more times within seconds and nothing else after that. I did not report this to anyone since it happened so quick and was over within a minute. I did stay a few stay in the area where I had the injection just in case. After about 15 minutes I left because I felt fine. No other effects afterwards.

Round 5:30 P.m. I started becoming nauseas, I had a terrible headache , OTC Ibuprofen did not help, nasal congestion ,, Only slept 2 Hours Wednesday night.. the next day 7am stayed in bed all day , headaches, congestion was worse. Could not sleep. Feeling better today but I am super tired 10/02/2020 Was tested for COVID-19 . The test was confirmed positive the next day.

metal taste, left left ear

In between my shoulder blades and back feels like something is there. I've got worse exp headaches have history of migraines in the past. In August 2020 was exposed to Covid 19 headache was worse than now. In the past have seen neurologist for migraines and not exp migraine felt like this in 5 yrs. On 12/17 body pain, headache, and high grade, diarrhea(loose stool) and fever 101.7.After checking temp on 12/18 was 98.8.Pt had to miss one day of work on 12/17.

Employee waited for 15 minutes after injection in the Department, 40 minutes after the employee left she called employee health and was instructed to return to the hospital ED if she was able. Dr. and the ED physician evaluated her. She had peri-oral numbness, and some cheek numbness, no motor deficits. SBP was 200 in ED. Single dose of Catapress and then improved B/P. D/C to home. 12/17/2020 - AM mild chin numbness - everything else resolved. B/P remained stable 12/18/2020 - resolved

Caller stated that 12/15/20 had pain in the vaccination area , headache and exhaustion that lasted about 24hours

Sore muscle around site of injection, starting the day after injection

Patient reports 1 hour post vaccination symptoms: jittery, feeling lousy. 12/18/20 Am reported bodyaches, red/watery eyes, chills, and blurred vision. States she can see better in dark than in bright lights. Previously hx of COVID 19 illness November 2020. Took Tylenol and Allegra 12/18/20. Reports improvement in symptoms 12/18/20 12:40pm but continues to report mild blurred vision. Advised to seek immediate medical care if condition not improved or worsens.

Not all or limited to: anaphylactic reaction: Feeling lump in throat, tongue feeling funny with numbness, feeling of hard to swallow, throat tightness, shortness of breath, tachycardia, tachypnea, pressure, tingling, and numbness from head to toe, dizziness/lightheartedness, cough, voice changes.

metallic taste

Hx COVID in June, with resolved problems. By 4 hours after inj adm had flu like symptoms. Took Tylenol prior to vaccination & now with bed. Swollen & redness (L) arm: 76cm began within 6 hours of vaccination. Diarrhea, now resolved. Txt with steroids - antihistamines.

day 1: none day 2: woke at 0530 with chills, general malaise & body aches, took ibuprofen, went to work, continued with same signs/symptoms, afebrile at 1430 - 98.0 degrees, sent home at 1500 day 3: woke feeling better

1208- Flushed/warm, scratchy throat. lethargy, decreasing oxygen saturation, placed on 4L NC, EMS called 1211- Diphenhydramine 50mg, Solumedrol 125mg, Epi pen injector adult 1231- EMS arrived, patient transferred to ER on 4L NC, SP02 94%

headache, pain at sight of injection, body ache, upset stomach, fatigue

felt some skipped heart beats about 2 hours after shot and then my arm has started hurting at site about 4 hours after

metal taste for approx 3 min

Patient began experiencing itching on side of cheek about 10 minutes after IM injection. Itching began to spread to face, then on to neck/chest area. Patient given 50 mg of benadryl PO and famotidine 20 mg PO. Symptoms have resolved within 20 minutes and will be observed for another 30 minutes. Patient counseled to inform primary care physician of itching event and to follow up with physician if any new effects arise.

She received vaccine at 2:00 pm. Around 3 hours after injection began getting a rash on her face that spread to other parts of body. Felt some tightness in her chest. She took Pepcid and 50 mg of Benadryl. Rash and tightness in chest improved. Began to come back around 9pm. Took 1 more 50 mg of Benadryl. On 12/18 she reported to Employee Health. Rash was still visable . 1-25 mg Benadryl was taken. She reported she would take 50 mg of Benadryl at lunch.

Hives, scratchy throat but no swelling or change in phonation

Headache and increased HR followed by dizziness (room spinning), and throat tightening. Evaluation in vaccination clinic revealed tachycardia and elevated BP. Brought to ER to monitor throat tightening. Upon trip to ER (roughly one minute), experienced nausea. Experienced chest pain after being admitted to ER, roughly 20 minutes after vaccination. Chest tightness and throat swelling lasted for roughly about 30 minutes. All symptoms subsided with the exception of the headache about an hour after injection. Discharged from ER and went back to work. Headache continued into the afternoon, along with general weakness.

Pallor, Diaphoretic, dizziness

Patchy Maculopapular rash starting in bilateral upper extremities, then radiating to trunk. No itch,.

Pt. expereince immediate swelling below injection site.

Tightness in throat, throat swelling, tachycardia. Treated with epinephrine IM x 1, benadryl, famotidine, methylprednisolone,

Headache, increased heart rate (115) for approx 30 min.

Numbness 20min after vaccine & persisted rest of day then 12hrs later pain @ site. Then redness @ injection site 16hrs. 3cm erythema & swelling deltoid to deltoid.

I didn't eat after because I lost my appetite. I was nauseous with chills , sweating and vomitting and tired.

"Patient initially felt dizzy which resolved after a couple of minutes. Patient stated she felt better, just ""tired"". She went to her locker, felt dizzy and went to Nursing office at 10:57 pm via wheelchair."

"Approximately 4 minutes after administration, patient complained of ""tightness"" in her upper middle quadrant of her stomach, near the xiphoid process. At that time her HR was 140. At 1840, her HR was

96. At 1844, patient had a red, splotchy rash on her neck. Patient received 25 mg of bendadryl. Patient noted that she was sweaty and she felt slightly dizzy, particularly when moving her head side to side. At 1847, patient's HR was 80. At 1852, HR was 84 and at 1858, HR was 68. Patient stated she felt much better, dizziness seemed to resolve quickly per patient's report. She was able to ambulate and turn her head side to side with no further difficulties. Throughout the episode, patient denied nausea, shortness of breath, itching, urticaria or any other rash besides the redness on her neck. After discussion with MD, RN and PharmD who were present for the vaccine administration and reaction, it was determined this was more than likely anxiety and not an allergic/anaphylactic reaction."

Patient c/o dizziness immediately after receiving the vaccine. She walked from the vaccine station to the waiting area and alerted staff that she felt dizzy. No SOB, no rash, no throat tightness. She had a similar episode in October. Recently increased Lisinopril dose. She was laid down on a stretcher. Vitals were stable. Glucose=105. Transported to ER for further work-up. Dizziness resolved prior to transport.

lightheaded,dizzy,increased heart rate, increased blood pressure

lightheaded,dizzy,increased heart rate, increased blood pressure

After the vaccine I'm fine for 5 mins but when I reached my car I felt a weird taste it's not bitter but it tastes like the outside of an orange and I still taste it today 12/18/2020, it feels like I have sand in my throat and I keep drinking water but it is not helping, my arm is really sore and I have jaw pain,

Patient developed hives on lower back to the side and left leg. 25mg of benadryl tablet was given in ER and later a dose of 500mg tylenol was given by patient herself at home. The next day patient reported woke up with joints stiffness all over whole body . Hives has been diminished by day 2.

At about 4pm, started to get migraine, neck pain, both sides of head. Took Tylenol. I was at work, finished shift. 12/17/2020 - 12/18/2020 still have migraine, both sides; 'feels different'. History of migraines. If worsens refer to ER

"Shortly after vaccine felt dizzy; nurse gave me water and a granola bar to eat. Employee took a bite or two and then felt dizzy. Employee sat down and blood pressure taken 170/ 80 and then 10 minutes later B/P 200/90. Nurse manager came and recommended employee go to ER for assessment. Blood sugar was checked and employee states ""they were not low"""

Tired

C/O Chest heaviness approx. 7 minutes after injection. Pulse=60 B/P 172/82

"Patient is a very pleasant 62 year old gentleman with a history of HTN, hyperlipidemia who presented with left facial numbness and left UE numbness. He states that it is worse medially on his arm. Present in upper and lower face. He states it started around 730 am this morning. He also notes intermittent ""foggy"" sensation since Monday associated with some blurred vision that comes and goes. Denies focal weakness, unsteady gait, difficulty with speech and swallow. He denies f/c, cp, sob, rash, pruritis, n/v/d, edema. He did receive the Pfizer COVID vaccine yesterday"

"Patient reported ""don't do well with injections"", she was escorted to the wait area. She appeared nervous and denied symptoms. After ~10 mins she because anxious, reported feeling light headed to employees. Patient was assisted to gurney in supine position, O2 applied via nasal cannual by employee, Patient calm and appears in no distess laying supine. She was observed for additional 30 mins. She voiced no complaints and was asymptomatic. She was discharged without difficulty or incident. Patient was instructed to request laying down for second injection."

Tingling in lips and left side of face felt numb 20 minutes after vaccine. No treatment, resolved in 3 hours.

metallic taste in mouth, stomach cramps resolved after approx. 30 minutes, and chills

Body aches, nausea, headache I took ibuprofen and it helped the body aches and headache but the nausea is still lingering.

About 5 minutes after receiving the shot I had an off taste that lasted for a few hours. Around 5 in the afternoon my body started to ache and swell around my wrist. Went to bed and work up feeling not very sore. Around 1 pm I noticed I had a huge nodule on my elbow. I get them occasionally but this was the largest one has ever gotten. I could feel it through my sweater. Wrist and ankles still sore more that normal.

metallic taste, fever

Burning in neck and arms, flushed, and skin pain through arms and neck.

left arm paid, headache and fatigue that about 48 hours.

"She had seven (out of 10) occipital face ""pressure"" of her right neck face .With 30 minutes of observation, pressure improved to 3 (out of 10). She had unlabored breathing and stable vital signs."

metallic taste, tingling of tip of tongue

12/16/2020 woke up at 10 am and had severe body aches, chills and HA. Took Tylenol and Ibuprofren. The fatigue and chill came back later that day. Symptoms didn't go away till went to sleep. Felt better on 12/17/2020.

Was monitored for 15 minutes with no symptoms. On my way home around 810 my left arm felt numb with some tingling to my left hand. By the time I got home it was about 830 and my left lower face and jaw felt numb and a little off. My face was still symmetrical and it was just in the lower left area of my mouth and jaw region. I took Tylenol and when I woke up my face felt normal. Since then occasionally I still feel tingling in my left hand.

Vaccine recipient reported becoming slightly lightheaded at the end of their 15 minute observation period following vaccination. The recipient was awake, alert, and oriented. Vitals were within normal limits. The vaccine recipient was offered water. During re-examination, vaccine recipient felt better with no medical treatment and was able to be discharged from the vaccine clinic safely. Next day on

12/18/2020, the vaccine recipient was contacted for follow-up and reported they were no longer felt lightheaded and just had mild pain at the injection site that did not interfere with activity.

Localized soreness, redness and swelling to site. Ibuprofen for pain

left arm numbness and tingling, aching forearm

1225: 25 min after Covid vaccine pt started experiencing itching to her neck, waist and arms. Her left arm where the injection was given felt heavy and fingers were tingling. She also felt like her top lip was swollen. Pt was given PO famotidine and 25mg of Benadryl. Spoke with physician and he also wanted her to have 25mg IM Benadryl. 1236: IM Benadryl given 1245: Feeling better. Itching improved. Lip doesn't feel as swollen. 1250: Dr in room. Continues to get better-itching still improving. Lip no longer feels swollen. 1255: Pt able to return to work at the hospital. Advised to go to the ER immediately if she begins to feel worse.

I felt a little lightheaded about 5 min after receiving injection, but thought it was because I hadn't eaten that much earlier in the day and it was dinner time. Stayed in observation area for 20 min with no changes. 10-15 min into my drive home started to feel like the back of my throat was scratchy and slightly numb. Had the sensation that a cholresceptic spray had numbed the back of my throat. A few minutes later the numbness spread to my tongue and then lower lip. I never experienced trouble breathing or swelling or rash. I meet up with some nursing/paramedic friends. I took 50mg of benadryl and a pepcid tab both orally. My symptoms didn't worsen and seemed to have resolved when I woke up this morning around 6 am.

10 min. after vaccination, pt felt lightheaded, dizzy, and queasy. Intense fatigue & blurred vision 20 min later.

Vaccine injection went fine it did not hurt at all, but I sat down for observation and within 2 minutes I felt mildly dizzy and then brief chest pressure and a wave of nausea. The chest pressure went away quickly but I was more flush then usual, about 15 min in my eyes felt watery and itchy. Went to ER to be observed, EKG came out fine. 118/72 HR 68 . Everything was fine. No meds prescribed, just observation, stayed about 90 min in observation by the time I eft I was just mildly nauseated. By the time I arrived home, 2 hours later all symptoms were resolved.

"at 12:55 pm ""enormous hot flash"", became diaphoretic, chest tightness, immediate need to have BM, ""uneasy"" feeling. Waited 40 minutes, then went to ED. No meds given. 1 Liter IV fluids given. VS monitored and within ""normal"" range. Cardiac enzymes and other labs drawn and within normal range. Released to self after 2 hours. Returned to work next morning."

Pfizer-BioNTech COVID-19 Vaccine EUA. Itching and redness on the chest, back and side

rash on face, chest, abdomen, warm and itchy skin blurred vision Itchy throat Took 50 Benadryl orally 2 hour post injection around 9p,.

Hives on trunk, thighs, and arms. They were very sore and itchy. Took two 25mg benadryl and the hives cleared up in 2-3 hours.

Caller stated that about 4:00 in the morning 11/17/20 she had chills and fatigue lasting about 8 hours.

Fever 101, Headache, body aches, increased heart rate 140-160, chest pain.

Tachycardia to 130s Fatigue, low grade fever

metallic taste

Patient experienced some facial swelling while in the observation area. Patient didn't realize there was any swelling until he looked in the mirror. He also reported feeling a little flushed and light headed. No diaphoresis noted. EMS called to assist, asked him allergic to anything, he said no known allergies but suffers a lot from seasonal allergies. I offered, and he took one 25 mg PO Benadryl with water @ 11:32 a.m. EMS took @ 11:33 BP: 160/110, HR 70, R 16, Pulse Ox 97% he said this BP was high for him. Second reading @ 11:44 BP 144/104, HR 62, R 16 Pulse Ox 97% Third reading @ 11:48 BP 130/88, HR 64 R 16 Pulse Ox 97%, vitals back to more normal for him. Glucose 77 @ 11:42. We kept him for 30 minutes post vaccination, and he was said he was feeling fine, no additional symptoms, swelling above eyebrows decreased and no more flushing symptoms. EMS offered to take him to the hospital, he refused said he was a physician and was feeling better after given the Benadryl.

Within 5 minutes of receiving the COVID vaccine, patient experienced face numbness, flushing of face, lightheadedness, nausea, elevated heart rate, elevated blood pressure. Patient had premedicated with 25mg benadryl 25 minutes prior to receiving the vaccine due to having had previous adverse reactions to vaccinations. At 1010, 15 minutes after receiving the COVID vaccine, patient was given Benadryl 25mg PO. She was then evaluated and monitored by her primary care physician.

Shot at 8:24, at 1700 left arm , injection site pain 6/10. 20:33 sharp joint pain to right knee and left great toe. Then over the next 30 minutes start to have chills, no fever and joint pain 9/10 to bilateral knees, hips, shoulders, elbows, wrists. 22:00 extreme fatigue as well. Slight HA 3/10. had difficulty falling asleep but once I did, was able to sleep thru the night. This morning Joint pain 5/10, fatigue 6/10 and HA 1/10. No chills or fever. injection site discomfort 2/10

28 year old female complained of feeling flushed and ?foggy? at 2:06 pm. Patient was placed on stretcher in the Fowler?s position. Vital signs taken: BP 141/91, HR 71, RR 16, 02 99% on room air. PERRL. Lung sounds clear, CV- regular rate and rhythm. Was directed by MD to give patient Diphenhydramine 50 mg IM. Medication was given in the left deltoid at 2:11 am. Patient tolerated well. VS re-checked at 2:13 pm- BP 134/92, HR 72, RR 16, 02 98%. Patient stated she was feeling drowsy and dizzy after diphenhydramine injection. Patient requested water and was given water at 2:15 pm. She then complained of feeling feverish. Temperature 99.4. VS re-checked at 2:16 pm BP 134/73, HR 72, RR 16, 02 98%. Patient continued to be monitored with improvement in her symptoms, vital signs as follows: VS at 2:22 pm BP 133/91, HR 72, RR 16, 02 98% VS at 2:28 pm BP 129/96, HR 72, RR 16, 02 98% At 2:34 pm patient stated that she was having some difficulty taking deep breaths. Stated she was not

short of breath. Denied chest pain. MD was called over to assess patient as well. MD evaluated patient and patient?s symptoms improved. Was instructed to continue to monitor patient. VS at 2:35 pm BP 129/96, HR 73, RR 16, 02 98% VS at 2:58 pm BP 124/90, HR 70, RR 16, 02 98% At 3:04 patient stating she was feeling better, but was drowsy from the Benadryl. VS at 3:05 pm BP 117/80, HR 69, RR 16, 02 98% 3:10 pm Dr examined patient with ok to leave for home. Patient agreeable with plan. Educated on red flag s/sx and when to call 911. Instructed patient that provider will call her tomorrow for follow-up. Patient left clinic in stable condition with boyfriend driving her home.

I was at home night of 12/16 ex headache, chills upon checking temp 99.3. My arm was swollen and couldn't move my arm .I took Ibuprofen 400 mg and went to sleep. On 12/17 felt like flu symptoms and voice raspy sound and took 400 mg Ibuprofen. Then 12/18 today felt better and gaining voice back.

Headache that began at 8:00 pm on the night that the vaccine was given and mild pain and swelling at the injection site. Headache has not gone away (and she does not describe as a migraine).

"Within 2 minutes after injection, patient started to feel very hot and with increased heart rate. Pt states that she feels ""tingly"" and is tearful. Pt denies difficulty breathing. Patient then started to have a red blotchy rash on her neck and chest. No redness at injection site. Pt brought to Emergency room for evaluation/observation. Pt able to talk in full sentences. Pt states that she has a history of anxiety and has gone into SVT because of anxiety in the past. Pt received steroids in ER."

After the shot I felt dizzy, sweating profusely, felt throat tightness, my heart was racing. They gave me an epinephrine shot in the leg and I was sent to the ER at Hospital. By the time I got to the ER m symptoms were gone. They did monitor me, put me on oxygen and hooked me up and around 2:45 I got up to use the restroom and they did not have to hook me up anymore. I took the day off because after the Benadryl and epinephrine I just feel groggy for about 24 hrs.

metallic taste

Tingling lips and tongue. Symptoms have started to resolve on their own.

"Patient reported being nervous about getting her vaccine. Denied any current medical issues on her pre-vaccination questionnaire. During her observation period. Patient stated that she felt her ""throat was closing"". Pt assisted supine. Epinephine and Benadryl given IM. Emergency protocol implemented. Dr. present. No hives, wheezing, or swelling noted. After treatment pt stated she is getting worked up for WPW syndrome. VS stable. Pt transferred to ED for monitoring 1040."

About an hour after vaccine, felt itchy inside, watery eyes and congestion - treated with 25 mg Benadryl. No anaphylaxis

I received my vaccination in my left deltoid. 3 hours post-vaccination I developed swelling around my right eye. Vision was in fact. No other symptoms, I did not take anything to treat it. It is still present 1 day later, but seems to be improving on its own.

5 min into the vaccine my heart began to beat faster. 30-40min later I began to have heart burn (mild midsternal chest pain) that lasted 3 hrs. I also have mild body aches and pain at the insertion site.

Headache, sweats, low grade temperature (99.3), fatigue, and myalgias. These resolved within 24 hours with two separate doses of 650mg tylenol, but the fatigue persisted for 48 hours.

12.17.20 around 2:00pm, my stomach started cramping, I had diarrhea, started cramping up really bad, got home and had diarrhea episode 5-9:00pm. Body felt hot, i did not have a thermometer to check my temp. Woke up around 6 am, and had another cramp and diarrhea episode, and had one every other hour. Today, 12/18/2020 from 10am -3:30, I have not ate anything. Last episode has been at 11:00am. I am scared to eat and I am still experiencing cramps. I have the feeling of nausea that comes and goes. I had to miss work due to the events of my illness.

12/17 at 2?3 pm- Had a mild headache that progressed to severe within an hour. Became diaphoretic, felt dizzy, nauseated. Had GI distress and vomiting episode. Medicated with Tylenol and slept for 8 hours. 12/18 feel back to normal. No fevers

The patient began experiencing a fever of 102.7, body aches/back pain, fatigue, and headaches the next morning after receiving the vaccine. She denies any respiratory symptoms. She tested positive for COVID19 on 12-01-2020. She was advised to remain off duty for 3 days, which accounts for the time period that these adverse effects have been observed per CDC data. If symptoms worsen, she was instructed to please follow up with a physician and to quarantine according to CDC guidance.

injections site pain, chills, headache, nausea

Symptoms developed the night of the vaccine. Fever, 100.1, Joint pain, Muscle pain, headache, dizziness (intermittent), chills, feeling unwell, currently taking Tylenol, still has symptoms. Will send to physician

Right ear felt hot and had metallic taste. Felt shaky

I felt a little bit dizzy and tasted like saline in my mouth. I kept feeling dizzy, like I had a brain fog and felt lightheaded and nauseous, I started having tunnelling vision, my BP as high, I got confused and nauseous, had headache and was sent to ER to be observed. Had fever last night and still feel weird and still have headaches, treating it with tylenol. Took the day off from work since symptoms did not subside.

Recipient felt hot and described 'lump' in throat feeling for about 3 minutes

Pfizer BioNTech COVID Vaccine EUA -- Nurse gave undiluted 0.3ml dose of vaccine out of vial without diluting it

Pt with h/o of multiple environmental allergies plus latex. Received vaccine at 1115am and reported itching eyes and itching ears at 1129am. She was escorted via wheelchair to the ED for f/u treatment.

metallic taste

Excruciating headache upon waking up 12-18-2020 at 0800 along with vomiting . Took Tylenol and Fell back asleep for 4 hours which I never do. Feeling very tired today but functional.

Took the vaccine at 2:55 pm on Dec 17th. Went home at slept at 8:00 PM, felt fine. Woke up at 12:00 AM feeling low-grade fever, tired, mild headache. Took 15ml day quill 40 minutes before going to doctor's office at 2:30 PM on Dec 18th. Calculated temperature was 100.5 at the entrance. Heart rate was 122 inside the office. No treatments/medications given yet.

"Itching to hands, feet, ears. ""Tight"" feeling to skin of face. Given Zyrtec and solumedrol"

Patient reported feeling hot shortly after receiving her vaccine with an itchy arm. We provided and ice pack and laid her down on a stretcher. Patient became slightly erratic and we proceeded to wheel her down to ER. ER summary below. ED Course: Patient's pertinent past medical, social, family medical history were reviewed from both the nursing notes and the electronic medical record. This is a 27-year-old female with a past medical history as above presenting with a chief complaint of concern for urticarial rash in anaphylaxis following a COVID-19 vaccination. á I did speak with Occupational Health who stated that this patient is well-known to the hospital, stating specifically that she becomes very anxious with vaccinations/needles and breaks out in hives on previous injections. This information was given to his after her initial presentation. Patient had already been removed provided epinephrine given concern of possible anaphylactic reaction given her area, diaphoresis, pruritus and diffuse urticaria. á I was called into the room multiple times as patient continued to ask to be discharged. I did have multiple conversations with her in regards to need for continued monitoring given possibility of anaphylactic reaction. She feels that this was due to her anxiety and states that she is completely asymptomatic and at her baseline at this time. She once again is asking to leave. I did discuss my recommendation for continued monitoring as well as the risks of leaving without continued monitoring. The patient is able to choose, communicate and make choices clearly and understandably. The patient is able to understand risks, benefits and alternatives of therapy explained by myself. The patient can make a logical and rational decisions according to my assessment. The choice made by the patient is consistent with the patient's values and is consistent with character and decision capacity in the patient's past, according to friends and family present. There is no impending medical risk to this patient to warrant my holding the patient against their will. á Patient will be discharged in stable condition at this time with strict return precautions and instructions for close outpatient follow-up. She was provided EpiPen given possibility of anaphylactic reaction in the future.

R arm numbness, tingling sensation and rash

"Caregiver received first dose of Pfizer COVID-19 vaccine. After 10:00 minutes of observation phase, patient c/o lips tingling and ""on fire"". Lips not swollen, denies SOB, skin WNLs, denies difficulty swallowing. MERT called. Patient assessed, states tingling 8/10, no other symptoms. Patient given bottle of water and tolerating that fine. Allegra 60mg ordered and administered at 8:52am. Patient statedwas at a 2/10 10 minutes after getting the Allegra. Patient drinking water without difficulties. Patient remains without further symptoms, lips still 2/10 with tingling. Outpatient labwork ordered. Left at 1000

ambulatory to outpatient lab. Educated her to notify administrator of her symptoms prior to her second vaccine."

28 year old female returned to observation clinic at 11:18 am stated that she was feeling flushed again. She stated symptoms are similar to her symptoms she had yesterday. States symptoms started 5 minutes after returning to work and donning her PPE. States she had the COVID-19 vaccine at 9 am on 12/27/20. She states she feels like she has ?flu-like symptoms?. Patient was placed in wheelchair. Vital signs taken: BP 118/80, HR 108, RR 22, 02 98% on room air. PERRL. Lung sounds clear, CV- regular rate and rhythm. Patient was wheeled to the audiology room to be monitored with provider and MA. VS re-checked at 11:28 BP 121/88, HR 88, RR 18, 02 98%. Patient began to complain of feeling feverish and ?foggy?. VS at 11:35pm was 127/91, HR 97, RR 20, 02 97%. Patient was given Diphenhydramine 50 mg IM. Medication was given in the left deltoid at 11:36 am. Patient tolerated well. VS re-checked at 11:38 pm- BP 118/82, HR 104, RR 22, 02 98%. At 11:40 lung sounds clear, HR regular. VS re-check at 11:48 BP 132/65, HR 71, RR 16, 02 99%. Patient stated she was feeling better.. Consulted with Dr. who also evaluated patient. Ordered CBC and CMP. VS at 11:53 BP 122/90, HR 82, RR 18, 02 99%. At 11:58 lab tech came and drew CBC and CMP. Patient tolerated well. VS re-checked at 12:15 pm BP 109/75, HR 91, RR 20, 02 99%. Dr. ordered EKG at 12:22 pm. EKG NSR. Labs resulted and were unremarkable. Patient stated she was feeling much better. Was assisted to the bathroom at 12:28 pm. VS re-checked at 12:32 pm BP 108/74, HR 86, RR 20, 02 99%. Dr. reviewed EKG and labs and orders to release back home. Patient agreeable with plan. Educated on red flag s/sx and when to call 911 Patient left clinic in stable condition with co-worker driving her home.

Vomiting, lightheadedness, floating feeling, nausea, tachycardia within 15 minutes of vaccination

Vomiting, lightheadedness, floating feeling, nausea, tachycardia within 15 minutes of vaccination

12/16/2020 @7:00pm caller started feeling flush with hives and nausea. Caller took Ibuprofen and next day got relief.

Dizziness, Rapid Heart Rate

Hot, flushing, tingling, metallic taste, pounding heart rate.

aproximately 10 minutes after vaccine taken, I developed problems with my vision. I had double vision, and Kaleidoscopic vision with floaters in both eyes . Lasted about 30 minutes. Did not keep me from reading or walking. no pain.

Nausea, vomiting x 3, and hyperglycemia (BG: 350s) 30 to 60 minutes following 0.3 mL IM injection of Pfizer-BioNTech COVID-19 vaccine in the left deltoid.

fatigue, headache

Shortly after receiving the vaccine I experienced a warm sensation near my sternum. The sensation was internal and radiated from my left side to my sternum. I also felt slightly dizzy, but it eventually resolved. In the evening (7:00 pm) I felt fatigued and experienced headaches, body aches and pain in my left arm.

It was painful to move my left arm and difficult to put clothing on. It is still painful today (12/18/20), but I'm managing it with Tylenol.

metallic taste - like pennies

severe flushing and complaint of hot ears. tachycardia on monitor

Flushing, hot flashes, elevated heart rate and high BP (never have a problem with that), Evaluated at the ER and received Benadryl immediately. After coming home (discharged around 1:30), felt fatigued and started with a mild headache. Also joint pain in my hips and my knees. Woke up this morning pretty fatigued and with headache feeling better this afternoon. Still have a mild headache.

Tongue swelling, seen in ED and discharged. Works in hospital ICU and will continue to monitor during shift.

Patient felt flushed with tenderness at the vaccine site. Patient remained under observation for 1.5 hrs and then felt well enough to leave without further care.

After the vaccination I got really fatigued and nauseous but it resolved the next day

Itching on arms, face, back, eyes. Mild raised rash on upper back. Face flushed.

Dizziness started 30 min after vaccine administration last for a few hours, also started feeling palpitations and noticed pulse to be 100-110s. 6-8 hours after the vaccine I started feeling chills and myalgia and some chest tightness. The next morning woke up with chills and rigors and severe body ache that made me unable to go to work. The entire day I have felt fatigue, abdominal pain and nausea. Taking Tylenol and my Salbutamol inhaler helps me.

"Pt was being observed in hospital for reactions per Dr orders due to Pt's history. Pt reported ""itchy"" feeling at 9:50am. At 10:20am Pt reported generalized ""itching provider notified at 10:34. 11:05am Pt received Benadryl at this time Pt had itchy watery eyes and generalized itching. 11:50 Pt sleepy but ""itching better"" dr notified and Pt returned to Assisted Living."

Patient felt dizzy approx 10min after vacciantion. Patient drank some water and layed down for 15min and sx resolved.

Tongue and throat swelling about 30 minutes after receiving vaccine. Took Claritin about 15 minutes after onset of symptoms. Symptoms mostly subsided about 1 hour after taking Claritin. Slight throat swelling and difficulty swallowing until a dose of Benadryl was taken the following day.

Swollen lips Nerve pain -sciatic Body ache Fever Headache Chest tightness Back pain Rib pain Cold then hot in waves Burning eyes Swollen lymph nodes in throat Joint pain Kidney pain Short of breath Fatigue Trouble sleeping Mental focus off

Palpitatations, shaky, lightgheaded, irregular heartbeat

Tingling in left arm, hand and fingers

Approximately 15 minutes after receiving the Covid-19 vaccine, I started to feel a tingling in my throat. It prompted me to repeatedly try to clear my throat. I then felt a sensation of my throat getting tight mildly restricting my airflow. Next my throat became sore. I experienced pain when swallowing. I then became hoarse and lost my voice for about 8 hours. Currently (19 hours after receiving vaccine), I am still experiencing a sore throat, but all other adverse effects have since resolved.

At 10 minutes post vaccine developed itching. Then became flushed and dizzy, then developed diffuse hives.

Caller stated that after vaccine about 12 in the afternoon she felt nausea, fatigue and a headache. Caller took the Zofran and slept for 20 hours and felt better.

Patient received IM vaccination. Was observed for a period of 15 minutes with no symptoms and was released. Had no symptoms but started developing numbness and tingle sensation in left arm. Patient felt cold sensation in left arm. Patient is being monitored for signs and symptoms in observation room. Will council patient on reporting to primary care physician. Will continue to monitor patient until resolution of numbness. Currently, patient does not feel any coldness in left arm anymore and is starting to feel normal.

"5 Minutes after vaccine, patient said she started feeling really hot and nauseous. All vitals stable. No other symptoms at that time. 15 minutes later, she said she was feeling ""out of it"" and it was hard to re-call names, she had a metallic taste in her mouth. Attending doctor on duty came to assess patient, emergent care was not deemed necessary. Vitals remained stable. 30 minutes after vaccine, she said her joints were starting to get achy. Since we are a pediatric hospital, I told her she should be seen at a higher level of care facility, she refused. She was monitored for 2 hours, after that she was better. At 12:30, 2 hours after vaccine, she said she was felt much better and her mind was much clearer and her other symptoms were much better. At 3, she said all her symptoms were gone, she was just tired. She got into contact with her Lyme Disease Specialist and they said it sounded like an autoimmune reaction, but they would still like her to get the second dose in 21 days. I will remain in contact with patient to ensure she does not have other adverse effects."

Patient became light headed and dizzy, patient stated often reacts this way after injections. Minimal po intake prior to immunization. Patient laid flat on the floor, drank 10 ounces of water, 4 oz. Orange juice. BP went from 94/50 to 108/62 ten minutes after first measure. Prior to leaving BP was 110/64, pulse 64 and patient reported no symptoms. Patient refused transfer to ED and felt fine prior to leaving after 30 minutes of observation. She left in care of two co-worker RNs feeling asymptomatic and ambulating independently.

patient got hives on the left arm that began 5 minutes after vaccination on her right arm

Fevers, Chills, dizzy body aches, pain and swelling at the injection site

About 1.5 - 2 hours after receiving the vaccination I felt very dizzy and disoriented. This was around 11:00. Around 2:00 I was still feeling disoriented, so I went to report it to my doctor. They took my blood

pressure, temperature, and observed me for 30 minutes. My nurse had reported that my BP was high. After 30 minutes they took my vitals again and my BP was still high. Today on 12/18 I got my blood pressure done at 10:30 AM and my nurse had reported that my BP was still fairly high. 144/88. They then took my BP manually and it was 138/82.

She felt a little warm in the chest and stomach area. She felt her heart was racing. She didn't have shortness of breath or difficulty swallowing. She felt it was the same reaction as when she had her TDap vaccine

She felt a little warm in the chest and stomach area. She felt her heart was racing. She didn't have shortness of breath or difficulty swallowing. She felt it was the same reaction as when she had her TDap vaccine

Tachycardia, chills, nausea, and light headedness

diffuse itching immediately after injection

Dizziness, numbness and tingling bilateral legs and arms, developed after 5 minutes of vaccination. Vaccine at approx 1:00 PM, 1:05 dizziness, 1:07 numbness and tingling legs, spreading to arms. Denied SOB, chest pain.

Itchy all over body.

Metallic taste in mouth

Body pruritus, generalized, diarrhea Treatment: Benadryl 50mg Solumedrol 125mg Pepcid 20 mg

Swollen lymph nodes, sore throat, flank pain, aching joints, dizzy, feeling faint, fatigue, back pain, diarrhea

PT RECEIVED COVID VACCINE. WAITED THE REQUIRED 15 MIN OBSERVATION TIME. AFTER THE 15 MINUTES PT STATED SHE NOTICED SOME LIP SWELLING AND THROAT TIGHTNESS. PATIENT ALERTED STAFF. PT ASSISTED TO SITTING POSITION. PT REFUSED TO LAY DOWN. BP AT 1233 WAS 160/102 HR 99. PT VISABLLY SHAKING. PT STATED NO DIFFICULTY BREATHING. PT ADMINISTERED 25MG IM BENADRYL PER EMERGENCY ORDERS AT 1235. BP BP AT 1238 WAS 150/91 HR 80 SAT 96. CALLED TO PATIENT. NO INCREASED SYMPTOMS. PT WAS TOLD TO STAY TO BE MONITORED FOR FEW HOURS. RECHECKED PT AFTER 15 BP 151/76 HR 90 O2 100% ON RA. AT TIME OF THIS ENTRY PATIENT NO LONGER COMPLAINS OF FURTHER SYMPTOMS AND IS IMPROVING.

Throat tightening and patient started to tremble 30 minutes after vaccination. Also became tachycardic. Patient was treated with methylprednisolone 80 mg IV x 1, famotidine 20 mg IV x 1, and diphenhydramine 50 mg IV x 1.

Fever (temp 101.1) and headache for 8 hours

Flushing of face, mild headache, blotchy skin on truck (front and back), upset stomach Gave Benadryl 50mg at 11:15am Symptoms not progressing

Angioedema

nausea, headache, rash, hot all over

1020 Dizzy and lightheaded after she sat down for observation time. After 5 minutes complained of tongue tingling. No SOB , no swelling of the throat or lips. Vital signs normal. Injection site , no swelling or redness noted. Water was given to drink , no adverse reaction. 1040 Tongue tingling resolving. Vital signs normal. 1100 All symptoms resolved and she was released to return to work per Occupational Health Nurse.

5 minutes after receiving vaccine I felt like I was going to pass out. They took me to the ER. Heart rate went up to 160 at one point. Was given steroids, Benadryl, and Pepcid and that helped. This helped and then heart rate went up again. Tremors and BP was up.

diaphoresis, pallor, nausea, vomiting over 20 minute period

Metallic taste, headache

Rash and tingling lips approximately 40 minutes after Pfizer-BioNTech COVID-19 vaccine 0.3 mL injected IM into the left deltoid. Presented to ED to report symptoms. Symptoms mild enough that patient did not want to have any interventions. She just wanted to report them for tracking purposes. Instructed to return in symptoms worsen or if new symptoms develop. Patient did not return, so assuming no new or worsening symptoms.

Rash and tingling lips approximately 40 minutes after Pfizer-BioNTech COVID-19 vaccine 0.3 mL injected IM into the left deltoid. Presented to ED to report symptoms. Symptoms mild enough that patient did not want to have any interventions. She just wanted to report them for tracking purposes. Instructed to return in symptoms worsen or if new symptoms develop. Patient did not return, so assuming no new or worsening symptoms.

I initially had to sit down for about 15 min and felt my mouth dry, my tongue was kind of tingling, not swollen. I was checked for anaphylactic shock. I felt like an adrenaline shock, and felt my heart racing, my BP was high - stayed in the ER for an hour for observation. I felt the same kind of sensation when I had COVID in July. This morning, had chills early in the morning around 1AM but it is all gone now.

Hives, itching, warmth on bilateral face and neck and chest. Tachycardia. Facial swelling.

Chest tightness, sob, tachycardia Treatment: Benadryl 50mg Solumedrol 125mg

Patient reported numbness and tingling on the tongue 5 minutes after receiving the COVID-19 vaccine, she has a history of anaphylactic reaction to sulfa, epi pen administered at 13:50pm. Took by ambulance to emergency room at 14:10pm today

Shingles-like rash on torso and back with burning sensation and nerve pains. This began approximately 30 hours post vaccine administration. Patient has not yet received treatment for this rash however intends to go for treatment in the next day.

Vaccine recipient reported bilateral hand tingling (paresthesia) in fingers shortly after vaccination. Vaccine recipient was sent to the ED for further evaluation. She reported to be also feeling anxious. She was alert and oriented to person, place, time, and situation. No focal neurological deficit. After re-evaluation, her condition was improved/stable and was subsequently discharged to home the same day. Followed up with the vaccine recipient the same day. They are resting comfortably at home and reported that symptoms have resolved.

pt reports approx 4-5 hours after injection, low grade fever (Tmax 100.4), +emesis/vomiting, generalized body aches. pt reports resolved as of 3:00 pm on 12/18/20.

12/16/2020 five hours after the injection Pain at the injection site no redness or swelling, intense soreness, shortly after severe chills, shaking, without fevers, myalgia every muscle in my body was sore and heavy feeling and was difficult for me to walk or move and had to hold on to things to walk, intense fatigue I should not have tried to work and 36 hours later I felt better, I never felt hot and this morning 12/18/2020 I felt recovered 90% with mild lower extremity pain

local erythema and raised skin at site of injection measuring 5x4x1cm, non tender, mild warmth to site. No pain, loss sensation, no loss strength, no LAD axilla or chest, normal ROM, no tenderness to this site. NO constitutional symptoms and the patient was unaware of a local skin reaction.

"About 20 min after injection she reports feeling flushed, heart racing. Face, neck chest and upper arms are red and warm to touch. Initial Vs-198/106, HR 113, SpO2 100% on RA. Lungs CTA. Given 25mg Benadryl with HR decreased to 100 and BP 161/92 after 25 minutes of observation. Left after 30 minutes of observation to return to work, stating ""I feel much better""."

Individual started to feel light headed, tongue felt numb, felt hot. Skin had some light-red blotches around collar-bone.

Patient reports rash and burning sensation to face and some discomfort at neck. Claritin and ibuprofen OTC and if any worsening symptoms, instructed to report to the ED.

Pt complained of dizziness. Headache pain 7/10. flushing and fatigue. BP was 207/120. Pt sat down in treatment, She took 650 of APAP. She eventually had to lay down. Eventually she seemed fine but was recommended to got to the ER. Pt went to ER, got a ketorolac shot, and BP was down to 130/100.

Radiating pain to neck and back. Felt like a flare up myalgia. Also headache, nausea and feeling very dizzy .

Dazed look with nausea and dry heaving; staff standing near her said she looked green

Body Aches, Headache, Congestion, Fever, Right Eye Swollen

10 minutes after the administration of the vaccine, the patient complained that she felt very hot. She was visibly flushed and diaphoretic. She developed nausea. At 1532, BP 142/94, P88 and O2 sat 100%. She was given cold water to drink and monitored. At 1540 BP 144/93. Applied cool compresses to forehead and neck. Patient continued to drink cold water. Continued to monitor patient. No further nausea. At 1555 BP 135/87. Stated that she felt much better but still felt a little off. No longer flushed or hot, no longer diaphoretic. At 1604, stated feeling even better. BP 119/87. Walked around a bit with patient and she stated she felt ok. No further symptoms. At no time did she have any rash or respiratory issues.

A few minutes after vaccine was given patient notes numbness in L thumb then L arm felt heavy and slightly numb; This resolved completely within 30 min

"Patient described ""pulse like stinging"" at injection site shortly after injection and continued through the 15 minute observation time."

Patient felt light headed; tingling all over body which resolved within 30 min

Rash and itchiness

About an hour after the shot my face felt flushed and itchy. When I looked in the mirror I saw raised, bumpy rash on both cheeks, left for than right side, on both ears. I took benadryl and tylenol - for my itch and generalized malaise. Next morning rash spread to my neck and left antecubital. Rash on my arm continues to spread and is as itchy as poison ivy.

sob, nausea, malaise, vomit, chest pain, throat tightness

numbness in left jaw; seems superficial; feels like local anesthetic

Couple of hours after started feeling body aches, chills, subjected fever, never had a response like that to a previous vaccine. Took some advil, feel about 95% better now.

"Upon conclusion of the 15-minute observation period, when asked how he was doing, he said he felt fine but that he noticed a ""tingling sensation"" of his left (injection) arm and left leg. He was offered the option to stay for further observation, but repeated that he otherwise felt fine. He was contacted on 121820, and he reported resolution of symptoms without intervention."

12/16/2020 I experienced severe body aches and chills, severe headache, and I had a low grade temp about 95 instead of 96, I did have dizzyness about an hour after the shot and I developed a cough about 6 hours after shot, fatigue and wore out from the chills and body ache I alternated ibuprofen and tylenol for 24 hours. Today 12/18/2020 the cough is gone and I feel better

Resident became short of breath 7 hours after vaccine, went to hospital, was COVID+

Woke up the morning after the vaccine with light headedness, chills, body aches, headache, nausea.

"A 56 year old FEMALE who has been waiting at monitoring area after Covid 19 vaccination, provided called to evaluate patient c/o: Chief Complaint: Patient was being checked at 1039 for final 15 min wait time after Covid-19 vaccine. Patient states she is feeling light headed and nauseated Doctor was informed. Took patients vitals. 11:06 patient was put on 6 liter of O2 with face mask 11:08 patient was out on to 4 liters 11:10 patient states ""I'm feeling better, flutter in my stomach"" 11:17 Doctor instructed RN to give Solumedrol (IM) injection to patient 11:22 Patient states ""I'm having a heartburn feeling, tightness in my chest. I put patient in a sitting position. 11:31 Patient states ""I'm feeling better"" 11:35 Employee came and gave patient solumedrol injection (IM) RT Deltoid @11:36 11:41 Patient states ""I'm feeling better, heartburn is going away slowly, I can breath now"" 11:49 Patient states ""I'm feeling better"" 11:50 Doctor states ""I will be putting in an order for epi pen for patient and she can pick that up from pharmacy when she leaves"""

Racing heart rate, 101 at rest, palpitations

chills, muscle cramps, headache, and low grade fever 99.8

caller stated that she had fever, chills, vomiting, diarrhea and fatigue. Caller took Tylenol and slept for 20 hours and awoke this morning feeling rested.

extreme runny nose, occurred immediately after injection

Body Aches, Headache, Chills, Congestion, fever started on 12/18/2020 at 0300 AM Itching - right after injection given Benadryl and pepcid 15 min after the vaccination

Dizziness, nausea, dry mouth; felt hot; later developed chest tightness sour taste in mouth; rapid heart rate; tingling on same arm vaccinated (L arm) some numbness in same arm L arm; felt shaky for 15 min; Blood pressure elevated

I had a fever of 100.5 and migraine and a sore throat.

Severe headache onset, mild muscle aches, and fatigue starting 6am, the morning following vaccine, diminishes with ibuprofen and Tylenol but does not go away. Still ongoing at 4pm the day following vaccine.

tachycardia, flushing, severe hives on arm received vaccine, dizziness, palpitations

Day following vaccine, fever, sob - went to hospital, COVID+

severe body aches, rigors, fever, headache, joint pain,

metallic taste, sob, joint pain, cephalea tx: solumedrol 125mg Benadryl 50mg

Throughout the day following vaccination, I have felt extremely sleepy, fatigued, with generalized muscle soreness.

developed itching, nausea, light headedness - required transfer to the ED for observation

Head felt like she was swimming, headache, heaviness in chest, lump in throat, BP spiked then dropped, Fainted - was given benadryl by mouth and Solumedrol IM

Patient developed shortness of breath, cough, chest tightness, and tachycardia

"A 54 year old FEMALE who received Covid 19 vaccine today and c/o ""lightheadedness and puffy/itchy throat a few minutes after injection"" while was on monitoring area after vaccination. Nursing note:11:16 I was told by co worker that patient was going to need vitals, so I took vitals notes given to me: throat tingling/tightness, light headed, nausea, allergic to aspirin 11:17 staff gave orders to RN to give Solumedrol (IM) to patient. she took patient information to get medication 11:26 patient states ""I'm feeling okay"" 11:32 patient states ""I'm feeling good"" 11:37 RN gave patient solumedrol (IM) injection to patient on left deltoid @11:38 11:42 patient states ""my left arm hurts"" 11:47 Patient states ""my left arm is really hurting after that injection"" pain scale 10/10 11:50 staff states ""I will be putting an order in for epi pen and to pick up at pharmacy"""

blister at site of injection tiredness tx: tylenol

Patient received injection at 14:05 at 14:12 he reported not feeling well. Patient was diaphoretic, clammy, pale, described the inability to see, had difficulty following commands. Patient transferred to gurney with max assist and transferred to E.R. Patient symptoms resolving during transport. Left patient in E. R. care at 14:15.

pain at injection site mild, nausea and vomiting, body aches, migraines,fatigue

Headache, body aches, fatigue, malaise, chills starting about 12-18 hours after. Symptomatic relief with Tylenol 500 mg PO q6h helpful. Symptoms were self-limited by 48 hours post-vaccination.

Rash started on scalp and then trunk and arms. itching all over body

I felt kind of like daze and light headed 10-15 min after the vaccine. The remainder of the evening felt fatigue also felt pain at the injection site on left arm . On12/16 left arm was still hurting and wasn't able to participate physical activities couldn't go to the gym.

Pt received Covid 19 Vaccine on 12.18.20 at 10:46am in Right Deltoid. Pt presented to the ED at 1:50pm with suspected throat swelling. Denies itching, redness or tongue swelling. Treatment: Epinepherine 0.3mg SQ- 1:55p Benadryl 50mg/IV- 2pm Methylprednisolone 125mg IV- 2:02p Pepcid 20mg IV- 2:06p Discharged at 3:53pm with all symptoms resolved. Pt prescribed an epi-pen

Notes 12/18/2020 á á á á Subjective No chief complaint on file. Patient is a 25 y.o. female who had no chief complaint listed for this encounter. á á á History of Present Illness á Patient is at the Covid vaccination clinic Received her vaccination and approx 5 min following administration notified staff that she was feeling a little lightheaded Was also c/o feeling hot at time Patient admits that she did not have breakfast this AM and has not had anything to drink Denies throat discomfort or tingling No shortness of breath or headaches Patient brought to the bay for evaluation á á á History Review / Additional history á Review of Systems á Patient's medications, allergies, past medical, surgical, social and family histories

were reviewed and updated as appropriate. Objective á Blood pressure 126/74, pulse 88, SpO2 98 %, not currently breastfeeding. Physical Exam HENT: Head: Normocephalic. Cardiovascular: Rate and Rhythm: Normal rate. Pulmonary: Effort: Pulmonary effort is normal. Musculoskeletal: Normal range of motion. Skin: Capillary Refill: Capillary refill takes less than 2 seconds. Neurological: Mental Status: She is alert. Psychiatric: Mood and Affect: Mood normal. Behavior: Behavior normal. á á á á Assessment / Plan á VSS on arrival to evaluation bay Following laying down for 10 min, drinking water, and eating a granola bar patient reports feeling much better. Sat at the bedside for an additional 5 min with no recurrence of symptoms. Repeat VSS Instructions given to go to the ED if worsening symptoms, lightheaded, throat swelling or shortness of breath. Encouraged to eat and drink prior to next immunization. á

Red neck and face 10min after injection lasting 15-20min Short episode of self resolving tachycardia

throat swelling, heart palpitations, trouble swallowing

Moderate left arm pain throughout the whole arm, feeling cold in the arm. The patient has normal pulses, normal motor and sensory function.

My left arm has had pain and still hurts today. It's hard to use it to dress and undress. I got a fever that would not come down and the worst heachache that felt like a migraine and I never have ever had one before, body aches, joint and muscle pain, fatigue and I couldn't stay awake , nausea, upset stomach with diarrhea within 10 or 15 minutes of getting the vaccine. It felt like a really bad flu that lasted 8 hours.

Patient received COVID-19 Vaccine 12/17/2020. Upon waking 12/18/2020 around 8am noted swelling, itching, and redness in face. Denies any shortness of breath. Patient seen in clinic and given benadryl 25mg at 1230pm. Symptoms improved.

Patient came over and advised me he felt like his throat was swelling and he was having a little difficulty swallowing. He was able to drink water which he thought helped. He was given Benadryl 50 mg IM. Symptoms resolved completely.

chest pain on right side immediately after vaccine administered. nausea, headache, right side neck stiffness

Pfizer-BionTech COVID 19 Vaccine EUA. Received injection one in right upper arm. One hour later started to experience some nausea and mild headache. Within several hours later, headache throbbing, nausea worsening with vomiting. Eight hours later, right arm throbbing, pain going up and down arm. Hand and fingers throbbing. Pain in back of head, neck and down back into right hip. Nothing relieved pain or nausea. Tried ice packs, cool rags, motrin, tylenol, maxalt, zofran. 24 hours later, still have symptoms, not as violent, but pain and throbbing continue and unable to eat or drink anything.

nausea, low grade fever, weakness

Shortness of breath and throat tightness 45 minutes after injection

metallic taste, could not swallow

65-year-old female received COVID-19 vaccine at the Urgent Care Center. She waited around 15 minutes after the vaccine and had no reaction. About 10 minutes later while in her car she noted a numb feeling of her tongue and that the tongue felt swollen but was not necessarily swollen. She subsequently felt that her lips were tingling and had swollen feeling. She returned to the facility and was given an EpiPen shot at around 10:15 AM. Patient was transferred to ED via ambulance. Gradually the symptoms resolved and was discharged from the ED in stable condition

Patient experienced redness, itching at the injection site with tingling through fingertips within about 10 minutes of receiving injection.

"t 3am she woke up and noticed some facial tingling on the ride side that felt like ""pins and needles"" - she reports like ""when you get a numbing shot at the dentist"". She also had some right arm and right leg tingling. She reports the leg tingling as ""normal"" as she has a hx of sciatica. She she woke up for the day then this morning the tingling in her arm/leg had resolved. She had coffee and cinnamon roll then started to clean the hou also had inner eye lid with itchiness. She began to have mild chest tightness so she took her inhaler - Albuterol and she took Claritin."

Light headed and flushed

c/o chills, nausea, hypertensive (170/100), flushing of face, redness and blotching of chest and neck

Dizziness sense of throat swelling

body aches, very tired

Patient felt like he was going to pass out. Reports this is normal and occurs when he gets shots or labs drawn.

20 min, c/o slight burning and itching to R arm, declined vital signs. Sx resolved and requested to leave.

"Pt complaint: ""heart racing, hot flash, feeling like fainting if I stand up"" approx. 10 mins post 16:30 vaccine admin. RN & another RN checked pt's vitals & BS. 16:45- BP 130/105, HR 160, O2 100%. 16:48- BP 148/93, HR 96, O2 98%. 17:00- BP 123/86, HR 68, O2 100%. 17:20- BP 122/86, HR 97, O2 92%. BS 83 @17:15. Pt received H2O, ice pack & elevated feet on chair. Pt noted symptom resolution & MD evaluated & walked pt back to work site."

carpopedal spasm of both hands immediately following receipt of vaccine

Vasovagal response

"Patient recieved first dose of covid-19 Vaccination on 12/18/20 at 11:49 am. Went into observing area and at 11:54 felt hot flush that moved upwards from chest to top of head. Vital signs taken 98.9, p117, bp 172/95, 100% oxygenation per pulse ox. Repeated blood pressures 128/84. Patient states that she is always in 90's systolically and 60's diastolically. The whole time patient stated that she had a ""cold""

feeling throughout the chest area. Pulse fluctuated from high 80's to low 100's, Patient stated she also had a "" lump in her throat"". Decision was made to transport her to the ED via Wheelchair where she was assessed and dx of Adverse reaction to the covid vaccine. EKG, CBC, BMP, Troponin 1 with high sensitivity done as well as a chest Xray. All tests within normal range and patient discharged home with orders to follow up with primary care physician as soon as possible."

1759 BP 135/79 HR 78 Reports feeling woozy, like she just gave blood, hands shaky, lunch was eaten at noon, brownie eaten mid afternoon 1800 8oz water given and 8oz of orange juice and granola bar 1809 Associate reports feeling better- less woozy, less shaky 1818 B/P 134/57 HR 77, no rash, no swelling, no respiratory complaints; dr evaluated associate and offered ED for continued support and associate declined.

About 5 minutes after receiving the vaccine, recipient reported tightness in the arm he received the vaccine. Five minutes later reported feeling light headed and tightness in his throat. Blood pressure taken--142/80 with 102 pulse. Reports no difficulty with breathing. Respirations easy and nonlabored. SaO2 99%. After reporting to healthcare provider, instructed to give Benadryl and call 911. Vital signs @ 3:30pm 139/81 with 79 pulse, temp 97.6 SaO2 100% Paramedics arrived at 3:35pm Recipient refused transport. Agreed to be escorted to ER via shuttle. Arrived at ER @ 3:53pm

Dizziness

The patient received the vaccine and reported shortness of breath, pallor and feeling that her throat was closing. Patient was given 25mg PO Benadryl and brought to the ED. On arrival patient continued to report feeling tightness in throat but states that she is breathing well.

headache, chills, and fever at 102

Severe headache and body aches beginning 20 hours after vaccine, lasting 3 hours.

Pfizer-Biotech COVID-19 Vaccine EUA, PT DENIES ANY SIGN OR SYMPTOMS OF SIDE EFFECTS OR ADVERSE EVENTS AT THIS TIME. PT WAS ADMINED DOSAGE THE WAS RECONSTITUTED WITH 0.8ML INSTEAD OF 1.8ML.. WAS NOT UNTIL 4TH DOSE FOR 4TH PT WAS DRAWN UP WAS IT REALIZED THERE WAS NOT ENOUGH TO COMPLETE 6 INJECTIONS FROM MULTI DOSE VIAL. FOR REMAINING RECIPIENTS. ADMIINISTRATION WAS STOPPED, MED RETURNED TO VIAL PLACED IN SEPERATE BAGGIE AND RETURNED TO PHARMACY. PHARMACIST, PFISER AND HOSPITAL ADMIN WERE NOTIFIED. aLL REMAINDER DOSES FROM FOLLOWING VACCINE VIALS AND ADMINS WERE RECONSTITUTED WITH 1.8ML OF PRESERVATIVE FREE SODIUM CHLORIDE AS ORDERED, THE VACCINE THAT WAS RECONSTITUTED WITH INCORRECT CONCENTRATION WAS PLACED IN PHARMACY FOR PHARMACY TO FOLLOW UP. # DOSES WERE GIVEN TO 3 SEPERATE PTS OF HIGHER CONCENTRATION DOSAGE. there WERE A TOTAL OF 5 0.3ML INJECTIONS IUN THE BOTTLE INSTEAD OF 6.

"Patient did well the vaccine, then during the observation period almost 15 minutes patient stated, she felt like she was have a panic attack. Felt like her heart was racing and felt like she wanted to cry, Took vital signs and gave her a beverage and pudding. She called her mother. She felt better after she spoke

with her mother. Took another set of vitals and pt. stated, ""I feel better and the staff handed patient off to her mother. Time it took was maybe 25 minutes after receiving the vaccine."

Within half hour of receiving COVID vaccine, patient developed headache, then began feeling lightheaded and began pale. Attempted to lay down, upon standing felt lightheaded and noted some numbness around her lips, arms, and legs. Symptoms include faintness, near syncope, and numbness. After about 10-15 minutes of not feeling well, patient was escorted to the Emergency Room. Patient received fluids and was discharged home. Patient reports at 5pm that she continues to have slight headache and arm soreness with no further near syncopal episodes.

Itching

Pfizer-BioNTech COVID-19 Vaccine EUA: Approximately 10 minutes after receiving vaccine patient reported itching in her right arm and back and traveled to the rest of her body. Patient sat in chair with vital signs: blood pressure 133/70 mmHg, oxygen saturation 96%, temperature 97.3 degrees Fahrenheit, respiratory rate 18 breaths per minute, and heart rate of 62 beats per minute. Diphenhydramine 25mg oral liquid administered and at 6:54 am patient stated reaction started to go away. Repeat vital signs: blood pressure 128/68 mmHg, heart rate 68 beats per minute, respiratory rate 16 breaths per minute, oxygen saturation 97%. Patient left vaccine clinic independently in stable condition.

stomach ache, elevated heart rate, eye drainage. No treatment. Stomach pain is continuous.

Hives

Following her vaccination during the post-observation period of 15 minutes, she began to be dizzy, short of breath, and right-sided chest pressure. Also c/o headache. BP 156/102, pulse 76, O2 Sat 99%. She was evaluated by Dr. and determined to transfer to the ED

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Moderate swelling, redness & pain at injection site, warm to touch for just over 24 hours. Moderate muscle & joint pain continuing over 48 hours. Dull headache more than 48 hours. Moderate fatigue continuing more than 48 hours. Alternating taking Tylenol & Motrin since vaccination with little relief.

Employee states that after one hr she felt her heart pounding and took her pulse and it was 158 and no other symptoms. Denies chest pain. Staff took her R BP and it was151/113 on a machine. Recheck 10 minutes later BP 151/112, P 126. Patient was brought to the Occupational Medicine Dept. Recheck at 20 min BP 125/68 and an apical pulse of 88. HR regular, rate and rhythm. Employee states she feels fatigued currently, denies shortness of breath, chest pain, itching, swelling of oral cavity.

migraine, pain from shoulders to head, stomach pain, vomiting. For treatment, patient took Zofran, insomnia

Patient presented with hives to upper extremities approximately 2 hours after receiving the vaccine.

"Patient experienced tingling throughout body (""from tops of feet to earlobes"") approximately 10 minutes after the injection. It resolved after 30 minutes. Patient went home without further reported issues."

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Approximately 10 minutes after receiving vaccine, patient felt light headed. Patient drank juice and felt better. Approximately 20 minutes after vaccine administration, patient began to complain of tongue tingling. Patient received Benadryl 50 mg IVP. Rash developed on her chest. Patient given Solumedrol 125 mg IVP, Famotodine 20 mg IVP and NS wide open. Epi pen 0.3 mg IM was administered and patient became tachycardic. At that point, patient was transferred to the ED.

pt with n/v diaphoresis and hypertensive with SBP 180's

itching, starting with the arms and went to the legs and the trunk. Hot flushed ears. Tiny red pin point red rash to the inside of arm and legs. Gave benadryl 50mg for treatment. Partial resolution of symptoms.

Light headed, Itchy Chest, Chest tightness, Heart racing, Throat tightness, Tingling legs

Shooting pain and weakness in legs bilaterally, tingling around mouth, right knee is swollen and painful/stiff in the joint, Generalized muslce and joint pain/aching, headache, lightheadedness, nausea, vomit x 1, temp of 99.9, Low BP 88/60

diaphoresis, rigors, chest pain, slight sob.

PATIENT HAD AN UNEASINESS WITH RASH TO LEFT SIDE OF FACE AND TINGLING OF LIPS. PATIENT WATCHED FOR ADDITIONAL 15 MINS UNTIL RESOLVED

Was walking to car when she felt her throat become stratchy, sore, and a lump in it. She came back in to be evaluated. Was escorted to ED for further evaluation.

She had the vaccine at 0700 and at 0800 she developed Lightheadedness, sore throat, body aches, chills, headache, nausea. She was not having these symptoms before the vaccine.

numbness and tingling sensation to right hand 4th digit and ulnar border of right hand palm

Dizzy H/A Shakey Stable vitals pt monitored for an additional 30 min provided fluids pt brought to the ER at 816 am

Started to feel strange about 10 minutes after the vaccine. Dizziness, disoriented, foggy, high blood pressure that lasted about 11hrs. Monitored BP and then sent home to rest and checked blood pressure through out the day. Body aches, chills, fatigue, headache the next day.

Very vague, did not feel well, felt concerned enough to come to emergency department

Runny nose, body aches, fatigue, slight nausea

"A 44 year old FEMALE who c/o lightheadedness and ""general discomfort"" while in the monitoring area after getting Covid 19 vaccine. Denied hx of HTN. Provided PO hydration. vitals re-checked at short intervals. Patient BP stabilized. Discharged to work area w/o symptoms."

Hot flushed itchy throat monitored vitals provided fluids vials stable pt monitored for an additional 40 min Sx resolved pt ok to leave

Tingling in throat for the first 15-20 minutes, then it stopped. Had an EpiPen just in case. Painful arm after injection. Still having pain. Had headache after injection. after 4-5 hours headache started again. Hard to keep eyes open, having a lot of pressure in head, osteroarthritis has flared, back pain is worse, arm hurts even she's not moving, having joint pain in wrist, swollen lymph nodes, and feeling very tired. Having a lot of joint pain. Everything has been harder to do today. Still having throbbing headache with pressure. Did not take any medication yesterday. Took prescription medication today after about 16 hours after vaccination.

Slight non-itchy rash noted after vaccine administration. Rash well demarcated, nontender approx 4x4 cm, no desquamation. No other sxs, no respiratory sxs.

Fatigue,fever ,pain at the site of injection

Patient c/o throat tightness 16:02 T 98.2 BP 145/95 99% room air HR 76 16:08 BP 145/96 HR 73 99 % room air Patient was given Epinephrine 0.3 IM in left deltoid. Patient AAo x3, talking. Transported to ER for closer observation.

pt had c/itchiness at the injection site quick onset of HA Diaphoretic numbness upper and lower lips dry throat Monitored vitals vitals stable fluid provided Sx continued advised assessment at the ER pt agreed pt escorted to the ER denied SOB or chest pain

Mild pain in left deltoid, moderate headache for 10-12 hours

at 11pm started to lot of soreness, lump in armpit. Periods of feeling very hot, chills and profuse sweating. woke up at 11pm, 1am, 3am, 5am 'woke up every few hours with intervals of profuse sweating'. 12/18/2020 feels like 'never happened' other than some soreness in arm.

"A 42 year old FEMALE who received Covid 19 vaccine today, provider was called at monitoring site due to pt c/o headache after about 10 min of injection and ""throat tightness/scratchy"", headache, palpitations. Discussed with patient current symptoms and multiple food allergies. Medications ordered STAT as below. Patient started feeling better of her pharyngeal/laryngeal symptoms after Epipen inj applied. Headache had improved also. BP rechecked at discharge from monitoring area as below. TODAY'S ORDERS: EPINEPHRINE PEN INJ,SOLN INJECT ONE INTRAMUSCULARLY STAT Quantity: 1 Box Days: 1 Refills: 0 *Chronic Med: NO Dispense as Written: YES Indication: Adverse reaction to vaccine product | METHYLPREDNISOLONE SOD SUCC INJ,SOLN 125MG/VIAL INJECT 125MG INTRAMUSCULARLY NOW *MED GIVEN IN CLINIC OR ER* Quantity: 1 Vial Days: 1 Refills: 0 *Chronic Med: NO Dispense as Written: YES Indication: Edema of pharynx |"

Individual started complaining of an itch in her throat and felt some degree of lymph node swelling on the right side. Collective symptoms include: anxiety, flushing, short term paresthesia, right sided facial swelling, difficulty swallowing, right sided facial droop, medicinal taste. some slurring. Individual was taken to the ed in house, triaged, treated and released. Reporter is not privileged to details of treatment, but aware of release within hours of being seen.

Lightheadedness, numbness of bilateral lower extremities (below knee)

A 35 year old FEMALE who presents to monitoring station after getting Covid 19 vaccine, after a few minutes c/o lightheadedness, no other accompanying symptoms. Discussed with patient current symptoms, only lightheaded, no other accompanying symptoms. Initially HBP. Provided PO hydration. Patient recovered after a few minutes. Discharged to her working area w/o symptoms. Advised to return to ER if any headache, increased lightheadedness, chest pain, asthma exacerbation, abdominal pain, N/V. Employee agreed understanding instructions.

Patient complaint of rash,hives,difficulty breathing and swallowing, wheezing, throat tightness, hoarseness, itching and feeling light headed less than 10 minutes after receiving the vaccine. Patient received Benadryl 50mg IVP, Pepcid 20mg IVP, 0.3mg epi IM. EMS arrived and transported patient to ED. In ED, patient received second dose of 0.3mg epi IM. Patient monitored in ED for approximately 4 hours. Epi drip started and plan to admit patient for observation.

Patient complained of chest tightness, L hand tingling and throat tightening less than 10 minutes after receiving the vaccine. Patient received Benadryl 25 mg IM and NS IVF. EMS transport to ED. In ED,

Solumedrol 125 mg IVP and Famotodine 20 mg IVP. Patient monitored in ED for approximately 4 hours. Discharged home on Prednisone.

Fever Chills Fatigue Nausea Headache Sore injection site

5 minutes after shot administered, became very hot and flushed. Felt tingle in throat. Turned bright red. Sent to ER. Throat tingle subsided after about 30 min. No anaphylaxis. Given Zyrtec for slight itchiness

12/15/2020 Strong diarrhea 1x. 12/16/2020 felt 'not right'. temperature 99.3,99.5. took tylenol. headache. Temp went down. Felt weak. 12/17/2020 tylenol, nausea, light headache 12/18/2020 Felt the 'most weak'.

Described numbness to left side of face, inside of mouth and leg and arm. Arm and leg numbness quickly dissipated but left facial numbness continued.

Patient began feeling numbness/tingling in left hand. Began to feel nauseated, dizzy, flushed, and light headed. Symptoms would come in waves. Felt shaky. A few nurses and pharmacist on duty came to assess her. Heart rate was 110, SpO2 was 99. Assisted her into a wheelchair and brought her to a separate room so she could lay flat and elevate legs Checked blood pressure, 122/58. 10 minutes after reactioni started heart rate had lowered to 87. Once she was laying down she did not experience any additional dizziness, flushing, or nausea. After she sat up for a couple minutes, ambulated in the hall with nurse she was released at 6:20pm and a friend drove her home.

-Received COVID vaccine 2:15-2:30 pm -Felt fine during 15 minute observation -Came home (about 25 minute drive) -Put on new plastic gown to help 88 yo father sit up in his hospital bed. He was clean and dry. -As I was fiddling with the blue plastic gown, I felt mild itchiness on right forearm and started scratching. -I looked at right volar forearm (supine position) and noted about 6 raised 2-4 mm blanching bumps with central darkening (like a small scab almost) - 4 below antecubital fossa, one in the actual fossa and another one immediately proximal. Mild itching, nothing distressing. -Lesions still persisting (To Dec 18). I am not scratching/taking anything for it. Lesions are visible. -No other family members (including father) with any skin rashes, no bed bugs, spouse who also lifts/cleans elderly father has no skin rashes -Evening of Dec 17 and persisting to mid day Dec 18: mild sore throat, nasal congestion, mild myalgia, fatigue, subjective fever but when took temp- no fever. Then all of a sudden, the sore throat/nasal congestion, myalgias, tiredness abated all around 3:30 pm. Skin lesions still present. -All of these symptoms were mild. -Again, skin lesions on right volar forearm persist.

15 minutes into her event she begin to feel tingling and numbness, the left side where she received the vaccine became very colder, the associate blood elevated to 148/88. The associate normally have low blood pressure. by 18:45 the tingling and coldness went away.

Presented with periumbilical pain to emergency department (patient works at Medical Center). Admitted to hospital for small bowel obstruction. Labs were consistent with dehydration (Hct 55, Cr 1.25), as well as CRP 1.10. A CT Abd/Pelvis identified proximal dilation and fecalization of small bowel, with a transition point in the left lower quadrant. Distal to the transition point, the small bowel appears

thick, with hyperenhancement and inflammation progressing into the cecum. General Surgery was consulted and patient admitted to hospital for management of this small bowel obstruction.

Headache; treatment ibuprofen and excedrin; improved most with excedrin

Large painful rash over injection site of right shoulder. Sever upper arm pain over injection site.

About 3hrs after administration (1800) pt presenting with bright red rash covering bilateral arms, hands, face, ears, neck, stomach, legs. Reporting pruritus on rash sites, inside mouth, inside ears, inside nose. Rash red in color, raised, splotchy, and warm to touch. Patient took OTC diphenhydramine 50mg at approximately 1815. As of 1930 pt reporting no relief in symptoms. No reduction in rash sites observed. Pt at this time has not sought professional medical treatment.

Lightheadedness, nausea, dry heaves and lump in throat

rash appeared at site of injection, very painful, hot to touch, hard, with rash spreading to torso

"Patient stated she waited the full 20 minutes downstairs without any reactions, however started feeling itchy and swollen shortly after, which prompted her to come up to the caregiver health office. An RN visually assessed patient and patient was not SOB and able to speak in full sentences. Patient states she felt as if she was ""about to have a panic attack"" because of a possible reaction. The RN prompted the patient to go down to the ED if she felt she was having a reaction to the covid vaccination. Patient checked into Medical Center Emergency Department"

21 hours post injection patient feeling body aches, arm soreness at injection, headache, and short of breath with exertion

Chills, malaise, fatigue, muscle and joint aches, left shoulder pain at and around injection site, mild fever: 99.6; took Tylenol. Haven?t taken temps when feeling at worst. Second day symptoms continues, but not as bad. Temp 99.5 second day.

Severe arthralgias, myalgias, headache, nasal congestion noted within 12 hours

Itching started immediately, throat tightness SOB in about 10 minutes with hives on chest

Rash and severe itching/burning sensation on face and neck began the night after vaccine received. 2 days after vaccine primary doctor gave a Kenalog injection.

PVCs, tachycardia from 6:30pm to 12:00am. Took diphenhydramine, omeprazole, acetaminophen at 8:30pm. Went to sleep at 11:30. Heart rate normalized. PVCs continued. All symptoms resolved by 4am on 12/18/20.

At 4pm I began having chills. By 5:30 I began having body aches. I took my temperature at 6pm and it was 100.4. I rechecked my temp at 7:30 pm and it is 100.8

PATIENT HAD WEAKNESS/UNEASINESS (MALAISE) PATIENTS SYMPTOMS RESOLVED BEFORE LEAVING

Patient noted abdominal cramping and then later today vaginal bleeding. LMP two weeks ago.

Headache, not feeling well, slight nausea, dry throat No treatment at this time

Chills, severe headache, body ache, malaise. Recommend ibuprofen and tylenol. Testing for symptoms lasting longer than 24 hours

Pt started tonight with hives on the back of his neck. When talking to patient, he states he developed one on his arm that was spreading quickly. Encouraged to take benadryl and seek medical attention.

anxiety, palpitations, and HTN

Immediately after vaccination, pt had arm, neck and facial pain, which improved, but did not go away. Rash developed on her abdomen this evening. Recommended benadryl and close observation for anaphylaxis and medical attention if it continues to spead.

Severe Headache, sweating, ice and time

Physician 16 weeks pregnant; Administered at 7:45pm, went to observation area; experienced tachycardia; HR: 107; BP: 148/88 O2: 100% approximately 20 mins after injection; Appeared flush. Water offered, transferred to room for isolation; drank 2 bottles of cold water; offered additional medical care; denied need; rested for 1 hr after vaccine; HR: 80s; O2: 100%. Spouse picked up for transfer home; referred to PCP for any additional needs.

The day of vaccination, this employee did not experience symptoms. She woke up on 12/18/2020 with paresthesia to R side of face, that became progressively worse, and is now on the entire R side of her body. This employees face has a slight droop and asymmetric smile on the R side.

Within 5 minutes of receipt of vaccine, reddened ears and reddened blotches on chest appeared. No worsening after 10-15 minutes, but after 20 minutes appeared to worsen, and transport to ED via wheelchair initiated. Pt treated in ED with epinephrine, solumedrol, Benadryl, famotidine and 1 liter of 0.9% Normal Saline IV on arrival time to ED.

Patient reported feeling lightheaded after vaccination around 1111AM. Patient pale in color and sweaty. Patient instructed to lay down. Feet were elevated. MD called over to assess patient. Radial pulse weak. 911 called at 1112 AM. Blood pressure assessed to be 100/76. Patient began to feel better. Water given to patient. EMS arrived to assess patient and vital were reassessed by EMS. Patient confirmed feeling better and was released from EMS care. Patient observed until husband arrived at 1155AM. Released from facility with husband.

Clammy, fever to 101, light headed, malaise, joint pain, fatigue

I developed pain in right first MTP joint at about 8 hour. No prior h/o gout or other arthritis in that joint in past. Over the next 30 hours pain intensified and was associated with swelling, warmth, but no redness. Limited range of motion d/t pain and restricted activity as a result. No other joint issues or arthralgias, myalgias, fever, chills arm pain at injection site or any other significant symptoms. I took 3

doses of naproxen 440 mg 12 hours apart and the swelling and pain are significant ly improved at about 50-60 hours after vaccination. I researched gout as this seemed suspicious and it is reported in the literature that vaccination is a risk factor for precipitating gout attacks which I have never experienced. It never reached the point of severity that I wanted to get arthrocentesis done to prove it was gout, but since this vaccine is new I felt it was important to report my experience.

Woke up at 1 AM this morning with a throbbing headache and inability to go back to sleep. The headache went away after 30 minutes, but I was still unable to sleep. I felt fine enough to go about my day as usual (working out, going to work, etc.), albeit exhausted.

10 minutes after injection developed numbness and tingling in left arm and left foot. Stayed in observation an extra 15 minutes and the returned to work. Symptom persisted for the day

Following COVID19 vaccine employee returned to work and began to feel dizzy/lightheaded/shakey. Went to ED for further eval.

tachycardic, site edema, shortness of breath, dizzy, and felt like her throat was getting tight. She got one dose of epi and 50mg of oral benadryl

Developed a migraine and became really fatigued approximately 8 hours after receiving dose and lasting about 36 hours.

All over warm feeling Dizzy Generalized weakness/Tingling

Rash on his back with welts, mild itchiness of the lips and mouth and no SOB.

c/o tingling of hands/ feet

Associate had hand numbness and tingling in her left hand, left arm extermity was cold. Blood pressure was elevated to 149/96, which is not normal for the associate. She was monitior for a hour. After being monitor for a hour, the associate stated that there is no more numbness or coolness in her left extermity, and no resiratory issue so she was sent home @ 19:50.

Had numbness and tingling in the upper extremities ,associated w/dizziness .

Extreme cramps, diarrhea

Had numbness and tingling in hands , and pain feet. Observed for 30 minutes given OJ. Departed on her own after reporting s/s resolved.

3 episodes of diarrhea after receiving COVID-19 Vaccine Refused Evaluation in the UC or ER and reported will see her PCP if symptoms continued .

Patient experienced an itchy mouth after the administration of her COVID vaccine. She has a known allergy to melon and bleu cheese. She has never needed epi for these allergies. We gave her 50mg of Benadryl and she began to have resolution of symptoms at the 30 minute mark-10 minutes after her Benadryl was given, so not likely in er system yet. Her VS are stable, sats 99 on room air, BP 127/84, HR

84. Our pharmacist weighed in and felt she would be safe to be picked up by her husband so he could monitor her. Our MD concurred with this plan. As of writing this email, we are still monitoring and will continue to monitor for another 45 minutes to see the effects of the Benadryl. We will deliberate with the ED MD on call prior to her release.

"Symptoms of generalized purities ,and rash on skin and taken OTC Cetrizine. 11:20 Escalating symptoms of abdominal pain w/vomiting ,tachycardia ,mouth dryness and >BP was given Epi. 0.3 injection. 11:27 am Benadryl 50mg orally. 11:30 Transported to local ER via paramedic. """

I had a persistent mild headache all day as well as moderate fatigue starting around 2pm EST.

Throat closing sensation, lightheadedness

Soreness, tenderness at injection site

flushing, nausea, vomiting, diarrhea, chest tightness. Gradually improving over subsequent 30min. Treated in ED with 1 liter IV fluid, ondansetron 4mg, acetaminophen 1000mg.

Associate started having arm aches and pressure. She also had right ear pressure. The associate started having generalize aches (myalga). The associate denied to be seen in the ER. The patient left @ 19:50.

Exactly 3 minutes post vaccine administration, I was sitting in the observation area ?the right side of my face started tingling (pins & needles feel), HR went to high 120?s. The staff in that area recognized I was not feeling right, they brought me water and oral Benadryl 25mg and Pepcid 20mg . I sat for approx 30min. My throat started feeling funny?scratchy and like I had a lump in my throat. I kept feeling like I needed to clear throat . At this time at staff took me to a monitored bed in PICU. They gave me another 25mg of Benadryl. Vital signs were stable after approx an hour. I was discharged to family.

Perioral numbness and anxiousness starting 11 minutes after administration and terminating approximately 1 hour later soon after presenting to the emergency department.

The individual developed a quarter size welt immediately after receiving the vaccine. Within the first 5-10 minutes post vaccination, the individual was complaining of pain at the injection site going down her arm, red streaks were visible from the injection site, and she did develop some difficulty breathing, which may have been related to the situation and the mask she was wearing.

unexplainable taste in mouth and burning in her nose.

4hrs after receiving the vaccine. Right arm was swelling, red rash/flushing skin present on arm, neck, abd, and chest. Delayed cap refill on right hand with cold extremities, pallor and purple dusky discoloration. Treatment was 50mg prednisone PO, Benadryl 50mg PO around 1630 At 1700 checked in as a patient to ED and clocked out as staff. Severe chills and muscle ache present no fever. Received 1L NS, IV Pepcid, IV Benadryl 50mg. Unsure of time d/t feeling fatigued Observed in ED till 1920, chills and redness resolved. Left with only localized swelling and slight redness to site. Was instructed to take several more days of prednisone.

noted scratchy throat and lip tingling and feeling puffy- though no signs of edema

urticaria on all extremities, chest, abdomen and head. Took PO 50mg benadryl at 2000 and awaiting outcome at this time.

Joint pain (pelvic at first, then all joints over next 24 hours), body aches, fatigue (and sore arm)

numbness of the upper and lower lips on the right side, numbness of the right side of the tongue

Pfizer-BioNTech COVID-19 Vaccine EUA Fever, malaise, chills, headache, body aches, weakness

received 1526, returned 1708 with hives on chest, short of breath, itchy head to toe. phone consult with physician, taken to ED for care

Dizziness immediately after when I stood up. Within fifteen minutes increased heart rate and breathing, shortness of breath, and lips having a weird feeling. At 10 pm sore throat and injection site soreness.

pain at injection site. Encouraged patient to medicate and warm compress.

RECEIVED REPEAT VACCINATION DUE TO USER ERROR/MALFUNCTION OF RETRACTABLE NEEDLE UPON INJECTING VACCINE., AND MAJORITY OF VACCINE NOT BEING INJECTED. UNSURE OF AMOUNT INJECTED ON FIRST ATTEMPT, SO POSSIBLY RECEIVED GREATER THAN RECOMMENDED DOSE.

"The employee received 1st Covid Vaccine today at 1804 1834: Patient complained of a ""severe headache and suddenly not feeling well"". She told staff she hadn't eaten recently and was given crackers and 120ml of orange juice. 1845: Patient was assisted from the chair to a wheel chair and moved her to a cot in the back of the conference center. Her vital signs were stable at T-96.9F-HR-87 RR-20 BP: 145/78. She was responsive to questions, but had trouble opening her eyes. She did complain of feeling very cold and blankets were placed on the patient. 1905: Vitals remain stable. Patient was only responsive with direction. She was flushed in the face for a short duration, 3-5 minutes. She denied shortness of breath or trouble breathing. Notified patient's husband she was going to be transferred by EMT to Hospital for further evaluation. 2300-Spoke to patient and husband. Patient was discharged home in stable"

Patient received the Pfizer Covid-19 Vaccine at 1918. 1950 Patient reports numbness and tingling to left arm. Patient denied allergies to any previous vaccines, food, or medications. Patient stated no significant medical history. 2000 Patient reports numbness, tingling, and cold temperature from left shoulder to fingertips. Capillary refill <3 seconds. 2015 Patient reports nausea-crackers and water given by staff. 2030 Nausea resolved. Patient reports numbness, tingling, and cold temperature in bilateral feet. Elevated legs and feet. Warm blanket given. Capillary refill <3 seconds. 2045 Patient reports numbness and tingling to right arm. 2050 Called IMT. Patient called husband to pick her up and take her to be seen by an adult physician at an outside facility. Patient transferred to vehicle by wheelchair in stable condition. 2315 Spoke to patient and she stated symptoms resolved and home resting.

severe headaches, body chills, fever, bone pain, joint pain, abd pain, vomiting, nausea, sweating so much my bed sheets were damp . note: all symptoms were so severe I thought I was going to have to call off of work the next day. symptoms lasted about 12hrs

HIVES ON BOTH ARMS, LEGS, AND CHEST AREA. TAKING ANTIHISTAMINE TO RELIEVE THE PAIN.

"I noticed my body temperature becoming warm approximately 1 1/2 hours after receiving the vaccines. I then noticed at 2/12 hours, I had a red, blotchy rash on my chest, neck, back, arms and abdomen. It was not itchy, I was warm and red. I did feel a slight fullness in my throat, but I was not short of breath. For treatment, I was given 50 mg of oral benadryl immediately. I was admitted to the emergency department and given 10 mg of IV decadron and pepcid (I don't know the dose). The redness dissapated at 1 hour after the decadron. And I felt ""normal"" without any side effects approximately 3 hours after the decadron."

Fever, chills, body aches, runny nose, fatigue

Around 0300, I was awakened abruptly by a sharp pain in my Right TMJ region. This happened 2 times. It felt worse than a dentist shot. Around 0430, I went to the restroom and notice my right nasolabial fold is less prominent than my left nasolabial fold.

I initially had tingling of the lips that started 40 minutes after the injection. I took Benadryl and Pepcid. Now the tingling has progressed to upper and lower lip swelling, consistent with an allergic reaction.

Injection site pain. General feeling unwell. Low grade fever. Tiredness. Headache. Symptoms ongoing. Planned treatment: rest and fluid replenishment.

At 1:51 AM started to have throbbing headache, chills, and muscle aches mostly at the injection site 4:30 AM worsening headache, lightheaded and fever temperature of 38.7. Took Tylenol 1 Gram. 5:30 AM headache improved but still have fever temperature 38.6. Took a shower

palpitations with HR in 120s bpm for 1 hour after vaccine was administered

Injection site IMMEDIATELY felt hot, felt flushed from chest up to face, felt throat tightness, got tachypneic, tachycardic and lightheaded/weak. Throat tightness diminished after less than 30 seconds. I was immediately attended to. Was hypertensive 160/110's, pulse 140's, SPO2 100%. Less than five minutes later I developed uncontrollable generalized intermittent rigors. I was given IM Benadryl at that time. I was transferred to ED approximately 10min after initial reaction. Throat tightness came back again while in ED, EpiPen administered. PO Famotidine and 1L IV fluids given. Rigors diminished but lasted approximately two hours. I was observed in ED for four hours, felt well, VSS, was discharged home. Once home approximately six hrs post inoculation I developed more intense throat tightness, radiating to right jaw, no difficulty breathing. It resolved on its own in less than five minutes. Developed a mild headache the next day.

dizziness, low blood pressure, tingling in legs, light headed shaky

Metal taste under tongue starts about 30 seconds after injection. At the beginning, the metal taste was strong, but gradually disappeared in three to four hours. The tip of tongue started to feel tingling, numb within two hours, the symptoms are gradually improving. The tip of tongue also felt swollen within three to four hour, but improving. The pain on the injection site was getting worse in two to three hours, but stable for next twenty hours.

After initial 15 minutes dizzy, seeing stars, pale hypotensive, shaky

12/18/2020 Patient developed a rash on forehead, burning sensation in the back of throat, and chest heaviness. Patient stated that she had similar reaction to a previous vaccine that she received. Patient was reluctant to go to the ED and refused to ride in wheelchair, but was walked assisted by staff. ED RN reported patient was feeling better approximately 1 hour after injection. FROM ED REPORT 12/18/2020 Had a vaccine about 10 minutes later she states she felt a little warm. A little tingly. Had some blotchiness to her forehead and chest. She reports that she also had some similar symptoms after receiving vaccines. These were short-lived. She presents now for evaluation. She denies any chest pain abdominal pain. No trouble breathing. Pulse ox on arrival is 100%. No abdominal pain Patient does have some papules to the forehead. She states this is chronic. It is little red. Cheeks are little red. I see no urticaria on inspection

left side chest pain, warm feeling on the inside, dizziness, feeling that she couldn't stand up without getting lightheaded, nausea. Gave patient a bottle of water and a chocolate bar. Sent to ED FROM ED NOTE: She states about 10 minutes after the injection she felt a warm feeling. A bit of nausea. She had a little chest tightness. She describes this as similar to IV contrast studies. This is resolving. She denies trouble breathing. Did have a little chest tightness on this persist. On the monitor patient has pulse ox of 100%. Respiratory rate of 18.

Within 30 minutes - Skin flush to hands and forearms. Denied shortness of breath or problem with swallowing. Declined Epinephrine. Monitored for 45 minutes then she was escorted back to work within the building. 15-25 minutes later stated she was having trouble swallowing and was jittery. She walked herself to the Emergency room for triage.

Local injection site reaction, mild soreness

15 minutes after getting the vaccine began itching that quickly developed into rash/hives to face, neck, chest, abdomen. At 20 minutes post vaccine developed severe leg weakness with lightheadedness, chest tightness, and SOB. 22 minutes out collapsed to the floor unable to bear weight due to leg weakness and had severe cramping and tingling in legs, still unable to move them. Was rushed to the ER from employee health and arrived approximately 30 minutes post vaccine administration at that time there was significant mottling to arms and hands with polar nail beds. Vital signs were stable, no strider. Given Solumedrol, Benadryl, and Pepcid STAT. Rash/hives and SOB improved, but legs weakness/tingling, cramping did not and noted purple feet with cyanotic nail beds and mottling to hands/ arms that would come and go. Rash/hives reappeared much worse 2 horse post meds to face, neck, and upper chest. Was given another series of Solumedrol and Benadryl and admitted to the hospital. I am now 19 hours post vaccine with improved but persistent leg weakness, now able to bear my own weight

independently and walk a few steps, but still having legs cramps and intermittent tingling to feet. Color has improved with resolved mottling/cyanosis. I continue to have hives reappear with scheduled Benadryl, Solumedrol, and Pepcid.

Low grade headache for 24 hours

The day I received the vaccine, 8 hour post inhection, I began to have numbness in both hands and it went up my arm on the injection site arm. Almost 24 hours after getting vaccine, I woke up the following morning around 4am to body aches, chills, low grade fever, nausea, numbness in both hands, neck stiffness, and excruciating pain in the arm I received the vaccine in (unable to lift arm). I began taking Tylenol, every 4 hours and zofran for nausea. The symptoms proceeded to get worse. At 3pm the same day I decided to go to the urgent care. I was febrile 101.2, tachycardia, hypertensive, I was tested for the flu- results came back negative.

Chills fatigue muscle aches and severe pain in arm beginning five hours after vaccine.

lightheadedness, elevated BP, hives, wheezing, hot flashes, pressure on chest

pain at site, metallic taste 1 hour after , headache, fever 100.5, body ache

Nausea and fatigue 6 hours after vaccination. Resolved at 24 hours post Vaccination.

Patient had episode of hypotension First bp reading several minutes after vaccination was 82/46, second reading several minutes was 88/57, several minutes later was 93/62, next reading was 112/79 and resolved.

Started having strong chills that lasted an hour and was sweating although I felt cold. Felt dehydrated and heart was reaching. Woke up in the morning and felt sweaty, had temperature of 100.9F axillary. Took Tylenol. Still having body ache and headache through all this.

I awoke to severe upper abdominal pain centralized in the midline, just distal to Xiphoid process, and radiating across abdomen at 2AM (Approximately 14 hours post vaccination). Pain was an 8/10 and felt like somebody was squeezing my guts. Pain was worse when laying down or sitting and completely interfered with any type of sleep. I?m a paramedic and didn?t seek treatment. Pain subsided for about and hour and I was able to sleep a little bit until it came right back and lasted from about 07:00 AM until now at 09:18 AM. The pain finally seems to be subsiding. No Nausea, vomiting or Diarrhea.

lol swelling , shortness of breath

Right Foot Pain - sudden onset/similar to gout pain, however affecting the entire foot region and not the large toe.

the day of the vaccine I felt site swelling on injection site. A day after the vaccine I started to feel a headache and fatigued. I also felt sore from the vaccine and had what felt like itchy throat

Severe hives, from torso down to toes first day, and upper body and arms as well second day.

Pfizer-BioNTech COVID-19 Vaccine EUA About 5 minutes after receiving the vaccine my heart rate increased and sustained in the 140s-150s for about 10 minutes, it then subsided. My jaw and ears felt tight, then subsided. After about an hour, I felt normal.

tingling, heart racing

10/17/2020 after the injection on Thursday I had a sore body, sore throat ringing ears joint pain, my self esteem was very low, my boss sent me home because my voice sounded so rough, I checked my temp around 100 and 101 and I took Panolol and it went down to 99. Fri I woke up with sore throat every time I take a breath I have chest pain sore body ringing in ears, chills and I went to the ER Friday 12/18/2020 they gave me some anti inflammatory injection and I went back home that day, they gave me a medical order to take a covid test today 12/19/2020. ER Dr gave me good results on tests.I have a headache and sore my body feels heavy but other than that I'm trying to avoid contact and staying at home until the results come through

slight fever 99.7 (normal 97.4) , allover body aches 4/10

nausea, elevated blood pressure, syncopal episode x3, ?? seizure

PATIENT EXPERIENCED RED HOT SWOLLEN AT INJECTION SITE BP 1 WAS 154/93, 137/81, REMAINS RED AND SWOLLEN SATS AT 100%, RECEIVED 50 MG BENEDRYL PO GIVEN 0956 .

Patient received vaccine at 18:16. Approximately 18:50 the patient complained of numbness and tingling around her bottom lip. Lips were noted to be slightly swollen and cyanotic. Speech was observed to be slurred. Diphenhydramine suspension 50 mg PO was administered. At 19:15 patient was noted to have hives on her neck, upper chest and upper arms which continued to become more prominent. 911 was subsequently called and epinephrine administration was advised. Epinephrine 0.3 mg IM was administered at 19:34. Improved coloration and reduction in hives was observed after epinephrine administration. Patient was transported to the ED.

metallic taste

Pt. received vaccine at employee vaccination clinic at 1pm on 12/18, and received phone call from patient at 6:20pm at the vaccination clinic on 12/18. Patient reported Redness on thighs, arms, chest, throat and face, no redness below her knee or on her trunk. Reported itching all over where there was redness. She described tingling and burning down her right arm (compared to nerve pain) and cold hands. Patient was on her way to store to pick up Benadryl, advised patient to take 50 mg of Benadryl and to report to the emergency room or call 911 if symptoms did not resolve or worsened to involve any difficulty breathing. Called patient on 12/19 at 8:30am to follow up. Patient reports worsening symptoms overnight including developing leg cramps in calves, restless legs, chills without a fever, and a scratchy throat. Patient called family friend (ER Physician)- patient was instructed to take 60mg of prednisone, 1 tab of zyrtec, 2 tablets of magnesium. She currently reports fatigue, scratchy throate and headache with other symptoms resolving around 10pm on 12/18. Instructed patient to call on call physician at PCP office for a predisone taper prescription.

metallic taste

Patient reported feeling faint and nauseous. Placed on monitor, oxygen saturation was normal. Rapid Response Team called. Patient reported feeling that tongue was swollen. RRT escorted patient to Emergency Room.

metallic taste

The evening of 12/17/2020 pain started in the left deltoid. Over night the muscles in the left arm contracted and would no release, a hematoma developed, and constant pain was through the entire left arm. The morning of 12/18/2020 the muscle contractions and hematoma were still present and tachycardia and fatigue developed. Highest heart rate at that time was 147 with a blood pressure of 148/82. Was a pt. in the ED and received benadry, dexamethasone, and pepcid. Swelling and muscle contraction subsided and heart rate was stable in the 100's. Later in the evening tachycardia and fatigue started again with the highest heart rate being 210 (when resolved nearly immediately with rest). Heart rate was 110-130 until I went to bed. Heart rate waking up this AM was 110bpm. Injection sight is slightly painful.

Pfizer-BioNTech COVID-19 vaccine. Nearly immediately with numbness and decreased sensation to left pinky and ring finger.

"Arm is ""burning"" at injection site, sometimes the pain increase to a ""stabbing"" feeling. Pain is a 5 on the 1-10 pain scale Patient did not want any pain medication. She will take some when she returns home if she needs to. Denies any trouble breathing. States she feels fine, but because this is a new vaccine she wanted to report her symptom. Patient asked to wait and extra 15 minutes."

I had fever 101.5 body ache chills malaise and fatigue they were all moderate, I could not work and that lasted 24 hours post vaccine and continued to 48 hours and got better and after 48 hours I just had a headache, fever and chills improved I just had a worse headache and I did a virtual urgent care visit on 12/18/2020 and didn't prescribe anything. I refused to take any medication. 12/19/2020 right now I have a moderate headache . I don't have fever anymore and can function.

Patient experienced tachycardia and diaphoretic. His heart rate was in the 170s. He was taken to the hospital emergency room. He had an EKG - results normal. Lab work was performed - basic metabolic panel and CBC. All results normal. Symptoms resolved - he was discharged. No further treatment needed.

8:10pm tongue swelling noted. 6:00am woke up with head to toe hives and migraine.

Pfizer-BioNTech COVID-19 Vaccine EUA Beginning approximately 10 minutes after the injection I felt increased anxiety and possible light headedness. This could have been anxiety about the injection and its short development and some unknowns. I felt quite stimulated through the evening on the day of vaccination and kind of tingly all over like I had too much caffeine (which I had not). The only real scary part was waking up the night of the vaccination with high anxiety, tingling, and an elevated heart rate around 100-120 bpm if I had to guess. This lasted about 1-2 hours until I was able to fall back asleep. I

am now two days out from vaccination and still have increased anxiety over baseline and some diffuse tingling/hyperstimulation.

Chest Tightness and shortness of breath

Sore arm - Tylenol temporarily relieved this symptom - continues through 12/19/2020 - milder Fatigue - Rest relieved this symptom20

Patient had tingling sensation to her right arm and right arm heaviness and dizziness that started approximately 1-2 minutes after receiving vaccine. She was also dizzy so sent to ER. She was given juice and monitored in the ER. Sensations come and go in different areas of the right arm. The lightheadedness resolved after a couple of hours in the ER. She was told to rest, increase fluid intake, alternate Tylenol & Motrin every 4-6 hours as needed for pain control and follow up with her PCP in 1 day.

Tachycardia on 12/18 at 4:10am

Immediately throat tingling (thought it was me being nervous) by an hour later started to get slight headache. By two hours I was losing my voice and exhausted, coughing, chills, dizziness. Jaw pain, throat lymph nodes swelling and painful to swallow, my knees and neck hurt to bend and move, weak and bilateral ear pain. Left work by 2pm and by the time I got home last night I was unable to breath well and extremely chilled with no voice and extreme headache. Took Benadryl and headache medicine and went to sleep. This morning voice still gone, jaw still tender to move, headache is slightly better, congestion, chest pain and cough, still weak, lymph nodes are no longer swollen. Neck and joints still painful to move.

PFIZER-BIONTECH CIVUD-19 VACCINE EUA, I RECEIVED ON 12/18/2020 0730AM, BY 1230PM I STARTED NOT FEELING WELL, WITH A SLIGHT HEADACHE AND NAUSEA. I TOOK TYLENOL AND ZOFRAN. THE HEADACHE CONTINUED THROUGHOUT THE NIGHT, AND PRESENT NOW. JUST TAKING TYLENOL AND ZOFRAN TO COUNTERACT THE REACTION

Patient received dose one of the Pfizer vaccine at 1150am and around 1230 begun to feel tingling in the right of her face/cheek. She then noticed significant swelling of the left cheek and bottom lip. She was taken to the emergency department and received steroids, benadryl, and fluids. She was observed for a few hours and then discharged. She was feeling well the same day.

Faint metallic taste with injection

Rash in the back and buttock area/ patient was treated with Decadron 8 mg Intramuscularly

was in waiting area and about 10 min after vaccine said she got tachycardiac and checked her heart rate on the apple watch and it was 140. She felt tunnel vision also did not alert staff in waiting area as did not want to call attention to herself. Symptoms subsided after 1-2 minutes. said she would have passed out if she stood up at the time. Went back to work and told coworker. Vaccine clinic staff called her this am and she is fine- no further symptoms.

Mild tongue tingling approximately 15 minutes s/p vaccination and palpitations with chest pressure approximately 40 minutes s/p vaccination (HR 150-170 x 5 minutes and intermittent PVCs after for approximately 1 hour). No treatment needed, s/s resolved spontaneously approximately 2hrs s/p vaccincation.

Chest pain, dizziness, headache. Received fluid and pain meds via IV at Hospital ER. Not admitted.

Sore throat Headache Fatigue

I received the Covid Pfizer vaccine. By 6pm 12/18/2020 I started having arm pain and pain lifting right arm as well as nausea. By 11:30pm on 12/18/2020 I started having joint pain in the hips and knees and shortly after body aches. Upon waking up at 7am on 12/19/2020 I still had previous symptoms as well as right underarm tenderness.

itchy palm - right

ITCHING AND HIVES ONSET 2 DAYS AFTER ADMINISTRATION OF VACCINE

Adverse Event: Joint pain in knees bilaterally within the first 12 hours after receiving injection. Right knee joint pain subsided after 24hrs. Left knee joint pain has been constant for more than 48hrs. Treatment: Extra Strength Tylenol 500mg x 2 q6hr and left knee joint pain has not subsided Outcome: Still left knee joint pain after more than 48hrs

R arm felt numb and cold during vaccination; 30 min following vaccine pt had nausea and lightheadedness

Itching and erythema to left arm that lasted about 2 hours. Sweating without feeling hot or ill relieved by ibuprofen at hour 3 and returned at hour 9 post vaccine. Self resolved at hour 12 post vaccine.

Tingly sensations all over body on and off, like crawling feeling for 12 plus hours. No shortness of breathe noted or blisters/break outs.

feels elevated heart rate, sweaty, dizziness

"Patient reported dizziness and ""adrenaline-like feeling"" during administration of covid vaccine."

fever and rash at injection site

Tingling/numbness of lips, tongue and Area surrounding mouth 15 minutes after injection. Swelling of right upper lip Confirmed in car mirror at 20 minutes. Returned to employee clinic and was evaluated by MD, escorted to ER. Was giving Benadryl and 2 hours later was given prednisone 40mg. Was sent home with 3 day course of prednisone and was told to take Benadryl before bed and prn.

Burning in eyes, excessive, bloodshot eyes

Swelling, erythema, extreme pain over vaccination site. Full body myalgias. Night sweats.

Pt received COVID-19 vaccine and approximately 4 minutes later patient began to feel flushed, racing heart, and faint. On exam, pt was slightly tachycardic with flushing to the face and anterior chest. Symptoms relieved after IV Benadryl. Symptoms improved after Benadryl with a resolution of racing heartbeat and flushing. Patient was then monitored for 2 hrs without recurrent in symptoms. Pt discharged home.

Within minutes of getting the vaccine I experienced warm facial flushing followed by shortness of breath and palpitations. Symptoms lasted less than 5 minutes. No chest pain. Some mild dizziness during event. I was able to breathe through the event and I still drove myself home 30 minutes after receiving vaccine. I took 1000mg Tylenol before bed and went to work later that day. I admit I initially thought I was just having some anxiety but I have never had any history of anxiety or adverse reactions to vaccines.

Patient reported racing heart, tachy 88-100, tingly lips following covid vaccination. Administering RN assessed, provided emotional comfort, provided water/snacks. Continued monitoring. Tachycardia did not resolve after continued observation. Patient escorted to ED by w/c for further observation. Patient discharged from ED in stable condition.

After injecting needle in the patient's arm, upon injection of vaccine, the vaccine started to leak from the hub.

Approximately 8 hours after injection: sore shoulder Approximately 10 hours after injection: body aches, joint pain, chills, HA, nasal congestion; extreme fatigue These symptoms continued from Thursday Dec 17 approx 10pm to this morning Dec 19 at 8am. I also had a low grade temp on 12/18 of 99.4 at 5pm. Today, Dec 19 at 11:13 am my R deltoid, arm, armpit, and side is still sore; other symptoms have resolved. Still experiencing fatigue; however I had Covid in September and have had residual fatigue since then anyway.

Patient is a CCU nurse who received the COVID19 Pfizer vaccine on 12/17/20. The following day she reported to work and that afternoon at 3:50pm had nausea, vomited x1, pale, tachy. Fellow coworkers provided basic care and then transported patient to ED when symptoms persisted. Patient evaluated in ED and later sent home.

I got my vaccine on the 15 on the 16th when i woke up I felt really hot and had weakness, and the next day I already had nasal congestion on the day of the vaccine but it wasn't bad then two days later I wasn't able to smell or taste it was very faint and thought it was a cold . So I went and got covid tested Thursday the 17 and the 18th I got my covid results and tested positive.

Resident short of breath approximately 10 minutes post vaccination. Staff noted that his baseline upon activity and transferring is generally shortness of breath. Resident wears 2L NC, O2 saturation was 92%, increased to NC to 4 Liters O2 saturation up to 96%. 170/80, heart rate 94, regular rhythm. Sent to hospital.

Received vaccine on right arm. Tingling and numbness on left side of my body from my lip all the way down to my foot. Tingling and numbers started two hours after vaccine was administered. Tingling and numbness are still present.

A Lymophoedema on the left side of the body, with 3mm eduration in the arm left, no erythema no suppuration o edema.

About 5 minutes after vaccine, patient noticed mild itching at injection site, small area of redness around injection site and injection site is warm. Denies pain. Offered Hydrocortisone Cream for topical administration to injection site, but patient declined. Patient stated she had some at home that she would apply if needed. Patient waited a total of 30 minutes. Site did not appear to change. Patient denied any further allergic symptoms.

Patient received vaccine 07:52 am at 08:11 am he reported hand tingling, we noticed some swelling to left hand. BP 143/94 sat 99% P-81, patient initially declined going to ER, administered Benadryl 25 mg by mouth per protocol at 08:21 am, repeat BP 08:23 139/96 P-84, sat 98%, 08:42 BP 141/97, P-92, sat 99%, 0843 noticed rash left forearm (not sure if there before) noticed after removing watch, patient agreed to Emergency Room check in, while waiting for ER check in patient had increased swelling, spread to forearm, notified ER intake nurse and transferred care to Emergency Room

patient felt hot, sensation of tingling in her throat, sensation of heart racing, heart rate was 130. Rapid response called, patient received epi pen injection and IM Benadryl, sent to ED For evaluation with subsequent discharge home.

Patient experienced dizziness and felt like she may pass out. Given a sip of water and felt better. Declined to be taken to the ED for further evaluation.

Pfizer-BioNTech COVID-19 Vaccine EUA PATIENT DEVELOPED HIVES ON INCISION SCARS ON HER RIGHT FOREARM AND CHEST AT 15 MINUTES POST VACCINATION. AT 24 HOURS POST VACCINATION, PATIENT DEVELOPED PETECHIAE ON INCISION SCAR ON CHEST AND LEFT COLLAR BONE.

Patient received covid vaccination number one; about one minute post vaccination, patient became very light headed. Upon taking vitals, patient tachycardic at 145 bpm; patient's neck turned red and splotchy; after about 60 seconds, the redness and splotchiness went away; patients blood pressure went up to 170's/90's and heart rate remained in the 130's sustained. Patient was given cold rag and water with no improvement; she was transported to the ED upon request

Pt presented to the monitor with c/o of racing heart rate (HR). Monitor referred pt to myself. Pt reports after feeling like her heart was racing she checked and noted a HR of 110. Pt was provided a seat in the more private monitoring location. Coat removed and water provided. 9:40am = HR now 6. Pt continued to be seated. 9:50am = HR of 80. 9:55 am = HR of 78. Pt has drank 6 ounces of water. No other changes noted on physical assessment. Asked pt to stand and no dizziness reported. Pt counseled to follow with her MD in anything was to happen and noted the V-safe information. Pt d/c.

extreme sleepiness approximately 5 hours after administration. Sweats and lightheadness/dizziness 6 hours after vaccine.

Patient felt sensation of being hot and heart racing, heart rate was 80 and pulse ox was 99%, denies resp symptoms, patient requested to go to ED to be evaluated, was seen in ED, observed, and discharged home

Headache

diarrhea at 0200 on 12/19 (~ 12 hours after vaccine), patient doing fine now ~ 22 hours after vaccine

Pt reports dizziness, nausea and vomiting

The vaccine was administered on the following date: 12/18/20áand at approximately the following time: 1pm á She reports that she didn't feel great after vaccine but thought just normal post-vaccine symptoms. She felt itchy and wheezing that evening. She took benadryl and felt better. á She woke up the next morning and her face was flushed and she felt palpitations. Went to work and checked her vitals, tachycardic to 120s-130s. About 11am felt lightheaded and was taken down to ER. HR was 150s. Has history of bee sting allergy and this felt like that. No Epinephrine but was given 25mg IV bendaryl and IV fluids (1L NS). Took another 75mg of benadryl last night and Allegra this morning feels fine. á From ED visit note: Vitals at triage BP 106/73, HR 95, RR 18, O2 100% EKG HR 104. Vitals with HR 77-95 No labs, COVID negative á The symptoms began the following morning after administration of the vaccine.á The symptoms were: tachycardia, lightheadedness, flushing, itching, wheezing The treatment of the reaction was:áá o Antihistamines:áIV and PO benadryl á Other medications taken on day of reaction:ááTylenol

Patient reported feeling lightheaded, dizzy, and anxious with early heart palpitations with covid vaccine administration. Patient observed and provided food and water, reported full recovery.

At 1:10 pm, I felt warmth all over my body, face, my heart started racing up to 109 per minute. I felt dizzy soon after. The nurse observing checked my vital signs and found my blood pressure to be at 190/92. After 30 minutes, my face and ears felt really hot, my face was flushed, eyes were hot. My temperature was taken and it was 101.3. At around 6:30 pm, I developed mild headache and body aches. The next morning, my left arm was sore.

Moderate headache upon waking at 0630; treated with excedrin and resolved within 4 hours. Sore arm - mild to moderate, started within 4 hours of receiving vaccine

Pfizer-BioNTech COVID 19 vaccine EUA Shortly after receiving this vaccine (about ten minutes or less) I felt tingling throughout my body for no more than 10 minutes. It lasted the longest in my legs. I didn't think much of it as it resolved in about 10 minutes and another woman said she felt it too. I am reporting because I have seen an article that medical center has halted vaccine administration due to workers experiencing this.

Began experiencing numbness/tingling in right hand and arm approximately 20-25 minutes after receiving vaccine. Nurse and pharmacist went to monitor more closely. Began to feel flushed, lightheaded, sweating. SpO2 99. Dr ordered 25mg diphenhydramine po. Placed in wheel chair and taken to ER for further observation.

10 min after receiving vaccine had symptoms - Tachycardic, BP elevated, chest tightness, flushing, mouth felt weird. Tongue felt strange but doesn't think it was swollen and then developed throat tightness. Immediately given 50mg PO benadryl and symptoms improved over 20 min. 90% improved at 60 min.

Started with a stiff neck with aches at about 9;00pm 12-18-2020 and it lasted about 3 hours. I woke up about 4:00am and my armpit, on the side of injection, was very itchy. I looked in the mirror and it was swollen and red lump in my armpit. I?m guessing lymph node swelling. It resolved about noon 12-19-2020.

Tingling of lips and throat. Received treatment with dexamethasone, benadryl

Slightly swollen rash around the mouth and between the eyebrows with small pustules, accompanied by itching. Around 18 hours post-vaccine (received ~6:30 pm 12/18/2020, noticed symptoms ~12:00 pm 12/19/2020)

Left sided facial tingling, achiness, and heaviness approximately 45 minutes after vaccination.

Nausea, headache, ill feeling, rhinorrhea, chills, cough, loss taste

None stated.

Pt reported not feeling; tachycardia @ 110 approximately 20 mins after vaccine. sweaty, BP WNL 15L O2 given to pt along w/ 10 mg cetirizine and 25 mg diphenhydramine

Patient reports she received at 1330 than was working and had a sudden onset of chest pain and became diaphoretic and skin appeared red/blotchy

None stated.

None stated.

Mild tingling in the body, mild lightheadedness, mild nausea, brief heat and tingling of lips, face, and ears, mild swelling of the upper lip

Immediate after pain in jaw and nausea. 24 hours after started with headache, general joint pain, cough, low fever, chills, fatigue.

pain at injection site, right shoulder/neck pain

"Employee of hospital received Covid-19 vaccine, was moved to respite area and began to ""feel flushed"" and had (2) syncopal episodes. B/P 160/93, HR =80, Pulse Ox-100%. Employee transported to the ED via stretcher."

Pt reported scratchy throat, itchy lips, slight rash on chest approx. 10 min post vaccination. 25mg of Benadryl given PO. Transported to ER for continued observation.

I started having chills before bed 12 hours after receiving vaccine. I woke up late morning (now 24 hours later)with a terrible migraine and continued to have chills. I went to the bathroom after I woke up and felt very nauseated and sick. I then started seeing black dots and felt very dizzy. Soon after my vision went completely black for what seemed to be about 5 min. I was shaking, having difficulty breathing and fell to the ground. My fiancT called 911 and an ambulance was on its way. The EMTs showed up and took my vitals. At this point I was able to see again and was sitting down. My blood sugar was normal along with my oxygen stats. My blood pressure was low while sitting and standing. I was starting to feel better and didn?t end up going to the hospital. I continue to have chills, body aches and a headache but so far no more blackening out episodes. It was the scariest experience of my life!

"Nurse injected the vaccine as she removed needle the employee started to feel weak and short of breath. The employee repeated said ""I am weak"" and ""I can't breath."" A rapid response was called, checked her oxygen level (94%). Due to employee stating she could not breath the team gave her a dose of epinephrine and started oxygen. Her oxygen saturation increased to 98%. They took a blood pressure - 150/88. EMS arrived and took her to local hospital for observation."

Tingling and numbness in bilateral lower extremities. Symptoms began 40 minutes after receiving vaccine (which was received on 12/18/20 at 10:50) and are still present at this time (12/19/20 at 13:35). I have not received treatment for it.

"stated she felt ""hot, dizzy, tingling to face"" HR 84, BP 129/84, O2 Sat 97% RA, temp 100.4. Taken to ER for observation."

I received my vaccine at 1615 down in our hospitals clinic, I work as a floor nurse, I returned back to my unit to resume work, I walked in to talk to my charge nurse and felt completely fine within a minute or to (approximately 15 minutes since the vaccine was given) my legs felt like very weak, they became tingly and extremely heavy, my face and chest felt warm and I had to sit down to drink water. The nurses working with me that day took my vital signs, my blood pressure was 157/101, heart rate 80-90s and temp was 97.5F. I notified the pharmacist working on our floor about my symptoms and he directed me toward the infection control line, the pharmacst on the phone directed me to go to the emergency department. When I was admitted to the emergency department via wheelchair, the pharmacist met me there along with the Emergency medicine MD, a neurological exam was done and general assessment. While I was in the ER my heart was monitored, my CBC with diff, Mag and BMP was monitored all of which were normal. I was given a 1L bolus of IV LR through an IV in my left antecubital. Gradually the tingling wore off over a few hours in my legs bilaterally however they still felt very heavy. I was admitted from approximately 1645 until approximately 1900 and returned home.

Right side nostril broke out into ulcer sores & throbbing after vaccine

Lightheadedness onset at 3 minutes (approximately) after the vaccine. Felt like I would be unsteady on my feet if I stood up. So kind of a dizziness/vertigo.

Flushing, rash, dizziness, lightheadedness, slightly elevated BP and heart rate

Patient experienced swelling underneath injection site immediately after administration

initial left arm injection site pain. Then developed quick onset ~22 hours after receiving vaccine of significant facial, torso, and upper extremity flushing and redness. No fever. patient felt nausea and vomited. Also experienced tachycardia and a headache. Patient used an ice pack, pepto bismol, and ibuprofen. Resolved in about 2 hours, but headache persisted until the next day.

Numbness to Lips , Teeth, Toungue, Face

1 day after receiving vaccine both of my hands became cyanotic appearing (blue/purple). Outside of minor tingling sensation, I did not lose feeling of my fingers/hand and my capillary refill was normal. My 02 saturation remained at 100%

Tingling injection side arm and face rash

5-6 hives on right hand and forearm on 12/19 at around 1100, took 25mg of PO Benadryl and went away. Intermittent tingling to right foot/ calf and hand (more to foot and calf) started 2100 12/18. Tender right axillary lymph nodes.

On day 3 after the vaccine, I had been experiencing sinus issues and toward the end of the day I experienced body aches, chills, sweating, shortness of breath, and tachy up to 175 last night when walking. It has been better today in the low 100s but still persistent with some shortness of breath, covid test pending.

Bilateral lower extremity rash

Patient presents after a near syncopal episode. Was at work when she felt dizzy, nauseous and flushed. Felt like she was going to pass out. Patient appears pale and uncomfortable, but nontoxic. She is tachycardic but blood pressure stable. Has a faint erythematous rash on her neck. Give IV Benadryl, IV solu-Medrol and IV fluid in Emergency Department. Basic labs were obtained and are unremarkable.

Redness; Hives; elevated HR and BP

Minutes after the vaccine, developed perioral numbness, tingling, mild difficulty swallowing. Complained of SOB and had marked diaphoresis. BP dropped to 87/50. Maintained sats 100%RA, lungs were clear. Has a hx of a vagal response after blood donation

Body ache, coughing

Associate states he started to have a fever this morning. Associate had a COVID swab performed at the COVID drive thru this morning and was told to call the hotline to report event.

performed 30 min observation, left to go back to work, said he felt like his heart was racing and looked at his smart watch and HR was 168. Upon arriving back at clinic, denies dyspnea or resp concerns. Reports feeling hot, anxious, heart racing, pt was sweating. HR 152 BP 150/100, Pulse ox 99%. Patient taken to ED to be evaluated.

Fevers to 104.8, myalgias, chills, rigors, fatigue, diarrhea

Signs of passing out. Then numbness and tingling in all extremities, lasting longer in the lower extremities (roughly an hour and a half) then felt as if a hair was on my body for roughly 8 hours, woke up with night sweats yet all resolved by 9am.

reported eye vision changes, flashes of light, and a headache. Was treated in the emergency room.

"Patient began to feel lighththeaded and ""woozy"" about 20 minutes after injection. No loss of consciousness, BP 118/78, HR regular, color pink, began to complain of ""sore"" on one side of throat, began clearing her throat frequently,"

Approximately half hour after injection patient reports tingling in tongue, heavy chest, SOB, slight difficulty swallowing and flushing in face, at that time HR was 44, O2 sat 99%, and BP 138/80. 50mg of oral benadryl was given at that time. Patients symptoms continued and 911 was called and at 4:30 epinephrine was instructed to be given IM via epipen. Approximately 5 minutes later EMS arrived, evaluated the patient and no visible signs of allergic reaction were detected. Patients HR and BP were elevated from epinephrine. Myself and another pharmacist remained with patient until approximately 5:30 and at that time the patient was going home. I called her at 6pm that evening and again 11 AM the following morning and no other allergic symptoms were noted.

Lightheaded, heart racing in initial monitoring station, placed supine, transported to triage via wheelchair. Initial pulse ox 98%, HR 76 at 1250, denied SOB, tingling, no rash. Pulse ox 98%, HR 91 at 1256, no SOB, tingling improved. At 1300, c/o lightheaded, fuzzy vision, shaky, some chest tightness, some throat tightness, increased saliva. Diphenhydramine 50 mg IM administered 1304. Pulse ox 98%, HR 92 at 1318. Solid food intake 1322. Continued lightheaded, bilateral arm tingling, still shaky, but less cold at 1327. Self-reported weight 130. 1339, throat tightness not resolved, no difficulty swallowing or breathing, pulmonary auscultation no stridor., continued body tingling, c/o throat tightness, Pulse ox 99, HR 96. 1343, continuous monitoring to Pulse ox 90%, HR 110. Medical director updated 1347, decision to move to ER and transport initiated 1352.

Pfizer-BioNTech COVID-19 Vaccine EUA: Patient experienced flushing and dizziness after administration of Pfizer-BioNTech COVID-19 vaccine with blood pressure: 143/90 mmHg and pulse 80 beats per minute. Cold pack applied and patient ambulated and drank water. Five minutes later blood pressure was 137/85 mmHg and pulse was 63 beats per minute and patient continued to report waves of flushing. Patient ate a banana and another cold pack was applied. After another ten minutes patient reported

feeling better but stated felt lightheaded. After an additional 20 minutes blood pressure was 123/76 mmHg and pulse was 78 beats per minute. Patient stated felt much better and was discharged from clinic in stable condition.

7 minutes after her vaccine she complained of tongue numbness which progressed to swelling. No wheezing, no rash, no nausea no vomiting. She was transferred to the ED for further management

Headache, dizziness, nausea, chills, chest pain, fatigue, injection site pain. Started about 2 hours after injection. Took Tylenol. Symptoms resolved within 36 hours

Left arm soreness around injection site that started about 3 hours after the injection and remained constant until the next morning. Fever (subjective as I did not have a thermometer at home) and chills that began about 14 hours after injection and last about 4 hours. Fever and chills resolved with 1000mg Tylenol.

Scratchy throat, lip swelling and numbness

After receiving the vaccine, I waited in the facility for 15 minutes as instructed by my company and the staff who administered the vaccine. When I left and got a few miles down the road, I started to feel my heart increase and I became short of breath. My heart rate was fast and pounding. My mouth started tingling and then I started feeling the tingling on my chest and neck. I started sweating and then started to panic and called 911 because I didn?t think I would make it back to the vaccination site or to the hospital in time. When the ambulance got to me I was still experiencing tachycardia, mild shortness of breath and tingling. The symptoms started to subside after approximately 20-30 minutes after they started. The paramedics assessed me and my blood pressure was 170/90 and HR was in the 120?s. I declined to be sent to the hospital due to my symptoms subsiding

I woke up with shooting pains/cramping running down the sides of my body/arms to the bottoms of my feet. It felt like a cramp but worse, kind of like nerve pain. I tried to walk it off but it persisted for about five to ten minutes. I had never felt that kind of pain before.

My blood pressure was 172/95 right after I took Vaccine, since then my BP was 155/100 last night , 147/101 this morning. I never had h/o high BP

10:30 am on 12/19/2020 Fever of 100.6 F, malaise, nausea, muscle aches, increase HR to 111 at rest. Tylenol 500mg taken

approximately 25 minutes past receiving the COVID vaccine I felt numbness in my neck and clavicle area. This resolved on its own after about 2 hours of receiving the vaccine

Within 10 minutes of receiving vaccine patient reported arm feeling tingly and numb which progressed to a squeezing feeling. Slight shortness of breath.

Anaphylaxis within 15 minutes of administration

I got the vaccine at 0750 in the morning and was fine right after getting it, my arm was a little sore no big deal, then by 0900 both arms were sore and my neck, by 1100 I had aching and chills, but I powered through because those are common symptoms by 1300 I had a headache, by 1500 I had some abdominal cramping, by 1600 some dizziness and nausea, 1730 diarrhea, 1830 more diarrhea and 1850 hives all over my chest. By 1900 my tongue felt heavy and tingly So I walked down to the ER. When I got to the ER I felt like I was going to pass out. By 2040 I was admitted to the ER and given Benadryl, Prednisone, Pepcid, and Zofran. I was Held for observation until 0300.

brief lightheadedness Pt arrived at observation area at 1500. Was informed she has a history of allergies in teh past so instructed patient to wait or 30 minutes in observation area. Around 1505, pt stated she was feeling lightheaded, near syncope. Advised pt to lay on ground. Vitals taken - BP 140s/90s, with HR 118, pulse ox 100%. After 5 min, pt stated she was feeling better while laying down. At 1515, vitals retaken with BP 120s/80s HR 90s. At 1520, pt sat up from floor still feeling better. At 1525 pt sat in chair feeling better and at 1530 pt stated feeling no side effects.

Right after I got the injection I felt my right hand tingle. I assumed it was because I was squeezing it so I dismissed that. However later around 7:45 my right side of my face felt like it would if I had gotten nova Caine and was wearing off kind of tingly but my face moves fine. I then read that other hospitals stopped the injections because of something possibly like this and I did begin to worry. The sensation is not strong it is only on my right side. My face moves ok just feels like when your foot goes to sleep but very mild .

Within 30 minutes of receiving vaccine patient reported feeling light headed, hot and heart palpitations. BP increased to 158/110, Pulse 100. Patient was CRNA working in ICU environment and was monitored by other staff present. Signs and Symptoms resolved over the following hour.

Several minutes after the vaccine, I noticed my arm going numb. It progressed up the side of my neck and down to my fingertips. The numbness lasted over an hour. Extreme nausea vomiting and fatigue started 12 hours later. Which hasn?t yet dissipated. It has now been 34 hours since vaccination.

Numbness and tingling in left wrist and hand lasting approximately 1 hour after injection

Numbness and tingling in left wrist and hand lasting approximately 1 hour after injection

Employee developed rash at site on left deltoid, that spread across upper chest. No SOB, Chest Tightness or Itching. Transported to ED on-site.

GI symptoms, loss of appetite, fever, body aches Between 10am-2pm day following vaccination.

Within 30 minutes of vaccine patient's left pupil was dilated greater than right and reacted sluggishly to light with slight fuzzy vision. No other signs or symptoms. Pt to follow-up with Ophthalmologist next week.

Approximately 30 seconds after the injection (which was painless), I suddenly developed tachycardia and felt like my heart was pounding out of my chest. My entire body was extreme tingling and I could

not feel my hands or feet. I also got a sudden strong metallic taste in my mouth. I thought I was about to fall down, but right before I was going to ask for help, the symptoms stopped as suddenly as they came on. I probably should have said something then, but I felt fine so I walked back to my unit. About 20 minutes after my injection, I then developed an intense hot flash and soaked my clothes with sweat. I sat down with cool rags on my head and this subsided after about 10 minutes. I have felt fine ever since, other than a little bit of a sore arm and mild headache (expected). I?m not sure if my tingling, heart palpitations, and hot flashes with sweating are expected, but I thought I should report it just in case it would be helpful for the manufacturer to know.

About 3 min post vaccination I experienced a transient sensation of warmth in my chest followed approx in a minute by tachycardia and a slight tightening sensation at the base of my throat which was transient - may 15-30 seconds. It recurred in a few min and I began to feel little lightheaded . With a 3rd episode of tachycardia only I felt more lightheaded and was taken to the ED in a wheelchair. My extremities felt cool with each episode as well.

high fever, chills, swollen arm, fatigue, nausea

Fever , muscle aches, joint pain, tiredness, headache Took ibuprofen 400 mg when temp reached 38.9C

Rach, tachycardia, palpitations, shortness of breath shortly after receiving vaccine - given epi, solumedrol, Benadryl. persistent symptoms the following day.

Reports becoming flushed shortly after covid vaccine. Then developed dizziness and was diaphoretic. Laid sown on stretcher. VS 128/84, 99/ 97.6, and sat 96% on room air. Observed and repeated VS x three. Was able to sit up and drink water prior to leaving observation area. Remained stable

I received the vaccine at 0915, was observed until 0936 and felt fine. While driving home, around 0949, began to feel heart racing/beating fast. I then felt very shaky and proceeded to get off the highway exit as the symptoms continued to worsen My daughter called 911 at 0953 at my request. No throat swelling, respiratory issues, or mouth or lip swelling. No rashes noted. I then began to feel sweaty and then became a little dizzy and proceeded to lean my car seat back. My daughter called 911 again as they instructed her to call if any new symptoms began prior to ambulances arrival. Ambulance crew arrived, I ambulated myself to the ambulance, felt a little lightheaded while walking. The feeling of my heart racing had started to lessen but still not normal at this point. Pulse ox was 98% on RA, no respiratory distress at all. I'm not exactly sure of what my HR was as I couldn't see the monitor but I believe they said around 100, I'm normally in the 60's. Systolic BP's were 138, then 120's, then 101 prior to me leaving ambulance. Finger stick was 140. I was in the ambulance for about 15 minutes and was feeling much better the last 5 minutes or so of that. I declined need to go to ER, my daughter then drove. I then went to a store and while walking around at 1105, began to feel my heart racing again but not as intense. Had slight feeling of being shaky but nothing like previously. After that, I have felt fine for the rest of the day. I took 400mg Ibuprofen for a slight HA around 1130 but not unusual for me, especially since the events that occured. I called the hospital where I was given the vaccine when I got home and informed one of the employee health MD's who requested I report this here.

Approximately 45min after the injection, I started feeling dizziness, palpitations and racing heartbeat. Another 15min after that there was red hives that broke out on my upper chest but no where else on my body.

Woke up Friday morning around 5:30am and had significant fever and chills (100.8F). In the morning fever, during the day increased heart rate. Took tylenol about 3 times a day. Felt burning up all day. Felt like I was on fire. In the evening about 6PM very nauseous, muscle aches, laying down uncovered and I felt like I was burning up. Went to bed early. No taste in the evening. This morning I feel pretty good other than no taste and a little bit of nausea.

Within 15 minutes of vaccination, developed mild headache. Was resolving when left observation area. Employee reported at 1:45 had developed right sided face and arm tingling and numbness and lips numb and tingling. Consulted with ED provider -Dr Plan to observe by Employee Health and refer to ED triage if symptoms do not improve. . Symptoms improving. Employee observed by Employee health and symptoms had resolved by 2:15 . No admission to ED

Morbiliform rash on torso Tiredness

Fever chills nausea which went away next day however now I have no sense of taste or smell

heart rate increased feels that it is racing,

I felt fine other than a sore arm but then Friday morning I woke up coughing and i had a 100F fever and about an hour later it was 100.6F. I had chills, shivering, headache, took tylenol, fever was down to 100F. Went to the local UC and had a COVID 19 test and was negative (rapid test). Today I woke up, no fever, a headache in the morning, but now it is gone, no fever at all today.

"Patient reported feeling sensation of ""warmth"" around 5 minutes post immunization. á Patient was escorted to waiting area and sat in seat within range of nurse site line. á RN later sat with patient 5 minutes later as she continued to have feeling of ""warmth"" / flushing. Patient given water and moved closer to nurse area. á Patient then shortly after c/o light headedness and now feeling cool. Remains alert / oriented. á BP: 142/80 HR: 127 RR: 20 SPO2: 100% á ICC called. Medic and Dr arrived for patient handoff. RN escorted patient to ICC with Medic and MD following. á Patient to finish visit in ICC for final dispo."

Myalgia, malaise

Throat closing, feeling faint, fast heart rate. Was taken to er, was given epinephrine as well as steroids. Kept me on er for awhile to watch me.

Chills, body aches, at about 10:30am on 12/19/20. Improved with 1g of Tylenol

On the evening of the vaccination at approximately 11 PM experienced tightening around the rib cage that lasted the night, went away in the day and came back the next night and some pain at the injection

site. Noticed a light rash at and below the injection site on the second evening. Rash continues on the 3rd day.

tingling in tongue, sore throat and deeper voice, heaviness in chest took diphenhydramine tablet, also took prednisone she is prescribed

20 minutes after receiving vaccination, tingling tongue. 'first sign for shellfish reaction', noticed tongue swelling. took 2 benadryl @130. at 1:45 took Albuterol, got to hospital / ER at approximately 2pm. Elevated BP, HR increase, lungs tight and 'barely diminished'. Epi @ 4:25 Albuteral @ 4:35 Prednisone @454 IV pepcid @5pm Tongue was still swollen but improved, lungs stable. Discharged at 6:10. Continued Benadryl and med pack. F/up appt w/ Allergist the following week;

Chills, aches, mild nausea and fever up to 100.8 for 6-8 hours. Headache and fatigue for 20 hours.

After receiving vaccination, right arm was swollen and felt cold to the touch, kept arm elevated to try to keep the swelling down and took hydroxine at night to try to help it go down. Still could feel my radio pulse, felt like pins and needles. Not cold anymore, now feels warm/burning sensation.

1) flushing, sweats, and dizziness 2 hours after dose #1. Resolved after about 15 minutes. 2) severe fatigue next day with poor concentration and forgetfulness 3) whole body palpable rash with redness, itching, and development of patches of petechiae

Approximately 8 hours after injection- headache and soreness at the injection site, fatigue, very mild sore throat. Headache and fatigue progressively got worse. About 24 hours after the injection noticed small red rash to the abdomen, progressively spread throughout the abdomen to to the truck. Rash looks similar to the chicken pox and is itchy at times.

12 minutes after injection, I felt flushed and dizzy. They hooked me up to a vital sign monitor which showed my heart increasing to 133 bpm, SaO2 98%. A manual blood pressure check was 168/110. My heart felt like it was pounding, I was hot and sweating. After 10 minutes or so, I felt increasingly dizzy and my vision started fading. VS still showed tachycardia and hypertension. It became difficult to swallow and my tongue was feeling fat. A Rapid Response Team was alerted, they started and IV, and took me to the Emergency Department. I became very cold and shaky. My hands and feet became a little mottled. They gave me 50 mg IV benedryl, 20 mg IV pepcid, a dose of solumedrol, and IM epinephrine 0.3mg, and 1 Liter of fluid. My symptoms resolved and I was discharged home a couple hours later.

Headache, dizziness, lightheaded, nausea, tired all lasting for a half hour after vaccination

Within 5-10 minutes after vaccine given, patient started feeling tingling of the hands and fingers. Shortly after, she felt the need to clear her throat because she felt like there was a furball in her throat. She drank some water, which didn't help. She then started feeling hot and became flush. She then felt her inner ear and tongue swelling. Shortly later, she felt chest pain and felt like she couldn't breathe. She was given IV Benadryl 50mg, IV dexamethasone 4mg, and IV Pepcid 20mg without symptom resolution. Epipen was administered by vaccine clinic staff, and the patient felt a little better. Her shortness of

breath continued and her chest felt heavy as she was transported to the ED. She also complained of blurred vision, which could have been due to Epipen administration. In the ED, the patient still felt that her throat was tightening up. She was given IV Pepcid 20mg, IV Benadryl 25mg, IV SoluMedrol 125mg, racepinephrine & albuterol nebulizer. By 2150, she felt better. By 2257, she did not have any more tingling in hands or weakness and she stated she felt she was back to normal. Patient discharged home in stable condition at 2336.

Patient presented to the emergency department at 8:45pm on 12/18/20 with lower abdominal pain, nausea, vomiting, and constipation that started approximately 2 hours prior to presentation, at approximately 6:45pm. Her labs were significant for a lipase of > 6000 IU/L, and a CT scan of her abdomen/pelvis was done that demonstrated evidence of acute pancreatitis. Given the fact that she does not have a history of heavy alcohol use, with normal triglycerides and no evidence of gallstones on her current admission, and no recent gastroenterology procedures, there is no clear etiology of her pancreatitis; concern for post-vaccination pancreatitis. The patient is currently admitted to the hospital, on hospital day #1 of her current condition.

12/18 0815 receive vaccine 2100 slight cough and very tired 2200 chills and chattering teeth; no fever 98.9F 2230 feeling very cold; went to sleep 12/19 0430 wake up with fever of 102.6F and headache 0845 still exhausted; fever 101.1F Stayed in bed most of the day 1730 get out of bed; temp 99.9F; notice slight rash on face across nose and cheeks ; slight redness and pain at injection site

Lower facial numbness, cheeks, lips, chin, decreased sensation similar to dental injection numbness. Lasted about 12 hours. I took 25mg of benadryl.

Minutes after the vaccine, C/o throat feeling dry and SOB. NO Diaphoresis. Breathing does not appear to be labored. Iv was started as a precaution. Pulse oxygen was 100%. NO meds given on scene. Taken to ED to be evaluated. Believed to be anxiety related.

Employee has history of allergies and was being monitored for 30 minutes. About 10 minutes the vaccine injections she began to feel faint. She was sitting at time and slide to floor and was unresponsive. The team begin checking vital signs and gave her a dose of epinephrine. A rapid response team and EMS was called. The rapid response team checked vitals: BP 100/60, HR 90, O2 99%, Glucose level-77. An IV was started and bolus of normal saline 500 ml given along with 50 mg of benadryl. Vitals checked: HR 108, BP-106/60, O2 93%-it was reported she was cold and shivering-hands were cold. Employee was calm, alert, and oriented.

12/17/2020, 15 minutes after vaccination started to experience tingling on forehead and radiated on left side of face, nauseas, light headed, HR increased, 'funny on tongue' , 'felt like going to faint'. The BP was 149/109. The medical crew tried to calm down. BP would not come down. Placed in gurney, administered oxygen, given a 'benadryl and some sort of shot' to slow down the reaction. Given rest of the day off. 'I slept for a few hours' and after 4 hours, my chest started to tighten, radiated to back 'tightness' , felt like heartburn. I didn't sleep that whole night, had to keep sitting with the tightness in the chest. By morning I was better, I went to work, took inhaler (flovent and albuterol). Headache at work, took Tylenol. At 12, I went to each lunch and felt there was a lot of mucous in throat / acid reflux

feeling ; 'felt full in throat'. I went in a coughing spell, 'bubbly mucous'. I couldn't talk, drank water, sat in car until I had to go back to work. I couldn't breathe when I walked back into work. At approximately 2:15 they rushed me to urgent care, 25 childrens benadryl, administered oxygen and omeprezole for reflux. I stayed with the oxygen till 4:45; BP 140/98 and slowly came back down. 'At same time, co worker was experiencing same thing that just had had vaccination'. My asthma 'kicked in', white blood count was elevated to 17. Work in urgent care and where i was rushed to. flu shot 2 months prior TB skin test one month prior; negative

Erythema in cheeks, right greater than left. No hives, no itching, MILD edema on right cheek I took Benadryl 25mg PO. Symptom persisting, but less than initial response.

Difficulty breathing, elevated heart rate, dizziness

10 minutes after vaccination felt lightheaded and dizzy, pulse 64 resp 18 - given water and put feet up. 15 minutes later better but still woozy - pulse 80 resp 20. 15 minutes later walked around pulse 72 resp 18 20 minutes later - still feeling dizzy wishes to go to ER - transported via wheelchair.

Within 1min after administration: Tachycardia, mental fog, dizziness Within 5min after administration: Tachycardia resolved, mental fog worsening, dizziness, muscle weakness Within 15min after administration: Nausea, dizziness, mental fog (feeling like an out of body experience), muscle weakness (feeling like my legs wouldn't support me). Two hours post- administration: Severe nausea and mental fog Six hours post-administration: Muscle aches and joint pain. Nausea and dizziness resolved. Soreness and muscle ache in arm with injection site. 12 hours post-administration: Diarrhea, increase in nausea, and vomiting. Dull headache. Tylenol taken. 22 hours: Fever (99.1F), chills, sweating 32 hours: Fever (99.9F), chills, sweating, muscle weakness, body aches, headache. Tylenol taken. 43 hours: Tested for COVID by nasal swab d/t recent exposure at place of employment and presence of S&S. Test pending. Fever 99.0F. Tylenol taken. Dull headache.

Tingling of tongue, tickle in throat Benadryl 50 mg IM given Patient taken to ED

Patient began reporting a feeling of light-headedness 5-10 minutes after injection. Also reported nausea and feeling clammy, as well as numbness and tingling of both her arms. She laid on the ground in reverse trendelenberg position with some improvement in symptoms, but upon sitting upright, symptoms returned. Patient was transported to the ED for 1 L NS IV bolus with improvement of symptoms and discharge.

Sore arm, Headache, Body aches, Severe fatigue, Abdominal cramping, Brain fog (disconnected feeling)

Covid 19 vaccine was given in my right arm subcutaneously. Was not looking when vaccine was given, felt administer rub my arm with alcohol swab, and pinch skin. Did not feel vaccine...however when bandaid was placed knew it was injected subcutaneously instead of IM. Took pictures immediately after.

muscle aches. resolved in about 8 hours.

"About 24 hrs after vaccine I had chills with NO fever. Strong headache which I could feel going down my neck into my back between my shoulder blades. I just had this all over ""I feel awful feeling."" Took Ibuprofen 800mg about 3 hours later. Went to bed and woke up in the middle of the night feeling better. Felt just tired the next day until about 2pm and a slight headache until about 4pm."

Patient received covid vaccine at 1606. At 1616, pt reported feeling lightheaded and tingly. Was assisted to supine position, BP 128/79, HR 62. Was monitored by administering and RRT nurse. At 1630, pt reported symptoms completely resolved. Pt discharged at baseline status.

"Felt dizzy and lightheaded 10 minutes after injection. Client drank some water and reclined in cot. BP 142/71 Pulse - 80 O2 Sat 100% Client was evaluated by EMS, and felt better after resting for 15-20 more minutes. Total observation time after vaccine 45 minutes. Client reports ""feeling more like myself"""

She report had vaccine in AM 12/18 then later that night developed fatigue, muscle aches, and head ache. This has worsened overnight and this morning 12/19 had new symptom of sore throat that has persisted. Given sore throat has been advised to follow-up with employee health prior to potential return to work.

Pt received Covid vaccination and reported feeling dizziness at 13 min mark. HR 70, regular. Consumed water and a granola bar and then reported feeling back to 100% baseline. Was discharged from vaccine clinic after 30 min observation period. HR 72

Chills and fever of 101.F

Low grade fever of 99.9F, body aches, chills and diarrhea.

induration and bleeding at injection site, immediately after injection. Bleeding quickly controlled.

Patient experienced a rapid heart rate measured at 100 BPM. Recovered shortly with no issue.

After administration of covid vaccination, patient c/o feeling warm and diaphoretic. HR 78, pt appeared slightly pale. No other complaints. Ice pack applied to forehead. Patient reports feeling better at 1840, O2 98% RA, HR 74 regular, BP 140/96

Bleeding at injection site immediately after injection. Bleeding was quickly controlled.

Tingling sensation to left hand, traveled up to elbow and upper arm. Then tingling sensation traveled to right hand to upper arm. Both shoulders started to feel achy. Then tingling sensation switched to pins and needles sensation. Later on the day, left foot noted to have tingling sensation. Symptoms noted around 11am to current time 7pm, and continues to have tingling, pins and needles sensations.

Received vaccine around 1700-1730. At 0300 the next morning woke up in severe gi distress. Abdominal cramping, diarrhea. No fever. I was sweating but I believe that was pain related. Diarrhea lasted until 0600. Then abdominal distention and gas persist. It is currently 2000. I am able to eat and keep food in but the pain is pretty extreme for a vaccine. Right now it?s a 5/10. At 0300 it was 8/10.

Intermittent Cough (new onset) I did not see it on the list of common side effects. Not sure if its of concern or not. Started approx 8 hrs after vaccine. Other symptoms I have appears to be normal such as site soreness, fatigue and mild headache. Just wanted to make you aware of cough. Day #1 still. Thanks!

Induration at injection site immediately after injection.

I feel dizzy and woozy, almost like I'm drunk. S/S started 20 minutes after injection. Also nausea w/o emesis, fatigue

Vomiting every 20 to 45 minutes from 8:30 am to 2:00 pm. Resolved after 2:00 pm.

Itchy throat 10 minutes after injection. No shortness of breath, no breathing problem, no cough, no difficulty with swallowing. no facial swelling. Client was evaluated by EMT. BP177/91 Pulse 91 O2 Sat 97% Client did not take all of her blood pressure medication today. She felt her symptoms resolved after drinking water and resting. Client was observed for 30 minutes after injection.

Pain in the injection site, felt tired and felt feverish but normal temperature

Bilateral ears because hot, red, swollen, blistered, and painful approximately 1 hour and 20 minutes after vaccine was administered.

Patient complained of tongue tingling/numbness and feeling of swelling at 6:58pm. No shortness of breath or other symptoms. Vitals at 7:01pm HR 89, BP 125/85, O2 98%. At 7:11pm patient still felt tongue as numb but not worsening and not other symptoms. Provided Benadryl 25mg. Patients HR 92 and O2 98. AT 7:25pm patient stated she felt fine and HR 95, O2 99. Patient released to husband to drive home.

I received the dose approximately 7:15pm. Within about 8 minutes of receiving the Pfizer COVID-19 vaccine I experienced pins and needles sensation on the left side of my body in my left arm and strong muscle pain in my left neck. I felt nauseous intermittently. The nurse stated that my skin looked a little blotchy on my chest. Joint pain in my left knee and left arm was intermittent as well as intermittent pins and needles sensation in my left ear and burning in my left fore arm. I felt somewhat lightheaded. This lasted for about 15-30 minutes on and off. The nurse measured my BP and oxygen saturation which were in acceptable ranges. I kept moving my arm to relieve the strong and at times painful muscle cramping sensation in my neck and massaged my neck. By about 8pm the light headedness and nausea passed enough that I could drive home. On the way home the left side of my throat felt thick and somewhat swollen but not enough to prevent me from driving or breathing in any way. At home I focused on drinking a lot of water and gently moving my arm to relieve the pins and needles sensation. After eating dinner and hydrating I felt some improvement and most pins and needles sensation and neck soreness/throat thick sensation was resolved by about 11 pm. I was able to rest fairly well through the night until 7am the next morning when pain at the injection side woke me up. Soreness at the injection site, headache, fatigue, nausea, and mild chills are what I noticed today which appears to be more typically expected from the vaccine.

Warm flushed feeling, racing heart, dizziness that started about two minutes after injection. It dissipated after about 3-5 minutes.

Right arm burning sensation as injection was started. Right arm soreness at injection site immediately. About 45 minutes after vaccine, new onset of facial numbness and tingling (in cheeks and forehead). Symptoms went away after about 10 minutes. Facial numbness/tingling returned 3 hours post injection for >30 minutes. Woke up the next day and facial numbness/tingling was still present and also included both sides of face. This resolved around 1:00pm. Headache and significant right arm pain continued. Took 600mg of ibuprofen which reduced pain. Saturday (today) mild right arm soreness.

9 minutes after administration heart started racing, heart up to 154, lightheaded, dizzy, felt like I was going to pass out. Informed the medical team. Heart rate came down to 130s, started having chest itchiness, neck rash, and facial hives. 50mg IM Benadryl given. Heart rate came down to 90s and hives subsided. Started feeling normal but out of it. Discharged home. Slept for 24 hours. Injection site pain/leg muscle pain/joint pain/fatigue for 48 hours.

Elevated heart rate Warmth Shortness of breath

At approximately 9pm the day of the vaccination I developed a very aggressive and pounding headache, I went to sleep at about 11pm. The headache progressed throughout the night and I could feel that I had a fever. At 5:45 the following morning I got up and checked my temperature. It was came back as 101.2¦F. I took 2 tablets of 200mg ibuprofen and the headache and fever subsided in about an hour and my temperature was within normal range. For several hours I felt fine, however in the early afternoon my body felt extremely fatigued and the headache was returning and I had a few bouts of chills. At 4:30pm this afternoon (the day after vaccination), I took my temperature again and it was 100.4¦F. I took 2 more 200mg tablets of ibuprofen and took a nap. Approximately 90 minutes later, I rechecked my temperature and yielded a 100.1¦F fever and still had a mild headache. As of right now, at 9:30pm the day after vaccination, I no longer have a headache nor a noticable fever, just minor fatigue.

Patient felt throat was scratchy, then became flushed and slightly itchy. A rapid response was called and patient was brought immediately to ED by RN. Patient stabilized without any treatment within 10 minutes. Blood glucose found to be 44, given glucose and improved. Cetirizine 10mg was administered for itching, patient instructed to restart OTC antihistamines and see PCP the next day

Numbness on the right side of face (not severe)

Erythematous facial and neck rash

On 12/18/20, I woke up with a fever of 103.6, so I took Tylenol and applied wet wash cloths to my face and body to cool down. I initially was successful, and passed the temperature screening gates at work. But later that day at work I needed to take Tylenol every 8 hours because my fever returned, and I spent the whole day working while febrile. I am a respiratory therapist, so I knew that my fever was Covid vaccine related, and not because I was infectious. I also experienced base of the skull headache, bilateral

eye orbital pain, and tachycardia on my pulse ox about 130 HR, probably due to fever. I also had joint pain, mostly of hip girdle.

Flushing, racing pulse, rash (stomach, back), faint, dizzy, nausea, feeling unwell

Arm pain, controlled by heat and massage, no adverse event

10 minutes after injection in my left arm The right side of my face felt numb and was tingling. It felt like my right eye was swollen (which it didn?t appear to be) also the numbness extended to my jaw Lasted about 15 minutes then slowly went away

1520 patient reported numbness of bottom lip. Had this response in past--2005 or 2006 with preservative in influenza vaccination. Has not occurred since with use of preservative free influenza vaccination. 1522 numbness to tongue. No swelling of oral cavity on assessment. Face symmetric. 1526 feels slightly nauseous. BP 122/82, HR 72, RR 14. 1530 Patient states still has numb sensation to bottom lip and little on tongue. Denies SOB, denies difficulty swallowing, denies pain/tightness/tingling. Speech is clear. Mentation unchanged. BP on retake 124/80, HR 70, RR 12. Patient refusing further eval and treatment at ER. Patient verbalizes last time she took benadry and zantac and was fine. 1545 Patient left building. Sister driving patient. Instructed patient on signs/symptoms to call 911. 1630--Telephone call to patient to check on her. Patient states she took benadryl and zantac. States bottom lip and tongue are still numb. Highly encouraged patient to return to ER and get evaluated by physician. Patient said she was fine but knew what to do if needed. 1800--Telephone call to patient to check on her. Patient states she feels much better and is inquiring about second dose. Informed patient that we would follow up with her next week regarding next steps.

Chest tightness Hot flash for 1 minute Tight throat High heart rate 120s-130s

Chills, body aches, headache, nausea

Vaccination given at 12:50 12:54?started feeling lightheaded. Sitting in chair in observation waiting area. RN present in observation area. 12:55? feeling not right. Water given. Feeling nauseated. 1302?unable to hear BP via manual cuff in chair times 2 Lowered to floor and feet elevated 1305 ?88/54, 60 HR still nauseated and lightheaded. 1309?911 called 13:10?felt she was improving. Nausea better. 104/66, 68 13:12?110/68 HR 68 13:15?felling better. Sat up on floor. 98/50, 88 13:18?EMS arrived. BS 98. BP 112/72 Refused to go to ER by ambulance. Medics left. 13:25? RN and RN assisted patient to wheelchair. After talking with patient she did agree to going to ER to be seen by physician. Wheeled to ER and care assumed by ER team. Patient never lost consciousness and never had change in mentation. She always maintained conversation and orientation. She states didn?t feel sick enough to go to ER. Patient was discharged from ER to home.

Arm soreness, headache, fatigue

28 hrs after vaccine, woke up with tinnitus R ear, partial hearing loss R ear - went to Urgent care - Dr diagnosed with right sensorineural hearing loss with left side unrestricted hearing - prescribed prednisone 60mg a day x10days. Audiology test to be scheduled next week.

Puritic rash with multiple sites of itching all over patient's body. Lasted for about 30 minutes after onset of symptoms. Given 50mg Benadryl after initial onset of itching & 125mg of Solu-Medrol 10 minutes later.

Reports sharp, frontal chest pain worse with deep breathe/movement. began 25-30 minutes after recieving Pfizer's COVID-19 vaccination. 11:20am Vts: BP 109/54, P83, Sat 98%on RA. Exam: Alert, in NAD. airway no swelling, wide open. talking and sitting comfortably. No dyspnea. Hrrt RRR no murmur. CTA c/l. Left sternal border around rib 5 tender point reproduces her pain. Laughing and talking. Repeat bp at 11:30 109/63, P 79. Respirations 12 and normal.

Angioedema, hives, tachycardia, shortness of breath

Fever and myalgia. Temp 101.2 Left arm soreness to the point of unable to raise left arm

102F Fever since 12/18, chills, fatigue, body aches, vomiting, swollen neck/lymph nodes, severe headache. Self-medicated with Tylenol

Immediately (no delay) after injection, tingling in arm followed by flushing of face and subjective SOB, no wheezing noted, face and anterior chest with uniform erythema, no hives. Epinephrine administered immediately by vaccinating nurse. No further development of symptoms. Developed some palpitations and chest discomfort - normal EKG. Discharge home after 6 hour observation, no recurrence of symptoms.

Pfizer-BioNTech COVID-19 Vaccine EUA 12/17/2020- 12/18/2020 First day into overnight: temperature that ranged between 99-100.5 F. severe body aches, chills, extreme skin sensitivity, slight rash on right arm near injection site and on right breast, right arm pain significantly increased, fatigue, cough, temporary confusion, joint pain, nausea. 12/18/2020 Second day: Fatigue, slept for most of the day but still did not feel rested, nausea, arm pain, joint pain, headache 12/19/2020 Third day: Felt better but still drained and slightly short of breath. Joint pain, slight headache and side of face pain.

Pleurisy and pleuritic chest pain..sharp stabbing pain in left chest with every breath.

Fatigue, myalgia, chills, HA persistent for three days now

Menstrual spotting around 8:30pm the same day of vaccine injection. This was outside of my menstrual cycle. Occurred 1 time.

I was monitored for 15 minutes and felt completely fine and left the location. On my way home approximately 25 minutes after my vaccination I felt a tingling and numbness in the back of my throat. I decided to call the center and let them know how I was feeling. They suggested I return. During the 10 minute ride back the tingling and numbness had progressed to the back of my tongue. Once I arrived there they continued to monitor me and my symptoms remained stable with numbness in my throat and back of my tongue. I was not having any difficulty breathing and felt otherwise fine. There was a concern that the symptoms would progress and they initiated EMS. I was taken via ambulance to Hospital where they continued to monitor me and check my airway.. In route to the hospital I was

hypertensive with a BP of approx 190/100. I did not ask what my heart rate was. I was surprised my blood pressure was so high. They said it was probably because I was nervous however I was not feeling nervous because I knew since I could breathe I really was fine, and sending me to the hospital was simply out of an abundance of caution as this vaccine is new. Upon my arrival they took my blood pressure again and it was 140s/80s I believe with a heart rate of 106. My O2 sat we?re in the upper 90?s throughout the situation. My blood pressure tends to be in the 110s/70s with a heart rate in the upper 60s to mid 70s. So it was surprising to me that I was hypertensive and tachycardic despite not feeling like my heart was racing or that my blood pressure was high. I felt completely fine other than the numbness in the back of my throat and tongue. Since the symptoms remained stable and there wasn?t really anything for anybody to do they did release me. Between 6:30 and 7 PM I noticed the tongue numbness was subsiding. By 8 PM my throat felt completely back to normal.

12-18-20 at 0900 nausea and dry heaving started. 0920 felt freezing cold. 1000 feeling cold intensifies. 1000 headache begins. 1100 headache worsens. 1115 full body ache grows in strength. By 1200 body pain and fatigue increase. By 1300 headache and pain all over body maxes out at 8/10 on pain scale. For the rest of the day couldn?t warm up. Headache, body pain, and feeling cold lasted the rest of the day and throughout the night. 12-19-20 at 0730 headache extreme, body pain fading, feeling of cold not as intense. By 12-20-20 at 0600 only headache remains. feeling of cold, nausea, and body pain are gone.

Red rash on back, arms and legs. 101.2 oral temperature. Joint pain, bruising

Approximately 2-4 minutes after injection I began to get hot. Once sitting down I noted my hair under my hat was sweaty. Noted elevated HR at this time (did not check). No sweating anywhere else. Not clammy. I have a history of anxiety...was thinking that maybe I got hot due to room temperature / size and then my mind reacted. Symptoms started to settle around minute 12 - 15. Sat in my truck for a few minutes after the 15 minute holding time. Started to feel back to baseline. I have had no issues since. Again, thought it was anxiety however I did talk to my Aunt who experienced similar symptoms after her injection. Decided to report. No chest pain No SOB No angioedema No rash or hives No swelling

Dizziness, fever, nausea, pain at injection site, inguinal lymph node swelling, chills, generalized weakness Took 2 acetaminophen 500mg, but to no relief, symptoms passed on their own.

Pain in the injection site for several hours (probably 5 hours or less), with a pain scale of 3/10. Pain is manageable, can still use the affected arm, no pain medication taken.

acute, mild pancreatitis, associated with symptoms associated with Nausea and vomiting and abdominal pain. Patient's symptoms started 1 day after her vaccination.

"After 3-5 minutes after injection felt anxious, shaky, lightheaded and stated he ""felt off"". Patient in chair and notified observation staff who notified POD manager RN. Patient stated he had not eaten today, given water, peanut free snack and room temperature made cooler. At 1535, patient states all symptoms are resolved."

Coughing, chest tightness, decreased saturation, itching forehead and back, rash on upper back

Patient received vaccine at 0845 and left after the specified 15 minute waiting period. At 0940, the patient returned to the vaccine clinic stating that he was short of breath and his throat felt tighter than before. Arm examined and no hives or redness present, patient denied itching and hives. Patient denied that throat tightness was getting worse. PharmD and RN present and took vital signs and called house manager. Verified NKDA and then administered 25mg of PO diphenhydramine. Pt then transported via wheelchair for further workup.

Patient received COVID 19 vaccine at 1636 12/19/2020. Patient returned to clinic at 1733 complaint of throat closed and hard to clear. Patient had declined observation period and returned to work. Vitals 131/79, HR 90, 97.7 F, 98%, RR30. Complaint of dyspnea and palpations and occasional chest pain. Patient states history of asthma and hypertension.

Patient received vaccine 5 min prior, then left lightheaded, nausea, put head down, sat back up got worse then felt jittery and heart beating faster. Patient assisted to stretcher, cool cloth applied and vitals taken. Patient reassured and education given about vaccine and side effects.

Patient complained of tingling lips and tachycardia. BP 159/90 HR 105. RRT called. Patient transported to Emergency Department.

Within 5 minutes, started feeling very tired and dizzy, leaned head back trying to relax. Approximately 15 minutes after vaccine had seizure lasting up to 15 seconds possibly. Brought to floor carefully. Then had small second seizure (about 5 seconds in duration). Difficulty Breathing immediately. Then extreme trouble breathing/stopped breathing , given 0.3 mg EpiPen in right thigh, gasped and began breathing again. Checked pulse (80 b/pm) then waited about 3 minutes and EMTs arrived. BP was 140/90 ish. Both higher but not terribly high.

5pm: quick hot sensation with associated increased HR, hot sensation went away after a few seconds and HR returned to normal shortly after 5:15 pm: slight tingling in tongue, lasted only a few seconds and then went away no other side effect since, except for a slightly sore injection site.

Enlarged lymph nodes on axils initially walnut size then progressed to golf size edema/lump on Left breast

Stomach ache and slight achiness

Left arm pain.

I am an employee of Medical Center. I went to Hospital for my vaccine since it was only 5 minutes away from my house. At 5:00 PM I received the vaccine. 10 minutes after I noticed my throat felt tight and as if it was closing. This felt similar to the reaction I felt when I had morphine in Jan 2020 (that I am allergic to). I notified the nurses and they watched me for 10 minutes. It then stayed the same. They brought me back to their tent area and gave me 50 mg of benadryl. I immediately felt relief. However, maybe 3-5 minutes after the throat closing sensation came back. They then had to take me to the ER. I was then put on fluids, steroids, pepcid, and ativan. I was released after they watched me for a couple hours.

sore throat

The patient first started to feel really warm. The patient felt like her head was swimming. Then the patient had chills. Her vital were prefect.

Low grade fever 99.1 Severe myalgias Headache

Nasal congestion, headache, fatigue, 2-2.5 inch swollen, red, firm area @ injection site

two hours after getting the vaccine i had nausea/ vomiting and body aches. two days later i am still having body aches.

"Patient screened prior to vaccination for previous history of allergic reaction to other vaccine or injectable medication. Patient confirmed past history of ""numbness of lips and tongue"" secondary to iodinated contrast media. Patient was counseled and instructed to wait 30 minute observation period following vaccination. Following the injection, within 15 minutes the patient reported feeling flushed and heart was racing and felt that their throat was closing. Patient was triaged in the vaccine observation area with HR in 120's and BP of 182/60. Upon evaluation by the hospital's rapid response team she was administered 12.5 mg IM diphenhydramine and transferred to our ED for further evaluation. Upon evaluation by ED provider no additional treatments were administered and her symptoms abated. She was discharged home in stable condition without any further complications as those noted above."

Severe arm pain x2 days - injected in shoulder not deltoid Sudden onset of chills, severe shaking, shortness of breath, 02 sat = 89% that lasted 15 minutes (took Tylenol 1000 mg immediately). This occurred about 1.5 days after injection

SOB, fever,headache,body aches, chills,feeling unwell,tired for over 24 hours than on Saturday 2 days later developed injection site pain swollen lymph node under right armpit with severe pain

"28 minutes after PT. received vaccine she told RN on duty she felt funny""heart fluttery"", , light headed, dizzy B/P 190/110 HR 70-80,98-99% RA per facility RN. 0932 182/105, HR 60-70, 99% RA per RN 0945 Continue to monitor 180/95, HR 60-72, 99%RA blood glucose 90(PT ate breakfast) RN @ bedside chair 0954 119/91, 99% RA , 60-73 HR feels better but has headache 10:00 ambulance called10:08 208/96, 68-76 HR 99.24% 10:13 Ambulance arrives,report given 40 Medic 10:20 210/112 per EMS monitor HR80 100% RA 10:28 Loaded onto stretcher left with EMS"

40 hours after receiving the vaccine I am experiencing dizziness.

On 12/18/20 @ 2:58 PM, the patient experienced a really bad headache directly after received the vaccine. Her heart rate elevated 135 with heart palpation. Her BP was 178/92. She was very dizziness, short of breath, her had a hives all over her chest.

Approximately softball sized rash developed on LUQ and with additional around left flank area approximately 2 hours after injection. The redness/rashes went away spontaneously after another 2

hours. During that time, a little discomfort in left side of throat, but no change in lung sounds, uvula or any other respiratory concerns. Later in the day (approximately 4-6 hours), baseball sized redness presented on triceps bilaterally and splotchy redness on lumbar area (about 2-3 areas). Redness/rash is still present on both triceps the next day 22 hours after injection.

Fever of 102 F that developed within 12 hours of vaccination and resolved within 24 hours of onset.

Fever 102 Sinus congestion dry cough runny nose body aches

Patient is a pleasant 83 y.o. female pediatrician with history of Sjogren's, hypothyroidism, hyperlipidemia, hypertension who had been at Hospital to get her Covid vaccine. 30 minutes after doing so she reports being in the lobby and about to walk upstairs and feeling fine. The next thing she knows she wakes up on the stairs with her nose and face bleeding surrounded by healthcare team. She denies any precipitating symptoms such as chest pain, shortness of breath, fevers dizziness, headache. She reports feeling well otherwise in the last few days. I did a thorough bony palpation exam including spine and he only point of tenderness besides on her face was the area above her right ankle. She does not have a history of syncope or collapse

Patient had vaccine at 1330 on 12/20. At around 1815 she began experiencing heart palpitations. She presented to the ED and she was found to have a heart rate in the 130s. EKG showed junctional tachycardia. She was given 6mg of adenosine and an EKG was repeated and showed sinus tachycardia. Eventually her heart rate decreased to the 70s-90s. She was noted to have a potassium of 3.4 which was repleted. She was admitted overnight for observation. In the morning her potassium was normal and she remained in sinus rhythm. She was discharged later that afternoon.

Headache, fatigue, nausea, tachycardia, muscle pains, chills, subjective fever and subjective shortness of breath

Swelling and redness at injection site, swelling of lymph nodes in the same arm as injection site, painful

"Employee reported chills, shaking, dizziness ""like you feel after you faint, spacey""."

Patient became lightheaded. Felt palpatations. No shortness of breath.

Metallic Taste

Numbness and tingling throughout body

The patient experience tightness of her chest. She was hook up to be monitored. Her BP was 185/91. Her heart rate was 122. Her O2 level was 100. The nusre notice swelling at the area of the site with mild erythema (redness).

Most severe symptoms was injection site soreness initially, followed by overall myalgias, chills, and fatigue. Recovered in 2 days.

Nausea, initial SBP is 155/87 and heart rate 101. Repeat BP was 134/84 and heart rate 94.

Anaphylaxis type reaction, stridor, treated with 02, epi pen, moved to hospitals ED

8am EE noted fanning herself, states she feels warm but just got off nights. Ice pack given for neck. 8:03 C/O itchiness on chest, heart racing, neck and chest with mild redness. No SOB or tightness in throat. RN notified and came to assist. Left arm vaccine injection site asymptomatic. EE refused Benadryl. BP 143/105, P81 PO 100% 8:08am Continue to feel itchy on chest and neck BP 153/91 P-76 PO 100% continue to refuse Benadryl 8:10am Benadryl 25mg po given, juice and crackers 8:14am BP 151/86 P-65 PO 100% changed to reclining chair to elevate feet, no tightness in chest or throat. 8:20am EE c/o left arm tingling/numbness down to fingers, denies CP no SOB, states it is like she hit her funny bone. BP 151/86 P75 PO 100% RN notified and evaluated her. 8:35am EE feeling cool. BP 131/88 P-69 PO 100%. EE states she feels like the Benadryl is working , redness less on neck and states she feels more relaxed, continues to have left arm numbness. 9am EE states she feels better, a little itchy on neck but no redness. BP 123/87 P 73 numbness decreased and almost gone. OK to go home per RN and instructed to take Benadryl when she gets home and to call the Covid vaccine hotline if needed or 911 if any resp. distress or CP. Requested her to text or email RN when she arrives home. EE states she understands. RN states she heard from EE and she is home. RN

slightly elevated temp (99 deg), chills, body aches, headache over 18 hrs period

Immediately after the vaccination my arm got super sore. On, 12/17 at 10am while at work I developed a 99.1 fever, chills and severe body aches all over called Employee Health and management and was given a COVID test which was neg and was sent home. I took 600 mg motrin and around 8pm that night I began to feel better. I previously had symptomatic COVID in July.

12/19- nausea & headache. 12/20- bodyache, sore arm & headache

8:33am EE states she feels flushed and heart racing. BP 141/83 P-96 PO 100% Refused Benadryl. Denies SOB, chest or throat tightness, no itchiness. RN notified. 8:40am C/O warmth, no itchiness, no SOB, no tightness in chest or throat. BP 137/81 P-77 PO 100%. 8:50am 138/83 P-65 PO 98% abdomen with some light rash. 8:55am Benadryl 25mg given per RN 9:05am BP 129/87 P68 PO 100% c/o left eye feeling warm, no redness. 9:30am BP 127/84 P69 PO 100% denies heart racing, feels fine, Instructed to take Benadryl again if has reoccurrence and to call the Covid vaccine line or 911 if any resp distress. EE states she understands. RN

Patient states my lip feels like it is swelling, patient lower lip with swelling noted. Patient assisted to Emergency Dept via W/C 02 sat 99%, B/P 150/88, HR 99

12/17/2020 Woke up at about 7am, pain at injection site, swelling. At end of day, started to have extreme HA and joint pain. Tried to sleep as much as possible. But 12/18/2020 felt even worse. Was unable to report to work. Mgr recommended the rapid test for Covid on 12/18/2020. *drive up test. Didn't want to take tylenol to mask fever. Rested friday and sat. Felt better 12/19/2020. Symptoms were mild to moderate. Temp highest was 37.9 12/20/2020 'still feel warm', body aches, joint pain, headache are 'still there' but 'more tolerable'.

Recurrence of the exact symptoms I had when I had COVID in March, 2020, but less intense and for only one day. These were severe fatigue and wet cough. No fever. It was like deja vu, but only lasted 24 hours. No other new symptoms.

Started feeling confused. Stated felt like she was drunk. laid her down on the gurney progressed to abdominal pain, nausea and vomiting. Light headed confused, tingling in legs. Sent to the Emergency room

swelling at site of injection, fever 102.3F, muscle ache, chills

30 min, c/o feeling light headed, BP 129/71, 98% RA, HR 66, R 16. Sx resolved.

Increased Fatigue on day one after 1st dose. mild Left axillary lymphadenopathy. Axillary swelling, and tenderness radiating into left breast and very mild into left anterior neck. . 2/10 on pain scale. Constant Dull discomfort. Not really worse with movement. Axillary lymphadenopathy and tenderness more noticeable on day 2 after receiving 1st dose of vaccine. NO SOB, dyspnea, fever, change in heart rate.

Patient became very flushed and ee stated she was not feeling well. BP: 156/96-176-96 HR: 80-98. Patient states this was not normal bp. continued to monitor pt and noted to have reddened rash on face. Patient to ED for further evaluation.

9:50 am patient states she does not feel right, feels funny, leaning over in chair, denies SOB no CP c/o of heart racing, NKA RN and RN summoned to help. Patient laid down on floor. BP 192/103 P-112 PO 100%. Eyes noted to be pink, denies itchiness. RN called 911, advised not to give Benadryl. 9:55am BP 178/99 P-119 PO 100% patient continue to feel heart racing but no SOB, chest or throat tightness. 10am BP 177/100 P-114 PO 100% continues to be A&O x3 no resp. distress 10:03 EMS arrived and took her to the ER. Patient states her 15 min observation time was up at 10:05am. RN

Woke up out of sleep and felt very warm, and a tingling sensation which started mid thoracic region which then traveled up to base of my neck and then spread bilaterally to both arms and hands; was brief and then just dissipated

30 min, c/o L hand (btw 2nd and 3rd finger) swelling, no pain, no itching.

Nausea- started about 48 hours after injection. Began with a feeling of slight motion sickness and progressed over the next 12 hours to be severe enough to cause vomiting. Nausea only present when standing and improves when laying down.

30 min, c/o slight numbness, tingling at injection site arm (L) vitals taken WNL. Sx resolved.

Initially started as numbness of the lips, then progressed to angioedema (swelling of the lips) with face itchiness. Then progressed to throat tightening and swelling feeling, consistent with anaphylaxis.

shortly after receiving COVID vaccine, patient complained of arm hurting with shooting pains down to her elbow and fingers. Patient started shivering, HR 129, BP 131/78 o2 sat 98%. continued to monitor

employee. physician at side 800mg ibuprofen given. Patient hr down to 111 and bp 135/97. Patient refused evaluation in ED. was released and escorted by physician out of department.

Very painful to injection site that woke me up the night of 12/17 into 12/18. Became febrile at 100.5F oral Friday 12/18 with body aches, joint pain, extreme fatigue, skin hurt between 4-5pm. 600 mg ibuprofen helped, however became flushed and sweaty. Saturday 12/19 woke up feeling fine. Around 3pm, body aches started again with bilateral hip pain, extreme fatigue, sweating. Temp was 101.1F oral at 7:15pm. I took 500mg acetaminophen and 600mg ibuprofen. Today, again woke up feeling fine at 9am, felt asymptotic. On the way to work at 10am, became sweaty/fatigued/body aches again. At work, 10:45am temp was 99.6F oral. I took 500/600 of Tylenol and ibuprofen.

Experiencing decreased sensation in bottom lip. No decrease in function. No facial droop. Just decreased sensation/numbness. Started on the second morning after the vaccine. No exposure to known allergies.

Injection given 07:58 am, at 08:12 Patient described feeling dizzy, was diaphoretic V/S at 0812 178/99 Temp 97.0, 0813- 182/101 P-112, O2 Sat 98% on room air Respirations within normal limits, alert oriented, patient described feeling a little shortness of breath able to speak in full sentences, transferred to gurney and taken to Emergency Room, skin pale. While waiting for intake patient stated shortness of breath was feeling a little better, repeated BP 0827- 146/94 care transferred to Emergency Room

Within 5 minutes of receiving vaccine, Pt.t started to feel shaky and nauseous, became tachycardic, however patient stated she rushed to get here and was not sure if that was the reason. Pulse at this time was 100. She felt she was going to pass out. I got water for the patient and also gave her peppermint candy, after about 10 minutes she didn't feel she was getting worse but she didn't feel much better. She did not want RRT called. I gave 25mg of Benadryl. Within 5-10 minutes after the Benadryl she started to notice symptoms improving. After 20 minutes patient is standing and no longer feels she is going to pass out. Patient called her husband to pick her up.

Patient stated he didn't feel well after receiving vaccine. Patient stated his throat felt funny, BP 186/94, HR: 117, o2 99%. Patient went to ED for further evaluation.

at 1am after vaccination, woke up with body aches, couldn't sleep, restless till 0430. Woke up with mild congestion, cough, fatigue, lt. arm sore at site. Body aches continued throughout day. Contributed it to shot. Slept good Friday night, woke up Friday with mild cough, congestion, fatigue, runny nose, sore throat. Tested for COVID Friday morning with Binax and was positive. Symptoms have worsened since then; loss of taste and smell. Has had temp as high as 101 on Saturday, low 99's on Friday. Chills, SOB, and fatigue. on Saturday

12/18/2020 scrotal pain. Evening onset of rash 12/19/2020 Rash lower lumber, left butt cheek, scrotum and penis. Took picture and sent to Consult with infectious disease. Doctor deemed rash to be SHINGLES and prescribed Valtrex. By evening, rash had progressed all over and pain associated with shingles. 12/20/2020 Stable but rash is still prominent. Consult over tele

Pt is currently breastfeeding. Pt reported having 4 clogged milk ducts. 3 on the same side as injection and one on the other. All have resolved at this time through breastfeeding and pumping. No other symptoms.

I had aching muscles, headaches, diarrhea, nausea, pain in my arms and legs and vomitting.

12/19 1000 developed chills, 1230-body aches, nausea, and headache, fever 101.5 (self reported), 1300 fever increased to 102 (self reported), fever then increased to 106 (self reported). Pt reported dizziness. Visited ER. Fever 100.8 on arrival. Patient reports taking PO advil, tylenol, and benadryl. Used ice packs at home to decrease fever. TX in ER with IVF, tylenol, and zofran. D/c from ER. OHN f/u 12/20-patient feeling better, resting at home, denies fever.

headache and nausea around 2am...throwing up...reso;ved by 2:30am

Patient complained of tachycardia. Dr. examined the patient who stated he had a regular rhythm. After one minute of sitting, he felt better. After sitting for another 5 minutes the patient stated he was feeling tachycardia again. Denied any dizziness or lightheadedness. Dr called down to the ED. Patient escorted down to ED where they did an EKG and discharged him.

Approx 45 minutes after injection, patient reported generalized itching. Patient was given Zyrtec 10mg. Itching continued. Patient was given Diphenhydramine oral. Itching resolved.

Reactivation of HSV2 virus, outbreak on left buttock/flank and related lymphnode tenderness, flank pain, body aches, malaise.

The patient was well prior to vaccination (12/17). The day after, he felt mildly unwell and had a low grade fever. The following day, he had a fever of 102. He received 1L of fluid at Urgent Care and had a BP ion the 80s. Shortly thereafter, he felt palpitations and developed AF. He came to the hospital where he was tachycardia to 200 bpm and hypotensive to SBP70s. He received aggressive fluid resuscitation (4L), IV metoprolol and was started on empiric Abx. Within several hours, the HR lowered, BP increased, and AF spontaneously converted to sinus. He had no dysuria. Curtures so far have not shown growth at our hospital. Urinary culture from urgent care has reportedly shows 20k gram positive cocci.

Approximately 15 hours after getting vaccine, the morning after, noticed slight tongue discomfort. Feeling slight swelling of tongue, noticed scalloped appearance. Noticed for about 24 hours, seems to be mostly normal now. Did not take any medication. Was not in any distress really, just seemed to be an uncommon side effect and thought I should report. Only medication allergy in past was keflex many years ago and was described as serum sickness and treated with Prednisone.

15 minutes after injection. Tachycardia, Diaphoresis, mildly hypertensive, facial flushing, waxing and waning symptoms

Headache, injection site pain, blurry eyes, hoarseness, sore throat

Tingling in face shortly after dose for approximately. Symptoms resolved after eating a meal.

Symptoms: light headedness persisting 3 days after administration, high BP occasionally

102 temperature started around 11pm on the 17th. Fever went back to normal evening time on the 18th- treated with ibuprofen. Body aches started same time as fever and lasted until the 19th- treated with ibuprofen. Severe fatigue started the night of the 17th and has lasted until the 20th. Severe headaches started the night of the 19th.

A slight small itchy rash in left hand that stopped itching pretty quickly

Received 1st dose of Pfizer vaccine on Left Arm at 1630 on 12/18/20. Within 8 minutes of receiving vaccine, tongue experienced numbness and tingling. At 9 minutes post administration, symptoms intensified. And at 10 minutes post administration throat was scratchy was a tickle. At 12 minutes post administration notified Pharmacy and Employee Health Workers. By approximately 1650, health care professional administered Benadryl 50 mg IM to Right Arm. Observed. Symptoms decreased but then intensified to include numbness and tingling in lips. Transferred to Emergency Department for observation. Received decadron 10 mg IM to Right Arm at 1915 due to symptoms not resolving. Discharged from ED with prednisone course. Discharge diagnosis Angioedema. Symptoms decreased approximately 6 hours post administration of vaccine. On 12/19/20 at approximately 1425, experienced tightness of throat, with numbness and tingling of tongue and lips. Took over the counter Benadryl 50 mg p.o. at 1440. By 1520, symptoms intensified with hoarseness in voice with coughing spells. Returned to Emergency Department for observation. Noted to have rash on chest in ED. Received Pepcid 20 mg in ED. Discharged with instructions to take Benadryl 50 mg p.o. every 6 hours, famotidine 20 mg p.o twice daily, continue taking prednisone, and received prescription for epinephrine auto injector. Emergency room physician wrote to return to work on 12/22/2020 with follow up with Employee Health on 12/21/2020.

Petechiae - very mild on proximal area of right thigh. Noted two days after vaccine. Appears to be resolving.

Periorbital edema upon wakening that resolves throughout the day but reappears the next morning

Patient reported onset of mild headache immediately following injection of vaccine. Resolved after 30 min observation.

The patient expericence lightheadness, flushed, heart palpation, and chest tightness. Her vital are BP 119/54, 62 heart rate, O2 was 99. The patient was monitored until the symptoms went away. It all passed within 20 minutes. The patient was walked to her car by employee.

Patient reported onset of slight headache immediately following vaccine injection. Resolved at time of dc after 30 min obs.

Swollen lymph node on right side of neck the morning after receiving the vaccine. Telehealth appt with PCM who prescribed 800mg ibuprofen. Took 200mg motrin for swelling because i have not had the chance to pick up prescription. The following day, swollen lymph node continued and broke out in hives approx at 1300. Went to emergency room and was given an oral steroid (dekadone?). Prescribed

prednisone, claritin, and Benadryl. Have taken 1 claritin a day. Hives have disappeared within 5 hrs of oral steroid. Swollen lymph node persists and has enlarged. Painful and swollen past the jaw line. Will return to ER today for pain and continued swelling as directed by ER.

Burning at injection site, then elevated heart rate, flush, and light headedness. I was kept and observed for another 30 minutes at the hospital and everything returned to normal. Then, I developed severe dry mouth and congestion, post nasal drip, headache, and nausea. I drank 3 liters of water with continued dry mouth, intermittent feelings of flush and light headedness for the next 3 hours, but no fever. After that subsided, I had only chills and headache that were resolved by the next morning. Now I have only arm soreness and mild fatigue.

"Felt an initial ""cool"" feeling all over immediately following vaccine injection, this resolved immediately as well."

After the vaccine I immediately got a mild minor headache which passed pretty quickly. At around 9pm I noticed a bump at the base of my neck on the top of my right collar bone. I reached out to Employee Health Nurse and my PCPs nurse who agreeed it could possibly be a swollen lymph node. Today I am currently monitoring this bump and if it doesnt desolve I will reach out to my PCP in the morning.

Patient reported numbness in lips immediately following vaccination, resolved within 15 mins.

I have nasal congestion, loss of taste and smell and fever.

Pt reported feeling light headed following vaccination, resolved after 15 mins.

12/18/2020 morning I started to have runny nose, achy 'like coming down with a cold'. Late evening and early morning 12/19/2020 tender lymphnodes, same side of vaccination. As of 12/20/2020 barely palpable anymore. Temperature was normal. I took ibuprofren and tylenol; 12/18-12/19. Congested, nasal drip ' 48 hours of feeling worn down and achy'. Flu shot in October 2020

Patient received vaccine and became dizzy, nauseous, and hypertensive and was taken to the emergency room.

Light headed, cold clammy skin, pale, cold sweats and numbness to left arm where she received vaccine.

Mild dizziness followed by jitteriness and heart pounding. Increased blood pressure. Lasting for about 1-2 hours.

Received vaccine, waited 15 min. Walked to car. side of face went numb, dry mouth. Patient walked back to vaccinate location. Pulse 115, O2 Sat. 96.

Extreme fatigue, generally unwell, body aches, headache, abdominal pain, nausea, ear fullness. Near syncopal episode the morning after the vaccine.

Tachycardia (150?s), dizziness, shakiness, flushing beginning 5-10 min after injection. Lasted for approximately 45 min. Approx 24 hrs after injection, developed a rash on torso?bilateral arms, chest, neck and back.

Malaise on 12/19. Right (collateral) axillary lymphadenopathy about 1 inch in diameter noticed on 12/20 (today).

Red spot about 1 inch in diameter with swelling and warm to the touch. Muscle soreness around injection site. Still present two day later with no relief as of reporting.

Painful, Tender and redness next to injection site (not directly on). Red mark approximately 2 inches in height and 1 1/2 inches wide

Diarrhea (5 hours post-injection), duration 48 hours Fever (11 hours post-injection), duration 6 hours Feeling of lump in throat (24 hours post-injection), duration 24 hours

Itching; Hives; Patient declined Benedryl ; took Claritin with some relief

About 23 minutes after the vaccination I started feeling tightness in my throat, began coughing and wheezing and had SOB, was taken to a secure area and given 25mg benedryl and they waited a few minutes and gave another 25mg of benedry. I was given an EPI pen injection in the left thigh and was given an albuterol enhaler to help with the breating. The symptoms resolved after the EPI and the albuterol and I was released from their care

Felt flush and throat started to get scratchy and started to get tighter and was having difficulty swallowing about 4 minutes after vaccination. Continued to get more flush and laid down. Rapid response was called and taken to the emergency room.

I had an existing mild rash after I ate crabs on 12/18/20. I never had allergies to any food. My rash got worse 6 hours after receiving dose yesterday. Both ears are swollen and red. Rashes behind ear look like hives, welt-looking. It spread to my neck and upper back area. Took Benadryl and it slightly improved. Also applied Cortisone cream. Took Zyrtec as well. Slighty better. It's been 24 hours since injection.

Fever, chills, fatigue. Occurred at noon 12-19-2020. Sent home from work (ER RN) and had covid test.. awaiting results.

I had sneezing and a cough.

Injection arm very sore by 20:00 day of vaccine. Awakened with body aches at 03:00 and chilling. No fever. Went to work (frontline healthcare worker) at 08:00 but left work early (14:00) for worsening body aches moderate joint pain and increasing fatigue. Polyarthralgias and myalgias intensified as did chilling. By 10:30, abdominal pain had begun. And diarrhea had begun. The next 12 hours were continued intensity of abdominal pain (diffuse intense cramping), and severe myalgias and poly arthragias. I took additional naproxen (440mg w good 16 hours from am dosing at 07:00). I was unable to do any thing but try to rest between bouts of diarrhea. Nausea developed (moderate) but no

vomiting. No fever despite intense and unrelenting chills for about 24 hours. Continued fatigue into post vaccine day 2 (12/19/20) but improved pain and resolution of GI symptoms. On 12/20, only mild polyarthralgias of hands, arms, low back, knees, feet, and hips.

Patient took 50mg Benadryl prior to injection at 1300. She also took Xanax at 1000 prior to injection. Immediately following the vaccination, patient reported onset of slight headache and tingling lips. No SOB. O2 100%, HR 80.

Persistent headache which started night of vaccine, unrelieved with Tylenol, continues today (12/20). Fatigue which has gotten worse, to today where I struggled to function and had to call in for tonight?s shift at the hospital.

Headache, body aches, injection site soreness.

for 2 days continues fever upto 104 chills rigors sweating myalgia extreme fatigue . i am a physician by profession i had covid in may 2020 and had antibodies igg checked in september

Chills, throwing up, runny nose

Sensation of tightening in throat and sensation of difficulty swallowing. No rash. No dyspnea. No stridor/wheezing. Vital signs unremarkable. Suspect globus sensation. Plan observation until resolution or progression to anaphylaxis.

Slightly after injection I began to feel light headed, flushed, dry throat, and increase in heart rate. I was monitored after for about 15 minutes which the symptoms seem to have resolved on their own. No treatment was needed. I didn?t think much of it until I realized some people were getting same side effects.

Within 24 hours , headaches nausea, muscle and joint pain. Approximately 24 hours facial rash/hives , itching and puffiness. Within 48 hours rash spread to neck and chest , day 3 rash/ hives continued, headache and body aches improved, urgent care visit started on Mederol pack with dx of allergy to COVID vaccine. With steroid dosing facial rash some improvement. Occasional headache no unusual body or joint discomfort above baseline

12/17/2020; 1158 am had injection. at 2pm, noticed trunk itching around waist, abdomen, back. No visible rash. mild soreness and redness to injection site on left deltoid. 530/6pm developed SOB, rash is now visible, non raised, very itchy trunk. Took 10 mg Zyrtec. Went to ER nausea, vomiting, moderate to severe abdominal pain, flared angina and chest pain with the shortness of breath. ER; DR. CONTINUED WITH BENADRYL 50MG 4-6 HOURS, DUE TO ONGOING ITCHING. FAMOTIDINE 20 MG 2X/DAILY Had flu shot between 09-10/2020

Sudden onset of fainting sensation . Followed by dizziness moderate shortness of breath lightheaded ness panic tingling in hands feet top of head headache distress.

Thurs 12/17 : aching in left arm infection site. Later evening : ?flu-like ? symptoms Fri 12/18 : 04:30 am : vomiting , headache, Started work at 06:00 am. - continued nausea, chills/ warmth (but no fever) Around 1:00 -small pupils (but dilating) , increased weakness, & dizziness begins. No appetite. Slept all evening. All vitals normal range. Took 2 capsules (200 mg) q 6 hr. Sat Dec. 20 : weakness in am . Increased appetite.

Constriction of airways, rash/hives and o2 sat low (80?s). Used pt albuterol inhaler, no relief. Coughing and wheezing continued. Staff escorted me to ED where I was give IV Benadryl and solumedrol. Within 2 hours post-vaccination I was ok to leave.

Nausea, diarrhea lasting approx 12 hours

Patient with symptoms of severe myalgias, low back spasms, fevers, chills, headache, SOB since Saturday. Treatment included intravenous fluids, Tylenol, magnesium repletion, frequent reassessments, infectious disease consultation in the Emergency room.

Numbness in face and tongue, feeling of tongue swelling and touching the back of my throat, difficulty swallowing with need for more effort and more swallows. These symptoms started about 45 minutes after the injection and got worse. I went to the urgent care and received Benadryl, Pepcid, and an IM Solu-medrol. The PA said he did not see any edema and I had a patent airway so they monitored me and sent me home with an epi pen in case symptoms worsened. Symptoms started improved approximately 2-3 hours after receiving the medications and the epi pen was not needed.

Ventricular tachycardia. Defibrillator paced me out of rhythm. I have had my ICD for 3 years. This is the first abnormal rhythm I have had where it delivered a therapy to abort it.

Had full body numbness and tingling about 6 minutes after administration, while waiting in observation area. Felt lightheaded, dizzy. Laid down, symptoms resolved about 5 minutes after, except bilateral Upper extremity tingling. This resolved after an hour, with tingling then localized only to left arm. This also resolved within 2-3 hours from time of administration (estimate)

12/16/2020 7:20am After the injection few later I felt my chest started to hurt gradually increased the pain and started to have palpitations it lasted hour and thrity. Vital Sigh the time of the event BP 138/80, HR 78, RR 24, Sat 99%. I was sent to ER they blood samples, EKG, Chest X-ray and monitor my heart rate.; all was normal. The same day I was discharged home.

Patient reported metallic taste in mouth, slight tightness in upper chest. Observed chest tightness deceased over 20 min. Metallic taste almost gone. 30 min. almost all gone. Benadryl 50 mg. given at 25 min. condition improved. Instructions given to patient re-symptoms worsen, S.O.B, etc, husband driving patient home.

Within 10 minutes of receiving vaccine, I experienced shortness of breath, irritation in my throat, felt flushed and was dizzy. I was immediately transported to the emergency room where I received benadryl and was monitored.

3pm developed sore throat and rhinorrhea. Concerned that I was positive, left work and scheduled symptomatic test next day. Noted on home pulse ox that my heart rate was in 140s (otherwise vital signs were normal and I was afebrile). Symptoms got better and after pushing fluids I was able to get my heart rate under 100 by end of the day. 12/20 woke up heart rate 140s now down to 105 at time of reporting. Sore throat and rhinorrhea are getting better but tachycardia is concerning and I am worried I may have developed an arrhythmia as my Apple Watch consistently marks my rhythm as inconclusive

Throat closure (angioedema/anaphylaxis) requiring ambulance transport to Hospital emergency room and stay IV infusion of Benedryl, solumedrol, and Pepcid with excellent results. Observed twelve hours, then discharged.

Approx. 10 minutes after vaccine administered I became suddenly tachycardic while sitting in a chair. Heart rate up to 140. I started to feel some chest heaviness with some difficulty breathing. Felt like my heart was galloping. Was transported to ER and monitored for 2 hours. I was orthostatic with talking, and walking. Heart rate to 135 walking to the bathroom despite having had a liter of IV fluid given. I was discharged home with instructions to follow-up with my doctor. I have an underlying problem with exercise intolerance with elevated heart rates. It seems that the elevated heart rate made my symptoms worse. Otherwise I have just a mild headache and mild fatigue. No previous adverse reactions to vaccines.

patient vaccinated, waiting the 15 min, left clinic. in 30 min. Sudden onset of Headache. 38 min. Horse voice, Cough. eventually improved. Reported reaction at 1pm.

After receiving the vaccine I was fine. Wednesday afternoon I had a headache and at night I started feeling my sore throat. Thursday night the sore throat felt like it was on fire. I started having fever (100.2F) and it felt like I had step throat. Runny nose, headache, next day Friday the sore throat and fever was gone and right now I just have the runny nose. I was screened for COVID on Friday and it was negative.

"Slight rash/redness along face and neck and upper torso; hypersensitivity on scalp, face, upper torso (borderline painful tingling on head/face/arms, chest). Even clothing rubbing against the skin ""hurts"" a little."

Patient recieved first dose of Covid vaccination to left arm and was being observed in observing area. Patient noted that the lymph nodes in her neck, on the left side were very raised and swollen. She stated this happens after her flu shots but this was much more pronounced at this time. She has no medical history at this time. Patient was seen by Md in the room Dr who stated she had no issues noted. She was watched for 30 minutes and released with advise to follow up with her primary care physician.

Swollen upper lip Rash and itching on back And legs Took benadryl

20 to 30 red blotches on my upper torso and arms

Approximately 20 hours after receiving, I had normally pain at the injection site. The day after receiving the vaccine I started having a dull headache, Chills, fatigue, mild nausea and vomiting once (all mild to

moderate symptoms). It is tolerable and normal for most vaccines; mild enough to not seek treatment at this time. I?m expecting it to resolve in the next 48 hours. If it gets worse, I will seek treatment. I?m only reporting these side effects to help people in the future, due to it being fairly new. I will be getting my second dose if my symptoms resolve within a few days.

Within 45-60 seconds of receiving the vaccine, I experienced acute-onset of tachycardia of 130-140s BPM. For context, my resting heart rate is 65-80. At first, I assumed it was anxiety, however, I had no preconceived notions or negative thoughts regarding the vaccine. I took slow, deep breaths and performed a vagal maneuver which did not lower my heart rate. I took two Claritin pills, thinking this was a mild allergic reaction. 30 seconds later, I tried to vagal again and successfully slowed down my HR to approximately 100-105 BPM. The tachycardia resolved after 10-15 minutes.

Pt stated she felt dizzy/lightheaded while on her phone nearing the end of her observation period. She got up to leave stating she thought she just needed fresh air and promptly returned to the observation area with dizziness and palpitations. This was 45 minutes roughly post vaccine administration. B/P and heart rate were elevated. Pt began feeling short of breath and a rapid response was initiated.

Recieved vaccine and sat to be observed. Noted flush from chest up to head of heat and then racing heart as well as increased blood pressure. First set of vitals @ 0445 pm 97.7, bp 167/89, hr 74, r 20 . Pulse felt fast but was normal per assessment. Second set of vitals @ 0458. 97.7, p68, BP 141/93, hr 92, O2 97. Pulse higher. Md saw him and stated was ok to discharge with follow up with primary care MD. Discharged at 5:10 pm.

Metallic taste in mouth

Elevated blood pressure Dizziness and heaviness in legs Went to Er to be monitored and sleep Lasted about 6 hours

Neuropathy in arm resloved on own.

Less than 24 hours after getting the Pfizer Covid vaccine, pt experienced severe tinnitus and moderate hearing loss in R ear. Seen by me in urgent care with demonstrated hearing loss, which progressed the next day. Diagnosed with acute sensorineural hearing loss in consultation with Ear, Nose and Throat specialist, started on high-dose steroids, referred to audiology. It is unknown if this reaction is short-term or long-term, but if it persists long-term it would result in disability.

Metallic taste in mouth

Myalgias, low grade temperature, injection site pain

Headache, feeling tired, temp of 100

Developed rash that itches on trunk, bilateral arms and bilateral legs 2 days after received Pfizer Covid vaccine #1.

Relactation

Lymphedema right underarm and breast Treatment- ice, ibuprofen, acetaminophen, light massage and light exercise

Sore deltoid muscle starting 10 hrs after injection lasting 24 hrs. No treatment required. Menstrual cycle 3 days late as of today. Negative home pregnancy test. Menstrual cycle is normally very regular.

About two to three minutes after the Covid vaccine was administered in the vaccine clinic at my hospital where I work, I began to experience pre-syncopal symptoms (mostly light-headedness and nausea). I stood up to get help and walked to the back of the auditorium where they were observing us for 15 minutes post-vaccine, and due to standing and walking, I became much more dizzy and lightheaded and then sat down on the floor and was eased to a lying-down position on the floor by a nurse as I briefly lost consciousness. I regained consciousness very quickly (maybe 10-20 seconds, but I'm not sure) and was taken care of by a set of nurses who noted me to be hypotensive and pale, with I think a bit of a lower heart rate, though I'm not sure what my vitals were exactly. They had me then stand to do orthostatic vitals and I was orthostatic. I was too dizzy to remain standing and felt very nauseas so I was taken to the ED (in the hospital where I work) to be observed. I had a normal EKG, blood glucose, and urine sample there. After having some juice and lying down, I felt better but was very cold and had some chills. After a little over an hour, they released me from the ED and it seems to have all been an episode of vaso-vagal syncope. I've had vaso-vagal responses before, but not in response to a vaccine since I was about 13, so I was surprised by how quick and severe the vaso vagal response was. Later in the day, I felt better but was fatigued and had a headache. I also had a lot of pain at the injection site. The day after the vaccine I felt tired and had a headache, and for part of the day a mild sore throat. Now two days after the vaccine, I feel much better, and the arm pain is more mild.

About 5 minutes after the injection I felt lightheaded/ presyncopal lasting about 5 seconds. I had several more episodes of the same symptoms over the next hour. My vitals were checked after the first episode and my pulse was 130 with blood pressure 179/99 and oxygen sat was in the high 90?s. I was taken on a gurney to the ER. I was told my blood pressure and pulse improved a few minutes after the initial episode and I was observed for 2 hours with resolution of my symptoms.

"Patient alerted team to feeling dizzy and left neck muscles tight 5 mins after arriving in recover area. Recovery RN assisted patient to bench area to lay down. Vitals signs obtained (stable but patient states BP runs low, no rash or hives, color pink. Patient lied down for approximately 30 mins. Felt better, denies dizziness. Left neck remains ""sore"". Patient has boyfriend at home to watch her, was advised to call 911 or primary care if any reaction after leaving."

Swollen Lymph node in right neck supraclavicular area and diarrhea.

- 1121: Patient reported being light headed. Patient stated it might be because of the excitement of getting the vaccine. Patient has a history of hypertension, arthritis (remission). Patient has a history of Bell's palsy and takes medication for that. Patient stated normal B/P normally 130s/80s.

In the first 24 hours I had soreness of the injection site and from hours 18-24 I was quite fatigued. Around 36 hours post vaccination I developed local swelling and itching, hive like in appearance

surrounding a skin nevi on right upper abdomen. Redness, swelling and itching improved some with Pepcid, Claritin and topical steroid.

Pt was found lying on cement at base of steps. Recovery RNcalled outside to the back. Patient was alert & oriented. Stated that he fell and landed on the cement walkway. Complained of left food pain and said he heard a crack when he fell. 911 was called per patient's request. Was able to talk inside with assistance and Vitals obtained (stable). Noted swelling in posterior back of ankle, pain with palpitation. Ice was applied. 911 arrived and taken to hospital

Pt reported feeling light-headed after 15 minute monitoring period post vaccine. BP 146/94 Left arm. Pulse 68, regular rhythm. SpO2=99 Offered water to drink and continuing monitoring period with pt sitting in recliner. Pt has spouse able to drive her home when ready. Pt reports no known allergies. 1743: BP 144/92, pulse 77, regular rhythm. Resp rate 14, SpO2=100 1755: BP 139/87 (101), Pulse 64, regular rhythm, Resp rate = 16, SpO2=100. 1800: Pt stood without any dizziness, steady gait. Pt reports no further light-headedness and feels comfortable leaving monitoring area. Instructed pt to call EMS with any concerning symptoms once at home. Husband will drive pt home.

Day following vaccine, throbbing pain developed on opposite arm/shoulder, leading to decreased/limited range of motion.

"Immediately after the injection my right shoulder felt ""odd"" and seemed to be popping and clicking more than usual. I experienced severe pain of the shoulder joint about 4 hours after the injection. At this time I took 400 mg of ibuprofen and the pain was eased by about 50 percent after about an hour. The next day I went to work without any medication and could barely lift my arm without severe shoulder pain inside the joint. The muscle did not feel too bad. Mobility of the joint was possible but limited by pain. I mostly used my other arm to adjust the position of my right arm. After work that day I took 800 of ibuprofen and went home to bed. I felt better the next day but took another 600 mg of ibuprofen to get through the work day. Same for day 3. It is now approximately 80 hours since the injection and my shoulder joint is still fairly tender and stiff but improved. I fear possible SIRVA because the shot seems to have been delivered fairly high on my arm. I do have a history of rotator cuff issues with this shoulder but it was never as painful as it was on the day of the vaccine and the shoulder has been well for the last two years. I received the flu vaccine in the same arm a few months ago with no problems."

received COVID-19 vaccine on 12/19 at approx 1750. At 1804 pt c/o headache, racing heart, itching, and shakiness. Vaccine Commander called rapid response team (RRT). Upon arrival of RRT pt c/o increasing sx. Pt escorted via wheelchair to ED.

Approximately 10 minutes after the vaccine was administered, reported starting to feel light headed, sweaty and nauseous. Then reported throat was feeling tight and RN on site reported hearing change in breathing. RN administered EpiPen and called 911. EMS responded and transported to ED. ED record shows resolved symptoms. No rash, edema, difficulty breathing. In ED was monitored and discharged. Received no medications or additional treatment in ED.

3 minutes after injection felt flushed and a rapid heart beat which self resolved within a few minutes .

Patient developed flushing, diaphoresis, tachycardia approximately 7 minutes after injection into L deltoid, while waiting under observation. The symptoms resolved spontaneously after approximately 3-5 mintues. Patient was then observed for 45 more minutes and felt fine the entire time. Upon leaving to have her spouse pick her up, patient developed symptoms again while walking out of the building. Patient was then taken to the emergency department for further monitoring. Telemetry and further observations for 4 hours revealed no further abnormalities and the patient was discharged home with no more issues.

None stated.

Fever chills myalgia

left sided facial, ear, and neck paresthesia. Felt similar to numbness after dental procedure. Initially felt my ear become hot and then touched it and noticed it felt numb. Then feeling spread to side of cheek and jaw and down the side of my neck on same side. Same side as injection. Onset was about 12-15 minutes after injection, immediately prior to being told it was ok to leave the observation area. Seems to have resolved almost entirely 1.5 hours after injection, though ear still seems to have slightly abnormal feeling.

Within a few minutes of taking the vaccine, my lower lip began swelling. I was moved to the emergency department of Hospital and monitored and treated for four hours. Then I was released. At around 1:30 p.m. I felt my skin singling and started having difficulty breathing. Since I was no longer at my work (Hospital) I went to the closest hospital. This reaction was much worse. My husband drove. My heart rate increased. I was released at around 6:30 pm

I had no reaction following the vaccination. The next day I had very mild soreness at the injection site. The next morning (about 36 hours after the vaccination) I woke up with fatigue and a sore throat. I had breakfast and about 10 minutes later I vomited everything (projectile vomiting, no nausea or abdominal pain). An hour later I had episode of severe watery diarrhea (just one episode). Felt very weak so I decided to sit down, stumbled to a chair, and then proceeded to have a syncopal episode with about 4 minutes of seizure like activity (witnessed, I don't remember that part). Decided to go to the ER, where I had labs, EKG, CXR, head CT scan, MRI and EEG. I was admitted for 24 hour observation, all the tests were normal.

None

Soreness at site of injection

Patient was sitting in a chair approximately 20 minutes after vaccine administration when she became pale and quiet. Monitor asked if she was ok, and she said she was itchy on her face and that her feet were really hot and hives were noted on her cheeks and forehead at 1803. She was moved to a bed with help from other staff and the rapid response team was called. Her blood pressuree was noted to be 155/101, HR-115, O2 sat 99% on RA at 1807. 50 mg IM diphenhydramine administered to L arm by RN. Patient txported to ED for further evaluation.

Sharp pain left arm starting the morning of Dec 19th that worsened throughout the day, limiting active range of motion. Fever started in the late morning, and by that evening my temperature was 102.7. By the morning of the 20th my fever has resolved. L arm soreness improving but not gone, and still feeling fatigued throughout the day.

"Prior to injection, patient stated she was nervous and gets dizzy with shots and cries, but will be fine. Consent given and injection given in L arm. Second after injection, patient stated that she wants to be a pediatrician when she grows up, and then said ""Wait! I am not making sense..."", and her head dropped back slightly and the nurse held her head and asked the monitor for help. Both nurses carefully lowered patient to the ground without incident. She started jerking and then started crying. Others arrived and began taking her blood pressure and provided ice packs. The rapid response team was called, and they checked vitals which were all WNL. After approximately 20 minutes, patient felt good enough to stand on her own. Approximately 20 minutes after that patient felt good enough to leave under her own power."

Sore arm, 12-18-2020, low grade fever (99.2), cough and some chills 12-20-2020 am.

Generalized Rash all over upper torso with feeling itchy. Apparent to RN at approximately 15 minutes post vaccination. Patient (Health Care worker/employee) did not seem aware until it was brought to his attention. 15mg Benadryl administered and sent to Emergency Department for observation. No further symptoms occurred and patient dismissed.

Left sided chest pain Lasted for 10 min Awoke me from sleep

Hives, initially on wrists and arms, chest, then on face (very itchy), chest tightness

Tachycardia, dizziness, headache, vomiting, flushed, cold sweats

Left 2 finger, tenosynovitis, felt most back of hand, worse with extension/flexion second fingers has lasted >24 hours, better with motrin

Sweating profusely, dizzy, throat closure, hard to swallow

My symptoms started 30 minutes after the injection. My throat and tongue started to get very itchy and scratchy. I had to keep clearing my throat. My throat felt thick with secretions.

12/19: After injection: Minor pain at injection site (L deltoid) After 30 minutes: Mild headache and single episode of feeling lightheaded (lasting few minutes): drank juice and water After 1 hour: Additional mild lower back/R buttock pain After 4.5 hours: Moderate L deltoid pain and stiffness, moderate headache, moderate eye pressure/pain, mild body ache, fatigue, moderate dull lower back pain, severe sharp and dull R buttock/leg radiating pain: limping After 6 hours (and retuning home): Symptoms continue to progress, and noted moderate swelling around eyes 12/20: Moderate swollen lump and stiffness to L deltoid, moderate headache, mild/moderate body ache, moderate fatigue, mild swelling around eyes, moderate eye pressure/pain

I am the patient submitted this form, but also a physician. Within 3-4 minutes of receiving the vaccine, my left arm felt heavy/weak, and then began to tingle (full arm paresthesias). This was followed within probably 30-60 seconds by a sense of lightheadedness. Then acute tachycardia, heart pounding (I estimate around 130 BPM). I did deep breathing. Tachycardia was brief, lasting probably 2 minutes. Symptoms slowly got better. I was observed with vitals. All normal, except BP was high (140/90). Arm felt not entirely back to normal for about 30 minutes. Dull soreness in upper arm, left posterior neck/shoulder has persisted since vaccine.

Migraine Nausea Dehydration Low grade fever Fatigue

Had a numb left hand about an hour after vaccination that lasted about 5 minutes.

nausea, fever, chills, aches

12/18 received injection 12/19- woke up at 0700 with fever, spine pain-Lumbar region into the coccyx. Pain radiates down into hip joints and down bilateral femurs. Low grade fever most of the 19th. Nothing higher than 101. Arm soreness at the injection site, not bad, just sore. 12/20- fever broke around 11:00 am, still having this weird bone pain in my lower spine and both legs. 8:00 pm, no fever, arm soreness gone. Still have the low back and leg pain.

Experienced achy muscles, low grade fever, hot and cold flashes, and head ache. Very sore at the site of the injection.

#1. Injection site pain---3 hours after injection, starts injection site pain, progressivly worsening and last for 48 hours. difficult to raise the left arm #2. chills/low grade fever--started around 9 pm 12/18/20, received by Tylenol and ibuprofen, reoccurring after 6 hours, it lasted for about 36 hours #3. severe headache--feeling pulsating pain, starting around 9 pm and relieved by Tylenol and ibuprofen, but reoccurring after 4-5 hours, lasted about 36 hours #4. body aching, especially the lower extremities, coincidence with fever/Headache

Body aches Low grade fever Fatigue Loss of taste

Pfizer-Bio Tech COVID 19 Vaccine EUA #18 Facial flushing, facial warmth, fever 101.4 (post 650mg Tylenol) headache, dry mouth, loss of appetite

Pfizer-BioNTech COVID-19 Vaccine EUA Chest pain starting evening after vaccination and continued through 12/19/20. The chest pain is described as dull/heavy and continued to get worse so was advised to go to the ER. I went to the ER at 7pm on 12/19/20 and had 2 EKGs and blood drawn. It is 12/20/20 today and I still have constant mild chest pain with times that it feels moderate.

Developed Hives about 30 minutes after getting the COVID vaccine. Was given vaccine at 815 am, arms had a burning feeling and hives started to develop. Was also feeling very anxious and hyperventilating. I had no swelling or shortness of breath. Went back to vaccine clinic immediately and there they administered EPINEPHRINE at 846 am. Started to calm down around at 849 am. Burning feeling in arms started to go away and hives started to disappear. Was then taken to the ED department to be

monitored. Because I have had an recurrent hives after EPINEPHRINE, I was given Benedry IV, Solu-Medrol IV, and Pepcid IV. I was also sent home with a prescription for Prednisone as well as an Epi-pen. I am feeling much better now. Hives have not come back, yet. Fingers crossed they don't!

Woke the night following the vaccine with a fever of 100.4, body aches, a headache, and sharp pain at the injection site that made me unable to move my arm. I was unable to sleep or move around without fatigue. These symptoms continued throughout the following day and ibuprofen had little effect. My fever broke after a Tylenol PM and on the second day following the injection the other symptoms started to alleviate.

I had tachycardia within the first 5 minutes of receiving the vaccine. Heart rate increased to 151

Severe facial flushing (redness and burning warmth) radiating to ears and neck beginning suddenly about 48h after receipt of vaccine and has continued without relief for 10 hours. Tylenol and ASA taken after symptom started did not relieve the flushing or burning discomfort. Not accompanied by any other symptoms. No rash present. Felt fine up until the flushing onset at about 48h mark. Feels as how I?ve heard patients describe niacin flushing (I have personally not ever taken niacin).

"About 3-5 min after injection I felt tingling and warmth/flushing in my entire left arm and anterior chest, upper back and achy pain in my left upper trap- felt like a warm IV running through my arm. Associated with tongue tingling. Symptoms lasted about 10 minutes with the exception of the achy upper trap pain which lasted a couple hours - being a health care provider I associated these symptoms with anxiety/excitement about receiving the vaccine but subsequently developed other unexpected symptoms. Over the course of the next several hours noted metallic taste and transient extremity tingling (all extremities) also with some extremity and facial itching - no rash. Now >24 hours after still have the intermittent and transient extremity tingling (most notable in LE's and feet, but also in arms) and skin itchiness/prickly sensation though improved. Had one episode this afternoon (~28 hours after vaccine) of lightheaded, nausea, chills and profound sensation of extremities being ""heavy"" - felt like pre-syncope - which resolved in about 30 min with rest, hydration ."

1.5 hours post soreness at sight and left elbow fold; fatigue, left arm weakness, left neck stiff, right face numb, mouth numb more on left side similar to novacaine wearing off from dentist. Numbness and weakness lasted 30 minutes. Soreness over 24 hours. Friday evening generalized aches and chills. Saturday all day aches, chill, low grade fever. Slept late afternoon due to exhaustion for 4.5 hrs. Sunday morning sweat and slight fever. Sunday evening site slight sore only.

Began having body aches on 12/19/20. Today 12/20/20 feet and hands began to swell badly. Took Benadryl, not effective.

Within minutes of receiving vaccination i had blurred vision, rapid heart rate, extreme nausea, rapid heart rate, shivering but a warm sensation that started in my abdomen that went into my chest. I became blotchy on left arm where injection was per nurse and my eye started to roll back in head per nurse. I was rushed down to Er where i was given water zofran and Benadryl and steroids. BLood pressure was high and pulse was elevated. Was sent home a few hours later w Epi pen and steroids to

take over the course of four days. After coming home i developed at headache and fever and severe leg pain and fatigue that last until Saturday the 19th around the evening. I?m feeling better today Sunday the 20th. My main concern at this point is the arrhythmia and sometimes having shortness of breath.

A very bad headache that kept me awake all night and was making me nauseous

Bottom lip numb and lower jaw and throat tight

Dizzy, tired, weak, nausea, joint pain. I am resting and still feeling the effects. But slowly getting better.

Pfizer-BioNTech COVID-19 Vaccine EUA

Tachycardia, nausea, tingling

Rash, Headache, sore throat.

Previously diagnosed with COVID 19 11/7/2020 and had a mild residual cough that was improving and almost completely resolved. Post vaccine this cough recurred. The presentation and frequency increased and was similar to that of when I was actively infected. This cough has worsened over the days following the vaccine.

Pfizer-BioNTech COVID-19 Vaccine EUA Woke with very swollen and numb upper lip. Took Benadryl and Acetaminophen. Symptoms have greatly reduced over the course of the day.

Pfizer-BioNTech COVID-19 Vaccine EUA Pain at injection site Fatigue Felt ?feverish?

12/19/2020 in the evening Started with frequent flatus . Then stomach cramps early in the morning of Sunday 12/20/2020 at 4am following with diarrhea. Took Imodium 2 tablet after first loose stool. Then another 1 tablet with the second loose stool. Diarrhea continues intermittently. Took another anti-diarrheal medication: Pepto-Bismol Liquid form. Since then diarrhea slowed down.

Metallic taste

shakiness, tachycardia, breathing feels tight - went to emergency dept

syncope following vaccine

Pfizer-BioNTech COVID 19

rash across chest. numbness tingling across arm (injected arm). Bendadryl & solumedrol given, returned to ed the next day with tightness in throat & trouble swallowing - Benadryl & solumedrol given - improvement

Night sweats and fatigue on 12/19/20-Current

Severe right ankle monoarticular arthritis that woke from sleep. (did experience flu-like symptoms ~36 hrs after inoculation but these were short-lived). Unable to weight-bear despite high dose NSAIDS. While have hx of mild enthesitis, have never had these symptoms before.

left arm itchiness, observed patient itchiness did not worsen patient went home

I started having chills at 3pm At 10pm that night, I developed a fever, continued chills, body aches, fatigue, and nausea

Experienced angioedema approximately 24 hours post inoculation. Administered 50mg oral Benadryl with no response. No respiratory distress.

Morning after injection patient reported bilateral rash with some itch from elbow down

felt hot, lightheaded, nausea

Headache for 1 day Severe nausea lasting more than 3 days

Patient stated that 45 minutes after receiving the vaccine he became dizzy and foggy, requiring the individual to sit down for a period of time as they felt unsteady on their feet. No treatment was given, patient decided to have spouse pick them up and go home.

Headache, sore throath

"Approximately 14 minutes post vaccination -- developed numbness and tingling in L arm and ""swelling"" in throat. Denies antecedent illness, allergies, medication use. Member was observed for 1 hr and 45 minutes. No dyspnea, wheezing or chest pain. BP 142/100, P 98, SpO2 98% on RA. Released to home after symptoms largely resolved."

Left axillary enlarged lymph node. The lymph node has increased in tenderness and size

Hives and Throat Swelling - treated with epinephrine and steroid

STRONG PERSISTENT HEADACHE GENERALIZED MYALGIA BACK PAIN UNQUANTIFIED FEVER WEAKNESS

"Within 15 minutes, patient experienced itchy, tight throat ""felt like a tickle in throat"". Airway remained patent. No rash/hives."

Approximately 29 hours after my first dose of the Pfizer COVID 19 vaccine I started experiencing right axillary pain that was accompanied by swelling. Lymph node enlargement was not felt. Symptoms are still present at the time of filling this survey out.

Chills, sweats at night time Body aches Headache

Patient report itching and rash of the neck, upper arm and upper back on Saturday 12/19/20 . 50 mg of Benadryl taken on 12/19/20 and symptoms resolved on 12/19/20.

12/18/2020 ALMOST IMMEDIATLY FELT CHEST TIGHTNESS, RIGHT SIDE OF FACE ITCHY, BACK OF THROAT AND TONGUE WERE ITCHY, LIPS WERE TINGLY; 'FELT LIKE SOMETHING WERE WRONG'. CONTACTED CLINIC AND SPOKE TO PHARMACIST; RECOMMENDED BENADRYL. DID HELP RELIEVE

SYMPTOMS. 4-5 HOURS SYMPTOMS CAME BACK, TOOK MORE BENADRYL. AS OF 12/21 SYMPTOMS HAVE NOT COME BACK. FLU SHOT 10/29/2020

Left arn deltois with swelling hardness and redness at site ~ circumference 3 inches painful non-puritic

Left arn deltois with swelling hardness and redness at site ~ circumference 3 inches painful non-puritic

Left eye puffiness, left eye paresthesia Tx benadryl, solumedrol, head ct scan

Started feeling hot and flush pretty immediately felt dizzy very shortly felt throat closing, like I had a golf ball my throat and my heart started heart racing. Staff provided medical treatment immediately put me on a pulse ox and my heart race was up, kept monitoring me. Pretty quickly I started feeling better in about 10 min. No tests were done or meds administered. After about 10 min all was better I just feel tired and a little bit dizzy. They monitored me about 30 min - I received gatorade and was observed for about 30 min and they let me go since I just felt tired.

1. Severe chills on first night 2. Body pain and ffatigue 2nd snd 3rd day 3. Severe Radiating pain in arm of injection from day 4th and 5th continue

Employee woke up the next day with conjunctive hemorrhage of the left eye

Started with a rash to left hand and rest that spread to bilateral upper arms with scalp itching

Day 1: palpitations, dizziness Day 2: headache, redness, swelling, itching on vaccination site; GI disturbance Day 3: vaccination arm had paresthesia, heaviness, almost stroke-like symptoms; the symptoms started suddenly ** treated in the ER; IV steroids- for possible allergic reaction; tpa- for the stroke-like signs; halfway through the tpa, I felt an improvement with the arm

+ fever (Tmax 100.4), last documented fever at 10:00 pm on Saturday (12.19.20), generalized body aches, swollen L axillary lymph node, + ?knot? in L arm at injection site, endorses redness and warm to touch at injection site

Ear pressure and swelling on same side as injection

Patient refers that about 45 minutes after vaccination felt with frequents palpitations . This episodes repeat during the course of the day. Note: I was notified by patient after he was vaccinated, that he had plans to travel by airplane on Dec 18,2020.When patient call me notifying his symptoms I advised him to report to nearest emergency room for evaluation .

At 9PM I started having rigorous chills,body heat/aches. I took two Extrastrength Tylenol, went to bed. One hour later the chills stopped but the heat/aches continued for several hours. At 8:00 AM I took two more Tylenol and had no more problems.

headache unrelieved by Tylenol or ibuprofen

Within 10 minutes after the injection my left shoulder began to itch was super red and hot. I notified them and per policy I was transported to the ER and was given IM 50mg benegryl, 40mg oral

predinosone and I was monitored for another 1.5hr. 1/2 after the benedryl I still had the redness and flush in the neck and chin area the chest area redness had cleared up. I was released with a prescription of benedryl for 4 days to take every 8hrs for the symptoms. I continued with the benedryl for the next day and the symptoms subsided a little so I stopped taking the benedryl and I continued to take the prednisone.

12/18/20 10pm nausea with vomiting lasting one hour 9 pm headache, persistent and continues today at 12/1/20 at 8:30 am 8pm diarrhea lasting 2 hours

So I got up from the chair to go to the other room to be on the 15 min observation. I started feeling a little weird within a minute. A sharp shooting numbness in my jaw and my head felt a little dizzy, and a burst of heat in my spine. I felt off and sat down and took my BP and my BP was 185/80. Within a couple of minutes I was at the walk in clinic where they monitored me for a couple of hours. The jaw experience went away but I still felt a little shaky. I also had a numbness/tingling in the face and jaw. They gave me a Benadryl injection and it did not resolve. They gave me prednisone it felt a little better (about 30min) afterwards. They checked my airways and it was ok. I had elevated BP but within a couple of hours it was ok . They discharged me since I felt ok and a friend drove me home. Symptoms were better next day but in the afternoon I felt the numbness again on my lips. They decided to prescribe me medro and I started taking it since Friday evening. I still feel a little head ache and like I am a little sick. The headache is still lingering. Left side of my face since yesterday I have a stiff neck. It is like a pain in my face.

Patient stated that she started with cough, runny nose and no fever, she has a hx of alleriges and normally takes Claritin

0845 received injection 0900 started to have palpitations and feeling of ?jittery? BP 132/88, HR 98, RR 14 0912 states feeling better. BP 126/82, HR 88, RR 12 0915 palpitations resolves, states feeling ?normal?. Patient left clinic. Instructed S/S to report or seek medical attention.

Fever 102.4, Headache, Joints, Muscle aches, lymph node swelling, generalized soreness at site anticipated symptoms but more severe lasting more than 48 hours. Taking Tylenol around the clock. Tylenol did not help at first but feeling somewhat better now. However, lymph nodes still swollen and hurting.

on 12-20-2020 complained of arm soreness, muscle aches, low grade fever and cough for 24 hours.

No soreness of injection site until next date, 12-19-20. Slight soreness at injection site but woke up with body aches/pain, very stiff neck and head on left side of body, migraine type headache. Extremely fatigued. Symptoms were throughout entire day. Was flushed in the face that early evening, took temperature, normal, 97.9. Took 3 Alleve every 3 - 4 hours throughout day. Felt best for that date about 8pm. Woke up on 12-20-20 with headache still but overall felt much better though did have some upset stomach with diarrhea. 12-21-20 feel fairly well. Went to work. Left arm still slightly sore. Slight stiffness in head and neck with slight headache still remain.

Patient refers that on December 18,2020 developed headache (left side) and pulsatile pain in left eye, also generalized body ache associated with hot flashes . She took Iboprufen , Relafen and Acetaminophen with improvement for about one hour and pain later returned. If condition worsen she was advised to go to the nearest Emergency Room.

Symptoms started at midnight 12/16/20 and ended approximately 5:00pm 12/16/20, body aches, extreme fatigue , sore throat, sinus congestion, headache , pain and redness at injection site.

Approx. 5 minutes after receiving the shot in my right upper arm, my right hand and fingers felt like they were asleep - numbness & tingling. I had use of the hand but it felt like something was blocking the sense of touch and fine motor skills - touching fingertips to fingertips, were impaired. Situation lasted for about 24 hours before appearing to resolve. Sense of touch in fingertips still a little odd but hand is fully functional at this time. Thank you.

Pfizer-BioNTech COVID-19 Vaccine EUA 2 hours after injection: body aches and chills (duration approx. 8hrs) 9 hours after injection: nausea and vomiting 18 hours after injection: severe heartburn, nausea, and vomiting 24 hrs after injection: nausea and all over body soreness 48 hrs after injection: mild nausea and arm pain at injection site 72 hrs after injection: no symptoms present

on 12-20-2020 arm soreness, muscles aches, low grade fever and cough for 24 hours.

HEADACHE INFRAORBITAL PAIN GENERALIZED PRURITUS

9:11 am received injection 9:15 cool feeling from left arm injection site radiating to abdomen 98% on room air pulse 111 bp 141/89 9:21 cool sensation dissipating in arm. Cool sensation in stomach. Benadryl 25mg IM administered. Localized rash at left injection site. Pulse 111 100% on room air 9:27 still an intermittent cool feeling in stomach

Became unable to swallow and mouth got dry. Was given Epinephrine, Benadryl and Famotodine. The symptoms subsided within 2.5 hours.

light headedness, claminess, parasthesias of the hands and feet, worked night shift and day shift. no treatment

12-28-2020 body aches especially back pain, dizziness, headache and fatigue for 24 hours

Headache, fatigue, vomiting

"Patient described Hive, approximately 3 inches in diameter on her left thigh, Intermittent fever and ""Bone Aches"". Patient reported taking OTC analgesic and antihistamine. Otherwise did not seek Medical Attention."

Within 15 minutes of receiving the vaccine, patient began complaining of rapid heart rate. RN came over to monitor, and found HR @130 BPM. Rapid response/medical emergency was called. Refused further medical treatment. Stayed 5-10 mins longer than the 15 minutes recommended observation period, and felt better before leaving.

rash on neck and chest, felt flushed

symptoms started 8:00 pm 12/16/20 as of 3:00 pm on 12/17/20 she still had symptoms, headache, body aches, chills shortness of breath and fatigue. 12/21/20 RN called patient the symptoms have all resolved at this timel.

12-28-2020 body aches, back pain, dizziness, fatigue and headache for 24 hours

Began complaining of dizziness shortly after getting hte vaccine. She did not eat anything since the day before. Gave juice and a granola bar. Shortly after finishing food, began complaining of her heart feeling fluttery, a medical emergency was called. She was evaluated and found to be tachycardic. Refused further medical treatment, then ate lunch, and returned to work. She was observed on site for an additional 30 minutes beyond the 15 minute observation period.

About 8min after the vaccine I got a severe headache on the top of my head and was at a 10/10 and dropped to a 7/10 after a few moments and finally went away on its on. I was very flushed and hot. I was laid down and given ice pack. Started feeling a littler better but experienced riggers and was transported to the ER where I was given benedryl, fluids and was monitored for a few hours. I was released but for the next 2 days after I was super tired and laid around and slept for 2 days. Today I am at work but I feel very tired and fatigued

Chills, Muscle pain, headache, joint pain, tiredness

Rash shortness of breath

Pfizer-BioNTech COVID-19 EUA After receiving the vaccine, during observation period (about 10 minutes after the dose administered), patient became tachycardic and nauseous. Patient was brought over the the ER at 7:05 am with non-intractable viomiting with nausea. Ondansetron inj 4mg IVP x1 given at 7:40am, at 7:45am P 135/95; P 105 ; R 20; WBC 16.2 Patient felt better, tolerating PO, asymptomatic and discharged home at 8:34am

Patient began to complain of feeling dizzy. Was found to be anxious, flushed and tachycardia. Was asked to lay down. Medical emergency was called to respond. Patient refused further medical treatment. Continued monitoring for an additional 45 minutes after receiving the vaccine, and left in good condition.

"""Pfizer-Biontech Covid-19 Vomiting since Saturday."

difficulty breathing, paresthesia, dizziness. 1.5 hours after vaccine worsening dyspnea, tingling in fingers and toes, felt like a ball was in her throat, previous anaphylactic reaction. Pepcid, benadryl, solumedrol with continued worsening epinephrine IM give. O2 sat 81% room air, O2 provided with increase sat to 100%, second dose of epinephrine 0.3 IM. Weaned of O2 and discharged with prednisone.

Employee calling to report a reaction after receiving a COVID-19 vaccine. Vaccine Name - Pfizer Vaccine Lot # - EJ 1685 Vaccine Date and time - ? 12/18/2020 @ 9:40am Is this your first or second dose? First

Date and time of symptom onset - ? 12/19/2020 @ 12am Symptoms - ? Headache, nausea, fatigue, runny nose, no fever, cough, rash on left eye, itching Last day of work and shift - ? Friday 12/18/2020 Home remedies? - Claritin 5 mg 12/20/2020 @ 8:30pm, Warm steamy shower this morning 12/21/2020 Any improvement? - Patient noted symptoms are better and gone except for on & off headache. Recommendation? To continue to monitor symptoms & take ibuprofen or Tylenol when headache comes back. Call back if experienced any other symptoms. She's not back to work til 12/23/2020. advice to call work if she's unable to work and notify employee health for missed work. If 4 or more days, to send doctor's note for back to work clearance. Employee voiced understanding Employee of information ? yes Employee voiced any concerns ? no Employee?s questions answered to employee?s satisfaction - yes

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Needle retracted during vaccine administration and some spillage occurred. It is estimated that this person received about half the prescribed dose.

Complained of nausea, and feeling light headed. Turned very pale then got extremely flushed after. Complained of feeling warm and hot. Vision turned a little blotchy. Stayed for longer observation. Felt better when left vaccine clinic.

FELT DIZZY ABOUT 20-25 MINUTES AFTER SHOT, GIVEN GATOR AIDE AND REMOVED MASK IN AREA WITH NO OTHERS ...FELT LIL BETTER ITS BEEN ABOUT AN HOUR AND HALF STILL FEELING LIL DIZZY OR OUT OF IT BUT OTHERWISE OK.

Approximately 12 hours later, I started experiencing shortness of breath and felt my airway was closing off. I immediately took 25mg of Benadryl and monitored signs and symptoms.

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"Staff member stated that she had an allergic reaction ""after the vaccine""...unsure of time frame and was still at work. She has a rash, hives and swelling around eyes....no immediate anaphylaxis. She verbally described her incident. Was treating with Benadryl (even though there was a stated allergy

from 2013), then followed up with her family doctor, for steriod therapy on 12/18. She has not communicated with me further or have any absences from work at this time."

Felt Flush, Elevated Blood Pressure, Nausea, Tight Throat

"I was ok for first 15-20 mins post vaccine and was sitting in chair and calling family and friends When I stood up I felt 'funny""- kind of hard to describe I walked around and mostly felt ok but not hundred % but didn't feel dizzy but didn't feel 100% myself either I checked my radial pulse and it felt normal and there was no BP machine there to have a check done I left hoping to feel 100% soon I walked to my car in the parking lot and started driving home Around 200 yards from the hospital I felt weird warm rush like feeling through my whole body Knowing that anaphylaxis can occur at this stage I panicked and turned car around and went directly to ER to be checked out My BP was not low and I was observed for short duration and discharged home then- vitals were taken almost half an hour post vaccine Further records can be sought from ER as they should have reported this as well I also had arm pain/malaise and low grade temp of 100.5 at home for 24 hrs that resolved subsequently The initial symptoms within first half an hour made me file this report"

Felt dizzy

Pt states she felt short of breath, had a hard time catching her breath, and fatigued.

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Right side of lower face and lip began feeling numb. No drooping or issues with movement. Numbness continued from about 830p on 12/20 and is still present at the time of this report.

States after receiving vaccine, reported tingling/electrical felling in legs & arms. 4 hours after, rhinorrhea. At 48 hours after vaccine started having nasal and head congestion. States body aches X 12 hors but improved at 48 hours. States is feeling better with body aches now, is also having HA x 24 hours. Is having them moderately, also noticing fatigue at 12 hours after injection,

Low grade fever T-max 99.6F lasted about 12 hrs. broke with Tylenol. L arm soreness - improving but still ongoing (today day 4) after injection. Additionally have injection site reaction - red tender firm lump at left arm approx 2-3cm - slowly improving but still present. Now being more itchy. No drainage.

Lymphedema, Right Axillary and Right Neck.

Fever and chills 100 F for 2 days, Body ache injection site pain for 2 days Injection site itching 2 days

dizziness 5 minutes after vaccination. no other symptoms released after 35 minutes. completely resolved

12/15/2020 30 minutes after vaccination, started to taste a metallic taste; lasted 24 hours ;'like chewing on tin foil'. Pain at injection site 48 hours. 12 hours after vaccination, joints hurt, left hip is 'excruciating' . 72 hours later, joint paint dissolved. But the left hip, the pain is awful. Taking motrin, muscle relaxers, physically walking with a limp, cannot bend over, have assistance with sit or stand. Had COVID19 in

05/2020. Same hip pain when had COVID. Went away after 3 months. 'Hip pain now is 5x's worse than when had COVID'; debilitating; constant pain. appt with PCP 12/30/202; xrays, mri, etc. May go to the ER if worsens but Chief Officer Urgent care for COVID19 and cannot take the time away.

nausea right after vaccine Sore arm at the injection site. I could not lift my arm, chills, could not sleep, body aches, headaches,

Patient/Employee became dizzy 15 min after covid vaccine

Rash on chest with a burning sensation, bruise on lower leg, applied hydrocortisone on rash. Leg still showing some bruising, Rash is mostly gone now, but burning sensation is still there.

Friday night same night of vaccine. Arm started aching and hurting. After my shower, my whole arm was in pain. Pain then moved all the way to my back. I took two tylenol, and it calmed it down. At 3 am, it started hurting really bad, I had to take a lortab - a stronger pain med at 5am that morning. Around 10am, my whole back started hurting, and that evening, it still was hurting. I ended up taking 3 lortab that day. The pain went to my neck. On Sunday, I ended up taking two lortab . All together, I took 5 lortab to ease pain from this vaccine. I was scared that I was getting another blood clot from the feeling of the pain. I am still just sore. NOTE: I am on blood thinner

palpatations increased heart rate, slightly hypertensive 20 minutes after vaccination resolved on own

I felt extremely hot, headache and dizziness - pressure on left temple and top pf head - next day had diarrhea.

Throat and chest tightness following vaccination- went to ER and received epinephrine, solu-medrol, benadryl, famotidine, and EKG due to tachycardia.

Fever, body aches, migraine, swelling/redness/warm/hard lump at injection site, nausea. Symptoms started approximately 6:00pm 12/18/20

injection site pain, tiredness, severe headache, muscle pain, chills, injection site swelling, nausea, not feeling myself, difficulty breathing, fast heartbeat, dizziness and weakness in lower extremity and excruciating lower back pain. Immediately after vaccine was given, I got the side affects. Felt a little better for 2-3 hours and then it hit me hard again and lasted till the next day. Currently my arm is swollen.

Headache

12/16/20- body aches, chills. congestion, stuffy, runny nose, occasional cough from drainage, fatigue
12/17/20- congestion, stuffy, runny nose, some cough and drainage.

Developed hives/welts on her torso, chest, arms and legs. The hives hitch. Taking Benadryl and topical antihistamine lotion.

intense arm pain, migraine, nausea & vomiting

Pfizer-BioNTech COVID-19 vaccine EUA On Friday December 18th at 2:45 p.m. I received my first dose of the vaccine. After the injection while waiting in the observation area, I noticed my arm felt cold and felt weaker. I was able to move my hand and did not have tingling. I was cleared to leave after 15 minutes. While driving home approximately 35 minutes after the injection I had a quick onset hot flash (felt like it came from my left arm which is where I received the injection). Then my heart started pounding. I noticed my heart rate was climbing. It topped out at 170. I was having difficulty in breathing but that was related to my heart rate. I pulled over and called 911. I felt as if I was going to pass out. After 2 minutes or so my heart slowed and stayed at a rate between 120-130. I never lost consciousness. I canceled the ambulance and felt as if I could drive home. 30 minutes later the episode happened again. All the same symptoms as the first. The pounding felt harder and it was slightly harder to breath until the rate came down again. Again, I felt as if I was going to lose consciousness but never did. Each episode lasted about 2 minutes from hot flash to slower heart rate. This time the ambulance came. No rash. No hives. No swelling. BP-160/90 HR-120-130 Sinus Tachycardia on a 3 lead EKG I did not need transport to the hospital. I started feeling much better around 5:00 p.m. The coldness I felt in my arm was gone. My arm no longer felt weak. The hot flash, rapid heart rate and faint feeling did not return. I am a Paramedic with the Fire Department. Provided the Vaccine to EMS workers. I received my vaccine at the: Fire Department December 18, 2020 Injection time 2:45 p.m.

Have swollen lymph node on right side arm pit. Got vaccine on right side of arm

Facial flushing, bright red and itchy splotches over the face, arms and chest. Had diarrhea for 24 hours. She took a Benadryl and got relief of symptoms.

The patient reported the following symptoms approximately ~24 hours after receipt of the Pfizer BioN-Tech COVID19 vaccine: tachycardia, dry mouth, and itching between the toes and behind the ears. The patient stated she took oral diphenhyramine with relief of symptoms.

Headache, Fever, Chills, Loss of Smell, diminished taste, Nausea & Vomiting, Diarrhea

Itching began approximately 30 minutes after vaccine was administered. Itching started on the right arm and then the left arm and then the legs. Redness on the arms was noticed. Redness on the chest, but no itching on the chest.

Patient complained of light headedness, stated right arm cool, and bad taste in mouth. BP 123/80 initially. Pt stood up and became light headed BP 154/90 HR 76 SPO2 98%. RRT called. Pt transported to Emergency Department.

Pain at injection site. 24hrs after injection site, my left arm started hurting and painful to the touch. At 48 hours, the injection site is very raised and red. It's approximately 3inches long by 2inches wide. It's very sensitive to the touch and very hot. I went back to the medical clinic and was told to draw a circle around the site, and watch for further spreading, apply an ice pack, and submit this reaction to Vaers.

Patient reported feeling lightheaded, dizzy, tingling, itching, hot feet bilaterally, racing heart, and feeling flushed. Increased BP and heart rate were noted. This reaction lasted approx. 15 minutes.

Employee began experiencing tingling in roof of her mouth, watery eyes and itchy throat. She was taken to ED for further evaluation and treatment.

Runny nose, congestion, loss of smell for 36 hours

*Pain at injection site; 10 hours after injection; lasted 48 hours *Myalgia, primarily in shoulders; 12 hours after injection: lasted 24 hours; Ibuprofen 400 mg *Chills; 14 hours after injection; lasted lasted 15 minutes *Joint pain (hip, knee): 12 hours after injection; lasted 24 hours *Diarrhea; 72 hours after injection; lasted 6 hours; unsure if related

within 12 hours: sleepiness (very), pain at injection site & around to muscles in right shoulder; slight pain in moving injected arm above 45 degrees, slight generalized muscle aches.

12/16/20 awakened to an unusual headache and feeling more sluggish. Checked temp and it was 100.4. Supervisor notified and advised to get COVID testing. Throughout the day 12/16/20 temp stayed 100 and I developed body aches, arm was very tender at injection site. 12/17/20 afebrile and HA nearly resolved.

1505 right eye heaviness, BP: 114/61, 02 saturation: 100%, HR:74, pt sent to ED

One hour after receiving vaccine, my entire body became bright red and hot, the thick black lines on my tattoos on my right arm became so hot they felt like a burn and became raised, and the lymph nodes in my neck became swollen. My skin was hot to touch for the next 20 hours. The next 4 days I felt very lethargic. On Sunday (day 4), I developed a rash to the front of my abdomen that was in clear lines not extending to my abdomen. The rash also spread to my anterior neck. My hands also became bright red within an hour of the rash developing. This all disappeared with in 2 hours. My arm was extremely sore until I woke up yesterday morning (almost like I never received the vaccine). On Sunday as well, I had diarrhea and extremely painful gas. This stopped by 1600 Sunday night. Today, Monday, I feel generally back to normal other than mild lethargy.

Employee reported itching to roof of her mouth and numbness to right side of her throat. She also had elevated HR of 113. She was taken to ED for further evaluation and treatment.

Felt Flush and hot around 3 min after vaccine given. Had a slight taste change that lasted for a second. Heart rate, normal 60s, increased into the 80s.

Aches, fever, large swelling in left armpit

Headache, dizziness, muscle aches (head, neck, shoulders). Onset 5 minutes after vaccination. Symptoms resolved within 30 minutes.

"Pt received the COVID Pfizer vaccine at 1324 and at 1335 pt c/o feeling anxious and flushed. Pt VS: 143/94 91 18 99% AA. Pt admitted she had not eaten before coming in for vaccine. Pt put in recliner chair and taking water and rice crispy treat without difficulty and symptoms resolved. Pt kept for continued monitoring. 1350 pt c/o of ""not feeling right"" and that she was going to pass out. Pt layed

back in lab chair; 02 at 2L per NC applied. B/p 140/100 HR 127 02 sat 100% pt pale, cool and shivering; pt c/o she didn't feel right. Benadryl 50mg IM given at 1351 and 911 called. Pt had no hives, No itching lungs clear, HR 103 and 02 sat remained at 100%. Continued to monitor pt: VS 1400 140/90 103 18 100% on 2L/NC. Pt reports no NKA, Meds: Esterace VAg Supp started 4 days ago Levothyroid 75mcg po daily Pt has never had reaction to medication or vaccines in past. Pt still c/o feeling week but better--held off on Epi since EMS had arrived 1400. Pt transferred to ER in stable condition. 1405: ER called and report given."

left sided non positional chest pain. seen in ER . Was treated with Toradol and resolved. Negative work up in emergency room. for cardiogenic or pulmonary causes.

pain and itchying over L cheekbone, HTN Solu-Medrol 125mg IVP, Benadryl 50mg IVP slowly, Lisinopril/HCTZ 10/12.5mg PO symptoms resolved in 2 hours of observation and management

Reported tongue tingling and increased heart rate from low 90s to 130. No airway compromise resulted and tongue tingling resolved after 1 hour.

runny nose, chills, diarrhea, shortness of breath, HA tiredness and chest pain

Symptoms started early morning hours following the shot, chills, extreme body aches, extreme headaches, fatigue to the point that it was difficult to get out of bed. The skin on certain areas of my body are very sensitive and have a tingling sensation.

Employee reports 20 minutes after receiving vaccine she began to have pain across neck and shoulders, stiffness, nausea diarrhea, headache, body ache

Itching. Was given Benadryl PO by Walk-in clinic. Observed for 4 hours. Sent home with family member.

Sudden onset of intense rush of heat through body, intense increase in heart rate and inability to swallow, trembling and shaking. Employee was in car, returned to hospital ER. ER administered fluids, and diphenhydramine.

12/17/2020 VERY ORGANIZED. AFTERNOON/EVENING SORE ARM. 12/18/2020 WORKING IN ER WEARING M95 MASK AND MASK OVER PER EMPLOYER, TO WEAR WHOLE SHIFT. 9:30 NOTICED A 'FLOATER' IN RIGHT EYE, SHAPE OF A CLOUD., 10-12 WAS QUITE LARGE. 11AM NOTICED BLIND AREA IN EYE, DECIDED TO NOTIFY OPTOMETRY. EXAMINED BY DR. HEMORRAGE IN RIGHT EYE, COTTON WOOL SPOTS IN BOTH EYES. F/UP IN 1 MONTH WITH OPTOMETRY. FLU SHOT 10/2020

anaphylaxis

COVID like symptoms including fatigue, body aches, runny nose and HA.

Chills around 3am night of vaccine, moderate myalgia, specifically in neck and lower legs day after vaccine. Resolved completely 2nd day. No fever noted.

metallic taste in mouth, nausea

throat and face swelling, headache rate 10/10, nausea, vomiting and diaphoretic-Was seen in the emergency room and was given Toradol, Benedryl, Pepcid

Fever

1712 tongue tingling, 02: 100% 1725 complain lip tingling, transferred to ED

PAIN , REDNESS AND IDURATION ON VACCINATION SITE

Employee calling to report a reaction after receiving a COVID-19 vaccine. Vaccine Name - Pfizer Vaccine Lot # - EJ1685 Vaccine Date and time - ? 12/19/2020 @ 2pm Is this your first or second dose? First Date and time of symptom onset - ? 12/19/2020 @ 9pm Symptoms - ? Fever, body ache, headache Last day of work and shift - ? 12/19/2020 Home remedies? - Tylenol Any improvement? - Resolved. No more symptoms Recommendation? Continue to monitor and call us back if symptoms comes back. She off work today, scheduled to go back to work tomorrow. Employee voiced understanding Employee of information ? yes Employee voiced any concerns ? no Employee?s questions answered to employee?s satisfaction - yes

Employee reported purple discoloration to Right Arm and Right fingers. She stated her cap refill was sluggish, she had chills and a redness across her chest and stomach. Employee was evaluated and treated in emergency department.

Pt sitting in observation area. c/o L arm whole arm aches and pinky finger feels numb on outside. does have feeling, can move fingers equally, blood flow to finger with blanch test slightly slower. no redness/swelling noted on arm. no bleeding under bandaid. not improving. no s/sx distress. (dizzy, SOB,) directed to ED (where pt works) for assessment at 0810. Pt will complete workers comp form.

fever and chills for approximately 3 hours on 12/16/20

Received Pfizer COVID-19 Vaccine in right arm. 1 hr later noted left sided facial tingling lasting 48 hrs.

Fatigue, night sweats, chills, body aches

None stated.

Palpitations - patient stated he may have anxiety attacks when getting shots. Patient sent to ER for evaluation

Itching

Clammy, flush, dizziness, syncope, tachycardia

1845: hand numbness HR: 102, shaky, reports last meal was 3 hour previous 1904: HR:72, feeling better and requests to go home, decline further care

The day of the vaccine I had a sore arm. The next day I woke up extremely tired, weak, like I was in a mental twilight zone, no sneezing no coughing, notice on the right lower lip a little herpes, very little

about 2mm wide 3-4 mm long,, never had it in that location before, the blister is gone. Mild nausea, headache and joint pain (intermittently) for about 24 hours.

sx: itching treatment: Benadryl, pepcid & solumedrol.

tiredness, body ache, nausea

12/18/2020, 11pm, swollen itchy hands duration 7 hours, 12/19/2020, 6am swollen itchy hands and feet duration 5 hours, 12/19/20, 12pm body rash/arms, legs, abdomen duration 2 hours, 12/19/20, 3pm B/L UE lymphadenopathy duration 3 hours, 12/19/20, 8pm, injection site/L arm/shoulder/L clavicle swollen duration 3 hours.

Received vaccine around 7pm on December 18, 2020 and worked the midnight shift. Went to lay down during the day of December 19 and stated joints and body were severely achy way beyond normal. Did take a narcotic for pain control with no relief. December 20th symptoms had resolved.

Ten minutes after receiving the vaccine she experienced throat tightness and numbness and tingling of her extremities. She was seen in the ED and given oral pepcid and benadryl with relief of symptoms within an hour.

severe body aches, chills, left arm pain, red, warm and swollen lump at injection site

12/21@11:50-Caller stated that he had vaccine at 9am and had a seizure about 4am the next morning. Patient also had slight head. Caller stated that he is feeling better no medications were given .Caller had Cat scan and EEG. Caller has follow up 12/22.

"COVID vaccine was administered by local health department in hospital setting. Approximately 10 minutes after receiving the vaccine, the patient reports feeling ""weird,"" short of breath, heart racing, dry mouth, & anxious."

Patient reported tingling in tongue for ~30 minutes following vaccination. Monitored for 40 minutes and left clinic without symptoms.

Patient reported twitching to right eye and a warm sensation 5 mins after injection. Resolved by 10:41am.

Pfizer-BioNTech COVID-19 Vaccine EUA I received the first dose of the vaccine at the end of a vaccination clinic during which I had been administering the above vaccine. I completed screening, received the injection and waited under medical observation for about 20 minutes post-vaccination. Approximately 10 minutes after leaving the clinic (30 minutes after receiving the injection), I experienced a sensation of facial flushing, palpitations, a sense of anxiety, mild chest tightness, and lip numbness that spread into my face. I did not have any shortness of breath, tightness of the throat or any apparent swelling of the lips, tongue or face. The above symptoms lasted about 10 minutes and gradually dissipated over the next hour.

Do no suspect that vaccine caused patient condition and resulting inpatient admission. Suspect patient had COVID-19 at time of vaccination, but had not developed symptoms yet. Here is timeline: Patient went to ED on 12-18-2020 at 22:51 with complaint for fever and shortness of breath. Patient ended up testing positive for COVID-19, 12-19-2020 00:09, but was not symptomatic at time of vaccine. As of 12/21/2020 12:04 pm, patient is still inpatient and on comfort care/hospice.

Arm soreness. Small bump at injection site.

About 15 minutes after the injection employee reports her throat began feeling tight and she was having some trouble swallowing.

5 minutes after (4:28 pm) receiving the vaccine I experienced dizziness and nausea with stiffening of my neck on the left side. After laying down for a while I felt better. When I got home I wasn?t feeling right so I took it easy (6 pm). Last night I couldn?t fall asleep because I was very achy and weak with a sharp pain in my chest. This morning (5 am) I woke up feeling dizzy, with cold sweats and general malaise.

Patient endorses hx of vasovagal reactions with vaccines, patient reports slight lightheadedness 1-2 mins after injection, patient denies syncopal episode and reports feeling better during the ?observation? window. 12/19: upon awakening, noticed redness and swelling to injection site. 12/20: Patient reports improvement of redness and swelling at injection site. 12/21: Patient endorses at time of wakening red rash (blancheable per patient), mildy pruritic to L side of chest wall. When patient called (at approx. 10:35 am), reports rash has now become ?generalized.? Patient denies changes in hygiene products.

Light head, oral & generalized itching feeling flushed 25mg Benadryl PO - Resolved Sx

Hives Pharyngeal Irritation Improve with IM Epinephrine

"08:15 am - Pt reports ""feeling flushed and my heart is beating fast"". HR 96 08:23 am - Pt states ""I really don't feel very good. I feel very dizzy"". Assisted to supine position on cot. HR 100 08:26 am - No longer feeling dizzy, but still feeling flush. HR88 BP 156/93 (L) arm 08:30 am - HR 92 BP 161/101 (L) arm. Symptoms unchanged. 08:33 am - HR 97 BP 173/100 (L) arm. Symptoms unchanged. 0841 - HR 94 BP 170/98 (L) Pt reports ""No longer feeling flush, but still shaky and still feeling my heart beating fast with palpitations. 0842 - HR reg 90 BP 164/95 (R) arm 0845 - HR reg 84 BP 163/93 (R) arm 0848 - Pt reports that she is still feeling like she has a rapid heart rate. 0850 - Pt sitting up on side of cot. HR reg 83. BP 163/95 (R) arm."

Pfizer-BioNTech COVID-19 Vaccine EUA: Vaccine recipient has a history of losing consciousness after administration of injections and drawing blood for laboratory work. He stated that he did not have issues after his recent seasonal flu vaccine. After administration of the COVID-19 vaccine, the vaccine recipient drank some orange juice. The APN who was monitoring him after vaccination watched him become unresponsive shortly after. The APN raised his legs in an attempt to stimulate him and check his pulse. A CODE-10 (Medical emergency for outpatient, visitors, and employees) was called. Vaccine recipient regain consciousness and refused to go to the emergency room for follow-up. The vaccine recipient felt better, checked out of the vaccine clinic, and walked out on their own.

During the 10 minute observation period, patient developed tightness in chest as if she was having an asthma attack. Assisted to stretcher where she used her albuterol inhaler. Her SaO2 was 99% RA. After 10-15 minutes, she began to feel better.

pain at injection site malaise muscle aches fatigue

"patient felt ""very hot at 10:05 became flushed, skin was reddened all over. waited 10-15 minutes improved went home and developed red blotches all over. took benadryl po at 1100 am at home and symptoms resolved. tc to client today 12/21/2020. he is fine at this point."

severe joint pain, starting day 3 after and worsening since then

On 12/18/20 the next day at ~0830 he experienced SOB, heart palpitations, and fever. He was taken to the local hospital via ambulance. He was tested for Covid-10 at hospital. Unknown result. Discharged from hospital around 1545.

Pfizer-BioNtech COVID-19 Vaccine EUA: Pt brought up after rapid response to COVID vaccine. Pt c/o throat itching, back itching, hot, and flushed. Denies diff swallowing at this time. Upon arrival to ED, AOx4. NAD. Flushed/WD. GCS 15. Ambulates independently with steady gait upon arrival. Pt. has documented allergies to Latex, ciprofloxacin and Amoxicillin-pot Calvulanate.

Shortness of breath and cough started about 24 post vaccine. Symptoms continued and slightly worsened over next 48 hours.

Patient associate stated later that evening she felt her heart was racing, she felt dizzy and had chills. This patient stated the evening she received the shot she developed a headache. Patient took advil and felt better

39-year-old female with history of ADHD, anxiety, melanoma presents with palpitations. Patient received a Covid vaccine today and started having palpitations, lightheadedness, shortness of breath and feeling flushed a few minutes afterwards. Rapid response called and patient taken to ED for assessment. Patient denies facial or oral swelling, rash. patient denies any recent fever, nausea, vomiting, cough, diarrhea. Denies chest pain, abdominal pain. Last menstrual period end of November. Has allergies to Bactrim and clarithromycin. Presentation concerning for possible vaccine reaction, no anaphylaxis. EKG and labs within normal limits. Patient was rehydrated in the ED. Patient was discharged home on same day (12/20/2020). Pt alert and oriented x 4. Pt ambulated out of ED with a steady gait in no apparent distress.

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Headache, nausea, tiredness, feeling unwell and injection site pain. Warm to touch injection site, raised lump on left arm.

Numbness un lower lip. Soar throat Headaches, patient allegedly took Maxal 10 mg at 9:00am. Erythema in the neck area.

Caller stated @ 10:15 am and about 5pm that afternoon nausea, itching and welts on the face and burning the ears. Caller took 50mg Benadryl. Once at hospital she received Decadron injection 4mg. Caller slept for two hours and symptoms had dissipated.

"Approximately 12 hours after receiving my Covid vaccination, I experienced onset of severe pharyngitis and BL earache along with severe swelling of the glands in my neck and jaw. I developed a severe headache, photophobia and BL eye pain. I developed lesions and ulcerations on the skin surrounding my mouth. My lips cracked and developed blisters and ulcerations. I developed intra-oral and buccal lesions and ulcerations. I developed nausea and severe diarrhea. Severe myalgia, skin sensitivity and fatigue. Later in the day on 12/19/2020, I developed changes in my sense of taste and smell. Everything had a metallic or ""coppery"" taste, and my sense of smell was diminished. The next day, 12/20/2020, the disturbances in taste and smell worsened. The symptoms were severe on Saturday 12/19/2020 and Sunday 12/20/2020, and have begun to improve today--Monday 12/21/2020. No further skin or oral lesions, blisters or ulcerations, and the existing lesions are now healing. Continued diarrhea and GI upset. Other symptoms are improving."

Muscular pain, general malaise Treatment: Famotidine, Acetaminophen

Fingers started tingling , progressing to numbness ascending up the left upper arm. Symptoms started approximately 10 minutes after receiving the vaccine in the same arm.

Pt left triage vm, said she received the Covid vaccine Thursday, on Sunday began having frequent stomach cramps that have not eased up. She is at work today, but is nauseas, still having frequent stomach cramps

Complaints of tingly in left leg, warm feeling all over body. This happened one hour after vaccination. Tingly resolved, but leg is still sore.

Patient reported metallic taste in the mouth immediately following vaccine, dissipated after five mins.

Severe soreness at injection site, uncontrollable shaking and chills, severe joint pain, muscle aches, heaviness of limbs, migraine like headache, abdomen bloating and weakness all within 12 hours of vaccination. Continued off and on over next 48-72 hours although symptoms were more mild within 48-72 hours.

Patient states that she is experiencing a headache, low grade fever 99-99.7, neck and shoulder soreness and is 12 weeks pregnant.

Muscle soreness at sight of injection

severe abdominal pain experience 2 days post vaccination of dose 1 of 2. Diagnoses with early acute appendicitis on Friday December 18th and had a laproscopic appendectomy on Saturday December 19th.

Had dose #1 at 1620 and started feeling itchy on her head and face about 1700. Face red. No difficulty breathing. Given 25 mg benadrly po. Observed and improved. Returned to clinical unit as a patient care tech about 1745. At about 2200 she started having swelling in her face and lower lip and tingling in tongue and left upper and lower lip. Taken to ED in our Facility. Given benadrly 25 mg, famotidine 20mg, and prednisone 60 mg all PO x 1. No difficulty breathing, or swallowing, no wheezings or angioedema of mouth or throat. Sxs improved . diagnosed with allergic reaction. given instructions when to return. Given instructions for Benadryl and famotidine otc use. given script for prednisone 40mg x 5 doses. DC at 12/19 /20 at 0144 to home. 12/21/20 1000 this rn called patient at home. She is doing much better with redness in her face and itching in her back and face. No swelling or rash. Last had benadryl last night. has been taking multiple times a day for the itching. had famotidine x 1 on 12/19. She has not filled the script for prednisone. I told her if she could tolerate itchiness tomorrow w/o use of benadryl she could work her 1600-2400 shift. I will discuss her taking covid vaccine #2 with Medical Director for Employee Health, Dr.

Approximately 10-15 minutes after receiving COVID-19 vaccine, patient reported itching, tingly feeling, face appeared more flushed. Seemed anxious due to history of allergic reactions and reported slight shortness of breath. Treated with diphenhydramine 50 mg po and epinephrine 0.5 mg IM and transported to Emergency Department. Observed in that area and released a few hours later as symptoms resolved.

Employee calling to report a reaction after receiving a COVID-19 vaccine. Vaccine Name - Pfizer Vaccine Lot # - EJ1685 Vaccine Date and time - ? 12/19/2020 @ 2:40pm Is this your first or second dose? First Date and time of symptom onset - ? 12/19/2020 @ 10pm Symptoms - ? congestion, dry cough, harsh voice Last day of work and shift - ? 12/20/2020 11:30am-8pm Home remedies? - none Any improvement? - no Recommendation? Referred to Employee Health command center for Covid-19 testing Employee voiced understanding Employee of information ? yes Employee voiced any concerns ? yes Employee?s questions answered to employee?s satisfaction - yes

Vertigo. No treatment required. Resolved spontaneously.

Joint inflammation with pain, developed knot at injection site with severe pain for 3 days

One hour after vaccination had warm feeling all over face, not flush and did not have fever. Lasted all night long and patient was also nauseous. She then stated she had numbness along left jaw, this

happened hours after vaccination. The next day she felt better, nurse told her if it happens again or doesn't resolve follow up with PCP. The following day, associate felt better.

GENERAL MALAISE, CHILLS, LEFT ARM PAIN, INFRAORBITAL PAIN, NAUSEA. SYMPTOMS LASTED 1 DAY.

Patient complained of fluctuating tachycardia between 110-150BPM after waiting about 10 minutes after receiving vaccine. Patient skin was hot and moist to the touch. Facility RN escorted patient to ER where she was seen. More information is not available at this time.

2 day post vaccine right arm is red, swollen, hot and itching. Site was initially painful on day 1. Also night of vaccine had generalized itching which was relieved with benadyrl.

Lip swelling within 24 hrs

Shortness of breath, tachycardia

1830 began experiencing numbness and tingling to R arm, the nurse there evaluated associate and noted equal movement/strenght to both arms. 1840: reported feeling better and requested to leave.

Patient had sudden onset of tachycardia - heart rate 120s - 140s. Felt lightheaded.

The patient pre-medicated with oral diphenhydramine because she had an allergic reaction to another vaccine in the past. The patient developed some upper body redness and slight eyelid swelling, and she continued to treat with oral diphenhydramine until symptoms resolved.

Patient received Pfizer COVID 19 vaccine last Thursday 12/17. Admitted today (12/21) with bleeding and low platelet count - working up for ITP, TTP. Given recency of vaccination and no known contributory allergy or medical history, physician thought potentially associated with vaccination.

Dizzy, headache, blurry vision, fatigue

Pfizer-BioNTech COVID-19 Vaccine EUA Fevers Muscle Aches Joint Pain Sweats Headaches

"Patient experienced tingling in left fingers and hand that progressed to ascending numbness up the left arm and up the left shoulder and left neck area up to under the left ear. Patient feels like there is a ""lump"" in the throat that she has experienced during dental work when mouth is numb. This occurred within 10 minutes of vaccination. Symptoms progressed to feeling of having fluid in the ear approximately 50 minutes after vaccination."

one hour post vaccination, patient had tingling on left face. Near ear to jaw line radiating to neck. Lasted one hour then resolved.

On 12/20 at 9am started having left sided facial numbness, tingling, flushing. Near syncope episode (tachycardia, diaphoretic, blurred vision) around 1130am. Took Benadryl seemed to help. On 12/21- around 7a near syncope episode, tachycardia, diaphoretic, facial flushing, itching. Took Benadryl- improvement in facial itching, decreased heart rate.

REDNESS ON THE UPPER LIP, SCALE AND ITCHING IN THE AREA.

Rash on chest pounding headache fever of 104 left side rib pain elevated heart rate 106

The shot site was swollen for two days after the injection. I had nausea, dizziness, and tiredness. Three days after the injection (today), I had shakiness, extreme fatigue and felt like I was going to pass out.

started to develop injection site soreness on the night of vaccine then by 10am the next day was having all over body aches, nausea, headache which continued to get worse and by 3pm that day had nausea, vomiting , severe body aches and cramping all over, fever, headache, and a hard warm lump at the injection site. was applying heat to cramps and taking Tylenol which was not helping much for body aches, did not want to take ibuprofen due to nausea. by noon on the 3rd day most of it was resolved

Patient described feeling numbness under the right eye. The numbness radiated down the right side of the face. Patient reported that the numbness subsided after 2 minutes

"Right arm with 2.5-3"" long 1.5-2"" wide reddened, warm to touch, developed the day after vaccine. Seen by OHS rec. Ice, Benadryl, Antihistamine. Today she returned with decreased swelling & redness."

Started 15 minutes after vaccination and it lasted for 30 minutes. Tingling arms and fingers and heaviness in shoulder. Resolved.

Employee reported redness and swelling to Right Wrist. She also noted itching to left neck/back area. Employee was taken to ED for further evaluation and treatment.

Approximately 30 minutes after COVID vaccine administered, patient reported tongue swelling/itching sensation to tongue and roof of mouth. This lasted about 15 minutes and resolved on its own without treatment.

Patient experienced nausea and fatigue a couple of days after getting the vaccine

Significant Cervical/thoracic joint pain and stiffness which referred to R shoulder girdle region, limited cervical ROM to the R. Dull, achey pain in area even without movement. Took acetaminophen and tumeric for anti inflammatory, use of heating pad and then biofreeze cream for analgesic purposes. By next morning pain and stiffness centralized back to spinal region and R shoulder girdle was pain free with normal ROM. Same treatments used again.

Mild Edema Left Side of Face

injection site pain, slight fever, tiredness, headache

Patient received Pfizer vaccine dose 1 IM in L deltoid per portcol. During 15 min post vaccine monitoring, patient developed a cough, SOB, diff swallowing and hive like rash within 10 minutes of vaccine administration

chills, body aches, skin hurt, nausea, lack of appetite and diarrhea (along with sore arm)

24 hours after injection developed muscle aches and fatigue. Approximately 36 hours developed severe vertigo with nausea. Headache present. Continued 12/19 to present. Taking Dramamine for symptoms which on 12/21/2020 is helping with vertigo and nausea. Fatigue, headache and muscle aches continue 12/21/2020.

at 1805; associate c/o lightheaded and noted to be diaphoretic. BP was 138/92 with HR 85 and room air sat 98%. at 1830; reported feeling better. BP 127/83. HR 76. room air sat 100%. at 1845: felt better 143/101 1905: discharged to home. BP 136/92

Soreness in arm

Rash on arms and legs . resolved after taking a dose of Benadryl

fatigue

The reaction to the shot was that she had alcohol taste, nausea, wretching, and a rapid response team was called and she was taken to the ED.

"Pfizer-BioNTech COVID 19 Vaccine 42 y.o. female had just received her vaccine when she became very lightheaded, was placed on a stretcher and brought to ED further evaluation. Patient has hx of rheumatoid arthritis.á Stated that she has not eaten since earlier this morning, did have some nausea vomiting earlier that is now resolved, feels that it was related to ""an adrenaline rush just prior to her vaccination.ááUpon arrival to EDáshe is denying any headache, fever, sweats, chills, cough, shortness of breath, angioedema, chest pain, palpitations, vomiting, edema, claudication, urticarial.á Diagnosed with near syncope."

"Approximately 10 to 15 minutes after vaccination, patient reported feeling dizzy with slight headache. Also reported tingling starting on the left fingers and hand that progressed to tingling (not numbness) up both arms and both sides of the upper body. Body felt ""weird"". Headache progressed to a ""pounding headache"" with pain in the eyes because the headache is ""so bad"". Patient reports feeling tired and ""drained"". Patient being frequently monitored by nursing staff."

fatigue, weakness

The night of vaccination patient had a metal taste in mouth and lost all sense of taste. 12/19/2020 she developed a fever, body aches, and chills. 12/20/20 Continued to be febrile, then was told to follow up with PCP.

fatigue, muscle soreness and weakness, headache, nausea

I had heart palpitations and extreme fatigue for 48 hours.

Fatigue, mild fever, joint ache, muscle ache, headache, eye pain (had underwent LASIK recently, date of vaccination was LASIK POD#18, but that eye pain had entirely resolved at least a week ago, now recurring), mild chills. (Instructed by employer to include this in Item 18: Pfizer-BioNTech COVID-19 Vaccine EUA)

5 in red spot underneath the injection site

Approximately 15 minutes after injection, patient reported nausea/vomiting, difficulty breathing, being clammy and having numbness/tingling in the L side of face and L arm. Cold packs were applied, BP 165/104 obtained at that time, O2 sats 99% on RA. O2 via facemask applied. Sats continued in upper 90's throughout event. Rapid response called at onset of symptoms. They connected to monitor upon arrival. HR maintained 70's-80's throughout event. At 2304 BP 165/102, HR 85, patient reported feeling better. At 1108, BP was 159/100. Patient reported feeling well enough to go home at that time and did so.

"Pfizer/BioNTech COVID 19 vaccine EUA C/O ""heart coming out of chest"", itching, and hot feeling approximately 10-15 minutes after injection. She took 25mg Benadryl PO one hour before vaccine. Was given 25 mg oral Benadryl at 1410. HR and blood pressure returned to normal and pt was released within 20 minutes of reaction."

Hypertension (220/110) and shortness of breath after Pfizer-BioNTech COVID-19 0.3 IM injection in the right deltoid. Presented to ED within 6 minutes of injection for evaluation. Symptoms resolved within 10 minutes in the ED except BP remained in 160s/90s. Blood glucose, CMP, and ECG normal. No medications given. Patient asked to leave following resolution of symptoms.

general malaise and abdominal discomfort after vaccine, three days later started with facial rash and fever Treatment: Famotidine, Benadryl

The night patient got vaccination she had abdominal pain, muscle aches and sinus congestions. She was also exposed to a positive covid 19 case and is going for testing 12/21/2020.

"I have had symptoms of a low grade fever on and off and a cough has developed that sounds like ""whooping cough"" . This is the 4th day. Is this normal or does it get better . do you need to see a dr??"

Felt achy, headache, neck sore, possible low grade fever, tired, chills occasionally. Treated with motrin and rest.

Approximately 10 minutes after the vaccine, patient became tachycardia hr 110, diaphoretic, and pale. Felt back to normal around 12:30 pm. Patient did not develop any additional symptoms until Saturday evening around 5pm when similar symptoms developed but milder.

"Approximately 30 minutes after receiving the vaccination, patient reports itching started on left arm, then the head, then both arms and then lower back. No redness, erythema, or hives. Itching progressed to the ears and throat started to feel ""sticky/funny"" within 1 hour of receiving the vaccine. Diphenhydramine 50 mg and Famotidine 20 mg administered. Itchiness resolved 15 to 30 minutes after receiving diphenhydramine and famotidine. However, lips and tongue feel ""tingly""."

Slight difficulty with exhalation. Denies difficulty with inhalation, swelling of face or throat, palpitations, rash, or dizziness and weakness. Advised to continue to monitor. Strict UC/ER precautions advised.

1813: reported feeling nauseated and was noted to diaphoretic. HR 110. BP 142/82. Room Air sat 100%. 1830: reports feeling better HR 89. BP 141/75. Room air Sat 100% 1840: symptoms resolved. associate sent home per request. HR 86 no interventions done.

Fever, chills, body aches 24 hours. Continues 72 hours later to have swollen axillary lymph right arm. Pain at injection site.

Hello to all. Patient reported feeling dizzy right after sitting down for the 15 minute wait period. I asked her if she would like to lay down. I took her in the side room to lay on the hospital bed. Her bp was 177/115. She is a physician and so is her husband. He was with her. He suggested we had a bad cuff , and he wanted a manual one. Staff went to the ER to retrieve it. Her husband took her BP and BP was elevated with the manual cuff as well. I provided juice and water for the patient and got her rags. Her blood pressure stayed elevated for the whole 30 minutes she was there. Her husband wanted to know what I had to give her. He wanted lisinopril 5mg. I explained that we only had benadryl and epipens for allergic reactions. He decided to take her home. He stated he would give her one of his blood pressure pills and that she would be fine. She was able to get up and walk out without assistance

Approximately 30hrs. post vaccine I experienced hearing loss in my right ear. I could hear very little and it became worse within the next few hours. 12hrs after this began, my hearing came back and I then acquired a ringing in my right ear. This progressively lessened, and about 24 hrs after the initial hearing loss started, all the symptoms dissapated.

flushing, felt dizzy. given Benadryl 50mg and resolved in 15 minutes

During the 15-minute observation period the patient became flushed and began complaining of a headache. She then went unconscious and had tonic-like activity for approximately 2 minutes. The patient subsequently stopped the seizure-like activity and woke up but was confused and was acting in a postictal fashion. She was evaluated emergently upon arrival in the ED and noted to have an altered mental status. Physician noted that this does not appear to be an allergic or anaphylactic reaction. There was no evidence of rash and lung sounds were clear with no wheezing. Subsequent CT showed a diffuse subarachnoid hemorrhage and patient was transferred to the Medical Center for further treatment.

Approximately 2 hrs 30 min post administration I experienced mild parasthesia in my left ring finger and pinky finger and mild left arm muscle weakness and mild lady hand grasp weakness. This episode lasted about 40-45 min, self resolved completely with no intervention.

Woke up middle of night, severe muscle aches/cramps, chills/fever, debilitating headache.

Patient reported feeling dizzy shortly after the vaccine. Symptoms resolved after she laid down and we got her a drink.

Pt experienced temp of 103.8 at 3am on 12/18/20. Temp decreased to 100 on 12/19-12/20. As of 9am on 12/21 temp was 99.3. On 12/19 pt began experiencing diarrhea, cough and stomach pain. Cough and stomach pain continued to report of 12/21. Pt had COVID + test on 10/11/2020. She stated that it was as if the symptoms she had in October were back.

Patient presents to the emergency department less than 20 minutes after getting her first COVID-19 vaccine, feels like there is a tickle in her throat, patient has some blotchy erythema on the front of her neck and chest. Patient very hypertensive on arrival here to the ED. Patient was given IM epi 300 mcg, was also given Solu-Medrol 125 mg IV, Pepcid 20 mg IV, and Benadryl 50 mg IV. Patient reexamined at 9:45 AM, states that symptoms are better. Blood pressure actually has improved down to 172/91. She no longer has the erythema edema on the front of her neck and chest, feels as though symptoms are improving. We will continue to observe patient here for the next 2 hours after epi. Pt. asymptomatic by 1230. Discharged to home and advised to not get the second COVID-19 vaccine shot in three weeks.

tingling in throat, rapid heart rate, flushing

Fatigue and shakiness in diabetic patient. Fingerstick blood sugar showed low blood sugar of 49 three to four hours after vaccine. Patient reports no other changes in diet or routine that morning. Issue resolved on its own with eating.

Patient endorses feelings of ?tired? approx. 30 minutes after vaccine. Patient reports he went home after his work day and reported feeling more and more tired. Patient reports he ordered dinner with his girlfriend and at approx. 20:00/21:00 reported bilateral swelling to lymph nodes in neck, and feelings of his ?throat closing up.? Patient endorses, ?I felt like I was having a panic attack.? At approx. 22:00 patient took 3 tabs of Benadryl and 2 tabs of acetaminophen and noticed improvement and then went to bed. Patient reports improvements in symptoms but persistent bilateral lymph node swelling in neck throughout the weekend. Today (12/21): Patient endorses increased lethargy, persistent bilateral lymph node swelling in neck and + sore throat. Patient denies fever. Patient took 2 tabs of Benadryl at 10:00 today while at work. Patient called PCP today while at work describing symptoms and advised to leave work and to get COVID tested. During call with RN, patient is awake/alert and in NAD acute respiratory distress. Pt endorses able to move air freely, no SOB, and difficulty breathing. Patient reports scheduled telemedicine appointment tmw am. Patient denies recent travel of self or girlfriend, and denies known covid exposure in community or workplace.

Rash in pectoral, shoulder and back area.

GI : nausea, dyspepsia. Headache, Myalgia

I developed vertigo and it is bad when I lie down. The room is spinning It started the night after the vaccine and it has not gone away. I feel the motion sensation all day. It feels like I am drunk all the time.

General malaise, nausea, chills, headache

Patient was in observation. She stated she saw the room take a shift. She then got a headache in the back and on the top of her head. Her heart was also racing and she was dizzy. We got the patient some juice and her lay down. Symptoms resolved other than headache. She reported it was still 5/10 when she left.

Pain at injection site after 6 hours followed by malaise, fatigue, upper body muscle soreness, chills, feeling hot which started 12 bourse after the shot and lasted till 3 days after shot. Partially improved symptoms with ibuprofen 600mg but short lasting.

Tingling on right side of lip and right of face. Felt like numbness from local anesthesia at dental office. Felt like throat was a little numb. Numbness has mostly resolved approximately 1.5 hrs after vaccination. Some lingering tingling on lips at 1 hr 45 mins post-vaccination.

48hrs after vaccination I developed axillary lymphadenopathy in my R axilla (same side vaccine was given.) Injection site is well appearing- glands remain swollen and painful.

Started having bad headache the day after shot. Also very bad fatigue. Now on 12/21/20 I?ve had a very severe migraine with visual aura.

Flu like symptoms: Headache, Muscle Ache/Soreness and Fever. Pt is currently taking Tylenol/Ibuprofen at home to treat. Will continue to monitor pt closely. If symptoms don't resolve soon, will have patient to come to hospital for further evaluation.

Pt expressed feeling tachycardic, jittery, shaky, site edema, shortness of breath and dizziness. Pt received epipen 0.3 mg IM injection x1 dose and benadryl PO, responded favorably and transported to ED for follow up care.

I had a fever of 101, body aches, fatigue, nausea, dizziness. Did not see a doctor. I am feeling better now.

Tingling, numbness down Left arm. Hot flushing across chest and left side.

Pfizer-BioNTech COVID-19 Vaccine EUA: Allergic reaction after receiving a COVID shot. Pt reports a rush of dizziness, diaphoretic, nausea, and near syncope. Pt appears pale but alert and oriented upon arrival. Patient was given IM epi, IV Solu-Medrol, Benadryl, and Pepcid, placed on a cardiac monitor. He was given 1 L of normal saline. Patient observed here in the ED for almost 8 hours. He has been persistently tachycardic; Admitted as inpt. for observation. Discharged from inpt status on 12.18.2020 @ 2152.

11started with intense itching in scalp and neck54:received COVID vaccine, within 3 min she felt flushed, dizzy and heart rate increased. 1205:she felt less lightheaded and heart rate was slowing 1208: she felt intense itching in scalp and neck 1215:itiching increasing, given Benadryl 50 mg IM 1245: itching not as intense, but itching had moved to arms, trunk and legs

Tongue felt thick, tingling in extremities, shortness of breath. Given 50mg Benadryl, 20 mg famotidine

Shingle like symptoms on left side of scalp/ face/ neck/ left arm and left torso.Extreme sensitivity to touch/cold/heat on affected side.Left neck muscles sore and aching.

Right when the patient sat down at observation she stated she was flushed and got hot in her head. She said her chest felt funny and her tongue was tingly. Her blood pressure was 169/95 and heart rate was

100. She stated she was nervous. We kept her in observation for 30 minutes. All symptoms resolved by the time she left.

Symptoms began 12/18/2020 at 9pm with severe fatigue and chills. Woke up at 0030 12/19/2020 with severe shaking chills, headache, body aches, dry cough and nausea, temperature spiked to 103.2 @ 0230, took 600mg Motrin and 500mg Tylenol but fever stayed at 103 until 0600 and slowly came down to 98 by 0900 12/19/2020; symptoms were resolved except for fatigue until approx 5pm 12/19/2020 when fatigue increased and chills came back with headache and body aches, fever spiked to 102.3 and lasted until approx 9pm after taking 600mg Motrin and 500mg Tylenol, I was able to sleep well Saturday night. Woke up Sunday 12/20/2020 at 0730 feeling well but within an hour I developed a dry cough and shortness of breath with exertion and noted elevated heart rate (90-120bpm). This lasted all day. At 3pm 12/20 I began to get fatigued again. I felt very clammy and flushed and checked my temperature and it was back up to 101.6. Fever came down to 100 by 7pm and stayed there until approx 930pm. I woke up this morning feeling slightly better. I still have a cough and shortness of breath

The day after at 1 am exp chills, low grade fever, nausea, headache and fatigue. After Tylenol after 24 hrs the symptoms was better. I was able to to return to work.

The vaccine was administered at 1130 without immediate complication. At approx 1800 the pt began to develop symptoms of general malaise. At approx 2200 the pt developed a fever and chills. Initial oral temperature was 101.3 The pt has continued to have a fever and general malaise since the injection, now for almost 5 days.

Tightness in back of throat. Received 50 mg Benadryl.

Employee complained of feeling lightheaded. She reported blotchy spots on neck and chest; tingling to back of throat. Employee was taken to ED for further evaluation and treatment.

Patient began experiencing bilateral leg weakness, chills, shortness of breath, and headache

Edema in left side of face, hand, knee, and shoulder.

Pt reported roof of mouth itchy, body itching, ears ringing and felt fullness/clogged, headache. Benadryl 50 mg PO provided with additional monitoring and resolved.

Patient states that evening of vaccination she started to have pain and swelling radiating from injection site to shoulder, up neck to under eye area and then across left clavicle. Patient states that jaw was sore. Following morning, the patient experienced joint and muscle pain and a headache (similar to when she had COVID in Oct 2020). Patient also had a cold sore occur 24 to 48 hours post vaccine. Patient called pharmacy on 12/21/20 to report ADR and pharmacist recommended contacting PCP as well.

injection site sore, sluggish, stomach pain

Nausea and tingling in hand

Several running nose that wont stop, Headache, and red watery eyes .

Arm soreness, I had dinner and maybe it was the food I ate, my stomach really hurted and lots of pain. I laid down and rested and next morning my stomach pains were gone. My arm was still hurting a lot the next day, not anymore.

After 15 minutes of monitoring post injection, I developed itching to left shoulder with diffue hives to shoulder and chest

dull headache in beginning became intense with nausea and diarrhea for 3 days, pain at the injection site.

12/17/2020 12:30 PM -- Nausea, severe; fever 101.00, fatigue, pain at injection site for 3 days ending 12/20/2020. Nausea and fatigue still persist. Employee Health at vaccine Facility site provided prescription order for Sofran to patient pharmacy of choice; patient has has no relief with prescription.

12/16 - 11AM VACCINE RECEIVED 12/17- 6AM HANDS SWELLING SEEN 12/18 - 6AM EYELIDS AND CHEEKS SWELLING SEEN

"Chest and back pain, and then ""limbs went numb"". Couldn't lift glass of water. All limbs were weak and shaky."

Rash on arm morning after injection at injection site

Developed fever to 100.5, body aches, swelling at the injection site.

Patient felt a sudden rush of tingly feeling from chest down to arms. Did resolve, lasted a few minutes.

Patient emailed 12/21 and described on set of annoying, cool tingling sensation of lower extremities that began last evening. Writer called patient to obtain more information about symptoms. States is experiencing an annoying, cool, tingling sensation in lower extremities that is hard to describe. Reports it feels almost like it's asleep, but cool. The symptoms began in the lower extremities and is now into the hips. Says has had difficulty sleeping due to the symptoms. States is able to walk, and not experiencing any shortness of breath. Instructed to notify her provider right away or report to the Emergency Department for evaluation and treatment.

39 yo male employee with history of Covid 3/2020, and SVT s/p ablation x 2 (2002, 2008) who came to hospital S/P Covid vaccination for recurrence of SVT. Given 50 mg IV benadryl prior to arrival to hospital. Prior to discharge had recurrence of SVT to HR 170. Placed in Obs overnight for telemetry monitoring. No events overnight. No dyspnea, fever, body aches, or hives. Discharge patient home with follow up with MD for possible holter monitor.

Body aches; chills; fatigue; sore arm lasting 48 hours post vaccination. Resolved with Acetaminophen

Noted headache just over an hour after receiving vaccine. No fever and subsided after about an hour. Awakened 12/19 with a headache that was relieved by Advil.

2 hours after injection patient experience hives on upper torso, and mid and low back. Hives started spreading on the neck. Patient had NO shortness of breath. Itching on left knee. Patient given oral benadryl and then 30 minutes later received 20mg of pepcid. Patient cleared of hives by that night but reoccurred Saturday afternoon with a mild case of hives on the neck. Patient took dose of benadryl. Patient does have a few small areas of redness noted on right arm.

Sinus tachycardic with rate in 130s, dizziness, hypertension 138/92. Symptoms began 20 minutes following vaccination and resolved after 30 minutes.

12/18/20 4 hrs after injection redness& swelling at site started. 12/19/20 severe fatigue, muscle/ joint aches, severe migraine with nausea, dizziness, started at around 11am at 1pm chills started& lasting through 12/21/20 1450. Headache at a pain level 8

Fever of 100.6, chills, nausea, fatigue, pain at injection site. Started 24 hours after injection, lasted about 12 hours.

Started with slight headache and sore arm, felt tired and diarrhea about 5 hours past vaccination - 3 bowel movements within 1 hour. That night around 1:30AM (next morning) I felt a little itchy all over with a throat irritation and I took some Benadryl. Just itchiness and sore throat, no fever. Had pretty bad fatigue on the 17th and had nasal congestion, cough, chills, sneezing. I worked on the 17th but felt terrible throughout the day. Got home and I could not eat anything , could not hold anything on my stomach. On the 18th at night woke up with sweats, no fever, dry cough, nausea. Chest discomfort (minor chest pain - was sure was not cardiac, could be acid reflux). Woke up with nausea and irritation and intermittently felt fatigued and would feel better, throughout the day. Also felt back pains on the 18. That same evening I felt a little better and then on the 19th I had some shortness of breath. I then decided to go to the UC on Saturday the 19th and got a COVID test. Sore throat was gone but still feel back pain and nausea. Around 11PM on the 19th I got itchy again in my arms and chest. Also got chest pains and took a Pepcid and Benadryl. On the 20th I am feeling a little better, still have a cough and some stomach upset and headache (in the AM). About 1:30PM diarrhea came back again. Had it 2X and low back pain and abdominal pain and also chills. There was a time I could not take care of my kids I just had to stay in bed (19 and 20th - I spent in bed most of the day). My heart rate has been good. The evening of the 20th I felt a little bit better and able to eat a little bit easier. This morning felling a little better. Had diarrhea this morning and a headache that I can't get rid of. Took Tylenol but it has not helped. Also low back pain.

sore arm lasting 72 hours post injection.

Patient had warm to touch injection site and experienced headache. Gave water. Patient felt better but still symptomatic.

Swollen tongue, racing heart, lightheaded

The patient was sitting in a chair and began feeling flushed, scratchy throat, and tingling in bilateral arms. Treatment included 25mg Benadryl by mouth at 1851, repeat dose at 1902.

Developed chills, body aches, swelling at vaccine site. Improved after 2 days. She did have COVID in April 2020.

Leg pain, back pain, chills, fever, headache. Unable to walk or stand still for more than a minute. Unable to sit upright back pain travels to mid back.

Left knee pain when standing up

Pfizer-BioNTech COVID-19 Vaccine EUA. Symptoms: shaking, chills, sore arm, fever: 101 beginning at 11:30pm. Took Tylenol Extra Strength prior to bed at 2am. Woke up with headache and fever of 99.4 approximately 6 hours later and took more Tylenol Extra Strength. Felt tired during the day. Rechecked temperature at 8:00pm (12/19) and fever remained at 99.4 , but did not take Tylenol.

Patient experienced Temperature increase to 99.3 oral; increased blood pressure 136/94 with dizziness about 30 minutes after injection. Blood pressure remained elevated for about 2 hours; normal blood pressure 112/64 for this young man. Vitals were taken every 30 minutes. BP and temp 134/84, 99.5 140/92, 99.1 128/92, 99.1 112/76, 97.8 vitals prior to patient leaving. Dizziness improved and patient taken home by friend. Dizziness continued. Patient taken home and told to report to ER if symptoms return

Dry Cough, Fatigue, Arthralgia, Low Grade Fever.

15 Mins after I started noticing tightness in chest, tongue swelling , heart rate 130 , 25 mg of Benadryl,, irregular heart

I developed a temp as high as 101 degrees. Terrible headache that lasted for 5 days Muscle aches Fatigue, Weak (I did have covid on March 27- was ill for 3 weeks. Had antibodies still present when tested in August) Chills alternating with sweating

12/18/2020 10:30PM body aches, chill, left arm pain. 3:00 AM pain in arm 800mg Tylenol. AM next day, arm still sore . 12/20/20 midday discomfort in l armpit. 11:30 12/20 swelling in l armpit. 9:00 Ice swelling of l armpit -- Tylenol. Some swelling persists at area of l armpit.

"0650-Within 5 min of vaccination: Lightheadedness, dizziness, ""floaty"" feeling, cleared after sitting 15 more minutes. 0900-Returned to clinic, after vaccination : recurrence of lightheadedness, sudden onset of HA 6/10 (no migraine aura), nausea and 2 episodes of watery stool, diaphoresis. No rash, no Shortness of breath, no difficulty swallowing, no throat swelling. 1000- taken to ED for continued monitoring: given Zofran 4mg SL, Benadryl 25 mg PO, Pepcid 10 mg PO, Tylenol 975 mg PO , ibuprofen 600 mg PO. DC'd from ED at 1335 with Zofran for continued nausea. Other symptoms resolved."

I developed a rash on both arms right away.

c/o of tingling and burning to right side of face and lips Covid Vaccine injection was administered. Pt. She also states develop a small blister inside her lower lip. She denies any SOB or swelling to face and throat she states has allergies to red dyes and has a hx. of DM, HTN, Anemia and breast CA. VS were taken BP

154/90 , 02 sat 100 %, HR 56. Pt. had some water and walked to the restroom, she stated was feeling much better, and said her husband was driving her home. BP recheck again 139/89 pulse 62, sats 100. She left via walking without any difficulty.

Patient said that she felt sick while in observation. She ended up dizzy, shaky, and a fast heart rate. We got her to get a drink and lay down for a bit. Her initial bp was 143/107 with a heart rate of 108. After resting for some time, she felt back to normal.

c/o problems swallowing despite drinking water. Sat pt in chair, VS taken and monitored. Epinephrine IM given when pt c/o problems swallowing worsening. 9-1-1 called and responded but pt declined escort to ED because he stated he was feeling better after Epi so instead I and patient transport escorted pt to ED via wheelchair.

Dizziness occurring approximately 4 hours after receiving vaccine. Patient presented back to vaccine clinic. Blood pressure lower than patient's reported normal blood pressure. Close monitoring by nurse. Blood pressure increased during monitoring period.

Vaccine recipient reported experiencing numbness, tingling of the arm after receiving the COVID-19 vaccine. Vaccine recipient thinks that the vaccinator most likely hit a nerve when administering the vaccine. The vaccine recipient went to the emergency department for further evaluation. The vaccine recipient was monitored, felt better, and was discharged to home subsequently the same day. On Monday, I called the vaccine recipient to follow-up and they report that they no longer have the numbness or tingling.

Developed fever , cough, congestion 1 day after vaccination.

12/16/2020 I had a fever at night I woke up with fever and chills and body aches and I also had a pretty bad headache, it lasted throughout the next day 12/17 I took tylenol and just felt tired, my headache was also off and on it just depended when I took tylenol

Patient felt some dizziness 15min post vaccination, itchiness behind both ears, some nausea, tingling feeling all over body. Pt denies worsening of symptoms 10 minutes later, reports itchiness behind ears feeling slightly better. Does report an area on abdomen feeling itchy as well as random spots on both legs. Pt agreed to 50mg of Diphenhydramine, tabs, PO 20 minutes after first sx developed. Lot# 205355, exp. 05/2023, NDC 0904-5306-61. Patient was monitored for an extra 15 minutes post medication, was feeling better and had her husband outside waiting for her to drive her home. Advised to continue to monitor sx and call PCP with new sx or for emergent sx, go to ED. Patient denied trouble breathing, chest pain/tightening, trouble swallowing throughout whole event.

39 yo male with history of Covid 3/2020, and SVT s/p ablation x 2 (2002, 2008) who came to urgent care S/P Covid vaccination for recurrence of SVT. Given 50 mg IV benadryl prior to arrival to urgent care. Prior to discharge had recurrence of SVT to HR 170. Placed in Obs overnight for telemetry monitoring. No events overnight. No dyspnea, fever, body aches, or hives. Discharge patient home with follow up with EP MD for possible holter monitor.

Flushing and lightheadedness

Patient became dizzy, vital signs -10:32 am 162/101, P-96, sat 98% on room air, hot clammy, blurry vision, heart palpitations, repeat vitals 1036- 171/102 P-85 sat 98% on room air, transferred to Emergency Room 10:43 am

Thursday night at around 11pm I lost control of my right arm. Friday I spent the day in Urgent Care doing CT scans and MRI scans of my brain and body and also did some blood work. All test came back negative. It is now Monday the 21st and the mobility in my right arm is extremely limited and I am slowly regaining the use of my right arm.

Weakness; fatigue lasting about 1 hour.

"""felt like throat scratching"""

One hour post vaccination my top lip felt tight. On inspection my buccal mucosa of my top and bottom lips were swollen greater on the top lip. My soft palate felt numb as well as my tongue from the tip to middle. My nose was also slightly swollen. 24 hours later the I have a slight swelling of areas mentioned with the exception of my nose. I was instructed to take Benadryl on the day of the event 25mg x 2 doses. the day after 12/21 I was given Claritin 10mg x 1 dose and Famatodine 20mg x 1 dose by mouth.

10 minutes after injection started to feel hot, developed a headache and nausea. had blood pressure taken and it was elevated along with heart rate in the 120's. Started feeling itchy and short of breath, along with red and blotchy on the arms and face. Was transferred to the ED and given IV fluids with Solu-Medrol, Benadryl, and Famotidine and released 1 hour and 30 minutes later with a prednisone prescription.

The evening of 12/16 my headache begin at the next day fever of 103 stayed for 7 hrs took administered Tylenol exp chills, body aches, and rash on face around the eye spread to right side of nose, side went to hand area lasted from 12/17 to 12/21.The headache started effecting my neck contacted my PCP on 12/19. I went to ER on 12/19 ran tests CT scan check for clots negative, lumbar puncture and chest X-ray was fine and dint exp respiratory problems. I missed 3 days of from work 12/9 to 12/21.

Day after the vaccine I had body aches, fatigue , headache and temp of 101.5

Patient had swelling of tongue 45-60 minutes after vaccination. Received PO benadryl. Had eyelid and facial swelling requiring IV Solu-medrol. Monitored for short period of time in emergency department and released. No further symptoms.

Sore arm, could not sleep on it about 8-10 hour post vaccination.

Spontaneous hives on face, Associate does have a hx of spontaneous hives and has been seen by allergist. Had an episode in January, February, May and October of spontaneous hives. Hives noted 5.5 after vaccine and about 1.5 hours after taking Advil

She was sore at injection site later on day of injection (12/20) that developed into whole body muscle aches the next day (12/21). She also reported a cough started on 12/20 and this has persisted and slight Shortness of breath started 12/20 that has become worse today 12/21 where if she is moving around she needs to stop and take a few breaths. She denied any feeling of life threatening shortness or breath or need to go to ER. She has been instructed to contact employee health prior to coming back to work given cough/SOB not typically a reaction to vaccine.

"felt lightheaded and a ""little off"" after doing errands at lunch about 2 hours after taking vaccine. BP was 190/110 while at work and was sent to the ER. BP there was 209/125. Was given Nifedipine CR 30 mg at 17:49. Discharged from ER with primary care follow up on 12/21. BP 4 months prior to vaccination was recorded at 168/110 at office visit."

6 min post injection felt cold, lightheaded, HR increased to 155, and became flushed.

"c/o ""I can't breathe, feels like my throat is closing"" VS taken. Pt crying, breathing rapidly possibly hyperventilating. Epi IM given, VS taken. Hospital emergency activated. Rapid team arrived assessing pt. Rapid team escorted pt via gurney for further observation."

Vasovagal reaction ashen color bradycardia for approx 1-2 minutes decreased B/P 90/60 with full recovery with ingestion of orange juice and recumbency

I had a rash that covered my neck, face and chest. A slight fever of 99.5 , soreness in the shoulder and joint area, mild headache the day I got the vaccine. Next day, rash still on face, joint pain and mild headache. Next day, joint pain. Today, a mild headache. Did a telephone call from Dr. and nurse from Health Dept. I was told to take Benadryl and go to ER if symptoms got worse. I took Benadryl one and one-half days.

She experienced nausea.

patient became dizzy, nauseated, received vaccine 10:00, at 10:09 patient became dizzy, lightheaded, nauseated, bp 125/85 p-85, sat 100%, 10:14 134/91 99% sat on room air, P- 98, 1020- BP 155/92, 1025 - 142/87, 1029- 98% on room air P-98, 1030- 129/91, 1047- sat 99% on room air, P- 89, 134/92, patient still feeling nauseated and dizzy transferred to Urgent Care

After receiving dose of COVID 19 vaccine patient reports the following: rash to both arms, right neck. Heart rate increased to 102. Reports slight shortness of breath. ER visit- administered Benadryl/Solumedrol IM

hot flushed, temporary weakness, temporary itching throat and back. lips tingling, lump in throat. 10 mins after injection symptoms started. all resolved except tingling in lips which persisted to the next day. area around mouth is itchy/burning but no other symptoms.

12/16/2020 WENT TO SLEEP AT 10PM 12/17/2020 - WOKE UP ABOUT 1:00 AM; 101 TEMP, SHAKING, CHILLS, BODY ACHES, RIGHT ARM VERY SORE, TRIED TO GO BACK TO SLEEP 12/18/2020 - FATIGUE, BODY ACHES, TEMP SUBSIDED; EVENING FELT SHAKY; 'CALLED OUT OF WORK' (NIGHTSHIFT NURSE)

12/19/2020 - ALL SYMPTOMS SUBSIDED 09/2020-10/2020 HAD FLU SHOT 'CANT REMEMBER EXACT DATE'

Patient pre-medicated with diphenhydramine due to infusion-type reactions in past. Patient with hoarse voice, itchiness to upper back, arms, and face, hives on bilateral arms. Per health system protocol (patient is health system employee) Patient administered diphenhydramine, famotidine, methylprednisolone succinate, epinephrine. All symptoms resolved by 1440.

18 minutes post vaccine dose 1, Pfizer COVID vaccine, development of globus sensation without airway compromise or stridor. Frequent throat clearing and swallowing. Followed by diaphoresis, loss of vision, extreme neuropathic tingling over entire head non painful. Bradycardic event to heart rate 35 recorded by Apple watch. Loss of consciousness with pupil dilation. Weak pulses but no loss of pulse. Heart rate recovered quickly. Blood pressure after initiation of iv fluids was normal in upright position once loss of consciousness subsided. Continued globus sensation. 30 minutes after initial event, again developed clammy hands, head tingling and worsening globus sensation but again no stridor or airway compromise. Given PO Benadryl 25 mg which did resolve globus sensation in next 30 minutes. Monitored for one hour post event with no subsequent symptoms other than fatigue.

"Tingling in right arm where vaccine was given. Hot at the site in her ""R"" hand. Still tingling 45 minutes after. Following up with Telemedicine."

Next day between 3 -6 AM - swelling of left eyelid followed by swelling and paresthesias of lips, followed by severe paresthesias of the left side of the face mostly lower half associated with a heavy sensation. Emergency treatment with 150 mg solumedrol and 50 mg benadryl. Symptoms persisted on and off for 3 days requiring benadryl 50 mg and claritin round the clock. On the second day post-vaccine headache, mouth blister (1), and diarrhea. Today (4 days post) very tired and fatigued.

Left arm erythema at injection site, lethargy, fever

Pt received Covid vaccine and afterward developed hives on chest and arms

Employee experienced headache and dry heaving

Patient complaint of itchiness, shortness of breath,tongue swelling, hyperventilating. Epipen was administered at 3:20pm

Body aches; cold symptoms; fatigue x 24 hours. ibuprofen

Widespread Pain; diarrhea; fever; vomiting; This is a spontaneous report from a non-contactable other healthcare professional. An 85-year-old female (non-pregnant) patient received first dose bnt162b2, intramuscularly on right arm on 14Dec2020 at 14:00 at single dose for immunization. Medical history included High cholesterol (no cholesterol lowering medication) edema, dementia, and no known allergies. Prior to vaccination, the patient was not diagnosed with COVID-19. Concomitant medication included influenza vaccine (INFLUENZA) on 30Nov2020 for immunization within 4 weeks prior to the COVID vaccine, other medications the patient received within 2 weeks of vaccination included daily

vitamin, diuretic, dementia medication, anti inflammatory. On 14Dec2020, the patient experienced widespread pain, diarrhea, fever, vomiting. The adverse event result in doctor or other healthcare professional office/clinic visit. No treatment was received for the events. Since the vaccination, the patient hadn't been tested for COVID-19. The outcome of the events was not resolved. No follow-up attempts are possible. Information about Lot/Batch could not be obtained. No further information is expected.

Headache, fever, chest congestion, cough, malaise, fatigue

Fast heart rate; Leg numbness; Hand numbness; This is a spontaneous report from a contactable consumer (patient). This 21-year-old male patient received the first dose of bnt162b2 (BNT162B2) (Lot # EH9899), via an unspecified route of administration at single dose in the left arm on 15Dec2020 12:00 PM at hospital for immunisation. The patient medical history and concomitant medications were not reported. On 16Dec2020 04:00 AM, the patient experienced fast heart rate, leg numbness, hand numbness. No treatment required. The outcome of the events was unknown. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, the patient has not been tested for COVID-19.

Yesterday my head felt heavy. I took swab. Started coughing 2 days after vaccine. Second day experienced swelling in arm. Runny nose. Waiting on test results. Messaged PCP and they advised her to be tested. Coughing on and off.

Headache; muscle and joint aches; muscle and joint aches; This is a spontaneous report from a contactable physician reporting for herself. A 44-years-old female patient received the first dose of bnt162b2 (BNT162B2, Pfizer product), intramuscular in the right arm on 15Dec2020 12:45 at hospital at single dose for immunisation. Medical history included was none. Concomitant medication included bupropion (unknown manufacturer). The patient experienced headache, muscle and joint aches on 15Dec2020 with outcome of not recovered. No treatment was performed. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, the patient has not been tested for COVID-19. Information on the lot/batch number has been requested.

Gradual onset of very mild rash and symptoms gradual improved with IM administration of diphenhydramine 50 mg and oral famotidine 20 mg. The physician was questioning if the mild rash was from where the patient was scratching secondary to anxiety vs allergic reaction. Patient was monitored for improvements.

She is feeling dizzy, a little wonky; Feeling bad like when she is about to get the flu; Her feet feeling like gelatin; Little nausea; Headaches; This is a spontaneous report from a contactable consumer (patient). This female patient of an unspecified age received BNT162B2 (Lot number EK5730) via an unspecified route of administration on 16Dec2020 at single dose for immunisation. Relevant medical history and concomitant medications were not reported. On 16Dec2020, the patient was feeling dizzy, a little wonky, feeling bad like when she was about to get the flu, with her feet feeling like gelatin, with a little nausea and headaches. The patient reported that when she got home after the administration, she reviewed the information provided after the vaccine and she found this information in the sheet,

realizing that she was feeling that way. At the time of the report, the outcome of the events was unknown.

Felt hot, chest felt different, BP elevated

Diarrhea; right arm pain; fatigue; This is a spontaneous report from a contactable nurse. A 27-year-old female patient received BNT162B2 (Pfizer-BioNTech COVID-19 mRNA vaccine, lot number: EK5730), intramuscular at right arm on 16Dec2020 at 08:15 at single dose for immunization. The patient medical history was not reported. Concomitant medication included paracetamol (TYLENOL) for headache. On 16Dec2020 at 09:00, the patient experienced diarrhea, right arm pain and fatigue. The patient outcome of the events was recovering.

Starting 5 minutes from vaccination left sided arm numbness and tingling down the arm into the fingers. Felt the entire day. 12/21/20, symptoms improved but again returned today.

Headache; Dizzy; Front of her calves and into her feet felt a little like jello; Lightheadedness; Nausea; This is a spontaneous report from a contactable consumer reporting for herself. This 45-year-old female patient received on 16Dec2020 around 7:30am first dose of BNT162B2 (Pfizer-BioNTech COVID-19 mRNA vaccine, lot number: EK5730) intramuscular in the right arm for vaccination. Medical history was none. Concomitant medications were not provided. She sat there for the 15 minutes following administration of the vaccine.After that initial 15 minutes passed she had onset of side effects. On 16Dec2020, while walking to her car, she experienced what she described as dizzy, but it was more like feeling a little wonky like when you are coming down with the flu, where she did not feel right. She was ok to drive herself home, she took a shower. She worked the following night. She noted that mostly the front of her calves and into her feet felt a little like jello. She has brief moments of lightheadedness, a little bit of nausea and a tiny bit of headache starting. The room is not spinning, she is walking fine, bending over and does not seem to be struggling at all. Outcome she initially reported as having subsided, but then reported ongoing, further details unknown. Final outcome was unknown.

I had a fever and that's all

After sitting and waiting the 15 minutes, I left and as I was walking, I had the strongest taste of metal in my mouth. It lasted for about a minute, then slowly went away.; This is a spontaneous report from a contactable consumer. A 54-year-old female patient received first dose of bnt162b2 (BNT162B2; lot EK5730), via an unspecified route of administration on 16Dec2020, at 11:00 AM at single dose (right arm) for immunization. Medical history included asthma, hypertension (HTN), and allergies penicillin (PCN), medications, food or other products, many seasonal items, grass, trees, molds, dust mites, carrots, apples, celery, and walnuts. The patient did not received any other vaccines within four weeks prior to Covid vaccine. Concomitant medications were not reported. Patient reported that she had other medications received within 2 weeks of vaccination. On 16Dec2020, at 11:15 AM, after sitting and waiting the 15 minutes, the patient left and as she was walking, she had the strongest taste of metal in her mouth. It lasted for about a minute, then slowly went away. There was no treatment for the event. The patient did not have Covid prior the vaccination and was not Covid tested post vaccination. Outcome of event was recovered on 16Dec2020.

Anxious, tachycardiac and hypertensive.

felt very warm, overheated; clammy; started feeling slightly light headed; Thought I would pass out; This is a spontaneous report from a contactable consumer (patient). A 41-year-old female patient received the first dose of bnt162b2 (BNT162B2; lot:eh9899) via an unspecified route of administration in the left arm on 16Dec2020 10:00 at a single dose for immunization. Medical history was reported as none. Concomitant medication included paracetamol (TYLENOL) for an unspecified indication. On 16Dec2020 11:30, the patient started feeling slightly light headed and thought she was going to pass out. On 16Dec2020 11:50, she felt very warm, overheated and clammy. The patient sat down, attempted to eat her lunch and the events slowly subsided. The patient's blood pressure and pulse were checked on 16Dec2020 and they were relatively normal. The events were reported as non-serious and the patient did not receive treatment for the reported events. Outcome of the events was recovering.

Sore arm lasting about 24 hours post injection. Ibuprofen

received the vaccine on 12/18, 12/19 woke up with a headache and fatigue: lasted until the end of the day.

mild fever; chest pressure; dizziness; This is a spontaneous report from a contactable consumer. A 29-year-old female patient received dose number 1 of BNT162B2 (solution for injection, lot number Eh9899/expiration date unknown) via an unspecified route of administration on her right arm on 16Dec2020 at a single dose for immunisation. Medical history included penicillin allergy and allergies to gluten. Concomitant medications were not reported. The patient experienced chest pressure and dizziness that later turned into a mild fever on 16Dec2020; all of which prompted visit to the emergency room/department or urgent care. The patient received Tylenol for the events. The patient did not receive any other vaccines within 4 weeks prior to the COVID-19 vaccine. She was not diagnosed with COVID-19 prior vaccination and was not tested for COVID-19 since vaccination. The outcome of the event was recovering.

Circum-oral numbness; This is a spontaneous report from a contactable consumer reporting for himself (patient). This 59-year-old male patient received the first dose of BNT162B2 via an unspecified route of administration in the left arm on 15Dec2020 at 18:00 at single dose for immunisation. Relevant medical history included penicillin allergy. Concomitant medications were not reported. On 15Dec2020 at 18:30, the patient experienced circum-oral numbness. The patient did not receive corrective treatments for the reported event. The facility where the vaccine was administered was hospital. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient was not diagnosed with COVID-19 prior to vaccination and since the vaccination he had not been tested for COVID-19. The outcome of the event was unknown. The information on the lot/batch number has been requested.

tachycardia, flushing

a fever of 99.5; body chills/chills; Not feeling well; Body itch; Pain; This is a spontaneous report from a Pfizer-sponsored program, received from a contactable healthcare professional (patient). A 36-year-old male patient received BNT162B2 (lot number: not provided) solution for injection, via an unspecified

route of administration on 15Dec2020 at a single dose for an unspecified indication. Patient has no medical history. There were no concomitant medications. The patient reported having a fever of 99.5 and body chills/chills after getting the Covid vaccine yesterday (15Dec2020). This was the first dose. The patient reported he was not feeling well, he had body itch, and pain on 15Dec2020. Patient stated he was just trying to think, he actually was feeling like drinking a lot of water and probably have some Tylenol. He asked if he should have the Tylenol or not really. The reason he was calling was because he was trying to figure out what was going on with his system before he do whole 8 to 10 minutes thing. He asked if this was required to find out if he could just drink some water and just take the Tylenol. He just wants the answer before he goes any further. Patient reported he was taking Tylenol for fever and chills. He reported he was in pain and he just needed to see if everything was alright. Outcome of the events was unknown. Information on the lot/batch number has been requested.

Patient states that after receiving the vaccine she felt lightheaded and dizzy. In the days following the vaccine she has experienced periods of vertigo and photosensitivity.

Site soreness - no treatment required.

swollen eyelids; cotton mouth; This is a spontaneous report from a contactable Nurse. A 43-year-old male patient received first dose of BNT162B2 (lot number EK5730), intramuscular on 16Dec2020 09:30 at a single dose in left arm for immunization. Medical history included smoker, overweight and known allergies with PCN. The patient's concomitant medications were not reported. The patient experienced swollen eyelids and cotton mouth on 16Dec2020 with outcome of recovered on an unknown date in Dec2020. The patient was given Benadryl and was under observation. The event was assessed as no-serious and did not caused hospitalization.

Mild sore arm at injection site; This is a spontaneous report from a contactable pharmacist. A 29-year-old male patient received bnt162b2 (BNT162B2), intramuscular (Arm Left) on 16Dec2020 11:00 at single for an unspecified indication. There were no relevant medical history and concomitant medications. The patient experienced Mild Sore arm at injection site on 16Dec2020 15:00. The outcome of the event was recovering. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

developed soreness at injection site 3-4 hours after the injection; This is a spontaneous report from a contactable consumer. A 50-year-old female patient received the 1st dose of bnt162b2 (BNT162B2) at single dose on 15Dec2020 for immunisation. The patient medical history and concomitant medications were not reported. The patient experienced soreness at injection site 3-4 hours after the injection on 15Dec2020. The outcome of the event was unknown. Information about Lot/Batch no has been requested.

The night after receiving the vaccine, I developed fever, severe muscle aches, nausea, headache, and a red area on my arm. These symptoms progressively got worse through the next day. Fever got up to 102. On 12/20/2020, I felt some better with temp 100.2 headache and body aches. Today is better with temp just 99.4. Still have minor headache and some chills. There is still a pinkish/red area about 2 inches

long and 1 inch wide on my arm where the vaccine was given. I did have a covid exposure at work last week and the employee health is going to test me before I go back to work.

Rash starting behind ears, moving to neck and trunk. Patient took a 2nd generation antihistamine (unsure which one) and this has helped with the itching. Rash is still present.

Moderate abdominal cramping; diarrhea; This is a spontaneous report from a non-contactable consumer (patient). A 37-years-old male patient receive the first dose of bnt162b2 (Pfizer-BioNTech COVID-19 mRNA vaccine batch/lot number: Eks730), via an unspecified route of administration on the arm left on 16Dec2020 16:15 at a single dose for immuninzation at the hospital. Medical history was reported as none. The patient had no allergies to medications, food, or other products. There were no concomitant medications. Prior to vaccination, the patient not diagnosed with COVID-19 and the patient has not been tested for COVID-19 since the vaccination. On 16Dec2020 17:30, the patient experienced moderate abdominal and diarrhea. The patient did not receive any treatments for the events. The patient was recovering from the events. No follow-up attempts are possible. No further information is expected.

my Doctor had a broken blood vessel that was like really bad, like a little hemorrhage; my Doctor had a broken blood vessel that was like really bad, like a little hemorrhage; This is a spontaneous report from a non-contactable consumer. A patient of unspecified age and gender receive dbnt162b2 (BNT162B2) at single dose on an unspecified date for immunization. The patient medical history and concomitant medications were not reported. The patient stated that the doctor had a broken blood vessel that was like really bad, like a little hemorrhage on an unspecified date. The outcome of events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

patient reports rapid heart rate 110-120

"burning in her throat; This is a spontaneous report from a contactable nurse. A 37-year-old female patient received bnt162b2, intramuscular from 16Dec2020 at 11:45 to at 0.3 mL, single for immunization ()COVID-19 vaccine). Medical history reported as ""none"". There were no concomitant medications. On 16Dec2020 11:48, three minutes after receiving the vaccine, the patient experienced burning in her throat . It was further described as it felt like constant reflux in the bottom of her throat. The patient was monitored for about an hour and forty five minutes. The burning was not more or not less. She was swallowing fine. She was breathing fine. Her vital signs and ""sats"" (saturation) were stable. Outcome of event was unknown."

"mild abdominal cramp; an episode of loose stools; profuse sweating; lightheadedness; headache; severe weakness; entire body felt cool and clammy; entire body felt cool and clammy; This is a spontaneous report from a contactable physician (patient himself). A 34-year-old male patient received the first dose of bnt162b2 (BNT162B2, Solution for injection; batch/lot number: ek5730), intramuscularly on the left arm on 15Dec2020 at 19:30 at a single dose for immunization at the hospital facility. Relevant medical history included childhood asthma and attention deficit hyperactivity disorder (ADD). Concomitant medication included lisdexamfetamine mesilate (VYVANSE) from an unspecified date in Dec2020. The patient had no allergies to medications, food, or other products. The patient did

not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. Roughly 13 hours after the vaccine administration, on 16Dec2020 at 08:00, the patient had mild abdominal cramp. He went to have a bowel movement and had an episode of loose stools. Within seconds after that, he started experiencing profuse sweating, lightheadedness, headache, severe weakness and his entire body felt cool and clammy. He managed to drink some water and laid down on the floor for the next few minutes. The episode lasted for a few minutes. All the events occurred on 16Dec2020 at 08:00 AM. The patient was not hospitalized for the events. Therapeutic measures were taken as a result of mild abdominal cramp, an episode of loose stools, profuse sweating, lightheadedness, headache, severe weakness, and entire body felt cool and clammy, which included acetaminophen (TYLENOL) 1000 mg. The patient recovered from the events ""mild abdominal cramp, an episode of loose stools, profuse sweating, lightheadedness, headache, severe weakness, and entire body felt cool and clammy on an unspecified date in Dec2020."

"Arm soreness at site of injection; This is a spontaneous report from a contactable consumer. A patient of unspecified age and gender received bnt162b2 (BNT162B2, also reported as ""COVID vaccine,"" Solution for injection; lot/batch number and expiration date were not provided), via an unspecified route of administration on an unspecified date at a single dose for immunization. The patient's medical history and concomitant medications were not reported. On an unspecified date after use of the product, the patient experienced arm soreness at site of injection. The outcome of the event was unknown. Information on the lot/batch number has been requested."

minor soreness; This is a spontaneous report from a non-contactable consumer. A male patient of an unspecified age received BNT162B2 (lot number was not reported) solution for injection, via an unspecified route of administration on an unspecified date at a single dose for an unspecified indication. The patient's medical history and concomitant medications were not reported. The patient experienced minor soreness after his injection on an unspecified date. Outcome of the event was unknown. No follow-up attempts are possible. Information about lot/batch number cannot be obtained. No further information is expected.

"hives on my neck and above my ear/few sparse hives; This is a spontaneous report from a contactable nurse (patient). A 49-year-old female patient received bnt162b2 (BNT162B2) lot number and expiration date were not reported, via an unspecified route of administration on 16Dec2020 at 07:15, 0.3 ml single dose for immunization. Medical history included seasonal allergy and seasonal asthma. The patient's concomitant medications were not reported. The patient stated that she received the product this morning (16Dec2020) at 0715. She mentioned that she took a shower this evening, 13 hours later, and observed hives on her neck and above her ear. She confirmed that she was not having an anaphylaxis and there are no other symptoms. She also denied any soreness at the injection site or pain. She stated that she has no other symptoms and no pain, no soreness. She added that she received vaccine on 16Dec2020 and wondered if there was a side effect of some hives, she meant that she was not having an allergic reaction and she got the vaccine at 7:15 this morning and she have been fine, but she just have like a few sparse hives at 20:30. When asked about causality, the nurse stated ""Yes I do. I have never had hives before."" She did not think that she needed treatment but she was wondering if it was

common or she wasnot having any anaphylactic reaction and they were sparse. She doesn't have it on her trunk, she just have some on her neck and there was like one above her ear. She put BENADRYL cream on them, they are fine, and they don't itch. She was just like preemptively treating them because of her high risk for work. Therapeutic measures were taken as a result of hives on my neck and above my ear (urticaria). The outcome of the event was unknown. Information on the lot/batch number has been requested."

Nausea 10 minutes after injection; This is a spontaneous report from a contactable consumer. A 25-year-old female patient received first dose of bnt162b2 (Pfizer-BioNTech COVID-19 mRNA vaccine), via an unspecified route of administration on 16Dec2020 18:15 at single dose (right arm) for immunization. Medical history included polycystic ovarian syndrome. The patient had no allergies to medications, food, or other products. Concomitant medication included ethinylestradiol, norethisterone (DASETTA 7/7/7) as Birth control. On 16Dec2020 18:15, the patient experienced nausea 10 minutes after injection. The Covid-19 vaccine was administered at the workplace clinic. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient did not received treatment for the event. The patient was not diagnosed with COVID-19 prior to vaccination and since the vaccination, the patient had not been tested for COVID-19. Outcome of event was recovered in Dec2020. Information on the lot/batch number has been requested.

muscle pain in thigh area; felt like muscle pain, cramp; This is a spontaneous report from a contactable consumer. A 52-year-old female patient received BNT162B2 (solution for injection, lot number EH9899/expiration date unknown), via an unspecified route of administration on 14Dec2020 at a single dose for vaccine. Medical history included blood pressure (abnormal). Concomitant medications included unspecified blood pressure pills. The patient experienced muscle pain in thigh area in Dec2020. She further reported that she was asleep and when she woke up somewhere around it went wave like 1-2 minute. It felt like muscle pain, cramp. The outcome of the event was unknown.

woke up today had a headache just on the right side of her head and injection site is sore and a little knot at the site; woke up today had a headache just on the right side of her head and injection site is sore and a little knot at the site; woke up today had a headache just on the right side of her head and injection site is sore and a little knot at the site; This is a spontaneous report from a contactable nurse. A 60-year-old female patient started to receive bnt162b2 (BNT162B2), via an unspecified route of administration on 16Dec2020 12:45 at SINGLE for immunization. The patient's medical history and concomitant medications were not reported. On 17Dec2020, it was reported that the patient woke had a headache just on the right side of her head and injection site is sore and a little knot at the site. Headache woke her up, no discoloration at injection site. The outcome of the events was unknown. Information about Lot/Batch has been requested.

"her arm is sore, to move or to lift; This is a spontaneous report from a contactable nurse via a Pfizer-sponsored program. A female patient of an unspecified age received bnt162b2 (BNT162B2), via an unspecified route of administration on 16Dec2020 at a single dose for COVID-19 immunisation. Medical history and concomitant medications were not reported. The nurse that received the COVID-19 vaccine on 161Dec2020 and described ""her arm is sore, to move or to lift"". She asked if Pfizer could tell her to

take Tylenol or Advil for her arm soreness. Clinical outcome of the event was unknown. Information on the lot/batch number has been requeste"

tingling; warmth and coolness in ears, head and face radiates to arms, legs and back; painful teeth; nausea; extremely flushed; goosebumps; This is a spontaneous report from a contactable consumer (patient) and healthcare professional. A 35-year-old female patient received the first dose of bnt162b2 (BNT162B2; lot number: EH9899), via an unspecified route of administration on the left arm on 16Dec2020 18:30 at single dose for immunization. Medical history included eczema. Concomitant medication included vitamin D3, zinc, ascorbic acid (VITAMIN C). The patient previously took trimethoprim / sulfamethoxazole (BACTRIM) and cefaclor (CELOR) and experienced allergies. The patient experienced tingling, warmth and coolness in ears, head and face radiates to arms, legs and back, painful teeth, nausea and extremely flushed with goosebumps on 16Dec2020 18:45. Outcome of the event was not recovered. It was reported that patient had no prior COVID vaccination and did not test positive for COVID. Reporter considered that events non-serious. It was unknown if treatment was received for the adverse events.

"both her hands were feeling pressure in her knuckles; redness in her hands; Itching; feeling headachy; feeling fluish; This is a spontaneous report from a contactable nurse. A 61-year-old female patient received the first dose of bnt162b2 (BNT162B2; lot number EK5730), intramuscularly in the right upper arm on 16Dec2020 at 15:40 at 61-years-old at a single dose for COVID-19 immunization. The vaccination facility was a hospital. There were no additional vaccines administered on the same date of the Pfizer suspect or prior vaccinations within 4 weeks. Medical history included ongoing asthma (asthma began sometime in her 50s and was ongoing) from an unspecified date. The patient had no other adverse events to any other vaccines in the past and there was no relevant family medical history. There were no concomitant medications. On 16Dec2020, the patient experienced: both her hands were feeling pressure in her knuckles, redness in her hands, itching. On an unspecified date in Dec2020, the patient experienced feeling headachy, feeling fluish. There was no visit to an emergency room or physician office. The clinical course was reported as follows: The patient was a nurse and she had a Pfizer lot number EK5730. The patient said she got the shot on 16Dec2020 at about 15:40 and when she got home both her hands were feeling pressure in her knuckles and they were red. Since then she had not stopped inching. The patient took cetirizine hydrochloride (ZYRTEC) and that made it stop enough; however, she could sleep but she still felt like she was itching all over. The patient clarified the pressure in her hands was primarily in her knuckles and then once that resolved she went to itching and feeling headachy. The patient clarified the redness was on her hands when she was having the pressure, her hands kind of got red. The patient reported the pressure in her knuckles had resolved completely and the redness in her hands and knuckles had resolved as well. The patient reported the itching began about an hour and a half after the injection and was ongoing, but it was not as bad since taking cetirizine hydrochloride twice. The patient reported the itching had improved. The patient did not have the NDC or expiration date. The patient did not know what dose was given. The card was all she had, and it just had the lot number and was to remind her to return for the next shot. The patient was calling Pfizer primarily about the itching and how she was feeling kind of ""fluish"", which she assumed was normal. The patient wanted to know, should she get the second shot, would she have a worse reaction to the second one.

The patient needed to know because she was ""miserable itching so bad and she thought the second one could be worse than the first."" There was no relevant testing Therapeutic measures were taken as a result of both her hands were feeling pressure in her knuckles, redness in her hands, and itching The clinical outcome of the events: both her hands were feeling pressure in her knuckles, redness in her hands, was recovered on an unspecified date. The clinical outcome of the event, itching, was recovering. The clinical outcome of the event, feeling headachy and feeling fluish, was unknown."

Palpitations and lightheadedness after vaccination.

scratchy throat; fever of 100.0 [units unspecified]; Headache; Nausea; body aches; Diarrhea; This is a spontaneous report from a non-contactable consumer. A 35-year-old female patient started to receive bnt162b2 (BNT162B2; unknown lot number and expiration date), via an unspecified route of administration on 16Dec2020 to 16Dec2020 single dose for an unspecified indication. The patient medical history was not reported. The patient has no allergies to medications, food, or other products. Concomitant medication included levothyroxine. The patient reported that she had scratchy throat several minutes (reported as 02:30 AM) after receiving the vaccine (16Dec2020). It did subside but then 14 hours after receiving the vaccine, she had different symptoms, She had a fever of 100.0 [units unspecified], headache, nausea, body aches and diarrhea. The events did not cause hospitalization/ prolonged hospitalization. The patient has not received other vaccines in the last four weeks. The facility where the most recent COVID-19 vaccine was administered in a hospital. There was no treatment received for the adverse events. It was unknown if the patient was diagnosed with COVID-19 prior to vaccination and the patient has not been tested for COVID-19 since the vaccination. The outcome of the events was recovering. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

Headache about 3-4 hours post vaccine gone 45 minutes post acetaminophen; sore arm later that day. Acetaminophen.

Right hand felt cold at first but that sensation has subsided; Within less than 10 minutes I had a warm tingling feeling; heaviness in my legs which still continues over an hour later; Dry mouth; This is a spontaneous report from a contactable consumer reporting for herself. This 44-year-old female patient received on 17dec2020 10:00 first dose of BNT162B2 (Pfizer-BioNTech COVID-19 mRNA vaccine, lot EK5730) at single dose in the right arm for immunization. Medical history included reflux. No allergies to medications, food, or other products. Concomitant medications included omeprazole (PRILOSEC). On 17Dec2020, within less than 10 minutes, the patient had a warm tingling feeling, heaviness in her legs which still continued over an hour later. Right hand felt cold at first, but that sensation has subsided. Also had a dry mouth about 15-20 minutes after the vaccine. All symptoms subsided after 2 1/2 hours. Patient went to emergency room. Final outcome was recovered on 17Dec2020.

Employee calling to report a reaction after receiving a COVID-19 vaccine. Vaccine Name - Pfizer Vaccine Lot # - EK5730 Vaccine Date and time - ? 12/18/2020 @ 4:30pm Is this your first or second dose? First Date and time of symptom onset - ? 12/19/2020 @ 11am Symptoms - ? Fever of 104.6, headache, BLE pain Last day of work and shift - ?Friday 12/18/2020 @ work today 2:30pm-11pm Home remedies? -

Tylenol Any improvement? - Denies any headache and fever. Both leg pain are still present. Recommendation? Continue to monitor, take OTC Tylenol for pain and follow directions on the label and call PCP if concern arises. Employee voiced understanding Employee of information ? yes Employee voiced any concerns ? yes. She asked if it's a symptoms of covid-19. Mentioned that leg pain is not signs or symptoms of covid-19 Employee?s questions answered to employee?s satisfaction - yes

He woke up this morning and had a temperature of 100.8 degrees Fahrenheit; This is a spontaneous report from a contactable consumer reported for himself. A 27-year-old male patient received BNT162B2 (Pfizer-BioNTech COVID-19 mRNA vaccine, lot EH9899) via unknow route at the right upper arm at single dose for COVID-19 Vaccination on 16Dec2020 11:45. The patient had no medical history. Concomitant medications included zinc and Vitamin D. On 17Dec2020 08:30 the patient woke up and had a temperature of 100.8 degrees Fahrenheit. He was supposed to get the second dose on 06Jan2021. He was planning on taking Tylenol for the fever if that was ok. The patient had no history of previous immunization with Pfizer vaccine and he did not receive other vaccine on the same date. The event did not require a visit to Physician the patient felt ok. The outcome of the event was unknown.

No chief complaint on file. Patient is a 25 y.o. female who had no chief complaint listed for this encounter. á á á History of Present Illness á Patient is at the Covid vaccination clinic Received her vaccination and approx 5 min following administration notified staff that she was feeling a little lightheaded Was also c/o feeling hot at time Patient admits that she did not have breakfast this AM and has not had anything to drink Denies throat discomfort or tingling No shortness of breath or headaches Patient brought to the bay for evaluation á á á History Review / Additional history á Review of Systems á Patient's medications, allergies, past medical, surgical, social and family histories were reviewed and updated as appropriate. Objective á Blood pressure 126/74, pulse 88, SpO2 98 %, not currently breastfeeding. Physical Exam HENT: Head: Normocephalic. Cardiovascular: Rate and Rhythm: Normal rate. Pulmonary: Effort: Pulmonary effort is normal. Musculoskeletal: Normal range of motion. Skin: Capillary Refill: Capillary refill takes less than 2 seconds. Neurological: Mental Status: She is alert. Psychiatric: Mood and Affect: Mood normal. Behavior: Behavior normal. á á á á Assessment / Plan á VSS on arrival to evaluation bay Following laying down for 10 min, drinking water, and eating a granola bar patient reports feeling much better. Sat at the bedside for an additional 5 min with no recurrence of symptoms. Repeat VSS Instructions given to go to the ED if worsening symptoms, lightheaded, throat swelling or shortness of breath. Encouraged to eat and drink prior to next immunization. á Per Attending APRN Electronic Signature 12/18/2020 10:10 AM á á

Injection site pain; This is a spontaneous report from a contactable consumer (the patient). A 27-year-old male patient received BNT162B2 (Pfizer-BioNTech COVID-19 mRNA vaccine), via an unspecified route of administration on 16Dec2020 14:15 at single dose for immunisation. The patient medical history and patient's concomitant medications were not reported. The patient experienced injection site pain on 17Dec2020 07:00. The vaccine was administered at Hospital Facility. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient was not diagnosed with COVID-19 prior to vaccination. The patient had not been tested for COVID-19 since the vaccination. The event was non-serious with outcome of recovering. No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.

Immediately after receiving the dose of vaccine, rash, tickle in throat taken to ED treated with Benadryl on 12/20 developed swollen lips taken to ED treated with epinephrine, steroids, Pepcid discharged from ED 12/21/20 symptoms resolved

Complained of scratchy throat and feeling like throat was swelling.

painful chills; fever (101.7 f); body aches; headache; some tenderness at injection site; This is a spontaneous report from a non-contactable nurse. A 45-year-old female patient received BNT162B2 vaccine (Lot number EK5730) intramuscular in the left arm on 16Dec2020 at 18:30 at single dose for immunisation. Relevant medical history included high blood pressure and seasonal allergy. Concomitant medications included lisinopril and over the counter allergy pill. On 17Dec2020 at 10:00, the patient experienced painful chills, fever (101.7 F), body aches, headache and some tenderness at injection site. Corrective treatments taken as a result of the events included paracetamol (TYLENOL). The patient was not pregnant. Facility type vaccine: Hospital. The patient did not receive other vaccines in four weeks. The patient did not have COVID-19 prior to vaccination, and she was not tested post vaccination. At the time of the report, the patient had not recovered from the events.

15 minutes after vaccination start experiencing nausea and vomiting

Arrived to drive through as passenger in car. á He did let RN know before vaccine he has felt faint and has had syncopal episodes after injections or blood draws. Immediately after injection he had a loss of conciseness. Lasting approximately 1 min. Partner states this was a normal reaction. He then had a second episode lasting longer than first. Partner states this was not a normal reaction for him. He was not responding to voice or touch . After approx 1-2 mins he was alert and responsesive to person, place and situation. RN stayed with Patient as he remained in car. á á 911 called to evaluate RN gave report and hand of to EMS. EMS evaluated and found pt stable.

Significant arm soreness at injection site; body aches; chills; mild headache; restless night's sleep; This is a spontaneous report from a contactable nurse. A 46-year-old female patient received BNT162B2 vaccine (Lot number EH9899) intramuscular in the left arm on 16Dec2020 at 08:45 at single dose for immunisation. Relevant medical history included recent Urinary Tract Infection (UTI), treated and recovered. Concomitant medications included sulfamethoxazole/trimethoprim (BACTRIM), famotidine (PEPCID) and melatonin. Past drug reaction included allergy to doxycycline. On 16Dec2020 at 14:00, the patient experienced significant arm soreness at injection site, body aches, chills, mild headache and restless night's sleep. Corrective treatments taken as a result of the events included ibuprofen (ADVIL). The patient was not pregnant. Facility type vaccine: Hospital. The patient did not receive other vaccines in four weeks. The patient did not have COVID-19 prior to vaccination, and she was not tested after vaccination. At the time of the report, the patient was recovering from the events.

Patient got dizzy immediately and wanted to sit down, he also stated he was short of breath. His blood pressure was 160/111 and pulse 107. Rechecked shortly after that blood pressure check and it went to 176/115 and pulse 138. Patient stated he was feeling well and requested to go to ED, staff called 911.

he most painful vaccine he's ever gotten - arm hurts a lot; felt heavy; tired; This is a spontaneous report from a contactable consumer (patient's wife) A 64 year-old male patient received bnt162b2 (BNT162B2) , via an unspecified route of administration on 16Dec2020 at single dose for immunisation . The patient medical history and concomitant medications were not reported. The patient felt heavy on 16Dec2020 with outcome of unknown , tired on 16Dec2020 with outcome of unknown , arm hurts a lot on 17Dec2020 with outcome of unknown. The patient stated this was the most painful vaccine he has ever gotten. Information on the lot/batch number has been requested.

chills, body ache, sore throat, sever cough with chest pain

Approximately 10 minutes after receiving vaccine, patient experienced itching of lips, tongue and throat. Itching also on neck and left arm. Some erythema around neck and upper chest. Lips swelling. Symptoms resolved within about 30 minutes of administration of oral diphenhydramine 50 mg and famotidine 20 mg.

FATIGUE , HEADACHE, I WOKE UP WITH A MIGRAINE . Mild headache for two days

Repetitive intense sneezing night of vaccination which ended with overnight sleep. Arm pain the next day followed by swelling of lymph nodes with intense aching pain. Swelling lasted 24 hours, pain in lymph nodes has now lasted 36 hours.

Asymptomatic patient who had an immediate temperature of 100.8 degrees F, which they felt was too fast; This is a spontaneous report from a contactable physician. A male patient of an unspecified age started to receive bnt162b2 (BNT162B2) , via an unspecified route of administration on 17Dec2020 at single dose for immunisation . The patient medical history and concomitant medications were not reported. The patient experienced had an immediate temperature of 100.8 ¦F, which they felt was too fast . The patient resulted positive to Covid 19 virus immediately after receiving the vaccine when the temperatura was 100.8¦F. Five minutes later the body temperature was 99.8 ¦F, the patient returned negative the Covid 19. Information about lot/batch number has been requested.

At one and a half hours after receiving her vaccine, developed tongue and throat swelling, went immediately to the ER. She was treated in the ER and was discharged to home with EPI pen. She still has the following symptoms headache, dizziness, lightheaded, fever 99.2. Difficulty concentration and talking. She is following up with her primary care physician on 12/21/2020

approx. 5 minutes after injection, palms were itchy and lips felt tingly. After 30 min observation, pt returned home and noticed her lip felt tight. When she looked in the mirror, she saw one side was swollen.

This is a CCU nurse who received vaccine on 12/18/20 and later that day while at work developed nausea, vomited x1, became tachy and pale. Coworkers provided basic care. Patient went to ED at approx. 4p that day and was later discharged.

Severe fatigue; Myalgia; Head aches; Weakness; This is a spontaneous report from a contactable other hcp reporting for himself. This 33-year-old male patient received the first dose of bnt162b2 (BNT162B2),

intramuscular at single dose in the left arm on 16Dec2020 12:00 at hospital for immunisation. Medical history included atypical cluster headaches. Concomitant medication included docusate sodium (COLACE), verapamil and vitamin D3. On 16Dec2020 18:00, the patient experienced severe fatigue, myalgia, head aches, weakness. No treatment required. The outcome of the events was recovering. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, the patient has not been tested for COVID-19. Information on the lot/batch number has been requested.

15 minutes after vaccination Employee began to experience light headiness, and rapid dehydration

approx. 10 min after injection felt light headed, flushed, and pre syncope. BP and HR were taken by staff and ER physician,, BP was hypertensive for me 145/90, 145/104, 137/89, 138/86, 132/91. I am normally 116/74. HR was 100. Oxygen was 100%, At 12;33 was given 50mg IM x 1 Benadryl. 12:40 felt loopy and shakey. 12:54 moved to room in PACU and monitored by nurse. BP remained in the 130-140's until appox 1430 BP returned to normal 118/80 and Benedryl had worn off. My co-worker took me home.

Left facial nerve tingling; discomfort especially around orbital area and cheek; discomfort especially around orbital area and cheek; Left posterior neck and head discomfort; Left posterior neck and head discomfort; This is a spontaneous report from a contactable Nurse reporting for herself. A 54-years-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK5730), intramuscular in left deltoid at hospital on 16Dec2020 08:45 at single dose for COVID-19 immunization. The patient was not pregnant at the time of vaccination. Medical history included colitis ulcerative as a child, colectomy total 27 years before. The patient previously experienced allergy to IV contrast as hives. Concomitant medication included loperamide hydrochloride (LOMOTIL) and bifidobacterium breve, bifidobacterium infantis, bifidobacterium longum, lactobacillus acidophilus, lactobacillus bulgaricus, lactobacillus paracasei, lactobacillus plantarum, streptococcus thermophilus (VSL#3). The patient experienced left facial nerve tingling, discomfort especially around orbital area and cheek; left posterior neck and head discomfort lasting 60-90 minutes on 16Dec2020 18:00 with outcome of recovered on 16Dec2020. The events resolved on own, no medications taken. Prior to vaccination the patient was not diagnosed with COVID-19 and has not been tested for COVID-19.

hives on hands that appeared next morning and still remain 3 days post vaccination

hives on hands that appeared next morning and still remain 3 days post vaccination

Sore arm; This is a spontaneous report from a contactable consumer reporting for herself. A 63-years-old female patient received the first dose on BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration in the right arm on 15Dec2020 at 16:30 at single dose for COVID-19 immunization. Medical history included chronic angioedema and hops allergy. Concomitant medication included simvastatin (SIMVASTATIN), losartan (LOSARTAN). The patient experienced sore arm on an unspecified date with outcome of recovered. The patient was not treated for the event. Prior to vaccination the patient was not diagnosed with COVID-19. The patient underwent sars-cov-1 test (nasal swab) with unknown results on unspecified date and negative on 16Dec2020. Information on lot/batch number has been requested.

"stomach upset and then felt ""hot and cold"" and Temp was 99.3. Relieved with Tylenol and sleep. Next morning felt ""blah"" and slept and symptoms resolved"

Itching all over

Nurse reports that patient had no problems after receiving vaccination. Patient went home and EMS was called early the next morning and team administered vaccination was contacted physician that the associate works for stating the patient had a heart attack.

Nausea, lightheaded, some throat swelling, difficult to swallow. Transported to ED. No respiratory distress. Stable

Nausea; vomiting; diarrhea; This is a spontaneous report from a contactable consumer. A 42-year-old male patient received first dose of BNT162B2 (Pfizer-BioNTech COVID-19 mRNA vaccine, lot number: EH9899), via an unspecified route of administration at arm left on 16Dec2020 at 12:30 at single dose for immunization. Medical history included hyperlipidemia from an unknown date and unknown if ongoing. Concomitant medication included rosuvastatin calcium (CRESTOR) and finasteride. On 16Dec2020 at 22:30, the patient experienced nausea, vomiting and diarrhea. The patient outcome of the events was recovering. No follow-up attempts are possible. No further information is expected.

On 12/20/2020 I received the Pfizer covid vaccine at 3pm and 10 minutes after vaccine, felt tingling and a heavy sensation on my right eye. Was seen in ER at same facility. Per MD, no facial asymmetry noted and was sent home. On 12/21/2020, I woke up with mild right facial numbness and sensation of heaviness and very subtle right labial dropping. When closing my eyes tight felt the muscles of my right eye were mildly weaker but I was able to close my eye. I presented to the ER. Blood work normal and per MD, did not feel the need for steroids and told to monitor at home. Since then, the sensation on my right cheek is slightly better, my eye still bothering me slightly and the numbness still present but a bit less.

random metallic smell; This is a spontaneous report from a contactable physician (patient herself). A female patient of an unspecified age received bnt162b2 (lot number: EK5730; Expiration date: 31Mar2021), via an unspecified route of administration on 17Dec2020 at single dose for immunisation. The patient's medical history and concomitant medications were not reported. About a half hour later, the patient experienced random metallic smell on 17Dec2020. The outcome of event was unknown.

Body/joint pain Headache Joint Stiffness Injection site pain and soreness of the arm malaise Symptoms begin approx. seven hours after the injection and continues

Runny nose, sore throat

headache; dizziness; nausea; This is a spontaneous report from a contactable other health professional. A 56-year-old female patient received bnt162b2 (BNT162B2), via an unspecified route of administration on an unspecified date at single dose for immunization. The patient medical history was not reported. The patient's concomitant medications were not reported. The patient experienced headache, dizziness and nausea on an unspecified date with outcome of not recovered. The patient received the vaccine in

the emergency department. The reporter stated that the symptoms began immediately after getting the vaccine and are persisting. Information about batch/lot number has been requested.

Migraine (similar to the one I experienced when I had COVID in July/August) began a few minutes after the shot was adminstered. It started mild but continued to get worse. It started to get better the following night (12/16/2020) and was gone by the time I went to bed. The day after I got the shot I felt extremely nauseous when I woke up. It was bad enough that I missed two days of work. This lasted for several days and only just went away completely today (12/21/2020. I took ondansetron to treat the nausea. I felt lightheaded and fatigued around the same timeframe as the nausea, but did not use anything treat either. I am not a regular caffeine drinker but tried it every day to help combat the fatigue. It did nothing to help and made me anxious. I still do not feel great but I am well enough to work.

Fever (100 degrees Fahrenheit); Violent chills; she was shaking/Her hands shake terrible; she slept the entire night, which she never does; This is a spontaneous report from a contactable consumer reporting for herself. A 72-years-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), intramuscular in the left deltoid on 16Dec2020 08:05 at single dose for COVID-19 immunization. Medical history was none. There were no concomitant medications. The patient experienced fever on 17Dec2020 with outcome of not recovered, violent chills on 16Dec2020 19:00 with outcome of recovering. The reporter described the events as pretty bad violent chills where she was shaking, and she could not get warm. Her hands shake terrible. She did not realize she had a fever until she slept the entire night through 16Dec2020-17Dec2020 which she never does. She took her temperature after she woke on 17Dec2020 09:50am and her temperature was 100 degrees Fahrenheit which is her ongoing temperature at time of the call. She asked if there are any recommendations regarding treatment or management of fever following administration of the vaccine; like if it is ok to take Tylenol or something. Information about lot/batch number has been requested.

Nausea, headache, epigastric pain, feeling flushed, metallic taste

5 days after vaccination on 12/20, patient developed a mild, erythematous rash on left hand (dorsal) and forearm. The character of symptoms is redness, no pain, no itching, and no swelling. Radiating symptom(s): spreading proximally. The degree of symptoms is minimal.

Initial arm pain, then nausea and dizziness while at work 2 hours after administration. Presented to the emergency department at the same facility where he works as instructed per occupational health. Symptoms were almost fully resolved 3 hours after receiving the vaccine, after a dose of ondansetron. Patient discharged and instructed to follow up with primary MD.

tiredness; This is a spontaneous report from contactable pharmacist via Pfizer sales representative. A 50-year-old patient of an unspecified gender received the first dose of bnt162b2 (BNT162B2; lot and expiry date was not reported) via an unspecified route of administration on an unspecified date at a single dose for immunization. Medical history was reported as none. The patient's concomitant medications were not reported. The patient experienced tiredness on an unspecified date following

administration of bnt162b2 vaccine. Outcome of the event recovered on an unspecified date No follow-up attempts are possible; information about lot/batch number cannot be obtained.

Felt like I had covid. Headache, nausea,light headed, hot and could not cool down. Overall tried. This was the next day after receiving vaccine.

Sore arm after injection; This is a spontaneous report from a non-contactable pharmacist received via a Pfizer sales representative. A 32-year-old female patient received BNT162B2 (solution for injection, lot number/expiration date unknown) via an unspecified route of administration on her arm in Dec2020 at a single dose for immunisation. Medical history and concomitant medications were not reported. The patient experienced sore arm after injection in Dec2020. The outcome of the event was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

10 minutes post-vaccine - tingling in both arms, all the way down arms. Right arm subsided after 20 minutes, but left arm continued to be warm and tingly. Left leg and foot tingly. 2 hours post-vaccine - Left side of face warm and tingly. Left back muscles heavy and fatigued, 24 hours later subsided. 12/21/20 - Left forearm to pinky tingling, palm numb. Left side of face pink and heavy.

Swollen, painful right armpit. It was present Sunday 12/20/2020 when I woke up. It has not reduced or improved over 24 hours.

Nausea was first noted followed by a sudden tachycardia with pulse in the upper 130's. With this my tongue and mouth began to tingle and it felt like I had something stuck in my throat. The facility gave me liquid benadryl immediately (50mg). Symptoms began to improve over the hour and a half that I was monitored and had fully resolved 3 hours post injection.

"feel lightheaded; I have a bright red, itchy, raised and warm welt at the injection site as well; Pain and itching at the injections site immediately; Pain and itching at the injections site immediately; Throat tightness across the front; Tongue began to tingle, felt a little ""fat"" and then went numb for approximately 3-5 minutes; Swallowing feels like a ""lump"" in my throat, but does feel obstructed; I have a bright red, itchy, raised and warm welt at the injection site as well; This is a spontaneous report from a contactable Nurse who reported for herself. A 51-years-old female patient received the first dose of bnt162b2 (BNT162B2, lot number EK5730), intramuscular in the left arm at hospital on 17Dec2020 09:45 at single dose for immunisation. The patient medical history and concomitant medications were not reported. The patient previously took bacitracin zinc, neomycin sulfate, polymyxin b sulfate (NEOSPORIN) and experienced rash. The patient experienced pain and itching at the injections site on 17Dec2020 at 09:45 (reported as immediately), lasted approximately 3 hours (as reported), the final outcome was recovering (as reported). Throat tightness across the front, but not ""inside."" Tongue began to tingle, felt a little ""fat"" and then went numb for approximately 3-5 minutes. Swallowing felt like a ""lump"" in her throat, but did feel obstructed. Ate lunch without difficulty. Drinking without difficulty. The front of her throat, distal from jawline, to top of breast-line felt like she had a very light weight resting on it, even 8 hours post injection. Approximately 30 minutes after injection, the patient began to feel lightheaded. Lightheadedness became more intermittent for the next 4 hours and resolved. She had a bright red, itchy, raised and warm welt at the injection site as well, 8 hours later, on

17Dec2020. The patient did not receive any treatment for the events. The outcome for the event lightheaded was recovered, for the other events was recovering. Prior to vaccination the patient was not diagnosed with COVID-19 and has not been tested for COVID-19.; Sender's Comments: The reported information is limited. Based on the close temporal relationship and the description of the events, there is a reasonable possibility that the events are related to BNT162 vaccine. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate."

Sudden consent of right sided facial numbness paralysis

About 4 hours after the vaccine during dinner felt tired. Around 11, midnight I felt achy, body hurts, I had chills, and developed cough and shortness of breath. By Thursday I felt horrible and now I can not even taste or smell anything. My body aches are gone I feel somewhat better. No shortness of breathe and no cough, still fatigued. Took Ibuprofen and Tylenol on Thursday Friday and Saturday. Was tested for COVID on 12/18 - tested positive.

Uncontrollable chills; Fever; Headache; Arm is sore a bit; This is a spontaneous report from a contactable consumer (patient). A patient of unspecified age and gender received BNT162B2 (Pfizer-BioNTech COVID-19 vaccine), via an unspecified route of administration at on an unspecified date at single dose for COVID-19 immunization. Medical history included Covid. The patient's concomitant medications were not reported. On 16Dec2020, Last night, about 12 o' clock, patient woke up with the same side effects that patient had Covid. Patient had uncontrollable chills and a fever. Those were better. Patient still had a headache. Of course, his/her arm was sore a bit, that was expected. Outcome of uncontrollable chills and fever were recovering, outcome of other events was unknown. Information on the lot/batch number has been requested.

Swelling and redness in my left eye. Severe pressure on the left side of head.

I am breastfeeding my 20 month old and she developed a rash on trunk. Maculopapular.

Right Ear red and purple and warm.

Migraine; Migraine; fatigue; nausea; diarrhea; This is a spontaneous report from a contactable consumer reported for herself. A 36-year-old female patient received the first dose of BNT162B2 (Pfizer product, lot number EH9899) , via an unspecified route of administration on 15Dec2020 13:30 at single dose on left arm for immunisation. Medical history included migraine. There were no concomitant medications. No allergies to medications, food, or other products. No other vaccines in four weeks and no other medications in two weeks. The patient experienced migraine, fatigue, nausea, diarrhea starting the following day around 10 am (16Dec2020 10:00). The patient was not pregnant. No Covid prior vaccination, and no Covid tested post vaccination. No treatment was received for the events. The outcome of the events was resolved on an unspecified date in Dec2020. The report was assessed as non-serious.

"Date: 12/21/2020 á Subjective Patient is a 33 y.o. female who was seen at COVID Vaccine Clinic today for her first dose of the COVID 19 vaccination. á She denied any history of previous adverse reactions to vaccines. á She was given the Pfizer vaccination in the left deltoid muscle. á During her 15 minute waiting period after the injection, the patient began to experience feelings of hypoglycemia. She checked her blood glucose with her own monitor and had 77 at 1104. She chewed 1 glucose tab that she had in her purse. She noted some difficulty with swallowing it and notified clinic staff. Associated dizziness and was escorted by clinic staff to the emergency bay. á This provider was notified of patient reaction and she was then assessed in the emergency bay area. She denied difficulty breathing and chest pain, history of adverse reactions with prior vaccinations or allergies to medications with the exception of spironolactone. á Pateint had already been given a bottle of water by clinic staff and reported that the glucose tablet went down easier following the water. She took a second glucose tab sometime before 1113. She rechecked her sugar and had slight increase of 79. She did eat breakfast this morning about 0800 and had a protein bar right before her arrival today. á Monitored patient for severe reaction symptoms, including rapid progression of symptoms, respiratory distress with dyspnea and increased work of breathing, vomiting, abdominal pain, hypotension and chest pain. á Review of Systems HENT: Positive for trouble swallowing. Negative for facial swelling, hearing loss, rhinorrhea and voice change. Eyes: Negative for redness. Respiratory: Negative for cough, chest tightness and shortness of breath. Cardiovascular: Negative for chest pain. Skin: Negative for color change, pallor and rash. Neurological: Positive for dizziness. Negative for syncope and speech difficulty. Psychiatric/Behavioral: Negative for agitation and confusion. The patient is not nervous/anxious. á Objective Vitals There were no vitals filed for this visit. á á Physical Exam Constitutional: General: She is not in acute distress. HENT: Head: Normocephalic and atraumatic. Nose: No rhinorrhea. Cardiovascular: Rate and Rhythm: Normal rate and regular rhythm. Pulmonary: Effort: Pulmonary effort is normal. No respiratory distress. Skin: General: Skin is warm and dry. Coloration: Skin is not pale. Findings: No rash. Neurological: Motor: No weakness. Psychiatric: Mood and Affect: Mood normal. Behavior: Behavior normal. á á á Assessment/Plan Patient is a 33-year-old female who has a 15-year history of type 2 diabetes, and experienced a hypoglycemic event without complaint of chest pain or shortness of breath. á Vital signs obtained at 1105 with blood pressure within normal limits at 132/88, heart rate 83 and 98% O2 saturation on room air. Patient continued to compensate appropriately and reported feeling slightly better. Glucose checks repeated by patient at 1117 was 84, vital signs were blood pressure 116/80, heart rate 89, O2 saturation of 98% on room air. She continues to deny chest pain, shortness of breath or difficulty swallowing at this time. á At 1117 a 10 mg cetirizine was administered by mouth. Patient was able to swallow this with a small sip of water without any difficulty. á 1121, patient continues to deny chest pain or shortness of breath. She continues to be compensating appropriately and sitting at the edge of the bed. She states that she is feeling better. á Vital signs obtained at 1123 with blood glucose per the patient's own meter, continuing to elevate at 103, blood pressure within normal limits at 116/91, heart rate at 85 and 100% O2 saturation on room air. á At 1126, the patient continues to feel better. She is provided a granola bar to eat. She does note feeling sleepy though attributes this to this being the first day she has had off after working 4 days last week. She notes that she has been sleepy even prior to her arrival at the vaccine clinic today. She is able to eat the granola bar and continues conversing appropriately without difficulty. She continues taking small sips of water without issues. Continues to deny chest pain or shortness of breath. Blood sugar is rechecked at 1138 and continues to

elevate to 116. She reports that her meter says her sugar is ""stable."" á Final set of vital signs obtained at 1138 revealed blood glucose within normal limits at 116, blood pressure of 119/84, heart rate 83 and 100% O2 sats on room air. Patient denied complaints of chest pain, shortness of air, nausea, dizziness or blurred vision at this time. She felt much improved and we discussed her leaving the clinic and heading home to have lunch. She had no further complaints. She was able to rise to standing on her own without any further issues and ambulated out of the clinic without difficulty. á She was advised with strict return precautions should she develop chest pain or shortness of breath to present to the ED or call 911. She expressed understanding of this. á LPN, RN, PharmD present through this encounter and assisted as asked of the, by this provider. á Follow up response to treatment:excellent. á Patient discharge: Stable to go home and follow up with PCP. á Orders Placed This Encounter Procedures ? COVID-19 MRNA LNP-S PF á PA-C Electronically Signed 12/21/2020 11:17 AM á á"

Burning at injection site followed by tachycardia and lightheadedness within 2 minutes. Lasted over half an hour

sore arm; This is a spontaneous report from a contactable pharmacist (patient). A 35-year-old female patient (who happened to be a pharmacist) received BNT162B2 (Pfizer-BioNTech COVID-19 vaccine), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced a sore arm following administration of Covid 19 vaccine on an unspecified date with outcome of unknown. No follow-up attempts are needed. Information about lot/batch number cannot be obtained.

Patient has known anxiety and diabetes. Blood glucose 220 - patient admitted that they had not taken DM medications. Patient did not required any medication.

EE stated that she started feeling itchy within 30 minutes of receiving her vaccine but she didn?t tell anyone because it was not bad, the next day she noticed a rash on her chest (left side), it then spread down the left side of torso to the left leg, EE has a history of eczema and took her prescribed steroid, she also started using hydrocortisone cream on her rash, no reported fever, EE stated that she was fatigued with body aches and joint pain, EE does not have a history of Covid positive testing, she has not been around anyone with Covid, she has not traveled or live with anyone who has traveled, She stated that she went to see her PCP today, 12/21/2020 and was instructed to continue the hydrocortisone cream and do not get the 2nd dose of the Covid Vaccine.

36 hours after injection lymph node pain in back of neck, this flared my trigeminal neuralgia. Took 800 Ibuprofen 1 hour later that pain stopped and massive headache. Headache was followed by drunken type vertigo. I took 20mg steroid, Benadryl, Afrin, Albuterol. Two hours later better but still had vertigo. By 4am symptoms light enough to do light work out, legs felt fatigued. Today no symptoms.

Injection site pain; myalgia; arthralgia; congestion; neck pain; fatigue; This is a spontaneous report from a contactable consumer (patient). A 62-year-old male patient received first dose of bnt162b2 (lot number EK5730), via an unspecified route of administration in arm left on 16Dec2020 07:15 at single dose for immunization. Medical history included hypertension and CAD (coronary artery disease). Patient had no allergy history to medications, food, or other products. Concomitant medication included

ticagrelor (BRILINTA), lisinopril, acetylsalicylic acid (ASA), ergocalciferol (VIT D) and magnesium (MAGNESIUM). Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. The patient experienced injection site pain, myalgia, arthralgia, congestion, neck pain, fatigue all on 16Dec2020 20:00. Treatment paracetamol (TYLENOL) were taken as a result of reported events. The outcome of the events was recovering.

Left arm feels swollen - resolved on own.

Developed numbness and tingling to face, forehead and lips about 45 minutes after administration. Everything but nose resolved in 5-10 minutes but nose remained feeling numb - had some sensation but not normal. 2 1/2 hrs later felt like it was continuing to improve, but not normal yet.

Patient developed hives 30 minutes after receiving injection. Received Benadryl and seen in ER for evaluation. No further issues reported.

About 5-7 minutes after the injection, I was sitting in the waiting area for my 15 minutes observation period. After about 5-7 minutes I noticed that it was hard for me to swallow and I became really flushed and hot and tachycardia. I was not anxious or upset about getting the shot. I am actually an ER physician and have had lots of shots in my life without any adverse reaction. The flushing and tachycardia resolved after about 20 minutes but the sensation of difficulty swallowing did not subside completely until I took dose of Benadryl 50mg orally. Symptoms resolved after about 1 hour post Benadryl. I also had a recurrence of symptoms the next day at around 24 hours where I felt again like I couldn't swallow, so I took Benadryl 50mg again, but this time I also had some numbness of the left side of my tongue and the left side of my face. The abnormal sensation in the left side of my face subsided over about an hour or so.

lots of pain on the site radiating from shoulder to hands; lots of pain on the site radiating from shoulder to hands; lots of pain on the site radiating from shoulder to hands; swelling; This is a spontaneous report from a contactable consumer. A male patient of an unspecified age received bnt162b2, via an unspecified route of administration on an unspecified date at single dose for immunisation. The patient's medical history and concomitant medications were not reported. The patient experienced lots of pain on the site radiating from shoulder to hands and swelling on an unspecified date. The outcome of event was unknown. Information on the Lot/Batch number has been requested.

headache; dizzy; ringing in her ears for hours -high pitched ring; sore arm where injection was administered; This is a spontaneous report from a contactable nurse (patient). A 28-year-old female patient (not pregnant) received first dose of bnt162b2 via intramuscular in arm right on 17Dec2020 11:30 at single dose for immunization. The patient medical history was not reported. The patient had no medications, food, or other products allergy history. The patient's concomitant medications were not reported. The patient reported 8 hours after administration of vaccine, on 17Dec2020 8:00 pm, the patient started to get a headache then dizzy then ringing in her ears for hours -high pitched ring, and sore arm where injection was administered. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. No treatment was

received in response for reported events. The outcome of the events was recovering. Information on the lot/Batch number has been requested.

"complained of ""chest tightness"" after receiving the vaccine; being nervous; This is a spontaneous report from contactable Pharmacist. A patient of unspecified age and gender received bnt162b2 (Pfizer-BioNTech COVID-19 Vaccine), via an unspecified route of administration in 2020 at single dose for immunization. The patient's medical history and concomitant medications were not reported. The patient (healthcare worker) received the Pfizer-BioNTech COVID-19 vaccine in 2020 and complained of chest tightness after receiving the vaccine. Chest tightness resolved quickly and the patient attributed it to being nervous. No medical interventions were received and the patient left the observation area without issue. The outcome of the events was resolved in 2020. Information about lot/batch number has been requested."

feeling tired; achy; This is a spontaneous report from a contactable consumer. This consumer reported similar events for two patients. This is 1st of two reports. A patient of unspecified age and gender received bnt162b2 (Covid-19 vaccine) , via an unspecified route of administration on 16Dec2020 at single dose for immunization. The patient's medical history and concomitant medications were not reported. The consumer had two friends who are health care professionals who received the Covid-19 vaccine on 16Dec2020. They just reported feeling tired and achy in Dec2020 to the consumer. The outcome of the events was unknown. Information on the Batch/Lot number has been requested.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2020501305 same reporter/drug/event, different patient

feeling tired; achy; This is a spontaneous report from a contactable consumer. This consumer reported similar events for two patients. This is 2nd of two reports. A patient of unspecified age and gender received bnt162b2 (Covid-19 vaccine) , via an unspecified route of administration on 16Dec2020 at single dose for immunization. The patient's medical history and concomitant medications were not reported. The consumer had two friends who are health care professionals who received the Covid-19 vaccine on 16Dec2020. They just reported feeling tired and achy in Dec2020 to the consumer. The outcome of the events was unknown. Information on the Batch/Lot number has been requested.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2020501278 same reporter/drug/event, different patient

Left arm swelling; rash throughout body; left leg going numb; loss of balance; This is a spontaneous report from a contactable Other healthcare professional reported for herself. A 22-year-old non-pregnant female patient received first dose of bnt162b2 (pfizer-biontech covid 19 vaccine), intramuscularly on left arm on 17Dec2020 at 08:30 at single dose for immunization at workplace clinic. Medical history included known allergies to watermelon, cantaloupe, honey dew, kiwi. There were no concomitant medications in two weeks nor other vaccine in four weeks. There is no prior covid vaccination nor covid tested post vaccination. The patient experienced left arm swelling, rash throughout body, left leg going numb, loss of balance on 17Dec2020 at 09:15 with outcome of unknown. No treatment was received for the events. Information on the lot/batch number has been requested.

Physician receiving Pfizer BioNTech COViD 19 vaccine experienced sore arm; This is a spontaneous report from a contactable physician (patient) via Pfizer sales representative. A patient of unspecified age and gender received BNT162B2, via an unspecified route of administration in 2020 at single dose for immunization. The patient's medical history and concomitant medications were not reported. The physician receiving pfizer biontech covid 19 vaccine experienced sore arm within 24 hours of receiving vaccination dose in 2020 with outcome of unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

Pain in injection site; slight nasal congestion; This is a spontaneous report from contactable Nurse (patient) via Pfizer Sales Representative. A 27-year-old female patient received BNT162B2 (Pfizer-BioNTech COVID-19 vaccine), via an unspecified route of administration on an unspecified date at single dose for immunization. The patient's medical history and concomitant medications were not reported. The patient experienced pain in injection site, and slight nasal congestion on an unspecified date with outcome of unknown. Events took place after use of product. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

Has pain around injection site of COVID vaccine; This is a spontaneous report from a non-contactable Physician. A patient of unspecified age and gender received BNT162B2 (Pfizer-BioNTech COVID-19 vaccine), via an unspecified route of administration on an unspecified date at single dose for COVID vaccine. The patient's medical history and concomitant medications were not reported. The patient had pain around injection site of COVID vaccine on an unspecified date with outcome of unknown. No follow-up attempts are possible. Information about lot/batch number cannot be obtained.

sent to the emergency room for body rashes and hives.; sent to the emergency room for body rashes and hives.; This is a spontaneous report from a contactable pharmacist. This pharmacist reported similar events for 4 patients. This is a third of four reports. A patient of an unspecified age and gender received BNT162B2(Solution for injection) via an unspecified route of administration on an unspecified date at single dose for immunization. The medical history included allergies to bee stings. The patient's concomitant medications were not reported. The patient sent to the emergency room for body rashes and hives. The outcome of the events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2020502532 same reporter, drug, event different patient

Mild throat swelling, not enough to obscure airway, went home and took Benadryl and went to sleep. Symptoms gone post nap (also had fatigue and mailase both gone after nap)

flushed face, shortness of breath, feeling like I was going to pass out, tightness in my throat but could still swallow, had heart palpitations and feeling like my heart was going to come out of my chest. Those symptoms lasted for about 5-10 minuets and slowly the flushed feeling went away and heart stopped racing after about 10 min. I was very shaky and still had a bit of tightness in my throat. I left the area out 40min but was still very jittery. Currently its 1510 and I still have some localized flush feeling in my cheeks and continued jitteriness but am breathing fine.

Fatigue Headache Pain at injection site

Approx 5 hours after receiving vaccine, developed an aching sharp pain between my shoulder blades worsening with inspiration, intermittent mild chills, and fatigue. Pain between my shoulder blades lasted 4 hours, until i took tylenol and went to bed.. i woke up 5 hours later and the pain was now a dull ache.

Fatigue: 18 hours after injection to current time. Dizziness: 24 hours to current time, Vertigo: 36 hours to current time, subsiding with use of Dramamine Nausea: coincides with the dizziness/vertigo Spoke with PCP office 3 times who referred me back to hospital, the provider of the vaccination. Hospital COVID-19 Incident Command pulled me from employment until I get a back to work note from my PCP. PCP states this is a Hospital issue, they pulled you, they need to reinstate you. Hospital Occupational Health agrees in principal and is working on an outcome.

Chest pain and diffuse, severe myalgias, as well as persistent tachycardia to 110's and hypertension resulting in ER evaluation. No abnormalities found on basic labs and studies. Symptoms started one hour after injection and worsened over the next 24 hours.

The evening of the shot, patient reported he had headache and nausea. Next day nausea and Headache continued and also included Body aches, chills, achy joints which lasted for 3 days.

Flushing Hives Nausea Heartburn Throat itching and swelling Hot flash Blood pressure and pulse spiked All of this happened within 5 minutes of administration. Patient was given benedryl and Pepcid and sent to the Emergency Room.

-Sore injection arm (left) starting at 4pm on day of injection (12/16/20) and resolved on 12/20/20. -Chills starting at 5pm on second day (12/17/20) and resolved on 12/18/20.

"PATIENT REPORTS RECEIVING VACCINATION AT APPROXIMATELY 830AM. SHE WAS BUSY THROUGHOUT THE DAY BUT ONCE SHE RETURNED TO HER OFFICE AROUND 120 PM, SHE STARTED TO NOTICE HER ARM IN WHICH SHE RECEIVED HER VACCINE WAS PAINFUL AND SHE WAS UNABLE TO ""LIFT IT UP"". SHE ALSO NOTICED HER TONGUE BEGAN TO FEEL ""WIERD AND TINGLY"". SHE THEN REALIZED HER TONGUE WAS PUSHED UP AGAINST HER TEETH AND COULD SEE A VISIBLE TOOTH MARK ON HER TONGUE. SHE ALSO REPORTS THAT HER BRAIN FELT ""FOGGY"" DURING THIS TIME"". ADDITIONALLY, SHE REPORTS THAT ONSENT OF ALL HER SYMPTOMS PRESENTED PROGRESSIVELY. SHE RECIEVED IM BENADRYL ONSITE PRIOR TO TRANSFER TO THE EMERGENCY ROOM FOR EVALUATION. AT THE EMERGENCY ROOM SHE WAS GIVEN THREE MEDICATIONS, SHE RECALLS ONE WAS A STERIOD AND BELIEVES ATLEAST ONE WAS AN ANTIHISTAMINE. HOWEVER, SHE IS NOT COMPELTELY CERTAIN WHAT THE OTHER MEDICATIONS WERE. SHE REPORTED IMPROVEMENT OF SYMPTOMS WITH MEDICATION. SHE WAS PRESCRIBED BENADRYL AND A MEDROL DOSE PAK AT TIME OF DISCHARGE. SHE WAS NOT ADMITTED TO THE HOSPITAL."

headache, dizziness, hypertension, subjective mild shortness of breath, BP 160/100 Taken to the ER for evaluation

"Received COVID-19 vaccine the afternoon on 12-18-2020 on 12-19-2020 developed chest pain and ""heart racing"" intermittently. Lasted approximately 1 hour . Patient did take Nitroglycerin 2 times ."

"Per documentation of other RNs invloved, at 1009, patient began reporting sensation of numbness in right arm and ""feeling funny"", she also presented with visible flushing and reported itching and feeling anxious. We monitored the patient's vital signs q5min and administered 25mg Benadryl IM. Over the course of aproximately 1.5 hours, the patient's flushing had visibly diminished, she reported significant improvement in her anxiety and stated that the itching was ""nearly resolved."" Her vital signs also improved and were WNL, including pulse, O2 saturation, temperature and blood pressure. The patient stated that she felt well enough to return to work and verbalized understanding that if any symptoms develped or worsened she was to report immediatley to the ED."

Injection site pain, malaise, fatigue decreased appetite, chills, joint pain

transient dizziness, history of dizziness with piercings and shots

Staff reported numbness, tingling and heat all the way down her left arm. She was sent to ER for further evaluation and monitoring.

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Fever, headache, body aches, arm pain for two days at site of injection. Approaching 72 hours with fever.

"Patient woke up 3 am next morning and felt like she couldn't move limbs hardly at all and ""felt like a boulder sitting on my chest"". She also felt nauseous, dizzy and a headache. By 5 am the ""heaviness"" of her limbs and her chest and throat felt so heavy patient was scared and was transported to ED by her husband. ED physician didn't think it was an anaphylactic reaction, but just thought it was an extreme adverse reaction. EKG, labs including Cardiac enzymes, and chest xray were all normal. Given IV benadryl, IV zofran, Aspirin, tylenol and norflex. during ED visit. Discharged from ED 10:30 am. Took Benadryl and Solumedrol dose pack once home. by Saturday patient felt 95% better, but as of this report, still says arms still feel heavy and she is fatigued. Went back to work today."

Injection site pain

Vaccine on Wednesday. Sneezing (allergies) around the time of injection. Sore arm for a day. Felt fine on Thursday and Friday. A little off on Saturday. Myalgia, headache w temp of 99 on Sunday. Took Tylenol at 2000 and went to bed. Did not sleep well. Temp at 0400 was 100. Took additional Tylenol. Achfnese returned at 1100 on Monday. No fever. Shaking chills but no fever from 1400-1500. Resolved but temp of 101.2. This is where I am now.

12/18/20 @1400 - light headache 12/18/20 @2100 - extreme soreness at injection site (right arm). Difficulty sleeping on right arm during night. 12/19/20 @1030 - extreme fatigue. Took a 1.5 hour nap and awoke with chills. 12/19/20 @ 1230 - extreme fatigue and chills. Took a hot shower to help relieve chills. After about 15 minutes in shower, began to sweat profusely and my face was flush. *I did not take my temperature, therefore it is unknown whether or not I had fever, but I would assume so* Finished shower and slept until 1830, but only because my daughter awoke me. I was still tired when I awoke.

12/19/20 @ 2200 - Fell asleep and slept through the night. Awoke at 0930 the following morning and felt better, feeling almost normal by 1200.

Began to feel slight pain at injection site Friday, 12/18/2020, evening and was experiencing significant pain when trying to raise left arm above shoulder height. This sensation subsided by Sunday, 12/20/2020, morning Began to have a numbing sensation in both cheeks, nose, and throat on Saturday, 12/19/2020, early evening. The sensation was similar to that feeling of getting Novocaine at the dentist. There was no facial swelling, no difficulty breathing, no facial drooping, or slurred speech. Began to feel dizzy on Saturday, 12/19/2020, evening and this lasted until Sunday, 12/20/2020, morning. No sensation of nausea or vomiting. I contacted my Director and Occ Health dept as instructed. Occ Health felt that these symptoms may be an inflammatory response to the vaccine, I was advised to take Motrin to see if any relief could be obtained. Minimal numbness noted in mouth and nose on Monday, 12/21/2020.

Injection site pain. No redness or swelling. Fatigue, dizziness, lightheadedness, night sweats, body aches.

Shingles right arm 2 days after COVID 19 vaccination. Evaluated 12/21 and prescribed topical acyclovir and oral vatrex 1g TID x 7 days. Labs obtained and pending (CMP, CMP, ESR, CRP, Zoster IgG,M, viral swab)

Within two minutes of receiving the vaccine I experienced tachycardia and dizziness that were severe for approximately five minutes and improved over the subsequent ten minutes. Beginning approximately twenty minutes after receiving the vaccine I experienced another bout of dizziness accompanied by chest tightness. This resolved within approximately ten minutes.

I had nausea starting about 2 hours post vaccine and 7 hours later I was vomiting, I had Zophran I was taking and was still unable to keep anything down tuesday in the AM. I had a Teledoc appointment and was prescribed 2mg of sinofren, I was still vomiting with both meds until saturday morning and since then I've had nausuea that have been getting lighter everyday since. I am back to being able to eat solid food with light use of the Zophran

Patient is a 72 y.o. female who was seen at COVID Vaccine Clinic today for her first dose of the COVID 19 vaccination. á She denied any history of previous adverse reactions to vaccines. á She was given the Pfizer vaccination in the right deltoid muscle. á During her 15 minute waiting period after the injection, the patient began to experience lightheadedness and tingling to right upper and lower arm. Also c/o pain to mid forearm. She denied hives, difficulty breathing, difficulty swallowing, wheezing, throat tightness, itching and tongue swelling. When walking to the emergency bay reports some lightheadedness and generalized weakness Denies facial drooping or weakness. No loss of strength and normal ROM to hand and arms á This provider was notified of patient reaction and she was then assessed in the emergency bay area. á á Monitored patient for severe reaction symptoms, including: rapid progression of symptoms, respiratory distress with dyspnea and increased work of breathing, hypotension and chest pain á Review of Systems á á Objective á Vitals Vitals: á 12/18/20 1023 12/18/20 1025 BP: (!) 175/93 (!) 182/85 BP Location: Left arm Left arm Pulse: (!) 115 (!) 112 á á Physical Exam Constitutional: General: She is not in acute distress. Appearance: She is not ill-appearing. HENT: Head: Normocephalic. Mouth/Throat: Mouth: Mucous membranes are moist. Pharynx: Oropharynx is clear.

Cardiovascular: Rate and Rhythm: Normal rate. Pulses: Normal pulses. Pulmonary: Effort: Pulmonary effort is normal. Comments: Initially with slight shortness of breath After 3-4 min was able to return to normal rate of breathing SpO2 remained 99-100% for duration of observation Musculoskeletal: Right shoulder: She exhibits tenderness (where identified). She exhibits normal range of motion, no swelling, no effusion, no deformity and normal strength. Arms: Comments: C/o generalized tingling and mild weakness to right arm. Point tenderness where identified. Grip strength equal bilaterally Full ROM Injection site to right deltoid covered with bandaid Skin: General: Skin is warm. Capillary Refill: Capillary refill takes less than 2 seconds. Neurological: Mental Status: She is alert. á á Assessment/Plan á Treatment included antihistamines. Zyrtec given po at 1025 Follow up response to treatment:no change Patient discharge: Transported by ambulance á Report provided for Medical Record Patient reports some improvement in arm tingling, but pain to forearm and weakness remains á APRN Electronically Signed 12/18/2020 11:31 AM á á

Flu like systems, chills, headache , fatigue . Next morning I had a headache for the rest of the day .

Tingling in the back of throat with possible decreased ability to breathe and swallow. She was given oral Benadryl, 2 doses of IM Epi. Reaction improved. She was sent to the ER to be evaluated. Received IV Decadron. Clinically improved. Discharged home on Decadron, Zyrtec and Pepcid as well as an Epi pen. Discussed to follow up with primary care physician.

4 hours after injection, got right medial subconjunctival hemorrhage, 14 hours after injection, experienced chills, headaches x 2 days

On 12/19/20 Woke up at 4:30 , 3 hours after going to bed (9.5 hrs after receiving vaccination) with left arm throbbing. Was nauseated, whole body violently shaking, feverish (never took temperature). States he could not control shaking. Lasted about 30 minutes, could barely walk. Afterwards felt achy and very weak. Felt better on awakening, but whole body aching and weakness returned around 600PM and again at 1000PM. Took Tylenol/Ibuprofen for relief. On 12/20 at 600PM also experienced whole body aching and felt generally poorly. 12/21/2020 Doing well today.

She c/o of numbness and tingling on left side of entire body. 98.8, 92,142/84, o2 sat 99, rr 16. denied other compliant. emerenccy response team called. taken to ED

Minor pain and swelling at injection site, mild fever responsive to tylenol, fatigue. Fully recovered from all side effects at 48 hrs. Reporting only due to the fact that this is a new vaccine for tracking purposes.

Metallic taste in her mouth Itchiness to site, then progressed to whole body and back pain Arm pain

10 minutes after vaccine, leg itching, checked for redness. Between 2200-2330 swelling of tongue, and lips swelling, administered epipen and prednisone. No 911 or did not notify her PCP. Today she feels fine but still has fine pink rash over body.

Following vaccine, pt became nauseated and lightheaded. Offered water. Refused need to lie down

Patient reports redness and swelling around the injection site the size of an egg in terms of shape. She also reported red fingerlike projections that wrap partially around the arm. Offered patient acetaminophen and patient declined. She would prefer to ice injection site. She is to follow up with provider if issue persists or worsens

Right arm weakness; heavy chest. Given Orange juice due to low blood sugar, transported to ED.

Hives, rash, and tingling to lips 14 minutes post injection

Injection site / l arm soreness - 2-3days Headache - 2 days, treated with Tylenol

12/17/2020 deep sharp pain in my arm and not just at the injection site it was the entire upper arm where I couldn't pick up my daughter. I took tylenol 12/18/2020 and within an hour later I had no pain in my arm and I was fine

palpitations, shortness of breath, warmth in throat

Rash with itch to the extremities (upper and lower) as well as itch/ irritation to the vaccination site (right upper arm/ deltoid

45 minutes after receiving injection I got generalized large hives all over my body, my chest started to feel tight, and under my chin up to my bottom lip felt numb and tingly. Took 50mg Benadryl, Zyrtec, and Pepcid, symptoms subsided. Went to ER for follow up and they prescribed me 18 days of tapering prednisone and an epi pen, advised me to not get 2nd dose.

12/18/2020 ABOUT 5 MINUTES AFTER VACCINATION, STARTED TO FEEL DIZZINESS. 'IT WAS VERY WEIRD. LIKE I WAS MOVING. I MADE IT TO THE OTHER CHAIR'. I FELT MY LEGS GO NUMB, TINGLING IN ARMS AND LEGS. STAFF CALLED NURSE OVER. TOLD ME TO LIE DOWN ON THE FLOOR, STARTED TO CRY, 'DONT LIKE HOW MY FEET FEEL NUMB'. TOOK ME TO THE ER. TOLD MIGHT BE A 'NASAL VASOVAGAL REACTION'. DIDN'T LOSE CONSCIOUSNESS. BUT THE TINGLING IS STILL GOING ON .

Patient returned back to clinic after her observation time stating she had some heart palpitations and slight chest tightness. Declines medical attention at this time.

About 10 minutes after the injection I started feeling dizzy and hot. Then the headache started with pain moving up my head. Throat became dry. Started feeling nauseous. RN's started to check my vitals. Temperature was at 99.4. O2 was at 99%. Blood pressure was 135-92. Symptoms were not getting better and I started feeling worse. RN (House Supervisor) encouraged going to the ER. Was checked into ER where they gave me Benadryl, Tylenol, Zofran & steroids. Symptoms stayed about the same. Received second dose of Benadryl. Started to feel a little better about 30 minutes after. Spent about 3 hours total in ER. We home to sleep for about 7.5 hours. Woke up the next morning feeling very fatigued with a terrible headache. Continued to dose with Benadryl and Tylenol as needed.

All day Saturday the right side of my face felt tingly and when pressed hurt. Was able to smile, talk and move my face. Tongue tingled a little, and lips (right edge of mouth) off and on until it finally stopped

Sunday morning. Haven?t had any issues with it since then. Never had that happen before, so was a bit concerning.

Extreme dizziness

Paresthesia of part of tongue starting about 5 min. after injection; no swelling or airway problem. No other signs of allergic reaction. Observed x 30 min. w/o worsening. Given 25 mg diphenhydramine as precaution.

"Employee complained of metallic taste in mouth. Then complained of scratchy throat and a feeling of ""throat swollen on the inside"""

"Pt c/o diffuse itching ""all over"" approximately 2 hours after the vaccine was administered. no rash or other sx reported. treated with claritin, water. followed up at end of shift around 4:30 Pm and reports improvement, but still feeling ""itchy"". instructed to take PO benadryl once got home if didn't subside."

Hypersensitivity to touch all over body and joint pain, headache fatigue the day after vaccine administered. No medical intervention warranted

felt nausea, lightheaded and dizzy. developed itching and redness on chest. 25mg benedryl IM administered. Called emergency response. Patient taken to ED. Reports in ED not remembering the events.

Dizziness, Hot flash. Laid supine for 30 minutes, while repeatedly checking blood pressure.

Patient observed for over an hour due to symptom development including complaints of pressure in head, diaphoretic, swelling and increase muscle tone/rigidity in her left arm, tongue feeling thick. Brought to ED for care after an hour of observation. In the ED, left arm rigidity/spasm worsened. Here is the physician note: Patient's headache is improved. She has no neurological deficits or subjective complaints or objective exam consistent with a recurrent CVA. She has no evidence of significant anaphylaxis related to the immunization. May be a recurrence of her underlying medical problems that she has been seen by neurology for something similar. Possible unmasking of this is related to the Covid vaccine is difficult to determine. We will have her work individually with our pharmacy, infectious disease team to determine whether she is a candidate for a second vaccination. She would like to return home right now her CT labs are otherwise unremarkable I think this is reasonable. Return precautions for more significant etiologies were discussed at length. Received lorazepam 0.5 mg IV x1, diphenhydramine 25 mg IV x1, and methylprednisolone 60 mg IV x1.

approximately 30 minutes after the vaccine the patient began to experience itching and swelling of the throat and tongue.

Patient felt dizzy and tired after receiving the vaccine, additional monitoring, no further treatment.

I had diarrhea, aches, nasuea and fatigue

Patient was sitting in observation area after vaccine. Approximately 5 minutes (1050) after administration the patient reports feeling a 'head rush', like he was going to pass out, and nausea. Patient taken to exam room via W/C. Skin pale, cool, moist. BP taken with feet elevated. Denies SOB, itching. 1115 patient reports nausea has resolved. Denies dizzy, lightheaded, SOB, nausea, itching. Patient not as pale. Transitioned to sitting with feet down. 1125 patient denies dizzy, lightheaded, SOB, itching, nausea. Color natural. Blood pressure WDL. Patient standing and walking in exam room with no symptoms. Patient dismissed to home. 12/21/20 no symptoms reported.

Dizziness, Vertigo, Tachycardia, nausea, numbness and tingling of both arms

felt itchy on back, and then throat became scratchy.

Dizziness, chest tightness. Laid supine for 30 minutes while repeatedly check blood pressure.

Lacerations and blisters in mouth.

1645- Patient gave vague reports strange taste in her mouth and shortly after that began, strange sensation of tongue and heaviness in chest. VS 118/64, pulse74, SaO1 97, Resp 16. 1655- no change in symptoms. Ambulated around clinic with no change in symptoms. 1710- Patient reported some numbness and itching of her face and arms along with the heaviness in the chest. Denies lightheaded/dizzy. Benedryl given per allergic reaction protocol. 1730- patient report itching of face and arms continues. 1735- patient ambulating in clinic with steady gait. 1745- patient reports slight improvement of itching and chest heaviness resolved. Dismissed to home. 12/21/2020 Asymptomatic.

Dizzy first 20 minutes lasted all day. Very tired. 1:30 very tired. Went home slept the entire next day. Headache took motrin. Had palpitations on Sunday.

Left face/lips with decreased sensation. Intermittent left hand and foot tingling.

"Admin vx at 1530. Developed itching on lips at 1535. Pt reports this as a reaction to the surgical mask she was wearing. Exchanged surgical mask for cloth mask. 1555-Pt reports increased itching. BP 120/84, P 82, O2 96%. OHN offered Benadryl per S.O.; pt declined. 1600 BP 122/83. 1605-BP 133/84 P 84 O2-96%. Pt continues to report increased itching. Reports ""internal itching"" and itching of feet. No obvious rash visible. Offered Benadryl, pt declined. Offered to set up appt with Med Group to be seen now; patient declined. OHN again encouraged pt to f/u with OH doc. Pt seen in clinic at approx 1645. Dr. reports admin of depomedrol and phenergan."

"felt lightheaded, flushed about 10 minutes after vaccine administration while still within the observation period. The patient was laid on a gurney, given water to drink and vitals were taken. Patient was hypertensive, blood sugar was normal. She was examined by an emergency room MD in the vaccine room and it was determined unlikely to be an anaphylactic reaction. There was scattered blotchiness on the neck region, but no raised areas, swelling or other appearance on the face, trunk or at the site of the injection. The patient recovered well and was observed an additional 15 minutes. She did have a brief recurrence of the same symptoms approximately 10 minutes later but attributed it to a ""hot flash""."

"within 5-10 mins of receiving vaccine she started to feel light headed and jittery and ""floaty"" - she says she feels like, ""I am not here, right now"" - there are no hives - no swollen lips or tongue - pt denies SOB. pt was sent to ED at 8:18 AM for further evaluation. no significant findings and patient was discharged at 10:22 AM"

10 minutes after receiving the vaccine the patient began to vomit, stated her throat felt scratchy, face became flushed. patient taken to the ER

tingling in arm & chest directly after vaccine given. Tightness in throat and a little feeling of short of breath. Went to emergency dept and received bendaryl & solumedrol - symptoms resolved except arm tingling.

Pt arrived for her COVID vaccination. Dose received and during monitoring period she reported throat tightness and difficulty swallowing. VS WNL with BP 130/88, HR 90, O2 sats 98% on room air. Pt ambulatory and escorted by staff to ED for further monitoring.

Within 35-40 minutes after vaccination; lips became a little swollen and tingly. Benadryl taken within 10-15 min and s/s subsided.

Vaccine #1 12/19/2020. No immediate reaction. 12/20/2020 started to get burning around Left eye. 12/21/2020 started to get swelling and puffiness around both eyes, also started with cough and back pain. Feels like symptoms improving. Taking Benadryl.

One and a half hours after receiving injection redness, rash and itching to right arm from palm up to forearm. Given 25 mg PO Benadryl with resolution of symptoms in 30-45 minutes.

FEVER, FATIGUE, BODY ACHES, NAUSEA, HEADACHE

My arm was very swollen from the injection site to my fingers, pretty sore and I had a bit of a rash on my right arm. Nauseous, felt like I was going to pass out. Fatigued.

My lips and throat were swelling and I felt like my airway was being compromised. I was also experiencing neck pain and general malaise. I did not have a fever but have experienced adverse reactions in the past and knew that with the increased secretions and feeling like my throat was closing that I needed to administer my epinephrine pen injection. I administered my epinephrine pen at 11:18 am and within 1 minute my airway was clear and the secretions subsided. My upper lip/periorbital area are still somewhat numb and feel swollen but I no longer feel as if I cannot breathe.

Received the vaccine Wednesday evening, after work. Waited the recommended 15 minutes, then went home and went to bed. Woke up Thursday feeling fatigued and had injection site pain, no other side effects or fever. Thursday evening, I developed body aches and a low-grade fever. I took Tylenol and went to bed. Friday, when I woke up around 1pm, I noticed a small rash behind my left knee. I took Benadryl and ended up falling back asleep. When I woke up Friday evening, I had the rash, and hives, and red/white splotches all over my legs. I took Benadryl and consulted my doctor. The rash continued to spread to my arms, and stomach. The rash itched and burned. I went to the ER Friday night for it.

Before they gave me medication, I started coughing, couldn't breathe for a minute, and got lightheaded. They gave a steroid, Pepcid, Benadryl, and fluids. They observed me for several hours. I felt better then was discharged. They told to continue to take Benadryl or Zyrtec for a couple days. 5 days later, the rash/hives are still red, itchy and present, especially when Benadryl wears off.

9:00 pm. heart palpitations and pressure in midline. Heart felt like it was beating out of my chest. A little light headed. Took antacids. Lasted about 60 minutes. Woke up around midnight with a painful muscle cramp down back of left leg. lasted about 5 minutes. woke the next morning and have felt fine since.

Change in sense of taste; had a perpetual salty taste since the day after vaccination. Has lasted so far 5 days post-vaccination

Arm felt sore at the injection site (very sore) and it went away within a day. Mostly headache and fatigue, that was the worse of it. Almost like flu symptoms, but mild, like scratchy throat, a little bit of body aches, I noticed it at night, not so much during day time

Experienced a vasovagal response about 30 minutes after receiving the vaccine. I felt it coming on and knew I needed to elevate my legs above my heart but could not at the time, so I sat down and put my head down. I had intense cold sweats and loss of vision for about 2 minutes until my blood flow returned to my head. I was then able to get to a recliner to elevate my legs with assistance. The entire episode lasted approximately 30 minutes. I was able to stand and walk after this time without dizziness. I contacted my doctor today 12/21/20 and he advised I report this episode.

Fever 101.3F, fatigue, body aches 12/20 2245 Chills overnight & cough, fatigue remain 12/21(time of this report).

Itchy Throat 30 minutes after, throat swelling reported and hour later, SOB.

"PT WITH KNOWN H/O SEVERE ALLERGIC REACTION - APPROXIMATELY 15 MINUTES AFTER INJECTION, BEGAN TO COUGH AND EXPERIENCE ITCHY THROAT. SHE REPORTED THAT THIS IS WHAT HAS HAPPENED WITH OTHER ALLERGIC REACTIONS. SHE REQUESTED ORAL DIPHENHYDRAMINE HOWEVER SYMPTOMS WORSENED QUICKLY - DETERMINATION WAS MADE TO ADMINISTER EPINEPHRINE. SHE WAS GIVEN A DOSE OF 0.3 MG EPINEPHINE IM AT 1402. PT QUICKLY BEGAN TO FEEL BETTER. SHE WAS GIVEN ORAL BENADRYL 100 MG (PER HER REQUEST - SHE SAYS THIS IS HOW MUCH SHE TAKES EVERY TIME SHE HAS AN ALLERGIC REACTION). DOSE GIVEN AT 1410. SHE DID HAVE COMPLETE RESOLUTION OF HER SYMPTOMS. SHE WAS KEPT IN THE CLINIC FOR OBSERVATION. AT 1430, PT AGAIN BEGAN EXPERIENCING SYMPTOMS AGAIN, SHE WAS COUGHING AND HAD ITCHY THROAT. SHE WAS IMMEDIATELY TAKEN TO THE ED. SHE HAD COUGH, RUNNY NOSE, RASH ON FORARMS ONLY - NOT PRESENT ON CHEST OR BACK OR FACE. AN IV WAS PLACED BY ULTRASOUND IN HER LEFT AC. AT 1438, EPI 0.3 MG IM GIVEN 1440 - FAMOTIDINE 20 MG IV GIVEN 1441 - METHYLPREDNISOLONE 125 MG IV GIVEN 1442 - FAMOTIDINE 20 MG IV GIVEN 1443 - DIPHENHYDRAMINE 50 MG IV 1444 - VITALS - 136/94, HR - 92, OXYGEN SAT - 96% ON RA 1445 - PT C/O HEADACHE, STILL COUGHING, RASH PERSISTS 1450 - IPRATROPIUM / ALBUTEROL + RACEMIC EPI GIVEN 1453 - STILL CONTINUOUS DRY COUGH, RASH BETTER 1455 - BREATHING TREATMENT COMPLETE - COUGH MUCH BETTER 1457 - HEIGHT - 63""

WEIGHT - 87.7 KG, 97.4 TEMP, HR - 77, OXYGEN SAT 96% 1504 - PT REPORTS FEELING MUCH BETTER, NO COUGH, NO RASH, LUNGS CTA BIL, NSR - HR - 75, 127/89, 96% ON RA 1610 - PT DOING WELL - PLANNING TO BE DISCHARGED - WITH RX FOR EPI PEN AND PREDNISONE 50 MG DAILY X 3 1616 - SYMPTOMS RETURNED, CONTINUOUS COUGH RETURNED, RASH PRESENT ON ARM, OXYGEN SAT 93%, 146/102, HR - 91, RUNNY NOSE 1619 - IPRATROPIUM / ALBUTEROL + RACEMIC EPI GIVEN - LUNGS DIMINISHED IN BASES WTIH STRIDOR HIGHER UP NEW IV PLACED IN LEFT HAND 1620 - 151/91, OXYGEN SAT 99% ON RA, HR - 86"

None stated.

Treatment dugs:

12/17 6:30 pm- started to have general malaise to the point I couldn't cut carrots in the kitchen, then 645pm- 9pm general chills, sweating, muscle ache and pains, severe headache (unresponsive to ibuprofen 600 mg x1 and APAP 1 g x1), 10pm fever of 100.4 F, at 11 pm, symptoms started to decrease, by 12 pm 12/18, all symptoms suddenly stopped 12/19 woke up with sore throat, and overall consistent general malaise 12/20 sore throat continues, mild headaches 12/21 sore throat continues and muscle pain/chills returned note all other activities remained the same, and no new introduction of OTC/prescription medications, or change in daily activities

monitor vs 70 MIN, feels hot, NO HX OF PREVIOUS REACTIONS REPORTED, left at 1620

Approximately 30 minutes after vaccination developed intense pins and needles sensation to the left side of my face. I then developed a heavy, aching, tingling sensation to the left side of my face. I returned to the facility and was evaluated post vaccination. Symptoms persisted still 2 days later so I was evaluated by my PCP today and diagnosed with Bells Palsy. I was prescribed high dose steroids today.

8 minutes after injection I began to get dizzy. The nurse right away put ice packs on my neck. She checked my blood pressure and it had spiked. She had me drink a full bottle of cold water. She monitored me. Then after 25 minutes I was transported in a wheelchair to a observation area. About 1 hour later the dizziness went away. I also broke out in a rash on my neck for 3 days

12/16-headache/abdominal pain 12/16 3am nausea/headache/dizziness 12/17 headache/dizziness 12/18 dizzy/diaphoretic 12/19 headache/dizziness/night sweats 12/20 headache that worsened at night, dizziness, night sweats 12/21 headache/dizzy-went to doctor -pulse thready EKG was performed (normal). Dr felt I was dehydrated and suggested drinking plenty of water and following up with him.

Burning pain in site, starting to get numb down my arm, pain on side of breast going down to rib, chest pain in the middle ..

monitor for 45 min, vaccine at 1845, felt flush, NO HX OF PREVIOUS REACTIONS REPORTED, LEFT AT 1930

Within 3 minutes of receiving vaccine, had extreme nausea, dizziness, diaphoresis, and motion sickness. Had vomiting 30 minutes after vaccine. Within 3 hours injection site had swelling the size of a baseball with purple/blue discoloration and tenderness around the site.

Pt states that ~ 20 minutes after receiving the COVID-19 vaccine on her right deltoid, the R side of her face felt numbness and tingling on the R-side of her face. States her muscles felt weaker. Improved after waiting another 10-15 minutes. Advised to monitor and record her symptoms, speak with her doctor if necessary, and enroll in the V-safe reporting app.

After having the vaccine, felt out of breath, decided to take a shower, heart rate 155 bpm. Yesterday it was 133 bpm. Took it now it is 134 bpm. Feeling very anxious. Having some soreness in the arm.

About 20 minutes after vaccination patient vomited several times and experienced increased blood pressure and heart rate. Physician assistant consulted and recommended to continue to monitor for patient improvement. Patient blood pressure and heart rate began to decrease.

Received the vaccine approximately 1pm on Saturday 12/19/20 while working at the hospital. Slight pain at injections site but no other problems that day. Did not sleep well that night due to achy muscles especially in my neck. Next morning went to work and felt chills and I could not seem to warm myself up. Also felt very sore with all my muscles aching as though I has been exercising every muscle in my body. This continued during the day but was helped by Ibuprofen 800mg. Also very tired and exhausted during the work day. (10hrs) Went home and went to bed and slept well. Monday am I felt fine again.

Sustained HR 130's for 20 minutes, no chest pain, no SOB, taken to ED for evaluation.

stated she felt like she has cotton balls in her throat, and that was the same feeling she had when she had her allergic reaction to Gain detergent.

approximately 30 minutes after receiving the vaccine, patient reported development of symptoms including increased HR, chest tightness and mild shortness of breath. She presented to the ED and was evaluated. She was given diphenhydramine 25 mg IV x 1 1629, famotidine 40 mg iv x 1 @ 1630, methylprednisolone 125 mg iv x 1 at 1629. patient was observed for 90 minutes. She was without further symptoms, VSS and she was discharge to home in stable condition at 1800

After administration, employee stated feeling dizzy; place head btw knees; continued feeling dizzy; place employee lying on floor on side and attempted to give OJ - blood sugar 80; no LOC; called rapid response; vitals and EKG WNL; transported to ED via gurney; seen by ED MD; D/C home.

Patient received Pfizer COVID-19 vaccine on 12/21/20 at 15:24. Approximately 10-12 minutes later she reported having chest tightness, became pale, diaphoretic, short of breath, and looked unwell. She also had a feeling that the her throat was closing. She was given EpiPen 0.3 mg Inj. She had a reaction to Benadryl IV in the past, so we refrained from giving her an IM injection of benadryl. She did not feel like she could swallow so we did not give her benadryl. After Epipen Injection, she immediatley looked better and was taken to the ER for further workup and observation. Of note, she mentioned an

unspecified allergic reaction in the past. In the ED she was given pepcid IV,, solumedrol IV, and a bolus of saline.

Bilateral upper extremity myalagia. Headache. Fever to 100.5. Overall fatigue

COVID Vaccine administered 12/21/20 @ 15:16 and about 15 minutes later, pt reported feeling tachycardic. She felt short of breath and had a tingling sensation on her tongue. 25 mg of benadryl PO was given to her at 15:30. She continued to feel SOB and her voice sounded much more compromised so an additional 25 mg of benadryl PO was given and she was taken to the ED for observation. In the ed she was given prednisone and pepcid.

Shortly after receiving vaccine she began to have a scratchy throat with some mild increase work of breathing. No distress. Transported to ED for further evaluation and discharged to home approx. 2 hrs later.

Shoulder joint pain. Both sides but more on my right side. Had same pain sensation my back, right side. A few seconds. Right elbow pain sensation. Left calf pain sensation. few seconds. Wave of dizziness and feeling weakness. Experienced it 3x. Had a sensation of little itchiness similar to my radish allergic reaction. Drop and spike of blood pressure Some swelling of eyelids. Lasted for 30 min. Pain in between left knuckles Left shoulder back pain lasts few seconds Left upper shoulder warm sensation a 2-3 minutes, Consistent warm slight burning pulsing pain sensation Right forearm warm burning sensation no pain. Pain in right hip, lasted few seconds. Sudden fatigue feeling suddenly extremely drained

Left sided weakness of face, arm and left leg, onset 15 minutes after receiving vaccination Brought immediately to ED, subjective feeling of closing of throat. Given IM epinephrine 0.3mg x 1. Upon evaluation in the ED by tele-neurology consult, she received 88.5mg of alteplase on 12/20/20 at 1721 She was admitted to the Intensive Care Unit on 12/20/20 at 2208 Seen by neurology on 12/21/20 at 1227. Evaluation showed weakness on the left side but is noted that it could be effort-related. Neurologist noted that patient was treated with alteplase; CT angiogram showed no significant blockage or stenosis. Noted that this is could be related to a vasovagal effect, psychogenic or an acute ischemic stroke. As of 12/21/20 at 1615, attending provider noted left-sided paresthesia, left-sided tics and possible transient ischemic attack

About an hour after, I felt slightly lightheaded. About 4-6 hours after, I felt slightly achy, slight headache, slight nausea, and general mild unwellness. All symptoms were resolved by the following morning. I also had a very sore injection site the day of and day afterwards.

About 10 minutes after the injection, I experienced sudden onset of dizziness and shortness of breath, followed quickly by rapid heart rate. The shortness of breath and dizziness resolved in less than a minute. The rapid heart rate a few minutes later.

I?m having real bad muscle aches. I can barely walk and I?m in a lot of pain when I do walk.

Fast heart rate, palpitations, whole body flushed feeling

tiredness nausea- baking soda in water, with some relief last night. 30cc of mineral water today, with short term relief

Tingling and numbness in the face. Some itching

Reports dizziness, light headeded, heaviness on top of head 10 minutes after injection. No sob, chest discomfort, palpitation or weakness. AAOx3. VVS. States that she worked last night and did not eat breakfast yet, also ran two miles prior to getting vaccine.she was given fluids and was closely monitored. Symptoms mildly improved after about 30 Minutes but continues to keep the heaviness. States that she is likely very sleepy and tired. No acute distress. Instructed to contact clinic/ED/PCP if symptoms worsen or persist.

Injection site got swollen, big bump, red, hot to touch, painful to touch, headache, lower back pain, muscle aches, face warm to touch no fever at time temp 99 oral.

flushed face, facial swelling, lips and tongue swelling, elevated HR, elevated BP , light headedness, after vaccine I waited for 20 min with no symptoms, once I left the facility I immediately felt symptoms of face flushing and swelling and elevated heart rate . I immediately turned around and went to the ER,

headache, slight dizziness, injection site pain. symptoms started about 8 hours after vaccination.

Severe swelling, hard lump, hot to touch, severe itching

Pt. felt palpitations about 5 minutes after vaccination while seated. Pulse check revealed rapid regular rhythm at about 130 bpm

10 min post dose, I experienced a lump in my throat and tingling in my face as if I was about to break out in hives. I took an antihistamine (Zyrtec) when I got home about 20 min post dose.

Approximately 45 minutes after the injection, I felt a gradual tightening of my chest. I took about 6 puffs of my Albuterol inhaler over the next 45 minutes and still got no relief. The pharmacist took me back down to the clinic where I was told to then go to the ER. My blood pressure was 204/133 and my pulse was 136. The doctor determined that I was having a severe allergic reaction to the vaccine. I was given an epinephrine injection, 10mg of Decadron and 50mg of Benedryl. I was monitored for between 3 and 4 hours in the ER before I was discharged. The doctor told me that I should not receive the second dose of the vaccine.

severe pain at injection site radiating to elbow. Duration was 72 hours. Lightheadedness started 6 hours after injection and last 36 hours

Began with pinkish neck and chest approximately 15 minutes post vaccine administration. Within 10 minutes of further observation, more reddened splotches noted on chest, and c/o tightness in chest. Taken to ED via wheelchair immediately. Treated with Benadryl, solumedrol and famotidine. Pt discharged to home within 2 hours.

"The patient was in her normal state of good health prior to the vaccination. Almost immediately after receiving the vaccination, she began having a headache, then got an urticarial rash. She then felt a ""lump in [her] throat."" She was coughing uncontrollably. She was brought immediately to the Emergency Department where I assessed her with my resident. She had signs of a Type I Hypersensitivity Reaction including a hoarse voice, globus feeling and diffuse urticaria. She was treated at the vaccination site in the hospital with Benadryl 50 mg PO prior to ED evaluation and she self-administered Ibuprofen 400 mg. She did not have stridor or airway swelling. She was able to speak in full sentences. She was NOT treated with epinephrine, as she was in stable respiratory condition and improved with Benadryl (as previously administered at the vaccination clinic, Pepcid IV and Solumedrol IV. My concern over this reaction is that the patient has NO PRIOR HISTORY OF ANY ALLERGIES AT ALL. I have read and seen in the media reports of anaphylaxis with a history of allergies, however, this is the first case I have heard of regarding an anaphylactoid reaction in a patient with no prior history."

Generalized hives with onset not until the day after vaccination. Still an ongoing issue.

c/o lips numb. Observation 60 minutes after the reaction and gave OJ. Patient stated it was resolving and departed on her own.

~1 h 15 min after receiving experienced flushing, dizziness, near-fainting, arrhythmia, progressed rapidly to a rapid heart rate, elevated BP, hives, cool extremities, diaphoretic treatment: NS 1 liter, Benadryl 50 mg IV, Solumedrol 125 mg/ml discharged after 6 h with Rx for Epi Pen experienced dizziness/near-fainting episodes off/on for 3 days, slight headache, chest tightness, green/bloody nasal discharge for 2 days

Left armpit lymph nodes swollen and painful. Started as tender to touch on the morning of 12/20/20 and became increasing painful throughout the day and by end of day throbbing. On 12/21/20 throbbing has stopped but still painful to arm movement. Occassional tingling down the left arm.

Patient received dose #1 COVID-19 vaccine administration on 12/17/20. A day later on 12/18/20, patient experienced cold sweats, cough, body aches, fatigue, H/A, vomiting x2, chills, shaking, fatigue, and diarrhea.

Employed as a nurse at this hospital. Around 8 PM she received her COVID-19 vaccine. She waited the 15 minutes she was required to wait and then walked to her car. She reports that as she walked to her car she had a pain in her left shoulder which was short-lived but followed by numbness and tingling of her left arm and the left side of her face going up the back of her head. Symptoms started around 8:20pm. She reported back to the clinic to report the symptoms--she lives along and wanted to be assessed before going home. In the clinic, she was assessed by myself. Employee noted that she had not eaten. She ate in the clinic and had something to drink. While in the clinic over the next 10-15 minutes, she noted that she had some numbness and tingling in her feet and calves bilaterally. No leg pain or swelling. Around 9pm, the clinic was closing and she could no longer be monitored under observation. She opted to go to the ER for observation. Per ER note-- She denies any headache. She denies any left-sided weakness. Patient is right-handed. She also reports some mild chest heaviness that lasted for about 20 minutes and then resolved. No shortness of breath. No dizziness, syncope or presyncope. No

nausea or vomiting. No rash. No visual or speech changes. No ataxia. Patient continues to have the left-sided numbness and tingling but states that it is less intense than it was. She denies any other complaints. Follow up this AM-- Pt is only fatigued and has some muscle soreness where she had the vaccination. All of her symptoms have resolved and she is not having any further sxs of chest tightness or numbness

pt was given the vaccination for COVID on friday the 18th (2 days ago) had moderate aches and diarrhea yesterday and began to have rash on Saturday . Pt is a nurse where there has been a large number of children with gastroenteritis. Pt with h/o immune reaction (? Stills disease) where she breaks out in a urticarial rash ,previously only with illnesses in the past Now pt has a rash. However Pt states this rash feels different to her normal one and she has never had a reaction like this to vaccine befores. The rash began similarly to how it usually starts on upper ext and then spreads to trunk now she has swelling around eyes and rash is getting worse. benadryl ineffective pt also has swelling around her eyes and overall with irritation which she has not experienced before. pt was sent to the Emergency department for full evaluation concern for sjs type reaction with

Right after the injection I became acutely lightheaded. I tried to wait it out and it improved somewhat but not all the way. I then started to drive home after the 15 min. observation period. About 5 min into my drive home, I developed trouble swallowing/throat tighness and worsened lightheadedness. I called 911 who stayed on the phone with me as I drove back to the hospital. It started to imrpove rather soon and was resolved within 30 min later.

2 min post injection developed tingling around site, and then urticaria on left upper arm. Then diffuse flushing diffusely and headache. HR=130's, normal BP. Difficulty swallowing during EMS transport. Received EPI sc, Pepcid IV, and Benadryl 50mg IV PTA. HR+140 on arrival post Epi 6 hour obs. NS 1L D/c home with precautions, epilepsy pen rx, and allergist follow-up

Sore deltoid

Associate tested positive for COVID 12/21. Now reports symptoms of cough starting 12/18 not revealed at time of vaccine

Vaccine recipient became nauseas and light headed approximately 30 minutes after vaccine. Recipient also had started menses which was very heavy, also she said she saw the needle and she shouldn't have looked.

Within 3 minutes of receiving the vaccine, I felt a fluid like sensation trickle down my right bicep. I think proceeded to feel tachycardia, dizziness, lightheaded, and was hypertensive. My chest appearance was red and blotchy as well as my face. I was monitored in the ED for 2 hours. My vitals stabilized and the redness dissipated. I continued to feel a bit anxious and a headache. I was told to go home, take Benadryl as needed, and to follow up with an allergist.

About 10 minutes after the injection I felt something in my throat like when I have a sore throat. I was checked by the nurse and she said my pulse is beating a little faster. My breathing was fine. I was

brought to Er and my blood pressure was elevated than usual. About almost an hour after the vaccine my forehead started itching and but I was given benandryl so my hives didn?t continue to develop..

While sitting in chair in observation area after vaccine was talking on phone to friends and suddenly felt very weak with tachycardia to the 120s, SOB, pre-syncopal, very lightheaded. Weakness. No chest pain or tightness. Waved to the staff,. wanted to lay flat. They raised my legs and as there was no stretcher available. Felt heart racing and a sense of doom. HR settled down after about 3-5 mins. Tried to stand so staff could get orthostatic BP but could not support my weight. Remained under observation by the staff for about 45 min. symptoms improved. Was directed to go to ED for evaluation. My husband picked me up.

Full vial of 0.3ml concentrated vaccine administered undiluted with normal saline.

Very soon after receiving vaccine experienced some tingling in the left arm, left leg, left side of face - especially left arm in approximately C8 distribution - down into ring and pinky fingers. Left arm tingling has been intermittent since then. Today noticed a rash in both arms, but worse on the left side in the same distribution. There is numbness, tingling, slight burning along with the rash in that area.

Developed headache, chills, body aches and sore left arm

Jittery and involuntary muscle movements. Chills. Dizziness when I would try to lay down. Nausea followed by abdominal pain. Dry heaving. Later in the day I developed a headache. Resolved at 11pm that night.

around 1730 Patient was given vaccine and d/t allergy history was brought in the 15 minute observation. Patient stated that she was feeling dizzy and throat feeling funny also the same way when gets the flu shot. Patient was kept in observation while being monitored and Code Blue Team arrived d/t the possibility of an anaphylactic reaction.

Around 0800 the patient got her vaccination. During the registration process, she was seen by An Employee (Pharmacy) and associate stated that she never had any allergic reactions in the past and filled in both forms that she does not have any allergic reactions to either the vaccine components, food, and medication. She was then escorted to the Observation room for 15 minutes where she felt dizzy at first. The observation nurse and pharmacy was also present at site. After a few minutes, associate complained of more dizziness, some tightening of the jaw but was still able to speak and swallow. Associate was then given Benadryl around 0804 and connected to the vitals machine for continuous monitoring. Around 0806 patient was feeling worst and Observation RN took her vitals and her HR went down to the 30?s associate was given epinephrine and hence the CODE BLUE was called on 0807. During the CODE BLUE, ED was notified, and a gurney was sent to the Observation Room. Patient was then transported to ED for further evaluation and observation.

35yo female urgent care physician in normal State of Heath when while seeing patients I got lightheaded. Sat down, drank water, ate sugar cookie for about 10/15 minutes but symptoms persisted.

Tried to keep working, but found myself just thinking about how I am going to pass out. No LOC. Evaluates by colleague. Received 2L of IVs (Cr wnl) with transient improvement in symptoms.

Rapid heart rate of 203 bpm

Around 0320 on 12/20/20, approximately 12 hours after my vaccination, I experienced uncontrollable chills for an hour and had an onset of a headache, nausea and weakness that lasted until about 1500 on 12/20/20. Side effects have since resolved.

Woke up 2 days later with pain and swelling under my eyes and in my chin. These are places that I have had dermal filler. I started steroids immediately, swelling went down after 2 days.

Pt noted tightness/swelling around eyes along with itching/burning sensation at same. Then developed itchy erythematous rash starting right shoulder (near where injection was done) and spreading to back. Benadryl 50mg IM given. Was sent to ER for continued monitoring; she did well without further treatment (other than 500mL of saline IV) and was released in good condition. She did not have lightheadedness, lip/tongue/throat swelling, SOB, GI symptoms, or hypotension.

Numbness and tingiling on fingers (both hands and feet). Unable to extend without feeling severe pain on ring and pinky fingers on right hand.

Employee, 1st Pfizer COVID19 vaccine today. ~6min s/p shot, he felt a little itchy just @injection site, then got anxious & felt woozy, sweaty. Wearing big mask and a face shield, seemed anxious. Walked independently to go lay down. No syncope. BP up to 140/90, HR 90, RR 20, breathing fine, no itchy throat/swelling/hives. Improved w laying down. To ER out of an abundance of caution-- vitals nL, nL exam, still itchy at shot site. Got 1L NS IV, 25mg PO Benadryl for itchiness- likely anxiety > severe allergy

Migraine greater than 24 hours, included headache, photosensitivity, noise sensitivity and nausea/vomiting.

Day 2 December 20 woke up with dizziness and nausea, and soreness to left arm Day 3 December 21 having continued constant dizziness and waves of nausea thus far Spoke with Dr per phone she suggested to take Dramamine, which eased dizziness but feeling odd. Unable to register for v-safe not going thru from your end?

30 minutes after receiving the vaccine, I (the patient) felt tingling in my lips, nose, and feet. I then developed a non-itchy, macular rash on my chest and back, associated with flushing. No fevers, chest pain, shortness of breath, nausea, vomiting, or diarrhea, I was taken to the emergency department, where I had normal vital signs. I was given Benadryl 25 mg PO with complete resolution of rash and tingling sensation within one hour.

Urticaria to arms started on the eve of December 20, 2020, took benadryl and applied triamcinolone ointment to rash, woke up and found more rash all over the body took benadryl again, after an hour of taking the benadryl, my face started to itch, that;s when I went to the ED where they gave me, a steroid IV , Benadryl IV and Pepcid IV.

Numbness and tingling in face from ear to ear and forehead to jawline, especially lips

Pfizer-BioNTech COVID-19 Vaccine EUA Currently having fever up to 101.8¦F, malaise, headache, and fatigue.

L ring and pinky finger tingling/numbness

Pfizer-BioNTech COVID-19 Vaccine EUA Erythema and pain noticed at injection site at 22:00 Pain worsened over night The next morning around 0700, noticed worsening Erythema, inflammation, tenderness, warmth No fever 12/21 borders of Erythema have expanded

"Patient notes that she received the COVID vaccine around 1800 today. After receiving the vaccine she notes she had developed a headache. She was otherwise doing fine until around 2000-2100 when she noticed her left arm become numb with paresthesias from her left bicep to her hand with whole arm localization. She felt her hands and wrists were puffy at this time and somewhat swollen. She reports feeling ""floaty""/Dizzy at this time, and at least once had to sit down due to this. She started feeling her heart race and some associated SOB, this has since resolved. She notes that she had two loose stools around this time as well. This progressed to develop into right numbness/paresthesias from her mid right forearm down to her hands. As the evening progressed she developed itchiness of her bilateral arms and torso. She notes that she has had a waxing/waning reddish rash on her arms that has been pruritic. She has since developed intermittent nausea, and still endorses feeling some ""skipped beats."" While in the ED from Triage to repeat evaluations her lips began having progressive swelling. She had been given Benadryl 50mg, Zofran 4mg, 1L IVF. Given ongoing tachycardia and lip swelling she was given Prednisone 40mg and Epinephrine for allergic reaction and concern for anaphylaxis."

Fever, Nausea, Vomiting, body aches, Diarhea taking po fluids trying to stay hydrated with po fluids. rest

7 hours post vaccine, I had very runny nose, thick clear mucus kept coming out of my nose. I felt feverish although my temperature is within normal limits. I had a mild headache and very sore arm on the vaccine site, body aches and malaise which I know are part of the list of side effects I would experience post vaccine, but then about midnight, I developed a huge rash or hive near my left armpit. Then, on Sunday, 12/20/2020, more big hives appeared on my body and my left hand is very itchy and the palm looked red and more swollen than my right hand. I took some antihistamine and notified my doctor via an e-mail. He told me to take diphenhydramine 50 mg every 6 hours. The hives are still present and much bigger and appear in more areas of my body.

Around 1230pm I started to itch, then got nausea, then felt palpitations, checked my own heart rate using and I watch and heart rate was on svt with a rate of 160. I held my breath and heart rate came down after 5 min to a rate of 80 Sinus rhythm.

Rapid heart beat, difficulty breathing, itching, rash, clamminess, cold sweats, nausea

About 1 1/2 hour after injection, one hive appeared on face. Face and arm, head itchy. No rash.

Fever of 101.2F. Cold chills. sweats. Muscle aches. Headache. Lasted for 14 hours and treated with OTC tylenol and advil.

Patient reported felling light headed and dizzy after vaccination. Immunizer questioned patient as to last known meal. Patient had not eaten breakfast. Given orange juice and a light snack. Side effects subsided within 20 minutes and patient was able to return to work. Immunization given under emergency protocol. Patient is a healthcare worker in a long term care facility. Was able to resume normal duties after being monitored by immunizing staff.

redness, swelling and pain at injection site

Fever 102' Chills Body Aches Fatigue

redness, swelling and itching at injection site

"Pfizer-BioNTech COVID-19 Vaccine EUA: Shortly after receiving Pfizer-BioNTech COVID-19 vaccine patient experienced dizziness and ""shakiness"" in extremities. No hives, no swelling, no shortness of breath, no chest pain, no loss of consciousness, no numbness, and no tingling noted at any time. Initial vital signs: blood pressure 140/78 mmHg, temperature 98.7 degrees Fahrenheit, pulse 106 beats per minute, respiratory rate 20 breaths per minute, oxygen saturation 98% on room air. Repeat vitals 14 minutes later: blood pressure 125/88 mmHg, temperature 98.6 degrees Fahrenheit, pulse 110 beats per minute, repiratory rate 18 breaths per minute, oxygen saturation 98% on room air. Thirty minutes after repeat vitals assessed patient stated they felt much better and able to leave clinic ambulatory with a steady gait. Patient was awake alert and oriented the entire time."

Woke up this morning around 5:30 with chills, could not get warm, took temperature around 6:30- 100.4, right side of the throat is slightly scratchy, took temperature again at 7:15am- 99.7, feel very flushed and warm, starting drinking water and took Tylenol

About 1-2 hours after receiving the vaccine, I began to have tongue Hb and throat swelling?mild to moderate. About 3-4 hours later, I had one episode of diarrhea, followed by chills and palpitations. I took Benadryl and Zantac around 8P. When I woke up in the morning, I still had tongue and throat swelling (no trouble breathing), so went to the ER and was treated for an allergic reaction with IV Benadryl, Solumedrol, and Pepcid.

Employee had tingling and numbness in arm a few minutes after injection. This improved within 30 she left the clinic at 40 minutes post vaccine injection. While driving home employee reports having a sudden onset of headache, palpitations and thick speech. Her sister with whom she was taking on the phones told her that her speech sounded strange. Employee had pulled over and called 911. EMS spent time with her and her symptoms subsided so they released her to her own care. She went home and noted nausea, chills then had the onset of a migraine. She took po Benadryl thinking this would help if she was having an allergic reaction. Employee reports feeling achy and chilled so missed work on Saturday. Sunday she was well enough to report to work. Monday upon checking in with this employee she reports mild soreness at injection site, otherwise no residual symptoms

"Patient developed sudden onset of headache with hypertension (BP 205/112), tachycardia (HR 137), redness and hives around 10 minutes after receiving the Pfizer covid vaccine (time 1600). She described ""feeling a wave of heat climbing from her feet up to her face"". 911 called and patient was transported to ER at around 1630. Upon arrival her BP trended down to 129/89 with HR of 78. She did not report difficulty breathing, and she did not receive additional medications while in ER. She was monitored for around 2 hours and discharged at 1847."

Pfizer-BioNTech COVID-19 Vaccine EUA Woke up 12/21 feeling feverish, fatigued, and myalgia, as well as injection site soreness, got worse in the afternoon, peaked around 6pm but started to improve in the evening. Completely gone the following morning 12/22. No treatment taken

Within 1-2 minutes of vaccination, pt felt flushing. He sat down in waiting room. He started to sweat and felt dizzy. Pt requested help. He was brought back to medical room. Pt laid down for 5 minutes and felt better. He ate a snack and drank some water. BP was 162/102 initially. BP was 144/96 after 13 minutes. Pt states he has had similar reactions after giving blood.

Started to have more and more soreness at injection site after administration. Then soreness turned into muscle and joint pain. After about 6-7 hrs from injection time started to feel really bad. I took an Advil before trying to lay down. Was unable to sleep, started getting chills and headache. I took my temperature and it was 102.4. I then took some Tylenol and put some wet clothes on. Temp stayed at 102.4 for a few hours and then finally broke. My temperature went down to 101.4 and stayed there for awhile and now is 99.2. Feeling better than I was, still have severe headache and soreness in body.

Woke up with fever, chills, muscle aches, joint pain, headache, fatigue. Nausea, loss of appetite. treated with Tylenol which controlled fever. Slept a lot.

light headedness; shortness of breath; headache; some nausea; get some redness to her neck and upper chest; Had elevated BPs; This is a spontaneous report from a contactable pharmacist. A 41-year-old female patient (non-pregnant) received first dose of bnt162b2 (Pfizer-BioNTech COVID-19 Vaccine, Batch/lot number: EH9899), intramuscularly on right arm on 15Dec2020 at 13:30 at single dose for immunization. The COVID-19 vaccine was administered in hospital. Medical history included arrhythmia - right bundle branch block, GERD (Gastrooesophageal reflux disease), spinal headache, allergy to gabapentin, adhesive, duloxetine hydrochloride (CYMBALTA). The patient wears contact lenses. Prior to vaccination, the patient was not diagnosed with COVID-19. Concomitant medication within 2 weeks of vaccination included hydrocodone bitartrate, paracetamol (HYDROCODONE/ACETAMINOPHEN, 5-325 mg), omeprazole, meloxicam, docusate sodium, sennoside a+b (SENNA AND DOCUSATE SODIUM). The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Within a few minutes of receiving the shot on 15Dec2020, the patient developed lightheadedness, shortness of breath, headache, and some nausea and was taken to the ED (emergency department). She did get some redness to her neck and upper chest, had elevated blood pressure. O2 saturation was fine. The patient received treatment for the events which included acetaminophen (TYLENOL), dexamethasone, diphenhydramine, famotidine, ketorolac, ondansetron, and 1 L normal saline in ED. The patient was prescribed adrenalin autoinjector (EPIPEN) and prednisone and discharged home. Since the vaccination,

the patient hadn't been tested for COVID-19. Outcome of reactions was resolved in Dec2020.; Sender's Comments: Based on the close temporal relationship and the description of the events lightheadedness, shortness of breath, headache, nausea, erythema and high blood pressure, there is a reasonable possibility that the events are related to BNT162b2 vaccine. The case will be reassessed upon receipt of follow up information.

the patient received five times the recommended dosage; the patient received the unreconstituted dosage; body aches; headaches; This is a spontaneous report from a contactable Other Health Professional (pharmacy student) reported on behalf of a pharmacist. A 37-year-old female patient received first dose of BNT162B2 (Pfizer product, batch/lot #: EH9899, NDC number: 59267100001, Expiry Date: 31Mar2021), intramuscularly on 15Dec2020 at single dose (five times the recommended dosage) to prevent the development of COVID 19. There were no medical history and no concomitant medications and no investigation assessment. They did not reconstitute the vial. The patient received five times the recommended dosage and the dosage was unreconstituted on 15Dec2020. The patient experienced body aches and headaches on 15Dec2020 with outcome of not recovered. Reporter seriousness for the patient received five times the recommended dosage was: Medically significant. Seriousness of body aches and headaches was: Too soon to tell. The seriousness of receiving it unreconstituted was: unknown.; Sender's Comments: The reported information is limited. Based on the close temporal relationship and the description of the events body aches and headaches , there is a reasonable possibility that the events are related to BNT162 vaccine received unreconstituted and five times the recommended dosage. The case will be reassessed upon receipt of follow up information.

patient started feeling weak, dizzy and even blacked out a couple times; patient started feeling weak, dizzy and even blacked out a couple times; patient started feeling weak, dizzy and even blacked out a couple times; This is a spontaneous report from a contactable consumer. A female patient of an unspecified age received BNT162B2, via an unspecified route of administration, on 16Dec2020 at 12:00 PM at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. On 17Dec2020, at around 1:00 in the morning, the patient started feeling weak, dizzy and even blacked out a couple times. The outcome of the events was unknown. The batch/lot number for the vaccine, BNT162B2, was not provided and will be requested during follow-up.; Sender's Comments: The reported information is limited. Based on the close temporal relationship and the description of the events feeling weak, dizzy and blacked out, there is a reasonable possibility that the events are related to BNT162 vaccine. The case will be reassessed upon receipt of follow up information.

Severe fatigue until 48 hours; severe headache still present; fever; chills; nausea; This is a spontaneous report from a contactable physician. A 30-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), intramuscularly in the left arm, on 15Dec2020 at 15:15 (at the age of 30-years-old) at a single dose for COVID-19 immunization. The patient had no medical history or concomitant medications; there were no other medications the patient received within 2 weeks of the vaccination. The patient was not pregnant at the time of vaccination. Prior to the vaccination, the patient was not diagnosed with COVID-19. The patient had no known allergies to medications, food, or other products. The patient did not receive any other vaccines within four weeks

prior to the vaccination. The patient experienced severe fatigue until 48 hours, severe headache still present, fever, chills, and nausea on 16Dec2020 at 03:00. The events were reported as non-serious. No therapeutic measures were taken as a result of the events. The clinical outcome of severe fatigue until 48 hours, severe headache still present, fever, chills, and nausea was not recovered. It was also reported that since the vaccination, the patient had not been tested for COVID-19. The batch/lot number for the vaccine, BNT162B2, was not provided and was requested during follow up.

Hives; This is a spontaneous report from a contactable consumer. A 43-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot number: GH9899), via an unspecified route of administration in the left arm, on 17Dec2020 at 09:00 (at the age of 43-years-old) at a single dose for COVID-19 immunization. Medical history included allergic to unknown food. The patient's concomitant medications were not reported. Prior to the vaccination, the patient was not diagnosed with COVID-19. The patient did not receive any other vaccines within four weeks prior to the vaccination. The patient experienced hives on 17Dec2020 at 16:00. The event was reported as non-serious and did not cause/prolong hospitalization. Therapeutic measures were taken as a result of the event, which included treatment with diphenhydramine hydrochloride (BENADRYL). The clinical outcome of hives was recovering. It was also reported that since the vaccination, the patient had not been tested for COVID-19. The batch/lot number for the vaccine, BNT162B2, was not provided and has been requested during follow up.

waves of flushing through out her body; severe dry mouth; nausea; elevated heart rate into 120s; panic attack; This is a spontaneous report from a contactable consumer. A female patient of an unspecified age received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration in 2020 (at 0810 her time) at single dose for immunization. The patient's medical history and concomitant medications were not reported. The reporter is a Certified Nursing Assistant (CNA) who received the Covid 19 vaccine at 0810 her time. Five minutes after receiving the vaccine (2020) she reported having three episodes of the following symptoms: waves of flushing through out her body, severe dry mouth, nausea and elevated heart rate into 120s. She denied any shortness of breath, swelling or anaphylaxis. She was treated in the Emergency Room (ER) with fluids and lorazepam (ATIVAN) and sent home. She contacted her doctor who advised she was probably having a panic attack and was told her to take lorazepam. She reported sleeping when she got home but experienced the elevated heart rate and flushing again after waking. She spoke to her doctor a second time and was told to return to the ER to be treated for the elevated heart rate. She did not go to the ER because she took more lorazepam and the HR declined into the 90's. She stated her doctor was prescribing a beta blocker for her but advised to go to the ER if her heart rate goes over 100 again. She would like to report and Adverse Event. The outcome of the events was unknown. Information regarding lot/batch has been requested.; Sender's Comments: Based on the information available as reported at this point, a possible contributory role of the suspect products cannot be excluded for the reported event flushing, dry mouth, heart rate increased, nausea and panic attack due to temporal association.

Hearing loss; Severe tinnitus; This is a spontaneous report from a contactable pharmacist. A male patient of an unspecified age received first dose of BNT162B2 (solution for injection, lot number: EK5730, Expiry Date: 31Mar2021, NDC number: 59267-1000-01), intramuscularly on 16Dec2020 at 0.3

mg, single in deltoid for prevention of COVID viral infection. The patient's medical history and concomitant medications were not reported. The patient's wife is COVID positive, but he has not been tested and has no other symptoms. On 17Dec2020, the patient experienced hearing loss, and severe tinnitus. There is no additional vaccines administered on same date of the Pfizer suspect. The outcome of both events was not resolved.; Sender's Comments: The reported information is limited. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

Feeling of going to pass out; PVC's; PVC's; Shaking feeling internally from neck down to ankles; Sweating; palpitations; This is a spontaneous report from a contactable consumer (patient herself). A 60-year-old female patient received bnt162b2 (lot number: FK5730), via an unspecified route of administration at site of right arm at 10:15 on 17Dec2020 at single dose for immunisation. Medical history included Chronic migraine. Occasional PAC/PVC's. Concomitant medication included clonidine (strength: 0.02 mg). Within about 5 minutes of receiving the vaccine, the patient experienced shaking feeling internally from neck down to ankles, sweating, feeling of going to pass out. Some palpitations and PVC's. Shaking Symptoms lasted approx 4 hours. The patient visited emergency due to events. No treatment received for events. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. The outcome of events was recovered on 17Dec2020.

severe hypersensitivity; swelling of tongue; dyspnea; skin rash; This is a spontaneous report from a non-contactable consumer. A 35-year-old male patient received BNT162B2 (Pfizer-BioNTech COVID-19 vaccine), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient administered vaccine and developed swelling of tongue, dyspnea, skin rash on an unspecified date. There is a report of severe hypersensitivity for his awareness. The patient was treated with dexamethasone, Benadryl, IM epinephrine in ER. Outcome of events were unknown. No follow-up attempts are possible; information about batch/lot number cannot be obtained.

Bilateral itchy rash, mostly with small areas of erythema especially around arm pits, but also on abdomen, back, neck, arms, forearms, thighs, legs; Bilateral itchy rash, mostly with small areas of erythema especially around arm pits, but also on abdomen, back, neck, arms, forearms, thighs, legs; some less erythematous areas of swelling with well-marked borders at most 1cm in diameter; This is a spontaneous report from a contactable physician. A 28-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), intramuscularly, on 15Dec2020 at 02:45 (at the age of 28-years-old) at a single dose for COVID-19 immunization. Medical history included hypertension (HTN). Prior to the vaccination, the patient was not diagnosed with COVID-19. Concomitant medications, taken within two weeks of vaccination, included lisinopril (MANUFACTURER UNKNOWN), melatonin (MANUFACTURER UNKNOWN), and vitamin D (MANUFACTURER UNKNOWN) taken for supplement. The patient had no known allergies to medications, food, or other products. The patient did not receive any other vaccines within four weeks prior to the vaccination. The patient experienced bilateral itchy rash, mostly with small areas of erythema especially around arm pits, but

also on abdomen, back, neck, arms, forearms, thighs, legs and some less erythematous areas of swelling with well-marked borders at most 1cm in diameter on 16Dec2020 at 08:00. The events did not cause or prolong hospitalization. Therapeutic measures were taken as a result of the events, which included treatment with diphenhydramine hydrochloride (BENADRYL) and loratadine (CLARITIN). The events improved with loratadine but started to reoccur 18 hours after loratadine use. The clinical outcome of bilateral itchy rash, mostly with small areas of erythema especially around arm pits, but also on abdomen, back, neck, arms, forearms, thighs, legs and some less erythematous areas of swelling with well-marked borders at most 1cm in diameter was not recovered. It was also reported that since the vaccination, the patient had not been tested for COVID-19. The batch/lot number for the vaccine, BNT162B2, was not provided and has been requested during follow up.

extreme pain in her arms feeling like they are dead and heavy; extreme pain in her arms feeling like they are dead and heavy; She was unable to continue working; This is a spontaneous report from a non-contactable other health professional via Pfizer Sales Representative. This other health professional reported for a 50-year-old female patient (nurse) received BNT162B2 (Pfizer-BioNTech COVID-19 vaccine), via an unspecified route of administration at on 15Dec2020 at single dose for COVID Vaccine. The patient's medical history and concomitant medications were not reported. Nurse was administered the Pfizer COVID Vaccine on 15Dec2020. On 17Dec2020, at work she complained about extreme pain in her arms feeling like they are dead and heavy. She was unable to continue working and went home. Event took place after use of product. Outcome of events were unknown. No follow-up attempts are possible; Information about batch/lot number cannot be obtained. No further information is expected.; Sender's Comments: The reported information is limited. Based on the close temporal relationship and the description of the events, extreme pain in her arms, feeling like they are dead and heavy and unable to continue working, there is a reasonable possibility that the events are related to BNT162 vaccine. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

Headache; Dizziness; Nausea; This is a spontaneous report from a contactable other health professional. A 56-year-old female patient received bnt162b2 (BNT162B2) via intramuscular in right arm on 17Dec2020 at single dose for vaccination. There were no medical history or concomitant medications. The patient experienced headache, dizziness, nausea all on 17Dec2020. The reporter described that immediately after patient was administered the COVID-19 vaccine injection she was handed the paperwork, stood up and had sudden onset headache, dizziness and nausea. As of time of the report the headache had subsided slightly but came and went in waves. The dizziness and nausea remain persistent. She reported the seriousness criteria as probably medically significant or somewhere between not serious and medically significant. Patient was currently under observation in the ED (emergency department), but had not been admitted to the hospital. The patient had been in the ED for over 30 minutes at time of report, so patient did not believe that these events are vagal. The reporter called to report these events and to ask for recommendations on how to respond to these events relative to this product. The reporter verified that there had been no relevant testing, imaging, lab work

or investigations done at this time. The outcome of the event headache was recovering while for all other events was not recovered. Information on the Lot/Batch Number has been requested.; Sender's Comments: The reported information is limited. Based on the close temporal relationship and the description of the events, headache, dizziness and nausea, there is a reasonable possibility that the events are related to BNT162 vaccine. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

waves of heat feeling; tachycardia; chest tightness; This is a spontaneous report from contactable physician via Pfizer Sales Representative. A 50-year-old female patient received bnt162b2, via an unspecified route of administration in 2020 at single dose for immunization. The patient's medical history and concomitant medications were not reported. The patient experienced waves of heat feeling, tachycardia, chest tightness 15 min after receiving the vaccine in 2020. Patient received several doses of steroid and was kept overnight in hospital and recovered. The outcome of events was recovered in 2020. Information on the Lot/Batch number has been requested.; Sender's Comments: The reported information is limited. Based on the close temporal relationship and the description of the events, waves of heat feeling, tachycardia, chest tightness, there is a reasonable possibility that the events are related to BNT162 vaccine.The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this reviewas well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

Some mild nausea; This is a spontaneous report from a contactable consumer. A male patient of an unspecified age received BNT162B2, via an unspecified route of administration on 16Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced some mild nausea on 16Dec2020. The reporter indicated that the patient had some mild nausea that lasted for an hour or two but that it had completely passed. The outcome of some mild nausea was recovered in Dec2020. No follow-up attempts are possible; information about batch/lot number cannot be obtained.

At 18:45 patient reported development of numbness in back of throat. Pt. reported no difficulty swallowing. Patient ate her evening meal without difficulty and symptoms begin to resolve. Patient took 25 mg of diphenhydramine PO before going to bed. Patient reported no symptoms the next morning.

Patient was nauseas but did not vomit. Had the patient lay down and took the patients blood pressure first reading was BP 98/65, second reading was 94/62 with pulse rates of 80 and 67 respectively. Patient started to feel better after 30 minutes

Patient began having tingling around her mouth on 12/20/20, stated that cold sore has gotten larger and is worse than previous sores. Patient is cautious to not spread fluid from sores but they are spreading. Patient was advised to contact PCP.

Headache, nausea, subjective fever and injection site arm pain.

Patient was nauseas and lightheaded. She was instructed to lay down in which she felt better.

Shortly after receiving injection, I began feeling some lightheadedness.

Itchiness and rash on skin.

"Employee reported ""tongue thickness"" and dry mouth. Employee was taken to ED for evaluation and treatment."

generalized hives

Nausea and Vomiting

Fever, chills, body pain

fever of 101, fatigue, lethargy

Body aches, chills, dry cough

Nausea and vomiting, dry cough, sore throat

Headache, Tiredness, arm soreness

Patient became slightly tachycardic (HR 145, BP 140/75) and light-headed. Described as anxiety attack. Patient laid down and feet were elevated and heart rate and blood pressure returned to normal. Patient was observed for another 30 minutes and released

Caller stated on 12/18/20 and on 12/19/20 she had some arm pain and nasal drainage. Caller stated that she went to doctor on 12/21/20 and was diagnosis with Cellulitis and was prescribed steroids and cefalexin for 7days x three times daily. Caller stated that physician does not recommend second injection. Vaers report completed over the phone.

Headache, injection site soreness

Headache, injection site soreness

Stomach pain, nausea, vomiting, diarrhea

Nausea

Employee reported headache, flushing, and a sweaty feeling. He was taken to ED for evaluation and treatment.

12/21/2020 3:00PM Abdominal l quad pain, nausea sore arm, headache, fever 101.9 with chills -- tylenol, ibuprofen some relief. 12/22/20 tylenol in AM-- low grade fever persists with headache, some nausea.

Histamine reaction 2 hours after injection and still present at 15 hours from injection: itchy runny nose, post-nasal drip, mild itchiness around body (torso, arms, ears, head), Left ear pain on side of injection . Took 50mg benadryl at bedtime and this morning took 10mg claritin and 10mg syngulair.

Evening following receiving vaccine: Severe Dizziness, Chills, Body Ache, Increased Heart Rate (racing sensation). Following day: Minor/Noticeable Joint Pain throughout body (knees, shoulders, spine). Continuing symptoms: Minor Redness/Itchiness around injection site.

Na

Palpitations, BP 113/78, HR 115 - treated with prone position, resolved at BP 122/91, HR 111

worsening peripheral neuropathy feet/legs/hands/arms

Employee stated after 15 mins observation, that he experienced heart palpations for 2mins. This nurse then obtained employees vitals. BP - 126/80, P-80, O2-97. Employee was then observed by this nurse for 40 more mins. Employee stated @ 0902 he felt fine. Denies any prior anxiety/cardiac issuses when asked. Employee left observation @ 0905.

10 minutes after initial vaccine was given patient experienced numbness and tingling to tongue, lips, and fingers. No shortness of breath or respiratory distress noted

Immediately after vaccination developed tingling in soft palate. Pale. sat for 15 minutes and symptoms remained and was given 25mg benedryl.

fever/chill, extreme fatigue, body aches, headache, near syncope, nausea

Headache, diarrhea

Pain at injection site

Severe chills, fatigue, arm pain, dysuria

12/18/2020 5 MINUTES AFTER INJECTION, FELT HOT. TEMP KEPT GOING UP. TEMP WOULD NOT GO DOWN. STAFF PUT COLD PACKS ON ME. ITCHING STARTED BUT NO RASH VISIBLE ON ARMS AND BACK. DR. STATED TIME TO TX TO ER. THE HEAD HAD INCREASED EVEN MORE. COULDN'T BREATHE DEEPLY, 'AIR STOPPED', COULDN'T SPEAK PROPERLY. PREDNISONE, ANXIETY AND BENADRYL ADMINISTERED. MONITORED O2 STATES, MONITOR HEART. AT HOME BODY STARTED TO ACHE, NOT MEDICINE TYPE PERSON. HELD OFF TILL 1AM, TOOK 2 TYLENOL 500MG. BY 3 AM ABLE TO SLEEP. HEAT SENSATION WAS STILL THERE. BY 12/20/2020, INJECTION SITE SORE, LUMP. I WAS TIRED. BY 12/21/2020 THE SITE WAS SORE, I RUBBED WITH ALCOHOL. PROBLEMS WITH SWALLOWING, EATING GINGER CANDY TO HELP WITH DRYNESS. THROAT BOTHERS AFTER TALKING, TIGHTENING. DR. STATED AT 2ND INJECTION WILL

PROVIDE THE BENADRYL, PREDNISODE, AND ANXIETY MEDS 30-60 MINUTES BEFORE ADMINISTERED. 'I DO BELIEVE I NEED OTHER SHOT TO BE COVERED'. 'CLOSE TO ER FOR SECOND SHOT'. I DO HAVE PROBLEM WITH VACCINATIONS; I GET INTO TROUBLE. MY BODY HAS REACTIONS, TROUBLE BREATHING. 'SOLE PROVIDER FOR WHOLE FAMILY; I HAD TO TAKE THE SHOT' 'FEELING ABOUT 100%'

2hrs after vaccination, begun feeling right arm pain (on vaccine site), headache mild but continued until 4 pm same day, dizziness, felt cold though heavily dressed, right cheek tingling. Visited ED was evaluated however found to be hypertensive 170/95 (no prior history) later improved some mild headache, pain right arm improved e discharged when pain became g pain and dizziness mild , no more sensation of being cold, and assured by ED doc symptoms will improve x24 hrs. If worsen contact primary care physician

Immediately after receiving the vaccine, I felt tingling sensation in my extremities. I felt flushed, my chest became red, and I felt like my heart was racing. It generally lasted about a minute. Now, two hours later i am still feeling some tingling in my left arm.

Fast Heart Rate and light headed 10 minutes after receiving the injection and lasted around 5 minutes.

12/19/2020 Received vaccine 12/20/2020 around 2am woke up with strong body aches, pain at injection site, chills, and fever 100.9. Continued with extreme fatigue, headache, body aches and high fever through out the day. 12/21/2020 fever gone,arm still sore and headache returned mid day.

Left arm numbness/heaviness 15 minutes post injection, mostly resolved with minimal parasthesia at departure. Patient advised to go to ED for any additional symptoms.

pain at injection site, fatigue, headache, malaise, body aches, irritability

On 12/18/2020 when I woke up at 10am. The site area of the vaccine was sore, then my neck started hurting. When I went to the bathroom to view it, my right lymph node is swollen, and sore to touch. My lymph node is swollen on the same side I received the vaccine. It's still swollen today 12/22/20 and still sore to the touch. It was stated that reactions were to last 24-48hours, but this has lasted past then. No fever, no dizziness, and no nausea, just swelling in my neck.

phone call

Muscle and joint pain started 12/19/2020 and ongoing

PVCs developed about 20 minutes after administration of vaccine. Placed on Zoll cardiac monitor. Vitals to include BP, heart rate, respiratory, pulse ox several times during additional monitoring period. No respiratory distress or other issues during this monitoring period. Monitored until 1510, patient contacted primary care provider via patient portal.

12/17/20 10-mintues post injection headache, l numbness in face (15 mins, then resolved), injection site l arm and pain in r upper arm (has not resolved), nausea, loose bowel movements. 12/18/20 severe

body muscle pain has not resolved not as severe today 12/22/20, 12/19/20 joint pain in fingers more severe to l hand than the r hand, unable bend from pain today 12/22/20

Hour after vaccination: muscle and joint pain bilateral arms (still ongoing next morning but feels better after ibuprofen), right side face felt weird (numb/weakness) spouse said it looked a little swollen (face felt better next morning after benadryl)

Approximately one hour after receiving the vaccine her arm was very sore by 8pm, 12 hours later, she was very fatigued and had an upset stomach. She slept from 8pm to 5am with a very sore arm, upset stomach, pounding headache and bad body aches. She continued to sleep the remainder of the day after the vaccine.

"Employee reports onset of slight headache after vaccination on 12/17. It was relieved by motrin. On 12/18 she had ""a little dizziness"" with shifting positions. She hasn't taken any medication. The symptom has become much better. She also had mild nausea which has improved. She feels like she is not well enough to be at work today. She is going home."

Fatigue and redness around injection site about 5 hours post vaccination. Symptoms resolved by next morning.

Pt reported mild tachycardia within 15 minutes of receiving the injection with tingling in her legs. She returned to work and did not note the tingling again until the next evening. At that time, she noted tingling and a sense of weakness in her legs, though no manifestation of weakness (i.e. no falling down or legs giving out). Symptoms persisted through the 18th and 19th but were noted to resolve on the 19th.

Arm pain, shoulder pain, neck pain, back pain, fatigue, headache, chills, body ache, slight dizziness. Tylenol and Motrin taken, ice pack applied to arm

redness, hot and slight swelling in left arm and itchy all over

gout attack

TIGHTENING OF THROAT, VERTIGO - 50MG IV BENADRYL

"Initially she felt flushed and ""foggy-headed"". Then developed a metallic taste in mouth and elevated blood pressure, required extended monitoring period with continued elevation in blood pressure. Heart rate and respiratory rate stable, no respiratory distress noted. Highest BP 195/93 ranging 180s/90s, however denied need to be seen in emergency department. Final BP 155/93, less foggy, no dizziness or lightheadedness; feeling flushed remains however, declines emergency treatment. Total monitoring time: 83 minutes, without significant distress."

Fever, chills, rashes, CP, fatigue, diarrhea, congestion, pain at injection site and numbness to left arm

Head ache- started around 1pm on 12/18/20. Small joint pain started around 7pm on 12/18/20 and continues to present

About 10 hours after receiving the vaccination I became acutely lightheaded and dizzy. I walked to my bed and laid down. After 4 hours I was no longer dizzy.

Moderate soreness to injection site, mild fever, chills, body ache and head ache all started the day after the vaccine, and lasted for 2 days.

Pfizer-BioNTech COVID-19 Vaccine EAU I started with bilateral leg aches about 6-7 hours after receiving my COVID-19 vaccine. It slowly progressed through the evening. Upon awakening this morning at 4:45 am, I feel like every muscle and joint in my body is aching and hurting so bad! I am nauseated, have chills, sore throat, and fatigue.

12/21/20 fever 101.9, body aches, lower back pain, congestion and cough -- tylenol . 12/22/2020 mortin for fever AM 101.9 some relief, symptoms less today.

Headache, Angina & sore throat ALTEPLASE 2 MG ONCE left upper arm@ 12/17/20@1522

Body chills then a fever Body aches Diarrhea Headache Feeling very unwell

patient has a history of minor allergic reactions. She developed some difficulty swallowing and tightness in throat. She was not in distress and requested oral benadryl as this has worked for her in the past. Vitals monitored, benadry given 50MG PO. Patient improved over 45 minutes. Returned to work with instructions to report to ER if symptoms return.

Headache

19 y/o fully immunized female with history of anxiety presents for dizziness and nausea x 2 hours. Received COVID vaccine at 14:30. At 16:30 went from sitting to standing, felt dizzy and nauseous. No syncope. No palpitations. Similar reaction to influenza vaccine. No intervention required to previous vaccination. No history of anaphylaxis. BP 125/88, pulse 88, RR 18, 02 95%, temp 37.3.

After about 10 min, she noted numbness and tingling in the 4th and 5th digits of the hand on the side where the injection was given. She felt SOB and like she might pass out though admits this may be from anxiety. She remained in the vaccine waiting area for 45 minutes, she notified staff and was provided something to drink. She was eventually dismissed and returned to work where she completed her scheduled shift on Med Surg. On Friday, she felt numbness and tingling in both hands, both feet, and her face intermittently that persisted into Saturday. On Sunday she noted swelling in both hands to the point that she could not put her rings on. The numbness and tingling was improved in hands and face but persisted in her feet. Monday she reported that swelling is improved but still present, and there is still slight tingling in her hands. She also notes that she has been fatigued since receiving the vaccine. She had injection site pain and some generalized muscle achiness for about 36 hours after receiving the vaccine, but that has resolved. Today (Tuesday) she reports continued sensation of mild swelling in hands, reporting that they feel tight. Otherwise symptoms appear to be resolving.

A little bit of arm and neck pain still. Today I am feeling great.

Pt. received part one covid vaccine on 12/15 at 4:30 pm. The next morning at 10:30 when she woke up, she had moderate facial swelling and redness. (No rash, no GI discomfort, no difficulty breathing) Pt. took Benadryl, Zyrtec, and iced face. The following day it resolved after another dose of Benadryl.

Seen in ED - mild symptoms of feeling like his throat is swelling and he has shortness of breath. Physical exam was normal. Vital signs normal. EKG with sinus tachycardia at 106. Given PO benadryl and prednisone. Observed in the ED for a couple hours without further worsening of his symptoms. Impression/plan: possible reaction to Covid vaccination. Improved. D/C home

Vaccine was given in the ED because the employee had a history of allergic reaction to shellfish. She reported feeling like her throat was closing up and she was having shortness of breath soon after receiving the Covid vaccination. By the time the physician evaluated her she reported her symptoms had resolved. She was observed in the ED for an hour with no return of any symptoms. No medication or other treatment was required.

12/19 - onset of abdominal pain which is like her usual chronic necrotizing pancreatitis which she has had off and on for 10 years. This was accompanied by nausea. The pain & nausea last for about 3 hours. 12/20 - nausea and diarrhea. Today 12/21 she reports that she has recurrence of the abdominal pain, nausea, and feels hot. She is at work today. Advised to contact her physician for assessment and treatment as needed. Will follow-up with her

"Chills, body ache, fatigue 100.9 fever-lasted 24 hrs Injection site very sore + approximately 48hrs after injection soreness mored toward armpit. Arm is warm, red, itches slightly almost entire upper arm (5"" long x 2"" wide) + still tender to touch on 12-21-20"

Had vaccine shot on Saturday 12/19/20. Slight tingling/numbness in cheek and upper jaw for 45 minutes on Sunday 12/20/20.

Given the vaccine at 712 pm on 12/20/20. At approximately 715 pm, she began to clear her throat and then became unable to speak, followed by audible wheezes and short, shallow breaths. At 1923, Epinephrine was administered. At 1928, she was able to speak again and was transported to the ED. The patient reports after arrival to the ER, the symptoms returned. She was given PO Benadryl, followed by IV Benadryl, and then a 2nd dose of Epinephrine. She was admitted to the ICU for observation.

DEVELOPED LEFT LOWER EXTREMITY WEAKENSS for 72 hours post vaccination. Loss of sensation in left foot continues.

12/16 vaccine date 12/16 - fatigue, H/A, low grade fever 12/17 - fatigue, body aches, moderate headache 12/18 - resolution of all symptoms

At work patient had ALOC x10 minutes. Rapid response called. Transf to Hospital (12/18-12/20). D/C Dx ACUTE CORONARY SYNDROME (NON-STEMI)

"12/18 - developed headache and nausea. 12/19 - developed fever and fatigue and cough. 12/20 - temp to 100.7 with cough and some body aches. 12/21 - feels the same as 12/21 but with bad headache and

fatigue. She is taking TYLENOL and ibuprofen for the symptoms. She feels she's the same today as she was yesterday. She stayed home from work 12/21. Because of her prolonged symptoms and fever with cough - a COVID-19 PCR nasopharyngeal swab test was performed. This case back as ""DETECTED"" on 12/21."

Feels unwell. Temperature is at 100.3F.

None stated.

fever, body aches, light headness/dizzy, vomiting

chills, fever 102, fatigue, headache, sore throat, cough, SOB with exertion

Mild rash to neck and upper back- not itchy, just red starting at 9:30 pm on the night of the injection. The following morning- Body aches, headache, sore throat- moderate in severity.

Within the first 15 mins I felt flushed , the left side of face hot and red , headache , ears started to ring, hour later I felt nauseated, light headed .Left side of face felt numb , really tired . The next morning I was fine , left arm was sore couldn't lift my arm . Since the Vaccine I've been having headaches daily

Within 20 minutes of receiving the vaccine, experienced tingling on both sides of mouth and sensation of numbness in lower lip. Symptoms lasted for 15 minutes or so and resolved. No other symptoms noted.

Fatigue. Joint pains. Muscle pains. Numbness and tingling of hand/feet. Fever 101.2 . Headache

Fever, chills, sweats and a few hours later headache and myalgias

I woke up the next morning with a little puffiness in my face, my eyes and my cheeks

Very bad HA, almost migraine, 21 hrs post injection. Then added nausea. Some neck soreness. Slept/rested for 8 hours. Took excedrine and advil intermittently.

Ten minutes after received the vaccine, patient felt lightheaded, weak, diaphoretic, dizzy, nauseous, and experiencing palpitations. At that time BP 112/78 mmHg, pulse Ox 99%, HR 102. Patient was transferred to the Emergency Department for monitoring. Patient was discharged without any further sequalae.

First night local pain (1/10) only. At 45 hours post vaccine, few palpitations. At 49 hours, a few more. At 53 hours, multiple continuing palpitations without letup so went to ER Friday night 12/18. Many PVCs, some bigemminy. This is also now only 5 hours after my BID dosing of carvedilol 25mg. Cardiac and metabolic workup negative -- all normal. Went home after 4 hours. Mild chills at times but never fever. Amount of ectopy and annoying symptoms declined during following day. My internist placed me on additional propanolol beta-blockade to add to carvedilol. Still required some extra propanolol day 5 post-vaccine but otherwise felt basically normal.

hives on neck and chest 20mins after the injection. The hives burned no itching

Felt fine after vaccine. Approximately 9 pm, I went to bed and began experiencing paresthesia in right arm, then noticed the paresthesia in both hands, both feed and also in right leg. The following morning, was primarily in my hands. I went to work, and as the day progressed, noticed in my feet, and right leg again, but hands not right arm. On Sunday & Monday, the paresthesia was more intermittent with timing lengthening between bouts. Monday, I went out in my car, and noticed that the paresthesia was worse in my right foot, Mid plantar to toes, Couldn't feel the gas pedal with right right foot. No paresthesia in left foot, left hand. Also noticed besides not feeling well, that I felt like was in mental fog, unable to articulate some things. That was intermittent, also (have had poor appetite for @ least a week prior to vaccine). This morning (Tuesday) I have paresthesia from my right shoulder down to fingers, and continue with right foot from mid plantar to toes. Mentally feel a little bit better, not as foggy.

Fever, chills, body aches muscle and joints, headache, ringing ears, eye pain

Patient stated burning sensation upon administration of Pfizer-BioNTech COVID-19 Vaccine.

Hives at day 2 treated with OTC medication like benadry. Day 4 reported shortness of breath and patient being seen in the ED.

Felt pain after vaccine. I had some diarrhea. Then this morning, I had more diarrhea with my throat soreness, and congestion, and still diarrhea.

dizziness, light headedness, severe nausea, rash/hives over chest and back and forearms, severe chills/shivering

Right jaw numbness, resolved with 1 hour, did not seek medical attention.

20 minutes after receiving the vaccine this employee experienced nausea

At 35min post vaccine patient noted with redness to the chest, neck and going up to face and bilateral ears. Ears were swollen. Patient transferred to the Emergency Department where she was noticed to have swollen lips

Bodyaches, headache and chills that started the next morning after the vaccine.

nausea that night, Vomited that night and the next morning , Fatigue, headache

57-year-old female history of hypertension, hyperlipidemia, type 2 diabetes, COPD, subsegmental PE is not on anticoagulation, multiple cardiac stents presenting with greater than 12 hrs of worsening left-sided chest pressure, headache and shortness of breath. Patient takes a daily aspirin and had no improvement of symptoms with her at-home nitroglycerin. Here afebrile, HTN, remaining vitals wnl. Non-toxic, in moderate distress 2/2 to pain. EKG with minimal ST depressions in leads II and III. Will plan for CXR and labs. Pt given zofran and morphine for pain control. Will give additional aspirin for total 324 mg in last 24 hrs. On re-evaluation, pt with mild improvement in pain. Troponin elevated at 0.18, remaining labs wnl. At this time concerned for NSTEMI, pt treated with 1 mg/kg of lovenox and MOD consulted for admission. MOD evaluated pt and cardiology was consulted. Given concerning PMHx and

current hx of chest pain with findings consistent with NSTEMI, cardiology at recommended likely transfer for cardiac cath. Will pend repeat troponin and EKG for dispo decision.

Employee described being fatigued, dehydrated, and low grade fever

Woke up in the middle of the night on 12/20 and noticed that the left side of tongue felt like he had bit it. He woke up again on 12/21 at 1:10 AM with a swollen tongue. He also had left sided unilateral edema. NKDA or significant past medical history. No past allergic reactions. Went to the ED and was treated with benadryl and a methylprednisone. Sent home with additional medications in case condition worsened again.

Employee reports itching and tingling to right arm that traveled to elbow, employee reported sensation was 'easing up' 5 minutes after it started. She also reported itching to flank area, no rash was noted. Employee was taken to ED for evaluation and treatment.

Increased heart rate, increased blood pressure, cold/clammy feeling, urticaria (neck), swelling in neck and chest. At vaccine clinic area, Benadryl 50mg IM given. Rapid response called via overhead page. Patient taken to ER from vaccine clinic. In ED, given famotidine 20mg IV, methylprednisolone 125mg IV.

Tongue tingling, throat tightness @0520 Chest heaviness, lips numb @0525 Voice hoarseness @ 0530 IV Benadryl given approx 0550 PO prednisone given approx 1000 Left side of face still numb after 24 hours

Employee experienced nausea and headache

ain at injection site 8 hrs after injection, fever, chills, joint and muscle pain, tiredness 16 hrs after infection. temp reached 101.0.about 20 hrs after injection. temp down to 99.6 after 36 hrs, just still running some low grade temp. soreness, joint pain better.

12/17/2020 INJECTION. 12 HOURS LATER, NAUSEA W/ TACCYCARDIA, PROXIMAL. HEARTRATE 150. WENT TO ER. HAD TESTS DONE. NO HISTORY OF ANXIETY; HAD PRETTY ANXIETY. LASTED ABOUT 45 MINUTES. ATIVAN PRESCRIBED BY ER DOCTOR. DIAPHORETIC. I AM WORKING BUT STILL DIAPHORETIC AND STILL FEEL A LITTLE FATIGUED. DON'T KNOW IF RELATED TO VACCINE.

Exhausted, dizzy, nauseated, rapid heartbeat, pain in joints all over body, fatigue

1 episode of vomiting and diarrhea 12 hours after administration. Afebrile. No other events of nausea/vomiting yet during pregnancy. 4 weeks, 4 days pregnant. EDD 8/27/21.

Began developing tightness/soreness in his throat, some DOB, and increased blood glucose. NKDA or history of adverse reaction to vaccines. Benadryl 50 mg given IM at clinic site. Noted to improve after 15 minutes. Was sent home with instructions to return to the ED with worsening of symptoms.

Approximately 65 hours post-vaccination patient felt profound fatigue, no appetite, and had increase in baseline chronic cough, and anosmia. Patient was admitted to the hospital on 12/21 due to worsening respiratory symptoms that required supplemental oxygen-initially 2L via nasal cannula. Patient was

upgraded to ICU-level of care at 6:30PM 12/21 to receive high-flow nasal cannula, and has had one episode of fever (100.6) 12/22 at 7:00 AM.

Post-dose 1 of COVID-19 Pfizer vaccine, pt started feeling lethargic and lightheaded. Lightheadedness start 12/18(post-dose Day1) and it became more significant 12/19-12/20.

fever, chills, headache, dizziness, lightheadedness, body aches

I have a sore throat, runny nose. Also, I am having chest discomfort as my chest feels heavy, the mask did not effect my breathing, but now since I received the shot it is hard for me to breath while wearing a face mask. I am taking deep breaths to try and catch my breath. My hands are swelling with fluid and going numb. I feel warm/hot but no temperature

12/18/20 approximately 10:00am 1st COVID injection administered. within 30 minutes I had a mild headache (was not throbbing but nerve shooting in nature). later that evening i noticed heart palpitations and rapid heart rate max 130 reps. the heart rate quickly normalized but heart palpitations remained intermittently that night. Saturday morning I woke with stuffy sinuses, chest little tight but chest tightness clear with coffee intake. sinus remained irritated and then as day progressed i began feeling aches/fatigued/temp 99.0F/mild headache with shoots ear pain bilateral/mild chills/loss of appetite. woke Sunday feeling fine with the exception of loss of appetite. As Sunday progressed i attempted to eat lunch approximately 2:00pm (first meal of day). could not eat much, felt heavy on stomach, began to feel aches/chills/no Temp/loss of appetite with stomach pain and nausea after eating solid food/fatigued again. since then these symptoms have remained. reported to necessary provider and Employee Health.

swelling to uvula seen in Emergency department observed for 4 hours in Tele unit sent home on 12/21/2020

Slight tingling in injection arm

None stated.

employee self-administered epipen prior to going to ED (community)

Employee received vaccine in hospital. Waited through 15 minutes observation period and went back to his shift. There he felt some throat irritation and lip tingling. Manager took him to the ER where they evaluated him - vital signs stable, no shortness of breath, no rash - and gave him benadryl and prednisone and he was able to return to his shift and complete his entire shift.

None stated.

None stated.

Was taken to Emergency Department within the same hospital facility where vaccine was administered. No other side effects other than those mentioned above: scalp itchiness and erythema to right knuckle.

Immunized at 9:15 AM- no symptoms, 2-3 episodes of palpitations throughout the day, resolved spontaneously; 9:00 PM chills and palpitations lasting approximately 1 hour- resolved spontaneously with no further symptoms outside of a sore (expected) injection site.

Left arm pain radiating down extremity, mostly resolved immediately

About 4-6 hours after I had the vaccine, I experienced severe tenderness at the injection site. I had a low grade fever of 99.6 for a short period of time. Dizziness, headache, and body aches have continued over the past 9 hours (~2AM - 11:30AM).

All started 2 days after injection Severe Headache, Diarrhea , Chills, congestion nose

Patient provided immunizations, after injection and retraction of needle, member has some fluid seepage from injection site. Concern not entire 0.3ml were absorbed. No pain or redness at site. Member scheduled for follow up 2nd dose in 21 days.

States she had headaches lasting several days, back and hip pain, shoulder and upper back soreness, chills. Took Ibuprofen, did not alleviate symptoms. Slept and rested until symptoms subsided. Symptoms lasted for about 3-4 days.

Pfizer-BioNTech COVID-19 Vaccine EUA On 12/21/2020 13:17 the patient received the first dose of COVID-19 vaccine. During monitoring, the patient experience itching skin. Hives and welts were not located. The injection site was read and hot. No wheezing occurred, no tachycardia observed. The patient report a history of anaphylactic reactions to food (Sesame), but has never had an anaphylactic reaction to vaccines in the past. Patient also reports anaphylaxis to lidocaine. The patient was treated with ice pack on injection site, 50 mg diphenhydramine, 10 mg cetirizine, and 20 mg famotidine. Patient was observed for a full hour. Advised to pre-medicate at 2nd dose and to alert vaccinator of this reaction.

My arm was not that sore or anything but Friday morning when I woke up my throat was really really sore and I felt congested. My nasal mucus was green and I was also coughing up some green phlegm. I went to the walk in clinic because I had to go to work and wanted to make sure I was well enough.

12/19/20 AM tender arm-- PM arm/ hand tingling numb, itching hands and lips. 12/20/20 Nurse triage line advise to take medication for Loratadine 10mg, Symptoms have not resolved; not as intense today 12/22/2020.

headache and extreme pain in left arm

Dizziness, muscle aches, sore throat

Itching at medial surface of left upper arm (injection site on lateral L UE). Also reported numbness down ventral surface of L forearm into hand. No weakness. She received Benadryl 50mg po at 10:00am. Itching began to improve during this documentation. No airway compromise. Clear mental status. She is recovering from the itching, but the numbness in the hand is still present.

12/16/2020 around 2300 body aches, followed by chills progressed to rigors, developed a migraine 6 to 8 hours after fatigue, insomnia, temp was 100.4. Those symptoms progressed and stayed stable for 24 hours until the next night and didn't resolve until the 18th and late that night I developed lymphadenopathy in left axilla, al nodes very swollen and large. That subsided since then. I took Tylenol and 10mg Rizatriptan for migraines and that resolved. **I was in a double blinded study for the AstraZeneca trial and am still unsure whether or not I received the placebo or the actual shot. Nov 30th

within 10 mins of receiving the vaccine I had a burning sensation across my chest, arms and face, developed hypertension, tachycardia and had perfuse sweating. Blotchiness was noted on my face. I felt like the inside of my body was on fire, only in my torso area. I was given an ice pack, vitals were monitored and the symptoms resolved after 10 mins. Then within 5 mins, the symptoms returned. They again last for about 10 mins and resolved enough for me to leave the vaccination observation area. I was monitored closely for over an 1hr post injection. I did have itchiness in the roof of my mouth, so I took Benadryl 50 mg when I got home and the next morning had major fatigue and mild soreness in the injection site.

I would just say not sure if it's from vaccine exp severe headache 12-18 hrs after vaccination. No other symptoms was unable to return to work.

Headache, Chills, sore throat, muscle weakness, fatigue

Symptoms occurred approximately 30 minutes after vaccine administration

Chest tightness and shortness of breath since 12/19/20

"Patient noted that approximately 18 hours post vaccination, began to experience ""COVID"" symptoms, including aches, chills, dizziness, shortness of breath, fatigue, difficulty focusing, some lower limb weakness. Patient did conform past COVID infection and symptoms are consistent, yet milder than when actively infected."

Had chills at 3 am, took Tylenol 750 mg PO. Skipped work that day due to unexpected chills. Had a fever of 100.3 F, neck pain, headache and muscle aches around noon the same day. Took another Tylenol 750 mg. At 9:00 PM and next morning at 6:00 AM took Tylenol 750 PO. No more symptoms observed.

Itchiness in throat and edema at the mouth.

Sore arm, chills but no fever, body malaise

Pfizer-BioNTech COVID-19 Vaccine EAU

12/18/2020: Pain/heat at injection site, dizziness, muscle aches, nausea, increased mucus production, fever, chills. 12/19/2020: Fatigue, tiredness, headache, nose congestion, muscle aches, injection site was very painful/muscle stiffness left deltoid/applied heat didn't even help, left arm wasn't red, swollen, or hot to the touch. 12/20/2020: Fatigue, tiredness, increased mucus production, cough,. ADHD medication was not taken this day to specifically rest the majority of the day because I thought that would help

alleviate the symptoms. 12/21/2020: Cough, headache, nasal congestion and drainage. I did take a short jog (2mile) this day because I was felling overall better. 12/22/2020: Cough (no chest congestion), increased mucus production, headache (sinus), tiredness, slight confusion/unable to focus well, nausea, diarrhea.

Pt noticed discoloration/mottled appearance of skin near joints on lower extremities. Adverse event lasted less than 36 hours and resolved without treatment.

1st day- started to have left arm pain, sore, heavy at around 6PM 2nd day - started at 5 am noted my left arm was swollen, still sore & painful, having chills, headache muscle aches and later on having fever 99.8F-100.2F. Took Tylenol x 3. 3rd day - still having muscle aches and left arm pain & soreness. 4th day - still having mild left arm pain.

Left UE injection site soreness 4 hours post. Severe vertigo approximately 10 hours after, lasting about 4 hours.

Dry mouth and dry throat. Symptom began 15 minutes after injection and lasted about 3 hours.

Employee calling to report a reaction after receiving a COVID-19 vaccine. Vaccine Name - Pfizer Vaccine Lot # - EK5730 Vaccine Date and time - ?12/18/2020 @ 5:30pm Is this your first or second dose? First Date and time of symptom onset - ?12/22/2020 @ 9:00am Symptoms - ? mild dizziness, feeling hot but no fever, very mild sore throat, intermittent cough, fatigue Last day of work and shift - ? 12/22/2020 7a-3p Home remedies? none Any improvement? - n/a Recommendation? Employee asked her manager to go home early because of her symptoms. She wanted to be tested cause her family from out of states are coming over for the holiday. Advised to continue monitoring at home & call us back if symptoms worsen. Employee voiced understanding Employee of information ? yes Employee voiced any concerns ? no Employee?s questions answered to employee?s satisfaction - yes

Shortness of breath, chest tightness. Treated with epipen, benadryl, pepcid, solumedrol in ED. Symptoms resolved.

Hives

Employee reported diminished sense of smell and taste and 12/18 the day following vaccine. A nasopharyngeal swab was performed for PCR testing for COVID-19 on the day (12/18) and was negative for COVID-19 (Not Detected).

Notes APRN (Nurse Practitioner) ? ? Pediatrics Cosigned by: MD at 12/20/2020 11:30 AM Expand All Collapse All á COVID VACCINE CLINIC 12/18/2020 á Patient: Date: 12/18/2020 Subjective Patient is a 36 y.o. female who was seen at Vaccine Clinic today for her first dose of the COVID 19 vaccination. á She denied any history of previous adverse reactions to vaccines. á She was given the Pfizer vaccination in the right deltoid muscle. á During her 15 minute waiting period after the injection, the patient began to experience throat tightness. She denied rash, hives, difficulty breathing, hoarseness, lightheadedness, dizziness, facial swelling, lip swelling and tongue swelling. á This provider was notified of patient reaction and she was then assessed in the emergency bay area. á Monitored patient for severe reaction

symptoms, including rapid progression of symptoms. á Patient has PMH of mild anxiety á Review of Systems Constitutional: Negative for activity change, appetite change and fever. HENT: Negative for congestion, facial swelling, rhinorrhea and trouble swallowing. Initially with some throat tightness. Resolved within 10 min Respiratory: Negative for cough and shortness of breath. Neurological: Negative for dizziness, weakness, light-headedness and headaches. á á á Objective á Vitals Vitals: á 12/18/20 1251 BP: 130/82 BP Location: Left arm Pulse: 98 SpO2: 100% á á Physical Exam Constitutional: General: She is not in acute distress. Appearance: She is not ill-appearing. HENT: Head: Normocephalic. Mouth/Throat: Mouth: Mucous membranes are moist. Pharynx: No posterior oropharyngeal erythema. Cardiovascular: Rate and Rhythm: Normal rate. Pulmonary: Effort: Pulmonary effort is normal. Musculoskeletal: Normal range of motion. Skin: General: Skin is warm. Capillary Refill: Capillary refill takes less than 2 seconds. Neurological: Mental Status: She is alert. á á Assessment/Plan á Treatment included no therapy. Follow up response to treatment:excellent. Patient discharge: Stable to go home and follow up with PCP. á Monitored patient for 15 min in the emergency bay Within 10 min of arrival the throat tightness resolved Patient felt comfortable to be discharged home - feels that she was anxious about the vaccination. Strict orders to go to the ED if shortness of breath, throat tightness, or other allergic symptoms develop or worsen. Patient verbalized understanding. á Orders Placed This Encounter Procedures ? COVID-19 á á APRN Electronically Signed 12/18/2020 2:17

None stated.

chest pain, across bottom of rib cage, pain with deep breathing, Motrin did not help

Sore arm, shortness of breath, swollen lymph nodes, anxiousness, and tiredness.

First 10 minutes felt cold, headache and numbness in both legs. Tingling in legs and headache remained for 30 minutes. But then indicated felt much better after 30 minutes. Patient also stated that he felt he needed to urinate right away. Patient stated he is blood pressure medications and did not take his medications the morning of the vaccine administration. Pre administration BP 143/76 and Pulse 92 Post administration BP 235/135

Employee experiences nausea and injection site pain

Hives on left leg above the knee (ventrolateral surface)

Self-limiting Pain at injection site (lasted 3 days) Self limiting Tingling in left arm (pins and needles feeling) starting morning after the vaccine and lasting for 3 days and mild hand tingling (lasting 4 days).

immediately after the injection was administered, pt experienced a vagal response; experienced instant lightheadedness, dizziness, and diaphoresis. after elevating feet and sipping cool water, all symptoms resolved after about 15 minutes and pt was able to leave the clinic on her own. pt also reported high level of anxiety prior to receiving injection.

Pt called to report rash on arms and legs on day 3 after receiving the vaccine.

Entire left arm pain that radiated up left side of neck, fever, chills, body aches, joint/muscle pain, teeth hurt, hair hurt, sweats, nausea

Developed body aches and fatigue the day of the vaccine. Developed fever of 100 and high bp and p 12/22 (day after vaccine). BP 151/108, p 116. Referred to clinic for f/u.

Developed body aches and fatigue the day of the vaccine. Developed fever of 100 and high bp and p 12/22 (day after vaccine). BP 151/108, p 116. Referred to clinic for f/u.

PT states he began feeling tired the afternoon of the vaccination, approx 1500. He rested and woke during the night at 2am with temp of 103.0 and headache, muscle aches. Temp at 3 am was 100.7 and headache/muscle aches. Temp 0900 was 100.0 with headache/muscle aches. Pt denies nausea, vomiting, sore throat. will continue to monitor

"12/21/2020 4:30PM itching throat, clearing of throat, lump in throat, coughing, very dry throat, coughing sensation to remove ""something"" in throat, fat tongue/throat feeling, throat feeling as if closing, coughing fit --- pt transferred to ER. Panic attack, unable to breath feeling --medications via IV -- Benadryl (flushed), Pepcid and steroid for inflammation) administered. Heart monitored while receiving treatment. Discharged at 08:00 PM with prescription for Benadryl and steroid Prednisone."

Headache Fever- temp as high as 102.7

Patient self reported day after vaccine having an adverse reaction and taking benadryl. He reported to work today.

Developed numbness in legs and back of neck. Swelling on left side of face. Given Benadryl 50 mg PO and sent to emergency room.

Employee began to experience light headiness right after receiving the vaccine

Headache ,whole body ache , back pain ,low grade temperature 99.2 since yesterday

Dizziness, headache, body aches. Temp 99.4-99.6. Supportive measures.

Itchy rash on face and neck, slight body aches, fatigue

Shortly after receiving the vaccine I developed a headache followed by muscle aches, fever, chills, nausea, joint pain, brain fog, fatigue, dry cough.

20 mins after receiving vaccination experienced lightheadedness, palpitations, and faintness; was assessed (BP, HR, RR) which were elevated; rested, water, and started to feel better; 20 mins later had another wave of lightheadedness and my vitals increase again which was more intense then the first time; put me on O2 and sent me down to the ER where they monitored me on telemetry, general blood work, EKG, and assess me for swelling, rash and further reaction; BP got to 134/100 but other then that no outstanding numbers; 15 mins after arriving at ER they gave me benedryl and a steriod per IV and IV fluids; right after they gave me that had another wave of lightheadedness which didn't last a long as the

others; symptoms seem to subside and then the let me go home; had no further issues that night other then insomnia; Next day had shortness of breath on exertion but was able to go about my day and just ease up is I was tired; at 6pm that night I started having redness, hottness from the injection sight and the redness (like flushing, not rash) spread from my left arm across my chest to my right arm, and up to my face; felt over heated like I was having a hot flash and my left ear (side I received the vaccine) start to ring; took a dose of benedryl per the bottle instructions and it seemed to calm down; today (day 2) I woke up feeling somewhat ok but as the day is progressing my head feels floating and having trouble concentrating, my upper body from my chest up feels tingly, heavy and weak like I just worked out my muscles and my had are really cold esp on my right hand; my vaccine site is still very warm;

"Patient states that she received the vaccination at 10:24 AM. Patient states approximately 2 minutes after that she felt pain and swelling and erythema in her left arm at the injection site. Patient states she felt like she had a somewhat of a ""apple in her throat"". Patient states that her left arm was tingly. Patient states that she has a headache in the bitemporal area. She states that she has a history of headaches. Patient states that she has no visual changes. Patient states that it started after the immunization. Patient states 5 minutes before I came into the room she vomited and now feels tremendously better. She is talking in a complete sentences. Patient is somewhat tachycardic on initial Patient states that she received the vaccination at 10:24 AM. Patient states approximately 2 minutes after that she felt pain and swelling and erythema in her left arm at the injection site. Patient states she felt like she had a somewhat of a ""apple in her throat"". Patient states that her left arm was tingly. Patient states that she has a headache in the bitemporal area. She states that she has a history of headaches. Patient states that she has no visual changes. Patient states that it started after the immunization. Patient states 5 minutes before I came into the room she vomited and now feels tremendously better. She is talking in a complete sentences. Patient is somewhat tachycardic on initial presentation. Patient presents via BR RT for evaluation. Patient has a host of allergies.Patient is anxious upon presentation. Patient does have a history of anxiety. No other travel or trauma. Patient states that her pain is severe. States that she has some pressure in the bitemporal portion of her head and her left arm injection site. Otherwise nonradiating. No other known aggravating, triggering or alleviating factors. Patient dates its concurrent with the injection time. Otherwise nonradiating. BP 180/100 at 1045, O2 sat 98%, ECG sinus tachycardia Repeat Vital Signs BP 133/82 | Pulse 82 | Temp 36.9 ¦C (98.4 ¦F) (Oral) | Resp 16 | Ht 1.702 m (5' 7"") | Wt 197 lb 1.5 oz (89.4 kg) | SpO2 98% | BMI 30.87 kg/m¦ Constitutional: Well developed; well nourished; in no apparent distress; non-toxic appearance HEAD: Atraumatic. Normocephalic. Eyes: PERRL; EOM intact; conjunctiva and sclera normal to inspection. HENT: TM's normal; no rhinorrhea; normal pharynx with no erythema or exudates. Mucous membranes are moist. Uvula is midline. No hemotympanum or foreign body. NECK: Supple; non-tender; no cervical lymphadenopathy. Respiratory: No respiratory distress; normal breath sounds; breathing non-labored Cardiovascular: Normal rate; good peripheral perfusion. No murmurs or rubs CHEST: Nontender. There are no retractions. GI: Normal bowel sounds; non-distended; non-tender to palpation; no palpable organomegaly GU: Musculoskeletal: Extremities non-tender; normal range of motion; no edema; Normal distal pulses Back -Normal tone; no tenderness Integument: Well hydrated; no lesions; no significant rash or palpable nodes. Neurologic: Alert, appropriate; oriented to person; place and time. No focal deficits. Motor 5/5. Sensation intact in all 4 extremities. Psych: Mood and affect are anxious.

Mental status appears normal at time of exam. Patient upon presentation is anxious. Patient did vomit x1. Patient was talking in complete sentences upon my evaluation. Patient feels that she has some discomfort to her injection site with a headache. They feel no warmth or erythema. Patient was given Tylenol for the headache which did improve. Also received ondansetron, diphenhydramine, famotidine, methylprednisolone, NS 1000mL. Patient was monitored for an extended period of time and has had no return of symptoms. I am uncertain whether this is a true allergic reaction since the symptoms started approximately 2 minutes from the time of the injection. Patient does have a history of anxiety and this may have played a role within the symptomatology. At this time patient feels much better. Patient be dismissed we will send the patient home with a prednisone taper. She can take oral Benadryl and Pepcid. Follow-up with her family doctor next couple days not feeling better. Patient is dismissed. Patient returned to ED on 10/22/20 0100. Presents to ED complaining of numbness and tingling all the way from her head to her left toe on the left side. Has taken Benadryl 3 times today. She states that she woke up this evening with her heart racing. She still has a little bit of a headache. No fevers. He was nauseous. Again she says the whole left side of her body is tingling. All other systems negative/without deficit. HR 124, BP 168/107. Repeat Vital Signs: BP 129/77 | Pulse 99 | Temp 37.2 ¦C (98.9 ¦F) (Temporal) | Resp 20 | Wt 206 lb 2.1 oz (93.5 kg) | SpO2 100% | BMI 32.28 kg/m¦ EKG showed a sinus rhythm without acute ST changes. She is anemic but she has a history of that and her hemoglobin is not significantly lower than usual. Sed rate is little bit elevated but her C-reactive protein is normal. Her glucose slightly elevated at 173 but the rest of her labs are normal. CT and CTA of her head and neck were normal. I do not know at this time if this is a reaction we will have her continue the prednisone taper she was started on earlier as well as Benadryl and have her follow-up with her primary care physician."

Left arm soreness and pain. Began overnight. No skin changes. Painful to touch. Painful with abduction and lifting. Empty Can Test positive.

Around 1-2am I developed a fever and chills associated with moderate diffuse myalgia, arthralgia in my left elbow strangely enough (injection was in right deltoid), and fatigue. My symptoms were constant until around 1pm when I took 500mg Tylenol. Of note, I had COVID in March 2020.

Lightheaded, dizzy, nauseous, and heart palpitations about 5 minutes after getting vaccine. Laid supine for 30 minutes with blood pressure continuously taken. BP 188/93

Developed numbness and burning to left arm. Had tingling on left side of face. Given Benadryl 25 mg PO and sent to emergency room.

30 minutes post vaccination, pt started feeling flushed and itchy (mostly in the anterior neck, Rside of face and R ear). Positive pruitis and flushing, vital signs taken, within normal limits for pt

Employee Experienced hotflashes

Weakness, low fever, chills, sensitivity to touch/light/sound, headaches, muscle aches, shakey

Contracted associate received vaccine on 12/18/2020 at 1000. Within 1/2 hour began to feel very hot and extremely tired. She left and had to rest in the lobby before she could drive home. She finally drove home and all weekend was short of breath, hot (not sure if she had a fever), fatigued. She went to the ED this morning (12/21/20) had a Rapid COVID test that was neg and is now waiting for PCR test results. She has been instructed to quarantine for 20 days. She has lupus and a history of kidney transplant in 2004.

Shoulder pain, arm pit pain, deep scapula pain with inability to move arm without significant pain starting on 12/20.

Felt dizzy with blurred vision for a few seconds. Began to have chills for a few minutes, with concurrent shaking.

Temperature of 99.6 and fatigue

Numbness to left arm with shoulder blade pain and neck pain. Resolved on own.

Severe fatigue, Brain fog

Employee Experienced high blood pressure, headache, and light headiness

7 hours after vaccination onset of fever, lethargy, headache, dizziness. 1 Liter Normal Saline

"Patient reports headache 7/10 not relieved by motrin. Onset of the headache was upon awakening at 0500 on 12/17. She denies visual changes, nausea, and vomiting. She also reports that her back is sore. She has a history of migraine headaches and has not taken her migraine medication for this headache. She says she gets headaches ""all the time"" and this headache is different for her in that she didn't experience the visual aura she usually gets with her migraines."

following vaccine administration, patient verbalized dizziness and became pallor. rapid response team notified for further disposition. patient denies chest pain, SOB, N/V. patient remain AAOX3 with no LOC. treatment resolved with no ED escalation. Patient exited vaccination area ambulatory with no concerns.

Patient started new blood pressure medication this morning. Vitals at beginning of ADR: BP 91/56, HR 66 therefore, rapid response called, vitals were BP 105/67, HR 73.

phone call visit

phone visit

Arm soreness, swelling achy, cold, headache

Pfizer-BioNTech COVID-19 Vaccine EUA given to RD on 12/16 @ 12pm. Loss of feeling in right arm started @ 4pm & lasted until end of day on 12/17, along with muscle weakness & migraine. All symptoms resolved by 12/20 & she felt great.

Ee stated she started to feel dizzy. V/S as followed B/P: 96/60 P: 63 O2: 99. Ee stated she was feeling clammy and she usually gets this way when given vaccines. Adverse reaction started appro 7:38 pm. Ee felt better approx. 7:46.

phone call

Right after given the covid vaccine. When I stood up to go to another desk, I sat down and my throat started to feel funny, and my tougue started to swell and I had a hard time swallowing. I informed the nurses that I have a problem. I was taken to the emergency room right away. I was treated with an epi injection and it did not relieve my reaction. They then gave me another injection, then later my throat started to swell again, and I was given another dose of an epi injection. I was release at 7pm after observation. Last night, I had another delayed reaction, I took a benadryl, and a zertec, and prednisone and the symptoms went away. This morning, I am fine. Today, it feels a little tight, but it's not bad.

"PATIENT STATES ""I FEEL LIKE MY HEART IS RUNNING"" HEART TAKEN AT 9:30- 90 IRREGULAR TAKEN AGAIN AT 9:49- 72 IRREGULAR PATIENT STATES THAT SHE IS FEELING BETTER PATIENT OBSERVED ADDITIONAL 15 MINUTES AND RELEASED"

Tingling all over the body, nausea, pale-looking, hot/cold, clammy, duration approx. 2 hours but not as severe.

had fever, chills, body aches?..a rough night. Still have body aches beyond just the arm

Headache, myalgias, fever, chills for 24 hours, starting 18 hours after vaccination

Severe headache for four days after vaccine, trouble keeping temperature below 100, extreme fatigue, shortness of breath, chills, nausea, loss of appetite, body aches, chest pain.

About 10 hours after I received the vaccine I developed chills and a slight fever (99.4). About 18 hours after I received it I developed shaking chills, fever of 100.6, and severe body aches. The fever responded to ibuprofen. It is now approx 28 hours after I was vaccinated and my fever and chills have returned along with the body aches. It is hard to tell if this is from the vaccine or if it from an unresolved pneumonia, as these are symptoms I had with the pneumonia and strep infection.

After I got home from work, around 7 pm I started to feel side effects such as the following: fatigue, muscle aches, feverish, malaise, injection site soreness/pain. This lasted for about 48 hours.

Temp spike at approximately 32 hours post vaccination. Mild flu-like symptoms that resolved 72-80 hours post vaccination

Racing & pounding heart, dizziness, tingling feeling prior to dizziness, then shaking hands. After shaking, heart rate returned to normal. No blood pressure change was noted. Whole event lasted no more than 5-10 minutes.

Arm/injection site pain within first 12 hours, then chills, followed by fever and severe headache, muscle aches and fatigue. Symptoms continued into 48hrs post injection.

I was awoken around 1 in the morning to severe calf muscle cramps - right and left leg, fever, body aches all over for about 15 hours. Tylenol, rest and water.

Notes APRN (Nurse Practitioner) ? ? Pediatrics Cosigned by: MD at 12/20/2020 11:30 AM Expand All Collapse All á COVID VACCINE CLINIC 12/18/2020 á Patient: DOB: Date: 12/18/2020 MRN: 10148412 á Subjective Patient is a 48 y.o. female who was seen at Vaccine Clinic today for her first dose of the COVID 19 vaccination. á She denied any history of previous adverse reactions to vaccines. á She was given the Pfizer vaccination in the right deltoid muscle. á During her 15 minute waiting period after the injection, the patient began to experience tingling in hands and feet. She denied rash, hives, difficulty breathing, difficulty swallowing, wheezing, throat tightness, hoarseness, lightheadedness, dizziness and tongue swelling. á This provider was notified of patient reaction and she was then assessed in the emergency bay area. á Patient with PMH of fibromyalgia and rheumatoid arthritis No history of vaccine or medication reaction previously á Review of Systems Constitutional: Negative for chills and fatigue. HENT: Negative for congestion, facial swelling, rhinorrhea, sinus pain, sneezing, sore throat and trouble swallowing. Respiratory: Negative for cough and shortness of breath. Musculoskeletal: Negative for back pain, myalgias and neck stiffness. Skin: Negative for rash. Neurological: Tingling in hands and feet bilaterally á á á Objective á Vitals Vitals: á 12/18/20 1255 12/18/20 1318 12/18/20 1345 BP: (!) 143/86 (!) 129/91 131/83 BP Location: Left arm Left arm Left arm Pulse: 79 72 69 SpO2: 100% 100% 100% á á Physical Exam Constitutional: General: She is not in acute distress. Appearance: She is not ill-appearing or diaphoretic. HENT: Head: Normocephalic. Nose: Nose normal. Mouth/Throat: Mouth: Mucous membranes are moist. Pharynx: Oropharynx is clear. Cardiovascular: Rate and Rhythm: Normal rate. Pulmonary: Effort: Pulmonary effort is normal. Musculoskeletal: Normal range of motion. Comments: C/o tinglinig to feet and hands bilaterally Normal ROM Grip strength equal bilaterally No lightheadedness or weakness Skin: General: Skin is warm. Capillary Refill: Capillary refill takes less than 2 seconds. Coloration: Skin is not pale. Findings: No erythema or rash. Neurological: General: No focal deficit present. Mental Status: She is alert and oriented to person, place, and time. Psychiatric: Mood and Affect: Mood normal. á á á Assessment/Plan á Treatment included antihistamines. Follow up response to treatment:good Patient discharge: Stable to go home and follow up with PCP á Benadryl given at 1314 At 1330 reports significant reduction to tingling in hands and resolved in feet 1340 - tingling has resolved 1350 - Escorted by pharmacist out of building. VSS á Patient provided with paperwork about immunization Strict instruction to go to the ED if shortness of breath, cough, difficulty swallowing, tingling/weakness, or other allergic symptoms occur. Patient verbalized understanding APRN Electronically Signed 12/18/2020 2:00 PM á á Division of Health 3 of 3 á

Rash to neck with itching

Day 1: Initially left arm soreness around the site About 4 hours later I developed generalized body aches/felt foggy Day 2: Left arm soreness

Pfizer-BioNTech COVID-19 Vaccine EUA Diarrhea, shortness of breath, tachycardia, elevated blood pressure, 101F fever, dizziness, weakness, fatigue, flushing, chills

SOB/swelling of face, hands, feet, tongue lasting from 12/21/20 0200h to approx 1000h (resolved with diphenhydramine 50mg PO) Flu-like symptoms/malaise/chills lasting from 12/21/20 0200h to approx 12/21/20 1800h Headache from 12/21/20 0200h; continuing as of 12/22/2020 1130h

Hx of chills and not feeling well with flu shot but generally feels better the next day 12/18/2020 at 9pm: chills, diarrhea, itchy bumps on lower legs, rapid HR, no fever 12/19/2020 at 2pm: itchy bumps on lower legs, gets worse with scratching, chills, nausea, diarrhea, left arm soreness 12/20/2020: painful swollen lymph nodes left axillary, felt like 2 golf balls, reached out to a friend who is a doctor and was told to take Tylenol 12/21/2020: left arm soreness, chills, rapid HR, diarrhea Currently: still has the bumps on both legs and are itchy ? left leg is worse, Cortisone and Benadryl not really working, the rapid HR, chills and diarrhea come at random times January 2020, patient had the Flu

Mild soreness to upper left arm which was still present the following morning.

Pfizer-BioNTech COVID-19 Vaccine EUA Injection site pain that started 7 hours after injection and has continued to now. Pain is lessening as time goes on. Tylenol has helped. Headache, Nausea and ear ache all started this morning (7am). Headache is continuous; nausea and ear ache are intermittent

20 hours after vaccine, I had uncontrollable shaking, fever 99-101, headache, and I am still experiencing on the left side of my neck - clavicle, and in my axilla under my arm, clusters of lymph nodes that wont go away. Fever, chills, head ache and body ache all went away and lasted only for 2 days. The lymph nodes are still pretty big and are still here .

0843 vaccine administered. 0855 patient reported a rapid heart rate (112 beats per minute) and tremors. No airway complications.

High fever, upto 101.5, severe myalagias, nausea, similar intensity as of my actual infection. Took Acetaminophen with no effect. Responded to Ibuprofen. Better on day 3 12/22/20

Approximately 10 minutes after vaccination c/o feeling shaky, she then stated her neck itched and she exhibited generalized urticaria. Was given .5ml Epinephrine IM at 1000. Stated she was having thickened feeling in her throat, had high blood pressure on 191/126 and was nauseated. Was given 1ml of Benadryl IM. Ambulance called at 0958 and transported to hospital at 1008.

Flushing Sweats Chills Heart rate was ranging between 45-190 according to watch Nausea Vomiting

Next day developed approx. 2.5 x2.5 inch, round, reddened area around vaccine site, told to ice site & contact if any worse. 12/22/2020 improved site reaction

Yesterday had no energy, real tired, heart beat rapid. Not normal for him. Slept yesterday a few hours. and then again at night. Called facility and they stated that he should go to ER if needed and to call VAERS to report AE. Patient is a DOD Firefighter.

Petechiae developed on 12/19 on legs and torso and back Took Benadryl although not pruritic.

ITCHY, HARD TO BREATH,HEADACH I WAS GIVEN EPIPEN RUCHED TO ED FOR FUTHER TREATMENT

Received vaccine Saturday 12/19/20 around 0700AM. ON 12/21/20 patient began developing rash and redness around injection site. Took diphenydramine and recovered.

Nausea, headache

11 minutes into the vaccination, patient noted to have tongue and mouth tingling and heart racing. No noted tongue/lip/throat swelling, dyspnea, n/v, abdominal pain, rash, near-syncope. Started to improve after 30 seconds.. H/o tachycardia secondary to salmon, no prior anaphylaxis or use of epinephrine in the past. Sent to ED for evaulation

Developed tachycardia, tremors, hypertension, rash. Given diphenhydramine and fluid bolus in ED and discharged home.

within one hour facial prickling sensation and mild dizziness -- by 6pm same day, moderate aching all over and moderate headache also. Next day continued symptoms but milder and intermittent facial prickling

Fatigue, headache, body aches, chills, nausea, diarrhea, fever, joint pain, cough, sore throat, nasal drainage. All started 2 hours after vaccine, although she states she had a headache at time of vaccine, but stated this is not abnormal for her. She also reports that she had an exposure at lunch to co worker on the 10th, that then became symptomatic on the 15th and tested positive. Also states she had sore arm at injection site for 4 days.

5-10 minutes after the vaccination, I experienced tingling and numbness in my tongue. Very similar to the feeling when you go to the dentist and he uses the numbing agent before procedures. Comparing to the dentist, my adverse reaction is not as severe, 10 being a whole injection of numbing agent to prevent sensation in the mouth, this is likely a 4/10 tingling/numbness feeling. It has persisted for 3 hours now, the intensity of the feeling has slowly decreased overtime, but I still notice it after 3 hrs. My right arm where I get the injection is also a little sore, but that is expected and very similar to all the other vaccines I get.

Left side vaccine administration, site reaction, slightly reddened. Iced

Patient woken by sore arm in the middle of the night following vaccine. Over the next 3 days had intermittent headaches, some nausea, and fatigue.

Patient experienced tingling on lips and back of the tongue as well as coughing. Then benadryl was administered which led to resolution.

Saturday 12/19 early am, sore shoulder when rolled onto in sleep. HA through out day Sunday 12/20 quarter size red area surrounding shot Monday 12/21 knot at site of injection that others could feel through my shirt-painful. Swollen left arm pit but no distinct lymph nodes felt. Arm pit tender when palpated. Tuesday 12/22 arm pit swelling remains as well as knot at site and pain when either or both palpated.

Vaccinated at 9:00am through employee health. Within 5 minutes of vaccine administration, developed palpitations and flushing. These persisted and worsened and I was transported to the ED. During transport I developed chest tightness and throat tightness. On arrival to ED, HR 125, BP 150/97. Observed for 2 hours, given normal saline but no medications. Over time, palpitations and flushing subsided first. Then chest tightness persisted for about 2 hours. Was discharged from ED within 2 hours. Throat tightness persisted for approximately 8 hours total and gradually resolved.

PATIENT IS EXPERIENCING ELEVATED BLOOD PRESSURE OF 170/101

Burning in throat, flushed face and neck. Developed stridor. Benadryl 25 mg PO given, Epinephrine 0.5mg given IM, albuterol inhaler 4 puffs. Transferred to the Emergency department and admitted to the hospital.

"Nurse who had worked the shift and had drank an "" energy drink"" prior to vaccine. she felt palpitations and and elevation of blood pressure. No itching hives or angioedema. No dyspnea. Pt observed and discharged home without any therapy"

fever of 101.4 reduced with Tylenol administration

Next morning, patient had a rash and swelling on forehead and back of hands. She took a benadryl and went to the emergency room.

0755 Pt notified other Nurse that he is feeling nausea; slight dizziness. He reported to Nurse that he did eat light breakfast this AM prior to COVID #1 Injection. Pt resting with eyes closed. Nurse spoke with pt, DOB, pt works in, Nurse offered pt Water, Crackers, snack. Pt offered to be taken to ER or to call Rapid Response so vitals can be taken and closer monitored. Pt refused ED and Rapid Response. Pt stated he will just sit longer and complete his Observation time. Nurse provided Continuous Monitoring; checked on Pt symptoms every 5-8 minutes. Pt stated he is fine and symptoms are subsiding. After 15-20 minutes of Observation; Pt was ready to leave. Pt stated he is well, symptoms have resolved, he is fine; per pt. Pt left Observation at 0808; steady gait, denies chest pain, SOB, any further Dizziness, or any further Nausea.

Patient became Lightheaded, dizzy @ 11:24 am BP 155/92, Sat 100% on room air, P-100, repeat BP 11:25 141/94 Sat 99% P-98, 11:28 154/91 sat 100%, P-99, patient described having palpitations, transferred to ER via gurney for increased BP, light headed, dizzy palpitations

Patient received the first dose of the Pfizer covid vaccine on 12/16 and on 12/17 in the afternoon she developed a rash on her chest. She reports the rash was little raised bumps and was itchy and red. The rash extended to her abdomen, back, neck, arms and legs on 12/18-12/19. The rash began to fade on 12/20 and is almost completely gone now 12/22. Patient not treat with rash with any topicals or oral medications.

Fatigue- On going body aches Muscle pain-Torso Headache- On going - Head aches when moving around chills- 3 hours

Patient was administered the Covid19 vaccine. She was advised to wait 30 minutes post vaccination. While the patient was waiting, she reported having an itchy throat, throat tightness, then a hoarse voice and a cough developed. This happened at about 20 minutes after she received the vaccine. The patient was assessed by the nursing and provider staff. She received an adult epi pen injection and EMS was called. Patient was taken to the ER by EMS. She reports she received two more epi injections, benadryl, and Solu Medrol. She was stabilized. Patient was discharged from the ED after several hours. She then reports a second episode of throat tightening and worsening cough at 12:30 am and was taken by ambulance to the ICU and admitted. She is still in the hospital at this time 12/22/2020.

17 minutes after vaccination, had itching all over body, inside mouth; noted itching palate and tongue, hot flashes and given famotidine and diphenhydramine and sent to ED for evaluation. in ED: given diphenhydramine 25mg PO one time felt abdominal discomfort and radiating up to the chest and given GI cocktail with temporary improvement. also mild nausea given ondansetron x2; also NS IVF given for 2L Discharged with ondansetron and prednisone 40mg PO daily for 5 days.

After receiving the shot and getting up to walk across the room to sit down for the waiting period, I started to experience extreme dizziness and weakness. My heart rate jumped and I felt extremely hot. I thought I was going to faint. Within about 10 minutes I got an extreme headache that felt like someone was squeezing my head. I was given a heavy dose of benadryl as I was not experiencing difficulty breathing and we did not feel like I needed an epipen. After the benadryl kicked in my symptoms became less intense and I just had periodic bouts of sweating and chills. I am now on my third round of benadryl but have been able to lessen the dose, I do not anticipate having to take a fourth dose.

Explosive diarrhea that started nearly 24 hours after vaccination

When I got the vaccination I was 32weeks pregnant and on Saturday I had spontaeous rupture of the amnotic fluids and went immediately to the hospital and was immediately given steroid, magnesium for the baby. And on Sunday around 3:45PM I got a second round of the steroids and was transferred for observation. On Monday, at 8:06am I went into early labor I delivered my baby at 33weeks gestation and she weighed 3lb 11oz. Expected Date of Delivery-2/8/2021. I was a high risk patient d/t Fibroids but have experienced no issues the entire pregnancy and my last ultrasound was 12/17 and baby was healthy with no complications at that time.

Initially employee experienced flushing, palpatations, nausea. ER- developed hives on arms TX:Prednison 60mg po given at 11:53am Benadryl 50mg po given at 11:52am Observed for 2 hours with symptom resolution. Discharged with oral steroids.

seizure, resident sent to er and in CCU

Chills, fever over 100, body aches, tiredness, fatigue, injection site pain, feeling unwell, nausea

Received COVID19 vaccine at 730am, developed erythematous patchy rash on anterior neck and chest around 1130am. Initially began on neck, spread, then resolved over about 1 hour. No itchiness, no irritation, no fever, asymptomatic. No PMH, allergies, medications.

She went to the Emergency department 12/20 and received a high dose of Benadryl. She reported tachycardia all day yesterday in the 130?s and was itchy all over. Subsequently she developed a rash.

Pain in the site of injection

5 minutes post vaccine, while sitting in the socially distanced observation area the patient felt dizzy. While getting a gurney to the area, she had a syncopal episode. We moved her to the gurney and elevated her legs. She regained consciousness promptly. She told us she was diabetic and her glucose was 101 that morning. We gave her juice and observed her for 30 minutes more. She had no focal symptoms and felt well at discharge. No previous history of vagal episodes, hadn't eaten before the vaccine. The patient is an RN.

From patient interview: The patient stated feeling dizzy with lightheadedness and seeing spots. She felt like she was going to pass out. She was transported to our emergency department for examination. When I spoke with her she was resting and felt she had returned to baseline. From medical record:Patient Stated Complaint SYNCOPE, Narrative of Presenting Problem Patient is a 35-year-old female with history of vasovagal episodes during her prior pregnancy was in the hospital getting a Covid vaccination and became weak dizzy and sweaty and had a syncopal episode while in a chair. Patient did not hit her head. Upon evaluation patient is awake alert lying supine with no complaints. Patient states she has been suffering with Covid related anxiety and depression.

Conjunctivitis in both eyes. Uveitis in the right eye.

pain in right shoulder immediately after injection. then shortly after felt nausea and thinking I might puke. did not feel like myself. this lasted about 2 hours. (8am-11am) I also felt muscle pain, laterally in my neck on both sides.12:00pm I did not feel nauseated or neck pain anymore but felt general malaise still. and this came and went all day. today, the following day I have no symptoms.

Hypertensive to 190/80; shaking; chills; after 30 minutes, BP reduced 159/80; sent to ER; monitored; sent home; resolved, per follow-up call following day.

Patient started to experience some periorbital edema. No respiratory distress

Fever Headache Left arm discomfort Malaise; Fever Headache Left arm discomfort Malaise; Fever Headache Left arm discomfort Malaise; Fever Headache Left arm discomfort Malaise; This is a spontaneous report from a contactable physician. A 33-year-old non-pregnant female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), intramuscular in the left arm on 16Dec2020 at 10:45 (at the age of 33-years-old) as a single dose for COVID-19 immunization. Medical history included generalized anxiety disorder, gastrooesophageal reflux disease, vague gallbladder, and lactose allergy. Prior to the vaccination, the patient was not diagnosed with COVID-19. Concomitant medications included escitalopram oxalate (LEXAPRO) for an unknown indication from an unknown date and unknown if ongoing. The patient did not receive any other vaccines within four weeks prior to the vaccination. On 16Dec2020 at 21:00, the patient experienced fever, headache, left arm discomfort, and malaise. Therapeutic measures were taken as a result of fever, headache, left arm discomfort, and

malaise and included treatment with paracetamol (ACETAMINOPHEN). The clinical outcomes of the fever, headache, left arm discomfort, and malaise were recovered on an unknown date in Dec2020. It was also reported that since the vaccination, the patient had not been tested for COVID-19. The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up.

patient received vaccine at 10:31, at 10:43 am reported left arm tingling, BP unable to read, sat 98% on room air, switched vital macine, 10:46 am sitting BP 188/102 sat 100%, P-71, 10:58 repeat 179/106 sat 100% P-69, tingling remains, no shortness of breath, took patient to Urgent Care for evaluation

Upon initial injection (0940)pt reported some lightheadedness, pt sat for aprox 20 min and then stated feeling better. She returned to her clinic to work and at 1030, reported return of s/s with increased severity. She was brought back to vaccination area an evaluated by MD, given 50mg of po liquid Benadryl and then taken to ED via WC. VS: 155/77, 105, 18, 96% on room air.

headache; Body aches; induration at the vaccine area; This is a spontaneous report from a non-contactable consumer (patient). A 34-year-old female patient received bnt162b2 (BNT162B2), via an unspecified route of administration on the left arm on 16Dec2020 11:00 at a single dose for immunisation. Medical history included sever dermatitis. The patient's concomitant medications were not reported. The patient previously took influenza vaccine and experienced drug hypersensitivity. The patient experienced body aches, headache, induration at the vaccine area on 16Dec2020 11:00. Ibuprofen was given as treatment for the adverse event. Outcome of the events was recovering. The events were considered non-serious. The patient was not diagnosed with COVID-19 prior to vaccination and has not been tested since the vaccination. No follow-up attempts are possible. Information about Lot/Batch could not be obtained. No further information is expected.

12/16/2020 2:30 AFTER VACCINATION, STARTED TO FEEL INCREASE HR. STARTED TO FEEL WOOZY, UNABLE TO FOCUS. CHECKED VITALS IN ICU; HR 116. WENT TO ER, TRIAGE BP WAS 163/101; HR 115. GIVEN LITER SALINE, DREW LABS. BP AND HR CAME DOWN. TOLD TO REST COUPLE DAYS. WAS CONCERNED AS HX OF STROKE. F/UP WITH CARDIOLOGIST 'DOESN'T THINK THE SECOND VACCINE WOULD BE HARMFUL' BUT 'I JUST DON'T KNOW'. FAMILY HAS HX OF HEART DISEASE. I KNOW ANXIETY BUT NEVER HAD HR DO 'WHAT IT DID'. DON'T FEEL LIKE IT WAS ANXIETY. I KNOW MY BODY. I HAD TAKEN CARE OF COVID PATIENTS THE WEEK BEFORE. I DON'T KNOW WHAT TO THINK. TRYING TO LOOK AT ALL FACTORS. 12/17/2020 HEADACHE; FOLLOWING DAY I WAS FINE

Have nausea, malaise, headache, chills.

The vaccine recipient received the vaccine on 12/16/2020. On 12/17 they reported pain at the injection site. On 12/18 and 12/19 they reported that they became with the following symptoms: swollen glands, body aches, fatigue, and sore throat. During a follow-up phone call they reported that the symptoms have resolved 12/20.

After receiving the vaccine earlier, patient had difficulty swallowing for 3 minutes and also dizziness-- > went to ED for evaluation. Symptoms resolved after rooming in ED. ED physician DX with possible

allergic reaction and he was given diphenhydramine 50mg PO x1 and prednisone 40mg PO x1 in ED-- > discharged home with PRN diphenhydramine, cetirizine 10mg daily and epi pen PRN.

Developed headache, tachycardia and urticaria 12 minutes post immunization. Transfer to ER for care. Had NS 100 ml. bolus, Benadryl 25 mg IV, Solumedrol 125 mg IV, Pepcid 20 mg IV, Tylenol 1 Gm PO. Symptoms resolved. Discharged home from ER same day with Rx for Benadryl and Pepcid.

Headache ,muscle pain , join pain , chills , runny nose.

itchy, dizzy right after injection

Rash on arms

Palpitations and elevated heart rate from Friday 0600 until wake up on Sunday. Felt tired and aching on Thursday night however, no fever

Within 30 minutes I began to feel somewhat jittery and felt very hot . Then I began sweating profusely. I was not tachycardic but my pulse felt very strong. The sweating lasted about 20 minutes. The jittery nervous feeling about two hours.

Dizziness, headache, abdominal pain. Supportive measures.

Headache Low grade fever 99.7 Back ache Body ache Chills Cold hands Nausea These started Dec 20, the night of my vaccination. My symptoms continued on Monday the 21. On Tuesday Dec 22 I still have a slight headache and body aches. I just feel run down. I took regular strength Tylenol I-II PRN

Diaphoretic and tachycardic within 5 minutes of receiving vaccine. Rate up to 151 with BP 146/82. Rate would go down after 5 minutes sitting quietly and then return to 150. Back down and then 15 min later, up. gave 25 mg of po benadryl at 11:30 am. This continued and 911 called. Paramedics assessed. Patient brought to ed for additional monitoring and assessment in private car. D/C'd at 2:30pm with no other interventions.

Severe headache and limb numbness ~ 30 minutes after vaccination Sent to emergency department - no treatment needed

headache - pt reports she will take Tylenol , reports head is ongoing tingling between shoulders - resolved

After I ate lunch I had watery stool, Next day I had hot flashes , body aches, eyes watering, chills,

Redness and ache at injection site since noted 12/21/2020, left arm itchy since 12/20/20

"Reported ""Heart going fast, it might be anxiety"". 1400: O2 Sat 99% 65HR 12RR 154/101 1405: 02 99% 68HR 12RR 139/95 1417: O2 99% 66HR 1430: O2 100% 69HR 12RR 129/89 Symptoms began resolving between 1405 and 1430. Afterwards was escorted to work station."

Employee was being monitored post Covid19 vaccine, approximaetely 10 minutes after recieving vaccine she complained of feeling dizzy and light headed and then became unresponsive. 911 was called and employee was taken to ER

Subconjunctival hemorrhage (R eye)

Pt received vaccine around 1302. Pt experienced some minimal injection site bleeding, which was stopped gauze and a non-latex bandage was placed. While patient was at the vaccine table she reported itching around the injection site. Bandage was removed and patient was monitored further. Patient then reported that itching was worse at 1320, spreading to her thigh, head and back. 25mg PO diphenhydramine was administered and the patient was monitored for worsening symptoms. No further symptoms were reported and itching relieved by PO benadryl.

Patient developed tingling in back of throat and back of tongue. No swelling, vomiting, trouble breathing, hives. Symptoms lasted about 1 hour, did not get progressively worse and seemed to resolve within 1-2 hours. No medication, treatment or intervention was needed.

Reported received the vaccination at approx. 10am on 12/18. Developed headache during her 12 hour shift at the hospital. At 830pm after getting home from work, she developed elevated heart rate 130s, heart palpitations, body aches, severe nausea, muscle pain, and fatigue.

Abdominal pain, upset stomach, and nausea

After receiving the vaccine, within 10 min I developed a headache that lasted no more than 20 min. The day after, I developed a sore throat (don't think it's related to vaccine) in the morning and gradually got worse in the day.

12/18, 0905: metallic taste in mouth lasting all day 12/19: fatigue all day, 2200-nausea and low grade fever 12/20: fatigue lasting all day 12/21: woke up at 0400 with congestion and sore throat. Swollen lymph nodes and swollen glands over right clavicle. 12/22: congestion, drainage, sore throat, swollen glands/lymph nodes as described yesterday and fatigue

Day after vaccine patient started feeling fatigue, body aches, headache. By 1700 that evening she was running a 102 fever and her back was hurting. She took Famotidine and Benadryl and Tylenol and Ibuprofen. She went home and rested, pushed fluids. Felt completely better by the afternoon on 12/19/20

Patient's wide noticed a hive on upper chest below clavicle on L side. No resp. distress. 1435: VS: 126/80, 75 HR, 16RR, 97% O2 Sat Patient reported skin on neck blotchy. Benadryl 25mg 1448. 1453: 151/88, 97%, 76 HR, 16RR, 1512: 120/82, 97%, 75 HR, 16RR, Seen by RN Supervisor. Hive diminishing at 1528. 129/84, 97%, 75HR, Discharged w/wie at 1545.

Upper left arm/shoulder pain. Also reported 36 hours of low grade fever and body aches after injection Left arm at deltoid felt somewhat warm to touch, very mild erythema, tender to palpation. Pt sent to Urgent care for evaluation

Chest tightness; Tiredness; Headaches; Joint pain; Low grade fever; Nausea; Swollen lymph nodes in neck; Chills; Muscle pain; This is a spontaneous report from a contactable healthcare professional (patient). A 33-year-old female patient received the first dose of BNT162B2 (Pfizer-BioNTech COVID-19 mRNA vaccine; Lot Number: EH9899), intramuscular in right arm on 15Dec2020 07:45 at a single dose for an COVID-19 immunization. The vaccine was administered in a hospital. Medical history included celiac disease, allergy, and diagnosed with COVID-19 prior to vaccination. Concomitant medication included fexofenadine hydrochloride for allergy. The patient experienced tiredness, headaches, muscle pain, joint pain, chills, low grade fever, nausea, swollen lymph nodes in neck, and chest tightness on 15Dec2020, 03:00 PM. No treatment was received for the events. The outcome of the events was not recovered. The events were reported as non-serious.

"15 minutes after vaccination, started to have SOB, numbness on legs and extremities-- > sent to ED for evaluation. She c/o funny feeling in her mouth and tingling in her arms and legs after vaccination. She felt short of breath initially, but not at ED. No rash. No swelling that she is aware of. She just doesn't feel right. States she feels ""jittery"" and shaky. Received 2 L NS and epi 0.3mg IM x1 and diphenhydramine 25mg IV x-- > symptoms improved. Observed for 4 more hrs in ED. Discharged home on Epi pen."

Dizziness; hypertensive to 109/80; nauea, sweating, sent to ED for monitoring; follow up call next day: symptoms resolved.

Employee was being monitored post Covid19 vaccination. Approximately 10 minutes after vaccination employee had an allergic reaction and developed Hives all over her body and became itchy with hot flashes. Employee was given 50MG of Benadryl which was effective.

Pain at injection site; This is a spontaneous report from a contactable other healthcare professional (patient). A 54-year-old male patient received the first dose of bnt162b2 (lot number: EH9899), intramuscular on the left arm on 15Dec2020 09:00 at a single dose for immunization. There were no medical history and concomitant medications. The patient have no known allergies. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient was not diagnosed with COVID-19 and had not been tested for COVID-19 since the vaccination. On 15Dec2020 18:00, the patient experienced pain at injection site. No treatment was received for the adverse event. Outcome of the event was recovering.

Headache, tachycardia, body aches, malaise, lethargy,

Injection site tenderness for 48 hours Myalgias for 72 hours Morning nausea for 4 days post-injection Chills for 48 hours Headache for 72 hours

Arm pain at site; This is a spontaneous report from a contactable nurse. A 59-year-old female patient received bnt162b2 (lot number: EH9899), intramuscular on right arm from 16Dec2020 15:45, at an unspecified dose, single, for immunization. Medical history included hypertension. The patient's concomitant medications were not reported. Patient had other medications the patient received within 2 weeks of vaccination. On 16Dec2020 at 19:45, the patient experienced arm pain at site. Outcome of

event was unknown. Event occurred in a country different from that of the reporter. This may be a duplicate if the reporter also submitted directly to his/her local agency.

Patient states 20 minutes after receiving the injection she began having a scratchy throat and began having shortness of breath. She also developed some itching to the site. She presented to the Emergency Department and noted to have hoarseness but no severe dyspnea. Patient was given steroids and Benadryl. Her symptoms did not worsen and she was discharged home.

Patient waited her 15 minute time of observation. She said she felt her throat closing . Moved her into the observation area. Dr. was present and ordered for 25mg of Benadryl to be administered po. This was given at 16:00. Dr. observed patient for approximately 45 minutes until all symptoms resolved. Patient was allowed to leave at 16:45. Patient was provided with the instructions to please go to the ED if she should have any new symptoms tonight.

Body aches, joint pain, chills, headache, injection site pain; Body aches, joint pain, chills, headache, injection site pain; Body aches, joint pain, chills, headache, injection site pain; Body aches, joint pain, chills, headache, injection site pain; Body aches, joint pain, chills, headache, injection site pain; This is a spontaneous report from a contactable nurse (patient). A 29-year-old female patient received bnt162b2 (BNT162B2) lot number and expiration date were not reported, intramuscular (arm right) first dose on 16Dec2020 13:45 at a single dose for immunization. Medical history included migraine with aura, ovarian cyst and paragard IUD. Concomitant medication included fluconazole (DIFLUCAN), probiotics and famotidine. The patient previously took codeine and experienced drug hypersensitivity. The patient reported adverse events of body aches, joint pain, chills, headache, and injection site pain on 09Dec2020 at 03:45 PM (pending clarification). The patient had not taken any other vaccine in 4 weeks. The events were considered non-serious. The patient recovered from the events body aches, joint pain, chills, headache, and injection site pain on an unspecified date. There was no treatment given due to the events. The patient was not diagnosed with COVID-19 prior to vaccine nor was she tested positive for COVID-19 since vaccination. No follow-up attempts are possible; Information about batch/lot number cannot be obtained. No further information is expected.

"Severe Headache (""Felt like someone hit me with a bat in the head""; water/tylenol given; sent to ED - given Toradol; later: chills; resolved per follow-up call prior day."

Pfizer-BioNTech COVID-19 Vaccine EUA Headache, body aches and extreme fatigue started on 12/20/2020. I had a doctor appointment on 12/22/20 for a routine visit and I told my doctor about these symptoms that had occurred and he stated that I needed to be tested for COVID since these were symptoms. He also ordered blood work and I had blood drawn. I had informed him at the beginning of the visit of my recent COVID vaccine last week.

Phizer-BioNtech COVID-19 Vaccine EUA pain at site of infection. Fatigue, maliaise, dizziness, nausea, low grade fevers

Pt reports joint pain, nausea, headache, fatigued.

"25 mins after the vaccination his right arm became tingly ranging from the lower part of the arm to his pinky. fell asleep. He was touching it and could not feel it, like it was ""asleep"" . Felt himself get hotter and sweaty. Patient was advised to go to the ER, but refused. Called patient one hour after the event, and they reported that arm started to feel less tingly."

pain at the injection site; felt some numbness; slight headache; This is a spontaneous report from a contactable consumer. A 49-year-old female patient (not pregnant) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, batch/lot number: unknown), intramuscular on arm left on 16Dec2020 (10:00 AM) at single dose for COVID-19 immunization. The patient's medical history included rheumatoid arthritis and COVID-19. Concomitant medication included secukinumab (COSENTYX) (received within 2 weeks of vaccination). It was reported that prior vaccination, patient diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. No known allergies. The patient reported that after a few hours of initial injection she felt pain at the injection site. In addition, she mentioned that she also felt some numbness and had a slight headache on 16Dec2020 (08:00 PM). There was no treatment received for the reported adverse events. The outcome of event was recovered on an unspecified date. Information about lot/batch number cannot be obtained.

dizzy; funny feeling on the throat; vasovagal reaction; This is a spontaneous report from a contactable physician. This physician reported similar events for two patients. This is the second of two reports. Only the first case is serious. This case is non-serious. A female patient of an unspecified age (reported as 59, unit unknown) received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 17Dec2020 22:00 at a single dose for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient stated that she felt dizzy, funny feeling on the throat and ED (emergency department) assessed vasovagal reaction as normal; no rash or major allergic reaction was noted. Outcome of the events was unknown. Follow-up attempts are completed. The following information on the batch number has been requested.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2020500236 Same reporter, product, and event, different patient

tingling sensation around the mouth; tingling sensation around the mouth and in her arm; This is a spontaneous report from a contactable physician. A 59-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE lot/batch # not provided), via an unspecified route of administration on 17Dec2020 22:00 at SINGLE DOSE as COVID-19 immunization. The patient's medical history and concomitant medications were not reported. In Dec2020, the patient felt tingling sensation around the mouth and in her arm. Outcome of the events was unknown. Information regarding batch number has been requested.

Intermittent tachycardia; headache; left shoulder pain, increases when lifting elbow above pectoral; This is a spontaneous report from a contactable nurse, the patient. A 30-year-old non-pregnant female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot Number: EK5730), intramuscular in the left arm on 16Dec2020 at 16:45 (at the age of 30-years-old) as a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. Prior to the vaccination, the patient was not diagnosed with COVID-19. The patient did not receive any other vaccines within four weeks prior to the vaccination. The patient previously took

amoxicillin (MANUFACTURER UNKNOWN) from an unknown date to an unknown date for an unknown indication and experienced drug allergy. On 16Dec2020 at 21:45, the patient experienced intermittent tachycardia, headache, and left shoulder pain (which increased when lifting elbow above pectoral). Therapeutic measures were taken as a result of the intermittent tachycardia, headache, and left shoulder pain and included treatment (self-medicated) with acetaminophen (TYLENOL) and diphenhydramine hydrochloride (BENADRYL). The clinical outcomes of intermittent tachycardia, headache, and left shoulder pain were unknown. It was also reported that since the vaccination, the patient had not been tested for COVID-19.

Patient felt lightheaded & dizzy 10 minutes after receiving vaccine. Layed down flat with feet elevated for 10-15 minutes.

tingling to the tip of the tongue and further back to the middle of tongue, oral tingling (upper lip and then into the lower lip); mild swelling to the tip of the tongue; This is a spontaneous report from a contactable nurse. A 51-year-old non-pregnant female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot number: EH9899), intramuscularly in the left deltoid on 17Dec2020 11:15 at a single dose for COVID-19 immunization. Medical history included palpitations multiple premature ventricular contractions (PVC)s from 11Jan2020 to an unknown date. The patient's concomitant medications were not reported. Patient denied any history of previous adverse reactions to vaccines. The patient previously took dexamethasone (DECADRON) and experienced tingling of lips and tongue and sulfamethoxazole trimethoprim (BACTRIM) and experienced allergies and acute kidney injury. The patient experienced tingling to the tip of the tongue and further back to the middle of tongue, oral tingling (upper lip and then into the lower lip) and mild swelling to the tip of the tongue on 17Dec2020 11:15. During the 15-minute waiting period after the injection, the patient began to experience oral tingling (upper lip and then into the lower lib). It then progressed to the tongue and she reported tingling to the tip of the tongue and further back to the middle of tongue. She thought there might be some mild swelling to the tip of the tongue. She denied rash, hives, welts, difficulty breathing, difficulty swallowing, wheezing, throat tightness, hoarseness, stridor, itching, lightheadedness, dizziness, facial swelling and lip swelling. The patient went to the emergency room/department or urgent care. The patient received diphenhydramine hydrochloride (BENADRYL) as treatment for the events. The outcome of the events was recovered in Dec2020.

"feeling ""Sort of dizzy""; arm is sore; just doesn't feel well; This is a spontaneous report from a contactable consumer (patient). A 61-year-old female patient started to receive bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK5730), via an unspecified route of administration on her left upper arm on 17Dec2020 13:25 at a single dose for covid-19 prevention. The patient's medical history included blood pressure abnormal. Concomitant medications included blood pressure medicine at night. The patient went to the hospital today where she works, to have a vaccine for COVID, and then she drove herself home. After she got home, she decided to rest a bit before her shift at work tonight, she laid down for a little while, and she started feeling sort of dizzy and her arm was sore. She just doesn't feel well. She does not feel like she needs to go to the hospital or anything, but she may need rest. Patient was wondering if these are known side effects of the product. She started feeling the side effects maybe 20 or 25 minutes after getting the vaccine and after she had left the hospital. She was just

thinking at the time that it was okay and maybe she just needed rest. She takes blood pressure medicine at night, but she does not think that has anything to do with how she is feeling. Outcome of the events was unknown."

Within just over half an hour of receiving it my lungs and throat started burning. Shortly after that my upper lip started to swell. Over night my lip swelled more and my face became itchy.

She noticed that she got breakthrough bleeding, when she just got her menstruation last week; This is a spontaneous report from a contactable healthcare professional, the patient. A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), via an unspecified route of administration on 16Dec2020 at 17:00 as a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. On an unknown date in Dec2020, the patient noticed that she had breakthrough bleeding and she just had her period last week. The stated that she was very regular when it came to her period. The clinical outcome of the breakthrough bleeding was unknown. The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up.

developing a cold sore (herpes simplex type 1) the following morning/She usually develop a cold sore with an illness; developing a cold sore (herpes simplex type 1) the following morning/She usually develop a cold sore with an illness; This is a spontaneous report from a contactable consumer (patient). A 52-year-old female patient received the first dose of bnt162b2 (lot number and expiration date were not reported), via an unspecified route of administration on the right arm on 16Dec2020 16:15 at a single dose for immunization. The patient's medical history included cold sore and celiac disease. The patient was not pregnant. Concomitant medication included cetirizine hydrochloride (ZYRTEC). The patient reported that it was not necessarily an adverse event but she noticed that she was developing a cold sore (herpes simplex type 1) the following morning on 17Dec2020 10:00. She usually develop a cold sore with an illness. She also typically take valacyclovir to treat but opted not to take it (did not want to interfere with the vaccine and body developing antibodies). No treatment was received for the events. The patient was not diagnosed with COVID-19 prior to vaccination neither had been tested for COVID-19 post vaccination. Outcome of the events was recovering. The events was considered non-serious. Information on lot/batch number has been requested.; Sender's Comments: Based on the information currently provided, cold sore (herpes simplex type 1) onset more likely represents the recurrence of the underlying herpes viral infection. Currently no biological plausibility indicated the event is attributed to the vaccine use.

Red raised rash 48 hours after Extreme nausea and dizziness; Red raised rash 48 hours after Extreme nausea and dizziness; Red raised rash 48 hours after Extreme nausea and dizziness; This is a spontaneous report from a contactable healthcare professional. A non-pregnant 45-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), intramuscularly on 15Dec2020 15:45 at a single dose for COVID-19 immunization. Medical history included ulcerative colitis, hypothyroidism, allergies: sulfites. sulfa. Concomitant medication included amfetamine aspartate, amfetamine sulfate, dexamfetamine saccharate, dexamfetamine sulfate (ADDERALL), dhea (MANUFACTURER UNKNOWN), levothyroxine, liothyronine (NP THYROID),

progesterone (MANUFACTURER UNKNOWN), fluoxetine hydrochloride (PROZAC), levothyroxine sodium (SYNTHROID), bupropion hydrochloride (WELLBUTRIN). On 15Dec2020, the patient experienced red raised rash 48 hours after extreme nausea and dizziness. No treatment was received from the events. The outcome of the events was not recovered. The batch/lot number for the vaccine, BNT162B2, was not provided and will be requested during follow-up.

Client started to feel faint about 10 minutes after she had the vaccine administered. She informed the nurse. Her blood pressure was 100/62 hr 58. She sat for a few minutes and then vomited. She had bcome very diaphoretic. Her bp was 146/100 and hr was 96. She was responsive and she refused a shot of Benadryl. We called for an ambulance. We continued to monitor her bp and hr. Her husband arrived. She left with her husband. Her last bp was 136/100 hr was 70 ab she was not longer diapheretic. He husband took her to the ER. I spoke to patient today at (9:10 am. The ER doctor told her she had a vasovagal incident. He told her she can get the second dose if she is in a supine position with monitoring.

Pain at the injection site for 2 days.; This is a spontaneous report from a contactable consumer. A 23-year-old non- pregnant female patient received the first dose of the bnt162b2 (BNT162B2; also reported as COVID 19, brand=Pfizer-BioNTech; Lot Number: EH9899), via an unspecified route of administration in the left arm on 15Dec2020 at 08:30 at 23-years-old at a single dose for COVID-19 immunization. The vaccination facility was a hospital. It was also reported that there were no other vaccinations in four weeks, and there were no other medications in two weeks prior to the vaccination. The patient's medical history was reported as none. The patient did not have COVID-19 prior to the vaccination and was not tested for COVID-19 post vaccination. The patient has no known allergies (allergies to medications, food, or other products: no). Concomitant medications were not reported. On 15Dec2020 at 21:30, the patient experienced: pain at the injection site for 2 days. There was no treatment for the adverse event; nor did the event require hospitalization. The clinical outcome of the event, pain at the injection site for 2 days, was recovered on an unspecified date in Dec2020.

patient experience slight congestion; This is a spontaneous report from a contactable physician (patient) via Pfizer Sales Representative. A patient of unspecified age and gender received bnt162b2 via an unspecified route of administration on an unspecified date at single dose for administration of Covid-19 vaccine. The patient medical history was not reported. The patient's concomitant medications were not reported. The patient experienced slight congestion on an unspecified date with outcome of unknown. Event took place after use of product. Information on the lot/batch number has been requested.

episodes of facial and head numbness and heaviness, lasting 15-30 min or so; isolated to the side of injection site; episodes of facial and head numbness and heaviness, lasting 15-30 min or so; isolated to the side of injection site; This is a spontaneous report from a contactable physician. A 41-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot number: 0E51685), intramuscularly in the left arm, on 17Dec2020 at 09:00 (at the age of 41-years-old) at a single dose for COVID-19 immunization. The patient had no medical history. Concomitant medications, taken within two weeks of vaccination, included zinc (MANUFACTURER UNKNOWN), quercetin (MANUFACTURER UNKNOWN), and multivitamins (MANUFACTURER UNKNOWN). The patient

was not pregnant at the time of vaccination. Prior to the vaccination, the patient was not diagnosed with COVID-19. The patient had no known allergies to medications, food, or other products. The patient did not receive any other vaccines within four weeks prior to the vaccination. The patient experienced episodes of facial and head numbness and heaviness, lasting 15-30 minutes or so; isolated to the side of injection site on 17Dec2020 at 22:15. No therapeutic measures were taken as a result of the events. The clinical outcome of episodes of facial and head numbness and heaviness, lasting 15-30 minutes or so; isolated to the side of injection site was not recovered. It was also reported that since the vaccination, the patient had not been tested for COVID-19. No follow-up attempts are needed. No further information expected.

non-anaphylactic allergy reactions to the Pfizer BioNTech COVID-19 vaccine; Rash; Mild swelling of the throat; This is a spontaneous report from a non-contactable pharmacist. This pharmacist reported same events for 2 patients. This report is for 1st of 2 patient. A patient of unspecified age and gender received BNT162B2 via an unspecified route of administration on an unspecified date at a single dose for COVID-19 immunization, propylene glycol via an unspecified route of administration from an unspecified date at unknown dose for an unspecified indication. The patient's medical history and concomitant medications were not reported. On 17Dec2020 at 2:50 pm, PharmD, Clinical Pharmacy Manager, shared with the reporter that two employees had non-anaphylactic allergy reactions to the Pfizer BioNTech COVID-19 vaccine, this patient is one of them. She reported rash and mild swelling of the throat. They suspect it was a reaction to propylene glycol and will be doing skin testing. The action taken in response to the event for propylene glycol was unknown. The outcome of events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2020501257 same reporter/drug/event, different patient

Rash; mild swelling of the throat; non-anaphylactic allergy reactions; This is a spontaneous report from a non-contactable pharmacist. This pharmacist reported same events for two patients. This is 2nd of two reports. A patient of unspecified age and gender received BNT162B2 via an unspecified route of administration on an unspecified date at a single dose for COVID-19 immunization, propylene glycol via an unspecified route of administration from an unspecified date at unknown dose for an unspecified indication. The patient's medical history and concomitant medications were not reported. On 17Dec2020 at 2:50 pm, PharmD, Clinical Pharmacy Manager, shared with the reporter that two employees had non-anaphylactic allergy reactions to the Pfizer BioNTech COVID-19 vaccine, this patient is one of them. She reported rash and mild swelling of the throat. They suspect it was a reaction to propylene glycol and will be doing skin testing. The action taken in response to the event for propylene glycol was unknown. The outcome of events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2020501256 same reporter/drug/event, different patient

Little pain at the injection site; Felt flush afterwards; This is a spontaneous report from a non-contactable nurse. This nurse reported similar events for two patients. This is the first of two reports. A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot number: EK5730), via an unspecified route of administration on 16Dec2020 at a single dose for

COVID-19 immunization. The patient's medical history and concomitant medications were not reported. In Dec2020, the patient experienced little pain at the injection site and felt flush afterwards. The outcome of the events was unknown. No follow-up attempts are possible. No further information is expected.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2020501389 same reporter/drug/event, different patient.

Little pain at the injection site; Felt flush afterwards; This is a spontaneous report from a non-contactable nurse. This nurse reported similar events for two patients. This is the second of two reports. A patient of unspecified age and gender received the BNT162B2 (BNT162B2; also reported as PFIZER COVID-19 VACCINE; Lot number: EK5730), via an unspecified route of administration on 16Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. On an unspecified date in Dec2020, the patient experienced little pain at the injection site and felt flush afterwards. The outcome of the events was unknown. No follow-up attempts are possible. No further information is expected. ; Sender's Comments: Linked Report(s) : US-PFIZER INC-2020501372 same reporter/drug/event, different patient

Throat numbness; Lymph node swelling; Felt flush; This is a spontaneous report from a non-contactable consumer. A 28-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot number: EK5730), via an unspecified route of administration in the right arm, on 17Dec2020 at 15:15 (at the age of 28-years-old) at a single dose for COVID-19 immunization. The patient had no medical history or concomitant medications. The patient was not pregnant at the time of vaccination. Prior to the vaccination, the patient was not diagnosed with COVID-19. The patient had no known allergies to medications, food, or other products. The patient did not receive any other vaccines within four weeks prior to the vaccination. The patient experienced throat numbness, lymph node swelling, and felt flush on 17Dec2020 at 15:15. The events were reported as non-serious. Therapeutic measures were taken as a result of the events, which included treatment with diphenhydramine hydrochloride (BENADRYL). The clinical outcome of throat numbness, lymph node swelling, and felt flush was recovering. It was also reported that since the vaccination, the patient had not been tested for COVID-19. No follow-up attempts are possible. No further information expected.

Sore injection site; This is a spontaneous report from a non-contactable healthcare professional. A 29-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot number EH9899), intramuscular into the left arm on 17Dec2020 at 06:15 as single dose for COVID-19 immunization. There was no medical history. The patient's concomitant medications were not reported. The patient experienced sore injection site on 17Dec2020, at 14:00. The event was reported as non-serious. The outcome of sore injection site was recovered in Dec2020.

Fatigue; nausea; stomach ache; malaise; post-nasal drip; This is a spontaneous report from a contactable healthcare professional. A 30-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), intramuscularly in the left arm on 17Dec2020 15:00 at a single dose for COVID-19 immunization. Medical history included COVID-19 (prior to vaccination). Concomitant medication included sulfamethoxazole, trimethoprim (BACTRIM) and escitalopram (MANUFACTURER UNKNOWN). The patient had no known allergies or other medical history. The patient did not receive

any other vaccines within 4 weeks prior to the COVID vaccine. On 18Dec2020 03:00, the patient experienced fatigue, nausea, stomach ache, malaise and post-nasal drip. No treatment was received for the events. The outcome of the events was recovering. The batch/lot number for the vaccine, BNT162B2, was not provided and will be requested during follow-up.

Strong medicine taste in the back of my mouth within 5 mins of injection. Over the next hour after the injection, the taste got stronger; Over the next hour after the injection, the taste got stronger and lead to a tingling sensation in the back of my throat and tongue; This is a spontaneous report from a contactable consumer (patient). A 47-year-old female patient received bnt162b2 (BNT162B2) Lot number: FH9899, via an unspecified route of administration on the right arm, first dose on 17Dec2020 08:15 at a single dose for immunization. Medical history included glucose-6-phosphate dehydrogenase deficiency (G6PD), gastrooesophageal reflux disease (GERD) and allergies to Sulfa which is contraindicated for G6PD. Concomitant medication included famotidine and cetirizine. The patient previously took methylcobalamin and quinine (which is contraindicated for G6PD), and experienced drug hypersensitivity on both. On 17Dec2020 at 08:30 AM, the patient experienced strong medicine taste in the back of her mouth within 5 mins of injection. Over the next hour after the injection, the taste got stronger and lead to a tingling sensation in the back of her throat and tongue. These 2 symptoms are still present 22 hrs after receiving the vaccination. The medicine taste and tingling has decreased from strong to mild over the 22 hours. She mentioned that she did not have Covid prior vaccination nor did she tested positive post vaccination. She did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The events were reported as non-serious. No treatment received and the patient was recovering from the 'Strong medicine taste' and 'Strong medicine taste'.

Patient c/o lightheadedness, dizziness & nausea about 4 hour after receiving vaccine.

having aches and a fever of 100.2 so far; having aches and a fever of 100.2 so far; This is a spontaneous report from a contactable consumer (patient's wife). A male patient of an unspecified age received the bnt162b2 (BNT162B2; Lot Number, Expiration Date, NDC and UPC: unknown), via an unspecified route of administration on 17Dec2020 at 11:30 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. On 17Dec2020, the patient experienced: having aches and a fever of 100.2 so far. The patient underwent lab tests and procedures which included body temperature: 100.2 on 17Dec2020. The clinical outcome of the events was unknown. The batch/lot numbers for the vaccine, BNT162B2, were not provided and will be requested during follow up.

Fevers throughout the night of the date received, up to 101.5; This is a spontaneous report from a contactable healthcare professional. A 43-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), intramuscularly in the left arm, on 17Dec2020 at 20:00 (at the age of 43-years-old) at a single dose for COVID-19 immunization. Medical history included hypothyroidism and COVID-19. The patient was not pregnant at the time of vaccination. Concomitant medications, taken within two weeks of vaccination, included levothyroxine (MANUFACTURER UNKNOWN). The patient had no known allergies to medications, food, or other products. The patient did not receive any other vaccines within four weeks prior to the vaccination. The patient experienced

fevers throughout the night of the date received, up to 101.5 on 17Dec2020. The event was reported as non-serious. The patient underwent lab tests and procedures, which included body temperature: 101.5 on 17Dec2020. No therapeutic measures were taken as a result of the event. The clinical outcome of fevers throughout the night of the date received, up to 101.5 was recovering. It was also reported that since the vaccination, the patient had not been tested for COVID-19. The batch/lot number for the vaccine, BNT162B2, was not provided and has been requested during follow up.

About 20 minutes post vaccine, right sided chest pain, intercostal. Injection was in right arm; This is a spontaneous report from a contactable nurse and a non contactable physician. A 37-year-old female patient received bnt162b2 (reported as COVID-19 Vaccine, Pfizer, Solution for injection, lot no. and expiry date was unknown), via an unspecified route of administration (right arm) on 17Dec2020 13:30 at a single dose for COVID 19 immunization. The patient medical history was not reported. No allergies to medications, food, or other products. Prior to vaccination, patient was not diagnosed with COVID-19. Since the vaccination, patient has not been tested for COVID-19. Not pregnant at the time of vaccination. The hospital was where the most recent COVID-19 vaccine was administered. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Concomitant medication included sertraline, fish oil, colecalciferol (VITAMIN D), lactobacillus acidophilus (PROBIOTIC), and unspecified vitamin. About 20 minutes post vaccine, the patient experienced right sided chest pain, intercostal. The injection was in right arm on 17Dec2020 13:45 with outcome of recovered. There was no treatment received for the event. The event was considered as non-serious (did not result in death, was not life threatening, did not cause/prolong hospitalization, not disabling/incapacitating, congenital anomaly/birth defect. Information on the lot/batch number has been requested.

mild headache; This is a spontaneous report from a non-contactable nurse. A 25-year-old male patient received bnt162b2 (BNT162B2, Lot number: EH9899), via an unspecified route of administration on 18Dec2020 at single dose for immunization. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient's medical history and concomitant medications were not reported. The patient previously took amoxicillin and experienced allergies. The patient experienced sudden onset of mild headache approximately 10 minutes after receiving vaccine on 18Dec2020. The most recent COVID-19 vaccine was administered in the hospital. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. There was no treatment for the event. The outcome of the event was unknown.

Injection site reaction and vertigo.; Injection site reaction and vertigo.; This is a spontaneous report from a contactable pharmacist. A 63-year-old patient of an unspecified gender received first dose of bnt162b2 (Pfizer-BioNTech COVID-19 vaccine; lot EH9899), intramuscular on 17Dec2020 10:30 at single dose (left arm) for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient had no allergies to medications, food, or other products. On 17Dec2020, at 10:30, the patient experienced injection site reaction and vertigo. The patient was administered at the hospital. It was reported that the patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. There was no treatment received for the events. It was unknown if the patient was diagnosed with Covid-10 prior to vaccination and it was unknown if the patient had been tested for Covid-19 since the vaccination. Outcome of events was recovered on an unspecified date.

bleeding gums; This is a spontaneous report from a contactable nurse (patient). A 56-year-old non-pregnant female patient received first dose of BNT162B2 (Pfizer-BioNTech COVID-19 mRNA vaccine), via an unspecified route of administration at left arm on 16Dec2020 at 02:00 at a single dose for COVID-19 immunization. The patient did not have covid prior vaccination, and no covid test done post vaccination. The patient has no known allergies to medications, food, or other products. The patient has no other medical history. The patient did not receive any other vaccine in four weeks. Concomitant medication included marijuana (MARIJUANA CANDY). The patient noted bleeding gums 2 days later on 18Dec2020 at 06:30. It was not usual for her. It was just blood streaked spit with brushing teeth. The patient did not receive treatment for the reported event. The outcome of the event was unknown. The event was not considered serious. No follow-up attempts are possible; information about lot/batch number has been requested. No further information is expected.

Pain, redness, swelling and hives at the site of injection (left arm). Pain spread out from the injection site to the left shoulder blade, side of arm, left ribcage, left side of neck, and left collar; Pain spread out from the injection site to the left shoulder blade, side of arm, left ribcage, left side of neck, and left collarbone; Pain spread out from the injection site to the left shoulder blade, side of arm, left ribcage, left side of neck, and left collarbone; Pain spread out from the injection site to the left shoulder blade, side of arm, left ribcage, left side of neck, and left collarbone; Pain spread out from the injection site to the left shoulder blade, side of arm, left ribcage, left side of neck, and left collarbone; Pain spread out from the injection site to the left shoulder blade, side of arm, left ribcage, left side of neck, and left collarbone; Pain, redness, swelling and hives at the site of injection (left arm); Pain, redness, swelling and hives at the site of injection (left arm); Pain, redness, swelling and hives at the site of injection (left arm); heart palpitations; weakness; dizziness; This is a spontaneous report from a contactable other healthcare professional. A 66-year-old female patient received her first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot:EH9899) intramuscularly at the left arm on 16Dec2020 12:45 at a single dose for covid-19 immunisation. Medical history included migraine from an unknown date. The patient's concomitant medications were not reported. On 16Dec2020 15:45, the patient experienced Pain, redness, swelling and hives at the site of injection (left arm). It was further reported that the pain spread out from the injection site to the left shoulder blade, side of arm, left ribcage, left side of neck and left collarbone. The patient also experienced weakness, dizziness and heart palpitations on 16Dec2020 15:45. The events were reported as non-serious. The patient did not receive treatment for the reported events. Outcome of events was not recovered.

injection site pain 8 hours post injection. Fever 100.1 overnight with body aches and chills, headache; injection site pain 8 hours post injection. Fever 100.1 overnight with body aches and chills, headache; injection site pain 8 hours post injection. Fever 100.1 overnight with body aches and chills, headache; injection site pain 8 hours post injection. Fever 100.1 overnight with body aches and chills, headache; injection site pain 8 hours post injection. Fever 100.1 overnight with body aches and chills, headache; This is a spontaneous report from a contactable consumer. A 52-year-old female patient received the first dose of bnt162b2 (BNT162B2, lot number: EJ1685), via an unspecified route of administration in right arm on 17Dec2020 11:00 at a single dose for immunization, administered in the hospital. Medical history included allergies to Penicillin, crustaceans. Prior to vaccination, the patient was diagnosed with

COVID-19. Concomitant medication included herbal remedies: Guanyin Pearls, Shu Gan Tang. The patient experienced injection site pain 8 hours post injection, fever of 100.1 overnight with body aches, chills and headache on 17Dec2020 07:00. The outcome of the events was recovering. The events did not caused hospitalization. Since the vaccination, the patient has not been tested for COVID-19.

Left arm pain for 24 hours; This is a spontaneous report received from a non-contactable physician. A 39-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK5730), intramuscular in left arm, on 17Dec2020 09:00, at single dose, for COVID-19 immunization. The patient has no medical history and has no known allergy. Concomitant medication included lansoprazole. The patient experienced left arm pain for 24 hours on 17Dec2020 12:00. The patient was not diagnosed with COVID-19 prior to vaccination. The patient had not been tested for COVID-19 since the vaccination. The event was reported as non-serious. The outcome of the event was recovered on 18Dec2020 12:00. No follow-up attempts are possible. No further information is expected.

waxing and waning redness and intense itching of both palms; waxing and waning redness and intense itching of both palms; This is a spontaneous report from a non-contactable consumer. A 63-year-old female patient received first dose of bnt162b2 (BNT162B2, lot number EH9899), via an unspecified route of administration in left arm on 15Dec2020 17:30 at a single dose for immunization, administered in the hospital. Medical history included seasonal allergies (dust, mold, juniper pollen), allergies to erythromycin, coconut, blueberries, banana, cocoamidopropyl betaine in anything (shampoo, toothpaste, soap). The patient was not diagnosed of COVID 19 prior to vaccination. Concomitant medication included multivitamins, ergocalciferol (VIT D), ascorbic acid (VIT C), and zn [zinc] (ZN [ZINC]). On 16Dec2020 11:30, about 18 hours after injection, developed waxing and waning redness and intense itching of both palms. This lasted for about 6 hours. The patient reported that she never had this before following a vaccine. Never had this before related to any food or seasonal allergy reaction. The patient was concerned about getting the second injection of the series. The patient's BMI was 30. The patient was not tested for covid 19 after the vaccination. The outcome of the events was recovered on 16Dec2020. The events was considered non-serious. There was no treatment for the reported events. No follow-up attempts are possible. No further information is expected.

Nausea; Vomiting; Fever; This is a spontaneous report from a contactable consumer. A 25-year-old female patient received bnt162b2 (BNT162B2), via an unspecified route of administration arm left on 16Dec2020 18:44, single for immunization. Medical history included Delta granule storage pool deficiency. Concomitant medication included fluoxetine. On 16Dec2020, received vaccine at 6:44pm; On 17Dec2020- woke up with nausea/ vomiting and a fever, had to call off work; 18Dec- continued to have nausea/vomiting and low grade fever, symptoms and fever resolved by 10 am. The outcome of the events was recovered. Information on the Batch/Lot number has been requested.

Sore throat; nausea; This is a spontaneous report from a contactable nurse. A 52-year-old female patient received bnt162b2 (BNT162B2, lot number: EK5730), intramuscular on the right arm on 15Dec2020 17:30 at a single dose for COVID-19 immunisation. Medical history and concomitant medications were none. On 15Dec2020 19:30, the patient experienced sore throat and nausea. No

therapeutic measure was taken as a result of the events. Clinical outcome of the events was recovered on an unspecified date.

right eye fullness; blurred vision; This is a spontaneous report from a contactable consumer. A 42-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), lot number: EK5730, via an unspecified route of administration in the right arm on 17Dec2020 11:30 at single dose for immunization. Medical history was reported as none. The patient's concomitant medications include multivitamins within two weeks of vaccination. The patient experienced right eye fullness and blurred vision on 17Dec2020. The patient was vaccinated in the hospital and no other vaccine in four weeks was given. No treatment given for the events. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. Patient had no known allergies. The events was considered non serious. The outcome of the events was unknown.

Tingling mouth; This is a spontaneous report from a contactable physician. A patient of unspecified age and gender received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration in Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced tingling mouth in Dec2020. The event happened during the observation period after the vaccine was administered. The reporter thinks that the patient just panicked and overreacted and doesn't think they had a reaction. The patient did go the emergency room (ER) and was discharged the same day. The outcome of tingling mouth was unknown. The batch/lot number for the vaccine, BNT162B2, was not provided and will be requested during follow-up.

chills; low-grade temperature; dizziness; This is a spontaneous report from a contactable consumer. A 25-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration in the left arm, on 17Dec2020 at 07:45 (at the age of 25-years-old) at a single dose for COVID-19 immunization. The patient had no medical history. It was unknown if prior to the vaccination, the patient was not diagnosed with COVID-19. The patient was not pregnant at the time of vaccination. Concomitant medications, taken within two weeks of vaccination, included cetirizine hydrochloride (ZYRTEC) and progesterone;estrogens (MANUFACTURER UNKNOWN) oral contraceptives. The patient had no known allergies to medications, food, or other products. The patient did not receive any other vaccines within four weeks prior to the vaccination. The patient experienced chills, low-grade temperature, and dizziness on 17Dec2020 at 08:45. The events were reported as non-serious. The events were reported to have occurred within 90 minutes of vaccination. The patient underwent lab tests and procedures, which included temperature: low-grade on 17Dec2020. No therapeutic measures were taken as a result of the events. The clinical outcome of chills, low-grade temperature, and dizziness was recovered in Dec2020. It was also reported that since the vaccination, the patient had not been tested for COVID-19. The batch/lot number for the vaccine, BNT162B2, was not provided and has been requested during follow up.

Fever; Headache; Chills; This is a spontaneous report from a contactable other healthcare professional (patient). A 53-year-old female patient (not pregnant) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, batch/lot number: unknown), intramuscular on right arm on 16Dec2020

(08:45 PM) at single dose for COVID-19 immunization. The patient's medical history included diabetes mellitus, hypertension, and COVID-19. Concomitant medications were not reported. It was reported that prior vaccination, patient diagnosed with COVID-19. No known allergies. Since the vaccination, the patient has not been tested for COVID-19. The patient experienced chills, fever, and headache on 17Dec2020 (09:00 AM). There was no treatment received for the reported adverse events. The outcome of events was recovering. This case is reported as non-serious. Information on the lot/batch number has been requested.

Tongue numbness and sensitive; Tongue numbness and sensitive; This is a spontaneous report from a contactable nurse (patient) and a physician. A 31-year-old female received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot EK5730) intramuscular on17Dec2020 13:30 at a single dose on right arm as COVID-19 vaccine. Medical history was not reported. The patient had no known allergies to medications, food, or other products. Concomitant medications were not reported. On 17Dec2020, she received the vaccine and an hour after getting it, her tongue went numb and became sensitive (tongue numbness and sensitive on 17Dec2020 14:00). Today, it was not as numb feeling but was still sensitive. The events were assessed as non-serious, did not result in death, not life threatening, did not cause/prolonged hospitalization, not disabling/incapacitating, did not cause congenital anomaly/birth defect. Treatment was not received for the adverse events. The patient was not pregnant at the time of vaccination. The facility where the most recent COVID-19 vaccine was administered was noted as other. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. There was no expiry date for the vaccine. The card she has, only has the received date: 17Dec2020 and when to return for the second dose: 07Jan2021. She had submitted a claim about the side effects experienced but it wasn't clear what would happen next. The patient inquired if someone would reach out to her and would there be a follow-up. She wanted to know what the process would be regarding reporting. The outcome of the event 'numbness of tongue' was recovering while 'sensitive tongue' was not recovered.

fever; Malaise; chills; muscle and joint aches; muscle and joint aches; extreme fatigue; nausea; headache; both arms started itching on lower arm, not at site/the face and scalp started itching; This is a spontaneous report from a contactable healthcare professional. A 36-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, lot number EH9899, expiration date unknown), dose number 1, intramuscularly on 16Dec2020 10:00 at a single dose for COVID-19 immunisation. Medical history included Hashimotos Thyroiditis, MDD (major depressive disorder), and acne. Concomitant medications included zinc, ergocalciferol (VIT D), venlafaxine, levothyroxine sodium (SYNTHROID), and spironolactone. The patient had vaccine at 10 AM. At 11 AM, both arms started itching on lower arm, not at site; injection arm was worse than non injection arm. At 11:45, the face and scalp started itching. By noon, all symptoms had resolved. The patient did not medicate. Two days post vaccine, on 18Dec2020, the patient had all symptoms on warning sheet: fever, malaise, chills, muscle and joint aches, extreme fatigue, nausea and headache. The outcome of the event was recovered for itching and not recovered for the other events.

Soon after the shot I had a big headache, almost like a migraine headache; I am having tough time right now; Soon after the shot I had a big headache, almost like a migraine headache; I am having tough time right now; I have slight fever 99.6; Muscle ache; This is a spontaneous report from a contactable healthcare professional, the patient. A 58-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot Number: EK55730), via an unspecified route of administration on 17Dec2020 at 13:00 (at the age of 58-years-old) as a single dose for COVID-19 immunization. Medical history included high blood pressure, lupus, stroke, and diabetes. Concomitant medications included lisinopril (MANUFACTURER UNKNOWN). On 17Dec2020, soon after receiving the vaccine, the patient experienced a big headache, almost like a migraine headache; slight fever of 99.6 (no units provided), and muscle ache. The clinical outcomes of slight fever of 99.6 and muscle ache were unknown; while that of the big headache, like a migraine was not recovered.

HCP caller is complaining of a fever after vaccine got wed; Chills; felt tired; This is a spontaneous report from a contactable nurse (patient). A 64-year-old female patient started to received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899, expiry date: 31Mar2021), via an unspecified route of administration on 16Dec2020 at a single dose for Covid-19 immunisation. Medical history was reported as none. There were no concomitant medications. The patient called to report on the COVID vaccine, and explains that she received the vaccine on Wednesday, 16Dec2020 around 2:30pm. She received the vaccine at work. It was administered in the left upper arm. The following morning (17Dec2020) around 2am she woke up with chills and a fever that lasted all day yesterday, so she didn't go to work. She was running a fever of about 99.7-100.0 on 17Dec2020 and that was with alternating Advil and Tylenol. She felt tired and so she rested the whole day. The patient explained that she thought it would go away after a day but today she woke up at 5am with chills. She didn't take her temperature at that time but took some medication. Then on 18Dec2020 at 9am, she woke up with chills again and she still was at 100.8. She called to see how long does the fever last after the vaccine. Outcome of the events fever and chills was not recovered and for fatigue was unknown.

Patient developed a delayed onset rash 12 hours after getting vaccine and has no resolved in 3 days; This is a spontaneous report from a contactable pharmacist. A female patient in their 40's received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration at single dose on an unspecified date for immunisation. The patient medical history and concomitant medications were not reported. On an unspecified date, the patient developed a delayed onset rash 12 hours after getting vaccine and has no resolved in 3 days. The outcome of the events was not recovered. Information on the Batch/Lot number has been requested.

At first it was just muscle ache in the left arm; then I started having body aches; headache; I'm feeling very nauseous; This is a spontaneous report from a contactable consumer or other non hcp. A 24-year-old female patient received bnt162b2 (BNT162B2; lot number: EH9899, expiry date: unknown), via an unspecified route of administration arm left on 17Dec2020 08:15 at, single (Dose Number: 1) for immunization. Medical history included asthma. Concomitant medication included colecalciferol (VITAMIN D [COLECALCIFEROL]). Allergies to medications, food, or other products: Tylenol and Midol. On 17Dec2020 23:00, At first it was just muscle ache in the left arm and then I started having body aches and a headache and now I'm feeling very nauseous. The outcome of the events was unknown.

"lips/mouth swelling; lips/mouth swelling; tingling sensation in throat and on tongue; tingling sensation in throat and on tongue; This is a spontaneous report from a contactable other healthcare professional (HCP, also the patient). A 28-year-old female patient started to receive BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), intramuscular at right arm on 17Dec2020 10:45 at single dose for COVID-19 immunization. The patient's medical history included asthma, hashimoto's thyroiditis, depression, anxiety, seasonal allergies, known allergies: latex, banana. Concomitant medication included levothyroxine, amfetamine aspartate, amfetamine sulfate, dexamfetamine saccharate, dexamfetamine sulfate (ADDERALL XR), bupropion hydrochloride (WELLBUTRIN XL), escitalopram oxalate (LEXAPRO), trazodone, alprazolam (XANAX), fexofenadine hydrochloride (ALLEGRA), salbutamol (ALBUTEROL) (as needed), cyanocobalamin (VITAMIN B12), colecalciferol (VITAMIN D), zinc, all reported as other medications in two weeks. No other vaccine in four weeks. The patient previously took codeine and experienced drug alergy (known allergies). The facility type of vaccine was hospital. No COVID prior vaccination and no COVID tested post vacccination. The patient was not pregnant at the time of vaccination. On 17Dec2020 11:00, the patient experienced ""lips/mouth swelling tingling sensation in throat and on tongue"". Therapeutic measures were taken as a result of ""lips/mouth swelling tingling sensation in throat and on tongue"" included over the counter (OTC) Benadryl. The outcome of the event ""lips/mouth swelling tingling sensation in throat and on tongue"" was recovered (assumed in Dec2020). Information about lot/batch number has been requested."

"Itching and redness on chest, back, and side; Itching and redness on chest, back, and side; This is a spontaneous report from a contactable pharmacist. A 46-year-old female patient (no pregnant) received her first dose of bnt162b2 (reported as ""COVID 19 vaccine"", lot number: EJ1685), via intramuscular on 18Dec2020 on her right arm at single dose for COVID-19 immunization. Medical history included fibromyalgia, anxiety, gastrooesophageal reflux disease (GERD), post-traumatic stress disorder (PTSD) and depression, all from an unknown date and unknown if ongoing. Concomitant medications that the patient received with 2 weeks of vaccination included cyanocobalamin (B12), citalopram, pregabalin, celecoxib (CELEBREX), omeprazole, tizanidine, trazodone, vitamin D3. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. The patient experienced itching and redness on chest, back, and side on 18Dec2020. No treatment was received for the adverse event. The outcome of the events was recovering."

pretty strong chest pain; heart pain; some kind of back pain, behind her heart; This is a spontaneous report from contactable consumer (reporting for her daughter). A 29-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration on 17Dec2020 at 10:00 AM at a single dose for COVID-19 immunization. The patient's medical history were not reported. Concomitant medications included unspecified bipolar medications. The patient experienced pretty strong chest pain on 18Dec2020 at 07:00 and heart pain and some kind of back pain, behind her heart in Dec2020. The pretty strong chest pain lasted about 10 minutes and then went away. The outcome of pretty strong chest pain was recovered on 18Dec2020 and of some kind of back pain, behind her heart and heart pain was unknown. The batch/lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up.

headache; achy; weak; This is a spontaneous report from a contactable other healthcare professional (HCP) (patient). A 45-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) intramuscular on 17Dec2020 14:00 at single dose on the left arm as COVID-19 vaccine. Medical history included allergies to penicillin; allergies, ITP. Concomitant medication was noted as other vaccine in four weeks reported as allergy shots on 08Dec2020 (advance ENT). The patient also had other medications in two weeks such as zinc 50mg, 5000 Vit D, venlafaxine 225, levothyroxine sodium (SYNTHROID) 100, spironolactone 100. The patient experienced headache, achy, and weak, all on 17Dec2020 21:00. Treatment was not received for the adverse events. The patient was not pregnant at the time of vaccination. The most recent COVID-19 vaccine was administered in the hospital. The patient received other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. The events were assessed as non-serious, did not result in death, not life threatening, did not cause/prolonged hospitalization, not disabling/incapacitating, did not cause congenital anomaly/birth defect. The outcome of the events was recovering. Information about lot/batch number has been requested.

Pain at injection site; This is a spontaneous report from a contactable nurse (patient). A 51-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot EH9899) intramuscular from 16Dec2020 22:00 at a single dose on the left arm as COVID-19 vaccine. Medical history included ulcerative colitis. The patient had no known allergies to medications, food, or other products. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine and did not receive other medications within 2 weeks of vaccination (no other vaccine in four weeks and no other medications in two weeks). The patient experienced pain at injection site on 16Dec2020 23:00. Treatment was not received for the adverse event. The patient had no Covid prior vaccination and did not have Covid tested post vaccination. The event was assessed as non-serious, did not result in death, not life threatening, did not cause/prolonged hospitalization, not disabling/incapacitating, did not cause congenital anomaly/birth defect. The patient was not pregnant at the time of vaccination. The most recent COVID-19 vaccine was administered at the hospital. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. The outcome of the event was recovering.

Bifrontal headache; This is a spontaneous report from a contactable consumer and contactable physician. A 56-year-old female received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: unknown), via an unspecified route of administration at left arm on 17Dec2020 at 15:15 at single dose for COVID-19 immunization. The patient medical history and concomitant medications were not reported. The patient previously took cephalexine and experienced allergies. On 18Dec2020 at 06:00, the patient experienced bifrontal headache. The patient outcome of the event was recovered. Therapeutic measures were taken as a result of bifrontal headache and included treatment with MIDRIN.

feeling a little lightheaded; feeling hot at time; This is a spontaneous report from a contactable nurse. A 25-year-old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: HE9899), intramuscular on the right arm on 18Dec2020 10:00 at a single dose for COVID-19

immunization. The patient's medical history and concomitant medications were not reported. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. On 18Dec2020 10:05, the patient was feeling a little lightheaded. She was also feeling hot at the time. She admitted that she did not have breakfast in the morning and had not had anything to drink. She denied throat discomfort or tingling. No shortness of breath or headaches. Outcome of the events was unknown. The events were considered non-serious.

Scratchy Throat; tongue swelling; This is a spontaneous report from a contactable consumer (patient himself). A 36-year-old male patient received bnt162b2 (BNT162B2, lot no. and expiry date were not reported), via an unspecified route of administration on 18Dec2020 05:30 at single dose for Covid-19 immunisation. The patient had no known allergies. There were no medical history and concomitant medications. No other medications the patient received within 2 weeks of vaccination. The patient experienced scratchy throat and tongue swelling on 18Dec2020 (06:00 PM). The most recent COVID-19 vaccine was administered in the hospital. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. Therapeutic measures were taken as a result of the events which included Benadryl. The outcome of the events was not recovered. Information about Lot/batch no has been requested.

Swelling at injection site; headache; slight nausea; pain at injection site; This is a spontaneous report from a contactable consumer. A 43-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), lot number: EH9899, first dose via an unspecified route of administration on 17Dec2020 13:00, in left arm at single dose for immunization. The patient's medical history was not reported. Concomitant medication included emtricitabine, tenofovir disoproxil fumarate (TRUVADA). The patient was vaccinated in the hospital. No other vaccine was receive in four weeks. The patient experienced swelling at injection site, headache, slight nausea and pain at injection site on 17Dec2020 18:00. No treatment was given to the patient for the events. The patient had no COVID prior to vaccination and no COVID test post vaccination. The events was reported as non serious. The patient has no known allergies. The outcome of the events was recovering.

diaphoresis; rigors; chest pain; This is a spontaneous report from a contactable nurse. A 38-year-old female patient received first dose of BNT162B2 (Pfizer-BioNTech COVID-19 mRNA vaccine, lot number: elo140), via an unspecified route of administration at right arm on 18Dec2020 09:45 AM at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient has known allergies to flu vaccine. On 18Dec2020 at 10:15 AM, the patient experienced adverse events of diaphoresis, rigors, and slight chest pain. The adverse events resulted in emergency room/department or urgent care. It was unknown if treatment was received due to adverse events. The outcome of the events was unknown. The events were considered non-serious.

Slight headache; sore throat; This is a spontaneous report from a contactable consumer. A 61-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number EK5730/expiration date unknown) dose number 1 via an unspecified route of administration on the left arm on 18Dec2020 11:15 for COVID-19 immunization. Medical history included polycythemia

vera, high BP, and GERD (gastrooesophageal reflux disease). Concomitant medications included omeprazole, aspirin [acetylsalicylic acid], hydroxyurea, tapentadol hydrochloride (NUCYNTA), and amlodipine besilate (NORVASC). The patient experienced slight headache and sore throat on 18Dec2020 12:15. The outcome of the events was not recovered.

Arm swelling; sore; swollen; This is a spontaneous report from a contactable other healthcare professional (patient herself). A 55-year-old female patient (no pregnancy) received first dose of bnt162b2, intramuscularly at site of left arm at 11:15 on 18Dec2020 at single dose for COVID-19 immunization. Medical history included atrophied kidney, high BP, high cholesterol and allergies to medications, food, or other products. Concomitant medication included atorvastatin calcium (LIPITOR) and benazepril hydrochloride (LOTENSIN). The patient experienced arm swelling, sore, and swollen at 18:00 on 18Dec2020. No treatment received for events. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. The outcome of events was not recovered. Information on the Batch/Lot number has been requested.

Foggy feeling; headache; body aches; low grade fever; This is a spontaneous report from a contactable consumer (patient herself). A 44-year-old female patient (no pregnancy) received bnt162b2, via an unspecified route of administration at site of right arm at 15:45 on 14Dec2020 at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced foggy feeling, headache, body aches and low grade fever at 12:00 on 18Dec2020. No treatment received for events. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. The outcome of events was unknown. Information on the lot/batch number has been requested.

Soreness at injection site; mild diffuse myalgias; fatigue the following day; This is a spontaneous report from a contactable physician. This 30-year-old male physician (patient) reported that he received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot# EJ1685), via intramuscular on 16Dec2020 15:30 in arm left at single dose for covid-19 immunization. Medical history included exercise-induced asthma and allergies: certain types of deodorant. The patient's concomitant medications were not reported. The patient had no covid prior vaccination and was not covid tested post vaccination. The patient experienced soreness at injection site, mild diffuse myalgias and fatigue the following day on 17Dec2020 07:00. All events were reported as non-serious. Outcome of events were recovered in Dec2020. The patient received the treatment-ibuprofen for events.

Flushed red skin upper torso and face; Flushed red skin upper torso and face; This is a spontaneous report from a contactable nurse (patient herself). A 55-year-old female patient (non-pregnant) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via intramuscular on 18Dec2020 08:00 am in left arm at single dose for covid-19 immunization. Medical history included chronic migraines and allergies: shellfish. Concomitant medication included famotidine, memantine and ascorbic acid, ergocalciferol, nicotinamide, retinol, riboflavin, thiamine hydrochloride (VITAMINS). The patent previously took pethidine hydrochloride (DEMEROL) and experienced allergies. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. Patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The

patient experienced flushed red skin upper torso and face on 18Dec2020 13:00 with outcome of recovering. No treatment was received for flushed red skin upper torso and face. Information on the lot/batch number has been requested.

Fever; body aches; nausea; vomiting; severe fatigue; headache; abdominal pain; site pain; This is a spontaneous report from a contactable consumer (patient herself). A 61-year-old female patient (non-pregnant) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot# Ek5730), via an unspecified route of administration on 16Dec2020 16:15 in right arm at single dose for covid-19 immunization. Medical history included asthma, hypothyroidism, hyperlipidemia, allergies: codeine and sulfa. Prior to vaccination, the patient diagnosed with COVID-19. Concomitant medication included levothyroxine within 2 weeks of vaccination. Since the vaccination, the patient has not been tested for COVID-19. The patient experienced fever, body aches, nausea, vomiting, severe fatigue, headache, abdominal pain and site pain on 17Dec2020 04:00 with outcome of recovering. All events were reported as non-serious. The patient received the treatment ondansetron (ZOFRAN) for events.

sensation in throat/a menthol cough drop stuck in the throat; flushed; diaphoretic; burning into my chest; some random hives; This is a spontaneous report from a contactable consumer (patient herself). A 38-year-old female patient received first dose of bnt162b2 (lot number: EL0140), via an unspecified route of administration at site of left arm at 11:30 on 19Dec2020 at single dose for COVID-19 immunization. Medical history included Oral Allergy Syndrome, ADHD (attention deficit hyperactivity disorder), multiple food allergies, and allergies: PCN, Ceclor and Lovenox multiple. Concomitant medication included cetirizine hydrochloride (ZYRTEC), montelukast sodium (SINGULAIR), diphenhydramine hydrochloride (BENADRYL) and amfetamine aspartate, amfetamine sulfate, dexamfetamine saccharate, dexamfetamine sulfate (ADDERALL). Within minutes after vaccination, the patient became flushed and diaphoretic followed by a sensation in her throat, it felt that she had a menthol cough drop stuck in the throat and the burning into her chest. Once the medics administered IV Benadryl, the sensation in her throat went away. She was in the emergency room for about 3 hours and had some random hives throughout the rest of the evening. She had anaphylaxis previously to avocado and to an allergy shot. This was definitely nothing close to anaphylaxis. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. The outcome of events was recovered in Dec2020.

muscles aches; really tired; This is a spontaneous report from a contactable consumer (patient himself). A 37-year-old male patient received bnt162b2, via an unspecified route of administration at site of right arm on 16Dec2020 at single dose for COVID-19 immunization. Medical history included lung surgery from 2019. There were no concomitant medications. The patient experienced muscles aches, really tired on 17Dec2020. The outcome of events was unknown. Information on the lot/batch number has been requested.

top of her left arm was swollen; she had pain all down the left side of her body, the whole left side; This is a spontaneous report from a contactable consumer (Patient). A 37-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration in left arm on 17Dec2020 at single dose for COVID-19 immunization. The patient medical history was not reported.

The patient's concomitant medications were not reported. The patient got the shot in her left arm and the top of her left arm was swollen, she had pain all down the left side of her body, the whole left side in Dec2020. The patient only took paracetamol (TYLENOL) for treatment. The outcome of the events was unknown. Information on the lot/batch number has been requested.

"Felt like arm was going to ""fall off"" for 18 hours after receiving COVID vaccine; Felt like arm was going to ""fall off"" for 18 hours after receiving COVID vaccine; This is a spontaneous report from a contactable consumer (patient). A 33-year-old patient of an unspecified gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date in 2020 at single dose for COVID-19 immunization. The patient medical history and concomitant medications were not reported. The patient felt like arm was going to ""fall off"" for 18 hours after receiving COVID vaccine in 200. Event took place after use of product. The outcome of events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained."

little discomfort felt in the deltoid from the shot; This is a spontaneous report from a non-contactable consumer (patient, Pfizer employee). A female patient of an unspecified age received BNT162B2, via an unspecified route of administration on an unspecified date in 2020 at a single dose in deltoid for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced little discomfort felt in the deltoid from the shot on an unspecified date. The outcome of event was unknown. No follow-up attempts are possible, information about lot/batch cannot be obtained. No further information is expected.

After first dose, experienced sore arm, feeling foggy, headaches but better the next day.; After first dose, experienced sore arm, feeling foggy, headaches but better the next day.; After first dose, experienced sore arm, feeling foggy, headaches but better the next day.; This is a spontaneous report from a non-contactable consumer. A patient of unspecified age and gender received the first dose of bnt162b2 (BNT162B2) vaccine , via an unspecified route of administration on an unspecified date at single dose for covid-19 immunisation . The patient medical history and medications were not reported. The patient experienced sore arm, feeling foggy, headaches but better the next day on an unspecified date with outcome of recovering. No follow-up attempts are possible ; information about lot/Batch number cannot be obtained.

Severe dizziness; This is a spontaneous report from a contactable Physician reporting for herself. A 61-years-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EH9899), via an unspecified route of administration on 18Dec2020 at single dose for covid-19 immunisation. Medical history was none. There were no concomitant medications. The patient experienced severe dizziness on 18Dec2020 with outcome of recovering. No treatment was performed. The patient underwent CMP test on 07Dec2020 and it was normal.

felt dehydrated; pain in the arm; but it was still hard; arm swelling where she got the injection; Dizziness; This is a spontaneous report from a contactable consumer reporting for herself. A 26-year-old female patient received first dose BNT162B2 (Pfizer product, lot number EH9899), via an unspecified

route of administration on 17Dec2020 06:00 at single dose on left arm for COVID-19 immunization. There were no medical history and concomitant medications. No prior vaccinations (within 4 weeks); no adverse events following prior vaccinations. The patient reported that she was the unit secretary in the hospital. She got the first dose COVID vaccine yesterday (17Dec2020 06:00). Vaccination facility type was hospital; vaccine was not administered at military facility. She was reading the paper they gave her at work. She had arm swelling where she got the injection, it had gone down a little, but it was still hard. She also felt dizziness and dehydrated. The dizziness started about an hour ago (on 18Dec2020). Since laying down it had improved a little. She has felt dehydrated since around 11am (18Dec2020 11:00). She was sipping on Gatorade, but still felt dehydrated. She took a Tylenol today (18Dec2020) for the pain in the arm and swelling. She had gone to the website and it didn't say what to do about the side effects besides call #. She didn't think she needs to call # for a swollen arm. Therapeutic measures were taken as a result of arm swelling where she got the injection, pain in the arm and felt dehydrated. The adverse events did not require a visit to emergency room or physician office. The outcome for events arm swelling where she got the injection and Dizziness was resolving while for other events was unknown.

ringing in his ear on the left; This is a spontaneous report from a contactable Physician(patient). The 37-year-old male patient received first dose of vaccine BNT162B2(Batch/lot number: EK7530, Expiration date: unknown), via an unspecified route of administration on 18Dec2020 at single dose for prevention of Covid. Medical history included gastrooesophageal reflux disease(GERD). Concomitant medication included omeprazole for GERD. The patient stated in the hospital, he had the Covid vaccine 2 hours ago and he just want to report a possible side effects, about hour after the vaccine he had ringing in his ear on the left on 18Dec2020. No treatment was received. It was not that bad. It was improving. Outcome of event was recovering.

soreness at injection site at hour 3; low grade fever at hour 8; This is a spontaneous report from a contactable physician reporting for him/herself via Pfizer sales representative. This patient of unknown age and gender received on an unknown date a single dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) for COVID-19 immunization. Medical history and concomitant medications were not reported. On an unknown date, the patient noted soreness at injection site at hour 3, and low grade fever at hour 8. Outcome was unknown. No follow-up attempts are possible, information about batch number cannot be obtained.

numbness in my 'ear'/numbness in my hands; Numbness in the beginning and right now numbness and pain; right now numbness and pain; This is a spontaneous report from a contactable consumer (patient). A 48-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot/batch number and expiration date unknown), via an unspecified route of administration on 18Dec2020 at 15:00 at single dose for COVID-19 immunization (just got the vaccine). The patient's medical history and concomitant medications were not reported. The patient reported that she just got the vaccine today (18Dec2020) and she took it in her hospital, she felt numbness in her 'ear', her hands and right now going through the pain. Patient reported that numbness in the beginning and right now numbness and pain. She got the vaccine exactly at 3O'clock (15:00) and after20-25 minutes later, she started feeling numbness and pain. She did have pain right now. She had not taken anything as

treatment. The outcome of the events was unknown. Information on the Lot/Batch number has been requested.

Recently feeling chilly; I just feel very nauseous and weaken like my body some parts are hot and some parts are cold; I just feel very nauseous and weaken like my body some parts are hot and some parts are cold; weaken like my body some parts are hot and some parts are cold; This is a spontaneous report from a contactable consumer (patient). A patient of unspecified age and gender received BNT162B2 (reported as COVID Vaccine, lot number and expiration date not reported), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient received the COVID Vaccine and had been recently feeling chilly and also just really weak and nauseous and patient guessed just never felt this way before. The patient know that they were side effects but just felt very nauseous and weaken like the patient's body some parts were hot and some parts were cold. The outcome of events was unknown. Information regarding lot/batch has been requested.

light headed; tingling all over body; This is a spontaneous report from two contactable consumers. A 49-year-old female patient started to receive first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899), intramuscular at left arm on 17Dec2020 at 14:00, single dose for COVID-19 immunization. Medical history included asthma and allergy to sulfa, both from an unknown date and unknown if ongoing. Concomitant medication included salbutamol (PROVENTIL), omeprazole and cetirizine hydrochloride (ZYRTEC). The patient previously took morphine and tramadol and for both experienced allergies on an unspecified date. On 17Dec2020 at 14:10, the patient experienced light headed and tingling all over the body. The patient outcome of the light headed was not recovered, the patient outcome of tingling all over the body was recovered within 30 minutes.

allergic reaction; This is a spontaneous report from a contactable physician. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration in Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced allergic reaction in Dec2020. No further details were provided. The outcome of allergic reaction was unknown. The batch/lot number for the vaccine, BNT162B2, was not provided and will be requested during follow-up.; Sender's Comments: Based on the information available, a possible contributory role of the suspect products cannot be excluded for the reported event allergic reaction due to temporal association. However patient past medical history regarding allergy would have been helpful for a meaningful causality assessment. Case will be reevaluated upon further information

Swelling of Right arm below the elbow not at the injection site. Soreness and tightness of the right hand. After 72 hours these symptoms resolved however on 12/19/2020 developed burning and itchy hives over abdomen, back and trunk. On 12/21/2020 the hives developed on the scalp.

Low-grade temperature ranging from 99.8-100.3; chills; body aches; fatigue; This is a spontaneous report from a non-contactable nurse (patient). An adult female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date were not reported),

intramuscular on the right arm on 16Dec2020 18:00 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient was not pregnant. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. On 17Dec2020 05:00, the patient experienced low-grade temperature ranging from 99.8-100.3, chills, body aches, and fatigue. No treatment was received for the adverse events. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, the patient had not been tested for COVID-19. Outcome of the events was recovering. The events were considered non-serious. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

"bronchitis or pneumonia; pain down arm into fingers; injection site tingling; Chest felt heavy and difficulty breathing; Chest felt heavy and difficulty breathing; bronchitis or pneumonia; rash on both arms with bright purple skin; rash on both arms with bright purple skin; felt like everything was numb and like she was on drugs; felt like everything was numb and like she was on drugs; Severe headache; This is a spontaneous report from a contactable consumer (nurse) via a Pfizer sales representative. A female patient of an unspecified age received the first dose of the bnt162b2 (BNT162B2; also reported as COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. On an unspecified date, the patient experienced: bronchitis or pneumonia (medically significant), pain down arm into fingers, injection site tingling, chest felt heavy and difficulty breathing, rash on both arms with bright purple skin, felt like everything was numb and like she was on drugs, and severe headache; all of which required hospitalization. The clinical course was reported as follows: The female patient (nurse) took the first dose of the vaccine and experienced pain down arm into fingers, injection site tingling. The patient's chest felt heavy and difficulty breathing; however, the ""tongue never swelled."" Rapid response was called, and the patient was taken to the hospital. The patient was given a ""cocktail"" to treat the reaction. The patient ""felt like everything was numb and like she was on drugs"" The patient also felt like she had bronchitis or pneumonia. The patient also experienced a ""rash on both arms with bright purple skin""; along with a severe headache. Therapeutic measures were taken as a result of pain down arm into fingers, injection site tingling, and chest felt heavy and difficulty breathing. The clinical outcome of the events was unknown. No follow-up attempt possible; information about batch/lot number cannot be obtained."

Chills, severe headache, joint pain, muscle aches; Chills, severe headache, joint pain, muscle aches; Chills, severe headache, joint pain, muscle aches; Chills, severe headache, joint pain, muscle aches; This is a spontaneous report from a contactable consumer. A 48-year-old female patient received bnt162b2 (BNT162B2, lot number: EH9899), via an unspecified route of administration on the left arm on 17Dec2020 10:45 at a single dose for COVID-19 immunisation. Medical history included asthma and COVID-19 (patient was diagnosed with COVID-19 prior to vaccination). Concomitant medications included ascorbic acid, biotin, calcium carbonate, calcium pantothenate, calcium phosphate dibasic, chromium picolinate, colecalciferol, copper sulfate, cyanocobalamin, ferrous fumarate, folic acid, magnesium borate, magnesium oxide, manganese sulfate, nickel sulfate, nicotinamide, panax ginseng root, phytomenadione, potassium chloride, potassium iodide, pyridoxine hydrochloride, retinol acetate, riboflavin, sodium metavanadate, sodium molybdate, sodium selenate, stannous chloride, thiamine

mononitrate, tocopheryl acetate, zinc oxide (CENTRUM ENERGY), and pantoprazole sodium sesquihydrate (PROTONIX [PANTOPRAZOLE SODIUM SESQUIHYDRATE]). On 17Dec2020 13:00, the patient experienced chills, severe headache, joint pain, muscle aches. Therapeutic measure was not given as a result of the events. Clinical outcome of the events was not recovered.

Injection site pain; Fatigue; This is a spontaneous report from a contactable healthcare professional. A 50-year-old female patient received bnt162b2 (BNT162B2, lot number: EK5730), intramuscular on the left arm on 17Dec2020 09:00 at a single dose for COVID-19 immunisation. Medical history and concomitant medications were not reported. On 18Dec2020, the patient experienced injection site pain and fatigue. Therapeutic measure was not given as a result of the events. Clinical outcome of the events was recovering.

Arm soreness; fatigue; This is a spontaneous report from a contactable consumer. A 23-year-old female patient received the 1st dose of bnt162b2 (BNT162B2) at single dose at right arm on 18Dec2020 08:00 for immunization, administered at hospital. The patient medical history was not reported. No known allergies. Concomitant medication included MultiVitamins and colecalciferol (VITAMIN D [COLECALCIFEROL]). The patient has not received any other vaccines within 4 weeks prior to the COVID vaccine. The patient experienced arm soreness and fatigue on 18Dec2020 11:00. The patient has received not treatment for the events. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. The action taken in response to the events for bnt162b2 was not applicable. The outcome of events was recovering. Information on the lot/batch number has been requested.

mild dry mouth; felt a little foggy; This is a spontaneous report from contactable consumer via a Pfizer Sales Representative. A 52-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration, on 18Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced mild dry mouth and felt a little foggy on 18Dec2020. The clinical outcome of mild dry mouth and felt a little foggy was recovered on 18Dec2020. No follow-up attempts are possible; information about batch/lot number cannot be obtained.

100.5 fever/chills, body aches. Treated with ibuprofen. Resolved within 24hrs of vaccine.

One day after vaccination, patient returned to the injection clinic and reported noticed shoulder and arm swelling with a patchy rash to her R shoulder. Symptoms resolved. She was advised to call the call center and f/u with PCP.

Urticaria, tachycardia at 10 minutes post injection in left arm and neck Treated with oral cetirizine and montelukast. Resolved within 15 minutes of treatment. Discharged in good condition with PO diphenhydramine as needed.

Headache, explosive diarrhea, nausea & vomiting, fever, slept for 18 hours, body aches

Patient recieved dose one of the Pfizer Covid 19 Vaccine. Within ten minutes scratchy throat started. Patient was monitored for 30 minutes and throat irritation became worse. Transferred to urgent care for follow up. Received a dose of diphenhyramine, symptoms lessened, and was able to leave urgent care for home.

Patient developed dizziness shortly after receiving Pfizer Covid-19 vaccine on 12/21/2020. Patient was brought to the Emergency Department. SBP initially in 70's, rapidly improved to 90's without intervention. Patient denied SOB. No e/o angioedema on exam. SBP improved to 110's after 500cc of NS.

Body aches, and fatigue started 6 hours after vaccine administered. The next day I had a moderate headache that I took ibuprofen, and Tylenol for. Body aches, and fatigue continued the next day. It was difficult for me to participate in ADL's. Headache, nausea, and fatigue continued to two days post vaccine.

Myalgia, Fever, Chills, swollen joints

Pfizer-BioNTech COVID-19 Vaccine EUA metallic taste immediately following 1st IM dose

While driving home after receiving the vaccine I was very close to losing consciousness. After laying down in my car for 20 minutes I was able to drive home. I developed a headache that did not subside fully until three days later. On Friday December 18th, I woke up with a very sore arm, from my shoulder to my wrist, I still had a headache, developed; fever, chills, body aches, and nausea.

Dizziness, headache, nausea started 12/19/20. Vomited on 12/20/20. Came in on 12/21/20 to be seen by provider.

Vaccine recipient received vaccine on 12/19/2020.On 12/20 experienced symptoms of headache, fatigue, chills, fever 101.8 F, lower back pain, and nausea. The vaccine recipient took acetaminophen and managed symptoms at home. Reported to have slept for most of the day. On 12/22, during a follow-up phone call reported that most of the symptoms have subsided and only nausea remained.

Approx 5 minutes after receipt of vaccine, patient reported experiencing palpitations. Vitals signs were checked and HR elevated to the 130s (regular rhythm) and systolic BP elevated to the 160-170s mmHg; pulse ox within normal limits. Some mild tremors noted in left > right hand. Patient placed in supine position and given 12.5mg IV benadryl and 4mg x2 doses =8mg total IV dexamethasone with symptomatic improvement and normalization of HR / BP. No hypotension or hypoxia throughout the event. No angioedema or urticaria.

Employee reported a bloody nose and blood in urine this morning (slight tinge) Has not exhibited any other side effects at the time of this report. Noted in afternoon on 12/18/2020 urinated and no blood present.

1. Day 1- (same day) didn't feel anything until later that night, I felt a lump at site with a quarter size area around the direct shot red and sore. 2. Day 2- Sore arm, felt a bit restricted to move arm around,

minor weakness, still red quarter size and lump at site. 3. Day 3- Arm same as day 2, but by the evening I was extremely tired. Joint pains, body aches, and random chills all severe. 4. Day 4- Arm issues gone but continued with the body aches, weakness, extremely tired, and chills. A bit cloudy, and a bit forgetful. 5. Day 5- Same as day 4, but worse. Completely unable to accomplish daily activities, had to call in to work, weakness at one point as bad as struggling to lift and open a water bottle. 6. Day 6- I am here, slightly better than the day before. Still severe joint pains, body aches, and body chills.

Pfizer-BioNTech COVID-19 Vaccine EUA immediately after 1st IM dose pt experienced itching at injection site, itching resolved with 10 minutes

anaphylaxis

"Employee stated she felt her heart racing and felt ""off."" Appeared to RN to be diaphoretic and pale but remained alert, oriented, speaking full sentences no shortness of breath, scratchy throat or rash. 50mg Benadryl PO at 06:25am. Highly encouraged patient to stay for additional 15 minutes. Patient refused to stay stating she didn't have childcare beyond 7am. Instructions given to patient re: symptoms to monitor for and to seek medical assistance if symptoms worsened or persisted. Additionallyasked patient to contact employee health."

injection site soreness and slight swelling. chills, fever 99 F

Extreme swelling of lymph nodes on left side of body (specifically armpit) Fever Muscle Pain Swelling Headache Nausea Vomiting

After the injection I stayed on a recliner for 15 min before returning to work, nothing happened, I felt good. After I arrived home, about 3 hours later when I was home I felt a mild headache. The next day I felt muscle pains/body aches, specially on the right side of my body, my right shoulder was hurting really bad. after 48 hours the symptoms went away.

12/21/2020- 1 called with increased BP 12 hours after vaccination. Was seen by MD and went to ER. Med for BP increased and modified until stable.

"Patient describes flushing, upon examination: ""heart was pounding in my head"". Patient felt like she was going to ""pass out"". and ""throat fullness"" Medical team reported patient was tachycardic . Administered 25mg (oral) benadryl X1 Alerted covering physician (per protocol)"

Approximately 20 minutes following COVID-19 vaccination the patient suddenly developed hives, itching - Hives around face and upper chest. Throat was red and slightly swollen. Was brought to the Emergency Department within out hospital for assessment and medical care. Acute treatment included methylprednisolone 125 mg IV x 1 dose, diphenhydramine 50 mg IV x 1 dose, epinephrine 0.3 mg IM x 1 dose, and famotidine 20 mg IV x 1 dose. The patient felt better following this treatment Upon reassessment oropharyngeal swelling had improved, the patient no longer had hives and the throat appeared clear. The patient stated he no longer feels itchy but does feel a little short of breath. Lungs were clear with pulse oximetry 97%.

"Felt lightheaded upon standing and stated "" my body felt whooshy ""; HR-52-- baseline and remained alert and oriented x3; Benadryl 25 mg given --observed patient for 30 minutes; ambulated patient and she stated she felt fine--funny feeling gone"

Fever, Fatigue, Weakness, Body Aches, Chills, Muscle Pains lasting until Monday 12/21/2020

Patient expereinced pain at vaccination site 2 hours after administration. in 20 hours it had become red and swollen. Swelling and redness have steadily decreased to time of individual reporting today at 13:00 (Jan 22, 2020 reported)

Ten minutes after vaccine was injected pt started having elevated heart rate and mild flushing.. She was sent to the emergency department for clinical evaluation and further observation. She refused medication while at the vaccination site.

Migraine headaches chills diarrhea

About 12 hours afterward the initial injection (0330) I began feeling very cold, started shivering violently to the point where I seemed to feel like I was a Parkinson's patient and nearly froze my jaw with severe muscle aches. Was able to calm the symptoms after standing by a hot oven. Only reason I'm fairly certain this was some kind of reaction as I had a similar event happen when when I last got a tetanus shot 14 years ago where I was in the ER overnight, staff at the vaccine clinic even held me for a longer period (30 minutes) then other due to that issue and were given full disclosure of prior events before receiving the injection . I was diagnosed with Covid 19 on 12/10/20 (They discussed giving the injection with a health dept worker before giving it to me and declared it ok) and troughout the entirety of my quarantine I have never experienced something like that.

Patient developed mild lightheadedness and tingling of the lips. No SOB, CP, swelling of the throat or lips, or rash. Patient was observed for one hour from vaccine administration. She was given water and crackers. Symptoms improved at 60 minute reevaluation. Vital signs stable. Discharged to home.

Employee reported continuous chills off and on for over 12-24 hours, and major-severe headache.

Chills and headache

Vaccine recipient reported symptoms of tingling in the tips of index and middle finger on left hand at the time of COVID-19 administration. Symptoms resolved 15 mins later and vaccine recipient continued on with their day with no further issues.

She was given the Pfizer vaccination in the left deltoid muscle. á During her 15 minute waiting period after the injection, the patient began to experience localized tingling at the injection site that radiated into her 4th and 5th digits and proximally along the sternomastoid muscle. She denied rash, hives, difficulty breathing, difficulty swallowing, wheezing, throat tightness, hoarseness, stridor, itching, dizziness, facial swelling, lip swelling and tongue swelling. á This provider was notified of patient reaction and she was then assessed in the emergency bay area. Monitored patient for severe reaction symptoms, including rapid progression of symptoms, vomiting, hypotension and chest pain. Patient was

observed for approximately 30 minutes post injection with no evolution of sx. Injection site tingling that extended along the ulnar nerve distribution was improving at the time of discharge.

Day 1-4 large raised bright red injection site warm to touch Day 3 Bright red raised rash all over face and scalp, going down neck

Mild shortness of breath, heartburn

Small raised bumps on bilateral posterior hands. Roughly 1/8 cm width and 1/8 cm high. Dispersed evenly in random patches. Not red. Flesh-toned color.

Patient received the covid vaccine on Sunday12/2020. He found out that his roommate tested positive for covid on 12/20/2020 when he got home. He started to have dry cough on 12/20 evening. Had HAs but resolved 12/22. Still coughing. No fever/chills/bodyaches.

Headache, muscle aches, joint aches, photophobia, pain at site (arm pain), and fatigue

Scratchy, irritated throat with metallic taste in mouth.

I have a swollen lymph node in arm pit, and elbow and injection site is swollen and hard. -

Severe abdominal cramping, diarrhea, rectal bleeding. Went to ED.

After I got the shot I could feel it going into my system (histamine). I had myalgia on my right shoulder and up into my neck, those I felt first. I felt like a histamine release. It is like I felt a drug being released in my body, a strange feel. Made me feel woozy. Not a major reaction, no airway constrictions, just felt uneasy. As I was walking to my vehicle to leave the hospital my arms started feeling tingly so I decided to walk to the ER and get checked. Vitals were taken and a shot of Benadryl - 50mg, sat around until it kicked in about 30/40 min and it made the symptoms subside. Next morning I felt fine , arm was sore from the injection but that was all.

Patient states that he went home was slightly fatigued. By 4am patient woke up and was severly fatigued. Patient states this moring it was difficult to wake up because how fatigued he was.

body aches, headache starting 24h after injection; lasting ~12 hours

Injection site pain, muscle aches , Headache , body ache , Muscle ached lasted through the rest of the week

Chills at 5-10 min after vaccination, with voice change and SOB 15-20 min after vaccination concerning for anaphylaxis. Epi given im x1. given immediately at voice change and immediately taken to ED.and currently receiving care

Patient reports 5 minutes after getting covid vaccine she became flushed, heart was pounding and felt dizzy. Patient denies hx of allergic reactions.

For first 5 minutes after injection i had taste in mouth of iodine and warm feeling in my chest - it felt almost like ct contrast does - went away after 5 minutes - felt fine after that - nurse wanted me to report side effect just in case

Hypotension and syncope without tachycardia, 15 minutes after injection. Patient was repositioned supine, which caused her to regain consciousness. Give 1 liter NS over 2 hours and discharged in good condition.

"From the patient (a employee) ""So, I think I am having a reaction to the vaccine. I did call my PCP to check in and they also said to notify you. I felt fine until last night about 8 PM. Then I got body aches, headache, nausea, tachycardia, no fever. During the night I had to use my nebulizer 3 times to keep sat > 86. As I did some research through the night, some Covid patients were found to have positive Epstein Barr. That is what I had in September (EBV) that put me down for 3 months. So I am wondering if it caused a relapse of that. Hope not."

Received COVID-19 vaccine on 12/18/2020 around 1225pm, ten minutes later while being monitored I started to feel hot flash, got dizzy like about to pass out, I asked to let me lay down, I felt the medication bitter taste in the back of my throat, I was clammy pale, I lay on a stretcher and put my feet up elevated, rapid response was called and BP was checked and Spo2, my hands were getting cold and tingling I was talking to RN, another RN, after laying down for ten minutes I sit up I was getting my BP back to normal, I sat down in the chair again for another 10 minutes, I was offered to go to the ER but I decline, I said I was getting better, after 15 minutes I left monitored by my supervisor I felt the medication in my stomach, after the tingling my fingers were numbed for the next days until present.

Following morning after getting vaccine woke up with chills headache and a fever of 100.8. I spoke with my PCP and she advised that I take some ibuprofen.

Increased heart rate and blood pressure. Rash on anterior right side of neck. She laid down and was given water. Blood pressure and heart rate monitored. She was also reassured by friends that she was okay. The patient said she was anxious and that's why she had a reaction.

Throat and chest tightening, as was all warm and flushed feeling in throat and chest

12/21: woke up with full body aches, pressure in ears bilaterally. Took 200mg motrin, body aches resolved by early evening. 12/22: Right tonsil inflamed/irritated, painful to swallow. Ear pain bilaterally. Went to clinic, temp 99.1, some fluid in ears; strep and influenza tests came back negative. Given zyrtec, flonase, and tylenol for symptom management and advised to get a covid test when possible.

Arm Soreness Started diarrhea on the 19 of Dec, went away on the 20th. Woke up on the 22nd around 1am with really bad abdominal pain and diarrhea.

Metallic taste in mouth. Progressed to numbness of throat and tongue. No swelling. No rash. No shortness of breath. Remained alert and oriented and speaking full sentences throughout. Benadryl 25mg PO. EMS in to assess. 186/98, HR 94, SpO2 100% Remained onsite for extra 30 minutes. Patient refused transport to BMC for monitoring. Patient refused to be driven home. Throat/tongue numbness

improved. BP before leaving 156/90, HR 82, SpO2 99%. Patient stated when she received Flu shot in early October this year, 2020, she had scratchy throat which resolved independently.

Pt states that she received her vaccination at 10:00am and felt chest tightness immediately. This resolved within minutes and pt left testing site. Pt states that around 11:00am she felt numbness and tingling in her bilateral forearms and fingers. By 11:45 when we spoke, the numbness and tingling had improved but was still present.

I had joint stiffness, my body ache, abdominal pain, diarrhea and headache.

Patient is describing feeling as if he took Niacin, he is flushed, red in the face but cool to the touch and itchy skin

rash and dizziness

Within 15 min. of vaccine,I had some brief mild shortness of breath,a stab of pain in the center of my left chest,I felt strange, had 3 stabs of pain in my right ear and 3 pressure type pains in my left ear.

HEADACHE, NAUSEA, BODY ACHES, INJECTION SITE PAIN, MALAISE

Chills, body aches, mild cough, headache

"Approximately 10 minutes after receiving the vaccination the patient began complaining of dizziness and ""not feeling right"". Vital signs indicated the patient to be hypertensive, vital signs otherwise within normal limits. Patient denies rash, itching, shortness of breath, chest. Patient transported to the ER for evaluation within 15 minutes."

Swelling and numbness of right side of the face.

"Patient was done receiving vaccine at 0921, approximately 5-10 minutes later reported feeling flush, metallic taste in mouth (first symptom), heart racing. VS taken: 152/93, HR 120. Pt seated, calm, given water to drink, speaking full sentences, NAD and no difficulty breathing or swallowing. At 0948 VS: 132/91, HR 96, SpO2 98% room air. At 0955, patient continued to feel waves of heart racing, HR on monitor 90-108, SpO2 98%. At 1002, notified ED charge nurse that patient will be escorted for further monitoring, work up if necessary. Still no respiratory or swallowing symptoms. At 1002, patient escorted to ED by RN, ambulated without difficulty. Upon ED arrival, patient reported feeling ""fine"" without symptoms."

Started having shortness of breath a couple hours after vaccine, then some fatigue and headache. Woke up next morning with sore arm, worsening headache and fatigue. Those side effects dissipated as the day went on, next day arm still a little sore, but by afternoon, felt back to normal.

Moderate pain and mild swelling at injection site occurring about 16 hours after injection. Swelling and pain resolved within 2 days after onset. No other adverse events or side effects to report to Pfizer COVID-19 vaccine. No flu like symptoms, no fatigue, no fever, no chills, no headache.

Headache , Fever , Diarrhea , Muscle Aches .

12/18/2020 in PM dry cough, body aches. Symptoms resolved on 12/19/2020

Dizziness, Flushed, Light headed, Near Syncopal Episode.

It started with a tingling in my tongue, my BP went super high and my face was all red and a headache afterwards. My BP went down about 25 min later. I was just monitored at the vaccination site, did not go to the ER.

Low grade fever 100.6, took Tylenol, fever decreased 99.3, took 2 more Tylenol at 3am 12/22/2020 and hasn?t had a fever since, was tested for Covid in the past with negative results, has not been around anyone with Covid that she is aware of, she has not traveled, however her son has traveled home from college but tested for Covid twice with negative results. Patient states that she is not experiencing any other symptoms.

12/19 - hour after the vaccine had diarrhea that lasted until about 11pm that night 12/20- 2pm started to have general malice. Took a nap and woke up at 6:10 pm with a fever of 99.5 orally. 12/21- Woke up to R armpit pain. Upon examination, R armpit was visibly swollen compared to left. No redness, tenderness, pain at the injection site. Could not feel swollen lymph nodes. Fever gone in AM.

Approximately , 11am started getting chills all over, temperature 101.6 around 1pm with headache. I would take Motrin/ Tylenol when I felt my fever go up . The fever, headache and chills lasted Friday ,Sat , Sunday. On 12/21/20 had no more fever, no headache or chills. I have a great appetite, have no other symptoms.

Woke up with elevated temperature of 102.0, Chills, elevated glucose level of 499, body aches, headache, Nausea

During 15 min observation, employee reported tingling in her lips. She is allergic to grass and has experienced this feeling when she is having an allergic reaction. Employee taken to gurny, VS taken. No hives noted. Reported her throat feels a little tight. 50 mg of Benadryl given. See attachment for VS record. 1:1 observation by RN. No further s/s. Employee states points to her flowers and says it could be the flowers my mom sent me for vaccination day. Monitored employee until 1950 when she was taken home by a co-worker. Employee states she has improved s/s and is now just drowsy. Informed to discuss reaction with PCP and/or EH. Instructed to call EMS or go to ED if symptoms come back.

HEADACHE, UPSET STOMACH, INJECTION SITE PAIN, GENERAL BODY ACHES, MALAISE

Injection was given low on upper arm, below deltoid. Became red, swollen, and painful in 12 hours, worsening over 3 days, resolved in 5 days.

I received the Covid 19 vaccination at 3:00 pm on 12/18 no trouble went home. Upon going to sleep the left arm was numb thought and got up to use the bathroom had diarrhea. While in the restroom hit face

had a Syncope episode regain conscience went to ER had 4 stitches in chin. Since 12/20 felt fine and was able to return to work.

12/17/20 Received Pfizer COVID vaccine 12/18/20 Sore arm, no other side effects 12/20 Headaches refractory to ibuprofen, and vertigo 12/21 Worsening HA and vertigo 12/22 Feels lightheaded. She has multiple sclerosis and has had vertigo as a part of her MS in the past. HA onset was about 72h after COVID vaccine. Currently been having HA, vertigo for about 2 days, seems to have peaked.

"Hard lump and redness at injection site on right deltoid almost immediately after injection. Patient describes a ""fireball"" in her throat. Denies swelling. No difficulty swallowing, maintaining airway independently. Headache. In E.D., patient received NS 1000 ml at 2000 ml/hr at 19:34, Diphenhydramine 25 mg IV x1 at 19:36, Methylprednisolone 125 mg IV at 19:38, Ketorolac 30 mg IV at 19:41, Famotidine 20 mg IV at 19:42. Forty minutes post injection, all symptoms gone. Discharged from E.D. at 20:52 with prescription for prednisone 50 mg po daily x4 days, diphenhydramine 25 mg po q6h prn, and famotidine 20 mg po nightly prn."

Progress Notes PA-C (Physician Assistant) ? ? General Surgery/Trauma Cosign Needed Expand All Collapse All á COVID VACCINE CLINIC 12/22/2020 á Patient: DOB: Date: 12/22/2020 MRN: 5380787 á Subjective Patient is a 23 y.o. male who was seen at COVID Vaccine Clinic today for his first dose of the COVID 19 vaccination. á He denied any history of previous adverse reactions to vaccines. He does report recent hx of GI symptoms that he is currently being worked up for. He reports onset of similar sx around time of vaccine injection. á He was given the Pfizer vaccination in the deltoid muscle. á During his 15 minute waiting period after the injection, the patient began to experience dizziness, throat dryness, and nausea. He denied rash, hives, difficulty breathing, difficulty swallowing, throat tightness, hoarseness, stridor, itching, facial swelling, lip swelling and tongue swelling. á This provider was notified of patient reaction and he was then assessed in the emergency bay area. á Monitored patient for severe reaction symptoms, including rapid progression of symptoms, respiratory distress with stridor, vomiting, abdominal pain and hypotension. á á á Review of Systems Otherwise negative, except for above á Objective á Vitals Vitals: á 12/22/20 1131 BP: 118/66 Pulse: 88 SpO2: 96% á á Physical Exam Constitutional: Appearance: Normal appearance. HENT: Head: Normocephalic. Nose: Nose normal. Mouth/Throat: Mouth: Mucous membranes are moist. Pharynx: Oropharynx is clear. Neck: Musculoskeletal: Normal range of motion and neck supple. Cardiovascular: Rate and Rhythm: Normal rate and regular rhythm. Pulses: Normal pulses. Heart sounds: Normal heart sounds. Pulmonary: Effort: Pulmonary effort is normal. Breath sounds: Normal breath sounds. Abdominal: General: Abdomen is flat. Palpations: Abdomen is soft. Neurological: Mental Status: He is alert. á á Assessment/Plan á Treatment included no therapy. Follow up response to treatment:no side effects. Patient discharge: Stable to go home and follow up with PCP. á Patient was monitored in the emergency bay without worsening or evolving sx. Orthostatic vitals signs were negative for hypotension or tachycardia. He was able to ambulate well without assistance and reported improvement of sx prior to discharge. Signs and symptoms of systemic hypersensitivity were reviewed and discussed with instructions to call 911 or report to the ED if SOB, throat/lip/tongue swelling, chest tightness, n/v, abdominal pain, or pruritic rash develop. á á PA-C Electronically Signed 12/22/2020 12:08 PM á á

45 minutes after vaccination felt faint, palpitations, nausea and tremor in hands followed by syncope, after awoke had ongoing muscle spasm/tremor in legs. Taken to ED and labs, IVF, CXR. Observed x 90 minutes and discharged- returned to work as scrub tech in OR. Left early, no further issues that day. Next am on arising had <30 seconds of postural imbalance which resolved spontaneously and no other symptoms since.

COMPLAINT OF REDNESS TO FACE

COMPLAINT OF REDNESS TO FACE

Dry mouth, lightheaded, dizziness, increased Hear Rate (89), normally in the 50s. Initial symptoms resolved within 90 minutes. Increased heart rate lasted longer than other symptoms. Reports additional metallic taste in mouth the following day.

Dry mouth, lightheaded, dizziness, increased Hear Rate (89), normally in the 50s. Initial symptoms resolved within 90 minutes. Increased heart rate lasted longer than other symptoms. Reports additional metallic taste in mouth the following day.

About 3 hours after vaccination, she began having hives and itching all over body. No difficulty breathinc etc. She went to ER that noted reaction to vaccine. She was Administered Benadryl 50mg PO X1 and Prednisone 60mg . She also received one dose of Pepcid 20mg PO. No signs of distress noted in ER.

Employee received vaccine and had no signs of adverse reaction after vaccination. Employee went to eat something and fainted. Shortly after employee had an emesis as well. Felt fine afterward and vitals were within normal limits.

bilateral rash/itching on ear lobes, rash/itching/swelling suborbital region, diffuse rash on forehead. bump on right side cervical region.

Nausea, deep harsh dry cough, HA, burning and tightness across shoulder blades. Arm very sore the next morning

Woke up at 12:30 am with severe body aches/feeling light-headed, had near-syncopal episode with large amount vomiting and diarrhea. Also had chills, unsure if febrile. Symptoms lasted for about 1 hour. Felt better the next morning but still with body aches

Diarrhea, hot flashes, chills all over body and in isolated areas, numbness/tingling in face/cheeks towards ears and neck.

Gave me shot did not feel anything. Probably 2-3 minutes later, it started to feel flush and chest tightening, and heart started racing. I did sit down, because they were monitoring us. Had my Apple watch on and heart was going up and down. They kept me monitored for about 30-45 minutes before I was hooked up to BP pressure machine. First reading was 180/110. At that point, they asked if I wanted to go to ER. I went to ER and they did an EKG which was normal. Heart rate came down with Benadryl. I was still feeling little tight in chest. Blood pressure 167/97 upon discharge. Sent home instructed to take

Benadryl. At home was relaxing, few hours later, heart rated spiked again and stayed for 15-20 minutes. Took Benadryl and heart rate came down. Did not take BP at home. Next day one other time where heart rate spiked again.

Severe muscle aches. Using local treatment to injection site and anti-inflammatories.

Patient had onset of a rash not abated with oral Benadryl. Sent to ED after 30 minutes of observation. In ED received IV Benadryl and symptoms resolved after appx 2 hours.(urticarial rash) resolved.

Pfizer-BioNTech COVID -19 Vaccine EAU increase muscle and joint ache.

Patient was pale and nauseous with abdomen pain. patient stated this may have been from her mensural but cycle. Patient put to lye down and left with her guardian to go home and seek medical attention.

Shortness of breath, heavy chest, heart racing, flushed, nausea

At the 10 minute mark patient reported not feeling well. She was noted to be pale. Then she reported having slight breathing problems along with her heart racing. Call for ER staff to report to vaccinating area. Patient's breathing concern resolved on its own by the time ER response team arrived within 2 minutes. Patient slowly gained her color back. Heart palpitations lessening but still reported by patient. Blood pressure / O2 Saturations / Respiratory rate monitored. No oxygen or treatment required at this time. Patient taken upstairs to be monitored by ER staff.

General malaise; body aches; chills; severe headache; low grade temperature (100.0F).

Dizziness for 48+ hours. Feeling of hypersensitive skin to touch

Tingling and numbing on the L arm where injected.

I developed a morbilliform, pustular rash 48 hours after the first injection of the Pfizer COVID-19 vaccine. The rash consists of pustules on an erythematous base on the ventral surface of both arms. It is mildly pruritic. It is not painful. I have no other associated symptoms and feel otherwise fine. I took ibuprofen 600 mg 24 hours ago. I have never had a vaccine reaction before. A dermatologist has seen pictures of the rash and thinks it is likely acute generalized Exanthemata's Pustulosis. Employee health has been notified.

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Heart racing , 15 minutes after vaccine was administered, lasting for about 10-15 min. Itching and rash on chest and upper back about an hour after vaccination.

About 5 minutes after receiving vaccination patient noticed her left arm was very cold and then it went numb from the base of her left ear to her hand. Tested strength in both hands and it was equal. After 20 minutes the patient stated that the numbness was going away but the coldness was still present in the left arm.

mild arm tenderness at injection site, upon waking at 10-11AM the next morning I experienced body aches, chills, and intermittent dizziness.

5mins after vaccine, pt c/o flushing, dizziness and fatigue. Pt monitored for 45mins. No treatment given. Flushing and dizziness resolved. Pt still fatigued. Pt vommitted four times within an hour after leaving vaccine clinic. Pt unable to work the day of vaccination.

Progress Notes; Nurse Practitioner Cosign Needed Expand All Collapse All COVID VACCINE CLINIC 12/22/2020 á Date: 12/22/2020 á Subjective Patient is a 60 y.o. female who was seen at COVID Vaccine Clinic today for her first dose of the COVID 19 vaccination. á She denied any history of previous adverse reactions to vaccines. á She was given the Pfizer vaccination in the left deltoid muscle. á During her 15 minute waiting period after the injection, the patient began to experience Headache over the front of the head. She denied rash, hives, welts, difficulty breathing, difficulty swallowing, wheezing, throat tightness, hoarseness, stridor, itching, lightheadedness, dizziness, facial swelling, lip swelling and tongue swelling. á This provider was notified of patient reaction and she was then assessed in the emergency bay area. á Monitored patient for severe reaction symptoms, including respiratory distress with stridor, wheezing, dyspnea, increased work of breathing, persistent cough and cyanosis. á Finger stick BS 101 12:15 pm granola bar and water given á Review of Systems Neurological: Positive for headaches. All other systems reviewed and are negative. á á á Objective á Vitals Vitals: á 12/22/20 1203 12/22/20 1226 BP: (!) 158/81 (!) 153/75 BP Location: Left arm Left arm Patient Position: Sitting Sitting Pulse: 76 72 SpO2: 98% 98% á á Physical Exam Vitals signs and nursing note reviewed. HENT: Head: Normocephalic. Nose: Nose normal. Mouth/Throat: Mouth: Mucous membranes are moist. Eyes: Pupils: Pupils are equal, round, and reactive to light. Neck: Musculoskeletal: Normal range of motion. Cardiovascular: Rate and Rhythm: Normal rate and regular rhythm. Pulmonary: Effort: Pulmonary effort is normal. Breath sounds: Normal breath sounds. Musculoskeletal: Normal range of motion. Skin: General: Skin is warm. Capillary Refill: Capillary refill takes less than 2 seconds. Neurological: General: No focal deficit present. Mental Status: She is alert and oriented to person, place, and time. Psychiatric: Mood and Affect: Mood normal. Behavior: Behavior normal. á á á Assessment/Plan Treatment included: no therapy. Follow up response to treatment: no side effects. Patient discharge: Stable to go home and follow up with PCP. á Pt reports headache went away after she ate. No new symptoms manifested. Pt released at 12:30 pm á á á Electronically Signed 12/22/2020 12:29 PM á á á

5mins after vaccine, pt c/o flushing, dizziness and fatigue. Pt monitored for 45mins. No treatment given. Flushing and dizziness resolved. Pt still fatigued. Pt vommitted four times within an hour after leaving vaccine clinic. Pt unable to work the day of vaccination.

Temp 100.8 next day, took Motrin and all issues resolved Outcome: Resolved and fine

"Employee complained of feeling hot, heart racing, stating ""I feel like I am going to pass out."" Vital signs taken, BP and HR WNL. Employee states she has not eaten since 0200, water and snack provided. Vitals retaken in 15 minutes WNL and employee states she is back to baseline following 30 minutes of monitoring. Dr. present at this time and assessed employee, occupational health to follow-up."

Started with Rash/Hives on Neck and upper chest and shoulder. Inside of nose rash and mouth itchiness. Progressed to arms and palms of hands. Started to get stomach upset. mouth got warm and throat warm. Breathing was OK but started to get tougher. Went to the ED Given Benadryl Pepcid and solumedrol Gave you prednisone 50mg for home 3 tablets once a day and OTC pepcid

Employee received COVID-19 vaccine on 1:45pm

Fever started at 8pm around 99.5F and then around 1:30am fever went to 101.5F, took 2 advils and fever went down in the 99s. Fever didnt break until after 4 pm next day after 2 advils were taken. Feeling tired/weak since had the shot.

Pt reported being dizzy and a headache

I was unsure whether to report this, and I will preface this by stating that as a child I got nosebleeds frequently. However, I had not gotten a nosebleed in 15+ years and on the day I received the first dose of the COVID-19 vaccine I got a nosebleed that lasted about 10-15 minutes.

Rash on neck, back, and chest

Metallic taste started several hours after injection and lasted several minutes

2 hours after vaccine started with itching face and body, eye swollen like my allergy symptoms 12 hours after vaccine got light headache, body aches, chill , throat hurt

2 hours after vaccine started with itching face and body, eye swollen like my allergy symptoms 12 hours after vaccine got light headache, body aches, chill , throat hurt

Pfizer-BioNTech COVID-19 Vaccine EUA: Systemic: Anaphylaxis, Fainting

On the first day shortly mild pain in left arm around 08:00pm exp brief pain in chest that occurred twice and went to bed. I woke up on 12/16 after resting on right side and tried to rollover upon waking up was in excruciating pain. arm around 5am woke up for work couldn't move my arm, barely could dress to put my shirt on on a scale 1-10 rate 7. As a result it was hard to due my daily activities or hygiene. The following day 12/17 pain felt mild and on 12/18 felt no more pain.

0835 the patient was given the vaccine in the right deltoid IM, at approximately 0838 the patient started feeling tingling and tightness in her upper chest and neck. She stated her throat was feeling funny and the back of her tongue felt like it was getting bigger and swelling. The patient did not have any difficulty breathing. At 0845 Benedryl 25mg IM was administered. Patient vital signs BP 156/88, HR 86, R 22, O2 Sat 98%. Respirations were even and unlabored. Patient was observed and within a few minutes stated that she felt better and was no longer feeling the tingling, tightness or tongue swelling. We continued to

observe the patient for 45 minutes after her initial reaction. 0855 Dr. assessed the patient and determined her to be stable. 0945 At time of dismissal, VS BP 125/82, 74, 18, 99%. Patient had no complaints other than drowsiness and respirations were even and unlabored. Patient left by ambulation in stable condition.

Body aches, fatigue and chills day after vaccine and following day, symptoms then resolved

Body aches, fatigue and chills day after vaccine and following day, symptoms then resolved

Pain local site, tenderness at local site, restriction of moving left arm, body ached, headache , Feeling feverish

Joint pain this morning- than itching in different places... some numbness all over my arm.. than at 1pm sudden onset of tachycardia, lip numbness and tongue numbness with nausea. I immediately took 10mg Benadryl. - but bc my tongue was feeling different I had to call 911. Upon arriving in the ER - they checked vitals and found tachycardia. They administered Benadryl 25mg.

Nausea and headache started approximately 21:00. Body aches and chills continued through until 12/22/2020 . On 12/22 I vomited at 7:00 and have continued to have low fever of 99.5-100.0 , chills, fatigue, body aches and headache all over.

Pt received vaccine on 12/17/20 and started experiencing side effects such a dizziness, body aches, nausea and vomiting, and body weakness shortly after. The symptoms got progressively worse as the days went by and pt came to the ED on Tuesday, 12/22/20, since symptoms were not improving and acetaminophen and ibuprofen did not help.

Chest pain, shortness of breath, tongue numbness and tingling

28 HOURS AFTER INJECTION, DEVELOPED BODY ACHES AND PAINS, 99.5 FEVER, CHILLS, SIGNIFICANT FATIGUE REQUIRING ME TO GO TO BED - SLEPT 12 HOURS

Woke up next morning around 6:30 AM the 18th with a few drops of blood on pillow. Nose was dripping blood. Was able to plug nose and stop bleeding within 15 minutes. No further issues that day, however did wake up with dried blood in nose on the 19th. No further issues after that.

"Patient received COVID-19 vaccine at 330pm. Approximately 15-20 minutes later the patient felt well, was released. At around 4:00pm patient then developed ""tongue fullness"" and felt flushed. She returned to vaccine clinic. No reported rash, voice changes, wheezing, shortness of breath at the time she presented back to the vaccine clinic. 153-173 sbp, HR 60; Doctor on call advised to give Benadryl 50mg IM and send to the ER for evaluation and monitoring for 4 hours. Benadryl was given to patient at around 4:15pm. Patient was taken to ED around 4:30pm. Patient requested early discharge from ED as she stated she "" Feels normal now. Requesting DC as she is a nurse and feels better and wants to be with her family."" Per ED note: patient discharged with antihistamines and epipen."

Employee complained of runny nose following receiving vaccination. Dr aware. Follow-up with employee done in the afternoon and employee advised symptom has resolved with no other issues.

significant headaches, nausea, fatigue and local redness/swelling/hard lump/itching.Outcome: Resolved and fine

Few hours post-vax developed headache. Took Tylenol. Went to bed, no symptoms. Woke up with cough and experienced headache and fatigue throughout the day. Seen by NP at Employee Health, below tests performed. Symptoms persisted through 12/18. By 12/19 symptoms resolved.

HPI: 56 y.o. male with no pmhx c/o generalized bruising for 2 days, noticed small blood tinged spots generalized. Gradual onset, severe on severity, no alleviating or aggravating factors. Patient denies fevers, chills, N/V/D, abdominal pain. In ER: Platelet <1. Platelet transfusion in ER. Admitted for Thrombocytopenia/ITP

Fever (102.5), Elevated Blood Pressure, Pulse resting 130 bpm, Red/swollen left arm, General body aches all lasting about 24 hours then all side effect subsided.

About 5 min after I got the vaccine I was on observation and I started getting a rapid, pounding, heartbeat, they waited about 5 min and it started getting faster and stronger, so they called paramedics to take me to the ER. It seemed it could be a severe reaction, I had fast rate for several hours and also broke up in hives while I was at the ER. They did a cardiac workup and noticed I had change on my heartrate according to the EKG they had previously done.

Local pain, heaviness in the arm, soreness for about an hour. Took 500 mg Tylenol. It kind of helped. Took Benadryl before she went to bed. Early this morning, everything felt heavy, felt nausea, mild palpitations, and dizziness. Took Famotidine this morning. Took Motrin and Benadryl this morning also. Having chills. Afterwards a couple hours was able to sleep a little bit. Pain in lymph nodes on the left side under arm by left breast area. Advil helped with the local pain. Having pain at the injection site.

Pfizer-BioNTech COVID-19 Vaccine EUA: Systemic: Rash (other than injection site), Nausea, Vomiting. Rash developed on the rash, per dr doctor, gave one dose of EPIPEN on the left upper leg. rash subsided.

Pt. (employee) reported prior to receiving vaccine that she had an allergic reaction to a measles vaccine as a child - classified as severe. Reaction thought to be related to egg. Vaccine ingredients reviewed with pt. & pt. indicated she did not recognize any ingredient with known intolerance & requested to proceed with vaccination. 20 minutes after vaccination pt. reported feeling like her throat was swelling, Vitals checked, WNL - no difficulty breathing. Continued monitoring for 15 minutes, continued feeling of swelling. 50 mg Benadryl PO given. Monitored for 20 minutes more with resolution of symptoms.

"Employee complained of a ""very mild headache,"" that she attributed to being a little dehydrated. Water given to employee. Symptoms resolved with no other issues."

1. Lip tingling started 20 minutes after injection, lasted about 30 minutes. 2. Mild chest tightness started 14 hours after injection and lasted about 30 mintues.

"Vaccinated 12/21 at 6:00 am. symptoms began roughly midnight. ""horrible headache"". notes that her left hurt badly and difficult to move. Reports she has taken advil and Tylenol and notes that these have been effective. reports still feeling fatigued, but isn't sure if that's related to lack of sleep from the headache or part of a reaction. Arm is still sore, but is not really painful the way it was last night. Still has a slight headache."

After the vaccine, patient said he felt hot. Later that day,he was starting to have muscle aches and then he noticed testicular and prostate swelling. He followed with his PCP and the PCP prescibed an antibiotic; however, patient did not recall the name of it. He is still being treated. He noticed an improvement. He started the antibiotic on 12/21/2020.

facial numbness to the left side with neck and shoulder pain. symptoms only started after 24 hrs

"At 10:30 pm felt sudden loss of feeling in right hand- unable to use right arm. ""Felt numbness on top of forearm-feels like muscles are no longer working."" Went to urgent care on 12/18/2020 (another clinic)- arrived at 0845."

After 24 hours felt tired, achy, arm hurt my head hurt for 48 hrs little longer. Upon waking up on Sat felt same symptoms. Due to patient exposure I contacted Covid hotline for that hospital employees. Then I was informed to go get tested ER for Covid results negative. I had to miss work on 12/21 due to taking Acetaminophen being a hospital criteria couldn't work while taking that medication.

Patient with a reported history of anaphylaxis to several things and carries her own EpiPen. She was brought to monitoring room at 1835 With complaints of cough and at that time had taken two puffs of albuterol inhaler. Patient also reports some medicating with 50 mg of Benadryl two hours prior to vaccine. O2 sats were 99% heart rate 69 and lungs CTA. At 1845 patient self dosed another 2puffs ofalbuterol. At 1845 HR 130 and sats 98%. At 1850, BP 173/139 HR 127. Patient continued to develop a progressive cough and SOB. Consulted Dr. by phone. We dosed with Zyrtec 10 mg po and assisted pt with administration of her own epi-pen. Followed up with ED next day. Pt had been escorted there from vaccine clinic after epi-pen administration and progressive SOB. ED reported pt remained hemodynamically stable and A&O x 4. Treatment consisted of Benadryl 50 mg IV, Pepcid 20mg,IV, solumedrol 125 mg IV, fluids 1L, and racemic epi. Discharged home after 3 hours.

15 mins after the vaccine I had a bad headache and very dizzy blood pressure 168/109 very hypertensive Possibly stoke after vaccine (No stoke) Took ibuprofen Had Tylenol before the vaccine 12/22/2020 slight high blood pressure still

funny taste in mouth, then 5 minutes later throat tingly. was given Benadryl x2 @ 14:35, at 15:04 patient reports no change. At 15:25 top of throat taste only, fullness in throat gone, at 15:35 patient normal and returned to work

Pt experienced headache and dizziness immediately after injection. Approximately 30 mins later the patient began experiencing chest tightness. The patient received 50mg Benadryl and was transferred to the emergency department within about 20 mins.

Fever of 100.2-101.1 (axillary), heart rate > 100 all day, palpitations, PVCs, ventricular bigeminy for 20-25 min (verified with ECG app on apple watch). Symptoms started at 4am (almost 12 hours after receiving vaccine) and lasted until I went to bed at 9pm. I took advil throughout the day and when I woke up at 5am Tuesday (36 hours later) I felt completely normal.

Patient presented for SARS-CoV2 Vaccination, about 15-20 minutes after vaccination patient complained of feeling a little altered but there was no swelling, rash, or any other indication of a reaction, about 5 minutes later the patient had a weird taste in her mouth and was observed to have a wheal forming on her R forehead. She was phonating ok with questionable swelling to her tongue, but airway intact with non-labored or constricted breathing. She was administered 50mg of Benadryl per pharmacist recommendation. She was monitored for an additional 15 minutes (total of 45-50 minutes after vaccination) with resolution of the wheal and no further symptoms. Patient was advised return/ED precautions and she checked in with vaccine clinic staff an hour later (via text) with no further symptoms.

12-18 vACCINATIJON 12-20 0100 LEFT EYE BEGAN TO SWELL, ALSO NOTICE 2 SMALL RAISED BUMPS, NOT FLUID FILLED. RINSED EYE WITH COOL WATER, THEN APPLIED WARM COMPRESS. 12-20 IN MORNING WHEN SHE GOT OUT OF BED BOTH EYES WERE SWOLLEN W/ DARK CIRCLE BELOW. 12-20 LATE MORNING, EDEMA SUBSIDED, EYES NORMAL. 12-20 LATER IN DAY, TOOK BENEDRYL FOR SEASONAL ALLERGIES. 12-21 NO ISSUES 12-22 1300 BOTH EYES BEGINNING TO SWELL AGAIN, L MORE THAN RIGHT.

"staff member/ pt. had vaccine at 1500, no prior allergies. after 15 min observation, staff felt ""weird"" but returned to work in building. approximately 5 minutes later felt lightheaded, dizzy & became flushed & diaphoretic. returned to vaccine clinic for observation. was found to have BP of 143/103 on a normally normotensive person.HR 70. Provided recliner, rest & monitoring. BP decreased to 128/85 after 1 hr. of monitoring. pt continued to monitor BP and self medicated at home with Benadryl & Ativan (unknown dose). Continued to feel disoriented and unwell X 48 hrs."

Speech difficulty and bilateral lower extremity tingling and numbness after COVID-19 vaccine administration. Symptoms improved at ED with IV Hydration

12/20/2020 Fatigued, brain fog, 12/21/2020 extreme fatigue and was sleeping more than normal, diarrhea, low grade fever 99.2, 12/22/2020 around 3am woke from sleep with a really bad headache, patient stated taking Tylenol to help with symptoms, never tested for Covid however she lives with her brother who had Covid in May, no travel history

"7min after vaccination ee developed ""dryness , heaviness and need to clear her throat""-- Just on the right side of throat"" 25 mg ofBenedryl given-- symptoms resolved."

Started feeling chills night of receiving vaccine, then dizzy 4 days later, with severe nausea. Still not feeling well, queasy, dizzy.

Reports within 15 min of covid vaccine she had facial pressure, throat tightening, headache, light headed, increase in BP-179/123

15 minutes after injection: headache, 10.minutes after injection: flushed skin, rapid heart rate - taken to the ER where she developed SOB, Chest heaviness, nausea, tingling in the hand- Treated with Benadryl, Pepcid, Solumedrol, Zofran, Elevated heartrate, BP stable, no O2,normal EKG 1445 client released from ER

tongue was tingly, woozy and nauseous 10 minutes after receiving injection. Drank Apple Juice and symptoms subsided about 10 minutes later. I also took Benadryl when I got home 20 minutes later. Also, left arm is sore.

flushed, tingling in face

"fatigue, light headedness, low grade fever of 99.0, nausea, ""foggy"" headed, dizzy"

Employee reports nausea, fatigue, muscle pain and feeling hot denies fever

Severe headache chills, body aches, arm pain, Nausea, fainted on standing, dizziness

Pfizer-BioNTech COVID-19 Vaccine EUA Within 5-10 minutes of vaccine, burning and tingling sensation started in chest, moving into throat, tongue, mouth, nose, and ears. Flushing sensation and red ears. Increased heart rate, resolved after a few minutes. Was treated in the ER and released from hospital. EKG and vitals were checked, no labs drawn. Occasional burning and tingling sensation but resolves within a few minutes, mainly in chest and tongue. Occasional symptoms ceased in about 3 hours.

nausea, colic, diarrhea

Reports after covid vaccination while she was driving home she experienced swelling of the tongue, dry mouth, legs twitching, and diarrhea. Went to ER for treatment.

Patient started with tingling in hands/lip approximately 10 minutes after administration. Tingling in hands/lips worsened and pt started to c/o tongue swelling. Epi and IM benadryl were administered and a rapid response was initiated.

Had symptoms after shot of: electrical shooting pain down legs, chills, dizziness, fatigue, profuse sweating.

Really bad headache. She was fine when she was sleeping but when she was awake it was bad. Still has a small headache but not as bad as the first day.

Patient describes feeling hot, clammy and lightheaded about 5 minutes after vaccine administration. BP:109/69 P:72 O2Sa:100% Patient states that injection site feels ok. Got patient a juice and had her sit for another 15 minutes. BP: 118/63 P:74 O2Sa: 99% Patient has normal hand and arm strength bi -lat. After patient had cold juice and was able to breath without her mask on she felt much better. Patient

was able to stand and walk without dizziness. Patient stated the she did not feel she needed further treatment.

Patient felt lightheaded and dizzy. She was seen to by a nurse on staff and by Dr. After laying down for a while, patient felt better and wished to return to work. When contacted to following day, she said that she was feeling better, but felt a bit foggy the day before.

Tachycardia and poor taste in the mouth

Approximately 15-30 minutes after receiving the vaccine the patient reported numbness on the left side of her face. Also reported intermittent tingling in fingertips of both hands and feet. Prescribed a medrol dose pack that evening and had taken one dose. By 0630 today (12/22) reported that the numbness was 95% improved.

"A 36 year old FEMALE who received Covid 19 vaccine today at 1009, started c/o mild lightheaded and ""tingling throat"" at 1026 am, nurse notified this provider. NOTE: This is a late entry due to documented reaction was on paper and not available for documentation at the time of adverse reaction complaint. Oral hydration, patient stable, symptoms subsided at 1037. Employee discharged to work station."

Employee reported to the employee health clinic 3 days after receiving the Pfizer COVID vaccine and had complaints of a 30mm indurated area on her right arm. She states she vomited once that night and had a headache. Took Tylenol and seemed to help. Encouraged employee to apply cold compress to arm and notify if symptoms of arm swelling get worse or any new symptoms of a reaction arise.

complaints of general itching of arms - resolved in 5 minutes. HR 80 and regular, No rash. Treatment of clolse observation for further symptoms x 10 minutes. No medication treatment required.

Pt developed throat tightening, shortness of breath, hives on the anterior chest after receiving COVID-19 Pfizer vaccine. She received vaccine around 9:15 AM and symptoms began at 9:28 AM. Received epi pen by vaccination station staff. Reported to ED. Observed for 3 hours with no further adverse effects. Treated with steroids, Pepcid, Benadryl. Discharged home with epi pen, medrol dosepak, and allergy/immunology follow up.

Pain and numbness in the left arm From the shoulder to the fingers. Cannot raise arm, nor leave it down. Relief with a sling. Also, to manage pain, she is taking Tylenol every four hours. By medical order she started diclofenac potassium 50 mg tablet.

fatigue,fever 99.5F and cold sore

Metallic taste onset within 10 minutes of injection

About 5 minutes after the vaccine was given patient describes numbness and tingling from injection site to pinky and that lasted about 5 minutes. Patient started feeling a flush/warm feeling across chest about 15 minutes after vaccine. No dizziness or lightheadedness. Flushed feeling lasted about 30 seconds.

Patient feels much better after 25 minutes of waiting time. She states she does not require any further treatment.

Hot Flashes and headache, patient reports that she feels weird and not herself. No spike in actual temperature reported.

Received Covid Vaccine on 12/18/2020, 72 hours later on 12/21/2020 had left sided tongue numbness.

Chills, fatigue, left arm soreness, joint pain, temp 99.1

My throat was swollen and sore, a rash on face and neck, runny nose, lost voice, SOB

12-18-2020 SLEEPY FELL ASLEEP 3 HOURS POST VACCINE ADMINSTRATION, THAT EVENING HE WOKE UP WITH HEAD HURTING. SLEEP A LOT ALL WEEKEND . DEVELOPED COUGH 12-22-2020. RECIPIENT STATES HE HAD MIGRAINE TWO DAYS PRIOR TO VACCINE ADMINISTRATION. RECIPIENT REPORTS HE TAKES PERCOSET FOR BACK PAIN AND IT HELPS MIGRAINES. COUGH CONTINUES AT THIS TIME 12-22-2020.

0850 Client came in to receive COVID-19 Vaccine sent to observation for 30 minutes due to allergic to latex. At 0855 client started itching and breaking out in hives, complaining of shortness of breath and scratchy throat. Nurse escorted client to ER, where client received IV fluids, Benadryl, Solumedrol, Pepcid.

anaphylactic--started with mild itching, progressed to throat tightness--patient was given IV Benadryl, Pepcid, Solu-Cortef, Epi-pen x 2, oxygen

I was at the observation area and all of a sudden I started rapidly coughing and my throat felt itchy. I notified the nurse and she started observed me. The back of my tongue started feeling weird. She then hit me with an epi-pen as a precaution. Because of that I was moved to the ER for observation for 2 hours to make sure everything was ok. After the epi-pen all symptoms went away. Before I left they drew labs to check if I was having an allergic reaction. And the results came next day and it was 0.

pt had reaction of mouth and BIL cheek numbness, SOB, chest pain, sore throat irritated throat , chest pain approx 20 mins after vaccine was given. Pt was monitored and EMS called, pt was stable after 45 mins EMS directed her to return home.

Left facial numbness and tingling.

PT WAS OBSRVED IN HOLDING AREA LEANING FORWARD IN HER CHAIR ABOUT 7 MINUTES AFTER RECIEVING THE VACINE. RN ASSESSED AND NOTED: AUDIBLE WHEEZE, RESP 40/MIN, LIP SWELLING AND PT COMPLAINED OF NAUSEA. PT WAS ESCORTED TO ER IN WHEELCHAIR ACCOMPANIED BY 2 RN'S (2 MINUTE WALK) ONE HOUR LATER - AS REPORTED BY DR (ER) WORKING DIAGNOSIS - ANAPHYLAXIS / STATUS ASTHMATICUS MEDS RECIEVED: SOLUMEDROL 125, DIPHENHYDRAMINE 50MG, FAMOTIDINE 20MG --ALL IV EPINEPHERINE 0.3MG IM X1 FOLLOWED BY 0.3MG IV X 1 FOLLOWED BY 0.1MG IV X1 PT IS RECIEVING O2 - AND PROGRESSING TO BIPAP

soreness in L arm-2 days, back pain 1/2 day, chills 1/4 day

Lymph nodes are swollen on the left side It sore and tender on the left side

Patient reported becoming dizzy 12 minutes after receiving injection. Patient felt like she was going to faint. Patient was placed on floor with legs elevated and given a snack and a sugary drink. Felt better left facility and called in reporting when she got down to go inside her home she had a repeat episode of vertigo.

Fever to 100.2 with chills lasting all day very sore arm, fatigue

Complaints of dizziness with chest tightness.

Chills, body aches, diarrhea about 24 hours after vaccine. Cough, severe headache, temp of 100.0 started about 36 hours after vaccine and are still present

Patient refers to itching and rash. Refused treatment. The event occurred approximately 35 minutes after administration of vaccine.

Left arm NumbNess going from the forearm to the side of his Neck. Chills and slight HA. No fever Noted.

Per report from LPN monitoring patient--complaining of chest tightness and anxiety. 02 sat 99, Pulse 67, BP 114/83 and repeated at 126/94. Monitored for 30 minutes, patient continued to report symptoms. Monitored for additional 15 minutes. Patient left clinic with improvement in symptoms.

Vaccine administration site was above the deltoid.

mild swelling and tingeling sensation of the lips. No significant swelling.

Sore Arm

left leg feels heavy, headache, body ache, upper back pain.

Headache Sore arm

Day 5 started having hives on arms and inner thighs

pt after receiving vaccine, felt tight chest, difficulty breathing. 25mg Benadryl po. pt hypertensive 160/100. pt remained hypertensive and with chest tightness and CP. EMS called. EKG done. EMS found no need to go to ER at this time. Pt remained in observation then d/c home with friend.

I got very sweaty and hot feeling, nauseated and light headed, my BP and O2 were stable but got a little tachycardia, it passed after I laid down for a couple of minutes but once I stood up again the symptoms returned. That is why they sent me to the ER. Also had tingling in both hands. I recovered in about 2 hours (I had covid in early november)

@ apprx 1315 patient started feeling heartbeat beating fast, then racing. States she felt hot, dizzy, ears were ringing-the ringing resolved upon being seated. Patient was given 25 mg liquid diphenhydramine

(and seated with legs elevated- back of exam table elevated to an approx. 60 degree angle). HR 109, BP 144/87, afebrile, o2 sat 100% on room air.

A dry metal taste in mouth, Sore throat, Tired, Sore arm

Developed itching to lips and left arm 10 mins after injection. Benadryl 25mg oral given. Symptoms progressed to tongue and mouth itchiness. Pt transferred to ED for further eval and care. IV NS famotidine and methylprednisolone given. Discharged home.

1406, Monitored pt 1:1. She reported feeling fine for the first 15 minutes then reported itching involving her face but not forehead. Gave 25 mg IM diphenhydramine. pulse ox Reading was wnl. Within 5-10 min after diphenhydramine pt reported itching involving her arms, facial flushing but no shortness of breath. extra 25mg diphenhydramine IM given and Epinephrine IM administered. medical director notified. Dr. came and assessed and monitored patient. Symptoms resolved while on site. Pt escorted by medical colleagues to workplace ER where she agreed to stay for further monitoring. Dr followed up with pt later in the evening and she was doing. Patient updated progress December 20, 2020. I have had continued symptoms since Thursday though initially I felt that they were just typical post-reaction type symptoms. Thursday night I just had some itching and occasional hives. Friday I woke with a terrible headache and could not lift my left arm above by head due to pain but figured that these were vaccine effects. I had intermittent hives and itching that I was able to suppress by taking Allegra, Zyrtec and Claritin (each once) throughout the day. I was also taking Pepcid at night. Saturday, I tried to decrease my antihistamines to just Allegra BID, Pepcid once and Benadryl just last night. I woke with hives and worse itching again. I also appeared to have what looked like eczema on my hands that was new. So I took Pepcid and Allegra prior to going into my shift this morning. I took Zyrtec around 9 am as I had not yet had any improvement in my hives or itching. My co-attending noted that I was progressively becoming more flushed and around 11 am I started to experience an odd sensation in my throat with a persistent cough. My vitals were normal (HR 75, sat 98%, BP 113/78), so I talked the other attending out of more epinephrine and she prescribed me dexamethasone 16mg. I took the dex plus a Claritin at noon today and by 2 pm, had resolution of all of these symptoms. I also noted that my chest felt significantly less tight and retrospectively think I have been experiencing chest tightness and pressure since Friday but hadn't realized it because it occurred gradually. As of December 21, 2020, patient was to start prednisone 40 mg daily x 5 days.

Pain in arm of injection site including numbness and pins and needle tingling in the lower arm and hand, loss of feeling in hand and loss of sensation and strength; difficulty holding onto objects. Dizziness and weakness, severe joint pain. Throbbing Headache.

Felt sleepy, Took a nap woke up around 8:30 pm. Felt nausea. Drink 7-up Laid back down. Woke up still felt nausea. Drink another 7-up, felt sick to your stomach. No appetite. Felt really nausea. Still felling nausea.

Visible hives twice, and stinging eyes.

"Patient complained of ""racing heart beat, dizziness"" BP noted 141/92 P104 oxygen 99 repeat temp 97.6 BP 145/89 P96 repeat BP 145/95 Pulse 104 taken to ER for further evaluation and treatment. Temperature rose to 101 while in ER. Patient reports symptoms resolved approximately 1 1/2 hours after injection ""feels fine"" now Discharged home steady gait."

Dizziness

"Pt returned to her work area. At 1314 - Team member was taken to the ED. She reported feeling like her tongue was swelling, she attempted to each chips and felt like her throat was sore and needed to be cleared. Pt had a syncopal episode and c/o chest pressure, and difficulty swallowing (able to control secretions). Hives were noted to her face, neck & chest upon arrival to teh ED. At that time - pt reported feeling like her tongue started swelling 15 minutes after the vacciation. Pt was confused and ""extremely"" anxious. VS: 209/102, HR 125, RR 30 SaO2 96% r/a 1321 -diphenhydramine 25mg IV, pepcid 40mg IV and IV NS started VS: 159/105, HR 118, RR 31, SaO2 100% r/a 1322 - epinephrine 0.3mg SQ, Solumedrol 125mg IV 1332 - Zofran 4mg IV 1351 - Ativan 1mg IV 1359 - 128/91, HR 100, RR 22, SaO2 99% 1411 - pt calm- redness improved. still c/o of feeling something in her throat. 1441 - Calm, asking for a drink - tolerated well. BP 110/72, HR 82, RR 18, SaO2 98% 1635 - d/c orders written."

Dizziness and headache , Sore Arm

I had a headache, body ache, chills, fever, sore throat, cough, fatigue.

Anaphylaxis/Angioedema Patient was given EpiPen 0.3 mg IM; Methylprednisolone 125 mg once; Diphenhydramine 25 mg IV push once; Famotidine 20 mg IV push once; Dexamethasone 10 mg IV push once Patient was intubated and put on propofol and midazolam drips for sedation

PT REPORTS A FULL FEELING IN HER THROAT - PT IS AN MD AND DESCRIBES IT AS GLOBUS

Approximately 48 hours after the vaccination was received I developed moderate headache, body aches,chills, dizziness and nausea and was completely bed ridden.I was unable to complete any activities or work. On day two, the dizziness and nausea worsened and I began vomiting. On day 3 of symptoms, I was able eat, sit up and walk around, but still have moderate headache. I also developed diarrhea on day 3.

at about 3am (15 hours after vaccinated), I had the chill, I was freezing from the shoulder down. I had to put on 2 coats and 3 blankets because I was shaking/tremoring. also, headache and body ache. I whole body is hot and my back felt weak. the chill was more apparent toward the night.

High temperature up to 103.2F. Hypertensive episode 165/105 with temporary blurry vision. Three days of high fevers otherwise 101-102 despite alternating Tylenol and Ibuprofen every 3-4 hours and hydrating. Also had an additional episode of hypertension with blurry vision when I wasn't febrile.

continous nose bleed - unable to stop it.

Can't taste or smell is off

States had generalized itching and ask for benedryl. 50mg Benedryl Tablet given PO after 10 minutes ask for Pepcid. After 15 minutes states he feels better and issues resolved

PARASTHESIA IN LEFT ARM - ARM THAT INJECTION WAS ADMINISTERED IN - LASTING LESS THAN 1 MINUTE WITH SPONTANIOUS RESOLUTION - PT IS AN MD

Patient had a temperature of 100.2.

Sore arm last evening (no more than a flu shot), this morning I got tired around 11:30 after a full night of sleep and ended up taking a nap during lunch. I woke up feeling foggy and went back to sleep after finishing my work for the day and slept for over 3 hours, woke up and continue to feel very foggy

Shakes(chills)/ Tachycardia/altered mental status/sent to the hospital for evaluation

After injection had L arm pain, the following day (12/17) pain continued . 12/18 onset of fever max temp 38, chills, fatigue, muscle pain and nausea. Treated with Tylenol for symptom relief. Symptoms continue and worsened 12/19 and 12/20. 12/20 underwent video clinician visit for symptoms and inability to return to work for continued symptoms 4 days after vaccination, last day of fever. 12/21 covid and flu swab negative symptoms all continued fatigue very evident going to and from swab exam. 12/22 morning near syncope while getting ready for day, tachycardia, underwent ED eval was given fluids and labs drawn and discharged home with improvement in tachycardia and lightheaded/dizziness with fluids, another covid swab was negative along with negative RVP. Continued to have fatigue 12/22 evening.

Patient had a fever of 99.1.

Fever 100.6 24 hours after vaccination , Headache chills and body aches, muscle ache .

12-19 Received Vaccine @ 0930 12-20 Did not sleep well, woke up and was dizzy, nauseaous; this has been constant.

Received vaccine around 10:40 am, by 10:50 started to feel dizzy, eyes felt full, dry, tingly, swollen, voice became raspy and throat itched. Received 25 mg Benadryl PO at around 10:55. Face, arms, chest and abdomen developed a fine red itchy rash, tongue swollen and itchy, lips tingling, wheezing, blood pressure elevated, pulse thready given 25 mg PO Benadryl, taken to the Emergency Room, symptoms persisted, stomach hurt became nauseated, received IV solumedrol, Pepcid, IV fluids, nebulized albuterol. Sent home once stable after 3 hours, with instruction to take Benadryl every 4-6 hours fir the next 2 days, albuterol as needed, and prednisone for the next 5 days.

Swelling left deltoid and left neck followed by feeling of throat closing. began 14 min after administration; Code Assist called and taken downstairs to ED; received epinephrine, Solumedrol, Benedryl. Prescribed prednisone and Pepcid 40 mg bid .

Pfizer-BioNTech COVID-19 Vaccine EUA within 5-30 minutes: dizziness, weakness, palpitations, chest tightness, injection site pain, left arm numbness and weakness, headache, nape pain, drop in BP, high

BP, left shoulder and elbow joint feeling like to be detached. Sent to Hospital ER, was given Zofran and Ativan

During 15 observation period I developed tachycardia rate in the 140?s. Hypertension 180/100. Rapid response was called and sent to ER. I also became flushed, chest rash, chills low grade temp 99.4. I was given a 500cc bolus of Normal saline. Benadryl 25mg IVP and my morning dose of carvidelol 6.25mg. On discharge Bp was 102/ 74, Hr 76.

Pt hx of DM Type I, HTN, reported pruritic uritcarial rash 5AM 12/21/2020 inner wrists, anterior distal LE bil. Resolved aprox 30 mins later. Urticaria recurred mid day 12/21/2020, pt treated with Benadryl 25mg PO, resolved. Urticaria returned evening of 12/21/2020 wrists, axilla, nape of neck. Pt treated with Benadryl 25mg PO, resolved. Urticaria returned 5AM AM 12/22/2020 similar distribution as evening of 12/21/2020. No air way or facial involvement. Pt treated with Benadryl 25mg PO, urticaria resolved. Sought medical eval 12/22/2020 around 10AM: no sx nor urticaria present. 1:30PM 12/22/2020 after eating lunch pt called to report recurrence of urticaria now involving face, lips tingling, itchy back. Administered 50mg Benadrly IM, observed, urticaria/pruritis resolved x 45 mins. Urticarial sx and lip tingling returned in 2 hours, pt transferred to ED for treatment with epinephrine, steriods, observation.

Headache, stomach problems and body aches.

Chest pressure and headache followed by generalized itchiness and hives. Progressed to facial swelling and airway swelling. Treated with EpiPen x1 IM, 50 mg diphenhydramine PO, 20 mg famotidine, and 10 mg dexamethasone. Immediate reaction improved. Itchiness and intermittent hives continued. The headache continued along with other common/expected side effects of vaccine.

On 12/16 about 10pm I began having arm pains and took tylenol. 12/17 woke up feeling exhaused with severe body aches, headache and a 101 temp. I went to work but had to leave because I just wasnt feeling good. On 12/18 I went back to work but could not perform so I had to leave again and was still experiencing the severe body aches and headaches but no fever. I was suppose to work on both 12/19 and 12/20 but had to call in. On 12/19 still same symptoms with no fever but around 5pm I began to have palpations and heart racing which caused me to go to the ER. I was given fluid and labs was done and monitored for a few hours and was released after the fluid was given. On 12/20 felt pretty good still tired and exhaused feeling and on 12/21 I felt good but later that evening I noticed my forearms began to feel stiff, tingly and heavy. My hands began to feel stiff and is very sore. Continue to feel very tired with body aches and continued to take tylenol. This morning I felt ok but after fixing breakfast the symptoms came back and they feel like the same symptoms I had when I had the vasculitis in 2009-2010 and that concerned me so I discussed it with a Neurologist and Immunologist who I will reach out to after the holidays to schedule an appointment. I have an appointment scheduled with my PCP for additional labs on tomorrow 12/23 and I have not been able to work since getting the vaccine. My hands feels clumsy and I am constantly dropping things since yesterday

"Pt with dizziness and chest pain that started about 10 minutes after getting the Moderna Covid19 vacccine. No shortness of breath, no rash, no fever, no swelling, no weakness. Feels pain in center of chest and on L side. Pt also has been having stress with work. Pain started in the R side of the chest and

migrated to the L side. It improved with Nitro and Aspirin but pt states he still feels, ""fussy."" He has no symptoms of allergic reaction or anaphylaxis. Pt has no known hx of cardiac dz, nonmoker, nondrinker. His Mom has a cardiac murmur but no other known history of heart disease."

I have face numbness, a nose bleed

headache, injection site sorenesss, nausea (moderate), fatigue (moderate), body aches/chills (moderate), temp 99.4 deg, notified employee health, had a Covid test (came out Negative), sent home for the day.

30 mins later I became completely dizzy, flush and had hard time focusing. I was placed on a gurney and blood pressure was taken. 158/103. Usually runs 110/60. Was told to go to ER but I declined. They monitored BP for about 45minutes. I then went home and did same thing. BP stayed high for two days. With headache. I stayed on the couch for those days. Monday I went to work because blood pressure was down. But now my HR is up. Highest in 130?s I felt a little dizzy. I had stomach upset and nauseous with mild headache. Left arm pain Today Tuesday as soon as I exert myself my heart rate goes up. I have mild headache

Red hives under chin, on neck, and on chest beginning 30 minutes after dose and lasting approximately 1 hour.

This nurse was notified that the worker was having tachycardia post vaccination. The worker had a baseline HR of 75 while at rest, per wrist band monitor belonging to worker. Worker's HR steadily increased as high as 94 BPM. The worker was shaking and the worker complained of throat not feeling right and dizziness. Worker described their throat as feeling tight. This nurse brought the worker to the back area of the clinic, asked the observer to initiate a MET, and this nurse went to med room and took an EpiPen from the box. This nurse administered the EpiPen into the right thigh at 1600. by 1604 the MET team had arrived. The MET team spent 20 to 25 minutes with worker. The MET team included two PICU physicians, one being a fellow. This nurse was advised that the worker was asked if wanted to go to the ED (by the worker) and worker declined. This nurse agreed to observe the worker until the close of clinic at 1730. Vitals take at 1720 were as follows: 89 HR, 94% O2 sat, 124/66 BP (RUE), 16RR. Worker was no longer feeling dizzy, no throat symptoms, and refused ED observation and went home. Nothing further reported.

itchiness in throat, mild tongue swelling. Administered Benadryl 50 mg. sx resolved 5-6 minutes after medication administered

Tingling in head, headache, mouth, itching

1015 c/o chest heaviness, scratchy throat, heart racing states injection site feels warm. taken to cot to monitor VS 173/86 P 126 RA100 States worked last night, drank Monster drink, tired and little anxious. 1020 states sx are decreasing VS 143/85 94 100 RA sitting up drinking juice and eating granola no distress noted 1035 states throat is little scratchy still given Bendadryl 25 mg PO per VO Dr. no distress noted, very calm states some chest heaviness 1/10 pain scale denies any other sx at this time sitting on

edge of bed 1048 BP130/73 87 100RA pain 1/10 chest discomfort decreased, denies HA, SOB, states throat still little scratchy but not bad at this time denies any pain at site. Site is warm to touch denies any pain at site no redness noted at this time 1100 BP 125/79 82 100 RA denies pain 0-1/10 sitting up states feeling much better denies pain in chest, minor scratchy throat but relieve 1115 Monitored for 60 minutes released to girlfriend given instruction to go to ER if any other sx.

Fever of 102 degrees F, chills, body aches, extreme fatigue, headache, weakness. Started at 10pm 12/18/20 and ended at 10am on 12/20/20.

6 weeks pregnant HCW, states she received COVID vaccine on 12/19/2020 around 1400 and at around 2200 last night started to have migraine headache and neurological symptoms , claimed that she couldn't find words to complete sentences and having numbness on the R hand- patient went to ED- per patient symptoms resolved after less than an hour. Now she is concerned if she should take the second dose,

Headache Dizziness Muscle pain (not injection site) Mild shortness of breath

Itching, shortness of breath, throat hurting

Syncopal episode

Lips tingling and burning, top and bottom. no visual effect. no redness or swelling

Swelling, Tenderness, Redness at Injection Site

warm all over, headache, feels like something in her throat

12 minutes after injection, patient started experiencing jaw discomfort on the left side with sharp intermittent pain in the left ear

On second day developed marked headache and nausea, very mild disorientation I went to office to try and sleep it off. Headache got worse so went home to bed. 5 hours later I am feeling much better

1046 states feels nauseated brought to cot to monitor VS 130/74 HR 86 99 RA site cool to touch denies pain at site just states very nausea. States she had breakfast and had fluids this am. given OJ and crackers per her request. denies any pain or other issues at this time 1056 129/75 81 100RA states feels better just needed the crackers denies any more nausea does state has a small headache starting but not bad 2/10 1110 125/68 78 100 RA denies any more nausea and headache is subsiding . She will go to ER if any more sx released at this time. 1836 called to check on pt states she was a little tired the rest of the day denies any more nausea or HA . Instructed to go to Er if any other sx occur.

Patient was dizzy at vaccine clinic and was taken to ER as a precaution. She left the emergency dept before being seen, stating she felt fine.

EMS called after patient displayed a heart rate of 160, a little over an hour after vaccine administration. Patient was taken to the hospital and diagnosed with an episode of RVR Afib; she was admitted to the hospital.

Patient experienced bronchospasm with coughing and tongue itching approximately 10 minutes after the injection.

1126 states felt funny VS 86/63 HR 79 100 RA taken to cot to monitor/evaluate denies any pain or discomfort only just weak and funny, requested drink of water and leaned back on bed 90 degree angle noticed she was not focusing 1130 VS 78/45 58 100 RA taken to ER via WC due to Hypotension. 1830 LM for her to call me on her cell for follow up

Urticaria on bilateral extremities, chest, torso, and neck No shortness of breath, closed airway, or any other signs of a severe allergic reaction

After 5 minutes of the vaccine, I felt lightheaded, pulse got week, tongue tingly and slightly swelling. The ER doctor at the vaccination site administered an epi-pen and I got sent to the ER via rapid response, received 15 liters of oxygen for 1 hours, rapid shallow breaths respiration in the 30'. 2 hours later received decadron orally then observed for 1 more hour. Symptoms resolved and went home. The following day, I woke up with a massive headache and lightheadedness.

"Per patient, she had received the COVID vaccine at her workplace and developed 30-40 minutes later symptoms of throat tightness, chest tightness and difficulty swallowing and was given at her workplace in the ED oral Benadryl, oral Decadron and IM epi. About an hour and a half later she developed symptoms of recurrent throat tightness and was given another dose of IM Epi and was then transferred to this hospital for further evaluation as per the patient ""all of her symptoms are pretty much ""unchanged""""". She was observed for many hours in the ED without evidence of recurrent symptoms and was later discharged with a 3 day prescription of prednisone and prn diphenhydramine for itching."

"1600 Patient c/o itchiness to neck and face felt on coming rash 1625 notified me of reaction, advised to take Benadryl 50mg 1630 notified Pharmacist of reaction 1645 follow up with patient ""doing okay"" 1700 follow up call feeling the same not worse, leaving work for home, aware to go to ED if symptoms worsens"

Warmth tingling on tongue and Lip 15 mins after vaccine Accelerate heart rate 120-130 7 hours after vaccine accelerated heartrate 120 10 pm 5am 12/19/2020 Heartrate of 100 12 Noon 12/19/2020 Heartrate of 100 12/202020 10 am Accelerate heart rate of 100 12/20/2020 5 pm Accelerate of heartrate of 100 oral Benadryl 25mg in the ER

"Patient was vaccinated on 12/20/2020. Four hours later, she felt dizzy at work. Her BP was 92/68 (normal BP 110s), also c/o""hot flashes"" (LMP 12/16/2020), and headaches. As the day went, she started to have sore throat, runny nose, dry cough, body aches, and neck pain. Her temp was 98.6. Denies SOB, swelling of the neck. No problem with wallowing. Still has dry cough, HAs, bodyaches, neck

pain, and off and on dizzniess. This is not normal for her. She is scheduled off from work on 12/21/20 and 12/22/20. Not well to return to work."

"began to have a ""foggy head"" feeling and then started to feel chest pressure - was NOT short of breath"

Patient felt heart racing immediately after getting vaccine. Vital signs taken: BP163/84 P:150 O2Sa:100% Patient felt hot flush all over face. Got patient ice water and had patient call for a ride home. Friend is coming to get her. Vitals taken 1802: BP: 147/116 P122 SaO2: 100% Patient sitting resting. Vitals taken: 1809: BP 156/90 P:113 Sao2:100% Patient started having chills - warm blankets given. Vitals taken 1820: BP: 138/94 P: 109 SaO2:100% T:98*F Patient resting in chair. Friend arrived to provide ride home. Vitals taken 1830: 142/84 P:94 SaO2: 100% Vitals taken 1850: BP:127/87 P:102 SaO2: 99% Patient did state that she has been under extreme stress with the death of her husband in November. And today was her first day back to work. Had patient stand and walk around a little, no dizziness noted. Gave her some pretzels to snack on and after 5 minutes she stated she was feeling almost back to normal. Patient's friend is an RN and was going to have patient spend the night at her home. Patient stated she did not feel she needed to see a provider and felt that she would be ok in her friends care.

Swelling and redness around the injection site immediately after injection at 10:50 AM, 12/22/20. Site was slightly raised with erythema, about size of a quarter (coin). Symptoms lasted >5 hours after vaccination; still ongoing at time of writing (3:18 PM). No other symptoms noted. Patient monitored for 30 minutes post-administration and line drawn around area with swelling to monitor for growth/worsening.

1000 came back to the clinic from her department states just feels fuzzy/dizzy taken to cot VS 109/77 72 100RA denies any other issues witnessed far away gaze when talking with her . She states got back to department and just didn't feel right and had a bit to eat and drink and told coworker and they brought her back down to the clinic. She was monitored as denied any pain 0/10 or any other symptoms. 1010 112/60 70 100 RA denies any pain A&O times three able to focus no more distant feeling 10/20 114/78 72 100 RA denies any pain A& O times three denies any pain, nausea SOB, chest discomfort at this time 1030 116/76 75 100 RA denies any pain states she is not fuzzy or disoriented at this tiem feels much better but just feels tired. instructed to monitor herself and if any issues to go to ER. states she will comply. 1833 spoke with pt states went home slept and is feeling much better just felt fuzzy and disoriented for that hour after the vaccination.

Flushing 3 minutes post injection. Did not report at center because I attributed it to it being very hot in the injecting center. 30 minutes post vaccine I began to have body flushing starting in my chest spreading to my face through my torso, down arms, and legs. , dizziness, clammy hands, nausea 1 hr post vaccine with facial tingling, jaw constriction, and palpitations. Pulse was not elevated, but never had difficulty breathing, wheezing, swelling, or rash. Flushing continued, Benadryl taken 1.5 hours after vaccine with relief of symptoms. Symptoms returned around 7pm which was approximately 9 hours post vaccination. Benadryl taken again.

began to have a burning sensation inside body & felt light headed

Fever to 101F, which resolved with acetaminophen 625mg PO and did not recur. Flare of existing hidradenitis lesion in left armpit, resulting in 24 hours of pain and drainage. Within 24 hours returned to baseline condition.

At the time of the injection, I felt dizzy about 5 minutes afterward but I went away rather quickly. I also started coughing, but as I have asthma and I was rather anxious, I used my inhaler. I did mention I had felt a little dizzy at the appointment but it was going away. Then, around little that same night /the next morning (12/20), I got a little short of breath and chest tighteness, but nothing major. Around 2pm that day, the tightness got worse and my inhaler stopped helping as much and I got a cough. Then, around 3 am today (12/22), I woke up with chills but no fever and nausea and threw up several times and then it went away. Around 6pm tonight, I was taking a nap and woke up with what I think was sleep apnea. I felt like I wasn't breathing quite right, and like it almost hurt to breathe because my chest was so tight. I checked my oxygen levels while sitting quietly, but not laying down like I was before and they were 95-97%. Chest tightness remains and is worse than before, breathing is ok. I have a lot of muscle pains and body aches, some cough, and very mild phlegm. No fever. I did not go to see a doctor because I don't have health insurance right now and I don't want to pay for the bill.

Vaccine received 12/18/20. Experienced fatigue, chills, body aches, fever on 12/19/20 ~3pm. Temperature ranged 101.3-102.6 deg F. Reduced with Tylonel. Temperature 12/20/20 ranged 100.5 deg F down to 99.5 deg F by end of day with no antipyretic medication taken on 12/20/20.

BEGAN TO HAVE ITCHING ON TOP OF HEAD APROX 20 MIN AFTER INJECTION - TOOK BENADRYL 25MG PO

Tachycardia 124- 132 started 10 minutes after vaccine. Resolved spontaneously about 2 minutes later

Joint ache Chills

Patient received Moderna COVID vaccine at 1926. She completed standard 15 min observation time and was dismissed from clinic. Patient returned to clinic at 2000 with redness at injection site, itching, chills. BP 126/90 and pulse 86, patient able to speak comfortably. Diphenhydramine 25 mg given orally. Patient observed for 36 minutes. All symptoms resolved and observed redness to left deltoid completeely resolved. No complaints of shortness of breath or difficulty breathing. Patient discharged from clinic to another facility with appropriate follow up instructions. Patient texted ahead to her preceptor that she is en route.

Severe pain at injection site Left upper molar tooth broke off

patient felt slightly nauseated at 10 minutes after injection, then developed slight sweating; BP 160/81; 83 at 5:45 and then 158/87 with HR 82 at 5: 52 pm. Her lungs were clear, she was speaking in full sentences and was denying any chest pressure, her usual sense of asthma exacerbation. At 6:05 it was 164/83 with HR 79 and patient developed a dry cough; we decided to have her wait just a bit longer, then cough worsened, so at 6:25, decision was made to have patient seen in ER for further assessment, and en route in wheelchair to ER the dry cough became persistent, spasmodic and patient was unable to

speak. Epi-Pen was injected in right mid thigh, and patient transported to ED urgent eval. She noted immediate palpitations, and slight improvement of breahting, was able to speak in four word sentences. On arrival to the ED, patient was administered Duonebs, Albuterol neb, IV Benedryl, IV Solumedrol; CXR was obtained, with results pending. Patient was sent to observation for ongoing monitoring and assessment of breathing. at 6:30 PM in the ER, she

Noticed a full trunk , neck and back red raised rash Tuesday night

Developed a cellulitis in the abdomen around umbilical area that has pain,itching,redness around it , seek dr.attention and put on doxycycline

Dizziness/wooziness, shortness of breath, muscle aches, high BP and heart rate

Itchy rashy hives all over. Swollen itch burning eyes. Throat inner ears tingly itchy

itching and rash - no tongue swelling, sob or throat closing stable vitals treated with benadryl 25, solumedrol 125 and pecid 20 mg IV She had gradual improvement and resolution

approximately at 3;32pm felt heart racing, then 2-3 minutes later tongue tingling, few minutes later felt a lump on throat. 25mg benadryl taken, hoarse voice and anxious, then another 25mg benadryl taken. I was then taken to ER for observation. I was given pepcid and prednisone in ER. Continued to feel lump in throat but no shortness of breath or difficulty breathing. Felt calmer and normal heart rate. Discharged approximately at 5:30 pm

Right side facial swelling and right eye twitching sensation. Given Benadryl 50mg.

numbness lower chin,

Patient felt lightheaded and dizzy. B/P 74/34 HR 92 RR 20 Water provide Legs elevated. B/P after 5 min 138/86 Feeling better

patient had immediate onset of metallic taste in her mouth and felt a slight tingling in mouth and slight need to focus on swallowing without any difficulty with breathing; no sense of doom, no lightheadedness, no palpitations, no problems breathing. blood pressure was 196/112 with HR of 110 at 4:20 pm, then was 204/112 at 4:28 with pulse of 90; her heart and lung exams were normal without any wheezing; speaking in full sentences; she sat and rested for the 30 minutes and her blood pressure returned to 142/97 with pulse of 68. injection site looked fine and patient was comfortable to go home.

Tachycardia, hypertension, flushing and tingling around mouth within minutes after injection. Lasted about an hour

c/o pain and erythema at the base of posterior scalp. no tenderness with palpation. full rom of neck, recommend ibuprofen

Dizzy, heart palpitations. Was taken to the ED for evaluation

1 cm area of induration following vaccine, no erythema, no pain

"dry mouth, feels ""different"", no dizziness, no headache"

I received an IM injection at 4:40 pm at my place of work. I sat down as per our protocol after the injection. Within 5 minutes, I felt a flushing effect start from my head and travel down my body to my toes. I became light-headed and felt like I was floating in my chair. My legs, from my knees to my toes, felt very warm, numb and tingling. After the 15 minute period of monitoring ended, I walked back to my unit. While walking, I felt light on my feet and as if I were walking on a bunch of thick blankets. There was a numbness sensation to the soles of my feet. I informed the doctors and nurses that I work alongside with once in my unit. The light-headedness dissipated within approximately 30 minutes. The numbness, tingling and warm feeling from my knees to my toes lasted approximately for 2 hours (until 6:30 pm). I had no issues after that point.

40 minutes after vaccination, developed hives, chest tightness, lip/cheek/tongue numbness/tingling, nausea Took Benadryl 50 mg and Pepcid 40 mg at 7:15pm. Continued with Zofran every 8 hours

acute onset parasthesias in left arm and bilateral lower extremity weakness within 15min of injection. Unable to stand without assist. no radicular symptoms

13:40 dizziness/vertigo feeling. 14:25 nausea, headache, dizziness. Went to Emergency room in our hospital to get checked out. My blood pressure was severely elevated, felt unwell, headache increased in intensity, nausea worsened & dizziness.

noted immediate development of swelling right at the site of the injection on right deltoid - slightly warm, 3 cm in diameter, non fluctulant, no streaking; no respiratoyr distress, no hives, no systemic symptoms. drew a line around the redness and asked patient to put cool compresses on it, monitor for worsening or genrealization, other skin findings. no change after 30 minutes.

Within minutes of admin of Pfizer vaccine, developed dry mouth, peculiar sensation through extremities/trunk/abdomen (akin to being injected with contrast), elevated BP, tachycardia, flushing, lowerabdominal cramping. Symptoms lasted app 30 minutes. Eval by RNs at the vaccine site. Eval by MD at facility. Discharged after improvement in symptoms.

"patient was very anxious and nervous prior to the vaccine, and felt fine at the time of the shot, but became slightly nauseated and felt ""nerves"" and ""like I was a nervous wreck"" - she felt overheated and was speaking calmly, in full sentences. her HR and BP were normal at 76 bpm and 129/70. her lungs were clear, heart was regular (known heart murmur), no skin changes, not sweating. she rested and upon further evaluation was feeling fine."

Arm soreness at site of injection., sore throat, tactile fever (did not measure temp), mild malaise. Not severe enough to impact daily activity meaningfully.

Headache, nausea, dizziness, lightheadedness, lack of concentration and memory issues

On the initial day about 5 minutes getting the shot I had right eye cramping lasted 25 minutes 12/18 neck stiffness worst on 12/19 On 12/19 I had extreme fatigue and headaches also on 12/20, and 12/21. Felt very dehydrated as well.

About 10-15 minutes after receiving vaccine patient reported that her heart began to race and throat began to swell.

The patient experienced a headache, nausea, metallic taste and BP was 140 and it is usaully 120. Pulse and O2 was within normal limits. Patient received water and cold compress and she felt safe to drive home.

6:45 pm asthma attack requiring albuterol inhaler. Attack was not triggered by any particular event. I was at rest when it started.

Redness, swelling and tenderness at the injection site Rash appeared at the injection site after 8 hours of administration. Chills and low grade fever

Shooting pain down my left arm about 3-5minutes after the shot was given.

headache, soreness on injection site, hives on the day of injection until current day.

About 30 minutes after vaccination while driving home, tingling was noted in injection arm, traveling up the left arm into the left neck and around the lips. Tingling resolved but the next day tingling was noted to be diffuse, light and scattered through arms, hands, fingers, and legs equally and bilaterally. No dermatomal or distinct nerve distribution. Tingling worsened by sitting on legs, became dense tingling in the anterior shins upon standing, but then resolved a few minutes later to the more diffuse light tingling. No notable difference in strength (able to hike and cook). No notable numbness. No rashes, no shortness of breath, no changes in heart rate.

(I'm a physician who received the vaccine at my medical clinic). 5 minutes after receiving the vaccine, I felt very dizzy and faint. We checked my BP (which is usually 120/70; I do not have hypertension), and it was 190/120, HR 120-130 bpm. We rechecked it several times and it stayed there. After 5 minutes, I suddenly felt better and my BP had dropped to 140/70, HR 70. I felt exhausted. No other problems. They watched me for 30 minutes and I felt fine. I had my husband drive me home. As we were driving home (now one hour after the vaccine), I realized that my throat was closing up. I was breathing fine but I realized I was having an anaphylactic reaction from the vaccine. I have never had any allergic reactions before to vaccines, etc. He drove me back to the emergency room of my hospital, where they diagnosed me with an allergic reaction/anaphylaxis to the vaccine. They gave me emergently IV solumedrol (steroids), pepcid, and benadryl, which fortunately worked immediately. They observed me for several hours and I was fine. They sent me home. The next morning, I felt exhausted and my throat was hoarse and sore, but that went away several hours later. It was a terrifying, terrible experience. I thought I was going to die. I had to pay $1000 out of pocket for the ER deductible.

Pfizer-BioNTech COVID-19 Vaccine EUA Hives/Rash on the right side of the body, Itching, Arm Pain (1 day after vaccine) Benadryl was taken and reduced the hives and itching

HIVES starting 32 Horus vaccines, unclear if related, took Benadryl,

Fever 100.4¦ F , headache; body aches , trouble focusing

Vaccine at 10 am 12/18/2020 That same day: Feet numbness at 10:45 am - resolved at 4 pm L hand numbness around 11 am - quickly resolved lower face numbness around 11 am - intermittent throughout the day all symptoms resolved by evening/overnight 12/19/2020 mild facial numbness about 4-5 hours during the day fully resolved by 12/19/2020 evening, without any further symptom recurrence at any site

48hr following dose 1: mild nausea, dizziness, foggy brain.

Numbness and tingling on left hand and left arm. Lasted a few hours. Started in fingers of left hand, progressing up to left arm.

Anaphylaxis reaction with hives, stridor/airway edema, wheezing

Congenital anomaly or birth defect; This is a spontaneous report from a contactable consumer (patient). A 57-year-old female non-pregnant patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for covid-19 immunization. Medical history included high blood pressure and hypertension and more epileptic seizures. Concomitant medication included unspecified pneumococcal vaccine on 12Dec2020 for immunization. The patient previously received flu shot (Influenza virus vaccine) and pneumonia shot (Pneumonia vaccine) both on 20Oct2020 for immunization. The patient experienced congenital anomaly or birth defect (as reported) on an unspecified date with outcome of unknown. Information on the lot/batch number has been requested.; Sender's Comments: The reported information is unclear. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

Pfizer-BioNTech Covid-19 Vaccine EUA Nausea, vomiting, body aches, fever 100.6

developed swelling of tongue; dyspnea; skin rash; This is a spontaneous report from a non-contactable consumer. A 35-year-old male patient received BNT162B2, via an unspecified route of administration on an unspecified date in 2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. This is a call from CDC this morning regarding a new case, the patient was administered vaccine and developed swelling of tongue, dyspnea, skin rash on an unspecified date in 2020, then treated with dexamethasone, diphenhydramine hydrochloride (BENADRYL), via intramuscular (IM) epinephrine in emergency room (ER). The outcome of events was unknown. She will alert him each time there is a report of severe hypersensitivity for his awareness. Further, the CDC is in the process of appointing a contact who will be able to meet with us regularly on this topic. Their conversation was amicable and demonstrated a willingness to work closely with us as we navigate the issue of hypersensitivity. No follow-up attempts are possible; Information about

lot/batch number cannot be obtained.; Sender's Comments: The reported information is limited. Based on the temporal relationship and the description of the events, swelling of tongue, dyspnea, skin rash, there is a reasonable possibility that the events are related to BNT162 vaccine. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

extreme arm soreness, fever of 101.4, chills, body ache

erythematous papular rash scattered throughout abdomen, torso, neck with areas Onset of symptoms noticed 6hrs from vaccine, rash has continued to spread 4 days from time of vaccination sparing most of the extremities.

itchy throat; itchy throat/back of the tongue reaction; This is a spontaneous report from a contactable physician. This physician reported similar events for two patients. This is the first report. A female patient of an unspecified age (reported as 50, unit unknown) received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiry date were not provided), via an unspecified route of administration on 17Dec2020 22:00 at a single dose for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient experienced itchy throat/back of the tongue reaction. No rash, then they gave her epi 10, ED (emergency department) doctor assessed for 2 hours. No evidence of tongue swelling, hemodynamics was normal. Outcome of the events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Based on the close temporal relationship and the description of the events, itchy throat/ tongue reaction there is a reasonable possibility that the events are related to BNT162 vaccine. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.,Linked Report(s) : US-PFIZER INC-2020500303 Same reporter, product, and event, different patient

Extreme arm pain alternating with numbness and tingling, joint pain in shoulder, elbow, and wrist, chills, low grade fever (100.5), fatigue

Patient developed bilateral lower extremity numbness and tingling, as well as weakness that resolved after several hours of observation in the Emergency Department. It is highly likely that the response may have been in part related to anxiety. After several hours of observation the patient had return of motor strength and was able to discharge. She continued to have paresthesia that was improving at time of discharge.

Pfizer-BoiTech COVID-19 Vaccine Immediate burning at injection site following dose. (Similar to the sensation of receiving contrast for a CT scan) which I found odd. Injection site pain continued over night, swelling and site redness to follow and A 1.5 inch welt appeared approx 24hrs after receiving vaccine.

Pain is localized to the injection site only . Treatment includes rest and Tylenol with little effect. Continuing to monitor for any further developments or additional side effects.

Swollen hands; dizzy; This is a spontaneous report from a contactable nurse. A 38-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot number: EK5730), intramuscularly in the left arm, on 17Dec2020 at 14:00 (at the age of 38-years-old) at a single dose for COVID-19 immunization. Medical history included non-ongoing COVID-19 (previous well recovered from COVID-19 months earlier) from 2020 to an unspecified date. The patient was not pregnant at the time of vaccination. The patient's concomitant medications were not reported. It was unknown whether the patient received other vaccines within four weeks prior to vaccination or other medications within two weeks of vaccination. The patient experienced swollen hands and dizzy on 17Dec2020 at 15:00. The events resulted in emergency room/department or urgent care visit. Therapeutic measures were taken as a result of the events, which included cetirizine hydrochloride (MANUFACTURER UNKNOWN) and monitoring. The clinical outcome of swollen hands and dizzy was recovering. It was also reported that since the vaccination, the patient had not been tested for COVID-19. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

40 minutes later, I became flushed, hot, sweaty and clammy and tachycardic along with a syncope episode. Nausea came after, and only treatment was fluids. This episode happened after discharge around 9:45pm and then returned to the hospital for the same course of action.

Slight intermittent headache, neck and shoulder soreness, left arm soreness. Right hip and thigh pain when getting up from the chair about 3 times over the course of a few hours. Stabbing left heel pain x1 in the middle of the night. The next morning (12/22/2020) my right thigh was just slightly sore. Later in the day I had slight right hip discomfort again but it went away quickly. About 30 hours after the injection I had right knee discomfort lasting a few hours.

Possible allergic reaction - paresthesias of L tongue and throat; Possible allergic reaction - paresthesias of L tongue and throat; Possible allergic reaction - paresthesias of L tongue and throat; Sensation of tongue and throat swelling; Sensation of tongue and throat swelling; This is a spontaneous report from a contactable Health Care Professional. A 48 years old non-pregnant female patient received BNT162B2 (Pfizer-Biontech covid-19 vaccine) on 17Dec2020 at 15:15, at single dose, for COVID-19 immunisation. The vaccine was administered at hospital. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Relevant medical history included food and drug allergy. The patient received concomitant medications (unspecified, received within 2 weeks of vaccination). Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, the patient has not been tested for COVID-19. On 17Dec2020 at 15:15, the patient experienced possible allergic reaction - paresthesias of L tongue and throat, with sensation of tongue and throat swelling. No anaphylaxis. No abnormal physical exam findings. Emergency Room Visit required and the patient received the following treatment: diphenhydramine hydrochloride (BENADRYL), prednisone, and loratadine (CLARITIN). Clinical outcome of the adverse events was unknown at time of this report. The case was assessed as non-serious. Information on the lot/batch number has been requested.

Next day after vaccine was given, I had whole body aches and low grade temp of 100.8. Off and on chills. It felt like I had covid all over again (I tested positive end of October). Very sore L arm.

"not getting any Covid nothing, always negative; "" I got 2 shot I feel like I have Covid ""; This is a spontaneous report from a contactable nurse (patient). A patient of unspecified age and gender received BNT162B2, via an unspecified route of administration in Dec2020 as single dose for COVID -19 immunization. The patient had already received two doses. The patient's medical history and concomitant medications were not reported. The patient reported not getting any COVID nothing, always negative; "" I got 2 shot I feel like I have COVID "" on an unspecified date. The patient underwent lab tests and procedures which included negative COVID; the patient indicated that it was always negative. The outcome of not getting any COVID nothing, always negative; "" I got 2 shot I feel like I have COVID "" was unknown. The batch/lot number for the vaccine, BNT162B2, was not provided and will be requested during follow-up."

Pfizer-BioNTech COVID-19 Vaccine Swollen & inflamed (right) eye, right (axilla) tenderness, & fatigue.

Tachycardia, body aches, chills, headache.

Limited ROM; Cannot move arm; Severe arm pain; sharp pain while at rest; This is a spontaneous report from a non-contactable consumer. A 26-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration, in the left arm, on 17Dec2020 at 11:00 (at the age of 26-years-old) at a single dose for COVID-19 immunization. The patient's medical history was not reported. Prior to the vaccination, the patient was not diagnosed with COVID-19. Concomitant medications included unspecified birth control. The patient had no known allergies to medications, food, or other products. The patient did not receive any other vaccines within four weeks prior to the vaccination. The patient experienced limited range of motion (ROM), cannot move arm, severe arm pain, and sharp pain while at rest on 17Dec2020 at 11:45. No therapeutic measures were taken as a result of the events. The clinical outcome of limited ROM, cannot move arm, severe arm pain, and sharp pain while at rest was not recovered. It was also reported that since the vaccination, the patient had not been tested for COVID-19. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

AT 12:30AM MIDNIGHT I BEGAN WITH A LIGHT HEADACHE AND STARTED MY BODY FEELING ACHY. I TRIED TO GO TO SLEEP, BUT I COULD'NT, IN FACT IT TOOK ME A LONG TIME TO BE ABLE TO FALL ASLEEP. I DID NOT HAVR TACHYCARDIA, BUT I DID FEEL ANXIOUS-LIKE. I WOKE UP AT AROUNF 5 AM WITH A FEVER OF 101.1 F, CHILLS, LIGHT BODY ACHES AND MY INJECTION SITE FELT AS IF I HAD BEEN PUNCHED OR HIT REALLY BADLY. I THEN TOOK TWO TYLENOL, EACH 250MG, AND I BEGAN FEELING NORMAL AGAIN.

Moderna COVID-19 Vaccine- Fever, Chills, Muscle and joint aches, headache, fatigue. Self limiting, went to bed and woke feeling better. Only fatigue now.

Fever, body aches, chills, headache

My period bleeding more than usual

my eyes were painful; my eyes were itchy; Eyes swelling; my face were swelling; A little short of breath; Hands are still swollen, my arms are slightly swollen and so is my eyes; Dry rash on hand almost looks like dry eczema rash or psoriasis like it looks like it's a dry patchy rash; Severe headache almost like a migraine; I started to feel little bit, a little off; This is a spontaneous report from a contactable nurse, the patient. A 49-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot Number: EJ1685), intramuscular in the left arm on 16Dec2020 (at the age of 49-years-old) as a single dose for COVID-19 immunization. Medical history included hypertension and hot flashes. Concomitant medications included clonidine (MANUFACTURER UNKNOWN) taken for hot flashes, fish oil (MANUFACTURER UNKNOWN) for an unknown indication, omeprazole (MANUFACTURER UNKNOWN) for an unknown indication, spironolactone (MANUFACTURER UNKNOWN) as a diuretic, and multivitamin (MANUFACTURER UNKNOWN) for an unknown indication; all from unknown dates and unknown if ongoing. On 16Dec2020, the patient experienced eyes were painful and itchy, eyes and face were swelling, a little short of breath, hands swollen, arms slightly swollen, dry rash on hand almost looks like dry eczema rash or psoriasis like it was a dry patchy rash, severe headache almost like a migraine, and felt a little bit off. The clinical course was as follows: the patient received the vaccine on 16Dec2020 and waited 15 minutes and did not have any reaction. She went back to work. As she proceeded to work her shift, she started to feel little bit, a little off. She couldn't really describe it but thought it may have been psychological because she was just really watching heavily for any type of symptoms. She had worked an hour over her shift and it usually took her about 40 minutes to get home. When she got home around 21:00, her eyes were painful and itchy and when she looked in the mirror her eyes and face were swelling. Then, she became a little short of breath not to a point where she thought she needed oxygen, just a little short of breath. She called the hospital where she worked and talked to the manager and then they advised her to go the emergency room. At the emergency room, she received intravenous fluid, diphenhydramine hydrochloride (BENADRYL), famotidine (PEPCID), and dexamethasone (DECADRON) for treatment. She also took cetirizine (ZYRTEC), prednisone (MANUFACTURER UNKNOWN) and triamcinolone cream for the dry patchy rash. The patient stated that she had lab work done earlier in Dec2020 (before the vaccination) and everything was normal. The clinical outcomes of the itchy eyes, eye swelling, hands swelling, and arms slightly swollen were not recovered and ongoing; while that of the little short of breath, dry patchy rash, headache, and feeling a little off, were unknown. The outcome of the eye pain was recovered on an unknown date in Dec2020; while that of the face swelling was recovering.; Sender's Comments: Based on the close temporal relationship and the description of the events, there is a reasonable possibility that the events are related to BNT162 vaccine. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate

Extreme Fatigue (started 3 days after vaccine), 'skipped heart beats' at least 4 times during the date of report (6 days post injection), daily morning headaches (started 2 days after vaccine) with runny nose and sneezing (started 4 days after vaccine) and myalgias with chills intermittently,

tiredness/body ache/fever/respiratory distress

arm pain at the injection site; This is a spontaneous report from a contactable consumer. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot number unknown), via an unspecified route of administration on 17Dec2020 as single dose for COVID-19 immunization. The patient's medical history and/ concomitant medications were not reported. The patient experienced arm pain at the injection site in Dec2020, reported as non-serious. Therapeutic measures were taken as a result of the event; patient took ibuprofen (ADVIL) 200 mg. The outcome of arm pain at the injection site was unknown. The batch/lot number for the vaccine, BNT162B2, was not provided and will be requested during follow-up .

felt dizzy; elevated blood pressure; This is a spontaneous report from a contactable pharmacist. A 51-year-old female non-pregnant patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number EJ1685, expiry date unknown) intramuscular on 18Dec2020 at single dose for COVID-19 immunization with her right arm. The pharmacist informed that COVID-19 vaccine was administered in a hospital facility. The patient's medical history and concomitant medications were not reported. The patient previously took doxycycline and experienced allergies. The pharmacist informed that the patient did not receive any other vaccines within 4 weeks prior to the COVID-19 vaccine. On 18Dec2020, the patient felt dizzy and has elevated blood pressure, the patient's pulse was normal. The pharmacist informed that the patient was not diagnosed with COVID-19 prior to vaccination and has not been tested with COVID-19 since vaccination. The pharmacist informed that no treatment was received due to the events. The outcome of the events felt dizzy and elevated blood pressure was recovering. The pharmacist considered the events non-serious and did not result in death, not life threatening, did not cause/prolonged hospitalization, not disabling/incapacitating, and not a congenital anomaly/birth defect.

Starting at 9am, had jaw pain, that subsided, nausea at dinner, severe chills when I went to bed, generalized fatigue and body aches throughout the day and night and continue to still have both

"Tingling throat; This is a spontaneous report from a contactable physician. This physician reported the same event for two patients. This is the first of two reports. A patient of unspecified age and gender received the first dose of the bnt162b2 (BNT162B2; also reported as COVID-19 vaccine; unknown lot number, NDC number and expiration date), via an unspecified route of administration on an unspecified date at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. It was also reported that it was unknown if other products were received or if an investigation assessment was performed. On 16Dec2020, the patient experienced: tingling throat (non-serious). The physician called regarding the COVID-19 vaccine since they had two events that happened on 16Dec2020; however, the physician stated she needed to ask a question before speaking with Pfizer's Drug Safety Unit (DSU) and reporting the events. The physician stated that two patients reported tingling in their throats during the observation period after the vaccine was administered. The physician thought ""they just panicked and overreacted "" and she did not think they had a reaction. The patients did go the ER (emergency room) and were discharged the same day. The physician wanted to be able to give the second dose. The physician wanted to ask about the side effects

of the vaccine. The outcome of the event was unknown. The batch/lot numbers for the vaccine, BNT162B2, were not provided and will be requested during follow up. ; Sender's Comments: Linked Report(s) : US-PFIZER INC-2020504906 same reporter/drug/event, different patient"

Fevers, headache, fatigue, myalgia about 12 hours after vaccine.

fever/mild side effect of fever; This is a spontaneous report from a contactable other healthcare professional (HCP, patient himself) via Medical information team. A 24-year-old male patient received the first dose of BNT162B2 (Pfizer-BioNTech COVID-19 mRNA vaccine; NDC/batch/lot number and expiration date were unknown), via an unspecified route of administration on the left shoulder on 17Dec2020 at 13:30 at a single dose for COVID-19 immunization. The patient had no medical history. There were no concomitant medications. The patient previously received a flu shot [influenza vaccine (INFLUENZA)] for immunization when he was a kid (a long time ago) and experienced the same reaction, fever. The patient was having a fever/mild side effect of fever on 18Dec2020. He said he just called the number on the packet they gave him at the site, where he got the vaccine and he was wondering if it was okay to take ibuprofen. He did not think they provided him with an NDC, lot, and expiration as it was not on the packet he got; he said they might have put the information on the little card they gave him, but he did not have it with him at the time of the report. He did not know the dose that he was administered. This was the first injection with this COVID 19 vaccine. He further stated that fever started on 18Dec2020; when he woke up, it was like that, but he woke up at 9AM. The event did not require a visit to an emergency room or physician office. The patient had no prior vaccinations (within 4 weeks). The patient had no investigation assessment. Therapeutic measures were taken as a result of fever/mild side effect of fever. The patient was not recovered from the event. No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.

headache, fatigue, fever

Symptoms include light headedness that was immediate; 30 minutes later had a headache and neck pain; 30 minutes later had a headache and neck pain; Diarrhea started 2 hours after the shot and now symptoms are improving.; This is a spontaneous report from a contactable nurse. A patient of unspecified age and gender received bnt162b2 (BNT162B2), via an unspecified route of administration on an unspecified date at a single dose for COVID-19 immunisation. Medical history and concomitant medications were not reported. On an unspecified date, the patient had symptoms that include light headedness that was immediate, 30 minutes later patient had a headache and neck pain, and then diarrhea started 2 hours after the shot and now symptoms were improving. Clinical outcome of headache was not recovered while for the other events was recovering. Information on the lot/batch number has been requested.

Fatigue and severe headache x 2 days. Moderate arm pain x 4 days. Slept for 2 days straight

Mild headache; injection site soreness; This is a spontaneous report from a contactable consumer. A 48-year-old female patient received the 1st dose of bnt162b2 (BNT162B2, Lot # EH9899) at single dose at left arm on 17Dec2020 for an immunization, at Doctor's office/urgent care. The patient medical history and concomitant medications were not reported. No known allergies. Prior to vaccination, the patient

was not diagnosed with COVID-19. The patient had not received other vaccines within 4 weeks prior to the COVID vaccine. The patient experienced mild headache and injection site soreness on 17Dec2020. The patient received no treatment. Since the vaccination, the patient has not been tested for COVID-19. The outcome of events was recovered in Dec2020. The events were assessed as non-serious.

Low grade temperature of 100.6 Friday at 1:30am; This is a spontaneous report from a contactable nurse reporting for herself. This 28-year-old female patient received on 16Dec2020 08:00 first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) at single dose in the left arm for COVID-19 immunization. Medical history and concomitant medications were not reported. On 18Dec2020 01:30 am, the patient had low grade temperature of 100.6 F. The patient recovered in Dec2020 without treatment. Information on the lot/batch number has been requested.

Nauseated; This is a spontaneous report from a contactable nurse (patient). A 54-year-old female patient received bnt162b2 (BNT162B2, Batch/lot # EK5730, Exp date Mar2021) at single dose at right deltoid on 17Dec2020 08:15 for immunization, administered at hospital. Medical history was none. There were no concomitant medications. No additional vaccines administered on same date of BNT162B2. The patient had not received any other vaccines within 4 weeks prior to the COVID vaccine. No adverse events followed prior vaccinations. The patient was really nauseated last night on 17Dec2020 from 21:00 and has been slightly nauseated 18Dec2020. The outcome of event was recovering. The event was assessed as non-serious.

Hives in her face; This is a spontaneous report from a contactable consumer (patient). A female patient of an unspecified age received BNT162B2 (Pfizer-Biontech covid-19 vaccine, Lot. PAA156051-EK5730) on 18Dec2020 at 10:15, at single dose, for COVID-19 immunisation. The vaccine was administered at hospital. Relevant medical history was none. Concomitant medications were unknown. On 18Dec2020, the patient experienced hives in her face. The patient was treated with diphenhydramine hydrochloride (BENADRYL). Clinical outcome of the adverse event was unknown at time of this report.

Mildly sore arm where injection; This is a spontaneous report from a contactable physician (patient) through a Pfizer sales representative. A patient of an unspecified age and gender received BNT162B2 (Pfizer-Biontech covid-19 vaccine) on an unspecified date, at single dose, for COVID-19 immunisation. Relevant medical history and concomitant medications were unknown. On an unspecified date, one day after the vaccination, the patient experienced mildly sore arm where injection of vaccine was given. Clinical outcome of the event was unknown at time of this report. Information on the lot/batch number has been requested.

Mild headache; This is a spontaneous report from a contactable consumer (patient) through a Pfizer sales representative. A 32-year-old female patient received the first dose of BNT162B2 (Pfizer-Biontech covid-19 vaccine) on an unspecified date, at single dose, for COVID-19 immunisation. Relevant medical history and concomitant medications were unknown. On an unspecified date, the patient experienced mild headache within 45 minutes of first Covid vaccine. Clinical outcome of the event was unknown at time of this report. Information on the Lot/Batch number has been requested.

sore arm; This is a spontaneous report from a contactable pharmacist. A male patient (physician) of an unspecified age received the bnt162b2 (BNT162B2; also reported as Pfizer-BioNTech COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. On an unspecified date, the patient experienced sore arm (non-serious). The clinical outcome of the event was unknown. No follow-up attempts are possible; information about batch/lot number cannot be obtained.

headache and feeling overheated; headache and feeling overheated; fatigue; GI symptoms; loose stool; gas; mild tightness but not so much like a cramp; This is a spontaneous report from non-contactable physician via a Pfizer Sales Representative. A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration, in Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced headache and feeling overheated, fatigue, gastrointestinal (GI) symptoms, loose stool, gas, mild tightness but not so much like a cramp in Dec2020. The clinical course was reported as follows: The patient was symptom free for the first 20 hours after vaccination, had mild symptoms from the 20-28 hour mark, and felt fine since then. The patient woke up at 3:30 in the morning one day (day of reporting) with a headache and feeling overheated. The temperature was checked several times on an unspecified date, with no fever. For the next 3-4 hours, there were a wave of symptoms; mostly a headache, fatigue, and GI symptoms. The symptoms responded pretty well to increasing water intake, taking an electrolyte supplement (MANUFACTURER UNKNOWN), and breakfast. The patient also had gas, loose stool, and mild tightness but not so much like a cramp. Therapeutic measures were taken as a result of the events as aforementioned. The clinical outcome of headache and feeling overheated, fatigue, GI symptoms, loose stool, gas, mild tightness but not so much like a cramp was unknown. No follow-up attempts are possible; information about batch/lot number cannot be obtained.

Intractable nausea and vomiting with excruciating stomach pain for 4 hours - only relieved by Zofran.

patient complained of burning when vaccine was being injected. no swelling or redness noted.

Woke up from a dead sleep in extreme joint pain at 1:20 am. (Almost went to the er as I have never had pain like this) Finally went back to sleep woke up at 7:30 am. No pain.

"""Patient was given their first COVID-19 vaccine dose. Patient was given VIS sheet and informed of all potential side effects and when to seek emergent care. Patient was given a follow-up plan and scheduled for administration of second dose. Patient tolerated procedure well. At 15 minutes post vaccine 1147 patient reports that she had just experienced chest pain sharp on left side of chest followed by nausea and slight sensation of tightness in her throat. She reports this lasted about 30 seconds and then subsided and went away. Vitals taken BP 118/76 HR 66 R 16 pulse ox 100% on room air. Patient denies any cardiac history and no history of allergic reaction in past to any medications or injections. Vaccine was given in right deltoid. She was monitored an additional 15 minutes with during which time she was asymptomatic. I consulted with ARNP provider across the hall in care clinic prior to letting patient leave clinic and she was agreeable with plan of care. Patient was advised is symptoms

chest pain, tightness in chest, any shortness of breath she needs to seek emergent care by calling 911. She communicated understanding. Patient discharged to home."""

Injection site pain; tiredness; headache; muscle pain; chills; joint pain; nausea;

Patient complained of burning on injection. No redness or swelling noted.

"Employee received covid19 vaccine without issue. At discharge became diaphoretic and tachycardia. Medical proceed out called and ED team arrived. On arrival vital signs patient was hypertensive, A&O x3, able to answer questions. ED offered to transport employee to ED for observation. Employee chose to stay at the Administration Clinic to be monitored. After 30"", vital signs were within normal range, employee stated he felt fine, no tachycardia, no diaphoresis. Ambulated out of department with out issue."

I didnt notice but evidently my eyes changed because the CNO looked at me and asked if I was ok. Im not sure of what they looked like to make her cue in on I wasnt feeling well but she came over and began to monitor me at that time. I felt light and fluffy and when I got up to get juice I felt like I was disassociated from my body, my movements were awkward, I was severely weak and was not steady on my feel. I felt as if my mind was moving but my body couldnt keep up. I was very laggy and felt as if I was intoxicated. The head of the ER made me drink alot of cold water about 24oz of water and 4 oz of juice which then caused me to get super cold and shivery. Vitals were stable the whole time but my BP shot up to 170/90 a few moments after the water. I was transferred to a monitoring room where I was covered with alot of blankets and allowed to lay down until I warmed up until my BP lowered and I was released. My arm didnt begin to hurt until about 6-8 hours after and I have a red mark and the top layer of skin just do not want to heal. I am still today having to put bandages on the spot because its red and the skin on top keeps coming off. I had joint pain and aches into the next day after causing me to take an Aleve gelcap for the pain. Nausea here and there also.

Sore/Itchy throat - 25mg Benadryl IM. Relief 8 minutes post Benadryl

"Patient received Pfizer -BioNTech COVID-19 vaccine in the clinic. At check out, patient reported 'heart racing, dizziness, and feeling flushed"" ED Proceed Out called. Patient evaluated by ED team. Patient transported to ED for further monitoring. In ED, patient complained of mild throat tightness which was resolved by Benadryl. patient was monitored for 4 hours and was discharged home on benadryl"

12/22/2020 08:00 AM Nausea, chills, slight headache, sore arm; 12/23/2020 symptoms have slightly relieved

patient complained of burning while vaccine was being injected

Notified by girlfriend. Patient woke up this morning with arm soreness. States temperature 102.3 this am. Instructed to call primary care. Instructed patient could have COVID or flu not related to shot. Waited 30 minutes post vaccination, without complication.

panic attack sunday night around 1030-11pm. Had to seek treatment from my family physician to get some antianxiety pills. As of 12/23/20 I still wake up with severe anxiousness. If COVID weren't around I would have went to the ER. I have never experienced anything like that in all my life.

Vomiting, Cheeks feel tingling, Slight difficulty swallowing. Rest and will take oral Benadryl when gets home. Will take Phenergan for nausea when gets home as well. Starting to feel better after 2 hours.

recipient became flush and began itching all over

Recieved the vaccine 12/21 and on the evening of 12/22 my arm became very sore, more than usual for other shots such as the flu shot I received in October this year. It kept me awake it hurts at the injection site down to my middle finger and up my neck. No redness or swelling that I could see. No fever that I can tell.

Approx 10 min after receiving vaccine- patient developed rash and hives on neck and chest with complaints of itchiness on R arm at vaccine site. Also developed redness to right ear. no respiratory difficulties noted. Patient transported to ED for further evaluation and treatment

After administration of COVID vaccine - pfizer, patient noted that he didn't feel that it went into the deltoid, that the injection site had been too low. Questioned if he should be administered another dose. No symptoms. consulted with other clinic staff, ID oversite and will follow-up to determine if patient develops appropriate response to vaccine or if will require additional vaccination

*Describe the adverse event(s), treatment, and outcome(s), if any: (symptoms, signs, time course, etc.) S: 35 yo F who received Pfizer vaccine at 16:47 w/acute onset of left sided facial swelling and difficulty swallowing. Within five minutes of being administered vaccination, pt reported pain at the injection site radiating up to her jaw followed by left sided facial swelling. She started reported palpitations and subsequently reported a ball in her throat O: Pulse was in the 60's, BP of 128/72, pulse of 88-97 satting at 99% on RA. General: young female, anxious. HEENT: NC, AT, mild left sided cheek swelling, OP clear, MMM. Neck: Supple, left sided tender cervical LN. Lungs: CTAB. CV: tachycardic rate, regular rhythm. Extremities: Hands are clenched and cold. Neuro: Alert & oriented. A/P: Anaphylaxis -Given left facial swelling, 25 mg Benadryl PO administered. pt tolerated well. -17:22-Throat swelling reported. EPI #1 administered right thigh. -17:32-EPI #2 administered. Throat felt better at 17:35. 17:36-FD EMS arrived. BP 194/126. -17:38-EPI #3 administered right thigh. HR 135, BP 154/105. -17:43-EPI #4 administered left thigh. -17:46 pt transported to ER via EMS.

Warm feeling to face and ears. Tingling or burning feeling to face. Started 25 minutes after injection. still with mild tingling. No breathing issues.

Severe itching, irritation, took oral Benadryl, proceeded to nearest Emergency Room

Headache, nausea, chills, runny nose, cough

"employee initially complained of itching on arms, noted slight redness bilaterally upper arms. itching progressed to neck slight redness noted around neck area. complained of feeling ""hot"",Denied

difficulty swallowing. Placed in room and Rapid Response called. Given Epi injection in right upper thigh, INT inserted. and Bendryl 50mg IV, solumedrol 125 mg IV, and Pepid 20 mg IV given IVP. placed on EKG and B\P monitor. RR nurse and Covid Nurse at Bedside. employee transported to ER for continued observation. Client remains alert, talking via transfer to ER. continues to complain of some ""itching"""

Mild rash on bilateral upper extremities, non-pruritic rash. No associated symptoms or shortness of breath.

1300 Recipient had transiet HR of 136 sustained for 5 min. Tachycardia started during 15 min. observation period. HR stabilized to baseline 80's by 8PM.

Patient called Employee Health department c/o diarrhea, cough + headache one day after receiving vaccine.

Flush, throat itchiness, red Tx Benadryl IV, EpiPen 1mg IM, Solu-medrol

Patient with hx of SVT stood up after receiving COVID-19 vaccine and did not feel well - sat back down. put pulse ox on and HR was 180. Pt vagaled twice, HR sitting in the 90s - brought to ED for evaluation.

Fever body aches chills fatigue starting 16 hrs after vaccine. Symptoms continued for 4 days after vaccine before reducing in severity. All symptoms still present today, 5th day after vaccine . Max temp recorded 100.7

After receiving the vaccine, the patient developed a hard quarter sized bump above the injection site. Ice applied to site. No bruising, bleeding, pain, or redness noticed.

Patient received vaccine during the day and overnight pateint developed chills, rigors, headache and body aches. Tylenol has helped a little but did not completely resolve symptoms

About 30-40 minutes after patient received COVID-19 vaccine, she felt that she was having difficulty swallowing. Denied respiratory distress. Some swelling felt in middle of throat. No fever, chills, pain, shortness of breath or wheezing.

facial swelling, numbness in face, red patches on neck and face.

Headache with Pressure on eyes, body aches

Woke up with severe bodyaches worse on injection site with fever of 100.6 degrees farenheit.

Next day after vaccination redness and swelling to injection site. Later that day and still today redness, swelling and now itching.

On the date of the vaccine that night my blood pressure went up to 143/130 which is higher than it has ever been. My blood pressure the bottom number would not go under 100. The entire night my head felt like I was in a tunnel and my heart and chest felt tight. I was unable to work the following day due to not getting any sleep out of fear of something tragic happening to me. In addition last night or early this morning at 3 AM I woke up and my body was itching all over. The palms of my hands were itching my

gums were itching I had red marks on my body and had Not done anything out of the ordinary or eight anything out of the ordinary. I took two Benadryl?s and was able to fall back to sleep for a little while and now the itching has stopped but my eyes are swollen.

dizziness, chest tightness, light headedness, SOB

Lightheaded, dizziness, flushed face, sweating

Patient experienced severe symptoms such as severe headache, severe myalgias, brain fog, and dizziness. Upon waking up currently he is currently fine, but symptoms yesterday were very severe

Past 24hours after being vaccinated, I got home from work and realized I had a rash over my stomach and both arm. Felt achy and had a sore throat. The rash was tiny red spots all over. I still have rash on me today, and same symptoms. It has not gotten any worse.

12/22/2020 07:00PM Rash on back

RASH ON FACE, NECK, CHEST AND ARMS. MILD NAUSEAS AND ELEVATED BLOOD PRESSURE. TREATED WITH BENADRYL 50MG IV. RASH LASTED 15 MINUTES AFTER IV TREATEMENT.

About 5 min after receiving the vaccine, I got dizzy, 15 min after I stumbled after I tried to stand up. I have not had breakfast so they thought could be low blood sugar, and gave me some trail mix with m&ms and water. About 40 min after that I stated jerking and then they called the MERT team (emergency) and was transferred to the ER. My speech was delayed. They gave me clonapin and it stopped maybe between 20-30 min later. I believe it was all caused my my PNES. Somehow the vax triggered it, it has been in control for over 2 years. After that I was just fatigued for 24 hrs later. Now I am fine

12/23@9:35am EST- Caller stated on12/22/20 at midnight he felt fever 103.0, chills, muscle soreness and aching, nausea and extreme fatigue. Caller called Primary and was told to take Tylenol 1gr. Benadryl and naproxen for headache and body aches. Rash covered arms , neck and thighs and patika on elbow and armpit. This morning rash is still prominent, eyes are swollen and urine is bright red. Caller is awaiting primary to call back.

Itching started on left arm and then around the temples of the head and on right shoulder.

Sore arm, fever (Max 100.5), body aches, chills, headache, fatigue, general malaise

Itching started on left arm and then around the temples of the head and on right shoulder.

Patient descrived a metallic taste in her mouth 10 minutes after getting the COVID19 Vaccine. Soon after, she described the posterior left side of her tongue was feeling numb. No itching of throat, no swelling of lip or tongue. No respiratory or GI symtpoms. No urticaria or pruritis. She was treated with loratadine 10 mg and famotidine 20 mg orally. She was observed for 2 hours with no progression or additional symptoms. She was discharged to home.

Pfizer-BioNTech COVID - 19 Vaccine EUA Had injection at about 1230 on 12/22/20, woke up at 6am on 12/23/20 with chills, fever of 100.1, headache, dizziness, body aches, sore arm. I had COVID 3 months ago and some of these side effects are worse now then when I had COVID.

12-22-2020 1am- arm soreness at sight 12-22-2020 7 am -arm, armpit, and chest muscle soreness 12-22-2020 1 pm chills, muscle pinches , shooting muscle pain (legs, body upper body) 12-22-2020 4 pm additional pain in right toes along with same symptoms above, facial muscle pain, irritable, tiredness 12-22-2020 10 pm headache

Patient feels metalic taste on the right side of her tongue, along with pain behind the right eye.

approximately 12 hours after receiving the Covid 19 vaccine on 12/18 that I had nausea and vomiting. The vomiting lasted about 2 hours from approx 5:30 AM to 7:30 AM on 12/19. Also, I was extremely fatigued for the rest of 12/19. I slept the entire day only being awake for approx 4 hours. The next day I was slightly nauseated but able to go about my day as normal.

Shingles, left T4 dermatome. Treated with valacyclovir. Adequate response to treatment.

urticarial rash to bilateral upper extremities

swollen and painful testicle

12/21/2020 2:20PM Facial spasms, left side of face-- eye, nose, lip (prominent) - occurring for minutes at time, symptoms have not resolved

First day I was in PPE I started to get really hot , trouble breathing , feeling flu like symptoms Second day . was extremely hot, trouble breathing again , Tiredness , chills, headaches ,

tiredness, muscle ache for approximately 12 to 14 hours

Patient was given covid vaccine, and within 3 minutes, began to develop tachycardia. Patient was placed in chair to be assessed, vital signs done. HR was 160 to begin, dropping to 140, and 117 when being transported to ED for evaluation. Patient stated that she felt like her chest was on fire, and heart was going to beat out of chest. Rapid Response Team called, and team responded, bringing patient to ED for closer evaluation. From the ER MD: 39 year old female patient who was a rapid response after receiving her Covid vaccination. She began to have palpitations and was tachycardic. She appeared to be very tremulous and anxious. She has no known history of allergic reactions. She denies recent illnesses including fevers and chills. Patient felt short of breath. She had an O2 sat of 100% on room air. Lorazepam 1mg po x1 dose ordered and was administered.

Patient felt like back of tongue swelling and itchy ~ 15 min after administration Patient received 12.5 mg Benadryl, 125 mg soul-Medrol in ED Sent home with an epi pen and steroids x 4 days

Reported fever of 100.8, nausea, headache, chills, arm pain- which is common reported side effects of vaccine. Patient reported walking up in the middle of the nights gasping for air- short of breath. Only lasted 3 times during the night, no interventions were done. Went away on it's own.

c/o (L) cheek NUmbness 3/10 scale at 9:50 AM BP 118/52, 100, 20, 98% RA. Rechecked VS at 9:57 BP 127/77, 91, 18, 98% RA. (L) cheek numbness 2/10 scale. Rechecked VS at 10:11 AM BP 137/83, 91, 18, 99% RA (L) cheek numbness 2/10 scale.

2-3 MINS after vacciNE Administered SHE BEGAN TO EXPERIENCE SHORTNESS OF BREATH FEELING OF A FUZZY TONGUE & DIFFICULTY SWalloWING. SHE WAS SEEN IN ED WHERE SHE gOT Benadryl & DECADRON

Patient c/o feeling dizzy + lightheaded 10 minutes after receiving vaccine. Treated in ER

Employee presented to COVID Clinic for Moderna COVID 19 vaccination 1st dose. Given to right arm. Left clinic after waiting 15 minute observation time. She returned to work and returned about 45 minutes reporting she was having difficulty taking deep breaths, numbness to bilateral extremities, abdominal discomfort and lightheaded, NO rash or hives noted. VSS stable A&O, Within a few minutes employee started vomiting, shaking, and C/O of severe abdominal discomfort, Epinephrine injection 0.5mg given to left arm. Employee transported to ED.

Employee presented to COVID Clinic for Moderna COVID 19 vaccination 1st dose. Given to left arm. Left clinic prior to completing 15 minute observation time and told an MA in waiting area that she felt ill ot her stomach and having trouble taking deep breaths. Employee found in nearby Bathroom sitting on the floor, she had vomited, reported she was lightheaded, couldn't breath, shaking, abdominal discomfort sweating, attempted to move employee to wheelchair, did respond well to transfer to Wheelchair, She reported symptoms worsening: HA, abdominal pain and developed blotchy skin, hyperventilating, and dizzy. CODE Blue called, patient given Epinephrine injection 0.5mg patient sent to ER

Employee presented for COVID 19 vaccination: Survey reviewed, no history of Anaphylaxis reaction Moderna 1st dose given today to Left arm. She immediately developed Numbness to her body, chest tightness, and abdominal discomfort. Remained Alert and oriented, voiced concerned she felt like she was going to pass out. She developed blotchy skin to chest and neck area within minutes of injection. Patient sat in a wheelchair. Vital taken: BP 140/98 Pulse 123, given water to drink, tolerated well. She quickly reported she continued with above stated ymptoms, and continued with nausea, blotchy skin, heart racing and weakness. She was given 0.3mg of Epinephrine IM to right arm and taken to the ED

Patient reporting pressure behind both of her eyes and some mild eye pain with extraocular movements. Patient also had generalized myalgias, arm soreness where vaccine was administered along with some chills.

tingling in throat, swelling of tongue Became very anxious upper lip swelling

Seen in urgent care approx. 30 minutes after vaccination for diffuse muscle aches, nausea and dizziness, her BP was elevated. Treatment dugs:

The day after vaccination development of abdominal cramping, urgency, repeated episodes of diarrhea. Some nausea, no vomiting. Abdominal cramping still episodic 3 days later. No fever.

Patient began feeling lip numbness shortly after receiving the vaccine. Patient reported feeling tightness in throat that felt like muscle tightening, not airway compromise. Refused IM epinephrine. Patient awake, alert, mild symptoms. Patient given water and is resting. 0704 HR 70, oxygen saturation per pulse oximetry 95%, BP 130/70. 0712 BP110/80, pulse 80, 0732 BP 116/74 and 25 mg Benadryl given. At 0830 lip tingling and throat symptoms have resolved. Patient report lips feel cool, but all other symptoms have resolved.

Woke up the morning after receiving vaccine with some queasiness, and stomach gurgling. Still having the queasiness and gurgling. No diarrhea or vomiting.

Development of flushing, hives, throat and tongue swelling, difficulty breathing, all developed within 30 min of administration, and resolved after admin of epinephrine and IM Benadryl.

Employee had tongue tingling after injection denies swelling, SOB, chest pain. She waited 30 minutes and declined ED evaluation there were no further symptoms after observation.

3hrs after had normal arm pain. 1030 am following day woke up with shivers, soo cold my bones of my spine and arms were hurting. Headache, dizziness and heart rate over 130 (normally low 60s)

she has a cough and itchy throat.

Client received Pfizer COVID vaccine at approximately 8:42am and reported that he immediately felt tingling in upper left leg/ hip area. The tingling continued and moved down his leg to his foot. First Aid and EMS assessed client. V/S WNL. Client given aspirin and leg massage. Client declined transport to ED for further evaluation. The tingling remained only in foot at time client left.

rash on chest and neck progressing to numbness & tingling of face & tongue. Went to ED, treated with Benadryl, solumedrol, famotidine. some improvement after med administration & observation. Pt sent home with steroid rx & Benadryl.

Woke up this morning with dizziness, weakness, headache, aches. Unable to come to work.

Muscle and joint pain, headache, vomiting (could be from the headache), fatigue, shortness of breath.

Sore throat, swollen lymph nodes in the neck

muscle and shoulder pain, with warmth and redness, congestion, headache, R leg soreness, with redness and warmth

This morning 12/23/20, the site is very tender and very sore.

2 Hours after vaccinated I felt hot from my neck to my head, with slight headache. went away after 3H. Had chills, slight fever and Body aches that night. Took Advil 400mg, felt better. The following day the site of injection was sore, felt warm, temperature was 99.9 degrees F, had chills and sneezing, like my seasonal allergies, with body aches. Took Advil 400mg and Zyrtec. Felt better. Today I had body aches and soreness @ the site of injection. Took Advil 400mg, now I am feeling better.

lightheadedness & dizziness soon after receiving vaccine - went to ED for evaluation

"Approximately 1-2 minutes after vaccination she felt a ""fullness"" in her throat, Felt ""woozy"" and ""altered"". given 25mg Benedryl with lessening of symptoms."

Patient was vaccinated and within just a few minutes of vaccine administration began to feel throat tightening, difficulty getting air, tachycardia, and dry mouth. Admitted to a past history of anaphylaxis with shell fish and endorses similar symptoms. Employee was treated with an epi pen and taken to the emergency room for additional monitoring and treatment as needed Treatment dugs:

Sore arm Fever 99.9 took Tylenol and it went away.

Vaccine at 1245pm on 12/16/2020, severe migraine 12/16/2020 at 6pm vomiting 8pm 12/16/2020 both continued all night and the next day 12/17/2020 I couldn?t eat or drink I would vomit it back up even water, went to Urgent care at 11:30am 12/17/2020 where they covid tested me with a Rapid swab and a PCR swab, gave me zofran for the nausea and a shot of Troradol for the migraine, called me in a prescription for Zofran and Ibprophen 800mg. Couldn?t work that night due to still feeling ill tired and weak, and dealing with the headache. 12/18/2020 no more vomiting or headache just feeling extremely tired and drained, slept most of the day and started having stomach cramps became constipated so I had to take Miralax and use a suppository and stool softener, 12/19/2020 finally went to the restroom and after that had diarrhea for the rest of the day. All symptoms subsided by 12/21/2020.

""" injection site red hot swollen and itching getting worse. having symptoms of nausea, vomiting, tired and a headache that feels like a migraine."""

Developed fever 4 days after vaccination. This patient also had a tonsillectomy done on 12/17/20 and it is unclear if fever was due to post-operative infection. No other symptoms.

The healthcare worker felt a systemic sensation of warmth and tingling throughout the entire body immediately following injection. The sensation of warmth remained with onset of weakness and dizziness requiring rest period. Noticeable rubor- flushed skin on the chest and torso area. Weakness followed by episode of tachycardia and pulse rate of 120 bpm. Episode lasted 30 minutes and fully resolved with no residual effects. No emergency or follow up medical treatment needed.

Immediate reactions were slight fuzziness of vision lasting approximately 30 minutes and body fatigue throughout the day (12/22/2020). At 2:30am I suffered from diarrhea and nausea lasting approximately 2 hours. I woke up at 9:00 am (12/23/2020) with a lowgrade fever of 99.0F.

day after vaccine started to have sweats, body ache, headache, fever. Self resolved after 24 hours. Did not report until 12/23/20 at 10:40. vaccine recipient completing RL

Right eye became heavy within 2 minutes of receiving vaccine and resolved 20 minutes following injection. No visible deficit. Bilateral eye blurring R>L that has lasted for 2+ hours following injection.

Soreness on injection site Chills Body aches Fever101

Stuffy nose-resolved. States that's the first symptom she has with any reaction body aches, injection site pain

15 mins after arm pain , neck pain, headache, cough and shortness of breath Lungs expanded Chest felt weird , took a decongested Breathing was uncomfortable took Tylenol right after for pain . Third day after lung wasn't feeling better Pain finally went away in neck and shoulder on 12/21/2020 Breathing is still not better , scheduled to see a doctor

Pfizer-BioNTech COVID-19 Vaccine EUA Injection site pain 12/22/2020 05:30 to 12/23/2020 05:30 Tiredness/Headache/Muscle pain/Chills/Fever/Feeling unwell 12/22/2020 approximately 11:15am to 12/23/2020 06:30; Took Ibuprofen on 12/22/2020 at approximately 06:15pm Minor headache 12/23/2020 06:30am; took Tylenol

Arm soreness and mild fatigue

Fever blisters appears the next day

I woke up at 2AM with a funny sensation in my esophagus, it felt tight and hot, the trouble breathing woke me up, I had chills, shaking, but no fever, extreme muscle weakness, I could barely walk steps. My main issue was the trouble breathing. Went to the ER and pulse/ox was 96/97 so it was good my oxy saturation was really good. They just observed me for some hours and by 5AM and I discharged and on Saturday I woke up ok but felt weak. I still feel some muscle weakness.

"Patient's reaction(s) noted during COVID vaccine observation period: Pt states that after 17 minutes of receiving the Covid vaccine she developed feeling of lips tingling and tongue ""prickly"". She denies SOB or dysnpea. á 1533: 180/74, HR 59, O2 98% 1544: 144/67, HR 60, O2 99%; states that her lips and tongue have stopped tingling and feel back to baseline. áActions Taken: Pt states that she is fine to drive home. áDisposition: Patient declined ED visit"

Employee had onset of chills nausea on 12/17/20, headache, body aches, fatigue, dizziness on 12/18/20 symptoms relieved by Tylenol. Treatment dugs:

12 minutes after injection developed acute onset tachycardia with HR increase from 64 to 160s (monitored on apple watch), dizziness, flushing, tachypnea. No rash, no wheezing. BP 140s-150s/90s (baseline 110s/70s). HR improved to 100s-120s in ~30 minutes and remained elevated with symptomatic orthostatics for several hours. Monitored on telemetry for ~2 hours. EKG sinus tachycardia. Given 1L NS bolus, no further treatment required. HR 80s-90s upon discharge from ER ~4.5 hours after injection

Patient had a fever of 101.0.

I was dx with possible bell palsy mainly effecting my right eye. I was prescribed prednisone and famciclovir.

diarrhea Nausea pain in upper abdomen extreme fatigue chills adverse event was over in 48 hrs

Vaccine administered at 0800. 5-10 minutes later, patient reported tightness in throat and shortness of breath. Patient became dizzy, nauseous, diaphoretic, reclined back and elevated feet. Patient was taken to emergency department for further treatment.

Patient began to experience numbness and tingling of her mouth and lips 40 mins after administration. Denies SOB, wheezing, airway compromise or oral swelling. Symptoms lasted 48-72 hours. She was prescribed a Medrol dose pack and antihistamines by her PCP.

Chest tightness and arm heaviness starting from the left arm to the right arm, with a burning sensation in the chest. Brought to the ER.

Received vaccine aprox 0745 am 12/22/2020, aprox 09:00pm 12/22/2020 while at work onset tachycardia at rest 140's-150s, , chills, flushing, and light headiness. Employee continued to work through her 12 hr shift, she advised tachycardia persisted throughout the night 140s. She reported taking Tylenol at 3am, and chills resolved. She reported to Employee Health at 0730am 12/23/2020, vitals HR 142, BP 103/72 (she advised that was her normal BP), resp 14, Temp 97.2. She denies chest pain, shortness of breath, weakness, headache, cold symptoms, n/v/d. Advised the chills, flushing and light headiness had resolved, but the tachycardia continues. Employee denies any medical history, takes no daily meds, reports recovered from COVID early November. Discussed with Employee the need to seek higher level of care, she was escorted to the ED.

Patient had a fever of 99.0.

Rash, redness, hot to the touch(fever feeling), swelling, and severe headache

Employee calling to report a reaction after receiving a COVID-19 vaccine. Vaccine Name - Pfizer Vaccine Lot # - EJ1685 Vaccine Date and time - ? 12/18/2020 @ 8:30am Is this your first or second dose? First Date and time of symptom onset - ?12/21/2020 @ 06:30am Symptoms - ? Fatigue, body ache, shortness of breath but resolved after taking albuterol breathing treatment (hx of COPD) Last day of work and shift - ? today, never missed work Home remedies? - Tylenol & Ibuprofen Any improvement? - yes Recommendation? Continue to monitor symptoms and take Tylenol as needed Employee voiced understanding Employee of information ? yes Employee voiced any concerns ? no, her manager told her to report her symptoms to vaccine support line Employee?s questions answered to employee?s satisfaction - yes

Initial c/o Lightheadedness within 15 min. of vaccine. Episodes of tachycardia 70's - 140's B/P 126/90 Patient monitored & revitaled 1620 B/P 120/72 HR IRREgular 1635 BP 120/72 HR Regular 1645 MD ON SCENE to ASSESS 1655 exited w/husbanD

EMPLOYEE STILL SYMPTOMATIC AT THE TIME OF VISIT; Treatment dugs:

nausea, headache, fever, chills

Acute change in systolic BP < 90 mmHg or > 200 mmHg and numbness

Takes promethazine for nausea and took Excedrin Migraine for her headache, has history of migraines. Low grade fever ranging from 100.1F to 100.5F

64y/o FEMALE presents to the ED for evaluation of facial itching after COVD vaccine in left arm. The patient states shortly after the vaccine (about 10 minutes) her nose and mouth started itching. She was given PO Pepcid and IM Benadryl PTA in ED. She denies any associated SOB, nausea vomiting wheezes or near syncope. Denies fever/chills, n/v/d or other complaints at this time. IMPRESSION/PROBLEM LIST:----------1. Adverse Reaction to Vaccine for COVID

37y/o FEMALE doctor was brought to the ER via gurney from the vaccination area after getting Covid 19 vaccination, patient felt SOB, buffy eye and become pale, she took immediately Claritin and Pepcid, patient was brought to the ER. she denied light headedness. Swelling of lips or the tongue. IMPRESSION ----------Adverse reaction to the Covid 19 Vaccination-Resolved

Employee was observed in emergency room for one hour Treatment dugs:

12/16/2020 - woke up at 2 in the afternoon with a sore left arm at the site of injection. (She works nights.) She also had a headache and her stomach felt bloated. She developed a temperature of 101.4 on 12/18 and it went down on Sat to 99.6. H/A, body aches and low grade temperature lingered through 12/20. She woke up feeling normal on 12/21.

Patient reported significant arm pain with the injection that within about 24 hours progresses to COVID like symptoms inclusive of vision issues (blurry, loss of peripheral vision, felt like falling), fatigue and endurance issues, resulting in lost work time second to symptoms. Patient is approximately three months post COVID infections and endorses that symptoms were similar.

44 y/o MALE doctor with no hx of allergic reaction with previous vaccination was brought to the ER from the vaccination area, patient stated he become tachycardic, dizzy and nauseated 10 min after the vaccination shot was given. Patient denied rash, SOB, wheezing or Swelling of the face and the tongue. Benadryl & Zofran given 1.Adverse Reaction to Vaccination-resolved

Nausea, headache, more SOB fatigue

Bumps on tongue

Patient's reaction(s) noted during COVID vaccine observation period: diaphoretic, pale, clammy, nausea occurred 10 minutes after vaccine administration. Pt states that she has not eaten since breakfast. á1422: 97/67, 66 BPM, O2 94% 1432: 146/93, 91 bpm, O2 96% (states she is feeling better, color in cheeks, not diaphoretic; eating cracker and drinking Sprite) 1445: 130/77, 84 BPM, 96% She states that she does not want to be further evaluated in ED. She is stable and states she is okay to drive home. Actions Taken: vitals, comfort, water, graham cracker áDisposition: Patient declined ED visit

Received the injection at 17:20 on 12/22/20 and had no immediate symptoms. At 23:00 hives and itching on chest, arms, back, and legs. Arm soreness at injection site. Soreness improved with oral

tylenol. Hives did not resolve. Asymptomatic after taking oral benadryl at approximately 7:00 on 12/23/20

Patient called vaccine clinic on 12/22/20 to report loss of bowel function. He reported that it happened on 12/21/20 on the way to work. The patient could not make it to the bathroom in time and soiled his pants. On 12/22/20 in the morning it happened again on the way to work and the patient soiled his pants. At this point the patient called the vaccine clinic with this information. The nurse at the clinic did inform the patient that there are some GI side effects that have been reported with the vaccine. She also recommended the patient get tested for Covid since GI side effects are also reported with Covid and the vaccine has not had enough time to offer immunity yet.

Pt started to complain of dizziness and feeling flushed. Pt states she has a history of SVT. Pt states the incident feels like her SVT symptoms. Pt's symptoms went away after 5 minutes. EMS was called and pt refused transport to the hospital.

"Medical History: severe anaphylactic shock requiring intubation related to rattlesnake bite August 2019. On September 2019, I went to the dentist and received septacaine, mouth and face swelled up immediately. Toxicologist said this was due to me still being in a ""cytokine storm."" 12/22/2020- I received my COVID-19 vaccine by Moderna. Within 5 minutes of me receiving the vaccine I first experienced tachycardia, felt my heart pounding, dizziness, and tunnel vision. Three hives, dime sized, appeared on my chest within 10 minutes of the vaccine. I felt difficulty swallowing (may have been anxiety related). The dizziness was intermittent for the next hour. I took 25 mg of Benadryl 15 minutes after the shot. My blood pressure was elevated for an hour, 170s/100 s, Osat maintained above 94%, and heart rate 80s-90s. My resting HR and BP are 100s/60 and HR 61. I also started to feel bloated and burping. An hour and a half after the shot, the symptoms resolved and I drove home"

Arm pain.

Irregular, skipping heartbeat, improved. Diarrhea, resolved.

hypertension, hyperglycemia, mild rash

Pfizer-BioNTech COVID-19 Vaccine EUA. This last night I experienced chills and a low grade fever, along with weakness. It doesn?t feel like I have a fever currently but weakness is still apparent.

extreme fatigue, sore throat, cough, facial swelling, extreme arm pain

Dizziness, Flush, Shortness of Breath

Onset of symptoms began approximately 1.5 hours after vaccination. Patient became weak c/o tongue swelling, nausea, difficulty breathing, numbness especially in lower extremities. Felt she couldn't breath, numbness continued to get worse and affected her upper extremities as well, weak speech.

Injection site aching, chills, body aches, fatigue, tiredness, nasal congestion. 12/23/2020 in AM All symptoms starting to resolve - feeling better; Nasal congestion, Fever 102.1, Tylenol and Ibuprofen some relief; fever at time of reporting 100.5.

The patient was doing great. After 30 min later, the pt started to have numbness on the face. Felt like the face was completely numb. Came back to clinic and numbness started to go away. It would wax and wane. It started to improve. Now the patient is doing great. Other vitals fine. NO SOB, No intervention done. Pt released home.

48 y.o female with history of atrial tachycardia who presents to the ED via EMS for a possible adverse reaction to Covid vaccine. Patient received her Covid vaccine around 1600 today, and soon became diaphoretic, shaky, and lightheaded. She had presented to the emergency department. Currently she denies any chest pain, difficulty breathing, throat swelling, tongue swelling, or any other symptoms currently except for palpitations. áAllergic Reaction The primary symptoms are shortness of breath. The primary symptoms do not include cough, abdominal pain, vomiting, dizziness or rash. The current episode started 1 to 2 hours ago. The problem has not changed since onset. The onset of the reaction was associated with a new medication. Significant symptoms also include flushing. 48-year-old female with a history of atrial septal defect, status post atrial septal defect repair in 1980. She works as a nurse at Hospital and has been experiencing increasing rapid palpitations associated with chest pain, and hypertension. With her episodes, she experiences marked lightheadedness, dyspnea, and feeling marked anxiety, as well as chest tightness. She received the COVID-19 vaccine today and while waiting in the observation room,she started feeling unwell, with rapid palpitations, associated with lightheadedness and dyspnea. She last had a sustained episode 2 - 3 weeks ago and had presented to ER and Hospital. No syncope. No orthopnea, PND or increased lower extremity swelling. Active Hospital Problems á Diagnosis ? Atrial paroxysmal tachycardia ? History of repair of atrial septal defect á á á 1. Paroxysmal atrial tachycardia in setting of prior atrial septal defect repair - she is having breakthrough episodes through flecainide/digoxin - it is likely her atrial tachycardia is related to her ASD patch. Will hold flecainide/digoxin for now, and try to schedule an ablation during her hospital admission due to highly symptomatic episodes resulting in multiple ER visits. á 2. Acute renal insufficiency - most likely pre-renal - iv fluids started. á 3. Possible COVID-19 vaccine reaction - she probably had an incidental atrial tachycardia episode post vaccine administration, rather than an actual adverse reaction. Continue to monitor.

COVID vaccine admin 1645 around 1715 sudden onset heart palpitations feels like heart racing, employee heart rate was noted to be 170s, employee was escorted to the ED. 12/23/2020 1030 spoke with Employee she advised d/c from ED last pm, this am resting heart rate 90s, but 140's-150's with ambulation. Denies chest pain, shortness of breath, palpitations, cold symptoms, n/v/d. Has reported moderate fatigue this am.

Loose stool on 12/20/20, post nasal drip 12/21/20, nasal and chest congestion, fever of 100.7 on 12/22/20.

injection site soreness, mild headache, fatigue, muscle aches with hear palpitations x 2 days then it started to improve and resolved on day 3. I am also breastfeeding an infant. There were mild heart palpitations the day prior to getting vaccine as well, which are not uncommon to patient during times of stress.

At 0030 (about 12 hours after receiving shot), awoke to sudden development of severe epigastric pain, severe headache, fever (temp 101 F, maximum later at 102 F), and rigors. Rigors quickly abated, while abdominal pain, fever and headache maintained for next 12 to 14 hours. Abdominal pain was unrelenting, could not sit up, work, sleep, or interact. Mild nausea, no vomiting or diarrhea. Pulse ox 99%, pulse in the high 90s (baseline 50s). Took 325 mg acetaminophen at about 1100 (11 hours after symptom onset) with mild relief. Experienced more relief by about 1500. Was able to eat a small meal about 1700. Mild post-flu-like symptoms the next day, and no symptoms after that.

Tachycardia, rate 135

Patient reports having horrible symptoms such as sweats, chills, bad HA, nausea and vomiting, arm pain, extreme fatigue and tachycardia. She states she feels much better now and is taking Motrin for the HA.

I received the first Pfizer Covid 19 vaccine on 12/22/2020 at Hospital. I woke up on 12/23/2020 with a fever of 102 degrees, body aches and headache. I was advised by Employee Health that if my symptoms are still bad that I should follow established protocol and take the next day off of work. December 23rd is my normal day off of work. I am scheduled to work on December 24th. I was also advised that if I felt I could work with a fever that I should go into work tomorrow. I filled out a form and a Covid 19 questionnaire. Someone is supposed to call me within 24-48 hours. I suppose I should take Tylenol for the fever/headache. Employee Health had no advise for me as to what I should do for the symptoms.

Caller stated that 30 minutes after vaccine she developed tingling sensation in lips and feet. Rash over the chest and back. Caller took Benadryl 25mg . Caller stated that symptoms lasted about 1hr and half. Symptoms have subsided. Vaers report successfully completed over phone

Staff member complained of a stiff arm. Was seen by Dr. and advised to see personal physician if problem persists. Stuff arm went away.

Patient began with hives and itching all over. Patient given 50mg IM Benadryl Patient watched for 40 minutes. All sx improved.

Dizziness, nausea, vomiting. Elevated BP. Shortness of breath. Headache. Went to ER, improved with solumedrol.

Patient reported experiencing fever, night sweats and nausea. Patient called out from work next day due to symptoms.

I received the vaccine and the sat to wait the 15 minutes of observation. Within 5 minutes of receiving the vaccine I started to feel flushed and felt my heart rate increasing . They took my vitals and my heart rate increased to 175. I was taken to the Emergency room. Given IV fluids, IV benadryl, and monitored.

My heart rate came down but continues to stat at 90-100s at rest. Almost 24 hours in now and I am very weak with no energy. I still get dizzy intermittently and my heart rate increases easily.

fatigue ,headache ,myalgia ,arthralgia ,diarrhea , stomach ache ,bloating & blood pressure dropped down . still have stomach ache , bloating & low blood pressure

Headache started a couple of hours after the vaccine . Tried 600 mg of Motrin that evening. The next morning still had headache tried excedrin. 6 hours later tried zomig. Still have the headache.

Patient had metal taste in mouth upon administration of vaccine that lasted the duration of patient's observation period of 15 minutes.

Tongue tingling and throat swelling

Diarrhea and stomach issues. They were resolved by 8pm. I took an Covid Test and it was negative

12pm started feeling fatigue and sickness throughout body. 3pm nausea. 6pm body aches and chills. Slept horribly like I was getting the flu. Up at 4:30am to go to work. Still fatigue, nausea, chills and some little bit of upper back pain, between shoulder blades. Went home early today from work.

Pt stated experiencing the onset of itching in her left arm and face after receiving the Covid vaccine in her left arm. Pt also stated experiencing a mild episode of feeling light headed after the administration of Covid vaccine. No Redness, Swelling, or Rash at injection site or on face. 25mg Benedryl administered p.o. at 9:21am.

Migraines, body aches, severely sore Lt arm, extremely fatigued, nausea, and congestion

Migraines, body aches, severely sore Lt arm, extremely fatigued, nausea, and congestion

Fever 27 hours after injection. Started with chills prior to me checking my temperature.

3 hrs after shot: chills, fever 100.7, joint pain, muscle aches, headache pain in upper left arm

injection site pain, L arm pain resolved in 24 hours

c/o dizziness, HA, nausea, went to ED on 12/18 for tx, will f/u with rheumatologist on 12/21

Soreness had spread to neck at 6:45 when patient woke up

The day after I received the vaccine I noticed some redness and swelling at the injection site. Over the next 2 day the swelling increased to about 2-2.5 inches in diameter and became itchy. At the time this form was filled out, the swelling had decreased to about 1.5 inches in diameter but the redness had not decreased and there was still mild itching at times.

Moderna COVID-19 Vaccine EUA Left arm pain started 15 min post vaccination and has not subsided. General fatigue started 2 hours post vaccination and has not subsided. Nausea started 5 hours post vaccination and subsided by 4:45AM the following day. Tinnitus usually sits at 2 on a scale of 1 to 10

with 10 being obnoxiously loud and distracting causing lack of concentration. Tinnitus started to increase 2 hours post vaccination and topped out at about 8 at around 6 hours post vaccination. Could not sleep well and maybe got 2 hours of sleep due to tinnitus and increasing left arm pain.

Some burning, discomfort in the injection site within the first 15 minutes, which dissipated after about an hour later. Some itching/irritation in the back of the throat, about 30 minutes after injection, that turned into a inflamed/sore tonsil on the right side around 8:00pm in the evening. Waking this morning the day after, around 7:00am, the soreness and irritation in the throat is on both sides, but has dissipated after a few hours, and drinking dome water. My arm has increased soreness the next day, described as a dull ache at rest, and painful with movement. I also have a residual headache that has not dissipated since waking up, but is barely noticeable, and will treat most of these side effects with Ibuprofen.

Patient noticed mild tingling and itching after vaccine was given. Patient denies the need for any medications or creams to treat her reaction.

Systemic: Rash (other than injection site)-Mild, Systemic: Headache-Mild, Systemic: EpiPen was given by nurse. Her vitals were fine 140/82, Oxy 98%. 2 benadryls were also given. Pt will be pretreated before second dose

Staff member felt a buzzing sensation was concerned that she may be having an anaphylactic reaction. She took a Benadryl and called 911. EMTs evaluated her and determined that she was fine. No further follow-up was needed.

None. Resident was given Shingrix vaccine (2nd dose in series) on 12/14/2020

fever, malaise, light headedness-- taking Tylenol

Patient felt chilled and very tired. She started falling asleep while sitting upright. She also became acutely confused and could not identify what year it is, what her phone code was, etc. 911 was notified, but pt felt better about an hour later and did not go to the emergency department for evaluation.

Sensation of palpitations. Then, she felt warm and flushed.

12 hours after dose - headache and bodyaches 18 horus after 1st dose - rigors, chills, hot flashes (flushing). Severe sore arm (could barely move arm that received dose, could not touch it) 24 hours after 1st dose - fatigue, bodyaches, headache, persistent flushing without fever (max temp 99.1 F) 36 hours after 1st dose - headache, flushing. Arm soreness significantly improved 48 hours after 1st dose - mild flushing, rest of symptoms resolved

Redness, pain, swelling hardness injection site Ice/Cold compress, Ibuprofen

Associate complained of headache and that she didnt feel well. Associate noted to have a swollen tongue and rapid response was called. Associate was taken to ED. HR 80. BP 100/70

c/o throat tightness, neck hot and tight about 8 minutes after injection. Gave Epipen at 17:10 and taken by wheelchair to our ER. Employee states she was monitored and given 1 liter of IV fluids and benadryl. States she was discharged home about 3 hours later. Felt exhausted 12/22/20. Today feeling better. Planning to see primary MD 12/24/20 for follow up.

Seizure (Grand mal)

Mild headache the day of injection. Moderate nausea and overall malaise on day 1 after injection. Mild nausea, overall malaise, mild fatigue on day 2 after injection.

Patient reported that she developed tingling in her face on the same date of her vaccine. Was evaluated by provider on 12/22/2020 and Kenalog 40mg IM given as one time dose. Patient was contacted that same evening and reported that her symptoms had resolved.

Became flush and clammy 2-3 times. Recovered after 30 minutes of observation

symptoms started afternoon following day (Saturday)around 3 pm as chills denied fever, muscle aches and pains, soreness all over, Tx Motrin as needed. The following day (Sunday) had 2x loose bowel movement last episode 6 hours before showing up for work. Denied any more symptoms.

phone call

Anaphylactic with throat swelling , tachycardia and high BP. Pt was given steroids, epi pen, Benadryl and observed in ICU overnight.

headache, injection site arm pain

Initially; confusion/difficultly focusing. Secondary: imbalance. Then developed, dizziness (room spinning sensation).

The morning after receiving the vaccine I woke up with a headache. I drank lots of fluids and tested, but the headache seemed to get worse. It was throbbing with associated light-headedness and general fatigue. Maximum temperature after vaccine so far has been 98.8

Right arm weakness

Left axillary lymph nodes swelling and pain; Left arm pain Headaches Cough Dyspnea with exertion Body aches

Vaccine recipient received COVID-19 Vaccine on 12/22/20 and 3 minutes after felt that they were going to pass out and developed dizziness and headache. Vaccine recipient was administered ketorolac 15 mg IV, acetaminophen 650 mg, IV fluids in the emergency department. Patient felt better and was subsequently discharged to home. During a follow-up phone call on 12/23, vaccine recipient reported that their symptoms have resolved and they were able to return to work.

cough, sob, sweating, belly pain for 48 hours after vaccination, body soreness, advised to contact PCP.

Patient summoned nurse over while waiting 10 minutes post-vaccination. Stated felt heart racing and like she was alternating getting hot/cold however skin was warm, pink and dry on palpation. Radial pulse 140 bpm. SpO2 100%. Stated she had a history of anxiety; nurse reassured and distracted her which helped symptoms initially but then symptom of heart racing returned accompanied by dry mouth and numbness of upper lip. Was transported in wheelchair to ED by RN. Discharged from ED after 2 hour observation diagnosed as suspected anxiety attack; was instructed to follow-up with PCP and Employee Health regarding receipt of 2nd dose.

"Individual developed rash 5-7 minutes after vaccination. Denies other symptoms including difficulty breathing or itchy/scratchy throat. Says ""I'm fine"". Individual self administered benadryl. went back to department and later called Employee Health. Employee Health instructed individual to go home and self monitor"

Muscle aches and temperature of 100.3 began 1 day post injection, headache additional symptom on day 2 post injection.

Soreness at injection site and surrounding area, deltoid muscle soreness

Vaccine administered around 10:45(am) on 12/21/2020. Around 23:00(pm) (12/21/2020) I was feeling chilly, put my jacket while at work (night shift) on but continued to feel tired, eyes hurt a little, slight headache, general muscle soreness, and increasing pain in my left arm where I got the shot. I took 600mg Advil, felt fine most the night but still really tired. End of shift (07:30(am)) I was very tired with symptoms returning. Got home (08:00 on 12/22/2020), went right to sleep but at that point had chills, felt cold, headache, body aches, pain in left arm worse / really hurting - tender to touch but not swollen or red, neck glands ?felt swollen? but I don't think they actually were swollen. I woke up 4 hours later (12:00 - 12/22/2020) around noon exactly sweating, with all the same symptoms. No GI discomfort. I took 975mg Tylenol. Checked my temp, 99.9F. I couldn't fall back asleep for several hours and my body temperature felt like it was all over the place (sweating and hot, then cold, repeat). Finally fell asleep again from 16:00 to 21:30. Symptoms were all still present. Took Tylenol 1,000mg and stayed up until 05:00 (12/23/2020) with good relief from the Tylenol throughout the night and then went back to sleep from 05:00 to 10:00 (12/23/2020). Woke up symptom free and have remained symptom free.

Patient presents palpitations

Employee complained of lightheadedness/dizziness after vaccination which was at 9:15am

Date and time of symptom onset: 12/17/20 at 4:15 PM Symptoms: 12/17 during 30 minute observation window, patient reports the following symptoms: felt dizzy, heart palpitations, shortness of breath and difficulty breathing. Patient reports, ?I didn?t tell anyone because I didn?t know who the monitors were. I tried to get eye contact with someone, but I wasn?t able to. I didn?t want to stand up because I was afraid I would pass out and would be really embarrassed for causing a scene.? Patient was tearful on phone when describing account. Patient verbalized concerns with being unable to determine who was assigned to be monitoring employees after vaccination administration. Patient reports she did not notify anyone of her symptoms/what she experienced and remained at designated ?monitoring? location for

40 minutes before she drove home. Patient endorses, ?I probably shouldn?t have driven, but I did anyway.? Patient reports she struggles with anxiety and wondered if what she was feeling was a result of hx of anxiety. Patient reports resolution of SOB approx. 1 hour she got home. Patient endorses hx of ADHD, depression, thyroid issues and hypoglycemia. Patient reports compliance of prescribed medications. Patient reports the following timeline for symptoms listed: Dizziness: Patient reports continued intermittent dizziness (denied at time of call) and feelings of ?cloudiness/spaciness?, currently experiencing today Headache: began with severe headache on night of 12/17 and continued with headaches, pt denies headaches today (12/23). Patient with hx of migraines Heart palpitations: continued with heart palpitations through evening of 12/17, intermittent palpitations on 12/18 and 12/19, denies palpitations today. Fever: low-grade fever on 12/17 (pm) and 12/21 (am), denies fever since 12/21 and has not taken antipyretics since 12/21 at approx. 9:30 pm. At time of call: Patient endorses continued ?cloudiness and feeling spacy.? Patient reports feelings of fatigue. Last day of work and shift: 12/23, working from home Home remedies: Rotated Tylenol and motrin, last dose of motrin at 9:30 PM on 12/21 Patient scheduled PTO on 12/18 and 12/21 due to concerns of not feeling well after vaccine.

coughing, itching IM soul-medrole given seen entry detail

phone visit

Rash, generalized weakness

"Patient pre-medicated with diphenhydramine, albuterol, Claritin, and singulair. After roughly 10 minutes after administration the patient reported tingling in her lips and ""felt like she needed to use her inhaler"". Our administration station is in our front lobby, when the patient reported her side effect she was taken to the Emergency department for observation. The patient was hooked up to the monitor and a set of vitals were taken. On arrvial she was tachy in the 100's wtih a BP of 140-90. On the repeat vitals in 15 minutes she was within normal limits. The patient was treated with Diphenhydramine 12.5 mg PO and Albuterol 2 puffs via spacer. The patient was observed for ~3 hours, the patient had mild angioedema and a numb tongue/lips. After resolution symptoms the patient was discharged from ED."

Diarrhea, Fatigue, headache, injection site pain, injection site swelling, malaise, new or worsened join pain and new or worsened muscle pain. more than 23 hours of severe all over pain, horrible pounding headache and nausea

Injection at 12:46, Experienced Tingling on tip of tongue at 1303 took oral Benadryl 25 mg, reported symptoms at 1309- 161/93 sat 100% on room air, P-84, Repeat 1310 135/94 sat 98% P-81, 13:13 152/101 sat 99% P-87, 13:17 145/87 sat 99% P-86, 1330- 141/82 sat 99% P-89, reports tingling decreasing, 13:38 149/83 Sat 98% P-84 13:45 still having tingling transferred to Urgent Care

Pt developed a rash on her entire upper trunk and face. Started behind her ear on day one and by the next day had spread all over with extreme itching and discomfort.

Fever 102

Chills, Headache, Body Aches, Runny nose, congestion, dizzy , nausea

Nexk to my head feel really hot, nauseous, dizziness, high blood pressure, shaking feel Hot and cold

extreme fatigue, itching at site, some redness on deltoid.

Reports had joint pain & shoulder pain, shortness of breath, pale-instructed to go to ED for medical treatment.

patient covid +,on day 13 since identified. received covid 19 vaccine 19 hours prior to fever presentation. patient to receive full medical work up to rule out other medical contributions for fever. Confusion, Fever, HYPERtension & FEVER 101.5 fahrenheit, weakness

Per Vaccine recipient approximately 4-4 1/2 hours after receiving vaccine she noticed facial swelling in and around nose, to neck area, to R elbow and a petechial rash near R elbow. She immediately took Benadryl and Pepcid and then went to ER for further evaluation, where she was given a dose of Zyrtec and 5 day course of Prednisone. She left ER with no further complication.

Headache Arm soreness Swollen Uvula

History to allergic to IVP dye, after the covid vaccine and said felt itchy in face. Patient given dexamethasone 10 mg diphenhydramine 50mg ,epinephrine 0.5 mg and lactated ringers. Patient issue resolved and will be discharged home.

"Pfizer-BioNTech COVID-19 Vaccine EUA Patient stated that 2 1/2 to 3 hours after receiving vaccine she had 2 ""red dots"" on the arm she received the vaccine in. States one dot was where vaccine was administered and second dot was next to area where she received vaccine. The next day patient stated ""the two dots became red, raised, and sore to touch"". States they were not warm or hot to touch. 2 days following vaccination, the 2 ""dot areas"" were still present. Patient stated ""running through the dot I got the shot in, I developed a red line that ran through the place I got the shot and was about 2 inches long down my arm. "" Patient described red line as ""It looks like a cat scratch"". 3 days following vaccination, states ""Bumps are still there but faint"" also states ""red line is still there"". States line is not raised, tender, or hot to touch. States no other reactions. States no fever or fatigue."

Headache Sore injection site

vasovagal syncopal reaction. I experienced sudden onset of feeling flushed and warmth body wide, sudden metallic taste in mouth, muffled hearing, dizziness, lightheaded, began to lose vision and consciousness, pallor noted by nurse caring for me, blood pressure recorded was 90/60. I have never experienced this type of reaction before to any vaccine or blood donation but know it can occur occasionally.

BODY ACHES, MIGRAINE

Itching started on left wrist approximately 20 minutes after receiving vaccine and progressed to other arm, back, and legs. Patient has no other complaints. Initial blood pressure elevated 180-210 / 120-130.

Patient reports no history of hypertension. Patient reports having taken Zyrtec approximately 30 minutes prior to receiving vaccine. Benadryl offered, but declined by patient at this time.

Staff member experienced a fever of 101.7 and chills through the evening. Symptoms then resolved.

On 12/23/2020 woke up with Fever 100.6 F, significant muscle aches, headache, diarrhea, and dizziness.

Developed SOB, chills, fever 102.0, cough and posterior back pain with symptoms improving on 12/20/2020 in the PM. He did not seek care or report issue until now. States he feels fine now.

Cellulitic response to injection site.

Stated fever 99.5, body wide aches, fatigue

Took NSAID (ibuprofen) to relieve pain and reduce fever. Applied local analgesic to injection site (Methyl/M-salicylate, camphor, menthol ointment).

rash to lower back & itching some pain @ site of injection No swelling, HA, fatigue, fever. Txt with antihistamines

Employee developed fever of 101 initially. Was 102 by 12/22/2020 @ 3AM. Alternating Tylenol/Ibuprofen and reports improvement in symptoms.

IM given 12/18/2020 at 2:40 pm , evening time 9pm claimed fever(no temperature was taken) ;; chills, myalgia, headache on and off tolerable on and off; nauseated (common symptom even in situations employee does not feel well); Took Motrin alternating with Acetaminophen at least 2 tabs a day of each. Medications alleviate symptoms but recurs again until after 48 hours Showed at work but decided to leave work to return to residence. Advised to contact primary care provider to inform provider of the signs and symptoms. Employee was advised to get Covid TEST (PCR)

12 hours after vaccination -->generalized muscle aches and arthralgia (of major joints symmetrically painful (both knees, lateral movement of neck stiff) no joint swelling; felt chills no fever. No URI symptoms; and both thigh pain aggravated by change of position (standing from sitting to rising from chair)and even going down flight of stairs. Generalized malaise, felt sick and tired. NO diarrhea no loss of taste. The following day (Sunday) all complaints resolved. No meds taken throughout post vaccination

Has allergy with prior reaction to sulfa drugs that she had the same symptoms of warmth and then developed hives. Her left upper extremity was warm to the touch when compared to her right, which was where she received her injection 20 minutes prior. Treated with motrin and benadryl 50mg po and symptoms resolved.

patient had left arm numbness and tingling, lips numbs, and headache at 15 minutes. Symptoms continued to increased headache, SOB, nasal congestion, nausea and vomiting, all extremities numb. face pale.

Employee was called 5 hours after medication administration, referring improved but still having Shortness of breath. Referred will go to the ER if symptoms continue

Soreness, stiffness, fatigue, headache nausea

Developed diarrhea x 10 episodes on 12/17/2020 through 7:00PM on 12/18/2020. Treated with Zofran, Pepcid, and Lactaid.

Developed headache and body aches by 11:00PM following injection. Fever of 100.6 on 12/19/2020.

Phone call- already 80% improved

Developed a 101 fever along with body/joint aches on 12/19/2020

One hour after injection I was at the store felt disoriented like I was on a strong pain pill. I felt impaired and used caution driving home from the store. That feeling lasted for 3 hours. I still feel a little foggy headed today at work.

developed itching within a few hours of vaccine administration. developed a rash all over body on 12/20/2020. Took Benadryl and symptoms now resolved.

Headache, lightheadedness, fatigue 5 to 10 min post vaccination

NauseaVomiting

NauseaVomiting

phone call

12/23 patient transferred out to acute care hospital for treatment/evaluation of gi bleed. patient does have h/o PPI use that was d/c 5/2020 and no recent gerd symptoms requiring intervention >60 days. NauseaVomiting, GastricBleeding & heartburn

12 hours after receiving the vaccine on saturday afternoon experienced severe headache sunday morning. was able to work through it. subsequently developed vertigo on monday night and missed work on tuesday. very unusual for this employee. now on tuesday evening symptoms are wearing off. did not seek medical attention.

Approximately one hour after receiving the vaccine, as the patient was driving home he began experiencing throat tightness and tongue swelling. Once home, they call 911 and administered 0.3 epi (had previous severe allergy to lidocaine). EMS then administered iv benadryl and an albuterol treatment. The patient was reported to go unresponsive en route and received bag and mask ventilation very briefly as well as additional 125g solumedrol and another IM epi injection. On arrival he was reported to be stable, talking, tolerating secretions, without significant complaints. He was observed in the ER for several hours without any symptoms nor objective findings to support anaphylaxis (tongue and airway normal, no wheeze, no rash). He was anxious in the ER and the treating physician wrote that he felt it may likely have been anxiety and not anaphylaxis based on their evaluation.

96hrs later still feel disoriented

About 12 hours after the vaccine I started to get a fever that got up to 101.2 degrees, headache, body aches and flank pain. I took Tylenol, which helped break the fever and body aches but still have a low grade fever and headache. I believe I have COVID antibodies from a previous infection back in September so think that having the antibodies already could have caused this.

Yesterday afternoon, she developed a loss of taste and smell. This morning around 0400, she awoke to a splitting headache. She took some Advil and tried to go back to sleep, hoping she could maybe come in to work today a little later. Around 1030 this morning, she began to have significant swelling to her face and eyes along with her skin becoming flushed. She has taken some Benadryl and been instructed to follow up with her PCP

I received the vaccine at 1:40 PM in my left arm. They had me wait 15 minutes for observation. 15 minutes later, I left feeling fine. I went back to work. Around 2:15 I started getting chills. I ignored it thinking that I was psyching myself into it thinking about the shot. But then the nausea began. I was at work and started feeling horrible. I started cramping in my stomach. I was alone at work, and then I started throwing up. It started at 3:40. I left work at 4:30 with the most body wracking chills and went to the emergency room. I was violently heaving at this point and they rushed me into a room where I received an IV drip of fluids and anti nausea medication. It wasn't until after the medication was administered that I felt better. I would say this was around 5 pm. They sent me home with an anti nausea medication. I was released to go home around 730-8 PM. I felt so much better after the medication was administered.

"Patient reported a metallic taste on vaccine administration, after ~ 10 mins reported a tongue tingling. The patient was escorted to the emergency department for observation. Patient was slightly hypertensive 140's/90's which is not normal for her. Some of this could be attributed from the ""white coat effect"". The patient had no visible angioedema, just a mild rash on her trunk/upper torso/chest. The patient was treated with 50mg PO diphenhydramine and 40mg of Famotidine. The patient's symptoms resolved within 30 minutes of medications administered. Patient was discharged after ~ 2 hours in the ED."

Patient experienced immediate and severe nausea and then tachycardia ~140 bpm within 30 minutes of dose monitored by nursing home physician assistant and sent home from work.

2 hours after the vaccine felt like she was hit by a bus. Had facial droopiness. Has Migraines with the same facial droopiness. Left eye blurred vision. Stroke like symptoms. Fatigue, weakness.

Acute onset nausea and abnormal throat sensation shortly after receiving COVID vaccine. Hemodynamically stable in ED, saturating well on RA, did receive Epi .3 mg IM for concern of throat sensation, tolerated well.

Patient received Covid vaccine while sitting without issue. Within minutes of receipt of the vaccine he had a vagal reaction (fell off his chair). Initial eval was notable for supine position, pale face, HR in 30's,

clammy skin, small lac to L forehead (not actively bleeding). Pt was alert and oriented initially then was noted to slow his speech/had decreased responsiveness <1 minute. He was then alert and able to answer all questions. Denies any past medical history, not on any meds, NKDA, no hx of reaction to vaccines. He denies any itching, rash, swelling, difficulty breathing/SOB/Wheezing, or GI sx. Exam remained unchanged with no objective signs of allergic reaction. His color improved as well and he reported feeling better, was able to sit up. He reports eating minimal breakfast this morning. Has a history vasaovagal reactions with blood draws. Decision made to call EMS for transfer for additional observation. EMS arrived at 1115 and transported patient to ER for observation.

Minutes after being vaccinated; patient felt flushed and arms and back and chest developed hives/rash. Hyperventilation with throat tightness. Healthcare worker was immediately transported to the Emergency Department and was treated with Benadryl, Epinephrine, Solu-medrol, Pepcid and Ativan.

Left arm swelling, redness, heated/ burning, bruise, rash, low grade fever 99.4, hardened area somewhat similar to a knot on site Took Benedryl

Right arm pain

Employee calling to report a reaction after receiving a COVID-19 vaccine. Vaccine Name - Pfizer Vaccine Lot # - EK5730 Vaccine Date and time - ?12/16/2020 @ 06:15am Is this your first or second dose? First Date and time of symptom onset - ? 12/20/2020 @ 09:00 am Symptoms - ? Dry Eyes Last day of work and shift - Yesterday 7a-7p? Home remedies? - eye drops, Zyrtec, flonase Any improvement? - no Recommendation? Manage per illness in the workplace policy. Told her that dry eyes is not an adverse reaction of the vaccine received. Recommend to consult her PCP about it. Employee voiced understanding Employee of information ? yes Employee voiced any concerns ? yes Employee?s questions answered to employee?s satisfaction - yes

Pfizer-BioNTech COVID-19 Vaccine EUA Patient had eaten before the vaccination, but had walked to the location of the vaccine administration, administration facility heat was on/very high, approximately 8 minutes after receiving the vaccine the patient stated that she felt hot, prickly, lightheaded and weak. She laid on the floor, remained conscious but used an ice pack on her forehead. She was able to walk to another chair located away from the heater and was observed for 30 additional minutes at which time she had a snack, drank water and was cleared to leave. Patient states that she feels okay today.

Head aches; Nausea; Fever; Metal flavor on mouth; This is spontaneous report from a contactable consumer. A 38-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), unknown route (site of vaccination left arm), on 16Dec2020 05:00 PM at single dose for COVID-19 immunisation. Medical history was none. Concomitant drugs were unknown. The patient experienced headache, nausea, fever, metal flavor on mouth, all at 07:30 PM on 17Dec2020. Patient was treated with acethaminophen. The action taken in response to the events for BNT162B2 was not applicable. The outcome of the events was recovered Information about lot/batch number has been requested.

Nausea, severe headache, very dizzy, started 22 hours after Very flushed, fever 100.6 at 28 hours after

Hand feels tingley for 15 minutes

mild pain at injection site 24 hours after receiving vaccine dose; This is a spontaneous report from a contactable via a Pfizer sales representative. A 40-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration in Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced mild pain at injection site 24 hours after receiving vaccine dose in Dec2020. Patient is healthy and within weight parameters. The outcome of the event was recovered in Dec2020. No follow-up attempts are possible; information about batch/lot number cannot be obtained.

Sore arm, body aches, headache, and fatigue.

Fever 101.7F Rigors Nausea Vomiting

"Hoarseness; Nausea; Loss of appetite; Weakness; Headache; whole body ached; pain in the area the shot was applied; some swelling at the injection site; This is a spontaneous report from a contactable nurse. A 49-year-old female patient received the first dose of the bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot Number: EH9899), via an unspecified route of administration in the left arm on 15Dec2020 at 15:30 at 49-years-old at a single dose for COVID-19 immunization. The vaccination facility type was a hospital. History of all previous immunization with the Pfizer vaccine considered as suspect (or patient age at first and subsequent immunizations if dates of birth or immunizations are not available): none. There were no additional vaccines administered on the same date of the Pfizer Suspect. The patient's medical history was reported as none. The patient was not a smoker. Family Medical History Relevant to adverse events: none. Concomitant medications included routine medications. On 15Dec2020, the patient experienced: pain in the area the shot was applied (non-serious). On 16Dec2020, the patient experienced: weakness (non-serious), headache (non-serious), whole body ached (non-serious). On 17Dec2020, the patient experienced: loss of appetite (non-serious). On 18Dec2020, the patient experienced: hoarseness (non-serious), nausea (non-serious). On an unspecified date in Dec2020, the patient experienced: some swelling at the injection site (non-serious). The events did not require a visit to an emergency room or physician office; there was no prior vaccinations (within 4 weeks), there was no adverse events following prior vaccinations. The clinical course was reported as follows: The patient (nurse) had the vaccine administered on 15Dec2020 at about 15:30; and was told to notify if she had any side effects. On the same day, the patient had a lot of pain in the area the shot was applied. The patient received the shot in the left arm and after that, she was feeling weakness, headache, her whole body ached, she had difficultly speaking, and nausea. The patient was advised to call and report anything she experienced after the vaccine. The patient first started with strong pain in the area where the vaccine was administered. It was very painful, and she had some swelling at the injection site. Next, she had a headache and loss of appetite. The patient had weakness in her body. On 18Dec2020, the headache started with some nausea. There was a very strong pain in her whole body and hoarseness (like she had no voice). The patient clarified later in the call she had a headache prior to 18Dec2020. The patient reported that the "" pain in the area the shot was applied"" was better. The patient reported ""it is not too annoying like it was yesterday."" The patient took acetaminophen for pain and applied ice packs. The patient reported that the weakness was better

on 18Dec2020. The headache was better because she took medication. The whole-body aches: were about the same, a strong pain in her back, in her arms, everywhere. The hoarseness which was clarified by the patient as what was meant when reporting difficultly speaking: The patient clarified she had no voice. On 18Dec2020, in the morning, she felt a hoarseness. The patient never presented this symptom until 18Dec2020. Loss of appetite: This started on 17Dec2020 and it was about the same since starting since she really had not eaten anything. Nausea: Started on 18Dec2020 in the morning when she woke; she had not done anything because she had lost her appetite. The patient had only fruit juice. The nausea was about the same since starting. "" When asked a seriousness criterion for the events: She would describe it has had a cold."" The patient reported that there was no difficulty breathing and so she felt it was not so urgent that there was a need for her to go to the emergency room. The patient received a call from the place where the vaccine was given; and was told if her symptoms were to get worse, she would have to go to the emergency department. The patient will get the card after her second dose; The patient was given a piece of paper. There was no expiry date or NDC provided on the paper. The patient reported that she takes nothing other than routine medications. The patient had no other vaccines on the day she received the COVID vaccine. The patient reported she had no important medical history and has had no reactions to any other vaccines previously. There was no relevant family medical history. The patient had been able to manage the symptoms herself at this point and did not require any additional trips to the hospital or doctor's office. Therapeutic measures were taken as a result of pain in the area the shot was applied, and headache. The clinical outcome of the events: pain in the area the shot was applied, weakness, headache, was recovering. The clinical outcome of the event, whole body ached, loss of appetite, hoarseness, nausea was not recovered. The clinical outcome of the event, some swelling at the injection site, was unknown."

light nausea and headache, dizziness, and vertigo, chills, overall unwell, prior to vaccine, patient states she was fine.

light nausea and headache, dizziness, and vertigo, chills, overall unwell, prior to vaccine, patient states she was fine.

MILD RASH, TINGLING IN THRAOT

Nausea, dizziness, states body feels like jelly, shaky. No vision changes or shortness of breath. Given oral Benadryl and oral Pepcid and discharged in stable condition after 2 hours.

Rash on face and neck, redness, itching, rash

The patient received the vaccine at about 1500, did wait 15 minutes for observation, and left around 1515 with no reported complaints. At around 1535 while driving home patient started having difficulty swallowing and contacted hospital advice nurse who referred the patient to the emergency department.

Elevated blood pressure Elevated pulse Heart palpitations Light headedness All started within 3 hours of receiving injection

12-22 HPI 53-year-old female with a history of Addison's disease, anaphylactic reaction who presents to the ED complaining of hives and shortness of breath. Patient reports that 3 days ago she received the COVID-19 pfizer vaccine. She reports that since that time she has developed progressively worsening hives on her legs and arms. Approximately 1 hour ago she began to develop shortness of breath and so she presented to the ER. Patient reports a previous history of anaphylactic reactions multiple times. Denies any other acute complaints at this time. MDM Patient came in with shortness of breath and hives. Suspect allergic reaction to the COVID-19 vaccine. Patient had already taken 50 mg of Benadryl. She was given Solu-Medrol and EpiPen. She reported feeling better with improvement in the pruritus. She reports that she has had rebound reaction requiring EpiPen at 24 hours. Given the distance that she lives from adequate medical care and the possibility for recurrent severe reactions, the patient will be hospitalized for further observation. 12-23 Female with history of asthma and addison's had anaphylaxis to covid vaccine. Admitted over night to ensure that she did not rebound. Received IV Dex and this am has had no reoccurrence of hives or shortness of breath. Will discharge home on epipen, hydrocortisone prn, prednisone bid for 5 days. Return to ER or go to PCP for worsening symptoms.

Patient reported that 2 days after the injections she had bilateral arm swelling (left more than right, injection was in the right arm) and hand swelling. She had some facial edema around her eyes. No difficulty with breathing, swallowing or tongue swelling. This all occurred at home.

Prior to receiving the vaccine I was feeling well, history of asthma, seasonal and environmental allergies, and no history of significant symptoms after previous vaccinations. Shortly after administration of the COVID-19 vaccine I began to feel nauseous which lasted in duration for approximately 3 days. On the vaccine administration day, several hours after administration I developed retrobulbar pain, bilateral eyelid edema, erythema of the right eyelid, this was one of the most significant symptoms that persisted for several days. In addition, on 12/20 I experienced a several hour episode of tinnitus and diminished auditory acuity in my right ear, this has also resolved. From day 2 until current I have experienced decreasing myalgias and arthralgias, the most significant has been lower back midline pain which has been improving. I developed a temperature of 99.7 Fahrenheit, with administration of acetaminophen. Although the symptoms have improved this is certainly the most significant constellation of symptoms I have experienced after any vaccination.

Dry mouth and itching on the back 20 minutes after receipt of vaccine. Throat feeling blocked. Headache. Diphenhydramine 50 mg PO x1 given. Symptoms started to subside approximately 20 to 30 minutes after administration of diphenhydramine. Blood pressure initially elevated at 178/84 but decreased to 142/82 approximately 15 minutes following administration of diphenhydramine. Patient a little drowsy from the diphenhydramine. Ears ringing and itching began 1 hour 15 minutes following administration of vaccine (and approximately 45 minutes following administration of diphenhydramine). Famotidine 20 mg PO x1 administered.

Weird taste in mouth.

After patient received the vaccine at 3:20pm, he was cleared to return home at 3:48pm. At approx. 8:20pm, patient became faint while laying down, experineced hot and cold flashes and observed

darkness closing in on his vision. He then expereinced auditory disrutpitions and became highly disoriented. He was ice cold to the touch on his forehead, expericning cramping and sweating profusely on his back. Thereafter, he had diarrhea and continues to be symptomatic. He currently has no fever, but continues to remain confused and feels like he needs to lay down from this experience. He also has a metallic taste that has developed.

Chills, fever, fatigue, muscle pain

Patient reports she also had severe flushing, burning pain in her chest dizziness. tachycardia, nausea and throat tightness.

Onset about 1 hour after injection with mild left deltoid pain. Then over course of 3 hours developed left arm pain, frontal headache, and posterior neck pain. No rash.

Progress Notes APRN (Nurse Practitioner) ? ? Nurse Practitioner Cosign Needed Expand All Collapse All COVID VACCINE CLINIC 12/22/2020 á Date: 12/22/2020 á Subjective Patient is a 23 y.o. female who was seen at COVID Vaccine Clinic today for her first dose of the COVID 19 vaccination. á She denied any history of previous adverse reactions to vaccines. á She was given the Pfizer vaccination in the left deltoid muscle. á During her 15 minute waiting period after the injection, the patient began to experience Headache and felling warm. She denied rash, hives, welts, difficulty breathing, difficulty swallowing, wheezing, throat tightness, hoarseness, stridor, itching, lightheadedness, dizziness, facial swelling, lip swelling and tongue swelling. á This provider was notified of patient reaction and she was then assessed in the emergency bay area. á Monitored patient for severe reaction symptoms, including respiratory distress with stridor, wheezing, dyspnea, increased work of breathing, persistent cough and cyanosis. á á á Review of Systems Neurological: Positive for headaches. All other systems reviewed and are negative. á á á Objective á Vitals Vitals: á 12/22/20 1554 12/22/20 1623 BP: 132/73 121/73 BP Location: Right arm Right arm Patient Position: Sitting Sitting Pulse: 94 85 Temp: (!) 96.7 ¦F (35.9 ¦C) á SpO2: 99% 99% á Physical Exam Vitals signs reviewed. HENT: Head: Normocephalic. Nose: Nose normal. Mouth/Throat: Mouth: Mucous membranes are moist. Eyes: Pupils: Pupils are equal, round, and reactive to light. Neck: Musculoskeletal: Normal range of motion. Cardiovascular: Rate and Rhythm: Normal rate. Pulses: Normal pulses. Pulmonary: Effort: Pulmonary effort is normal. Musculoskeletal: Normal range of motion. Skin: General: Skin is warm. Capillary Refill: Capillary refill takes less than 2 seconds. Neurological: General: No focal deficit present. Mental Status: She is alert and oriented to person, place, and time. Psychiatric: Mood and Affect: Mood normal. á á á Assessment/Plan Treatment included: no therapy. Follow up response to treatment: no side effects. Patient discharge: Stable to go home and follow up with PCP. á á Pt was told to take Tylenol for HA. Continue to monitor symptoms. á á APRN Electronically Signed 12/22/2020 4:27 PM á

About 1 hr after started to have muscle pain/soreness. Still sore ~40 hrs out.

Employee received vaccine, stayed 15 minutes and left ?. came back within 5-10 minutes c/o throat tightness and difficulty breathing

Warmth and tingling that started in the injection site (right deltoid) that ran down the arm and to the hand a couple minutes after injection. Warmth and tingling in moderate intensity lasted about 20 minutes and decreased with increased arm movement but lasted the first 24 hours with mild aches in the same arm. An enlarged and painful lymph node occurred in the armpit of the same arm two days later and lasted (although decreasingly) for at least the next 5 days.

Warmth and tingling that started in the injection site (right deltoid) that ran down the arm and to the hand a couple minutes after injection. Warmth and tingling in moderate intensity lasted about 20 minutes and decreased with increased arm movement but lasted the first 24 hours with mild aches in the same arm. An enlarged and painful lymph node occurred in the armpit of the same arm two days later and lasted (although decreasingly) for at least the next 5 days.

Injection site soreness

sore throat, lower back pain, fatigue, 101.8 fever, stuffy nose, joint pain, difficulty breathing

Fatigue upon waking up at 07:00 until 7 pm (12 hours)

Fatigue, Headache, Muscle Aches and Joint Pain.

Patient received covid 19 vaccine. She began to experience itching throat and swollen tongue. She was sent to the Emergency Department. She received IV Benadryl 50 mg, IV famotidine 20 mg and 125 mg IV solu-medrol. Around 930, patient stated that symptoms had resolved, except for tongue being slightly swollen. Patient was admitted to the observation unit of the hospital.

Patient complained of anxiety, palpitations, and tachypnea. Patient was laid supine, VS monitored, reassurance, fluids, and snack. Went home after feeling better. Stated some mild nausea the day after.

Employee received vaccine, within 10minutes, c/o of weakness, dizziness, shaking.... no complaints of Shortness of breath or tightness... refused to receive any additional treatment. Continued monitoring for another 2 hours, no additional symptoms, then developed numbness and tingling around mouth and trouble swallowing.... sent to ER.

Pfizer-BioNTech COVID-19 Vaccine EUA numbness in left arm and hand post injection

HEADACHE, EXCESSIVE CHILLS, EXCESSIVE SWEATING, FEVER, BODYACHES, STOMACHACHE

Blotchy skin from chest; full rash on torso and back from hips up to chest/slight rash on thighs/rash on back of knees and legs/Looks like a drug rash; Noticed being a bit itchy that evening; This is a spontaneous report from a non-contactable consumer (patient). A 41-year-old female patient received her first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot: EH9899) via an unspecified route of administration at the left arm on 15Dec2020 16:00 at a single dose for covid-19 immunisation. Medical history included Iga nephropathy from an unknown date. Concomitant medication included lisinopril. On 15Dec2020, the patient noticed being a bit itchy before going to bed. On 16Dec2020 18:00, the patient noticed blotchy skin from chest up, full rash on torso and back from hips up to chest. The

patient also noticed slight rash on thighs and more rash on back of knees and legs by 18Dec2020; looked like drug rash. The patient had no shortness of breath, fever, swelling, etc. The events were reported as non-serious and no treatment was given. Outcome of the events was recovering. No follow-up attempts are possible. No further information is expected.

sent to the emergency room for body rashes and hives.; sent to the emergency room for body rashes and hives.; This is a spontaneous report from a contactable pharmacist. This pharmacist reported similar events for 4 patients. This is the 1st of four reports. A patient with unspecified age and gender received BNT162B2 via unspecified route of administration on unspecified date at single dose for COVID-19 immunization. Medical history included allergies to bee stings. Concomitant medications were not reported. On unspecified date, the patient was sent to the emergency room for body rashes and hives, and they were recommending that those with a bee sting allergy hold off until they know more. The outcome of events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2020502533 same reporter/ drug/ events, different patient;US-PFIZER INC-2020502534 same reporter/ drug/ events, different patient;US-PFIZER INC-2020502535 same reporter/ drug/ events, different patient

4 different individuals sent to the emergency room for body rashes and hives.; 4 different individuals sent to the emergency room for body rashes and hives.; This is a spontaneous report from a contactable pharmacist. This pharmacist reported similar events for 4 patients. This is a second of four reports. A patient of unspecified age and gender received BNT162B2 (lot/batch number and expiration date not provided), via an unspecified route of administration on an unspecified date at single dose for immunization. Medical history included allergies to bee stings from an unknown date. The patient's concomitant medications were not reported. The patient was sent to the emergency room for body rashes and hives. They are recommending that those with a bee sting allergy hold off until they know more. The outcome of the events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2020502532 same reporter, event and drug but different patient

sent to the emergency room for body rashes and hives.; sent to the emergency room for body rashes and hives.; This is a spontaneous report from a contactable pharmacist. This pharmacist reported same events for 4 patients. This is the 4th of four reports. A patient of unspecified age and gender received BNT162B2 via an unspecified route of administration, on an unspecified date at single dose for immunization. Medical history included allergies to bee stings. It was reported that the patient sent to the emergency room post vaccine for body rashes and hives. There seemed to be a commonality of allergies to bee stings for the 4 different individuals. The pharmacist wondered if there are other reports of this. They are recommending that those with a bee sting allergy hold off until knowing more and wondered if any guidance from Pfizer. Event took place after use of product. Outcome of the events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2020502532 same reporter, drug, event but different patient

"more than likely anxiety; red, splotchy rash on her neck; sweaty; felt slightly dizzy, particularly when moving her head side to side; ""tightness"" in the upper middle quadrant of her stomach, near the

xiphoid process; ""tightness"" in the upper middle quadrant of her stomach, near the xiphoid process; HR was 140; This is a spontaneous report from a contactable pharmacist. A 41-year-old female patient received the first dose of BNT162B2 (Pfizer-BioNTech COVID-19 mRNA vaccine; lot number: EK5730), intramuscular (IM) on the left arm on 17Dec2020 at 18:30 at a single dose for COVID-19 immunization at the hospital. The patient's medical history and concomitant medications were not reported. The patient had no other vaccine in four weeks. Approximately 4 minutes after administration, on 17Dec2020 at 18:34, the patient complained of ""tightness"" in her upper middle quadrant of her stomach, near the xiphoid process. At that time (18:34), her heart rate (HR) was 140. At 18:40, her HR was 96. At 18:44, the patient had a red, splotchy rash on her neck. The patient received 25 mg of diphenhydramine (BENADRYL) orally. The patient noted that she was sweaty and she felt slightly dizzy, particularly when moving her head side to side. At 18:47, the patient's HR was 80. At 18:52, HR was 84 and at 18:58, HR was 68. The patient stated she felt much better, dizziness seemed to resolve quickly per patient's report. She was able to ambulate and turn her head side to side with no further difficulties. Throughout the episode, the patient denied nausea, shortness of breath, itching, urticaria or any other rash besides the redness on her neck. After discussion with the physician (MD), nurse (RN), and doctor of pharmacy (PharmD), who were present for the vaccine administration and reaction, it was determined that this was more than likely anxiety (17Dec2020 at 18:45) and not an allergic/anaphylactic reaction. The patient had no Covid prior vaccination and not Covid tested post vaccination. The events were assessed as non-serious. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. Therapeutic measures were taken as a result of ""more than likely anxiety; ""tightness"" in the upper middle quadrant of her stomach, near the xiphoid process; HR was 140; red, splotchy rash on her neck; sweaty; and felt slightly dizzy, particularly when moving her head side to side."" The patient recovered from all the events on an unspecified date."

last night legs began burning like she had rubbed icy hot on them, extending down feet/the feeling was all over her body; This is a spontaneous report from a contactable nurse. A 56-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), intramuscular from 17Dec2020 09:30 at single dose for immunization (reported as COVID-19 vaccine). Medical history included vertigo and small whole in heart. Concomitant medication included acetylsalicylic acid (BABY ASPIRIN), ergocalciferol (VIT D), magnesium taurate, selenium and zinc. The patient previously took Kepra, Oxtellar and Sulfa which she had allergies. The patient experienced that last night (17Dec2020) her legs began burning like she had rubbed icy hot on them, extending down to her feet. Then woke at 2am and the feeling was all over her body. Awoke again at 6am and feeling was still there. She went to work, feeling wass not confined to ankles and feet...icy hot although warm to touch. The patient underwent lab tests and procedures which included sars-cov-2 test: negative on 13Nov2020 and sars-cov-2 test: unknown results on Dec2020. Outcome of event was not recovered.

lost sense of taste; Headache; arm was hurting; fatigue; sinus congestion; sneezing; nose hurting because it was dry; nose hurting because it was dry; flu like symptoms; increase in urination; erythema; at the site of injection; swelling at the site of injection; malaise; pain and achiness; This is a spontaneous report from a contactable other healthcare professional (nurse practitioner) reported for himself. A 29-

year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number EH9899, expiry date unknown) via an unspecified route of administration on 17Dec2020 06:30 at single dose for COVID-19 immunization with his left deltoid. The reporter informed that the vaccination facility was a hospital and not administered at military facility. The patient's medical history included autoimmune stuff going on and the patient understand that the vaccine could intensify it. The patient informed that his autoimmune condition was psoriasis; lichen planus, irritable bowel syndrome (IBS), everything hypertension and other generic condition, migraine without aura. There were no concomitant medications. The reporter informed that no additional vaccines was administered on same date and within 4 weeks prior. The patient previously took thimerosal and was allergic. The patient had flu shot/flu vaccine (influenza vaccine) when very young and experienced allergic reaction. The patient experienced almost immediately had a headache (17Dec2020 06:35). He had the pain and achiness (Dec2020) like generic symptoms, something else was lost sense of taste that was 12 hours (17Dec2020 18:30) after taking the vaccine. His first dose was yesterday 17Dec2020 at 6:30 am. He clarified further that the headache started within 5 minutes of receiving the vaccine, arm was hurting within an hour, had the fatigue after 2 hours, and about 12 hours after noticed a loss for sense of taste. He also experienced sinus congestion and sneezing that started around 1 or 2 o clock on the same day (17Dec2020) and it was 8 hours after. The patient's headache was very mild now, fatigue was hard to say because the patient just woke up after sleeping 9 hours straight, sinus congestion greatly oscillates back and forth between being congested and not able to clear his nose at all and then it change in the matter 3 minute to suddenly his nose hurting because it was dry (Dec2020). The congestion could last half hour. The patient clarified that yesterday it was completely congested and today it was going back and forth. The patient informed that his side effects were flu like symptoms (Dec2020). The patient experienced increase in urination, erythema and swelling at the site of injection (Dec2020). The patient informed that he was tested maybe 2 months ago and at that time it was negative, but he didn't have a recent one. The events did not require a visit to emergency room and physician office. The patient took Advil for the achiness malaise (Dec2020). The outcome of the events headache was recovering, lost sense of taste, sinus congestion, sneezing was not recovered, while pain and achiness, arm was hurting, fatigue, nose hurting because it was dry, flu like symptoms, increase in urination, erythema and swelling at the site of injection, malaise was unknown. The patient's second dose was unknown, he was given a separate card for the second date and was having issues finding it. The patient has misplaced the card but knows it was his calendar, he will go in the office today and find out, he knew it was scheduled on a Friday.

Chills; fatigue; malaise; joint and muscle aches all over body as well as at and around injection site; joint and muscle aches all over body as well as at and around injection site; joint and muscle aches all over body as well as at and around injection site; mild fever: 99.6 oral Fahrenheit; This is a spontaneous report from a contactable consumer (patient). A 39-year-old male patient received bnt162b2 (BNT162B2) lot number: Ek5730, expiration date: not reported, via an unspecified route of administration in the left arm, first dose on 17Dec2020 09:45 at a single dose for immunization. Medical history included allergies to cephalosporins. The patient's concomitant medications were not reported. The patient did not receive any other vaccines within 4 weeks prior to the covid vaccine. On 17Dec2020 at 04:00 pm, the patient experienced chills, fatigue, malaise, joint and muscle aches all over body as well

as at and around injection site, mild fever of 99.6 oral Fahrenheit, lasting two days with lessening severity so far.The events were reported non-serious with no treatment received. The patient had no covid prior vaccination nor had he tested post vaccination. The outcome of chills, fatigue, malaise, joint and muscle aches all over body as well as at and around injection site, mild fever: 99.6 oral Fahrenheit was recovering.

anxiety was kicking in really bad/anxiety episode/triggered her anxiety; metallic taste; arm pain at the injection site; This is a spontaneous report from a contactable consumer (patient). A 34-year-old female patient received the first dose of BNT162B2 (Pfizer product, lot EK5730, expiry date Mar2021) via an unspecified route of administration on 18Dec2020 (reported as today at 11:45, unknown if AM or PM) at a single dose on the arm as Covid 19 Vaccine. Medical history included cervical cancer since 2010, both mother and father have had cancer; post-traumatic stress disorder (PTSD); anxiety; had been on therapy counselling. Concomitant medications included hydroxyzine, sometimes uses medical marijuana, sometimes taking prenatal vitamins just because of the whole virus and stuff thing going around; the patient might not be pregnant but become pregnant (consumer was unsure- PENDING CLARIFICATION). She's in the middle of a divorce but she just takes the prenatal vitamins because of the higher doses to help run her immune system because of the virus. The patient received the vaccine today (18Dec2020) and she was not sure what these ingredients were. She's a single mother and an EKG and EEG tech working around Covid positive patients. She inquired if any of the ingredients or the vaccine itself do cause cancer. She really had a bad anxiety and PTSD and she didn't know but her anxiety was kicking in really bad right now. She's currently having anxiety episode now. The more she got home, the more she's thinking and that's kind of triggered her anxiety. She already has anxiety taking the vaccine/have anxiety about this Covid19 vaccine. She inquired if the lady knew like what triggered the anxiety if there's like any ingredient that could potentially cause cancer, do they spike protein, do those cause cells to mutate which causes cancer, so many answers and questions the patient had and there were no answers to her questions, nobody knew because it's still being studied and that's also where her anxiety was getting triggered and all about this was just unknown. She was just trying to figure out if there's a chemical ingredient made to be administered in the vaccine because being a mother she was trying to find answers and nobody seemed to have any answers and all she heard was she did not have. It was also stated that after she got the vaccine, she had really metallic taste for about an hour and a half and it finally went away. She also had a regular arm pain at the injection site, it's normal like how one get flu shot and stuff. The patient had no investigation assessment. Treatment for the events was reported as no. The outcome of the event metallic taste was recovered on 18Dec2020 while the rest of the event was unknown.

About 5 minutes after the injection, got a flushed feeling for a couple of minutes.; This is a spontaneous report from a contactable Other Health Professional. A 43-year-old female patient received bnt162b2 (BNT162B2) lot number: EK5730, intramuscular (left arm), first dose on 16Dec2020 19:00 at a single dose for immunization. Medical history included high blood pressure and known allergies to penicillin and sulfa. Concomitant medication included escitalopram oxalate (LEXAPRO), lisinopril and omeprazole (PRILOSEC [OMEPRAZOLE]). It was reported that about 5 minutes after the injection on 16Dec2020 at 07:15 PM (as reported), the patient got a flushed feeling for a couple of minutes. The patient recovered

from flushed feeling for a couple of minutes (16Dec2020). The event was reported as non-serious with no treatment received. The patient had no covid prior vaccination. She had covid tested post vaccination on 18Dec2020 through nasal swab with negative result.

soreness at the site of injection.; This is a spontaneous report from a contactable consumer, the patient. A 54 year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), lot number EK5730 via an unspecified route of administration on 18Dec2020 at 10:45 (at the age of 54-years-old) as a single dose in the left arm for COVID-19 immunization. The patient had no relevant medical history. The patient had no known allergies to medications, food, or other products. Prior to the vaccination, the patient was not diagnosed with COVID-19. Concomitant medications included loratadine (CLARITIN) from an unknown date and unknown if ongoing, or an unknown indication. The patient did not receive any other vaccines within four weeks prior to the vaccination. On 18Dec2020 at 12:00, the patient experienced soreness at the site of injection. The patient did not receive any treatment for the event. The clinical outcome of the soreness at the site of injection was recovering. It was also reported that since the vaccination, the patient had not been tested for COVID-19.

Fatigue; Nausea; This is a spontaneous report from a contactable consumer (patient) and contactable Other healthcare professional. A 41-year-old female patient received the first dose of bnt162b2 (BNT162B2, lot number: EH9899), via an unspecified route of administration (left arm) on 18Dec2020 08:45 at single dose for immunization. Medical history included endometriosis and allergies to lavender and stevia. Concomitant medication included levonorgestrel for birth control. The patient previously took metoclopramide hydrochloride (REGLAN) experienced allergies. On 18Dec2020 03:00 PM, the patient experienced fatigue and nausea. The most recent COVID-19 vaccine was administered in the hospital. She did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. No treatment was received for the events. The events recovered on unspecified date in Dec2020.

Tiredness; Muscle pain; Chills; Fever; Joint pain; Vomiting; Nausea; Feeling unwell; This is a spontaneous report from a contactable nurse, the patient. A 54-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot number: EH9899), intramuscular in the right arm on 16Dec2020 at 09:30 AM (at the age of 54-year-old) as a single dose for COVID-19 immunization. Medical history included hypertension, sleep apnoea syndrome, glucose tolerance impaired, breast cancer (5 years ago), and anxiety. The patient was not pregnant at the time of vaccination. Prior to the vaccination, the patient was not diagnosed with COVID-19. Concomitant medication taken within two weeks of vaccination included HCTZ, losartan, anastrozole (ARIMIDEX), escitalopram oxalate (LEXAPRO), calcium, ergocalciferol (VITAMIN D), and fish oil; all for unknown indications from unknown dates and unknown if ongoing. The patient did not receive any other vaccines within four weeks prior to the vaccination. The patient previously took Bactrim and experienced drug hypersensitivity. On 17Dec2020, at 10:00 AM, the patient experienced tiredness, muscle pain, chills, fever, joint pain, vomiting, nausea, feeling unwell. The events were reported as non-serious. The patient did not receive any treatment for the tiredness, muscle pain, chills, fever, joint pain, vomiting, nausea,

and feeling unwell. The clinical outcome of the events tiredness, muscle pain, chills, fever, joint pain, vomiting, nausea, feeling unwell was unknown. It was also reported that since the vaccination, the patient had not been tested for COVID-19.

Very painful injection site 5 hours after injection; Headache; Nausea; Myalgia; Arthralgias; Severe fatigue; Mild confusion; Chills but no sweats or fevers; This is a spontaneous report from a contactable physician. A 59-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; lot number: EH9899), intramuscular on the right arm on 15Dec2020 06:30 at a single dose for immunization. Medical history included treated hypertension; he had no known allergies. Concomitant medication included chlorthalidone and nifedipine (PROCARDIA). The patient did not receive any other vaccines within four weeks prior to the COVID vaccine. On 15Dec2020 10:30, the patient experienced very painful injection site 5 hours after injection; 8-10 hours after: headache, nausea, myalgia, arthralgias, severe fatigue, mild confusion, chills but no sweats or fevers; had to take 2 days off work due to severity of symptoms; symptoms decreased but some continue on day 5. The events were reported as non-serious. No treatment was received for the events. The patient was not diagnosed with COVID prior to vaccination and has not been tested post-vaccination. Outcome of the events was recovering.

Headache; Metallic taste; This is a spontaneous report from a contactable nurse (patient). A 25-year-old female patient received bnt162b2 (BNT162B2; reported as Pfizer-BioNTech COVID vaccine; lot number: EL0140; expiration date: unknown), intramuscular left arm on 19Dec2020 06:45 AM at single dose for immunization. The patient's medical history and concomitant medications were not reported. It was reported that the patient received the COVID vaccine in a hospital. The patient did not have other vaccine in the last four weeks. The patient reported that she had headache and metallic taste on 19Dec2020. The events were non-serious and did not result in hospitalization or prolonged hospitalization. The patient received naproxen (ALEVE) as treatment. The patient was not diagnosed with COVID-19 prior vaccination and the patient has not been tested for COVID-19 since the vaccination. The outcome of the events was recovered on Dec2020. The following information on the batch/lot number has been requested

Tingling; Tachycardia; This is a spontaneous report from a contactable nurse. A 38-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number: EJ1685; Expiration date was not reported), intramuscularly on the left arm on 17Dec2020 at 1 DF, single for Covid-19 vaccination at the hospital. The patient's medical history and concomitant medications were not reported. The patient was not pregnant at the time of vaccination; and reportedly did not have Covid-19 prior to receiving BNT162B2 vaccination. On 17Dec2020 (03:00), the patient had tingling and tachycardia. The patient did not receive any treatment for the adverse event. The outcome of the events, tingling and tachycardia, was recovered in Dec2020. The patient was tested for Covid-19 post-vaccination. No follow-up attempts are possible. No further information is expected.

pain at the injection site; I had discomfort in my arm; sore throat; cough/Bit of a cough; This is a spontaneous report from a contactable nurse (patient). A female patient of an unspecified age received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE lot# not provided), via an unspecified

route of administration in Dec2020 at SINGLE DOSE for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. On Thursday (in Dec2020), the patient received her first dose of COVID vaccine that Pfizer makes. By Thursday night and yesterday (Friday), the patient had pain at the injection site. The patient also had discomfort in her arm. It was also mentioned that by Friday afternoon until night, she developed a sore throat and a bit of a cough (she doesn't know if the coughing was because her throat was sore or it's other way around). She also mentioned that she doesn't have a fever and still have her sense of taste and smell. Outcome of the events were unknown. Information on the Lot/Batch has been requested.

"left lower leg paresthesia in the left lateral sural nerve dermatome / felt like a tingling sensation localized to dermatome lateral to shin; felt like a burning sensation localized to dermatome lateral to shin; This is a spontaneous report from a contactable consumer, the patient. A 33-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot number: E51685), via an unspecified route of administration on 17Dec2020 05:45 (at the age of 33-years old) as a single dose in the left arm for COVID-19 immunization. Medical history included penicillin allergy from an unknown date and unknown if ongoing. Prior to the vaccination, the patient was not diagnosed with COVID-19. The patient's concomitant medications included an unspecified multivitamin received within 2 weeks of vaccination. The patient did not receive any other vaccines within 4 weeks prior to the vaccination. The patient experienced left lower leg paresthesia in the left lateral sural nerve dermatome which felt like a tingling/burning sensation localized to dermatome lateral to shin on 18Dec2020 08:00 (reported as about 12 hours after injection). There was no loss of sensory, ""temp"" or pain detected, as reported. The patient did not receive any treatment for the events. Since the vaccination, the patient had not been tested for COVID-19. The clinical outcomes of the lower leg paresthesia in the left lateral sural nerve dermatome which felt like a tingling/burning sensation localized to dermatome lateral to shin was not resolved."

sore and tenderness on left arm; soreness on left arm; slight HA (headache) in the morning; This is a spontaneous report from a contactable consumer (patient). A 49-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; lot number: EH9899), via an unspecified route of administration on the left arm on 15Dec2020 09:45 at a single dose for immunization. Medical history included iron deficiency and was diagnosed with COVID-19 on an unspecified date; no known allergies. Concomitant medications included ascorbic acid (VIT C), tocopherol (VIT. E), cetirizine hydrochloride (ALERCET). The patient did not have other vaccinations within four weeks prior to the COVID vaccine. The patient experienced slight HA (headache) in the morning of day 0 (15Dec2020), occasional HA and increased soreness on left arm on day 1 (16Dec2020), still sore and experienced tenderness on left arm on days 2 to 4 but was mild at the time of report. The events were reported as non-serious. The patient took Tylenol and applied heating pad on her left arm. She was diagnosed with COVID prior to the vaccination and has not been tested for COVID post-vaccination. Outcome of the events was recovering.

Mild grade fever (99.8); Unable to leave bed for 24 hrs due to extreme fatigue and muscle soreness; Unable to leave bed for 24 hrs due to extreme fatigue and muscle soreness; Unable to leave bed for 24 hrs due to extreme fatigue and muscle soreness; This is a spontaneous report from a non-contactable healthcare professional. A 32-year-old female patient received the first dose of BNT162B2 (Pfizer-

BioNTech COVID-19 mRNA vaccine; Lot Number: EH 9899), intramuscularly in the right arm on an unspecified date (at the age of 32-years-old) as a single dose for COVID-19 vaccination. The patient did not receive any other vaccines within 4 weeks prior to the vaccination. Medical history was reported as none. The patient was not pregnant at the time of vaccination. Prior to the vaccination, the patient was not diagnosed with COVID-19. Concomitant medication included ethinylestradiol, etonogestrel (NUVARING) for an unknown indication from an unknown date and unknown if ongoing. The patient did not have any allergies to medications, food, or other products. On 04Dec2020 at 09:00 (as reported), the patient experienced a mild grade fever (99.8), was unable to leave the bed for 24 hours due to extreme fatigue and muscle soreness. The patient was not treated for the mild grade fever (99.8), was unable to leave the bed for 24 hours due to extreme fatigue and muscle soreness. Since the vaccination, the patient had not been tested for COVID-19. The clinical outcome of the mild grade fever (99.8), was unable to leave the bed for 24 hours due to extreme fatigue and muscle soreness was resolved on 06Dec2020 at 9:00 (reported as resolved in 48 hours). No follow-up attempts are possible. No further information is expected.

Numbness and pain in left jaw line; Numbness and pain in left jaw line; This is a spontaneous report from a contactable consumer (patient). A 41-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number: EH9899), via an unspecified route of administration at the left arm on 18Dec2020 at 11:15 AM at single dose for COVID-19 immunization. The patient was not pregnant at the time of vaccination. The patient was not diagnosed with COVID-19 prior to vaccination, and the patient has not been tested for COVID-19 since the vaccination. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient had no medical history and no known allergies (no allergies to medications, food, or other products). Concomitant medication (other medications in two weeks) included cephalexin (CEPHALEXIN) stopped 1 week prior, and fish oil. The patient experienced numbness and pain in left jaw line on 18Dec2020 at 11:45 AM. The patient did not receive treatment for these events. The clinical outcome of the events was not recovered. The report was reported as non-serious.

Fever of 101 for hours; chills; shakes; severe joint pain; body aches; dizziness; This is a spontaneous report from a non-contactable consumer (patient). A 45-year-old female patient received the first dose of BNT162B2 (also reported as Pfizer-BioNTech COVID-19 mRNA vaccine, lot no: ELO140, expiry date not reported), via an unspecified route of administration on the right arm on 18Dec2020 at 10:45 at a single dose in the hospital for immunization. Medical history included having had COVID-19 prior to vaccination on an unspecified date. The patient had no known allergies. Concomitant medication included bifidobacterium lactis, lactobacillus acidophilus (PRO-IMMUNE) powder (as reported). The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient experienced fever of 101 for hours, chills and shakes, severe joint pain, body aches, dizziness all on 18Dec2020 at 22:45. Treatment was not received for the reported events. The outcome of the events was recovering. Since the vaccination the patient has not been tested for COVID-19.

Headache; neck and back ache; neck and back ache; injection arm very tender; Nausea; fatigue; This is a spontaneous report from a contactable consumer. A 49-year-old female patient started to receive BNT162B2 (Solution for injection, lot number and expiry date was unknown), via an unspecified route of

administration on 18Dec2020 10:00 at single dose in the left arm for immunization. Medical history included migraines and COVID-19 from an unknown date. Concomitant medication included acetylsalicylic acid (ASPRIN), potassium, curcuma longa (TURMERIC [CURCUMA LONGA]), ospemifene (OSPHENA) and black cohosh [cimicifuga racemosa] (BLACK COHOSH [CIMICIFUGA RACEMOSA]). The patient previously took penicillin and experienced allergies. On 18Dec2020 19:00, the patient experienced headache, neck and back ache, injection arm very tender, nausea and fatigue. No treatment received all the events. Since the vaccination, the patient has not been tested for COVID-19. The outcome of the events was recovering. The following information on the batch number has been requested.

had a high level of anxiety with a heart rate of approximately 100-120 bpm for about 1-2 hours; had a tingling feeling all over during this time; This is a spontaneous report from a contactable consumer. A 31-year-old male patient started to receive bnt162b2 (BNT162B2), via an unspecified route of administration from 17Dec2020 08:15 to 17Dec2020 08:15 at a single dose for COVID-19 vaccine. Medical history included intermittent anxiety. There were no concomitant medications. It was reported by the patient that the night of vaccination he woke up from sleep around 0200 and had a high level of anxiety with a heart rate of approximately 100-120 bpm for about 1-2 hours. He also had a tingling feeling all over during this time. The outcome of the events was recovering. Information about Lot/batch no has been requested.

transient (1-2 minutes) flushing; chest tightness (on the same side as vaccine); lightheadedness; This is a spontaneous report from a contactable consumer (the patient). A 33-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, lot number EK5730), via an unspecified route of administration in the left arm on 18Dec2020 at 08:45 (at the age of 33-years-old) as a single dose for COVID-19 immunization. Medical history included Hodgkin's lymphoma from Nov2019 (treated for cure Nov2019 through Feb2020). The patient did not have any allergies to medications, food, or other products. The patient was not pregnant at the time of vaccination. Prior to the vaccination, the patient was not diagnosed with COVID-19. The patient had received unspecified concomitant medications within 2 weeks of the vaccination. The patient did not receive any other vaccine within 4 weeks prior to the vaccine. On 18Dec2020 at 08:45 (as reported), the patient stated that 5-10 minutes after vaccine administration, she experienced transient (1-2 minutes) flushing, chest tightness (on the same side as vaccine), and lightheadedness. The patient was treated for flushing, chest tightness, and lightheadedness with BP measurements (as reported) and oral hydration. The clinical outcome of flushing was recovered on 18Dec2020, while chest tightness and lightheadedness were recovered in Dec2020. It was also reported that since the vaccination, the patient had not been tested for COVID-19.

Chills; shakes; headache; nausea; This is a spontaneous report from a contactable consumer (patient). A 37-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), via an unspecified route of administration on left arm on 18Dec2020 at 11:45 (dose number: 1) as a single dose for COVID-19 immunization. The patient medical history included anxiety. Concomitant medication were not reported. The patient was not pregnant at the time of vaccination and the facility where the most recent COVID-19 vaccine was administered was a hospital. The patient

did not receive any other vaccines within four weeks prior to the vaccination. Prior to the vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. The patient previously took clindamycin and had allergies. On 19Dec2020 01:30, the patient experienced chills, shakes, headache and nausea for 2 hours, 13 hours after administration (as reported). The patient did not receive any treatment for the events. The events were assessed as non-serious. The reported outcome of the events was recovering. Information on lot/batch number has been requested.

Fatigue 24 hrs after vaccination; Swelling and redness at injection site 36 hrs after vaccination; Swelling and redness at injection site 36 hrs after vaccination; This is a spontaneous report from a contactable consumer (patient). A 27-year-old female patient started to receive started to receive BNT162B2 (Solution for injection, lot number: Eh9899 and expiry date was unknown), via an unspecified route of administration on 17Dec2020 15:00 at single dose in the left arm for COVID-19 immunization. The patient was not pregnant at the time of vaccination. Medical history included allergies to sulfa drugs and diagnosed with COVID-19 prior to vaccination. The patient's concomitant medications were not reported. On 18Dec2020 18:30, the patient experienced fatigue 24 hrs after vaccination and swelling and redness at injection site 36 hrs after vaccination. No treatment received for all the events. The outcome of the events was unknown. The following information on the batch number has been requested.

shaking chills for at least 4 hours; nausea; fatigue; This is a spontaneous report from a non-contactable nurse. A 68-year-old female patient started to receive bnt162b2 (BNT162B2), via an unspecified route of administration from an unspecified date at a single dose unspecified dose for an unspecified indication. Medical history included covid-19 (Prior to vaccination). The patient's concomitant medications were not reported. It was reported that 24 hours after the first vaccine, the patient had shaking chills for at least 4 hours. She was wrapped in 2 heavy blankets and a heating pad. She also had nausea and fatigue. Symptoms gone the next day. The outcome of the events was recovered on an unspecified date. No follow-up attempts are possible. Information about lot/batch number cannot be obtained. No further information is expected.

Sore throat; This is a spontaneous report from a contactable Nurse (patient). A 21-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection) via an unspecified route of administration on 17Dec2020 06:00 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. No other vaccines received in four weeks prior to Covid-19 vaccine. No Covid-19 prior vaccination. It was unknown if patient was tested for Covid-19 post vaccination. The patient was not pregnant at the time of vaccination. The patient experienced sore throat on 18Dec2020 05:00. No treatment was received for the adverse event. The event was non-serious. The outcome of the event was recovered on unspecified date in Dec2020. Information on Lot/Batch number has been requested.

"Light headed; hypertension lasting approximately an hour/hour and a half; ""Mental fuzziness"" lasted until the headache took place.; ""Mental fuzziness"" lasted until the headache took place.; photo sensitivity; This is a spontaneous report from a contactable consumer. A 27-year-old female patient

started to receive BNT162B2 (Solution for injection, lot number and expiry date was unknown), via an unspecified route of administration on 18Dec2020 14:30 at single dose in the left arm for COVID-19 immunization. The patient was not diagnosed with COVID-19 prior to vaccination and since the vaccination, the patient has not been tested for COVID-19. The patient was not pregnant at the time of vaccination. There were no medical history. The patient has no known allergies. The patient's concomitant medications were not reported. On 18Dec2020 14:30, the patient experienced light headed, hypertension lasting approximately an hour/hour and a half, ''Mental fuzziness'' lasted until the headache took place and normal side effects accompanied such as a headache and photo sensitivity. No treatment received for all the events. The outcome of the events was recovered in Dec2020. The following information on the batch number has been requested."

"headache; This is a spontaneous report from a contactable nurse (patient) via Medical Information Team. A 31-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; lot number: EJ1685, expiry date: Mar2021), via an unspecified route of administration on 18Dec2020 at a single dose for immunization. The patient's medical history and concomitant medications were not reported. The patient reported that she was experiencing a ""really super bad headache"" on the day of report (19Dec2020) after receiving the covid vaccine the day before (18Dec2020). She took Tylenol and wanted to know if she can take Advil. She was suffering from a terrible headache and did not know if she can take Advil and there was nobody that can tell her whether it was okay with the vaccine. Outcome of the event was unknown."

have had a metallic taste since then, it has dissipated slightly; This is a spontaneous report from a contactable health care professional (patient). A 37-year-old female patient received the first dose of BNT162B2 (also reported as Pfizer-BioNTech COVID-19 mRNA vaccine, lot no: EK5730, expiry date: 01Mar2021), intramuscular on the on the left deltoid on 17Dec2020 (reported as 'at about 12:40 PM') at 0.3 mL at a single dose for COVID-19 immunization and ipratropium bromide (manufacturer unknown, specified as non-Pfizer, lot no: 348501, expiry date: May2022), nasal from an unspecified date to an unspecified date, 2 sprays, in each nostril as needed for rhinitis. Medical history included seasonal allergy for which the patient receives allergy injections regularly but have not received one recently or within the last 14 days and ongoing rhinitis. Concomitant medication included fexofenadine hydrochloride (ALLEGRA) and fluticasone propionate (FLONASE [FLUTICASONE PROPIONATE]). The patient stated that she was a healthcare worker and received the vaccine at her workplace. She called as she had a question about a very benign symptom that she was wondering if it's related to the vaccine or if it's something separate. She developed a metallic taste in her mouth about 2 hours after getting the vaccine, it's slowly dissipating but it's still there. She said no one else said that they did have it and actually one other person who she works with said that they also had a slight thing (upon further clarification it was unspecified) but it's not in the list of expected symptoms so she just wanted to call and check. The patient did not receive any treatment for the event. She stated that she also used a nasal spray, Ipratropium Bromide Nasal Solution because she has rhinitis and she did use that and she never had a symptom or side effect with that because she uses it chronically but she did use that right before and noticed the taste develop so she doesn't know if there is a possible interaction between that and the vaccine. That morning she did 2 sprays in each nostril about 6 o'clock in the morning and then she

did 2 sprays in each nostril about 2:15 PM and got her vaccine at about 12:40 PM that day. The patient got blood test for serology antibodies on 04Dec2020 with unknown results. The outcome of the event was recovering.

sore arm; patient received BNT162B2/ breastfeeding a 14 month old; patient received BNT162B2/ breastfeeding a 14 month old; This is a spontaneous report from a contactable consumer (patient). This consumer reported information about mother and baby. This is the mother case. A 36-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), via an unspecified route of administration on left arm on 17Dec2020 07:30 (dose number: 1) as a single dose for COVID-19 immunization. The patient's medical history included uncomplicated vaginal delivery (14 month old has no diagnosis. Was born 41 +5. Mother and baby have no issues postpartum). The patient had no known drug allergies. Concomitant medication were not reported. The patient was not pregnant at the time of vaccination and the facility where the most recent COVID-19 vaccine was administered was a hospital. Prior to the vaccination, the patient was not diagnosed with COVID-19. The patient did not receive any other vaccines within four weeks prior to the vaccination. Since the vaccination, the patient had not been tested for COVID-19. The patient was breastfeeding a 14 month old. The patient was not having symptoms except for a sore arm on 19Dec2020 (12:00AM). The patient did not receive any treatment for the events. The event was assessed as non-serious. The outcome of the event was not recovered. Information on the Batch/Lot number has been requested.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2020504610 baby case

Lightheadedness; This is a spontaneous report from a contactable pharmacist. A 52-year-old male patient started to receive bnt162b2 (BNT162B2, lot number EJ1685), intramuscular from 19Dec2020 10:45 to 19Dec2020 10:45 at a single dose for an unspecified indication. Medical history included hypertension. The patient's concomitant medications were not reported. The patient experienced lightheadedness on 19Dec2020 11:00 and took ondansetron. The outcome of the event was recovered on 19Dec2020.

having soreness to her arm at the injection site of the vaccine; This is a spontaneous report from a contactable healthcare professional (patient). A 26-year-old female patient received first dose of bnt162b2 (BNT162B2 lot number and expiry date were not reported), intramuscular on the left arm from an unspecified date at a single dose for immunization. The patient's medical history and concomitant medications were not reported. The patient experienced having soreness to her arm at the injection site of the vaccine on an unspecified date. Outcome of the event was unknown. Information on the lot/batch number has been requested.

puffiness and itchiness around her upper eye/last night she had a puffing, her eyes were puffed; it was itchy and she experienced itchiness everywhere/itchiness around her upper eye; This is a spontaneous report from a contactable consumer (patient herself). A 33-year-old female patient received first dose of bnt162b2 (BNT162B2, lot number: EK5730), intramuscular on Dec2020 at single dose for COVID-19 immunization. The patient has no medical history and stated that she had no other medical conditions, stated that she was generally healthy. Concomitant medication included ibuprofen and paracetamol (TYLENOL). The patient received the bnt162b2 and she had a puffing, her eyes were puffed, the upper

eye and it was itchy and she experienced itchiness everywhere on an unspecified date in Dec2020. Patient mentioned that there was no rash or hives. She said she took Benadryl and it helped with the puffiness around the eyes, it did help with itchiness but she was still having some itchiness so she wanted to go just ahead and report that to our safety department. Patient clarified that Benadryl helped with the puffiness around her eyes but the itching part was still there, it (Benadryl) helped but not that much. Patient reported that she had a CBC recently and she got her antibodies checked few days before she got the vaccine. Patient reported that there were some mild generalized itchiness. It was just mild right now. Outcome of eyes were puffed was recovering while outcome of itchiness was not recovered.

fatigue; fever; body ache; chills; headache; injection site soreness and swelling; injection site soreness and swelling; This is a spontaneous report from a contactable consumer (the patient). A 22-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, lot number EJ1685), via an unspecified route of administration in the left arm on 18Dec2020 10:15 (at the age of 22-years-old) as a single dose for COVID-19 immunization. The patient had no medical history. The patient did not have any allergies to medications, food, or other products. The patient was not pregnant at the time of vaccination. Prior to the vaccination, the patient was not diagnosed with COVID-19. The patient's concomitant medications were not reported. The patient did not receive any other vaccine within 4 weeks prior to the vaccine. On 18Dec2020 at 20:30, the patient experienced fatigue, fever, body ache, chills, headache, injection site soreness and swelling. The patient did not receive any treatment for the events. The clinical outcome of fatigue, fever, body ache, chills, headache, injection site soreness and swelling, was recovering. It was also reported that since the vaccination, the patient had not been tested for COVID-19.

body ache; fever; headache; This is a spontaneous report from a contactable consumer reporting for herself. A 52-year-old female patient received bnt162b2 (BNT162B2, lot number and expiration date were not reported), via an unspecified route of administration on 18Dec2020 at a single dose for immunization. Medical history and concomitant medications were not reported. The patient stated that she took the covid vaccine the day before (18Dec2020) and was experiencing body ache, fever and headache on an unspecified date in Dec2020. The outcome of the events was unknown. Information on batch number has been requested.

Swelling of throat; lightheaded; right arm injection site arm pain; This is a spontaneous report from a contactable consumer. A 27-year-old female patient received the first dose of bnt162b2 (BNT162B2, lot number: EK5730 expiry date: unknown), via an unspecified route of administration on the right arm on 19Dec2020 09:30 at single dose for immunization. Medical history included cervical spine disc herniations. Concomitant medications included sulfamethoxazole and bisacodyl (DULCOLAX [BISACODYL]). The patient had no known allergies. The patient was not diagnosed with COVID-19 prior to vaccination. The patient has not been tested for COVID-19 since the vaccination. The patient did not receive any other vaccine within 4 weeks prior to the COVID vaccine. On 19Dec2020 10:00, the patient experienced Swelling of throat, needing to keep clearing my throat, lightheaded, right arm injection site arm pain. The event was considered as non-serious. The patient received BENADRYL as treatment for the events swelling of throat, lightheaded, right arm injection site arm pain. Outcome of the events swelling of throat, lightheaded, right arm injection site arm pain was not recovered.

Left jaw pain slightly radiating into ear. Pain level 4/10; Left jaw pain slightly radiating into ear. Pain level 4/10; This is a spontaneous report from a contactable consumer. A 57-year-old female patient received the first dose of bnt162b2 (BNT162B2, lot number: EK5730, expiration date was not reported), via an unspecified route of administration on the left arm on 18Dec2020 09:30 at single dose for immunisation. Medical history included controlled hypertension (HTN) and allergies to milk products. Concomitant medication included meloxicam (MOBIC), escitalopram oxalate (LEXAPRO) and irbesartan. The patient was not diagnosed with COVID-19 prior to vaccination. The patient did not receive any other vaccine within 4 weeks prior to the COVID vaccine. On 19Dec2020 at 07:00, the patient experienced left jaw pain slightly radiating into ear. Pain level 4/10. No treatment was given for the events. The patient has not been tested for COVID-19 since the vaccination. The patient has not recovered from the events.

swollen lymph node on left side reddened and painful throat (left part)

today she has redness around the site; This is a spontaneous report from a contactable consumer (patient). A female patient of an unspecified age received bnt162b2 (BNT162B2, lot number and expiration date not provided), via an unspecified route of administration on 18Dec2020 at a single dose for immunization. The patient's medical history and concomitant medications were not reported. The patient took the Covid shot the day before (18Dec2020) and said it was ok, but on the day of the report, 19Dec2020, she has redness around the site. The patient wanted to know if she can put the ice pack around it, and also stated she should have not taken the shot. The outcome of the event was unknown. Information on the batch/lot number has been requested.

Heart rate 110; This is a spontaneous report from a contactable nurse. A 39-year-old female patient received bnt162b2 (BNT162B2 lot number and expiration date were not reported) intramuscular at the right arm first dose on 19Dec2020 09:00 at a single dose for immunization. The patient had no relevant medical history. The patient's concomitant medications were not reported. On 19Dec2020 11:00, the patient experienced heart rate 110. No treatment was received for the adverse event. The most recent COVID-19 vaccine was administered in a hospital. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. No other medication was received within 2 weeks of vaccination. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, has the patient has not been tested for COVID-19. No Allergies to medications, food, or other products. Outcome of the event was unknown.

Tattoo raised out of ski hours 6-14, forearm hot and red 24-36h; Tattoo raised out of ski hours 6-14, forearm hot and red 24-36h; bodywide itching 6-48h; This is a spontaneous report from a contactable physician reporting for herself. A 33-year-old female patient received first dose of bnt162b2 (BNT162B2, lot number: EK5730), intramuscular in the left arm (also reported as left deltoid) on 15Dec2020 15:15 at single dose for COVID-19 immunization. Medical history included asthma, environmental allergies, anxiety, and history of C. diff. The patient had known metal allergy (contact dermatitis). Concomitant medication included vortioxetine hydrobromide (TRINTELLIX), amfetamine aspartate, amfetamine sulfate, dexamfetamine saccharate, dexamfetamine sulfate (ADDERALL), ethinylestradiol, norethisterone (ALYACEN), all given on an unspecified date in 2020. On 15Dec2020 at 18:00, the patient reported that her tattoo raised out of ski hours 6-14, forearm hot and red 24-36h, bodywide itching 6-

48h. The events were reported as non-serious. The patient has COVID prior to vaccination and no COVID test post vaccination. The patient recovered from the events without treatment.

Aches; mild nausea; chills; fever up to 100.8 for 6-8 hours; Headache; fatigue; This is spontaneous report from a contactable consumer. A 63-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via intramuscular (left arm), on 16Dec2020 at single dose for COVID-19 immunisation. Medical history included type 1 diabetes mellitus, hypothyroidism, Raynaud's phenomenon, drug hypersensitivity (to sulfadiazine, erythromycin). The patient experienced aches on 16Dec2020 18:00, mild nausea on 16Dec2020 18:00, chills on 16Dec2020 18:00, fever up to 100.8 for 6-8 hours on 16Dec2020 18:00, headache on 16Dec2020 18:00, fatigue on 16Dec2020 18:00. The action taken in response to the events for BNT162B2 was not applicable. The outcome of the events was recovered in Dec2020 Information about lot/batch number has been requested.

nausea; This is a spontaneous report from a contactable consumer (patient). A 41-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date in Dec2020 at SINGLE DOSE for covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient received almost exactly the covid 19 vaccine 48 hours before 19Dec2020 and now experiencing nausea in Dec2020. The patient wanted to know the time to onset of the side effects. The action taken in response to the event for BNT162B2 was not applicable. The outcome of the event was unknown. Information on the lot/batch number has been requested.

Headache all day; This is a spontaneous report from a non-contactable physician. A 38-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) intramuscularly in right arm on 19Dec2020 07:30 at single dose for COVID-19 immunization. Medical history was none. There was no other vaccine received in four weeks prior to the COVID vaccine, no other medications received in two weeks. The patient experienced headache all day on 19Dec2020 08:30 AM. No treatment received. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. Facility type vaccine was hospital. The outcome of event was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

extreme diaphoresis; Diarrhea; shaking chills; shaking chills; visual disturbances; This is a spontaneous report from a contactable nurse, the patient. A 47-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE) solution for injection via an unspecified route of administration in the left arm on 10Dec2020 at 23:30 (at the age of 47-years-old) as a single dose for COVID-19 vaccination. The patient was not pregnant at the time of vaccination. Medical history and concomitant medications were not reported. The patient did not receive any other vaccine within 4 weeks prior to the vaccine. Prior to the vaccination, the patient was not diagnosed with COVID-19. On 11Dec2020 at 00:15, the patient experienced extreme diaphoresis, diarrhea, shaking chills and visual disturbances. No treatment was provided for the events extreme diaphoresis, diarrhea, shaking chills and visual disturbances. The outcome of the events extreme diaphoresis, diarrhea, shaking chills and visual disturbances was recovered in Dec2020. Since the vaccination, the patient had a Nasal Swab, Covid test

name post vaccination on 11Dec2020 was negative. The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up.

received vaccine @ 725am noted itchy ears back & (R) wrist @744 am denied SOB, difficulty swallowing, nausea rash, hives given Loratadine 10mg @ 7:50 VS BP 110/70 HR 72 O2 sat 98% RA 7:59 reported symptoms resolved

"almost unmanageable amount of jaw pain/hurting/terrible pain/jaw is sore/the worst pain ever; almost unmanageable amount of jaw pain/hurting/terrible pain/jaw is sore/the worst pain ever; Jaw is sore and swollen; This is a spontaneous report from two contactable other healthcare professionals (HCP, one of them is also the patient). A 37-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: PF12N EJ1685), intramuscular on 18Dec2020 13:00 at single dose for COVID-19 immunization at a hospital. The patient's medical history included root canal done on 07Dec2020, which was healing nicely with some jaw pain managed effectively with ibuprofen. Sore, easily manageable. Resolving nicely. No known drug allergy. No COVID prior vaccination, the patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. No COVID tested post this vacccination. The patient's concomitant medications within 2 weeks of vaccination included ibuprofen for jaw pain/Sore. No other vaccines in four weeks. It was reported that the patient had an almost unmanageable amount of jaw pain in the ""12ish"" hours after getting the first dose of vaccine. The patient received the vaccine around 1300 on 18Dec and within an hour (at 1400) it started hurting terribly. So much that he wanted to pull the tooth out with pliars. Terrible, terrible pain all through the night that would not abate at all with ibuprofen and ""tylenol number 3"". By morning, the patient started feeling better. Jaw was sore and swollen. Ibuprofen started working again. It seemed to be resolving. The patient saw the dentist urgently that morning and the dentist didn't see anything amiss in the gum line, and had the thought that some systemic response/inflammation in response to the vaccine contributed to this. The patient commented it to be literally among the worst pain he had ever experienced in his life. The outcome of the events was recovered in Dec2020."

chill; temp at 1200 was 100.4 and at 1830 101.7; shortness of breath; body aches; headache; This is a spontaneous report from a contactable consumer, the patient. A 59-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE) solution for injection via an unspecified route of administration in the right arm on 18Dec2020 at 16:30 (at the age of 59-years-old) as a single dose for COVID-19 vaccination. The patient was not pregnant at the time of vaccination. Medical history and concomitant medications were not reported. The patient previously took cefadroxil (DURICEF) and experienced allergies. The patient did not receive any other vaccine within 4 weeks prior to the vaccine. Prior to the vaccination, the patient was diagnosed with COVID-19 in Apr2020. On 19Dec2020, the patient experienced chill, temp at 1200 was 100.4 and at 1830 101.7, shortness of breath, body aches and headache. No treatment was provided for the events chill, temp at 1200 was 100.4 and at 1830 101.7, shortness of breath, body aches and headache. The outcome of the events chill, temp at 1200 was 100.4 and at 1830 101.7, shortness of breath, body aches and headache was not recovered. Since the vaccination, the patient has not been tested for COVID-19. The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up.

heart began to pound; a warm tingling through my abdomen and chest with flushing to my face; a warm tingling through my abdomen and chest with flushing to my face; a warm tingling through my abdomen and chest with flushing to my face; a metallic sort of taste in my mouth; This is a spontaneous report from a contactable consumer (patient). A 32-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EJ1685), via an unspecified route of administration on left arm on 18Dec2020 at 10:00 AM at single dose for COVID-19 immunisation at hospital. Medical history included history of svt (supraventricular tachycardia), patient had no allergies to medications, food, or any other products. Concomitant medication included escitalopram oxalate (LEXAPRO), colecalciferol (VITAMIN D) and levocetirizine dihydrochloride (XYZAL). About five minutes after vaccination on 18Dec2020, the patient experienced a warm tingling through her abdomen and chest with flushing to her face, a metallic sort of taste in her mouth and her heart began to pound. The tingling subsided after a couple minutes and heart rate returned to normal over the next 10 minutes. The patient was monitored by the clinic nurses for another 30 minutes before released. The patient felt warm for the rest of the day but no further effects. Prior to vaccination, the patient was not diagnosed with COVID-19; Since the vaccination, the patient hadn't been tested for COVID-19. The patient did not receive any treatment for events. The outcome of events was recovered on 18Dec2020.

I got a strong metallic taste; About 30 seconds later my entire body started to tingle and I couldn't feel my hands or feet; My heart started to pound out of my chest; headache; I got an extreme hot flash and all my coworkers said I looked bright red and glassy eyed; became drenched in sweat and had to sit down for about 15 minutes with cold packs; she looked bright red and glassy eyed; This is a spontaneous report from a contactable consumer (patient). A 36-year-old female patient received her first dose of bnt162b2 (PFIZER COVID-19 VACCINE, Lot Number: EK5730), via an unspecified route of administration on 18Dec2020 at 14:15 on her left arm at single dose for COVID-19 immunization. Medical history included hypothyroid- well controlled with levothyroxine and known allergies: Penicillin, sulfa, cephalosporin. Concomitant medications in two weeks included levothyroxine, multivitamin, ascorbic acid (VIT C), colecalciferol (VIT D3). It was reported that on 18Dec2020 at 14:15, the injection was painless and she felt great. About 30 seconds later she entire body started to tingle and she couldn't feel her hands or feet. Her heart started to pound out of her chest. She got a strong metallic taste. This subsided after 1-2 minutes. She went back to feeling good. Then about 15 minutes later, on 18Dec2020, the patient got an extreme hot flash and all her coworkers said she looked bright red and glassy eyed. She became drenched in sweat and had to sit down for about 15 minutes with cold packs. Then it subsided again. She had a few more hot flashes and headache the remainder of the evening, but felt generally pretty good ever since. No treatment was received for the adverse event, prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, the patient had not been tested for COVID-19. The outcome of the events was recovered in Dec2020.

erythema and swelling on injection arm below the actual injection site; erythema and swelling on injection arm below the actual injection site; Face and neck rash; This is a spontaneous report from a contactable physician. This physician reported for herself. A 42-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK5730), via an unspecified route of administration on 16Dec2020 18:00 at single dose for covid-19 immunization. It was the first dose. The

COVID-19 vaccine was administered at Hospital. The patient's vaccine location was left arm. Medical history included hypertension (HTN), and mild asthma, the patient's known allergies included Black pepper, hydroxychloroquine sulfate (PLAQUENIL), hydrochlorothiazide (HCTZ), almond extract. Concomitant medications included Losartan, spironolactone, progesterone, metformin. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient experienced face and neck rash, erythema and swelling on injection arm below the actual injection site, adverse event start date was provided as 16Dec2020 06:00 PM. The patient Took fexofenadine 360mg for facial rash. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, the patient was not tested for COVID-19. The outcome of the events was Recovering.

"Numbness at the tip of her tongue; This is a spontaneous report from a contactable nurse (patient). A 39-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 19Dec2020 at time of 15:40 at single dose for COVID-19 immunization. Medical history included Irregular heart beat. Concomitant medication included potassium, magnesium; both for irregular heart beat. The patient just had a baby 9 weeks ago, and was breastfeeding. She also mentioned that her daughter just had her 1st round of her vaccines (other vaccines: rota, mmr vaccines, etc.) last week. She wanted to know if it's still okay to nurse her daughter considering that she just had her Covid 19 vaccine this afternoon on 19Dec2020. The patient also wanted to know what was the risk or potential complication of passing her milk, which contained the Covid 19 vaccine, to her daughter. The patient also wanted to know why it was contraindicated to take the Covid 19 vaccine if she has taken other vaccines within the 2 weeks timeframe before getting the Covid 19 vaccine. The patient experienced numbness at the tip of her tongue. Her tongue was numb, just the tip. The patient stated, ""I have two things I got my vaccine today at 15:40 for now it is just passing 18:00 anyway. That's all my tongue is numb, no other symptom, nor I am feel tiring. I don't have numbness in my hand or feet anything but there is my tongue is numb."" Nurse stated, ""Just a tip (of tongue)"". The patient stated, ""I do have another questions. I had a baby 9 weeks ago so one of the question is asked is that I had not any vaccine over the past two weeks and I have not well my daughter has, she just got her a week ago. So am I okay to breastfeeding?"" The outcome of event was unknown. Information on the lot/batch number has been requested."

scratchy throat, stiff neck ,

Headache, dizziness, fatigue; Headache, dizziness, fatigue; Headache, dizziness, fatigue; This is a spontaneous report from a contactable physician. A 50-years-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE): EJ1685, via an unspecified route of administration, in left arm on 18Dec2020 at 1845 (at the age of 50-years-old) as a single dose for COVID-19 immunization. Medical history included asthma and an allergy to penicillin. Concomitant medications were not reported. The patient was not pregnant at the time of vaccination. The patient did not receive any other vaccines within four weeks prior to the vaccination. The patient experienced headache, dizziness, fatigue on 19Dec2020 at 19:00. The patient was not treated for the events. The outcome of the events was recovering. It was also reported that since the vaccination, the patient had not been tested for COVID-19.

Within 2 minutes of injection, I became tachycardic; shaky; a bit dizzy; This is a spontaneous report from a contactable consumer (patient). A 49-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL0140), via an unspecified route of administration on 18Dec2020 07:15 AM at right arm, at SINGLE DOSE for covid-19 immunization. Medical history included anxiety and depression, allergies to IV dye, Bee stings. Concomitant medication included famotidine (PEPCID), diphenhydramine hydrochloride (BENADRYL), ergocalciferol (VIT D), acetylsalicylic acid (BABY ASPIRIN). The patient previously took levofloxacin (LEVAQUIN) and experienced allergy, ceftriaxone sodium (ROCEPHIN) and experienced allergy. The patient was not pregnant at the time of vaccination. Within 2 minutes of injection, the patient became tachycardic, shaky and a bit dizzy from 18Dec2020 07:15AM. These events resulted in Emergency room/department. No treatment was received for these events. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The action taken in response to the events for bnt162b2 was not applicable. The outcome of the events was recovered in Dec2020. No seriousness criteria: no Results in death, no Life threatening, no Caused/prolonged hospitalization, no Disabling/Incapacitating, no Congenital anomaly/birth defect.

flushed 15 min post inj. tickle in throat then tongue tingling and raspy voice 20 min post inj.

Approx 36 hours after receiving the vaccine I woke up feeling tired and nauseous; Approx 36 hours after receiving the vaccine I woke up feeling tired and nauseous; Over the next 6 hours I had chills and vomited profusely twice.; Over the next 6 hours I had chills and vomited profusely twice.; This is a spontaneous report from a contactable consumer (Patient). A 58-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 17Dec2020 17:15 at single dose for covid-19 immunization. The COVID-19 vaccine was administered at Hospital. Medical history included sleep apnoea syndrome (OSA), High blood pressure (BP), depression, anxiety, chronic fatigue syndrome (CFS). Concomitant medication included methylphenidate hydrochloride (CONCERTA), bupropion hydrochloride (WELLBUTRIN), chlorthalidone, magnesium. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Approximate 36 hours after receiving the vaccine she woke up feeling tired and nauseous. Over the next 6 hours she had chills and vomited profusely twice. Adverse event start date provided as 19Dec2020 08:00 AM. No treatment received for the events. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, the patient was not been tested for COVID-19. The outcome of the events was recovering. Information on the lot/batch number has been requested.

employee received vaccine at 1525 1535 noted lightheadedness & shaky feeling. Hx of vasovagal responses to injections & blood draws. Denies SOB, difficulty swallowing, nausea (+) hand/fingers tingling - VS- tachycardia to 120, O2 sat 97% became syncopal to ED

Headache; the patient was pregnant at the time of vaccination, gestational period was 23 weeks; This is a spontaneous report from a contactable consumer (patient). A 30-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration at left arm on 18Dec2020 19:45 at single dose for COVID-19 immunization at a hospital.

For the patient's medical history, no allergies to medications, food, or other products. For concomitant drugs, no other medications was received within 2 weeks of vaccination. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient was not diagnosed with COVID-19 prior to vaccination, and since the vaccination, the patient been had not tested for COVID-19. It was reported that the patient was pregnant at the time of vaccination, gestational period was 23 weeks. The last menstrual date was reported as 08Jul2020. The patient was due to deliver on 14Apr2021. On 19Dec2020 19:00, the patient experienced headache. No treatment was received for the event headache. The outcome of the event headache was recovering. Information on the lot/batch number has been requested.

About 30 minutes after injection felt brain fog and had a hard time finding words; About 30 minutes after injection felt brain fog and had a hard time finding words; It's like we were having to concentrate more than usual to do routine stuff; This is a spontaneous report from a contactable consumer (patient himself). A 44-year-old male received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number Ej1685), intramuscular on the left arm, as first single dose on 20Dec2020 (at 06:30) for COVID-19 immunisation. The patient did not have a relevant medical history. No relevant concomitant medications were provided. About 30 minutes after injection felt brain fog and had a hard time finding words. Another nurse that got vaccinated at the same time felt the same way. It's like we were having to concentrate more than usual to do routine stuff. The patient was not treated for the events. The patient did not perform COVID test before vaccination but after vaccination Nasal Swab, Rapid PCR, was Negative. He was recovering from the events.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2020504556 same drug, same event and different patient

chills; fatigue; headache; arm soreness; nausea; Tingling in lips/mouth; itching; low grade fever; vomiting; This is a spontaneous report from a non-contactable consumer (patient). A 31-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number=14-202012170004), via an unspecified route of administration on right arm on 17Dec2020 at single dose for COVID-19 immunization. Medical history reported as none. Concomitant medication included sertraline hydrochloride (ZOLOFT) and minerals nos, vitamins nos (PRENATAL VITAMIN). The patient experienced tingling in lips/mouth, itching, nausea, vomiting, chills, headache, low grade fever, fatigue, arm soreness on 17Dec2020, all events reported as non-serious. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient hadn't been tested for COVID-19. The patient did not receive any treatment for all events. The outcome of events was recovered in Dec2020. No follow-up attempts are possible; Information about lot/batch number cannot be obtained.

Dizziness, Headache, dry mouth, arm swelling; Dizziness, Headache, dry mouth, arm swelling; Dizziness, Headache, dry mouth, arm swelling; Dizziness, Headache, dry mouth, arm swelling; other vaccine same date vaccine date on 20Dec2020; This is a spontaneous report from a contactable other health professional (patient). A 33-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot umber: Ej1685), intramuscularly on 20Dec2020 08:00 AM at left arm, at SINGLE DOSE for covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient received other vaccine same date on 20Dec2020 (lot number: Ej1686),

and experienced dizziness, headache, dry mouth, arm swelling all on 20Dec2020 08:30 AM. No treatment was received for these events dizziness, headache, dry mouth, arm swelling. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The action taken in response to the events for bnt162b2 was not applicable. The outcome of the events dizziness, headache, dry mouth, arm swelling was not recovered. No seriousness criteria: no Results in death, no Life threatening, no Caused/prolonged hospitalization, no Disabling/Incapacitating, no Congenital anomaly/birth defect. No follow-up attempts are possible. No further information is expected.

chills; myalgias; fatigue; increased cough; This is a spontaneous report from a contactable physician(patient). A 58-year-old male patient received first dose of BNT162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EJ1685), intramuscular on 11Dec2020 18:00 at left arm at single dose for COVID-19 immunization. Medical history included COVID-19 diagnosed prior to vaccination and cough. No other medical history. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine but received other medications within 2 weeks of vaccination. The patient previously took ilosone and experienced allergies. The patient experienced chills, myalgias, fatigue and increased cough on 12Dec2020 14:00. No treatment received for the events. Since the vaccination, the patient has not been tested for COVID-19. The outcome of the events was recovering.

Chills; muscle aches; fever; Not able to work; Extreme tiredness; This is a spontaneous report from a contactable consumer (patient). A 53-years-old male patient received the first dose of BNT162B2 (Lot number: eH9899), via an unspecified route of administration, in arm left, on 18Dec2020 17:00 at single dose for COVID-19 immunization. Facility where the most recent COVID-19 vaccine was administered was hospital. Medical history included heart valve replacement. Prior to vaccination, the patient was diagnosed with COVID-19. Since the vaccination, patient was not tested for COVID-19. No allergies to medications, food, or other products. No other vaccines were received within 4 weeks prior to the COVID vaccine. The other medication that the patient received within 2 weeks of vaccination was atenolol. The patient experienced chills, muscle aches, fever, not able to work and extreme tiredness on 19Dec2020 06:00 AM. The events were reported as non-serious. No treatment was received for the events. The outcome of the events was recovered in Dec2020.

sore arm (right arm where injection was administered); Headache; This is a spontaneous report from a non-contactable consumer (patient). A 25-year-old female patient received the first dose of BNT162B2 (lot number: EK5730), via intramuscular in right arm, on 18Dec2020 09:00 at single dose for COVID-19 immunization. Facility where the most recent COVID-19 vaccine was administered was hospital. The patient was not pregnant at the time of vaccination. The patient was not diagnosed with COVID-19 prior to vaccination. Since the vaccination, the patient was not tested for COVID-19. No allergies to medications, food, or other products. Relevant medical history included Ulcerative Colitis. No other vaccines were received within 4 weeks prior to the COVID vaccine. The medications received within 2 weeks of vaccination included Mercaptopurine, Remicade, Mesalamine and Junel Fe. The patient experienced headache and sore arm (right arm where injection was administered) on 19Dec2020 12:00

PM. No treatment was received for the events. The outcome of the events was recovering. No follow-up attempts are possible. No further information is expected.

Fever of 101; myalgias; injection site swelling and pain; injection site swelling and pain; This is a spontaneous report from a contactable physician. This physician reported for himself. A 34-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899), intramuscular on18Dec2020 09:00 AM at single for covid-19 immunization. The COVID-19 vaccine was administered at Hospital. Vaccine location was Left arm and it was the first dose. The patient's medical history and concomitant medications were not reported. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient experienced fever of 101, generalized myalgias, injection site swelling and pain on 18Dec2020 21:00. Acetaminophen 500 mg q6h (Every 6 hours) for 2 days was received as treatment received for the adverse events. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, the patient was not been tested for COVID-19. The outcome of the events was recovered on an unknown date in Dec2020.

lethargic; Right arm pain; body aches; tingling both arms and face; flu like symptoms; This is a spontaneous report from a contactable healthcare professional (HCP) reporting for himself. A 34-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot#EL0140) via intramuscular in right arm on 17Dec2020 16:00 at single dose for COVID-19 immunisation. The patient received the vaccine in hospital. The patient had no known allergies or other medical history. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient did not receive any medications within 2 weeks of vaccination. Prior to vaccination, the patient was not diagnosed with COVID-19. The patient experienced right arm pain, body aches, tingling both arms and face, lethargic, flu like symptoms on 17Dec2020 23:00. Since the vaccination, the patient had not been tested for COVID-19. No treatment was received for the events. The outcome of events was recovered in Dec2020.

Chills; injection site pain/tenderness; body aches; headache; fatigue; This is a spontaneous report from a non-contactable consumer (patient). A patient of unspecified age and gender received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: Ett9899), via an unspecified route of administration on 19Dec2020 09:00 on left arm at single dose for COVID-19 immunisation. The patient medical history and concomitant medications were not reported. The patient had no known allergies. The patient experienced chills, body aches, headache, fatigue, injection site pain/tenderness on 20Dec2020 at 12:00 PM. The treatment of the events included Tylenol. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, the patient had not been tested for COVID-19. The outcome of the events was not recovered. No follow-up attempts are possible. No further information is expected.

Immediate bitter/metallic taste. Lasted 1 hour post vaccination.; This is a spontaneous report from a non-contactable consumer (patient). A 42-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration at left arm on 20Dec2020 09:15 at single dose for COVID-19 immunization at a hospital. The patient's medical history

was not reported. Concomitant medication included sertraline hydrochloride (ZOLOFT), ergocalciferol (VIT D). The patient previously took butorphanol tartrate (STADOL) and experienced drug allergy (known allergies). No other vaccine in four weeks. No COVID prior vaccination and no COVID tested post vaccination. The patient was not pregnant at the time of vaccination. It was reported that the patient experienced immediate bitter/metallic taste, which lasted 1 hour post vaccination. No treatment was received for the event. The outcome of the event was recovered on recovered on 20Dec2020 10:15. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

Slight headache and aches; Slight headache and aches; This is a spontaneous report from a contactable consumer (patient). This 65-year-old-female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration in the left arm on 19Dec2020 at 14:30 at single dose for COVID-19 immunisation. Vaccination facility type was workplace clinic. The patient did not receive other vaccines in four weeks. Relevant medical history included allergy to latex. Concomitant medication included levothyroxine sodium (SYNTHROID). On an unspecified date, the patient experienced slight headache and aches. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, she had not been tested for COVID-19. The outcome of the events was unknown. The information on the lot/batch number has been requested.

Headache; muscle aches /pain; lethargy; dizziness,lightheaded; joint pain; nausea; GI upset; other vaccine same date vaccine date=19Dec2020; This is a spontaneous report from a contactable consumer (patient). This 50-Year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) Lot number Unknown, at single dose on 19Dec2020 08:30 AM on left arm at Hospital for COVID-19 immunisation. There was no medical history. The patient had no COVID prior vaccination. The patient did not have COVID tested post vaccination. The patient had no known allergies. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Concomitant medication included clonazepam (KLONOPIN) which was received within 2 weeks of vaccination. Other vaccine was received on the same date on 19Dec2020. The patient experienced headache, muscle aches /pain, lethargy, dizziness, lightheaded, joint pain, nausea, GI (Gastrointestinal) upset on 20Dec2020 06:00. No treatment was received for all events. The outcome of the events was not recovered. Information on the lot/batch number has been requested.

muscle fatigue; pain; skin feels tight over the injection site; she could not lift her arm without severe pain; This is a spontaneous report from a contactable Consumer reported for herself. A 33-year-olfd female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) at single dose for COVID-19 immunization on unknown date. Relevant medical history and concomitant medications were not reported. On unknown date the patient stated the shot felt like a flu shot at first then at bedtime the muscle fatigue increased and her pain was a 7 out of 10. After taking Tylenol, her pain was a 5-6 out of 10. No rash or redness but the skin feels tight over the injection site. Caller complains of severe soreness. When she woke up, she could not lift her arm without severe pain. The outcome of the events was reported as unknown. Lot/Batch number has been requested.

mild chest pressure/tightness; chills; slight cough; Within 5 min after shot I had mild dizziness/30min later I experienced moderate to severe dizziness/feeling faint; left hand tingling which subsided/tingling

of hands and feet; This is a spontaneous report from a contactable consumer (patient). A 34-years-old female patient received her first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration in arm left on 19Dec2020 19:30 at single dose for COVID-19 immunization. Medical history included eczema. There were no allergies to medications, food, or other products. Concomitant medication included patch birth control within 2 weeks of vaccination. Within 5 min (19Dec2020 19:35) after shot the patient had mild dizziness with left hand tingling which subsided. Then 30min later (19Dec2020 20:00) the patient experienced moderate to severe dizziness, feeling faint, tingling of hands and feet, mild chest pressure/tightness, chills, and slight cough. The feeling lasted about 1 hr. Chest tightness resolved after taking Benadryl. No treatment received for other events. The patient was no pregnant at the time of vaccination. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. The events were reported as non-serious. The outcome of the events was recovered in Dec2020. Information on the lot/batch number has been requested.

moderate pain at injection site; congested nose; This is a spontaneous report from a non-contactable consumer (patient's husband). A female patient (frontline health care professional) received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration on Dec2020 as a single dose for COVID-19 vaccination. The patient medical history and concomitant medications were not reported. On Dec2020, the patient experienced moderate pain at injection site and congested nose. In Dec2020, the pain was mild around the injection site and her congested nose was now clear. The clinical outcome of the moderate pain at injection was recovering and the outcome of the event congested nose was recovered Dec2020. No follow-up attempts are possible; information about lot number cannot be obtained.

Temp 99.6 and congestion.; Temp 99.6 and congestion.; This is a spontaneous report from a non-contactable nurse. A 24-year-old female patient received first dose of BNT162B2, intramuscularly on 18Dec2020 08:00 at a single dose for COVID 19 immunization. The patient medical history was not reported. The patient is not a pregnant at the time of vaccination. Concomitant medication included sertraline hydrochloride (ZOLOFT), ethinylestradiol, ferrous fumarate, norethisterone acetate (TAYTULLA). The patient experienced temp 99.6 and congestion, both on 18Dec2020. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. No treatment was received for the adverse event. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. This is a non-serious report. The outcome of events was not recovered. No follow-up attempts are possible, information about lot/batch number cannot be obtained.

Muscle pain; Joint pain; Sore throat; Feeling unwell; stated she feels very weak; stated she had initially had a fever of 102 degrees Fahrenheit, and now has a fever of 100 degrees Fahrenheit; Chills; injection site soreness; Headache; This is a spontaneous report from a contactable consumer. A 60-year-old female patient received the first dose of bnt162b2 (BNT162B2, lot number: EK5730), via an unspecified route of administration on 17Dec2020 09:30 on the right upper shoulder at single dose for immunization. Medical history included stomach cancer over 20 years ago, clarifying she no longer has

stomach cancer. The patient's concomitant medications were not reported. On 17Dec2020, the patient experienced injection site soreness, headache, chills, she initially had a fever of 102 degrees Fahrenheit and now has a fever of 100 degrees Fahrenheit. Yesterday evening (17Dec2020) she developed a fever with chills, saying she couldn't get warm, so she went to bed. She said when she got up this morning (18Dec2020), she had the other side effects: muscle pain, chills, joint pain, sore throat, feeling unwell, and she feels very weak. Reported she couldn't function when she woke up this morning. For the treatment of headache, the patient took 1 Ibuprofen 600mg tablet. She said she still has a headache, but her headache has improved. She said she took an over-the-counter Tylenol 500mg tablet. She received the COVID-19 shot at the hospital she is employed. The reported events did not require a visit to Emergency Room and Physician Office. The events headache, muscle pain, chills, joint pain, fever, sore throat was recovering, and the outcome of the remaining events was not recovered.

tenosynovitis L 2 finger, felt most on back of hand, worse with flexion, extension; This is a spontaneous report from a contactable physician. A 64-year-old male patient received first dose of bnt162b2, intramuscularly at site of left arm at 09:15 on 19Dec2020 at single dose for COVID-19 immunization. Medical history included allergies: bananas, kiwi, avocado, latex. Concomitant medication included atorvastatin in Dec2020. The patient experienced tenosynovitis l 2 finger, felt most on back of hand, worse with flexion, extension at 13:00 on 19Dec2020. The patient took advil 600 TID as treatment received for event. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. The outcome of event was recovering. Information on the Lot/Batch number has been requested.

Swollen Lymph Nodes; This is a spontaneous report from a contactable nurse (patient himself). A 39-year-old male patient received first dose of bnt162b2, intramuscularly at site of left arm at 12:00 on 17Dec2020 at single dose for COVID-19 immunization. Medical history included COVID-19. There were no concomitant medications. The patient experienced swollen lymph nodes at 09:00 on 19Dec2020. No treatment received for the adverse event. Prior to vaccination, patient diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. The outcome of event was recovering. Information on the lot/batch number has been requested.

Fever; Chills; muscle aches; Fatigue; Joint pain; nausea; vomiting; This is a spontaneous report from a contactable nurse (patient herself). A 33-year-old female patient (no pregnancy) received first dose of bnt162b2, intramuscularly at site of left arm at 10:00 on 18Dec2020 at single dose for COVID-19 immunization. Medical history reported none. Concomitant medication included iron, cyanocobalamin, pyridoxine hydrochloride, thiamine hydrochloride (VITAMIN B 1-6-12) (reported as vitamin B supplement) and birth control pills. The patient experienced fever, chills, muscle aches, fatigue, joint pain, nausea and vomiting at 21:00 on 18Dec2020. The outcome of events was recovering. Information on Lot/Batch number has been requested.

Patient experienced sore arm following COVID vaccine; This is a spontaneous report from a contactable consumer (patient). A patient of unspecified age and gender received bnt162b2, via an unspecified route of administration in 2020 at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced sore arm following COVID

vaccine in 2020. The outcome of event was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

fever; body aches; headache; sharp pain in my left arm; limited in mobility to bed; This is a spontaneous report from a contactable consumer reporting for herself. A 21-years-old non-pregnant female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE Lot Number: EH9899), via an unspecified route of administration in the left arm on 18Dec2020 13:45 at single dose for covid-19 immunisation. Medical history included asthma, factor v deficiency, covid-19 and allergy to bee venom. The patient was tested positive for COVID on 10Nov2020 and was asymptomatic. Concomitant medication included benzathine benzylpenicillin (DEPO PEN). On 18Dec2020 at 23:00 (the night following the vaccine) the patient woke with a fever, body aches, headache, and a sharp pain in her left arm. She was limited in mobility to bed. these symptoms continued throughout the next day. The patient took ibuprofen but that had no effect. Diphenhydramine hydrochloride; paracetamol (TYLENOL PM) was able to reduce her fever on the second night so that she was able to sleep. Most of her symptoms started to clear up by 20Dec2020. The outcome of the events was recovering.

fever/Her body is very hot (99.8F); This is a spontaneous report from a contactable consumer. A female patient (mother of the reporter) of an unspecified age receive BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 18Dec2020 at single dose for covid-19 immunisation. The patient medical history and concomitant medications were not reported. The patient woke up with fever on 19Dec2020 with outcome of unknown. Her body was very hot. The temperature was 99.8F. Information about lot/batch number has been requested.

injection site pain; Feeling more tired than usual the day off and after; headache; This is a spontaneous report from a contactable consumer. A patient of an unspecified age and gender (reported as the front-line physician) received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, batch/lot number: unknown), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. It was reported that the patient got COVID-19 vaccine and reported some injection site pain, feeling more tired than usual the day off and after. The patient also mentioned having a headache on an unspecified date. The outcome of events was unknown. No follow-up attempts are possible. No further information is expected.

Itching hands, feet, to arms, legs, scalp, inside ears, Benadryl 25 mg Qhs

"1245: Patient vitals taken, BP 169/122, HR107, 02 SAT 98%, Temp 98.4. Patient advised he no longer has the headache but still feels flushed . 1257: vitals taken again BP 167/122, HR 101, O2 SAT 98%. Patient also advised he was having GI upset (diarrhea). Dr. monitoring patient with this RN, aware of patient vitals, Allegra 80mg PO given at 1300 by CNO per protocol. 1315: BP 172/116, HR 108, O2SAT 98%. Dr. has advised patient to log BP's at home and that he may have underlying hypertension. Dr. has advised patient that he will be called for a follow-up appointment tomorrow with a physician. 1326: BP 174/104, HR 103, O2 sat 99%. Patient states he is now felling back to normal, denied headache and flushing at this time. Dr. had given the patient clearance to return to work at this time. Advised patient

that if he starts to have any s/s again to go to Urgent Care or ER. RN will follow-up with Caregiver. 1537: Spoke to patient states he currently had a mild headache and is fatigued. States he left work an hour early and is going to go home and rest. 1547: Spoke with Dr., MD advised for Caregiver to be seen at Urgent Care today for follow-up. Patient states he feels ok to drive and will make his way to Urgent Care now. 1653: Patient called RN back, states he is feeling better and declines going to urgent care at this time. He advised his headache and fatigue is resolved, stating ""I only have mild soreness at injection site."" Patient states he will go to Urgent Care tomorrow for a follow-up. RN will follow-up with Caregiver tomorrow."

Immediate pain in right arm with administration of vaccine. 30 mins after administration noticed shooting pain in to elbow. Shooting pain has continued through today. Also reports palm sized hardness at injection site.

Approximately 35 minutes after patient received the vaccine, she noted redness around her chest and neck, goin up to her face and both ears. Ears were swollen. She was transferred to the ED for evaluation, where it was noted that she had redness of her throat and chest with slight swelling of her lips. In the ED, she was given prednisone 40mg PO and famotidine 40mg PO. She was observed and discharged after ~90 minutes.

Mild headache, mild fatigue, dry non productive cough, soreness in injection site, and 100.6 ¦F temperature.

chills; pain at the injection site; This is a spontaneous report from a contactable consumer, the patient. A female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration on 17Dec2020 in the as a single dose for COVID-19 vaccination. The patient medical history and concomitant medications were not reported. On Dec2020 the patient experienced chills and pain at the injection site. The clinical outcome of the chills and pain at injection site was unknown. Information regarding lot number has been requested.

12 hours after receiving vaccine patient experienced pain in right arm, headache, fever (did not have working thermometer to check her temperature), chills and hallucinations. Symptoms persisted for 36 hours. She did not report symptoms until they had resolved.

Tingling in lips and throat, sensation of swelling in lips, not visible, that started 25 min. after the vaccination and lasted about 2 min.

feeling similar to a slight hangover; This is a spontaneous report from a contactable consumer and a non-contactable consumer. These two consumers reported for a female patient of an unspecified age who received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration on 17Dec2020 as a single dose for COVID-19 vaccination. The patient's medical history and concomitant medications were not reported. The patient experienced feeling similar to a slight hangover on 18Dec2020. The clinical outcome of feeling similar to a slight hangover was unknown. The lot number for the vaccine, VACCINE BNT162B2, was not provided and will be requested during follow up.

Lightheadedness, blurry vision, dizziness, chest tightness, nausea, red splotchy rash Pt was treated with benadryl and pepcid by mouth and Solumedrol IM. Pt's symptoms lasted 90 minutes.

Sore arm; Mild fever; Flushing; This is a spontaneous report from a non-contactable Other-HCP via Pfizer sales representative. A patient of unspecified age and gender received BNT162B2 (Pfizer-BioNTech COVID-19 vaccine) via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. It was unknown whether the patient received any other vaccine within 4 weeks prior to the vaccine. On an unspecified date, the patient experienced sore arm, mild fever and flushing after use of the product. Clinical outcome of the sore arm, mild fever and flushing was unknown. No follow-up attempts are possible. Information about batch number cannot be obtained.

Patient started experiencing dizziness, flushing and rash. Vital signs obtained at 10:19, patient was feeling better and less dizzy, slight HA, swallowing fine. BP 166/57; HR 79; Temp 99.4. At 10:20 temp was 99.7. 650 mg of APAP given po at 10:22. At 10:30, patient c/o tension across shoulders, no c/o pain or pressure. At 10:32 dizziness improving with BP 167/63; O2 sats at 100%; HR 70, Temp 99.3. Benadryl 25 mg po given at 10:25. 10:47 O2 sats 100%; HR 72; BP 152/64.

EYE AND THROAT SWELLING

flushing of face; chest arms with slight red rash slight itch; chest arms with slight red rash slight itch; This is a spontaneous report from a contactable consumer (patient) via Pfizer Sales Representative. A female patient of unspecified age (age:33, units: unknown) received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 18Dec2020 19:30 at single dose for COVID-19 immunization. The relevant medical history included idiopathic urticaria. Concomitant medications were not reported. After administration of vaccine, the patient experienced flushing of face, chest arms with slight red rash, slight itch in Dec2020. Events took place after use of product. She was given Benadryl and held in Emerge-department for 90 minutes until symptoms were better. The outcome of the events was recovering. Information about Lot/Batch number has been requested.

aches; This is a spontaneous report from contactable nurse via Pfizer Sales Representative. A 53-year-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), the first dose via an unspecified route of administration on an unspecified date at single dose for immunization. The patient's medical history and concomitant medications were not reported. One day after receiving the first dose of the COVID vaccine the patient experienced aches. Outcome of event was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

Severe dizziness and nausea 3 days after vaccine with fatigue for approximately 24 hours

Pfizer-BioNTech COVID-19 Vaccine EUA metallic taste in mouth, tingling in hand

Reported arm soreness and headache after being administered the COVID 19 vaccine; Reported arm soreness and headache after being administered the COVID 19 vaccine; This is a spontaneous report from a non-contactable Physician via Pfizer sales representative. A patient of unspecified age and

gender received BNT162B2 (Pfizer-BioNTech COVID-19 vaccine) via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. It was unknown whether the patient received any other vaccine within 4 weeks prior to the vaccine. On an unspecified date, the patient experienced arm soreness and headache after being administered the vaccine. Clinical outcome of the arm soreness and headache was unknown. No follow-up attempts are possible. Information about batch number cannot be obtained.

I was tachycardic and hypertensive.

Metallic taste in mouth, started shortly after vaccine administration (during 15 min waiting time after administration). Persisted for approx 24 hours.

Progress Notes APRN (Nurse Practitioner) ? ? Nurse Practitioner Cosign Needed Expand All Collapse All COVID VACCINE CLINIC 12/22/2020 á Patient: Date: 12/22/2020 á Subjective Patient is a 34 y.o. female who was seen at COVID Vaccine Clinic today for her first dose of the COVID 19 vaccination. á She denied any history of previous adverse reactions to vaccines. á She was given the Pfizer vaccination in the left deltoid muscle. á During her 15 minute waiting period after the injection, the patient began to experience dizziness. She denied rash, hives, welts, difficulty breathing, difficulty swallowing, wheezing, throat tightness, hoarseness, stridor, itching, facial swelling, lip swelling and tongue swelling. á This provider was notified of patient reaction and she was then assessed in the emergency bay area. á Pt has history of anxiety and takes Hydralazine prn. She presents with rapid breathing and anxiety. á Monitored patient for severe reaction symptoms, including respiratory distress with stridor, wheezing, dyspnea, increased work of breathing, persistent cough and cyanosis. á á á Review of Systems Neurological: Positive for dizziness and light-headedness. All other systems reviewed and are negative. á á á Objective á Vitals Vitals: á 12/22/20 1425 12/22/20 1428 12/22/20 1434 BP: (!) 141/119 122/84 121/73 BP Location: Right arm Right arm Right arm Patient Position: Sitting Sitting Sitting Pulse: (!) 134 (!) 109 92 SpO2: 97% 98% 98% á Physical Exam Vitals signs reviewed. HENT: Head: Normocephalic. Nose: Nose normal. Mouth/Throat: Mouth: Mucous membranes are moist. Eyes: Pupils: Pupils are equal, round, and reactive to light. Neck: Musculoskeletal: Normal range of motion. Cardiovascular: Rate and Rhythm: Normal rate and regular rhythm. Pulses: Normal pulses. Musculoskeletal: Normal range of motion. Skin: Capillary Refill: Capillary refill takes less than 2 seconds. Neurological: General: No focal deficit present. Mental Status: She is alert and oriented to person, place, and time. Psychiatric: Mood and Affect: Mood normal. Behavior: Behavior normal. á á á Assessment/Plan Treatment included: no therapy. Follow up response to treatment: no side effects. Patient discharge: Stable to go home and follow up with PCP. á Pt's breathing slowed and felt less anxious by the time she left. á á á APRN Electronically Signed 12/22/2020 2:36 PM á á á

metallic taste; This is a spontaneous report from a contactable nurse. This nurse reported similar events for two patients. This is the first of two reports. A patient of unspecified age and gender received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration, in Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced metallic taste in Dec2020.

The clinical outcome of metallic taste was unknown. The batch/lot number for the vaccine, BNT162B2, was not provided and will be requested during follow-up.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2020504716 same reporter/drug/event, different patient

Severe headache and fever up to 100.4 no treatment, resolved on own in a few hours

at 7 minutes after vaccine administered, reported feeling shaky and lips tingly, anxiety. Did not immediately notify monitoring staff thinking she was anxious, by 10 minutes after started to experience some coughs and felt voice changed, Epinephrine administered via EpiPen at 13 minutes post vaccination with immediate relief. No visible hives or swelling.

metallic taste; This is a spontaneous report from a contactable nurse. This nurse reported similar events for two patients. This is the second of two reports. A patient of unspecified age and gender received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration, in Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced metallic taste in Dec2020. The clinical outcome of metallic taste was unknown. The batch/lot number for the vaccine, BNT162B2, was not provided and will be requested during follow-up.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2020504715 same reporter/drug/event, different patient

MODERATE TO SEVERE PAIN ON INJECTION SITE WITH REDNESS AND MODERATE SWELLING. PAIN INCREASED WITH ELEVATION OF EXTREMITY. COUGH STARTED ON 12/22/2020. MILD DYSPEPSIA.

chills, and cold , pain to injection site

increased left upper arm soreness; mild injection site pain; This is a spontaneous report from a non-contactable consumer. A 51-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 18Dec2020 15:30 at single dose for COVID-19 immunization. The patient medical history was not reported. The patient's concomitant medications were not reported. The patient developed mild injection site pain that evening on 18Dec2020 and reported as increased left upper arm soreness on morning no limitation in movement on 19Dec2020. No other local/systemic events. Event took place after use of product. The outcome of the events was unknown. No follow-up attempts are possible. No further information is expected.

Starting the evening of the 5th day after receiving the vaccine I noticed a sore, irritated throat. By the 7th day it was a more severe sore throat, runny nose, violent sneezes and the beginning of a deep painful cough. No fevers have been noted to date, with the highest oral temperature of 98.6F on the 7th day. I called the employee hotline, had a virtual visit with a Dr and took the drive up COVID test around 11:00 am on 12/23/20. I am in self quarantine currently awaiting results of the COVID test.

vomiting a lot; This is a spontaneous report from a Pfizer sponsored program . A non-contactable consumer (patient's partner) reported that a male patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration in Dec2020 at single dose for covid-19 immunisation. The patient's medical history and concomitant medications were not

reported. Caller's partner received the vaccine yesterday morning and drank a lot of alcohol in the evening. In Dec2020, her partner (patient) was vomiting a lot. She was worried if this was due to the vaccine and wanted to know what else could happen. Outcome of event was unknown. No follow-up attempts are needed. Information about lot/batch number cannot be obtained.

Slight tingling/numbness in cheek and upper jaw, lasted for 45 minutes. No medication taken.

Moderna COVID-19 Vaccine EUA pain in injection site, fatigue, sneezing, runny nose

Nausea; have really bad runny nose; have really bad stuffy nose; I had a fever; I got flush rash, itchy rash kind of all over my body; I got flush rash, itchy rash kind of all over my body; Headache; This is a spontaneous report from a contactable Nurse (patient). A 32-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 18Dec2020 at single dose for COVID-19 immunization. The relevant medical history and concomitant medications were not reported. The patient stated that she got the first round of COVID vaccine the day prior the report and she was told to report her symptoms. She had a fever and got flush rash, itchy rash kind of all over her body and a headache on 18Dec2020. She took Tylenol Benadryl, it had helped with symptoms. At the time of the report morning she woke up with headache and she had really bad runny nose and stuffy nose and nausea on 19Dec2020. The outcome of the events was unknown. Information on lot/batch number has been requested.

After 15 min patient had tingling in her left arm all the way down to her hand, then started to travel to left side of face. 5 min later tingling started to travel to her left leg. Pulse ox- 96% HR 57. 1251- ED lead RN was then contacted to evaluate patient in the ED.

Nauseous; This is a spontaneous report from a contactable consumer (patient). A patient of unknown age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), at an unspecified dose via an unspecified route of administration, on 19Dec2020 at single dose for COVID-19 immunisation. Medical history and concomitant medications were unknown. The patient reported she got the vaccine yesterday (19Dec2020) and she is really nauseous right now (Dec2020). It was unknown if a treatment was received. Outcome was unknown. Information for Lot/Batch number has been requested.

In the evening, the day I got the vaccine, I started feeling body aches all over. The arm that got the vaccine hurt the most, as to be expected, and there is a knot in the muscle where I got the injection. I have felt pain all over since then. It has not been touched by naproxen sodium. A cold shower gave temporary relief.

Patient complained of a rush of feeling very hot. Patient was offered an ice pack for the back of her neck and was monitored until she felt better. Returned home following observation period.

My upper lip swell up, it is swollen, it is all swollen; This is a spontaneous report from a contactable consumer (patient). A 38-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899) first dose on 16Dec2020 around 3 o'clock in the afternoon intramuscularly in left arm at single dose for COVID-19 immunization. Co-suspect product included

mepyramine maleate, pamabrom, paracetamol (PAMPRIN) with unspecified date and dose for cramp. Medical history was none. Concomitant medication included sertraline. Patient took it on Wednesday (16Dec2020) around 3 O clock in the afternoon and then last night (18Dec2020) her upper lip of mouth swell up, it is swollen, it is all swollen. Patient worked in a hospital and they started the vaccination program for the employees and of course she wanted to take the shot and then she went in and took the shot. It was the first dose. Consumer stated she was completely healthy. Consumer further added last night she did take something for cramp it's called Pamprin, it's for, like when you have your period and you have like cramping, headache, back ache all of that, it's over the counter. For treatment for lip swell, Consumer stated No, just put ice on it. The action taken for mepyramine maleate, pamabrom, paracetamol was unknown. The outcome of the event was unknown.

Severe neck and spine pain. No neurological symptoms noted but severe pain. Feels muscle related.

Body pain and headache, second day.

Fever; Chills; My arm was killing me; Not feeling well; This is a spontaneous report from a contactable consumer (patient). A 35-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (lot number: EH9899) at single dose via unknown route of administration on 18Dec2020 for COVID-19 immunization. Medical history and concomitant medications were reported none. Consumer stated, she got the COVID vaccine yesterday (18Dec2020). And she woke up and she had fever and chills, and like her arm was killing her and it was just like she was not feeling well. So she was just wondering how long this was supposed to last. Due date for next shot was 08Jan2021. About the Indication, Consumer stated, Juts to get it she guessed. Because they worked at the hospital, they were providing it to all of them. Consumer stated, the adverse events probably started like around 4 O' clock this morning (19Dec2020). Consumer stated, she took some Ibuprofen as treatment. The outcome of the events was unknown.

Patient waited the mandatory 15 minutes and felt fine. Left for a few minutes and then came back in to the vaccine clinic with symptoms of lips tingling and possible her tongue swelling. She was given 50mg of PO Benadryl (Diphenhydramine) and was taken to the emergency department. Patient was monitored for 4 hours in the emergency department with no additional symptoms noted. Spoke with patient this morning, was still having some tingling of the lips but was being controlled with Benadryl. No problems breathing or swallowing

Headache; This is a spontaneous report from a contactable consumer (Patient). A 49-years-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EH9899, reported as BioNTech SARS-CoV-2) on right arm at single dose for covid-19 immunization. Medical history and concomitant drug were not reported. Patient stated a side effect to the vaccine (BioNTech SARS-CoV-2), she was just having the headache that won't go away. Treatment: consumer stated just took some over the counter Aspirin. Outcome of the event was not recovered. Follow-up attempts have been completed and no further information is expected

Body aches, mild headache sore throat,mild cough. Started 12/20/20

ache all over, back pain, burning in thigh, numbness in foot

Upper body hives, Low grade fever 99.6, dizziness, weakness, tiredness, upper body muscle pain, nausea. All lasting 24 hours+.

"""Equilibrium off"", nausea, headache, and nasal drainage"

"woke up with the chills and fever; woke up with the chills and fever; I don't feel good; This is a spontaneous report from a contactable consumer (patient). A patient of unspecified age and gender received BNT162B2 (Pfizer product) via an unspecified route of administration on 18Dec2020 at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient received the COVID Vaccine yesterday (18Dec2020). The patient was a health care worker (Further clarification was unknown, hence captured as consumer or Other non HCP) and stated that, ""they have gave us a paper that has a bar code to scan to report the side effects and I don't have that with me because I left work and that was regarding. I have it at the work but I cannot go to the work because I woke up with the chills and fever (Dec2020), so I just need to talk to someone regarding the side effects besides with Tylenol (incomplete sentence). Is there anyone I can talk to? I need to report this and see is there anything I need to do besides take Tylenol (Intent: Treatment) and rest."" In response to further probing, consumer stated, ""I am so sorry, I don't feel good. I don't want to talk on the phone right now."" Therapeutic measures were taken as a result of woke up with the chills and fever. The outcome of the events was unknown. Information on the lot/batch number has been requested."

"Staff was advised that patient had a brief episode of palpitaions ""30 seconds"" after receiving the COVID19 vaccine on 12/22/20 that resolved. Per report on back of patient consent, vitals done at 1513: BP 145/102, HR 84, O2 SAT 99%, RR 18, TEMP 97.6. Re-take at 15:21, BP 124/86, HR 86, O2SAT 100%, RR 18, TEMP 97.8. Patient was monitored for 30 minutes, Dr. was present at time of event."

Patient received vaccine and entered waiting queue. Within 1 0 minutes, pt requested help from pharmacy vaccination team because she felt severely dizzy. Patient ended up passing out in seated position. Systolic blood pressure dropped to ~80. Patient normalized 5-10 minutes after syncope. Blood pressure normalized. Patient escorted out in stretcher.

Patient complained of anxiety, feeling cold and clammy, and being lightheaded. Patient was laid supine, Vital signs monitored, reassurance, fluids, and snack. Patient left for home following an extended period of observation.

developed a lump in my throat within a half hour after receiving vaccine. I took Benadryl at 7pm without any improvement. Feeling of lump improved by Monday and today feels irritated in that affected area. No other treatment.

fever of 99.9 all night; Body ache; Pain in my arm from the vaccine; This is a spontaneous report from a contactable consumer. This consumer reported similar events for two patients (herself and her husband). This is a first of two reports. A female patient of unspecified age received bnt162b2

(BNT162B2, lot number: EH9899, expiration date was not reported), via an unspecified route of administration on arm on 18Dec2020 (morning) at a single dose for immunization. Medical history and concomitant medications were not reported. The patient reported that she received the Pfizer vaccine (COVID Vaccine) yesterday morning (18Dec2020) and last night (18Dec2020) she had fever of 99.9 (unspecified unit) all night. And then at this morning (19Dec2020), she came to work at the hospital. And she has been with 99.2 all day. She also experienced body ache and pain in her arm from the vaccine on 18Dec2020. She added that her husband was experiencing the same way who also got the shot yesterday (18Dec2020). The outcome of the event fever was recovered on 19Dec2020, while outcome other events was unknown. Information on batch number has been requested.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2020506517 Same reporter/ drug/ event for different patients.

A few minutes after vaccination, sitting in chair started to feel dizzy, tachycardic, almost an anxious feeling- lasted about a minute or so, then subsided. I did not report it that day because I thought it may have been anxiety

Tingling around the mouth and throat, sensation of swollen lips, but not visible. Started around 25min after vaccination, did not last more than 1 min.

The day after had chills with no fever, fatigue, and palpitations. The second day had palpitations on and off. On the third day had palpitations that did not go away with a heart rate sitting in the 140s.

lost taste and smell; lost taste and smell; This is a spontaneous report from a contactable other HCP (patient). A 21-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL0140, Expiry Date: Mar2021) (reported as COVID Vaccine), intramuscular in right deltoid on 18Dec2020 at single dose for covid-19 immunization. Medical history included had a fever on Monday and took Tylenol Cold and Flu (lot number: SHA101, Expiry Date: Jun2024) as the treatment; had an intra uterine device. There were no concomitant medications. Patient was a frontline health worker (a CNA, Certified Nursing Assistant) and received a vaccine yesterday (as of 19Dec2020) and since then she lost taste and smell, patient was not sure if this is due to the vaccination or if its due she had a fever on Monday and broke and was unknown if it's okay to get the vaccine, patient was not sure if it's like a bacterial infection or related to the vaccine. She still doesn't have taste and smell but its really congestion. The outcome of events was not recovered.

Fever 101.0 f dry cough nasal congestion

12/23/2020 10:00 am swollen , tender glands in my throat, left side, slight headache.

"site was red, it was painful, it hurt across her shoulder and up her neck; site was red, it was painful, it hurt across her shoulder and up her neck; Headache; Diarrhea; it hurt across her shoulder and up her neck; it hurt across her shoulder and up her neck; This is a spontaneous report from a contactable Nurse(patient). A 65-year-old female patient received BNT162B2(lot number EH9899) via an unspecified route of administration at arm on 17Dec2020 at single dose for the vaccine for COVID. The patient medical history included Blood pressure high and Low thyroid. The concomitant products included losartan for Blood pressure high, levothyroxine sodium(SYNTHROID) for Low thyroid. The patient got the

BNT162B2yesterday afternoon on 17Dec2020 and her site was red and she had got a headache and stuff and she was supposed to report the adverse reactions on 18Dec2020. Her site was red, it was painful, it hurt across her shoulder and up her neck and she had got a headache and diarrhea on 18Dec2020. The patient stated she didn't have it before. The patient got it for work, she didn't have a doctor prescribed it. The patient took some Advil yesterday it helped a little bit but she haven't taken anything today. For the vaccine for COVID because the patient work in ICU. The patient was given the product in her arm. The reporter consider the events ""site was red, it was painful, it hurt across her shoulder and up her neck , headache and diarrhea"" were related to BNT162B2. The outcome of the events was not recovered."

Vaccine recipient developed mild nausea, acid reflux, and stomach pain 10 minutes after vaccine administration. Vaccine recipient then developed nasal congestion and cough at 19 minutes, and then shortness of breath at 21 minutes. The vaccine recipient was then sent to the emergency department. While in the emergency department it was determined that the vaccine recipient had an allergic reaction. When vaccine recipient had shortness of breath the oxygen saturation went to 89-90%. The vaccine recipient received albuterol, diphenhydramine, famotidine, methylprednisolone, and fluids. During re-examination, the vaccine recipient?s condition improved and stable. Vitals were within normal limits. 89-90. They were discharged to home. At follow-up phone call on 12/23/2020, the vaccine recipient reported that they felt much better but was still experiencing voice hoarseness.

15 minutes after getting the vaccine, she developed a pruritic rash over her neck, chest, and precordium. Also became tachycardic up to 130-140 (may be attributed to anxiety of having a rapid response called). She reported feeling a lump in her throat but no facial swelling or angioedema, no lymphadenopathy. Was treated with diphenhydramine 50 mg IV, famotidine 20 mg IV, and methylprednisolone 125 mg IV. After 1 hour of observation and ongoing feeling of lump in her throat with new mouth tingling, was also given 0.15 mg epi IM. Was observed with resolution over 8 hours, and discharged to home with instructions to contue treatment with oral prednisone, famotidine, and cetirizine over the subsequent few days.

Arm is kind of sore; Pretty tired; This is a spontaneous report from a contactable consumer (parent). A 21-year-old female patient received bnt162b2 (BNT162B2, lot no. and expiry date was unknown), via an unspecified route of administration on 17Dec2020 at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient had the Pfizer vaccine, the new Covid vaccine yesterday (17Dec2020). The consumer reported that her daughter's arm is kind of sore and she is pretty tired on unspecified date in Dec2020. The patient was given the vaccine because she interacts with Covid patients, she works in the Intensive Care Unit, so they provided the vaccine to her. The patient gets a Covid test every three days and she has been always negative on Covid test. The outcome of the events was unknown. Information on the lot/batch number has been requested.

First night following after vaccine I woke up with chest pain (i though pleuritic) which went away. I had mild body aches and fatigue, chills. next day I experienced chest(again I thought pleuritic) discomfort especially when taking a deep breath. i felt better then had mild fatigue and body aches again. day 3

post vaccine I woke up with discomfort when taking a deep breath with continued discomfort. i felt tired through the day. Then that evening i developed SOB, severe palpitations and chest pain and went to ER. Diagnosis New onset rapid A fib. I was hospitalized and once my work up was finished and I had normal sinus rhythm I was discharged home the next evening.

Patient presented for COVID-19 vaccine (Pfizer-Sars-COV2-vac), pt received the vaccine and then 15 minutes later started feeling some lumpiness in her throat, watery eyes, and ear fullness. Pt denied feeling any itchiness, difficulty breathing, lip swelling, or throat swelling. Pt received two doses of oral diphenhydramine 25 mg each without improvement in symptoms. Patient was observed for 1 hour and 20 minutes. After consulting with Dr., it was recommended to have the patient go to the emergency room for more observation. The patient was then escorted to the ER by one of the volunteering staff. In ED, reported throat tightness without SOB or difficulty swallowing. Also reports feeling sense of ingestion/gas bubble in chest. Had COVID, dx'd 12/1/20, recovered fully. States that sensation in chest was also felt during her COVID illness and seemed to be brought back by vaccine this afternoon approximately 90min pta, Observation for additional 90min in ED. with possible mild improvement, no progression/worsening. Discharged home

itchy, red, hives and pain at injection site and generalized muscle soreness, especially left arm

I woke up I really tired, tired/I got tired and fatigue; headache; when I came to have my breakfast I felt that food doesn't tastes nor regularly as it was before; This is a spontaneous report from a contactable physician (patient). A 75-year-old male patient received bnt162b2 (lot/batch number and expiration date not provided), via an unspecified route of administration, on 18Dec2020 (reported as yesterday of 19Dec2020), at single dose, for COVID. The patient medical history included COVID and changing his taste, both in Apr2020 and not ongoing. The patient's concomitant medications were not reported. It was reported that the patient got COVID himself what it started changing his taste in April and he was sick and come to better at the bottom month and he was fine. He started to work full time. Then he got a vaccine yesterday morning and today (19Dec2020) he woke up he really tired, tired. He know these the side effects of vaccine fatigue, muscle pain and headache but these are not he was concerned. The concern is he is losing his taste that he had when originally diagnosed with COVID in April of 2020. When this morning he got up, he got tired and fatigue and headache then when he came to have his breakfast he felt that food doesn't tastes nor regularly as it was before. The same thing he had before when he diagnosed with COVID in April. His question is, probably this is not connected, question is could that be side effects of vaccine or by the he checked his antibody week ago, he had antibody, could that he got another COVID or it is the side effects of COVID Vaccine? It was also reported that the patient deal with COVID patient every day. The outcome of the events was unknown. Information on the lot/batch number has been requested.

NONE

Two days after vaccination, I felt a little bit headache after I woke up. It was getting worse at noon. Then I took one pill of advil and felt better after that.

Itchy blotchy spots, left arm, left ear, back

Got the itches today; Got the runs; Maybe from the runs that's making me tired; Got the runs; Maybe from the runs that's making me tired; This is a spontaneous report from a contactable consumer, the patient. A 61-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot Number: KN5730), via an unspecified route of administration on 17Dec2020 (at the age of 61-years-old) as a single dose for COVID-19 immunization. The patient had no known medical history. There were no concomitant medications. On 18Dec2020, the patient had the itches and runs, and was tired. The clinical outcomes of the itches, runs, and tired were unknown.

Several minutes after the injection, my right little finger was tingling. ~0815 I was driving home and lost function in my right little finger. The left side of my jaw felt tight, the left side of my tongue felt thick, and my vision was blurry in both eyes. I also noticed that my heart was out of rhythm and beating rapidly. I had a near syncopal episode. I began having mid-sternal chest pressure. I drove to my home - took 50mg of liquid Benadryl and had someone drive me to the ER. Symptoms started to resolve within 20 minutes of taking Benadryl. I was seen at Medical Center.

Progress Notes APRN (Nurse Practitioner) ? ? Nurse Practitioner Cosign Needed Expand All Collapse All COVID VACCINE CLINIC 12/22/2020 á Patient: Date: 12/22/2020 á Subjective Patient is a 55 y.o. female who was seen at COVID Vaccine Clinic today for her first dose of the COVID 19 vaccination. á She denied any history of previous adverse reactions to vaccines. á She was given the Pfizer vaccination in the right deltoid muscle. á During her 15 minute waiting period after the injection, the patient began to experience Racing heart rate. She denied rash, hives, welts, difficulty breathing, difficulty swallowing, wheezing, throat tightness, hoarseness, stridor, itching, lightheadedness, dizziness, facial swelling, lip swelling and tongue swelling. á This provider was notified of patient reaction and she was then assessed in the emergency bay area. á Pt presented with Rapid heart rate and palpitations. Had episode of chest pain 6 weeks ago and was seen in ER. D-dimer was positive and CT negative. No FU since. á Monitored patient for severe reaction symptoms, including respiratory distress with stridor, wheezing, dyspnea, increased work of breathing, persistent cough and cyanosis. á á á Review of Systems Cardiovascular: Positive for palpitations. All other systems reviewed and are negative. á á á Objective á Vitals Vitals: á 12/22/20 1453 12/22/20 1505 12/22/20 1526 BP: 133/87 133/85 123/81 BP Location: Right arm Right arm Right arm Patient Position: Sitting Sitting Sitting Pulse: 95 96 96 SpO2: 100% 99% 95% á Physical Exam Vitals signs reviewed. HENT: Head: Normocephalic. Nose: Nose normal. Mouth/Throat: Mouth: Mucous membranes are moist. Eyes: Pupils: Pupils are equal, round, and reactive to light. Neck: Musculoskeletal: Normal range of motion. Cardiovascular: Rate and Rhythm: Regular rhythm. Tachycardia present. Pulses: Normal pulses. Heart sounds: Normal heart sounds. Pulmonary: Effort: Pulmonary effort is normal. Breath sounds: Normal breath sounds. Musculoskeletal: Normal range of motion. Skin: General: Skin is warm and dry. Capillary Refill: Capillary refill takes less than 2 seconds. Neurological: General: No focal deficit present. Mental Status: She is alert and oriented to person, place, and time. Psychiatric: Mood and Affect: Mood normal. Behavior: Behavior normal. á á á Assessment/Plan Treatment included: no therapy. Follow up response to treatment: no side effects. Patient discharge: Stable to go home and follow up with PCP. á Pt released to go home at 3:25 pm. No symptoms at that time. á á á 12/22/2020 3:30 PM á

I had a cough , hives and a fever of 101

My lips, my cheeks inside and out, my jaws and the back of tongue all went numb; My lips, my cheeks inside and out, my jaws and the back of tongue all went numb; This is a spontaneous report from a contactable consumer (patient). A 58-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date in 2020 at single dose for COVID-19 immunization. Medical history included gastroparesis. Concomitant medication included lisinopril. In 2020, the patient reported she had an odd reaction to the COVID vaccination, her lips, my cheeks inside and out, her jaws and the back of tongue all went numb. There was no investigation assessment. No treatment was received for the events. The outcome of the events was resolved by itself in 2020. Information on the lot/batch number has been requested.

Within 15 minutes after the vaccine patient started to have tachycardia, dizziness, and light headedness with syncope episode. She was taken to the ER where she improved . No further syncope episodes and released.

LOW GRADE FEVER- 99.3, BODY ACHES, CHILLS, HEADACHE, MALAISE, FATIGUE, LEFT ARM SORENESS

Swelling and induration at site

Headache; Fatigue; This is a spontaneous report from a contactable physician (patient-pending clarification). A 34-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, batch/lot number: unknown), via an unspecified route of administration on 18Dec2020 at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced headache and fatigue on 19Dec2020. The outcome of events was unknown. Information on the lot/batch number has been requested.

Fever 102. - 101, Chills for about 12 hours, bed rest for 24 hrs took Tylenol every four hours and fluids. The Vaccine site is red, swollen and hot size of an orange. After 12 hours fever broke, exhausted for additional 12 hrs. No symptoms 12/22 or 12/23/2020

"Got this biggest heat flash to my face; Nervous; Everything's swollen; face numb; Everything's swollen; face numb; This is a spontaneous report from a contactable consumer (patient herself). A 49-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number EK5730), as first single dose on 19Dec2020 for COVID-19 immunisation. No relevant medical history and concomitant medications were provided. The patient is an X-ray tech, mammography tech. She stated ''I had the COVID-19 Vaccine yesterday and I had there like they told me for 50 minutes. I went home and I started driving home and, on my way, home yesterday I got this biggest heat flash to my face and then I think became numb for about 2 hours."" The patient also stated 'I came home and my husband watched me and I was like I am nervous. I was like I may try get swell because everything's swollen, I would have called but it was just my face numb."" The outcome of the events was unknown."

Employee reports right sided eye and facial droop 2 hours after receiving vaccine but did not report the incident until 12/23/20. BP-140/89, light headache. Did not seek any treatment since , BP checked today 12/23/20 was 90/60. slightly facial asymmetry still noted, no other associated s/s. Neuro check intact as of this date. Employee referred to f/u with PCP.

Itching, Tingling to scalp, trapezius area of the back and arms. Experienced this 1 week after the vaccine. Patient took Allegra and symptoms resolved after 1 hour. Patient continues to have no symptoms 24 hours after taking the Allegra.

Body ache; pain in arm from the vaccine; fever; This is a spontaneous report from a contactable consumer (patient's wife). This consumer reported same events for two patients. This is 2nd of two reports. A male patient started to receive BNT162B2 on 18Dec2020 (reported as yesterday, as of 19Dec2020) at single dose for covid-19 immunisation. Medical history, concomitant medications or past drug history were not provided. He experienced body ache, pain in arm from the vaccine and fever in Dec2020. Outcome of the events was unknown. Information about lot/batch number has been requested. ; Sender's Comments: Linked Report(s) : US-PFIZER INC-2020506072 Same reporter/ drug/ event for different patients.

awoke with chills fever nausea diarhea as well as tinitus and dizziness

"Woke up in middle of night with sore arm to include down arm to pinkie and ring finger. Next morning did not look in the mirror unknown if woke with hives. Around 11am 03/18/2020, noticed ""hives on neck, face and eyelids"". States purple dot rash ""reminded me of a hickey all over my neck."" Did not take any medications, call doctor or notify anyone until she saw her supervisor Monday. Started to Clear up almost gone away. States resolved now."

Incredible pain at the injection site that radiate down her arm, lasting through the night; Felt very fatigued after the vaccine; She didn't sleep well due to pain; This is a spontaneous report from a non-contactable consumer. A 33-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via intramuscular, on 18Dec2020 at first single dose on the arm for COVID-19 immunisation. No relevant medical history and concomitant medications were provided. The patient reported incredible pain at the injection site that radiate down her arm, lasting through the night. Also felt very fatigued after the vaccine. She didn't sleep well due to pain, fatigue may also be caused in part by this. The outcome of the events was unknown. No follow-up attempts are possible. No further information is expected.

"Woke up on 12/18 with chills, fever of 102, and achy. Also, noticed red rash on back (from shoulders to waist), under both upper arms, and belly on 12/19 (but said it could've been there on 12/18). On 12/19, spread to around neck. Pruritic (""couldn't stand it"") and used hydrocortisone."

Had a fever about a 102; This is a spontaneous report from a contactable consumer (patient's wife). A 54-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number EH9899), via an unknown route, at single dose on 18Dec2020 for COVID-19 immunisation. The patient did not have a relevant medical history and concomitant medications. On 19Dec2020, the patient had a fever about a 102. The outcome of the event was unknown.

the day she got the shot she had arm pain. The next day she had chills, fever and body aches. As of the 23rd she still has body aches.

Felt some palpitations, racing heart, scratchy throat, dizziness, a little shortness of breath. Alerted the professionals observing and was monitored. Starting feeling a little better, then got a second wave of above symptoms again. I felt tingly all over and my lips felt tingly. They ended up taking me to ER. I started to also feel nauseous. They ended up giving me 1L of fluid, 25mg of diphenhydramine, 125mg of solumedrol, and 20mg of Pepcid. Monitored me for a few hours and then discharged me home. I was instructed to take another 50mg of diphenhydramine before bed, which I did. I ended up missing work the rest of my shift since I was in ER, then missed work the next day.

Fever; Mild headache; Fatigue; This is a spontaneous report from the Pfizer-Sponsored program received by a contactable consumer. A 55-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number EH9899 with Expiration Date Mar2021), via intramuscular, on 17Dec2020 at single dose for COVID-19 immunisation. The patient did not have a relevant medical history and concomitant medications.. On 19Dec2020, the patient developed mild headache and fatigue. On 20Dec2020, the patient experienced fever. She stated ''I will take some paracetamol (TYLENOL) whatever for next couple days, if it is not then I need to get COVID Test''. The outcome of the events was unknown.

About 15 minutes I started to get hives, skin reaction and felt chest pressure, I let Dr. know I wasn't feeling well, administered Epinephrine with own EpiPen, noticeable hives and redness across neck and upper chest. Transported to the ED. 2nd dose of Epinephrine at 1:20pm for throat swelling and bronchospasm.

Patient misunderstood when to return for second Covid vaccine dose. Patient returned for dose #2 four days after dose #1. Screening process did not catch timing discrepancy. Patient received dose#2 four days after receiving dose#1. Patient did not experience any adverse effects from either injection.

Headache; This is a spontaneous report from the Pfizer-Sponsored program received by a contactable consumer (patient herself). A female patient of unknown age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via intramuscular, in Dec2020 (three days ago, as reported) at single dose for COVID-19 immunisation. No relevant medical history and concomitant medications were provided. The patient stated she took the COVID-19 shot three days ago and she started having headache. The outcome of the event was unknown. Information on the Lot/batch number has been requested.

No immediate A/E. At the one hour post-vaccine reported mild nausea, hot flashes on/off for another hour, and bumps on the forehead. Bumps we not visible, mildly palpable, not itchy, and possibly contact dermatitis from face shield - this vaccine is a nurse that returned to duty after the 15 minute observation time. No treatment, self monitor only .

Pfizer-BioNTech COVID-19 Vaccine- Chills, low grade fever 99.8, body aches/ joint pain, fatigue, start 12/19/20 and continued symptoms to present 12/23/20

She is not feeling well; Chills; Sweating; Fever; This is a spontaneous report from a Pfizer sponsored program from a contactable consumer reported for her daughter. A female patient of an unspecified age received her dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of

administration on an unspecified date at single dose for COVID-19 immunization. The patient medical history and concomitant medications were not reported. The reporter She mentioned that the patient got her vaccine this morning and unfortunately the patient was experiencing some side effects or symptoms. The patient who was a nurse who just received the vaccine, the Pfizer vaccine yesterday from the hospital where she worked. And today she was not feeling well, she got chills and she was sweating, and just not well. It sounded like she was having some side effects 30 percent (Further clarification was unknown), to get the Chills and fever, 15 percent of (incomplete sentence). The reporter asked how long they had to wait if someone was feeling unwell from the shot. The patient got to start her 12 hours shift and should she be going back to work and doing 12 hours shift, if she was not feeling well with fever, she had got chills. The reporter asked how long it anticipated her feeling like this. The outcome of the events was unknown. Information about Lot/batch number has been requested.

Pt received the Pfizer-Biontech COVID19 Vaccine, Lot #EH9899 around 1830 today (12/22). A few minutes after the vaccine was administered in the left arm, the patient started having itching on her left shoulder that spread up to her neck. This was followed up by a warm feeling and mild blotching on the neck and face, more so on the left side of her body/face. When the patient brought this to staff attention, we began very close monitoring and started taking vitals regularly. Blood pressure ranging from 141/91 to 139/86, HR ranging from 120-86 bpm. . Around 1905 the patient was given Benadryl 25 mg tabs- 2 tablets by mouth one time only. Around 1908 the patient said her L ear started to itch also. We took vitals multiple times and the blood pressure and heart rate had decreased. Around 1935 the patient said she was feeling better, the mild blotching on the L side of her face and neck had almost completely resolved. The patient stated she felt much better and felt that she can could drive home safely. The patient spent a total time of one hour being monitored. á Of note: the patient admitted that she has white coat hypertension and today it was probably even worse. She said she had a lot of caffeine today and that could have also led to her being tachycardiac.

Employee had itchiness and rash on both arms almost 30 minutes after receiving vaccine. She denied shortness if breath, tachycardia, lightheadedness, and difficulty breathing. She denies a similar reaction from any other vaccines.

Little sinus pressure; may be a little bit of soreness of the throat; Little bit a soreness in throat, scratching of little bit but not too sore; or just allergies; Heart rate low/60 beats per minute; Ache in right side of my ribs; This is a spontaneous report from a contactable consumer (patient). A 53-years-old male patient received BNT162B2 (lot number: EJ1685) via an unspecified route of administration on 18Dec2020 at single dose for COVID-19 immunization. The patient medical history was not reported. Concomitant medication included fluticasone propionate. The patient was given vaccine shot (later clarified as Covid 19 vaccine) yesterday and just got a side effects of little sinus pressure, may be a little bit of soreness of the throat. About treatment, the patient took some Advil and he took some sinus pills, congestion pills a little bit earlier. It was clarified as nasal Decongestant, nasal congestion, 30mg, take 2 in 24 hours but he had taken two of them earlier along with 3 Advil pills. He deals with sinuses too but this one is like came on pretty much kind of overnight. He was wondering if doing the shot or something, he was not sure what's the matter or just allergies. It was just the sinus pressure yet. He didn't have the fever, not fever. Little bit a soreness in throat, scratching of little bit but not too sore. His

heart rate is 60 per minute so it is low, 60 beats per minute, very low. He had just low heart rate though. About lab work the patient stated that went in for side pain, side ache in right side of his ribs. They did ear analysis, CBC. They all came back normal. He just wanted a report in and see he guessed just find it out if the symptoms go away or maybe he is having sinus infection going on or this sinus be going on so. Events outcome was unknown.

lightheaded, dizzy, nausea, vomiting, tingling in the hands and face, diaphoretic, tachycardia

"I got the injection Friday Morning I had a little soreness and tiredness and when I drove home at 7pm I was having bad arm pain , Saturday morning the arm pain was really bad I couldn't lift my arm, I called my Dr I assumed it was the same and my palanziq. Dr said the pfizer and palanziq both made my immune system hyperactive and was prescribed acetaminophen and 6 days steroid pack that starts with ""M"", after I took the steroid my mobility was better by Monday the arm pain was gone. one ear temp was 99.4 and the other ear was 98.6 I never spiked a fever"

Fever, fatigue, injection sight pain, join pain, rapid pulse, headache, feel unwell

pain at the injection site; headache; joint pain; fatigue; chills; This is a spontaneous report from a contactable Pharmacist. A female patient of an unspecified age received BNT162B2 via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient medical history was not reported. The patient's concomitant medications were not reported. The patient shared information about her experience after receiving the Pfizer BioNTech COVID-19 vaccine. The patient reported pain at the injection site, headache that she treated with Naproxen, joint pain, fatigue, and chills that lasted for 72 hours. Events outcome was unknown. Information on the Batch/Lot number has been requested.

Progress Notes MD (Physician) ? ? Endocrinology Date: 12/22/2020 á Subjective Patient is a 21 y.o. male who was seen at COVID Vaccine Clinic today for his first dose of the COVID 19 vaccination. á He denied any history of previous adverse reactions to vaccines. á He was given the Pfizer vaccination in the right deltoid muscle. Vitals: á 12/22/20 1838 12/22/20 1839 BP: á 129/81 Pulse: á 90 Temp: 97.4 ¦F (36.3 ¦C) 97.4 ¦F (36.3 ¦C) á Vitals are normal á Checked his blood sugars- normal at 96 98% o2 sat á á During his 15 minute waiting period after the injection, the patient began to experience dizziness. He denied rash, hives, welts, difficulty breathing, difficulty swallowing, wheezing, throat tightness, hoarseness, stridor, itching, facial swelling, lip swelling and tongue swelling. á This provider was notified of patient reaction and he was then assessed in the emergency bay area. á Monitored patient for severe reaction symptoms, including rapid progression of symptoms, respiratory distress with stridor, wheezing, dyspnea, increased work of breathing, persistent cough and cyanosis, vomiting, abdominal pain, hypotension, dysrhythmia, chest pain and collapse. á á á á Objective á á Physical Exam Constitutional: Appearance: Normal appearance. He is normal weight. HENT: Head: Normocephalic and atraumatic. Nose: Nose normal. Mouth/Throat: Mouth: Mucous membranes are dry. Pharynx: Oropharynx is clear. Eyes: Extraocular Movements: Extraocular movements intact. Conjunctiva/sclera: Conjunctivae normal. Pupils: Pupils are equal, round, and reactive to light. Neck: Musculoskeletal: Normal range of motion and neck supple. Cardiovascular: Rate and Rhythm: Normal rate and regular rhythm. Pulses: Normal pulses.

Heart sounds: Normal heart sounds. Pulmonary: Effort: Pulmonary effort is normal. Breath sounds: Normal breath sounds. Abdominal: General: Abdomen is flat. Bowel sounds are normal. Palpations: Abdomen is soft. Musculoskeletal: Normal range of motion. Skin: General: Skin is warm and dry. Neurological: General: No focal deficit present. Mental Status: He is alert and oriented to person, place, and time. Psychiatric: Mood and Affect: Mood normal. Behavior: Behavior normal. Thought Content: Thought content normal. Judgment: Judgment normal. á á á Assessment/Plan Treatment included: water, rest. Follow up response to treatment: excellent. Patient discharge: Stable to go home and follow up with PCP. á á á á MD Electronically Signed 12/22/2020 6:39 PM

After an hour the left foot was numb. Arm is sore at the injection site. Then it went away. Today having body aches, back pain. Temp is 99.7. Had COVID in April.

Just a tiny red mark; This is a spontaneous report from a Pfizer-sponsored program Corporate (Pfizer) Social Media Platforms. A contactable consumer (patient) of unspecified age and gender received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for Covid-19 immunisation. The medical history and concomitant medications were not reported. The patient did not have pain, swelling or anything. Just a tiny red mark. The outcome of the event was unknown. No follow-up attempts are possible. Information about batch number cannot be obtained.

Waited 30 minutes for observation. Driving back home. Left side of face got tingling and on left arm. Just going away. Tingling is going away. Walking up the stairs, and got long winded and feeling fast heart rates. Tried to get up feeling fatigue. Notified manager. Informed of Vsafe to register there as well Scheduled to work on Monday 12/28 on site. Last onsite worked day was 12/22/2020 Covid testing last August and was negative Per the algorithm, her recommendations were to monitor and call PCP and 911 if symptoms persists or worsens

Started with a very sore arm with redness and warmth to the arm around 11PM and by 2AM started with chills but no elevated temp and then nausea. She reports she slept 12 hours and was then doing well.

Tachycardia, light headed,very dry mouth, numbing of tongue

Sore left arm; This is a spontaneous report from a Pfizer sponsored program Corporate (Pfizer) Social Media Platforms from a non-contactable Other HCP reported for self. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) at single dose on an unspecified date for COVID-19 immunization. Medical history and concomitant medication were not reported. Other than a sore left arm, patient felt great. The outcome of event was unknown. No follow-up attempts are possible. information about lot/batch number cannot be obtained.

Chest pressure, dizziness, increased troponin lab value.

"Fine? I've never felt fine after antiviral inoculations.; This is a spontaneous report from a Pfizer-sponsored program Corporate (Pfizer) Social Media Platforms via a non-contactable consumer. A patient

of unspecified age and gender started to receive BNT162B2, via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. Medical history and concomitant medications were not reported. Patient reported ""fine? I've never felt fine after antiviral inoculations"". Outcome of the event was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained."

Scratchy, sore throat, cough, SOB, asthma like symptoms (closing/tightness of esophagus/throat. Lungs hurt with deep breath.

Feverish; Body is aching/I am in too much pain; This is a spontaneous report from a contactable consumer (patient herself). A patient (demographics unknown) received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unknown route, at single dose on 18Dec2020 (at 14:00) for COVID-19 immunisation. No relevant medical history and concomitant medications were provided. On 19Dec2020, the patient had feverish and body is aching/I am in too much pain. The outcome of the events was unknown.

feeling off, shaky, swollen hand and arm on injection side. slight slurred speech

At 1103 reporting feeling itching on chest and arms

1. Significant Tinnitus, no treatment. Severity decreased the following day, but persists until present (12/23/2020). 2. Numbness of front upper teeth. Resolved by 12/22/2020.

Abdominal cramps overnight with back pain, then awoke with fever, chills, headache, significant body aches including continued back pain and fatigue. Symptoms improved the morning of 12/23

12/18/2020 02:45 AM WOKE UP BECAUSE UPPER RIGHT SIDE OF BACK, WAS HURTING, THROBBING, WOKE ME UP. STOOD UP, KEPT HURTING AND GETTING MORE INTENSE. BROKE OUT IN SWEAT, UNCOMFORTABLE, PAIN, DRY HEAVES DUE TO INTENSITY OF PAIN; 10/10 PAIN LEVEL 'SOLID'; LASTED 45 MINUTES. FELL BACK ASLEEP, WENT TO WORK 12/18/2020 THAT DAY. FELT LIKE IT WAS BRUISED 'KIDNEY AREA' ON UPPER R BACK. I BELIEVE IT WAS EVENING, I URINATE AND FELT 'SLIGHT BURNING' SENSATION; THIS HAPPENED THE REST OF THE EVENING. 12/19/2020 WENT TO CLINIC. DR. STATED URINED SAMPLE WAS NEGATIVE; UNDISCLOSED DIAGNOSIS OF URTHRITIS. GIVEN SHOT OF ANTIBIOTIC, AND PRESCRIBED ANTIBIOTIC FOR 7 DAYS. 12/20/2020-12/23/2020 FELT FATIGUED AND MALAISE. FELT LIKE JOINTS WERE 'TIRED' AND 'ACHY'; 'SLIGHTLY OFF'. 2 HOURS AFTER VACCINATION ON 12/18/2020 - 'TICKLE IN MY THROAT', STAYED AND IRRITATED, BROUGHT ON COUGHING. STAYED UNTIL 12/19/2020 WHICH TURNED INTO A RASPY WITH EXCESSIVE THROAT CLEARING. I DO DRINK A LOT OF WATER, STAYING HYDRATED. FLU VACCINE IN POSSIBLY OCT 2020

Received the vaccine on Thursday December 17th. On Saturday December 19th at about 48 hours, started to have an intense nerve type itch on the right arm and the right leg. No rash visible. Treated with Benadryl oral. Itch keeps coming back and is now at Day 4 without resolution. Also has felt very tired for about 4 days.

patient complained off flushed face; waited 15 extra minutes until feeling better

Shortly after receiving the Moderna COVID-19 Vaccine (Within minutes) she complained of the injection site and that arm of feeling warm. Upon further inspection, her arm was warm to the touch and was red. Patient could feel warmth from inside and we could also feel the warmth with touch. She stayed 15 minutes and we monitored the site. There was no further reaction. The patient had been offered Benadryl and declined. This will be notated for her second dose and will pre-treat with benadryl if needed.

No side effects until 1PM on the 18th, hot flashes with dizziness and nausea, then I started feeling like I was going to pass out and then felt like the blood was rushing through my head. Also head headache. I received a shot of Zofran 4mg. 30 min later I was able to sit up up and 10 min later I was able to stand without being dizzy. Still having waves of nausea. Body aches and flu like symptoms on Saturday. Right now only the nausea. Monday I was fine, but today it started the nausea and dizziness. No intervention needed today.

Patient received COVID vaccine at approximately 9AM this morning. Stayed 15 minutes after injection for monitoring, felt fine and returned to department. Employee returned at approximately 11:45AM with possible symptoms of reaction. Admitted to a headache that started approximately an hour after injection. Symptoms now include heaviness of arm, chest, feeling emotional, light headed. Vitals taken at 11:48 BP 150/86, P 79, R16 Pox 97. Oral Benadryl 25mg administered PO 11:50AM. EKG run. Patients symptoms progressed to include difficulty breathing and swallowing. Epi pen adult 0.3mg administered IM Left thigh at 12:13PM. Vitals checked at 12:13PM BP 188/90, pulse 97, pulse ox97. Called for emergency response for transport to ER. Pt remained stable until transport by EMS to ER. Employee health informed of patient transport. ER informed of patient transport.

After leaving Clinic symptoms started within 10 minutes. Started with scratchy throat. Then tingling in my lips. Bottom lip slightly swollen.

"History Present Illness: 26 year old female presents to walk in clinic with c/o feeling dizzy, flushed and heart racing after receiving COVID-19 vaccine earlier today. She took a benadryl about 30 min before receiving the vaccination. She is 11 weeks post partum. She is still breastfeeding her baby and reports she has ""not drank very much today."" At time of visit, she reports she ""feels much better."" She denies PMH of heart issues or any prior anaphylactic reactions. She denies shortness of breath or trouble breathing. She does not appear to be in acute distress at this time. Her vital signs are WNL."

THERE WAS NO ADVERSE EVENT. We realized after administration that we had inadvertently given the vaccine to a 15 year old girl. She is not having any symptoms or problems. We have been monitoring her and encouraged her to speak with us if she has any issues at all.

general warmth and dry throat

Stayed for 25 minutes for observation and told to call in 24 hours. Sore arm

12/18/2020 Day after injection chestpain that was progessive day before visit to ER on 12/19/2020.Described pain as pressure in middle of chest, radiated to upper left chest under armpit,

with associated nausea, feelings of Heart Palpitations, EKG shows 98bpm, normal intervals, t wave inversion lead III, normal sinus rhythm. BP 151/83, sats 100% temp 98.4 HR 99. labs cardiac enzymes negative, Ddimer elevated,CT chest negative for pulm embolism and chest xray no acute process. scheduled to see her PCP on 12/22. diagnosed with lymphadenopathy and chest pain, the lymph nodes noted after injection of covid #1 vaccine. 12/22/2020 was given a steroid shot in the PCP office,

Patient complained of a rush of feeling hot, symptoms progressed to feeling light-headed and dizzy. Skin was warm and dry. Experienced hypertension which got worse when told her blood pressure was high. Patient was transferred to the ED for further observation.

10 minutes after receiving the injection I was experiencing dizziness and lightheadedness. As I was moved to a new location I was still experiencing aforementioned symptoms in addition to feeling hot and nauseous and I vomitted. I was moved to the ER for further evaluation. I was given a COVID test, an EKG and my vitals were monitored. I was discharged home.

Nausea and dizziness within 5 minutes of administration, continued for 2 hours, transferred by private to ED for continued monitoring.

dizziness, vertigo nausea diarrhea chills weakness headache

Employee received vaccine on afternoon of 12/22/2020 at clinic She states she did have COVID previously in November. She called in this morning with vomiting and now has fever of 101.9, headache, body aches,fever, productive cough, loss of appetite, She has contacted her PCP for suggesntions.

Pt C/O blurry vision, palpitations and sweating for 3 seconds. this occurred 10 minutes after receiving vaccine.

Developed redness and warmth and some swelling at injection site that began about 7 hours after injection and grew in size to about 3 inches the next day. It did itch but otherwise some discomfort pain to area. By day 5 the area had almost healed entirely.

Metallic taste in mouth immediately Headache that lasted days

"About 12 minutes after receiving covid vaccine, pt felt like she had a lump in her throat. No difficulty breathing or swallowing. No facial swellling. Pt was evaluated by PA from urgent care. Pt was transferred to urgent care for antihistamine administration. Vitals remained stable. 12/23/20 @ 1212: Note copied from UC Visit: Diagnosis Allergic reaction (ICD10-CM T78.40XA, Working, Medical). Summary: 0916 ""Lump is still there but much smaller"" Still no sign of intraoral swelling 0925 Patient reports symptoms have almost resolved completely, comfortable going home. Instructed to take Zyrtec tonight before work and for the next couple of days and to go to hospital for SOB, worsening sensation of lump in throat. Patient verbalized understanding and is in agreement with treatment plan. Opportunity for questions was given, all questions answered.. Pharmacy: diphenhydrAMINE (Benadryl) AMB (Order): 25 mg, IM, InOffice."

About 4 hours later I began have tightness in my abdomen and cramping, followed by gastrointestinal upset and diarreha and pain in my upper abdomen. I will wait and see if it resolves by tomorrow before going to the hospital for care.

Pt stated she had a reaction to the Covid-19 vaccine. Pt states she cannot raise her arm, where she got the injection is very hot to the touch, and she has pain all the way up to her neck. A slight knot at injection site.

mild transient rash with some welts, but mostly redness and itching located on right foot and ankle. Took diphenhydramine 50 mg po x 1 dose and used hydrocortisone cream x 1 application. Rash resolved in that location, but came up on both thighs just above the knee cap on both legs on Sunday. Repeated diphenhydramine 50 mg po x 1 and used hydrocortisone 1% cream x 1 application. Both events resolved within 2 hours, with no further issues. This could be unrelated since it was 4 days out, but I wanted to report it for consideration.

On 12/18 feeling congestion and stuffy nose was able to go work that night as well 12/19. Then on 12/21 realized lost taste/smell went to get test for Covid results positive. As of 12/23 still haven't gain taste/smell. I had to miss 10 days of work.

tachycardia, dizzy, dry mouth

Progress Notes MD (Physician) ? ? Endocrinology COVID VACCINE CLINIC 12/22/2020 á Patient: Date: 12/22/2020 á Subjective Patient is a 42 y.o. female who was seen at COVID Vaccine Clinic today for her first dose of the COVID 19 vaccination. á Afebrile 98.6 á She denied any history of previous adverse reactions to vaccines. á She was given the Pfizer vaccination in the right deltoid muscle. á During her 15 minute waiting period after the injection, the patient began to experience dizziness. She denied rash, hives, welts, difficulty breathing, difficulty swallowing, wheezing, throat tightness, hoarseness, stridor, itching, facial swelling, lip swelling and tongue swelling. á This provider was notified of patient reaction and she was then assessed in the emergency bay area. á Monitored patient for severe reaction symptoms, including rapid progression of symptoms, respiratory distress with wheezing and dyspnea, vomiting, abdominal pain, hypotension, dysrhythmia, chest pain and collapse. á Vitals were normal Checked her blood sugars-normal at 108 Offered her snack/water-she declined. á Repeat BP normal at 112/72 á Vitals: á 12/22/20 1737 BP: 126/82 Pulse: 87 SpO2: 100% á á á á Objective á á Physical Exam Vitals signs reviewed. Constitutional: Appearance: Normal appearance. She is normal weight. HENT: Head: Normocephalic and atraumatic. Nose: Nose normal. Mouth/Throat: Mouth: Mucous membranes are moist. Pharynx: Oropharynx is clear. Eyes: Extraocular Movements: Extraocular movements intact. Conjunctiva/sclera: Conjunctivae normal. Pupils: Pupils are equal, round, and reactive to light. Neck: Musculoskeletal: Normal range of motion and neck supple. Cardiovascular: Rate and Rhythm: Normal rate and regular rhythm. Pulses: Normal pulses. Heart sounds: Normal heart sounds. Pulmonary: Effort: Pulmonary effort is normal. Breath sounds: Normal breath sounds. Abdominal: General: Abdomen is flat. Bowel sounds are normal. Palpations: Abdomen is soft. Musculoskeletal: Normal range of motion. Skin: General: Skin is warm and dry. Neurological: General: No focal deficit present. Mental Status: She is alert and oriented to person, place, and time. Psychiatric: Mood and Affect: Mood normal. Behavior:

Behavior normal. Thought Content: Thought content normal. Judgment: Judgment normal. á á á Assessment/Plan Treatment included: no therapy. Follow up response to treatment: excellent. Patient discharge: Stable to go home and follow up with PCP. á á á á MD Electronically Signed 12/22/2020 5:38 PM á á á

Patient reports after she received the vaccine she reported to the observation area for the 30 minute monitoring period and reported feeling her heart racing. Patient with hx of histamine intolerance and angioedema, so carries epi pen with her. Patient notified monitors of her symptoms and her medical hx and that she had her epi pen with her. Patient reports ?heart racing? and recorded 130 BPM on activity tracker. Pt endorses history of anxiety and panic attacks. Patient reports resolution of symptoms at approximately 8:15 am, resting HR at that time 97-98 BPM. Patient denies any other symptoms.

Rash, Flush, felt hot, itchiness, headache, dizziness

Patient called and reported diarrhea, vomiting and nausea ~ 36 hours after vaccine was administered. Resolved in ~ 18 hours. Felt great the next day.

Right sided jaw pain started 12/22/20 in the AM progressed through the evening. When I woke I had numbness and weakness on the right side of my tongue which I quickly realized included the lower portion of my right face. An ER trip and a CT scan confirmed it was Bells Palsy. The upper portion of my face has is now included in the weakness and paralysis.

Temperature of 100.1 about 5 hours after administration with mild frontal headache. Today - about 24 hours after adminstration - herpetic rash developed along the left mandibular branch of the trigeminal nerve.

Patient given covid-19 vaccine at 1218, Symptoms started at 12:25 (dry cough, dry mouth). Benadryl 25mg by mouth given at 1238. No previous history of vaccination reaction. Of note: recent history of Clinically diagnosed bronchitis and treated with OTC medication (mucolytic) by pcp, no ATB given. No NKDA, no recent fever or illness in 24hours. Initial VS: BP: 142/84, HR: 111, RR: 24 Spo2% 99/RA, . End VS: BP: 118/94, HR: 82, RR: 16,, SpO2: 100%/RA. Patient denies shortness of breath or difficulty breathing, Lung sounds are clear. Patient states she feel better and is conscious alert and oriented X4. She was placed in he monitoring room within the vaccination clinic for intermittent monitoring of VS and reaction response at 1317.

on 12/16/2020 my arm was red from the injection like everyone else but my symptoms began the next day on 12/17/2020 I was in the shower in the morning it was noticeably sore and the following day the 18th it was quite a bit bigger and red, I could still move my arm. I was overly tired and very sluggish I went to the Dr on the 18th and they gave me a prescription for keflex and prednisode

Patient with past medical history significant for thyroid cancer was given Pfizer COVID-19 vaccine at approximately 1430 at our facility. After receiving vaccine patient felt flushed, face hot, felt something squeezing neck (similar to tight collar). 25 mg PO diphenhydramine given X 1. Patient having shivering on and off. Felt swelling progress up into back of throat. Had to clear throat and swallow harder. At 1511

patient was checked into the emergency department at our hospital. At 1527 famotidine 20 mg IV once given. BP was found to be 232/100. Amlodipine 5 mg IV once given at 1909. Labetalol 10 mg IV once given at 1812, labetalol 20 mg IV once given at 2034, clonidine 0.1 mg PO once given at 2127. Patient sent home at approximately midnight. Diagnosed with possible anaphylaxis and hypertensive urgency (no history of HTN).

Ten minutes after receiving Pfizer Covid vaccine shot in right shoulder, experienced partial numbing of the hands which persisted all day. Next day no numbing of left hand, but right hand still partially numb.

Patient complained of a rush of feeling hot. Patient was laid supine, VS monitored. Patient was transferred to the ED.

Right after patient was given vaccine injection he started to feel lightheaded and woozy. He had just worked the night shift and hadn't eaten anything. No prior illness reported. Patient brought to emergency department to be evaluated. Received 500ml of fluids and symptoms resolved and he went home. Diagnosis of near syncope.

Hives, administered Diphenhydramine 12.5mg po

Muscle aches, chills arm discomfort

Patient c/o numbness of arm and feeling like she is floating - resolved after 2-3 seconds

Diffuse hives started ~ 12 hours post vaccine, progressively worsened to involve entire body, and required solumedrol & antihistamines at an Urgent Care visit

"On the night of 10/22/20 patient sat up suddenly and had what she reports as, ""75% dimming of the right eye,"" that lasted for about 5 minutes. Vitals at that time were BP 122/82, p 72, o2 sat 97% on RA, and temp 97.8. (Patient is a CRNA) After confirming no other neurological deficits, patient laid down and experienced blurring of her left eye with left eye pain. No treatment given. Today she has no vision deficit or pain."

Frequent palpitations - never experienced before EKG on 12/23 revealed frequent PAC's, sometimes with runs of PAC's

Patient reports shortness of breath and persistent cough.

facial numbness and tingling, disappear in 24 hours

45-60 minutes post vaccination, patient experienced right eye twitching continuous for a few hours, then intermittent x 24 hrs; now resolved 12 hours post vaccination, patient experienced right ear/jaw numbness that lasted up to 36hrs 36 hrs post vaccination, the numbness is spreading to the right cheek no affect in muscle function, just numb pt seen at urgent care facility 12/23 @~0830 and prednisone initiated

Tingling down right arm into right hand, spread to left arm and hand. Stiffness in neck. After an hour progressed into muscle weakness in both forearms, more noticeable in the right arm. Best described as lactic acid buildup feel in forearm-had trouble lifting/pulling door handles. Has subsided over a day, no general soreness in both arms/ neck. Injection site has developed noticeable pain/soreness, somewhat like a tetanus shot . There was a fair amount of blood at the injection site (not typical for me), and the administration of the shot was a touch high in the arm.

Lightheadedness, tingling extremities and dizziness

Fatigue, sweaty, and dizziness

Staff member started to feel fatigue and chills the evening he received the vaccine. Symptoms continued the following day and a half. Fever was as high as 101.4. He had COVID nine months ago. Symptoms have resolved.

Nausea, fatigue, headache, flushing

PATIENT STATES HANDS TINGLING BUT WENT AWAY PATIENT HAD NOT INTERVENTIONS OR PROLONGED OBSERVATION

Lip and tongue tingling

TINGLING LIPS REPORTED

Soreness at injection site, Fever at 99.8 degrees F. Body Aches, headache

12/21/2020: fatigue, muscle ache 12/22/2020: fatigue, muscle ache, headache, fever, loss of appetite, nausea, and sore throat.

Patient became flushed, chest tightness and felt winded. BP was 130/70 and 02 saturation was 100%. Patient had not tongue swelling, previous reaction to a vaccine, medication or food and no shortness of breath. Patient was placed on gurney for 30 minutes and had no further symptoms after this time.

Fatigue, diarrhea, whole body aches, fever

Bad headache and sore on injection site

Injection site raised, firm area (size of quarter); redness but no streaking; extreme tiredness, chills, headache, neck pain. Patient went to walk in clinic and provider believed her to be having a localized allergic reaction to the COVID vaccine. She was given a steroid injection, and started on oral steroids.

1 hr post administration patient developed urticaria, pruritus

"Progress Notes PA-C (Physician Assistant) ? ? Orthopedics Cosigned by: MD at 12/22/2020 á9:48 AM á á Patient: Date: 12/21/2020 á Subjective Patient is a 34 y.o. female who was seen at COVID Vaccine Clinic today for her first dose of the COVID 19 vaccination. á á She was given the Pfizer vaccination in the right deltoid muscle. á During her 15 minute waiting period after the injection, the patient began to

experience generalized feelings of ""not feeling quite right"" as well as anxiety/nervousness, nausea and chills. She denied difficulty breathing, throat tightness, dizziness, chest pain, or other GI complaints. á This provider noticed her raising her hand from across the waiting area and tended to her where she noted the above complaints. she was then assessed in the emergency bay area. She was monitored for severe reaction symptoms, including rapid progression of symptoms, vomiting, hypotension, chest pain, collapse and Respiratory distress. á Past medical history includes anxiety for which she takes Effexor on a daily basis as well as type 2 diabetes, diagnosed approximately seven or 8 years ago during a pregnancy. She is on oral medication during the day and insulin at nighttime. She did take her oral medication today and last ate a pasta lunch right before arriving to the vaccine clinic. Last A1c was 6.5. Patient states that she generally runs a postprandial blood glucose following a heavy meal of about 180. á She reported a previous history of anxiety and nervousness following vaccinations in the past. Most recently, she experienced a 30-minute period of anxiety and nervousness following her flu vaccine this past October. These feelings passed without further incidents. á Review of Systems Constitutional: Positive for chills. HENT: Negative for drooling, facial swelling, hearing loss, rhinorrhea, sneezing and trouble swallowing. Eyes: Negative for redness and visual disturbance. Respiratory: Negative for cough, chest tightness and shortness of breath. Cardiovascular: Negative for chest pain. Gastrointestinal: Positive for nausea. Negative for vomiting. Skin: Negative for color change, pallor and rash. Neurological: Negative for dizziness, speech difficulty and light-headedness. Psychiatric/Behavioral: Negative for agitation and confusion. The patient is nervous/anxious. á á á Objective á She ambulates into the emergency treatment bay under her own power and without difficulty. She is seated on the gurney, and continues to answer questions appropriately. á Physical Exam Constitutional: General: She is not in acute distress. Appearance: Normal appearance. She is not toxic-appearing or diaphoretic. HENT: Head: Normocephalic and atraumatic. Nose: No rhinorrhea. Cardiovascular: Rate and Rhythm: Regular rhythm. Tachycardia present. Pulmonary: Effort: Pulmonary effort is normal. No respiratory distress. Skin: General: Skin is warm and dry. Coloration: Skin is not pale. Findings: No rash. Neurological: Mental Status: She is alert. Gait: Gait normal. Psychiatric: Mood and Affect: Mood normal. Behavior: Behavior normal. á á á Assessment/Plan Stress reaction secondary to vaccine administration and history of anxiety and nervousness following vaccinations. á Vital signs obtained at 1352 with blood pressure at 154/95, mild tachycardia at 109 and 97% O2 saturation on room air. Patient denies any chest pain, shortness of breath time. á She is given a bottle of water and assisted to lie down with the head of the bed slightly elevated. She continues conversating appropriately without any acute distress. Vitals reassessed at 1359 with blood pressure of 133/76, heart rate 97% on room air. Dr. at the bedside now. Suggested obtaining a blood glucose. Blood glucose obtained at 1405, elevated at 234. She continues to deny any chest pain, shortness of breath, chest tightness, swelling in the throat, nausea/vomiting or other GI complaints. á Vital signs checked again at 1406 with blood pressure 133/77, heart rate 107 and 97% on room air. á Vital signs last checked at 1415 to reveal a blood glucose of 219, blood pressure 127/82, heart rate 100 and O2 saturation of 97% on room air. Patient has no additional complaints at this time and reports feeling well. Her mother has driven her to the clinic today. She felt that she was able to safely walk out with any issues. She was assisted by nursing staff and ambulated out of the treatment bay independently. á Treatment included routine surveillance of vital signs at about a 5-minute intervals following notification of her feeling poorly. Vital signs continued to normalize and remained stable through the duration of her 30 minutes following her vaccination. á Follow up response

to treatment: excellent. á Patient discharge: Stable to go home and follow up with PCP. Recommend to patient that she present to the ED or call 911 should she develop any symptoms up to and including but not limited to chest pain, shortness of breath, chest tightness, signs or symptoms of angioedema, or syncope. She expresses understanding the above and has no further questions today. á Orders Placed This Encounter Procedures COVID-19 MRNAá PA-C Electronically Signed 12/21/2020 1:51 PM á á"

injection site soreness; myalgias; chills; fatigue; nausea; loss of appetite; enanthem (2 oral ulcers); enanthem (2 oral ulcers); This is a spontaneous report from a non-contactable consumer (patient). A 39-year-old female patient started to receive BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) Solution for injection (lot number: EH9899 and expiry date unknown) via an unspecified route of administration at the left arm on 18Dec2020 12:30PM at a single dose for COVID-19 immunization and monascus purpureus (RED YEAST RICE), via an unspecified route of administration from an unspecified date to an unspecified date at an unknown dose and frequency as supplementation therapy. The patient's medical history included elevated LDL cholesterol and supplementation therapy, both from an unknown date and unknown if ongoing. The patient had no known allergies to medications, food, or other products. Concomitant medications were not reported. The patient did not receive any other vaccines within 4 weeks prior to BNT162B2. The patient only received red yeast rice supplements within 2 weeks of vaccination. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. It was reported that on 19Dec2020, the patient experienced injection site soreness, myalgias, chills, fatigue, nausea, loss of appetite, and enanthem (2 oral ulcers). No therapeutic measures were done in response to the events. Outcome of the events was recovering. The events were assessed as Non-serious. No follow-up attempts are possible. No further information is expected.

fever; chills; malaise; This is a spontaneous report from a contactable physician (Patient) via Pfizer-sponsored program. A 27 year-old-male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 18Dec2020 at single dose for COVID-19 immunization. The patient medical history and concomitant medications were not reported. The patient experienced fever and chills on 18Dec2020 (in the night); the patient also experienced malaise throughout the weekend (in Dec2020). Patient had vaccine on 18Dec2020 and was still having symptoms 3 days later. As of 20Dec2020, patient stated he was feeling better but wanted to know if he should get tested or did the vaccine cause these symptoms. Final outcome of the events was reported as unknown. Information on the lot/batch number has been requested.

"Experiencing burning while urinating; This is a spontaneous report from a contactable consumer (patient who is Nursing assistant). This 56-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot # EK5730), via an unspecified route of administration, on 19Dec2020 approximately at 10:00 AM (age at vaccination 56-years-old) at single dose for COVID-19 immunisation. Medical history included blood pressure. Concomitant medications included losartan for blood pressure and colecalciferol (VITAMIN D). The patient experienced burning while urinating on 19Dec2020 afternoon after she came home and on 20Dec2020 morning too. About treatment consumer stated: ""Not really, long time ago I had that but yesterday I did like oh"". The patient had complete

blood count (CBC) and C-reactive protein (CRP) test, results are unknown. Outcome was not recovered. Next shot is due on 09Jan2021."

Increased heart rate up to the 115-120s for 3 hours - self reported

Sore arm at injection site night of vaccine and next day. Then resolved (without taking any acetaminophen).

I had the covid 19 virus in March 2020. Actually, I still have loss of taste and smell. When I received the vaccine on 12/21/2020, I immediately felt a burning sensation at the injection site and in my chest. A headache developed 5 minutes after the vaccine. I began to experience fatigue, nausea, muscle aches and joint pain. I have been treating myself with Tylenol and Ondansetron. I am still experiencing these side effects today (12/23/2020)

Migraine headache with nausea and aura, treated with Toradol 60 MG IM 12/23/20 at 13:35.

pt became lightheaded and nauseated. Elevated feet and given ice pack for neck. Pulse 70, resp 16. rested for 30 minutes, feeling much better - able to ambulate without difficulty. States she just feels a little off. Husband came to take her home.

"After she waited for 30 minutes after receiving vaccine she stated that she had generalized itching and 2 small hives on her right arm. She said it started about 3 mins after receiving the vaccine. She was given 25mg of Benadryl syrup po. She stayed at facility another 30 minutes before being cleared to leave after she said the itching was better and no further hives formed. 12/23/20 -9:56am She was contacted by phone. She said she woke in the night and felt like ""asthma"" and had a rash at the site. She took another 25mg of Benadryl. She took another dose of Benadryl at 06:00am. As of this time, 9:56am, she states, no shortness of breath, no more rash at site, and the itching has subsided. She will follow up as needed."

I was itchy only to find out it was Shingles

1049: CG called OH and advised she received the COVID19 vaccine yesterday and woke up this morning at 0630 with a rash to her right chest and right hand, and complains of fatigue. CG denies any SOB or any other symptoms at this time. CG advised she has a history of COPD, Asthma, and granuloma disease. Advised she spoke with her Oncologist about receibving the vaccine who did not have any concerns but also voiced that she did not speak to her PCP. Occ. Health advised CG that she be seen by urgent care or PCP for current symptoms and to go to the ER if symptoms worsen or she becomes SOB. 1106: Called CG to see if she was able to touch base with PCP, advised that she has a call out to her and messaged her PCP. CG states that the rash has remained the same since this morning and that it does not itch anymore. Again advised CG if worsens to go to Urgent care or ER. CG verbalizes understanding. Will follow-up with CG later today. 1448: Called CG states the hives are mostly gone, she took some benadryl and feels back to her normal self, just has some scabs from where she scratched herself. CG states her PCP responded back to you that if she felt necessary should go to the urgent care or do a virtual

appointment. Cargiver declined and states she is feeling a lot better. Advised CG to call OH with any changes and to go to the ER or Urgent care for any emergency symptoms. CG verbalized understanding.

30 minutes after vaccination pain occured on my left upper gums, left upper lip and into my left chee with swelling in the same locations, that have not resolved

EXTREME BILATERAL ITCHING ON BOTH ARMS THROUGHOUT

The day after receiving the vaccine, the arm that I got the vaccine in was in severe pain. I would say 7/10 pain. Anything even slightly brushing against it was very painful. It was a little red and hot to the touch. I woke up multiple times through the night because of the pain. I did NOT take anything for it. By the following morning it was just sore, like how you normally would feel after a vaccine.

11am on the 20th I noticed pain on my back torso and it came around to the left of my abdomen and was told it was textbook shingles rash and was prescribed valacyclovir 1gram 3x daily for one week, the pain is now mild and I can treat it with tylenol and I've only had to take it once, the rash is still there but it's not spreading I started the medication at 3pm after seeing the dr

25-30 min post injection patient reported feeling itchy and became flushed. Reported mouth tingling and difficulty swallowing. No difficulty breathing. Monitored the patient, sats were wnl BP was elevated. Cool pack placed on forehead, and patient took oral benedryl. After about 20 minutes color and BP had normalized, itching and tingling resolved. Patient ate and drank and felt well enough to leave on her own. No further issues.

after vaccination client had a weird taste in back of throat during 15 minute wait time. Had client wait additional 15 minutes and still had a weird taste in mouth.

First 30 min post-vaccine: flushing and lightheaded, self limiting. 1.5 hours post-vaccine: vertigo x10 minutes, palpitations, chest tightness. Palpitations were brief and at rest. BP 172/110, HR 95, O2 Sat 99% on RA. 2.5 hours post-vaccine: chest tightness has remained constant with mild restrictive sensation on full inhale, vertigo returned but briefer in duration, BP 173/100, HR 85, Temperature 98.5F, O2 Sat 97% with decrease during conversation. 3 hours post-vaccine: lightheaded with constant chest tightness, BP 168/110, HR 88, O2 Sat 98% on RA, 6 hours post-vaccine: symptoms resolved, BP 148/100, injection site burns and sore to touch.

Progress Notes 12/22/2020 á á Subjective Patient is a 46 y.o. female who was seen at COVID Vaccine Clinic today for her first dose of the COVID 19 vaccination. á She denied any history of previous adverse reactions to vaccines. á Pt has h/o hypothyroidism on LT4- last lab a few months ago Started feeling lightheaded and warm Doing a temp check á 135/94- repeat BP check Pulse between 72-90s on rechecked á á Blood sugar was just checked and normal at 76--repeat also normal at 86 á She is eating a snack and having some water. á She was given the Pfizer vaccination in the right deltoid muscle. á She said she has a h/o vasovagal episodes with shots, mammograms, etc. á During her 15 minute waiting period after the injection, the patient began to experience dizziness. She denied rash, hives, welts, difficulty breathing, difficulty swallowing, wheezing, throat tightness, hoarseness, stridor, itching, facial

swelling, lip swelling and tongue swelling. á This provider was notified of patient reaction and she was then assessed in the emergency bay area. á Monitored patient for severe reaction symptoms, including rapid progression of symptoms, vomiting, abdominal pain, hypotension, dysrhythmia, chest pain and collapse. á á á Objective á á Physical Exam Constitutional: Appearance: Normal appearance. HENT: Head: Normocephalic and atraumatic. Nose: Nose normal. Mouth/Throat: Mouth: Mucous membranes are dry. Pharynx: Oropharynx is clear. Eyes: Extraocular Movements: Extraocular movements intact. Conjunctiva/sclera: Conjunctivae normal. Pupils: Pupils are equal, round, and reactive to light. Neck: Musculoskeletal: Normal range of motion and neck supple. Cardiovascular: Rate and Rhythm: Normal rate and regular rhythm. Pulses: Normal pulses. Heart sounds: Normal heart sounds. Pulmonary: Effort: Pulmonary effort is normal. Breath sounds: Normal breath sounds. Abdominal: General: Abdomen is flat. Bowel sounds are normal. Palpations: Abdomen is soft. Musculoskeletal: Normal range of motion. Skin: General: Skin is warm and dry. Neurological: General: No focal deficit present. Mental Status: She is alert and oriented to person, place, and time. Mental status is at baseline. Psychiatric: Mood and Affect: Mood normal. Behavior: Behavior normal. Thought Content: Thought content normal. Judgment: Judgment normal. á á á Assessment/Plan Treatment included: rest, snack. Follow up response to treatment: excellent. Patient discharge: Stable to go home and follow up with PCP. á Discharge time 5:51pm á á á 12/22/2020 5:19 PM á á

visual disturbances and severe headache started about an hour after vaccine. This improved over night, then 24 hours after vaccine severe headache which lasted another 2 days, aches

Increased HR and BP 4 minutes after injection. Rest and VS monitored. Return to baseline at the 29 minute mark. Released after 30 minutes.

mild left upper arm swelling, quarter to half dollar sized lump under skin; sore tight muscle that interferes with daily activity; area is warm to the touch Symptoms started within 3 hours of dose and have continued to progress for 20 hours.

5 minutes after receiving the vaccine patient felt light headed and her heart rate was elevated.

So about 12 hours after receiving the shot I started experiencing COVID symptoms. I called employee health and they told me to come in and get tested for COVID and tested positive. Body aches, headache and a fever last night at 102.8. I took some Tylenol. Woke up and I was drenched from sweat. I also have a nagging cough and sore throat.

Severe vertigo, nausea and vomiting, and weakness presented to emergency department after 8 episodes of vomiting over 12 hours with no relief

Patient monitored x 15 min per guidelines. Returned within 10 mins c/o itching hands. 25 mg diphenhydramine given IM per order. Post adm VS stable. Symptoms resolved within 15 min.

About 22.5 hours after shot, she experienced extreme dizziness. She was shopping with husband and he had to drive home due to this dizziness. She got home and went to bed and slept 4 hours and woke up without any further issues. When she was dizzy she did experience some nausea.

DIZZINES WITH STANDING

Felt sick , sedated , as if she was going to pass out.

Immunization 12/22/2020 COVID Vaccine Clinic Need for vaccination Dx Referred by MD Reason for Visit Progress Notes MD (Physician) ? ? Endocrinology COVID VACCINE CLINIC 12/22/2020 á Patient: Date: 12/22/2020 á Subjective Patient is a 63 y.o. female who was seen at COVID Vaccine Clinic today for her first dose of the COVID 19 vaccination. á Arrived at 5:50pm á She denied any history of previous adverse reactions to vaccines. á She was given the Pfizer vaccination in the left deltoid muscle. á During her 15 minute waiting period after the injection, the patient began to experience dizziness. She denied rash, hives, welts, difficulty breathing, difficulty swallowing, wheezing, throat tightness, hoarseness, stridor, itching, facial swelling, lip swelling and tongue swelling. á This provider was notified of patient reaction and she was then assessed in the emergency bay area. á Monitored patient for severe reaction symptoms, including rapid progression of symptoms, respiratory distress with stridor, wheezing, dyspnea, increased work of breathing, persistent cough and cyanosis, vomiting, abdominal pain, hypotension, dysrhythmia, chest pain and collapse. á Vitals were normal Glucose was 100 á Felt better right away Normal BP is 110s per pt á Objective á Vitals: á 12/22/20 1759 BP: (!) 164/83 Pulse: 82 Temp: 98 ¦F (36.7 ¦C) SpO2: 95% á á Physical Exam Vitals signs reviewed. Constitutional: Appearance: Normal appearance. She is normal weight. HENT: Head: Normocephalic and atraumatic. Nose: Nose normal. Mouth/Throat: Mouth: Mucous membranes are moist. Pharynx: Oropharynx is clear. Eyes: Extraocular Movements: Extraocular movements intact. Conjunctiva/sclera: Conjunctivae normal. Pupils: Pupils are equal, round, and reactive to light. Neck: Musculoskeletal: Normal range of motion and neck supple. Cardiovascular: Rate and Rhythm: Normal rate and regular rhythm. Pulses: Normal pulses. Heart sounds: Normal heart sounds. Pulmonary: Effort: Pulmonary effort is normal. Breath sounds: Normal breath sounds. Abdominal: General: Abdomen is flat. Bowel sounds are normal. Palpations: Abdomen is soft. Musculoskeletal: Normal range of motion. Skin: General: Skin is warm and dry. Neurological: General: No focal deficit present. Mental Status: She is alert and oriented to person, place, and time. Mental status is at baseline. Psychiatric: Mood and Affect: Mood normal. Behavior: Behavior normal. Thought Content: Thought content normal. Judgment: Judgment normal. á á á Assessment/Plan Treatment included: no therapy. Follow up response to treatment: excellent. Patient discharge: Stable to go home and follow up with PCP. á á MD Electronically Signed 12/22/2020 6:01 PM

10 minutes after receiving the vaccine, I became tachycardic. Heart rate was in the 150s. I believe the rest of my vital signs were normally initially, but about 10 minutes after the tachycardia started, my BP was 170/110. I remained tachycardic so was sent to the ER. I continued to have waxing and waning tachycardia during my ED stay. Per MD, EKG, BMP, CBC were all normal. I did not receive any medications. After about 3 hours of monitoring, my heart rate was under 100 at rest so was discharged home. For the next 24 hours, with minimal exertion (talking, walking on flat surface) my heart rate would elevated into the 110-120s. 48 hours after vaccine, my heart rate returned to normal. I will be following up with cardiology 12/28/2020

Patient stated she was feeling sluggish, little to no appetite over last couple of days. Today her saturations dropped to 84% while at work.

LIGHTED HEADED

Shortly following vaccination, developed redness, skin rash, itchiness, dizziness and anxiety. Was given diphenhydramine 25mg with no relief and began worsening - walked over the Emergency Department in same building and treated there with the following: Solu-Medrol 125 mg IV Push, Diphenhydramine 50mg IV Push, and Prednisone 40 mg by mouth. Symptoms began to improve within about an hour and was given a prescription for Prednisone 20 mg Po X 3 days.

ANAPHLACTIC REACTION, SOB, CHEST PRESSURE, TIGHTNESS IN THROAT, TACHYCARDIA

swollen lymph node extends from injection site toward breast, shooting pain down side

High fever with chills approximately 12 hours after vaccination. Severe headache, mild nausea, loss of appetite, joint pain. Arm pain significant with almost no range of motion without pain. Swelling around armpit. Ibuprofen taken with minimal relief. Arm pain, headache, intermittent fever is ongoing at this point in time.

12/19/2020 MORNING WOKE UP AT 4PM FOR WORK, HAD HIVES ALL OVER EXTREMITIES AND TRUNK. WENT TO URGENT CARE; PRESCRIBED MENTHOPREDNISONE. TAKING THE PREDNISONE AND ZYRTEC SINCE THAT DATE. *HX 5-6 MONTHS OF HIVES. CONSULTING WITH ALLERGIST. SEEN 12/21/2020.

Resident noted to be experiencing a full body tonic/clonic seizure approximately one hour and forty-five minutes post receiving the vaccine. Supplemental oxygen via nasal cannula provided, vital sign monitoring, solu-medrol IM provided, epinephrine IM provided, clonidine tablet provided PO, stat labs ordered: CBC, BMP, depakene level, UA. Resident exhibited positive reaction to interventions. Seizure lasted approximately 5 minutes, afterwards resident presented at baseline: alert and oriented x3 and communicative. Oral intake tolerated approximately an hour and a half post seizure. Enhanced monitoring in place.

,headache, tiredness, chills, light headed, feeling unwell

Felt fine for first 30 minutes. Then face started to burn and tingle. 10-15 minutes later felt heart racing, slightly short of breath. Felt like I was going to faint. This only lasted 20 seconds or so. Base of the tongue felt strange. Took Benadryl 50 mg and prednisone 20 mg. Paramedics came. Hr was 68, O2 sat 99, bp176/126. Lungs clear. No trouble breathing. I felt better and they left. All symptoms improved except my face is still burning and tingling at 2 pm on same day (today). Face is mildly red but no hives. Bp is now normal 126/76, hr 50.

GI upset

Got the vaccine at 11AM. around 3PM very tired, headache wok me up around 3AM next morning I was fatigued, felt hot and cold (couldn't decide if I needed a jacket or not while at work), very tired, the next day still fatigued, chills, hot and cold, went to work and decided to leave after talking to one of the doctors. I was clammy, very sluggish, had a very mild headache, did not feel well overall. That was the worst day for me (Friday). My ears felt plugged. Slept almost entire day going through cold/hot chills,

even wore 4 layers of blankets. Back and forth with hot and cold chills. Next day ear pain and fatigue. Very mild hot and cold flasher.

A few minutes after vaccine administration, while sitting down for post-vaccine monitoring, she became dizzy and diaphoretic. Ice packs were given and the dizziness improved over about 5-10 minutes. Vital signs were taken and were normal: BP 125/80, Pulse 86, O2 Sat 100%. After symptoms resolved she went back to work.

Slight Fever of 100.4 degrees Fahrenheit

Vaccine was administered 11:45 am. Post vaccine (~30 mins) slightly nauseous and diaphoretic but resolved. Around 9:30 pm had 3 consecutive syncopal episodes. 911 was called and EMS arrived. Finger stick and BP were unremarkable; however, BP was slightly elevated for my usual (136/72 at time of reading where I am usually 110/80)

I have been experiencing intermittent, involuntary twitching of my my left thumb that started around 12;00 noon. There is no numbness or tingling (normal injection site ache, however) or recognizable pattern of when the twitching occurs, and the twitching does not seem to last longer than 10 seconds at the most before stopping. 1-3 minutes will pass before my thumb starts twitching again. Other digits do not seem to be affected. I did not experience this prior to the COVID-19 vaccine administration and not have any neurological conditions that this would be a symptom of.

Fatigue, headache, fever, muscle pain, chills

After shot arm was sore. Woke up felt not herself, tired achy. Took Tylenol went to sleep. The next day she couldn't move. Was in bed in a ball. Today she can walk a little bit. Went to pharmacy to get more Tylenol. Cannot concentrate. Chills and fever. Bolt of electricity down spine. Very tired.

visual changes- resolved within minutes; MD examined, no intervention required

Received the COVID vaccine, after the 30 min observation time she left the area and returned about an hour after her administration with complains of Shortness of breath, tightness in chest, elevated BP, Flushing and rash on upper extremities and neck.

Received the COVID vaccine, after the 30 min observation time she left the area and returned about an hour after her administration with complains of Shortness of breath, tightness in chest, elevated BP, Flushing and rash on upper extremities and neck.

Patient tested positive for Covid morning after vaccination with symptoms. Fever of 100.2, headache, eyes burning, head is heavy, chills, very fatigued

An 1 h and 20 mins after vaccine was given, driving home and felt some difficulty swallowing. Was able to drink water no difficulty but unable to do swallow without the aid of water. No SOB, some tachycardia. Went to closest ED.

I woke up and have been experiencing severe body aches, a dull headache, and it feels like I might have a low grade temperature but when I check my temperature it is normal.

hives, pruritus within 30 minutes

Increased heart rate and blood pressure, dizziness, chest tightness, tingling left arm , leg and foot, left should heavyness.

I had dyspnea and palpitations started about 5 minutes after vaccination, lasted about 2 minutes. I had similar another episode after about 9-10 minutes after vaccination which is less severe compare to first one. I was sent to ER after second episode for close monitoring. No event on tele monitor in ER.

At exactly the 10 minute mark, I started feeling very flushed and hot. 1-2 minutes later, I was very lightheaded and dizzy. Felt like my heart was going to beat out of my chest and that I might faint. Walked down to tell the RN and she could tell I didn?t feel well as I approached. She said she could see my pulse bounding in my neck. Asked me to sit down arm she checked my pulse. Said I was tachycardic, over 100bpm. She asked me to sit there another 15 min for observation and gave me some water. I started to feel less flushed but then a second round of flushing came. The bounding/tachycardic episode never stopped. They suggested I go to the ER for observation. I text the Dr I was working with and she came down and spoke with the vaccine nurses saying she was comfortable monitoring me for the next several hours. I continued to feel this way for 3-4 hours. Also very pale and shaky. The above symptoms finally lessened around lunch time. For the remainder of the day, I felt very exhausted and had a lingering headache. The next day (today) I feel better. Other than soreness in the injection arm and some general body aches.

Patient presented to ED 1 day after administration of COVID-19 vaccine. She had rigors and chills the day before and day of ED presentation. Denies having a fever prior to ED presentation but did note general body aches and nausea. Patient also had 1 episode of vomiting on 12/22. Patient's vital signs were BP 145/109, HR 75, RR 20, O2 sat 96, temp 98.7F. Receive IV bolus of NaCL 0.9% 1,000 mL in ED in addition to ketorolac 15 mg, and ondansetron 4 mg. Patient was discharged home from the ED.

Nausea

Calling in to report itching and rash after Pfizer COVID vaccination. she received a vaccination on December 18th and started having symptoms that same day. She contacted the emergency room where she received the vaccine and they told her to take Benadryl. Since that time the itching and rash has progressed and now she is having some difficulty swallowing. No difficulty breathing or speaking.

Itching followed by multiple Erythematous urticarial areas on face, chest and arm. Swelling of upper eyelid

JOINT PAIN, RIGHT HAND SWOLLEN, CAN'T BEND MIDDLE FINGER, PAIN RADIATES TO WRIST, FINGERS START TO TINGLE IF USES RIGHT HAND FOR EXTENDED PERIOD OF TIME.

fever, confusion, blurred vision, nausea

mild chest tightness, cough, feeling anxious and lightheaded minutes after receiving the shot pt received: Benadryl 25 mg iv push Solumedrol125mg iv push Normal saline 1000ml IVpb

"PT WAS ADMINISTERED MODERNA VACCINE AT HD ON 12/23 AROUND 1540. PT HAS EXTENSIVE HISTORY OF ALLERGIC REACTIONS (HEP A VACCINE AND TREE NUTS). PT ALSO COVID + ON 12/8/20 . HX REVIEWED WITH HD RN PRIOR TO ADMINISTERING. PT WAS ADVISED TO WAIT 30 MIN IN WAITING ROOM. EMS STAFF ON SITE FOR CLINIC. PT STARTED COMPLAINING OF ""ITCHY MOUTH"" AROUND 1620 AT WHICH POINT EMS ATTEMPTED TO ESCORT PT TO PERSONAL VEHICLE TO DRIVE HER TO LOCAL ED. PT MADE IT TO THE THE VEHICLE BUT DEVELOPED INCREASED RESPIRATORY DISTRESS AND AIRWAY RESTRICTION. AMBULANCE WAS CALLED. EMS ADMISNTERED .3ML EPI AT 1631 AND APPLIED 8L O2 VIA MASK. ABUMBULACE ARRIVED AT 1636. PT TAKEN TO LOCAL ED VIA AMBULANCE"

Redness and tingling of the hands, arms and then body about 5 minutes after vaccine administration. Was also hypertensive to 142/87. Did not have progression of symptoms and BP and redness improved after about 30 minutes of resting and monitoring. Did not require any medications.

After waiting 15 minutes after receiving the vaccine she complained of having generalized itching. No other adverse reactions. She was working in the Intensive Care Unit. It wad discussed with her and decision was made to let her return to work for the evening without taking any medications for the itching. She was to go to Emergency department if she had any other adverse reactions develop. She was followed up with this morning and she reported that she did not have to seek treatment. The itching had subsided, no other adverse reactions developed, she just had some soreness at injection site.

localized raised red rash at injection site - given diphenhydramine 25 mg PO x1 - increased monitoring for 30 minutes. Patient still had rash but it was improved. Was able to leave clinic to home

Patient complained that 3 hours post vaccination began to have sweats and feeling like he was running a fever. He checked his temp on 3 different occasions during a 3 hour period and it did go up to 99.2 from 97.6. The patient denies any other symtoms. He received his vaccine around 4pm 12-22. He reported his concerns at 9am on 12-23. There was soreness at the injection site. No redness. And he felt fine today. And indicated by the time he went to bed last night was feeling fine again. Advised patient to contact me if any further concerns on work cell #.

After the vaccine I was fatigued, had diarrhea, a 102 fever and headache which lasted exactly 24hrs I took tylenol and zofran and the symptoms resolved . At the time of the vaccination i was 23 weeks gestation, EDD-04/12/2021.

Lymphadenopathy in left arm pit sore arm Slight fever of 100.1 headache fatigue muscle and joint aches

"The evening after she received the vaccine, she had a HA and stomach distress. She reports waking up frequently due to sweating. On 12/22/20, her symptoms continued and got a bit worse - including soreness at the injection site with continued stomach distress and HA. She took ibuprofen 400 mg PO TID. Was unable to eat food, only drank Sprite. During the early morning hours of 12/23, was unable to

sleep due to severe pain in right upper arm. She felt a ""pulling sensation"" and felt an enlarged lymph node under her arm. It was very ""tight"" - she was able to come to work - sent to the ED for evaluation - found to have BP slightly above her normal range, mild tachycardia. Was released and told to continue symptomatic treatment and to call or come in if symptoms worsened."

Approximately three hours after receiving the vaccine I was violently puking and nauseous. I never had a fever, but I had uncontrollable shaking and chills.

Approximately four minutes after receiving the vaccine, I felt dizzy while I was seated. The feeling subsided and returned a couple more times within 15 minutes. After approx 10 min, I felt a burning sensation on the top of my right hand and it spread to both hands and arms. My skin looked a little blotchy and red. The girl next to me said my face looked flushed. I also noticed I was sweating. The Rn brought me a bottle of cold water to drink. I drank half the bottle and that seemed to help cool off my skin. Thereafter, I had the chills. Then I noticed a tingling sensation in my feet. My shoes started to feel uncomfortably tight , so, I loosened my shoe laces. That subsided after a while. After sitting for a few more minutes, I believed I was feeling better. I stood up to prepare to leave and I felt a little bit dizzy. I sat down again, notified the RN and waited some more. I tried to stand up again and I felt slightly dizzy again . I remained standing and I was talking with two RNs. At that moment, I became dizzy again. I remained seated for another period of time before being escorted by the RN back to my department where I sat down and ate my lunch. Thereafter I was fatigued with the occasional chills and hot spells . I went home and rested on my couch.

After receiving the vaccine I initially had some arm soreness that later progressed to a headache and just an overall run down feeling with some slight body aches.á I woke up for work this morning with worsened body aches and had felt like I had a fever throughout the night. I took my temperature just to be safe and it was 100.5 (take twice). I called into work and was told I was not allowed to come in today to contact employee health. I went back to sleep and now my temperature is 98.6. I still have some slight body aches but it seems improved.á I am sending this email at your request to state that I no longer have a fever as result of my COVID vaccine obtained 12/21. My temperature has returned to a range of 98.2-98.6.á Sx resolved

A little over 12hrs after vaccination experienced significant fever, chills, and body aches. Able to manage with acetaminophen PO.

Whitehead Zit over injection site Dry lips throat and mouth initial day Headache at 36 hours in Some low grade fevers

10 minutes after vaccination received, pt complained of fullness feeling in throat and itchy ears and head. Epi given, pt transferred to ED, rec'd another epi and IV fluids. Discharged after a few hours.

Patient flushed red and felt nauseated within 60 seconds of administration. Complained of difficulty breathing, became blotchy and began crying. Called 911. Paramedic on site for his own vaccine assisted. Airway sounded restricted. Administered 0.3 mg Epinephrine (Epi Pen). Color improved. Blotchy patches

improved. EMS arrived. Breathing became more labored. They took her to we assume was regional hospital

Age: 43 years 12/23/2020 12:21 Chief Complaint: ALLERGIC REACTION History of Presenting Illness: This 43 yo female presents from specialty clinic for an allergic reaction. Patient has just received the Moderna Sars-Cov2 vaccine. She has had covid in the past, and her Igg tested outpatient was positive at 5.2 (per patient). She had received the vaccine at 11, and says that she usually has a reaction to vaccinations and drugs. She began having some rash around the neck and felt like her throat was closing. She was brought to the emergency room.

tightness in chest, felt like when i get stung by a bee and my asthma is acting up. started about 7 minutes after receiving the vaccine, did not go away after about 1 1/2 hours felt increased tightness/shortness of breath/wheezing. used my albuterol mdi and felt better. lasted about 2 1/2 hours and then began to feel the tightness start again and felt need for albuterol inhaler, took albuterol again and a pepcid po. continuing to monitor and will inform primary MD also.

2am chills,achiness,shakes, temp 100 3am temp 100.7 no change 4am no change took advil no change all day 12/23 shooting pains level 8 ,chills body aches. no fever. no change all day will see employee health in AM

I got the shot on a Tuesday , woke in the middle of the night at 3 am with a fever of 101, body aches, and swollen lymph nodes on the sidt that I get the shot. Took tylenol and still had body aches until 3PM. My skin was sore afterwards.

Pt was vaccinated at Conference room COVID19, with PfizerBionTech vaccine, Lot# EK 9231, at 1258 hours, while waiting in monitoring area, complained of rash and facial flush at 1305 hrs, initially given PO Benadryl by APP's at 50 mg for the rash and seen by me at 1306 hrs and got vitals. BP 160/110, HR 120 -130, SpO2 was 100% on room air, not complaining of shortness of breath, no stridor noted, tachycardia noted with regular rate and full bounding pulse, no wheezing noted bilateral lung fields, initiated early response call for eICU staff, also initiated potential call for inhouse and 911 call as back. At 1315 hours she had mild chest discomfort, tightness and felt dryness of throat. Rash not significantly visible on chest, facial flush present, decided to go ahead and gave epinephrine 0.3 mg IM to right deltoid as she was a unitard Stat suit. She was put on continuous monitoring, had response from eICU (Tele-ICU) team and Dr., SBP still noted to be elevated to 160's and DBP 110, Pulse still around 130, additionally IV access was secured, given IV Solumedrol 125 mg and IV Pepcid 20 mg. She felt somewhat better, still felt very anxious, with chest tightness, EMS on site by 1340 hrs and moved to ED by 1400 hrs, was with patient all through and transitioned to ED care To Dr. When last discussed her condition, was still stable noted at 1745 hrs in discussion with ED RN, with still persistently elevated BP and heart rate. No clear cut evidence for typical anaphylactic reaction. Treatment and observation still ongoing in ED.

chest tightness, throat closing in, sent to Emergency room

developed dizziness, palpitations, shaky, headache

Within an hour developed a headache that got worse every hour. Within 24 hours from vaccination, felt extreme myalgia that I have not been able to find relief for. 48 hours after still feeling myalgia. Headache has gotten better but still have one.

hand shaking, chills, rash, nausea, lightheadedness ? reports hard to take a deep breath, given diphenhydramine 50 mg PO x 1 @ 10:15 in clinic and an additional 25 mg PO x 1 @ 10:30 in the clinic. Symptoms persisted - pt anxious - taken to ED for evaluation. After 10-15 minutes in ED, her symptoms subsided ? she only had mild tingling in the left hand along with two red spots on the back of her neck. Given prednisone 50 mg PO x 1 in ED. observed in ED for 2 hours ? pt feels much better ? pt felt comfortable going home ? told to continue to take Benadryl and prednisone for next 3 days. Instructions given to return to ED for any worsening of symptoms. Rx with Prednisone 50 mg daily x 3

5 minutes after administration of vaccine, patient states he does not feel well. He was sitting and passed out.

On the first day I had pain on injection site. The second day I had muscle aches, fever and chills.

approx 12 hours after administration of vaccination, teeth chattering chills for 1 hour followed by a fever with temperature increase of 2 degrees, extreme muscle and body pain, nausea, headache, runny nose, sore throat, cough, soreness at injection site and inability to lift right arm (injection site). Fever and chills resolved at 7 am on 12/22/2020. At that time I took Alka Seltzer cold and flu and finally slept and woke up with fatigue, muscle aches and headache. All symptoms, aside from bilateral shoulder pain, pretty much resolved by morning of 12/23/2020.

Fever 101, chills, aches, chest pain

site soreness and residual headache at base of skull x3 days On 12/18 at 12 noon, I found myself passed out in my office at work laying over my keyboard. My assistant had me on-hold at that time and estimated I was out for 1 minute. Was loopy the entire next day. Just hydrated and rested. Felt great by Monday

Patient developed diarrhea, chills and a measured fever 100.4 24 hours after receiving the vaccine.

Pruritus - Benadryl given at COVID vaccine area. Relieved. Symptoms advanced after the caregiver went back to work. Called vaccine provider. Went to ED. Received Solu-medrol and Epinephrine. Released in stable condition

PALPTATAIONS, ANXIOUS, MONITORED NO TREATMENT

Fever 100.9

I got the Pfizer COVID19 vaccine at a drive through site on 12/21/20 through Department of Health Services. This morning I woke up in the middle of the night with lower spinal discomfort which has increased as the day has continued. There is nothing visible on my spine externally that I noticed except a very faint pink line.

Extreme fatigue, head ache, chills, severe generalized body aches, (temp 95.5 F). Started the day after vaccine, 12/20/20, and lasted until 12/21/20. Tylenol was taken for immediately after vaccine and continued until 12/21/20.

Benadryl given at COVID vaccine area. To ED received Ativan, Decadron, Pepcid, Benadryl, and 2L NS.

I received the first dose of the Pfizer COVID vaccine on 12/19 at 3:30pm. The next day I began to feel fatigue, body aches, joint pain, headache, and a fever of up to 100.9 that began around 2:00pm. It was fully resolved by the next morning.

Malaise, brain fog, fatigue, fever (100.8), cough, runny nose, sore throat over the last 24 hr.

Injection site pain within 6 hour of administration. Mild fatigue after 8 hours. Upon waking up the next morning, fatigue, myalgias, slight headache resolved with 1000mg acetaminophen taken 3 hours afterwards. 5 hours after acetaminophen, chills, myalgias, generalized weakness are experienced. No fever. Another 500mg acetaminophen was taken.

Pruritic, erythematous, patches in forehead ans R side of face

Fever, chills, nausea, sore throat, headache, extreme body aches and cough. Fever elevated longer than 3 hours at 100.4. Had rapid heartbeat which happened about three times. Slight difficulty breathing. Had Covid 19 about a month ago and felt like she was having it again.

Developed painful lump/ knot left WRIST

Left arm injection site soreness started about 4 hours after administration. Left full arm tingling lasted about 12 hours then resolved. Left arm soreness lasted for about 36-48 hours with some mild nasal congestion and shortness of breath.

WAS HAVING MYALGIAS AND MILD FEVER STARTING ABOUT 12 HOURS AFTER VACCINE, BUT AT 2 AM, I WOKE UP TO URINATE, FELT SOME DIZZINESS. AT THE END OF VOIDING I COULD TELL I COULDN'T THINK RIGHT AND HAD TROUBLE FLUSHING. TRIED TO WALK BACK TO BED AND HAD A SYNCOPE AS I GRABBED THE DOOR HANDLE. STUMBLED DOWN SLOWLY AND LOSS CONSCIOUSNESS FOR A SHORT WHILE, SECONDS. LAYED IN THE FLOOR FOR A BIT AND WHEN I STOOD UP AGAIN AND WALKED TO MY ROOM HAD ANOTHER SYNCOPE. WOKE UP AFTER SEVERAL SECONDS AND WAS NOT CONFUSED AND DIDN'T REMEMBER THE SECOND TIME I FELL BUT COULD UNDERSTAND I HAD PASSED OUT. MY WIFE SAYS I HAD MY EYES OPEN AND WAS STIFF BUT NO TONIC CLONIC MOVEMENTS. AFTER THE EVENTS I WAS ABLE TO GET BACK IN BED AND AFTER A LITTLE WHILE TESTED FOR ORTHOSTASIS. WHEN I STOOD UP I STARTED FEELING THE LIGHT HEADEDNESS AGAIN AND PRODROME TO FAINTING AND LAYED BACK DOWN. HR 60, MY BASELINE IS 50-60. HAD A FEVER OF 100.7. I TOOK 650 MG OF TYLENOL AND WENT BACK TO BED. I DIDN'T SLEEP WELL BUT NOW (THE FOLLOWING MORNING) I AM FEELING BACK TO NORMAL MINUS SOME MILD SOARNESS. I HAD A RAPID COVID PCR TODAY THAT IS NEGATIVE. NO OTHER LABS. I HAD NEVER FAINTED BEFORE THIS EPISODE. I DID NOT HAVE ANY TRAUMA FROM SYNCOPE.

Right side of body (leg foot hand arm cheek neck torso ear, etc.) experienced tingling sensations, numbness, some burning sensations, mostly cold feeling, weakness (like moving through water) sensations have lessened in two days, but minor sensations and weakness persist. monday (12/21/2020) visited the E.R. for exam and testing. E.R. doctor reported current testing normal. 12/23/2020 visited normal MD to go over results from previous testing and get checkup.

Diagnosed with UTI Sat 12/19/2020 at Urgent Care Monday 12/21/2020 returned to urgent care for fever, flank pain, no relief from urinary symptoms, later went to Hospital for treatment Today 12/23/2020 have severe body pain, extreme fatigue, still having urinary symptoms; unable to do daily activities such as grooming and dressing without assistance

Dizziness and elevated BP

Patient stated that he had blurred vision. He was taken to the Emergency Dept at the Hospital where his vital signs were monitored to include blood pressure, pulse and oxygen. After 1 to 1.5 hours of observation, patient stated that he was no longer experiencing any symptoms.

Nausea Vomiting Fatigue

Vision changes, blurry and distorted vision lasted for about one and a half to two hours after vaccination. Vision return to normal.

Quarter sized raised red area at injection site that is warm to touch. It has gradually grown over the day.

Beginning at approx 16 hours after receiving the vaccine and continuing until approx 36 hours after the injection, I experienced fever of 100-101 that was relieved with ibuprofen and acetaminophen (alternating). Significant headache and fatigue also present during most of this time. Now appears resolved.

Patient presented to the ED vaccination clinic on 12/20. She received her first dose of the vaccine, and then went into the breakroom to finish the rest of her lunch break. Approximately 10 minutes after she received her vaccine, she noticed she was feeling very warm, like a hot flash. She asked her coworker if it was hot in the breakroom, who responded no. She then noticed that she was developing reds spots on her chest, back and neck. We moved her into a private area to monitor her, and allow her to undress and cool off. She developed redness to her chest, back, neck, and redness around the injection site. This mostly resolved within 45 minutes. At about 45 minutes, I was able to secure PO Benadryl and provided her 50 mg of Benadryl, which she took. The employee returned to work the rest of her shift with no other complications noted. The employee denied swelling or itching to the throat, denied SOB, and her vital signs were normal the entire time. The employee does want to get her 2nd dose of the vaccine, so we will plan on administering it in the ED, and may pre-medicate with Benadryl.

Difficulty breathing, no oral swelling, stridor, altered mental status. Bag valve mask ventilate. IM epi. Initial care by MD and nurse. 911 ACLS called, transported to ER.

Arm was sore and swollen, muscle pain, body aches, headaches, tireness and fever.

I had a headache, nausea, muscle soreness and stiff joints on the first day and the second day fatigue.

swelling of tongue, lips, throat

Pt was lighted and dizzy about 10 mins after vaccine. Vitals were all normal and after we changed him from N95 to surgical mask, laid him down and gave him water he recovered fully.

Vertigo. Nausea. Dizziness. Headache. On and off for 3 days. Still having symptoms .

Lightheadedness, chest tightness, body ache, fatigue, weakness,flu-like symptoms but without fever

After about 7 minutes after the vaccine she started having palpitations and generalized feeling unwell. Felt as though she had low blood sugar but did not feel lightheaded or faint. She had this reaction similar prior when she had anxiety surrounding getting TB testing. Felt anxious and did have elevated BP to 144/86. No shortness of breath, rash, nausea, chest pain, dizziness. Resolved with observation, deep breathing, crackers and water.

24 hours post vaccine developed itchy legs. Over the course of 5 days both thighs developed red hot blotchy rash that burns and itches, radiating heat. Not helped by benedryl, Zyrtec, hydrocortisone.

Fever 101.8, vomiting, mental status change

"itching, facial swelling, throat swelling ""lump in throat"", hoarse voice"

Patient became diaphoretic and nauseated about 10 minutes post vaccination with Moderna Covid-19 vaccine. Patient was assisted to stretcher who he had dry heaves and stated he felt nauseated. HR was low around 38 and we were unable to determine a B/P but patient had a very weak radial pulse which at times was unable to be felt at all (due to low B/P). Decision made to transport patient to the ED for further evaluation. Patient eventually discharged from emergency department.

On the fourth day after receiving the vaccine, I developed a rash in the anterior and posterior thoracic region consisting of dispersed 1mm - 3mm size dots ranging from the clavicle to the pelvic region. These dots appeared in a diagonal, going from superior and lateral to inferior and medial. On the second day of noticing the rash the bumps appeared as if they were blistering. No medication was used at this time.

30 mins after vaccination Felt rapid heart rate, tingling in lips, initial BP 100/60

Patient felt warm and had some tightness in her chest which subsided and changed to intermittent sharp pain at sternum. Physician's who had just received vaccine asked for her to be sent to the ER.

Severe whole body myalagia and weakness with inability to stand or walk without significant pain and weakness. Unable to work or do ADL . Doctors not sure what to do . Have seen pcp and ER with still severe pain and weakness over three days

Redness and swelling around injection site on day two (day one being day of injection). Redness and swelling on day three decreased to just small red dot. No other complaints.

Fever 102.3 , chills, body aches, headache, tachypnea,. All symptoms started 19 hours after injection. Besides that, soreness & swelling at injection site.

Incomplete administration by MD that lead to seeping of vaccine. Second dose was administered.

"About 10 min after receiving the vaccination, the patient described feeling of throat closing, coughing. Patient given IM epi with initial improvement in symptoms. No rash. On arrival to ED, no stridor, no oropharyngeal swelling, speaking normally in full sentences, clear lungs. Subsequently, patient complained of nausea, but resolved after Benadryl. Patient had recurrent ""funny feeling"" in throat about 3 hours into observation and had difficulty swallowing liquids, but had normal speaking voice normal oropharynx. Currently pending ENT evaluation."

Diarrhea/upset stomach

Employee reported reaction of hives approx 2 hours and 12 minutes after getting the covid vaccine. She was administered epipen and was sent to the ED. The ED observed her and then discharged her.

pt complained of dizziness that progressed to headache. BP taken at 1315 was 184/106, hr 106. At 1430 bp 183/104 hr 87. o2 97%. Patient stated that they forgot to take bp meds

Pain at injection site around 12 PM, Fatigue around 4 PM.

Day of injection, developed pruritus of back. Worsened the day after and started seeing a papular rash over multiple areas of back.

Received vaccine at 1259, remained for 15 minutes without symptoms and returned to work. At approximately 1600, felt itchy and discovered hives covering body. Went home and took Benadryl. When spoke with at 1900 stated that her hives were still there but improved.

Felt lightheaded since the vaccine

30 minutes after receiving her 1st dose of the COVID vaccine, she started feeling a burning sensation in her nose and in her chest when she took a deep breath. Symptoms persisted overnight, today reports to have had chills and a sore throat. She was seen by her PCP today, 12/23 for further instruction. PCP told her to take benadryl and to follow up with an allergist prior to second dose for clearance. Patient reports she was COVID positive July 2020.

Staff member felt brief lightheadedness. Blood pressure was 147/72 (normal for her). Staff member then felt fine.

The first night I had a headache, chills, soreness and bruising at the injection site.

hot all over her face, followed by itchiness on her face, tongue and throat. denies any shortness of breath or chest pain. She denies any difficulty speaking or swallowing

Staff member felt some dizziness. Then felt alright.

fatigue/fever for 48 hours of 101.5/ nausea/severe headache/ blotchy rash all over body 3 days after vaccine. Hot to touch to inchy. 4 days later still large ichy rash.

rash, vomiting, nausea, hives, migraines, tremors, facial swelling

Staff member started to feel dizzy and lightheaded a few minutes after the injection, with brief episodes of palpitation. Blood pressure taken by physician, measured 180/90. Staff member was given Amlodipine 2.5 mg at 3 pm. Another Amlodipine 2.5 mg given at 4 pm. At 4:30 pm blood pressure was 160/100. Patient symptomatically felt better. At 5:04 pm blood pressure was 150/90. Staff member was observed until 5:15 pm, the discharged home in the care and supervision of her husband. Staff member will follow-up with personal physician.

"Pfizer-BioNTech COVID 19 VACCINE EUA- within 2 minutes felt tingling on the tongue and then tingling around the mouth. Within five minutes, itching of the face that spread to scalp and neck. Continued to increase itching during the 15 minute observation time. Sensation of heart in my ""throat"" upper chest. Slightly light headed. Nausea 15- 20 minutes after receiving injection. Headache. Given 50 mg Benadryl IM that resolved symptoms of itching within 5-10 mins. Observed in ER x 1 additional hour. BP 149/90 approx. HR 88, estimated from .memory."

Generalized itching

After 5-10 min following vaccination pt began to exhibit itching of the neck and slight SOB

Pain and numbness in left side of face and lips; advil taken and improving but no resolved

Moderate body aches and headache beginning about 20 hrs after the vaccine, then progressed to severe headache, nausea, photophobia, phonophobia at about 27 hours after the vaccine and lasting about 4-5 hours, then reducing to moderate headache and fatigue until about 40 hrs after the vaccine, then gradually resolved over the following 6 hours.

"She exhibited no symptoms immediately after the shot and began driving home at approximately 6:30 pm. As she was driving home, she gradually developed perioral numbness with the sensation of a ""gummy"" throat and bilateral eye ""warmth and numbness"","

Initially started with nausea around min 5, shortly after then itching on arms. Around min 15 ?lump? sensation in throat. Around min 20 swelling of tongue, worsening feeling in throat, wheezing, itching around mouth. Sent to ER, received IM Epi, IV: Steroids, Benadryl, Zofran, Pepcid, Albuterol inhaler.

Within 20 minutes after I had the vaccine I developed a sudden feeling of warmth in my upper body, most intense over my face and especially my neck and back. I was sweating too and I also developed palpitations and chest pressure.

About 45 minutes after inject upper lip and chin tingle and itches. about 45 minutes after injection was have tickling sensation in throat which followed into voice lost, chest tightness, decrease in expiration

efforts, occasional coughing , increase breathing and heart rate. Use albuterol inhaler and called for the on call doctor. took zyzal, zertex, benadryl, Prednisone, and use nebulizer

10 min after inj. started with tingling at inj site, progresses down arm then to other arm and across chest, started to feel tingling in throat. Initial BP was high at 152/86 P94. Pt asked to defer Benadryl as was driving and symptoms were already lessening. No flush no chest pain denied other symptoms. Next BP 115/78 P85. Then 10 min later 113/81 P80. After watching, pt discharged to home with instructions.

Muscle soreness

sat 12/19/20 , approx 2000 , started to feel hot, burning, and itchy. went to emergency room 12/20/20 at 1200pm , was taking Benadryl since onset of symptoms, given peptid, loratadine, and have continued these medication as directed , called PMD , given hydroxyzine 12/21/20 due to severe itching and burning feeling, and currently taking at directed,

Woke up with just a sore arm the following day. As time progressed my arm got more sore; the site was hot, with a red circle and lump under the skin. Headache, muscle and joint aches, fatigue. Treated with some Nyquil, Excedrin, and sleep. Onset was about 16 hours after the original dose. almost 2 days later I'm still very fatigued, although the rest of the pain has largely gone away.

Injection was made into tricep and not deltoid. Tingling started town right arm into right pinky. Tricep pain when lifting arm above head. Symptoms started within 1 hour of injection.

Had chills and body aches one day after vaccine. Symptoms resolved the day after.

Approx 5 min after vac. inj started with flush and tachycardia Initial BP 137/80 P129. Given 50 mg po Benadryl Repeat BP123/76 p91 @1135 No further sx BP 124/74 P91 DC stable

Dizzy, pinching feeling in left shoulder, tingling down left leg, pins and needles. Gave patient banana and water, checked pulse and observed. Patient started to resolve in 10-15 minutes, at 8 PM, resolved, pulse back to normal. Called Chief Medical Officer to consult, patient detained for 30 minutes before release, at patient request and CMO approval.

Nausea, vomiting, headache, back ache, dizziness.

About one week after the vaccine, body aches, chills and shortness of breath began to occur. Overall fatigue and general malaise also persistent.

Left arm soreness at the injection site on 12/23 at 7:45 am

Started w cough ~15 min after inj. Cough was progressing, unable to complete sentence w/o cough even after water. Agreed to take Benadryl as stated had had 2 anaphylactic responses when she lived in (-unable to determine that cause). Initail BP 153/91 P71 Recheck BP 145/93 P 69. Coughing decreased after Benadryl 50 mg po. No other sx. Dicussed letting PCP know and possibly premedicate before booster.

12/23/2020 sore injection site, Nausea, fatigue

Headache, redness below injection site, mild swelling

headache post immunization

Patient reported numbness on left side of tongue, being lightheaded, rash under chin and excessive secretions in the throat within 15 minutes of covid-19 vaccine administration. Vital signs were stable, O2 was 98% and BG was 225. Patient reported not taking his DM and BP medication prior to vaccination.

fatigue started day after vaccine given and continued through today (two days post vaccination).

10/10 left lateral hip cutaneous burning sensation that radiated to the inguinal region in a dermatomal distribution.

More than 24 hours after getting the vaccine I noticed warm spots on my arms and legs and noticed red raised blotchy spots where it was warm. At the injection site there is a very warm raised hard lump. I took Benadryl and it helped me sleep. It got more painful and warm and I was very uncomfortable. Its not as bad 16 hours later, however the swelling is still pretty bad at the injection site

Fever of 39. Chills shakiness severe fatigue Arm soreness

soreness at injection site

Pt. c/o moderate anxiety during vaccine. Around 15 mons after the vaccine , she c/o mild headache and stated she has history of HTN. She was hypertensive and her pulse was WNL. She was rechecked in 15 mins and her BP decreased and HR stable with continued headache. The patient denied any other symptoms and declined going to the ED. She left without further complaints 45 mins after her vaccine.

Chills, headache, extreme fatigue,joint and muscle aches

My jaw felt numb. I was lightheaded, and a felt nauseated

Pt c/o tachycardia and maybe anxiety. Pt is an MD. Tachycardia at 15 mins post vaccine- radial pulse 132 and BP 150/90. Denied other symptoms. Rechecked in 15 mins and HR 84-91 and BP 154/95. Continued to deny any other symptoms to include CP or SOB. No change in mental status. Declined treatment in ED. Kept and monitored for 15 more mins. and left 45 mins post vaccine. Continued to state maybe he was anxious

Silver dollar size whelp at injection site, rash, abdominal pain, fatigue, chest discomfort requiring use of inhaler

"Pt states night of vaccine on 12/22 she felt dizziness and ""incoherent"". This resolved by 12/23 and today is experiencing headache ""10"" on 0-10 pain scale, fatigue. Advised Urgent Care or ER and pt has declined."

Headache and significant fatigue

About 20-25 minutes after injection as I was walking out I felt slightly dizzy, hot and nauseous. Lasted about 5 minutes and I felt OK to go home, but I would not have felt safe to drive after that (I had a friend drive me). This after and evening any exertion, causes the same symptoms now with a mild headache. I feel fine sitting down, but even mild activity brings back the nausea and dizziness in particular.

9:22 am tingling/itching of throat, followed by dizziness/generalized weakness and lightheadedness. Rapid HR and elevated BP .

Local injection site pain Generalized myalgias/ache diffusely

Difficulty breathing, numbness of the lips, redness of the face

Pfizer dose 1 received 12/18/20 via left deltoid. 12/19/20 the injection site had a half dollar size of redness and edema and was warm to touch. 12/20/20 the edema decreased by half and became itchy like a mosquito bite. 12/22/20 redness barely noticeable at left deltoid. Still warm to touch and indurated.

Headache Extreme fatigue Generalized body aches

Numbness to the tip of the tongue, no loss of taste 2pm the day after vaccination 12/22/2020, resolved after 1 hour, but person took one dose each of prednisone 40mg/benadryl 25mg/pepcid 20mg. Numbness recurred on the tip of tongue again at 11:50 pm the same day 12/22/2020. same one dose of 3 meds as above taken, and the numbness subsided after 30 min. no loss of taste. no reports of recurrence on 12/23/2020 as of now (6:41 pm)

severe headache

Mild to moderate headache, muscle aches, fatigue, nausea, tender armpit

Body aches, fatigue, mild headache, scratchy throat, ?foggy? feeling, sore arm

Patient experienced severe nausea and vomiting within 10 to 15 minutes after vaccination was given by the pharmacist at the clinic at the on 12/21/20 in the morning. In the afternoon patient was back to her normal service as well as the following day.

Patient experienced an anaphylactoid reaction within 20 mins of receiving the vaccine. Patient is a physician and attempted to self treat with diphenhydramine. After a short time of seemingly no resolution patient presented to the Emergency Department. Patient was examined. Elevated BP was noted (192/100), flushing, difficulty swallowing, and strange sensation of mouth and tongue were also present. An ECG was preformed and sinus tachycardia was observed at 105bpm. Patient received IM epinephrine and PO dexamethasone. Symptoms resolved. Patient was observed for 3-4 more hours.

Injection site pain, low grade fever and chills, fatigue

Migraine headaches, nausea, dizziness

Edit: about an hour after my vaccine I began itching on my neck and got a scratchy throat. Then felt blisters in my mouth and felt a tingly feeling on my face. I had swelling in my eyes, jaw, lips, nose and tongue. And hives on my neck and chest. I went to my local ER and was given IV PEPCID, benedryl and a steriod. Swelling came down significantly and I was discharged home after about 2 hours with a steroid dose pack, Claritin and Pepcid. I now have a strong migraine.

RASH, ITCHING

Patient reports allergy to potassium as itching with a history of hives. Patient was aware of the risk vs benefit and potential of ADE due to allergies prior to receiving the vaccine. Patient was observed for 30 minutes. Patient experienced itching about 25 minutes post vaccine. Diphenhydramine 25mg was given to patient.

After the vaccine on 12/21/2020 , I experienced mild muscle aches and fatigue. 12/22/2]20,I felt fine. 12/23/2020 at work I experienced an acute onset of nausea and explosive diarrhea.

Shortness of breath, fatigue, headache, muscle pain, joint pain, chills, nausea, fever

Headache, sore injection site, tiredness, some nausea, feeling unwell,

I experienced dizziness onset 5 minutes after the vaccine, mild. lasting about an hour. That night I experienced intense vivid nightmares, chills and temp 96.0. Friday night, dec 18th, awoke form intense vivid nightmares at 2 am. chills. arm 7/10 pain at injection site, all day, no erythema. On saturday chills but no fever all day. At about 10pm abrupt onset of severe abdominal pain and prolonged projectile vomiting that awoke me from sleep after eating normal dinner that I shared w family none of whom were having similar symptoms. This lasted for about 90 minutes accompanied by severe abdominal pain. afebrile, 97.Dry cough started , lasting thru Sunday morning. spontaneously resolved. Sunday dec 20th, chills, nightmares, Monday chills, sweats, 96, 97 temps. Dec 22 Tuesday 3:30 am, awoke from sleep with sudden excruciating abdominal pain and dry heaves . Family shared Monday night meal, no other symptomatic people. <30 min started itchy palms, tingling lips, tongue, and face felt prickly. Eyes swollen, and sclera puffy bubbly. I took two 25 mg Benadryl w water, had trouble swallowing - immediately proceeded to Hospital ER - admitted - steroids IV, Pepcid, IV and in 4 hours when nausea and abdominal pain began again IV Zofran. 2 liters total of NS. discharge home around 12:30pm . stable to home to rest.

Hives, joint pain, elevated B/P, elevated HR, flushed upper body and tingling

Warm and dizzy with hypotension; feet up and juice given; transported to ED; improved with rest

Throat felt tight and sticky, difficulty swallowing, anxious, tingling from waist up

Day of shot Left arm was sore after few hours Suddenly felt chills Around 930 pm and muscle ache then joint pain by 1030 pm Feverish but no fever Felt so weak by 11 pm Next day Woke up with joint pain and muscle pain slowly went away after advil came back around 7 pm then took advil by 8 pm all pain disappeared

Chills started at 1730, day of vaccine. Fever of 100.2 at 2100. Tylenol taken. Fever Returned at 0315 on 12/21/2020. Tylenol taken once more. Woke up with fatigue and mild fever at 0845 on 12/21/2020 of 99.9. Tylenol taken once more. Chills and fatigue through out the entire day of 12/21/2020.

The patient is a 57 year old female who presents to the ED with an allergic reaction. Patient received her COVID vaccine this morning at a vaccine POD at 0708, 5 minutes after receiving the injection she began to feel short of breath, with dry cough and felt tightness in her throat. Patient used her inhaler at that time and then her symptoms improved. Of note patient also took a Benadryl prior to receiving the vaccine because she has a history of allergies (reports allergy to codeine). She was evaluated by people at Covid vaccine site and cleared. She went to work at the clinic where she works as a tech but continued to have tightness in her throat, so a doctor at the facility told her to take another Benadryl. Patient states that an hour after taking the second dose of Benadryl she began to feel drowsy and nauseous. She had a sip of coffee and try to eat something but then became tremulous and vomited. She was given epinephrine at work and transferred here for further work-up and management. On arrival patient reports that she feels back to baseline. She denies at any time having any rash, pruritus, or angioedema.

Heart palpitations

Vaccination to right deltoid; 7 days later developed diminished grip strength in right hand, right thoracolumbar muscle spasm with tingling radiculopathy to right hand and leg

Hot; Cold sweats/having night sweats, like she was hot and cold; Cold sweats/having night sweats, like she was hot and cold; Chills; Shakes; intense nausea/ nauseous; just feels nauseous and depleted; it feels like she has the flu; she didn't know if maybe her body was low on oxygen, she didn't feel out of breath, but she just didn't feel well overall; This is a spontaneous report from a contactable other healthcare professional. A 27-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number: EH9899, expiry: Mar2021), via intramuscular route of administration (left deltoid) on 17Dec2020 17:40 at a single dose for COVID-19 immunisation. The patient's medical history included sulfa drug allergies. There were no concomitant medications used. The patient was having some intense nausea, and throughout the night, she had night sweats. It was further stated that she woke up a 12AM, today (18Dec2020), and she just felt like she had the flu. She was nauseous, and she was having night sweats, like she was hot and cold, and she tried to go back to sleep, but then she had an episode of chills and the shakes, and every time she was about to fall asleep, it was like her body would wake her up. Patient stated that in her mind, she didn't know if maybe her body was low on oxygen, she didn't feel out of breath, but she just didn't feel well overall. All these persisted until about 3AM, and then she went back to sleep. She woke up for the day around 530AM, and she feels a little better now, like she doesn't have the hot and cold fever feeling anymore, she just feels nauseous and depleted. She stated that she sees on her information sheet that these are possible side effects to getting the vaccine, but it feels like she has the flu. Outcome of the events was unknown. Follow-up attempts are completed. The following information on the batch number has been requested.

Anaphylaxis; This is a spontaneous report from a contactable pharmacist. A 55-year-old female patient received the bnt162b2 (BNT162B2; also reported as: PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 17Dec2020 at a single dose for COVID-19 immunization. The patient's medical history included eosinophil process allergic reaction, fish, iodine and shellfish allergy; all from an unknown date and unknown if ongoing. Concomitant medications were not reported. The patient previously took rabies vaccine for immunization and experienced anaphylactic reaction on an unspecified date. On 17Dec2020, the patient experienced anaphylaxis; which required hospitalization, and was assessed as medically significant. The patient was hospitalized for anaphylaxis from 18Dec2020 to an unknown date. The clinical course was reported as follows: The pharmacist called about a patient who received the COVID-19 vaccine on 17Dec2020 and started having a reaction approximately 30 minutes later. The patient used epinephrine (EPIPEN) and 50 mg of diphenhydramine hydrochloride (BENADRYL) and returned to the hospital on 18Dec2020. The patient was currently in the intensive care unit (ICU) receiving an epinephrine drip. The patient had a previous history of an anaphylactic reaction to the rabies vaccine, eosinophil process allergic reaction, fish, iodine and shellfish allergy. The patient was stabilized but continued to have reactions (not specified). The pharmacist had not seen the patient and was reaching out to Pfizer on behalf of the physicians. The pharmacist believed this had been reported by the hospital. The pharmacist had no patient information. Therapeutic measures were taken as a result of anaphylaxis. The clinical outcome of the event, anaphylaxis, was unknown. The batch/lot numbers for the vaccine, BNT162B2, were not provided and will be requested during follow up.; Sender's Comments: Based on the information available, a possible contributory role of the suspect products cannot be excluded for the reported event anaphylaxis due to temporal association. However patient previous history of allergic reaction cannot be excluded to have played a contributory role

"started to feel a warmth in her chest and abdomen; She felt like her heart was racing; Developed chest pain; This is a spontaneous report from a contactable other HCP (healthcare professional). A 45-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot #: EJ1685), intramuscularly in the left arm on 18Dec2020 at 15:30 (at the age of 45-years-old) as a single dose for COVID-19 vaccination. Medical history included known allergies to apple, cantaloupe, peach, avocado and IV contrast dye; all from unspecified dates. The patient was not pregnant at the time of vaccination. Prior to the vaccination, the patient was not diagnosed with COVID-19. Concomitant medications included ongoing famotidine and salbutamol (ALBUTEROL HFA) as needed (PRN); both for unknown indications from unknown dates. The patient did not receive any other vaccines within four weeks prior to the vaccination. The patient previously received hydromorphone (DILAUDID) and triamcinolone acetonide (KENALOG); both from unknown dates to unknown dates for unknown indications and experienced allergy. The patient also previously received diphtheria vaccine toxoid/pertussis vaccine acellular/tetanus vaccine toxoid (TdaP) vaccine on an unknown date for immunization and experienced allergy. On 18Dec2020 at 15:45, the patient started to feel a warmth in her chest and abdomen, she felt like her heart was racing, and developed chest pain. It was reported that ""patient started to feel a warmth in her chest and abdomen. She felt like her heart was racing. Developed chest pain. No shortness of breath or difficulty swallowing"". It was unknown whether the patient received any treatment for the events. It was reported that the adverse events resulted in emergency room/department or urgent care visit. It was also reported that the events were non-serious

and did not cause or prolong hospitalization. The clinical outcomes of the events started to feel a warmth in her chest and abdomen, she felt like her heart was racing and developed chest pain were all unknown. It was unknown whether the patient had been tested for COVID-19 since the vaccination."

dry cough; low grade fever/he had a low grade temperature of 99.0 Fahrenheit last night and 101.0 Fahrenheit this morning; body pain; body weakness; This is a spontaneous report from a contactable Nurse A 50-years-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration in the left arm on 16Dec2020 10:30 at single dose for covid-19 immunisation. Medical history was none (no relevant patient or family medical history). The patient's concomitant medications were not reported. On 17Dec2020 the patient experienced low grade fever, temperature of 99.0 F on 17Dec2020 and 101.0 F on 18Dec2020, body pain and weakness with outcome of not recovered. On unknown date the patient experienced also cough with unknown outcome. The event fever was considered serious as medically significant and was reported as worsened. The reporter wanted to know what to do. The caller read somewhere not to take Tylenol, though he did take one this morning. He was to increase fluid intake but what other treatment was recommended. Information on Lot/Batch has been requested.; Sender's Comments: The reported information is limited. Based on the close temporal relationship and the description of the events, fever, body pain, cough and weakness there is a reasonable possibility that the events are related to BNT162 vaccine. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

Nausea; Vomiting; Chills; Migraine like headache; This is a spontaneous report from a contactable consumer (patient). A 32-year-old female patient (not pregnant) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, batch/lot number: unknown), via an unspecified route of administration (left arm) from 18Dec2020 (01:15 PM) to 18Dec2020 13:15 at single dose for COVID-19 immunization. The patient's medical history included PDA (Patent ductus arteriosus) ligation, fatty liver disease, and anxiety. Concomitant medications included melatonin, escitalopram oxalate (LEXAPRO), balsalazide sodium (BALZIDE), multivitamin, and prebiotic. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. No known allergies. The patient was not diagnosed with COVID-19 prior to vaccination. The patient has not been tested for COVID-19 since the vaccination. The patient experienced nausea, vomiting, chills, and migraine like headache the night after she received the vaccine (18Dec2020 07:00 PM). There was no treatment received for the reported adverse events. The outcome of events was recovering. This case is reported as non-serious. Information on the lot/batch number has been requested.

body ache; muscle and joint pain; muscle and joint pain; fever; injection site pain; chills; headache; This is a spontaneous report from a contactable consumer. A non-pregnant 20-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot number: EJ1685), via an unspecified route of administration in the right arm on 18Dec2020 10:15 at single dose for COVID-19 immunization. Medical history included COVID-19 (prior to vaccination). Concomitant medication included ethinylestradiol, norgestimate (SPRINTEC). No other vaccinations were given within four weeks

and the patient had no known allergies. On 18Dec2020 23:30, the patient experienced body ache, muscle and joint pain, fever, injection site pain, chills and headache. No treatment was received for the events. The clinical outcome of body ache, muscle and joint pain, fever, injection site pain, chills and headache was recovering.

Fever; Shortness of breath; Headache; Muscle ache; This is a spontaneous report from a contactable consumer (patient). A 24-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) lot number: EH9899, expiration date unknown, 1st dose via an unspecified route of administration on 18Dec2020 14:00 at a single dose at right arm for COVID-19 immunization. Medical history included penicillin allergy. There were no concomitant medications. The patient experienced fever, shortness of breath, headache and muscle ache on 19Dec2020 01:00 am. There was no treatment received for the events. The patient underwent lab tests and procedures on 19Dec2020 which included COVID test post vaccination (Nasal Swab): unknown result (pending). The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine and no other medications received within 2 weeks of vaccination. Prior to vaccination, the patient was diagnosed with COVID-19 and since the vaccination, the patient has been tested for COVID-19. The action taken in response to the events was not applicable. The outcome of the events was recovering.

it felt as if pulsing was radiating was coming from the upper middle of my spine; feeling really achy in shoulders both arms and neck; left arm hurt with any motion; feeling really achy in shoulders both arms and neck; feeling really achy in shoulders both arms and neck; This is a spontaneous report from a contactable healthcare professional. A 28-year-old non-pregnant female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot number: EH9899), intramuscularly in the left arm on 16Dec2020 12:00 at a single dose for COVID-19 immunization. Medical history was none. The patient's concomitant medications were not reported. There was no known allergies. On 16Dec2020 at 16:00, the patient experienced feeling really achy in shoulders both arms and neck and left arm hurt with any motion. On 17Dec2020, it felt as if pulsing was radiating, coming from the upper middle of spine. No treatment was received for the events. The outcome of the events was recovered with sequel on an unspecified date.

fine rash noted Saturday evening on arms and chest w /slight itchiness; occasional itchiness on Friday w/ no rash noted/fine rash noted Saturday evening on arms and chest w /slight itchiness; face felt prickly and itchy; face felt prickly and itchy; This is a spontaneous report from a contactable nurse (the patient). A 54-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), lot EH9899, via Intramuscular route of administration in right arm, on 17Dec2020 at 16:30, at single dose for COVID-19 immunization. The vaccine was administered at Hospital Facility. The patient did not receive other vaccine in four weeks. The patient medical history included sinus infections and past history of mono. The patient had allergy to kindest care hand sanitizer, alcare and eucerine hand cleanser. The patient's concomitant medications included ascorbic acid, zinc oxide (IMMUNE BOOST OTC). The patient on 17Dec2020 at 17:15, felt face prickly and itchy. No airway distress. Benadryl was administered at 22:30 that night. Physician was made aware. Occasional itchiness was observed on 18Dec2020. No rash noted. Fine rash was noted on 19Dec2020 evening on arms and chest with slight

itchiness. No Covid-19 was diagnosed prior vaccination. Covid-19 was not tested. The outcome of the events was resolving.

Body aches; Muscle pain; Chills; Headache; Fatigue; This is a spontaneous report from a contactable consumer reporting for herself. A 28-year-old female patient received the 1st dose of bnt162b2 (BNT162B2, Manufacturer Pfizer-BionTech), via an unspecified route of administration, on 18Dec2020 at 12:00 PM, at single dose, for Covid-19 immunisation. Medical history was none. Concomitant included an unspecified birth control medication within 2 weeks of vaccination. The patient experienced body aches, muscle pain, chills, headache and fatigue all on 19Dec2020 at 07:00 AM with outcome of recovering. No therapeutic measures were taken as a result of the events. The events were considered non serious. The information on the lot/batch number has been requested.

arm pain at injection site; redness from injection site up over shoulder; Tired; chills; body aches; This is a spontaneous report from a contactable consumer (patient). A 42-year-old female patient (not pregnant) received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot/batch number and expiration date not provided), via an unspecified route of administration on 17Dec2020 at 12:45 on arm at single dose for COVID-19 immunization. The patient medical history included SVT (Supraventricular tachycardia) with ablation, silicone sensitivity. Prior to vaccination, patient was not diagnosed with COVID-19. The patient's concomitant medications were not reported. Patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. There was no any other medications patient received within 2 weeks of vaccination. The patient experienced tired, chills, body aches, arm pain at injection site, redness from injection site up over shoulder, all on 17Dec2020. All gone within 48 hours of injection. Since the vaccination, patient had not been tested for COVID-19. No treatment was received for the events. The outcome of the events was recovered in Dec2020 within 48 hours of injection. The report was reported as non-serious. Information on the lot/batch number has been requested.

Redness in cheeks, greater on (opposite side from injection) right cheek; Mild swelling on right cheek; This is a spontaneous report from a contactable nurse reporting for herself. A 37-year-old female patient received the 1st dose of bnt162b2 (BNT162B2) (Manufacturer Pfizer-BionTech, lot# EJ1685), intramuscular in arm left, on 19Dec2020 at 12:00 PM, at single dose, for COVID-19 immunisation. Medical history included type 1 diabetes mellitus and hypothyroidism both from an unknown date and unknown if ongoing. The patient had no known allergies. The patient was not pregnant. Concomitant medications included insulin lispro (HUMALOG), levothyroxine (unknown manufacturer), ascorbic acid (VIT C), folic acid (unknown manufacturer), minerals nos, vitamins nos (PRENATAL VITAMINS) dexamethasone (DECADRON), metoclopramide (REGLAN), ondansetron (ZOFRAN), propofol (unknown manufacturer), midazolam hydrochloride (VERSED) fentanyl (unknown manufacturer). The patient experienced redness in cheeks, greater on (opposite side from injection) right cheek on 19Dec2020 at 12:30 PM with outcome of recovering and mild swelling on right cheek on 19Dec2020 at 12:30 PM with outcome of recovering. Therapeutic measures were taken as a result of the events which included Benadryl 25 mg oral. The events were considered non serious.

After 2 hours of receiving the Vaccine I got joint pain, tiredness, and severe headache. It's been more than 24 hours and I'm still having the same symptoms.; After 2 hours of receiving the Vaccine I got joint

pain, tiredness, and severe headache. It's been more than 24 hours and I'm still having the same symptoms.; After 2 hours of receiving the Vaccine I got joint pain, tiredness, and severe headache. It's been more than 24 hours and I'm still having the same symptoms.; This is a spontaneous report from a contactable consumer and contactable other-Health Care Professional (HCP). A 33-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration in the left arm on 18Dec2020 07:45 PM (at the age of 33 years-old) as a single dose for COVID-19 vaccination. Medical history was unknown. The patient was not pregnant at the time of vaccination. Prior to the vaccination, the patient was not diagnosed with COVID-19. The patient's concomitant medications were not reported; however, there were no other medications the patient received within 2 weeks of the vaccination. The patient did not receive any other vaccine within 4 weeks prior to the vaccine. On 18Dec2020 at 09:30 PM, the patient experienced joint pain, tiredness, and severe headache. The report was reported as non-serious. Treatment was not received for joint pain, tiredness, and severe headache. The clinical outcome of joint pain, tiredness, and severe headache was not recovered. It was also reported that since the vaccination, the patient had not been tested for COVID-19. The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up.

flush; fast heartbeat (120bpm); rash; nausea; dizzy, lightheaded; feeling unwell; This is a spontaneous report from a contactable consumer (patient). A 25-year-old female patient (pregnant: no) received first dose of BNT162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiry date unknown) via an unspecified route of administration at arm left on 19Dec2020 11:45 at single dose for covid-19 immunization. The patient medical history was not reported. Concomitant medication included celecoxib (CELEXA), ethinylestradiol and etonogestrel (NUVARING) received within 2 weeks of vaccination. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient previously took cefalexin(KEFLEX) and cefdinir(OMNICEF) and experienced allergies. The patient experienced flush, fast heartbeat (120bpm), rash, nausea, dizzy, lightheaded, feeling unwell on 19Dec2020 12:00 PM, the events resulted in emergency room/department or urgent care. Treatment of Benadryl received for the events. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. The outcome of the events was recovered in Dec2020. Information on the lot/Batch number has been requested.

I got increasing pain at my injection site, it was very sore. The soreness spread through my muscles; I got increasing pain at my injection site, it was very sore. The soreness spread through my muscles; headache; general fatigue; This is a spontaneous report from a contactable consumer (patient herself). A 23-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number EJ1685), via intramuscular in the left arm, as first single dose on 04Dec2020 (at 17:30) for COVID-19 immunisation. Relevant medical history included allergy to Latex. Relevant concomitant medications included loratadine (CLARITIN), birth control and multivitamin. The patient stated 'I got the vaccine on Friday and today (Saturday) half way through my shift at around 3:00 pm I got increasing pain at my injection site, it was very sore. The soreness spread through my muscles and I got a headache and general fatigue''. The patient did not perform a Covid test prior vaccination but after vaccination Nasal

Swab, COVID test, Rapid PCR was Negative. The patient was not treated for the events. She was recovering from the events. Information on lot/batch number has been requested

Injection site pain 14 hours after with body aches; 28 hours after fevers 102 sever body aches rigors; Injection site pain 14 hours after with body aches; 28 hours after fevers 102 sever body aches rigors; This is a spontaneous report from a contactable physician (patient himself). A 27-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via intramuscular on the left arm, as first single dose on 18Dec2020 (at 12:45) for COVID-19 immunisation. Relevant medical history included acid reflux and allergy to cats. Relevant concomitant medications included omeprazole (PROTONIX). 14 hours after vaccination, the patient had injection site pain with body aches. 28 hours after vaccination, he had fevers 102, sever body aches and rigors. However, it was reported that onset of the events was on 19Dec2020 at 17:00. The patient did not have loss of smell, SOB, dyspnea, loss of taste or diarrhea. The patient did not perform COVID test prior or after vaccination. No treatments were given for the events. The patient was recovering from the events. Information on the lot/batch number has been requested.

Feel flushed and had a fast heart rate; Feel flushed and had a fast heart rate; This is a spontaneous report from a contactable other HCP. This other HCP reported for a 35-year-old male patient that: Reporter type: Healthcare Professional reporting for a patient Age group: Adult (18-64 Years) Current age: 25 Current age unit: Years Medical qualification reporter: Other Health Professional Covid vaccine details: [{Product=COVID 19, Administration date=18Dec2020, Administrator route=Intramuscular, Dose number=1}] If other vaccine in four weeks: Unknown Adverse event: Caregiver received his first COVID-19 vaccine, was observed without issues for 15 minutes; left ambulatory. States he got up to the top of the stairs and started to feel flushed and had a fast heart rate. Came back to observation area. Set timer for additional 15 minutes of observation. Patient appeared to be in NAD, skin color WNLs, no c/o SOB or difficulty swallowing. Given a bottle of water. No issues during additional 15 minute observation. Left ambulatory; stated feeling much better. Informed him to mention this before his 2nd vaccine dose so that he can be observed longer. If treatment AE: No If covid prior vaccination: Unknown If covid tested post vaccination: Unknown Serious: No Seriousness criteria-Results in death: No Seriousness criteria-Life threatening: No Seriousness criteria-Caused/prolonged hospitalization: No Seriousness criteria-Disabling/Incapacitating: No Seriousness criteria-Congenital anomaly/birth defect: No Reaction(s)/Event(s): Reaction/event as reported by primary source: Caregiver received his first COVID-19 vaccine, was observed without issues for 15 minutes; left ambulatory. States he got up to the top of the stairs and started to feel flushed and had a fast heart r Reaction/event in MedDRA terminology (LLT): Caregiver received his first COVID-19 vaccine, was observed without issues for 15 minutes; left ambulatory. States he got up to the top of the stairs and started to feel flushed and had a fast heart rate. Came back to observation area. Set timer for Drug(s) Information: Characterization of drug role: Suspect Route of administration: Intramuscular Date of start of drug: 18Dec2020 Dose number: 1 Active drug substance information: Active drug substances name: COVID 19 Narrative case summary and further information: Case narrative Age at vaccination: 25 Years Did the patient receive any other vaccines within 4 weeks prior to the COVID vaccine: Unknown Reported Event: Caregiver received his first COVID-19 vaccine, was observed without issues for 15 minutes; left ambulatory. States he got up to the top of the stairs and started to feel flushed and had a fast heart rate. Came back to observation

area. Set timer for additional 15 minutes of observation. Patient appeared to be in NAD, skin color WNLs, no c/o SOB or difficulty swallowing. Given a bottle of water. No issues during additional 15 minute observation. Left ambulatory; stated feeling much better. Informed him to mention this before his 2nd vaccine dose so that he can be observed longer. Was treatment received for the adverse event?: No Prior to vaccination, was the patient diagnosed with COVID-19?:Unknown Since the vaccination, has the patient been tested for COVID-19?:Unknown No follow up attempts are possible. Information about Lot and batch number could not be obtained. No further information is expected.

"Felt lightheaded and dizzy.; Felt lightheaded and dizzy.; skin pale; very fatigued; she was currently breastfeeding; she was currently breastfeeding; This is a spontaneous report from a contactable health care professional. A 34-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), intramuscularly on 18Dec2020 (at the age of 34-years-old) as a single dose for COVID-19 immunization. The patient medical history and concomitant medications were not reported. It was unknown if the patient received any other vaccines within 4 weeks prior to the vaccination. It was unknown if the patient was pregnant at the time of vaccination. Prior to vaccination, it was unknown if the patient was diagnosed with COVID-19. On 18Dec2020, the patient felt lightheaded and dizzy and was brought to the observation area, ambulatory. She denied shortness of breath, itching or difficulty swallowing. No rash was noted, but the skin was pale. Water was provided to the patient. It was reported that the patient was currently breastfeeding, was very fatigued, probably dehydrated and had not eaten breakfast. She stayed in the observation area until 10:37, drank a total of 3 bottles of water and was up to the restroom ambulating on her own. Her blood pressure was 131/83, heart rate was 83 and ""100% on RA"" as reported. She left ambulatory to drive home and was informed to notify the appropriate person of this episode prior to a second dose of vaccine. It was unknown if treatment was received for the events ""felt lightheaded and dizzy"", ""skin pale"", and ""very fatigued"". Since the vaccination, it was unknown if the patient had been tested for COVID-19. The patient recovered from the events ""felt lightheaded and dizzy"", ""skin pale"", and ""very fatigued"" on an unspecified date in 2020, while the clinical outcome of ""she was currently breastfeeding"" was unknown. No follow-up attempts are possible; information on lot/batch cannot be obtained.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2020504266 mother/baby case, same reporter /drug , different patient"

"Right wrist swollen and painful; Right wrist swollen and painful; Immediate itchy rash on lower left arm between wrist and elbow; This is a spontaneous report from a contactable consumer (the patient). A 55-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, lot number BH9899), via an unspecified route of administration in the left arm on 17Dec2020 at 10:00 (at the age of 55-years-old) as a single dose for COVID-19 immunization. Medical history included rheumatoid arthritis (RA), penicillin allergy, and contact dermatitis to multiple agents. The patient was not pregnant at the time of vaccination. Prior to the vaccination, the patient was not diagnosed with COVID-19. The patient's concomitant medications included: prednisone, leflunomide (ARAVA), hydroxychloroquine sulfate (PLAQUENIL), meloxicam, ""and more"" (as reported, unspecified), all for unknown indications from unknown dates and unknown if ongoing. The patient did not receive any other vaccine within 4 weeks prior to the vaccine. On 17Dec2020 at 10:30, the patient experienced immediate itchy rash on lower left arm between wrist and elbow. On day 2 post vaccine (19Dec2020),

her right wrist was swollen and painful. The patient did not receive any treatment for the events. The clinical outcome of immediate itchy rash on lower left arm between wrist and elbow and right wrist swollen and painful was not recovered. It was also reported that since the vaccination, the patient had not been tested for COVID-19."

Developed pain and swelling in right index finger late evening after injection of vaccine, same side as vaccine injection; Developed pain and swelling in right index finger late evening after injection of vaccine, same side as vaccine injection; This is a spontaneous report from a contactable physician (the patient). A 68-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, lot number EH9899), intramuscularly in the left arm on 18Dec2020 at 17:15 (at the age of 68-years-old) as a single dose for COVID-19 immunization. Medical history included hypertension and history of prostate cancer. The patient did not have any allergies to medications, food, or other products. Prior to the vaccination, the patient was not diagnosed with COVID-19. The patient's concomitant medications were not reported. The patient did not receive any other vaccine within 4 weeks prior to the vaccine. On 18Dec2020 at 23:00, the patient developed pain and swelling in his right index finger late evening after injection of the vaccine, on the same side as vaccine injection (as reported). The patient was treated for pain and swelling in his right index finger with ibuprofen 600 mg (MANUFACTURER UNKNOWN). The clinical outcome of pain and swelling in his right index finger was recovering. It was also reported that since the vaccination, the patient had not been tested for COVID-19.

Soreness at injection site; This is a spontaneous report from a contactable consumer (patient) and healthcare professional (HCP). A 52-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE) solution for injection via an unspecified route of administration on 18Dec2020 at 10:30 (at the age of 52-years-old) as a single dose for COVID-19 vaccination. The patient was not pregnant at the time of vaccination. Medical history included HTN (hypertension) and known allergies sulfa. Concomitant medications included pneumococcal vaccine polysaccharide 23valent (PNEUMOVAX 23) on 14Dec2020 in right deltoid and varicella zoster vaccine RGE (CHO) (SHINGRIX) on 14Dec2020 in left deltoid. The patient did receive other vaccines (PNEUMOVAX 23 and SHINGRIX) within 4 weeks prior to the vaccine. Prior to the vaccination, the patient was not diagnosed with COVID-19. On 18Dec2020, the patient experienced soreness at injection site. No treatment was provided for the event soreness at injection site. The outcome of the event soreness at injection site was recovered in Dec2020. Since the vaccination, the patient has not been tested for COVID-19. The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up.

Arm felt tingly after; This is a spontaneous report from a non-contactable nurse. A 30-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, Lot EK5730) solution for injection intramuscular in the left arm on 20Dec2020 at 12:30 (at the age of 30-years-old) as a single dose for COVID-19 vaccination. The patient was not pregnant at the time of vaccination. There was no medical history. There were no concomitant medications. The patient had no known allergies to medications, food, or other products. The patient did not receive any other vaccine within 4 weeks prior to the vaccine. Prior to the vaccination, the patient was not diagnosed with COVID-19. On 20Dec2020 at 12:30, the patient experienced arm felt tingly after. No treatment was provided for the event arm felt

tingly after. The outcome of the event arm felt tingly after was recovered in Dec2020. Since the vaccination, the patient has not been tested for COVID-19. No follow-up attempts are possible. No further information is expected.

"patient's several members of family tested positive for COVID 19 virus and was potentially exposed; it was like she got the flu/whole flu like symptoms; Sore throat; Joint ache; Body ache; Low grade fever; Running nose; Terrible headache; Laryngitis; Muscle ache; Loss of smell; Chest discomfort; Joint discomfort; This is a spontaneous report from a contactable nurse. A 53-year-old female patient started to receive bnt162b2 (reported as Pfizer-BioNtech vaccine; lot number: EH9899), intramuscular on left arm on 18Dec2020 at single dose for COVID-19 immunization. Medical history included migraine, arthritis, gastritis, and esophageal spasms all from unknown dates and unknown if ongoing. Concomitant medications included dicyclomine, biotin, tocopherol (VITAMIN E [TOCOPHEROL]), and ergocalciferol (VIT D). Patient reported getting the vaccine and is now having a reaction. Patient stated that she got the COVID vaccine on 18Dec2020 at 7 in the morning and she started to get sick 5 in the morning the next day. Patient stated she worked night shift the next day and got sick and it was like she got the flu from the shot. When the above concern was paraphrased, the patient stated, ""Yes I had all of my joint ache, body ache, I had low grade fever, running nose, terrible headache, just whole flu like symptoms"". The patient was informed the role of the Pfizer Drug Safety and permission to probe was asked from the patient. Patient also stated, ""Yes, I always get my flu shot every year for many years, two other times I have been sick from the flu shot (Further clarification was Unknown) and it was like this it was like the flu and I believe this because of the shot but you know I mean I still think it would have been, I think it is better than having received COVID itself"". Patient mentioned taking turmeric. Patient mentioned that she had a COVID test done on Thursday at the clinic that she works at and that must have been negative because nobody contacted her and it was just they do random testing because of the patients she works with. Patient further stated ""I got my vaccine between 7-8 am mornings Friday morning and then around 5 am on Saturday morning, I started feeling really bad and then when I woke up at 4 in the afternoon I was done. It is probably, yes 18Dec, 7 or 8 in the morning I got the shot and then 19Dec at 5 am is when I started getting sick, by the evening I was full grown sick and I had to call I am sick because I couldn't pull another 12 hour shift"". The patient also reported that she was much better today (unspecified date), had a sore throat and headaches but her joint pains were better, and she has no fever not even low grade fever. It was further stated that the patient received first dose of Pfizer-BioNtech vaccine on Friday 18Dec2020. Developed symptoms on Sat 19Dec2020 which included ""sore throat, laryngitis, muscle ache, loss of smell, chest discomfort, low grade fever, joint discomfort"". Patient mentioned that she took Theraflu and NyQuil. Patient also stated, ""And the only other question is because when I called up to work to tell them to give me COVID a day for COVID pay because it was COVID related and they said they were not sure if they could. This is COVID related they should pay me for a day of COVID pay, correct. Who would know that?"". It was also found out ""recently"" that patient's several members of family tested positive for COVID 19 virus and was potentially exposed. It was asked that if patient gets tested for COVID virus, will she be positive because of receiving the Pfizer-BioNtech vaccine and can patient test positive for COVID 19 virus after receiving the Pfizer-BioNtech vaccine. Outcome of the event 'Low grade fever' was recovered, unknown for event

'patient's several members of family tested positive for COVID 19 virus and was potentially exposed', while recovering for the remaining events."

had 1 episode of shortness of breath; tachycardia; dizziness / light headedness; This is a spontaneous report from a contactable consumer reporting for herself. This 29-year-old female patient (non-pregnant) received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 19Dec2020 at 15:30, at single dose, for COVID-19 immunization. No other vaccine was given within 4 weeks prior to the COVID vaccine. Medical history was not reported. The patient was not diagnosed with COVID before vaccination. Concomitant medications included vitamin C and sambucus nigra fruit (ELDERBERRY) and unspecified multivitamin and immune support. On 19Dec2020 at 23:30 the patient experienced one episode of shortness of breath, tachycardia, dizziness. Lasted for about 20 minutes and totally resolved within 1.5 hours. Continuing to have light headedness 24 hours after. Emergency room/department or urgent care required. No treatment was given. COVID was tested post vaccination on 20Dec2020 via nasal swab (rapid test), with negative result. The events were resolving. Information on the lot/batch number has been requested.

Near syncopal episode the morning after; Extreme fatigue; generally unwell; body aches; nausea; chills; ear fullness; abdominal pain; This is a spontaneous report from a contactable consumer (patient). This 26-year-old female consumer received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) Lot number EJ1686, at single dose on 17Dec2020 08:00 on left arm for COVID-19 immunisation. Medical history included Environmental allergies, childhood asthma. The patient had no covid prior vaccination. The patient did not have covid tested post vaccination. The patient had no known allergies. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Concomitant medication included cetirizine hydrochloride (ZYRTEC), birth control, multivitamin. The patient experienced Extreme fatigue, generally unwell, body aches, abdominal pain, nausea, chills, ear fullness. Near syncopal episode the morning after on 18Dec2020. No treatment was received for all events. The outcome of the events was resolving.

"blister on her index finger; injection site is ""typical bruise looking and is tender; injection site is ""typical bruise looking and is tender; This is a spontaneous report from a contactable physician (who is also the patient). This female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 19Dec2020 at single dose for COVID-19 immunisation. Relevant medical history and concomitant medications were not reported. On an unspecified date, the patient noticed a blister on her index finger and said it was a round, red, raised, red spot on the index finger of the same side of her vaccination. She also stated that the injection site was typical bruise looking and was tender but did not look red or raised. The outcome of the events was unknown. The information on Lot /Batch Number has been requested."

Disequilibrium; This is a spontaneous report from a contactable nurse (patient). This 38-years-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), intramuscular, on 18Dec2020 at 04:00 PM at single dose for COVID-19 immunisation. Vaccine location was right arm. The patient was vaccinated at hospital, age at vaccination was 38-years-old. No other vaccine was received in four weeks. Medical history was none. Concomitant medications were unknown. On 20Dec2020, the

patient experienced disequilibrium. The event was reported as non-serious. The patient was tested for Covid post vaccination through a nasal swab on 20Dec2020, results are unknown. Outcome was recovering. No treatment was received for the event. Information on the lot/batch number has been requested.

Chills; sweating; Fever (99.1F) started at 22 hours and peaked at 99.9 (approximately 32 hours after vaccine administration); Diarrhea at 18 hours after administration; Injection site pain; Muscle aches; fatigue; severe nausea (no vomiting); mental fog (last about 4-6hrs); Within one minute: tachycardia (lasted about 3mins); dizziness (lasted 4-6hrs); weakness (lasted 12hours); This is a spontaneous report from a contactable consumer reported for herself. A 27-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) at single dose for COVID-19 immunization on 17Dec2020 at 19:30 via unspecified route of administration at the right arm in the hospital. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient haven't known allergies. About 7 years ago the patient had received HPV vaccine on unknown date and she experienced reaction to excipient. Within one minute the patient experienced tachycardia (lasted about 3mins), mental fog (last about 4-6hrs), dizziness (lasted 4-6hrs), and weakness (lasted 12hours). Starting 15mins after vaccine, severe nausea (no vomiting) that last two hours. Muscle aches and fatigue started at two hours after vaccine administration. Injection site pain started 6hrs after administration. On 18Dec2020 chills and sweating. Fever (99.1F) started at 22 hours and peaked at 99.9 (approximately 32 hours after vaccine administration). Due to fever, other symptoms, and recent exposure to COVID at place of employment, COVID nasal swab was done on 19Dec2020 at 1300 to rule out possible active diagnose. Test pending at this time. Tylenol administered to reduce fever and symptoms. Outcome of events at the time of last observation was reported as recovering. Information about lot/batch number has been requested.

Left arm start swelling at the injection site and down to the elbow around 5:30pm; This is a spontaneous report from a contactable consumer reporting for herself. A 47-years-old female patient received bnt162b2 (BNT162B2; Lot #Eh9899) vaccine, via an unspecified route of administration in the left arm on 20Dec2020 10:00 at single dose for covid-19 immunisation . Medical history included hypertension from an unknown date , migraine from an unknown date , partial seizures from an unknown date , intracranial aneurysm from an unknown date. Concomitant medication included spironolactone (SPIRONOLACTONE), hydrochlorothiazide, triamterene (TRIAMTERENE & HCTZ), estradiol (ESTRADIOL). The patient was allergic to lisinopril , amlodipine , gentamicin sulfate; methylmethacrylate;polymethylmethacrylate;zirconium dioxide , zonisamide . The patient left arm start swelling at the injection site and down to the elbow around 5:30pm with outcome of recovering.

Generalised rash; Injection 15 mins later developed generalized rash, palpitations and rash to face. I had to go home and take medication.; Injection 15 mins later developed generalized rash, palpitations and rash to face. I had to go home and take medication.; This is a spontaneous report from a contactable Nurse for herself. A 29-years-old female patient received bnt162b2 (BNT162B2; Lot # FJ1685) vaccine , intramuscular in the right arm on 19Dec2020 08:00 at single dose for covid-19 immunisation . Medical history included drug hypersensitivity from an unknown date , food allergy from an unknown date , allergy to metals from an unknown date. The patient 15 mins after the injection developed generalized

rash, palpitations and rash to face. and had to go home and take medication. The outcome of the event was recovered.

I feel a little Tachycardia; This is a spontaneous report from a contactable nurse reporting for him/herself. A patient of unspecified age and gender received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for covid-19 immunisation. The patient medical history and concomitant medications were not reported. The patient experienced felt a little tachycardia on an unspecified date with outcome of unknown. The heart beat was 101 and body temperature was 97.7 F. The patient asked if she should go see her doctor or the emergency room or should she wait. Information about lot/batch number has been requested.

His blood pressure keeps going up right now it is like 191/111, which is really high; Has been experiencing like severe headache for the past two days; This is a spontaneous report from a contactable consumer. A 54-years-old male patient (reporter boyfriend, anesthesiologist) received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration in Dec2020 at single dose for covid-19 immunisation. The patient medical history and concomitant medications were not reported. The patient experienced severe headache for the past two days and his blood pressure keeps going up on Dec2020 with outcome of not recovered. On unspecified date the blood pressure was like 191/111, which was really high. As treatment the patient took some type of analgesic, ibuprofen (MOTRIN) or something, and he also took Propranolol to try to get his blood pressure down but it kept going up. The patient underwent COVID test on unspecified date with unknown results. Information on lot/batch number are requested.

I began intense itching & redness that began in hands & feet, then head, arms back of neck then torso turned red and itchy; I began intense itching & redness that began in hands & feet, then head, arms back of neck then torso turned red and itchy; This is a spontaneous report from a contactable consumer, the patient. A 52-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration on 20Dec2020 at 14:30 (at the age of 52 years old) as a single dose in the left arm for COVID-19 vaccination. Medical history included asthma from an unknown date. The patient was not pregnant at the time of vaccination. Prior to the vaccination, the patient was not diagnosed with COVID-19. No known allergies. Concomitant medication included progesterone (PROGESTERONE), estriol (ESTRIOL), diazepam (VALIUM) all for unknown indications from unknown dates and unknown if ongoing. The patient did not receive any other vaccines within four weeks prior to the vaccination. The vaccine was given at a hospital. On 20Dec2020 at 19:00, the patient experienced she began intense itching & redness that began in hands & feet, then head, arms back of neck then torso turned red and itchy. The event resulted in a doctor or other healthcare professional office/clinic visit. The patient received treatment for the events which included steroids and benadryl. The clinical outcome of began intense itching & redness that began in hands & feet, then head, arms back of neck then torso turned red and itchy was recovering. It was also reported that since the vaccination, the patient had not been tested for COVID-19. The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up.

tachycardia (HR 150s); hypertension (BP 180/110s); This is a spontaneous report from the contactable nurse. A 45-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date were not reported), via an unspecified route of administration on 17Dec2020 at a single dose for COVID-19 immunization. The patient's medical history included COVID-19 from Sep2020. Concomitant medications were not reported. On 17Dec2020, approximately 5 min after receiving the vaccine, the patient experienced tachycardia (HR 150s) and hypertension (BP 180/110s). Therapeutic measures were taken as a result of the events and included treatment with labetolol. Outcome of the events was unknown. Information about lot/batch number are requested.; Sender's Comments: The reported information is limited. Based on the close temporal relationship and the description of the events, tachycardia and hypertension, there is a reasonable possibility that the events are related to BNT162 vaccine. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

Headache and injection site pain; Headache and injection site pain; This is a spontaneous report from a contactable consumer. An approximately 40 year old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration on 17Dec2020 (at the age of 40 years-old) as a single dose for COVID-19 vaccination. Medical history was unknown. The patient's concomitant medications were not reported. On an unknown date, the patient experienced injection site pain and headache. The clinical outcome of injection site pain and headache was unknown. No follow up attempts are possible; information about lot/batch number cannot be obtained.

little fatigue on first two days; This is spontaneous report from a contactable consumer. A patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), unknown route, on 15Dec2020 at single dose for COVID-19 immunisation. Medical history and concomitant drugs were unknown. The patient reported so far there are no side effects except little fatigue on first two days from 15Dec2020. The action taken in response to the events for BNT162B2 was not applicable. The outcome of the events was recovered on 17Dec2020 Information about lot/batch number has been requested.

"left ankle is very swelling, redness, it's very painful; left ankle is very swelling, redness, it's very painful; left ankle is very swelling, redness, it's very painful; This is a spontaneous report from a contactable physician (patient). A 66-years-old male patient started to receive BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), Batch/lot number unknown, intramuscularly from an unspecified date (at the age of 66-years old) as a single dose (reported as I think it was 0.5 ml they gave me some card, normally it is 0.5 ml I believe, I don't know) for covid-19 immunization. Medical history included mild hypertension for which he was on blood pressure very low dose like 50 mg from an unknown date and unknown if ongoing. The patient is very active, four days of gym. He is not obese, not a smoker and doesn't drink. Concomitant medication included losartan. The physician reported he worked for the hospital so was exposed to COVID-19 patients. The hospital offered the COVID-19 vaccination and he got it on Friday like 1 O clock on unspecified date and since this morning like 3am (03:00) on unspecified date, his left ankle

is very swelling, redness, it's very painful. He read about the side effect its says joint swelling. ""I never had problem like gout or any degenerative joint disease"". He was healthy. He doesn't know if this is related with this. He was going to call the hospital. The physician further he never have swelling like this, he doesn't know what exactly happened. He cannot say 100 percent but nothing happened, he did not take any new medicine. He doesn't have any injury. He never had gout. He never have any degenerative joint disease. ""I cannot say 100 percent but there is a possibility."" For treatment the physician stated, ""no, it happened 3 am in the night since morning I am doing hot, I have put heater in front of my feet."" The patient did not have lab work performed. He was thinking to go ask hospital to rule out any gout, any arthritic pain, ""I am going for arthritic"". Outcome of the events left ankle is very swelling, redness, it's very painful was unknown. The lot number/batch for the vaccine, BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, was not provided and will be requested during follow up"

Headache; Last night was throwing up; Dizziness/light headed; nausea; just like overall unwell; This is a spontaneous report from a contactable consumer (patient). This 25-year-old female patient reported that she received BNT162B2 (COVID-19 VACCINE), via an unspecified route of administration on 18Dec2020 at single dose for COVID-19 immunization. Medical history included anxiety. Concomitant medications included bupropion for anxiety. Consumer stated she thought that she was having adverse side effects. Last night (18Dec2020), she was throwing up. She got COVID-19 vaccine yesterday (18Dec2020) around 5' O clock and last night around mid-night she was throwing up and had like dizziness, she was just getting a headache now (19Dec2020), she was light headed last night, just like overall unwell. Regarding treatment, she took like calcium carbonate (TUMS) (antacids) for like nausea and ibuprofen (ADVIL). Outcome of events was unknown. Information on the lot/batch number has been requested.

sore arm; lightheaded; This is a spontaneous report from a non-contactable consumer. A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot number: EK5730), via an unspecified route of administration on 19Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced sore arm and lightheaded on 19Dec2020. The outcome of sore arm and lightheaded was recovered in Dec2020. No follow-up attempts are possible. No further information is expected.

Chills; Experienced mild flu like symptoms; Fever; This is a spontaneous report from a non-contactable physician (patient). A 31 year old female patient (physician) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration on19Dec2020 as a single dose for COVID-19 vaccination. Medical History was reported as none. There were no concomitant medications. On Dec2020, the patient experienced chills, mild flu like symptoms and fever. In Dec2020, she was now fully recovered. The clinical outcome of chills, mild flu like symptoms and fever was recovered Dec2020 No follow-up attempts are possible; information about lot number cannot be obtained.

feeling arm soreness; This is a spontaneous report from a non-contactable physician. A male patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration in Dec2020 at a single dose for COVID-19 immunization. The patient's medical

history and concomitant medications were not reported. The patient experienced feeling arm soreness in Dec2020. No other symptoms were reported. The outcome of feeling arm soreness was recovered in Dec2020. No follow-up attempts are possible. information about lot/batch number cannot be obtained.

Headache; This is a spontaneous report from a Pfizer Sponsored Program A non-contactable consumer reported that a patient of unspecified age and gender received bnt162b2 (BNT162B2 lot number and expiration date were not reported) via an unspecified route of administration on an unspecified date at a single dose for immunization. The patient's medical history and concomitant medications were not reported. On an unspecified date, the patient had a slight headache the day after getting the vaccine. Patient had no arm soreness. Patient stated that this vaccine was the best bet at getting an excellent IgG titer level without actually getting sick with Covid. Outcome of the event was unknown. No follow-up attempts are possible. No further information is expected.

Started out as a sore arm about 4 hours after getting the shot. Then progressed to severe body aches and a headache about 8 hours after getting the shot. Then after about 10 hours post-vaccine it progressed into chills and a 100.0 degree fever. I took 2 Tylenol Extra Strength pills at 12 hours post-vaccine and the symptoms decreased significantly within an hour. Still experiencing mild symptoms of all of the above.

Severely delusional, elevated high BP, vertigo, chills, moderate fatigue, swollen ankles,

Headache, night sweats

Metallic taste

Nausea (dry heave), Light-headedness, slight hand tremors, increased respirations, pain and warmth at injection site, tiredness, slight facial skin tightening, tingling of hands and feet

"PT RECEIVED Pfizer-BioNTech COVID-19 Vaccine. During observation period, pt felt as though her tongue was ""thick"" and her lips were tingling. Pt took a Claritin Ready Melt 10 mg tablet and sat under observation for addition 30 minutes. Symptoms subsided and pt left pharmacy area. She will carry her Epi-Pen with her for the next couple days."

Leg muscle pain in quadriceps in both legs, headache, nausea, one instance of vomiting

No symptoms during the mandatory 15 minute post-vaccine period in clinic waiting area. Experienced mild fatigue/general tiredness approximately 6-7 hours after receiving vaccine (given 12:35 pm). Full body chills/muscle spasms then occurred around 9:30 pm and lasted about 40 minutes.

5 minutes post-injection onset of nausea. 10 minutes post-injection retching. 1 hour post injection intense abdominal pain. 2 hours post injection onset of full body itching with no rash or hives. Itching responded to 50 mg Benadryl po and 20 mg po pepcid. Next day light itching; no other symptoms

Tired since about 10:00 AM, lethargic, pain at injection site, muscle aches, brain fog, slight headache.

Seizure witness by wife who is a physician. Bit tongue. No history of seizure or other neurologic disease.

Had vaccine yesterday. Last night had body ache and fever 98. Today only had body ache. But when she check the temperature it was the same as yesterday.

Soreness at site, tiredness, headache, sleepiness, soreness at hand joints, lymph nodes inflammation.

I started to feel a little dizzy at work within hours of vaccine, had not slept well the night before but dizziness continued on and off remainder of the day, felt a little ?off?.

Received Covid 19 vaccine on left deltoid via IM. I felt warm in my left deltoid immediately after the injection. While I was sitting in the recovery area I started feeling palpitations and Shortness of breath. I actually felt I was going into cardiac arrest. Personnel started assessing me and upon checking my vital signs my SBP was in 150?s-160?s and DBP was in 100?s range. Normally my BP ranges in 110?s. I also started feeling numbness on my left arm. My bilateral lower extremities were also numb, tingling, burning and very weak. I was not able to stand up and bear weight. I then was taken to the ED where blood work was done and ATIVAN Po was given. I was then discharged at 2325. The next morning, I felt my legs are still heavy and sore. They are still very heavy and sore while I am writing this and I feel like they will buckle when I walk.

lip swelling, eye lid swelling began approximately 36 hours after vaccination. Patient presented to ED and was treated with benadryl, protonix and prednisone. Plan to discharge home with the same

Staff having running nose, cough, fatigue, arm/body ache. States its post nasal drip. Same symptoms she had after her last flu shot. Took sudafed and is feeling better.

Injection site pain from hour 6 of the day the vaccine was given (12/19/20) until day 3 (12/21/20).

Had vaccine on L arm on Mon. Mon afternoon stiff L arm and hurt. Tue evening felt a lot of pain to lymph note under left arm pain.

right sided tingling at corner of lip up towards top of eye approx 10 min post shot

Patient developed arm muscle twitching the day after injection.

three hours after vaccine, felt tired, dry throat, HA, loss of taste, chill, no fever, nausea

On day of vaccine, had migraines, took Excedrin yesterday for HA, Nausea started yesterday afternoon. Today feeling tired, chest tight, SOB.

c/o facial redness, sweating, and hives at 1015

Started on Monday: tired, body aches, chills, called out from work. neg test results yesterday . Today symptoms are getting better today.

1 hour after felt dizzy/nausea. Staff has back pain, pain in bone, knee and feeling cold last night. No fever. He is taking Comudin, blood thinner. Staff states feeling better.

Had body aches started last night, but is feeling better today.

Approx 54 hours after vaccination, the lymph node in my left armpit swelled up to the point it was painful and relatively uncomfortable. My arm was no longer sore at the injection site, but I was unable to lie on that side while sleeping in bed. I took 600mg of Ibuprofen every 6 hours to help with the pain and swelling. It has subsided some, but is still swollen.

Quite a bit of pain and swelling in the left arm around the injection site, chills,headache,abdominal cramping all presented within 12 hours.

Pt. developed chest tightness which she described as her usual feeling when needing her rescue inhaler for asthma about 5 minutes post vaccination, had felt very anxious prior to vaccine due to needle phobia. She denied any associated symptoms either cardiac or respiratory system related and no localized arm pain at the injection site. She was also fatigued having worked since 5AM as a medical screener at a nearby clinic and had not eaten in more than 8 hours

-Swelling, sore throat: lasted about 8 hours, exacerbated by continuous use of n95 mask. -Injection site swelling: so far, started upon injection, has stayed swollen for 3 days. Measures ~6cm wide, still itching and tender. Redness comes and goes. -Myalgia: Lasted about 4 days, exacerbated by physical nature of job.

Body aches for 24h, starting about 12 hours after vaccination. Fatigue for 24hours.

warm, raised, hard, painful to touch at injection site

Pt. developed a typical (for her) migraine headache about 5-10 minutes after vaccination. She also described significant flushing and feeling hot, quickly removing her head covering and scarf. She took her regular dose of aspirin which she carries with her and we applied cold compresses to her neck which relieved the flushing and hot flash. We turned the lights low above the cot, she rested and symptoms all resolved over about 20 minutes and she left feeling relieved her headache did not progress.

Fractured right shoulder/ dislocation while doing a work out lifting low weight

Moderna COVID 19 vaccine eua, lip swelling approximately 12 hours after injection, chills, fatigue and hardness at injection site approximately 10 hrs after injection

Approximately 2 hours after Vaccination developed body aches, feverish feeling, injection site pain Next morning woke up with severe body aches, fever 101degrees F

Generalized body aches, chills, fever

Severe nausea, headache, chills, temp 100 4 - 101 8, body aches, swollen lymph nodes under left arm, lethargy. Started at 1130 on 12/22/20. All symptoms except headache resolved by 3 am 12/24/20

patient received vaccine and walked to chair and immediately started to c/o headache 2 -advil were given, patient was allowed to lie down on stretcher, close here eyes and ice pack to forehead was given

Following Pfizer BioNTech COVID-19 Vaccine dose 1, patient complained of dizziness, nausea, and chills for about 20 minutes. Patient was placed supine and offered fluids and crackers. Symptoms improved. Vital signs taken and were stable. Patient raised to sitting position and ambulated without difficulty. She was observed in the clinic for 45 minutes after her vaccine was given and she was able to leave the clinic independently. She was advised to call her primary care provider for any return of symptoms, and to report immediately to the emergency department if symptoms become severe.

Patient broke out in hives across left chest and across her back following the vaccination. The patient did not notice this until approximately 25 minutes after her vaccination and had left the clinic area. She returned with these symptoms, and was taken to the emergency department for further evaluation. She denied any shortness of breath or difficulty breathing.

Approx 20 min after the injection a wave of dizziness came over me as I parked my car at home, I sat in the car it lasted 1 to 2 minutes. Approx 60 min after the injection the 2nd wave of dizziness came over me lasting less than a minute. I read the paperwork provided and noticed this was a reaction, not a side effect. I told myself if it happened again I would go to the emergency room. Luckily it did not happen again. I will make them aware of this when I go for my booster vaccine on Jan 8th, 2021 Happy New Year and thank you for all of your hard work on this project to help people all over the world.

Chills, Fever, Nausea and Vomiting, General feeling of malaise (not feel well)

5 minute bout of vomiting 11 hours after vaccine given. Resolved completely, did not recur.

Low grade fever, headache, muscle ahes

patient felt lightheaded for 20-30 minutes

Patient complained of a headache initially, and then several minutes later, began to experience chest pressure following the first dose of the Pfizer BioNTech COVID-19 Vaccine. She was taken to the emergency department for further evaluation.

Diffuse splotchy erythematous, mildly pruritic rash on arms, neck, trunk, and legs. More prominent on flexor surfaces of limbs.

The patient had a fever of 101.8 with increasing body aches. She was advised to go to the emergency room and her fever was 104 at the time of arrival. The patient received IV fluids and was discharged after being monitored.

Employee felt like headed pretty soon after vaccine and had never experienced that feeling before. He has had no reactions like this in the past. He was evaluated by EMS and was tachycardic and hypertensive at first. Blood pressure and tachycardia normalized. He reports his baseline heart rate is on the higher end. He was monitored for a total of about 30 minutes and felt back to baseline after he was evaluated.

about 30 min after vaccination, pt reports numbness in mouth that lasted about 1 minute then resolved. After that, he had nausea, which resolved quickly as well.

"The patient reported a numb feeling in his face for a ""short time"""

headache pain score 7 out of 10 and chills over 1.5 hours after receiving vaccine.

extremely Stiff muscles and joints. Fatigue. stuffy nose. Mild headache.

Moderna COVID 19 Vaccine EUA Next day 12/23 after 5pm Chills, Temp 100.9. 12/24 Temp Current 99

fever 101.1F mild headache body aches flu like symptoms

diarrhea, nausea, muscle aches, cough,

Chills over 1 hour after receiving vaccine. resolved in 10 minutes

Nausea the following day (12/22)--@ 11AM. Vaccination at 550PM the night before 12/21. no medications needed. mild arm soreness at injection site on 12/22. All have since resolved.

None stated.

Nausea, Lightheaded, sweating, dizziness, increased blood pressure, left ear pain and left tonsils felt swollen, felt ?off?

patient c/o nickel sized red round & hard around injection site, placed heat pack over site with good relief.

STARTED SOB AND DRY COUGH AND RASH WITHIN 15 MINUTES OF VACCINE

Vaccine administered at 0730. Pt went home and went to bed. Woke up at 0930 with shaking, chills and feeling like she was going to pass out. Evaluated in ER and noted to have sinus tachycardia in 140-160's. Given 5mg IV Lopressor which took heart rate down to 110's. Admitted to hospital 12/23/2020.

On December 22nd I became tachycardic with heart rate ranging from 105 to 130. I then went to the Ed thinking I may develop a pulmonary embolism. Fortunately, cta of chest was negative. On 12/23/20 at around 10:30 I develop diffuse erythema rash essentially from face to groin, arm. I went to the hospital?s employee health to report my adverse effects. I took prednisone 80 mg and benAdryl 50 mg and symptoms subside. However, I woke up this morning and the rash is more pronounced with slightly tachycardic.

Approximately 15+ minutes after receiving the vaccine, the patient stood up from the chair and felt dizzy and faint. She was escorted to a bed to lay down. Ice packs were placed on her neck. Patient said she felt tachycardic. Pulse was 86. She denied SOB, had appropriate mentation. No rash was visualized on face, neck, abdomen, or legs. She drank apple juice. At 4:26, patient tried to sit but again felt dizzy and faint. She was transferred to the ED via wheelchair.

Full body shakes and chills that woke me up out of a deep sleep. Felt like my body was convulsing, resolved about 4 hours Nausea and Vomiting for about, resolved after 2 hours Woke up and feel weak, and have a headache. Current as of 12-24-2020 at 8:30 AM No treatment was taken

Nearing the end of 15 minute observation period, patient began to experience palpitations, sweating and felt faint. We moved patient to a private area and RN checked BP, (144/98) and reviewed issues with patient. Patient then shared that she felt tingling in hands and arms. She then recalled that she may have experienced this before but continued to feel unwell. Two RN's continued monitoring of patient until EMS arrival in <3 minutes and they proceeded to check BP again, (slightly higher) and blood sugar which was normal. They were on site for approximately 10 minutes evaluating and both EMS and patient confirmed that she was able to leave and did not need to visit hospital.

Employee developed face/neck flushing, pruritis, and shortness of breath following receipt of COVID-19 vaccine.á There was no swelling of the lips, tongue, or throat.á She was moved to the ED for additional monitoring (not registered).á She was monitored for an additional hour in the ED.á Her flushing decreased and SOB improved.á She was released from the ED with no intervention needed.á The patient had a history of allergic reactions to multiple injectable meds and vaccines in the past.

None stated.

Shingles outbreak emerged about 72 hours after vaccine. Prescribed Acyclovir 800mg on 12/22/2020 Also had a co-worker develop shingles within 24 hours of the vaccine this week.

Right now starting to get some chills and body aches. Is any type of confusion normal?

Some Nausea, Headache, facial itching

Approx. 45 -- 60 minutes following the vaccine, pat c/o lightheadedness, blurry vision, tingling in Left cheek, x 1hour, skin turned bright red heart rate 147 BP 147/80. Iced back of neck/forehead, sat for a few minutes. Heart rate down to 104, went back to work, but continued to feel flushed. Upon examination, her skin was normal in color but she stated that she still feels flushed & hot.

Lightheaded, Dizziness, Tachypnea, Tachycardia, Diaphoresis

Scratchy throat, mild fever (100 degrees), vomiting, nausea, headache, diahrrea

None stated.

Headaches, dizziness, nausea started around 5pm. By 10pm did manual BP, was 84/48. Chills and mild sweats overnight and BP in AM was 90/50s despite 2L water intake overnight. Fatigue and generalized aches by 0500 on 12/24/20. No symptoms prior to vaccine. Of note I work as Hospitalist with ER and inpatient wards- always using ventilator mask.

Adverse events initially began with chills the night of injection. There is significant bodyaches malaise and severe headache as well as our palpitations. And aura was associated with the headache specifically difficulty visualizing through the right eye the following day for several hours. Symptoms continue

through the following day and night. There was also nausea and loss of appetite. Symptoms started to prove two days after injection at the time of this report

Patient felt flushed and hot and felt a sudden headache start. Escorted to a bed to lay down. Ice packs applied to forehead and neck. BP 137/87, pulse 92, RR 20, temp 98.2. Rapid Response team called. Patient drank apple juice. When asked about a hx of reactions, patient stated she had a hx of reactions to T-dap, Hepatitis, A, and flu. She stated her reactions usually occur 2 hours after the vaccines and has a high fever of 103.0F with chills. She stated she had pre-medicated with 1 gram of Tylenol prior to coming to the COVID vaccination clinic. Repeat vital signs BP 138/89, pulse 94, RR 22. No improvement on how she felt and was transported to the ED via wheelchair.

I woke up with my heart pounding in my chest at 0038. I put on my daughter's pulse oximeter (she has asthma) and my heart rate ranged from the 110s up to the 130s. I got back into bed and tried to relax, then took a Restoril, fell asleep, but woke up again around 0300 with the same symptoms.

Moderate chills, body aches, slight nausea and headache which developed approximately 48 hours after receiving the vaccine and lasted for approximately 4-6 hours during the middle of the night and then completely resolved.

fever, headache

None stated.

Patient received the vaccine @ 0830am in her Left deltoid, @ 10pm that night she developed chills, temp of 101.2, felt awful, mild/moderate headache. took motrin alternated with Tylenol, called out of work for one day, now present s with no temp. States she feels completely exhausted.

Pt reports heart rate in 130s x 45 minutes-1 hour. She reported shortness of breath and O2 sat 95%,. Symptoms resolved simultaneously after 45 minutes- 1 hour. She also reports weakness and fatigues that lasted x 1 day.

Had headache fatigue and sinus pressure

Patient said she felt burning hot inside and her throat had a tickle. Shortly after that, she said she felt nauseous. She was taken to the emergency department for further evaluation.

swollen glands, headache, fever 99.4, slight cough

Ringing of both ears, dizziness, headaches, body aches, temp 99.1, injection site soreness, nausea , fatigue.

I premedicated prior to injection with benadryl 50mg po and otc pepcid. Approx 25 minutes post injection felt some very mild chest pressure that slowly developed to moderate pain scale 4 over a period of approx 2 hours then returned to a mild pressure once again, all left sided and no radiation of pain noted. At approx 430pm the pressure began to increase again and became painful at approx a 5 on the pain scale, it was then I developed diaphoresis,dizziness and severe nausea/vomitting., Bright green

bile appearing vomitus. Went to ED where I was given IV,Zofran 4mg x 2 doses,Reglan 10mg IV and contiued go vomit violently. Recd prescriptions for antiemetic and dc home to ride out the vomitting.

None stated.

Developed rash about 90 minutes after receiving vaccine

Within 10 minutes of receiving the vaccine in her Left deltoid, pt. c/o tingling of the tongue & in the back of her throat & being diaphoretic. She sat down for a bit and returned to working. The next day (Saturday) she c/o mild headache & diarrhea all day. Called out of work on Sunday with continued headache & diarrhea. Denied fever & no reaction at immunization site. Back to work on Monday.

Shot received at 7:15 am. That night at 2 am I awoke after developing rigors that lasted for 1 hour then resolved. I took 600mg Motrin at 2 am and 1g of Tylenol at 2:15 am. I was able to go back to sleep around 3 am. I woke up for work at 7am feeling sweaty but temperature was normal at 97.3. Overnight temperature at time of rigors was also normal. It is now 9:15 am and I feel better with mild residual symptoms.

None stated.

MILD RIGHT NIPPLE SWELLING AND SORENESS

Right sided facial swelling involving right cheek and lower jaw. No eye involvement. No breathing or swallowing difficulty. Symptoms were noted around 21 hours after the injection

36 hours following vaccine patient c/o injection site left deltoid, being reddened, tender & swollen approx. 2.5-3 inch circle around site. Encouraged to ice, take Benadryl &/or antihistamine.

Approximately one hour after injection I noticed a feeling of slight numbness on the left side of my neck extending up the left side of my face to the top of my ear. Feeling of numbness extends to middle of my cheek on left. No neurological deficit. Sensation to touch of area intact. Sensation continues through current time with no changes.

None stated.

"vaccine administered 0900 with report of ""warmness"" around and in mouth area 0904. 25mg Benadryl given PO."

red, hard lump in arm at injection site

On the next day after vaccine, I woke up with chills. I ached all over, I had a headache and fever later. Then nausea and dizziness along with weakness. On the next day it was the same, until about 12:30pm, the symptoms started lessening and was not as severe. Today, on 12/24/20, I still have nausea and I am really tired , and injection site is bright red and really sore (about the size of a dime). Feels like I have fever around it. Swelling on both hands.

Awoke at 5am with fever of 101.5; fatigue; tachycardia (HR103-105) at rest, tenderness at injection site. Took 2000mg acetaminophen to break fever, Fever broke on Saturday evening. Slept all day Saturday.

red, swollen, hard lump at injection site

Received vaccine on 12/21, c/o injection site being very painful 7/10 24 hours later, site appears slightly pink & very tender to touch. Instructed to ice & take Tylenol & or antihistamine.

Left arm leg and face numbness bilateral legweakness Vaccine given at 915 am Symptoms started at 11 am Called Pfizer to report at 1151 am Saw primary doctor at 2 pm Return to primary md again 12/22/20 Referral to neurosurgeon 11/22/20 Hospitalized 11/22/20 to 11/24/20 lepto Meningeal inflammation hospital

None stated.

Body aches, slight dizziness, fever with chills, lack of energy/fatigue

Dizziness, nausea after the dose. Vitals; BP 135/70, pulse 91, O2 100%. After 10 minutes, both symptoms subsided

Pt described mild numbness on and around her lips and face that started within 15 minutes of vaccination and lasted several minutes.

left under arm along side of breast pain and swelling. swollen lymph node on left side of neck.

None stated.

patient felt tremulous and lightheaded after receiving the vaccine. patient had worked the overnight shift immediately prior to receiving the vaccine.

She reported having PAC via her fitness watch. She said this was a new event for her last a few hours.

Chills, fever, body aches and head ache that lasted 24 hours. Small rash near injection site and a slight arm pit pain. Patients took Ibuprofen 200mg x 4 tablets

Tender, red raised wheal, 4 cm in diameter. Began next morning, and is beginning to resolve after 48 hours. No rash, fever, pruritis. Was 26 pregnant at time of injection. No known pregnancy complications.

Moderna COVID-19 Vaccine EUA. Fever, pain at the injection site, generalized malaise, headache

Began with facial pain in my cheeks where my cosmetic filler is. Then I woke up on 23rd of December with facial swelling and a nodules in cheeks. Talked with one of the providers in the office and they said it has been happening to some with fillers. It literally happened over night. Still ongoing only day two.

None stated.

Patient received the COVID-19 vaccine. Patient described feeling dizzy and light headed. Patient placed on floor. Syncopal event / vaso-vagal. No signs of anaphylaxis or allergy, but epipen 0.3mg was

administered. anticubital IV line placed for access if needed. Patient taken to ED for observation. Returned to duties within 1 hour of the event.

Slight numbness in L cheek and inner L lip, symptoms worsened on the way home, seen in the ED (6:23PM), MRI completed, diagnosed with Bell's Palsy, discharged home (10PM)

fever with tmax 105, chills, tachycardia to 150, moderate headache, cough, lightheaded, dizzy, somnolence

Severe fatigue lasting approx 12 hours. If I sat down I felt like falling asleep. I left work early and rested

Caller stated after vaccine about 45minutes she began having pain in the neck down into her right arm with hives. Next day she had fever, shortness of breathe and extreme pain in injection site. Caller is not getting second vaccine due to bad reaction. Vaers report was completed successfully online.

Lingering fatigue. Recovered the next day.

None stated.

I was very tired at 18:30 after receiving the vaccine at 14:29. I went to bed at 18:30 that night awoke at 3 am for work and was still very tired and body aches. I was driving to work and notice that I was having a delayed reaction to such things as I was looking at Christmas lights and had to remind myself I was driving. The drive to work otherwise I do not remember. I felt as if I was just not processing things around me correctly. At work the symptoms were intermittent. The thought process or lack of continued. I began to have stomach pain felt like diarrhea coming on however I never had it. Then nauseated and thought I was going to throw up and felt like I was going to pass out. The passing out feeling continued until I had my coworker call a rapid because I knew my blood pressure was dropping and my hear rate became slow and I was passing out. I was then taken to the emergency room to where I continued to experience orthostatic blood pressure changes and bradycardia and hypotension. I was given fluids and potassium IV and was feeling slightly better. I went home and slept for the next 18 hours. When I did briefly awaken through the evening I had an elevated temperature 102, chills and an extreme headache and body aches. Today I awoke at 6 am and still sluggish with a slight headache and absolutely no appetite.

Approximately 1.5 hours after injection the patient reported right sided facial tingling, mostly around her lip.

dizziness, nausea, heart racing

Swelling, soreness, and redness at injection site on left arm. My shot was given pretty far back in my arm, and not in the deltoid muscle.

Systemic: facial and tongue swelling and tingling-Medium

After vaccine, 1 day later, I had body ache and fever, then the next day I had joint pain in elbows. On the 21st, of December, I started feeling very tired and fatigue. On the 22nd, Tuesday, I had the stuffy nose,

congestion and sore throat. Today is day three of me being sick. I was told to go get tested for the virus and report. Yesterday my husband woke up with a fever of 101 as well.

None stated.

Fever, Chills, swollen upper lip and eyes, rash on upper lip, tongue prickly and taste is some what lost

Left Jaw pain at temporomandibular joint, (Trigeminal neuralgia?). No numbness or paralysis. Jaw aches. Best description is after the anesthetic from dental work wears off and jaw aches from injections and dental procedure. Injection given at 1pm left arm. Painless injection. Injection site pain increased to moderate throughout day. Jaw pain began at 10:45pm. Next morning jaw pain still present. Took two naproxen 200mg tablets at 05:30 am.

1. Tingling and numbness to the teeth ? immediately after the vaccine (the feeling went away) 2. Tingling and numbness to the teeth, tongue, and lower jaw about 30 minutes after the vaccine (lasted for about 1 hour) 3. Experiencing residual (very mild) numbness to the lower jaw/teeth 17 hours after the vaccine

Felt fine when sitting (in monitoring room) but felt dizzy when she got up and started walking

Received vaccine Tuesday at 10:30. Woke up at midnight that evening (Wednesday morning) with fever of 101.5, heart rate in the 140s, body aches, injection site pain,and nausea. Still experiencing these symptoms today, Thursday, at 10 am.

"After employee took a hot shower 5 hours after receiving the vaccine, she experienced sensation of lump in throat and facial flushing. She also felt her tongue ""had a heartbeat"" but not swollen. She drove herself to our ED. Also after arrival to ED felt nauseous, but no vomiting."

None stated.

Received vaccine around 0700 this morning. Started itching around 1300, rash appeared on both hands around 1500. Arms also itch but no current sign of rash. Has taken benadryl. Talked to employee health and was directed to go to ED if rash spreads.

Within about 20 minutes of receiving the vaccine my lips began to tingle, throat became scratchy, and began to feel light headed. At that time, I returned the the vaccination room and took two - 25mg Benadryl capsules and just asked to have an eye kept on me incase it continued to progress. Denied epipen at that time because did not have shortness of breath and throat did not seem to be closing. Symptoms were mostly relieved within 30 minutes. Continued to have a metallic taste and itchy tongue throughout the day. Following day, no symptoms. Given underlying anxiety disorder, panic attack is not out of the realm of possibility though those have been well controlled for years.

Patient indicated feeling of nausea, arm became numb, head felt tight and a dull headache

Headache and nausea

Received the Pfizer COVID-19 vaccine on Wednesday 12/16/2020 at approx. 1700 and developed a mildly itchy, maculopapular rash under my jawline on bilateral sides of my neck, not extending onto my face or chest by Friday 12/18/20. The vaccine site is clean and without skin changes, and I have no respiratory symptoms or compromise related to the rash or otherwise. I have no changes in detergent, lotions, clothing etc to blame at this time that aware of. By Wednesday 12/23/2020 the rash has lessened and appears to be improving and has not spread.

None stated.

None stated.

None stated.

None stated.

None stated.

None stated.

None stated.

None stated.

None stated.

None stated.

12/19 - onset of abdominal pain which is like her usual chronic necrotizing pancreatitis which she has had off and on for 10 years. This was accompanied by nausea. The pain & nausea last for about 3 hours. 12/20 - nausea and diarrhea. Today 12/21 she reports that she has recurrence of the abdominal pain, nausea, and feels hot. She is at work today. Advised to contact her physician for assessment and treatment as needed. Will follow-up with her

Lymphadenopathy left axilla

None

Red blotchy skin reaction at injection site and up arm

Jaw tightness, itchy lips, throat tightness

Jaw tightness, itchy lips, throat tightness

Fatigue and tachycardia (heart rate ranging from 70-140) within 2 hours after receiving vaccine. Cardiac workup done 12/21/2020- No treatment at this time, observation of symptoms.

Woke up with lump at injection site. Very painful, red, and hot to the touch.

Chills, headache, body ache, tiredness

Visual aura, predominately in right eye, 1.5 hours after receiving vaccine. Resolved in 10 minutes, with no lasting effects. I did have a headache for 2 hours prior to receiving vaccine, but never in my life experienced an aura.

Patient tested + for COVID back in April 2020, recovered. Developed localized erythema and a circular swelling and induration that is 2-3 cm in diameter, with some pruritus at the center. Denies fever, chills, headaches, or myalgias. Advised that localized reactions to COVID vaccine are not uncommon, and to seek additional if she developed systemic symptoms, worsening pain or redness, blistering or suppuration of the localized skin rash.

Unknown / Lost due to computer system

Chills, shivers, fever (t-max 103.4), body aches, neck pain, headache, injection site soreness

2225 lower lip numbness, spread to top left. aching pain left cheek, then left sided head pain. Pressure in head especially forehead, tingling in feet. 2228 trouble swallowing. taken to ED: 2256 prednisone 20 mg x 1 Pepcid 20 mg iv x 1 Benadryl 25 mg x 1, NS 1000 ml bolus. 0123 felt like new woman, took nap feels better.

headache, tiredness, joint pain all over, muscle pain nausea, not feeling well at all

Body aches and headache

Chills and sweats, hydrated and rest. Symptoms subsided around 1530 12-21-20.

chill. nausia, headaches body aches pain in left arm

10 minutes after injection, patient began to have redness/flushing of her face/neck. Symptoms partially resolved. She flushed approximately 3 times. Reported tingling in fingers bilaterally. Kept rubbing her fingers together and shaking hands. Pulse 107, BP 154/101. Patient states normal BP for her is 120/60. Hives and itching also reported. Patient states often flushes/gets hives when stressed/upset. No issues prior to injection. Patient take to hospital ED for observation. Symptoms had resolved when she spoke to the ED doc but are lingering today 12/24 as of 1030 am.

Extreme arm soreness and stiffness starting evening of vaccination and continuing. No treatment at this time

"Patient experienced ""pounding headache"" during the 15 minute post-injection observation period. Patient was taken to the Emergency Room, treated, and released. She complained of continued symptoms the following day, noting improvement in severity."

Lightheadedness, dizziness, nausea starting 30 minutes after vaccination, bradycardia.

Sore muscle at injection site for 2 days.

Patient developed severe headache about 10 minutes post vaccination. Patient took Ibuprofen 800mg. Headache resolved approximately 1 hour later

Felt weak and congested. Called PCP, he ordered a COVID test. I tested positive 12/22. Husband tested positive for COVID 12/19. I don't think this is an adverse event, just a coincidence.

Felt weak and congested. Called PCP, he ordered a COVID test. I tested positive 12/22. Husband tested positive for COVID 12/19. I don't think this is an adverse event, just a coincidence.

Injection site soreness.

Itchy inner ears and throat 20 mins after injection

with severe muscle ache , low grade fever, eyes lids and eyes were heavy

Patient started with watery red eyes and face was flushed. initial vital signs after notice of reaction was Bp 120/88 then noticed mild hives on neck and behind ears. Decided to give patient Benedryl 50 mg IM in Right Deltoid at 1:12pm and retook vitals at 1:20 Bp 118/74 pulse 86 and SAO2 99% on room air. Vitals at 1:36 pm were BP 116/84 pulse 90 and SAO2 97% on room air. Redness and eye watering and itching improved. Spoke with patient again today she says she still has a slight itchiness between fingers and will consult physician prior to second dose.

Headache for 7 days intermittent requiring tylenol, ibuprofen 4 out of 7 days Dizziness transient on day 5 corrected with oral hydration Dizziness, presyncopal event, Sinus tachycardia, chills, nausea, headache at 930 AM on 12-22-2020. Sinus tachycardia lasted 12 hours and now improved. EKG twice, Holter and echocardiogram confirmed sinus tachycardia. Thyroid profile normal Normal comprehensive metabolic panel, CRP, ProBNP, ferritin levels are normal.

About 30 minutes after vaccine I felt heart palpitations. 1 and 1/2 hours later I felt slight chest pressure, throat swelling (still able to breath), and an adrenaline type rush causing anxiety, shakiness, and energy burst. I did not seek medical attention. Instead I managed it at home with 50mg Benadryl. I slept through the night without any distress. When I woke up my throat still had mild swelling (felt like when you have a sore throat and a lump in your throat). This continued the whole next day along with intermittent chills, mild body aches, slight shortness of breath on exertion. No fever. I did not take any medicine on this day. The next day, day 3 my throat swelling was gone. I did not seek medical attention during these symptoms because the were tolerable and able to be managed at home.

Hypersensitivity reaction. Redness, flushing, runny nose, watery eyes. Gave Diphenhydramine 25mg PO. Symptoms subsided after about 20 minutes. Patient stayed in the clinic for observation for approximately 1 hour. Advised to call 911 and seek emergency medical care if any symptoms started again after leaving the clinic. Patient expressed understanding.

"Sensation of lump in the throat and metallic taste in mouth approx. 10 minutes post vaccination while still in Vaccine Observation area. VS normal and stable. O2Sat 100%. Evaluated by on site physician. Received diphenhydramine 25mg PO at clinic. Remained stable and D/C'd home. F/U telephone call

12/24/2020. States additional 25mg diphenhydramine at home in ""evening"" for ""Scratchy"" throat. No problems overnight and all sxs resolved in AM of 12/24 2020."

Fever 101.2, chills, body aches

About 30 minutes after receiving vaccination, patient started to have tingling and mild swelling in her lips as well as tachycardia. Vital signs taken. Heart rate was 102 bpm, respiratory rate 18, blood pressure 144/80, O2 Sat 98%. Received cetirizine 10 mg PO. Symptoms resolved within one hour of receiving cetirizine.

102 fever, vomitting, headache, body ache, fatigue

Headache after 30 minutes Joint pain after 5 minutes Nausea after 30 minutes Hand/arm numbness after 3 hours Chills after 4 hours Injection site pain after a day

bp spike since Saturday, no fever head ache and nausea , Shortness of breath and big discomfort in the chest and last 2 days whole hands swelled up during night and goes during the day time

received vaccine at 1500 on 12/22. woke up at 0200 with mild headache and moderate vertigo. went back to sleep. woke up at 0730 with ongoing vertigo. vertigo resolved after 2 hours without any intervention

scratchy throat, hoarse voice, itchy ears inside. 1 1/2 hrs after vaccine. 12/23/20

12 hrs post vaccine- runny nose, severe headache, arm tenderness, and generalized body aches 24 hrs post vaccine- sluggish and achy; headache has lessened, but still there; dizziness < 1min, 1 time; Tylenol Extra strength taken 12/23 830pm, 12/24 230am, and 12/24 8am

Caller stated that he experience left side tingling and numbness that was continuous. Caller went to employee health under went neurology test. Positive for numbness on the left side of his face. Caller will be getting second vaccine 1/8/21. Vaers report was completed successfully online.

"6 hours after vaccination, chills and chest ""tightness"". Felt like reactive airways. Tight x 3 days with slow development of cough, continues to progress, feels like pneumonia. Unrelenting cough, frequent use of rescue inhaler. On day 6 full exam in ER. Chest x ray clear, covid negative, ekg normal. Day 9 back in ER. Unable to sleep. Constant cough so violent I am wrenching."

Patient was driving back to work. Became tachycardic during the drive and pulled over to a local pharmacy. She self administered 50mg of diphenhydramine and took her blood pressure at the pharmacy. The BP was found to be elevated. EMS picked the patient up and transported her to ED.

Fatigue and achiness about 6 hours after receiving injection. Developed chills, muscle aches and fever, 99.3-100.4, 8-9 hours after injection. Fever was gone by 7:30AM the next morning (11 hours after injection), however continued to have muscle soreness and increased fatigue for the remainder of the day

Pfizer-Biotech Covid-19 Vaccine. Adverse Effects: Fever (101.1¦F), Chills, Body Aches lasting 24 hours

Headache, arm pain, sleepy and very tired also I had a really bad sore throat very read and painful.

As employee entered observation area noted slight headache then complained of SOB VS BP 150/90 states took medication in am O2 Sat 99-100% HR-74 RR-24 lung sounds clear reported lightheadedness, confusion sent to ED via wheelchair

Employee received vaccine on 12/17/20 on 12/18/20 employee noted red rash to abdominal area. Raised no drainage

received vaccine at 9:30 am noted frontal headache @ 9:40am VS 124/76 HR 75 O2 Sat 95% Denied SOB, difficulty swallowing, numbness tingling given acetaminophen 650 mg 9:50 am given ibuprofen 600mg @ 10:22am VS BP 137/90 HR 71, O2 Sat 97%, feeling dizziness nausea, transported to ED

received vaccine @ 4:25pm within few mins noted red flush across face, neck extending to collar bones. No SOB, difficulty swallowing, hives, rash nausea BP 142/80 HR 64 O2 Sat 97% 15mg of liquid Benadryl @ 4:35pm resolved in 1 hr

None stated.

None stated.

15 minutes after vaccines became dizzy when she stood up. B/P elevated 158/85. Was extremely fatigued and localized site redness, swelling and pain.

Muscle aches, headache and congestion

Nausea/Headache

Rash from neck to pubic bone started 12/23 at 5am. Called and spoke with patient this am, 12/24 at 11am. rash is subsiding and she feels fine.

itchy nose and chin. Lasted about 5 minutes

At 1800 developed headache, 2000 developed chills, temperature of 99.6 (normal daily T on this thermometer 96.8-97.5), slight nausea, dizziness with standing. Excederin at 0000, sweating at 0100, T 98.2 at 0400.

"""Scratchy"" throat, dizzy, shortness of breath, and flushed approx. 10 minutes post vaccination. Evaluated onsite at vaccine clinic by physician. Received diphenhydramine 25MG PO. VS normal and stable. O2 Sat at 100%. Monitored and observed for 60 minutes and D/C'd in stable condition. Contacted by phone in AM of 12/24/2020 and states all sxs resolved yesterday evening. Will receive 2nd dose of vaccine in hospital Allergy Clinic."

At around 3 am. I woke due to excessive sweating and coughing. I also experienced a stuffy nose as well as feeling as though my saliva was thick. I drank water in an attempt to aid the coughing and the water also seemed 'thick'. I sweat throughout the remainder of the night; in addition to severe left arm pain.

The COVID vaccine was given at 2046. At approx. 2050 patient complained of tingling to her left leg and a headache. Her vitals were obtained at 2050. They are as follows; B/P 146/86, HR 111, Spo2 98 on RA. She denied any SOB, chest pain or discomfort, no difficulty swallowing. She was able to ambulate to the wheelchair without any issues. I called house supervisor at 2049. He came up to asses her and she was transported to the ED by 2 MA's and a nurse. She was transported via wheelchair on the monitor. She did not require supplemental O2

Had a low fever (99.5) last night. Minor aches. This morning I woke up and the lymph nodes under my left arm are swollen

12-18 0730- received vaccine at work. I am a registered nurse. 12-19 11am feeling extremely fatigued, chills, mild aches, and temp 100.1 12-19 2pm temp 101.8 and more severe arthalgia, myalgia, and shivering.... cant get warm 12-19 6pm temp 102.1 and rigors.... shaking head to toe and severe aches/ pains 12-19 11pm temp 104.1 12-20 temp 102.5 12-21 SOB, bradycardia to 41, dizziness, temp 100.5 12-22 SOB, vomiting, cough, temp 99.6 12-23 SOB, cough, diagnosed with Covid pneumonia

started to experience scratchy throat, lasted about 30 minutes and resolved on its own.

Developed severe epigastric pain and had a syncopal episode while at lunch. Individual lost consciousness for a few seconds and returned to baseline with in a minute. No further care was needed or given.

Headache beginning from time of wake-up about 0730. Pain slightly diminished but not relieved with migraine medication 4 hours later.

diarrhea, shortness of breath, chest pain, headache

blotchy rash flanks, not itchy. 'Flushed' head to toe. Dry Mouth

Fever starting at 5am on day after vaccination. Highest measured temperature was 102F. Also had associated fatigue and headache. Headache was helped by acetaminophen and ibuprofen. Fever was intermittent and lasted until about 6pm of the same day. Fatigue and headache also lasted until about 6pm on day after vaccine.

Headache: 2/10, global/ diffuse, responds to excedrin & getting, worse in the morning. +R Foot went numb and the resolved. No tingling, weakness, or numbness, dysphagia, slurred speech, seizures, blurry vision. Thirst: Very thirsty. ALtered Mentation: Slower in responding, Having to really think before she speaks Muscle Spasms +hot flashes no fever, chills, chest pain, or sob. hyper-emotional (Sponteneous crying).

Started 12/23/2020: Body Aches, Sore Arm, Fatigue, Cold Chills, Elevated Temp from normal.

Tasted the medication, felt flushed, heart racing, BP 166/118 P 125 PO2 100% Repeat BP 150/106 P90's Rapid response RN here BP 159/89 P 89

Received the COVID vaccine on 12/22/2020 - approximately 4 hours later started with body aches, took NSAID and went to bed, woke up with loss of taste and smell and other COVID symptoms

Achiness in neck

Patient was in the 15 minute post-observation window and was scheduling his appt for second dose. Patient noted that he has a fear of needles and mentioned that he was feeling light-headed and experiencing tunnel vision.. He subsequently became diaphoretic and syncopal. He spontaneously recovered and was helped back into the chair. Did not fall to ground or hit his head. A SWAT was called. During SWAT evaluation, patient was given cool compress for neck and mentioned that this has happened before with injections. Subsequently had another syncopal episode and witnessed clonic seizure of roughly 25 seconds in duration. Patient again spontaneously recovered and was brought to the ED. the patient was unable to recall the events and has no history of seizure activity. Patient was given crackers and juice in ED and monitored for approximately 3 hours. Patient was discharged to home.

My arm from 7pm-7am exp pain, tingling and purple in color. On 12/21 went to employee health nurse told to take Ibuprofen went home. As of today still purple and yellow in 3 to 4 inches in bruise. I dint miss any days of work.

I WOKE UP IN THE MIDDLE OF THE NIGHT WITH PAIN, SWELLING, HARDNESS AND REDNESS ON THE INJECTION SITE OF UPPER LEFT ARM.

Dizzy

sore in arm

Woke up in the night with c/o headache, malaise and soreness in the arm COVID vaccine administered.

I had a headache about an hour after the vaccine. Started feeling extremely tired around 8pm. Around bedtime I was really cold, my hands were like ice and I just kept trying to get warm. I woke up feeling fine this morning. The only pain I feel is that my left arm feels sore and aches when I move the muscle around.

12/22/2020 at 3:00pm Moderna Vaccine administered. 12/23/2020 at 2:00pm Strong shaking chills. Temperature started at 99.8. 12/23/2020 at 4pm Chills continue. Temp 101.4 Body aches. 12/23/2020 4:30pm Advil 3 tabs taken. 12/23/2020 6pm Temp 102 chills body aches. 12/24/2020 8am Temp 100.4 12/24/20 11:30 am Temp 99.5improving, body aches but no chills.

The day after receiving the vaccine, I developed rhinorrhea, ST, and dry cough. It worsened the next day, so I got a rapid COVID test that was positive. (This was confirmed with a positive PCR 2 days later). Two days after the vaccine (the day of the positive test), I developed fever to 103, chills, body aches, fatigue,

headache and worsening cough/congestion. Fever and chills resolved after 24 hrs, but mild congestion and cough has persisted until today.

within minutes after receiving vaccination employee felt lightheadedness,, clammy, nauseated and vomited x 1. slowly resolved, went back to work and totally did not resolve so sent employee to ED to be evaluated.

Immediately after I received the injection, my upper lip started tingly. My lip started getting bigger, I took Valtrex as a blister came upon my lip. About 6pm , I started getting a mild headache. I woke up this morning and my headache is getting worse, I have body aches, and fatigue. My arm is sore as well.

No adverse event reported. Found in paperwork that this person was only 16 years of age and should not have received Moderna Vaccine.

Pt received vaccination and immediately afterwards syncoped. Pt recalls receiving the inoculation and becoming acutely lightheaded before losing consciousness. No preceding SOB or palpitations noted.

Progress Notes PA-C (Physician Assistant) ? ? Orthopedics Cosigned by: MD at 12/22/2020 á9:46 AM Expand All Collapse All á 12/21/2020 á Patient: Date: 12/21/2020 á Subjective Patient is a 58 y.o. female who was seen at COVID Vaccine Clinic today for her first dose of the COVID 19 vaccination. á She denied any history of previous adverse reactions to vaccines. á She was given the Pfizer vaccination in the left deltoid muscle. á During her 15 minute waiting period after the injection, the patient began to experience dizziness/shakiness. This provider was notified of patient reaction and she was then transferred to the emergency bay via wheelchair where she was assessed. Monitored patient for severe reaction symptoms, including rapid progression of symptoms, respiratory distress with dyspnea, increased work of breathing, persistent cough and cyanosis, vomiting, hypotension, dysrhythmia, chest pain and collapse. á She denied difficulty breathing, throat tightness and tongue swelling, nausea. á She reports a history of atrial fibrillation and states that she had a procedure in the past and the anesthesia provider questioned her about this diagnosis. She reports taking metoprolol and methimazole on a daily basis. She took all of her am medications today, including an 81 mg aspirin. Reports history of watery eyes and blurred vision, takes Zyrtec daily. Denies any worsening of these symptoms outside of her baseline. Denies use of anticoagulant use or diabetes. Last ate and drank about 1130 or noon. á Review of Systems Constitutional: Negative for diaphoresis. HENT: Negative for congestion, drooling, facial swelling, rhinorrhea, sneezing and trouble swallowing. Eyes: Positive for discharge. Negative for redness. Respiratory: Negative for chest tightness and shortness of breath. Cardiovascular: Negative for chest pain and palpitations. Gastrointestinal: Negative for nausea and vomiting. Skin: Negative for color change, pallor and rash. Neurological: Positive for dizziness and headaches. Negative for syncope. Psychiatric/Behavioral: Negative for agitation and confusion. The patient is not nervous/anxious. á á á Objective Vitals There were no vitals filed for this visit. á á Physical Exam Constitutional: General: She is not in acute distress. Appearance: Normal appearance. She is obese. She is not toxic-appearing or diaphoretic. HENT: Head: Normocephalic and atraumatic. Nose: No rhinorrhea. Eyes: Comments: Watering of both eyes Cardiovascular: Rate and Rhythm: Normal rate and regular rhythm. Comments: At right radial pulse Pulmonary: Effort: Pulmonary effort is normal. No respiratory distress. Skin: General:

Skin is warm and dry. Coloration: Skin is not pale. Findings: No rash. Neurological: Mental Status: She is alert and oriented to person, place, and time. á á Assessment/Plan Stress reaction following vaccine administration. á Patient was transported to the emergency bay via wheelchair. á Treatment included no therapy, but did continue with vital checks at approximately 5 minute intervals. á 1603-blood pressure using the large adult cuff was 154/60 with large adult cuff, heart rate 69 with regular rate and rhythm at right radial pulse, 96% O2 sat on room air. Patient continues to feel slightly dizzy and shaky though denies any chest pain, shortness of breath, swelling of the lips or tongue. á 1611 vital signs reassessed with blood pressure of 150/63, heart rate 64, 97 percent on room air, continues to feel slightly dizzy/shaky, though, reports not nearly as bad. Patient continues to answer questions appropriately and is talking without any signs of further decompensation. á 1618-reports feeling better. Vital signs rechecked with BP of 121/55, 59 hearty rate and 96% RA. No new complaints. á 1624- patient reports a slight headache, but denies chest pain, shortness of breath, chest tightness, lip or tongue swelling. á Discharge vitals obtained at 1626-with blood pressure of 135/55, heart rate of 58, 95% on RA. No new complaints, except feeling a bit cold. Patient reports feeling better and feels that she can safely discharge. Discussed need for urgent evaluation at the emergency department or to call 911 if symptoms of chest pain, shortness of breath, angioedema present. Patient expresses understanding and all questions were answered to her satisfaction today. á Follow up response to treatment:excellent. á Patient discharge: Stable to go home and follow up with PCP. á Orders Placed This Encounter Procedures ? COVID-19 MRNA á á PA-C Electronically Signed 12/21/2020 4:05 PM á á

Appoximately 12:15pm patient Reporting itching all over her body, throat feeling scratchy, bumps forming on chest, ear itching. Vital signs taken Benedryl 12.5 mg given IM x2. pepcid given orally, continued to monitor x 60 min. Itching was Reduced over body, bumps on skin Resolved. Temperature Rose from 97.2F to 99.4F.

line of numbness from injection site down arm

Urticaria, allergic reaction to COVID-19 vaccine, treatment with famotidine and benadryl, along with prednisone for 5 days.

15 min post injection c/o heart racing, rate 160 on watch Skin flush Confirmed heart rate 160 RRT called , pt never LOC Pt stayed 1 hour for observation, heart rate 106.

Patient began experiencing hot flashes and chills a few hours after receiving the vaccine. The next day she experienced chills, fatigue, left arm pain (same arm as vaccine administration). Advised to obtain COVID19 testing, and seek immediate medical attention if symptoms worsen or severe symptoms appear.

"About 5 minutes after receiving the vaccine, the individual reported feeling light headed and stated that her ""vision wasn't matching up."" She was assisted to a laying position and symptoms did not resolve. She was given 50 mg of benadryl IM in her right arm. 15 minutes later, her symptoms resolved and she was able to go home."

flush on legs and arms, transient throat tingles that resolved. Arms heavy

A rash started under both armpits in the middle of the night. The armpits were swollen and welped . The rash continued to spread across my chest and back and down both arms . Went to doctor and got medrol dosepack and triamcinolone cream.

Fever, headache, chills, muscle pain all over, joint pain, general malaise

Feels like lump in back of throat, given Epi at clinic without resolution. No shortness of breath or pain

I THREW UP 4-5 TIMES AND HAD DIARRHEA AROUND 9PM, AND SLIGHT DIZZINESS PRIOR TO THAT

About 24 hours after the vaccine, arm became red and swollen at the injection site. Eyes became red and swollen. Experienced coughing if laying flat, had to sleep upright. Symptoms resolved around 12 hours later.

Progress Notes APRN (Nurse Practitioner) ? ? Nurse Practitioner Cosign Needed Expand All Collapse All COVID VACCINE CLINIC 12/22/2020 á Date: 12/22/2020 á Subjective Patient is a 34 y.o. female who was seen at COVID Vaccine Clinic today for her first dose of the COVID 19 vaccination. She denied any history of previous adverse reactions to vaccines. á She was given the Pfizer vaccination in the left deltoid muscle. á During her 15 minute waiting period after the injection, the patient began to experience lightheadedness and confussion. She denied rash, hives, welts, difficulty breathing, difficulty swallowing, wheezing, throat tightness, hoarseness, stridor, itching, facial swelling, lip swelling and tongue swelling. á This provider was notified of patient reaction and she was then assessed in the emergency bay area. á Monitored patient for severe reaction symptoms, including respiratory distress with stridor, wheezing, dyspnea, increased work of breathing, persistent cough and cyanosis. á Pt Presents with lightlessness and confusion. Blood sugar on presenting was 74. She has a history of fibromyalgia and Migraines. She had a gastric bypass in 2010. She was given a protein bar to eat. Fingerstick BS done 20 minutes later was 96. Pt was feeling better after eating. á Review of Systems Neurological: Positive for light-headedness. Psychiatric/Behavioral: Positive for confusion. All other systems reviewed and are negative. á á á Objective á Vitals Vitals: á 12/22/20 1612 12/22/20 1628 12/22/20 1639 BP: (!) 135/92 127/79 128/84 BP Location: Right arm Right arm á Patient Position: Sitting Sitting á Pulse: 98 74 88 SpO2: 98% 98% 98% á Physical Exam Vitals signs and nursing note reviewed. Constitutional: Appearance: Normal appearance. HENT: Head: Normocephalic. Right Ear: External ear normal. Left Ear: External ear normal. Nose: Nose normal. Mouth/Throat: Mouth: Mucous membranes are moist. Eyes: Pupils: Pupils are equal, round, and reactive to light. Neck: Musculoskeletal: Normal range of motion. Cardiovascular: Rate and Rhythm: Normal rate and regular rhythm. Pulses: Normal pulses. Heart sounds: Normal heart sounds. Pulmonary: Effort: Pulmonary effort is normal. Breath sounds: Normal breath sounds. Abdominal: General: Abdomen is flat. Musculoskeletal: Normal range of motion. Skin: General: Skin is warm and dry. Capillary Refill: Capillary refill takes less than 2 seconds. Neurological: Mental Status: She is alert. Psychiatric: Mood and Affect: Mood normal. Behavior: Behavior normal. Thought Content: Thought content normal. á á á Assessment/Plan Treatment included: no therapy. Follow up response to treatment: no side effects. Patient discharge: Stable to go home and follow up with PCP. á Pt was released at 4:39 with no symptoms at that time. á á á APRN Electronically Signed 12/22/2020 4:40 PM á á á Division of Health 3 of 3

Hives on arms face and chest

Pt. states an hour after, she started a 2-3/10 headache, after 2hrs, she had 7-8/10 headache. Tylenol 1000mg PO taken. After 5 hours, she was very fatigued, headache 5/10. Fell asleep. Fever started during the night, when she woke up today 12/23/20 @ 6AM, it was 101.3 - she had a cold shower and had a headache of 5/10. She took tylenol 1000mg PO at 6:30AM. at 8:30AM, temp. is 99 degrees and headache gone.

Fever, Chills, Muscle aches, joint pain, headache

Migraine at 0420 12/24/2020; Body Aches; Joint stiffness; Skin feels hypersensitive especially at injection site. Took Tylenol and symptoms are better.

Pt(I) report swelling, redness, and warmth at the injection site was first noticed in the morning at 6:30 am on 12/24/2020 currently 2.5 inches by 1 5/8 inches. Pt has history of hives. Hive type rash noted on inside of right arm. Hive do not itch.

feel flushed, warm all over, itchy, and an urticarial rash appeared on her upper chest and arms.. given diphenhydramine 50mg IM x1, methylprednisolone 125mg, famotidine 20mg. felt better and all symptoms improved except for pruritis by 1715 on 12/23. discharged home from emergency room

Eye dryness progressing to neuropathic type pain localized to the face (left upper face with clear demarcation, same side as injection). At the worst, felt neuropathic pain plus ear pain. Not improved with 1g tylenol and advil. 3 hours later with no improvement, took 10mg prednisone finally offering relief.

Patient states that she started experiencing mild arm soreness shortly after receiving the vaccine. Later that evening, she stated feeling slightly fatigued. Patient states that she was Covid positive in July. She has not been around anyone with Covid recently and she has no travel history.

Nausea Vomiting Shaking Chills Arm soreness

I received the injection at 08:15 arm after hung around upon me getting ready to go elevated heart rate and pulse started to race. Then I stayed there lips started to tingle after 10 mins heart rate came down. I went back to work 1 1/2 hrs tongue was till numb and tingling. I went back to facility where I first received my vaccine. I was told to go to the ED checked blood pressure and I was offered Benadryl I declined. I dint miss any days of work.

About 10 minutes after receiving vaccine, patient reported feeling hot and not well. Patient had not eatten breakfast prior to appointment. Patient's oxygen sat was 100% but heart rate initially 42 (normal range 55-65) and blood pressure 90/60 (normal for him). Patient was diaphoretic and was given crackers and juice. Patient's symptoms continue to progress with heart rate down as low as 34. Due to progression of symptoms, patient was taken to the ER.

"Returned to Vaccine Clinic approx. 60 minutes post vaccination with generalized itching, hive-like rash on chest, arms, and legs and ""mild"" lip swelling. VS normal and stable during clinic observation. O2 Sat at 100%. Evaluated by onsite physician. Received total of 5omg diphenhydramine during observation. D/C'd in 2 hrs with less itching and resolving rash. Accompanied and driven home by friend. Spoke with EH nurse on 12/24/2020 and stated additional 50 mg diphenhydramine at home 12/23/2020. Mild, fading rash today. PLAN: will be evaluated by Allergy Clinic and if cleared, will receive 2nd dose of vaccine in Allergy Clinic."

Had headache, Temperature of 100.3 degrees F took Tylenol 650mg Temp down to 99.7 degrees F. Also experienced Nausea, No vomiting. 12/19 in the evening Temperature was 99.6F. Called Primary MD and advised to rest.

- Swollen face - headache - area of injection raised and iches and sore Txt - steroid, antihistamine

Pt reports feeling dizzy and lightheaded & flush about 30-45 mins after vaccination. Pt reports that flush feeling resolved after 30 min however the dizziness & lightheadedness persisted. Pt ate lunch and did not feel any better and reported s/s to staff v/s were taken and were stable. Pt was given water and brought to lay down for continued observation

Pt was seated and suddenly became flushed and reported a strange taste in her mouth. Vitals taken. BP 116/65, pulse 87, O2 99%. Pt given water and continued to observe. Pt reported feeling better.

Within minutes I had lower chest pain and wired sensation in my lungs. My throat was swelling. I was very hot and red. I the gurney my right arm was tingling. Opposite arm from vaccine.

Achy, fatigue, headache, sniffles, nausea and diarrhea

Patient states she was receiving her COVID vaccination today, 12/23/20, in the left arm. About 5 minutes after the vaccine was administered, patient felt left arm pain that radiated into the left shoulder. About 10 minutes after the arm/shoulder pain began, she had left anterior chest tightness. She had her blood pressure taken, which was 109/104. She states the 104 diastolic is high for her.

Lightheadedness, dizziness, patient lowered to the floor and elevated feet. Moved to a gurney, symptoms improved with pursed lipi breathing

Chills, myalgia, fever, syncope and vomiting

severe arm pain

Severe asthma attack, duration a good 5 minutes. No history of asthma. Was given inhaler.

I had severe abdominal pain that changed at a day and a half to mild abdominal pain.

Pain and stiffness in neck and shoulders, some relief with Ibuprofen Pain in right thumb , new onset, worse pain in left thumb and wrist join

Body Aches - mainly on Left side - arm and leg - muscle and joint. Arm Sore at injection site. Took Tylenol, symptoms subsided

"Pt received vaccine at 1210. At 1220 said her throat was feeling a little scratchy. She stated that it just felt like she ""needed to clear her throat"". NP was called to assist, evaluated and epinephrine 0.3ml IM was given. Benadryl 50mg and Zantac 40 mg was also given po. Pt was monitored, 9-1-1 was called and arrived in 10 minutes. Pt was sitting up, stating that it just ""feels like my throat is thick"". After EMS arrived and assessed pt, she began to ease her anxiety and stated she was feeling less tightness and felt better. Pt was observed, VSS. She denied going to the hospital stating she was feeling better so called for a ride home. EMS left and within 10 minutes she began to feel a tightening sensation in her upper chest, not in her throat this time. She said she felt the tightness again and the back of her throat was scratchy. NP evaluated, Epi 0.3ml IM was given again and 9-1-1 was called again. Upon arrival her vitals were stable, although tachycardic running 100-120 after the epi, but her breathing was not labored or difficult. EMS loaded pt and took to hospital for evaluation where she was monitored, received IV steroids for edema in the back of throat and uvula."

Pfizer-BioNTech COVID-19 Vaccine EUA Increased site redness, swelling and pain, site is warm to the touch, also rapid heartbeat.

during our covid vaccine clinic, we ended up giving 62 doses out of 60 vials. this was not realized until the end of the day when we had 2 doses left after we filled the 60 patient slots. there is apparently a small amount of overfill in the vials where 2 extra dose were able to be retrieved out of the 6 vials used. the patients did not receive a 'short dose' they received the full 0.5ml. our state told us to report the overfill via VAERS. i will inform the nurses to only draw up 10 doses per vial at our next vaccine clinic.

Fever, chills, headache, myalgias, fatigue - 5 days

Pt felt tingling sensation throughout body and was feeling SOB. Patient given IM benadryl and symptoms subsided

Symptoms started with feeling slightly faint with legs feeling weak from knees down, followed by 3 minutes of tachycardia at 130-140 BPM. Resolved without intervention; At (12/23/2020 app 23:40PM) developed periods of hot and cold, muscle aches and restlessness

20 hours after receiving developed extreme fatigue and headache. 6 hours after that developed chills, bone pain all over and nausea. That lasted about 8 hours. When chills stopped temp was 100.2. Temp relieved by aleve.

Received 2 doses of vaccine one day apart; no adverse events

throat swelling, SVT

Patient became hot, nauseous, and blotchy five minutes after vaccine administered (09430). Clinic nurses and a physician in the clinic area responded immediately: history, comfort, pulse, BP, comfortable/safe position in chair. Approximately 8-9 minutes later (0938-9), patient asked that her

personally-owned Epinephrine Auto-Injector (EpiPen) be administered, as she was unable to do so. Her symptoms were worsening and she had developed a lump in her throat. At 0940 a clinic nurse (RN) administered the EpiPen in the patient's right anterolateral thigh. Symptoms improved. 911 was called. Paramedics arrived quickly, and transported patient to Hospital Emergency Department, less than one minute away.

Received 2 doses of the vaccine one day apart; no adverse events

vomiting, fever 101

dizziness and warm feeling in chest immediately upon receiving shot

"Intense headache started around 3 p.m (vaccinated close to 11:00 a.m.). Nausea followed. Took acetaminophen before bed because of the headache. Woke up in the middle of the night with shakes and chills. Headache worse. Was hot and sweaty. Took temp, was 99. Likely low due to high acetaminophen dose. Shakes lasted for about 2-3 hours. Slept until 12:00 p.m. today. Still having some ""hot flashes"" but feel much better."

Had a weried sensation in her head during the injection. 10 min after receiving the COVID vaccine she reported not feeling well ranf had a burning sensation throughour her body. Has burining sensation on face, rash on chest , face amd arms, started to sweat, hair and uniform became wet, she was them taken to the ED. B/p 166/100 became elevated, pule rate over 100. Was prescribed benadryl, epipen, prednisone. Next day felt better, had some itching rach under her breast and have light headaches. Taking prescribed medicine including Benadryl

Extreme body aches high fever chills nausea Extreme weakness. Felt like I was dying. Probably the sickest I've ever felt.

woke up with low grade fever 99.4, nausea, headache, injection site pain (continuously since injection), chills, tierdness

Experienced syncope after receiving vaccine injection. Clinical Assessment Team called but declined going to emergency department.

Approximately 5 minutes after vaccination, patient became diaphoretic and warm/flushed. Complained of nausea and had one episode of emesis. Patient given 50mg of diphenhydramine orally.

Fever and chills noted day after administration. Fever of 101.2 on 12/23 at 14:25 and returned to baseline at 12/23 19:03.

5:30 Chills, fever to 102, Tx with Tylenol. GI Upset, diarrhea. 11PM Difficulty sleeping; GI upset, LOC x2. Pallor. Transport to ER via ambulance. Treated with IVs, Zofran, toradol

Developed tremor, dizziness, and chills almost immediately after vaccine. She developed hives to her chest approximately 30 mins after the vaccine was given. She did get IM benadryl in the office which

resolved the hives. She was transported to the hospital via ambulance as the dizziness and tremor worsened over the time she was in the clinic. She was discharged from ER the same day.

My heart was racing, I was light headed and dizzy with 6 episodes for about an hour.

Employee received 1rt dose of COVID-19 vaccine on dec,16, 2020, two days later she developed rash at the chest, arms, swelling at Rt eye, and skin lessions on posterior aspect of thigh, legs.

Hives on wrists, under arms, groin and penis

Vomiting 5 minutes after inject.

Patient awoke at 2 am and felt like she could not breathe. felt hot, tight, and severely weak. Had chills and shaking. No fever. Patient was transported by ambulance, observed in the Emergency department until 5 am and discharged home. Patient received oral acetaminophen in the ED.

Unable to move left arm in any direction for 24 hours.

Mild itching began around injection site within 5 minutes of receiving vaccine then resolved. After another 20 minutes, mild itching noted on hand, forearms, stomach, leg (not all at the same time). Itching resolves after scratching then starts up in a new location minutes later. Itching still ongoing 24 hours after vaccination.

Developed redness, induration, warmth to touch at injection site

Fatigue, weakness in legs and arms, fever of 102.2 , tiredness, stuffy nose, headache, chills, and hot flashes with burning sensation of lips.

15-20 minutes after injection felt sore in neck and lower back; few hours later body aches, lightheaded and fatigue. Symptoms remain the same today 12/ 24/2020

INITIAL SITE PAIN FOLLOWED BY LOCALIZED ITCHING AND HIVES (30 MINUTES AFTER VACCINE). HIVES AND ITCHING SPREAD TO BILATERAL ARMS , TRUNK, NECK, AND FACE (60 MINUTES AFTER VACCINE) AND CONTINUED TO GET WORSE (90+ MINUTES AFTER VACCINE). ORAL LORATADINE TAKEN AT INITIAL ONSET OF SYMPTOMS. IV SOLUMEDEROL, BENADRYL, AND PEPCID GIVEN APROX 2 HOURS AFTER ONSET OF SYMPTOMS. SYMPTOMS HAD MOSTLY RESOLVED APROX 60 MINUTES AFTER IV MEDICATIONS. HIVES AND ITCHING RETURNED WITH FEVER/CHILLS APROX 0300, 50MG ORAL BENADRYL TAKEN AND RESOLVED SYMPTOMS.

Left-arm pain, axillary pain, and inflammation shooting down to left hand left side neck swelling, pain, shooting to the left side of the head.

Fever 100.2, taking Tylenol and GI upset post COVID vaccine 12/16/2020, resolution of symptoms in 3 days

First felt nauseous at 1103. Was moved to area where patient was able to lay down. At 1119 blood pressure was 139/78, pox 99 and HR 84. At 1124 sat up and was given diphenhydramine 25mg solution.

At 1144 was able to stand without any change in symptoms. Blood pressure, pulse ox and heart rate were monitored throughout and remained normal.

Patient had hives on right side of neck to the nape of neck, bilateral elbow creases, bottoms of bilateral feet. Redness and swelling of mouth. Patient was prescribed 80mg Depo-Medrol IM, 50 mg Benedryl IM, and sent out with 6 day Medrol Dose pack with OTC benedryl and pepcid.

Nausea, vomiting and light headed

Right after injection on 12/16, the employee developed rash, hot flush on the chest. Was sent to the ER for monitoring. Took Benadryl 50mg at home at 1500. Another rash appeared on her face at 2200, took another Benadryl 25mg. On 12/18 at 0430, she developed chills, fever of 101.7, and body aches. Took Motrin and Tylenol, continued to have low grade temperature on Saturday. No more symptoms on Sunday.

after receiving the covid vaccine 12/22/2020 in the observation area began to feel flushed in the face and head rushing, given PO Benadryl 25 mg by OBS nurse and monitored.

I received the vaccine at 11:15 am and felt fine all day, began coming down with chills, fever, body aches and headache and slightly stuffy nose about 9-10 pm that night. It is still lasting throughout today, the next day and I called off of work. Currently have a fever of 99.6, highest fever was 100.6. F.

Employee received vaccine at 1100. At 1400, rash developed on the chest and tongue and lips were swollen. Took Benadryl 25mg and symptoms resolved.

Pfizer-BioNTech COVID-19 Vaccine EUA initial IM caused intense pain at site, then through evening into night pain radiated to shoulder and neck, experienced sweats/chills during night, site swollen but not red, recovered next day but exhausted.

Day #1- Minimal Localized Right Deltoid Soreness Day #2 12-24 hours post-vaccination- Myalgias, Affected Arm Lymphalgia in axilla, Fatigue, Elevated Temperature to 100.1 despite Acetaminophen and Ibuprophen. Night sweats, worsening myalgia throughout night. Would not have been able to go to work and perform duties (fortunately did not have to work this day or the next) Day #3- Symptoms improving-still myalgias, fatigue, mild-moderate right axillary lymphalgia.

Vomiting X 3 12/24/2020

Headaches from 12/22/20-12/24/20 Nausea from 12/22/20- currently

45 mins post vaccination patient experienced severe dizziness, nausea, extreme vomiting, headache behind eyes, tachycardia (bpm 120), elevated BP (190/120), PVCs. Patient was an on-duty EMT and received Zofran and Benadryl in the ambulance. Patient presented to Emergency Room and received fluid bolus, acetaminophen, and metoclopramide. Symptoms resolved within an hour but some residual nausea existed 24 hours later.

Pfizer-BioNTech COVID-19 Vaccine Tingling from injection site to mid forearm

Tachycardia, muscle aches, fever.

"Pt states had some dizziness about 1/2 hr after Immunization Then started to have like a lump in throat- ""Frog in throat"" Provider ordered IV and NS with 25mg Benadryl PO Pt had no other complaints was transferred to ER per Emergency provider consult"

Arm started to be sore early afternoon after receiving the vaccine that morning. By that night, redness around the injection site started. This was about quarter size. The area was sore to touch., The next day I experienced generalized malaise and muscle aches. It is now 6 days post injection and I still have redness quarter size/half dollar size around injection site, but the redness has faded some.

c/o lip tingling, neck pain, & LLE heaviness x 30 mins

1915: associate had left facility, associate started feeling generalized itchiness. Associate took a dose of Zyrtec. Associate states she woke up feeling body aches that Saturday and Sunday. Itchiness had resolved. As of Monday morning, all symptoms had resolved.

Itchy arms, back, legs Noticed rash on bilateral arms, legs, and lower back

The employee received the vaccine on 12/17 at 0922. On 12/18 at 0200, he developed severe headache. At 0800, he started vomiting and had nausea until the evening. After the nausea/vomiting stopped, he took medications for headache. All symptoms were gone by 12/20 at 0200.

at 8:40 am patient felt dizzy and flushed, she asked for extra attention and indicated she felt embarrassed, but denied difficulty breathing, no trouble speaking in full sentences, no rash, no change of vision; BP was 158/108 with pulse of 95 and then patient was brought to a more quiet area and seated in a wheelchair. She was able to ambulate, a nd speak normally, but she said she felt very strange and shaky. she was visibly tremulous. She was seated, and vitals reassessed and her shakiness increased and she felt panicky. She was taken by stretcher to the Emergency room for further observation . in the emergency room, her symptoms gradually subsided. She was able to return to work after an hour of observation.

Palpitations with HR of 120 within 5 minutes after receiving the vaccine. Wheeled to the ER for further evaluation. Dizziness and high BP. Was given Benadryl, Pepcid and Solu-Medrol and a liter of NS. Discharged after 2 hours with Benadryl and Prednisone prescribed for home meds.

Moderna COVID-19 Vaccine Developed some blotchy bruising on the bottom half of both legs within 12 hours of receiving the vaccine

About 6 hours after injection, injection site pain worsened. This continued to worsen until about 48H post-injection. About 30 hours from injection, experienced aches and feverish feeling without elevated temperature. Aches primarily in joints of hands, feet, knees, back pain, neck stiffness.

Pfizer-BioNTech COVID-19 Vaccine Dizziness, headache, generalized tingling. No reactions to vaccines in the past. Rapid response called, BP 187/104, O2 sat 100% on Room Air. nauseous, vomited 2-3 times. admitted to ER, discharged 3 hrs later, BP normal 122/73

Started with sore arm and progressed to fever up to 103.0, chills, vomiting, body and joint aches.

Eyelids are itchy, neck itchy.

I had a fair amount of pain at the injection site, by night time I had crackling in my lungs and weezing and a low grade temparture.

Injection site sensitivity, unable to have anything on my arm without significant pain. Movement of any kind of my left arm, even wiggling a finger, cause significant pain radiating throughout my entire left arm

Received the vaccine on 12/18 and 1820. She developed lip swelling for 24 hours. Took Benadryl and the swelling resolved after 24 hours. No other side effects.

Pfizer-BioNTech COVID-19 Vaccine EUA metallic taste

- Received Vaccine 1045 AM 12/19 - Sore arm at injection site started later that day and persisted - On morning of 12/21 I had a mild headache, and by mid day had some muscle aches - Night of 12/21 could not get rid of fever, sweats, chills, muscle aches, headache - Symptoms persisted, and decided this may be something else as well - Tested positive for covid on 12/23 (got results today 12/24)

At 8:55am individual reported a tingling sensation down the right side of face radiating down to upper deltoid/arm area. Individual described the sensation as a feeling of pins & needles. At 9:10 individual reported the symptom was gone. At 9:12am Blood Pressure 120/76, Pulse 90 and Respirations 20. Blood Pressure and Pulse taken using an automatic machine using the left arm.

Pfizer-BioNTech COVID-19 EUA metallic taste in back of mouth

On 12/22:First noticed roof of mouth started to itch, back of throat itching, difficult to swallow, noticed hives on chest/torso, difficult breathing, wanted to vomit, close to fainting. Hives around injection site. Placed on gurney and sent to ER. In ER given epi-pen injection, benadryl injection, albuterol, pepcid, toradol, solu-medrol and observed for 4 to 5 hours. On 12/23: Hives still present, injection site has two large bruises on arm; arm in swollen down to elbow. Broke out in hives on chest and face. Re-evaluated in ER.

EE c/o pruritic rash on trunk and peeling of skin on hands

Patient developed face and periorbital swelling 3 days after receiving covid vaccine. Swelling continued next day, responding to antihistamine treatment

30 min after dose felt like my tongue was getting thicker, neck and throat felt tight, tingling around upper gum line near front teeth. Slight numbness in skin around upper mouth. Difficulty swallowing for

five hrs post dose and I took 50mg of Benadryl at 730pm when I got to my car. Swelling in throat and back of mouth remained same from 530-730, gradually noticed improvement at 1015 pm

Within an hour and half I started to experience Dry Mouth and Nausea, later that day my Lymph nodes in my neck/jaw were Swollen and I had a Runny nose and Cough. By the evening I was experiencing Body Aches, Chills, Headache, and Fatigue.

"REQUESTED BY THIS WRITER PRIOR TO INJECTION FOR HEALTH TO RECORD PROCEDURE ON PERSONAL CELLPHONE. INJECTION GIVEN TO RIGHT DELTOID. LESS THAN 1 HOUR APPROXIMATELY 3:50PM TINGLING, PINCHING FEELING TO RIGHT HAND BEGAN THEN NUMBNESS STARTED TO RIGHT ARM FOLLOWED BY SAME SENSATION ON RIGHT LOWER EXTREMITY. MEDICINE CUP STARTED TO FEEL HEAVY AND I WASNT ABLE TO WALK CORRECTLY (LIMPING). HEALTH VERBALIZED ""TO CONTINUE MONITORING YOURSELF WHILE WORKING"". APPROXIMATELY 4:35PM NUMBNESS IS FELT TO RIGHT SIDE OF FACE, FACIAL DROOPING VISUALLY SEEN ON RIGHT SIDE OF FACE. ADVISED HEALTH TO GO TO ER. HEALTH DROVE THIS WRITER TO THE ER"

Swelling and hard lump around injection site, I noticed it about 24 hours after the injection and it remains approx. 45 hours after the injection. The arm of the injection site has hurt since about an hour after the shot. I noticed some slight dizziness about 20 minutes after the shot but that was gone within about 10 minutes. I woke up with some congestion the morning after the shot.

Pain and swelling at injection site and radiating into shoulder, extreme fatigue and tiredness, headaches, dizziness and nausea. Overall feeling of maliase

Approximately 48 hours after receiving injection she began developing papular, erythematous rash to left arm spread throughout the day. Following day same rash description occurred to right arm. Papules clustered to left posterior leg, faint to anterior legs, anterior superior chest.

12/22 7 pm, severe leg cramps; 12/23 7 am: diarrhea, abdominal pain. noon: nausea requiring medication; 5 pm, shaking chills, normal temperature. 9 pm: bloody diarrhea, and what looked more like sloughing nonpigmented tissue rather than stool, continued abdominal pain. Woke with diarrhea and pain 1 am. This morning, frequent stool and moderate abdominal pain. No chills. Recovered from diverticulitis around 12/3, scheduled for colonoscopy 1/6/21 and probably colectomy 1/8/2021.

When I filled out visage I put the wrong brand of vaccine and need to change it.

Pain and slight swelling in left arm at injection site with pain upon movement and touching site, muscle aches all over body, severe pounding headache/migraine, fever up to 101¦ 12/24/2020 at 11:00 am, first fever at 100.3¦ at 3:14 am 12/24/2020, tachycardia at 164 bpm at 3:30 am 12/24/2020, tachycardia into high 120s with walking 12/24/2020 around 10 am 12/24/2020, chills, light sensitivity, weakness when fever spikes, and overall malaise.

Itchy rash on the torso

On 12/22/20 I began to feel fatigued and sore arm at 1900. By 2330 on 12/22/20 my left arm was hurting down to my fingertips and extremely painful. I took 2 325 mg Tylenol and went to sleep. I tried sleeping but felt like my heart was coming out of my chest. I checked my Heartrate and it was between 100-120. I could not sleep all night. My left arm was so painful that I could not sleep on it or lift it above the level of my heart. On 12/23/20 I was very fatigued. I went about my day but was not feeling well. By 1900 on 12/23/20 I was running a low grade fever 99.9 and felt terrible. I took 2 325mg Tylenol and 2 200mg ibuprofen to help with the pain. I went to sleep and woke feeling better.

Physician called to report an adverse reaction to the COVID-19 vaccine. Patient had a 6.5 cm x 6.5 cm reaction at her injection site. This included erythema, warmth, and swelling. The patient also reported chills. Patient's O2 saturation measured at 80% a few hours after the vaccination. Patient received a liter of oxygen on Saturday and Sunday. Patient was tested for COVID-19 and had a negative result. On Monday and Tuesday, patient was given 25mg of oral diphenhydramine as the injection site had not improved. Patient has a mild history of asthma, but is not currently taking any medications for that condition.

ARM EXTREMELY SWOLLEN; SHE SPIKED A HIGH FEVER OVERNIGHT; LOT OF REDNESS AT INJECTION SITE NO TREATMENT SOUGHT

I developed fever and chills and headach for 2 nights now my fever was a 102.3 lasted at least 6-8 hours had Pfizer-bioNTech COVID-19vaccine

Pfizer-BioNTech COVID-19 Vaccine EUA reported headache that she did not have prior to injection

Pfizer-BioNTech COVID-19 Vaccine reported headache that she did not have prior to injection

Severe total body muscle ache, fatigue,chills lasting about 40 hours after vaccine. Inabilty to lift left arm more than 45 degrees due to severity of arm pain. Improving

bumps on wrists with loss of hair, itchiness

Pfizer-BioNTech COVID-19 Vaccine EUA metallic taste, relieved after drinking water

Woke up with onset of left sided facial weakness, paralysis, and numbness around 0600. Was evaluated in the ER and diagnosed with Bell?s Palsy.

initial fatigue, chills. After 24 hours, extreme fatigue, lips tingled, went to bed. In am, about40 hours after vaccination developed swollen upper lip and swollen armpit on side where she was vaccinated.

None stated.

None stated.

None stated.

None stated.

None stated.

None stated.

None stated.

None stated.

None stated.

Treatment dugs:

Treatment dugs:

Treatment dugs:

Treatment dugs:

Treatment dugs:

None stated.

None stated.

None stated.

None stated.

None stated.

None stated.

None stated.

None stated.

None stated.

Resolved. Treatment dugs:

Phone call

phone call Treatment drugs:

Headache started AM of 12/23/20; Body aches started 1100 12/23/20; lymph node discomfort, same arm as vaccine, early AM 12/24/20; Alternating Tylenol, naproxyn and rest helps. Once meds wear off, symptoms return.

body aches, fever 100.5 oral, cough, upset stomach

Complaints of warm sensation on her throat @ 10:15 am. VS bp 165/77, Pulse 136, O2 sat 99%. 10:30 BP 133/96, Pulse 121 O2 sat 100% Had sips of water and tolerated well 10:40 complaining of warm sensation to the left side of body. Send to ED for further evaluation accompanied by an RN

Fever malaise headache tired slightly dizzy

None stated.

3-5 minutes following administration of vaccine patient experienced itching and swelling of upper lip, swelling of mouth, rash bilateral arms. Benadryl 50mg intramuscular was administered and additional 30 minutes of observation conducted. ER referral was offered to the patient, she declined. B/P 135/82 and HR 85 at time of check out.

nose bleed after injection

Headache,muscle ache,injection site pain, tiredness, chills,joint pain, feeling unwell.

I start to have allergic rashes on random places on my body. I need to take benedryl to stop the itchiness for the past 2 days and ongoing. It appears off and on.

Patient reported a headache and some itching.

Lightheadedness and palpitation

Swollen lymph node

Once I received the vaccine 2 secs immediately started feeling flushed , blood rush going up to face, heart beat more rapid, and exp difficulty breathing. I spoke with staff was taken for a observation area and had a EKG. While being observed after 5 mins felt as if I couldn't breathe. Around the 5 of 10 mins mark started feeling better and at 10 mins felt totally fine.

Headache Fatigue

I?m having sore muscles, joints pain, headache, reduced tasting, fatigue, nose congestion, sore throat, heavy chest, and facial swelling. It?s been like this since I got my shot.

"Pfizer-BioNTech Covid 19 Vaccine: Patient reports ""indescribable"" muscle pain beginning almost exactly 4 hours after vaccination which has persisted until time of this report (day 7). She notes minimal pain at injection site. Has had no fever, no nausea/vomiting/diarrhea. She states that her entire body hurts, including hair, teeth, toenails, and fingernails - she describes as throbbing pain. She also reports pain in back and thoracic muscles to the extent that she cannot bend down to put on shoes. She notes that the back pain was not initially present but started around day 5 (12/22/20). She describes this as muscle pain and does not have visceral pain. She reports some relief with acetaminophen and ibuprofen. She also describes alternating episodes of feeling ""freezing cold"" with shaking chills followed by profuse diaphoresis (describes sweat as pooling and dripping). Acetaminophen and ibuprofen have not relieved or lessened the episodes of chills and sweats."

Pt felt rush of warmth throughout body immediately after vaccine administered. About 30 minutes later, he felt itchiness at the back of his throat. Pt was accompanied to ER , where he received solumederol 125 mg, pepcid 20 mg and benadryl 50 mg IV. Pt symptoms resolved post medication.

Very mild, but unexpected nose bloody nose from left nostril. Only noted when blowing nose. With 1 clot.

Had sore throat, itchy throat, cough, running nose and shortness of breath started yesterday. But shortness of breath has gone away this morning. Anything she need to do?

Headache, Body aches, nausea

Pfizer-BioNTech COVID-19 Vaccine EUA ~30 minutes post injection developed bilateral visual disturbance best described as an aura (shiny waves) in my inferior visual fields. No associated migraine/HA, photophobia, N/V, etc. This lasted for ~ 2 hours, did NOT hinder my day-to-day activities that day.

Pfizer-BioNTech COVID-19 Vaccine 4 minutes after the injection, my heart felt like it skipped a beat and my heart rate raised to 110. I thought this was related to anxiety of getting the vaccine. My heart rate went back down to 84 within a minute. Then I felt fine, just tired so I did not report this feeling to anyone at the time. 25 minutes after receiving the vaccine, my Heart rate raised to 139-145, felt dizzy, numbness of nose and upper lip. Was in transit when this occurred. Pulled into a parking lot and rested. Heart rate decreased to 96. I called family to come pick me up. On the way hame I continued to feel tired and dizzy but my heart rate decreased to 96. By 11:45, I felt better just continued to be tired. Been working overtime so I was already feeling tired before receiving the vaccine.

patient was vaccinated at approximately 12:40 and began having an itchy face and itch throat at 1:30. Patient is breastfeeding and decided she was going to pump and toss her milk due to getting vaccine. When pumping she noticed that her milk was blue in color. Today patient is feeling achy, joint and legs week. States she feels like when she had COVID in July.

Nausea and tingling sensation in both legs

About 6am morning of 12/24 Dizziness , vertigo, extreme fatigue, nausea and vomiting (3 times) injection site pain May go to ER if condition gets worst or unable to keep anything down. Took zofran twice but has since thrown it up

Developed chills, fever 100.6, achy, nausea, hurt to move several days, sleepiness, fatigue, achy joints. Fever broke 12/19/20. 1/20/20 fever 99.3. 12/24/20 Working but still fatigued.

day after the vaccine, her arm started to hurt, the pain is radiating to the back. Fatigue Headache congestion cough weakness

Left sided facial numbness (ear, oracle, earlobe, cheek, jaw).Timeframe going on 25 hours and not yet resolved.

On administering Pfizer-BioNTech COVID-19 Vaccine 12/15/20 at 9:15 PM to recipient staff member, vaccinator did not dilute vial and administered undiluted vaccine, resulting in an estimated 5 -fold increase over the intended dose and at an increased concentration. The error was nearly immediately recognized and disclosed to the recipient staff member. They were observed for adverse reactions and before leaving the clinic they were counseled to immediately report and seek medical attention for any serious signs or symptoms. A follow up phone call was made the following morning 12/16/20 with soreness at the injection site being the only reported reaction. They returned to work on 12/17/20 with no additional reported signs or symptoms.

Rash, hives and redness, and swelling of the arms that soon improved with benadryl

Dizziness, light headedness, feeling faint. Lasted 1 day. Better with food and water, Tylenol and Ibuprofen alternating every 4 hours, rest.

The morning after the vaccine I had a sore arm, severe headache, 120 HR and felt achy all over. I took tylenol and felt a little better. Sunday my eye irritation began in the right eye. The right eye was hurting, had a little drainage and was severely swollen. Conjuctivitis set up in the right eye and the right side of my head hurted really bad with the right eye area throbbing. Contacted my PCP who prescribed eye drops for me. My eye is still a little swollen and my head still feels really strange and still hurts a little on the right side. I have consulted with the NP and the PCP who is currently monitoring the situation

90 minutes post injection experienced numbness and tingling in all extremities lasting 1 hour. Resolved in all extremities except left arm. Left arm pain radiating from shoulder to forearm became severe. She sought treatment 12/23/2020 PM at a hospital emergency room where she received IV fluids and IV Toradol. On 12/24/2020 the pain persists but has improved with continued Ibuprofen 600mg every 6 hours and a sling for support.

It started with itching hands and feet and then spread over my whole body. It all turned red. I had shaking.

Patient had an elevated temperature.

Soreness in injection site, headache, and tiredness.

1300: Pain to L upper arm 1400: increasing pain to L upper arm 1600: increasing pain from shoulder to elbow 1630: face feels hot, mild sweating, temp of 100.3 1700: fatigue, exhaustion; pain in L arm extends to forearm, pain with lifting L arm 2000: rotating between episodes of chills and sweating 0700 on 12/24/20: continued fatigue; no longer have chills/sweating/fever; significant decrease to L arm pain

12/18/2020: COVID19 vaccine received. 12/19/2020: Patient noticed petechiae/bruising on arms, legs and face. Worsened over next 48 hours. 12/21/2020: Patient had blood drawn (CMP, PT/INR, CBC) at lab. 12/22/2020: Labs resulted; CMP and PT/INR WNL (exceptions: SCr 1.24, TBil 1.7); CBC with platelet count of 1,000 resulting in patient admission to Hospital. At admission he received 80 mg of prednisone, 40 g of IV Ig and a unit of platelets. 12/23/2020: Continued hospitalization. Patient's platelets improved to 20,000 and he received another 35g of IV Ig. 12/24/2020: Patient discharged with platelets of 38,000.

sore arm at injection site, fatugue, general malaise, neck soreness on side of injection

None stated.

Pt c/o lightheaded, elevated BP 180/98. Pt was seated, given snack and water. Felt betterand was discharged 20 minutes later

Chills Fatigue Muscle soreness

Five minutes after the shot she had trouble swallowing her saliva. Dry Cough Tight Lungs

He was fine ate lunch, in a room with a patient, felt light headed and dizziness, passed out, he became unresponsive, he was hypotensive, he is now in the ER.

About 12 hours after receiving the vaccine, I felt weak, achy, and quite dizzy. I awoke approximately 20 hours after receiving the vaccine with a 101 degree fever, worsened body aches, soreness at site of injection, and increased dizziness.

Left infraclavicular and supraclavicular lymphadenopathy, severe myalgias, local injection site swelling and pain. Patient was diagnosed with COVID-19 on September 28, 2020 and was 87 days after diagnosis at the time of vaccine.

After a few minutes tingling in arms, anxious, tongue felt funny. Lasted 10 minutes. Prior medical history of panic attacks. Normal vital signs , verbal felt better sent to the ED for observation

Lightheadedness

EE states that she started feeling dizzy and fatigued but it quickly resolved. Today, 12/24/2020 at 1:20pm EE states that she was driving and started having chest pains, sternum area, pain 3 out 10, the pain comes and goes, it happens when she is moving and resting, when asked about other symptoms, EE states that the chest pain is her only symptom at this time, tested negative for Covid, no travel history. I advised the EE to go to the ER immediately for further evaluation. The EE stated that she prefers to go the Urgent Care.

Pt was dizzy became nausea, and developed a headache. BP was163/105. She was obcerved for almost an hour and then had dry heaves. She was sent to Er for further treatment and observation

10 hours after shot, back pain started then body aches and chills. Fell asleep then woke up feeling like I was on fire but not sweating. Body aches continued through the night. Took Tylenol at 945pm and again at 845am. I went back to sleep and by 1130am I only had a mild headache.

Around 8:00 pm on 12/23/2020, I began to experience headache, fatigue, soreness at injection of site, and nausea. Over the next hour, the headache and nausea intensified dramatically, and at around 9:00 pm, I vomited.

Approximately 20-25 minutes after the vaccine my lips and tip of my tongue started tingling, then approximately 20 minutes after that my nose and forehead started to feel numb. I was instructed to

take Benadryl and come into be observed. The tingling sensation decreased a little after a few hours but continued throughout the night. The numbness of nose and forehead went away later that evening around 9. When I woke up the next morning the tingling sensation of my lips was gone but then returned later in the morning around 11. Breathing and airway were not impaired.

Low grade fever, chills, body aches, sore arm.

It all happened next day when I woke up. My both hands were swollen, swelling went for four days in my hands, now its better, I was nauseated, and had joint pain, it first started on my left ankle I had pain in the joint, next day and still going I have pain in both my joints in the legs, for for four days I had headache but as I was reading that's normal it was controlled with Advil and now feels better. Only joint pain still going but its not something that its terrible pain its just there. I started wearing compression socks hopping that will help.

Patient vaccinated at Nursing home. Transferred to ER the following day when patient developed fever and altered mental status. Found to have acute kidney injury on chronic kidney disease, hyperkalemia. Required emergent hemodialysis for hyperkalemia with ECG findings of peaked T waves.

44 y F referred to clinic after allergic response to COVID vaccine this afternoon. Pt received dose of covid vaccine at 1713. at 1723 pt c/o itching R wrist and neck. 3 small reddened areas noted. Vaccine hypersensitivity protocol initiated; RRT initiated. Allergic reaction to COVID vaccine-pruritic hives without angioedema-resolved with Benadryl

Approx. 35 minutes after the injection Heavy feeling s in his body and light headed. New funny taste. PMH hypertension. No itching no rash no SOB normal VitalS igns . Sent to ED observed and released

2 hour 30 min after injection severe pain radiating down left arm from shoulder to forearm, unable to raise left arm. Persists through 12/24/2020. Acetaminophen start at midnight every 6 hours without relief. Pain exacerbated with any movement of left arm. Injection site high up on upper arm close to shoulder.

pt started having headache and body aches first, then fever 100.6 and chills and a red face

FULLNESS IN THROAT PERI ORIAL NUMBNESS CHEST TIGHTNESS PRESSURE IN CHEST PATIENT WAS GIVEN EPI PEN , TRANSPORTED TO ED DEPARTMENT IMMEDIATELY

Difficulty breathing, palpitations, feeling like she is developing hives

Pfizer-BioNTech COVID-19 Vaccine Slight headache on the morning of 12/22/2020, and feeling exhausted. These two symptoms persisted during the day but did not get worse. In the early morning of 12/23/2020, the headache was worse, I had chills and my fever was 102.1. I was very dizzy at the time when getting up. I took Tylenol and ibuprofen, alternating, to help with the headache and fever. On 12/24/2020, I still have a slight fever of 100.4 but symptoms are getting better.

Pfizer-BioNTech COVID-19 Vaccine Slight headache on the morning of 12/22/2020, and feeling exhausted. These two symptoms persisted during the day but did not get worse. In the early morning of 12/23/2020, the headache was worse, I had chills and my fever was 102.1. I was very dizzy at the time when getting up. I took Tylenol and ibuprofen, alternating, to help with the headache and fever. On 12/24/2020, I still have a slight fever of 100.4 but symptoms are getting better.

Low grade fever, chills, fatigue, headache

99.4 fever, headache, body aches, injection site inflamed , red and a hematoma. Aches especially in my neck

Fatigue, nasal drainage, no treatment, resolved

Parasthesia in left arm within 5 minutes of vaccination. Parasthesia radiated into fingers (tingling but not painful). Parasthesia in left arm resolved in about 1 hour with no treatment. Parasthesia in tongue within 5 minutes of vaccination. Parasthesia in tongue (tingling but not painful) lasted through the evening (~5 hours). Resolved without treatment. Heartbeat increased (bounding heartbeat) onset within 5 minutes of vaccination; resolved within 5 additional minutes with no treatment.

Was scheduled for 3:10 yesterday and received it at 3:25 ish. Did fine at first ? a little flushing/burning around neck and chest about 35 minutes after but then around 10:00 pm I had a full on inflammatory response throughout the entire body. Thankfully it was evening/bedtime but it was an awful night with significant pain everywhere with any kind of movement. Mild headache that has been intermittent. I wouldn?t call it true chest pain but did have intermittent, weird stabbing pains in chest at times. I dosed up on gallons of water and Tylenol and certainly felt better by around 7:00 a.m. but if that was my response to round one I am hesitant to go back for seconds.

The first 5 mins felt dizzy like small fainting I started relaxed. I went home took shower I had a mild fever took Tylenol. The next day some headache and weakness. On day 2 mildness and weakness again. Then on day 3 fever and weakness was almost gone and headache is sill there.

it really started on the 21st when I felt fatigue, wiped out ,runny nose, sore throat, and now I have a dry cough and I still feel it today 12/24/2020, I went to the dr on the 21st and they did not prescribe anything to me

patient felt SOB, coughing and having sensation as if something was in her throat. Epinephrine epi-pen administered VS 130/70 HR 106, O2 Sat = 99% after epi administration

After 15-20 minutes of receiving the vaccine I began to have tingling in my lips that felt almost numbing but not quite. This progressed into my mouth with the slight swelling of my tongue and lips. I had incredibly dry mouth as well. Felt very thirsty. I was given a Zyrtec (10mg I think). Swelling and numbness never progressed into anything serious, could swallow and speak fine. Did develop a small rash on my forehead that went away about an hour after the Zyrtec. 30 minutes after taking the Zyrtec the tingling and swelling in my mouth and lips subsided. Around 7pm my cheeks and face felt tingly so as recommended I took a benadryl. In the morning all symptoms were non existent.

1) rigors without fever; 2) severe HA. These both lasted approximately 6 hours.

numbness and tingling in both hands. after 5 minutes it spread to her body, tongue and lips. Maybe after an hour, left side of face was numb for a little while. Today, feel ok, except left hand still feels the same.

""""Moderna COVID-19 Vaccine EUA""; patient reported jaw and throat area felt numb approximately 30 min following vaccine. Patient vital signs were taken and patient was monitored the entire time: BP and heart rate readings: 140/89, HR 64; 126/85, HR 73; 136/99, HR 69; 139/94, HR 68; 100% pulse oximetry all readings, each approximately every 10 min. Patient stated she was not getting better, but able to speak. EMS was called and arrived; patient was taken to hospital."

Headache and nausea after 15 mins of vaccine. Headache lasted all day, even with taken 1000mg of Tylenol. On 12/23/2020 around 7:30 PM my left arm was extremely sensitive and sore. I could not lay on the arm or touch it. Very hard. This morning when I woke, I had ability to move the arm slightly more than day before. Now my arm is hard and injection sight is red measuring 3 inches wide and 1 inch long. It hurts to touch the upper arm. I cannot stretch my arm all the way or rotate it as normal.

Patient is a 47 y.o. female who arrived by Car presented to the emergency department for Stroke symptoms. Patient awoke at 6:15 this morning, some difficulty seeing out of the right eye and also was stumbling towards the left and to table. Concerned about things not being right so brought to the emergency department. Patient feels her speaking and swallowing are okay. She did drink a bit of coffee earlier. She denies headache or significant vision problems presently. Continues to not feel normal on her left side. No history of stroke and parents or siblings. She does give personal history of an occipital migraine many years ago at which time she did not have a headache but had some vision troubles. Physical Exam Vitals signs and nursing note reviewed. Constitutional: General: She is not in acute distress. Appearance: She is not ill-appearing or diaphoretic. HENT: Head: Normocephalic and atraumatic. Right Ear: Tympanic membrane normal. Left Ear: Tympanic membrane normal. Nose: Nose normal. Mouth/Throat: Mouth: Mucous membranes are moist. Pharynx: No oropharyngeal exudate or posterior oropharyngeal erythema. Eyes: Conjunctiva/sclera: Conjunctivae normal. Pupils: Pupils are equal, round, and reactive to light. Comments: Patient displays absence of left lateral movement Neck: Musculoskeletal: Normal range of motion. No muscular tenderness. Cardiovascular: Rate and Rhythm: Normal rate and regular rhythm. Heart sounds: No murmur. Pulmonary: Effort: Pulmonary effort is normal. Breath sounds: Normal breath sounds. Abdominal: General: Bowel sounds are normal. There is no distension. Palpations: Abdomen is soft. Tenderness: There is no abdominal tenderness. Musculoskeletal: Right lower leg: No edema. Left lower leg: No edema. Lymphadenopathy: Cervical: No cervical adenopathy. Skin: Findings: No rash. Neurological: Mental Status: She is alert. Cranial Nerves: Cranial nerve deficit (left facial droop, dysarthria) present. Comments: Patient's speech seems a bit slurred to me. Absence of ocular movements towards left noted as well as upward movements. Tongue is midline. Patient is unable to shrug the left shoulder or lift the left arm off the bed. Grip strength is 4 out of 5 on the left. Left leg strength is 3 out of 5. Extremity strength on right arm and leg is 5 out of 5. After consultation with a neurologist, the patient is being transferred from the ED.

This resident received the first dose of the Pfizer Covid vaccine at the Covid vaccine clinic at medical Facility. He had a rapid response, experienced low blood glucose and low heart rate. NP and medical director were in attendance. Heart rate remained low despite all measures. He was transferred to Hospital for bradycardia.

numbness soon after vaccine, as the day progressed difficult elevate left arm, resolved by next morning

Febrile 101.3F, body aches and chills.

She got very light headed immediately after vaccine was given. We had her sit and gave her a cold ice pack and bottle of water. I went to get her crackers as she said she didn't eat much today and when I got back from grabbing crackers my intern was attending to her and she ended up throwing up. She continued to throw up and still felt lightheaded for about 20 minutes. I monitored her and she ate a few crackers and had more water and then she started feeling better. No medical treatment was needed. Continue to monitor for remainder of 30 minutes after vaccine.

Patient was very anxious about getting her vaccination. After a couple minutes of receiving the vaccine, the patient went to stand up from the chair she was vaccinated in and became light headed. She then put her head on the table and began shaking. She was safely lowered to the floor and placed on her back. 911 was called and paramedics arrived within 10 minutes. The patient was lucid and responsive, but breathing quickly and shaking. She was taken to the hospital by paramedics and discharged shortly after arriving.

WHEEZING SHORTNESS OF BREATH FULLNESS IN THROAT RAPID PULSE PT WAS GIVEN ALBUTEROL, EPI PEN, TRANSPORTED TO ED DEPARTMENT

Five minutes after receiving the vaccine I started feeling slight nausea, which got progressively worse, started feeling lightheaded and had to sit down at about minute 6, at 7 minutes a clinical assessment team was called because I was feeling like I was about to pass out. Everything seemed far away and removed and sound distorted/muffled , I was extremely nauseated, lightheaded and extremely thirsty and was seeing ?spots? in my vision. When the team arrived only a minute or so later, they checked my vital signs and found that my blood pressure was low, at 89 for systolic, with my normal systolic being 120-130.. I got very pale all over and my arms and especially fingers became weak, numb and tingly, the left arm more than the right. I was told I had a vasovagal response and also that I was expelling too much CO 2 because I had been hyperventilating. I was monitored and given po fluids for about half hour at which point I felt recovered enough to leave. I was offered/recommended being checked out at the emergency room but declined

Went to sleep at 8am. Woke up at 1am with unilateral angioedema. Presented to ER, given 125 mg methylprednisolone, 20 mg famotidine, and 25 extra mg of diphenhydramine (in additional to 50 mg I had already taken). Observed in ER. Swelling decreased. I was not admitted because I'm a doctor. Symptoms resolved 10 hours later.

Whole body aches, fever, loss of appetite. Took Tylenol. Symptoms decreased after about 24 hours, but currently still present (still have a low fever).

Approximately 9 hours post injection, patient developed chills, fever, cough with phelgm production which then progressed into uncontrollable cough. Patient went to ER, treated with albuterol inhaler and released without restrictions. Pt using inhaler but symptoms decreased at this time.

"About 10 minutes after injection, c/o tachycardia and became diaphoretic and stated she felt ""weird"" Taken to ER for eval/tx."

"""Moderna COVID19 Vaccine ""; patient reported she was feeling flushed/hot. Vital signs were taken and patient monitored for over 30 minutes. BP and Heart Rate readings approximately every 10 minutes: BP 142/105, HR 110; BP 139/101, HR 110; BP 132/83, HR 104; 124/94, HR 102; 98 % pulse oximeter readings during episode. Patient's mother works at the facility as well, stayed with patient and decided to leave with patient to go home. Mother returned inside facility and stated daughter was vomiting outside. Dr. advise mother to take daughter to ER."

Temperature of 100.04, head ache, back ache, muscle ache Running nose

1-2 minutes after injection a whole body flush developed along with heart palpitations, tingly throat and tongue, and a rash across the chest and neck.

high fever, severe headache, myalgia, chills

Within 5 minutes of receiving the vaccine, patient experienced anxiety, shortness of breath, and body aches in her elbows, knees, and ankles. Vital signs were normal. No lip/tongue/throat swelling on exam. She was pale and diaphoretic. Symptoms resolved in 35 minutes with laying supine and applying cold cloth/compress to neck and upper chest. She developed a headache at 40 minutes, however it was mild and it did not cause her to stay for monitoring any further.

Lip swelling and tongue tingling

"Physician Assistant texted the Dr. this morning: ""High fever and aching all night. It feels like having the virus all over again. Temperature down now but still pretty achy."" At 1347, he texted clinic: ""My fever is down. I still fee achy, about like when I had the original infection."""

About 10 minutes after vaccine I was extremely hot, dizzy, disoriented. My blood pressure was 30 points higher than usual and 15 minutes after the first episode, I had another episode.

Nausea, bilateral hip joint pain, fever, headache. Currently approaching 42 hours.

Minor sore arm at the site of injection

Felt a rush in my arm 5 minutes after. Then one hour following the injection I started getting dizzy and vertigo. Driving home I felt like something was very wrong like impending doom. My heart started racing

almost pounding out of my chest. I was extremely dizzy and almost fainted. Flushed feeling and tightness in my chest followed. Flushed feeling felt all day. Also had a rash on my neck and chest.

Received vaccine before shift. Within 10-15 mins bilateral back of the tongue numbness and tingling. Walked to ER (my department) and asked charge nurse for Zyrtec. Advised to stay and be monitored, opted not to be checked in to ER. BP 146/105, 126-120 BP, abnormally high. Experienced red lips, itchy hands and feet, 'frog in throat' feeling. Convinced to check into ER. Swollen uvula, tonsils, lips red/swollen, stridorous breathing. Checked in to ER, given IV Benadryl, fluid, prednisone, and Pepcid. Hands and feet were mottled. Confirmed anaphylactic reaction. Became nauseous, given Zofran. Given Epi in left shoulder. Stayed for 4 hours for continued monitoring. Symptoms started to subside. Also given inhaled albuterol. Discharged w/ Benadryl, Pepcid, prednisone 5 days course, and prescription for Epi.

Metallic taste

32 y.o pregnant female (8weeks) receive covid 19 vaccine in left deltoid at 6:45 pm. Around 7:10 pm patient developed tingling/pins/needles feeling and decreased motor coordination of left arm. Tingling/pins/needles sensation progressed to left eye lid, mouth, face, neck, throat, left lower leg and right hand. Pt was monitored in ER for an hour and sensation gradually dissipated

Dizziness, lightheaded was starting 10 minutes after injection and subsiding in about two hours

"Patient received vaccine at 1005 and approx. 20 minutes later reports ""tickle"" in throat feeling the urge to clear throat. and ""tingling' of lips. Benadryl 50g given by mouth per standing order. Monitored for additional 30 min. 30 min after administration of benadry Patient reported no change to symptoms. Patient was escorted to ER to be seen."

Headache

Mild soreness at the injection site noted in the evening of 12/22 and felt chills at 11:50 pm 12/22 but no fever at that time. Woke up the morning of 12/23 at 5:30 am and had a fever of 104 general body aches and shaking rigors. Took Tylenol and the fever came down. I was extremely fatigued and was in sleeping for most of the day on 12/23 and had no appetite . I informed my place of employment on the afternoon of 12/23 that I may not be able to report to work as scheduled on 12/24. Stayed home 12/24 but noticed an erythematous rash on my trunk around 3pm 12/24. I continued to alternate Tylenol and Motrin on 12/23 and 12/24 for general aches.

Severe muscle aches/pain throughout my entire body as well a consistent headache which I believe caused the nausea. For a period of an hour, I was having muscle spasms which them subsided. My body hurt so badly that I had a very difficult time turning from side to side and getting out of bed. At one point, I felt so badly that I thought I would have to be hospitalized. I started feeling a bit better by 8am but then started feeling badly again around 10am or so. I'm feeling better now, 4:25pm.

12/24@5:00pm EST-Caller stated that on Sunday 48hrs after vaccine he was chills, lost of taste and smell, fatigue with fever. Nose and throat dryness with chest pain. Today caller has been spitting up dark

green mucus with red streaks. Caller is taking doxycycline for strep. Caller keeps having elevated temps of 102.0 and chills. Dry cough has been persistent since 12/23/20. Vaers report completed over the phone.

Monday night pain on arm at injection site, Tuesday pain still there, Entire body started to ache. Couldn't stand. Runny nose. Could barely walk that night. Hallucinations sleeping at night, chills, tired. Took1 Tylenol.

Vasovagal syncopal episode, fainted within 10 minutes of vaccine, rapid returned to baseline after episode

Observed for 15 minutes after vaccine. About 30 minutes later in my car, felt sharp shooting pains in left neck. About 8 hours after receiving first dose, started coughing up blood, bright red, with streaks and clots. No cough, fever. Seen in ER with chest xray and ct scan with contrast. No resolve. On second day after receiving vaccine? Continue to experience bright red sputum. No resolve.

Developed Bell's Palsy symptoms on the left side of my face almost exactly 24 hours after vaccine administered

Tingling of face difficulty breathing with a swollen tongue

Right arm tingling, felt as though asleep, improving but lasted at couple hours after

Sore arm & headache. Motrin helped.

Headaches, chills, runny nose sore throat body aches, 5 hours after the Vaccine

ABOUT 5 MINUTES AFTER THE VACCINE, THE PERSON EXPERIENCED LIGHTHEADEDNESS AND NAUSEA AND VOMITING

Since vaccine headache, diarrhea fatigue, dry cough and tinnitus

Starting that night 12/19/20 at approx 8pm I became nauseous with a 100.8f fever. I felt achy for the 2 days with the fever subsided. On Monday 12/21/20 I was at work (Firefighter) when I started to have palpitations. I was able to obtain a 12 lead EKG right away which showed a ventricular rhythm lasting for approx 5 min. After that I was having multiple PVC's / Ventricular beats. I was taken to Hospital where I was admitted. Over night the rhythm subsided, all my labs were good with other test's being done. I was discharged home. I have not had any other episodes since Monday. I was cleared by our Occ Health Doc who suggested I fill this out.

Hives on chest transient noticed at 4:30 pm, diffuse red raised patches and erythema, gone by 8 pm, no pruitis. Site injection deltoid soreness, beginning about 1hour after injection, soreness increasing through today.

I had a intense headache, nausea & vomitting, body aches, joint pain and fatigue.

Patient (RN who works at hospital) complained of jaw tightness about 15 minutes after the vaccination. Diphenhydramine 50mg IM x 1 was administered. Patient then developed a rash across her chest and stated that she was not feeling well. EpiPen x 1 IM was given at 11:17 and Code Blue was called per hospital policy. Patient's vitals were BP 175/99, HR 129, Oxygen 100%. Patient was alert and oriented but anxious. Patient was sent to ER at around 11:20 for observation

15 min after receiving Covid 19 vaccine patient started to feel like her heart was racing / felt faint. Burning feeling in upper thigh and pelvic area. BP 180/100 HR 130. Rapid Response called / transported to ER. Admitted for 24 hr observation.. Solu -medrol, Benadryl and Ativan given in ER. Released home the next day. 72 hrs later patient states she has numbness and tingling in hands and feet. 12/24/2020 patient reports she is feeling better today / no symptoms noted.

I started feeling week and had muscle aches and joint pain about 8hr after the vaccine. Then had stabbing sharp pains all over my chest like it was pain in my lungs. Severe aching for 10 hrs. Severe chills and dizzy for several hrs. Better now. Seemed important to report.

50Y female, with history of PTSD, anxiety and afib. Was seen in covid vaccine clinic during her break on 12/24/2020 at 1113, for covid 19 vaccine. At 1133, she reported scratchy throat and felt her heart was racing. Heart racing symptoms lasted only for a few minutes and then resolved. She reports mild scratchy sensation with swallowing. Reports that she had a lot stress since start of shift today. Also admits to stress while sitting in the clinic for observation, stressors include work related stress and responding to multiple phone calls related to codes. She was on the phone with husband prior to symptoms onset. She denies shortness of breath, dizziness, wheezing, chest discomfort, palpitations, change in vision, weakness or fatigue. She denies history of hypertension. Was previously on coumadin and diltiazem. But currently not on any medications. O: VS at 1140: BP 166/104, HR 75, O2 97% RA 1150: 164/93 HR 70 O2 99% RA 1158: BP158/83 HR 70 RR 17 O2 98% RA 1210: BP 147/82 HR 64 RR 15 O2 100% RA AAOx4. Employee was teary and anxious. Follow commands. Lung sounds clear. Heart sounds normal. No focal weakness, numbness, tingling. No respiratory distress. Able to tolerate fluids. A: Allergic reaction to COVID 19 vaccine. P: Employee was closely observed in clinic for an hour. Employee was provided fluids and emotional support. Symptoms gradually resolved. Her vital signs stabilized. Benadryl was offered but not given because employee reports symptoms improved and wanted to return to work. Employee was advised to monitor her symptoms. If her symptoms recur, she needs to go to urgent care or ED. Advised her to follow up with her PCP for further evaluation of her blood pressure and PTSD. She stated understanding and agreeable to plan. Employee returned to work and left in stable condition.

Fatigue, chills, fever, headache, body ache, right sided chest pain, neck pain, left arm pain at site of injection.

Headache, facial flushing, ears red/hot, nausea, diarrhea, chills, body aches, fatigue, arm pain

2:44p Stated felt dizzy, feet elevated, ice pack to neck and forehead, BP 151/99, HR 60, repeat six minutes later 152/94, and he stated he is not hypertensive. Within ten minutes stated was feeling fine, no longer dizzy. After about 15 minutes more he left the area.

Heart rate from 80 BPM to 128 BPM in 30 mins. and remained > 105 for 16 hours. Headache, Nausea with Vomiting, Shortness of breath. Chills No fever

Pain at sight of injection.

fever, Fatigue and Chills, Treated with Tylenol and Advil to ease the symptoms and lower the fever. Symptoms persisted for two days after taking the first dose of the vaccine.

Hyperacusis

Toes appeared bruised and painful upon touch. 15 minutes later, toes became inflamed and felt hot to touch. Also, experienced burning sensation. 10 minutes later, burning and erythema subsided and bruising reappeared. Bruises are still painful to touch, but both pain and appearance is improving since the event occurred.

Localized soreness and tenderness onset 1.5hrs post vaccination, peak at 12-24hrs post, slow improvement until 23hrs post after which improvement rate quickened. Still mild soreness and tenderness at 53hrs post vaccination. Low grade temperature (100 F), diffuse muscle aches, chills ~26hrs post vax, responsive to acetaminophen. Similar symptoms resurfaced at ~51 hrs post vax but acetaminophen taken prior to temperature elevation if it were to occur.

Angioedema, face swelling. Went to bed feeling fine and woke up with face swelling, mouth, throat and lips swelling. Delayed adverse reaction

Had some chills, headache the evening after vaccine. Next afternoon only had running nose.

Severe body aches and headache. Low back pain. Temperature between 100.6 and 101.8 today. Still 101.3 even after Tylenol.

Localized pain and some swelling. Swelling is approximately 1.5 cm in diameter and red.

nausea, vomiting, lightheadedness, chills, diaphoretic

Severe under arm pain on second, third and fourth day, enlarged lymph nodes.. Redness and swelling of shoulder on second day, Severe itching at injection site on third and fourth day, fever on third day. Urgent care thought it is expected symptoms for some.

Bilateral axillary pain

The Monday night I got the vaccine I had chills and headache all night. The next day (Tuesday) continued having chills and fevers and headache. Wednesday morning I woke up feeling great

On 12/20, I woke up to swollen eyes, ears, and face. I had itchy, red patches and welts on my legs and forearms, and a burning red rash across my forehead that circled my face and went around my chin. I went to the ER, where I was given benedryl, a steroid, and pepcid. I was sent home with a prescription for the same. On 12/21, I woke up with the same rash as described from the day before. I continued my prescriptions. On 12/22, I woke with with the rash only on my legs. I continued with my prescriptions.

On 12/23, I went to an immediate care facility where I asked for a COVID test. My rapid test was resulted as positive. I never had any of the listed COVID 19 symptoms. I continued my prescriptions. On 12/24, I woke up with no rash, no COVID 19 symptoms, and I continued with my prescriptions.

About 1-2 minutes after vaccination, I developed palpitations, tachycardia, tingling, and also a scratchy throat and full sensation in my throat. The palpitations, tachycardia, and sensations of a full throat lasted approximately 10 minutes and tingling several minutes. The scratchy throat lasted approximately 1.5 hours. Also, several minutes after the injection I developed twitching of my fave lasting several minutes as well.

NAUSEA

I started feeling palpitation after 2 minutes then was placed in the observation room. Vital sign showed heart rate of 145 with normal blood pressure and oxygen. Then after few more minutes I started feeling numbness and tingling in the mouth and started feeling dizzy and had cold sweats. Heart rate was 130s and BP was undetectable and my skin was severely pale. I administered my Epipen and rapid response team arrived after few minutes. I felt better 5-6 min after infection of the epipen but was still feeling dizzy and mildly short if breath. I was transferred to emergency room when I was treated with IV steroid, benadryl , pepcid and IVF. I was observed for 4 hours and was discharged with improvement in symptoms .

Pfizer-BioNTech COVID-19 Vaccine EUA Day of vaccine - Fatigue 1 day after - Sore muscle in left arm 4 days after - Achy left shoulder joint, sensation of heat, tingling sensation on left arm just above elbow. Minor swelling just above elbow. 5 days after - Rash on torso, red spotted

Subsequent idiopathic anaphylaxis event 1 1/2 days later

Patient complained about difficulty swallowing, and tongue swelling about 12 minutes after receiving vaccine. 50mg Benadryl given and EMS called. Patient transferred to Hospital.

Fatigue, Headache, myalgia, mild joint pain, extreme right deltoid muscle tenderness

Soreness at injection site.

Fatigue

Few minutes after vaccine heavy right side throat/tonsil, right are very sore and painful raising right arm, and headache next day.

Fever

Severe headache, muscle pain in whole body, fatigue, fever, inability to do any daily work due to sx

Hyperpigmentation of lower extrememities. Dark discoloration of skin from the pelvis down to ankle

Fatigue

Low grade fever

BODY ACHES, CHILLS, AND VIRAL RASH OVER ABDOMEN/BACK/FOREARMS

Swollen and tender at injection site.

"""Pfizer-BioNTech Covid-19 Vaccine EUA"" Had fatigue the morning after receiving the vaccine from 7:00 to approximately 7:00pm. Have injection site pain, swelling, and redness. Noticed on second day after the injection, but injection site was sore the first day after the injection, I just did not check for any swelling or irritation."

Subjective fevers, chills, myalgia, extreme fatigue, headache, severe injection site soreness Have persisted over the day after the vaccine

Tenderness at injection site.

Received dose at 0800. By 1730 was nauseated and achy. Fever of 104 by 2330 with vomiting, severe joint pain, shortness of breath, tachycardia, BP 174/110. Fever down to 101.8 in Emergency Department. Received nausea medicine and Tylenol. Chest X-ray negative. MD felt it was a severe hypersensitivity reaction. Fever continued through today (12/24 low grade, 99.8). I had severe Covid-19 the last week of March and was hospitalized. I?m just resting and waiting for the reaction to pass and have stayed off work.

Bell?s Palsy

Tenderness at injection site.

Injection site sore arm, pounding headache, fatigue, nausea

Headache, tenderness at injection site.

Headaches and body aches

Headaches and body aches

I experienced bleeding bilaterally from my lower gums and the inside of my lower lip ~1.5 hours after receiving the vaccination. I went through several tissues to try and stop the bleeding but it continued for 3-4 minutes at this rate until it spontaneously resolved.

My jaw hurts; feels like TMJ

Tenderness at injection site.

Tenderness at injection site.

Severe fatigue Sore throat Abdominal distention Dyspepsia/GERD Shortness of breath intermittently Moderate to severe headache Left arm pain (mild) Angina at rest Right claviclular/subclavian pain

12/22/20 at 1800 I noted angioedema in my face and itchy/sore gums. I went to two different urgent cares I did not receive any care at due to lack of physician at one and lack of epi at another. After being refused at the second urgent care my throat and chest started to feel tight. I then went to the ER for further evaluation. I received a dose of epinephrine IM and prednisone 125 mg IV at 1930. I was observed for 4 hours then discharged. I returned to the ER 30 minutes later because my throat started to feel tight again. I received a second dose of epinephrine at 2358 and noted some improvement. I was discharged at 0600 on Dec 23rd. I returned to the ER Dec 24 at due to my throat feeling tight and burning sensation in my chest. I got CXR, and troponin that were WNL. I was observed for 4 hours and discharged at 0900. ER physician felt that the sensation in my throat and chest could be related to the reaction from the 22nd.

About 20 minutes after vaccination, patient reported generalized itching and hand swelling (left). Patient had red spots on her face and complained they were itchy. EMS personnel were on-site and and MD administered 50mg oral diphenhydramine and 100mg oral prednisone. BP: 130/90, P: 92, R: 16 with no obvious signs of distress. Lungs were clear to auscultation and patient was sitting on her own and able to hold a conversation. Ambulance was called and arrived about 10 minutes after reaction started. IV with Normal Saline was started and patient was given 25mg IV diphenhydramine. Patient was taken via ambulance to a nearby hospital.

Patient presented with signs and symptoms of sepsis, developing over 12 to 24 hours 6 days after vaccination. was hypotensive and confused (beyond baseline)

Woke up at 0400 on 12/22/20 with tympanic temp of 100.8, chills, body aches, very tender left deltoid injection site pain. Ibuprofen resolved elevated temp. Spent all of 12/22/20 with fatigue and body aches despite ibuprofen - these symptoms fully resolved by 12/23/20. Tender left deltoid persisted for a total of 3 days, then became less tender.

Body Aches, Arm Pain, HA, Fever of 102- 12/24/2020

Initially no pain, then moderate-severe pain at injection site that radiated down towards my fingertips. This started approximately an hour after receiving the vaccine. Tingling in both hands and forearms, which began shortly after midnight. Today (12/24) I have mild swelling, as well as the same pain and tingling.

Fatigue, chills, myalgia, arthralgia, nausea, headache, soreness at injection site

Patient had redness and swelling on her face. Transferred to emergency room for observation

Pain at the injection site, general fatigue, myalgias, and chills starting about 6 hours post-vaccination and lasting for 24 hours

Hypertensive and had tongue and throat swelling. Epi was administered per protocol an d transported to ED.

Lots of physical pain and soreness, red and visibly swollen, hot to touch, pain in limbs and joints continuing for 2 days and counting.

Lymphadenopathy - left supraclavicular. Painful, onset approx 36 hours post vaccine. Arm soreness almost completely resolved at this time

patient has had hot and cold feelings on her body, feels like her chest is heavy, denies short of breath or difficulty. fever, chills, fatigue, arm soreness.

waiting in observation on a 30 minute wait time, reports change in voice, gravelly sensation in throat, clammy hands, not feeling right reports similar reaction to contrast dye, no SOB no audible wheezing

Dizzsiness, orthostatic hypotension, migraine, nausea

Nausea headaches light headed dizzy

Began with fatigue and nausea/stomach upset. This progressed all day and then 12/24/2020 late at night woke up in a sweat and noted a fever of 102F via oral thermometer.

12/21/2020 0200 hrs severe chills & Temp 104.2 F took Tylenol 500 mg , 0400 hrs Temp 103.4F. 0600hrs Temp 104F took Tylenol 500mg . 0700hrs 103.6F. all day temp ranges from 102.8F to 103.4F 12/22/2020 no chills Temp ranges from 101.6F to 103F 12/23/2020 Temp ranges from 99.5F to 102F

Fever, body aches

Begin to feel tingling and some numbness in left arm. Moved over into right also. About an hour after shot feeling chest tightness, winded with activity. Tingling stopped within an hour but tightness and breathing continued Did not feel bad enough to worry We but did not feel good for several days. Continue to have feelings of not being able to get deep breath. Have been in contact with my physician about issues. Have never been bothered with vaccines before but did not feel right pretty quick after this one.

Headache Fatigue Weakness Fever Sore Throat

About 0400 hours became extremely hot, dizzy, and nauseated. Threw up and then became short-of-breath. Felt hot and fever went up to 102.6 (oral). Charge nurse was notified and the house supervisor. Was sent home and told to fill out this form.

Dry, nonproductive cough , first day 12/24, fever 105.2 (temporal) 0700 12/25/20.

immediately after injection, facial flushing, then continuous waves of flushing and chills through body, from abdomen to toes, lightheadedness, cold hands and feet. This occurred for several hours and did not worsen nor did this improve. Tongue felt numb, and mouth was dry. Tongue felt swollen, however, the tongue size was normal. No rash, no fever and no shaking. Blood pressure, Oxygen saturation were normal. No breathing difficulties. I was observed in the ER and administered iv Benadryl 25 mg and pepcid, and iv fluids. I woke up a few hours later. I still had the rushes of chills, numb tongue, and cold

hands and feet. I was discharged to home. I still have the rushes of flushing and chills that flows through my body.

All mild Covid-19/flu like symptoms, in addition to sharp pain in armpit area, into the chest area, down the right side of upper body on side where vaccine was injected. Couldn't move right arm to should level or further without intense pain. Right armpit area swollen and extremely tender. Also experienced dizziness. This all began roughly eight hours after vaccine, lasting throughout the entire next day, and still in existence today.

Received the vaccine on 12/23/2020, felt great after, no allergy reaction, just a sore arm at the injection site. During the night of 12/24/2020, started having my lymph node in my left armpit swelling up, and feeling very tired. Felt like I was breaking a slight fever. Took ibuprofen in the morning, no fever (97.6), still having lymph node swollen and feeling extremely tired. Otherwise no other side effect so far. Will continue to self monitor and treat symptoms with ibuprofen. When i received the flu vaccine and tDap vaccine in my left arm, same situation, lymph node in my left arm pit started swelling within 24 hrs, and went away after 3 days. I'm expecting the same with this one.

Saturday around 2pm I developed intense body aches, progressed to chills, nausea and severe headache by 8pm. Next day improved but still had myalgias. Had some mild pleurisy and congestion starting on Tuesday. This would only be in an and resolve by evening time.

Pain at inhection site, fatigue, chills, fever 101.6, upset stomach, headache

Woke up Dec 24 with fatigue, chills, fever of 100.5, and phlegm, shortness of breath and cough. Tired throughout day and fever lasted til 6pm. Took Tylenol and Ibuprofen to break fever and chills. Recovered on Dec 25.

Reported sensation of tongue swelling during post-vaccination observation at 10 minutes. Epinephrine was refused and she was taken to ED for observation where she was given oral dose of Benadryl and Pepcid. Discharged with instructions to return PRN and follow up with PCP. Elevated BP noted.

red arm, swelling in arm , pain in arm

Pfizer-BioNTech COVID-19 Vaccine . Nausea started around 1:30, vomiting shortly after. Continued to throw up until approx 10am the next morning. Felt feverish as well. Had to lay in my car for several hours before my one hour drive home and threw up in plastic bag while driving. Had to stop and rest and throw up halfway home. Went to bed when I finally got home and continued to throw up all night

Fever 101.3, aches and pain, body Malaise

R arm pain and swelling at injection site starting about 24 hours after injection, still present 48 hours after injection Flushed feeling in face with headache starting about 33 hours after injection, lasting approximately 6 hours

Day 1. Queasy nausea, some soreness at injection site. Day 2 runny nose, itchy throat some cough, day3 muscle cramps up into shoulder a and back. Later day 3 muscle cramps in both calfs and some nerve pain. Left side face. Day 4 bowel cramps, fatigue, congestion and some loose stools. Day 5 symptoms subsiding.

Twenty-fours after injection, experienced fatigue, body aches, chills and high fever of 102.4. Took two Aleve. Fever kept spiking. Took Tylenol PM (that was the only Tylenol I had); it took one hour for Tylenol to take effect, which finally brought fever down to 100.8 then 98.3. Went to bed. Woke with bad headache. Took an Excedrin Migraine for relief from headache. Body aches and fatigue gone. Not looking forward to these symptoms again after the upcoming second dose on January 20, 2021, but will take the second vaccine shot in order to get the full effect.

Patient received Pfizer vaccination in Administration clinic. While in post vaccination observation, patient complained of feeling warm, lightheaded. At that time, patient reported she failed to inform nurse of current penicillin allergy. Proceed out called. Took vital signs at 15:05, 130/83, HR 83, 02 sat 99%. Repeat vital signs 15:24 BP 125/83, HR 83, 02 sat 97%. Patient transferred to ED for further monitoring. In the ED, patient was monitored for few hours where the light headiness has subsided. patient was discharged home.

Nerve pain in upper back started to increase and had a strange numbing feeling in my neck and face. Some pain in my abdomen as well.

C/o stomach ache that started after vaccine. 24 hours. LLQ, dull, no radiation. movement exacerbates and deep breaths. Constant. Mild, reported as a 3-4/10 in severity at it's worst. Responds to tylenol. Denies changes in BM, bloody bowel movements, obstipation.

1756 Pt c/o itchy throat. Vitals taken. 1758 Team alert called. 1759 c/o tingling in fingers . c/o shortness of breath and not feeling well. MD arrived.

10 min after injection hot flash, 1 hour p injection quarter size red welt, raised and hot to touch 24 hrs p injection dollar size red welt, raised size of goose egg and hot to touch. Also, all joints ache. 48 hrs p injection same as above 24 hrs

Hives

"Right side of face (from mid eyebrow-line to below temple) became numb and has a ""pins-and-needles"" sensation when touched."

I woke up around 4am at night because my feet were tingly, like pins and needles. At first I thought maybe I was wearing tight socks, so I took them off, but it wouldn't go away, so then I thought maybe it's just how I have been sleeping so I woke up and started to walk around. I noticed that my feet weren't only just tingly, but they also felt heavy to walk around. It felt like someone had put weights on my feet, and I could hardly pick them up to move. This was on going for about 45 min until I panicked, and I called the ER. They told me since there wasn't much information about adverse effects from the

vaccine to just monitor it, and if it didn't go away to go to the ER. It did take about 3 to 4 hours for the sensation to leave. It did gradually fade, so it wasn't the same height of sensation the whole 4 hours.

swelling and tenderness to left axillary area

Rash all over body

within a few minutes I became overly warm and feeling dizzy, my blood pressure went up to 189/80 and my pulse elevated to 99. My normal levels are usually 120/70 and pulse 54-60. I had acute anxious feeling and overall body shaking. I was taken down to the ED by stretcher, I received the vaccine in the hospital setting, I stayed in the ED for 3 hours and was discharged home. I felt fatigued and weak for 24 hours after.

Pain at injection site, body aches, chills

Sense of Taste and smell going in and out

Shortly after receiving vaccine, experienced soreness at injection site. Soreness continued to spread, encompassing area from shoulder to elbow. Soreness lasted approximately 24 hours. No medications or treatments administered.

I received my shot at 1347 and within 5-10 minutes after receiving the shot I got a hot flush feeling through my body. My heart then began to race and I became dizzy. I started to get a tickle feeling in my throat. Soon after my lips and tongue felt numb. My tongue had the feeling of having been burned by hot soup. I also had red splotches over my entire body (not a rash but redness). When I alerted the vaccination staff that I thought I was having a reaction they all seemed shocked. They didn?t really know what to do and asked me what I wanted to do. I, myself, was having a hard time making choices since I was in a bit of a panic. They wanted to give me oral Benadryl but since I was having the reaction in my throat and mouth one of the nurses suggested IM Benadryl. They gave me that shot around 1405. They watched me for about an hour and I still had the numbness in my lips and tongue and the red splotches over my entire body. (During this entire time no one took my BP or pulse). I had 2 work friends (RNs) come to check on me. It was only then that one of them took my pulse. I was still had tachycardia. Since my symptoms were not fully resolving they sent me to the ER where I got solumedrol and Pepcid. They sent me home still having slight numbness in my lips and tongue.

Individual woke up in the morning at 3:00am with complete numbness of the entire left and right arms/hands with concomitant tingling of both feet and lower legs. Tingling on the feet and lower legs resolved within 15 minutes with movement. Complete numbness on the arms and hands persisted until 7:00am when feeling in arms and hands began to return. Mild tingling in hands and arms persisted throughout the day and would worsen with use of hands and arms. Individual took a dose of ibuprofen 600mg with no improvement in symptoms. Symptoms seemed to improve by resting arms and hands. The tingling in hands and arms dissipated with complete resolution by 5:00pm on 12/24/2020.

Body aches, chills, fever (as high as 101, with 800 mg of ibuprofen) , nausea. Symptoms started around 600 pm. Woke up at midnight 12/25 with a fever still and I woke up 0600 am 12/25 with mild symptoms (body aches, fatigue)

- 5 hours after Covid vaccinated, I had sweating, chilly, and mild muscle ache for 2 hours. After that I had moderate pain at injection site till the next day. - The next day, I felt dizzy and heavy headache for 3 hours; after that I felt normal and no pain at injection site. I took Tylenol 500mg by mouth twice a day and Vit C daily to help for releasing symptoms.

Headaches, muscles pain, joint pain, nausea and fever

Headache, occasional chills, sinus head pressure throat irritation without closure, fatigue

Moderna COVID-19 Vaccine EUA Palpable 5cmx6cm lump/erythema/edema/soreness just inferior to injection site on R middle deltoid. Onset of sx was approx 5 hrs after injection. Localized moderate mm soreness began approx 3 hours after. Approx 1 day after vaccine, experienced chills, fever, generalized body aches, muscle soreness which has continued through Day 2 (today). Then came onset of grumpiness when I realized ...

Injection site soreness starting 12hrs after vaccine Fatigue and body aches starting 20 hrs after vaccine Fever max temperature 101 F after 28 hrs after vaccine

buccal edema herpes blister

Site reaction. Red, swollen, hard and warm. Fever. Severe body aches, chills, shaking, cough, SOA, headache, fatigue.

on 12/24/2020 the resident was sleepy and stayed in bed most of the shift. He stated he was doing okay but requested pain medication for his legs at 250PM. At 255AM on 12/25/2020 the resident was observed in bed lying still, pale, eyes half open and foam coming from mouth and unresponsive. He was not breathing and with no pulse

Moderna COVID-19 Vaccine EUA Received vaccine at 5:03pm 12/23, through night arm became increasing sore. I woke up 12/24 at 6:45 and the injection site was red, raised, and painful. The area then became very hot to the touch. By 9:00am that morning I began experiencing excessive dry mouth and thirst. I drank close to a gallon of water 12/24 and it was not satisfying this. Woke up 12/25 and now the injection site and surrounding area is extremely itchy.

arm soreness: started about 4-6 hours after injection and lasted 3 days; stabbing type stomach/intestinal pain (no nausea, vomiting or diarrhea): started the next day and lasted 3 days (completed this report 3 days after vaccine and still with GI symptoms) ; backache: started the morning after the injection and lasted 3 days. Overall, similar to flu-like symptoms. No significant fever or chills.

patient has a telephone appointment with me on urgent care shift on 12/25/2020 . he works in ICU in COVID positive patient's floors. he received COVID vaccine Pfiser on 12/18 and he had a phone

appointment with me today on my urgent care shift. he reports fever for the last week after getting the vaccine highest around 102 F. today his temp is 100.6F . no cough or SOB or respiratory sx other than generalized body aches.O2 sat is 98%. I consulted with our ID specialist on call today and they recommended that we test the patient for COVID-19 infection which I scheduled for tomorrow . ID specialist also recommended that I report the adverse effects in here . thank you

Client developed itchy rash to face, neck and chest approximately 15 minutes after injection. Client then reported that she had similar experience after her flu vaccination the past 3 years. Client took 25mg of Benadryl and was monitored for an additional 30 minutes at clinic site until rash was resolving. Client denied any issues/ complications with swallowing or breathing. Rash and itching was resolving prior to client leaving vaccination / monitoring site. Her significant other had brought her to the clinic and was available to drive her home. EMS was also on scene but did not need to provide assistance.

High fever Headache Tired Body aches Joint aches

Diarrhea every time since shot given. 5-6 qd

Pfizer-BioNtech COVID 19 Vaccine EUA: Developed throat itching, mild throat swelling, flushing, and mid upper back pain about 24 hours after the vaccine was given

Individual presented to outside hospital after receiving first dose of the Moderna COVID-19 vaccine 2 days prior at Hospital. Individual presented with possible SIRVA from injection. Patient had a stat neuro consult due to being unable to move her arm (same arm that received the vaccine).

Fevers 101F to 102F, severe rigors, diffuse myalgia, headaches leading to Emergency Dept visit at Hospital Rideout on 12/24/2020

Tachycardia Malaise

I was working at the Hospital and around 1000AM, I noticed a ?sideache? on my right side of my abdomen above my waistline going around to my back on the right side. It came and went throughout the rest of my shift. Came home, at dinner and went to bed after taking some Tylenol. I woke my Husband up at 1:30 AM due to worsening pain/discomfort and He took me to Hospital ER.

"Client began feeling flushed approximately 10-15 minutes following vaccination with COVID-19 vaccine. Client stated her ""chest had a heavy feeling"" and she was experiencing heart palpitations (which she also reports are normal for her). She was concerned as the heart palpitations were occurring along with chest pain. EMS on scene at clinic site (precaution) and escorted client to area where EKG was completed. Normal sinus rhythm was noted along with possible infarct age undetermined (as reported on strip)and client was asked if she would like to go to ER for additional evaluation which she refused. (Client signed refusal of medical treatment, transport and/ or evaluation form). Client was advised by EMS and health district staff to seek medical treatment or call 911 if symptoms persist or become worse. Client voiced understanding."

After have the vaccine done and taking my medications, I started have hallucinations of bugs all over my skin and coming out of my skin. the hallucinations lasted for about 20 hours. Called my doctor and he had to increase one of my meds to get the hallucinations to stop.

Fever, body aches, chills, fatigue, nausea around 19 hours after vaccination.

The evening of the 24th, I felt lightheaded, sore, and extremely fatigued. Waking up on the 25th, I had diarrhea, vomiting, headache, coarse cough, asthma exacerbation, chest pain. Chest pain subsided but other symptoms remained. Around 11am, I developed cervical neck pain in the back of neck, and lower pack pain. I started to experience loss of vision upon standing, tachycardia, tactile fevers, chills, and loss of appetite with extreme fatigue.

Vertigo, three episodes in early morning. Then quick episodes of dizziness throughout the day. No further dizziness or vertigo at bedtime nor after that.

Muscle pain all over the body, injection site sore to the point cant lift left arm, nausea, low-grade fever/chill, diarrhea, sore throat, congestion and runny nose.

Perioral and Tongue Paraesthesias-

Diarrhea and fatigue, day after vaccination

Fever, nausea, fatigue, pain at injection site, swelling at injection site, generalized pains

Supraventricular tachycardia--needing to be seen in ER twice before controlled

Fever 100.4 F/ Fatigue/ Headache/Body ache/ Chills.

Massive headache 7/10 take came on after I woke up from a 5hr nap after I got my vaccine I am also feeling tired. My arm is feeling a bit sore (esp if I raise it) but not worried about that. My headache really hurts more then my usual post covid headaches which I've recently gotten under control I took sumatriptan to see if it will help. Will eat and probably go back to sleep. (it's 3pm for reference)

dizziness shortness of breath tachycardia hypertension forceful heart contractions

SEVERE diarrhea

Fatigue/tired, nausea, body aches, chills started dec 23

Began just as sudden sharp headache on 12/21/20 at 6:00 pm, noticed after shift after showering, left upper extremity was slightly red, and slightly tender to touch. Not unbearable. 12/22/20 noticed redness was continuing to spread and arm was beginning to ache, still not unbearable. On 12/23/20 during shift, the redness in my left upper arm had spread from elbow to below injection site, arm was increasingly aching as well as new noticeable left sided facial swelling from directly underneath the left eye throughout the cheek area. and slightly tender. This is when I checked into the urgent care and was examined. At first the mid-level reported she thought I had experienced vaccine induced bellspalsey; however, after consulting with the MD, this was dismissed. Left upper extremity was diagnosed as

cellulitis and treated with bactrim and informed to take zyrtec or benadryl for facial swelling. If symptoms worsened, visit nearest ER. Also informed to report symptoms to CDC for tracking. Today I have been treated with 2 full days of antibiotics and the redness and swelling has reduced. left sided facial swelling remains present.

Moderate to severe unilateral headache unresponsive to Tylenol or Advil on day 3, 4 and 5 (today). The headache gets better after several hours but returns.

Day 1 (day of vaccination): dry mouth Day 2: pain in left arm and body aches Day 3: none Day 4 (today): tingling in lips and mouth, swelling of left side of face with numbness

Cough, fever, chills, diarrhea,fatigue, headache

Rashes/Hives started on the my left hand on the date of vaccination, about 30mins after vaccine administration. Then today, Dec 25, 2020 I have rashes on both forearms that are itchy.

Lightheaded, Metallic taste in mouth, and tingling in my throat for the first 15 min after vaccine given. Then after that just localized injection pain to site

Acute NSTEMI with symptom onset 4 days after vaccination

Sore arm, tingling sensation slightly numb, tingling numb sensation also in left 3 outside fingers (pinky, ring, middle). That started about 15 min after injection. The next day on 12/24, increased pain at site, redness, swelling and hard lump in area of vaccine. It is about 2 inches diameter round spot. Pain in arm continued. Fingers feel slightly improved as of 12/25. The injection site is the same as yesterday.

Moderna Covid -19 vaccine EUA

None

Localized upper lip swelling. No lower lip or tongue swelling. No rash. No shortness of breath. No throat swelling or pain. Resolved in approximately 1 hour with Claritin PO

Bilateral ear pain and ringing in ears. Varies in pain severity from 8/10 to 3/10 depending on activity.

more than usual bowel movements and body tingling all over at random. Body tingling would occur more during strenuous movements and would occur with presyncope sensations without having a syncope episode

Herpes zoster (intraoral - left hard palate and left scalp V2 distribution) which began 4 to 5 days status post vaccination. No prior history of shingles.

Rash on my stomach and legs day after and still present. Day after vaccine I had a light headache and felt very tired.

Immediately after the vaccination I felt warm and clammy. I did not have shortness of breath. I sat down for a few minutes and took off my shoes and I began to feel better. I went straight home and laid down.

Throughout the night I felt anxious to where I felt uncomfortable sitting still. I have anxiousness in my chest which travels down my body. My hands and feet are clammy sporadically.

Pfizer-BioNTech COVID-19 Vaccine EUA On 12/19/20 around 11:15 PM, patient experienced ?pinching? pain in armpit of left arm (arm of injection). Pain persisted throughout night with accompanying generalized underarm swelling (fluctuate). On 12/20, NSAIDs were taken to relieve pain. 1 dose of Advil were taken on 12/21 and 12/22 to manage pain. On 12/22, pain level on 1?10 scale was 8-9 in the morning with increased swelling, warmth, and discomfort. At night, swelling was less than that of morning. On 12/23 pain level was 3. No NSAIDs were taken and patient visited doctor at 10 AM. Upon examination, doctor made diagnosis of a localized lymph node/inflammatory response, possibly Cellulitis and prescribed Keflex to be taken 2 times daily for 10 days. Pain has mostly subsided (level 1 or 2 when it occurs), swelling has gone down but not completely resolved. Left underarm continues to feel fluctuate following day 2 of antibiotic regimen. Possible axillary lymph node reaction suspected. Patient has also experienced persistent redness, swelling, mild pain and itchiness at injection site. Most of swelling and pain has subsided, itchiness remains.

Headache, fever 101.2, chills, body aches, left knee joint pain, right arm lymph nodes swelling and pain.

Got vaccine 12/21/20.@1645. Felt fine until 1500 on 12/23. Started with severe H/A, then started with extreme dizziness. Had to have some drive me 100 yards home from the dog park. Needed my hiking poles to navigate from bed to bathroom. Even had bed spins.

Patient presented to ED states was sleeping when awoke with feeling of rapid heart. Has pulse oximeter at home and states HR was 150s felts sharp chest pain and sweat. Had husband bring her to Emergency room. Emergency room physician states patient is mildy anxious and mildy diaphoretic. Blood pressure 155/83 and pulse rate in 120 upon arrival. Patient was given Ativan 1 mg IV and 1 liter of normal saline HR in 90s upon discharge form ed. Admitted at 2134 discharged at 2353

Febrile to 101.4, vomiting, joint pain.

Extreme injection site pain day 1. Nausea the same night and following morning with vomiting. Massive headaches and extreme fatigue. Injection site pain got worse throughout the day and now I?m having several rounds of diarrhea.

listed before

Approximately 2 minutes after injection, felt flushed and tingly. This subsided, but developed a cough. Felt fine enough to leave the vaccination area after being monitored for 15 minutes. Cough continued, and developed a scratchy throat that eventually led to swelling of the throat at approximately 30-35 mins post administration. Sought care in the ED, where I was tachycardic and hypertensive. Received IV Benadryl, steroids, and IV fluids. Discharged home, but symptoms returned around 2pm. Sought care in a different ED, where I remained hypertensive and tachycardic. Received additional IV fluids, IV Benadryl and steroids. Eventually was treated with IM epinephrine after my heart rate was decreased to about 100bpm with IV metoprolol.

Moderate pain at site. Next day started with fever of 102.3, chills, severe body aches. Headache as well. Fever subsided by end of first day but started again the next day.

Received vaccine at about 0830 on 12/24/20, at about 0100 on 12/25/20 started feeling lethargic then developed nausea and vomiting, additionally had mild to moderate shaking chills and mild myalgias. Went to sleep and resolved when woke up in AM.

Moderate dizziness, nausea, chill, fatigue started around 5 pm lasted throughout evening. Had to take zofran 4 mg ODT for nausea. No known fever. Unable to drive home from work for 2 hours. Went to bed around 11 pm. Felt better the next morning with mild residual dizziness and chill and fatigue. Minimal chill and fatigue ongoing at 55 hours after injection. Left arm injection site pain started at time of injection and ongoing after 55 hours.

36 hours after vaccine, sudden onset tachycardia, shortness of breath, dizziness on the verge of passing out, called covid hotline, sent to ER due to resting heart rate of 130-150. Lasted approximately 9 hours, was going to be kept for observation in ED. Resting HR came down to 90 and sent home, following day unable to perform normal activities and unable to work for two days as of now

Diarrhea starting 12/25/20 at 11:00 am (5-6 episodes in a 24 hour period)

Approximately 10 hours after vaccination I developed sudden onset of fatigue, severe headache, lightheadedness, cyclical chills, tachycardia, bilateral conjunctival erythema, excessive tears and muscle spasm which lasted for about 4hours

Headache and lightheadedness right after vaccination which disappeared after a day. Headache returned 9 pm on Dec 24 with chills and sore throat. Fever of 100.7 on Dec 25 at around 6 am w/ chills, headache, sore throat and body aches.

Tingling og tongue and itchy eyes at 10min post admin Swelling/redness and flushing of head 20mins post admin Shortness of breath at 20mins Whole body hives and itching at 40min pot admin Swelling under the jaw and tightness/burning in chest at 40min After treatment in er...symptoms resolved after 5hrs. 14hrs later, symptoms reoccurred, with increasing severity. Went back to the ER for treatment. Again symptoms resolved after 5hrs. Now on 25mg benadryl 4x/day, 40mg prednisone 1x/day, zertec 20mg 1x/day and 20mg famotidine 1x/day for the next 4 days. Still being treated.

Fever/ runny nose/ sinus pressure/ extreme fatigue for about 36 hours

Pfizer-BioNTech COVID-19 Vaccine EUA: During vaccine administration patient complained of flushing, lightheadedness, dizziness, and arm tingling. No loss of consciousness, respiratory symptoms, or gastrointestinal symptoms reported. Inital vital signs: Blood pressure 147/84 mmHg, heart rate 115 beats per minute, oxygen saturation 95% on room air. Repeat vitals ten minutes later: blood pressure 123/60 mmHg, heart rate 77 beats per minute, oxygen saturation 98% on room air. Patient monitored for 30 minutes. Symptoms improved with time and snack. Patient was discharged in stable condition.

Left lymph node swollen next to breast. Warm to touch and painful to touch. Slightly red area noted as well. Currently taking motrin, did ice first day

Swollen lymph node in L arm pit and above L clavicle

Axillary lymphadenopathy

"Pfizer-BioNTech COVID-19 Vaccine EUA: Patient reports fever, body aches, chills, headache, and chest pain one day after receiving the vaccination. Patient had COVID before (November2020) and reports ""this felt very similar to one of my worst days with symptoms"". Patient reports only persistent symptom was feeling more tired than usual. On 12/22/2020, patient noticed a rash on back and under arms."

Soreness at site 48 hours following vaccine administration. General muscular and joint discomfort beginning approximately 48 hours out. Onset of fever (103.4) and chills at approximately 72 hours out. Fever between 99.4 and 102.0 for the next 48 hours.

At the time of the injection sharp pain across my back , then at about 5 mins after feelings of light headedness, progressing pain across my back, trouble feeling like I could get enough air in with breathing and dizziness and I tried to get to the floor to sit or lay down but passed out. Then the next event I recall was a sharp pain in my thigh(apparently administered Eli pen) . I regained consciousness and was gasping andI was told I had been given a shot of epi.

Sweating on first day, fatigue from first day persistent for 3 days. On day 5 (12/23) pain under the arm pit began. From 12/23-12/25 pain worsened into arm pit, down back, into breast, and into right side of neck. Swelling of lymph nodes in that area

Approx. 18-19hrs after receiving the vaccine I suddenly became nauseous and had an upset stomach, lack of appetite. Then shortly followed a headache, muscle aches, bone/joint pain, weakness, fatigue, dizziness, chills, fever of 102.4f, general feeling of illness or unwell, anxiety, tachycardia, painful breathing and slight SOB with exertion. O2 saturation?s 94% per my Apple Watch. Fever controlled with Tylenol, I have not sought out further medical treatment at this point. Full recovery of this adverse event is pending.

Pfizer-BioNTech COVID-19 Vaccine EUA: Patient reports dizziness, lightheadedness, and mild skin reaction (redness) at injection site soon after receiving vaccination. No respiratory or gastrointestinal symptoms reported. No loss of consciousness reported. Initial vital signs: blood pressure 141/72 mmHg, pulse 121 beats per minute, respiratory rate 24 breaths per minute, oxygen saturation 98% on room air. Repeat vital signs a few minutes later: pulse 105 beats per minute, respiratory rate 20 breaths per minute, oxygen saturation 94% on room air. Juice, snack, and ice pack provided. Vaccine administration site cleaned and patient monitored for one hour after vaccine administration and symptoms resolved. Patient left ambulatory in stable condition.

Headache several hours after injection with mild shortness of breath. I felt warm but did not seem to have an elevated temperature. Sore muscles and tired.

Headache, mild pain at injection site, lymphadenopathy, fatigue, nausea, malaise

Immediately after receiving the vaccine tongue felt fuzzy/a little swollen. Also lightheaded, dizzy, eyes not focusing very well. After 10-15 minutes, eyes focusing better but still lightheaded. ~1 hour later noted swelling of uvula, posterior palatal arches, tongue, neck, face, lips, intermittent wheezing. In addition the next day headache and rash started. Now day 9 with continued intermittent severe swelling, wheezing, rash and headache and some level of oral and facial swelling every day as noted above. Muscle aches started on day 8. Consulted with angioedema specialist; he felt was allergic reaction due to onset of symptoms. Had telemedicine visit with NP on 12/23/20. Had to go to Emergency Department on 12/25/20 for severe uvula, posterior palatal arch, face, lip, neck swelling unresponsive to oral Benadryl and oral steroids.

Severe fatigue, nausea, lightheaded, almost blacking out, eyes getting fuzzy/black around edges, fever 101.5 F, severe arm pain, swollen arm at injection site, chills, slept the whole day after getting the vaccine, rapid heart rate, excessive thirst. Most symptoms resolved by 12/25/20.

Migraine/headache, chills, nauseous/vomiting, body ache,l

Initially, lump and tenderness at injection site, which dissipated within 3 days. Chills, sweats, muscle pain, lightheadedness, headache began 3-4 days following vaccine and lasted approximately 3 full days

Oral ulcers on my looking like Aphthous ulcers with similar ulcer on my urethral meatus 24h after taking my vaccine

Moderna COVID-19 Vaccine EUA Afternoon after receiving the vaccine on 12/22/20, developed arm pain at injection site, 'can't keep eyes open' fatigue and sore throat. 12/23/20 symptoms were continued arm pain, manageable fatigue, and worsening sore throat with new drainage and sinus pressure. 12/24/20 arm pain noted to be much improved as with fatigue & sorethroat- sinus issues worsening. 12/25/20 sinus issues continuing but less severe. No fever at any time during past 3 days.

C8 distribution numbness directly after inject. 4th and 5th digits of hand on injection side felt like tight rubber bands at base of digits, improved with benadryl and dexamethasone). C8 sx followed by 35 min later abrupt onset central facial numbness (felt as if I had received dental block, and lip swelling Mild but noticeable (upper lip more than lower), per ED attending also some blotchy red areas, not hives on the neck same side as injection. No shortness of breath or swallowing difficulties. Bp higher than base line and slightly tachycardia compared to baseline. Treated with benadryl and dexamethasone . Facial symptoms lasted over night took additional 10 mg of prednisone, with improvement over the course of the day.

2 hours after vaccine sudden onset burning and cramping abdominal pain with cold sweat, generalized weakness, lightheadedness and flushed sensation required lying flat for 30 minutes before started improving. Day after vaccine arm moderately painful and hot, generalized headache, occasional sweats. Two days after mild generalized headache, arm mildly sore. Sweats less frequent.

Swelling in the injection site of 0.5 cm, hardness, Redness, Muscle pain for 3 days, Headache,

Injection received at 1330 on 12/24/20. Localized reaction about 2 hours after. By 2000 hours same day, severe muscle aches and joint pain. Nausea and vomiting at 2330 same day. Fever of 101.6, controlled with Tylenol but requires regular redosing. Chills and headache.

Severe swelling, erythema pain at at injection x for first 4 days Headache, first day. Day two fever, body aches started. Third day joint aches, cough, congestion, sore throat started and continue today.

Body/joint ache 18hrs post inj, slight fever 99.2 , 24 hrs later, w/ chills, dull headache, increased heart rate, pressure/heaviness around sternum, cough, tired. Feels like covid! Some dizziness when moving around

Rash to bilateral deltoids for 3 days, slightly itchy, felt like sunburn

I was very tired during the day. More so, as the day went on. Sometimes, I am tired during the day. It was only obvious that this might be a side effect later in the day. 1-2 cm blisters at antecubital site on left arm, which was the extremity of vaccine injection. My neck was sore. At first, I thought I had just slept so long that first night, that I was sore from that. It was more sore than from an odd sleeping position. My left neck/trapezius muscle at insertion in neck.

Received shot at 12:30 PM. Started feeling really tired about 8:30 PM. Severe body aches and chills at 9:30 PM. Wearing layers under blankets and teeth chattering. Started getting a headache. Took Aleve 440 mg at 11:00 PM, did not help. Sleep at midnight, woke at 2:30 freezing and very achy. Woke again at 0630 same symptoms, woke again at 11:00 AM, severe aches, headache, but being so cold was subsiding. Highest temp I had during this was 99.7, so not bad. Felt tired and very achy all day Thursday arm is red and have other red areas now on that arm that are hot and painful, no more chilling. Just feeling tired Friday and still have the red spots on the arm by the injection site. Aches and headache subsided. I still had a post Covid cough and palpitations when I received the vaccine.

Paresthesias, gait disturbance, vision disturbance

I am an RN and I received the Covid Vaccine on Friday, felt some expected fatigue and arm soreness on Saturday, but woke up Sunday for my shift with a dry throat and hoarse voice that progressive worsened that day. I got a Covid PCR swab Monday morning at 0900 and made an appointment to see my doctor that afternoon. At my appointment I had almost lost my voice, had some nasal drainage, slight sore throat, fatigue, and she felt I had decreased lunch sounds that warranted all abs and a chest X-ray. I was swabbed for strep, Flu A & B, and Covid antigen testing was done. All were negative. The CBC was mostly within normal limits. The chest X-ray show inflammatory process, a possible beginning pneumonia, and stranding. She prescribed a ZPak. I received a negative COVID PCR test result on Wednesday. I reported to my employee health nurse at my faculties where I work and received the vaccine and she asked me to fill out a VAERS report. Licensed provider note states ?December 21, 2020 To whom it may concern, This is a note to confirm that patient was seen in my office today for a doctors appointment. Patient was seen in office today, x-rays were taken, does as symptoms consistent with bilateral bronchitis, pre pneumonia right side of concern this started with the COVID vaccine. ?

developed a pruritic red burning rash on hands and arms 1 hour and 23 minutes after Pfizer covid vaccine. Itching all over and mild itchiness of throat. Had premeditated with 10mg zyrtec. Upon reaction took additional 10mg zyrtec and prednisone 10mg. symptoms resolve in 4 hours

Within 10 minutes lips were tingling and small hives on roof of mouth (1635). After 30 minute evaluation I left since I thought it might be anxiety or Placebo. Took 2 Benadryl. At 1830 decided I needed to go to the ER since symptoms were worsening. Tongue swelling, hives on roof of mouth getting larger in size and increasing surface area, larger hives on inside of mouth, lips noticeably swelling to those who didn?t know me, lips tingling, face itchy and discolored, getting harder to breathe to the point of being painful to swallow and talk. In the ER they have me a epinephrine shot in my left thigh and a intravenous dose of steroids in right arm. Observed for roughly 2-2.5 hours then sent home. Have a Rx for prednisone (3 20mg tablets for next 5 days) and instructions to contact allergist/ immunologist within 10 days. To date (12/25) symptoms are: still swollen lips although not as large, itchy face/ neck, sores on inside of mouth, throat still sore but can safely talk and eat without problems.

12/22 - Extreme fatigue 12/23 - Arm pain and swelling at the injection site, Feverish feeling but no actual fever

Hives and scratchy throat

Moderate full body myalgias and low grade fever 100.2 approximately 20 hours later. Resolved spontaneously by 48 hours.

2 days after receiving the injection I noticed a large amount of swelling under my left arm. It is tender and about the size of 2 golf balls. I have had COVID 19 in June and had antibodies in July and October during my blood tests.

24 hours after receiving the vaccine, patient discovered a rash approximately 1/2 inch in width extending from the left corner of their mouth to about halfway down their neck (approximately 5 inches in length). The rash was washed with cool water and soap, and monitored.

Slight weakness/tiredness, muscle soreness, low grade fever, general feeling unwell

20 minutes post vaccine to approximately 1 hour post vaccine: hot flushing from chest up to face. Flushing felt like nose and cheeks were numb. 12 hours post vaccine: left upper arm (injection site) with not only muscle soreness but arm was difficult to lift. 27 hours post vaccine: sudden onset of diarrhea (only 1 episode)

irritation an inch below the injection site. the size of a silver dollar. seems to be increasing size.

"WITHIN 5-10 MINUTES OF GETTING THE VACCINE. I STARTED FEELING LIGHTHEADED WHILE SITTING ON A CHAIR. I FELT LIKE I NEEDED TO LIE DOWN AND PUT MY FEET UP BECAUSE I FELT LIKE MY BP IS GOING UP. I TOLD SOMEBODY AND A NURSE CAME WITH A CRASH CART. I TOLD THE NURSE IF SHE COULD CHECK MY BP BECAUSE I COULD FEEL IT GETTING HIGH (I CAN TELL IF MY BP IS HIGH BECAUSE I TAKE BP MEDS FOR MY HTN.) I TRIED TO TAKE A DEP BREATH TO CALM MYSELF. NEXT THING I KNEW, A

NASAL CANNULA WAS PLACED ON MY NARES. I FELT TACHYCARDIC, AND STARTED TO FEEL PALPITATIONS CREEPING UP MY NECK AND CHEST. THEY DID AN EKG AND FS BLOOD SUGAR ON ME. I HEARD SOMEBODY SAID, 'HER BP IS 200!"". THE DOCTORS AND NURSES WERE STARING AT ME TO ASSES ME FOR ANAPHYLACTIC REACTIONS. I SAID ""I DONT THINK IT'S ANAPHYLACTIC REACTIONS"". A DOCTOR TOLD ME THAT THEY ARE BRINGING ME TO THE ED FOR FURTHER OBSERVATION. ON THE SECOND DAY POST-VACCINATION, I FELT SO TIRED, FEVERISH AND IT'S LIKE I HAD A HANGOVER."

extreme soreness and swelling at injection site, followed by soreness and tenderness up same side of neck

Sores on tongue Fatigue Diarrhea 6 days after shot

On 12/24 I started having muscle twitching in my back, shoulders, eyes and my mouth are felt drawn up. It subsided after about 15 minutes. On 12/25 the same thing happened, bit twitching muscles also affected my arms and hands. It lasted about 35 minutes.

I was at work (I am emergency doc) on the day following the vaccine. That day I woke up with some pain only at palpation of the right deltoid muscle at the site of the injection. At about 1p, I began to feel cold and soon after that my teeth began to chatter and I began to have rigors. I continued to work and left at 330p, as usual. I reached home at about 430p and took my temperature: 102.2F. I took 1000mg acetaminophen and 600mg ibuprofen. At that time I had stopped shivering. I had dinner without problems and went to bed at approx. 1000p, repeating the dose of both meds. I woke up at 5 the following morning and reached to work by 0700a. Symptoms did not reoccur. Deltoid pain was gone by morning as well. I rationalized the event as a boost reaction, as I had Covid-19 in July 2020.

Feeling that something was wrong, headache, racing heart beat, short of breath, dizziness, weakness, inability to stand, hot then cold, shaking, chills,

Fast Heart Rate of 107 24 hours after vaccination; sluggishness

Mild anaphylaxis with angioedema of the tongue within minutes of injection.

1-day post-vaccination, injection site swollen, raised circle about 1.5 inches in diameter, warm to touch. No past reactions to other vaccines.

Intermittent Abdominal cramping on 23rd and 24th. Diarrhea on 25th at night. I?m usual sensitive like this to some antibiotics. Feels similar.

Began experiencing pain in left arm shortly after injection, approximately 12 noon. Pain continued to worsen throughout day. Unable to move arm without severe pain by 5 pm same day. Began taking liquid advil gels approx 9 pm on the same day. . Pain continued throughout night. At approximately 10 pm I called the VAERS toll-free number to report this problem. I left a message and have received no return call as of yet. I have been taking 400 mg liquid advil gels every 4 to 6 hours since. I placed a call to my primary physician on December 25th. I was told this was a common reaction and to take Ibuprofen for pain. I am writing this approx 2:30 am on Saturday December 26th and pain has not subsided.

First and second night rigors, full body cramps. At 30 hrs ageusia following an exercise run with severe knee pain. Dry mouth starting at 48 hours. Chills continue 3 days later. No resp symptoms. Afebrile. Going on 4 days and symptoms continue

"FELT FLUSHED, ""TINGLY"" AND HER THROAT ITCHED"

Itching, urticarial rash, mild shortness of breath, headache, mild nausea.

Right arm is painful with a rash and redness in the area. There is also pain from the elbow to the shoulder. Pain especially with lifting my right arm or lifting something with right arm.

"Headache like I experienced with Covid, painful hips/back like I experienced with Covid - both only on 12/20/2020. I took Ibuprofen. My arm was sore at the injection site and it still is sore 12/22/2020. A small area around the site of the injection became red on 12/20/2020 and the red area continues to grow on 12/22/2020. What was the size of a thumb nail on 12/21 has grown to about 2"" long by 1"" wide."

Dizziness,Nausea, and Tense

low grade fever 99.3, fatigue, achiness, headache, congestion

Patient c/o of overall warm, tingly rush through her body, feeling shaky. Denies difficulty breathing or any other symptoms. BP 133/98, HR 95, O2 100%; BP rechecked after a few minutes, 116/81. POC 114. Reports feeling better right away and returned to monitoring area to be observed for 30 minutes.

fever to 100.8 around 1pm on 12/25, lasted for 1-2 hours.

Developed large hives on face, returned back to clinic. They gave me two doses of 25g Benadryl liquid. Vitals were taken. BP was 170-180/1-teens, pulse between 100-120. Was observed and hypertensive emergency remained, was then sent by ambulance to ED. Treatment given there was liquid Decadron.

RIGHT UPPER ARM STRTED FORMING A REDDENED AREA SATURDAY 12/19/2020. AREA KEPT GETTING BIGGER SITE MORE PAINFUL. tUESDAY 12/22/2020 RIGHT UPPER ARM HAD GRPE SIZE HARD AREA WARM TO TOUCH, VERY TENDER. DR EVALUATED, PLACED ME ON ANTIBIOTICS FOR 10 DAYS. WAS INSTRUCTED TO CALL AND SEE HIM IF ANY CHANGES/ WORSENING OF THE AREA.

Localized raised, reddened area. Warm and tender to touch. Took Benadryl-did not remedy the area but no worse. No systemic reaction. No further swelling of arm I have reacted this way to previous vaccines (tetanus being worse than this one. ----

I had bodyaches, fever of 101.4, nausea, chills, headache that started at 2230 on 12/24/2020. Tylenol was taken and fever continued to increase. Hip joint is stiff and walking is difficult.

Moderna COVID-19 Vaccine EUA Severe body chills(started at 7pm to 10am)) body aches (8pm to 10am)) headache (10pm to 8pm next night) Lethargy 10pm to present)

fatigue nausea vomitting

single episode of diarrhea 20 minute after vaccine administration, no other systemic symptoms, no other complaints or concerns

Stomach cramps, fatigue, diarrhea.

Feeling hot, redness

Dizziness. Lightheadedness. Fever (100.1)

Hypertension, hives on chest, arms and torso, sweating. 50 mg Benadryl administered

Day 2 post vaccination: Tinnitus. Ringing in ears, ears feeling plugged, hearing diminished, and every sound seems to echo around me.

Got covid vaccine around 0745, Driving home from hospital, felt like throat was warm and closing, heart racing and shakey, pulled over call 911 at 0816 and ambulance arrived. Blood pressure was elevated, symptoms subsided and took Benadryl. Minor tingling in throat post- event.

red, hard, painful, raised, warm area at injection site measuring 8cm x 5cm five days after injection

Approx 10 hours after receiving vaccine began feeling nauseous with headache that worsened. Followed by high fever of 102 came down to 100 with use of ibprofuen. Fever was on and off for another 12 hours fever and headache/body aches resolved by 3 pm on 12/25/20

Sharp pain in left arm shortly after injection with ROM of shoulder. Pain progressively worse over the next 48 hours to 5/10 at rest and 8-9/10 with ROM. Unable to work as scheduled as a OT for patient safety reasons due to limitations of left arm use.

I began to have itchiness on my eye lids, around my eyes, and on my neck. I took 2 Benadryl and went to sleep. Today, I continue to have itchy eye lids as well as some itchiness around my chin although that is less severe than my eye lids. I have no rash nor do I feel this possible reaction requires any immediate attention.

Woke up the morning of 12/24/20 and had Developed raised red rash with itching to right shoulder, chest and arm down to the hand. Rash only developed on The right side, did not move down to abdomen or legs at all. Also developed blister in the mouth only on the right side on the roof of the mouth. Took Benadryl and applied cortisone cream topically to rash. At this time 12/26 0800 most of the task has resolved only remaining in on the back of the right hand and wrist and the blisters in the mouth remain.

Patient had a syncopal episode after receiving her first dose of the COVID-19 vaccine.

lLeft arm was warm them whole body got warm. Heart Racing Broke out in hives

Vomiting w/o nausea. Chills

myalgia, chills and drenching sweats

Sore throat, fever , tested positive for covid

Experienced mild bloating, mild abdominal cramping, hyperactive bowel sounds, mild diarrhea, and mild nausea starting at 0130 on 12/23, with the worse of it 12/23, improving on 12/24, and resolved by 12/25. Symptoms were improved with over the counter gas medicine.

Numbness and tingling of face unilateral on same side as injection, nerve like pain shooting thru neck, followed with bilateral reynauds of hands and feet. Started within 15 min on injection side and was bilateral within one hour.

I got the vaccine on Tuesday, on Wednesday night In the middle of the night, I had extreme leg cramps, more severe than I have had before in both legs. I got nauseous and vomited, not sure if due to pain or a reaction. I took potassium and drank more water the next day. Again, I Thursday nIght, I had another EXTREME episode. Felt my whole body was cramping. It lasted about 5 to 10 minutes. I drank a lot again, took several vitamins, potassium and one gabapentin on Friday night. I did not have an episode on Friday night. I am not sure if this is related to vaccine but felt the need to report as I suspect somehow my electrolytes were affected.

I began feeling short of breath, heart palpitations, and dizziness. It felt the same as my reactions to bee stings and fire ant bites. This lasted about 10 minutes and started to subside on it's own. Then, I was also given 25 mg of benadryl by mouth. Within about 30 minutes I was feeling back to normal.

Body aches, fever, headache, sore throat, coughing, congestion, no taste, loss of appetite.

12/23 body aches - generalized all over, just don't feel well. 12/24 body aches, just don't feel well. 12/25 body aches, just don't feel well, skin on back feels itchy and burning - nothing is reliving it. 12/26 body aches, just don't feel well, skin on back feels itchy and burning - difficulty sleeping/getting comfortable.

Low grade fever, muscle soreness, chills, headache, disorientation, confusion

Nausea

Received Moderna COVID vaccination on 12/25/20 at 7:50am. Felt fine with vaccine and immediate period. woke up with pain in arm 1900. Upset stomach 3am. Vomited. Presented to COVID vaccination clinic at 9am. Headache on left side of head, nausea, malaise, achy. Tingling down left arm and into hand. Swelling at the site. Red skin size of a dime at injection site. Reports she worked last night 2300-7am. No fever. Iced the arm. Took Aleve.

Fever up to 100.8, treated with ibuprofen, body aches.

Sore arm about 4 hours after receiving vaccine. Next morning: woke up feeling fatigued and had 3 bouts of diarrhea in total (each time after eating).

Diarrhea, onset about 12-16 hours post dose. Multiple times for roughly 24 hours. Self limiting, not requiring any treatment beyond oral fluids. Injection arm soreness, swelling and small contusion,

starting about 8-12 post dose lasting for 48-72 hours. Self limiting did not require any treatment. Fatigue, developed within 18-24 hours post injection. Self limiting not requiring any treatment.

lightheaded, sweaty, and nausea. Past hx of vasovagal reactions to needles

12/26/2020 Generalized body urticaria/rash, itchy, Fever 100.9¦, headache, GI s/s, Sore arm 12/25/2020 2pm-nighttime Fever 101.1¦ (continued throughout evening), GI s/s, fatigue , Sore arm/shoulder 12/24/2020 7pm Scalp Itch, Sore Arm

Immediate: arm numbness and tachycardia Day 1: injection site swelling swollen, tender, red, and warm; myalgias; occipital headache; general malaise Day 2 & 3: injection site swelling swollen, tender, red, and warm (still ongoing)

intial light headedness. spotty vision and fatigue. Patient felt like they were going to faint. Vitals were taken and patient had elevated HR, and 90% O2. Resolved in 60 seconds from initial response. Patient was observed for 30 minutes post vaccination

severe myalgias, joint pain, bone pain, chills - lasting from hour 15 after vaccination till hour 45; associated with severe fatigue . slept all day on 12/24. took tylenol and ibuprofen every 4-5 hours. 80 % resolution of symptoms by hour 48. complete resolution of symptoms in 72 hours.

16 hours after injection- (6 am) and lasting 10 hours Nausea Vomiting Dry heaves Cold sweats Headache Fatigue Muscle aches

Chills fever over 102f headache cough body pain weakness 48 hours

12/24- bad headache 12/25 bad headache, sore throat, swollen lymph nodes, fever 101.6, chills, nausea 12/26 headache, temp 99.5, sore throat

On the 19 had a horrible headache and then at about the 24 hour mark I had really bad left ear pain almost like an ear infection but worse this lasted about 24 hrs then I felt like crap for 2 more days

LIGHTHEADEDNESS, HEART PALPITATIONS, SHORTNESS OF BREATH, FELT FAINT

Right side of face felt hot and slightly numb. Continued to persist for several hours. Appeared slightly puffy on right side. Muscles on right side of face felt stiff when moving them. Symptoms seemed to resolve but the next morning but returned around 1pm on 12/25. Additionally I noticed slight dropping in my face on the right side of my face.

Patient developed symptoms early the next morning after the Covid vaccine. Started with fever 102.8 and body aches. had fever for 5 days. Extreme low energy for 8 days and continuing. Headaches everyday. cough for the last 2 days. no SOB, no N/V D, no Sore throat, no nasal congestion. no loss of taste and smell. not pregnant.

Shaking chills, sweats, fever

complains of heart racing. Had patient site down checked bp 151/92 and pulse now 72. Patient reported heart rate no longer racing and has history of high BP

Body aches that started within 24 hours Low grade fever tmax 100.3 started late on the 25th and today.

Rapid onset of hoarseness, throat tingling and tightness

diaphoretic, shaky, nausea (transient)

dizziness resolved within 20 minutes

Chills, joint pain with redness and swelling, fever. Fever ranged from 99 to 101.7. Left foot pain causing issue walking for 24 hours, both elbows pain right shoulder. Right hand thumb, index finger and middle finger red and severely swollen. Fever continued off and on from 12 22 to 12-25 as of date. As of 12/25 pm, had episode again of chills, fever up to 100.1 again and left foot started hurting again.

Complains of heart racing. Had her sit down pulse 100 and BP 161/96 at 1120. At 1123 BP 161/96. At 1125 pulse 64 and bp 144/93 and states heart not racing and I feel better

Swollen armpit

Sneezing -12 hours, runny nose- 24 hours, mild cough 24 hours, fatigue for 36 hours, mild headache12 hours, muscle aches. Used OTC multi symptom cold medicine and Allegra.

Really bad reflux all day two days later (I don't get reflux unless I am pregnant, and it's been close to 4 years). Then the next day I had a really bad pain in my chest which occurred every time I swallowed. Was told this was probably an ulcer (I've never had one of these before).

Generalized rash

Injection Site Reactions included: pain, tenderness and swelling of the lymph nodes in the same arm of the injection (left arm) and hardness and some swelling around injection area of said left arm. Started on Wednesday, December 23, 2020 at approximately 5;30 pm and is still ongoing as of December 26, 2020 at time of this report. General Side Effects: Fatigue: Started on Wednesday, December 23, 2020 at approximately 5:30 pm and is still ongoing Muscle Pain, Joint Pain, Chills and Nausea: Started on Wednesday, December 23, 2020 at approximately 5:30 pm and subsided on December 25 at approximately 6 am. headaches and sporadic fevers: Started on Wednesday, December 23, 2020 at approximately 5:30 pm and is still ongoing - taking ibuprofen to keep fever and headaches down.

extreme dizziness a couple hours following the vaccine, headache for around 36 hours, weakness for 36 hours,

Headache, nausea, dizziness, dehydration, weakness, shaking

On 12/25 woke up with chills, body aches ,no appetite, mild nausea & extremely tired. Low grade fever 99.2. Only had orange juice to keep my blood sugar up. I have Type 1 Diabetes. Felt this way all day until I went to bed. Woke up today 12/26 feeling fine

Vomiting 1 week post injection followed by headache lasting 2 days

i developed mild cough at first, then fever and chills and body aches on the 2nd day up to present. I am taking tylenol fort he fever and Mucinex for coughing. Also Albuterol Breathing treatment Q 6 hours PRN Also the high temp and humidity of my CPAP at night helps

15 seconds after administration I felt tingling in my mouth and felt warmth come over my body from my feet to my head. I then experienced a sudden increase in heart rate. I was tachycardia to the 140s and BP 140/90s (high for me). This lasted for about 1 hour then resolved. The same event occurred 3 additional times, resolving in between episodes with a heart rate in the low 100s.. I was taken to my workplace Emergency Department. The entire even lasted over 4 hours.

Experienced numbness and tingling unilaterally to one side of face. Began 45 minutes after vaccination and lasted 4 hours.

Headache similar to migraine in location and intensity, first day of vaccine and every day since receiving vaccine. Nausea the day after the vaccine No appetite every day since receiving vaccine

At 72 hr marl I began having nausea and intermittent vomiting. Voming has subsided but nausea is persistent to the pint ive taken zofran many times.

Approximately 5 days later I began having symptoms which then developed into a shingles rash on the 7th day after receiving the vaccine. I wanted to report this to see if others had the same experience.

headache, upset stomach

Itching with redness and raised welts beginning 36 hours post injection, starting bilateral inner thighs and ascending bilaterally along groins, flanks, axilla, to arms and hands over a 36 hour period.

Fatigue, chills, fever, joint pain and pain at injection site

12/18 afternoon: asthma attack. This was the same as previous asthma attacks and occurred after my normal triggers (exercise in cold air). Symptoms resolved completely with albuterol. I was coughing continuously and strenuously for about 10 min before using albuterol. 12/18 evening: low-grade fever (100.1 F, baseline is <98) with chills. Also with altered mental status/delirium, which is typical for me while febrile. There was also nausea. 12/19: fever decreased to 99.2 F with normal mental status. New general malaise, worsened nausea. Single episode of vomiting, large volume of bile with some blood (streaks of fresh blood, larger volume of coffee grounds emesis mixed with bile). After vomiting I noted tachycardia to 130s--140s but this is a typical finding for me post-vomiting. 12/20: No further vomiting. Subsequent 2 bowel movements with moderate melena, since resolved. Fatigue and cold extremities, improving.

Within minutes of receiving first dose of Moderna COVID-19 vaccine, patient became lightheaded and pale, developed clammy skin, and was confused. He was assisted to a supine position with his feet elevated while his vitals were checked. His symptoms rapidly resolved in this position, and he was noted

to have the following vitals: P: 60; BP: 118/68; O2 Sats: 98% on room air. He remained supine for ~15 minutes and then was able to sit and ultimately stand without return of symptoms. He was monitored for 30 more minutes during which time he remained asymptomatic and was able to tolerate eating and drinking without difficulty. He was released to home with advice to seek immediate evalution for any symptoms.

"After injection patient reported feeling dizzy and ""woozy"". Patient states he is very anxious and nervous about injection today. Patient was assisted to floor x 2 assist with RN and Dr. and feet put up. BP 94/51 HR 90. Patient reported feeling nauseous initially. Patient responsed well to supine position. He requested a drink of water and reports he has not eaten today. Patient remained alert during the entire episode. Repeat BP at 1225 116/72. Patient was offered water with gramham crackers to eat, okay per Dr. Patient was assisted to a sitting position on the floor. Color improved, cheeks pink and patient appears in no distress. Patient was assisted to standing position at 12:30, reports no dizzy or light headedness and repeat BP 130/80 HR 74. Patient was assisted to the observation area with 1 assist. He will continue in observation area for 30mins."

Anxiety and slight shortness of breath that didn?t interrupt my sleep. I used my regular inhaler as scheduled. I felt better the next morning. Just arm soreness.

Full body hives beginning about 36 hours after vaccination. Angioedema in the hands, feet, and lips beginning about 48 hours after vaccination. Hives did not improve with Benadryl so doctor prescribed prednisone. No severe reaction such as anaphylaxis, but reaction was moderate enough to make daily life difficult.

Urticaria rash on bilateral arms and abdomen

Day off sensation going up my left arm to my head Headache dizzy lightheadedness and nausea almost fainting. Bp 115/70 hr 80. Tylenol helped with headache but head still felt heavy. 1st day Chills and extreme fatigue 2nd day fatigue nausea 3rd day fatigue nausea severe headache ?exploding? after getting up from picking up toys off the grown blood pressure 90/60 .

The day after I got my vaccine (a Thursday) my arm hurt really bad, and my body aches started as soon as I woke up, but were not severe. As the day progressed, the body aches got more severe and were accompanied by a headache and fever by around 7 PM. I literally felt like I was dying, and have never had body aches that bad before in my life. I laid on my couch and didn't move until 11 PM, with no apetite, and then went to bed. The day after that, when I woke up the body aches weren't as bad, and my temp was 98.8. Again, around 3 the body aches started getting worse, I was so tired I could barely function, couldn't eat without being nauseous, and laid in bed as still as possible until I could fall asleep. The Saturday following my vaccine, I woke up at 6 and my body hurt so bad it felt like I couldn't move, my head was so bad even the light from the shades felt like it was piercing me, and I still had no apetite. I stayed in bed until 10 until the body aches got a little better, and was able to go about my day almost as normal, just with my body feeling kind of like I slipped and fell on ice. On Sunday, I still had no apetite and was nauseous without even eating. My body still ached, but I was able to do things like the dishes and just hang out at home. My headache was still unbearable. I called the hotline number for my

hospital that was given to me when I got my vaccine, and they scheduled a COVID nasal swab test at 1. I put on sunglasses to drive the 10 minutes to the clinic, got my test, and went home and went to bed. Since I had a COVID test ordered by my employer, I wasn't allowed to work until I got the results and HR cleared me. The results were negative, and I didn't get cleared by HR until Monday morning. When I contacted my supervisor, he wanted me to stay home anyway since the body aches (even though they were getting better), fatigue, headache and nausea were still there, regardless of a negative covid test. He was worried I had the flu. I made an appointment with my primary care doctor for 2:10 on Monday, and he told me it was just serum sickness. I went home and went to bed. My body aches and fatigue fully went away by Wednesday, and my headache still remains, on the following Saturday. I haven't had a headache in maybe 5 years.

Patient received vaccine around 4:15pm on 12/24/20. Around 11pm he was feeling extremely tired, however, patient had been working very hard the week leading up to Christmas. Patient woke up in the early hours of the morning with chills and very fatigued. Chills and fatigue remained on and off through out the day and the patient realized he was running a temperature of 102.8 at some point during the day. Patient stayed at home and rested and took Ibuprofen and eventually started feeling better towards the evening and night. However, the fatigue still remains on 12/26/20.

Initially very mild tingling to nose and lips. Then in ED, BP 170s/110s. Then about 1 hour and 10-15 minutes later had rash start to pop up on random areas of my face. Then next morning with sore throat and rash around the next about 21-22 hours after the vaccine

Bodyaches, weakness, bone pain, lethergy, brain fog

Moderate soreness at injection site.

Moderna COVID-19 Vaccine EUA Severe teeth chattering chills, body aches, muscle & bone pain, temperature 99-101. Diaphoresis, Dizziness, Nausea, Vomiting & Diarrhea lasting 48 hours. Severe body aches, muscle & bone pain persisted.

12/18/2020 I HAD A LOT OF BODY, MUSCLE AND JOINT PAIN. THIS LASTED ALL DAY 9:00 AM - 9PM. I WENT HOME AT 5 AND WENT TO SLEEP FOR 90 MINUTES. SYMPTOMS WERE MILDER. I STARTED TO NOTICE L UNDER ARM PAIN, INTENSIFIED OVER THE WEEKEND. 12/21/2020 CONTACTED PCP; LYMPHNODES SWELLING. PAIN LASTED UNTIL 12/22/2020, LATER EVENING THRU 12/23/2020 12/25-/12/26 NO PAIN TELECHAT WITH PCP NOT VISIT; DR PRESCRIBED TYLENOL

12/23/20 0850 Stinging/burning at injection site right arm; 2000 entire arm right burning and feeling of sunburn across chest down to liver then to left flank and entire back; 12/23 2300 generalized joint pain; 12/24/20 0830 101.3, 1030p 100.6; Friday 12/25/2020 1030am 100.1; 5pm 99.3; Vomited 830p;11pm 101.3 Saturday 12/26/2020 1pm 100.0

C/O of tachycardia, dizziness 20 minutes post vaccine, placed on monitor. HR 80-100, B/P 157/102, SaO2 100%. Progressed to SOB & HR 174 @ 25min post vaccination. Epi auto injector 0.3mg IM x1 given,

called emergency response. Patient awake, alert, oriented x3. Verbalized improvement in SOB after epinephrine, taken to ED via wheelchair.

Patient had fever and malaise that lasted 48 hours

Flush feeling through entire body within 10 min with dizziness associated. Numbness of bilateral hands and feet as well as lips. Rise in Bp up to 150/100. Red, blotchy neck. Within hour, dizziness subsided, but numbness of extremities and lips lasted approximately 10 hours.

12/23/20 0000AM constipated like symptoms started; 0200AM woke up to severe stomach discomfort with refluxing feelings with body chills; 0300AM had bouts (at least4) of violent vomiting with very thin, liquid greenish vomitus, vomiting lasted for about 20 minutes then followed by loose bowel movements consecutively (about 6 times) with very liquid, greenish stools; stomach discomfort somewhat subsided right after but body chills remain and joints and back started to ache. Noticed that exposure to cold air would trigger bowel movement. Was afebrile all this time until about 1100AM where it was recorded to be mildly febrile at 37.8, took some tylenol with gatorade after which mild fever seem to subside. For much of the day of 12/24/20, body aches continues with intermittent loose bowel (especially after eating or drinking anything)still averse to cold, took some tylenol again 6 hrs. later for the body aches mostly. 12/25/20 felt much better for most of the day then at 1100PM reflux symptoms and body aches started again but no vomiting this time, still afebrile. 12/26/20 at the time of this reporting, stomach still feels queasy and still having loose bowel and body aches. No other symptoms experienced except for the ones described above.

Vaccination administration error - equipment syringe failure. While giving the shot, the cap (needle part) of the syringe came off. Nurse vaccinator stated that patient likely received 0.3mL or 0.4mL of the dose (full dose is 0.5mL). The remaining dose was pushed out of the syringe, so unable to see how much of dose was remaining that did not get into the patient. The patient displayed no signs and symptoms at time of this error. We called Moderna manufacturer after error occurred, while patient was still waiting in the room. Moderna Medical information stated that they do not have any recommendations outside of the information published to providers and to wait for call back from their experts regarding next steps. Patient was observed for recommended amount of time and then left the facility. We'll contact her if anything is needed besides the second dose that is scheduled in 4 weeks in order to complete the vaccination series.

Local site reaction: erythema, hard welt, warm to touch, burning at injection site at time of injection. Erythema grew over next 48hrs to a max of 2inches, warm, hard to touch with persistent burning. Resolved 12/25/2020. Beginning at 4:00pm 12/22/2020 generalized body, muscle, and joint pain, increased generalized neuropathy pain and generalized sensitivity to touch. Symptoms resolving 12/26/2020 at 10:00am.

Fever, body aches,

Left supraclavicular lymphadenopathy

Injection given on 12/21/20 at 0830 - Injection site pain noted for 12 hours. 12/22/20, tiredness, nausea, swollen lymph nodes noted and continued through 12/23/20. All side effects resolved by 12/24/20.

Extreme soreness at site of injection that has continued into third day. Pain worst the second day and is waning, but use of arm is still painful. Experienced lightheadedness shortly after injection, but with no bad effects. Like being high. Painful body aches began at end of day of injection and continued for 36 hours, with highest intensity after 24 hours. Body aches diminishing on third day, but arm soreness still quite evident

tingling, dizziness, tunnel vision, nausea

"I have been experiencing overall of ""being unwell"" including intermittent palpitations, nausea, lower GI upset/cramping, dizziness, fatigue, chills, low grade temp of 99.5 F, right sided neck pain, and Headache. Treatments: Tylenol PRN, and PRN Zofran Outcome: ongoing"

Very sore , swollen , red arm below injection site. Headache and chills for 24hrs

I received the shot at 7pm on the 23rd, when i woke up on the 24th i had some soreness around the site but I felt fine otherwise, around 10am on the 24th, I started by first having chills then feeling flushed, I started to have severe muscle and joint aching, headache and body sweats. my fever got up to 103. I was taking tylenol and ibuprofen about every 4-6 hours. this all lasted until 6am on the 25th, on the 25th i had some fatigue and headache, the night of the 25th around 10 pm i noticed a little swelling and tenderness under my left axilla and left upper chest near my collar bone. i think it is lymph node swelling or tenderness. Today is the 26th and i still have the tenderness under my arm and upper chest, but i feel better otherwise. I was told that people usually have worse side effects from the second shot, is there any reason you wouldn't get the 2nd shot??

Lip soreness 12/23 around 6p. Mild Lip swelling 0900pm and took 1000mg of acetaminophen. Severe lip swelling mainly on the left side at 0400am. Took Benadryl and 1000mg of Tylenol. Swelling went down slightly. Went to ED 12/24 around 1130AM with low grade fever of 100 F arm soreness and continued lip swelling. 12/24 at 0900p fever of 101, fatigue, aches, and lip still swollen, but less then AM-took 1000mg of Tylenol and Benadryl. 12/25 at 0500AM 102.2 fever, body aches, sever headache, night sweats, and other side of lip swollen took Benadryl and 1000mg of Tylenol. At 6 AM fever went down to 101.2. 1200pm fever of 100.5, severe head ache, muscle and joint aches, lips mildly swollen-took 100mg more of Tylenol. 6pm 101 fever, headache, and lips itchy/swollen. Benadryl taken and 1000mg of Tylenol. 1200AM fever of 100 and headache, lips sensitive-1000mg of Tylenol and Benadryl. 12/26 at 0930 AM fever broke with temp of 98.6, mild headache, lips sensitive, but minimal swelling.

*A small rash of around 10 mosquito bite size bumps appeared under left armpit and left torso only. Shot was given in left arm. There are no bumps anywhere else on body. *They do not itch, hurt, or bother me. *It has been almost 72 hours since shot and bumps still remain.

Small amount of fluid leaked at needle hub.

10 minutes after dose experienced tachycardia, dizziness shortness of breath, and flushing. It lasted about 30 minutes.

HAD FEVER TO MAX OF 101, BODY ACHES AND CHILLS AND EXTREME FATIGUE FOR ABOUT 36 HOURS AFTER INITIAL SYMPTOMS STARTED

-Arm soreness started almost immediately, worsened within 8 hours, much improved by 48 hours -Bilateral trapezius myalgia, started about 10 hours later, unrelenting with heat/massage/oil/relaxation but still able to go out with a heavy backpack and hike, about 60% improved by 48 hours

sudden onset of pain in throat, base of tongue and increase dry cough. Oxygen saturation 97% which patient reports is at her baseline, no increase work of breathing, slight dry cough x 3 but not other cough

Light headed and dizzy, funny taste(metallic taste),pins/needles in tonsil area, nausea/vomiting

Facial hives, ear ringing, happened around 1 hr and 30 min after vaccination

Patient described feeling flushed. We activated our rapid response and hooked the patient up to the monitor. The patient was observed by our ED physician and observed for ~ 30 minutes. All vitals were normal, the patient reported a Migraine for 1-2 days after.

Experienced High fever chills muscle aches and malaise

Pt had fever and headache within 1 hr. This went away about 9 pm. The next day patient was ok. On day 2 post vaccine (12/20/2020) patient woke up with lymph node swelling in his left armpit. It was about palm size. Pt took meloxicam on that day and next day. Swelling has started to decrease.

Dizziness, syncope, nausea, feeling of going to faint.

Pt stayed for 15 minute observation time and then went to the cafe to eat breakfast. Once she got in her car about 45 minutes after, she noticed her lips were swelling. Pt took 25 mg of Benadryl. She continued to have to take it q4h on day of vaccine. Over the next 2 days she started to cut back on the amount of Benadryl she was taking but lips were still swollen some. She saw her PCP on 12/21/2020 and was told to continue Benadryl as needed and to take Pepcid 20 mg daily until better.

Pt had injection site soreness the next day. On day 2 post vaccination, pt developed a golf ball size knot. Five days post vaccination, the knot is gone but injection site still sore. Pt took ibuprofen as needed and Benadryl at night.

Soreness at injection site 3/10 for 24 hrs. Soreness radiating down to elbow and up to neck and base of skull starting 3 hrs after injection lasting 11 hrs.

Headache and general fatigue

"several minutes after vaccination, complained of shortness of breath. Nurse used standing order protocol to administer epi 0.3 mg into right deltoid. Patient reports feeling a little better BEFORE the epi, but reported feeling ""strange"". Charge nurse notified the emergency department, an ED nurse advised

coming for workup in the ED (which is right down the hallway). Patient walked to ED. Appeared pale. Patient discharged from the ED with a prescription for zyrtec."

Employee had nausea lasting 2-3 hours following vaccination and malaise for the rest of the day

Blister at injection site. Skin peeled. Approximate size green pea. Red line less than an inch.

itching, fatigue

Chills, malaise, nausea, vomiting, diarrhea, currently at a total of 44 hours from symptom onset without significant improvement

Right Shoulder Muscle Soreness

Fever 100.5, shortness of breath, heart racing, wheezing, fatigue

Fever, all over body aches, severe headache and chills, all this started about 11:00PM on 12/23/2020, about 11 hours after I received the vaccine. lasted throughout the night, around 0830 the next morning, felt better, still had a headache. Had low grade fever and slightly achy (not as bad as evening before) on 12/24/2020 evening. Felt completey back to normal by morning of 12/25/2020. I tool OTC extra strength Tylenol and Advil for my symptoms.

fever 101.8, body aches , chills, back pain , cough, shortness of breath , loss of taste and smell, sore throat

Tachycardia, elevated blood pressure, tightness in throat

Body aches and pains (started at 8PM), shaking chills and really cold(1:30 AM), nauseous (1:30 AM), fever 100.5 (8:45AM and throughout the day). The next day, some coughs cause my head hurts, aches and pains, low grade fever. Treatment:aspirin and benadryl. Doing better than the day before.

nausea, cold sweat, dizziness

"Patient entered observation area and upon greeting states ""I feel something"". Patient stated ""feeling something when I swallow"" denies difficulty swalling or breathing. Patient appears comfortable, Dr. speaking with patient who reports similar episode in the past mostly after a long shift at work. Patient states she has a history of SVT and usually has this response when she gets nervous. Initial BP 165/108 HR 112 02 99%. Patient reports feeling anxious and denies all other symptoms including shortness of breath or difficulty swallowing. Repeat BP 143/92 HR 95 O2 99%. Patient offered bottled water and appears to be calm at 15:20. Repeat BP 134/94 HR 83 @ 15:30. Patient speaking on her cell phone with employer re: issues at work. Patient in no apparent distress at this time. BP 139/92 HR 89 O2 98%. Patient without complaints. Will discharge after 30 mins of observation. discharged at 15:45."

None . Just got vaccine shot today the first shot.

metallic taste headache

Period cycle is lasting more than 8 days without relief or a reduction of intensity. This is abnormal and hasn?t changed within the last 24 hours

dose 1 of vaccine at 11am 12/24/20, after vaccination I noticed some pain and burning that radiated down arm, lasted for seconds and resolved. This pain came and went throughout afternoon of 12/24. Upon waking around 730am on 12/25/20 I noticed slightly red erythematous ovoid rash that measured approx 3 in x 1 in in size, was exquisitely tender to touch, but smooth, without vesicles, pustules, non-fluctuant. Took tylenol and applied heat to area without relief of pain. Pain is burning in nature, with a soreness that radiates down the back of my upper arm. Pain worse with raising or using arm. Also have aching in neck and upper back. Also having increased fatigue and slight headache all of 12/25, worst at night and located on right side of head, throbbing. On 12.26.20 I woke and noticed rash has slightly increased from markings made on 12/25/20. I continue to feel tired, achy, with slight headache. Arm very sore and upper back very sore.

"Minutes after getting the vaccine dizziness, flushing, and racing heart present. I was taken to a back room, laid flat, cool washcloth, vitals taken. Rash began to develop on chest and spread across the body. No itchiness, but a mild burning sensation accompanying rash. Throat was hot and scratchy. Within 10 minutes taken down to the ER. Rash came and went in waves and would appear on different parts of body. Each wave had increased heartrate, dizziness, flushing, rash, burning. Was given 50mg benedryl at 10:45, oral 10mg dexamethasone, and 1L bolus of saline solution. Was monitored in ED for 4 hours. Last reaction ""wave"" experienced around 1pm. Discharged around 2pm. No reaction since discharge."

Received Moderna Vaccine at 11:36, waited 30 minutes per Dr. recommendation. Left hospital, starting driving home and felt lips tingling and bilateral sides of tongue feeling thick and words sounding thick. Return to the Vaccine clinic at the hospital in 5 mins . Escorted to the emergency dept. BP 203/95, HR 80s, O2 Sats 94% room air.

Sore throat Fever of 100.4

When I put food in my mouth around 3pm and then again around 5pm, I felt burning/tingling in my mouth which quickly resolved.

Heart rate of 159 with palpatations, tingling on the throat, (red, no hives), surface rash on throat, clear speech, clear lung sounds Local EMS was contacted at 1:17 p.m. and the patient was administered 50 mg of Diphenhydramine at 1:21 p.m. After admininstration visual signs of rash subsided, and patients status improved. Patient was handed off to Local EMS

near syncope, hypotension, nausea/vomiting, tachycardia (120-150) within 5 minutes of administration. did not resolve and worsened within 1 hour. Pt went to ER for workups. Received IV benadryl without improvement. Admitted to hospital overnight for continuous cardiac monitoring. Improved overnight and discharged in the afternoon 12/24/20.

next day mild headache (next morning) for 3 hours inflammation of the inferior lips (1 month ago i was inyected with fillers). for 2 hours

Severe injection site soreness- Start: 0100 12/23- end: 0800 12/24 Fatigue- Start: 1200 12/23- end: 0800 12/24 Nausea- Start: 1700 12/23- end 1900 12/23

Muscle aches. Chills. Fatigue. Started 2 days after the vaccine. Temp 99.4. Had Shingrix shot #2 2 weeks before the COVID shot.

Felt fine day of shot. Next day low fever 100.6 chills, tired , generalized aches rap hand joints. Now arm soreness atvi jection site and a red small rash distal to site

Went hiking in the morning of the 25th.. Got home at 1pm. At around 1;30pm started experiencing nausea and vomited 4 times. Went to bed, felt tired and nauseated but did not vomit again. By 8pm I felt much better and have had no symptoms since.

Chills, fever (101), bodyache, headache

Patient developed rash/hive 1 hours after receiving the vaccine. Patient self medicated with a dose of Benadryl when the hives started. Send to ER and was observed for 2 hours. Hives resolved in 24 hours with no further treatment.

Employee consulted with PCP regarding taking covid vaccine with a know allergy to flu vaccine preservative. PCP recommended taking covid vaccine and pre-medicating with Benadryl 50 mg 30 minutes prior to the injection. The employee followed those instructions. Thirty minutes after covid vaccine administration, employee started to lose her voice and developed some wheezing. Employee was taken to ED where she received a dose of epi and solumedrol. The employe was observed in the ED for 2 hours and symptoms were resolved at the time of discharge.

Within 5 minutes of received the vaccine employee became pale and felt faint. Employee was lowered to the floor and examined. BP 122/64, alert and oriented, HR 100. Employee stated he was nervous and had not had eated that day. Pt. received juice and a cookie. Felt better after ingestion of food. No hives, wheezing, or other symptoms of an allergic reaction.

Severe low back pain, had to take muscle relaxers and pain meds. Couldn't stand up straight and needed help with adls. I also had chills at night a day prior to back pain.

1800 Chills started. 2100 fever 100.8, hr 115, slight sob resp 28, spo2 96, achy, lost appetite Next day fever 100.5, resp 32, spo2 93, very achy, head ache, sob walking around house, bad reflux heartburn Day 3 fever 99.5, resp 28, spo2 93, same symptoms Day 4 normal temp, resp 26, spo2 95, same symptoms, now with loose stool Gradually improved but stayed very fatigued. Day

Swollen lymph nodes left side of neck, rash all over

Felt nausea and headache after receiving the vaccine. She was laid supine and had continuous blood pressure taken for 30 minutes. After that time her symptoms resolved completely.

Headache 5 days now, face flushing 1st day, face swelling 2nd day.

Bilateral lower extremity myalgias and chills lasting 3 hours.

Metallic taste after around 20 mins after the shot Muscle pain around the injection site - 20 mins after Mild headache after around 4 hours after the shot Mild headache on and of until two days after the shot Mild sore throat until two days after No treatment done

Injection site discomfort within 3 hours, increased pain day 1 & 2. Significant headache at 12 hours post-vaccine, persistent through day 3. Significant fatigue and drowsiness on day 2 (none like I've ever experienced before) - slept 18 of 24 hours. Mild on day 3. Sore throat day 3.

Her lips began to feel tingly and became swollen. She also reported a mild headache. Laid supine for about 30 minutes. After which she reports all symptoms resolved.

Fever, chills, sweating, shivers, myalgias, fatigue, headache, not feeling well in general.

Felt as though her throat was closing and fatigue. She was talking the entire time but kept clearing her throat.

this morning I noticed swelling and pain in the lymph nodes under my left arm, no redness or warmth just swelling and pain/tenderness

Felt a flushing sensation, nausea, and reported feelings of anxiety. Laid supine for 30 minutes. After which she reported a resolution of the symptoms.

Painful, extremely sore arm; stomach pain, headache, just feel generally not good

Painful and red contralateral side (right) olecranon bursitis (Ulnar Bursitis)

Vaccine given in Clinic on the 18th. No pain no issues then on 21 st started having nerves on my left leg firing during the day like I had a pinched nerve. Later that night I had lower back pain like sciatica nerve pain like 10/10 Tylenol 500 could not help added 400 md Motrin still no help got to 8/10. and also right hand finger next to the thumb was numb occasionally. I felt tightness on left hamstring area. Massaged it and all pain disappeared on the back after a while. But since that incident I have been having lower leg bil never firing and occasionally same numbness on the same finger . Today got slightly worse as seems like my right hand getting a bit more numb.

On 12/24 @3am I started vomiting and did so on and off for the next 4 hours. A felt very fatigued the rest of the day. On 12/25 I developed a macular pruritic rash to my chest that progressed throughout the day that covered my torso. By 9pm on 12/25 I was experiencing fatigue, headaches, muscle aches and chills. I took Tylenol and ibuprofen and went to bed. I current have a headache, worse pruritic rash and upper tooth pain .

Patient asked for extra monitoring in the observation area due to Sulfa and other antibiotic allergies. Patient states tongue was swelling. No difficulty breathing, no airway obstruction. Assessed by on site provider, 25 mg po Benadryl liquid ordered and given without difficulty BP elevated to high of 151/95. 911 call placed. EMS on site. Patient refused transport to hospital and was picked up by her mom after

signing AMA documents. Advised to not drive, not be alone and was being monitored by mom who was a physician. Patient states tongue swelling improving on discharge to mom. Last BP 140/90. Patient is obese.

Client is 17 year old and vaccine given. Unknown adverse reaction. Underage for vaccine approved.

Second day on December 21 had moderate arm pain extending up neck to base of head. Dec 22 pain was gone but began to have continuous twitching of left eyelid, Dec 23 eye pain. Started prednisone dose pack on Dec 22. Eye twitching gradually improved and am currently having minimal symptoms

APPROXIMATELTY 10 MINUTES AFTER RECEIVING MODERNA VACCINE, SHE REPORTED TO THE MONITORING PHYSICIAN THAT SHE FELT LIKE HER HEART RATE WAS HIGH A LITTLE BIT. DENIED ANY OTHER ISSUES. PHYSICIAN CHECKED MANUAL PULSE=100BPM, THEN DECREASED TO 84 BPM THEN DOWN TO 76 BPM WITHIN A 3 MINUTE TIME SPAN. PATIENT SAID SHE FELT BACK TO NORMAL AFTER THAT AND CONTINUE TO WAIT AN ADDITIONAL 15 MINUTES JUST TO BE SURE. NO FURTHER ISSUES NOTED. PHYSICIAN REPORTING THIS INFORMATION WAS AT THE COUNTY HEALTH DEPARTMENT

Numbness and tingling in lips and tongue - post 1 hour Dizziness day 2-3 Fever Low grade 99.4 post 1 hour Achiness day 4-5 Fever 100.4 day 5

Approximately 4 hours after receiving vaccine, patient broke out in full body hives. Patient took Benadryl and Claritin that night and Claritin the next day and symptoms subsided.

Nausea and intense vertigo

57 hours after vaccine, I woke up with stomach cramps, diarrhea, chills/sweats feeling awful and soon after had a sudden syncopal event while walking back from the bathroom. I recovered, laid in bed and then within 15-20 minutes had diarrhea again so went to the bathroom and had another syncopal episode on the toilet (both witnessed by my husband) with diarrhea during this episode. I then went to the ER and was treated with 3L IV fluids for hypotension, IV zofran and bentyl. I left the ER within about 3 hours. still have been fatigued but was up most of that night. my body all hurts but I fell into my bedframe face first during the first syncope so would relate that to those symptoms/injuries.

Within grove minutes of receiving the injection my throat closed, my heart raced. My pulse was 107 my oxygen was low around 89-90 I believe. My neck became red with a rash and I was shaking. I was taken to the emergency room as the shot clinic was attached to the hospital and received Benadryl 25mg and Predinose 50mg. I have no known allergies that have ever caused an anaphylactic reaction. I have never had vaccine reactions in the past either.

Day of vaccination (Monday) and day after vaccination (Tuesday) experienced a sore, tender arm and mild fatigue. Wednesday morning woke up with tender, swollen lymph nodes and sore throat. Arm still sore as well at injection site. Thought sore throat may have been due to acid reflux so went to work at the hospital as usual. Thursday morning woke up with a worsening sore throat with difficulty swallowing, cough, nasal/sinus congestion, ear fullness, fatigue with dizziness, and nausea. Was unable to perform daily functions. Notified employee health at the hospital who advised a covid test and

exclusion from work. A rapid strep test was also performed which was negative. Friday symptoms still present but slightly improved. Saturday morning received negative covid test result and approval to return to work if respiratory symptoms improved and under control. Today is Saturday afternoon, now returned to work (arrived late). Experiencing mild symptoms currently similar to the common cold.

within 3 min of receiving the vaccine, I experienced flushing, racing heart, lightheadedness, dizziness, mentally fog, winded/ shortness of breath, and felt like an adrenaline rush. All that calmed down by 30 min. Then experienced nasal congestion for an hour. within 3 hours of vaccine, developed a headache and later that day it worsened and chills developed. The next day was just slight headache. The second day was sore arm and fatigue that lasted for 1 to 2 more days.

Severe vomiting and diarrhea to where had to go to ER due to dehydration, lasted 4 days. Body aches, fever, muscle aches

I have a large bruise, found the next morning. Right foot tingling, and soreness on right calf and right leg hamstrings.

Injection site pain, no swelling or redness Fatigue (moderate) Headache Pain with eye movements Nausea Abdominal pain No treatments needed.

"Received Moderna Covid 19 Vaccine EUA Approximately 8 hours after receiving the vaccine I developed a cold sore (not unusual when I have had influenza shots in the past). Approximately 36 hours later, late at night, I developed pruritus on my left arm (near elbow, same are as injection). I examined it in the morning and there were small lesions as well as a circular ""bulls eye"" lesion, similar to when I was told I had contracted Cox Pox when doing surgery on farm workers at Hospital, 10 years ago. Acyclovir helped relieve the puriritis. At this time (60 hours after vaccination and 18 hours after pruritus and lesion developed) the condition has not progressed and has slightly improved."

pain in injection site (few hours after injection, all day), muscle aches(12/24/2020 in the evening into the next day, 12/25/2020, all day), numbness on entire left side (12/25/2020, few mins)

Fever 100.9 approximately 12 hours after injection, body aches, fatigue

Employee was waiting to be observed for the required 15 minutes post vaccination. She started to complain of not feeling well and feeling short of breath. She was immediately assessed by staff and transported to Emergency Department for further evaluation.

Pt began feeling flushed, tremulous, c/o weird sensation in throat. developed rash. Had near syncope. 1-2hrs of symptoms.

Nausea, vomiting, fatigue, muscle aches, headache, chills unrelieved by over the counter medicine lasting over 3 days

Had complete relief of my chronic back and leg pain for one day. Pain gradually returned in three days.

Transient pleuritic pain -- about 3 incidents lasting about 1/2 hour each, day following vaccination. Minor headache a few hours after vaccination. Mild abdominal discomfort off and on for a couple of days. Soreness in the arm at site of injection -- not unexpected. Resolved after three days.

Swelling at injection site with redness that became visible within 12 hours. At 72 hours site is larger, measuring 2 inches in diameter. Area is also swollen, slightly sore, periodically itchy.

lightheadness/weakness

Loss of taste. Body aches coughs

Swelling at injection site, redness, pain

Arm/sight pain pressure weakness x 3 days following vaccination, Nausea, diarrhea x 2 days following vaccination, tiredness, body aches x3 days following vaccination, mouth sore 5 days following vaccination

Migraine with aura and pain 1 hour after injection. Laid down, took OTC migraine medicine and applied ice pack to head pain area. Migraine disappeared after 3 hours.

Tender lymphadenopathy in left axilla. Began 12/24 (one week after vaccine administration on 12/17).

"Moderna COVID-19 Vaccine Vaccine administration was okay and without issue. Patient reports having sensation of ""vice around heart"" that spontaneously resolved less than 5 minutes after injection. No anaphylaxis or shortness of breath, but sensation of tightness in chest that subsequently resolved within the 10-15 minutes after injection."

Began to feel tired in afternoon. Woke from nap and began to vomit several times. Also malaise, fatigue and feeling feverish even with normal temperature.

Tachycardia and Dizziness

Headache, nausea , retroorbital pain, cough, shortness of breath, vomited once

Dysgeusia: a sweet, metallic taste in the mouth that started about 2 hours after the vaccine was administered. This effect lasted for about 3 hours and resolved on its own without intervention.

Shortness of breath and chest tightness

On 12/24- vomiting, severe chills, diarrhea On 12/26- woke up with head cold symptoms- stuffy nose, sinus pressure, fatigue.

Fever 102.8 Myalgia Chili?s Muscle spasm Severe headche

Today I am 36 weeks and 4 days pregnant, due on January 19, 2021. This is my first pregnancy, and going well so far. This is not a bad adverse event just something I noticed: I developed 2 ulcers in my

mouth and one inside my vagina today. I had ulcers pop up in my mouth when I tested positive for COVID on May 1, 2020. Just interesting, not bad.

Day 1/2 - Headache, Pain at injection site/slight arm sweeping, tiredness Day 2 - nausea, tiredness, dizziness, shortness of breath, feeling hot/flushed, fainted (led to a 911 call / ED visit)

swollen and painful possible lymph node on left clavicle left arm sore for 3 days numbness and tingling in left arm following injection for a few hours

Sore arm started ~5hr s/p injection and persisted for 2 days. Mild-moderate headache started ~5-6hr s/p injection and lasted for 2 days. 1 day s/p injection had eye itching that lasted 3 days.

After 5 minutes, tachycardia, lip tingling, tremors

About 25 min after receiving 1st dose, migraine headache, the right side of my body felt heavy and the muscles in my leg, lower back and neck hurt, I also had a lump on my right arm at the injection site. Within 6 hours the heaviness and the pain in my leg and back were gone. As of 12/26, the pain in the neck has decreased but it is still there, the lump in the arm still there and the migraine is still continual

Severe persistent joint pain on right arm extending down to right hip 24hrs after injection was administered.

Skin Rash, itch,inching, haves 12/20/2020 Skin rash, itching, haves 12/26/2020

Within minutes of innoculation, site area became extremely itchy. I brought this to the attention of the medics in the 15-minute observation room, and they immediately took me to an exam room where I was attentively cared for by several nurses, medics, and healthcare staff. I was given liquid Benedryl as my arm began to rash around the site. Within about five minutes of being in the exam room, my tongue began to feel like it was swelling in the back of my mouth, it soon began to feel swollen through the whole tongue, and it became increasingly difficult to swallow. Upon notifying the nurse nearby, I was immediately given an EpiPen injection. I do not know what may vitals were as everything happened very quickly, but I was told that my face, neck, and chest became rashy quickly, but subsided after several minutes from the EpiPen, at which time I was given more liquid Benadryl. Once stable, I was taken to the emergency room for monitoring for two hours. I felt better quite quickly after arriving in the emergency room, but the itching persisted through the evening. After 15 hours of sleep, I awoke to only a sore arm and thigh from each injection site.

Rashes on the neck started on 12/25/2020

Left side only , eyelid heaviness, feeling unable to lift eyelid that developed and has lasted since. Since then my eyelid sometimes droops and sometimes it appears normal but still feels heavy. All other facial movement has been symmetrical & without problems.

throat swelling, itchy eyes, flushed skin and a headache

12/23 Patient reported fever lots of body ache and headache

Day 1 (day of vaccination) - 6 hrs after injection extreme tenderness of left upper arm Day 2 chills, body aches, sore throat, headache, fatigue, sore injection site - sx lasted all day Day 3 sore injection site - no other symptoms Day 4 after doing some housecleaning - in afternoon, chills, body aches, sore throat, headache, dizziness and fatigue. lasted 5 hrs (is this from vaccination or post covid episode?)

A low grade fever started approximately 5 hours after the vaccine paired with overall feeling of being run down and achy muscles. The injection site was very sore and it was hard to move my arm. Symptoms subsided by 36 hours post vaccine.

About 10 hours after vaccine was received, severe headache started. Became terribly headache, no fever but chill even with 5 blankets, skin felt like it had been burned, nausea and vomiting, leg cramps though out night and most of the next day. Headache and fatigue for another 24 hours which are present now.

12/23 injection site pain immediately 12/24 arm pain and slept 11 hours - tiredness 12/25 no symptoms 12/26 returned with injection site stabbing pain

Exhaustion. Nausea joint and body aches mild headache

About 5 hours or so after the injection I began to feel a stiffness and soreness on my left forearm and left shoulder. The soreness in the forearm persisted for about a few hours and the pain was negligible unless I applied a slight squeeze to my forearm, which caused significantly more pain. At that strength I would normally not feel any pain at all, but it was strong enough to cause me to almost instantly release my grasp. The pain in the shoulder was also negligible but caused far less pain when pressed compared to my forearm. My shoulder symptoms lasted until I woke up the next morning.

Loss sense of taste and smell

Red rash, bumps that itch appeared 4 days after, mainly on arms.

I developed generalized pruritus, sore throat, lip and tongue tingling and numbness. Symptoms started 30 min after the injection and progressively got worse. Took Zyrtec without much relief. Took Benadryl 25mg when lip tingling and Buke ness started and went to bed. Symptoms resolved by morning.

12/17 Patient report sore throat, loss of smell, cough, muscle aches, loss of taste, shortness of breath and headache.

Symptoms started after 2-3 mins of vaccine. Started having numbness, tingling on face, arms, legs, tachycardia up to 144 bpm, dizziness, palpitations, chest tightness. Lasted up to 1 hour. Observed in clinic and went home after 2.5 hrs. At home continued to have on and off palpitations for 2-3 hrs with heart rate increasing to 110 bpm.

O had the vaccine at 9 am this morning waited 15 mins after vaccine before leaving while driving I had a pounding heart rate and hot I rolled down the window felt better. 1 hour later while at home.e started with nausea diarrhea rapid heart rate headed to medical office while in care tongue swelled I called 911

pulled over when the ambulance got to me my throat swelled and I had hives on chest they took me emergency while there I had sever pounding heart and vomiting treated with meds sent home with medication and benadryl

12/23 report feeling lightheaded, anxious, body aches, fatigue, headaches, chills without fever, dry cough and nasal congestion

Headache Runny nose Congestion Neck stiffness

Fever (101.1) Chills Headache fatigue

Dizziness, diaphoretic, wheezing, cough, hoarse voice, tingling to my throat and headache. Sent to emergency room, received medication. Decadron IV, Benadryl IV and Pepcid. I was monitored in ER. Eventually was discharged home with medications.

Lip swelling/tingling without airway compromise, full body itching, Covid symptoms. Lasted approx 48hours, took 50 mg benadryl every 4 hours and pepcid twice a day for 5 days

I had several episodes of dizziness on Saturday, December 26th, approximately 6. All of them occurred while I was sitting. In all but one case, I had been sitting for long periods and had not recently stood or moved around. They started in early afternoon and continued through late night. I hope they go away tomorrow.

Aching arm, loss of train of thought, deeper breathing, steady increase in heart rate with the occasional drop in heart rate.

Fever, nausea, dizziness, muscle pain, joint pain, headaches, vomiting

The patient developed palpitations, lightheadedness and nausea and came to the ED and was found to have sinus tachycardia. Unclear if it is a vaccine reaction or due to anxiety or severe iron deficiency anemia.

Left clavicle pain with point tenderness over the bone (not the muscle) no lymphadenopathy. Pain lasted few days and seems to start to improve today.

Approximately 30 minutes post injection experienced left jaw numbness lasting approximately 2 hours. Experienced left ear tingling and bitter taste in mouth lasting approximately 5 minutes. Experienced left sciatic numbness lasting approximately 10 minutes. No treatment. Self-resolved.

body aches, chills, feeling of being unwell, swollen lymph nodes. the body aches, chills and feeling of unwellness, i treated with aleve cold and sinus. but the swollen lymph nodes is on going.

Eyes twitching, headache, and nausea.

reddened rash with hives Benadryl to ED

24 hrs- lymphadenopathy, submandibular, ear pain 36 hrs- primary outbreak of VZV- trigeminal n involvement- tingling/burning 48 hrs- rash and vesicles in trigeminal n distribution

sore upper arm. mild reactoin

Severe chills, headache, lack of appetite and Temp of 101.9 for 5 days following injection.

Fever, chills, body aches. Improved with Tylenol and motrin

Employee states had vaccine on 12/20 and was monitored in Emergency Department for approx. 4.5 hrs r/t which started with metallic taste, then within 10 minutes lips/throat/tongue tingles, full feeling in throat followed by heaviness in chest with self-resolving (only IV fluids administered in the ER). Employee states took 50 mg of Benadryl when she went home after the ER. Employee endorse body/headache post vaccine on 12/21. Patient is unsure to take second dose and seeking advice, has already contacted her PCP.

Sugar spiked increased insulin till comes down to normal, tea and tylenol for the throwing up, fever ,headache body feeling like it weighs 1000pound. Calling Dr. on monday

About 6 hours after injection, sore arm At 3am awoke from sleep shivering uncontrollably. This went on for about 2 hours. Woke at 6am with muscle aches and temp 101.2. Took Tylenol. About 11am took temp - 100.1. Took several naps and laid around most of the day not feeling well. Temp went back to normal. 12/26 woke feeling fine, but took morning nap and afternoon nap, and still did not feel back to normal; tired. No fever and slight muscle aches. 12/27 feel back to normal.

Extreme muscle twitching in the left wrist muscles

Moderna COVID-19 Vaccine. Received the vaccine at 8:30 AM 12/24. Morning of 12/25 I started to feel a slight sore throat and tender lymph nodes. By the early morning of 12/26 I was experiencing a moderate-severe headache, fatigue, swollen/red tonsils, swollen lymph nodes, congestion, sore throat, and trouble swallowing. Around 2:00 AM on 12/26 I took NSAIDS which only mildly helped. I went to an urgent care center at 9:30 AM on 12/26 where after my examination the CRNP ordered a strep test and COVID test. Strep test resulted positive, prescribed amoxicillin 875mg twice daily for 10 days, and prednisone 20mg twice daily for 2 days. As of now, 12/27, symptoms have significantly reduced. Awaiting COVID test results.

Brusing Pain Entire arm soreness Nerve tingling pain Fingers moving on their own

Intermittent parasthesia, numbness and tingling to arm vaccine was administered

Generalized itching/rash, red bumps to arms and neck, scratchy throat.

Severe injection area soreness, mild-moderate fever (100.3 - 101.9), achiness, fatigue, mild headache (later in day)

Patient received Moderna COVID-19 vaccine IM in the Administration clinic. During the observation period, patient reported feeling flushed, warm, sweaty, with lip tingling. Vital signs 138/95, HR98, 02 Sat 98%. Proceed out call. Patient transported via wheelchair to ED for further monitoring. In ED, monitored with resolution of tingling of the lips, cheeks still with slight flushing to them. No sob or abd pain or tongue/lip swelling, no worsening rash. Encouraged followup with working well clinic. Patient was discharged home 4 hours later.

Dizziness, syncope, nausea, fatigue

Patient reported having reaction to flu shot in past so was being monitored closer. Upon her completion of 30 min observation, patient felt lump on throat, slight pain to touch on upper chest, slight headache, some redness to chest area and arms. Patient came prepared and took 25mg of chewable Benadryl at 10:13am, two minutes after symptoms began. 20 minutes later lump on throat was gone and redness to skin had disappeared. Symptoms resolved, patient was monitored for an extra 15min, asymptomatic upon leaving, had husband waiting outside to drive her home. Patient has EpiPen and understands if any sx return, chest pain, trouble breathing, should go to ED.

Patient began reporting of a tingling sensation in right arm approximately 15 minutes after vaccine administration in the right arm. Patient denied shortness of breath, chest pain, palpitations. Patient encouraged to wait in observation room for another 10-15 minutes with enhanced monitoring by MAs and RNs, patient agreed and complied to plan. Patient reported continuation of tingling sensation in right arm with noticeable tingling sensation beginning in left arm and lips as well. Vital signs taken on patient at 1300: BP: 165/84, HR 78, O2 100% on RA. Proceed out called, team arrived and transported patient to ED for further evaluation. In ED, patient was observed for few hours, and was discharged home.

Redness and swelling at injection site and surrounding area noticed ~day 1. Today is day 10 and the redness and swelling (same shape/area) and now warmth to touch (noticed warmth on day 9) have not gone away. No other symptoms of note.

""""PFIZER-BIONTECH COVID-19 VACCINE"" Adverse effects: Swelling under the left arm extending to the back to about under the shoulder blade. The swelling also extends to the left side of the chest area where there is also visible rash/hives with swelling. All of these areas are painful to the touch."

Patient reported tingling sensation in hands and feet ~15 minutes after Moderna Vaccine Administration. Patient states the tingling sensation was not present prior to receiving vaccine.

"Patient was given injection and mentioned she had a warm feeling and had tingling in her face. Patient stated, ""It made me very anxious."" Resp therapist checked her breath sounds no stridor or wheezing. B/P was taken- 116/83 Pulse of 73 bpm. Kept for 15 minutes and the symptoms resolved. Patient was offered Benadryl but stated he mother has had a reaction to Benadryl and patient refuse the medication."

Around 10 that night I felt chills, lethargy, and fever. Next morning a headache. Still have a headache.

Saturday 12/26/2020 received Moderna vaccine dose #1 of 2 at 12:00pm. 15 minute observation required (no symptoms) was able to leave. At 12:30 pm - 30 minutes post vaccine: experienced lip & tongue tingling & numbness, throat felt weird. Jaw line became itchy. Self-resolved 15-20 minutes after. At 2:00pm experienced severe migraine & lightheadedness - unable to perform daily routine due to pain & feeling of passing out. At 3:15 pm tongue became itchy & throat feeling weird again. Self-resolved 15 minutes later. Today 12/27/2020 only symptom is severe pain in left upper arm (where injection was) feels like solid mass & difficulty raising arm due to pain & tight feeling (this is very different than just having sore arm post flu vaccine). Pain in arm constant throbbing heavy pain.

Passed out twice - at 5pm on 12/26 & 8:30am on 12/27

Arm soreness at sight of injection ans involving shoulder. Extreme pain with arm movement. Difficult to move arm especially lifting arm over head.

Arm soreness at sight of injection ans involving shoulder. Extreme pain with arm movement. Difficult to move arm especially lifting arm over head.

Woke up with whole-body muscle aches, chills, and a slight cough. Feeling tired, weak, and fatigued. Headache.

Severe rash. Treated at ER with prednisone and recommended Benadryl.

General Itchiness, fatigue, joint inflammation, worsening hives on trunk and extremeties

Day 9 post vaccine started with local vaccine reaction. Itching, redness and swelling at site of immunization. 5.0 cm of erythema and induration.

Moderna COVID 19 Vaccine EUA Nausea and Bodyaches

Very large and swollen left supraclavicular lymph node

Intense Vertigo and tachycardia lasting for approximately 2 hours post injection, nausea/motion sickness lasting 5 days post injection

High blood pressure Pain in injection site Light headed Fatigue Headache Body aches Shaking

"B/p elevated, states ""feel swooney, like dizzy"""

Within two minutes of injection: started feeling flushed, light headed, elevated pulse, and tightening of my throat. Waited 30 minutes at site while physician monitored my symptoms. Flushness, pulse rate and feeling of throat tightness diminished over the 30 minute period and I was released to leave. On the way home I bought Benadryl and took 50 mg. I began to feel more normal 1-2 hours post injection.

"Patient stated, ""She got pain immediately during injection."" Next day she stated it was swollen at the site."" Went and saw her doctor who confirmed it was red and hot to the touch. Patient stated, ""I tried advil and it helped a little bit. I did not try Benadryl."" Staff stated, Patient's arm was fairly/pretty large (swollen)."

Couch, high fever, chills, body aches, headache, severe fatigue

Fever, chills, sore throat

severe headache and fatigue from 3 days after the shot continuing; the illness has not stopped and is now 8 days after the shot

Waited 15 min without issue. While driving home after approx 10 min developed acute throat fullness, lip tingling, hand tingling, nausea, clammy & lightheaded. Felt like going to pass out. Was able to call 911, pull over. After EMS arrival throat fullness & lightheadedness improved, still with lip tingling. Refused ER went home took Benadryl 50 mg with improvement after a couple hours.

Shingles, left side leg and foot

After 5 min of receiving vaccine felt woozy/dizzy, sudden burst of chills, elevated heart rate. Asked for someone to check HR; obtained VS. Discharged after acceptable HR and BP. Home (day of and after vaccine) - HR elevated after minimal exertion and temperature.

An inflammatory response noted in right hand joints (index and ring finger). Severe swelling and pain.

About 1830 (6 hours post-vax), I developed numbness/loss of sensation in the right side of my face from mid-eyebrow to just below the temple. I continue to have this symptom.

Swelling, redness, and warmth that emerged 8 days after vaccination.

On the next day exp fatigue last mostly that day. I woke up on Thursday no issues at all. The following Sat on 12/19 exp coughing and that was it. I stay home one day to rest but dint miss work.

Day one achy and nauseous. Day 2 sore arm swollen armpit temperature and nauseous.Took Tylenol and went away third day.Temperature up to 101.9F.

shingles, nasociliary branch. started with burning in the inside of my left Nare, vesicular rash appeared which spread to the tip of my nose. I immediately (day 2 of rash) started valtrex 1gm TID. After 48 hours on valtrex no progression of rash. I have not had any visual symptoms (herpes opthalmicus) yet and hopefully don't.

Vertigo started during the night following the vaccination. It felt like the room was spinning, while I was lying in bed and on getting up. It is mild, and I can still go about my regular activities.

Vaccinated member,. Recently received tetanus 9 days ago upon clarification

Received Moderna vaccine at approximately 4:05pm on 12/26/2020. Within 15 minutes, developed flushed feeling throughout body, developed strange taste in mouth, mouth and tongue felt numb and tingly. Was given 2 Benadryl, symptoms improved, resolved within 6 hours.

vesicular rash occurring on right upper arm, not at the injection site. small groups of nodular bumps that are now occurring on my right hand, left arm, back, and neck. they do itch but are not painful. they do not appear to be fluid filled. appeared about 3 days after initial vaccine.

I woke up with a fever 100 it did reach 102 afternoon, I exp alot of muscle ache and pain stayed in bed. I was uncomfortable sitting felt better laying down. After taking Tylenol I felt better also exp nausea and headache it dint feel overwhelming. I felt totally back to normal on 12/17.

Patient developed a feeling of warmth all over within a few seconds of receiving the IM injection. She had no other symptoms initially. Approximately 35 minutes after the vaccination, she had a brief (approximately 3 second) syncopal episode. No other symptoms developed.

Approximately 15 hours after vaccination I awoke with severe pain of the left fourth toe, medial aspect of the proximal phalange. There was a 3 mm pustule on a 1 cm erythematous base. At the time I also had mild routine constitutional symptoms from the vaccine: fatigue, headache, vague malaise. I had no fever. The pustule progressed over the following 15-20 hours. I was prescribed doxycycline 100 mg po bid and the pustule was incised and drained. A wound culture was not sent, but the assumption was that S. aureus was the pathogen. Over the next four days, the lesion resolved without complication.

12/25 10 pm: Chills, fever 100.2 congestion, slight cough, headache 12/26 1 pm: Chills, fatigue, 100.3, headache, fatigue 12/27 1:00 am: fever 102.5, headache, nasal congestion, fever broke after motrin, at 6am. 12/28- 11:00, chills, fever 100.2, fatigue, mild headache

Attempted to sleep but could not focus and kept having problems all night not being able to sleep. Woke up sore and with a headache and a bit of nausea. Was shaking a little in the morning.

"within about 5 minutes of receiving vaccine, pt states that tongue felt ""tight and swollen"". No difficulty breathing and no other airway symptoms. Given Benadryl 50mg IM at 1108. Symptoms quickly improved. By 1150, pt swollen feeling resolved and tongue just feeling dry"

Rash and pain at injection site, chills, fever, headache/neck pain, muscle pain, fatigue

Chest pain followed by Syncope approximately 5 minutes after injection.

Tingling, general flush, BP 132/82, HR 92 O2 98% - positioned supine, administered Benadryl IM

Within first 5 minutes, pt reports feeling dizzy and lightheaded and that throat was tight and it was difficult to swallow. Symptoms did not progress. Benadryl was considered but with medical staff, agreed to observe for worsening over the subsequent 5 minutes. Symptoms slowly resolved and by 12:10 throat just feeling dry. No dizziness reported.

Face became red with hives and swollen., sweating and clammy, chest tight and tachycardia. Went to emergency room. Given Benadryl. Occurred about 8 hours after vaccine

Exacerbation of vertigo associated with nausea and loss of appetite.

Woke up due to arm being very sore- went to get ibuprofen and got very light headed. Needed to sit down, ears began ringing and felt like I was going to faint/pass out. Went into bathroom, felt some what nauseated and weak. Suddenly felt hot, sweating and ears still ringing. Had to keep my head below my knees due to still feeling like I was going to faint. Eventually sat on floor doing deep breaths, feeling weak and hot/sweaty. Then started to feel very cold/clammy. Took temp at this point- no temperature. More deep breaths and eventually after possibly 5 to 10 minutes felt like I could walk to my bed. Still felt very cold but no longer like I was going to faint and ear ringing had stopped. Slept through the remainder of the night until approximately 7am without incident.

Pfizer-BioN Tech COVID19 Vaccine EUA Injection site soreness in deltoid and shoulder region starting next day lasting roughly 24 hours. No treatment other than Advil

I am a healthcare provider, received first dose of Vaccine, had slight tachycardia about 5 minutes after receiving. Tachycardia resolved after about 5 minutes, chills lasted about 5 minutes. Most concerning when driving home about 20 minutes after vaccination right side of my face began tingling and numbness. This numbness and tingling lasted throughout the night until sleeping. There was no facial paralysis. When I woke up symptoms had resolved. Throughout the next 48 hours would have intermittent tingling on right side of face only for a period of a couple minutes. After 48 hours no symptoms.

R temporal tingling, numbness, treated by supine positioning, resolved

Dizzyness, resolved with juice, crackers

Adverse event: developed papular rash to right flank 12/24, treated with topical hydrocortisone cream, rash remained through 12/27. OTC PO benadryl taken the night of 12/26. Developed another papular rash to right neck and subclavian region on 12/27 @0800. Papular rash to left neck smaller but also developed 12/27 @0800-0900.

Moderna COVID-19 Vaccine EUA. Swelling, redness, soreness, itching from the injection site to the elbow. Soreness began 10-11 hours after injection. The injection site-related symptoms have progressed. Had headache and chills followed by a low grade temperature within 24 hours of injection. No longer experiencing any symptoms besides those associated with the upper left arm. Will advise primary care physician of the issue today.

Dizziness, dyspnea, neck swelling

Vaccine administered at 823am; at 0831, patient reported feeling warm and that her throat felt like it was swelling. 0834 pt placed on VSS monitor; 911 called; 0843 Pt was given epi pen 0845/0850 VS repeated; 0851 ambulance arrived and pt taken to ED

Headache Muscle pain Low grade fever Sweating Cough Sore throat

Headache on day 1 evening and all day 2 Day 5-7 tenderness on left side of face in distribution of trigeminal nerve. like trigeminal neuralgia. Gone by day 7 after vaccine. It only occurred on the left side (same side as left upper arm vaccination)

I am experiencing nausea, diarrhea, and a migraine.

Vaccine administered at 0924; 30 minute observation due to past history of allergic reaction to tetanus vaccine; 0948, pt notified RN of tickle in the back of her throat; 0951 VS taken and WNL, remained with tickle in throat. 1016 pt reports having muscle cramps on back of neck, radiating to shoulders; VSS 1026 pt reported new onset chest pain; pt agreed that symptoms were progressing and epi pen was administered at 1031, 911 called. 1034, pt reported improvement; 1036, 911 arrived and pt transferred to ED

About 12 hours after receiving the vaccine, woke up to use the restroom and while standing in the bathroom, I became dizzy, lightheaded, weak, and fell to the floor. My spouse was able to arouse me after a few attempts at shouting my name but informed me that I had lost all the color in my face, lips and face were very pale. I laid on the floor for approximately 30 minutes until I was able to sit up & stand without feeling lightheaded and dizzy.

The patient was vaccinated on 12/17/20. Wife was diagnosis with COVID-19 on 12/18/20. He was diagnosis with COVID-19 on 12/21/20. Symptoms woresen on 12/26/20. And he had chest exam (x-ray's), pneumonia bi-lateral and he was hostipalized on 12/26/20.

Client reported rash on left side of neck and facial tingling/slight swelling about 4 hours after vaccine; HR 88, BP 130/90 RR 18. Assessed by Medical Director - urticaria most consistent with an allergic reaction. Patient offered Benadryl and encouraged to stay at clinic for observation, but chose to go home - explained risks and danger signs to be aware of that would require immediate visit to ED. Client took 25mg Benadryl at 5pm and MD spoke with her at 6pm - she indicated there was improvement with her rash after the initial dose.

Had the expected side effects of arm pain, body aches, headache and chills beginning several hours after vaccination. The morning after the vaccination, I felt like I would be okay to go to work, so got up to take a shower. Felt very lightheaded in the shower and fainted. Fell to the floor outside the shower, hitting my head on the tile floor. Was later able to proceed with going to work. No other ill effects or treatment.

Covid vaccine received, was instructed to go to ?observation area? for 15 minutes. While walking, started to feel faint, sat down and started to feel okay. After 5 minutes, I started to feel faint again and felt my heart rate go up. My Apple Watch showed my heart rate at 144. I asked staff to check my vitals and I was instructed to go to the nurse area. Vitals showed heart rate of 140s-150 (Apple Watch registered my highest heart rate during that period was 160). Blood pressure about 135/90 (my normal is 115/80), SPO2 of 99%. After 5 minutes, heart rate down to 90, BP 120s/90s. Every 5-10 minutes I would feel faint, a sense of ?impending doom,? mild nausea, and my heart rate would go up to 140s, it would last about 2 minutes then go down to 90s. This cycle of heart rate going up and down kept

repeating for 30 minutes. No chest pain, no shortness of breath. Prior to going home, heart rate was 90, blood pressure was 125/98. Total time being observed was 40 minutes from time of vaccine to leaving observation.

Sudden onset of numbness and tingling in Left arm at 11pm (arm that received injection). Arm appeared to be mottled as well.

Progressive pain in arm

Nausea and vomiting

"Besides from the low grade headache, i started to have chills, then fever for 5 days, joint pains and generalized body malaise, observed "" petechiae rash"" on my face"

Splotchy Redness and extreme itching on both left and right arms, hands and feet started itching about an hour later. Took 1 dose of benedryl and redness subsided.

1120 informed staff was feeling lightheaded and dizzy- VS checked BP 83/63 58 100 RA reck at 1130 78/45 52 taken to ER via WC for evaluation

At approximately 11:30PM on 12/25/20, pain in my left axilla woke me from deep sleep. There was (is) a palpable, painfull swollen lymph node . It remains painful at the time of reporting (12/27/20 12noon). The pain is temporarily relieved with NSAID. Other than pain, there are no other associated symptoms. I had mild pain at injection site on day 2 but no other notable events following vaccination on 12/19/20. I will send a message to Dr , (my PCP) but do not think a visit will be necessary. I am scheduled for my second vaccination on 01/08/21 and intend to get it - in my right arm.

c/o dizziness not feeling right very anxious scratchy throat taken to ER via wheel chair

Moderna covid-19 vaccine EUA. Pain at injection site, pains on lifting injection arm next day. Diffuse muscle and joint pains next day. Extremely tired next day. Upset stomach next day. Peculiar feeling on the tongue - not burning just a weird sensation.

About half hour after vaccine had a headache woke up with a 100 temp fever. The next morning fever went away. The night of 12/18 my temp was 102. temp, lost taste/smell and felt fatigue. On 12/19 I went to get a Covid Test results positive. The week of 12/21 started to feel better and then on 12/26 OT started dropping. I had to miss 5 days of work.

About 10 minutes after receiving the injection I felt tightening in my throat. I then felt a hot flush all over, and some chest tightness. I notified one of the nurses at the site who took my VS: BP 200/100, P 100, R 22, O2 sat 99%. Symptoms resolved in about 20 minutes. I went back to work when the symptoms returned. As I was walking to the site where the injections were being given I saw a pharmacist from the hospital. He took me to the pharmacy and recommended Benadryl. Since I was at work and Benadryl makes me sleepy he gave me another Claritin, knowing I had taken one that

morning. He also suggested that I use my Albuterol inhaler, which I did. Symptoms resolved within the hour.

On December 25th at about 8 pm I became extremely lethargic and unable to think clearly. I had a temperature of 103.7. My face and tongue were swollen and I developed a rash on both lower limbs. I went to Emergency Room and was admitted.

did fine at time of vaccination and left after the 15 minute time period and went back to her desk and after 10-15 minutes in registration states started feeling funny dizzy starting to get a HA met her and manager in the hallway instructed to go to ER. Taken to ER via wheelchair for evaluation

Received Pfizer COVID-19 vaccine without untoward effects on 12/18. Given her usual allergy shot by her allergist on 12/22 (she has been receiving these for several years; I was told this is a protein antigen in a glycerine suspension). Within 15 minutes, patient developed anaphylaxis: generalized erythema, swelling, pruritus and hypotension requiring epinephrine, and diphenhydramine. Patient recovered over several hours.

Abnormal heart rhythm, mild tachycardia. 90 to 100 bpm.

c/o came back in after being discharged 10- 15 minutes and stated she was dizziness, scratchy throat, heart racing taken to ER via wheelchair for evaluation

periorbital edema, flushing, itching

Nausea beginning Sun Dec 20, in the late afternoon. Vomiting around 6:00 PM. Nausea a bit relieved then, but persisted until Mon Dec 21 evening. Headaches noticed daily until Dec 27. Soreness in arm for only a few days.

Pfizer-BioNTech COVID-19 Vaccine EUA headache, swollen L tonsil and L ear ache for 4 days post-vaccine; symptom treatment with Dayquil and Nyquil. resolved without further treatment

Fever, muscle aches, hypertension, rapid heart heart

24 hours after the vaccine injection I had severe chest and abdominal pain along with nausea and vomiting. I went to the ER where they did blood work, an ekg, and a chest xray, all of which were within normal limits. I was give IV morphine for the pain and IV pepcid. The symptoms went away after a couple of hours and I was released. The symptoms did not return.

"Received vaccine at 0930... was checked on and feeling well ?. at 0950, she raised her hand and stated she was having tachycardia, ""not feeling right"" and c/o numbness and tingling in legs. METs team called and pulse was 130 and was taken to ER here at MC via wheelchair."

Fever (100.4), chills, myalgia on the next day.

On 12/22/2020 between 2000-2100, while driving, I experienced a definite notice of sensation of absence of my heart beating between 6-10 times. At one point, I was able to safely pull over, but by that

point my right radial pulse palpated was 60 bmp and strong. Prior to this time but after the vaccination, I had felt instances of a similar lack of sensation but am not sure of the times, had paid little attention to the events ? presumably because they were very very short and, though not driving, I was never able to catch them/i.e. palpate my heart rate during the events. On 12/23/2020 at 2005, I again sensed my heart wasn?t beating. I immediately attempted to palpate my right radial pulse and felt no pulse for at least 3 seconds (I was not watching a clock to time). After the 3 seconds, I could suddenly feel a strong right radial pulse, HR was 56 bpm (my pre-vaccine HR). I had not taken my evening dose of Propanolol.

"I received my first dose of the Pfizer vaccine through employee vaccination for medical center at about 6:45 pm on 12/16/2020. The same evening, I had no side effects to report. The next morning, on 12/17/2020, I woke up with a sore arm (know this is a common complaint). As the day progressed on 12/17/2020, I became fatigued and developed joint aches. Took a normal dose of Tylenol, took a bath, and went to bed. Went to work at the hospital the following day, on Friday, 12/18/2020. Was fatigued for my twelve hour shift on 12/18/2020. Following my shift on 12/18/2020, I came home, ate a little supper, showered, and went to bed. I did not have much of an appetite at this time. The following morning, I woke up with vertigo, dizziness, slight nausea, and felt a little shaky. I informed my workplace that I did not feel well and my charge nurse instructed me to ""see how it goes.' I proceeded to go into work at 0630 that morning on 12/19/2020. Upon arrival at work, I stated that I did not feel well or normal and I was instructed to call the employee health hotline to report my symptoms. I did and spoke with a woman, over the phone. She instructed me to go get a COVID test to confirm I did not have COVID. I told her that I really felt like it had to be from my vaccination, but she insisted I get tested for COVID. She scheduled me an appointment at a walk-in across from our hospital and I went and was tested. I went home to wait for my results and ended up missing the rest of my twelve hour day shift. My test came back negative later that day. the following days, until 12/26/2020, I had nausea when I would wake up. I still had some vertigo and dizziness and fatigue. Today, 12/27/2020, I have felt better. I am a little scared to get my second dose and wanted to report what I experienced."

Almost immediately following vaccine administration I had tingling in my lips, followed by swelling and tingling of my soft palate. It was minimal and became worse at around 20min following the vaccine. I had left the facility and was having some increased mucous production. No difficulty breathing, but I had some slight difficulty swallowing. I took 50mg of Benadryl and after about 1.5 hours the symptoms had resolved. Now over 24 hours out. I have some swelling of my right bicep, as well as some tenderness with right elbow and right wrist pain. Some myalgia worse in my right shoulder and right sciatic area and right thigh. Slight fatigue.

Headache, fatigue, body aches, sharp abdominal pains

Progressive and fluctuating hives and red rash on the shoulders, chest, abdomen, back, and upper thighs. Began on December 25 in the afternoon lasting about 30 hours, waxing and waning until a final flare-up in the PM in December 26. No more symptoms Dec. 27

5:00 PM chills, felt freezing, arm sore, muscle aches , headache, congestion, tired. 11:00 pm same symptoms and nausea. 1:30 am dizzy, temperature 97.8, other symptoms slightly better. 8:45 am arm sore, muscles sore, thirsty, nausea, dizzy, mucus.

Red rash on left forearm and back of left hand. Lasted 48 hours. High, uncontrolled blood glucose, unable to correct using insulin pump and additional insulin delivery. (Held over 300 mg/dl) Lasted 30 hours. Within 48 hours all symptoms alleviated.

N/V with severe diarrhea approximately 24 hours after vaccine administration. Symptoms lasted for 36 hours and resolved.

35min after injection. Swollen, numb lips, hoarse voice, difficulty swallowing, nausea. Patient is RN and self treated with 50mg benadryl, zyrtec, and caffeine. Patient was somnolent for several hours with concurrent nausea. Reported full resolution of symptoms within 6 hours. .

"patient reports ""chest pain after 5 minutes of receiving the vaccine""; then in the past 6 days, body aches and intractable headache"

On the day of my injection approximately 20 minutes later i had tingling down the arm I received the vaccine in and in my face which lasted for about 2 hours but went away. Other symptoms began 12/25/20 including body aches, fatigue, chills, and fever.

I am 67 year year old physician and have been inline distance skater for more than 30 years. I normally skate 3-4 times per week ~ 15 miles over about 90 minutes. I only walked for the two days after I received the vaccine (about 5 miles each time)and developed some low grade myalgias following which responded to 600 mg. of ibuprofen. On December 26, 2020 (approximately 72 hours post vaccination) I skated about 15 miles and upon returning home developed more intense systemic myalgias, nausea, fatigue, and general malaise which lasted about 12 hours. Today (December 27), the myalgias resolved. I have never had anything like this before. Since I see firefighters in my practice on a regular basis (as well as other first responders) I was concerned that coincidentally I actually developed Covid. I feel fine now but will get a Covid test on December 28 through my office. Curious if others reported similar side effects after the vaccine with vigorous exercise?

approximately 1.5 hrs after my vaccine I started to feel lightheaded and flushed all over my body. My heart rate was 120's and my temperature was 100.2F. No difficulty breathing, SOB, chest pain or rash. I was checked into the clinic and monitored in the Nurse Treatment Center. I was placed on a bedside cardiac monitor, an EKG was done, labs drawn and IV fluids administered. I was there for approx 1 hr and discharged to home. Temp was 99.1 HR 100's.

Chills and fever for 3 days. Chronic Fatigue and headache starting on 12/25 until today (12/27)

Dizziness, numbness hands & feet (feeling cold) for 2 hours, extreme thirst, chills for 6 hours, injection site pain 2 days

Palpitations, shortness of breath, chest tightness, presyncope, which led to New onset atrial fibrillation with rapid ventricular response and required synchronized cardioversion and hospitalization. Discharged on anticoagulation and beta-blocker.

Site pain, fever ro 102¦F for 2 days, body aches, headache, fatigue, and weakness

10 minutes after the injection while I was sitting and relaxing, I felt my feet tingling with a pins and needles sensation. They also felt cold. The pins and needles and coldness then shifted to my hands as well. It also happened in my lips and nose. I occasionally felt a cold tight feeling in my chest. I felt a little weak and shaky, like maybe I would faint but I did not. This did not improve with eating some candy and drinking water. I later felt anxious but the anxiety was brought on by these symptoms, as I was definitely not feeling anxious prior to the tingling. I tried resting and that did not resolve it. It just eventually stopped after about 6 hours.

approximately 24 hours after administration, I had vertigo and nausea lasting for approx 6 hours. I was treated with zofran with some improvement. I was able to get to sleep and in the morning the symptoms had resolved

Rapid heartbeat, SVT

felt flushed, developed hives on forehead and forearm; took 25mg of Benadryl, symptoms went away.

2 nights on migraines with light headaches continuing during the day. Upset or sour stomach with pain and decreased appetite for several days. Vertigo on December 24. Headaches starting Monday morning and continuing off and on through today, December 27.

24 hours after vaccine: feverish but afebrile, chills, headache, nasal congestion, change in taste and smell, malaise lasting for 5 to 6 hours. 48 hours after vaccine: chills, intense headache, nasal congestion, change in taste ans smell, malaise lasting over 8 hours. 96 hours after vaccine: feverish but afebrile, chills, intense headache, nasal congestion, change in taste and smell, occasional cough, malaise lasting over the next 24 to 48 hours.

Diarrhea, severe cramping, lighter stools, 24 hours duration, improved after loperamide

10 min: light headed, very scratchy throat, flushed hot lasted 2 hrs took Benadryl/Pepcid/Claritin an hr after shot Started Motrin/Tylenol every 3 hours alternating about 4 hours after shot 3 hr: severe global headache lasted 48 hrs 5 hr: nausea/diarrhea last 30 minutes 7 hr: chills/severe body aches lasted 36 hrs 12: hr: fever 100, with Motrin and Tylenol lasted 2 hrs Unable to work the next day

Itching to right forearm and bilateral upper thighs, provided Benadryl 25mg po, and recovered

Stronger than usual hay fever symptoms: rhinitis, sneezing, runny nose, stinging or burning sensation in side if nose

Dec 21- vaccine Dec22- soreness right arm Dec23- nothing Dec24, 4pm... I was cleaning up, getting everything tidy for Christmas Day. All of a sudden, I felt very nauseated and sick and just bad. I laid on

the couch, and around 5, I noticed my left forearm getting swollen and splotchy. It continued to get more swollen, red and hot. I put an ice pack on my arm. It was very tender to touch or graze over. I realized then that I had a temp of 99.8. I had body aches, headache, was still nauseous, and I had diarrhea. Dec 25- felt terrible, fever, extreme fatigue, body aches,and arm still the same. Dec 26- get tested for Covid, only slight headache and little fever Dec 27-Covid test negative, arm still swollen, but not as red

Severe headache, chills, sweating, stomach upset, altered mental state, vision impairment, shaking. Started 30 minutes after injection and increased in severity over the next 48 hours then began to decrease. Headache is still present 4 days after injection.

Fine rash to arms and legs. Red, itch patches to abdomen, back, neck and chin. Hot, burning feeling to palms of hands and soles of feet. The rash started 5 hours after receiving vaccine. The rash improved the next day and was gone by 2 days.

5 minutes post administration complaint of lightheadedness. 15 minutes post administration bilateral hand tingling, hot flushed and sweaty. Oral Benadryl 25mg given. 5 minutes, resolution of sweaty/hot flushing. 15 minutes post Benadryl resolution of all symptoms. Monitored for 60 minutes, full resolution

Soreness at site of injection - 4 days. Soreness and inflammation in right armpit - 5 days, starting 1 day after injection. Pain on right side down to hip/groin area 1.5 days, 3 days following injection. I did not experience any drowsiness, back pain or nausea.

Swelling, redness, pain, itchin, achy

Intractable vomiting (12 episodes in 24 hours) with dizzyness, throat swelling, chills, headache. Took Zofran/benadryl with mild relief. Went to ED on 12/26/2020 and had IV fluids and Zofran. Improved and discharged. Symptoms slowly resolving with no longer vomiting and no dizzyness.

vaccine given 12/23. reported slight swelling and redness on 12/26. on 12/27, tenderness, redness, and warmth noted to the majority of the left upper arm along with slight swelling

Approximately @1900 day after vaccine I started experiencing a headache, stuffy nose, and drainage accompanied with cough. Since then it has steadily been getting worse. My head is achy and stuffy. I am fatigued, running low grade temp, and been sleeping a lot the past 2 days. I have been taking Benadryl liquid and ibuprofen. Symptoms still the same. I feel a bit dizzy but I associate that with Benadryl for 2 days.

Injection site itching (2 hours), redness and swelling (2 days). Chills and fatigue (2 days).

Experienced significant tachycardia (hr ~140) beginning about 5 mins from vaccination, lasting ~5 mins. Self limited.

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Rash

Rash

Left arm soreness, ~5pm Fatigue,8pm Chills, miss nausea ~10pm Fever (110.3') and headache, 12-4am Fever ended following 2 Tylenol tablets ~5am (98.1') Fatigue, mild headache, slight nausea, moderate left arm soreness, and intermittent chills remain 12/27/20

Itching on arms, trunk, legs. Hives on thighs, trunk, and arms. Took Benadryl and they went away and came back about 24 hours later. Took more Benadryl and they have not returned.

Within 12 hours of vaccination I had 24 hours of: fever as high as 103.7, regular tachycardia 120 at rest (likely fever related), generalized headache, malaise, fatigue, diffuse joint pain, severe right arm pain without redness/warmth radiating down my right arm and up to the right trapezius.

On post vaccine day #2, the onset of notable bilateral jaw pain, most intense at TMJ. Muscle fatigue also noted in the jaw and jaw clenching. No treatment has been taken at this time, just close monitoring of symptoms and noting progression of pain and constant symptoms. Currently on day 5 post vaccine and symptoms are still present, worsening since day 2 onset.

severe chills, achiness, fever

Severe body aches, feeling feverish (without elevated temp.), fatigue, headache, extreme arm pain at injection site, welt-appearance under injection site, redness and warmth at injection site. Treated with Tylenol (1000 mg) around-the-clock starting ~18hrs after injection.

Fever on/off up to 101. Tylenol makes temp go down to 98-99. Chills, sharp pain in face, chest pain, muscle pain, joint pain, hx of covid in June, aching, headache, chest feels hot, HR up to 140

redness, tenderness, and warm to touch at injection site (apprx palm-size)

On the morning of the 24th I noticed a large, circular, red, raised lump on the head of my humerus above the injection site. As the day went on, my neck became sore, and I could feel swollen lymph nodes. No fever, no sore throat, no cough.

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Diarrhea stomach cramps on Sunday afternoon Very sore arm Saturday to now Feeling like my nose is stuffy or tender but no congestion or mucus

Headache onset the night of vaccination. Body aches / congestion next day.

Patient reported she had been feeling anxious about receiving the vaccine all day due to its newness. About 10 minutes after receiving the vaccination she reported an elevated heart rate per her watch. Her hands were shaking mildly. She denied chest pain, shortness of breath and/or dizziness. Palpated radial pulse was 130s-140's. BP was 150's/70's. She was taken to hospital emergency room; she declined any medications. Through use of meditation techniques and calming practices, her heart rate lowered to 90's, then returned to 120's then lowered again to normal heart rate.

Within minutes of receiving vaccine, became pale with faint feeling, and elevated BP. Experienced this feeling in waves for an hour after the event.

My tongue & roof of my mouth was feeling numbness & I felt off. I told nurse I was leaving and she said no get reevaluated. An doctor checked my symptoms and vital signs were elevated. He gave me an Benadryl IM. Send me to ER and had me on observation for a couple of hours. My symptoms subsided and my vitals returned to normal. I went back to work.

I developed severe arm pain within 6 hours of getting the vaccine making it difficult to turn to my left side so I could sleep. The following day in less than 24 hours I spiked a 101 fever with chills and fatigue. Took Tylenol and it went away. My arm was still painful with warmth and swelling, noting a red circle approximately 2.5 inches in diameter around the site of injection which was noticed by a friend on 12/26. I continue to have pain in the arm on 12/27 with lessening of warmth and redness but still with swelling.

Patient experienced headache, nausea, and light-headedness after receiving the Pfizer BioNTech COVID-19 Vaccine. She was observed for 30 minutes and her symptoms resolved.

Shingles lasting about 5 days -mild case

Approximately 20 to 30 mins after vaccine i developed feeling of hot all in my body reminded me of broom injected worn contrast dye my heart was pounding tachycardia some chest heaviness jaw popping have self epi pen went to hospital monitored for 4 hours give ativan im had feeling of hot flushing tachycardia chest heaviness impending doom at least 10 or more times before it went away. Slept for 16 hours nausea threw up once. Mild confusion don't remember leaving hospital coming home or talking to some people on the phone

"Moderna COVID-19 Vaccine EUA Patient reported generalized pruritic rash upon waking up the morning of 12/27/20, also reports ""scratchy/itchy"" throat. Patient with stable vital signs, speaking in full sentences and hives over bilateral upper extremities and chest, examined at 815am. Patient given 20mg dexamethasone IM, zyrtec 10mg and sent home to take 50mg oral benadryl."

Arm tingling and soreness first 30 minutes, then just sore. About 6 hours later, extreme chills and pain throughout body, sore joints, lightheaded, fever.

Vision interference, tachycardia, hypertension, flush, rash, sweaty, hot, shakey, light headedness

Shortness of breath, chest pain, itching, near syncope, blood pressure spike

Severe cramping pains in the left calf that woke my up from sleep. I had difficulty moving my leg. I am assuming it was about 2 AM and it kept me up for at leas 20 minutes. However I did not look at the clock. I am an internist. I have not reported this to my PCP's office of to employee health yet as it is the weekend. It did not recur so far and I hope it does not

5 hours after shot administered developed a moderate amount of pain in my left arm that continued into the next day. On 12/25/2020 I developed a pretty constant left sided headache. Pain is moderate and is affected my daily life. Unable to complete household chores.

intermittent headache since vaccine given. Relief with Tylenol

""""Moderna COVID-19 Vaccine"" Developed rapid pulse and flat red rash across chest immediately after vaccination. Within 8 minutes developed metallic taste in mouth. Reported tongue swelling and throat tightness. Taken to Emergency Department after onset of symptoms. Symptoms resolved within 1 hours of vaccine and patient was at baseline with in 2 hours. Patient was discharged home from Emergency Department."

Fever up to 102 degrees Chills Fatigue Headache

Headache Fatigue Nausea

Dizziness, Shaking and Nausea

Received the vaccine on 12/21/20 without a reaction 15-30 minutes after administered. On 12/24/20 experienced flush, and rash on my face with swelling of the eyes and face. The swelling has progressed since then getting larger even after treating with Benadryl and cold compresses. It is now 12/27/20, and swelling is not decreasing. Am not experiencing difficulty breathing or any other symptoms.

Rash on both arms that is itchy

Left arm pain, headache, fatigue

12/24/2020- morning- noticed pain in R deltoid at site of injection (expected) and also L ankle pain not associated with any type of trauma and with no hx of injury to ankle in past. Also noticed mild aching pain to R knee (which has had extensive surgical repair several times) 12/24/2020- by midday, limping noted due to pain in L ankle, negative for swelling, bruising, or decreased range of motion 12/24/2020- 8pm- moderate to severe pain to L ankle, still no swelling or bruising. 12/25/2020- midday- still noticeable limp, however pain was moderate and tolerable all day 12/26/2020- increased pain in L ankle as day progressed, still no bruising, decreased ROM or swelling 12/27/2020- woke at 3 am due to pain, elevated L leg. Swelling noted in lateral aspect of ankle by 7am, decreased ROM and point tenderness had developed around lateral and anterior ankle joint. Took 2 Aleve for pain. Went to walk-in orthopaedic clinic when they opened at 9am for assessment,

Flushed, Headache, Hypertensive Event

Moderna COVID-19 Vaccine EUA dizziness room spinning had trouble standing, light headed, vomiting drinking water made it worse for a short time, shakiness, head ache the lights in the er room made this worse.

Mild Fever (max 100.3), Cough, Fatigue, Runny nose, Congestion, Headache, Dizziness, Nausea. Symptoms started within 3 hours of receiving vaccine. Symptoms continue still today 12/27/20. Taking Tylenol and ibuprofen to control the fever and afrin nasal spray for congestion.

Painful fluid filled bumps in a linear formation discovered this morning 12/27/2020 at 9am. I received the COVID vaccine on 12/19/2020 at 10:15am

Lips & Tongue became numb Tx with Steroids by PCP

Fatigue, Malaise, Back Pain/Joint Pain - From 12/24 at 11 am to 12/25 at 6 pm

rapid heart rate Difficulty breathing dizziness weakness

Body aches and Fatigue

Moderna COVID-19 Vaccine EUA 12/23/2020: Received vaccine at 1:00 pm. Experienced left arm soreness, injection site tenderness, body aches, and chills from 10:00 pm throughout the night. 12/24/2020: Awoke with left arm soreness, injection site tenderness, body aches, chills, and a fever of 100.6 F at 8:00 am. Fever rose to a maximum of 102.0 F at 9:30 am. Took acetaminophen and ibuprofen around the clock starting at 9:30 am until I went to bed that night. Symptoms were completely controlled with the acetaminophen and ibuprofen by about 3:00 pm. 12/25/2020: Arm soreness and injection site tenderness throughout the day. Chills with temp of 99.8 F at 2:00 pm. Took single dose of acetaminophen (1 g). Chills and low-grade fever resolved and did not recur. 12/26/2020: Mild injection site tenderness only (did not require treatment) 12/27/2020: all symptoms resolved

Sluggish , body chills , cold sweats

12/23- began to experience intermittent right lower quadrant pain in the morning, fever of 100.4 F in the evening which subsided with ibuprofen. 12/24- no fever noted but intermittent right lower quadrant pain continued, seen at the Health Clinic, sent to Hospital ER for CT scan, diagnosed with appendicitis, appendectomy performed.

c/o dizziness and increased heart rate. Assessed by attending and hospital MD present. HR went from 138 to 80 beats per min in 3 minutes. Able to walk to reclining chair from straight back chair without incident.

"S: Patient 41Y F unit assistant came to Covid vaccine clinic for vaccination on 12/27/2020. Received injection at 1436. Employee was instructed to sit in clinic for observation. At 1445, employee reported nausea, lightheaded, a ""floating' sensation and sore throat. The floating sensation was also described as a ""oozing sensation"". States that she ate noodle soup for lunch at approximately 1pm. Took Tylenol at 2pm prior to arriving to clinic for vaccine. She denies chest discomfort, palpitation, shortness of

breath, wheezing, or blurry vision. History of craniotomy in 2017 and pulmonary embolism in 2016. No history of HTN or GI conditions. á O: VS at 1445: BP 126/75, HR 75, temp 98.3, O2 sat 96% room air, RR 18, pain 0/10. Reports symptoms onset. At 1455: BP 123/76, HR 72, temp 98.3, O2 97% room air, RR 18, pain 0/10. Nausea resolved. Continue to have mild sore throat, lightheaded, and ""floating sensation."" At 1510: BP: 132/80, HR 69, temp 98.3, O2 96%, RR 18, pain 0/10. Sore throat improved. Denies lightheaded, floating sensation. AAO4, follow commands, lung sounds clear, heart sounds normal. No angioedema. No acute respiratory distress. á A: Adverse reaction to Covid-19 vaccine á P: Employee was closely monitored in clinic for additional 30 minutes. Employee was provided fluids. Employee states that her symptoms has gradually resolved. Employee was advised to monitor her symptoms. If symptoms worsen or persist, she needs to notify her manager and go to urgent care/ED for further evaluation. She stated understanding. Employee returned to work, left clinic in stable condition. No acute distress."

Sever Headache that progressed to a Migraine

Warm feeling all over the body possibly a slight fever and as of now later on in the day a warm tingly sensation on the injected left arm.

8 minutes after vaccine, started to feel dizzy, room got quite, started to feel hot around neck ears chest, red blotchy all over and continued to get worse. Started to feel a cold sensations. Nurse came over to assess had me sit and put legs up, rash got worse dizzines got worse, took me to a cot to lay on, had me take dose of pepcid and claritin, then decided i needed benedryl injection at 713pm. monitored my blood pressure, pulse ox and heart rate. heart rate was tachycardia. just felt off felt like something was wrong. about 30-40 minutes after benedryl injection the redness started to lighten in color. after more time of monitoring me i slowly started to feel a little better, after an hour and half or so i felt ok enough to be dropped off at home. Today 12/27/20 i have felt very jittery, nausea chills and fatigue started around 430p.

Lightheaded, metallic taste in mouth, and tingling in my throat at time of vaccine. Localized injection pain to site the next day, now joint and muscle pain the following day and to this day along with fatigue

WITHIN MINUTES SUDDEN ONSET OF PALPITATIONS AND SUBSEQUENT CLAMMINESS

about 45min after injection time, my lips started to tingle and my throat was scratchy. the muscles in my anterior neck and upper back felt acutely tight. I did not have any trouble breathing. the scratchy throat and muscle tightness lasted about 10 min. the lip tingling lasted about 20 minutes. after those symptoms resolved, I started to feel flu-like and fatigued/diffusely achy. those myalgia/fatigue symptoms lasted 5 hours. I never had a rash. I never had trouble breathing. I was back to normal about 6 hours after injection--other than an expected sore injection site.

Tired, body aches, fevers and cough

Dizziness, dim vision, sweating, flushing, metallic taste in mouth, chest pressure

Moderna COVID-19 Vaccine EUA. Side effects included arm pain at the injection site, chills and low-grade fever to 100.0 starting approximately 10 hours after receiving vaccine. Fever broke a few hours later and symptoms had resolved within 24 hours of vaccination.

At 4:00 today started feeling nauseous and vomited twice so far

Myalgias and mild head discomfort. Scratchy throat and cold symtoms

Extremely sore arm, full body aches, and headache the day after the vaccine. Resolved the following morning. Also presented with hive like raised red itchy rash on lower back starting approx. 9 PM the night of the vaccine on 12/24,. I still have the rash- it hasn't gotten any worse or any better. It hasn't changed in size either. I tried Benadryl spray with fair effect.

Swelling of lower lip 5 hours after injection. Resolved slowly over 9 hours after taking Allegra. Developed 2 hour episode of atrial fibrillation 11 hours after vaccination that lasted 2 hours and was treated with PO Diltiazem and Xarelto.

Localized reaction. Erythema initially 1 in diameter, indurated, sore arm. Worse 12/24. Induration/erythema up to 3 inch diameter. Soreness obviously worse. Took antihistamines, tylenol. Today induration down to 1 inch, bruised not nearly as sore.

Migraine was present at time of vaccination, but evolved and worsened after 36 hours. Nausea and anorexia developed after 24 hours. Severe aching back pain developed after 32 hours. Fever 101.5F developed after 36 hours. Symptoms lasted 24 hours and resolved. Diarrhea developed at 48 hours, was intermittent, and lasted 12 hours. Ondansetron 8 mg PO was taken once. Ibuprofen 400 mg PO was taken after 48 hours.

Had a sudden strong wave of nausea and felt very hot. That went away after a minute. Have had consistent mild nausea since then.

Headache beginning two to three hours after the injection. Generalized malaise approximately 9 pm. Awoke from sleep at 1 AM with severe chills and tremors lasting until 3 AM. Temperature of 103. Back to sleep and awoke at 4:30 with severe headache and N/V. Temperature 100.8. Muscle aches, headache extreme tiredness throughout the day on the 25th. Chills again around 11:00, temp 100.1. Generalized malaise, stomach cramping and headache lasted throughout the day. Awoke on the 26th at approximately 2am with night sweats. Went back to sleep and awoke at 8am on the 26ths with wet blankets and pajamas. Felt better after showering. Still had a headache but didn?t really hurt unless sneezing or coughing. Well enough to go to church. After returning had diarrhea a couple of times. Now only a lingering heaviness in center of my chest and need to cough that I have had since a week before my Covid diagnoses in November

"Pt was vaccinated at approximately 1135, exact time on consent form for vaccination. Pt was visitnig with another pt outside the lobby for about 15-20 min. then came iinto building stating that she had ""chest tightness"" pt was calm and able to descrive sesation. No distress. Pt was instructed to sit in chair and vital signs obtained, 2 sent obtained immedicately after. Pt still awake and alert able to

verbalize needs. Manual blood pressure taken. Dr called by Pharmacist. Pt was anxious and was verbally calmed by RN. 2 RN's and pharmacist at pt side. Pt c/o of dizziness, respirations elevated but able to maintian airway. Pt heart rate elevated. Dr arrived and asessed pt. After stabilation and meds administered, pt taken to urgent care for further monitoring and evaluation. Pt declined EMS transport to ER."

Myalgias, chills, dizziness and restlessness, feeling unwell. The dizziness and restlessness resolved with an antihistamine (Cetirizine 10 ml, one dose) and tylenol was used for myalgias and chills with good response.

Migraine headache, severe. Associated nausea, vomiting, light and sound sensitivity.

Fever (100.4) and chills starting approximately 12 hrs after administration. Temp was back to baseline by noon the following day. Some lymph node swelling to right armpit noted the day following administration. Subsided 2 days later

Employee was given moderna vaccine on 12/24/20. On Friday night, he started to get fatigued and sore. Today, he developed fever of 101 and still feel fatigued and sore.

Within 5 mins of receiving I had systemic tingling and felt very hot. My heart rate went into the 110s (usually 60s). Throat tightness occurred and I was given 50mg IV benadryl. Within 30 mins all of those symptoms subsided

Hot flashes, extreme headaches, extreme fatigue, muscle fatigue, lasting greater than 12 hours

Sore arm, sinus-type headache, and fever for approximately 7 hours.

Pain at injection site 2 days of severe fatigue Yellow/orange urine despite doubling water intake

Fatigue, headache and pain at the injection site all started within 6 hours of vaccination. Headache lasted about 1 day. Sever fatigue later about two days. And pain at the injection site for about 3 days. Yellow/orange urine despite doubling water intake for about 3 days .

All initial symptoms- soreness at site passed at day 3, At day 5 woke up from sleep with headache, did not respond to excedrine, progressed to migraine with photo and sound sensitivity, called out of work for next shift (bedside rn) vomited twice, telehealth urgent care proscribed imitrex and zofran, encouraged ER visit if headache not relieved by first dose of triptan. Migraine lasted about 9-10 hours from onset to pharmacy filling two new prescriptions for me to allowing medications time to work

Experienced L sided visual changes, including decrease in visual field and inability to focus eyes. No intervention, recovered 30-40 minutes after it began.

Headache, nausea, low-grade fever, malaise

Headache, took tlyenol

Subconjunctival hemorrhage in my right eye.

Chills Fatigue Joint Pain Body Aches Started 1800 on 12/27/2020 I took no medication but considering Tylenol

dizziness with horizontal nystagmus, improving the next day. No fatigue, no weakness, no headache, no fever, no aches or pains at any time, no other symptoms.

Flushed, hot feeling, sweating, rapid heartbeat, dizzy starting about 10 minutes after vaccine and lasted over 3 hours.

Pfizer-BioNTech COVID-19 Vaccine EUA: pruritic rash at injection site (localized), appeared 10 days after first dose

fatigue, muscle ache, joint ache, headache, nausea, chills

severe nausea and vomiting lasting 4 hours; moderate headache lasting 12 hours; mild left arm pain at site of injection

Chills, shivering, migraine , body aches, painful tinnitus, fever, elevated resting HR of 90 (normal is 46), bounding heart beat, tightness in chest, elevated resting BP 150/80 (normal 124/72) 600mg ibuprofen & 500mg acetametaphine made me comfortable to get about an hour and half worth of sleep. Went to ED for elevated HR, BP and chest pain. ED took EKG and monitored vitals. ED discharged with 975mg acetametaphine and 800mg ibuprofen with 24hrs quarters. I was able to get about 3 hours of sleep.

Decrease appetite-12/23,12/24, 12/25,,12/26,12/27 Increase Joint pain-same as above General muscle aches-same as above Numbness bilateral arms w/ tingling in fingers-12/24, 12/25, 12/26 Fever w/ chills - 12/25 Headache w/ nausea on and off 12/23, 12/25, 12/27 Dizziness and weakness 12/23, 12/27 Tiredness and feeling unwell 12/25, 12/26, 12/27 Chest tightness 12/27 I didn?t take any other OTC medicine, just tried to Go through

I developed left arm soreness (at the injection site) 12 hours after getting the shot. I also developed a temperature up to 100.7 associated with chills. I took Tylenol 1000 mg and fever subsided for 4 hours but fever and chills came back and now temp was 101.1 which was relieved by Aleve (took 2 of the 375 mg tabs). I had low-grade fevers up to 100-101 for 24 hours, associated with myalgia but no more chills for the whole Christmas Day. All symptoms resolved except for left arm soreness within 24 hours. Left arm is still sore even after 72 hours.

Joint pain. Most significant in hips. Effected my walking / sitting throughout the day.

Received the vaccine at 1038a. 1045 developed minor tongue tingling. Called the RN she gave me 25mg Benadryl. By this time whole tongue became tingly and the roof of my mouth started to feel numb. A minute later throat started to feel full and it became hard to swallow. This feeling of it being hard to swallow, came with a painful headache and some chest pain. Once in ER, was given more Benadryl, Epi, Lorazepam, and Protnox. The feeling in my throat and the difficulty swallowing slightly improved 25min after the oral Benadryl. It took about a little over an hour from the onset of symptoms to start to feel they were resolving.

Small bumps/mild rash on chest and a little itchy (but I?m also on Zyrtec)

Horrible debilitating non stop migraine like headache for three days following 1st dose of vaccine starting 12 hours after dose. Extreme tiredness, muscle pain, nausea three days duration. All symptoms resolved 3 days after vaccine

8:27 Hives, itching all over chest and on tongue, tongue swelling, slight difficulty swallowing. 8:30 epi administered/ benedrly 8:32 pseudo seizures begin off and on till the 27th

IM shot received at 0750. Went to sleep for the day since I work nights. I work up at noon with severe headache and numb bilateral hands. I took Tylenol 1000mg and went back to sleep. I woke up for work at 1630 feeling flushed. I took naproxen and went to work(in the ER). I developed a rash on my chest that evening. Over the next 3 days the rash progressively worsened across torso, back, and extremities. Since I received the vaccine on Christmas eve, employee health has not answered my calls or messages with the holiday. I also am scheduled to see PCP for this after the holiday weekend. I have been medicating with Zyertec BID, Benadry Q4hr, Pepcid BID, Tylenol TID since 12/24. I started a prednisone taper on 12/27.

I am sore throughout my body, muscles and joints, constant. I have never had any issues like this before. Tolerable pain/ discomfort 2-3 out of 10. Iwould guess what arthritis feels like. Also I?m very tired.

"I received the 1st moderna shot on 12/23/20. A couple hours later I experienced extreme fatigue. My memory became cloudy and I was so tired that I had difficulty walking. This fatigue lasted the rest of the day. I awoke the next morning with less fatigue but feeling hungover. I also had blurry vision that morning. The blurry vision abated within 5 hours. The fatigue was much improved within 36 hours. My allergy symptoms were triggered the day after the shot and my dermatitis flared within a couple days of that- super annoying because I have significant allergies and dermatitis that took specialists a couple years to control. All was ""in remission"" until the covid vaccine. Hoping that everything better by tomorrow- fingers crossed."

flushing , rash to face and chest. small bumps on the lips and tip of tongue. Improving symptoms with claritin and benadryl taken by the patient prior to arrival to the ER.

"10 minutes following vaccination, itchiness, ""fullness in face and chest"" She took benadryl and cetirizine due to known adverse reaction to H1N1 vaccine Overall resolved in 30 min no worsening Arm achiness x2 days"

12/18: First hour after vaccine: increased heart rate, felt flush and jittery - like I had drank a lot of espresso. Not debilitating but unpleasant. Then mostly went away, felt drained 12/19: headache and nausea started along with fatigue. Nausea would come in waves 12/20: Fatigued, headache 12/21: Headache, Nausea, waves of feeling flush (never had fever) and increased Heart rate. Worked all day but felt lousy 12/22: Continued symptoms from day before - feeling drained especially after episode of nausea/increased HR. Worked all day 12/23: Heached, Nausea - stayed home from work because they wanted a covid test to rule out that I had not contracted. Slept on and off all day. Cough started PM

12/24: Just headache, no nausea but no appetite, low energy 12/25: started feeling normal. still no appetite.

Facial numbness on side vaccine was given

Pain and generalized swelling to left arm for 3 days post injection. One day after injection fatigue and myalgia, Tylenol taken twice that day. Day 8 post injection a hot and painful red circle at injection site, approximately size of a quarter. Day 9 circle is size of half dollar and still hot and painful.

Weakness/ chills and fever.

Tongue went numb on right side. My face then went numb on the right side and spread to my ear. It then progressed up to my right eye lid. I took a dose of Benadryl and Flonase. Numbness stopped spreading. It lasted about 35 hours. No facial drooping noted. I was able to close my eyelid then entire time.

syncope, anxiety, nausea, vomiting, diarrhea, perceived tongue swelling although no visible swelling

fever of 100.4 deg F, took tylenol

Significant fatigue ~24 hours after vaccination. Muscle aches, joint pain, fatigue ~48 hours after vaccine. No fever noticed.

I took the shot at 11:45. By 3ish my shoulders and neck began to become stiff with slight pain which progressed throughout the evening until I developed a severe headache. By 6pm I had difficulty turning my head due to neck stiffness with a resting HR:98 SpO2:99%. I then developed a cough, SOB, dizziness, and balance deficit. Around 9pm my lips went numb with tingling when touched. I then developed small blisters around my lips. I was awake till around 4am with a severe headache. By 9am all these symptoms subsided except for the tachycardia and lips tingling with paresthesia which resolved by the next morning. 48hrs later I was back to normal.

Left sided facial numbness

Significant pain at injection site that lasted about 36 hours and prevented any touching of the site. Also had mild headache and some generalized myalgias. These also resolved after 36 hours.

Injection site pain, low-grade fever, bodyaches, sore throat, headache, tiredness - lasted from around 10 am to 9 pm, when I went to bed. I had a confirmed negative antibody test 11/24/20

Numbness of the tongue

Moderna COVID-19 Vaccine EUA Excessive shoulder pain with limits on range of motion. Has diminished in the past 36 hours but pain still persists and range of motion is not back to normal. Only took Tylenol, aleve, and albuterol.

Enlarged left cervical lymph nodes. Two palpable nodes that are hard and tender. Measuring about 3 cm in diameter today.

Chills, malaise, nausea, muscles sore, temp 100.1-100.5 13hrs post injection. All s/s gone within 36-48 hrs post injection.

Blood pressure has been 145/80 p.60 since 12/24. I do not have high BP normal pressure for me 110/75 Extreme muscle strain experienced 48 hrs after vaccine given.

12:30 pm injection given to left arm, after 10 minutes of waiting a sudden warm sensation began from left arm traveling across chest to right arm, up my neck and inside throat to my face and head. I found this sensation to be strange and describe the feeling similar to receiving contrast for CT scan and when administered you can feel the warm sensation as it travels through out your body. My vision became a bit blurry I tried to remain calm and asked others in the room if they experience similar symptoms in which no one had. I stood up and walked across the room to get some water. I had an unsettling feeling and coached myself to remain calm. I drank 2 cups of cold water and sat down. After about 5 minutes the hot flush went away. I decided to stay longer than the 15 minute observation time that I was told to do. After 30 minutes from injection I felt okay to leave.

Chills, fatigue, h/a, joint pain, bruising on forearm

-Dec 24: received -Dec 24 evening: fatigue, sore joints -Dec 25th: fatigue, generalized malaise, sore joints - especially those affected by the arthritis.. Moderate symptoms.Last all day. Bed rest. -Dec 26th. Symptoms improving. bed rest -Dec 27th: Much improved. Only symptoms remaining is sore joints (mild) Treatment: 1000 mg Tylenol q 4 -6 hr since Dec 24th

Prolonged symptoms. Pain, swelling to injection site that radiates down arm to fingertips and up arm into shoulder for 5 days and continuing. Swollen, painful lymph nodes in left under arm for 5 days and continuing. Pain so severe unable to sleep.

Within 30 minutes of vaccination, there was tongue numbness and tingling in addition to chest tightness. After 5 hours there was also upper lip numbness and tingling. Benadryl 50mg po was given in Emergency department of Hospital (where patient is a resident physician) and patient took another 25mg po Benadryl before bedtime. Tongue numbness improved by next morning, however upper lip numbness persisted. There was also upper lip swelling the next morning after vaccine, which was noticed when patient woke up (~ 16 hours after vaccination). This was treated with 20 mg cetirizine in AM and 10mg cetirizine at night by patient. Swelling persisted into the following day ~ 48 hours post vaccination before resolving. Patient?s initial chest tightness resolved within the few hours of observation in ED.

Agitated that night starting in 4 hours Resolved by am Mild arm pain and febrile sensation during night after injection Myalgia for 3-4 days

12-14 hours after vaccine, very sore injection site arm, fever, chills, viral syndrome symptoms and intensely sore, burning mouth. All symptoms came on simultaneously. felt great after one dose of NSAID except for sore mouth. Following day looked with flash light and have red based mucoid lesions multiple throughout the oral pharynx. no trouble swallowing. I take valtrex 1 gram daily as my dry mouth causes

chronic HSV outbreaks but these are NOT hsv as there are no central ulcerations and they burn but aren't intensely painful like hsv lesions.

Approximately 30 mins after injection I started to feel my heart racing. Checked my pulse and it was reading 130bpm. This continued on for approximately 60mins. I then started with a migraine that lasted 36hrs. Starting on 12/25/2020 I felt a lump in my throat and have been periodically choking on food and liquids. It feels like my thyroid is enlarged.

Pfizer-BioNTECH COVID-19 Vaccine EUA I had a mild headache 20-30 minutes after vaccine was administered on 12/18/20 that went away 4-5 hours later. I did not take any medication to help with headache. I woke up the next day with extreme fatigue, muscle aches and hot flashes/chills from Saturday-Tuesday morning. I had radiating pain down my arm to my fingers that lasted about a day on 12/19/20.

Arm soreness, Diarrhea, Headache, Nausea, and Fatigue. The last four were exact symptoms I had when I was ill with the virus. The side effects only lasted approximately 12 hours and most were alleviated with Zofran and Naproxen. No medication helped the headache, which was also my experience when I had the virus a month ago.

Muscle/body aches, fatigue/tiredness, and fever

Chills a couple hours overnight. Woke up on 12/17/20 with a moderate headache.

Mild pain and mild headache

Slight runny nose, mild rash, moderate headache lasted 14 hours

With in 5 minutes of receiving the vaccine, my feet began to burn. It continued to get worse throughout the day and turned into numbness and tingling in both feet and both hands. Still continuing to have these symptoms 17 hours post vaccine and unable to sleep.

Received COVID vaccine 12/22 at 1100. Noted hive on right wrist, opposite arm of vaccination at 1700; hive- 1 cm in dimeter, red raised in middle, not itchy. Benadryl at bedtime and when woke up red outline was present but not raised, 24 hours later completely resolved. Some fatigue and slight headache within the first 12 hours, resolved. Also reported mild chills and mild fever lasting less than 12 hours.

Excessive thirst 15mins post Heart palpation with fluttering sensations 30mins post HTN 156/96, 80hr, 1hour post Chills 1hour post Muscle spasms with cramping throughout body 45mins post Muscle weakness to left side 2hour post Facial twitches Treated with tylenol and Gatorade and rest. Symptoms lasted 48hours post.

Vaccinated on 12/23/2020 at 1 PM. Moderate pain and tenderness on injection site. One white pustule on left tonsil. Tender lymph nodes. Moderate generalized body aches. Mild headache, mild fever. Went to urgent care Negative for mono and strep. Got script for erythromycin if symptoms persist.

Developed cough, fever, body aches, and chest pain

Flushed skin, elevated HR, extreme feeling of internal heat, dizzy

nausea/vomiting, elevated heart rate and cough

Patient received COVID 19 vaccination and developed elevated heart rate. It is less likely that this was a reaction to the vaccine given no complaints of nausea, vomiting, itchiness, shortness of breath, abdominal or epigastric pain, wheezing which are typical signs of a reaction. Most likely this was an anxiety event.

Severe nausea/abd pain lasting 24 hours

Developed headaches the week of vaccine, especially Saturday, 12/26/2020. Experienced body aches on 12/26/2020, intermittent in nature and fatigue. Called Nurse to report symptoms and confirm clearance to return to work on 12/28/2020 and was instructed to complete potential vaccine reaction.

Woke with nausea/vomiting, chills, and dizziness

pt with history of anaphylaxis to latex and fruit, presents to ED with urticarial skin reaction with itching, throat itching, cough, lightheadedness soon after receiving Covid vaccine.

Day 1 injection site pain, Day 2 extreme fatigue and temperature of 100.4, injection site red, warm with a 5 cm hardened lump, Day 3 injection site red, warm with a 3 cm hardened lump, day 4 injection site remain red and warm, no longer swollen

Patient developed a soreness and then itching developed. She then noticed a knot to the left of the injection site. She has now developed approximately 2 inch long area of redness across her deltoid.

within minutes of being vaccinated, developed feelings of swollen lymph nodes, fullness and stiffness in her neck. She has redness across her upper chest. She has experienced side effects similar to this from other vaccines she's received in the past. She was observed in the ED but no medications were administered. Her symptoms improved and she was discharged with a prescription for an EpiPen and an appointment to follow up with an allergist.

12/27 woke up with pain in left armpit. Swelling increased throughout the day. Pain was manageable without medication, did hurt when swelling was palpated or I squeezed my left arm down to my side. Woke on 12/28 with same pain, does not appear to be further swelling, but hurts in my armpit to hold my arm above my head.

Approximately 20 hours later, I began getting chills. When I put on a jacket, I began sweating profusely., yet freezing cold. My head was pounding. Came home from work a couple hours later and took a nap for a few hours yet woke up multiple time covered in sweat, yet again freezing cold

Within 10 minutes of receiving the Pfizer COVID vaccine, she complained of chest tightness, feeling flushed, mild headache, and paresthesias in her hands and mouth. Symptoms lasted approximately 10

minutes and resolved spontaneously. No treatment was administered. The patient was observed and discharged to home with no additional treatment.

Erythema and edema at injection site measuring 4 inches by 2.5 inches lasting 3 days. Day 2 had an excruciating headache unrelieved by Tylenol or Aleve.

Patient received the Pfizer Vaccine. Mild rash was noted on the forearms by the patient

10 minutes after receiving vaccine patient complained of head heaviness, palpitations and feeling hot in the ears. BP = 166/97, HR = 129, O2 SAT = 100%, Temp. = 98

10 minutes after receiving vaccine patient complained of head heaviness, palpitations and feeling hot in the ears. BP = 166/97, HR = 129, O2 SAT = 100%, Temp. = 98

Pfizer-BioNTech COVID-19 vaccine EUA on 12/15/2020--12/19/2020 @ 0300 I woke up with joint pain in all joints including hands, feet, fingers & toes, also muscle aches. I had an occasional cough, nasal congestion, nausea and headache. The joint and muscle pain lasted approximately 48 hours and was relieved with Tylenol and ibuprofen every 4-6 hours. The HA lasted until 12/22/20. As of today 12/23/20 I still have some nasal congestion but no other symptoms. I never ran a fever.

Tongue swelling a bit. Postules formed. Bumps all over tongue. No fever or other symptoms

FEVER 100.1, HA, body aches

These are expected side effects, I was told I still need to fill out this form by my boss. Temp 100.2, extreme fatigue, chill, extreme muscle pain, cough, left eye irritaion

Serum sickness syndrome, fever not greater than 101, severe muscle and body aches/pains, nasal congestion, extreme fatigue, cough, nausea, loss of appetite First vaccination in 55 years

"12/23/2020 0200 Severe Tremors and Chills. Nausea, dizziness, & near syncope. Headache. 0700 Softball size lump(edema), 6""x6"" area erythema, hot to touch, and pain at injection site. Difficulty raising arm due to pain. Fatigue. 12/25/2020 0100 Awakened hot and sweating which lasted approximately 6 hours, fatigue. Arm issues continued. 12/26-27/2020 Arm slowly improving but fatigued and headache continued. 12/28/2020-Improved but headache continues."

Bruising at site of injection and multiple areas covering body (limbs, back, abdomen) that was noticed beginning 12/24/20 and has continued over several days

12/20/2020 12:00 PM DEVELOPED LAPID ATRIAL FIB. WENT TO ER WHEN IT PERSISTED, MEDICAL CENTER. ADMITTED TO INPATIENT; 12/21/2020 - ELECTRICAL CARDIOVERSION. MONITORED OVERNIGHT. 12/22/2020 - DISCHARGED *ON CHRONIC BLOOD THINNER

12-23-2020 severe chills, nausea, and severe body aches did not check temp. 12-24-2020 she still feels off, but not as bad. Temp is normal

Local redness, swelling, left upper arm at injection site.

Rash on abdomen approximately 2x4 inches with slight itching that lasted about 3 hours without requiring any treatment.

Almost immediately after vaccination the recipient felt faint. She was helped to lay on the ground, vitals were checked and monitored, and remained stable. She quickly felt better and stayed in observation a total of 25 minutes. She reported that she has experienced this in the past when getting a blood draw or vaccine. She returned to her work unit with a colleague. We checked in with her a few hours later and she was completely fine.

Arm pain

Patient reports developing a mild headache post vaccination within 15minutes that progressed in severity with nausea, dizziness and fainting. Occupational Health is following up with patient and recommending comprehensive provider evaluation

Immediately after receiving vaccine recipient stated that he felt faint. Eyes rolled back and he became limp. Two nurses laid him on floor. He came to within seconds but was diaphoretic. Vitals were checked and monitored (BP 130/70, 118/74, 120/72; pulse 57, 72, 68; pulse ox 98%, 99%, 99%). He quickly felt better (within a few minutes), was given water, chocolate and a granola bar. He stayed in observation a total of 35 minutes. He reports that he had been very nervous about getting a vaccination. He returned to his unit with a colleague. We checked in with him a few hours later and he reported that he felt well.

Muscle aches, fatigue. Treatment rest. Resolved by 12/27/2020

Fatigue on 12.26, fever 101f on the night of 12.26, fevers 101 to 102 from 12.27 to today 12.28. headache beginning 12.28

Moderna COVID-19 Vaccine EUA Headache for 2 days

Vaccine recipient received the vaccine on 12/18/2020. On 12/19/2020 reported that the injection site had prominent redness and swelling. On 12/22/2020, the site was warm to the touch and the pain was mild, but bothersome. Over these 5 days the injection site became swollen with increased redness and pain. On 12/23/2020, the vaccine recipient reported that they were feeling better and has followed-up with occupational health with no further issues.

low grade fever 99.8 F, slight nausea, over feeling not well, fatigue

Redness, swelling at vaccine site

12/25/2020 08:00AM patient awoke with left eye twitching, mouth drawn to left side. Neck severely aching from right earlobe to the back of neck, severe headache. Unable to close left eye. ER visit 12/26/2020 in the morning - discharge diagnosis, Bell's palsy. Prescription Valacyclovir hcl 1 gram tablet, Butalbital, Acetaminophen, Caffeine Oral tablet 50-325-40mg , solution eye drops , Azithromycin cream

Flu symptoms including headache, nausea, chills, joint pain and low grade fever of 99.3 Symptoms began in the middle of the morning about 10:30 - 11:00 am while I was at work; worsened through the afternoon and night; all better by morning; symptoms completed gone

Patient complained of tachycardia about 15 to 20 Minutes after receiving the vaccine

Quarter size swelling at injection site, entire deltoid became quite sore, firm, warm and extremely tender with significant decrease in ability to perform abduction and extension over the next hour. Pain and stiffness progressed to right shoulder blade and right trapezius. At this time these areas remain somewhat tender and sore, however ROM has improved. Of note, also developed some SOB and redness to neck and chest within 30 minutes of injection, Fexofenadine was taken and the SOB and redness to chest resolved by 4pm day of injection.

Within 12 hours of receiving the vaccine I developed sever flu-like symptoms - low grade fever, chills, body aches, extreme fatigue, runny nose

I had a headache, extreme fatigue, achy joints and muscles. I had a scratchy throat also.

who presents with complaint of rash , itching minutes after COVID vaccine. Also notes nausea and fatigue. Pt notes no throat swelling , pain , voice change , shortness of breath , abdominal pain , vd or other concerns. Pt has known allergy to flu vaccine and other medications as noted

Fever 100.1 to 101.5. 24 hours. I was very weak. I could barely walk to the bathroom. At 5 AM when the symptoms started I felt like it was going to faint or just collapse. I felt like I was going to faint on multiple trips to the bathroom. I had no energy .I felt like I had Covid symptoms all over again. I had cold sweats for almost 24 hours had to take my clothes off to get comfortable. I was so warm. exhaustion .slept for almost 24 hours. I just felt miserable my stomach was nauseated and felt very sore in my abdomen. aches and pains in my hips and legs.

After receiving the covid vax, I had shoulder soreness the first couple of days. That night, the vein , was a different color than the rest of my veins in my bicep. The discoloration of the vein was at the top of my bicep. Now, the vein is visually fine now.

Two hours after the injection my tongue started swelling and pain increased throughout the day to the point where I could not eat. The next morning (Dec. 23rd) I had painful white lesions under and on the sides of my tongue. This worsened over the next day and I was seen at an urgent care clinic who took culture swaps for lab test. (eventually negative for oral herpes). Pain and lesions continued to worse and I was admitted to the ER on December 26th. Breathing, heart rate, and blood work all normal. Diagnosed with Herpangina/Coxsackie Virus.

Injection site pain x 2 days, nausea x 5 days, fatigue x 3 days, chills x 2 days, muscle + joint pain x 2 days, headache x 1 day, weird dreams x 2 nights

Hive reaction began on day 7 post vaccine, isolated to left arm, back, trunk.

Experienced nausea, dizziness, felt hot and face flushed, and felt like he was going to pass out 15 minutes after receiving vaccine. Patient assessed in the emergency department and found to be stable but has complaints of nausea and dizziness with headache. Received IV fluids, meclizine, and prochlorperazine. Discharged from emergency department at 1454 after tolerating fluids and foods by mouth without difficulty, no recurrence of symptoms, vital signs remaining stable, and stating he feels like he is back to his baseline status.

pt received a COVID vaccine of moderna and within 15 minutes pt c/o throat feellng itchy and tight down low. Also, c/o of tingling in fingers and toes. Pt noticeably shaking. Pt has a hx of fainting with needles. Pt become more anxious and requested and ambulance to be called. Color was flushed. B/P 169/99 P146 SPO2 99%. For pts comfort gave O2 at 2L/min via NC. Pt remained alert and oriented and talking. EMT administered Benadryl 50mg IM. Ambulance escorted pt to ER where only observation was done. F/U with pt about 2 hours later. Pt states she believes she panicked and was doing fine right now. No other issues.

first start with sore arm and neck-then started hurting in chest- now have blisters on lip and throwing up

Cold extremities, warm face & diarrhea - Monitored for 47 minutes, no abnormal finding except for elevated BP. Client did not have any rash, hives, angioedema, difficulty breathing, wheezing or altered level of consciousness. She reported all symptoms resolved and discharged home. Additionally, she reported diarrhea overnight which had resolved by the next day.

severe cold chills started at 3am no fever used heating pad to get warm then had to work the next day severe aches and chills again with some nausea took ibuprofen at 9am and chills and aches went away for about 5.5 hours then returned but not as severe. right arm pain x 2 days

Muscle aches, subjective fever, headache, sore arm

Arm pain for 2 days and a very bad headache for 2 days and extreme fatigue.

"approx. one hour after receiving vaccine pt started having throat tightness, nausea, lips tingling, SOB and ""feeling weird"". States has had anaphylaxis in the past from nuts and uses an EPI pen. States she used her pen but did not get relief so went to ER where she received IV benadryl, tagment and steroids. EKG was abnormal. States no problems at injection site. F/U with patient appox. 7 hours after incident and pt states she is doing fine and not having any issues now."

Hello I received my Covid Vaccination on 12/23/20 7:56 am at Healthcare Clinic. I waited 15 minutes after the vaccination and then went and stayed home. Six hours later my arm started to become very painful (no surprise) I then felt an overwhelming fatigue and sadness. I had tears just streaming down my face for about 3 minutes. I laid down and awoke later that night still feeling very fatigued. I showered and crawled back to bed I awoke the next day at mid-morning, still tired but 60 % better. I stayed awake for a few hours, showered, changed the bed sheets and went back to bed for several hours more. I awoke tired ate a lite dinner and went back to bed. I awoke at 8:00 on Christmas day feeling fine, just like my old self. If you need any more information just call. Oh my vaccine information

is: PFIZER EJ1685 12/23/20 1st dose. Thank you, Medical Interpreter Center for Advanced Pediatrics Endocrine Department.

Headache, cough, Fever 99.9, wheezing, body aches, fatigue

15 minutes after vaccine pt c/o mild SOB, no tongue swelling noted, rapid response team called

Arms became achy and wasn't able to lift it. Extreme Fatigue, Headache and chills

Moderna COVID-19 Vaccine EUA Side effects started about 12pm on 12/23/20 Nausea, headache, body aches, cough, runny nose, congestion, very tired

Patient reports shortness of breath and persistent cough.

About 10 days after the vaccine, I developed, over the course of 30 minutes, pain/pressure from my left distal forearm to my hand, with stiffness and vague weakness in the area. Over the next hour or so I noted swelling of the wrist; swelling and pain in the dorsal and radial aspects of the left wrist have persisted until the following day when I am submitting this report. I had done some activities with the wrist prior to the onset of symptoms (opened a difficult jar, sat on my hand to keep it warm while using the computer) but these didn't seem outside of my normal daily activities.

For the first day or two after receiving the vaccine I experienced injection site soreness, fatigue and malaise, and sore throat. Symptoms resolved within 2-3 days and I was symptom free by the time I went back to work on 12/24

Initial symptoms included a feeling of slight panic with associated need to take deep breaths. Once I left the facility 20 minutes later, I felt slightly lightheaded with sensitivity to light and sound. These symptoms were mild overall. The feeling of anxiety and mild sensory symptoms persisted for several hours. That night, I experienced night sweats. I have been feeling fine overall since that point.

12/26/2020 Chills, headache, fever 105.00, occasional dry cough, throat tickle, body aches. 12/28/2020 low grade temperature- fever, occasional dry cough.

I am a 46 yo MD who received the Moderna vaccine lot#037K20A exp 6/22/2021 on 12/24/20. I had also just recovered from a COVID infection 5 weeks earlier. 18 hours after receiving the shot, I developed severe chills/fever/tachycardia and muscle aches and headache that lasted about 7 hours. I slowly recovered and was better at about 36 hours post vaccine.

Vomiting, Diarrhea, Fever, Chills, Muscle Aches

Axillary pain and swelling

Eyes started itching. On December 20th eyes itched so bad that contacts were not able to be worn. Redness on hands and were itching which began 12/19 but on the 20th bumps and itchiness on elbows. I suffer from eczema and take self injection shots for it so the rash appeared as if my eczema was triggered.

Dizziness moments after injection, mild-moderate severity. Duration 2 hours. Treatment -rest after driving 15 minutes to home. Resolved without treatment.

facial numbness

The evening I received the shot I spiked a fever and my body started aching really bad. The next morning my head hurt and my body ached. I took some ibuprofen which seemed to help but that evening I spiked another fever and my body ached again.

After receiving the vaccine, 30 mins later. I started feeling dizzy with a rapid heart rate. I started feeling really weak and delirious. Then I had a really bad headache with nausea and fatigue. Then I eventually laid down and fell asleep for about an hour, I had a headache and the other symptoms were gone. All of the symptoms lasted about 3 hours. The headache was the only symptom that lasted longer, about 6 hours.

Mild to moderate widespread muscle and joint pain Temporary localized pain around injection site

Throat itching and light headedness; symptom duration 20 minutes.

When I woke up at 0800AM, noticed with rashes on my back about 25%. I took Loratadine but not relieved. Went to ER at 05:00PM and they give Benadryl IV. Prednisone 60 mg tab & Pepcid 20 mg tab. After 2 Hours rashes resolved. Noticed with rashes also on both legs and adomen when I was in the ER.

PAtient with a history of vision abnormalities reported blurry vision after vax administration. Patient sat for 30min, reported minimal or no improvement and refused to present to ED

Roughly 8 hours after vaccination I had fever to 100.0 and fatigue for about 24 hours. Mild muscle aches. Extremely tender shoulder for 48 hours

Day 5 after vaccine (12/23) severe joint pain only to right upper extremity (shoulder, elbow, wrist, fingers). Day 6 mild joint pain to right upper extremity. Day 7-10 Mild intermittent joint pain along with shooting nerve pain on right upper extremity. Under arm and AC stabbing pain. Numbness and tingling to right upper extremity intermittently. All positional except feeling of ?nerve pain?.

Employee received the Pfizer Covid vaccine. She was feeling nauseous. Soon after she ate, she vomited. She refuse to go to the Emergency room. She felt better to complete her shift.

- R side HA and sinus congestion followed by left sided HA with sinus congestion - Fatigue - muscle and joint aches - resolved after 48hours.

Severe headache onset at 4pm only normal headache at this time, woke me up at 12:30am was severe. Took 2 regular Tylenol eased up after 30 minutes. slight headache lingering on day 3.

Tingling, light-headed, red blotches

Symptoms included fatigue, headache, muscle and joint pain, chills, nausea, dizziness starting approximately one hour after the injection and lasting 4 days for most all the symptoms. The dizziness

lasted for 2 days and the body aches for three. Still with a slight headache and nausea today 12/28/20 5 days after the injection.

Anaphylaxis - epi pen X 2, transported to the ED for evaluation and further treatment.

Dizzy, nauseous, headache, body aches, fatigue, black tary stools., diaphoretic, near syncope

Began spotting period blood, but at least two weeks prior to normal period week.

Moderna COVID-19 Vaccine EUA

Face Started itching, Throat felt weird, rash started appearing on both arms

Tingling in hands and arm soreness, feeling like they are asleep 1 hour after injection. No treatment. Symptoms eventually resolved.

Aching in right arm, then pruritus, then swelling. Went to ED immediately since she was at work when reaction began. In ED was given prednisone, Pepcid, Benadryl.

After 3-4h of the vaccine, patient suffered intermediate headache, 1st dose of Tylenol 750mg PO was given, symptom partially resolved. 15h after, patient had chills followed by high fever, another dose of Tylenol 750mg PO and naproxen 60mg PO were given, 2 hours later, fever and chills resolved. Continuously having fatigue, dizziness, nausea, diarrhea, myalgia, arthralgia for 1-2 days. Lymphadenopathy was felt but unable to touch any swelling lymph nodes in left axillary area. All of symptoms were resolved after 3-4 days. Due to a possible exposure notice, got COVID-19 tested on 12/23/2020, both rapid antigen test and RT-PCR were negative.

Flu like symptoms, HA, sore throat, muscle aches, runny nose, dizziness, chills, felt feverish-but no fever noted.

Vaccine received at 3:29 pm on 12/26/2020. By 4:00 pm she had complaints of a headache, dizziness alog with nausea and vomiting. S/S without resolution or decrease. Sent to Emergency Department for evaluation at 5:35 pm. She was administered the follwing @ 5:39 Sodium Chloris IV, 6:18 pm 1,000 mg IV tylenol, ketorolac 30 mg IV push and Ondansetron 4 mg IV. She was discharged no longer nauseated and headache decreased from a 4 to a 2. discharged in stable condition. on 12/27/2020 she stated she had fatigue, nausea and vomiting, diarrhea and a temp os 102.0. 12/28/2020 N/V, diarrhea and fever resolved. C/o's joint pain and body aches.

Patient came to receive her vaccine. While in the monitoring area. Patient stated her mouth was experiencing numbness/tingling. Patient stated she never has adverse reaction to vaccines. V/S. B/P 130/99 P: 85 O2.98. Patient stated feeling lasted approx 3 mins. Patient was further observed for additional 15 mins. Patient stated feeling had stopped and she was feeling much better. Patient left observation approx 8:10 AM.

After receiving Pfizer vaccine, patient reported some lightheaded ness and some chest tightness. B/P 131/95, P 73, R 16. She was given orange juice, cookies and continued to be observed for an additional 30 minutes. Patient left on her own.

In the evening of Dec. 16, my arm was very tender and hurt to touch or move. It got better by the next afternoon, at which point I shoveled the snow, only to come inside with chills, sweats, low-grade fever (100.5), dizziness and headache. The entire episode was only acute for a few hours and by the next day I felt mostly myself.

10 min-heart palpitations 20 min-heart palpitations, could not catch breath, angst/panicky sensation, all intermittent 1 hour- akathisia, heart palpitations/panicky sensation, all intermittent, resolved with benadryl 24 hours- heart palpitations/panicky sensation, intermittent

3 cold sores appeared by the next morning

Headache, chills, horseness, weakness, cough.

"Day 1: approximately 1 hours after vaccine - dizziness, extremely tired, dosing off, , injection site tender, approximately the size of a dime knot at injection site. Day 2: body aches all over, moderate headache, extremely tired, no energy, about 1700 hours: profuse sweating, full body chills accompanied with entire body shakes, extreme headache, nauseated, unable to eat, lose of taste and smell, extreme body aches, sense of falling. Lasted for 36 hours, lost 7 lbs. Swelling at injection site, followed by a knot in arm approximately size of a quarter, raised approximately 1 "", red rash and extreme itching. Day 3/4: symptoms subsiding, rash and pain in arm increasing. Rash spread from elbow and shoulder, raised approximately 2"" and almost encompassed entire upper arm, approximately 1"" gap on the inside of arm not affected. Day 5: Started feeling human again. Temperature was never higher than 99.5 degrees. Took Aleve and Tylenol"

Developed a rash on abdomen that was discovered at approximately 10 pm on 12/29/20, the day following the vaccination. Personal physician diagnosed it the following day as shingles and an anti-viral (valacyclovir) was prescribed. Last dose taken on 12/27/20. Rash is clearing.

Severe bilateral arm pain, fatigue, fever, chills. Onset 12/24/2020 10:00am until 2:00am. Ibuprofen. Person recovered.

"""Flushing"" feeling felt during monitoring period. Patient requested a Benadryl but then symptoms resolved with no intervention. Pulse- 99 BP 154/99 O2 - 98 R - 22"

Patient experienced/reported nausea post administration, approximately two hours after. Patient had emesis x1, to where Zofran given by mouth, w/ patient reported relief.

Treatment dugs:

None stated.

Treatments dugs:

Treatment dugs:

Treatment dugs:

Treatment dugs:

Treatment dugs:

had hives on back and L arm 1 inch medial to vaccine injection site; no lip or tongue edema, no wheezing or stridor Treatment dugs:

Treatment dugs:

Treatment dugs:

Treatment dugs:

She states that she had immediate pain at the injection site. On Saturday at 7AM, she developed malaise and frequent stools but would not classify them as diarrhea as well as a headache. She has never had a fever. Today, she continues to feel weak but reports that she is improving. Treatment dugs:

25mg po Benadryl given per vo Dr. at 9:20a -- 9:45 symptoms completely resolved Treatment dugs:

I was told to contact you and let you know that I have been having flu like symptoms since my vaccine Monday afternoon at 3:45. Started yesterday with the headache, body aches and chills. I stayed the day yesterday but i will be leaving early today as I am not feeling any better. Treatment dugs:

Treatment dugs:

12/16 - onset of fatigue and runny nose followed by headache and body aches. As of 12/23 he has a mild headache not requiring any medication for relief. He missed a day of work on 12/22. He did not seek medical attention. Treatment dugs:

Treatment dugs:

Throat swelling/closing feeling, outcome is anxiety, will take hydroxyzine. Feeling of throat swelling, throat closing

nausea, vomiting, severe enough to call out of work

headaches, mild but moved around mostly on right side; moderate to at times severe joint pain in hips, knees and hands. Headaches started 12/25/20 and continue today 12/28/2020. Joint pain started afternoon of 12/24/2020- was worst 12/26/2020 but some relieve with high dose ibuprofen. Still joint pain and stiffness, mostly in hips, knees, lower back and hands.

12/25/2020 Patient states that he started experiencing body aches and took Ibuprofen, on 12/26/2020 patient states that he wasn?t feeling well with flu like symptoms: fever 101, loss of appetite, fatigued, vomited once, body aches, continued taking Ibuprofen throughout the day, 12/27/2020 Patient states

fever decreased to 99, still feeling fatigued, shoulders are sore, feeling clammy, patient states that he has never tested positive for Covid, he has never been exposed to his knowledge , went away, still feeling fatigued, shoulders sore, clammy, temp no higher than 99. patient states that because of his flu like symptoms, he went to pharmacy for the PCR Covid Test and is waiting on his results.

Soreness to injection site, fatigue, fever, chills, body ache and nausea.

right after the vaccine she felt light headed felt better in observation after about 7 minutes employee c/o heart racing,Chest pressure, feeling light headed, throat scratchy and tight. allergy to MRI contrast dye only - Gadolinium. Has had lots of vaccines in the past without problems. Taken to ED via W/C was talking all the way not SOB admitted to ED. 12-28 States she was admitted to the hospital overnight for anaphalaxis on a second trip to ED. She will not be able to get her second dose of the vaccine. this should be entered into the VAERS reporting system. She is till using the benedryl.

facial rash - forehead/nasal area/ lips red and decreased swelling. Denies SOB.

Fever up to 102 degrees, muscle aches, fatigue, lymph node pain, injection site reaction, headache, chills, joint pain. Started about 26 hours after the vaccine and lasted about 48 hours. Injection site redness/warmth started about 96 hours after vaccine- large area on upper arm about 6 inches by 10 inches. The redness and warmth are still there, other symptoms have resolved.

Dermatitis.

Approximately 5 minutes after vaccine administration (8:14a) patient felt heart palpitations, Heart Rate up to 90, blood pressure 149/98. At 8:22a blood pressure at 153/98, At 8:37 a Blood pressue at 144/96 Within 30 min (8:43a) patient Heart rate down within normal limits to mid 60s and blood pressure to 130/80 (manually).

nausea and vomiting

Approximately 17 hours following vaccination, recipient experienced fever, chills, shortness of breath, nausea, diarrhea.

Supraclavicular adenopathy

After receiving the vaccine, I laid down at noon. When I woke up at 6:30 in the evening, I felt tired. Then by 9:15-9:30pm, I started getting chills. Then by 1:15am, I started running a temp of 101.5. When I got up this morning at 7:30am, My temp had gone up to 101.7. I took two tylenol at 8:30am and I have not checked my temp yet. Im just sitting in the chair sweating.

After receiving the vaccine, I laid down at noon. When I woke up at 6:30 in the evening, I felt tired. Then by 9:15-9:30pm, I started getting chills. Then by 1:15am, I started running a temp of 101.5. When I got up this morning at 7:30am, My temp had gone up to 101.7. I took two tylenol at 8:30am and I have not checked my temp yet. Im just sitting in the chair sweating.

The morning after the vaccine I woke up with a headache, took some Advil and it helped. On Monday I had the majority of other symptoms: chills, headache, nausea, mild abdominal discomfort, sore throat, congestion, muscle ache, joint pains. No fever.

During injection immediately felt itching at injection site. Over 3--45 minutes, itching spread up the deltoid to the left upper chest towards the mid chest. No airway involvement. Went to the ER and received prednisone, Pepcid, Benadryl. Discharged to home with prescription prednisone, Benadryl, and Pepcid, and Epi-Pen.

"Patient administered vaccine and remained in the vaccine clinic observation area for the recommended time period. Patient at that time had no reactions and returned to her nursing unit. Approximately 10-20 minutes after leaving clinic while working, patient developed: Right lip swelling,R scratchy throat,R tongue feels ""tingley"", No respiratory distress At onset of symptoms patient took her own benadryl 25mg po prior to re-presenting to clinic to notify staff of symptoms. Staff observe symptoms as listed above, again pt had no acute respiratory issues. Epinephrine offered to patient, refused by patient. Patient agreeable to repeat dose diphenhydramine, pt takes 12.5mg oral solution. Staff monitors patient closely, no worsening of symptoms and slight improvement noted within ~15-20 minute of presentation. Patient leaves against medical advice from clinic due to a rapid response call for one of her patients. Follow up with RN within an hour shows resolution of symptoms with diphenhydramine, no additional doses taken after the total of 37.5 mg"

Ran fever of 99 for 2 days

Immediately after vaccine my face started getting hot and itching. swelling to my face and neck area I took zyrtec for the adverse events

Severe chills, aches in hip and body, headache. Lack of energy the following day.

Moderna COVID- 19 Vaccine EUA Patient reported account of vaccination on 12/21/20: I received my 1st dose of the Pfizer Covid-19 vaccine yesterday afternoon and about 2 mins post injection I felt flushed, dizzy, and nauseous which disappeared quickly but then came back about 10 mins post injection and then never happened again. I felt completely normal after that and I feel fine today.

"1006: received vaccine 1022: 15 min observation complete - no difficulties 1034; lightheaded ""wash"" in my head lasting < 30seconds (as though standing too quickly) along w/ fleeting nausea then ""light"" numbness of face. Uncertain if subsequent tachycardia and hand tremors were from the initial lightheadedness and numbness or additional side effects. I was driving my car, alone and became nervous. 11:30 25mcg benadryl capsule taken ~13:00 numbness of face resolved."

15 minute post vaccination observation patient denied any symptoms. Later in the day patient experienced significant nausea and vomiting followed by mild SOB and throat swelling.

Developed red, blotchy, mildly itchy rash to anterior and posterior neck on the morning of 12/25/2020 (rec'd vax afternoon of 12/23/2020). The rash progressed throughout the day; extending to anterior

torso down to waist, right arm, and upper back. Took 25mg benadryl tablet. Rash began improving the next afternoon (12/26/2020) and completely resolved by morning of 12/28/2020.

DIARRHEA, FATIGUE, AND BODY ACHES AND SORENESS

About 8 hours post vaccine, at 2300 as I was going to bed I felt what I would describe as breathing resistance. I would not describe it as chest pain/pressure/tightness or SOB. It was just upper chest resistance to inhalation when lying down for bed. 12/24 started with intermittent gnawing epigastric during the day. Persisted through the night with gnawing epigastric pain radiating through to my spine, i was unable to sleep due to the pain. Attempted tums (I do not have GERD), motrin & tylenol however, nothing was helpful. 12/25 & 12/26 same symptoms persisted both day and night 12/27 asymptomatic 12/28 cramping/twisting epigastric pain returned, much more mild

Vasovagal like reaction after a light 1 mile walk. Lost consciousness.

Numbness in sole of feet. Unable to walk, develop high fever, resp failure resulting in intubation, acute kidney injury

Diaphoresis, syncope, and hypotension.

cold sweats and body aches day after vaccination

Patient had mild wheezing 15 minutes after vaccine injection.

Moderna COVID 19 Vaccination administered IM L deltoid. Client stayed 30 minutes for observation. Left and approximately 15 minutes later experienced numbness in tongue and neck area-felt like throat was constricting. Drove self back to clinic with epi and benadryl administered IM and oxygen placed at 8l. Blood pressure 170/98, HR 108. States felt better but after approximately 15 minutes became flushed and felt like it was returning. Left with practicing MD & NP to go to ER.

1. Injection site pain - more than typical with a flu shot - awakened in the middle of night with aching - took acetaminophine which remedied the problem. Continued general body achiness for 24-36 hours, again resolved withacetaminophine. 2. Next day, December 24 - (a very active day for me) - experienced fatigue as day progressed - had to stop in mid-afternoon and sleep - very uncommon for me. NOTE: The above symptoms were unpleasant but did not prevent me from playing the organ for 3 church services on the 24 and 25.

12/22/2020 Chills, body aches, fever 103.00 fever -- overnight fever unable to break 104.7 fever with Tylenol and Ibuprofen. Morning no change in temperature 104.7 no change -- ER Clinic Visit, XRAY-results: pneumonia , Covid test - positive; medications prescribed : 5day Z-pack

Shortness of breath had a terrible asthma attack very congested in my lungs weezing

Possible Bell's Palsy Rx of Prednisone 60mg Daily x7 days Valacyclovir 1000mg TID x7 days

Fever of 102.9 extreme body aches

About 2 minutes I received the vaccine I felt my right upper lip swelling and tingling, then left start and migrated to my ear and down to my jawline. Difficult to swallow.

Around midnight on day of vaccine, 12/23/20, patient experienced pain at the injection site, which lasted about 20 hrs. Patient also had a severe headache, which he says has abated as of today, 12/28/20. Patient starting having the following problems around midnight on 12/23/20 and is still experiencing them: fever (99+), occasional chills, difficulty in breathing, restless sleep, coughing, burning sensation in nose and sinuses.

12/20/2020 WITHIN MINUTES, I STARTED TO FEEL PINS AND NEEDLES. RADIATED LEFT TO RIGHT SIDE OF ARMS, AND THEN UP TO HEAD. NUMBNESS AND TINGLING. SEVERE PROFOUND WEAKNESS, DIZZINESS AND ORIENTATION. VISION FELT 'FAR AWAY'. HR INCREASED, HX SVT. 3 MINUTES BP WAS 'OK' BUT I BELIEVE IT BOTTOMED OUT. HR WAS 150. STRETCHER, TX TO ER. BLURRY, 'STAY WITH US'. ALERT, AWAKE, VERY IN AND OUT OF FOCUS. FEEL LIKE 'PTSD' FROM THIS EXPERIENCE. 'WHOLE BODY WAS BUZZING'. IV STEROIDS, IV BENADARYL, IV FLUIDS, IV ATTIVAN (NO EPI AS NO DIFFICULTY BREATHING) STILL FEELING 'DAZED' *FLU SHOT REACTION 2013 - BRONCHOSPASM, MILD. 2014 - BRONCHOSPASM, RINGING IN EARS, INCREASED HR, DRY HACKING COUGH, USED NEBULIZER AND TOOK BENADRYL. LASTED 4 HOURS. ALLERGIST APPT 2020 - ADMINISTERED FLU SHOT UNDER GUIDANCE; SCRATCH TEST; BROKEN UP INTO 2 DOSES. INFORMED NOT ALLERGIC TO FLU SHOW 'GOOD TO GET COVID SHOT'. *STILL HAVE TINGLING IN LEFT THUMB

chills, fever, extreme exhaustion

Uncontrollable shaking, muscle tremors, cramping of muscles in legs, calves and thighs, generalized fatigue and body aches, fever 103, diarrhea, vomiting, extreme headache, extreme soreness in arm where injection was given with limited range of motion. Egg size lump, bruising and rash at injection site. Most all symptoms lasting 2 days.

Within 8 minutes of receiving the COVID-19 vaccine, patient developed feeling of throat feeling itchy, tongue tingling, and progressed to throat tightness and difficulty speaking and squeaky voice within 15 minutes of receiving the COVID-19 vaccine. 911 was called with request for the facility's Rapid Response Team (RRT) to assist. While awaiting RRT arrival, patient was administered Epinephrine 0.3 mg IM via EpiPen, first dose within 18 minutes of onset of adverse symptoms, with short-lived improvement of symptoms. The Rapid Response Team arrived on the scene and when the same symptoms started to return, about 7 minutes after the first dose of Epinephrine, a second dose of Epinephrine was administered IM. Patient's symptoms responded positively to the second dose of Epi and patient was transported to the Emergency Department by the Rapid Response Team for observation and further evaluation/treatment as needed.

chills, fever of 103, bodyaches, headaches, and fatigue. Started 12/26/2020 and still active.

developed hives all over arms and thighs, few spots on calf. Slightly itchy at times. Arms were not painful welts, but the leg welt are very painful, feel almost like bruises. This along with generalized muscle aches

and pains. Took an antihistamine with no relief, hives have been gradually fading but pain in legs still persistent. no respiratory issues so did not go to ER.

About 8 hours after receiving the vaccine, I experience a severe migraine the radiated down my neck and was accompanied by nausea. I slept for 12 hours and the symptoms are almost completely resolved.

Severe injection site pain. Went to UC. Followed up with PCP. Supportive measures recommended.

"Left arm tingling down to fingertips within 15 mn of injection. Later down entire left side to toes. Later diffuse tingling. Resolved next morning 12/18. Lump at injection site for 1 week. Strong Left arm pain on 12/18 12/25 swelling and red rash (1.5"")around injection site. Strong itching. Used hydrocortisone x2 on 12/25and 12/26. Swelling and rash resolved. 12/28 lump is gone, minor skin discoloration remains."

Fatigue and arm soreness for 3 days following vaccine

Raised red rash to face, bilateral hands and forearms started approx 30 minutes post vaccination. Patient treated with PO Benedryl at home immediately following reaction. Applied hydrocortisone cream, but burned upon application, so she washed it off. Is now using topical diphenhydramine spray with good effect. Today, 12/28/2020, most of rash has dissipated; some reddened areas persist. Patient reports the rash affected areas feel much better. She will continue the topical spray and Tylenol prn.

Pt reports numbness above lip to right eye. Pt states she had some anxiety about injection and potential side effects, and wasn't sure if it was due to that. She states it resolved and is feeling fine.

Day 1: limited mobility in the left shoulder join, pain at the injection site Day 3,4,5: numbness of the arm and fingers on the left arm, unable to hold fingers together, whole left arm numbness occasionally, limited control of movements

Swelling and numbness around right eye and cheek; hives. Lasted for about 2 hours maximum. Took Claritin and showered.

possible anaphylaxis - throat itching, flushing, felt unwell

Developed a hardmlump at injection site within 1 hour of receiving. Several days later, lump subsided, but area because itchy. On 12-26-20 noticed a discoloration or pigmentation at injection site.

Around 2:00 am exp dull ache from arm to wrist ,tingling in fingers lasted all day. I called employee health was told to go to see PCP. The tingling went away after 3 days and the dull ache lasted 5 days. I was told to take Tylenol for dull ache. I dint have to miss any work.

extreme fatigue, nausea, dry heaving, headache, dizziness (all similar but milder than my covid19 symptoms from April); arm soreness, tender to touch (both expected), large knot in upper arm/injection area

Patient developed a fever 24 hours after vaccine administration

"Employee presented to COVID 19 vaccination clinic and received 1st dose of COVID 19 @ 13:48. Patient proceeded to wait in the waiting area 15 minutes and was about to leave to return to work when the contracted employee reported she developed a cough and flushed face. VSS @ 2:04 BP 172/105 HR 111, she was A&O, Employee was moved to stretcher, given water to drink unable to drink, she stated ""it feels funny"", VSS retaken BP 151/97, HR 91. She continues with intermittent non productive cough and C/O she was unable to clear throat and felt throat tightness. Within minutes, her face flushed, coughing worsened, difficulty swallowing, and she became diaphoretic. Solumedrol 125 mg IM Given to right arm. Patient reported she felt heaviness throughout her body, and was unable to move her Left arm as easy as before, with bilateral numbness to tingling to upper extremities and decrease strength to left arm. Patient crying out, stated she felt as if she could not breath, no hives present, no angioedema. Anxious, crying out that she felt ""heavyness on her chest"". VSS 2:19 158/108 HR 78. This writer attempted to call ED RN several times through operator: NO answer to each call. I left personal message with Unit secretary of COVID 19 reaction and needed to speak with RC or ED MD. I attempted to to call ED MD, no answer. Epinephrine 0.5mg IM given to right deltoid at 14:20 patient was taken to ED triage area, patient taken to room. Report given to RN and ED MD."

Upper lip swelling, associated with herpes labialis. Has history of occasional recurrent herpes labialis, though never with such swelling associated. Suspect possibly due to heightened immune response from recent vaccination. Patient did have slight right axillary swelling, likely lymphadenopathy, some time after vaccination, though this resolved.

Approximately one week after Pfizer Covid vaccine, experienced around 4 cm diameter area with redness, mild tenderness, and itchiness at injection site on left deltoid.

Palpitations felt after 15-20 minutes, subsided within 15 minutes. Fatigue set in after 4-5 hours. Fever the following morning to 100.8 F. Fever accompanied with dizziness and lightheadedness, syncopal event with brief LOC. Overwhelming fatigue until 3:30 pm the following day, with arm pain. On day #3 arm pain persisted, new development of neck pain and mild truncal rash.

Joint Pain, Fatigue, Nausea, Fever up to 102 lasting for two days.

Fever, headaches, myalgia/arthralgia, fatigue, decrease in breast milk production- treated with braids, resolved 3-4 days

Muscle soreness at injection site

Felt like throat was swollen

"C/o throat ""itchiness"" shortly after receiving vaccine - face also flushed. Received relief with Diphenhydramine 25 mg po"

C/o shortness of breath + chest tightness a couple of hours after receiving vaccine

12/22 c/o Low grade fever & malaise

12/22 Body aches, Joint pain, injection site swelling

12/21 PM - c/o headache, chills, night sweats

12/21 PM developed headache & fatigue - improved after Tylenol

12/22 Developed chills; 12/23 Chills, sore throat, body ache, headache by 12/24 only c/o headache

Patient received COVID-19 vaccine at 3:02 pm - approx 26 minutes after vaccine administration patient became dizzy/lightheaded/nausea. B/P-140/102, 98% RA, 98 HR, R 20 even and unlabored. Patient brought to UC for Evaluation. During UC Evaluation vital signs remained stable. Patient drank water. Tylenol was given for headache - 1 gram Acetaminophen at 3:40 pm. Patient had improvement in symptoms ER precaution were discussed, patient verbalized understanding of treatment plan. Patient discharged home.

One hour after administration, patient experienced a nose bleed. Approximately 2 hours after administration she noticed her heart rate fluttering which turned in to a strong throbbing feeling at the base of her sternum. This was regular rate, but very strong, intense feeling. This lasted until the next day when it decreased frequency and ended by afternoon. Also she experienced a mild headache the day after receiving the immunization. She states that she has a hx of seasonal allergies. Also states that she was very anxious about receiving the immunization prior to admin. She states that she was also a little dehydrated.

I received the vaccine on 12/23. I noticed my back was really itchy that day but didn't think much about it. The next day I had a rash on my arms, back, and chest. My eyes were swollen on 12/25. Rash still has not resolved today, maybe even worse.

facial flushing and dizziness experienced by the patient 10 minutes after administration.

Employee is complaining of chills, headache, dizziness, fatigue and feeling faint. She was tested for Covid on a rapid for the ID now and tested negative today.

Left arm was sore from shot and could not lift it, had to keep ice pack on arm. Fatigue, body ache, headache, Oxygen level drop Started on December 25, 2020, took Advil, noticed oxygen level drop on Saturday, December 26, 2020. Have been sleeping since Friday and had a hard time waking up on Saturday, so I started checking my oxygen level and it was 89. I got up and started walking and it helped to bring it up but every time I sit for any length of time it goes back down to 92 - 95. I have called Dr. my Pulmonary Doctor and waiting on him to call me back.

"21 y.o. female who arrived by from on-campus presented to the emergency department for Nausea, face/tongue/distal extremity numbness 5 minutes after receiving Covid vaccine. Patient states that the symptoms are intermittent and ""come in waves."" She states that she was simply sitting in a chair doing nothing on the symptoms started. She does not feel like her tongue is swollen, she has no difficulty with breathing, no new rashes, and her nausea is not persistent. She has no history of anaphylaxis. She has no history of food or other allergies, and has never used an EpiPen. She does not

typically have symptoms after receiving injections and is a phlebotomist and does not have fear of needles. Patient's symptoms resolved within 1 hour of her stay. She felt well, had no difficulty with breathing, did not notice any development of rashes, abdominal pain, nausea. She states that her heart rate is typically 80s/90s when she checks it. á After her fluids are complete, and she is observed for 4 hours, patient has no symptoms, and feels safe to go home."

I felt very dizzy afterward

During 15 minute monitoring time, patient developed throat irritation and tachycardia.

10 hours after vaccine woke with moderate body aches and chills. Tylenol and Motrin take every 3 hours alternating x 48 hours. Symptoms completely resolved after 4 days.

Sore arm with general swelling noted in deltoid and upper shoulder on post-vaccine day 0 and 1. Managed with acetaminophen and resolved by morning of post-vaccine day 2. Headache started in morning of post-vaccine day 2 and increased in intensity throughout day. Initially managed with acetaminophen. Difficult to manage as day progressed. In addition, dizziness and slight vertigo not dependent on position/posture manifested in moderate intensity in late afternoon. Rested in reclined position which did not ease symptoms of headache or dizziness. Was able to sleep and woke up in morning with no symptoms. Dizziness did manifest in mild intensity on post-vaccine day 3 off an o, not dependent on activity or position, but was manageable. No further symptoms since day 3.

Took vaccine 12/21/2020 12/22/20 Slight sore throat, injection site barely sore (left arm) 12/23/20 AM:slight sore throat, discomfort, pain left axilla PM:sore throat gone, pain under left axilla with sore/swollen Lymph Node (golf ball size) 12/24/20 All day: Pain left arm and under left axilla with sore/swollen Lymph Node (golf ball size), swollen Lymph Node left subclavicular, overall feeling of unwell, headache, nausea, hurts to breath deep. No appetite. Fever 99.8 Feel worse than when I had Covid. 12/25/20 AM: Didn?t sleep well, symptoms same as 12/24 with additional swollen and painful Lymph Nodes on left side of neck (pea size), no fever PM: Feeling some better, less pain, Lymph Nodes still swollen, no fever 12/26/20 Feeling better other than Lymph Nodes (still swollen and axilla still sore) 12/27/20 Continuing to feel better, still swollen Lymph nodes less sore

Numbness in fingers Severe pain throughout whole arm Unable to lift arm

On 12/24/20 I received the vaccine at Pharmacy, later that night I woke up feeling very cold. My temperature for the first 2 days of 103.1, chills, body aches, veins in my eyes busted. The fever has continued, today 12/28/20, 100.8, I feel dizzy, tired. Due to the holiday, will be seeing my PCP today.

I exp sore arm, fatigue, body ache and after taking Ibuprofen was gone. The fatigue is still lingering not entirely sure if this is due to vaccine.

Noted tongue starting to swell on 12/24 at 1030. Started on left side, then progressed to right side. No SOB, difficulty swallowing or breathing, but staff noted difficulty understanding her speech. Presented to ED at 1300. 50mg Benadryl given IV on 12/24 at 1328 and 125mg solumedrol given IV at 1327. Pt reported improvement in tongue swelling at 1630.

"09:48am While waiting her wait time, reading emails, she felt flushed, like a ""hot flash"". Heart rate per her apple watch was 152. 09:54am Seated, placed on monitor for BP and O2 sat., 151/90, HR 111, 99% on room air. 10:05 158/87, 111, 99% - RA 10:10 147/85, 102, 100% - RA, States feeling nervous. 10:20 144/84, 96, 100% - RA, States feeling better, less nervous. No shortness of breath, no facial swelling. No other complaints. Allowed to leave facility. With instructions to follow up with Emergency Department if any life threatening symptoms develop and to follow up with Employee Health if needed. She verbalized understanding of above."

12/26/2020 2:00PM ears itching, hives - left wrist to elbow -- Urgent Care Visit -- Solumedrol shot received and Benadryl advised to take. Hives cleared on skin 12/26/2020

Shortness of breath, dizziness, vomiting, increased BP.

About 11:50 I sat down for observation and between 12 and 12:05 I felt tachycardia, I could even hear my heart and felt my heart really racing. I could feel something on my fingertips as well. The nurse came to check on me and at 2:08 my heart rate was 109 and one minute after it was already 110. So they brought 2 RNS to observe me. I did not go to the ER. They came about 10 min later and stayed with me 20 mins. They kept taking my vitals and checking my BP and told me that my vitals were stable. I left and when I went to my car and checked my heart race and noticed that it was stable, around 83 and decided to go home. I left the hospital about 1PM. After I had the vaccine, the next day I felt body aches, I was not sure if it was my sinus issues or related to the vaccine. I also had joint pains, back pains. But sometimes I have it with my sinus but today I feel fine. My arm the soreness increased with each day but by Friday it got better today I don't feel it anymore.

migraine headache, woke up 12/28 with 2 blisters near lower back

I received the Covid 19 vaccine at 12:30PM on Wednesday, 12/23/2020. On 12/24/2020, mid-day, I developed the following S/S (which were similar to a Lamictal rash): Fine raised red rash over my body, but significantly heavier to face, neck and lower legs; throat swelling with a high pitched cough (with no difficulty breathing) productive with clear thin secretions; diarrhea; I took 6 benadryl every 4-6 hours, Pepcid twice daily, and had an epi pen available (but did not need it). The cough and rash resolved by late Sunday evening. I did not report to ED because I felt the symptoms were manageable at home.

experienced nausea, diarrhea and chills about 14 hours after vaccination. Lasted a couple of hours, and by daytime patient was feeling ok.

Moderna COVID-19 Vaccine EUA

The patient experienced jaw tightness and tingling in the face. She felt better lying down. No treatment was given; she was observed for about an hour and went home. The patient did report having plastic surgery with facial fillers approximately 6 weeks ago.

metallic taste in mouth starting 2 minutes after receiving. No shortness or breath or respiratory/cardiovascular symptoms

Patient developed fever, chills, body aches, ocular migraine and then developed cramping and abdominal pain. Symptoms lasted 3 days and then resolved completely.

Right side of tongue was numb and swollen , could fell the right side of my tongue for a day 12/28/2020 5/10 Lost still today at a week post Received Benadryl incase of allergic reaction

Patient had hives on both arms. Assessed by EMT and provider on site 25 MG benadryl admin to right delt.

Chills, body aches, fever 101.8, headache onset 2100-0300.

Paresthesia of the left foot. Feels like water flushing over the outer aspect of dorsal foot. Occurs about every half hour for the last day and a half. Mild headache grade 1/10.

On 12/24/2020 started with slight headache and a sore throat. On 12/24/2020 tiredness and slight sore throat. At 15:30 on 12/24/2020 she noticed tenderness in right groin. By 1730 she had chills. On 12/26/2020 at 0230 she had throbbing in her right groin and 2030 she had cellulitis in the right groin.

Decreased strength and mild tingling in left hand.

Within minutes of the injection I felt very dizzy with associated palpitations. The triage RN took my BP 160/80 HR 110. The sensation quickly subsided and i left the triage area within 10 minutes. Over the course of the next 3 hours that same sensation would come and go every 10-15 mins, again lasting a short time with return to normal, I would feel very dizzy with palpitations lasting about 30secs-1min and then it would subside. At one point I had a metallic taste in my mouth, another time i felt nauseous. My coworker stated I was pale. By 12:30pm that day the sensations stopped and I just felt very tired the rest of the day. By the following day I felt completely back to normal.

General malaise; Body aches; Chills; Fatigue

Covid-type headache unrelieved with tylenol or ibuprofen lasting greater than 12 hours. We finally gone when i got up the next day. Fatigue and loss of appetite until following morning.

Itchy and bottom lip felt swollen. Went to the ED.

numbness and itching in roof of mouth

within 12 hours of the vaccine, developed and hives; 24 hour later wheezing - mild. took benedryl, Zyrtec, Pepcid - symptoms continued Sought care at Urgent Care - 12/27/2020 - was given an inhaler. Symptoms lasting at least 10 days

Patient began felling flush and hot. Throat itching. She was given 50 mg of diphenhydramine. She does carry an Epi-pen due to bee stings. She did not want to take the Epi-pen initially. we watched for about 10 more minutes. Voice was beginning to get raspy, and she reported increased feeling of swelling in vocal chords. We took patient to the ED triage area and she administered her Epi -pen. She was registered in the ED and was placed in a room for observation/monitoring. She was given an additional

25 mg of IV diphenhydramine and also 125mg of Solu-Medrol. Following this regimen, the patient began feeling much better. She was monitored for an additional 2 hours. I stayed with the patient while in ED and she recovered from the reaction with no additional sequalae.

12/17/2020 20 MIN AFTER INJECTION, FELT ITCHY AND WELTS. MEDICAL STAFF ADMINISTERED TYLENOL AND BENADRYL. 12/20/2020 AFTER RASH AND HIVES DISAPPEARED, WOKE UP TO JOINT AND MUSCLE PAIN ALL OVER. PINS AND NEEDLES, FELT LIKE ON FIRE. *MISSED 2 DAYS OF WORK DUE TO ACHES

arm stiffness, cough, dizziness, ringing in ears, muscle aches and spasms. Seeing Primary care for symptoms and dizziness has not improve and ringing in ears has worsen. Recommend from to get a MRI.

Swollen lymph nodes of the right arm with itching and redness began on 12/24/20. No treatment. Swelling is improving, itching and redness remains unchanged.

After vaccine, muscle aches, swollen lymph nodes, low grade temps to 100.5 for 4 days. On morning of 5th day, symptoms improved. Evening of 5th day, fevers to 103.0, severe headaches, cough, sore throat, fatigue x 4 days. Covid tested- negative.

About 20 minutes after receiving the vaccine both hands turned flame red from the wrists to fingertips. No itching or burning. Resolved after about an hour.

I was very lethargic, warm (without a fever), and very achy. This lasted until I went to bed at 9pm and I felt fine when I woke up the next day. I took no medication for this nor did I seek medical treatment.

Mild Flushing/itchiness, blood pressure dropped for a few moments, slight dizziness for a few minutes, then about 15 minutes after symptoms abated then Istomach felt uncomfortable, and a headache started about 45 minutes after injection.

Tingling of tongue, shortness of breath, swollen lip. The patient was observed in the Emergency Department for about an hour and discharged home without further treatment.

blood pressure issues and tightness of throat

recipient complained of feeling lightheaded and thought she would pass out. gotten a snack and drink and then laid down on stretcher. vital signs stable but then symptoms did not improve and began to complain of numbness and tingling in her left arm. transferred to the ED

Paramedic who administered shot gave it too high. I noticed this maybe 10 minutes after administration when I felt that the Band-Aid was high and a nurse practitioner I work with confirmed that it was too high by observing the puncture site. Pain started about 2-3 hours later, with restricted range of motion left shoulder joint

Next morning I woke up with a migraine and stiff neck. Following day I had multiple episodes of diarrhea and significant nausea. I woke up with another migraine and stiff neck on 12/23/20. I still had GI upset. On 12/24/20 I had migraine again with body aches and GI upset.

Pain at injection site, severe body aches, fever raning from 99.3 to 100.8. Hip and knee pain

"She got a Covid vaccine Pfizer at the Health Dept on Dec 18th in her L arm. Within 30 minutes, she felt tingling going down her L arm and in then she felt tingling on the L side of her face. Muscle aches, fatigue and chills lasted about 33 hours. On the 22th she had L leg weakness when she got out of bed, this lasted just a few seconds until she ""worked it out."" Later, she developed a sinus type headache. She developed muscle aches on 25-26th, she went to have a covid test that was negative. The L side of her face is tingly and her L jaw is sore--she describes it as feeling like she has had a novacaine injection for dental work since 4pm yesterday."

Muscle soreness, fatigue

Came to recovery area and within a period of 5 minutes or less complained of a headache. Face became flushed and was taken to lay down on stretcher. BP 142/80, HR 140, RR 20. Patient was given water, Ibuprofen 800mg and Benadryl 50 mg. BP 135/90, HR 78, SaO2 100% room air. Patient sat up and drank juice and ate granola bar. Patient left at 0925

Employee stated that she woke up at midnight with severe nausea and started vomiting intermittently throughout the night. She also experienced fever/chills/body aches and right arm pain. Had to call in sick.

Arm felt very sore for 2 days after the shot, felt feverish, body was very warm.

15 minutes after vaccine, patient starting having itchiness and eye pain, looks like starting to develop hives. Benadryl 50mg IM given x 1 dose.

Slight increase in pulse for approximately 3 hours after the injection. Duration 45 minutes to an hour. Eye lids puffy approximately 20 hours after the injection. Unknown duration.

Patient on left jaw felt dull discomfort from ear to center of jaw Lower lumber/ Spine felt numbness for 20 minutes. Area still remain tight

12/20 - symptoms presented as possible right ear infection. 12/21 - began taking Amoxicillin 875MG 2xdaily 12/25 - presented in urgent care, for treatment of worsening ear infection. In addition to Amoxicillin, Prednisone was prescribed. Did not fill or take the prednisone on 12/25 due to Christmas Holiday and no open Pharmacies. 12/26 Awoke with Bells Palsy on right side of face. Went to ER. Was diagnosed with Bells Palsy and potential ear swimmers ear. Placed on and began taking the following medications on 12/26/2020. Prednisone 10MG Tablets taking 4 tablets every day for 2 days, 3 tablets every day for 2 days, 2 tablets every day for 2 days and 1 tablet every day for 2 days CIPR/DEXAMETH 0.3-0.0% OTIC SUSP - instill 2 drops into right ear twice daily for 7 days. AMOX-CLAV 875MG VALACYCLOVIR 500NG Bells Palsy impacting right side of the face. Symptoms began 12/20, presenting as possible right ear infection.

12/27/20 10:30AM swelling at the injection site, muscle aches, fatigue; 4:30PM sharp, pounding headache; 06:00PM chills, body soreness, night sweats. 12/28/2020 nausea, loss of appetite, fatigue Tylenol, some relief.

severe injection site pain, radiating down the arm, and just not feeling quite right. the headache that was reported last night is still hanging around along with some nausea. experiencing an overall feeling of being really hot, but not running a fever. HR 90s-100s

At 11:20AM Patient returned to vaccination room to show that she had developed hives on the right side of body (back, side, and legs). Patient was experiencing redness and itching--no shortness of breath. Patient was given 25mg of diphenhydramine. At 12:30PM Patient returned to show that the rash had cleared considerably and was not having any other issues. Patient was instructed to be observed by a healthcare provider for 30 minutes, rather than 15, for her second dose.

Dizziness

At 6 hours post vaccine (1400 on 12/26/2020), I woke up from a sound sleep sneezing convulsively and experiencing a headache, nausea, and extremely runny (literally gushing) nose and eyes. Within several hours, I also experienced swollen eyes and face as well as scratchy throat and slight cough. No effect: ibuprofen; ibuprofen; phenylephrine; loratadine; fexofenadine Effective: benadryl 100mg. q6hr(I was unable to take this previously because it puts me to sleep; once I was pulled from the work schedule I was able to take this) I have now taken three doses of 100 mg- as it wears off, some of the symptoms return, but they are gradually lessening. Since I am an RN, I am comfortable doing home treatment with my employer/employee health representative aware of the situation.

Fever, fatigue, pain, weakness

The patient reports developing CP and SOB about 1 hour after receiving the vaccination which resolved within 3-4 minutes. The patient denies seeking medical treatment and these symptoms were reported to employee health on 12/28/2020.

Began to have facial flushing and hives about 5 minutes after the injection, followed by itchy throat, hoarse voice, abdominal cramping, joint pain.

Fever, weakness, aches, tired.

Fevers up to 103.1 (started at hour 10 lasted through hour 48) Nausea (at approximately 24 hours) Vomiting (at approximately 24 hours) Severe headache (hour 20 through Hour 31) Somnolence (started hour 9) Chills (Hour 10- hour 25) Extreme Shivering (Hour 10-25)

immediately upon inj had bad taste in mouth and inside my mouth and lips felt filmy. from there broke out in itchy rash within minutes and my voice was crackly the pharmacist checked on me and had to wait a few extra minutes before leaving of note the APRN i work with was there getting her injection as well and advised on the benadryl. I have used benadryl and claritin since the injection to help with symptoms . after about an hour after the injection my lips were very red I never experienced SOB i did

report to my PCP (MD) the next day and he said to continue as I was doing and to alert him if things worsened (also note I work at my PCP office) Employee from pharmacy called to check in on me on the 23rd and advised I report the event to you and questioned if I should take dose 2 and I told him i WOULD NOT be taking another dose. since the injection i have continued to have the under the skin itchy rash and inside mouth and lips felt irritated after and i have experienced several other persistent symptoms of ha on and off, blurry vision, facial swelling around eyes, nausea no vomiting ,decreased appetite ,fatigue ,upper gastric pain for a few days after, and felt weak in lower back, voice is crackly at times and the tip of my tongue will feel a burn\tingly feeling. AGAIN i have not had what i would call SOB I did let my PCP know today of the persistent symptoms and that I was reporting them over to you as the pharmacy directed. I did not have a formal office visit but my pcp did note the effects in my chart

Patient experienced fever, edema and redness to injection site, neausea, headache, and diearrhea as well as body aches for 3-4 days.

Approximately 6-7 minutes of observation she developed flushing and warm sensation about the face and neck. Also developed red rash, non pruritic about the neck and chest. Also behind both ears right greater than left. No shortness of breath and no wheezing. Rash only on upper chest and neck. Vitals signs taken BP 174/91, pulse 73, 173/86, pulse 68, 163/92, pulse 64. Benadryl 50mgs by mouth. Observed additional 15 minutes. Patient had complete resolution of symptoms. O2 saturations were 97-98% the entire time. Patient discharged ambulatory.

Pediatrician working in the hospital. Was exposed the an office contact wo had covid. Shoulder in soreness. At work on Wednesday. Felt lightheaded had to sit in chair. That's all he reminders. He workup to a CODE team putting oxygen on him. He has a seizure. Took the COVID test has COVID. Admitted to hospital for 2 days. Likely a syncopal event.

REDNESS SWELLING HEAT TO THE RIGHT DELTOID, STILL SPREADING. PT EXPERIENCED CHILLS, FATIGUE, PAIN SWELLING TO EXTREMITY AND NAUSEA.

The evening after receiving vaccine had headache, severe body and joint aches, chills. This lasted for 2 full days. Awoke on day#3 and symptoms were gone. Left arm soreness and tenderness at injection site for 2 days.

I exp arm soreness greater than other vaccines kind of lingered for awhile (48 hrs.) I had fever up to 103.4 couldn't distinguish between the Covid and vaccine. I had a Covid test on 12/21 results positive. I missed work due to Covid not thinking cause of vaccine the timing was odd.

30 minutes after vaccine administered, pt had irregular heart beat (felt like it was going to come out of his chest through his neck). Lightheadedness, and terrible headache. Skin of chest and stomach were red. Pt received treatment in the ER, received IV benadryl, IV steroids, and anti-nausea medicine, and IV fluids. Pt was cold and shaking, couldn't stay warm. 4 days later, patient is still cold and fatigued.

Insomnia Deltoid pain Deltoid induration

dizziness, nausea

Right arm soreness: onset 6-8h after vaccine -- > worsened to full body soreness/aches with point TTP over injection site (couldn't sleep on that side); Injection site redness: No initial redness on day 0 or day 1 post-injection. Slight redness and TTP as above on morning of day 2. Body Aches: began ~18h after vaccine, worsened throughout day 1 before bed; ~36h vaccine symptoms resolved Fatigue: Started morning after vaccine (~18h post-vaccine) -- > peaked ~36h post-vaccine (went to bed early and simultaneously restless but also exhausted) Headache: Moderate, primarily frontal headache (like a head cold with NO congestion); began ~24h after vaccine, continues today (~48h vaccine) but improving without intervention. Fever: Began ~36h after vaccine at peak of fatigue symptoms (peak T: 100.2). No intervention, self-resolved by 48h post-vaccine

shoulder pain day of vax, itching, swelling, warm at injection site, redness. ER on 12/26 stated that vaccination may have been injected incorrectly, possibly lower than should have. ER gave Benadryl to pt.

Reports circumoral numbness and tingling onset about 30 minutes after received vaccine. Then mouth felt numb and tingling and finally symptoms moved to the back of her throat. She states it was hard to swallow and felt as though her uvula was large. States looked in the mirror at uvula, but could not see a difference. She states she considered going to the Emergency Department, but ultimately did not. She states that at about 7:30 p.m. she took 25 mg of Benadryl. She waited a little while and then took an additional 25 mg of Benadryl. She states that by 10:30 p.m. symptoms had resolved and she felt safe to sleep.

Patient received the Covid 19 vaccine on 12/23/2020. Twenty fours after vaccination she started to cough and wheeze (Hx of not well controlled Asthma, DM). Cough and wheezes relieve with nebuilzer. No fever, chills, or HAs. Symptoms have improved significantly and are stable. She has reached out to her PCP and EH. Covid Testing is scheduled on 1/4/2021 but awaiting for a sooner appt at EH.

24 hours after vaccine woke up with significant body aches. Then rash started on left forearm and wrist. Following day it spread to right arm and back.

21 y.o. female normally healthy who arrived by to the emergency department for Post COVID-19 vaccination reaction. Patient states approximate 5 minutes after the vaccine, she started to feel lightheaded and nauseated. She does notice the sensation of throat irritation, but denies any shortness of breath or difficulty breathing. Denies any tongue/lip/airway swelling, abdominal pain, new rash/pruritus, diarrhea, emesis, fever/chills, chest pain. She has no history of anaphylaxis or use of EpiPen. No significant allergic reactions in the past Initial reevaluation approximately 30 minutes after arrival, patient status unchanged. She still felt lightheaded and nauseated with a sore throat. No new rashes, shortness of breath, difficulty breathing. Her voice was normal, and did not report any new GI symptoms. Heart rate was 109 with one half fluids given thus far. á On reevaluation 2 and 3 hours after arrival, patient's heart rate normalized into the 60s?70s, she was asymptomatic. She was slightly fatigued from the Benadryl. She felt safe to go home. Follow-up call a few days later and patient was doing fine with no symptoms.

According to Hospital ED record: This is a 38 yo male present to ED with complaint of tingling sensation and reaction after receiving COVID-19 vaccination. Symptoms started approx 30 min after he received

the initial shot. Patient was on his way home when he noted some tingling in his tongue and strange sensation to the mouth. Pt denieschest painSOB, LOC, AMS, neurological deficits. No abdominal pain, nausea or emesis.

later that night at home about 6:15 I stared to get a red rash across my chest and on to my left arm and was very itchy, then was hard to take deep breaths. I also got a pretty good size bruise on arm I got the shot in and arm was sore for 2 days. I also had lil bit of rash around where shot was.

Fatigue, lightheadedness, achiness, left arm soreness and pain at the site for 48 + hours.

I felt tired couple hrs in the afternoon felt better after laying down.. I started to feel completely around 5 pm. I did not miss any work.

Pfizer-BioNTech COVID-19 Vaccine At approximately 4 pm on December 23 (day of vaccine) I experienced sudden onset of fatigue. I also had a low-grade temperature of 99.0 F with chills. By 5:30 pm, I was also bringing to experience lightheadedness and dizziness. That night at approximately 10 pm I had a temperature of 99.1. On December 24, I experienced lightheadedness and dizziness the entire day, from waking up to going to bed later that night. My eyes were glassy and I would feel an impulse of dizziness go distinctly from the right side of my head to the left, and then feel more dizzy after that. It was constant throughout the entire day and would occur while I was sitting, standing, or moving around. On December 25, I was tired but the dizziness had gone away.

Tachycardia started the morning of 12/28/20 and was distressing enough to lead to calling 911 and then visiting the emergency department. Emergency department work up was negative. No previous history of tachycardia prior to this episode.

BP- 110/62 HR- 78 Temp ? 97.7 Resp ? 22 Reports feeling tingling and shaky, no visible shakiness and no unsteady gait noted

Began experiencing dizziness on 12/26/2020 at around 10:30 am. Dizziness was initially off/on for the remainder of the day. By 12/27/2020, I began experiencing dizziness and feeling ?swimmy headed? with no periods of relief (even when sitting still or laying down).

I received the first dose of the Pfizer Covid vaccine on Tuesday, December 22 at 0730 in my left deltoid muscle. I felt fine that day - just some injection site soreness later that day that radiated to my left neck. On Wednesday, I experienced some fatigue, headache and moderate backache and neck ache which were all side effects that I expected. On Thursday, December 24 at approximately 1330, I experienced tingling of the tongue. It began at the tip of the tongue, but spread to the entire tongue over a five minute period. At the same time, my throat became scratchy/itchy. I realized that this was an allergic reaction and took 2 25mg Benadryl capsules. The symptoms resolved in about 20 to 25 minutes. I never experienced trouble breathing, speaking or swallowing. I also reviewed everything that I ate, drank, etc. in the last 24-48 hours and there was nothing new. About four hours later, I developed an intensely itchy rash. It began on my trunk, then spread to my bilateral upper extremities, then neck. My face and scalp also itched although they did not have a rash. My face was just red. There were no other

symptoms. I took 2 more 25 mg Benadryl at this time. It took about 45 minutes or so for the symptoms to resolve this time. Since that time, I have experienced significant body aches and fatigue (more than initially), mild headache and nausea. Due to the holidays, I was unable to report this incident to employee health until this morning, Monday, December 28. I have received no further instructions. On Friday, December 25, I noticed that I developed multiple apthous ulcers on my gums and hard palate. Since that day, I have experienced extreme fatigue, body aches and a mild persistent headache and nausea.

"Patient received the Covid 19 vaccine on 12/22/2020. Four days after vaccination (12/26/20) she started to notice that she ""loss her sense of smell ""while brushing her teeth. The toothpaste tasted ""weird"". All of the sudden, she lost her appetite. These symptoms persist today. Covid test scheduled on 12/28/2020 at Employee Health."

The patient reported subjective sense of lip and tongue 'tingling', described in intensity of 6/10 prior to EMS arrival, down to 4/10 on EMS arrival, but without interventions. Per EMS report, the patient had stable vital signs and a normal physical exam. The patient refused transport to the hospital, and a refusal of medical aid (RMA) was taken by EMS. The patient was advised to seek medical care should symptoms return.

12/24, I woke up with arm soreness and headache. 12/25, I had a headache, fatigue, arm pain radiating down to my elbow and into my right side. 12/26, I had all the above along with swelling under right axilla. 12/27, all of the above along with pain in right ribs, swelling worse under right axilla, fever of 100.3 (up to 101.2), body aches, and joint pain. The symptoms all continued as 12/27 into 12/28.

Vaccine was received on 12/17/2020. Patient states that he did not start experiencing symptoms until 12/25/2020. Patient states that he doesn?t think his symptoms are related to the vaccine and that he may need to be tested for Covid. Patient states that his symptoms are sore and itchy throat, congestion and runny nose, no coughing, no fever, no chills, no body aches. Patient states that his kids go to daycare and came home with a runny nose, no travel history, no exposure to Covid that he is aware of, never tested positive for Covid.

the day after receiving the vaccine the patient developed a fever TMax 101.7 and loss of taste, these later developed into congestion, general malaise, body aches. the pt sought out her PCP who is running covid and flu testing.

Felt fine to begin with, ate supper per usual, then at 7:10 pm sudden onset of symptoms, nausea & extreme diarrhea and chills for 2 1/2 hours. Temp of 99.9 Then headache, very severe, trouble seeing, disorientated. Sat in chair all night. Left arm and left side hurt into teeth and jaw. Thought about calling ambulance at 4:00 am, but decided not to. Headache lasted through Sunday and Sunday evening, until 3 am on Monday. Now at 11:30 am on Monday it is a 2 on a scale of 1-10. Had Tylenol #3 on hand, and took every 5-6 hours since Saturday night. Missing work today 12/28/20.

Major chills, fatigue, stomach ache, runny nose,

Patient states about 20 minutes after vaccine she developed scratchy throat, itchy all over but no hives and dry cough.

23 y.o. male who arrived by to the emergency department for suspected allergic reaction. Patient received his Covid vaccine 3 hours prior to ED arrival. Initially he was asymptomatic however, as the morning progressed, he developed a redness around the injection site. He then noticed a rash all over his face, that was mildly itchy in nature and felt warm. He denies any associated wheezing, shortness of breath, facial swelling, throat swelling, severe abdominal pain, vomiting, lightheadedness, dizziness, or syncope. He has not taken anything for his symptoms, and they continue to worsen. He has no prior history of allergic reaction to vaccines or other known allergies in the past. He states this is mildly itchy in nature. Patient was given 50 mg of p.o. Benadryl and Pepcid for symptomatic control. He was observed in the ED for 2 hours without any progression of his symptoms, no associated facial swelling, wheezing, shortness of breath, abdominal pain, vomiting, or hypotension to suggest anaphylactic reaction. He was discharged home in stable condition

12/16 EVENING OF VACCINE, VERY SORE SHOULDER. LASTED 24 HOURS. 12/17 - 12/19 VERY FATIGUE, ACHY JOINTS.

The entire reaction was over in an hour started at 115pm 12/19/2020 I had pain in upper back and shoulder, within 5 mins it started hurting my left arm and traveled down to my wrist and then went into my left thigh and I had this sharp headache for 3 mins and then it all went away and I have not had any symptoms since. That day I went to the ER and they kept me for 2 hours for observation and I went back to my work, The only reason I sought care was because I was already in a hospital, I was taken by wheelchair, blood pressure was fine

Fever 101.4F, Chills, nausea, dry heaving, achy joints, Low back pain, headache Treated with Tylenol

EE states that within minutes of receiving the vaccine, she started experiencing itching at the site, tingling down the left arm to finger tips. She did not report her symptoms at that time because she has similar symptoms with the Flu vaccine. Later that evening, EE states that she started experiencing tingling down the left leg to the left foot/toes. The next day, 12/18/2020, the tingling stopped but there was a lump at the injection site. The lump was warm to touch and slightly sore. She did not report this of take anything because her symptoms were similar to the flu shot. On 12/25/2020, EE states that the lump started itching and she scratched it which caused redness and inflammation. She used hydrocortisone on the injection site. The lump is now gone with no itching, just a little discoloration at the site.

12/17/2020 at 1250 Pt complained of itching, noted slight red spots about circumference of small tangerine on right hand, left lateral hand, and lower left leg, S/P COVID 19 #1 Injection; about 5 minutes after injection.

the patient developed symptoms 3 days later which included body aches, headache, cough, runny nose. pt is seeking her pcp for further testing/workup.

Shortly after receiving the vaccine, patient began feeling numbness and tingling down right arm to finger tips and stated that her right arm felt cold. She also reported a hot flash after receiving the vaccine. She waited for 1 hour after receiving the vaccine with no reports of improvement but denied any worsening of symptoms. The RN assessed the temperature and grip of each arm, reporting equal in both sides.

patient developed general malaise, body aches, cough, and diarrhea, temperature 99-100 F. Sought out pcp for testing/workup.

"26 y.o. female who arrived presented to the emergency department for concern of an allergic reaction. Patient reports being at the COVID-19 clinic just prior to arrival receiving her first dose of the vaccine. However, after walking a few minutes later she began to experience an abnormal sensation in the back of her throat, describing it as ""spicy"" accompanied by a general wave of feeling ""hot and heavy"" with some tingling in her fingers and toes. Patient currently states that overall her symptoms are improving with only a continued feeling of ""hot and heaviness."" Denies a history of allergic reactions to vaccinations or medications, besides a possible allergic reaction to Penicillin when she was younger. Denies shortness of breath, nausea, emesis, or any other complaints at this time. Denies a history of GERD, stating that she has not eaten anything today. Patient is otherwise healthy with no use of daily medications. Patient was observed for one hour while here in the ED with no residual symptoms. Patient feels comfortable going home and will return for worsening symptoms. Agrees to follow up with her PCP. Vital signs are stable at time of discharge."

41-year-old male who presents to the ED today with a complaint of weakness in his bilateral arms and legs. He states he fell slightly weak yesterday but this morning when he woke up around 6 AM he was not able to get out of bed because he was so weak. He states he feels like he has no muscle strength in his arms and legs. He denies any fever. He denies any cough or shortness of breath. He denies any chest pain or abdominal pain. He denies any nausea, vomiting or diarrhea. He denies any numbness in his extremities. He denies any neck or back pain. He did receive the first Covid vaccination on December 17.

After I received the vaccine exp nausea at 2:30 pm continued to 1 am. The following day I continued nausea and took Zofran. On 12/17 I left work due to nausea and around evening nausea stopped.

Sore arm at injection site for 3 days

cough got worse runny nose headache sore throat chills body aches teeth sensitive all these symptoms started Wednesday night which is the day I got the vaccine they lasted all Thursday and felt nothing on Friday

12/17/2020 at 1530 Patient states she has a little anxiety from just having received the COVID-19 vaccine. Per patient, she already spoke with her PCP who recommended she get the COVID vaccine. Patient offered ER evaluation for severe or worsening symptoms. Provided patient with phone number to Occupational Health dept to schedule appointment. States she will give them a call before going home. á1545 Patient observed for 30 minutes after vaccination. States she feels fine at this time and does not feel dizzy. No further needs

Woke up at night after vaccine Pain was intense at vaccine site, radiated to shoulders, body aches, headache x3 days Took Acetaminophen, slow resolution then resolved by day 4

Severe Myalgia, Extreme fatigue, mild headache, chills and nasal congestion

Patient lists that she woke up during the night after receiving the vaccine feeling sweaty and feverish. Upon waking the following morning she took her temp and it was 100.8 and 101. Patient also reported injection site tenderness and localized redness.

"PATIENT IS A PHYSICIAN. ALMOST 12 HOURS AFTER INJECTION, BEGAN HAVING BODY ACHES AND CHILLS - RESTLESS ALL NIGHT. IN A.M. WAS 101.0 F, TOOK TYLENOL EVERY 4 HOURS, ABOUT 2100 WAS 104.3F. FEVER STAYED ABOUT 100 TO 101 THROUGH NEXT DAY. SUNDAY, FEVER BROKE, MINOR CHILLS. FEELING ""FINE"" TODAY - NO SX'S."

I am a nurse practitioner here at the facility. I received the vaccine on 12/18/2020 at noon. On Monday evening 12/21/2020 I developed floaters and flashes of light in my right eye. I awoke on 12/22/2020 with continued worsening symptoms. I went to my optometrist. I was diagnosed with Vitreous detachment of the right eye. The optometrist did not feel it was related to vaccine but our health nurse advised reporting.

Chills, Fever middle of the night, headache, sluggish. No appetite.

FLUSHING, HIVES, FACIAL NUMBNESS ON THE LEFT SIDE

Fever, headache, sore arm at injection site, 72 hours after injection. resolved in 48 hours

about 3 hours after injection, began feeling nauseous. the next day at about 8 am temp went up to 102.4. took ibuprofen and temp finally broke about 4 pm that day. had injection site soreness for the first 48 hours then developed large red wheal that covered 3/4 of upper arm. still with red area when this report was filed on 12/28/2020

"reported no s/s of adverse reaction at time of vaccination and for 30 minute post-vaccination monitoring period. States that approximately 4 hours after administration , he had elevated BP (148/92) and heart rate (115bpm). Normal readings are HR in the 60s-70s and ""normal"" BP 120/60s. Had fever of 102 the first night that lingered for 48 hours, accompanied by extreme fatigue, nasal congestion, shortness of breath, decreased appetite, He took tylenol for fever and afrin for nasal congestion. By the 26th, he felt well enough to get dressed. No fever, appetite back to normal. BP on the 26th was normal to low and heart rate 105. Adverse reactions required no further treatment."

Pt recieved the vaccine and was hospitalized the following day with a bowel obstruction.

Employee was vaccinated at 4PM on 12/23. Hives started to develop on 12/23 at 8PM. Employee came back to the vaccination site at 1:15am on 12/24, complaining of hives on trunk of body and arms. No hives on legs or face. Denies shortness of breath , just itching and hives. 50 MG of Benadryl given IM at 1:30am on 12/24 and instructed to go to ER. Employee refused ER attention.

Assigned to work at nursing location. I reported for duty on 12/23/2020 @ 1310 and was offered the vaccine. No reaction at that time. Several hrs into my shift I became ill. Nausea, vomiting, trouble breathing, tongue was feeling funny, dizzy, stomach pain, extreme fatigue and lightheaded. I immediately reported to the charge nurse on the floor then shortly called my registry informing them of the current events. Registry offered to call 911 and I declined. Registry gave permission to end of shift and go home.. However when I notifed the charge nurse on the floor she stated I can't leave because she was leaving for the day. She called supervisor. I spoke to him and explained the situation and he informed me another person whom was a MD also was experiencing the same symtpoms. He instructed me to stay in the room I was at and they will send orange juice it should make me feel better. I waited and waited. I called the sup back and informed him my symptoms are getting worse and need to go. At this time I had developed a severe headache. I was not able to continue with extremely HEAVY workload caring 29 COVID patients in my condition and sup allowed me to go home. He said he would talk to the floor nurse because he had already arranged for 2 nurses to come in 7 pm which was shortly. Once home, my husband said I had a blank stare and dazed. Several hrs later I developed a fever, cough and severe body pain. I remained in bed for several days and most symptoms resolved. However on the 4th day went out and within a few started to become short of breath and heaviness on my chest and attempted the following day going outside and the same thing. I continue to have intermittent stomach pains and coughing.

12/17/2020 at About 2pm pt complained of some blurry vision, slight jitteriness and some queasiness; pt requested water. Nurse assisted pt to Overflow Observation Room. Pt A/O x4, Nurse provided pt water, crackers. Nurse continued to monitor pt: Continuous monitoring; and asked if she need anything periodically/ every 8-10 minutes. Pt refused any further care or assistance from Nurse; Pt stated she is feeling better and will continue to be in observation ; pt continued to be monitored by Nurse. Pt talked on phone during observation time; A/O x4. Pt monitored for about 40 minutes. Pt stated she feels better and fine; pt stated she was going to leave. A/O X4, denies chest pain, SOB, has steady gait.

Fever of 101.0 F that lasted until the next morning. Fever of 101.0 F for 2 hours the next night. Fatigue for 2 days, Chills with the fevers, night sweats for 6 days.

On 12/27/2020, I woke up with body aches and a headache around 0530. At 1230, I began experiencing severe stomach pain. I went into the bathroom and began sweating profusely. I had a bowel movement and started dry heaving. I then fell on the floor, and felt extremely weak. I did not bare down when having a bowel movement, I do not believe this was a vagal response. At this point I was still sweating profusely, my body hurt all over, I couldn't catch my breath, and I was incredibly weak. I crawled down the hall way to get my phone as I was home alone. My arms then began to tingle and my hands completely spasmed, I couldn't move them. My fingers locked completely straight but my palms closed. I activated Siri on my phone because I couldn't use my fingers, and had her call 911. I was having a very hard time catching my breath. By the time EMS arrived (about 20 minutes on the phone with 911), I had started feeling better. I had chills, and still felt out of it, but I was breathing better and my hands unlocked. My arms were still tingling. I let them check me out. My BP was normal, my O2 sat initially said 88% but was 98 by the time they left. EKG was normal. I didn't go to the hospital with them, I stayed

home. I didn't move around much the rest of the day. I felt tired and had lack of appetite. Today on 12/28/20, I'm feeling better but I am still taking it slow, just in case.

Blood pressure rose 190/100; got headaches in 10 minutes and started getting heavy chest; got headaches in 10 minutes and started getting heavy chest; Throat started to get tight, voice changed; Throat started to get tight, voice changed; had heart palpitations; Fast heart beat, difficulty breathing, dizziness and weakness; Fast heart beat, difficulty breathing, dizziness and weakness; Fast heart beat, difficulty breathing, dizziness and weakness; Fast heart beat, difficulty breathing, dizziness and weakness; This is a spontaneous report from a contactable healthcare professional. A 42-year-old female patient received first dose of bnt162b2 (Pfizer-BioNTech COVID-19 vaccine; lot EK5730), intramuscular on 17Dec2020 17:00 at single dose (left arm) for Covid-19 immunisation. Medical history included diabetic, high blood pressure and allergies to fruits such as canaloo, and peaches. Concomitant medications included amlodipine, loratadine, metformin, and ascorbic acid (VITAMIN C). On 17Dec2020 17:15, the patient experienced headaches in 10 minutes and started getting heavy chest, throat started to get tight, voice changed and injection was given; blood pressure rose to 190/100 and had heart palpitations, fast heartbeat, difficulty breathing, dizziness and weakness. The patient was given Epi injection and benadryl shot as therapy for the events. The vaccine was administered at the hospital. The patient did not receive any other vaccines within 4 weeks prior to the Covid vaccine. The patient visited a doctor or healthcare professional office/ clinic due to the event. The patient was not diagnosed with Covid-19 prior to vaccination and since the vaccination, the patient had not yet been tested for Covid-19. Outcome of events was recovering.; Sender's Comments: Based on the compatible time association ,the reported events are possibly related to suspect bnt162b2 injection in this patient. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

joints were aching; nauseous; hot flushes that progressed; feeling really hot; can't recall names; had a glazed look; This is a spontaneous report from a contactable registered nurse A 34-year-old female patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot/batch number: 9899, expiry date: Mar2021), intramuscularly in left deltoid on 18Dec2020 at 10:20 am at 0.3 mL, single for COVID-19 immunization. Medical history included chronic lyme disease and anxiety both from an unknown date and unknown if ongoing. Concomitant drug included vivogen which is a stimulant to keep her awake during the day and took supplements, but reporter didn't have a full list. On 18Dec2020 at 10: 25, the patient had an adverse reaction within 5 minutes felt nauseous, hot flushes that progressed and feeling really hot, as it progress she started getting out of it, the patient also can't recall names, she had a glazed look, within 30 minutes (18Dec2020 10:50) joints were aching. She was asking for common adverse events during clinical trial study. The event was reported as seriousness for being other medically important condition. The reporter considered the events was related to the COVID 19 Vaccine. The patient still had the neuro symptoms. She was still very out of it and her joints were still hurting. The nausea had gone. The outcome of the nauseous was resolved in Dec2020, the outcome of joints were aching was not resolved, the outcome of other events was unknown.; Sender's Comments: The reported

information is limited. Based on the close temporal relationship and the description of the events, nauseous, hot flushes, feeling hot, can't recall names, glazed look and joints aching. there is a reasonable possibility that the events are related to BNT162 vaccine. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

A very slight droop of relaxed right lip (Smile is symmetrical and NO orbital involvement); tightness, swelling and tingling in right jaw; tightness, swelling and tingling in right jaw; tightness, swelling and tingling in right jaw; generalized itching; A small patch (dime-size)of non-raised erythema noted behind right ear; A brief period of feeling hot followed immediately by a chills; A brief period of feeling hot followed immediately by a chills; Rash; This is a spontaneous report from a contactable nurse. A 41-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot number: EJ1685), intramuscularly in the left arm, on 18Dec2020 at 08:45 (at the age of 41-years-old) at a single dose for COVID-19 immunization. Medical history included hypertension (HTN) and seasonal allergies. The patient was not pregnant at the time of vaccination. Concomitant medications, taken within 2 weeks of vaccination, included mometasone furoate (FLONASE) and cetirizine hydrochloride (ZYRTEC). Other concomitant medications included an unspecified antihypertensive. The patient had no known allergies to medications, food, or other products. The patient did not receive any other vaccines within four weeks prior to the vaccination. The patient experienced a very slight droop of relaxed right lip (smile is symmetrical and no orbital involvement), tightness, swelling and tingling in right jaw, generalized itching, a small patch (dime-size) of non-raised erythema noted behind right ear, a brief period of feeling hot followed immediately by a chills, and rash on 18Dec2020 at 09:30. Therapeutic measures were taken as a result of the events, which included treatment with oral diphenhydramine hydrochloride (BENADRYL) 50 mg. The clinical outcome of a very slight droop of relaxed right lip (smile is symmetrical and no orbital involvement), tightness, swelling and tingling in right jaw, a small patch (dime-size) of non-raised erythema noted behind right ear, and a brief period of feeling hot followed immediately by a chills was not recovered and of generalized itching and rash was recovered on an unspecified date. It was reported that jaw tightness and slight asymmetry of relaxed lips continued on 18Dec2020 at 16:15. It was also reported that since the vaccination, the patient had not been tested for COVID-19. No follow-up attempts needed. No further information expected.; Sender's Comments: Based on the close temporal relationship, there is a possibility that the events are related to BNT162 vaccine. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

experienced a strong medicine-like smell; a rush of warmth throughout my body; felt that my hands were swelling and slightly itchy but they did not appear to be swollen; felt that my hands were swelling and slightly itchy but they did not appear to be swollen; panicked; felt that my throat was tight but I didn't feel short of breath; My BP was elevated at 140s/80s; tachycardic; This is a spontaneous report

from a contactable nurse (patient). A 42-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number: EH9899), intramuscularly at the right arm on 18Dec2020 at 13:00 (1 pm) at single dose for COVID-19 immunization. The patient was not diagnosed with COVID-19 prior to vaccination and since the vaccination, the patient has not been tested for COVID-19. The patient was not pregnant at the time of vaccination. The patient's medical history included asthma r/t environmental allergies, anxiety, and known allergies to PCN, Sulfa, grass, trees, ragweed, weeds, mold, dust mites, cat and dog. Concomitant medication included cetirizine hydrochloride (ZYRTEC), venlafaxine hydrochloride (VENLAFAXINE XR), colecalciferol (VITAMIN D), ibuprofen, and montelukast sodium (SINGULAIR). The patient received the vaccine on 18Dec2020 at approximately 1 pm (13:00) and 5 minutes later (18Dec2020 at 13:05), she experienced a strong medicine-like smell and a rush of warmth throughout her body. She then felt that her hands were swelling and slightly itchy but they did not appear to be swollen. She was panicked and felt that her throat was tight but she didn't feel short of breath. Her BP was elevated at 140s/80s and she was tachycardic. She gave herself an epinephrine injection and about 10 minutes later the occupational health nurse gave her 25 mg Benadryl at her request. The adverse events results in Emergency room/department or urgent care. The clinical outcome of the events was recovered on an unspecified date.; Sender's Comments: Based on the close temporal relationship, the association between the reported events with BNT162b2 can not be fully excluded. The history of asthma, allergies, and anxiety may have been contributory. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

diagnosed with Bell's palsy; This is a spontaneous report from a contactable nurse (patient). A 33-year-old female patient received 1st dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number: EK5730, expiration date: Mar2021), via an unspecified route of administration in left arm on 19Dec2020 10:00 at single dose for COVID-19 immunization. No other vaccine administered in four weeks. Medical history included drug sulfa allergy. Concomitant medication included cetirizine, cetirizine hydrochloride (ZYRTEC) from 18Dec2020, and multivitamin from 18Dec2020. No Covid prior vaccination. No Covid tested post vaccination. About 40 min after the vaccine (19Dec2020 10:40) the patient developed left facial/ left tongue tingling/ numbness. By 20:30 at night (19Dec2020 20:30), the patient had a left sided facial droop as well, the patient was diagnosed with Bell's palsy. 20:30 (19Dec2020), she had facial asymmetry. She looked in the mirror and noticed her smile was not symmetrical. She then checked into the Emergency Room and the ER doctors diagnosed her with Bell's palsy. She was not admitted to the hospital. Steroids were given for treatment. The patient was still expirencing. Intermittent tingling but tingling was not constant. Smile was not normal yet. The outcome of event was not recovered.; Sender's Comments: Based on the close temporal relationship, the association between the event Bell's palsy with BNT162b2 can not be fully excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as

well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

bilateral periorbital swelling; Myalgia; Fever; This is a spontaneous report from a contactable physician. A 49-year-old male patient received BNT162B2, via an unspecified route of administration on an unspecified date as single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced bilateral periorbital swelling, myalgia and fever on an unspecified date, which were medically significant. Description was as followed: patient went to the emergency department. The vaccines was given on a Wednesday afternoon, and patient presented with bilateral periorbital swelling this morning, myalgias, and fever. Therapeutic measures were taken as a result of swelling, myalgia and fever; the only treatment given was diphenhydramine (BENADRYL) orally. The batch/lot number for the vaccine, BNT162B2, was not provided and will be requested during follow-up.; Sender's Comments: The reported information is limited. Based on the close temporal relationship and the description of the events, periorbital swelling, myalgia and fever, there is a reasonable possibility that the events are related to BNT162 vaccine. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

Diaphoresis; palpitations of 180-150 beats per minute, and SVT supraventricular tachycardia on the heart monitor.; palpitations of 180-150 beats per minute, and SVT supraventricular tachycardia on the heart monitor.; This is a spontaneous report from a contactable physician. A 56-year-old male patient received the first dose BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 18Dec2020 at 09:00 at single dose for covid-19 immunization. Medical history included hypertension, episode of SVT (supraventricular tachycardia) in the past. There were no concomitant medications. The patient experienced diaphoresis, and palpitations of 180-150 beats per minute, and SVT supraventricular tachycardia on the heart monitor on 18Dec2020. The events were reported as serious per medically significant. Event details: the patient received the vaccine 18Dec2020 at 09:00AM. About 40 minutes later the patient returned to hospital where he worked, where he received the vaccine, with diaphoresis, palpitations of 180-150 beats per minute, and SVT supraventricular tachycardia on the heart monitor. Reporter stated this was temporally related. Patient was given Adenosine 6mg IV with no response; then 12mg Adenosine with no response. Then the patient the spontaneously converted 10 minutes after the last dose of adenosine to 75 beats per minute and sinus rhythm, in one beat. The reporter was an emergency room (ER) physician and the patient was the ER right now. The patient was stable at time of reporting and expected to be discharged. The reporter did order a Troponin and cardiac workup. Troponin result was less than 6 which was normal. With regard to the Adenosine that didn't work reporter stated those vials usually went into a container and after consulting with another coworker stated the Adenosine vial had been discarded at this time and he was unable to provide NDC, lot or expiration date. The outcome of the events was resolved on 18Dec2020. Information on the lot/batch number has been requested.; Sender's Comments: Based on the close temporal relationship and the description of the events,diaphoresis, palpitations and SVT,

there is a reasonable possibility that the events are related to BNT162 vaccine. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

"fainted right after taking the vaccine; This is a spontaneous report from a non-contactable consumer (Pfizer company representative). A female patient of an unspecified age received the bnt162b2 (BNT162B2; also reported as COVID-19 vaccine; Batch/lot number, NDC number, Expiry Date: Unknown), via an unspecified route of administration on 17Dec2020 at a single dose for COVID-19 immunization. The patient medical history was not reported. The patient's concomitant medications were not reported. The patient experienced fainted right after taking the vaccine (medically significant) on 17Dec2020. It was unknown if the patient received other products, and any investigation assessment was unknown. The clinical course was reported as follows: The reporter stated they had seen quite a bit on social media and on the (site name), where people have been sending around a video regarding a healthcare worker who fainted. The caller was just wondering "" if Pfizer has been made aware of this. ""Apparently, this was on the news. This healthcare worker was taking the COVID-19 vaccine and as she was talking to the press, she apparently fainted. It looks as if she fainted as one would do when taking blood tests or faint from fear of a shot or being worried. However, this video has been sent all over social media, as seen as an AE, and telling people to not take the vaccine."" The reporter further clarified the healthcare worker was in (city name) and received the COVID-19 vaccine. As the healthcare worker was talking to the press, she fainted right after taking the vaccine. The reporter further clarified she was sent a link via (site name) from the news channel where it had the video recording. The reporter did not have a specific reporter. The reporter explained it was a "" whole group that was talking about it."" The reporter clarified she was in a (state name) group on (site name) with friends and family. The reporter also saw it on social media. "" People are sending it left and right."" When probed to determine if the reporter had any patient details or further details regarding the event, the caller stated the only information she had was that on (News name), and click on (City name) news and find the video of the healthcare worker taking the vaccine and fainting. The reporter clarified the news article was dated as 17Dec2020 ""so this event must have happened yesterday."" From the reporter's understanding from the news, the patient was fine, she got up. ""However, people are sending out on social media that she is dead"", which the reporter did not think was the outcome. According to the news, when the reporter opened the link, it was just a regular fainting, it was not a death. The reporter felt obligated to report and make sure Pfizer was aware of this since she had been seeing it everywhere on social media. The clinical outcome of the event, fainted right after taking the vaccine, was unknown. No follow-up attempts are possible; information about batch/lot number cannot be obtained."

"throat tightness; tingling of lips; allergic reaction; felt strange; This is a spontaneous report from a contactable Other-HCP (nurse practitioner). A 43-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, NDC, lot/batch number and expiration date unknown), via an unspecified route of administration on 18Dec2020 at single dose for covid-19 immunization (She wanted to be vaccinated against COVID 19). Patient history was no. She has no other history no other history of

reactions to vaccines or flu vaccines, no history of allergies noted before. She thought her weight was probably about 140. She did not have her height either, but she was about 5'4"" probably. Concomitant medication included atorvastatin (LIPITOR) and thyroid medications. It was reported that they have an employee that received the COVID 19 vaccination and experienced an allergic reaction. It had to be a brief call but it was there crazy. Patient received the vaccine and within 30 minutes she had throat tightness and tingling of lips. This happened on 18Dec2020(today) about 20-30 minutes after receiving the vaccine. The throat tightness had resolved after giving Epinephrine (Epi). She said the tingling of her lips resolved as well after Epi. She just said she felt strange but that could be from the Epi. She said it was an employee vaccination so there was no prescriber. She took Lipitor and thyroid medications. She said those were just her routine medications. She did not have a start date for the Lipitor. She had not been on anything new. It was definitely just the COVID vaccine. Outcome of the events tingling of her lips, throat tightness and allergy reaction was recovered on 18Dec2020, of other event was unknown. Information about lot/batch number has been requested.; Sender's Comments: There is a reasonable possibility that the events allergic reaction and throat tightness were related to BNT162b2 based on known drug safety profile and close temporal relationship. Based on the close temporal relationship, the association between the event tingling of lips with BNT162b2 can not be completely excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate."

Temperature up to 102.2; Numbness in fingertips; Chills; Nausea; Soreness in arm; Shaking too badly; This is a spontaneous report from a contactable Registered Nurse (patient) and Consumer (Patient's husband). A 64-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, batch/lot# EK5730), via an unspecified route of administration in Left deltoid on 17Dec2020 14:00 at single dose for COVID-19 immunization. Vaccination Facility Type: Hospital. Vaccine administered at site: No. Medical history included cervical dystonia. The patient had COVID back in Mar2020. Symptoms were similar but she doesn't remember having the numbness in her fingertips. Family medical history: None. The patient's concomitant medications were not reported. Additional vaccines administered on same date of Pfizer suspect: None. The patient previously took povidone-iodine (BETADINE) and experienced allergy to betadine. Prior Vaccinations within 4 Weeks: None. AES follow prior vaccinations: None. The patient experienced temperature up to 102.2 on 18Dec2020 11:00, chills on 18Dec2020 10:00, numbness in fingertips on 18Dec2020 10:45, nausea on 18Dec2020, soreness in arm on 17Dec2020, shaking too badly in Dec2020. No AES require a visit. Relevant tests: None. The patient received shot at 2PM. Had a little soreness in arm and took paracetamol (TYLENOL, Acetaminophen 500mg, Product strength and count size dispensed: 500mg caplets; quantity 100, Provided 0CE3259A above date of Jan2022, Provided 484782EF17 from bottle, NDC: 49035-308-78, Manufacturer is Unknown) as pain reliever before bed, Dose: 1000mg on 17Dec2020 at 9PM. Took Ibuprofen (Product strength and count size dispensed: 200mg tablets; quantity 100, Provided 0DE2612A above date of Feb2022, Provided 604782EF8 from bottle, NDC: 49035-308-78, Manufacturer is Unknown) at dose: 400mg on 18Dec2020 at 4AM this morning. Having chills, temperature up to 102.2, numbness in fingertips and a little nausea. Clarified she is referring to the COVID Vaccine. The patient was shaking too badly. Symptoms started

with Chills around 10AM 18Dec2020. Temperature was checked at 11AM Central time 18Dec2020 and checked now during report. Temperature was the same. Numbness in fingertips began 10:45AM 18Dec2020. Nausea had been on and on due to chills. Chills were aggravating the nausea. Had not thrown up. Temperature was going up and she was worried about getting dehydrated. Clarified EK5730 is from CDC Patient Card. Indication: Front line worker; lead nurse in Intensive Care and is in front of COVID all day long. A sample of the product is available to be returned, if requested, notified of mailer. Packaging is sealed and intact. The patient underwent lab tests and procedures which included temperature: 102.2 in Dec2020 and on 18Dec2020. The outcome of all the events was unknown. Serious: Yes, Seriousness criteria-Other medically important condition: No (as reported). Reporter seriousness for Temperature up to 102.2, Chills, Numbness in fingertips, Nausea: Medically significant. Relatedness of drug to reactions/events: Reaction assessed: Temperature up to 102.2, Chills, Numbness in fingertips, Nausea; Source of assessment: Primary Source Reporter; Source of assessment: Global Introspection; Drug result: Related. Verbatim event relatedness: COVID-19 Vaccine: Temperature up to 102.2, Numbness in fingertips-Related.; Sender's Comments: Based on the close temporal relationship and the description of the events, there is a reasonable possibility that the events, temperature up to 102.2, chills, numbness in fingertips, nausea, soreness in arm, shaking, are related to BNT162 vaccine. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

had a syncopal event and hit her face when falling; had a syncopal event and hit her face when falling; hit her face; This is a spontaneous report from a contactable consumer via Pfizer sales representative. A 41-year-old female patient received BNT162B2 (Pfizer product) , via an unspecified route of administration on 18Dec2020 at single dose for COVID-19 immunization. The patient medical history was none. The patient's concomitant medications were not reported. The patient had COVID vaccine administration yesterday (18Dec2020). She went to bed that night and woke up in the middle of the night to use the bathroom. She had a syncopal event and hit her face when falling. She required a trip to the urgent care and stitches. She was a healthy female with no underlying conditions. Event took place after use of product. Therapeutic measures were taken as a result of hit her face. The outcome of the events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

"Anaphylactic Reaction; felt like something was in throat; felt tingling on both hands and fingers; voice started to change; face turning red to white to purple; everything in mouth as tongue felt like it was growing; having chest pain radiating to left scalpel, and jaw; couldn't think of the words to say as it was hard to breath; chills; heart rate is racing; This is a spontaneous report from a non-contactable nurse via internet source via Pfizer Sales Representative. A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number: EH9899) via an unspecified route of administration on 18Dec2020 at single dose for covid-19 immunization. Medical history included had a lot of food allergies. The patient's concomitant medications were not reported. The nurse told that her manager (patient) had an anaphylactic reaction shortly after receiving Pfizer's COVID-19 BNT162b2

vaccine on 18Dec20. Patient stated via Social Media indicated that she received the Covid-19 vaccine right after work. Easy breezy didn't feel a thing. She was asked to wait for 15 minutes, 5-10 minutes of waiting, she felt like something was in throat, so she kept clearing it. Patient felt tingling on both hands and fingers. Her voice started to change. She informed the ER team there, the ER nurse described her face turning red to white to purple. ER nurse started an IV right on patient's right AC, gave her a shot of Benadryl, steroids and the epi pen right through pants. Patient felt everything in mouth as tongue felt like it was growing, but she can breath. Patient was route to the ED via wheelchair, everything started to look hazy, she was having chest pain radiating to left scalpel, and jaw. Patient couldn't think of the words to say as it was hard to breath. When got to the ED they gave her another dose of Benadryl, solumedrol, decadeon, HHN tx with epi and that worked. Patient felt her throat opening up and started talking but then came the chills. It took almost 3 hours to clear the symptoms, even though her heart rate is racing (prob due to the meds), she opted to go home. The outcome of ""heart racing"" was not recovered, of other events were recovered on 18Dec2020. No follow-up attempts are possible. No further information is expected.; Sender's Comments: A possible causal association between administration of BNT162B2 and the onset of anaphylactic reactions with tongue swelling/voice alteration/hard breath/tingling/something in throat/skin discoloration, chill and chest pain cannot be excluded, considering the plausible temporal relationship and the known adverse event profile of the suspect product. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate."

TTP; This is a spontaneous report from a non-contactable pharmacist. A 22-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), intramuscular on 17Dec2020 as a single dose for COVID-19 immunization. The patient did not have any known relevant medical history. The patient had no allergies to medications, food or other products. Prior to the vaccination, the patient was not diagnosed with COVID-19. The patient's concomitant medications were not reported. It was unknown if the patient received any other vaccines within four weeks prior to the vaccination. On 21Dec2020, the patient experienced thrombotic thrombocytopenic purpura (TTP); which was serious for hospitalization. The clinical course was as follows: The patient went to the emergency room/urgent care and was admitted in the early morning of 21Dec2020 due to TTP. Work-up was ongoing with no known results. On 21Dec2020, the patient also had a COVID-19 test which was negative. The patient was treated with unspecified corticosteroids and platelets. The clinical outcome of the TTP was unknown. The reporter assessed that it was unknown if the TTP was related to the vaccination. The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up.; Sender's Comments: Current limited information does not allow a full medically meaningful assessment, especially lack of medical history, concomitant medications, concurrent illness and diagnostic workups such as coagulation test, Combs test, bacterial/virologic/immunological biomarkers to identify the etiology. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any

appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

injection site pain; tiredness; headaches that come and go; muscle pain; few chill; severe joint pain; fever; This is a spontaneous report from a non-contactable healthcare professional (patient). A female patient of an unspecified age (Age: 60; Unit: Unknown) received single dose of (BNT162B2, batch/lot number and exp date not reported), via an unspecified route of administration on 21Dec2020 (last Monday), around 11amfor immunization. The patient's medical history and concomitant medications were not reported. Patient reported experiencing 7 side effects after receiving the COVID-19 vaccine on an unspecified date in Dec2020. She experienced injection site pain, tiredness, headaches that come and go, muscle pain, few chill, severe joint pain, and fever. Her temperature ranged between 99.9-100, at the low grade. Patient asked how long the symptoms would last and to what point does she assume that they relate to the vaccine. The outcome of the events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

Developed redness, swelling, and itching at injection site 6 days after receiving the vaccine.; Developed redness, swelling, and itching at injection site 6 days after receiving the vaccine.; Developed redness, swelling, and itching at injection site 6 days after receiving the vaccine.; This is a spontaneous report from a non-contactable nurse reporting for a patient. A 29-year-old female patient received first dose of BNT162B2 (Pfizer product, lot number EK5730), via an unspecified route of administration on 16Dec2020 on left arm at single dose for COVID-19 immunization. Medical history was none. The patient's concomitant medications were not reported. The patient was not pregnant. She had no known allergies, no Covid prior vaccination, no Covid tested post vaccination. The patient developed redness, swelling, and itching at injection site 6 days after receiving the vaccine (on 23Dec2020). No treatment was received for the adverse event. The outcome of the events was unknown. The report was assessed as non-serious. No follow-up attempts are possible. No further information is expected.

"chills; extremely dry mouth where she feels like she has no saliva; extremely dry mouth where she feels like she has no saliva; extremely tired; had a strange sensation of tingling in her skull, back of neck, and up her skull. Tingling sensation is more left sided than right/the tingling sensation in her head; This is a spontaneous report received from a contactable nurse (who is also the patient). A 63-year-old female patient started to receive BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899, expiry date: Mar2021), via an unspecified route of administration, on 22Dec2020, at single dose, for COVID-19 immunization. The patient medical history and concomitant medications were not reported. The patient reported that on 23Dec2020, she had a strange sensation of tingling in her skull, back of neck, and up her skull. Tingling sensation was more left sided than right. On24Dec2020, she experienced chills, which she knows is one of the normal effects. She also experienced an extremely dry mouth to where she feels like she has no normal saliva on 24Dec2020. She was constantly drinking ice water. She was also extremely tired. The patient reported that the most concerning to her is the tingling sensation in her head and the extreme dry mouth. The patient wanted to know if what she is experiencing is ok or not. She also reported that ""if it's urgent she cannot wait until USMI reopens, she will go to the ER"". The outcome of the events was unknown."

localized soreness in arm; This is a spontaneous report from a non-contactable physician via Pfizer sales representative. A male (nephew) patient of unknown age received on an unknown date BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) at single dose in the arm for COVID-19 shot. Medical history and concomitant medications were not reported. The patient, who is an ER doc, had localized soreness in arm from vaccination. Outcome was unknown. No follow up attempts are possible, information about batch number cannot be obtained.

"Patient states that she waited her required 15min at the vaccine clinic. She felt no symptoms. One hour later however she felt tired so she took a nap. That night she felt cold and had to grab a blanket. Before bed she felt that the skin on her abdomen was feeling ""tingly."" The next morning she noticed a rash on the abdomen that is itchy. She already takes 25mg benadryl daily for allergies so she started taking it twice a day but that hasn't helped. She now notices the rash in the b/l groin, left thoracic back and left arm (upper and forearm). The rash is still present and itchy 5 days later so she came to my clinic today. I prescribed her a 6 day dose pack of methylprednisolone and to continue benadryl."

Pain at injection site, fatigue

First day had chills, headache, body ache, body sweat, fever, fatigue for two-three days, first day slept for 21 hours, second day for 15 hours. Didn't start feeling normal until the fifth day. Arm swollen where the shot was given on right arm, 3 inches size. Today is the 6th day and still some visible swelling on the area down to two inches but itchy for two days now.

felt tired and had left elbow pain

Non-itchy slighlty raised rash that appeared about 24 hours after vaccine at location of shot that extended up to shoulder and down to elbow. It went away after another 24 hours. 1 week after vaccine, developed lip twitch on side of body that vaccine was administered. Still persists 1 week later, but is not as intense

0654 TACHYCARDIA. LIGHTHEADED, THROAT IRRITATION, HYPERTENSION, & FACIAL SWELLING

Arthralgia, sore throat, dry cough, congestion, pain to back of head and neck, leg pain, lower back pain, fatigue, fever 100.7 on 12/23/20 12/26/20- developed chest pain neck pain left shoulder pain lightheaded and nausea at night-resolved next morning

Severe headache causing mild nausea due to pain. Continues ongoing from 4hrs after dose to present. Itching all over they body from morning after the dose to present. Trouble concentrating, brain fog since morning after the dose to present. Restless from morning after the dose to present. Numbness around mouth, since the morning after the dose to present. Fatigue since morning after the dose to present.

7 days after receiving vaccine I?ve been having nausea without vomiting and headaches. It started on Dec 25 and has continued and is present as of today Dec 28th. I will make an appointment to be Covid tested as soon as possible. On the Vaccination record card it stated to report any possible adverse reaction. I?m unsure if this is related but felt I should report it.

Patient received the Covid 19 vaccine on 12/24/2020. On 12/26/2020 she c/o new onset fatigue, bodyache, cough, headache, sore throat. The dry cough and sore throat are worsening. Denies fever or chills. Covid test scheduled on 12/28/2020 at Employee Health.

vaccine at 11:30 am on 12/18/20 and after 15 mins she felt the room started to spin, dizzy and tunnel vision. nausea and dry heaves also 2-3 mins after. persistent dizziness. pruritic rash and was taken to the ER by wheel chair. About an hour after the vaccine, she felt something in the back of her throat, speech ok, able to swallow. No sob. She was treated with benadryl, pepcid, zofran and fluid. She felt very hot and shaking. In the ER, she noticed that the rash had progressed to her back. Notes chest redness, back with erythematous, raised pruritic bumps on back and arm (smaller size of dime) Within 4 hours of treatment, she had improved. That night at 2am she had a rash -not as pruritic. She took more benadryl. No rash after. No new meds, no nsaids. She has never had any medical problems or rashes before. Her symptoms are concerning for anaphylaxis but it is reassuring that her vitals were ok and that she did not progress and improved with benadryl and pepcid - advised to not get 2nd vaccine dose - will plan on skin testing her in the future

Arm pain and Migraine .. Took Migraine medication and that's when I had a anaphylaxis reaction . I have an appointment to see a specialist to verify if the reaction was caused by the COVID vaccine or the medication I took that day

Pt received COVID 19 Vaccine on 12/16/20. During 15 minute Observation; pt complained of Palpitations about 5 minutes into Observation. The nurse assisted pt to Overflow Observation room. Nurse Manually check Pulse; Pulse 68, A/O x4. Pt provided water and crackers. Pt stated her Palpitations have resolved on their own in about 4-5 minutes.

Around lunch time I felt inside my body a stinging sensation shooting down my body. 5-10 min it got worse and I felt my heart racing. I noticed I started getting a rash, it started on my chest, bottom and legs, I went to the ER where they recommended me a shot of Benadryl and a Pepcid. It took 3- 4 days for the rash to go away and 2 days for the itchiness to go away. It also broke out on my face a day later in the morning.

Approx. 3-5 minutes after receiving vaccine became lightheaded with blurry vision, tongue became thick and numb. About 10 minutes after vaccine pain in right arm and burning down my throat. My hands and arms became numb and tingly and were heavy to move. Symptoms got better with IV Benadryl and Solu-Medrol. Approximate 4 hours after vaccine developed vomiting and diarrhea.

numbness & tingling in tongue & throat after vaccine administration. Immediately taken to the ED, Benadryl & steroid given.

Difficulty breathing, catching breath then face flushing an hour after vaccination. She took her temp which was normal, went to sleep and woke up the next day feeling fine. No history of asthma or COPD. No history of AE from vaccines in the past.

Overall itchiness

Pt. received Covid #1 at 8:20 a.m. , 10 minutes later, she experienced palpitations along with heart rate of 90-100. Other vital signs stable. O2 sat 100% , afebrile. This went on for 1 1/2 hours on and off of wellness then again with the episode. She also experienced diarrhea X2 within the 1 1/2 hour span. This adverse event seems to be a vasovagal reaction to the injection and not to the vaccine itself.

Approximately 5 minuets after receiving Moderna, COVID-19 vaccine, while talking with writer, client became unresponsive and slumped over in chair. Client's extremities became stiff and his eyes rolled to the back of his head. Client was lowered to the floor with assistance and remained unresponsive for a minuet more. EMTs on site responded to event and monitored client for approximately 40 minuets before discharging client home in stable condition. During the monitoring period, client did have emesis x 1. His skin was also clammy after initially becoming unresponsive.

Red raised area to arms and chest that resolved within ten minutes without treatment

Nursing Notes: about an hour after COVID injection, severe vertigo, vomiting, severe headache, left arm completely numb, pt states she is sitting in her car in the parking lot of her apt, but not able to get out and walk bc the dizziness is too much. RN recommended ER disposition. Pt is going to take an Uber

The night of, I had vivid, strange dreams. I thought this was a fluke but have spoken with multiple people who had the same issue. I didn't have any weird dreams any other night, just the night of the vaccination. No treatment needed.

Patient tested positive for Covid-19 on 12/25/2020

angioedema face and hands, rash, fever, chills, fatigue, started menstruation all started about 7 hours post vaccination.

Myalgias, fever x24hrs

Employee developed heart palpitations shortly after receiving the COVID-19 vaccine. Heart palpitations lasted approximately 1 hour. No medical intervention needed. Pulse remained within normal limits (60-100).

Patient developed heart palpitations shortly after receiving the COVID-19 vaccine. Heart palpitations lasted approximately 1 hour. No medical intervention needed. Pulse remained within normal limits (60-100).

Awoke with a significant frontal headache. I considered that it might be sinus related, but decongestant did not help it. Awoke the following morning fine. So potentially could be related to vaccination.

"12.22.20 @ 20:30 injection site pain, radiating pain to right elbow and neck, tingling in right 4th, & 5th finger 12.23.20 @ 05:45 awoke with headache, body aches and continued pain in right arm 12.23.20 @12:45 headache worsened, continued arm pain, fatigue 12.23.20 @ 14:30 elevated temperature 100.2 and chest palpitations and nausea 12.24.20 @ 10:53 ""killer headache, and body aches. No fever since yesterday night w/o taking reducer fever medications."" BP1 164/106 Individual took her BP again in the

other arm: BP2 162/109 She stated she will take Tylenol, and rest for 30 minutes to take her BP again. She stated she will contact her PCP after this. 12.24.20 @ 12:03 BP 129/90 Individual stated she contacted her PCP and PCP is aware of this event."

Patient developed Covid 19 following vaccination.

8 hours after injection: itching, induration, pain @ injection site (left deltoid) Following morning: headache, earache & pressure, Post nasal drip, increased pain & itching @ injection site, ping-pong sized swelling at injection site with redness. Took Motrin for symptoms with some relief. 2nd Day: improvement in pain, swelling, itching, still present. Slight headache/bilateral earache. General malaise. Took Motrin with some relief. 3rd day: left arm tender to touch, swelling/redness further decreased, intermittent itching. Malaise improved. Remnants of headache/earache. No need for Motrin. 4th Day: arm pain/itchiness continues to decrease, no swelling now, no headache, no malaise, some ear pressure.

Patient had mild hypotension, decreased oral intake, somnolence starting 3 days after vaccination and death 5 days after administration. He did have advanced dementia and was hospice eligible based on history of aspiration pneumonia.

pt co fatigue over the weekend and then developed chest pressure and hypoxia per pt on 12/28/20

The sequence of events begins approx. 3:30pm on 12/23/20. 12/23/20 ? headache, nausea with vomiting, brief itching, chilled feeling, temp of 99.9, body/bone aches all over with legs hurting the most, very sore injection arm, husband and I debated on going to the ER, cried 12/24/20- headache, nausea without vomiting, body/bone aches, didn?t take temp, sore arm. 12/25/20- same as 12/24 12/26/20-body/bone aches but not as intense, headache, arm sore, neck was tad stiff. When I put on deodorant it hurt then felt pea sized lump painful to touch in left arm pit. Also felt lump on left side on my neck the size of thumb pad but not painful. Cold sore appeared on bottom lip 12/27/20- sore armpit-lump smaller, neck lump smaller non painful, nauseous 12/28/20-armpit feeling better lump almost gone still painful if I press on it otherwise not an issue, neck lump smaller -pinky pad finger size non painful June 2020 tested positive for COVID was moderate in symptoms

Less than 15 minutes after vaccination alerted lead of itching and hives. Noted rash. Has had similar reactions to medications in the past. No respiratory compromise. Per standing order was given Benadryl 50mg po with water at 1519. 1520 VS: 158/79-82-16-96.9 and 96% on room air. 1534 VS: 140/73-76-16-96.6 and 95% on room air. Employee was observed for an additional 15 minutes with no progression of symptoms. Instructed to call lead if any further symptoms develop. Returned to lab department to work.

I got vaccine tonight ~1750. I felt fine immediately after and stayed for the recommended 15 minutes. During my drive home, ~20 minutes, I had some expiratory wheezing and a sensation of something in my throat. No angioedema or swelling. No skin symptoms. This was mild but made me think twice so I drove back to the er. The wheezing resolved, but I felt like I was going to faint with hot flushing and nausea in the parking lot. I didn?t go in because things seemed better and my stomach was turning like I was going to have diarrhea. Since the wheezing was gone, I decided against going in. I stayed in the

parking lot for ~ 15 minutes and feeling of unease and presyncope waxed and waned, but eased. I continued with some nausea. I had waves of nausea, chills, flushing, and presyncope. The wheezing didn?t return. No tachycardia. I had chills and nausea on the drive home and at home. Took Tylenol and Pepcid when I got home and feel absolutely fine now after ~2 hours of fluctuating nausea, chills and sense of unease/anxiety. None were as severe as they were when I was in the parking lot. Throughout, I didn?t have high or low heart rate. After 8 pm or so, I feel just fine. I have zero symptoms now.

"patient became nauseated and began dry heaving. C/o ""tickle in back of throat"" with repetitive throat clearing. Mild periorbital swelling noted Given Zofran, Pepcid, Benadryl, epi-pen x 1, IV initiated EMS took patient to emergency department for further evaluation"

HR 101, anxious, BP cuff not reading, but patient indicates she has always has a low BP. Pt refused snack, symptoms have resolved. SPO2 100% and HR at 80 at discharge.

34 year old female who reports localized redness and itching within 5 mins after injection. Patient denied any shortness of breath, GI symptoms or rash. VSS. Patient received 50mg of Benadryl. Approx 5 min later patient developed throat tightness. Patient was promptly administered EPI. Patient developed urticarial like lesions. Patient reported improvement in throat tightness but continued to complain of itching at injection site. An additional 50mg of Benadryl was administered. Patient reported improvement of itching approx 5-10 min later. Patient VSS stable throughout but developed tachycardia.

Lightheaded, immediately resolved. HR 80 at discharge

Patient developed wheezing, c/o difficulty breathing. Denies tongue swelling, no visible rash. Treated with albuterol nebulizer and transported to hospital.

sharp pain in all my joints.

Injection site soreness starting on day of injection and has improved today. Headache, nausea and vomiting at least 6 times. Not pregnant but unsure if food poisoning

visible rash to anterior chest and left side of the neck (close to left ear). Client c/o of itching. Allegra 60 po given with water per protocol.

Headache, body aches, joint pains and low grade fever with feeling warm and fatigue x 36 hours. Headache with severe cervical/thoracic spine/neck pain, fatigue, fogginess has persisted x 10 days. Associated nausea when pain is severe. Sometimes headache is improved; but it usually worsens in the evenings.

Upper body flushing and dizziness (arms/face). Dizziness resolved in approximately 20 minutes. Pt left observation area still slightly flushed.

Pfizer-BioNTech COVID-19 Vaccine. Headache and fatigue

Friday patient experienced feeling fatigued and disoriented, Friday she reports muscle aches and headaches and Saturday patient reports feeling headaches and even more fatigue along with a sore throat on Saturday

Patient received the Covid 19 vaccine on 12/24/2020. On 12/27/2020 she c/o new onset fatigue, cough associated with slight itching of the throat and chills. Denies fever. Hx of allergic cough. Covid test scheduled on 12/28/2020 at Employee Health.

33 y.o. female who arrived by on-campus presented to the emergency department for onset of dizziness and a splotchy red rash after receiving the COVID-19 vaccine today. Patient states after onset of her symptoms she further sat down for approximately 15 minutes, but when she went back up to work she was further prompted to come down to the ED for evaluation. Denies wheezing, nausea, or abdominal pain. Denies a history of allergies. Patient tested positive for COVID-19 at the end of this past September. No prior immunization reactions Patient was given PO Benadryl and observed for one hour while here in the ED with no residual symptoms. Patient feels comfortable going home and will return for worsening symptoms. Will discharge patient with a prescription for Prednisone to use if symptoms return

Moderna COVID-19 Vaccine Nausea/Vomiting/Diarrhea upon awakening on 12/24. Lightheaded, near-syncope, diaphoretic. Lasted approximately 3 hours. Vomited then nausea subsided after about 1hr. Chills starting 12/26. Difficulty warming up after being outside in the cold. Prolonged effects that are not normal for me. 12/28 cold/clammy hands despite being in warm environment.

Hives to bilateral arms and chest

"""throat feels tight"" - no obvious signs of distress. Benadryl 50mg Po given and discharged at 1040 feeling better"

Just over 24 hours after receiving vaccine, began running low grade fever. First recorded at 101. Over the next 48 hours (approximately) fever fluctuated between 99-101. Also experienced pain at injection site and muscle soreness in left arm. Issues resolved on their own without medication. V-SAFE 1st check in, did not occur until 4 days post vaccine, at which time, fever had resolved.

Headache (akin to a tension headache, forehead location) almost instantly after injection that has persisted but lessened in severity since injection over the course of one week.

Same day after vaccine I started feeling tired. 2nd day i started having chills and muscle aches. Went to work and tried to work through it. Wednesday i worked 1/2 day. Thursday morning I started feeling light headed that afternoon I started getting hives on my legs. 12/24 I called internal med and spoke with Dr. He called in a rx for me a steroid. I took the 1st day and 1/2 of the 2nd and stopped because I started feeling nauseous and light headed but my hives started getting better(color change) He advised me to go to the ER but I started feeling better andf I told him i would follow up with Dr's office. if I wasn't getting better. I scheduled an appointment with Dr my PCP. I am still very weak and the back of my neck and shoulders are very tender. I still have hives on my legs but they are starting to clear.

5 days after I received the vaccine, I came down with severe abdominal pain, I went to the emergency department and was diagnosed with Acute Pancreatitis without a cause. I do not drink alcohol, and my gall bladder is working well, no gall stones noted to cause pancreatitis.

Shortness of breath, shallow breathing Fatigue Headache some body ache at first I went to the clinic, nothing prescribed but did take a Covid test which came out negative

Headache Fatigue Muscle Aches Nasuea

At 3:00 PM same say I started having arm pain 12:00 AM that night chills , back pain , muscle pain Next morning fever , I could Not stand up , eyes was burning , headache third day- Headache and arm pain

Sever dizziness, headache and nausea

12/17I had severe nausea I never threw up and fatigue and I had to leave work and Dr prescribed zophran, I was fine the next day on 12/18 I went to work I was just a little nauseous

12/23/20 - SEVERE stomach cramps, chills, low grade temperature, mild headache 12/24/20 - Fatigue

VACCINE 12/22 having congestion, cough, runny nose starting 12/24 and current 12/28

Left arm very sore, with some nausea (so far I haven?t thrown up).

Headache, neck pain & pain at injection site starting approx 2 hours after injection and lasting until bedtime on 12/18/20. Headache, swollen glands, neck pain, fatigue, nausea and fever beginning morning of 12/20/20 and resolved 12/22/20.

Fever over 100 degrees F

On 12/21/2020 at 1630, patient complained of anxiousness, feeling hot, and claustrophobia about 8-10 minutes S/P COVID 19 Vaccine administration.

tachycardia

vaso-vagal response to injection

First overnight after vaccination. No fever. Nightmares and vivid dreams all night long. Generalized myalgia and arthralgia (even my fingers and toes). I have had dengue (?break bone?) fever twice ?. It felt almost as bad. It?s like looking at your extremity wishing to move it, but it hurts so much that you just give up! Sounds dramatic but it is the best way I can describe it. Got better as I incorporated into the day. Some residual fatigue for 1-2 days. All resolved.

Patient had Hoarsness in her throat and felt like she could not breathe. Was given Benadryl, Prednisone and Pepcid.

Fever, sore arm, chills

Patient presents to the ED with complaints of an allergic reaction that started approximately 5 minutes after receiving the COVID-19 vaccine. Patient states that she started to experience throat swelling, tingling on her nose and lips, as well as feeling a little dizzy. Patient denies any trouble breathing but states that she has slight chest pain on inspiration. Denies any other symptoms, denies any significant medical history, has not ever had a reaction to a vaccine before.

Approximately 12 hours after the injection - started feeling that the L side of her face was numb and tingling. Also started with nausea (no vomiting); headache (located in the back of her head) and fever (102.2). She noted head felt very heavy and she had difficulty walking by herself (son was at her home to assist). Facial numb ness resolved in ~3 hours. She tried taking 800 mg ibuprofen but didn't have any relief so took Tylenol (this was still on 12/24) and then took another dose of each at around 5:00am 12/25. Fever was still coming/going (responded to the medicine but towards the end of that timeframe her temperature went up again). Last fever was on 12/26 - no fever since (reporting this on 12/28). Headache resolved on 12/27/2020. She also noted that her injection site had small vessicles and was red/tender to touch - as of 12/28 vessicles have resolved and injection area appears back to normal.

I had an elevated BP 218/116, shivering, sweating, light headed and had nausea.

lightheaded, nauseous, feeling faint. Manual BP was taken as automatic BP was unable to be obtained; manual BP was 80/52 mmHg. Water provided, cold pack applied to posterior neck. Patient recovered after 13 minutes and was walked out of building by RN.

Sore throat, body aches, and fever

"Very painful injection site; overall fatigue; muscle cramps in my legs; This is a spontaneous report from a contactable healthcare professional. A 50-year-old female patient started received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot number EH9899), intramuscular into the left arm on 16Dec2020 at 18:30 as single dose for COVID-19 immunization. Medical history included chronic bronchitis, asthma and hypertension from an unknown date. Concomitant medication included losartan (MANUFACTURER UNKNOWN). No allergies to medications, food, or other products were reported. The patient experienced very painful injection site, overall fatigue and "" muscle cramps in my legs "" on 17Dec2020, at 12:00. The events were not serious, and no treatment was required. The outcome of very painful injection site, overall fatigue and "" muscle cramps in my legs "" was recovering."

Muscle aches,Migraine, night sweat; Muscle aches,Migraine, night sweat; Muscle aches,Migraine, night sweat; This is a spontaneous report from a contactable healthcare professional. A 55-year-old patient of an unspecified gender received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), intramuscular on 16Dec2020 at 13:00 as single dose for COVID-19 immunization. Medical history included fibromyalgia, degenerative bone disease from an unknown date. The patient's concomitant medications were not reported. No diagnosis of COVID-19 was noted prior to vaccination. Since the vaccination, the patient has not been tested for COVID-19. There were no allergies to medications, food, or other products. The patient experienced muscle aches, migraine, night sweat on 16Dec2020, at 12:30, which was non-serious. The outcome of muscle aches, migraine, night sweat was recovered in Dec2020. The batch/lot number for the vaccine, BNT162B2, was not provided and will be requested during follow-up .

"The day after I am feeling very tired, achy and weak with a temp of 100.1.; The day after I am feeling very tired, achy and weak with a temp of 100.1.; The day after I am feeling very tired, achy and weak with a temp of 100.1.; The day after I am feeling very tired, achy and weak with a temp of 100.1.; This is a spontaneous report from a contactable healthcare professional. A 44-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), intramuscular on 17Dec2020 at 14:00 as single dose for covid-19 immunization. Medical history included hypertension and being pre-diabetic from an unknown date and unknown if ongoing. No known food or drug allergies noted. Concomitant medication included metformin (MANUFACTURER UNKNOWN), amlodipine besilate (NORVASC), metoprolol succinate (TOPROL). The patient reported "" the day after I am feeling very tired, achy and weak with a temp of 100.1"" on 18Dec2020. No other vaccines within 4 weeks prior to the COVID vaccine were administered. No treatment received for the adverse events. No diagnosed of COVID-19 was noted before or after vaccination. Vaccine Facility information available. The outcome of "" the day after I am feeling very tired, achy and weak with a temp of 100.1"" was unknown. The batch/lot number for the vaccine, BNT162B2, was not provided and will be requested during follow-up."

Sneezing, intermittent cough, congestion, body aches, fatigue, loss of appetite.

Headache, body aches (specifically to back), fatigue; Headache, body aches (specifically to back), fatigue; Headache, body aches (specifically to back), fatigue; This is a spontaneous report from non-contactable consumer, the patient. A 26-year-old non-pregnant female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot Number: EK5730), via an unspecified route of administration on 17Dec2020 at 20:00 (at the age of 26-years-old) in the right arm as a single dose for COVID-19 immunization. The patient's medical history was not reported. Prior to the vaccination, the patient was not diagnosed with COVID-19. Concomitant medications included omeprazole (PRILOSEC) and fexofenadine hcl (ALLEGRA); both for unknown indications from unknown dates and unknown if ongoing. The patient did not receive any other vaccines within four weeks prior to the vaccination. The patient previously took azithromycin (ZITHROMAX) from an unknown date to an unknown date for an unknown indication and experienced drug allergy. On 18Dec2020 at 04:00, the patient experienced headache, body aches (specifically to back), and fatigue; all reported as non-serious. The patient did not receive any treatment for the events. The clinical outcomes of headache, body aches (specifically to back), and fatigue were recovering. It was also reported that since the vaccination, the patient had not been tested for COVID-19. No follow-up attempts are possible. No further information is expected.

Woke up with hive-like bumps that itch; This is a spontaneous report from a non-contactable healthcare professional. A 32-year-old female patient received bnt162b2 (BNT162B2; lot number: EK5730; expiration date: unknown), intramuscular left arm on 17Dec2020 17:00 at single dose for immunization. Medical history included hives a few weeks ago. She is not pregnant. The patient's concomitant medications were not reported. The patient stated that she woke up on 18Dec2020 07:00 AM with hive-like bumps that itch. There was no treatment given. The patient added that it maybe unrelated as she had hives, a few weeks ago. The vaccine was given in a hospital. The patient did not have other vaccine in the last 4 weeks. The patient was not diagnosed with COVID-19 prior to the vaccination and was not COVID tested post vaccination. The outcome of the event was unknown. No follow up attempts are possible. No further information is expected.

Approximately 2 hours post injection, I began to feel fatigued and achy. At 3 hours post injection, I had a headache, muscle & joint aches. I also had slight nausea & a moderately severe stomach ache. These symptoms began to subside approximately 10 hours post injection with the stomach ache taking an additional 2 hours to resolve (12 hours total). The injection site was painful the day following the vaccine and did not resolve until 2 days post administration.

Fever, sore arm

Arm soreness; fever max of 101.9; cough; heart burn; fatigue; chills; headache; This is a spontaneous report from a contactable consumer (patient himself). A 35-year-old male patient received the first dose of bnt162b2 (BNT162B2, lot number: EH9899), via an unspecified route of administration on 17Dec2020 10:30 AM at single dose (left arm) for immunization. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Medical history included MI with Stent and diabetes type 2. The patient received other medications (unspecified) within 2 weeks of vaccination. The patient previously took amoxicilin and experienced allergies. On 17Dec2020 at 07:00 PM, the patient experienced arm soreness, Fever max of 101.9, cough, heart burn, fatigue, chills and headache. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. Therapeutic measures were taken as a result of the events which included Tylenol and Motrin. The events recovered on unspecified date in De2020.

Employee has history of anaphylaxis and was in the 30 min observation. C/O dizziness. Sits on gurney at 45 degree angles. No sob, chest pain or hives. VS obtained and employee hypertensive. Under observation of RN. Able to sip on water, but continues to have HTN and dizziness. Taken to the ED for further evaluation of symptoms.

Pain at injection site x 36 hrs.; This is a spontaneous report from a contactable consumer. A 50-year-old female patient received first dose of bnt162b2 (Pfizer-BioNTech COVID-19 vaccine; lot EK5730), via an unspecified route of administration on 16Dec2020 18:00 at single dose (right arm) for Covid-19 immunisation. Medical history included seasonal allergies, depression, elevated cholesterol and pollen and dust allergies only. The patient had no allergies to medications and food. Concomitant medications included fluoxetine, loratadine, Montelukast sodium (SINGULAIR), fluticasone and mul (as reported). On 16Dec2020 19:00, the patient experienced pain at injection site x 36 hrs. The patient was vaccinated at the hospital. It was reported that the patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient did not received treatment for the event. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, the patient had not been tested for COVID-19. Outcome of event was recovered on an unspecified date.

Reports dizziness started evening of 12/24/20 and ongoing. Reports dizziness is much better today and feels it has almost resolved. Is following up with PCP today, 12/28/20 . no other symptoms reported.

felt warm; blurred vision; light headed; arm pain; This is a spontaneous report from a contactable pharmacist. A 61-year-old male patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EJ1685), intramuscular on the left arm on 18Dec2020 at a single dose for COVID-19 immunization. The patient's medical history included atrial fibrillation (a fib). Concomitant

medication included flecainide and apixaban (ELIQUIS). The patient previously took pantoprazole sodium sesquihydrate (PROTONIX) and experienced allergies to pantoprazole sodium sesquihydrate. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. On 18Dec2020, 5 minutes after injection, the patient felt warm, blurred vision, light headed, and arm pain. No treatment was received for the adverse events. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, the patient had not been tested for COVID-19. Outcome of the events was recovered on 18Dec2020. The events were considered non-serious.

Pt verbalized he felt dizzy. Pt was sitting down at this time. The patient verbalized that the dizziness resolved after a duration of 30 seconds. No epinephrine or diphenhydramine was required for recovery. Pt denied distress or SOA.

10 min after the vaccine had sudden cold hands; palpit; dizziness; BP 150/90 - high for patient; a sensation of chest awareness (not pain, but a bit of tension); anxiety; a clear sensation of chest warmth; presyncopal episodes; chest tightness; Still with waves of chest warmth/heat/burning sensation and chest awareness; This is a spontaneous report from a contactable physician (patient). A 45-year-old female patient (not pregnant) received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 17Dec2020 15:00 at single dose at left arm for immunization. Medical history included hypothyroidism, migraine from an unknown date and unknown if ongoing. Concomitant medications included levothyroxine sodium (SYNTHROID), cetirizine hydrochloride (ZYRTEC), triamcinolone acetonide (NASACORT). There's no other vaccine in four weeks. 10 min after the vaccine patient had sudden cold hands (the kind of inside cold like Propofol gives you), with palpit and dizziness, self-limited in a few mins. BP 150/90 - high for patient. Similar episode but shorter and less intense within next half an hour. Also a sensation of chest awareness (not pain, but a bit of tension, which patient had experienced before with anxiety and put it on anxiety). Decided to go home and while walking patient noticed a clear sensation of chest warmth. Patient decided to stick around the hospital a bit more, pondering about going into the ER. Drank 2 bottles of orange juice and headed home. Then on the way home patient had 2 presyncopal episodes. The fact that patient had not eaten all day and wasn't well hydrated might have contributed. Patient didn't go to the ER. Patient ate, drank juice, took diphenhydramine hydrochloride (BENADRYL) 25 mg. The chest tightness got better. Still with waves of chest warmth/heat/burning sensation and chest awareness. Never had such sxs 2/2 anxiety. Patient received acetylsalicylic acid (ASPIRIN), diphenhydramine hydrochloride, clonazepam as treatment. Outcome of all events was recovering. Patient was not diagnosed with COVID-19 prior to vaccination, and no COVID tested post vaccination. Events were reported as non-serious. Information on Lot/Batch number has been requested.; Sender's Comments: Based on the close temporal relationship, there is a reasonable possibility that the events are related to BNT162 vaccine. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

Pt had Covid vaccine. 5 minutes after vaccine complained of tachycardia. HR initially to palpation was in the 220s. Pt assisted supine. Code Blue called per protocal. Dr. to room. Pts BPs were 160/80, 144/90,

140/84, and 138/80. HR 140, 134, and 123 bpm. O2 sat the whole time was 100% on RA. Pt c/o nausea and dizziness. Assisted to stretcher and brought to ER for evaluation. Pt state she had a previous history of Covid and anxiety but this experience felt different to her then her previous panic attacks. No rash, wheezing, oral swelling, pruitis.

Flushing and hot flashes that have persisted 2 hours after vaccine.; Flushing and hot flashes that have persisted 2 hours after vaccine.; Notable feeling of dizziness; This is a spontaneous report from a contactable consumer (patient) and physician. A 37-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE lot/batch # EH9899), via an unspecified route of administration on the left arm on 18Dec2020 11:15 at SINGLE DOSE for COVID-19 immunization at the hospital. Medical history reported as none. The patient had no allergies to medications, food, or other products. There were no concomitant medications. Prior to vaccination, the patient not diagnosed with COVID-19 and the patient has not been tested for COVID-19 since the vaccination. On 18Dec2020 11:30, the patient experienced flushing and hot flashes that have persisted 2 hours after vaccine. The patient also had notable feeling of dizziness. No treatment was received for the adverse events. Outcome of the events were not recovered.

Reporting on behalf of staff member. She received covid vaccine on 12/24. The following day, she experienced extreme weakness/fatigue, migraine, low grade fever, body aches, and tachycardia. She went to the ER, they gave her IV fluids, pain meds and tylenol with no relief. She was monitored for awhile and then sent home to rest and recover. 3 days later (12/27) she says she feels significantly better, but still a little tired.

No adverse events reported as of yet after patient was vaccinated in right deltoid except a sore arm; pregnant patient was vaccinated yesterday with the COVID-19 vaccine; pregnant patient was vaccinated yesterday with the COVID-19 vaccine; pregnant patient was vaccinated yesterday with the COVID-19 vaccine; This is a spontaneous report from a contactable physician via Medical information team. A 35-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), lot number: EH9899, in right deltoid via an unspecified route of administration on 17Dec2020 10:30 at single dose for routine vaccination. Medical history was reported as none. The patient's concomitant medications were not reported. It was reported that patient pregnant was vaccinated yesterday with the COVID-19 vaccine. She received vaccine while pregnant on 17Dec2020 which was non serious per report. The patient was an MD and her age was 35 years old. She was vaccinated yesterday with COVID 19 vaccine and she was pregnant. She was able to speak to Pfizer Drug Safety. The patient was a frontline Healthcare provider and there was no prescriber for the vaccine. She thinks there should be a pregnancy registry so she wanted to get on it so Pfizer can use her data. Her next dose will be on 07Jan2021. The reason she got it was because she was high risk and a front line healthcare worker. The patient was 21 weeks pregnant. She assumed this was going to be a normal pregnancy and normal delivery. The patient had the vaccination in the hospital. No additional vaccines administered on same date. No adverse events reported as of yet after patient was vaccinated in right deltoid except a sore arm. Onset time of arm being sore was 5pm (17:00) yesterday, 17Dec2020. This did not require a visit to the ER or physician's office. No prior vaccinations within 4 weeks. No AE for prior vaccinations and no medical

history or family medical history relevant and no relevant test. The outcome of the events was unknown.

headaches, back pain, fatigue, nausea, foul taste in mouth

"she got the vaccine 2 nights ago and started to develop itchiness all over her body 30 min post vaccination/head to toe itching; I had serious flu like symptoms, full body aches; Knuckles hurting on both hands; Rash; She stated she had"" body aches but feeling better today""; This is a spontaneous report from a contactable nurse (patient herself). A 61-year-old female patient received first dose of BNT162B2 (lot number: EK5730) via an unspecified route of administration, on 16Dec2020, at single dose, for COVID protection. Medical history included asthma. Concomitant medication included albuterol (SALBUTAMOL) for asthma. The patient mentioned that she got the vaccine 2 nights ago and started to develop itchiness all over her body 30 min post vaccination (16Dec2020). She stated she had body aches but feeling better today. Her body got very itchy and she spent that whole night head to toe itching. Itch was so bad. She had serious flu like symptoms, and full body aches. Patient stated that she understood everything was normal. Patient stated, ""I need to find out from you guys who do I call to find out if I have that itching, if I actually, I had an allergic reaction to the vaccine whether or not if I should take the second dose."" She also stated, ""I was going to say the first day about hour an half my it started with my knuckles hurting on both hands and then I just got rash, I mean not rash itching head to toe and it left with through the night I took some Zyrtec (further clarified as treatment) because I can't take Benadryl. So, I took and it (Zyrtec) helped with the it and itch was resolved by yesterday."" She had lab work two days ago. On the same day, she had the injection and had a test for her thyroid and COVID antigen test both with unknown results. The patient recovered from pain and pruritus on an unspecified date in Dec2020, while for the other events was unknown."

"felt like I was going to pass out; lightheaded/Dizzy; 9 minutes after administration heart rate up to 154; leg shakes; started having chest itchiness; neck rash; facial hives; Injection site sore; This is a spontaneous report from a contactable consumer. A 29-year-old female patient received her first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot: EH9899) via an unspecified route of administration in the left arm on 17Dec2020 08:00 at a single dose for covid-19 immunisation. Medical history included allergies to cephalosphorins. Concomitant medication include unspecified multivitamins. On 17Dec2020 08:09, the patient's heart rate went up to 154 after vaccine administration. On 17Dec2020 08:15, she felt like she was going to pass out, she was lightheaded and dizzy. The patient also experienced leg shakes, started having chest itchiness, neck rash, facial hives and injection site sore on 17Dec2020. The patient was treated with diphenhydramine (BENADRYL) 50mg intramuscularly (IM) for the events ""9 minutes after administration heart rate up to 154"", ""felt like I was going to pass out"", ""lightheaded/Dizzy"", ""leg shakes"", ""started having chest itchiness"", ""neck rash"" and ""facial hives"". The patient's heart rate came down to 130s then down to 90s and the hives subsided. The patient underwent lab tests and procedures which included heart rate: 154, heart rate: 130 and heart rate: 90; all on 17Dec2020. Outcome of the events ""9 minutes after administration heart rate up to 154"", ""felt like I was going to pass out"", ""lightheaded/Dizzy"" and ""facial hives"" recovered on an unspecified date while the outcome of events ""leg shakes"", ""started having chest itchiness"", ""neck rash"" and ""injection site sore"" was unknown."

after the administration of the first dose of the Covid Vaccine presented a leakage of about 2-3ml; the patient was administered Subcutaneously instead of Intramuscularly/maybe the product had been injected Subcutaneous rather than Intramuscular; This is a spontaneous report from a contactable physician. A patient of unspecified age and gender received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), subcutaneous at single dose on an unspecified date for Covid-19 immunisation. The patient medical history and concomitant medications were not reported. On an unspecified date, the patient after the administration of the first dose of the Covid vaccine presented a leakage of about 2-3ml, the patient was administered subcutaneously instead of intramuscularly/maybe the product had been injected subcutaneous rather than intramuscular. Information on the lot/batch number has been requested.

I'm not sure this is entirely vaccine related, but I wanted you to be aware. I occasionally experience unexplained swelling of my lips. It has been investigated by an allergist, but the cause is unknown -- doesn't appear to be a food allergy (no trigger foods identified, and it has never appeared immediately after eating), and may not even be histamine related. It could be something immune-system related, and my experience this weekend might support that. I had normal, expected symptoms on Friday evening (chills, headache). Those resolved Saturday. Saturday night, my lower lip swelled dramatically. Swelling spread into the upper lip as well. I have seen this before, but this was one of the more severe instances I have experienced. Lips remained swollen overnight. When I woke up Sunday morning and went to the restroom, I became suddenly lightheaded and passed out. That's a symptom I have never experienced before. I consulted with my primary care doctor and took it very easy the rest of Sunday. He and I will follow up to further asses what happened. No further light-headedness on Sunday or today. Lips eventually resolved late in the afternoon. This is all about 72 hours after the vaccine, so I can't be sure it is related, but I do wonder if it is related to having my immune system revved up by the vaccine. I reported it on the CDC check-in app and my primary care physician is noting it on his side as well.

fever of 38.6; cold fingers all day; very sore deltoid area from the night of 12/16 thru 12/17, cant raise my right arm; very sore deltoid area from the night of 12/16 thru 12/17, cant raise my right arm; very sore deltoid area from the night of 12/16 thru 12/17, cant raise my right arm; This is a spontaneous report from a contactable consumer (patient). A 48-year-old female patient received the first dose of the bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot Number: EH9899), via an unspecified route of administration in the right arm on 16Dec2020 at 18:15 at 48-years-old at a single dose for COVID-19 immunization; administered in a hospital. Medical history included Vertigo, chronic pruritus from Apr2020 to Jul2020 (Vertigo, chronic pruritus (treated and recovered with gabapentin). Concomitant medications included ergocalciferol (VIT D), krill oil (MANUFACTURER UNKNOWN), niacin (MANUFACTURER UNKNOWN), guaifenesin (MUCINEX), loratadine (CLARITIN); all taken for an unspecified indication from an unspecified date to an unspecified date (received within two weeks of vaccination). The patient previously took ketoconazole and experienced Known allergies, gabapentin for pruritus and vertigo; all from an unspecified date to an unspecified date. On 16Dec2020, the patient experienced: very sore deltoid area from the night of 12/16 thru 12/17, cant raise my right arm. On 17Dec2020, the patient experienced: cold fingers all day (non-serious). On 17Dec2020 at 17:50, the patient experienced: fever of 38.6 (non-serious). Prior to the vaccination, the patient was diagnosed

with COVID-19; and since the vaccination, the patient had been tested for COVID. The patient underwent lab tests and procedures which included body temperature: 38.6 on 17Dec2020, Oral Throat Swab PCR (polymerase chain reaction): positive on 22Nov2020, Oral Throat Swab PCR: negative on 10Dec2020. Therapeutic measures were taken as a result of cold fingers all day, fever of 38.6, very sore deltoid area from the night of 12/16 thru 12/17, cant raise my right arm. The clinical outcome of the events: cold fingers all day, fever of 38.6, was recovered on an unspecified date. The clinical outcome of the event, very sore deltoid area from the night of 12/16 thru 12/17 was recovered on 17Dec2020. The clinical outcome of the event, cant raise my right arm, was unknown.

Pfizer-BioNTech COVID-19 Vaccine EUA; Generalized Itchy rash with hives all over body not relieved by benadryl, zyrtec, claritin and pepcid.

"I got a mild headache. Within an hour it was severe; I became diaphoretic and felt flushed; I became diaphoretic and felt flushed; felt my heart pounding; GI upset; vomited; This is a spontaneous report from a contactable consumer (patient). This 39-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (Lot Number: ej1685), via an unspecified route of administration at single dose in the right arm on 16Dec2020 14:30 for covid-19 immunisation. The patient medical history was not reported. Concomitant medication included estradiol (ESTRACE), levothyroxine in Dec2020. The patient previously took amoxicillin and experienced drug allergy. The patient stated that ""on 17Dec2020 14:30, I got a mild headache. Within an hour it was severe. I became diaphoretic and felt flushed. and felt my heart pounding. Experienced GI upset and vomited once. Took Tylenol and went to sleep for 8 hours. Woke up feeling normal. Therapeutic measures were taken as a result of the events included Tylenol. The outcome of the events was recovered. The vaccine was administered at Hospital Facility. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient was not diagnosed with COVID-19 prior to vaccination. The patient had not been tested for COVID-19 since the vaccination."

"feels sluggish; had a little bit of fever yesterday; Warm feeling shooting in head; developed a warm feeling in his head that turned into a headache; This is a spontaneous report from a contactable consumer. A 57-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EM9899), via an unspecified route of administration (arm left) on 16Dec2020 at single dose for precaution for front line worker. The patient's medical history included blood pressure abnormal, blood cholesterol abnormal, diabetes, enlarged prostate, sleep disorder, on anticoagulant therapy, and migraine. Concomitant medications included lisinopril, simvastatin, metformin hcl, tamsulosin, dutasteride, zolpidem, aspirin [acetylsalicylic acid], and melatonin. It was reported that the patient experienced warm feeling shooting in head on 16Dec2020. It was further reported that the patient developed a warm feeling in his head that turned into a headache on 16Dec2020. The patient also experienced slight fever on 1Dec2020. The patient received the vaccine on Wednesday afternoon (16Dec2020). The patient stated, ""initially it felt weird; for a couple of minutes, it felt ok and then he felt a warm feeling shooting in his head, like when you take strong medications or do MRI. It gives you that strong feeling. It was cold or warm but shoots in head. He felt it, so he went to occupational health and it went away. He went home early and did not finish his shift. Then he got a headache and it did not go away and it is not severe. He feels sluggish and had a little bit of fever yesterday and took Tylenol and

it went away. He still had a headache and it bothers him. He cannot remember the name of the medication that he got the warm feeling shooting in his head, but he believed it was when they did a dye for an MRI. He does not have the name and did not have a lot or expiration. He works at a hospital but not as a healthcare provider. He got the vaccine a few day ago and later stated it was Wednesday, 16Dec2020 warm feeling started an hour after getting the vaccine. As soon as he went to occupational health, it went away and improved. He did not have the headache yet. He did not work his full shift. He got home at night and felt not too bad of a headache. He has a history of migraines and he can feel somehow, he is starting to have a headache. It is not severe though. The headache started that night and it is still there. It is not so severe, but it bothers him. When he had a slight fever, it is gone after taking Tylenol. He never actually checked his temperature, he just felt warm. He takes medications every day, so he took medications the night before and did not take other medications since then. He wanted to find out if there was any interaction with the vaccine before taking them again. The outcome of event fever was recovering, events warm feeling shooting in head and headache was not recovered, and the event feels sluggish was unknown."

35 y.o. female who arrived by to the emergency department for Allergic reaction. Patient got the shot at approximately 8:10 AM and subsequently developed tingling in the back of her throat and felt like she had some swelling. She alerted staff who brought her here for further evaluation. She currently denies any trouble swallowing, voice changes, tongue, lip swelling, rash, abdominal pain, nausea, vomiting, diarrhea. Able to speak in full sentences without difficulty, not in respiratory distress. She is also able to drink water in the emergency department without difficulty. Will dose with Benadryl and observe. Patient was observed for over 2 hours in the emergency department with event of her symptoms. Doubt anaphylactic reaction at this time as she had no other symptomatic involvement. Patient safe for discharge home at this time.

"patient received the vaccination and within a few minutes she developed sore throat, wheezing; patient received the vaccination and within a few minutes she developed sore throat, wheezing; This is a spontaneous report from a contactable nurse. A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 18Dec2020 at 08:30 at single dose for COVID-19 immunisation. Relevant medical history and concomitant medications were not reported. On 18Dec2020 at 08:30, the patient experienced sore throat and wheezing; within a few minutes she developed sore throat, wheezing. Facility where the COVID-19 vaccine was administered was workplace clinic. The adverse events resulted in Emergency room/department visit or urgent care. The patient received ""RT"" treatments. It was unknown if prior to vaccination the patient was diagnosed with COVID-19 and it was unknown if she was tested for COVID-19 since the vaccination. The outcome of the events was unknown. Information on the lot/batch number has been requested."

"a ""funny"" feeling in my mouth/A sore sensation; a ""funny"" feeling in my mouth/A sore sensation; It felt as if it had been burned; slurred speech; loss of taste; This is a spontaneous report from a contactable consumer. A 32-year-old female patient received the 1st dose of bnt162b2 (BNT162B2) at single dose at left arm on 17Dec2020 09:30 for immunization, administered at hospital. Medical history included asthma, allergies: aluminum, pet dander, trees/weeds/grass, seasonal allergy. She had not

Covid prior vaccination. Concomitant medication included montelukast sodium (SINGULAIR), colecalciferol (VITAMIN D [COLECALCIFEROL]), received within 2 weeks of vaccination. The patient had not received any other vaccines within 4 weeks prior to the COVID vaccine. On 17Dec2020 14:30, the patient experienced a funny feeling in my mouth/a sore sensation, it felt as if it had been burned, slurred speech, loss of taste. Course of events: Within 5 hours of injection she started noticing a ""funny"" feeling in her mouth. A sore sensation. By 19:30 her tongue was very sore. It felt as if it had been burned. she had nothing hot to eat that day and nothing new to eat. The soreness increased. She also had some slurred speech and loss of taste. The patient underwent lab tests: Sars-cov-2 test (Rapid nasopharyngeal, nasal swab): negative on 18Dec2020. She received no treatment. The symptoms have stayed steady and have not gotten better. The outcome of events was not recovered. The case was assessed as non-serious. Information on the lot/ batch number has been requested."

"thinks it is COVID toe; thinks it is COVID toe; an itchy toe/Her toe started itching. It is very red; an itchy toe/Her toe started itching. It is very red; This is a spontaneous report from a contactable nurse, the patient. A 49-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot Number: EK5730), via an unspecified route of administration on 16Dec2020 at 07:15 (at the age of 49-years-old) as a single dose for COVID-19 immunization. Medical history was not reported. Concomitant medications included zingiber officinale root (GINGER ROOT), clonazepam (KLONOPIN), progesterone (MANUFACTURER UNKNOWN), fluoxetine hydrochloride (PROZAC), spironolactone (MANUFACTURER UNKNOWN), vitamin D3 (MANUFACTURER UNKNOWN), and zinc (MANUFACTURER UNKNOWN); all taken for unknown indications from an unknown date and unknown if ongoing. On 18Dec2020 at 02:00, the patient experienced an itchy toe/her toe started itching and it was very red, reported as non-serious. The clinical course was as followed: the patient was at work on the night of 18Dec2020 and was having trouble with her toe. Her toe started itching. It was very red. She wondered if it was ""COVID toe"" as the picture she found looked exactly the same. The physician she worked with did not know what it was. She took a diphenhydramine hydrochloride (BENADRYL) and sprayed freezing agent on it to stop the itching. The clinical outcomes of the itchy toe, red toe, and ""COVID toe"" were not recovered.; Sender's Comments: The reported information is limited. Based on the close temporal relationship and the description of the events, there is a possibility that the events are related to BNT162 vaccine. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate."

herpes flair-up; herpes flair-up; I nerve pain, it happends all the time when I am under stress She mentioned this happened last night; I nerve pain, it happends all the time when I am under stress She mentioned this happened last night; This is a spontaneous report from a contactable Nurse reporting for herself. A 61-years-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EH9809, Expiry Date: Mar2021), intramuscular on 17Dec2020 at single dose for covid-19 immunisation (front line worker). Medical history included herpes treated with acyclovir (manufacturer: Calrsbad Tech), oral at 400 mg, as needed. The patient's concomitant medications were

not reported. The patient experienced herpes flair-up on 17Dec2020 with outcome of not recovered. On 17Dec2020 (last night) the patient had nerve pain, it happened all the time when she was under stress with outcome of unknown. The patient took acyclovir as treatment and wanted to know if there's any drug interaction with the covid 19 vaccine and if she will be eligible to get her second dose of Covid 19 vaccine while taking Acyclovir.

lightheadedness/feeling lightheaded/felt herself going backwards and caught herself; disappointed and upset; This is a spontaneous report from a contactable consumer (patient) who reported that a female patient of unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration, on 17Dec2020 at single dose for COVID-19 immunization. Medical history and concomitant medications were not reported. Patient was allergic to aspirin, if she takes it her eyes will come out of her head and quite a few other things will happen to her. Patient reported that she got the COVID-19 Vaccine on 17Dec2020 and it was like 1 hour after (also reported within 1 hour) she got the vaccine that she started feeling lightheaded which she had never experienced before, even today. Patient is an environmental service worker, she had so many discharges and so many COVID rooms to wipe down that she just kept pushing herself because they are just short staffed; but at one point she felt herself going backwards and caught herself, she decided to sit down and drink a water and continued to feel lightheaded. No one was available to relieve her yesterday (17Dec2020), she had to stay at the hospital until midnight and continue her activities with lightheadedness (pending clarification). Patient said, almost a day later, lightheadedness persists, she was still feeling the lightheadedness today (18Dec2020). Her concern is it's like 3-4 days afterwards that you will feel some effects. She wanted to know if this is what they are talking about, if this is expected. Patient initially reported being a healthcare professional (HCP), but clarified her profession is Environmental Service, working at (Institution name). Patient is allergic to aspirin, she wondered if the COVID-19 vaccine contains aspirin. Patient was suggested contacting her doctor to find out if she is allergic to any of the components in the vaccine. Patient was reminded it is possible to consult the ingredients as part of the Vaccine Fact Sheet on (Website name). Patient was disappointed and upset for experiencing lightheadedness after receiving the vaccine (Dec2020). She wishes she hadn't received it. As indicated in previous requests, was referred to an HCP for guidance after experiencing lightheadedness. Outcome of lightheadedness was not recovered, outcome of disappointed and upset was unknown. Information on the Lot/Batch number has been requested.

Fever, mild cough, headache & light-headedness

nausea; dizziness; Progressed to tachycardia; heart rate from 60-120; This is a spontaneous report from a contactable consumer. A 37-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK5730), via an unspecified route of administration at left arm on 18Dec2020 at 07:45, single dose for COVID-19 immunization. Medical history and concomitant medications were not reported. The patient, approximately 15 minutes after shot, experienced mild nausea and dizziness. Progressed to tachycardia, heart rate from 60-120. Felt it racing and pounding. Went to emergency room for evaluation. The patient underwent lab tests and procedures which included heart rate: 60-120. Therapeutic measures were taken as a result of the events and included electrocardiogram (EKG) and telemetry monitoring.

Extreme Vertigo and Dizziness 20 minutes following vaccination. Patient began to slowly feel better.

Right neck pain radiates from shoulder blade to occiput.; Tightness of chest and fluttering in chest that made me cough persistently; Tightness of chest and fluttering in chest that made me cough persistently; BP elevated 150/90; I had EKG report read occasional PVC.; This is a spontaneous report from a contactable nurse reporting for herself. A 45-years-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), intramuscular in the left arm on 18Dec2020 10:15 at single dose for covid-19 immunisation at hospital. Medical history included asthma, eczema, allergies to PCN (penicillin), whey, glutamate, gluten, sulfites. Concomitant medication included isosorbide mononitrate (FLO). On 18Dec2020 at 10:45 the patient experienced right neck pain radiates from shoulder blade to occiput. Tightness of chest and fluttering in chest that made her cough persistently. BP elevated 150/90, no prior history of hypertension. In ED for check-up, the patient had EKG report read occasional PVC. Labs all within normal limits and symptoms and BP better within 1.5 hours so discharged to home. The patient was not treated for the events. Prior to vaccination the patient was not diagnosed with COVID-19 and has not been tested for COVID-19. Information on the lot/batch number has been requested.

numberless shoulder/extends numbness left leg weak when stood(felt numb)/numbness; This is a spontaneous report from a contactable consumer. A 49-year-old female patient (not pregnant) received bnt162b2 (BNT162B2, also reported as Pfizer-BioNTech COVID-19), via an unspecified route of administration on 18Dec2020 13:15, single dose (dose number 1) in left arm, for immunization. Medical history included allergies to food, perfumes, fragrance, smoke and residual odor. Other medical history includes asthma, OSA (obstructive sleep apnea), borderline DM, anxiety and depression. The patient previously took VICODIN and had drug hypersensitivity. She had no other vaccines in four weeks but had other medications (unspecified) in two weeks. The patient reported that on 18Dec2020 at 13:30 she experienced left arm lateral numberless shoulder- last 3 finger, extended numb to pointer finger, extends numbness shoulder up left neck to lips midpoint the complete lips extended to right side of face and neck and then to right temporal, ear and down to clavicle; left leg weak when stood(felt numb). She developed asthma exacerbation by 0900 and started to resolve in ER. About 0018 numbness now in lips, around lips, tongue, and starting down neck. Treatment for the event were Epinephrine IM, Benadryl, Dexamethasone, ab. She also had CXR (chest x-ray), no results reported. The outcome of events was recovered with Sequel. Information on the lot/batch number has been requested.

Bell?s Palsy to the left side of my face. Woke up Wednesday morning with symptoms.

"Increased congestion about 12 hours after receiving the vaccine. Congestion in back of throat and feeling like I need to clear my throat often.; When I clear my throat there is phlegm; Slight nasal congestion; Slight itching and soreness of the throat; Slight itching and soreness of the throat; coughing once through the night; pain and swelling of the injection site; pain and swelling of the injection site; fatigue; This is a spontaneous report from a contactable consumer. A 36-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE) via an unspecified route of administration on 18-DEC-2020 09:00 AM (at the age of 36-years-old) at an unspecified dose in the left arm for COVID-19 vaccination. Medical history was reported as ""None"" and the patient did not

have any allergies to medications, food, or other products. Prior to the vaccination, the patient was not diagnosed with COVID-19. The patient was not pregnant at the time of vaccination.The patient was administered the vaccine in the hospital. Concomitant medication included zolpidem tartrate (AMBIEN), clonazepam (KLONOPIN) and ""MVI"" (not further specified). The patient did not receive any other vaccines within four weeks prior to the vaccination. On 18Dec2020 at 17:00, the patient experienced increased congestion ""about 12 hours"" after receiving the vaccine as well as congestion in back of throat which she described as ""feeling like I need to clear my throat often"" and ""when I clear my throat there is phlegm."" Further, on 18Dec2020 at 17:00 the patient also experienced slight nasal congestion, slight itching and soreness of the throat that lasted for about 30 minutes and she woke up coughing once through the night. Additionally, on 18Dec2020 at 17:00 the patient experienced pain and swelling of the vaccination site and fatigue. The patient did not receive any treatment for the events. The clinical outcomes of congestion in back of throat, phlegm, nasal congestion, sore throat, itchy throat, coughing, vaccination site pain, vaccination site swelling and fatigue were not recovered. It was also reported that since the vaccination the patient had not been tested for COVID-19. The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up."

Employee reports he developed tinnitus 8 hours after injection and has remained 4 days post injection with no history of tinnitus.

Eyelid and nasal bridge swelling; Eyelid and nasal bridge swelling; Swelling of hands and wrists; Swelling of hands and wrists; This is a spontaneous report from a contactable physician. A 35-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Batch/lot number: EJ1685), via intramuscular route of administration (right arm) on 18Dec2020 18:15 at a single dose for COVID-19 immunisation. Relevant medical history included depression, hay fever and acne. Concomitant medication included escitalopram, fexofenadine hydrochloride (ALLEGRA) and doxycycline. The patient was allergic to nickel and fragrance. On 19Dec2020 07:00, patient experienced eyelid and nasal bridge swelling; and swelling of hands and wrists. Patient received allegra due to the event. Outcome of the events was reported as recovering/resolving. Follow-up attempts are completed. The following information on the batch number has been requested.

Elevated heart rate (150-160)/ elevated heart rate of 160; shakiness/ shaky; dizziness; hives on her neck; This is a spontaneous report from a contactable nurse. A 37-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; lot number: EH9899), via an unspecified route of administration on the left arm on 18Dec2020 11:30 at a single dose for immunization. The patient's medical history and concomitant medications were not reported. The patient had no known allergies and did not receive any other vaccines within four weeks prior to the COVID vaccine. The patient wanted to know if she should receive the second dose after experiencing this type of reaction after the first dose. On 18Dec2020, she experienced elevated heart rate 160 (also reported as 150-160), shaky, dizziness and hives on her neck; stated she received the vaccine at 11:30 am and symptoms started at 11:40 am. She was monitored for one hour to make sure heart rate went down and stated that her heart rate went down after 35-40 minutes. The patient was not diagnosed with COVID prior to vaccination and has not been tested post-vaccination. No treatment was given for the events. Outcome

of the events elevated heart rate, shaky and dizziness was recovered and of hives on her neck was unknown.

Joint pain started in right hand, then right arm, to right shoulder and eventually across back to left shoulder.; This is a spontaneous report from a contactable consumer (patient). This 40-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (Lot number: EH9899) on 16Dec2020, via an unspecified route of administration, at a single dose in the left arm, for COVID-19 immunization. The patient had history of positive antinuclear antibody (ANA) without diagnosis. She had known allergies to penicillin. Concomitant medications received in two weeks included ethinylestradiol/ferrous fumarate/norethisterone acetate (JUNEL FE), acetylsalicylic acid (ASA), melatonin (MELATONIN). The patient did not receive other vaccine in the past four weeks. She had not had ever been diagnosed with COVID-19 prior the vaccination, not tested for COVID-19 post the vaccination. On 17Dec2020, the patient experienced joint pain which started in right hand, then right arm, to right shoulder and eventually across back to left shoulder. The event was non-serious. The patient did not receive any treatment for the event. The event was not resolved.

Soreness; Headache; This is a spontaneous report from a contactable Healthcare Professional reporting for herself. A 53-years-old female patient received first dose of BNT162B2 Pfizer-BioNTech COVID-19 Vaccine, Lot number: ER5730, by intramuscular route in right arm, in Hospital, on 17Dec2020 at 08:45, at single dose for COVID-19 immunization. The patient had no known allergies and no relevant medical history. Concomitant medications were taken, but they were unspecified. On 17Dec2020 at 15:00 the patient experienced soreness and headache, both assessed as non-serious and resolved on an unknown date in Dec2020 without any treatment.

unable to lift arm in active range of motion; difficulty sleeping; administered too high on the arm into the subacromial space; This is a spontaneous report from a contactable consumer (patient). A 41-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number: Eh9899), via an unspecified route of administration at the left arm on 18Dec2020 at 15:00 (03:00 PM) at single dose for COVID-19 immunization. The patient was not pregnant at the time of vaccination. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient was not diagnosed with COVID-19 prior to vaccination, and the patient has not been tested for COVID-19 since the vaccination. The patient's medical history was not reported (other medical history: yes). The patient had no known allergies. Concomitant medication included other unspecified medications received within 2 weeks of vaccination. The patient reported that the injection was given and she thought that it was administered too high on the arm into the subacromial space. By end of day, she was unable to lift arm in active range of motion, and had difficulty sleeping. Following day, still unable to lift arm. The events unable to lift arm in active range of motion, and had difficulty sleeping started on 18Dec2020 at 16:00 (04:00 PM). The clinical outcome of the events was unknown.

Developed dizziness, lightheadedness, warmth, sweaty and had a syncopal episode at 8:45pm. All symptoms resolved then within 15 minutes of laying down in bed and having a cold compress on forehead

red splotchy itchy face; red splotchy itchy face; This is a spontaneous report from a contactable consumer, the patient. A 29-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration in the right arm on 17Dec2020 at 16:00 (at the age of 29-years-old) as a single dose for Covid-19 vaccination. Medical history included Premenstrual dysphoric depression syndrome from an unknown date. The patient did not have any allergies to medications, food or other products. The patient was not pregnant at the time of vaccination. Prior to the vaccination, the patient was not diagnosed with COVID-19. The patient was not tested for COVID-19 post vaccination. The patient's concomitant medications included citalopram (MANUFACTURER UNKNOWN) and ibuprofen (ADVIL); all for unknown indications from unknown dates and unknown if ongoing. The patient did not receive any other vaccines within four weeks prior to the vaccination. On 19Dec2020 at 21:00, the patient experienced red splotchy itchy face. Therapeutic measures were taken for the red splotchy itchy face which included allergy medicine (unspecified). The clinical outcome of the events red splotchy itchy face was not recovered. The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up.

Fever 103F, Shaking Chills Responded to Tylenol. Afebrile 12 hours later

Fever 103F, Shaking Chills Responded to Tylenol. Afebrile 12 hours later

ringing in the ear; unable to hear out of the right ear; This is a spontaneous report from a contactable nurse. A 53-year-old female patient (and nurse) started to receive bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot Number: EJ1685), intramuscularly in the left arm on 19Dec2020 at 08:00 at 53-year-old at a single dose for COVID-19 immunization. The vaccine was administered at a hospital. The patient was not pregnant at the time of vaccination. The patient did not receive any other vaccines within four weeks prior to the COVID-19 vaccine. Medical history included asthma, mitral valve prolapse, Sulfonamide allergy, and allergies to tree nuts; all from an unknown date and unknown if ongoing. Concomitant medications included atorvastatin (MANUFACTURER UNKNOWN), escitalopram oxalate (LEXAPRO), fluticasone propionate (FLOVENT); all taken for an unspecified indication from an unspecified date to an unspecified date (received within two weeks of vaccination). On 20Dec2020 at 14:00, the patient experienced: unable to hear out of the right ear (medically significant). On 21Dec2020 at 02:00, the patient experienced: ringing in the ear (non-serious). The clinical course was reported as follows: Approximately 30 hours post-vaccination, the patient was unable to hear out of her right ear. It progressively worsened; however, by 02:00, the patient's hearing returned, and the patient developed a ringing in her ear. By 14:00, all the symptoms had disappeared. There was no treatment received due to the events. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. The clinical outcome of the event, unable to hear out of the right ear, was recovered on 21Dec2020 at 02:00. The clinical outcome of the event, ringing in the ear, was recovered on 21Dec2020 at 14:00.; Sender's Comments: A possible contribution role of bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE) to the onset of event deafness right ear cannot be excluded due to temporal relationship. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as

well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

After vaccine my mouth started to get dry while I was driving home. 1/2 body sore and chest pain felt like heart burn and I was having a heard time breathing. injection site started hurting all the way up to my shoulder. I started getting chills and tired. i started feeling better last night but I did not sleep well. I still have body aches and my chest is feeling better. If I do not feel better in the next 24 hours i will be contacting my HCP.

High blood pressure; heart rate in the 100's/High heart rate; light headed and dizzy; This is a spontaneous report from a non-contactable nurse(patient). This female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) at single dose via an unknown route on Dec2020 (reported as on Thursday) for Covid-19 immunization. Medical history and concomitant drug were not provided. Patient received the vaccine on Thursday and within 15 to 20 minutes, she got light headed and dizzy with high blood pressure with a heart rate in the 100's. She went to the ER and was sent home, but her blood pressure continues to be high. Her primary care physician wanted to start her on some blood pressure medication due to continuous high blood pressure. The reporter was asking if high blood pressure and high heart rate had been reported as an adverse event for the Covid vaccine. Outcome of High blood pressure was not resolved. Outcome of the other events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Sender's Comments: A causal association between BNT 162B2 and the events blood pressure increased, dizziness, and heart rate increased cannot be excluded based on a compatible temporal relation. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

diaphoretic; dizzy; This is a spontaneous report from a contactable nurse. A 51-year-old female patient (not pregnant) received her 1st dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/Lot Number: ek5730) at single dose on 21Dec2020 11:00 AM intramuscular on left arm for Covid-19 immunization. Medical history included known allergies with codeine. Patient reported similar reaction of diaphoretic and dizzy to giving blood. It was unknown if the patient received any other vaccines within 4 weeks prior to the COVID vaccine, or any other medications the patient received within 2 weeks of vaccination. It was unknown if the patient diagnosed with COVID-19 prior to vaccination. Concomitant drug was not provided. Patient became diaphoretic and dizzy approximately 11:15 AM on 21Dec2020 (also reported as 8 min after injection). The adverse event result in doctor or other healthcare professional office/clinic visit, and Emergency room/department or urgent care. Treatment reported as patient was laid down with feet up, cool compress applied, drank some juice. The events were reported as non-serious. Since the vaccination, the patient had not been tested for COVID-19. Outcome of the events was unknown.; Sender's Comments: A causal association between BNT162B2 and the reported events diaphoresis and dizziness cannot be excluded based on a compatible temporal relation. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse

events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

Rash and Hives

Extremely painful legs; abdomen spasms; abdomen spasms and cramps; severe chills; This is a spontaneous report from a contactable nurse (patient). A 52-year-old female patient (not pregnant at the time of vaccination) received her 1st dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) at single dose on 17Dec2020 04:00 PM Intramuscular in Right arm (also reported Arm Left) for Covid-19 immunization. Prior to vaccination, patient was not diagnosed with COVID-19. Medical history included hypothyroidism, hypotension, obesity, and allergies to onions. There were no other vaccines received in four weeks; however other medications received in two weeks. Patient experienced extremely painful legs and abdomen spasms and cramps, severe chills on 17Dec2020 09:00 PM. Patient applied arnica 35% on the affected area and it helped. Since the vaccination, patient had not been tested for COVID-19. Outcome of the events was resolving. The events were reported as non-serious. Information on lot/batch number has been requested.; Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of events of extremely painful legs, abdomen spasms and cramps, and severe chills cannot be excluded. The case will be reassessed if additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

respiratory distress with dyspnea and increased work; respiratory distress with dyspnea and increased work; rapid progression of symptoms; lightheadedness; tingling to right upper and lower arm; pain to mid forearm; generalized weakness; This is a spontaneous report from a non-contactable health care professional. A 72-year-old female patient received her 1st dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot_number= HE9899) at single dose on 18Dec2020 10:00 AM intramuscular in the right deltoid muscle for Covid-19 immunization. Medical history and concomitant drug were not provided. She denied any history of previous adverse reactions to vaccines. Concomitant drug was not provided. During her 15 minute waiting period after the injection, the patient began to experience lightheadedness and tingling to right upper and lower arm. Also complain of pain to mid forearm. She denied hives, difficulty breathing, difficulty swallowing, wheezing, throat tightness, itching and tongue swelling.When walking to the emergency bay reported some lightheadedness and generalized weakness, patient denies facial drooping or weakness. No loss of strength and normal ROM to hand and arms. This provider was notified of patient reaction and she was then assessed in the emergency bay area. Patient was monitored for severe reaction symptoms, including rapid progression of symptoms, respiratory distress with dyspnea and increased work. The events were reported as non-serious. Outcome of the events was unknown. No follow-up attempts are possible. No further information is expected.; Sender's Comments: A possible causal association between administration of BNT162B2 and reported serious events cannot be excluded, considering the plausible temporal relationship. The impact

of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

I received my first dose of Moderna vaccine at around 9:45 am on Dec 24 and I was fine for like 4 hrs after receiving it, until I started feeling similarly to the way I felt when I tested positive for Covid and had it at the beginning of November (feverish, headache, body ache, stuffy mucusless nose, fatigue, hangover sensation like nauseated and weird, etc...) Things got a little bit worse when all of a sudden I started feeling feverish and my heart started beating so fast I could hear it myself. I had to stop doing what I was doing and called (my insurance/MCD) because I was getting anxious and started hyperventilating, which did not allow me to breathe normal. They told me to take Tylenol which I did and little by little my fever started decreasing; it must have been almost 100 F at that moment. Then once again like 5 hrs after I had taken Tylenol I started getting fever again and this time I got extremely cold also and I was shaking so much and felt so weak I had to lay down and call once again; they told me to have someone take me to their urgent care center and I went there and they retested me for Covid but it was negative this time. Since I had taken Tylenol (2nd time same day, 6 hrs apart) just before I left, my fever was not that high when I showed up there. They told me studies have showed some people experience similar symptoms but when they get the 2nd not the 1st dose; however, they thought it could happen too. I had fever nonstop for almost 48 hrs; it was so high (101.7- highest reached). The rest of the time?at night when I was trying to sleep, obviously I could not take my temperature, I was half awake, half sleep hallucinating, shaking, cold, then hot and sweating a lot and speaking non sense in my sleep (according to my spouse)- this happened both nights. On Dec 26 I woke up feeling not great but definitely better but had a little headache and still felt somewhat nauseated. My last dose of Tylenol I took at 8 pm on Dec 25. I have been feeling better for the past two days but I still feel a little bit tired and not back to my normal self.

bells palsy; This is a spontaneous report from a Pfizer-sponsored program. A Consumer reported for herself. A 75-years-old female patient received bnt162b2 (BNT162B2) vaccine , via an unspecified route of administration on an unspecified date at single dose for covid-19 immunisation . The patient medical history and concomitant medications were not reported. The patient previously took mercury and experienced drug hypersensitivity. The patient experienced Bells palsy on an unspecified date with outcome of unknown. The patient is wondering if Bells palsy may be an adverse reaction to the vaccine. Information on the lot/batch number has been requested.

Low grade fever; fast heart rate; she sweated so much; she has body aches still; This is a spontaneous report from a contactable nurse (patient). This 25-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), (Batch/lot number: EH9899) via an unspecified route of administration on 20Dec2020 10:00 at single dose for COVID-19 immunization. There were no medical history and concomitant medications. Patient took COVID vaccine because she was exposure in hospital. Patient said she experienced reaction from the first dose of COVID vaccine. The patient got the first dose of vaccine by injection once on 20Dec2020, later clarified as COVID vaccine, and overnight she had a low grade fever on 20Dec2020, and she checked her heart rate from her Watch, and it said 108 to

like low 100s, stated not her usual resting heart rate, and she woke at 4AM and felt a fast heartbeat, other than that, she thought it was from fever. Low grade fever was right before going to bed around 10PM: she had body aches, headache, she was not feeling well, she was very hot, At 4AM, she thought to sleep it off, as her whole body ached, and she couldn't really move, and she looked at her Watch to check and her heart rate was 103 resting, and she didn't take her temperature again, but she sweated so much, and she turned down the temperature and as of today, she has body aches still, and a little bit of fast heart rate. Outcome of the events was unknown. Reporter seriousness for Low grade fever and fast heart rate was medically significant. Primary Source Reporter assessed Low grade fever and fast heart rate related by Method.; Sender's Comments: A causal association between BNT162B2 and the events pyrexia and heart rate increased cannot be excluded based on temporal association. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

Severe sore throat and tonsillitis, head ache

Vomit; Coughing; Felt like Throat was itchy; This is a spontaneous report from a Non-contactable Nurse. A 41-years-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (lot number: EH9899) intramuscular on Left arm on 21Dec2020 16:30 at single dose for COVID-19 immunization. Medical history included allergies to medications, food, or other products. There were no concomitant medications. The patient did not receive any other medications within 2 weeks of vaccination. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. On 21Dec2020, 10 minutes after the vaccine the patient began to vomit, felt like throat was itchy, and began coughing. Events resulted that she was taken to the ER (Emergency room). She received Epinephrine, Dexamethasone as treatment for events. Events outcome was recovered on 21Dec2020. No follow-up attempts are possible. No further information is expected.; Sender's Comments: A causal association between BNT162B2 and the reported events vomiting, cough, and itchy throat cannot be excluded based on a compatible temporal relation. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

"lost vision and had intense cold sweats for about 2 minutes; Vasovagal response; had intense cold sweats for about 2 minutes until blood flow returned to normal in upper body; This is a spontaneous report from a contactable healthcare professional, the patient. A 36-year-old non-pregnant female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot Number: EK5730), via an unspecified route of administration in the right arm on 16Dec2020 at 09:30 as a single dose for COVID-19 immunization. Medical history included polycystic ovaries syndrome with diabetes, depression, anxiety, attention deficit hyperactivity disorder, iron deficiency anaemia, and vasovagal issues. Prior to the vaccination, the patient was not diagnosed with COVID-19. The patient's received unspecified concomitant medications within 2 weeks of the vaccination. The patient did not receive any

other vaccines within four weeks prior to the vaccination. On 16Dec2020 at 10:00 AM, the patient lost vision and had vasovagal response and intense cold sweats for about 2 minutes until blood flow returned to normal in upper body. The clinical course was as follows: The patient had a vasovagal response 30 minutes after the vaccine and had to lie down. She lost vision and had intense cold sweats for about 2 minutes until blood flow returned to normal in upper body. The entire episode lasted approximately 30 minutes. She felt it coming and knew to sit down so she would not ""black out."" She was unable to elevate her feet above her heart at the time; however, she was able to walk and stand afterward without dizziness. The patient did not receive any treatment. The clinical outcome of the vasovagal response, lost vision, and cold sweats were recovered on 16Dec2020. It was also reported that since the vaccination, the patient had not been tested for COVID-19.; Sender's Comments: The reported vasovagal response with cold sweats and transient visual loss was possibly related to the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE) due to temporal relationship. However, it is worth noting that the patient had medical history including vasovagal issues. The case will be reassessed should additional information become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate."

Arm soreness, 18 hours after vaccine with SOB, CP, fever 99. took Ibuprofen. Numbness to left side of face and hand approx. 36 hours post vaccine, that resolved in 10 hours approx. 48 hours after the vaccine. Lung pain resolved within 72 hours of the vaccine

broke out in hives on face and hoarseness, tightness in throat; broke out in hives on face and hoarseness, tightness in throat; broke out in hives on face and hoarseness, tightness in throat; throat pain, coughing; throat pain, coughing; This is a spontaneous report from a contactable Other HCP. This Other HCP reported for self that the 57-year-old female patient received fist dose of bnt162b2 (BNT162B2, Brand Pfizer), via unknown route of administration in Left arm on 21Dec2020 12:00 PM at single dose for covid-19 immunisation. Medical history included Known allergies to medications, food, or other products: Azithromycin Flushing, Spinach-anaphylaxis, mild allergic reactions to the Ocrevus, azure and Seasonal allergies, Multiple Sclerosis, Irritable bowel syndrome (IBS-C), post herpactic neuralgia. Concomitant medications included other medications the patient received within 2 weeks of vaccination baclophen, clozapine (KLOPIN), ocrelizumab (OCREVUS), sertraline, cetirizine hydrochloride (ZYRTEC [CETIRIZINE HYDROCHLORIDE]), mo. She is not pregnant at the time of vaccination. Facility type vaccine was Hospital. No other vaccine in four weeks. The patient experienced within 15 to twenty minutes of vaccine, broke out in hives on face and hoarseness, tightness in throat then sent to ED where hives continued to form on back the arms, throat pain, coughing, hoarseness increased from 21Dec2020 12:15 AM. AE resulted in: [Emergency room/department or urgent care]. Outcome of the events was unknown. Treatment received included Epinephrine, solumedrol, Benadryl IV. No covid prior vaccination. Covid tested post vaccination. Covid test post vaccination: covid test type post vaccination was Other, covid test name post vaccination was Nasopharyngeal Sofia2 SARS Antigen on 21Dec2020 with result of Negative. Facility where the most recent COVID-19 vaccine was administered was

Hospital. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, has the patient been tested for COVID-19. Test Name was Nasopharyngeal Sofia2 SARS Antigen. Vaccine Facility information available. Information on the lot/batch number has been requested.; Sender's Comments: Based on the close temporal relationship, the association between the reported events with BNT162b2 can not be completely excluded. Medical history of known allergies may have predisposed patient to react this way. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

I elevated heart rate to 159, I was hot, flush, sweating, elevated BP 154/94 which is high for me. I stayed 15 more minutes and everything was back to normal. The next morning I had a headache. By noon, I had vomiting. I went for a COVID 19 test.

Heart racing; Felt flushed and warm; The initial case was missing the following minimum criteria: no adverse event. Upon receipt of follow-up information on 22Dec2020, this case now contains all required information to be considered valid. This is a spontaneous report from two contactable nurses. A 46-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration in right deltoid on 21Dec2020 18:30 at single dose for Covid-19 immunisation. Medical history included Graves disease, hypothyroidism and radiation from an unknown date and unknown if ongoing (all diagnosed about 12 years ago), dental infection (root canal that failed and said she had an infection) and teeth cleaning from an unknown date and unknown if ongoing. Concomitant medication included levothyroxine sodium (SYNTHROID) taking for many years for hypothyroidism, amoxicillin (500 mg tablet) from 21Dec2020 for dental infection. Prior vaccinations within 4 week was none. The patient experienced felt flushed and warm (non-serious) on 21Dec2020, heart racing (medical significant) on 22Dec2020. The patient received the COVID vaccine yesterday (21Dec2020). She called Pfizer Drug Safety yesterday and asked about if she could take amoxicillin with it for a dental infection. She got the vaccine last night (21Dec2020 18:30) and felt a little flushed and warm after receiving it, so they kept her for 15 minutes. Today (22Dec2020), her heart had been racing at 09:00. She was at rest and had not been exercising. Her heat felt like it will beat out of her chest. She had no history of anxiety. She was a little concerned since she got it at around 6pm yesterday and it has been about 18 hours ago. She would like to know if there have been any reports of any elevated heart rates issues occurring the day after. She called her doctor, but he did not have any information. She did start the amoxicillin yesterday before the vaccine. She got a teeth cleaning and had a previous root canal that failed and said she had an infection. She is not symptomatic. They said she needed another one root canal and crown. It is encapsulated and is not causing any issues, but it could down the line. Regarding the feeling warm and flushed, she said the room was warm and there were a lot of people in it, even though they were socially distanced. She said there was just some angst in the room. She did not have a history of getting anxiety. There was also no Air Conditioning on in the room. It subsided and she did not feel like it was alarming. At the facility, they were not documenting it. That went away within 15 minutes. Regarding

the racing heart, she does not know how long it could go on. She did have thyroid issues. She had not done thyroid labs. It could be her thyroid meds too. She took her Synthroid first thing when she woke up so it could be that too. She did not have a lot or expiration to provide. No emergency room or physician's office required. The outcome of felt a little flushed and warm was recovered on 21Dec2020 at 18:45, heart racing was not recovered. Information about lot and batch was requested.; Sender's Comments: The reported information is limited. Based on the close temporal relationship and the description of the events, there is a reasonable possibility that the events are related to BNT162 vaccine.The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

10:30am - Received the Vaccine Shot 11:30am- Warmth throughout face, then right had went all tingly, then numb and swollen. The numbness crept up the arm to the elbow. Then the nose started to get tingly and numb followed by the lips and gums. 12:00pm - Started to not be able to speak a sentence. The words were coming out of my moth very jumbled even though in my mind I knew what I was trying to say. Still numb in right hand, and on right side of face. 12:10 pm- Could not see fully out of the right peripheral of my eye as well to the other symptoms of not being able to speak a full sentence. I was able to speak less words than I had about 10 min prior. Numbness in my hand went away at this time. 1:15pm- I was able to speak mostly full sentences again. I got a pounding headache on the front to left side of my head and felt fatigues. 1:40pm- Finally able to speak full sentences again, I could feel my hand and all the parts of my face. Felt weak, still had headache and felt nauseous and dizzy. 2:15pm- Took 1 advil, fell asleep 4:00pm- Woke up, felt weak, disoriented, still had a headache. 8:00pm- Only a small headache left and a sore arm

Migraine; This is a spontaneous report from a contactable Other HCP reported for self. This 48-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 20Dec2020 via intramuscular at single dose (Lot # EH9899) for Covid 19 vaccine. None medical history and concomitant medications included. She got the first Covid 19 vaccine yesterday (20Dec2020) and got migraine one hour after on 20Dec2020. Stated that it has not gone away. Was not sure if specific course of action for headache since it did not occur until after 15 minutes. Outcome of the event was not recovered. Event assessed as serious (Other medically important condition).; Sender's Comments: The reported migraine was possibly related to the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE) due to temporal relationship. The case will be reassessed should additional information become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Reporting on behalf of patient. He self reported to the Medication Safety Coordinator, that he was woken up from his sleep the night after receiving the vaccination, with his jaw moving side to side

uncontrollably. This lasted for a couple seconds, would stop, and then would happen again. This occurred about 3 times total. He also felt twitching in his forehead a couple times. These episodes self resolved and did not happen again.

"pancreatitis; acute lower abdominal pain; This is a spontaneous report from a contactable pharmacist. A 46-year-old non-pregnant female patient received the first dose of the bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot Number: EJ1685), intramuscularly on 18Dec2020 at 08:00 (as reported) at 46-years-old at a single dose for COVID-19 immunisation. The patient medical history was not reported. The patient had no known drug allergy (NKDA). Concomitant medications included acetaminophen (MANUFACTURER UNKNOWN), propranolol (MANUFACTURER UNKNOWN), sertraline hcl (MANUFACTURER UNKNOWN), sertraline hydrochloride (ZOLOFT); all taken for an unspecified indication from an unspecified date to an unspecified date (which were received within two weeks of vaccination). On 18Dec2020 at 17:00, the patient experienced pancreatitis and acute lower abdominal pain; which required hospitalization and were assessed as medically significant. The patient was hospitalized for pancreatitis and acute lower abdominal pain for 3 days on unspecified dates. The clinical course was reported as follows: The patient received the vaccine "" at some point in the AM on 18Dec2020 (as reported)."" That evening, the patient presented to the emergency department (ED) with acute lower abdominal pain. The patient was diagnosed with pancreatitis and was admitted overnight. It was unknown if the patient received any other vaccines within four weeks prior to the COVID vaccine. Prior to the vaccination, it was unknown if the patient was diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. Therapeutic measures were taken as a result of pancreatitis and acute lower abdominal pain. The clinical outcome of the events was recovering.; Sender's Comments: The information currently provided is too limited to make a meaningful medical assessment. Other than a temporal association , there is no evidence or argument to suggest a causal relationship between BNT162B2 and the events pancreatitis and acute lower abdominal pain. The events are likely due to an underlying medical condition. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate."

Extreme fatigue, muscle weakness

Developed vomiting, four to five times; Diarrhea; Abdominal pain; Slightly flushed face and minimum facial flowing; Numb ears/Numb body; Bleeding; Anaphylaxis; This is a spontaneous report from a contactable consumer. A 43-year-old female patient received bnt162b2, via an unspecified route of administration on 19Dec2020 at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced anaphylaxis on 20Dec2020. Clinical course: the patient received the COVID vaccine on 19Dec2020, and since then she had developed onset of vomiting after 3 o' clock this morning on 20Dec2020, four to five times, numb ears, numb body. She also had diarrhea and bleeding. She had some abdominal pain and she also complained of having slightly flushed face and the minimum facial flowing. The outcome of events was unknown. Information for Lot/Batch number has been requested.; Sender's Comments: There is a reasonable

possibility that the event anaphylaxis was related to BNT162b2 based on known drug safety profile. Based on the close temporal relationship, the association between the event bleeding with BNT162b2 can not be completely excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

She gained some weight and she thinks she was told she was 84 or 86 kg at the clinic. She weighs about 175 pounds; An EKG was done and she was told she had a prolonged qt interval; Her blood pressure went really high to 177/110; This is a spontaneous report from a contactable consumer. This consumer [patient] reported that the 48-year-old female patient received bnt162b2 (BNT162B2, Batch/lot number: EK5730), via intramuscular injection in left upper arm on 19Dec2020 07:30 am at single dose for covid-19 immunisation (Preventative). Medical history and concomitant medications were none. She got the Pfizer Biontech covid vaccine on the 19Dec. She was sent over to ER from the (clinic name) since her blood pressure went really high to 177/110 on 19Dec2020. Her blood pressure stayed around 170/100 and then she would rest for 10-15 minutes, the ER kept her there till her blood pressure went to about 144 or 150 and then she went home. She confirmed she was not admitted. She was told to go back to the ER if her blood pressure went up. An EKG was done and she was told she had a prolonged qt interval on 19Dec2020. She has not had an EKG since and was told to follow up with her doctor. Treatment: declines any, they just monitored her. When querying weight, states she knows she gained some weight and she thinks she was told she was 84 or 86 kg at the clinic. She weighs about 175 pounds. Reports she had some blood work done at the ER and it came back normal. She does not have any health conditions. She has an allergy to Cipro and fexofenadine. Vaccination Facility Type was Hospital. No Vaccine Administered at Facility. History of all previous immunization with the Pfizer vaccine considered as suspect (or patient age at first and subsequent immunizations if dates of birth or immunizations are not available was none. Additional Vaccines Administered on Same Date of the Pfizer Suspect was none. AE(s) required a visit to Emergency Room. No Physician Office. Prior Vaccinations (within 4 weeks) was none. AE(s) following prior vaccinations was None. The outcome of the events was unknown.

Redness, swelling and mild itching at injection site.

"sudden rapid slightly irregular heartbeat; My pulse rate was in 148 and remained in the 140's/rapid heartbeat; associated nausea; This is a spontaneous report from a contactable nurse. This nurse (patient) reported that the 45-year-old female patient received first dose of bnt162b2 (BNT162B2, Covid-19 Vaccine), on Arm left on 19Dec2020 09:30AM at single dose for covid-19 immunisation. She is not pregnant at the time of vaccination. Medical history was none. Known allergies was none. Allergies to medications, food, or other products was none. Concomitant medications were none. Facility type vaccine was other. No other vaccine in four weeks. Other medications in two weeks was none. The patient experienced ""I had just received the vaccination was pulling into the area where you sit and wait in case you have an adverse reaction, was just looking at my phone and felt a sudden rapid slightly irregular heartbeat. Came on very suddenly with associated nausea I am a ER nurse with 22 years

experience and so I began to take my pulse and record it with my phone, I wasn't sure if it was a reaction because I didn't fell like I "" couldn't breathe"" . Just a very rapid heartbeat. My pulse rate was in 148 and remained in the 140's. I beeped my horn on my car in case it was an adverse reaction. They placed a pulse ox on my finger and my heart rate then was 138 and O2 sats 98% . I sat for a bit and then it just went away. My heart rate was back down to the 70's."" The events started from 19Dec2020 09:30 AM and outcome of the events was recoverd. No treatment was received. No covid prior vaccination. No covid tested post vaccination. Facility where the most recent COVID-19 vaccine was administered was Other. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. List of any other medications the patient received within 2 weeks of vaccination was none. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. Vaccine Facility information available. Location of injection information is available for all vaccines received on the same date. Information on the lot/batch number has been requested.; Sender's Comments: A causal association between BNT162B2 and the reported events heart rate irregular, heart rate increased, and nausea cannot be excluded based on a compatible temporal relation. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate."

left eye is getting puffy after receiving COVID-19 Vaccine today; left eye is getting itchy after receiving COVID-19 Vaccine today; This is a spontaneous report from a contactable healthcare professional (patient). A 62-year-old female patient received BNT162B2 (COVID-19 mRNA Vaccine BNT162B2), via an unspecified route of administration on 21Dec2020 at a single dose for COVID-19 immunization. The patient's medical history included allergies to a lot of antibiotics. The patient's concomitant medication included Non-specified anti-inflammatory. The patient's left eye was getting puffy and left eye was getting itchy after receiving COVID-19 Vaccine on 21Dec2020. The events were reported as serious, medically significant. She said she is wondering if her left eye getting puffy and itchy is an allergic reaction and if she needs to seek treatment. Reported she did not have a prescription for the COVID-19 Vaccine. Reported her left eye being puffy and itchy has not gotten worse, but her left eye has not improved. Declined any treatment as she thought if she called Pfizer, Pfizer could tell her if she should get treatment. Reported she took an anti-inflammatory twice in the past 2 weeks, clarifying the last time she took the anti-inflammatory was over 4 days ago. The outcome of the events was not recovered. Information on the Batch/Lot number has been requested.; Sender's Comments: The reported information is limited. Based on the close temporal relationship, there is a reasonable possibility that the events are related to BNT162 vaccine. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

The patient experienced diffuse rash on the upper extremities as well as a scratchy throat 16 hours after vaccination.

Blacked out; Vertigo; Diarrhea; Extreme Fatigue; sicker; This is a spontaneous report from a contactable nurse which is also the patient. A 48-year-old female patient received the first dose in the series of bnt162b2, lot number: EK5730, intramuscular in the left deltoid on 17Dec2020 at a single dose for COVID prevention. There were no medical history and concomitant medications. The patient received her COVID vaccine last Thursday evening, and she has been getting progressively sicker for the past couple of days on an unspecified date in Dec2020. On 20Dec2020, the patient experienced blacked out, vertigo, diarrhea, and extreme fatigue. The patient mentioned that she had extreme fatigue yesterday, with vertigo that started afternoon, and this morning her vertigo was so bad, that she blacked out in the shower, and the room is still spinning for her at this time. Outcome of the events blacked out and sicker was unknown, for the other events was not recovered. The seriousness of events blacked out, vertigo and diarrhea was reported as serious enough that she could not go to work, or get behind the wheel of a car so medically significant. Extreme fatigue was assessed as non-serious. The reported assessed the events extreme fatigue, vertigo, blacked out, and diarrhea as related to bnt162b2. The patient added that vertigo was worsened.; Sender's Comments: The reported information is limited. Based on the close temporal relationship and the description of the events, there is a reasonable possibility that the events are related to BNT162 vaccine. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

severe back pain/ back aches; body aches; inflammatory reaction; This is a spontaneous report from a Pfizer-sponsored program IBCC (Inbound Call Center for HCPs). A contactable female nurse (patient) of unknown age reported that she received BNT162B2 (COVID VACCINE), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. Medical history and concomitant medications were not reported. Patient got the Covid vaccine on Thursday (date not specified). She was taking ibuprofen (MOTRIN) (later clarified as ibuprofen) for anti-inflammatory. She went to a doctor visit yesterday (18Dec2020), and then her doctor told her that because ibuprofen was an anti-inflammatory, she shouldn't be taking it during, right after the vaccine because of inflammatory reaction and so patient stopped taking it and switched over to paracetamol (TYLENOL), now she was in severe back pain/ back aches and body aches, but anyways she was just going to end up taking it if this took much longer. Outcome of the events was unknown. Information about lot/batch number has been requested.; Sender's Comments: From the information provided it is unclear which event is the intended subject of this spontaneous report and what is the reporter's perceived relationship to the vaccine. In addition, the lack of critical information (e.g. immunization date) makes a global medical assessment impossible. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

Patient experienced HA and dizziness approximately 40 minutes after vaccination. Patient was monitored to have diaphoresis with slightly elevated BP ranging from 138/72- 142/88 with HR98. Patient was monitored while standing and had no changes with dizziness but had an elevated HR of 114 with BP 131/84. After sitting again patient's BP 129/81 and HR went down to 88.

hypertension; tired; Headache; This is a spontaneous report from contactable nurse, the patient. A 52-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot Number: EK5730), via an unspecified route of administration on 19Dec2020 as a single dose for COVID-19 immunization. Ongoing medical history included hypothyroidism. Other relevant medical history included anxiety and menopause. Ongoing concomitant medications included estradiol (MANUFACTURER UNKNOWN) taken for menopause, progesterone (MANUFACTURER UNKNOWN) taken for menopause, and venlafaxine hydrochloride (EFFEXOR) taken for anxiety. On 19Dec2020 at 18:00, the patient had a headache. On 20Dec2020, the patient experienced hypertension and was tired. The clinical course was as follows: the patient received her vaccine on 19Dec2020. At 18:00 on 19Dec2020, she started with a headache, and it was not a big deal. In the morning of 20Dec2020, her headache was bad, and then her blood pressure was 180/100. She had a headache and she was tired. She mentioned her baseline was 115/84. She had no coffee or anything, and as the day went by it was 140/90. She reported that the hypertension basically lasted for one day and in the morning of 21Dec2020 it was 120/88. As of 21Dec2020, she did not have a headache. The clinical outcomes of the hypertension and headache were recovered on unknown dates in Dec2020; while that of the tiredness was unknown. The patient assessed the hypertension and headache as serious for being medically significant and related to the vaccine; however, the seriousness and causality assessment were not provided for the tiredness.; Sender's Comments: A causal association between BNT162B2 and the events hypertension and headache cannot be excluded based on a compatible temporal relation. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

The patient felt very hot around 15 min post vaccine, felt anxious. Felt her HR was racing, Watch said it was 103. Let the RN know and HR was then measured at 125 bpm. BP was 140 which is high for the patient (baseline around 100 systolic). She felt shaky. The RN said she saw a few hives on her chest and it was a bit itchy. They gave her some water and juice. She felt better and the hives resolved on their own. She then was given Zyrtec. Her HR is 85 when I spoke to her, 30 min post vaccine, and BP is 130 systolic. No wheezing, no SOB, O2 sat was normal the entire time. She still felt shaky and anxious. Called 2 hours after vaccine administration and she felt normal.

itching really bad; This is a spontaneous report from a contactable pharmacist. A 43-year-old female patient received the first dose of the bnt162b2 (BNT162B2; PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot Number: EH9899 and Expiration Date: Mar2021), intramuscularly on 17Dec2020 at 43-years-old at 0.3 mL, single for COVID-19 immunization. The vaccination was administered in a hospital. There was no history of previous immunizations with a Pfizer vaccine considered as suspect; and there were no additional vaccines administered on the same date of the Pfizer suspect; and there were no

prior vaccinations (within 4 weeks). It was unknown if the patient had adverse events (AEs) following prior vaccinations. Medical history included obesity from an unknown date and unknown if ongoing, hay fever from an unknown date and unknown if ongoing. There was no family medical history relevant to the AEs. Concomitant medications included desvenlafaxine succinate (PRISTIQ) taken for an unspecified indication from an unspecified date to ongoing, metoprolol (MANUFACTURER UNKNOWN) taken for an unspecified indication from an unspecified date to ongoing, montelukast sodium (SINGULAIR) taken for hay fever from an unspecified date to an unspecified date, omeprazole (PROTONIX [OMEPRAZOLE]) taken for an unspecified indication from an unspecified date to ongoing. On 17Dec2020, the patient experienced: itching really bad; which was assessed as medically significant. There were no visits to an emergency room or a physician office as a result of the events. The clinical course was reported as follows: The patient started itching really bad within five minutes of receiving the vaccine. The patient was given a shot of diphenhydramine hydrochloride (BENADRYL) and the itching stopped. This was the patient's first dose of COVID vaccine. It was unknown to the reporter if the patient would continue the vaccine series. Therapeutic measures were taken as a result of itching really bad (pruritus). The clinical outcome of the event, itching really bad, was recovered on 17Dec2020. The causality assessment from the Primary Source Reporter was reported as related; via the Method of assessment.; Sender's Comments: A causal association between BNT162B2 and the event pruritus cannot be excluded based on a compatible temporal relation. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

Approximately 4 hours after vaccine, noted hives/welts on arms, took cetirizine. Went to bed. ~8pm (4 hours later) was very itchy, swollen, discolored face, face felt cold/body hot. No difficulty breathing. Lips purplish, arms swollen. Went to ED. Given benadryl, 2 other pills, watched for 30 minutes. No epinephrine. Hives improved, released, had headache. Next day improved, but still mild headache and groggy. Hives gone completely 48 hours. Mild headache persists. No prior experience like this.

profound dizziness; This is a spontaneous report from a contactable nurse. A 54-year-old female patient received BNT162B2 (lot number: EK5730), intramuscular at the right arm on 17Dec2020 18:00 at 0.3 mL for COVID-19 immunization at a hospital. There were no medical history and concomitant medications. The patient experienced which she described as bizarre side effect of profound dizziness, almost like vertigo, states she was having to hold onto a wall, considered medically significant by the reporter on 20Dec2020 12:00. The patient recovered from the event on 21Dec2020, 10:00.; Sender's Comments: Based on temporal association, the causal relationship between BNT162B2 and the event dizziness cannot be excluded. This case will be reassessed once additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate.

Experiencing some stool that had a little bit of blood and kind of mucus; Experiencing some stool that had a little bit of blood and kind of mucus; This is a spontaneous report from a contactable consumer. A patient of unspecified age and gender received first dose of BNT162B2 via an unspecified route of administration on 18Dec2020 at single dose for COVID-19 immunization. The patient medical history was not reported. The patient's concomitant medications were not reported. This past Friday, so on the 18Dec2020 got the first shot of the COVID 19 Vaccine and starting yesterday (19Dec2020), the patient started experiencing some stool that had a little bit of blood and kind of mucus. So, patient just wanted to know if that is a side effect of the vaccine that could happen or if anyone else have also reported symptoms like that. Events outcome was unknown. Information about lot/batch number has been requested.

freezing and could not get warm; shaking; sick; Chills; tired; lightheadedness; Redness at injection site; Believe the vaccine was given subcutaneous; This is a spontaneous report from a contactable nurse (patient). A 56-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) lot number: EH9899 and expiration date: Mar2021, via subcutaneous route in the back of right arm where the fatty area far away from deltoid, first dose on 17Dec2020 18:15 at a single dose for routine vaccination. The patient's relevant medical history was none. There were no concomitant medications. The reporting nurse was reporting for herself for the covid vaccine. She received the vaccine and believed it was administered subcutaneously versus in her deltoid muscle on 17Dec2020. She had redness at injection site on 18Dec2020. She also reported chills, lightheadedness and was tired on 18Dec2020. She added that the symptoms did not happen until after Friday night (18Dec2020). She doesn't think she could have continued working as sick as she was that night. She did not know if it was medically significant though. She went between not serious and medically significant and then stated she guessed it would be medically significant. She was freezing and could not get warm and was shaking. She did not notice the redness until Friday night around 3pm. The redness has improved, but it was still there. Unknown time for when it first started, but the first that she noticed it was around 3pm. Lightheadedness started around 1pm on 18Dec2020. The tiredness started around 3pm on 18Dec2020. The chill started around 7pm on 18Dec2020. They all improved by Saturday, 19Dec2020. Part of this report is that the doctor said it was in her triceps muscle and she does not think it was. They pinched the skin and put it in. She said her muscle was not sore. As a nurse, she believed it was not in her triceps area. It was not in the deltoid area and that was suggested from Pfizer. The reporting nurse's seriousness for 'believe the vaccine was given subcutaneous' was medically significant, while non-serious for 'Redness at injection site'. The patient had no ER nor physician visit required; she had no prior vaccines within 4 weeks. The patient does not have a positive test for SARS-CoV2. She does not have SARS-CoV2 antibodies at diagnosis as she has had blood test a couple of months ago, either end of Oct2020 or beginning of Nov2020, and there were No antibodies at that time. The patient was not hospitalized nor was she admitted to an Intensive Care Unit (ICU). The patient did not display clinical signs at rest indicative of severe systemic illness. She did not have supplemental oxygen (including high flow or ECMO) nor received mechanical ventilation. She did not receive any additional therapies for COVID-19. The events did not require the initiation of new medication nor other treatment or procedure. The outcome of the events chills, lightheadedness, tired and Redness at injection was recovering while unknown for believe the vaccine was given subcutaneous, freezing and could not get

warm, shaking, and sick.; Sender's Comments: The reported information is limited. Based on the close temporal relationship and the description of the events, there is a reasonable possibility that the events are related to BNT162 vaccine. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

itching; tingly feeling; face appeared more flushed; slight shortness of breath; This is a spontaneous report from a contactable pharmacist. A 63-years-old female patient received 1st dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot# EK5730), intramuscularly in right arm on 18Dec2020 14:30 at single dose for Covid-19 immunisation. Medical history included allergic reactions (allergies to medications, food, or other products: Yes, numerous). No other vaccines administered in four weeks. Other medications in two weeks was numerous. Approximately 10-15 minutes after receiving COVID-19 vaccine (18Dec2020 14:45), patient reported itching, tingly feeling, face appeared more flushed. Seemed anxious due to history of allergic reactions and reported slight shortness of breath. Treated with diphenhydramine 50 mg PO and epinephrine 0.5 mg IM and transported to Emergency Department. Observed in that area and released a few hours later as symptoms resolved. The outcome of events was recovered on 18Dec2020.; Sender's Comments: A causal association between BNT162B2 and the events pruritus, paraesthesia, flushing, and dyspnea cannot be excluded based on a compatible temporal relation. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

Nausea and lightheadedness began about 20 minutes after administration. Lightheadedness abated after about 1 hour, nausea intensified and persisted, abated after about 26 hours. Fatigue began about 2 hours after administration. Fatigue abated after 24 hours. Severe headache (migraine) began about 2 hours after administration, still persists at 28 hours mark. Injection site tenderness, swelling and redness (2-inch diameter, bright red) noted about 8 hours after administration, tenderness persists, redness beginning to abate at 28 hours.

Face swell, Heart rate 108, Blood pressure 133/87, pregnant 35 weeks

Admitted to the hospital with hypertensive basal ganglia bleed, had a head bleed; This is a spontaneous report from a contactable consumer. A male patient of unspecified age received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration in 2020 at single dose for COVID-19 immunization. Medical history included hypertension. The patient's concomitant medications were not reported. After vaccination, the patient was admitted to the hospital with hypertensive basal ganglia bleed, had a head bleed in 2020. The outcome of event was unknown. Information on the lot/batch number has been requested.

Redness around injection site, swollen, hardness at site, fatigue, hot/cold spells, chills.

resp distress; This is a spontaneous report from a non-contactable consumer (patient). An elderly male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration at 16Dec2020 12:00 pm at single dose for covid-19 immunization. Vaccine location was right arm and it was the first dose. The patient medical history and concomitant medications were not reported. No known allergies. Patient was not diagnosed with COVID-19 prior to vaccination. The patient didn't receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient experienced respiratory distress on 19Dec2020, he was hospitalized for three days. Patient received treatment for the adverse event. Since the vaccination, the patient has been tested for COVID-19 with nasal swab on 19Dec2020, it was negative. The action taken in response to the events for BNT162B2 was not applicable. The outcome of events was unknown. The event was serious, the seriousness criteria was Caused/prolonged hospitalization. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

late Friday had sneezing, mild coughing, scratching throat, mild body ache, headache. Still have same symptoms.

blood pressure shot up to 205/112/blood pressure went down to 136/75; head hurt; couldn't hear that well; pulse 137; a heat wave go through her body up to her head; red rash and hives; red rash and hives; This is a spontaneous report from a contactable other healthcare professional (Patient). A 62-year-old female patient (not pregnant) received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, lot number and expiration date not provided), via an unspecified route of administration on 21Dec2020 16:00 at single dose for COVID-19 immunization, vaccine location provided as Left arm. Medical history included Penicillin allergy. The patient's concomitant medications were not reported. After about 10 minutes receiving the vaccine on 21Dec2020 16:15, the patient felt a heat wave go through her body up to her head, couldn't hear that well and head hurt. Her blood pressure shot up to 205/112, pulse 137, red rash and hives. The patient was transported via parametics to the Emergency Room for observation. Her blood pressure went down to 136/75. No treatment was received for all the event. The outcome of the events was recovered on 21Dec2020. Information on the Lot/Batch number has been requested.; Sender's Comments: A causal association between BNT162B2 and the event blood pressure increased cannot be excluded based on a compatible temporal relation. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

Patient evaluated and monitored following vaccine. Developed nausea and lightheadedness approximately 20 minutes after dose given. Patient reports that she hadn't had anything to eat or much to drink in the hours leading up to vaccine as she and her husband were going to get lunch after the vaccination appointment. Patient has a history of syncope/presyncope after a blood draw in the past. Patient had no other stx other than very transient nausea and lightheadedness, which improved significantly in the hour that she was monitored. BP at time of discharge from clinic was 105/73; pulse 67

Pfizer. Only upper lip swelled slightly (noted by coworkers as well) for about 24 hours. Of note, I had Juvaderm filler to the upper lip only late January 2020.

elevated blood pressure/ elevation in blood pressure/ Highest BP 195/93 ranging 180s/90s/ Final BP 155/93; foggy headed/ less foggy; felt flushed/ feeling flushed; metallic taste in mouth; This is a spontaneous report from a contactable pharmacist. A 63-year-old female patient (not pregnant at the time of vaccination) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL0140), intramuscularly on 21Dec2020 15:30 at single dose on right arm for COVID-19 immunization. Medical history included Allergies to medications, food, or other products: IVP Dye, red ants. Concomitant medications received within 2 weeks of vaccination included celecoxib (CELEXA [CELECOXIB]) and atorvastatin calcium (STATIN [ATORVASTATIN CALCIUM]). The most recent COVID-19 vaccine was administered in Workplace clinic. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. On 21Dec2020 15:45, Initially patient felt flushed and foggy headed then developed metallic taste in mouth and elevated blood pressure, required extended monitoring period with continued elevation in blood pressure. Heart rate and respiratory rate stable, no respiratory distress noted. Highest BP 195/93 ranging 180s/90s, however denied need to be seen in ED. Final BP 155/93, less foggy, no dizziness or lightheadedness; feeling flushed remained. Total monitoring time: 83 mins, without significant distress. No treatment was received for the adverse events. The reporter reported the seriousness was no. It was unknown prior to vaccination, if the patient was diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. The outcome of the events was recovered (pending clarification) in Dec2020.; Sender's Comments: A causal association between BNT162B2 and the event blood pressure increased and foggy feeling in head cannot be excluded based on a compatible temporal relation. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

About 7 minutes into my observation period my heart rate rose to 170 bpm and I felt warm and shaky. It took around 15 minutes to return to 70-80; About 7 minutes into my observation period my heart rate rose to 170 bpm and I felt warm and shaky. It took around 15 minutes to return to 70-80; About 7 minutes into my observation period my heart rate rose to 170 bpm and I felt warm and shaky. It took around 15 minutes to return to 70-80; This is a spontaneous report from a contactable nurse (patient). A 36-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration at first dose right arm on 21Dec2020 11:45 am at single dose for covid-19 immunization. The patient medical history and concomitant medications were not reported. The patient previously took Zithromax and morphine both cause nausea and vomiting. Patient was not diagnosed with COVID-19 prior to vaccination nor tested for COVID-19 since the vaccination. The patient didn't receive any other vaccines within 4 weeks prior to the COVID vaccine nor received any other medications within 2 weeks of vaccination. About 7 minutes into patient's observation period, at 21Dec2020 11:45 am, her heart rate rose to 170 bpm and she felt warm and shaky. It took around 15 minutes to return to 70-80. Patient didn't receive treatment for the adverse events. The action taken in

response to the events for BNT162B2 was not applicable. The outcome of events was recovered. The events were non-serious.; Sender's Comments: A causal association between BNT162B2 and the event heart rate increased cannot be excluded based on a compatible temporal relation. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

A day after having the vaccine, I experienced eye soreness in my right eye. The next morning both my eyes were blood shot. I administered eye drops and went on about my day. Late that evening they were really red and watery and my vision was blurred. I went to the optometrist on Monday morning and was diagnosed with Primary iridocyclitis, bilateral. My iris had been attached to my lens from the inflammation, but had detached it self. I was put on steroid drops and made to keep my eyes dilated until my follow up appointment. Went to my follow up appointment today December 28, 2020. My eyes are looking better, but not back to normal yet. Advised to keep administering my steroids drops and only use the dilation drops every other day. I will follow up on Thursday.

New diagnosis of diabetes 5 days after receiving vaccine with no past medical of DM and no family history.; This is a spontaneous report from a contactable Nurse (patient). A 31-year-old female non-pregnant patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number=EJ1685), via an unspecified route of administration on 18Dec2020 14:00 at arm left at single dose for covid-19 immunization. The COVID-19 vaccine was administered at Hospital. Medical history included asthma and hypertension. The patient had no known drug allergies. Concomitant medication included cetirizine, budesonide, formoterol fumarate (SYMBICORT), escitalopram oxalate (LEXAPRO), montelukast and omalizumab (XOLAIR). No other vaccine in four weeks prior to the COVID vaccine. The patient experienced new diagnosis of diabetes 5 days after receiving vaccine with no past medical of diabetes mellitus and no family history. The event result in doctor or other healthcare professional office/clinic visit and Emergency room/department or urgent care. Adverse event start date was 19Dec2020 06:00 AM. Treatment received included fluid bolus, computerized tomogram (CT) scan and labs. The patient underwent lab tests and procedures which included computerized tomogram and laboratory test with unknown results on Dec2020. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, the patient was not been tested for COVID-19. The outcome of the event was recovered with lasting effects.; Sender's Comments: The reported diabetes was unlikely causally related to the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), considering the latency of the onset of the event. A possibility that the vaccination unmarked subject's diabetes cannot be completely excluded. The case will be reassessed should additional information become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Nurse that fainted after the vaccine; This is a spontaneous report from a Pfizer sponsored program received from a non-contactable consumer. A patient of unspecified age and gender received BNT162B2 Pfizer-BioNTech COVID-19 Vaccine, via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. It was reported that the patient was a nurse who received the vaccine and did a live press conference on TV 15 minutes later and, as a result, she fainted. The event outcome was not reported. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

Tightness in chest; This is a spontaneous report from a contactable nurse (patient). A 61-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (Batch/lot number EH9899), intramuscular on 15Dec2020 14:35 in left deltoid at single dose for covid-19 immunization. The patient medical history and concomitant medications were not reported. The patient states that she is on day 7 today, and yesterday, 21Dec2020, she woke up with tightness in her chest, like someone had wringed her rib cage. She states that she wakes up tightness in her chest again this morning 22Dec2020, patient states that as the day continues, it gets a little better. The action taken in response to the event for bnt162b2 was not applicable. The outcome of event was reported as not recovered. The event was reported as serious and seriousness criteria was other medically important condition.; Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of event Tightness in chest cannot be excluded. The case will be reassessed if additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Severe headache and mild nausea started ~ 3 hours after injection. Joint pain and muscle aches started ~6 hours after injection. 1000 mg of Tylenol taken twice over the next 24 hours with some relief. Work was missed the day following injection due to inability to perform daily functions. Mild residual muscle aches 2 days after injection (today).

Bell's palsy/facial paralysis; This is a spontaneous report from a contactable other Health Professional (patient). A 28-years-old female patient received first dose BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot/ batch number: 33121, brand: EJ1685), via an unspecified route of administration at left arm on 18Dec2020 09:30 at single dose for covid-19 immunization at hospital. Medical history included anxiety, depression, diagnosed COVID-19 prior vaccination. No known allergies. Concomitant medication included fluoxetine hydrochloride (PROZAC) in two weeks. No other vaccine in four weeks. The patient experienced bell's palsy/facial paralysis on 21Dec2020 19:00 with outcome of not recovered. The seriousness was reported as no. The adverse event result in doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care. The treatment received for the adverse event was reported as unknown.; Sender's Comments: Based on available information, a possible contributory role of the subject vaccine cannot be excluded for the reported event of Bell's palsy due to temporal relationship. However, the reported event may possibly represent intercurrent medical

condition in this patient. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Sore arm x 36 hours. 1 doses of Acetaminophen; 1 dose of Ibuprofen.

Weakness and tingling down left arm; Weakness and tingling down left arm; Lightheaded; PVC's every 3 beats; emotional too and just very tired; Can not read the vaccination card as she does not have her glasses; Palpitations; Fatigue; Slept a lot; Thready pulse and vertigo; Thready pulse and vertigo; Soreness in left arm at the injection site and down the left arm; Soreness in left arm at the injection site and down the left arm; This is a spontaneous report from a contactable nurse (patient). A 54-year-old female patient received first dose bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, reason for no lot number of COVID Vaccine: Can not read the vaccination card as she does not have her glasses, Expiry Date unknown), via an unspecified route of administration in the left arm on 18Dec2020 at single dose for 'Work with COVID patients'. Medical history included none. There were no concomitant medications. The patient experienced weakness and tingling down left arm (hospitalization) on 22Dec2020, lightheaded (hospitalization) on 22Dec2020, PVC's every 3 beats (hospitalization) on 22Dec2020, soreness in left arm at the injection site and down the left arm on 18Dec2020, thready pulse and vertigo on 19Dec2020, fatigue on 20Dec2020, slept a lot on 19Dec2020, palpitations on 21Dec2020. Details as follows: Caller says she received the vaccine, she is a nurse. She got the vaccine on Friday, 18Dec2020. She had soreness in her arm and at the injection site on Friday but that was it. On Saturday (19Dec2020) she noticed a thready pulse, but went on with her day with only a little arm pain. Sunday (20Dec2020) she was fatigued and the thready pulse continued. She slept a lot on Saturday (19Dec2020) and Sunday (20Dec2020). Yesterday (21Dec2020) she felt a little better, but had palpitations here and there. This morning (22Dec2020) she went into work, was very lightheaded, had tingling down her left arm, and had palpitations. So she hooked herself up to a monitor. Her pulse ox was between 97-99%. Her heart rate would be in the 90s and then drop to 48, so she went down to the ED. She has had a CT, and she is throwing PVC's every 3 beets. She has not been admitted as they are still waiting for results. She is still in the ED. They did a CT to see if there was a possible clot. On 18Dec2020 she received the vaccine around 2 PM. She had soreness at the injections site and down the left arm, which went away by Sunday (20Dec2020). She now (22Dec2020) has weakness and tingling down the left arm. It was never red or anything at the injection site. Saturday, 19Dec2020, she had thready pulse and Vertigo which lasted until Sunday 20Dec2020. She would be laying in bed and try to flip to the other side and having vertigo. When the fatigue started on Sunday (20Dec2020) she did not feel like herself. She was very emotional too and just very tired. Since she went to the ED she has had a CT scan, one with contrast and one without. She had a chest X-ray, and she is on a cardiac monitor. Results are pending. She has Trigeminy PVCs. She says she never goes to the hospital. But she is not admitted yet (pending clarification). Can not read the

vaccination card as she does not have her glasses. Unable to read off the NDC, lot, and expiration date. History: Has been on the same vitamins for two years with nothing new. Blood pressure: Normal base line is 130s/80s maybe lower. Heart rate: Currently within her normal limits of 80s-90s. Depending on what happens, it was asked if she should get the second dose. The patient underwent other lab tests and procedures which included blood pressure measurement: 163/76 on 22Dec2020, chest x-ray: unknown result on 22Dec2020 (Result: Pending), computerised tomogram (CT scan): unknown result on 22Dec2020 (Result: Pending), heart rate: 80s-90s on 22Dec2020, Pulse oximetry: 97-99 % on 22Dec2020, cardiac monitor: results are pending on 22Dec2020. The outcome of events weakness and tingling down left arm, pvc's every 3 beats, lightheaded, palpitations and fatigue was not recovered. The outcome of the event soreness in left arm at the injection site and down the left arm was recovered on 20Dec2020. The outcome of the events thready pulse and vertigo was recovered on 20Dec2020. The outcome of the event slept a lot was recovered on 20Dec2020. The outcome of other events was unknown. Information on the lot/Batch number has been requested.; Sender's Comments: Based on available information, a possible contributory role of the subject vaccine cannot be excluded for the reported events due to temporal relationship. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Shortness of breath; fast heart rate with just activity/increased heart rate; This is a spontaneous report from a contactable nurse. A 47-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EJ1685, expiration date: Mar2021), via an unspecified route of administration on 18Dec2020 10:00 at 0.3 mL, single (0.3ml constituted dose) on left deltoid for COVID-19 immunization. Medical history was none. The patient's concomitant medications were not reported. On 20Dec2020, the patient experienced fast heart rate with just activity, Shortness of breath. Reporter seriousness for Shortness of breath was Medically significant. This patient reported shortness of breath that resolved within hours and fast heart rate with just activity. Fast heart rate with just activity: In the morning around 08:00. It had resolved. Shortness of breath: In the morning as well. Resolved by the evening. Vaccination Facility Type was Hospital and Vaccine Administered not At Military Site. There was no additional vaccines administered on same date of Pfizer Suspect that caller was aware of. The adverse events didn't Require A Visit To. Relevant Tests: Did a COVID-19 test and it was negative. Per (website name), patient should not get a second dose. Wanted to know if this was true. Caller further reported that the patient receiving the COVID-19 vaccine experienced shortness of breath and an increased heart rate for a prolonged period, and was now stable. Caller saw recommendation from the (website name) indicating that the patient should not receive the second dose of the vaccine, and wanted to validate the information. The case safety report was considered as non-serious by the reporter in the further reported information. The outcome of the events was recovered on 20Dec2020.; Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a

possible contributory role of the suspect product BNT162B2 to the development of event Shortness of breath cannot be excluded. The case will be reassessed if additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Developed fever and cough on 12/25/20, tested positive for Covid-19 on 12/26/20

"splotchy rash that started on both of her arms; she was not ok, and she felt weird, and stated something feels wrong; she felt dizziness and like she needed to pass out; she felt dizziness and like she needed to pass out; her knees buckled and she lost her balance; her knees buckled and she lost her balance; hyperventilating and couldn't slow her breathing from fear; hyperventilating and couldn't slow her breathing from fear; This is a spontaneous report from a contactable nurse (patient). A 30-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) lot no: EK5730, via an unspecified route of administration in right arm on 21Dec2020 16:30 at a single dose for COVID-19 immunization. Medical history included bilateral mastectomy, total hysterectomy, breast cancer gene 2 (brca 2), ankylosing spondylitis (AS), allergies to penicillins and latex. The patient was not pregnant at the time of report. Concomitant medications included isotretinoin, estrogens conjugated (PREMARIN), cetirizine hydrochloride (ZYRTEC), meloxicam. The patient previously took ciprofloxacin and experienced allergies. On 21Dec2020 at 16:45, the patient reported that she showed a nurse a splotchy rash that started on both of her arms. At that time, she also stated she was not ok, and she felt weird, and stated something feels wrong. Then she said that she felt dizziness and like she needed to pass out. The nurse asked if she could still breathe and she said ""I think so."" They asked her to stand then when she did her knees buckled and she lost her balance and was dizzier and more fell back into the chair she was sitting in. Then they just lift her onto the gurney. On the way to the emergency department, she began hyperventilating and couldn't slow her breathing from fear. Upon arrival she was asked for her name and birthdate and she slowly was able to say it. She was told she was given epinephrine, 2 rounds she thinks for her hives that had showed and her respiration was in the 39-49 range. Then they gave her methylprednisone (reported as ""methypedisone""), famotidine (PEPSID), and steroids, and lorazepam (ATIVAN) to calm her breathing as well as IV fluids. Then she was able to breathe 20-35 rpm. The patient was not diagnosed with COVID-19 prior to vaccination and has not been tested for COVID-19 since the vaccination. The events were reported as non-serious. The patient recovered from the events.; Sender's Comments: The patient had medical history included allergies to penicillins and latex., and to ciprofloxacin. The reported events were probably related to the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), due to temporal relationship. Patient's drug allergy history and nervousness may have played to contribution role to the clinical manifestations. This case will be reassessed should additional information become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics committees and Investigators, as appropriate."

Autoimmune disorder, it just exacerbated when I got the shot; Autoimmune disorder, it just exacerbated when I got the shot; Joint pain; My immune system overreacted and it was like rash all over my body; This is a spontaneous report from a contactable Nurse for herself. A 32-year-old female patient received bnt162b2 (BNT162B2; Lot #EH9899) vaccine, intramuscular on 18Dec2020 at single dose for covid-19 immunisation. The patient medical history included autoimmune disorder. The patient's concomitant medications were not reported. The patient stated that she suffered from unknown autoimmune disorder, and it just exacerbated when she got the shot, and she had like rash all over her body and had joint pain. The patient was treated with steroids.; Sender's Comments: A possible contribution role of BNT162B2 to the aggravated autoimmune disorder, joint pain and rash cannot be excluded. The case will be reassessed should additional information become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

"low grade fever; Her blood pressure was high/ still really high/ blood pressure was up; headache; Fifteen to twenty minutes after she received the vaccine she became light headed and dizzy/ light headedness and dizziness; This is a spontaneous report from a contactable nurse (patient). A 36-year-old female patient received BNT162B2 (Lot#: EK5730) via an unspecified route of administration on 17Dec2020 afternoon at single dose in the left arm for COVID-19 immunization. Caller was unable to confirm the manufacturer of the vaccine that she received. It is not written on the card, and she didn't see the vial. The patient medical history was not reported. Concomitant medications included oral contraception pill, but the name was unknown. Fifteen to twenty minutes after she received the vaccine on 17Dec2020 she became light headed and dizzy. She had to catch her breath. She couldn't shake it off. The light headedness and dizziness lasted at that intensity for 10 minutes, but it never went away. They encouraged her to be admitted in the emergency room (ER). She would say that the seriousness of being light headed and dizzy was disabling. Caller didn't remember the exact numbers for her blood pressure. It was 160's over 105. Her heart rate was in the low 100's, around 105. She stayed at the first monitoring station in the vaccine area for 2 hours. They were taking her blood pressure every five minutes. She was given diphenhydramine hydrochloride (BENADRYL) there and lots of water. After 3 hours and she was not improving they called a ""code medic"" that got the medical director and nursing supervisor to come. They encouraged her to go to the ER for continual monitoring. She stayed in the ER for4 hours and was given meds to help with the blood pressure. She was discharged from the ER home. She was nervous because of all this stemming from the vaccine. She had a low grade fever on 18Dec2020 (Friday) night. Caller stated her work had already reported her reaction. Occupational safety and the medical director are aware. Caller does not have reference number to provide. On 18Dec2020 (Friday) she was not overly concerned because it was the next day. Her blood pressure was high and her heart rate was in the 100's. They monitored her for a couple of hours and she was given a diphenhydramine hydrochloride (BENADRYL). She went to the emergency room (ER) for a few more hours and received additional treatment. They sent her home to be monitored at home. She has been taking her blood pressure every day since and it had not come down. It was still really high. She called her primary care doctor. He was wanting her to start blood pressure for medication it. She was concerned about starting

it with the assumption that it was related to the vaccine. She would like to know the right thing to do. It seems safe to take the medicine, but it was unknown that whether it was going to mask the blood pressure and something else be going on. On 18Dec2020 she still had a headache and didn't feel well, but she thought she needed to give it some time. She had been anticipating not to feel well on 18Dec2020 (Friday). On 19Dec2020 she felt better considering she didn't have a headache. On 19Dec2020 (Saturday) her blood pressure was 138/90 and she felt good. Then on 20Dec2020 she had the bad headache and her blood pressure was up. On 20Dec2020 (Sunday) she had a bad headache and her blood pressure was 156/100. She came to work today and her blood pressure had been high all day. She still had a headache and the light headedness continued. The outcome of the event low grade fever was unknown, of other remain events was not recovered.; Sender's Comments: A causal association between BNT162B2 and the event dizziness cannot be excluded based on a compatible temporal relation. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate."

Soreness at injection site, severe fatigue

within 5 minutes of vaccination recipient felt lightheaded, pounding HR, and general weakness. recipient laid down, drank some water after 25 minutes, then proceeded to leave. Checked in with recipient at 2:30 PM and the recipient is back to normal no issues

101.5 Fever, HR 155, SOB

"Patient was experiencing congestion and was taking Zyrtec prior to Vaccine. He also states his ""stomach was off"" then night shift before his vaccine. States that his stomach started to feel better so he went ahead with the vaccine. After the vaccine he developed diarrhea in which he had about 6 episodes of, a head ache, nausea, and a dry cough. States he was feeling a little better this morning, but started having diarrhea again and had to take Tylenol for his head ache. States arm is sore from the injection."

Associate returned 45 minutes after receiving the vaccine. She was flush and had already taken 8 puffs of her inhaler. Difficulty breathing. Given two doses of orally Benadryl 25 mg each. Taken to the ER. Stated, She did not take her oral steroid that morning per patient

the following morning after receving the vaccination at around 0300 the patient developed Fv TMax 101.8 F along with chils, body aches, nausea and diarrhea. These symptoms lasted around 36 hours with the patient taking acetaminophen regularly.

5 days of Diarrhea 4 days of left ear pain 4 days of constant headache 5 days of lethargy 2 days of cough 4 days of hip joint pain 4 days of muscle pain TXT: Extra Strength Tylenol & 800 ibuprofen

Arm pain and fever of 100.5 began same day as vaccination. Fever went away after several days, but return on 12/28 with fatigue.

Right arm pain (injection arm) that began at 8:35 AM. Rated pain 6/10. Vital signs: T 98.1 F, BP 145/103, HR 90, RR 18, SPO2 98%. Assessed by onsite MD. Staff also complained of feeling tired. Returned to work after injection. Staff advised to take ibuprofen 800 mg with a meal and monitor symptoms. Advised to contact PCP if not improving over next 3 days. Also advised cool compress to area by MD.

Sun: got vaccine. Tue: 4 am started to have headache. Wed: sore throat until Thu. Thu: Went to work and started to cough, still coughing. no fever. today: cough, congestion, body pain but getting a little better.

Pt. c/o facial redness, flushing, eye puffiness and facial tingling within 30 minutes to 1 hour after receiving the vaccine. States facial symptoms resolved within 1 hour after beginning. Pt. also states started vomiting 2 days after receiving vaccine and lasted for 36 hours. Pt. states went to the emergency room but was unable to be seen. Went to urgent care clinic and had bloodwork drawn and IV fluids were given on 12/28/2020. States feeling much better today on 12/28/20.

My chest was hurting, my heart was racing, I woke up with bleeding from my mouth and nose, a thick film in the roof of my mouth. I was taken by ambulance. I have a cough, headache, fever, nausea, vomiting and diarrhea.

After receiving Pfizer COVID-19 vaccine on 12/18/20, patient c/o nausea.

Raised area with hardness with discoloration to the injection site. Itching occurred on day #2 of administration. Injection site is tender upon palpation.

On day of injection arm soreness, otherwise fine. Woke up at 6:00 am the next morning with my eyes ticking to the right and extremely dizzy. Couldn?t walk down the hall without leaning on the wall. Dizziness persisted all day on the day after injection but got slightly better as the day went on. Using a pulse ox I checked my heart rate which was resting around 100 and when I walked down the hall and back it rose to 135 which is much higher than my normal resting around 85. The following day (12/28), dizziness is gone but heart rate is still higher than normal.

12/16/2020 HEADACHE AND FATIGUE, RASH ON HANDS, RASH ON TRUNK AND ALL EXTREMITIES. 12/20/2020 HA WORSENED PRIMARY AT BASE OF SKULL, DEEP, NOT MUSCULAR. BOTH SIDES. FEVER, BODY ACHE, CHILLS, SKIN HYPERSENSITIVE. COVID TEST; NEGATIVE. 12/21/2020 URGENT CARE; COVID; NEGATIVE 12/21/2020 - AT ER ALL DAY 10/11 AM - 6PM ??? 'ATTRIBUTED TO DRUG ALLERGY; SULFA/BACTRUM' CYPRO, STEROID INJECTION STILL HAVING HA, UPSET STOMACH AND VERY WEAK. VITAL SIGNS WITHIN NORMAL LIMITS 'ROUGH NIGHTS' TELE HEALTH 12/29/2020 DR REQUESTING ANOTHER COVID TEST

Heart palpitations 12/26/20, approximately an hour after vaccine.

Headache and vomiting beginning night of vaccination on 12/24/2020 and continuing to 12/26/2020 accompanied by extreme lethargy. Patient states she was unable to do anything and stayed in bed for days. When I spoke with her today 12/28/2020 she stated she had a headache and was very fatigued still.

Patient had throat tightness and trouble swallowing within 7 minutes of injection. 30 minutes after developed tachycardia and hives. Received prednisone and Benadryl IV symptoms resolved. Patient is 16 weeks pregnant at this time

possible serum sickness 7 days after vaccine: Hand itching, angioedema to lips and face, swelling to hands and genitals, urticaria to chest, inner elbows, groin, genitals, extremities, flushing to face

Itchy throat, gulping to swallow, red eyes, flushed and diaphoresis

12/24/2020 started mild cough, still coughing, sneezing, no fever.

Moderate pain in injection arm. Muscle and joint pain. Headache

Shortness of breath, low oxygen level, cough, fatigue, nausea, vomiting, diarrhea, body aches, headache, chills

Staff received vaccine and sat in observation area at 1405. At 1420, staff complained of right arm pain (4/10) at injection site. Vital signs WNL. Patient was assessed by onsite MD at 2:35 PM and returned back to work at 2:37 PM. Advised by MD that he could use ibuprofen and he should monitor site. No redness or swelling noted at injection site. Normal range of motion

24 hours post vaccination, the patient developed hives. Patient was seen by her PCP for evaluation. Prescribed oral prednisone and OTC antihistamines.

Patient states that a few days after receiving the vaccine, she started to experience a little swelling and irritation at site. She did not report this because she experiences this with the flu shot. She is no longer having the swelling and irritation. On 12/28/2020, patient states that there is a raised, circular rash as the injection site that is similar to a ringworm. She states that is only itches when she touches it. Patient states that she is not experiencing any other symptoms.

Swelling (Lump) and discomfort to left neck area. Noticed it when I woke up Monday 12/28/2020

Experiencing throat congestion with mild tingling on tongue and chest tightness with a slight dry cough

Experiencing throat congestion with mild tingling on tongue and chest tightness with a slight dry cough

numbness below nose, outer upper lip, inner upper lip, tongue. reports symptoms occurred within 30 minutes of receiving vaccine. Took Benadryl and 40 mg of Pepcid. resolved within an hour.

Fever (101.8 - 102.3) and chills Fatigue Headache/stiff neck and pain Lasting 24 hours

I got the vaccine on Monday 12/21. The main symptom that I was having was tachycardia(HR-90?s to 130) for 3 days. Only other symptoms were injection site discomfort, myalgias, fatigue. I had lab work on Tuesday by PCP - normal. EKG showed sinus tachycardia. Resolved by Thursday 12/24.

I went to ER exp redness around the right eyebrow, rash, cheek was swollen. I was placed on Steriods and Benadryl finished the treatment on 12/26. The rash kind of came and went cheeks was swollen and

I felt jittery. I started to feel better on 12/27 and placed a call to my PCP to make sure receiving the second vaccine. My PCP is reaching out to a allergist and contacted Phizer about concerns of the second vaccine. I haven't be able to wear makeup due to my fair skin complexion and don't wont to irritate the rash on my face. I have missed 2 days of work

"Reported ""funny taste in throat."" Stated it was ""metallic"" and occurred five minutes after injection. No unusual foods in the morning prior to vaccination. No food allergies. Upon assessment by onsite MD, patient had mild heaviness in eye and frontal head area that began 15 minutes post-administration of vaccine. Had ""wooziness/lightheadedness"" 15 min after injection as well that resolved. Chest heaviness in left area that lasted 2 minutes, resolved. Reported some anxiety/nervousness. No history of cardiopulmonary disease. Negative EKG and stress test in 2006 that was conducted due to chest pain after walking. No history of GERD. Denied other signs and symptoms."

Possible itchy, red spots over torso and neck

Moderna COVID-19 vaccine EUA Developed throat, cough and throat clearing during observation period. Refused epinephrine. Code assist called and person was taken to ED where received Solumedrol, famotidine, Pepcid, and Benadryl; continued to refuse epinephrine in ED. Symptoms resolved and discharged home.

LocalizedL arm soreness, progressed to fatigue and chills, 12/27 developed severe nausea, fever 12/27 night 100.9, slept for 18 hrs,, awoke this am with a pounding headache,w/mild dizziness, no SOB,has runny nose,post nasal drip and a dry cough, right sinus tenderness

tingling in the back of the throat. Pt was flushed and sweaty. Pt vitals were 179/107, pulse 112.

Day 1-2: malaise, fatigue, muscle aches, chills, sweats, began ibuprofen Day 3 (12/24) sudden onset of severe L sided chest wall pain, lasting for several hours, other symptoms continued requiring ibuprofen. Day 4: moderate L chest wall pain, Day 5: In the AM pain was reduced, but at about noon after a 17 minute exercise program, pain was severe associated with SOB, went to ER and found to have a L pleural effusion, no pneumonia, no PE on CT angio. Due to lack of clear causative process: began augmentin, azithromycin, prednisone, aspirin and Tylenol... Day 6: Much improved, but still L chect pain with deep breathing coughing and recurrent hiccups. Day 7: a little worse in AM until prednisone 40 mg, aspirin 162 mg and 1000mg Tylenol

Muscle Pain, Nausea, Dizziness, Injection site pain

Palpitations, racing heart rate, lightheadedness

On 12/22/2020 we had 1 patient who had a severe allergic reaction to covid 19. after she was administered covid 19 vaccine at about 11 am she went in to the observation area for 15 minutes. while there under the observation of the facility staff members she reported to them that she was having some difficulty breathing and her lower throat was closing up. the staff member came over to the administration area to ask me to bring the epi-pen because they have someone with anaphylactic allergy reaction. I ran over there with a box of epi-pen and patient stated she is having difficulty

breathing and her throat is swelling up and I noticed her lips were turning blue. at that time I administered the epi-pen and asked the facility members to call 911. which the facility members did promptly. I kept her under observation with the 2nd pen ready just in case it was needed. the EMS showed up within 15 minutes and took over from there and transported her to the hospital. The staff members at the facility also called the patients doctor to inform him of the allergic reaction. I followed up with patient on 12/23/2020 at 4.37 pm. and at that time she was doing fine. she informed me that all of her symptoms of the allergic reaction have gone away and all she has is some cough and some shortness of breath. she had been discharged by the hospital and is on some steroids and under her physicians care. I talked to employee at store as he is the one charged with recording this incident and he has informed me that he talked to the facility administrator and facility administrator informed him that both patients have recovered completely and were back to work today on 12/23/2020

Sore Arm x 36 hours

Feeling foggy after vaccine Vitals PO2 100% Temp 36.6 P 85 b/p 112/76 No treatment required left after 30 min observation AMA

Developed itching and redness to bilateral arms and face approximately 20 minutes after vx admin. Admin Benadryl 25mg po x 1 per S.O. 1400-itching nearly resolved, redness decreased.

tingling of posterior tongue flushness of neck and upper arms

Body Aches, Fatigue, Soreness around injection site

Started having chest pain and shortness of breath approx. 10 hours after injection. Symptoms kept Worsening. Taken to the ER. Cardiac workup performed. It was negative. Diagnosed with Pleurisy.

The staff had the Covid vaccine in the morning 12/23/2020. In the afternoon, received a phone call from her boss saying that her boss was COVID positive. Boss only had headaches. Then the staff went to have Covid test, the result was negative. On Thursday she started to expreience headache, still having headache and mild body ache.

Sore arm x 48 hours.

Fatigue, Dizziness, Arm Pain, Redness, Swelling, Light sensitivity, Headache, Muscle Pain in arms and legs, Painful to touch the arms and legs, felt like she worked out extremely long, right knee/leg swollen. Dr. Prescribed cephalexin and Naproxen 500, helped swelling, started taking on 12/25. There was a break in between the pain, from 17th to 20th there were the first symptoms, and then a break, but muscle fatigue started on 12/23.

Received vaccine at work on 12/23/20 at 1600. No problems receiving it. No pain at site or afterwards. about 12 hours later (04am) on 12/24/20, I woke up with body aches and was especially across my shoulder blade area. Had headache. Up that morning. Spiked T-102.5 orally with horrible headache. Temp did break on 12/24/20, but did come back later that day T-101. Continued with horrible headache, body aches, became very sore at injection site. Lethargic. No appetite. Diarrhea.

approximately 3 hours after injection subject developed rapid irregular heart rate consistent with recurrence of her atrial fibrillation which she had not had for at least one year prior. Also noted chest pain and weakness. Took an extra dose of atenolol with some improvement. Symptoms completely resolved overnight without any recurrence since.

Injection site soreness, Heat flashes

Associate developed a rash and tachycardia. Received two doses of po benadryl. Symptoms resolved.

12/21 SITTING IN CHAIR, FELT TINGLING IN EAR, 'FEELING FAINT'. MOVED TO CHAIR AGAINST THE WALL, TOLD MEDICAL STAFF. FAINTED, SWEATING PROFUSELY, 'WANTED TO GO TO SLEEP'. MONITORED HR, BP. VOMITED. BP WAS STILL ELEVATED 136/100. 'FELT BETTER' AFTER VOMITING, COLOR CAME BACK, 'CAME TO'. ER: BASAL EVENT ABOUT TO DISCHARGE, TINGLING CAME BACK. NOTHING ON MONITOR INDICATED ANY PROBLEMS. EVENTUALLY DISCHARGED AS SYMPTOMS DECREASED. DIAGNOSED; SYNCOPE

The day after I received the vaccine, I developed chills, headache, fatigue. Approx. 23 hours after vaccine administration I noticed throat swelling/difficulty swallowing. I took 50 mg of benadryl and went to a local walk in clinic. O2 sat 98%, no respiratory distress, nurse practitioner reported my throat and rest of assessment were within normal limits. Instructed to continue taking benadryl and monitor symptoms. Later that evening I developed congestion, so the morning of 12/24 I called my work's COVID hotline and they instructed me to come in to be swabbed. I received negative COVID-19 results from my works Occupational Health department on the morning of 12/25. The throat swelling/difficulty swallowing has gotten better, but still not back to baseline as of 12/28. I have a appointment with my PCP, to follow up.

Soreness at Injection site

Slight headache for several days following vaccine, resolved as of 12/28. On 12/28 she had a sudden wave of severe nausea, one episode of vomiting and subsequent generalized achiness with mild residual nausea.

Warm, tingling & numbness 10 minutes post injection. Monitoring indicated elevated HR & BP. Team member released after 50 minutes. TM was driving to her clinic and developed left side numbness to her cheek, upper arm and lower left back areas. Supervisor completed incident report and had team member go to urgent care and then went to ER. TM drove herself. ER provider Dr. contacted EH and informed us that TM did not have anaphylaxis and has no known allergies. She also drew CBC, Mag, Urine pregnancy & performed a CT scan w/o contrast to rule out kidney stone. No significant findings were noted.

Patient reports symptoms following COVID-19 vaccine. Patient reports she had brief episode of heart racing, throat tightening, feeling lightheaded. Symptoms already improved within 1-2 minutes by the time this RN reached patient. Denies itching, hives, shortness of breath, or any other symptoms. Has history of anaphylaxis and anxiety attacks, was worried about having anxiety attack with vaccine today. BP and pulse normal on two repeat checks. Patient alert, oriented, speaking clearly and in no apparent

distress. Symptoms resolved and did not return by end of patient's post-vaccination waiting period. Patient works on campus in oncology with healthcare providers nearby for help if any further symptoms.

After receiving the vaccine I was immediately nauseated. I went back to my desk to work and was dizzy and felt like I would vomit. This went away after an hour or so. My arm felt totally normal right after the vaccine, but later in the evening it worsened and I had a dead arm for about 24 hours. The next morning when I awoke I felt there was an elephant sitting on my chest. I couldn't catch my breath or take in a deep breath. I tried to walk down the stairs to get my inhaler, but was so dizzy I had to hang on to the railing in order not to fall. When I got to my medication cabinet I had difficulty opening the cupboard. I took my inhaler and the chest pain seemed to ease up as the day progressed. I had such terrible body aches that I tried to open a bottle of Ibuprofen and had extreme difficulty with my fingers. Throughout the day my fingers were cramped up and I was unable to hold on to anything, even the steering wheel of my car to drive. My hands were so sore that I tried massaging them but nothing helped. I took ibuprofen and Tylenol every 4 hours to help and after about 48 hours the intense burning, aching, and cramping somewhat subsided. Over a week later, I am still struggling to use my cell phone and text messaging. My fingers are not working right so I am hoping that will go away. In addition, I have been achy with chills since the morning after getting the vaccine. I can not seem to warm up. I have tried warm baths and sleeping with hot pads, but I have terrible chills and aches. My joints and muscle hurt all over my body to the point that now I have made an appointment with a doctor to see if the vaccine caused some kind of autoimmune reaction. My fingers, hips, and knees are the areas that hurt the worst still. I am a marathon runner and was currently training and doing well. After the vaccine, my joints and muscles have been so painful that I haven't been able to maintain what I was currently doing with running. I have ended up icing or heating different parts of my body daily and gone through a lot of ibuprofen, naproxen, and Tylenol trying to find relief. My entire body is covered in Icy Hot as that seems to help a little. I am unable to sit for more than a few minutes without pain.

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"Early morning hours 0100 of 12/19/2020, awoke with SOB/dizziness/polyuria/anxious/Heart palpitations/Tachycardia (no tx/went back to bed thought I was just anxious) Afternoon of 12/19/2020 Fatigue/dizziness/HA (Motrin) Early morning hours 0130 of12/22/2020 awoke with SOB/dizziness/Polyuria/anxious/Heart palpitations/Tachycardia 120-130/felt something wasn't (right) (went to Hospital ER, cardiac workup, multiple PVC's some couplets, tachycardia. Given a liter of fluids) Told it was a Large Catecholamine release related to my immune response to the vaccine, Told Heart was ""irritated"""

10 minutes after the vaccination, she began clearing her throat, within 30 minutes began coughing, which led to chest tightness. Was evaluated in the ER and admitted for observation. Given: Prednisone 40mg po, Benadryl 25mg po Duoneb x 3 and Pepcid 20mg

Intractable headache that started 1 day after the vaccine was received. Still having headache as of today, 12/28/2020. Has been taking Ibuprofen around the clock with no relief

Patient woke up the morning after the vaccine and could not get out of bed. She felt horrible and disoriented. Her husband had to help her as she could not stand, was sweaty, nauseated and dizzy. BP 170/107. Did not feel well all weekend and was extremely fatigued and dizzy with a 10 on a scale of 1-10. Patient feels better today and is able to work.

Injection site pain

Injection site pain

Redness, Swelling, Fever, Pain to injection site. Achy and diarrhea for 1 week

"two days post-vaccination on 12/25/2020, had ""COVID sxs of H/A, cough, N/V/D. COVID Swab done early on 12/25/20 was negative. Went to ED for continuing sxs, re-tested for COVID by nasal swab, negative. In ED, states Hgb was 10.1 Gms which she states was a 35% drop from previous Hgb of apprrx. 16 Gms, approx. one year previous. Cponsulted with her PCP on 12/28/2020 and repeat Hgb pending. States her PCP advised against receiving Dose #2 of vaccine ""due to dramatic drop in Hgb. which he felt was due to COVID Vaccine on 12/23/2020."" She plans to decline Dose #2 vaccination."

One day after my COVID-19 injection, I noticed a large growth on my left elbow. It is painless and feels like there is liquid inside. It is about the size of a medium sized egg. The physician at the administration site said it appears to be olecranon bursitis or symovitis.

generalized itching that started in her left hand then spread to the rest of her body. Itchy ears, throat, eyes. Slight coughing and runny nose

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One day after my COVID-19 injection, I noticed a large growth on my left elbow. It is painless and feels like there is liquid inside. It is about the size of a medium sized egg. The physician at the administration site said it appears to be olecranon bursitis or symovitis.

generalized itching that started in her left hand then spread to the rest of her body. Itchy ears, throat, eyes. Slight coughing and runny nose

tingling in arm and hand - fatigue headache

Moderna Inj given: 0830 Pt complaining of difficulty swallowing: 0839 Epi-Pen given: 0840 Pt sx: Original complaint of difficulty swallowing. Upon assessment, glands were noted to be swollen and red. Pt was given Epi-Pen. Pt had notable peri-orbital edema and his face was flushed. Upon assessment of vital signs pt was noted to be tachycardiac with an elevated blood pressure. No adventitious lung sounds. When pt was loaded onto EMT gurney, his BIL LE were noted to be edematous. 0845 0849 0853 0856 T: 96.9 97.5 97.5 97.9 P: 110 95 77 78 R: 24 20 20 20 BP: 151/92 169/80 137/86 137/95 O2: 99% 99% 99% 97% Ambulance arrived at 0856. Pt transported via ambulance to Hospital for assessment and treatment.

Received the vaccine and 8 hours after had nausea. Was scheduled to work and by the time I got inside I also had chills, fever, muscle aches and fatigue. I was sent home. I took Tylenol and went home and went to sleep. The next day the fever was gone but I still had some fatigue and a sore arm at injection site. The next day I only had a sore arm at injection site. No other symptoms after that day.

Soreness at injection site

Soreness at injection site

racing heart, shakiness, dizziness

After vaccine I noticed an immediate metal taste in my mouth, 30 minutes after vaccine I noticed a tingle feeling to my tongue and the metal taste, 45 min after vaccine I noticed my tongue was swollen, Vaccination clinic called and recommended taking diphenhydramine and go to ER if symptoms got worse.

Flu like symptoms, Headache, sore throat, stiff neck, mild cough, fatigue, hot flashes, (left side of face hurts for 3 days and now just tender) and no fever at this time. All the symptoms are continuous even with over the counter meds with no relief.

Pfizer-BioNTech COVID-19 Vaccine Diaphoretic, SOB, Sudden Heat, BP 90/56, 98% O2 Room Air, HR 75 Pt states - likely due to anxiety from vaccine, will continue with 2nd dose in 21 days.

Chills, asthma, fever, congestion, cough, arm pain

tachycardia, hand tremors

The day after I had little bit of soreness on my deltoid, nothing major, but 3 days later, the Saturday I felt a sore throat and by night it was significant enough, I started taking Motrin. My lynphnodes were a little swollen. I contact employee health who set me up with a covid test (negative) and about 3 weeks earlier I had a similar sore throat that prompted me to have a covid test it was negative as well.

Complained of left arm & hand tingling, feeling warm and heavy

Soreness at injection site

Patient was found slumped over in wheelchair, drooling and unable to respond/follow simple instructions; sent to ED for evaluation. CT scans and MRI NEGATIVE for new/recent stroke; resident slurred speech likely due to hypertensive urgency

Blurry vision about 20 minutes after injection when stood up, lasted about 15-20 minutes. No other symptoms noted. Resolved on own. Blood pressure, O2 saturation, and pulse all within normal limits per healthcare provider.

Rt Arm no function/ no feeling.

Pfizer-BioNTech COVID-19 Vaccine headache 5 minutes after IM injection of dose 1, did not recover after 15 minutes of observation.

Extremely tired, chills, and body aches from 3 hours after the vaccine was given, lasting for 2 days. Took ibruprophen 300mg every 8 hours and slept when I was not working.

Nausea, lightheaded, chest pain, vasovagul

Pain at injection site, sore throat

Increased heart rate for several hours following injection Ongoing significant headache - constant dull headache with occasional sharp pain on the lift side of head

Fever (highest 101.5 degrees F while taking 1,000 mg acetaminophen every 6 hours and 600 mg ibuprofen every 8 hours), body aches, joint pains in knees, severe fatigue

Employee received vaccine dose and within 10 minutes developed facial flushing, felt slightly SOB, felt lip tightness, felt like voice was hoarse, with mild lip swelling noted-- reports history of nut allergies/ATBs-- no known history of allergic reaction to a vaccine previously. Employee was brought to ED and received benadryl, epinephrine, decadron, IV fluids in ED and was discharged home.

Fever, Fatigue

""""Pfizer-Bio-Tech COVID-19 Vaccine EUA"" Client given vaccine around 11:30 am, At 11:44 client with c/o increased HR, and flushing. No rash noted , VS monitor, Post 5 minutes she states she feels better , VS stable, 11:59 client left on her own."

Palpitations, chest tightness that has been intermittent, occurring 5-6x/day and lasting 30 minutes before resolving spontaneously since she received the vaccine. She says she has had similar palpitations in the past, with a negative medical workup

Pain at site of injection the next day. Swollen glands in neck/cervical area and armpit on day 2. By day 3 I was feeling better and by day 4 i did not have any soreness at all.

Elevated heart rate and blood pressure, headache and itchiness

Elevated heart rate and blood pressure, headache and itchiness

Fatigue, body aches occurred 1 day after receiving the injection. Symptoms lasted only for that one day. Rest and fluids were the only treatment.

Headache, low grade fever, runny nose starting 6 hours after injection lasting approx 24 hours

Broke out in welts and hives all over body for 4 days.

Stomach Cramps, Diarrhea, dizzy

I felt like I was having a hot flash and felt like I was hungover, tired achey, and nausea, the next day 12/18 I couldn't sleep on my left side because my arm hurt, no rash and Saturday I had horrible itching all over my body, I called the Dr and he had me take Claritin, and it calmed down after 6 hours . I have similar symptoms with extreme stress.

Hives to bilateral arms and chest

The next morning when I woke up I started feeling short or breath like my asthma was exacerbating and used my inhaler. 3- 4 hours later I had to use my inhaler again. And it started happening more often than every 4 hours. So that is when I reached out to my PCP and he prescribed me a nebulizer solution and prednisone.

Pain at injection site, arm stiffness hard to move

10:00 pm - Severe chills 1 am - Temp of 101.1 2 am - take tylenol 3 am - fever 100.4 and excessive sweat 6:30 am - 100.0 temp 8 am - 100.4 temp 9 am - excessive sweat All this time - muscle aches, joint pain

"The employee stated that he started feeling weird. Lips tingling, flushed face, feeling ""fuzzy"" headed, dry mouth, unsteady when standing. BP 130/94 pulse 60 ; at 12:20 Lips numb again and feeling fuzzy; Took to the ER In the ER, patient presented with lip numbness, diaphoresis, leg weakness. Patient states that symptoms were alleviated by sitting down but that the lip numbness returned, Administered- Solu-

Medrol 125mg ivp once; Pepcid 20mg ivpb once ,Benadryl 25mg ivp once Discharged from ER at 13:52 with symptoms improved"

Patient had a head ache, fatigue, loss of taste and smell. Went to doctor and she is being tested for COVID-19.

Injection site sorensss

"Pt received Moderna COVID-19 vaccine at 1023. Approximately 6 hours later, she began to develop ""hives"" which were primarily around her jaw and hairline on the right side. Pt also reports swelling around her eyes. Pt took Benadryl at home with no relief of symptoms. Pt presented to local Urgent Care, they directed her to the Emergency Department. Pt arrived in ED at approximately 8PM. The Pt received 10mg IM dexamethasone, 25mg IM diphenhydramine, and 20 mg PO famotidine. Pt reports resolution of symptoms after medication administration."

I got the vaccine on Thurs and worked the following day. On Sat morning I felt sick with fever, clammy and tired went to get tested results positive. I dint think this was a reaction to the vaccine. I have missed week of work.

Hives. Given benadryl. Taken to ED

12/24/2020 arm pain at injection site, body aches, mild headache, fatigue; 12/25/2020 symptoms worsened next day; 12/26/2020 loose stools, with continued previous symptoms, dizziness, weakness.;12/27/2020 Covid Test - Negative; 12/28/2020 sore throat, head congestion -- all other symptoms continue to persists.

Itchy, feverish, elevated heart rate, light soreness

At the 36 hour I was in severe joint pain with profound myalgia, and fatigue. The pain was an 8 to 9/10 and would have caused me to seek emergency medical care if I were not a physician capable of treating myself. I laid in bed writhing in horrible pain and after analgesics did fall asleep. The next day these pains continued as I had to work and had difficulty walking and maintaining professionalism. The pain continued through Saturday at which time I took a tapering dose of steroids and it seems to finally be letting up. I will not seek the booster injection for covid 19.

Sore arm Sniffles

Soreness at injection site

I was given Moderna Vaccine on 12/26/2020. I had Muscle pain by 11pm on 12/28/2020.Muscle pain was better by Sunday. I felt fine on Saturday 12/27/2020. On 12/28/2020 around 11pm I started with chills, fever and headache. My temp was 99.9. The fever is back to normal as of about 11 am 12/28/2020, but the headache is still lingering. I have not taken any OTC medication. I am drinking a lot of water to stay hydrated and overall feeling better.

Lip tingling, swelling and itching which last approximately 2 days. Treated with 25mg once a day for 2 days. Is now resolved.

11:33 Patient arrived to the observation area with nurse at side. Nurse observed upper body twitching and stated that patient voided in the chair. áPatient looks dazed and pale and requests to lie down. áPatient placed on stretcher with head down andáfeet up. Initials vitals taken. HR 38. Call was placed to EMS. áPatient states that she felt anxious while waiting and has a history of panic attacks. á 11:40 Patient appearance has improved. á2nd set of vitals taken show improvement. áPatient states that she feels better and placed a call to her daughter. Awaiting EMS arrival. 11:45 Patient transported via EMS to ED for further treatment and follow up. 15:00 Follow up call placed to ED. áPatient stable and may be admitted for further observation

Feeling weak, lips numb and tingly progressing up face and to right ear. Hot burning sensation right side of face to right ear. Became numb and tingly from chin to eyes within 5-10 min of shot. Nurse game me Benadryl. Numbness reduced within 30 minutes. Very tired. Slept for 3 hours. Woke up with headache.

PT. REC'D VACCINE AT 2:18PM, WAITED RECOMMENDED 15 MIN. AND CHECKED OUT AT 2:33PM. T/C AT 2:42 PT CALLED AND C/O TINGLING TO LEFT SIDE OF FACE AND LIPS, AND C/O A H/A THAT PT. REPORTS COULD POSSIBLY BE D/T STRESS/ANXIETY OF THE TINGLING SENSATION. STAYED ON THE PHONE WITH HER WHILE SHE COMPLETED HER DRIVE TO THE WORK SITE. SPOKE WITH HUSBAND AND ASKED THAT HE GET BENADRYL AND ADMINISTER ASAP AND TO CALL IF SYMPTOMS WORSEN. T/C TO PT AT 3:12PM HAS TAKEN BENADRYL AND FEELS FINE.

I started with a mild headache with chills body aches and fever of 100 degrees, rash and hives and chest pains. Into the next day I had a sever headache, chest pains and BP 176/126 that caused my cardiologist to add two additional meds to try and get me out of the hypertensive episode.

Kidney Pain

Body Aches

Bruise on back formed, hard to bend over, spinal pain.. chills, muscle aches

12/23 - dry, scratchy throat 12/24 - nasal discharge (mild) 12/25. - nasal discharge 12/26. - sinus congestion 12/27 - loss of taste / smell; diarrhea

Fever and fatigue for approximately 24 hours

Thrush - taking swish and swallow

Patient states she was vaccinated at about 3PM and around 9-10PM she started to feel like she may pass out (shortness of breath, vision changes). Patient states over the next couple of days she felt fatigued and feverish. She reported these symptoms to her DON who encouraged her to report her symptoms to us. Patient has completely recovered from these symptoms.

Tingling in tongue and lips.

patient report symptoms of facial tingling and seemed to have increased secretions with a dry cough. no facial swelling. she contributed to her reflux so she took tums. She was not given any medications while monitoring. The cough and increased secretions resolved and the tingling improved. She reports she took Benadryl and Claritin at home

After receiving the vaccine the patient experienced flushed feeling and perspired under both arms for 10 minutes. Employee began to feel a sharp electrical shooting pain in the axillary/armpit area which extends into upper arm. She is experiencing it intermittently with certain types of movement. She believes that shot was given too low in the arm.

Left side facial swelling, redness, bumps. Improved within 4 hours. Left cheek bone still swollen and red after taking 2 Benadryl. (Have not had any facial filler or anything done to my face what so ever)

Pt reports red itchy rash appeared on bilateral arms approx. 4-5 hours post-vaccination. Dry red rash noted on 12/28/2020. Pt states has been taking Benadryl and using topical hydrocortisone cream. Pt states has seen slight improvement.

"Patient with a history of severe anaphylaxis was observed for 30 minutes post vaccine. Right at the 30 minute mark, patient started to look pale, started with frequent throat clearing followed by sense of shortness of breath and chest tightness. 2:37p: No wheezing, good air movement, breathing was not labored, no cyanosis, no noted lip or tongue edema, able to speak. BP 160/54. P 98, O2 sat 98%. Severity of symptoms per patients = 8/10 ""tightness"" at time of medical evaluation/medical provider response. 2:38p 911 called, 2:39p epipen, benadryl 50mg oral, and solumedrol 125mg IM administered (patient tolerated well, able to swallow) 2:42p patient reports symptoms improved to ~4/10 severity O2 sat 98%, P97 2:46p , O2 96%, P 99, BP 148/52 2:48p patient reports symptoms still at ~4/10 severity/stopped improving, O2 sat 95%, p 85; discussed option of doing 2nd epipen 2:54p EMS arrived prior to administration of second epipen. Patient transported to Emergency Department for further evaluation for possible anaphylaxix"

Pt. Administered vaccine at 1355 at 1358 she complained of throat warmth, anxiety and feeling flushed. Pt. offered Benadryl 50mg, refused but agreed to 25mg. VS's at 1358, HR 84, resp.'s 16, BP148/102. at 1410 146/102, HR 76, resp. 16 1415 states feeling worse, can feel it in throat, to ER via wheel chair.

about 10 mins after the vaccine I had hot flashes started in my feet and went through my whole body , dull headache. It didn't last but a few seconds. the headache lasted a couple hours. I went to the ER for further monitoring and checked blood pressure and vitals for two hours and released me.

Patient received the Covid 19 vaccine on 12/22/2020. On 12/23/2020 she noticed a single, blister-like rash on her right eye. The rash got worse and spread to her face bilaterally and neck. Denies any tingling or numbness of the face. No swelling of the lips noted. Denies respiratory issue or fever, chills, HAs, or fatigue. Denies taking new medications, using new soaps, detergents, fragrance, or lotion, and food allergies, No outdoor activities. She has contacted her PCP and started prednisone 60 mg x 1 on 12/23/2020 - taper to 10 mg Total of 6 days treatment. Also, taking Benadryl 25 mp po q 4-6 hours per pcp. Her facial swelling is improving but not completely resolved. Has a FU appt with PCP .

tingling around body, episodic low-grade joint pains, low-grade foot pain in left foot (resolved), moderate dizziness, pain around head, pronounced left hand weakness, difficulty with daily tasks/had to leave work.

COVID19 Pfizer vaccine given at 10:30am on 12/26 12/27: Itching to left arm and hand at 430am- no treatment Continued itching with swelling of left arm/hand- Benadryl oral at 1230pm 12/28 3:30pm observed swelling to both legs, left leg more than right- leg elevation and rest 12/29 Reduction in swelling, Itching resolved.

Fever 101.1 x 1 day headache x 1 day muscle aches x 3 days fuzzy head x 3 days

patient stayed here for 15 minutes and did well. She went back to her job and developed flushed feeling, hives on neck and tingling on tongue. She improved with no treatment.

Mild Headache remaining

SNEEZING, STUFFY NOSE, LIP SWELLING, TINGLING MOUTH, THROAT CLOSING, UVULA SWOLLEN 1. Allergic reaction (Allergy, unspecified, initial encounter) . Pt. received Moderna COVID vaccine the morning of 12/22/20 and developed angioedema reaction the afternoon of 12/23 Vaccine is only new medication reported by pt. - denies any new products, foods, etc History of hives with spironolactone 2.5 months ago; taking HCTZ now - unknown if reaction is related to this med rather than vaccine? Due to severity of her reaction and uncertainty if all attributable to vaccine versus some other culprit I would recommend Epi pen at time of discharge Has received IM epinephrine, racemic epi neb, Solu-Medrol, Benadryl, Pepcid in the ED Continue with Benadryl 25mg IV q6h, Pepcid 20mg IV q12h, and Solu-Medrol 40mg IV q6h 2. Angioedema (Angioneurotic edema, initial encounter) . Arrived to the ED with R. side lip, tongue, and uvula and oral cavity edema Airway patent, room air O2 sats WNL - monitor throughout the night for any worsening of angioedema or airway involvement Treatment as above

Recipient received her vaccine and was sitting for observation when she reported feeling light headed about 5 min after the administration. 30 seconds after recipient became unresponsive and stopped breathing for 15 seconds, legs were elevated Code blue was called, after about another 30 seconds recipient become aroused and coherent. Vitals were taken- pt. was tachycardic- 120s- came down to 80s, BP 120/80, 90% O2-eventually went up to 98%. Temp 97.3. Med cue was called and took over to evaluate Pt. Pt. did report has had hx of vasovagal syncope.

Atopic reaction. Itching to Left arm, back, head.

Person had tingling and numbness of upper and lower lips, fullness feeling 10 minutes after vaccination given. vaccine given at 1402, started feeling the tingling at 1412. Lips were not swollen. No swelling of tongue. Oxygen sat 99% throughout the event. Blood pressure 150/88. Alert and oriented, injection site not swollen or red. Given Benadryl 25 mg orally at 1415. At 1430 patient feels like the numbness and tingling are getting better.

Metallic taste and dryness in mouth and burning in tongue

Pain at Injection Site

Approximately 30 min after injection pt reported burning in her throat, numbness and swelling of her tongue. At no time did she report shortness of breath. Vital signs were acquired , pt stayed in our vaccine clinic for approximately an hour without improvement and was then taken to our ER to be further evaluated

WOKE UP SNEEZING, RUNNY NOSE, TEETH HURT; SAT/SUNDAY. MONDAY CALLED PCP. PHONE VISIT WITH DR, BROUGHT IN FOR TESTING.

hypertension, tachycardia, lightheadedness, anxiety

Patient reports severe fatigue. Reports unable to walk across room without feeling like his body was giving out.

Had mild chest tightness 10 minutes after vaccination that resolved 10 minutes later. No shortness of breath, no swelling

Nausea, Pain at injection site

Excessive Sneezing, Sore Throat, Headache, Stuffy/Runny Nose. Symptoms started around 6:30pm and have continued through Sunday to Monday and are still on going.

Patient experienced pain at deltoid injection site which extended up to neck. Also report night sweats and rigor. Symptoms have resolved by 12/28/20.

Foreign body sensation in throat. Symptoms resolved and patient was discharged from ED after Benadryl and oral steriods

Eye hurt with pressure Headache body aches Chills Freezing

Headache, arm soreness

Fever, chills, body aches, headache, fatigue, and vomiting

"Headache, lightheaded, nausea, dizziness, muscle aches, malaise, and chest ""squeezing"" prior to syncopal episodes x 3. This occurred in OR where she works. ""I don't know when I passed out."" Rapid Response called s/p sternal rub by MD not effective. Taken to ED via stretcher. In ED, had EKG, IV fluids, Benadryl, and Phenergan. Regained consciousness on arrival to ED. Cleared to return to work on 12/24 by MD in ED. Will follow up with PCP."

Redness and firm area of swelling onset few hours after vaccine, at maximum erythema 25mm, swelling 20mm diameter. Headache reported day of vaccination and 2 days after vaccination, relieved by Tylenol and Benadryl. At day of reporting VAERS, pt vaccine site remain swollen/firm, redness improved but still present.

I had some of the normal side effects: Nausea, body aches, headache, HOWEVER!! the very strange side effect was this: I received the vaccine in my right arm since I am left handed. The following day, the entire right side of my head (the scalp) was burning and painful like a had gotten a bad sunburn. This lasted for three days, with improvement on the third day and my left side of the head being very sensitive. There was absolutely NO pain or burning on the right side of my head (scalp).

Pain at injection site

Patient described feeling light headed, nauseated, dizzy. She developed hypertension and HA over time frame of 5 minutes after vaccine to 1 hour and 30 minutes after vaccine up to a BP of 201/115. Range of BP was 163/94 up to 201/115 with HR 76-89, Patient was alert, oriented, able to move all extremities, transfer to chair and respond appropriately. Major complaint was feeling dizzy and nauseated with feeling of HA emerging.

the night of the 18th my right eye was bothering me so I was itching it in my sleep, when I woke up on the 19th my eye was red and I thought I had injured it in the night and it bothered me all day but I didn't get it checked, I went to urgent care the 20th because I noticed there were vesicles on my right eye. they gave me eye drops and diagnosed me with HSV keratitis, Valtrex was also prescribed trifluridine. I feel almost completely recovered

approximately 5 hours after vaccine the patient developed chills, body aches, cough, head pressure, and the sensation of feeling flushed.

12/20/20 FEVER 102, NO APPETITE, WEAK, VOMIT ONE TIME

Patient felt a sudden severe headache around her forehead, around her eye sockets. When she stood up, the pain worsened. She also felt very weak, but not dizzy or feeling like she was going to pass out.

I woke up at 7AM having migraines, chills, nausea and severe migraine. Contacted PCP for prescription.

Syncopal episode the following morning after received the first COVID19 Moderna vaccine

12/24/2020 COVID Vaccine received (IM injection, L deltoid), 12/25/2020: started with ONE hive on the abdomen 12/26/2020: started with full-body hives (pruritic) without mucosal or face involvement, no respiratory symptoms, no fevers, no swelling - itching improved with Benadryl 12/28/2020 - contacted employee health who said to contact MD; recommending daily Zyrtec with Benadryl at night and steroids if no improvement

Emesis

Reported tightening in face/jaw after vaccine. Subsided on its own with no treatment.

itchiness around the neck

Headache, Pain at injection site

Today fever with muscle and joint pain and fatigue.. feel so run down

Patient started feeling flushed about 30 min after vaccine and developed a headache about 6 hours after vaccine. The morning following vaccine her headache continued and her blood pressure was 168/90. Day 3 168/106 . Day 4 170/106 and has stayed elevated since vaccine given. Her BP was 154/70 in office today - 5 days after vaccine. She is no longer having headache or flushing. Her normal blood pressure is 110-120/70. Last elevated BP in office was in 2012 at 140/88.

Injection at 1109. At 1135 c/o of itchiness of hands and forearms. No other complaints. Benadryl 25 mg given orally. Improved--returned to workplace. At 1250 c/o of worsening symptoms. Tonsils mildly swollen and mildly erythematous. No significant swelling fo tongue and no difficulty swallowing. No redness of skin and no rash noted. Heart rate 118. B/P 118/78 Respirations 18. Oxygen Saturation 100% on room air. I made the decision to send her to the local hospital ER at 1305 as a precaution. At 1408 in ER she received Benadryl and Epinephrine. At 1428 she received solumedrol and Pepcid. Being observed in ER for 4 more hours.

15 min after injection-flushing, heart rate increase. 30 min some lip itching that went away within 30 min. Took Tylenol in morning (12-17)because started having a few muscle aches. Around 10 am- muscles tightening and needed to stretch them most of day. Fatigue but mild. Mild nausea about 11 am . 5 pm chills started. Ibuprofen taken. Muscles aches continued overnight Dec 17 until 10 am 12-18/ Ibuprofen in morning. Mild fever Friday 12-18--99.1-normal temp 97. Next 2 days mild fever continued and normal Monday 12-22. Muscle aches declined and gone 12-21. Heart rate has remained higher than normal since 12-16--normal is low 70's and has been high 80's and low 90's.

Patient reported numbness and tingling in lips and fingers on right hand at 5 minutes post vaccination. She was taken to the Emergency Room by Employee Health Nurse (walked) where tingling/numbness in lips had resolved upon arrival to ER and was decreasing in hand. She had full resolution after 1.5 hours. She was observed for 2 hours, no interventions, symptoms resolved, and then she returned to work.

Tingling in left hand for about 30 minutes Tingling and numbness in lips. Its been a couple hours now, and it feels like it might be starting to subside.

Tingling, Facial flushing, Felt like throat was swelling, Painful in injection site.

Tightening in face/jaw after vaccine. Subsided on its own with no treatment necessary. Somewhat red cheeks.

Patient reports tingling sensation on the right side of head and transferred to the back of the head. Reports knee joint, everything on the right side. Reports right side of body is either feeling pain or tingling sensation.

96hrs following vaccine (12/25/2020)developed acute submandibular gland swelling Visited physician (12/28/2020) performed ultrasound; dx acute Sialadenitis; rx Augmentin

Started plaquenil 12/18 due to new diagnosis of undifferentiated connective tissue disease per rheumatologist. Noticed itching and slight rash. Received Covid Pfizer BioNTech vaccine on 12/22. Rash became increasing worse each day starting 12/23, facial swelling 12/25 and 12/26. Hives in throat

12/26. Hives on tongue, continues head to toe hives and extreme itching 12/29. Last dose of plaquenil was 12/22.

Pain at injections site

Moderna COVID19 Vaccine EUA Metallic taste appeared within 5 minutes of dose. Smell and other taste not affected. Very subtle metallic taste right after injection

Five hours after mild arm soreness, mild chills and day two I was lightheaded

12/21- Vaccine administration 12/22 @ 12am Sore at injection site 12/22 @ 9pm soreness at injection site subsides 12/26 @ 10am severe headache and muscle aches; not relieved with Tylenol; cough, stuffy nose 12/27- headache and muscle aches still apparent, but moderate; not relieved with Tylenol 12/28- headache and muscle aches still apparent, mild.

Heart palpitations, shaking and feeling of adrenaline rush.

12/25/2020 EE states that she started experiencing right ear pain, she has ear frequent ear infections and used her prescribed eardrops for the pain, the pain was not resolved so she took Ibuprofen which helped with the pain. 12/26/2020 EE states that the right ear pain was resolved however, she developed an itchy rash on her right ear and down the right side of her jaw. She took oral Benadryl and used Benadryl ointment to relieve the itching. EE states that she went to her ENT today, 12/28/2020 to discuss her symptoms. Her ENT stated that it may be caused by the vaccine but he was unsure. There was no infection found in either ear. ENT treated it as a fungal infection. EE received steroids for her ear and jaw rash. EE doesn?t report any other symptoms, never tested positive for Covid, never been exposed to her knowledge, no travel history.

Received vaccination early morning (around 7 am). Headache started approximately 5-6 hours post vaccination and continued off and on for 72 hours. Explosive diarrhea approximately 18 hours post vaccination.

Received vaccination early morning (around 7 am). Headache started approximately 5-6 hours post vaccination and continued off and on for 72 hours. Explosive diarrhea approximately 18 hours post vaccination.

Individual was under 18 years of age

12/25/2020 felt funny. 12/26/2020 developed fever of 102, chills and body ache.

Feeling in her arm at the injection site, the pain kept getting worse. She couldn't even move her arm. around 8pm, she started getting chills, no fever with chills. Felt really cold. On the injection side she had pain in her neck and her shoulder blades. Body Aches Feeling fatigue Headache tired Took Ibuprofen around 9pm Stomach cramping and nauseas As of the 28, she is feeling fatigue and still has pain in her arm where the injection site is.

reports rash on back of R hand that started on 12/23 and spread to L hand, face, breast area by 12/26, went to urgent care on 12/26, dx with hives, placed on prednisone, advised to f/u with PCP to document.

Developed a fine maculopapular rash along b/l anterior upper & forearms. Some scattered on posterior, on 12/23/20. Mostly non-pruritic, except after shower on the 1st day. Took Cetirizine on 12/23 with some relief. Dues to persistence on 12/27/20 repeated cetirizine. Photos available.

Patient describes pain at injection, itchiness and experiencing pain. This hasn't had pin since but it did happen within 12 hours of injection

Pain at Injection site

States bruising shortly after injection. States on Dec. 27th around 4pm, developed redness 3-4 in x 2 in with lump (approx 1/4 in diameter in center). Area painful and warm to touch which affected ROM. On 28th states that he showed to a pharmacist that he works with Dr. who said it appeared to be an injection site reaction. At 4 pm on 28th, states bruising improving, but redness is still present, maybe even increased from earlier.

Pfizer-BioNtech COVID 19 Vaccine Left arm pain, mild to moderate from the time of receiving the shot until the next morning at which time left arm pain began to improve. The following morning, woke up with a fever of 102F, intermittent fever all day ranging from 99.9 - 102F. Dulled sense of smell and taste since the injection. Decreased appetite.

Reports that within 24 hours after receiving vaccination had a splitting headache, fatigue and was barely able to lift or move his arm that the injection was administered. The injection site was red and hot to touch, very painful and swollen. After 24 hours the pain started to radiate into that side of his neck as well. He then felt feverish with chills and was very fatigued and unable to get out of bed for 2 days. Also developed diarrhea in that time frame.

After administering the vaccine the Luer Lock needle fell off of the syringe. The nurse stated that a lot of vaccine ran down my arm and was not administered.

I became nauseated and had abdominal cramps for three days.

Headache, dizziness, shortness of breath

Pain at Injection Site

42 year old female who works as a pharmacy tech developed diffuse pruritus and throat tightness, nausea during her wait time. She was given EPIPEN and transferred into the treatment area. She was given 50mg benadryl x2 followed by an additional EPIPEN. Patient reported throat tightness resolution but persistent pruritus and nausea. She was transferred to ED in stable condition with plans to follow up in Allergy.

Pfizer-BioNTech COVID-19 Vaccine: Approximately 90 minutes after receiving vaccine patient returned to clinic reporting dizziness, flushing, nausea, claminess, and hot flashes. Initial blood pressure 133/97 mmHg, other vital signs reported as stable. Patient provided with ice pack, water, and snack. Patient was observed for one hour and symptoms improved. No loss of consciousness or respiratory symptoms reported. Patient left clinic stable.

Moderna Covid-19 Vaccine Patient started vomiting 6 and half hours later, staff reported it and we are reporting it as an ADR

"December 23, 2020, at approximately, 1645 patient noted right eye numbness that tingled into right cheek. At 1730, looked in the mirror and noted no movement in muscles on right side of face. Could raise right eyebrow, but right eyebrow and below numbness and no movement. Patient spoke with physician at Public Health Department and it was recommended patient go to Primary Care to see provider NP. Then at approximately, 1920 went to the local Emergency Department and was seen by Dr. in the ER department. Dr. consulted with on call neurologist. Patient states she was diagnosed with Bells Palsy and given oral steroids (""three pills), then started a Medrol Dose Pak the next morning. As of today, December 28, 2020 patient reports ""Face and eye area feel normal. My mouth is not drooping. I have at least 50% of my movement back."" Patient continues to take Medrol Dose Pak. On day 4 of Medrol Dose Pak has 3 more days. Emergency Department recommended patient follow up with pcp in 5-7 days."

Injection site pain.

"Given vaccine at 1352 on 12/28/2020, employee reports symptoms started almost immediately. Symptoms: tongue felt ""funny"" describes as tingly and thickness feeling that extended down to throat area. Employee did not report symptoms immediately-waited about 30 minutes to notify staff. Vitals taken right away: B/P 138/80, Pulse 64, Respirations 18 at 1425. Given Benadryl 50 mg orally, employee able to swallow. Refuses Epinephrine stating she can still breathe fine, still able to swallow and knows Benadryl will be able to help. Monitored x 30 minutes longer=stayed total of 1 hr post vaccine. Started feeling improvement at 1450 and by 1510 felt significantly better, vitals stable and was released. Aware that benadryl can cause drowsiness and she should not drive. Employee stated she was ""just fine""."

Shortness of breath starting 12:50 on 12/22/20 lasting up to the 5pm hour. Shortness of breath. Monitored O2 sats and deep breathing supine on sofa. Sats stayed in 90s and only for about a 30 min period, sats dropped to 88-93 percent.

Anaphylaxis symptoms starting about 45 minutes after injection. Initial symptoms were severe light headedness and tachycardia. Epi-pen self administered 5 minutes after onset of symptoms. Symptoms resolved within 30 minutes of Epi-pen administration.

Upper shoulder tenderness, appearing days after injection site tenderness fading away, told by coworkers early sign of possible SIRVA.

Patient did not eat prior to vaccination. Felt anxious about vaccine. Felt weak and lightheaded. Patient was brought to ER for monitoring and assessment. Was released back to work without treatment required after a few hours.

Pain at injection site

I am a nurse and I received the Pfizer vaccine on 12/26 at 1030am. I do have a history of food and outdoor allergies. I once got hives on my back from the flu shot, but since have been fine with it if I take Benadryl before it. About an hour after the vaccine, I felt itchy on my upper half of my body. I took a Benadryl without relief. I had a 100.1 fever that afternoon so I took another Benadryl and ibuprofen. It broke my fever, but the itching continued. I also had a couple of hives and a red blotchy rash over my body. I took a hydroxyzine and was able to sleep that night. The next morning I once again felt flushed and itchy. I worked and came home to the same rash, almost mottled looking all over my body. I took a Benadryl and ibuprofen and woke up early this morning itching again. As I was driving into work today (Monday), I noticed my heart fluttering and having palpitations. This continued throughout the morning. My skin rash is still red like I have a bad sunburn all over and is itchy with some red spots. I went to the ER to get checked out. My ekg was normal. They advised me that this is an allergic reaction to the vaccine and to continue 50mg Benadryl q6h for a couple more days and to see a PCP for follow up if it?s not better. I never had respiratory issues or swelling. I will continue to monitor symptoms and reaction.

"Patient received Moderna COVID-19 vaccine and within 5 minutes patient complained of fast heart rate and feeling ""not right"". Patient blood pressure at time 156/88 with heart rate 114. Patient given cool rag and then complained of tingling to her arm and hands and numbness to tongue. Patient was taken to Medical Center Emergency Room and given Epinephrine 0.3 mg per Auto-injector. Patient was then given Solumedrol 125 mg and Bendaryl 25 mg slow IVP. Patient observed in the ER and didn't experience any rash or swelling of lips and/or tongue."

Student went to administer vaccine. An unknown quantity of vaccine leaked out of the hub of the needle and dripped down the patient's arm to the floor. The exact amount given is unknown. Call has been placed to Moderna and CDC for guidance in regards to redosing.

Metallic taste was reported ten minutes after vaccination. Staff reported the reaction was fleeting (seconds long). Patient reported eating dehydrated strawberries just prior to vaccination but not sure if reaction was food related or vaccine related. Onsite MD assessed patient. No angioedema, respiratory distress, or any other complaints. Staff reported being back to baseline quickly after fleeting metallic taste.

Immediately after the vaccine administration had elevated heart rate, dizziness, difficulty breathing. Given a 2 doses of albuterol to help with breathing and transported to ER. Nearly 5 hours after visit, manageable but still difficulty breathing.

Dizzy and Nausea

patient felt a thickening in her throat. Throat also felt sore. IM Benadryl administered. Patient reported feeling better quickly. Monitored for an hour post benadryl.

39 y.o. firefighter, healthy without significant past medical history. He has a hx with cashew allergy in the past (required Epi pen use). He felt light headed, flushing sensation, and mild itchiness on the arm. His light headed felt worse and laid on ground. He remained alert and without apparent distress. There was no respiratory or cardiac complains. Vital signs were normal, O2 sat 100% on RA, BP 119/77, pulse 65, EKG NSR. Paramedics and his colleagues were present and assisted. Benadryl 50 mg IM once was given around 1300 pm. An IV 18 G was placed by paramedics to his right AC and NS tko. Patient left via ambulance.

Nausea, Cold fever, upset stomach, no appetite, pain, headache, vomiting, sore arm

Generalized itchiness, intermittent trunk hives and injection site herpes zoster-like rash. Benadryl 25mg tablets q4-6 prn with moderate relief. From onset (day 2 post vaccination) until present (day 7 post-vaccination)

Reported metallic taste in mouth 5 minutes after vaccination (vaccine received at 11:07 AM). By 11:37 AM, the metallic taste was still present but improving. Staff denied unusual foods prior to vaccination. No other signs/symptoms reported or found when assessed by onsite MD.

Moderna COVID-19 Vaccine EUA Severe sinus reaction - sneezing, congestion, runny nose, chest pain from excessive sneezing.

Body chills, site pain, nausea, and severe headaches.

Patient is a 60yoF who is presenting to ED on 12/28/20 complaining of decreased sensation and itching on left side of face as well as darkening of peripheral vision on the left side. She received her initial COVID vaccine today at 11am, first began noticing symptoms at 1230 and took 2 benadryl around 1pm. In addition, she is reporting some light headedness. She states that her face feels swollen, but knows that it is not. Itching improved after benadryl but face continues to feel numb on left side.

soreness of arm, dry throat

generalized malaise, weak, body aches.

Vaccine administered 10 am 12/26/20. Post vaccine experienced headache, sore arm and fatigue. Approximately 6 hours post injection developed a hot feeling like she was sunburned, pruritis and then a pepper rash/hives started to develop inferior to injection site on right arm, spreading to left arm, chest and neck. Went to ER and treated with IV steroids, diphenhydramine, and hydroxyzine. Discharged on a 5 day course of Famotidine, Hydroxyzine Pamoate, and Prednisone with PRN Diphenhydramine.

chills, slight fever (99.5) and some muscle aches in legs.

nasuea, emesis, throat irritation, hot/cold flashes. The individual was transported to the emergency department for further observation and if necessary treatment.

Injection site pain, Head to toe muscle pain, Joint pain, general unwell feeling

Approximately 5 minutes post vaccine administration, pt reported shortness of breath and chest tightness. Vital signs remained stable BP 100/65, O2 sat 97%, HR 80-100, respirations easy and unlabored. Pt also experienced nausea without vomiting, and possible tightness in the throat, and numbness in the left arm. No swelling, no redness, no rash. EMS was called, EKG showed NSR, pt was transported to the hospital via EMS

Swelling in right axilla, called PCP, no treatment

My left are fell asleep and numb, decreased motor functions and then the tingling sensation moved to my left eye, lips and whole face, left lower leg and right hand. It progressed for an hour or two and then went away. Employee health sent me to the ED for observation. I am due 08/01/2021.

Initial sore arm with associated chills. As day progress worsening generalized myalgias, chills and sweats, mild weakness with position change on standing. Eventually with 10/10 frontal headaches and rigors. Full course lasted ~30 hours.

Headache, fatigue, body aches, sore throat, ear pressure COVID 19 Swab-Neg.

I received the Covid19 vaccine on 12/22 @ 7:00 pm. On 12/23 ~1200 pm, I had a headache that lasted for about 12 hours. I took Tylenol and Motrin and it went away the next day but came back again on 12/24 @ 6:00 pm. On 12/25, 12/26, and 12/27, I just felt unwell. No symptoms but felt unwell and had shortness of breath while walking. I usually walk about 10 miles daily without issue but on those 3 days, I had to take breaks and was not able to walk an talk at the same time.

Woke up with severe nausea 5 days after vaccination. Thereafter, developed lower abdominal pain and constipation. Took a dulcolax that relieved constipation. Then developed retching, vomiting and cramps abdominal pain

Within 2 minutes, Severe allergic reaction, with diffuse erythematous rash, throat tightening, chest discomfort, nausea, and BP240/120. (Normal BP 124/74). Had premedicated with 50 po benedry. Required 50 mg IM benedryl, ambulance ride to the ER, 125 mg of IV solumedrol.

Staff reported a mild tingling in right hand (of injection arm). The tingling lasted for a short period of time and went away once he put his hand in a neutral position. No other signs/symptoms reported when assessed by the onsite MD. Patient was advised to avoid heavy lifting and to seek medical attention if symptoms worsened. Mild to no residual tingling noted at close of observation period (30 minutes).

Weakness, headache, arm ache, back pain, unexpected heavy breakthrough bleeding and cramping LMP was 12/13/2020 not expected to bleed until 01/10/2021

Pfizer-BioNTech COVID-19 Vaccine: One day after receving vaccine patient awoke with myalgias, fatigue, fever (maximum temperature: 100 degrees Fahrenheit), headache, and rhinorrhea. Patient was

evaluated via telehealth two days after vaccine administration and denied throat pain, chest pain, chest tightness, or wheezing. No difficulty swallowing or breathing. Patient was instructed to follow-up with a health care provider immediately for worsening, persistent, or concerning symptoms.

I have history of intermittent episodes of neurological dysfunction, with probable diagnosis of FND. I was symptom-free prior to vaccination today. Within 20?30 minutes my left arm (injection site) began to ache. Shortly after that my face began tingling and my thinking began to feel ?foggy.? By one hour post injection, I was having trouble speaking and walking. These are not brand new symptoms for me, but I do feel the vaccination caused a flare of my dormant symptoms.

Patient reports 2 minute episodes of numbness to hands and feet occurring every 5 minutes s/p receiving COVID-19 vaccine. She further reports associated heart pounding and difficulty breathing General ROS: (-) chills, fever, (-) unusual fatigue or weight loss ENT ROS: (-) nasal discharge, (-) cough, (-) sore throat Respiratory ROS: (+) shortness of breath CV ROS: (-) chest pain, (+) heart pounding Gastrointestinal ROS: (-) abdominal pain Genito-Urinary ROS: (-) dysuria Musculoskeletal ROS: (-) joint/bone pain Neurological ROS: (-) headache, (+) numbness to hands and feet Dermatological ROS: (-) rash Psychiatric: ROS: (-) SI/HI, (-) psych hx Patient improved her symptoms, discharged home

Headache, itchy, joint pain, nauseated, vomiting only twice, body aches, chills, slight fever nothing over 99.3,

generalized malaise, weak, body aches

Headache, extreme fatigue

Difficulty breathing 5 minutes after receiving first dose of Covid-19 vaccine by Pfizer/BioNTech, small erythematous spots to bilateral arms.

Developed a rash on face, neck, arms, stomach ? slight sore arm at injection site

"Initially reported an ""unbrushed teeth"" taste in mouth post-vaccination and for 5 minutes afterward. Reported he did indeed brushed teeth this morning. Unusual taste lasted 10 minutes. Reported no unusual foods consumed prior to vaccination. Onsite MD assessment reported slight headache but staff had prior to vaccine injection, not worsened. However, he has had history of headaches with vaccines. Some tingling also reported in left arm (vaccinated arm). Denied other signs and symptoms. Resolved symptoms after 30 minute observation period (post-vaccination)."

On 12/23 reports feeling fatigued all day. At approximately 4:30 pm on 12/23 began having fever (100.4), body aches, and headache. These symptoms subsided at approximately 11:00 pm on 12/23. On 12/24 had no symptoms and felt fine.

"After receiving vaccination, the staff reported ""cold sweats."" He went home sick after receiving vaccination."

Injection site Pain

Became very flushed in the face. Dizzy and nauseous & felt completely out of my normal. Received a rash all over my upper body. Rash remained until 12/26/2020. Benadryl and Tylenol used. Refuse to get 2nd dose and received documentation for this. Components in vaccine are bothering me and I will not put my body through it again.

fever/chills

Flushing, heart beating fast, pulse ox 96% hr 13-114 . kept for observation 45 min felt well when left pulse ox 99% hr 110.

33 y.o.ámaleáwith no significant past medical history except for obesity who has been working as a nurse in the emergency room department in our hospital and today he received COVID-19 vaccine and 30 minutes later patient started having increased saliva, cold hands and feet, left-sided pressure-like headache and some numbness in his legs at the same time he suddenly started talking only in first language and lost his ability to speak in second language. áHe understand second language but replying first language stating that he is talking in second language. áOn exam he was alert oriented confused by people not understanding his second language stating that his numbness and cold feeling in the hands and feet have improved. áInitially patient received 10 mg of Decadron for possible allergic reaction he had a head CT scan that was negative and his labs were remarkable only for hypokalemia. áPatient had no prior history of any neurological symptoms he was advised admission to the hospital for observation á á Patient symptoms resolved next day,he is alert oriented able to communicate in second language he had a head MRI and head neck MRA that came back negative and had an EEG that showed no seizure activities. Patient was seen in neurology consultation who felt that patient most likely had an episode of migraine headache. Patient is going to be discharged home and to have a follow-up with his primary care physician next week á

Throat itching and tongue swelling

Pt c/o itching at site of injection and back. Denied SOB. Hives, redness at site. Diphenhydramine 25mg po given at vaccination site. Transferred by EMT to ER. At ER, patient given Prednisone 60mg, additional diphenhydramine 25mg and famodidine 40mg. Recommended she take Prednisone x 2 days and diphenhydramine x 24hrs. Patient was discharged to home within one hour.

I had the typical local reaction for the first 3 days following the injection: redness, soreness, swelling at injection site, occasional itchiness and occasional burning, warm to touch. It was resolved by the 4th day. Then on the 8th day, I felt a little itchy and itched the site gently. Three tiny hives appeared and became a moderate-sized red swollen area by the evening with mild pain and some burning. The 9th day it was very red, moderate-to-large sized, some burning, warm to touch. The 10th day, today, it doesn't look angry anymore, is no longer warm to touch, looks like it's resolving but still some swelling that feels like it goes around my upper arm. I had it checked by an NP today and she thinks it's all related to the injection being administered lower than my deltoid, instead went into the subcutaneous/fat area. So we will watch it but she doesn't think it's infected or any reason to not take the 2nd dose when it's time.

Pain at Injection site

Nausea, vomiting, chill, headache. Lasted more than 2hrs. Taken to ED and treated for nausea and rehydrated.

Patient had a vaso vagal event, per the ED notes. Drop in blood pressure and had a fainting spell. Quickly improved after he arrived to the ED

None

Pfizer-BioNTech COVID-19 Vaccine: Patient reported dizziness and shakiness upon arising 15 minutes after receiving vaccination. Vital signs: blood pressure: 115/78 mmHg, pulse 73 beats per minute, temperature 36.8 degrees Celcius, respiratory rate 16 breaths per minute, oxygen saturation 99% on room air. Patient waited five minutes, stated she felt much better, and left vaccine clinic in stable condition. No respiratory symptoms or loss of consciousness reported.

Heart racing (Patient reports pre-existing heart condition) Soreness Aches

Swelling of the lips

Chills Rapid heart beat dizziness Onset of symptoms was within 5 minutes but were mild and subsided after approximately 20 minutes

Nausea, Headaches, Fatigue

Started with very bad cramps which lead to diarrhea, that lasted about 1 hour. Then my SI joint started hurting so bad I couldn't stand it and went to ER. They gave me a shot of Torridol and a prescription for Naproxen. I was also nauseous, lethargic, chills, ringing in my ears, headache . I believe my SI joint started hurting due to having arthritis in the joint. The Naproxen escalated all the above. My arm also very sore, but that I could deal with. Feeling a bet better by 12/28/2020. Going to try and get into doctors on 12/.

low grade fever and sore arm

Headache, strange eye feeling, floaty, dizzy, light headed.

She began to experience body wide tingling, headache and nausea. She did not have lightheadedness, chest pain, shortness of breath, pain at the injection site, rash or wheezing. She went to urgent care in the facility to be evaluated. Patient was placed on a monitor and observed. Vital signs remained stable. She never developed rash. For her nausea she was given Zofran 4 mg as a disintegrating tablet which was helpful. She received 650 mg of Tylenol for her headache pain. Observation continued during which time she was entirely stable. She requested to go home.

Felt like she was breathing fire, flushing, pain ran up left arm to neck, clavicle, joint pain muscle ache, chill, fatigue, swelling under left armpit. Tingling to the face, ringing in ears from covid got worse, neuropathy real intense.

Headache, Tired, Injection site pain

After I received the vaccine my arm was very hot and swollen. Also felt very fatigued, dehydrated, no fever.

Started to feel very dizzy about 3 hours after vaccination. Also felt some nausea and overall head felt very off. Very lethargic and spent many hours sleeping because of the extreme lethargy and woke up a few hours later, still experiencing some dizziness but not as severe as earlier. Also have mild headache but I chronically suffer from migraines so that is nothing out of the ordinary for me. Took one meclizine and two Tylenol after onset of symptoms. Symptoms are tolerable at this time, they were more debilitating earlier. I am still experiencing them now at 6:30 pm.

Phizer-BioNTech Covid-19 Vaccine EUA Nausea and fatigue beginning about four hours after administration. Diarrhea beginning about six hours after administration. Vomiting and chills beginning about eight hours after administration.

WARM SENSATION/FLUSHING ROLLED THROUGHT BODY FROM HEAD TO TOE. FELT DISORIENTED. ABLE TO WALK. DENIES DIZZINESS. THEN FELT TINGLING TO FINGERS ON LEFT SIDE. SYMPTOMS RESOLVED AFTER 5 MINUTES.

Headache, weird eye feelin, like fuzzy headed too

"Approximately 15-20 minutes after vaccine patient reported back to adminitration area complaining of a ""lump in her throat"" with halo vision. Administered 50mg oral benadryl. Patient report nausea and felt flush and lightheaded. Approximatly 20min after benadryl administration she felt better and was able to return to work."

"Approximately 15-20 minutes after vaccine patient reported back to adminitration area complaining of a ""lump in her throat"" with halo vision. Administered 50mg oral benadryl. Patient report nausea and felt flush and lightheaded. Approximatly 20min after benadryl administration she felt better and was able to return to work."

Reported diffused rash to chest and back ~2 hours after recieving Pfizer COVID-19 vaccine on 12/18/2020. Self-medicated with famotidine40 mg, cetirizine 10 mg, and Singulair 10mg at home. Rash improved next day,

Swollen lymphnodes on same side as vaccination site

BAD HEADACHE BEHIND LEFT EAR AND TOP OF HEAD TO RIGHT EAR

Patient complained of feeling dizzy. She had blood pressure checked and it was elevated. Blood pressure did decrease after 15-20 minutes. Patient was observed by 2 local staff nurses and myself. She was counseled to speak to her primary care physician as soon as possible. She was walked to her vehicle by nursing staff. The vehicle was driven by her sister. An administrator at the facility did inform me at about 5pm that patient was at home safe and feeling better

Dec 23 started having right side facial tingling, slight numbness, decreased sensation. Headache, fatigue. This facial symptoms came and went away daily in short intervals. On 12/27 I got dizzy, weakness, blurred vision, right face numbness, slight lip drooping, high blood pressure, trouble swallowing, tongue numbness on right side, and right arm tingling. Went to the doctor on 12/28 and got steroid treatment from being diagnosed with Bell?s palsy, and a ct scan that didn?t show anything abnormal.

I received the vaccine around 7:55 am in my left arm. I waited around the appropriate time then drove home. No problems until 12:30 or so. I was resting in my bed and immediate felt my heart start to race. I checked it with my pulse oximeter and my rate had shot up to 148. I got up and tried some maneuvers to try to get it down. It then went up to 152. I told my husband to call EMS. I also contact my co-worker. She is a physician and she agreed with taking some benadryl. I took 25 mgs of benadryl. EMS arrived about 10 minutes later. they monitor my blood pressure and heart rate. it did come down but remained around 100. I then went to ER by car for evaluation.

Patient developed intense itching 10 minutes following the administration of the COVID 19 vaccination while waiting in the post vaccination recovery area. Emergency personnel present, PO Benadryl and Epipen administered. Patient sent to ER via ambulance for observation.

shortness of breath, diaphoretic, heart racing

Patient reports taking Pfizer Covid vaccine and 2 hours after that she reports feeling not well. She recorded that one of the side effects was heart arrhythmias and hence she had her coworker checked her rhythm and she reported that her heart rate was in 180s and hence she was brought to the emergency department for further evaluation. She reports at the time she had palpitations and felt mild lightheadedness and dizziness. She was found to be in SVT with heart rate in the range of 1 80-220 and she received 1 dose of 6 mg Adenoscan after which she converted to normal sinus rhythm. At the time of my evaluation she is in normal sinus rhythm with heart rate in the range of 90-100. She denies any further palpitations. She reports she had chest tightness for the last 3 days which was assumed to be secondary to asthma and for which she was prescribed prednisone. Currently with the prednisone she does not feel any further chest tightness. She denies any chest pain shortness of breath, fever or chills. She reports remote history of arrhythmia following her foot surgery in the past however does not recall what arrhythmia she had at that time.

Cold sore on lip - used OTC abreva, it is still healing. It has been years since I have had a cold sore. I am not sure if it is related to the vaccine, but thought I should report it for more information.

Vasovagal syncope episode occurred right after receiving the Pfizer COVID-19 vaccine injection, patient became pallor, not diaphoretic, no c/o CP nor SOB, patient felt dizzy, HR in the50's, BP 78/50, glucose = 91, pt given water and OJ. After fluids pulse was stronger, bounding in the 60's, color improved, patient was still feeling faint, taken to cardiac intervention area to lay down, patient refused to go to ER, RRT paged and came to pod - escorted patient to lay down. Of note the patient only had 1 egg for breakfast. Patient continued to be pale, starting shaking and was escorted to the ED for IV fluids and monitoring.

Rash, hot sensation, anxiety Localized reaction in arm, hot, red, swollen

Later in the evening once home, the Eee took Benadryl for initial rash presentation on L arms (vaccination site). Took tylenol next AM for chills, body aches. hives spread to chest. Took more tylenol for itchy, burning sensation. On 12/24 Thursday she noticed new SOB, 101.7F, hives all over the body, Went to a local ED and got solumedrol, famotidine, benadryl, tylenol, IVF. DC'ed from ED on prednisone, benadryl. Had h/o COVID 4/2020.

Dizziness

65 YEAR OLD MALE PRESENTS TO THE EMERGENCY ROOM COMPLAINING OF COUGH WITH CLEAR PHLEGM AND SHORTNESS OF BREATH ONSET 8 DAYS. HE REPORTS SOME CHEST PAIN WITH COUGH. PATIENT REPORTS HE WENT TO SEE HIS PCP ON 12-DEC AND WAS PRESCRIBED PROVENTIL AND PREDNISONE. HE HAD A NORMAL CHEST X-RAY AT THAT TIME. HE STATES HIS SYMPTOMS WORSENED ON 17-DEC AND HE WAS THEN GIVEN LEVAQUIN. PATIENT REPORTS HIS WIFE TESTED POSITIVE FOR COVID-19 ON 05-DEC, BUT HE TESTED NEGATIVE AT THAT TIME AND HAD NO SYMPTOMS.

Patient reports numbness and tingling in both feet, temporary nausea, Sore throat and loss of voice (hoarseness)

Fever and chills

facial itching, flushed. IM Benadryl admined. Patient felt better quickly.

none

Tingling and numbness back and sides of back 1/3 of tongue

Patient developed a red rash on left arm starting at injection site and moving down arm towards wrist/hand. Patient stated her palms felt clammy and numb. Patient expressed feelings of anxiety.

headache all over head, so very tired, body sore, do not want anything to eat.

Dizziness and Headache that took 25 min. to resolve.

Hives. Vitals checked and BP 134/78, pulse 95, SPO2 99. Lungs clear. hives noted on posterior neck, back, upper arms, thighs. Patient given 50mg Benadryl at 630pm. Monitored x 1 hour. Improved. Sent home with scheduled benadryl. Patient already has EpiPen on hand. Instructed to follow-up with PCP.

Pfizer-BioNTech COVID-19 Vaccine EUA

- Fever, Tmax 101.16 occurred 12 hours after injection, febrile at least 2 hours. Afebrile by AM of 12/25, resolved without antipyretics. - Right arm pain: Onset 12/24, up to 6/10. Resolved by 12/26. - Fatigue: Onset 12/25, resolved by 12/26.

Immediately felt warmth and tingling to Left Deltoid at injection site, then started to feel itching and feeling of swelling to throat and mouth. Denies any SOB. No obvious hives. Treated with Solumedrol 125 mg IV, Benadryl 25 mg IV, Pepcid20 mg IV. Given Rx for Benadryl 25 mg PO every 6 hour PRN.

Left axial lymphadenopathy

100-101F fever and chills started on 12/27 @ 945pm 100-103.0F fever, nausea, vomiting, chills and diarrhea on 12/28 @0900am 103.5F on 12/28 @ 0640pm. Advil and Tylenol have been taken

Tachycardia, warmth and flushed body esp face, mucus production (throat), scratchy throat, tingling sensations in feet, pain in R arm and radiated to neck and L arm, weakness, lethargy, dizziness, nausea, and headache.

About 10-15 min after vaccination patient began to experience left side facial numbness and tingling to include her tongue and cheek

Generalized body rash started ~24 hours later; still has 4 days later.

Extremely sore and painful injection site beginning around seven hours post injection. Painful to touch and movement. Sx lasted approx. 36hrs.

Patient presents to the emergency department 12/26 complaining of dry cough associated with fever and chills and headache associated with myalgia and diarrhea for 1 week duration. She had Covid vaccine 12/20 and the symptoms started the same night, she denied any sick contacts at home however she works at the Covid unit and reports constant exposure to sick Covid patients.

Tachycardia (heart rate 90s-110s), adrenaline rush in chest, tingly in chest and neck.. No treatment. Called employee covid HUB and they sent me to get covid swabbed today (12/28/20) . Called NP and she did not want to see me until covid swab back, symptoms worsen or she told me to go to ED.

Patient began to feel nausea after several minutes and then approx. 25 minutes after vaccine patient began to cough. Patient was transported to ER department on same location as clinic to be monitored by ER.

Became dizzy, warm, tachycardic. Lost consciousness (fainted?), quickly regained consciousness and was taken to the Emergency Department. Before transfer, Benadryl IM 25mg administered.

tiredness began the Thursday following immunization, along with sore throat and sneezing. All symptoms were gone by Friday.

He got the COVID vaccine on 12/23/20 at 11. Stayed at the facility for 30 minutes and then drove to another facility. Upon arrival at 12, he started feeling flushed. No SOB, no breathing difficulties. He started feeling itchy about 2 hours post vaccine. He took an Aleve. At home in the evening, took Benadryl with improvement of symptoms The following day also took Benadryl. On 12/25/20 & 12/26/20 he still had some itching, but not bothersome enough to take medications. On 12/27/20 he was working cutting tile and wearing protective eye wear, but the dust that landed on his face caused hives. He has been taking Benadryl since. He says this has occurred in past when his body is hypersensitive, the hives. He has seasonal allergies but no allergies to food or medications. Case discussed with Bolaris and recommendation is to take a Claritin or anti-allergy prior to next vaccine.

After injection felt immediately tingling to bilat arms, face, swelling to face and tongue, Itchy feeling to chest, feeling of palpitations and general unease. HR was 120 BPM, scattered hives over chest. No appreciable airway swelling. Treated with Epinephrine 0.3 mg IM, Solumedrol 125 mg IV, Benadryl 25 mg IV, Pepcid 20 mg IV, Ativan 0.5 mg IV. Rx given for Benadryl 25 mg every 6 hr. PRN

Red spot on arm with knot

Injection site tender to touch and with movement. Fatigue, muscle pain, joint pain, chills.

Scratchy throat. Bendadryl 25mg PO administered. Observed and discharged from vaccine clinic.

"Approximately 7 hours after receiving the vaccine patient who is a L&D Nurse return to work in her area. She describes that after finishing with a C-section she felt burning in both of her eyes (she thought this feels like an allergic reaction, but I am not sweating and haven't rubbed my eyes). She went to the restroom to get a cloth to wash her eyes; afterwards she reports her vision went totally black in both eyes. She reports feeling frustrated that no one came to help and some panic in trying to figure out how to get out of the restroom. She did make it out of the bathroom. Her Staff reports she postured and turned arms inward, head going to one side and passed out. They also report ~ 10 minutes of incoherent conversation and stating ""I got the vaccine, maybe I was given the wrong thing and now I'm blind"". Upon waking, patient vision fully restored and patient does not remember incoherent conversation. Differential diagnosis- TIA vs. CVA > seizure disorder>>> complex migraine"

Injection site pain and headache Tylenol 1000mg taken

Tachycardia 160-170bpm, anxious, carpal pedal spasm. States she took Zyrtec and inhaler this morning (for asthma). Transferred to outpatient clinic for assessment.

"Patient received the covid vaccine on 12/23/2020. She reported that she had chills (temp was 98.0), sore throat, nasal congestion, sneezing, started on 12/25/2020. Chills (shivering lasted for 1 day and ""broke out in sweats""). Still has sore throat., stuffy nose, sneezing as of 12/28/2020. Denies rhinorrhea, cough, or fever. Had negative covid test on 12/28/2020."

"Pt received Moderna COVID on 12/28/2020 without event. She returned 45 minutes later complaining of chest tightness and ""feeling weird"". A code A was called and she was triaged by anesthesia. No angioedema noted. She was moved to nurse stat bay and 911 was called."

Left flank and back pain thats increasing in severity. It is now interfering with acts of daily living such as driving, bending down etc

Symptoms include, hot flashes. palpitations and shortness of breath five minutes after vaccine administration. Patient was given oxygen and Claritin 45 minutes after. Patient was sent to hospital for further monitoring after an hour of administration.

Pt received the covid-19 vaccine from Pfizer and started to experience symptoms 6 days later. Symptoms includes hives, low appetite, wheezing, coughing, and fatigue.

B/L LEG JOINT PAIN, AND MUSCLE PAIN NAUSEA - DRY HEAVING NECK/SHOULDER PAIN ONSET 12.25.20 DURATION/END 12/.27.2020

Chest tightness and flushing. Transferred to outpatient clinic for physician assessment

"PATIENT BEGAN WITH AN ITCHY THROAT AT 15 MINUTES AFTER VACCINE ADMINISTRATION AND LATER DEVELOPED AN ""UNUSUAL SENSATION"" TO THE BACK OF THE THROAT. EPINEPHRINE 0.3MG ADMINISTERED. IV NORMAL SALINE STARTED. DIPHENHYDRAMINE 25MG IV GIVEN. PATIENT'S SYMPTOMS RESOLVED. TRANSFERRED TO ER FOR FURTHER EVALUATION. CONTACTED ER AND WAS INFOMRED PATEINT DISCHARGED WITH NO COMPLICATIONS."

Dizziness, lower left abdominal pain, flushed, heart palpitations. Lasted so long I had to be seen in the ED. New onset of bigeminy. 5 days later I am still having dizzy, feel foggy in my head, overall don?t feel my self.

SHORTNESS OF BREATH, TROUBLE BREATHING, CATATONIC STATE, POTENTIAL SEIZURE

patient noted headache which started within 15 minutes post vaccination, patient was observed for 30 minutes post vaccination and headache remained but did not worsen. Stated she did not have any dizziness of lightheadedness was going back to work. Advised she could treat with OTC pain relievers

Tingling and numb feeling at back of tongue immediately after injection Weird sensation of lump in throat without anaphylaxis that got better with time

patient reported feeling nauseous and dizzy about 15 minutes post vaccination. Was brought to exam room to lay down, was given some apple juice to drink. Vital signs were checked, patient remained onsite for about 1 hour being monitored. Stated she felt better but was still nauseous when she was released to her husband to drive her home. No history of vaccine reaction in the past

She received vaccine and was sitting waiting for 15 minutes. After 10 minutes she came over and expressed that she felt dizzy and was about to pass out. We took her over to bed where she was extremely nauseous and dry heaving repeatedly. She was also extremely flushed and hot but no temperature and no problems breathing. Blood pressure was elevated when ems came. We called 911 and had a Dr. who was at clinic check on her. Ems came after about 10 minutes and took her to hospital.

Itching and mild hives started within 10 mins of the vaccine injection. Patient was treated with antihistamine and responded well. symptoms improved after 2 hours of monitoring.

Worsening, swelling, redness with warmth and itch around injection area and a few inches below

Moderna COVID-19 Vaccine fever, chills, myalgia

Sore throat and body aches began the Saturday following immunization and ended within an hour of starting

severe intractable headache from 12nn 12/23/2020 to 1500 12/24/2020 associated with photo sensitivity, nausea, generalized body malaise, pain & tenderness on injection site. Treated with Tylenol & neurofen tablets, rest in the night & whole morning.

Chills, Fever, body aches, fatigue. Took Tylenol. Resolved in 24-36 hours.

Patient stated had some minor tickle in throat and slight heaviness in chest. Eyes than began swell bilaterally after 25 minutes after vaccine was given.

patient started having dizziness when she got up to leave from the waiting room 15 minutes post vaccination, she also mentioned headache behind her right eye. She was taken to an exam room in a wheel chair as she was unsteady on her feet. She was laid down on an exam table and vitals checked. She states no previous vaccine reactions, has history of seizures and has had them with increased frequency recently. Patient was released to her friend to be driven back to work 1 hour and 27 minutes post vaccination

Tiredness at the second day of vaccination (12/23/2020) and swollen tender left axillary lymph node started (12/26/2020) and still ongoing till the date of filing the adverse event (12/28/2020).

Tiredness at the second day of vaccination (12/23/2020) and swollen tender left axillary lymph node started (12/26/2020) and still ongoing till the date of filing the adverse event (12/28/2020).

10 minutes post-inoculation, I developed an ice cold sensation in my chest that spread throughout body and extremities. I developed a metallic taste in my mouth, nausea, tingling in my hands and feet and lightheadedness. This lasted 15 minutes, then repeated approximately 20 minutes later reccured as I was set to leave vaccinations site.

Severe itchiness with associated hives

chills at about 2:00am, headache, tiredness most of the day

Fainted within a couple minutes of recieving injection. Rapid response team activated and I was lifted onto a bed. Very low blood pressure. And ultimately felt better after 30 to 45 minutes of monitoring by medical team.

Low grade fever and site arm sore

Fever 100 degrees Chills severe Body aches mostly legs Mild soreness in injection area (nothing more than a typical shot)

12/24 ! 13:15 - 15 min after vaccine was administered p t c/o dizziness and shaking. was monitoring for further 15 minutes by vaccine staff. Then apx 06:00 pm that night started c/o chills, N/V, tremors, Fatigue, headache, and feeling flushed. continued thru 12/26. then 12/27 woke up with headache, n/v, chills, tremors and body swelling. 12/28- c/o nausea and headache. Treated with Tylenol OTC 12/24 and 12/26 only. 12/28 Completed rapid COVID 19 test- results negative. EDD 07/30/2021.

Moderate muscle ache,fatigue,sinus congestion

APPROXIMATELY 20 MINUTES AFTER VACCINATION, SHE BECAME ILL, VOMITING THEN COMPLAINING OF CLOSING THROAT, FELT WEAK. EMT AND FACILITY DOCTOR ON SITE WAS CALLED, THEY DETERMINED SHE DID NOT NEED TO BE TRANSPORTED TO THE ER. CONTINUED TO MONITOR PATIENT .

overall body weakness for 3 days and 1 day of severe right leg muscle cramping.

tachycardia, hypertension <15 min post administration

Reported headache and twitching of right cheek. Took Tylenol and headache resolved day of vaccination; twitching resolved day of vaccination (unknown duration). 12/23/20 (day after vaccination) he reported a slight headache upon awakening that worsened as the day passed. He took 2 extra strength Tylenol at 10:00 AM (12/23/20). Tylenol partially effective - headache lessened but still present. 12/28/20 update - chills, nausea, and fatigue from 12/23 - 12/28. Improvement in symptoms but symptoms are not completely resolved as of 12/28/20 per patient.

Anxiety, headache, nausea, sweating approximately 15 minutes after injection. Observed 1 hour emergency room then discharged.

1600 reported petechiae to both upper arms and abdomen 1611 took 25 mg bendryl waiting for 15 min. didn't get any worse went home

Soreness in upper left side of arm where vaccine was injected. Similar feeling to getting soreness in arm after a flu shot.

numbness tingling started in hand moved up the left arm slight numbess r hand site slightly swollen beandyl 25mg given symptoms got better

Vaccination was given at 8:25 and she began itching at 8:32. Itching that progressed from bilateral arms to trunk, bilateral legs and back. She felt wheezes starting. Given 50 mg. Benadryl po at 8:35. Symptoms were getting worse and RN gave Methprednisolone 125 mg. IM at 8:45.Alburteral Inhaler 2 puffs was given at 8:50. At 9:00 patient C/O upper lip tingling. Visual swelling observed. She was transported to ED by WC. ED administered Pepsid po and observed her for an hour. She was then discharged.

Onset of tongue numbness a few hours after vaccination, which was gone the next day. Vaccinated on 12/16 - 10 days later on 12/26/20 tongue numbness recurred & he developed (R) facial droop - seen in ER on 12/17 had normal head CT, negative work up for stroke. Seen in clinic on 12/28 - diagnosed with Bells palsy, started on Valacyclovir. Patient will hold PrEP x7 days (precautionary), no sexual activity during that time.

Onset day 10 post injection of erythema, edema over an area of 5x7cm over the injection site. Associated with mild tenderness, and moderate pruritis. Slight increase in size over first 24 hours (to present).

Chills

Pain at site with Fever (temp. 101 degrees F). Patient was sent to the local hospital ER and returned to the facility with a diagnosis of Fever post vaccination. Tylenol was given and patient received IV HEP saline at the ER.

Pt developed hives on bilateral arms, wrist and hands. Vital signs stable, no other complaints of tongue or throat swelling. No other s/s of anaphylaxis. Pt given Benadryl 50 mg po and observed for 60 minutes. Hives resolved and patient sent home.

Developed localized reaction on day 8 after 1st injection - had no location reaction prior. No intervention needed. 28 weeks gestation at time of vaccine and due date 3/10/21.

Fever, chills, body aches, headache, exhaustion, swollen lymph nodes 12 hours past vaccination to present.

I have had continued ongoing dizziness/vertigo after receiving the vaccine. It has now been a week since my vaccination and I am still feeling this. It it tolerable, but continues and is annoying.

MD Notes in ED Patient is a 35yo female who presents with complaint of allergic reaction. This AM around 0945 received COVID vaccine. Some pain to injection site throughout the day. Today around 1700 started to note dizziness and hives throughout her body. Hives are itchy. Associated with nasal congestion and sore throat. Patient felt difficulty swallowing zyrtec/pepcid. No drooling. Patient without fevers/chills, no recent illness. Denies prior allergies to immunizations. Denies food allergies. No new medications. Another part of the record states she had hives 30 minutes after the vaccine and self-medicated with Zyrtec and Pepcid without relief. Treated in the ED with Epi 0.3 IM Solumedrol 125 mg IV Pepcid 20 mg IV Benadryl 50 mg IV IV fluids Arrived in ED 1836 / Discharged home at 2015

Muscle aches, cramps, paresthesia in extremities and feeling of joint stiffness starting at 3 days after vaccination and continuing intermittently even after 1 week from vaccination. Aches/cramps in the muscles of neck, back of thigh, butt, calves, lower back. Treated with heat pack and hot showers with some temporary relief. No response to acetaminophen.

fever , chills, migrane started around 3 am 12 24 20. Migraine lasted all day. Woke up 12 25 20 with slight headache all day. Physically tired. Woke up 12 26 20 feeling fine.

Intractable nausea, vomiting, fever (101.8), chills

Complaints of gradual joint and bone pain

Angioedema, throat swelling, itching, lungs tight-unable to take a full breath, tachycardia, anxiety, face flushed. I took 75 mg of Benadryl an hour before the injection. Had some caffeine after I became symptomatic. Was monitored for 1.5 hours.

I got the vaccine at 3:30 pm. My right arm where the shot was started to itch extremely bad around 4:30. Then around 4:50 my throat was swelling up and my ear felt congested. A few minutes later it was

hard to breathe. I let my staff know (i work at urgent care) that i was not feeling so good from the vaccine. i was checked into the urgent care and i had hives and i was itching all over.

Tingling in throat, heart pounding and racing, dizziness, flushed skin, sweating, feeling hot

96 hours post injection muscle and joint pain. Injection site pain for 96 hours post injection. 4 days of insomnia.

received COVID vaccine, dose 1, Pfizer, approximately 1600. During observation, became light headed, hot, tingling in hands and feet, with onset of nausea shortly after. given ice packs and encouraged to remain in observation another 15 minutes. denied SOB, itching, no apparent hives or swelling. At approx 1700, symptoms had not resolved, was taken to ED for evaluation.

patient initially complained of headache at 1502, then at 1507 stated tingling in fingertips and toes. Shortly after, complained of dizziness and began crying. Moved patient to cart and vitals taken - BP 160/80, P 104, R 38, SpO2 99% - patient feelings like heart is racing. Patient's hands cold but vitals improved at 1520 - BP 140/78, P 74, R 28, Sp02 99%. At 1527, patient feeling better, headache gone, and tingling improved. BP 120/78, P 73, patient sipping water. Attempted elevating HOB at 1530 and dizziness returned but vitals stable. Continued to improve with slight dizziness with progressive ambulation. By 1548, no dizziness with sitting on edge of cart and ambulated to bathroom, After continued walking with no further symptoms and continued stability of vitals, patient discharged from care at 1558. Final BP 128/78, HR 78.

multiple oral aphthous ulcers and tongue sores without a clear alternative trigger

Headache, nausea, abdominal cramping, elevated blood pressure, 5 mins after vaccination. At home the above symptoms continue plus joint pain, lower back pain, chills for 3 days.

Developed extremely sore arm at site of injection within first hour after vaccination; red rash developed (3 inch diameter) with localized swelling. Mild fatigue for first two days following vaccination. Beginning on Day 3 after vaccination, developed severe fatigue, muscle pain, back pain, joint pain, hot/cold chills, abdominal pain, nausea and diarrhea. Symptoms were severe for three days (Day 3-6 after vaccination) requiring bed rest and supportive care with OTC ibuprofen, benadryl and promethazine. Rash, swelling and muscle pain at injection site persisted through Day 5 following vaccination. Fatigue, muscle and joint pain persisted at moderate intensity through Day 8 following vaccination. Moderate nausea and abdominal pain persisted through Day 8 following vaccination. Still experiencing mild to moderate fatigue on Day 12 following vaccination.

Dull headache on Day 1 of receiving vaccine. Day 2 was primarily a sore arm (moreso than with influenza shot)

Left Shoulder pain that started as ?oh I slept funny? to not going away with ice/heat or rest. Worsening in severity daily and spreading towards base of skull and eventually into clavicle. The pain became excruciating and I was unable to turn my head at all to the left. So bad I had to use my hands to lift my head up. I eventually went to the ED on 12/27/20. And overnight the pain became so unbareable and

functionality so limited I couldn?t go to work or take care of my toddler. I returned the to ED on 12/28/20. Was advised to file adverse event and contact my employee health and safety department. I was initially examined in the ER the first time with a neck spasm. Sent home with an RX which didn?t work. At all. When I returned to the ER th next day, the physician felt my entire neck, shoulder and clavicle an noted swelling and prominent spasm. He diagnosed with a trapezius strain and a vaccine reaction. Gave me an RX for Valium which seems to help take the edge off.

Onset of slight itchiness noted minutes after injection, however did not report to hospital staff because did not realize it was a possible reaction (I have history of rash and skin sensitivity). Noted approximately 2 days later, injection site was increasingly itchy. Then I noticed there was also a red patch surrounding injection site slightly raised that has not subsided since, now 4 days since injection.

Itchy throat, tongue, Numb Lips, Flush, Redness and hives

About 1 hour after getting vaccinated i noticed that my left eye got puffier and I could feel the tingling on my eye. Being little confused and not knowing the cause after reading online I noted that this could be possible from Covid-19 vaccine. At this time few hours later my puffiness is slowly going away . I do have pictures taken at the time of being vaccinated and also when I noticed the possible reaction .

Overdose administered due to improper dilluent

Nausea, Diarrhea, Extreme chills, Fatigue, Bad dreams during nap, waking up in a very excessive sweat, gradually increasing high amount of motivation despite symptoms

low BP/low HR and went to the ER for evaluation

he felt ?oozy? and tingling in feet

Redness, heat, swelling that lasted for a week. Swelling went to around 3 inches circumference around the injection site. Now a lump under the skin and the start of a bruise forming.

Feeling of swelling of the upper lip and throat; Feeling of swelling of the upper lip and throat; Brief tongue tingling; her palms felt sweaty; her throat felt dry; This is a spontaneous report from a contactable consumer (patient). A 50-year-old female patient started to receive BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) Solution for injection (lot number: EH9899 and expiry date unknown) via an unspecified route of administration at the left arm on 19Dec2020 08:45AM at a single dose (dose number: 1) for COVID-19 immunization. The patient's medical history included rare, mild exercise induced asthma with cold a few times in the past; history of pre-eclampsia; and known allergies: wheezing with iodine injected for a hysterogram in 2014. The patient had no concomitant medications. The patient did not receive any other vaccines within 4 weeks prior to BNT162B2 and has not received other medications within 2 weeks of vaccination. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. It was reported that on 19Dec2020, 09:15 the patient experienced a feeling of swelling of the upper lip and throat. There was a brief tongue tingling about a half hour after the injection. Immediately after the injection, her palms felt sweaty and her throat felt dry. Therapeutic measures were taken in response to the

events. The patient took Claritin about 9:15 and Benadryl 50 mg twice so far; the first was taken about 9:30AM. At 1:30 pm, the feeling of lip and throat swelling came back and she took 50 mg of Benadryl again. At the time of the last observation, the outcome of the events was not recovered. The events were reported as Non-serious.

received COVID Vaccine on 16Dec2020 and was asymptomatic for active COVID carrier; received COVID Vaccine on 16Dec2020 and was asymptomatic for active COVID carrier; This is a spontaneous report from a non-contactable nurse. A 35-year-old female patient started to receive bnt162b2 (reported as product=COVID 19, brand=Pfizer; lot number and expiry date unknown), via an unspecified route of administration on 16Dec2020 at 09:30 AM at single dose for COVID-19 immunization. Patient's medical history and concomitant medications were not reported. The patient reported that she received COVID Vaccine on 16Dec2020 and was asymptomatic for active COVID carrier. Covid test type post vaccination was nasal swab on 16Dec2020 with positive results. It was reported that prior to vaccination, patient was not diagnosed with COVID-19. It was further reported that since the vaccination, the patient has been tested positive for COVID-19. The outcome of the events was unknown. Information on the batch number has been requested.; Sender's Comments: Based on the information currently available, a lack of efficacy with the suspect vaccine in this patient cannot be completely excluded.

Fatigue; moderate headache; This is a spontaneous report from a contactable Nurse reporting for herself. A 34-years-old female patient received bnt162b2 (BNT162B2; Lot # EL0140)vaccine , intramuscular in the left arm on 18Dec2020 15:15 at single dose for covid-19 immunisation . Medical history included hypersensitivity to medications including amoxicillin sodium + clavulanate potassium] (AUGMENTIN) from an unknown date. The patient's concomitant medications were not reported. On 18Dec2020 22:00 the patient experienced fatigue and headache (6/10) refractory to caffeine or hydration. The nurse did not try tylenol or NSAIDs as wanted to prevent interference with immune response. The outcome of both the event was not recovered.

lips began tingling; tongue was tingly/numb; tongue was tingly/numb; throat felt fuzzy like needed to clear it; This is a spontaneous report from a contactable nurse reporting for herself. This 36-year-old female patient (non-pregnant) received the first single dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot EH9899) on 19Dec2020 at 08:25, intramuscular, in left arm, for COVID-19 immunization. No other vaccine was given within 4 weeks prior to the COVID vaccine. Medical history included rheumatoid arthritis from 2014. The patient had known allergies to adalimumab (HUMIRA). The patient did not have COVID before vaccination. Family medical history relevant to AEs: none (sister allergic to cashews, dad allergic to bees).Concomitant medications included tofacitinib citrate (XELJANZ XR) from Feb2018, at 11 mg daily, for arthritis, ibuprofen (MOTRIN) at 600 mg, as needed (every day for years 600 mg PRN), vitamins NOS (MVI) daily, for years, omega-3 fatty acids. The patient received the vaccination on 19Dec2020 at 08:25 and waited at the facility 30 minutes. On 19Dec2020 at 09:10 the patient experienced lips began tingling, tongue was tingly/numb and throat felt fuzzy like needed to clear it. Symptoms persisted but did not worsen and at 09:37 she took diphenhydramine (BENADRYL) 25mg as treatment. At 10:30 symptoms were gone at 75%. Emergency room or physician office visit were not required. COVID was not tested after vaccination. Relevant tests: none. The events resolved on an

unspecified date in Dec2020. The reporter considered there was a reasonable possibility that the event was related to suspect product.

Arm swelling; red circle size of a 50 cent piece; severe itching; This is a spontaneous report from a contactable consumer reporting for herself. A 44-year-old female patient received the 1st dose of bnt162b2 (BNT162B2) (Manufacturer Pfizer-BionTech, lot# EH9899), via an unspecified route of administration in arm left, on 16Dec2020 at 01:45 PM, at single dose, for COVID-19 immunisation. Medical history included rheumatoid arthritis, Hashimoto's thyroiditis, vitiligo and alopecia all from an unknown date and unknown if ongoing. The patient had no allergies to medications, food or other products. Concomitant medications included unspecified drugs in two weeks. The patient experienced arm swelling, red circle size of a 50 cent piece and severe itching all on 16Dec2020 at 03:00 PM with outcome of recovering. The events were considered non serious.

right sided numbness; tingling to face,lips and arm to fingertips; slight headache within 15 minutes of vaccination; This is a spontaneous report from a contactable nurse. A 55-year-old female patient (not pregnant) received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, Lot number: elo140), intramuscularly on 19Dec2020 13:15 at single dose for immunization. Vaccine location provided as Right arm. Medical history included asthma. Prior to vaccination, the patient was not diagnosed with COVID-19. The patient's concomitant medications were not reported. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient experienced slight headache within 15 minutes of vaccination on 19Dec2020. On 19Dec2020 13:45, 35 minutes after vaccination reported right sided numbness, tingling to face, lips and arm to fingertips. No treatment was received for all the events. The outcome of the events was recovered in Dec2020. The events were assessed as non-serious.

Fever; chills; body aches; headache; fatigue; This is a spontaneous report from a contactable Other Health Professional (patient). A 42-year-old non-pregnant female patient received first dose of BNT162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number=EH9899) intramuscular at arm Left on 18Dec2020 15:45 at single dose for covid-19 immunization. Medical history included seasonal allergies, eczema, and diagnosed with COVID-19 prior vaccination. Concomitant medication included fluoxetine hydrochloride (Generic Prozac), krill oil, bifidobacterium lactis (PROBIOTIC), sambucus nigra (ELDERBERRY) and multivitamin. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient experienced fever, chills, body aches, headache, fatigue on 19Dec2020 12:00 PM, no treatment received for the events. COVID was not tested post vaccination. The outcome of the events was not recovered.

"Increased blood pressure; Rapid heart rate; Chills(shaking); Chills(shaking); Chest and neck tightness; Chest and neck tightness; Teeth tingling; This is a spontaneous report from a contactable consumer (patient). A 41-year-old female patient (not pregnant at the time of vaccination) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: Ek5730), via an unspecified route of administration on 19Dec2020 12:30 at single dose on left arm for COVID-19 immunization. Medical history included known allergies: Latex. Concomitant medications received within received within 2 weeks of vaccination included acetylsalicylic acid, caffeine, paracetamol (EXCEDRIN [ACETYLSALICYLIC

ACID; CAFFEINE; PARACETAMOL]); ibuprofen. The most recent COVID-19 vaccine was administered at Hospital. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. On 19Dec2020 13:00 (01:00 PM), the patient experienced rapid heart rate, Increased blood pressure, Chills (shaking), Chest and neck tightness, Teeth tingling. The adverse events result in Emergency room/department or urgent care. The patient received ER monitoring, EKG (reported as ""AE treatment"") for the adverse events. The events were non-serious. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient hadn't been tested for COVID-19. The outcome of the events was recovering."

fatigue; Fever 103.6/fever 100.3; headache; chills/chills with fever 100.3 after ibuprofen; Sore at injection site; body aches; This is a spontaneous report from a non-contactable consumer (patient). A 36-year-old female patient (not pregnant) received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, lot number and expiration date not provided), via an unspecified route of administration on 18Dec2020 14:30 at single dose for COVID-19 immunization. Vaccine location was Left arm. Medical history included migraine, transient ischaemic attack (TIA), allergies: Penicillin, the patient had covid-19 prior to vaccination. Concomitant medication included buspirone hydrochloride (BUSPAR), cranberry, vitamin c (ascorbic acid), colecalciferol (VITAMIN D). The patient was not received other vaccine in four weeks. The patient experienced Sore at injection site, body aches, chills with fever 100.3 after ibuprofen, headache on 18Dec2020 19:00. And then the patient had Fever 103.6, headache, chills, fatigue on 18Dec2020 19:30, sore at injection site on 18Dec2020 19:00, body aches on 18Dec2020 19:00. Therapeutic measures were taken as a result of events fever and chills, no treatment was received for the other events. The outcome of the events was recovering. All events were assessed as non-serious. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

About 30 minutes after injection I suddenly felt a rush of heat throughout my body; felt dizzy, weak and a bit nauseated; felt dizzy, weak and a bit nauseated; felt dizzy, weak and a bit nauseated; tired/ fatigue; have some minor injection site pain; This is a spontaneous report from a contactable nurse reporting for herself. A 42-years-old non-pregnant female patient the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE): lot number: EJ1675, intramuscular, in the left arm on 18Dec2020 at 13:15 (at the age of 42 years-old) as a single dose for COVID-19 immunization. The patient received the vaccine at a hospital. Medical history included an allergy to cilantro. Concomitant medication included colecalciferol (VITAMIN D), zinc (ZINC) intermittently, and paracetamol (TYLENOL) once, all within 2 weeks of vaccination. The patient previously took amitriptyline and experienced swelling of eyelid and palmar erythema. The patient did not receive any other vaccines within four weeks prior to the vaccination. On 18Dec2020, the patient experienced a rush of heat throughout her body, felt dizzy, weak and a bit nauseated and minor injection site pain. The clinical course as follows: At 13:45, about 30 minutes after injection she suddenly felt a rush of heat throughout her body, felt dizzy, weak, nauseated. This lasted about 30 minutes and then the warm feeling went away. She still felt a little dizzy, weak, nauseated and very tired. The dizziness lasted about 1.5 hours and the weakness, fatigue and mild nausea lasted about 6 hours. She reported that It felt as though she had taken diphenhydramine (BENADRYL). She stated that had she not been working (RN in an Emergency Department), she just

would have taken a nap and it would have been ok. Having to work through it was not pleasant she said. She never had a fever during this but had some minor injection site pain. She reported that she never experienced an immune response to any vaccine (has had 6 in a day before and was fine). The patient was not hospitalized for the events. The patient was treated with 600 mg of naproxen sodium. The clinical outcome for the events of a rush of heat throughout her body, felt dizzy, weak and a bit nauseated and minor injection site pain, was recovered on an unspecified date in Dec2020. It was also reported that since the vaccination, the patient had not been tested for COVID-19.

"ear infection; This is a spontaneous report from a contactable other HCP (patient). A female patient of an unspecified age received bnt162b2 (reported PFIZER-BIONTECH COVID-19 VACCINE, Covid-19 Vaccine), via an unspecified route of administration on 18Dec2020 at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. PCT asked, ""I got the Covid 19 vaccine yesterday, and this morning I woke up and went to the doctor because I had an ear infection. I was prescribed with oral antibiotics. Is it okay to take the antibiotics?"". Patient stated, ""I had a question about it actually. I got the vaccine yesterday and then today I was at the doctor, I have an ear infection and I was wondering if that would be a bad thing if I took antibiotic while still recovering from the vaccine."" The outcome of the event was unknown. Information on the lot/batch number has been requested."

Numbness on the right side of my face (jaw to just above right eye, not severe); This is a spontaneous report from a contactable consumer. A 44-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (lot number EJ1685), via an unspecified route of administration at first dose right arm on 19Dec2020 07:15 AM at single dose for covid-19 immunization. None medical history. No known allergies. Patient was not diagnosed with COVID-19 prior to vaccination nor tested for COVID-19 since the vaccination. Concomitant medications included cetirizine hydrochloride (ZYRTEC), fluticasone propionate (FLONASE). The patient didn't receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient experienced numbness on the right side of her face (jaw to just above right eye, not severe) on 19Dec2020 07:45 AM. Patient didn't receive treatment for the adverse event. The action taken in response to the events for BNT162B2 was not applicable. The outcome of event was recovering. The event was non-serious.

Classic Herpes Zoster(shingles) left T5 and T6 dermatomes. Received injection at 10AM and noticed rash when I got home from the hospital at 8:00PM same day. Not likely related but felt should report any; rash; This is a spontaneous report from a contactable physician (hospital based neurologist) reporting for a himself. A 64-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot #ELO140) via an unspecified route of administration in left arm on 18Dec2020 10:00AM at single dose for COVID-19 immunization. The patient received the vaccine in hospital. Medical history included coronary artery disease (CAD), status post stent placement right marginal branch in 2015. The patient had no allergies outside of seasonal. The patient did not received any other vaccines within 4 weeks prior to the COVID vaccine. The patient received medications within 2 weeks of vaccination. Prior to vaccination, the patient was not diagnosed with COVID-19. The patient experienced classic herpes zoster (shingles) left T5 and T6 dermatomes and noticed rash when he got home from the hospital at 20:00 on 18Dec2020, same day of vaccination. The patient started on valacyclovir (VALTREX) 1 gm every

8 hours for treatment of events. Since the vaccination, the patient had not been tested for COVID-19. The outcome of events was not recovered. The reporter considered not likely related but felt should report any.; Sender's Comments: Classic herpes zoster (shingles) /rash occurred on the same day of vaccination with BNT162B2 represents a coincidental viral infection caused by Herpes zoster, unrelated to the vaccine use.

"tired/exhaustion; cough; runny nose; fever 100 ""oral""/fever 100.3; This is a spontaneous report from a contactable consumer (patient). A 63-year-old female patient (not pregnant at the time of vaccination) received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899), via an unspecified route of administration on 16Dec2020 08:45 at single dose on right arm for COVID-19 immunization. The patient's medical history reported as none and no Allergies to medications, food, or other products. Concomitant medications received within 2 weeks of vaccination included exemestane, thyroid (ARMOUR THYROID), ergocalciferol (VIT D), ascorbic acid (VIT C), acetylsalicylic acid (ASPIRINE). The most recent COVID-19 vaccine was administered in Workplace clinic. It was reported that nothing on Wednesday. On 17Dec2020 19:00 (07:00 PM) (Thursday evening), the patient was very tired, cough, runny nose and fever 100 ""oral"" (as reported), Friday (18Dec2020) exhaustion and fever 100.3 with cough and runny nose. The events were non-serious and no treatment was received for the events. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient hadn't been tested for COVID-19. The outcome of the events was not recovered."

"Mild maculopapular rash across arms and facial and neck flushing. Rash did not itch; facial and neck flushing; other vaccine same date vaccine date on 17Dec2020; This is a spontaneous report from a non-contactable consumer (patient). A 56-year-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot/batch number and expiration date not provided), via an unspecified route of administration on 17Dec2020 at 07:30 on Right Deltoid at single dose for COVID-19 immunization. Other vaccine was received on the same date on 17Dec2020 Right Deltoid. The patient medical history included Hypertension. Prior to vaccination, patient was not diagnosed with COVID-19. The patient's concomitant medication included Lisinopril (strength: 20 mg). Patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient previously took tramadol and experienced allergy. The patient experienced mild maculopapular rash across arms and facial and neck flushing on 18Dec2020 at 13:30. Rash did not itch and resolved spontaneously in 24 hours. Since the vaccination, patient had not been tested for COVID-19. No treatment was received for the events. The outcome of the events ""mild maculopapular rash across arms and facial and neck flushing"" was recovered in Dec2020 in 24 hours. The report was reported as non-serious. No follow-up attempts are possible; information about lot/batch number cannot be obtained."

"Chills; Headache; Fatigue; injection site soreness and redness; injection site soreness and redness; Shortness of breath; nausea; feeling unwell; This is a spontaneous report from a contactable other health professional (HCP) who reported for herself. A 24-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE) intramuscularly in the left arm on 19Dec2020 at 08:45 (at the age of 24-years-old) as a single dose for COVID-19 vaccination. Medical history included being diagnosed with COVID-19 prior to vaccination, on an unspecified date. Otherwise,

other medical history and known allergies to medications, food, or other products were all reported as ""no"". The patient was not pregnant at the time of vaccination. Concomitant medications were not reported. The patient did not receive any other vaccines within four weeks prior to the vaccination. On 20Dec2020 at 00:30, the patient experienced chills, headache, fatigue, injection site soreness and redness, shortness of breath, nausea and feeling unwell. The events were reported as non-serious and the patient did not receive any treatment for the events. The clinical outcomes of the events chills, headache, fatigue, injection site soreness and redness, shortness of breath, nausea and feeling unwell were all recovering/resolving. It was also reported that since the vaccination, the patient had not been tested for COVID-19. The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up."

Fever 100.5; chills; pain at injection site; muscle soreness; joint pain; very mild nausea; This is a spontaneous report from a contactable nurse (patient). A 32-year-old female patient (not pregnant) received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: 5926710001), intramuscular on 19Dec2020 10:00 at single dose for COVID-19 immunization. Medical history included covid-19. Concomitant medication in two weeks included bupropion, sertraline, ascorbic acid, betacarotene, calcium sulfate, colecalciferol, cyanocobalamin, ferrous fumarate, folic acid, nicotinamide, pyridoxine hydrochloride, retinol acetate, riboflavin, thiamine mononitrate, tocopheryl acetate, zinc oxide (PRENATAL VITAMINS), cetirizine hydrochloride (ZYRTEC), ergocalciferol (VITAMIN D). The patient previously took minocycline, tetracycline and, amoxicillin; experienced drug hypersensitivity. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. The COVID-19 vaccine was administered at Hospital. The patient experienced fever 100.5, chills, pain at injection site, muscle soreness, joint pain, very mild nausea on 20Dec2020 04:30 AM. The patient received paracetamol (TYLENOL) as treatment. The outcome of events was not recovered.

Muscle aches; back pain; nausea; fatigue; headache; This is a spontaneous report from a contactable nurse reporting for the patient. A 32-year-old female patient received dose 1 of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), intramuscular on 18Dec2020 at 14:15 (at the age of 32-years-old) as a single dose in the left arm for COVID-19 vaccination. Medical history included postural orthostatic tachycardia syndrome (POTS), Fibromyalgia, Migraines, Post-traumatic stress disorder (PTSD), anxiety, depression, and gastrooesophageal reflux disease (GERD), all from an unknown date. The patient did not have any allergies to medications, food or other products. The patient was not pregnant at the time of vaccination. Prior to the vaccination, the patient was not diagnosed with COVID-19. The patient was not tested for COVID-19 post vaccination. The patient did receive concomitant medications within 2 weeks of vaccination (unspecified). The patient did not receive any other vaccines within four weeks prior to the vaccination. On 18Dec2020, the patient experienced muscle aches, back pain, nausea, fatigue, and headache. Therapeutic measures were not given for the events. The clinical outcome of the events muscle aches, back pain, nausea, fatigue, and headache was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

Felt body needed to defecate but could not; Severe lower abdominal cramping on day 3 post vaccination. Intermittent pains throughout day but increased at night.; Intermittent pains; Some nausea;

This is a spontaneous report from a contactable consumer, the patient. A 40-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration on 10Dec2020 at 10:45 (at the age of 40-years-old) as a single dose in the left arm for COVID-19 immunization. The patient previously received clindamycin and experienced allergy. The patient had no other relevant medical history or concurrent conditions. The patient was not pregnant at the time of vaccination. Prior to the vaccination, the patient was not diagnosed with COVID-19. Concomitant medications were not provided. The patient did not receive any other vaccines within four weeks prior to the vaccination. The patient did not receive any other medications within two weeks prior to the vaccination. On 05Dec2020 (as reported) at 16:30, the patient experienced severe lower abdominal cramping on day 3 post vaccination. The patient experienced intermittent pains throughout day but increased at night. The patient experienced some nausea. The patient felt her body needed to defecate but could not and pain persisted. The pain improved on day 4. Therapeutic measures were taken as a result of the events and included the patient received Pepto Bismol. The clinical outcome of the events severe lower abdominal cramping, intermittent pains and felt body needed to defecate but could not was recovering. The outcome of the nausea was unknown. It was also reported that since the vaccination, the patient had not been tested for COVID-19. The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up.

Approximately 3 to 4 minutes after injection site I started to get hot with a feeling of an elevated heart rate; Approximately 3 to 4 minutes after injection site I started to get hot with a feeling of an elevated heart rate; This is a spontaneous report from a contactable consumer (patient). A 35-year-old male patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot/batch number and expiration date not provided), via an unspecified route of administration on 16Dec2020 at 12:00 on left arm deltoid at single dose for COVID-19 immunization. The patient medical history included anxiety, depression and prior to vaccination, patient was diagnosed with COVID-19. No known allergy. The patient's concomitant medications received within 2 weeks of vaccination included escitalopram oxalate (LEXAPRO) and cetirizine hydrochloride (ZYRTEC), both on 16Dec2020. Patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient reported that approximately 3 to 4 minutes after injection site he started to get hot with a feeling of an elevated heart rate on 16Dec2020 at 12:00. Took off his hat and noticed his hair was sweaty. Was not clammy anywhere else. Symptoms improved around minute 10 to 12. After sitting in car in parking lot for an additional five or 10 minutes started to feel more baseline. He never experienced any chest pain, shortness of breath, angioedema, hives, difficulty breathing, swelling, he had a history of anxiety, which seemed to coincide with the symptoms. Since the vaccination, patient had not been tested for COVID-19. No treatment was received for events. The outcome of the events was recovered on 16Dec2020. The report was reported as non-serious. Information on the Batch/Lot number has been requested.

had fevers and chills up to 104.7 degrees Fahrenheit for a 36-hour period; lethargy; This is a spontaneous report from a contactable Physician. A 40-year-old non-pregnant female first dose of BNT162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number=EH9899) intramuscular at arm Left on 19Dec2020 11:00 at single dose for covid-19 immunization. The COVID-19 vaccine was administered at Hospital. Medical history included COVID-19 in Mar2020 with 10 days of fevers and chills and bilateral

interstitial pneumonia. The patient had no other medical history and no known allergies. Concomitant medication included silicon dioxide (VIVISCAL), ascorbic acid (VITAMIN C), calcium, colecalciferol (VITAMIN D) and Gummy vitamins. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient was administered at 11am on 19Dec2020, fevers and chills up to 103 Fahrenheit, and lethargy were started around 11pm. It was reported that the patient have had fevers and chills for 36 hrs after getting the first shot of the vaccine. She had fevers and chills up to 104.7 degrees Fahrenheit for a 36-hour period. The patient wanted to know if this response of fevers and chills was related to her being positive last march with accompanying Pneumonia and that if it still safe for her to take the 2nd dose, if it was due to a second time being exposed to Covid which was through the vaccine, could this be a robust immune response. COVID was not tested post vaccination. Outcome of the events was not recovered.

arm soreness at injection site; Body aches; chills; sore throat; This is a spontaneous report from a contactable other health professional (patient). A 43-year-old female patient (not pregnant at the time of vaccination) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: Ek5730), intramuscularly on 17Dec2020 10:15 at single dose on left arm for COVID-19 immunization. The patient's medical history reported as none and no known- allergies. Concomitant medications received within 2 weeks of vaccination included colecalciferol (VITAMIN D [COLECALCIFEROL]), thyroid (ARMOUR THYROID), zinc vitamin, magnesium vitamin. The most recent COVID-19 vaccine was administered at Hospital. On 19Dec2020 19:00 (07:00 PM), the patient's arm soreness at injection site for 2 days. Body aches and chills and sore throat. No treatment received for the adverse events. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient hadn't been tested for COVID-19. The outcome of the events was not recovered.

"Extreme fatigue, slept for most of Saturday; Extreme fatigue, slept for most of Saturday; This is a spontaneous report from a contactable health care professional, the patient. A 27-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), intramuscularly on 18Dec2020 at 13:00 (at the age of 27-years-old) as a single dose in the left arm for COVID-19 immunization. The patient medical history and concomitant medications were not reported. The patient was not pregnant at the time of vaccination. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. On 19Dec2020 at 09:00, the patient experienced extreme fatigue and slept for most of Saturday (as reported). Treatment was not received for the events. Since the vaccination, the patient had not been tested for COVID-19. The clinical outcome of ""extreme fatigue, slept for most of Saturday"" was resolving. Information on the lot/batch number has been requested."

SOB; fever; tired; headache; chills; not feeling well; injection site pain; lymph node swollen under right arm; This is a spontaneous report from a contactable Consumer. This 55-year-old female patient received the 1st dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on right arm on 17Dec2020 at 11:30 am at single dose (lot number: EK5730) for COVID-19 immunization. Medical history included having Covid in Jul2020 and husband had Covid prior to being vaccinated. Concomitant medications included escitalopram oxalate (LEXAPRO), estradiol,

hydrochlorothiazide in two weeks. The patient experienced SOB, fever, tired, headache, chills, not feeling well for over 24 hours than on the 19th noted lymph node swollen under right arm with severe pain along with injection site pain from 18Dec2020 03:00 AM. All events were reported as non-serious. Age at vaccination was 55 years old. Not pregnant at the time of vaccination. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. No treatment was received for the events. Outcome of all events was not recovered.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2020504434 same reporter/same drug/different event

feeling symptoms and that she felt like she had the flu; felling sick; This is a spontaneous report from a contactable consumer (patient). A female patient of an unspecified age received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EY1685), via an unspecified route of administration on 18Dec2020 at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. Caller reported receiving Pfizer Bontech covid 19 vaccine on 18Dec2020. She was feeling symptoms and that she felt like she had the flu (Dec2020). Consumer further stated she work here at the Hospital and Friday she appeared for the shot (Covid Vaccine) and she was just felling sick (Dec2020) and she didn't know what she had to do if it was normal, she had to report it to somebody for this or be around people or can she went back to work tomorrow, she didn't know. The outcome of the events was unknown. No follow up attempts are possible. information about lot/batch number cannot be obtained.

Initially pain at injection site; headache; Next day had body aches; low grade fever 100 degrees; This is a spontaneous report from a contactable consumer. A 27-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration at first dose left arm on 18Dec2020 08:00 at single dose for covid-19 immunization. None medical history. No Known allergies. Patient was not diagnosed with COVID-19 prior to vaccination nor tested for COVID-19 since the vaccination. The patient's concomitant medications were not reported. There was no other vaccine in four weeks or two weeks. The patient experienced initially pain at injection site next day had body aches, low grade fever 100 degrees, and headache on 19Dec2020 07:30 AM. Patient received acetaminophen as treatment for the adverse events. The action taken in response to the events for BNT162B2 was not applicable. The outcome of events was recovered in Dec2020. The events were non-serious. Information on the lot/batch number has been requested.

"Caller states she cant focus/She just can't focus; this is horrible/I have a hard time focusing; I'm like you know fogged; I just want to sleep/I have been sleeping all weekend that was horrible; I have some headache; I just don't feel right this is terrible; This is a spontaneous report from a contactable consumer (Patient). A 58-year-old female patient started to receive BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EJ1685), intramuscular in the arm on 18Dec2020 at single dose for covid-19 immunization. Medical history included seizure. Concomitant medication included celecoxib (CELEXA), levothyroxine sodium (SYNTHROID), phenobarbitone [PHENOBARBITAL] for seizure. The patient stated that she could not focus, this was horrible and had a hard time focusing on 18Dec2020, the patient also stated that ""like you know fogged"" on 18Dec2020, the patient just wanted to sleep and she had been sleeping all weekend that was horrible on an unspecified date in Dec2020, the patient

had some headache on an unspecified date Dec2020, she just took some Ibuprofen for the headache, the patient just didn't feel right this was terrible on an unspecified date in Dec2020. The outcome of 'could not focus' was not recovered and the outcome of the other events was unknown."

"his entire body is hurting; It's flu like symptoms but not really; feeling run down; it's like skin sensitivity/if touch his skin it kind of hurts, more like skin sensitivity versus body ache, touch his arm it hurt; a bilateral inner thigh rash to knee, that was non irritating non itchy but was uniform in pattern; a sore throat but it was like a tickle a throat tickle and then a dry cough; a sore throat but it was like a tickle a throat tickle and then a dry cough; a sore throat but it was like a tickle a throat tickle and then a dry cough; sore arm at injection site; This is a spontaneous report from a contactable nurse (CRNA anesthesia, also the patient). A 39 years old male patient received a dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899), via an unspecified route of administration at arm on 16Dec2020 at single dose for COVID-19 immunization. The patient's medical history included psoriasis (he took biologic for pre-existing psoriasis), arthritis and that ""he thought he had direct exposure"". Concomitant medications included unspecified biologic for pre-existing psoriasis. The patient initially called because he was asking that if it was reaction to the injection or if it was possible Covid 19 because he thought he had direct exposure. The patient mentioned ""his chest and stuff"" and got received a Covid test on 11Dec2020, 02Dec2020 and 24Nov2020 and they were consecutive test and he took these test because they were few of his coworkers down to Covid so he just wanted to be sure that he was not infected with them, these are all negative. So last result he had for Covid was 14Dec2020 and that's two days before he got the vaccine and they were all negative and ""it started like all his activities, it was like going to work, going to get food like at the grocery store or other places for takeout"". He had not been in a situation where he have been gathering with a lot of people or having dinner or lunch and sort of anything like that, just the point that he was not in the one of high risk people. For the possible ""side effects similar to covid 19 from vaccine"", the symptom presentation/progression per patient were are as follows: the patient initially had sore arm at injection site on the day of injection which was Wednesday (16Dec2020) and then the following day (17Dec2020) he started having a sore throat but it was like a tickle a throat tickle and then a dry cough. On Friday (18Dec2020) he had a bilateral inner thigh rash to knee, that was non irritating non itchy but it was uniform in pattern. And then on Saturday (19Dec2020), he continued to have a dry cough and said he did apply some steroid cream that he has for his psoriasis and the rash is going away/almost gone and reported feeling run down, has skin sensitivity, he said that if touch his skin it kind of hurts, it's more like skin sensitivity versus body ache, when he touch his arm it hurt, it's like skin sensitivity. And then on Sunday (20Dec2020, the date of reporting), he still has cough and his entire body is hurting. It's flu like symptoms but not really. The patient's weight was around 175 pounds on an unspecified date. Therapeutic measures were taken as a result of the events included some steroid cream and over the counter Zicam (its tablet for cold). The outcome of the event dry cough was not recovered, bilateral inner thigh rash to knee was recovering, for the other events was unknown. When probed for the causality between events and the suspect product, the patient said ""hope it is not from that"" ."

chills; low grade fever to 38.4; body aches; felt very tired; This is a spontaneous report from a contactable nurse (patient). A 57-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-

19 VACCINE, lot number EK5730), intramuscularly on left arm at 18:15 on 18Dec2020 at single dose for COVID-19 immunization. Medical history included COVID-19 (Prior to vaccination, the patient was diagnosed with COVID-19). There were no concomitant medications (No other vaccine in four weeks, no other medications in two weeks). The patient had chills, low grade fever to 38.4, body aches and felt very tired at 15:00 on 19Dec2020. All events were reported as non-serious. The patient did not receive any treatment for all events. The outcome of events was recovering. COVID was not tested post vaccination.

1.5 hours after the vaccine, one eye vision was down to light perception only. The event lasted 15 minutes and resolved completely. ER eval and Ophthololgy eval did not find a cause for the event.; This is a spontaneous report from a contactable physician. A 66-year-old male patient received bnt162b2 (reported as COVID 19, Covid vaccine, lot/batch number and expiry date were not provided), via an unspecified route of administration from 17Dec2020 12:30 at single dose for covid-19 immunisation. Medical history included gout, abnormal glucose, hyperlipidemia, hypertension. Prior to vaccination, the patient was not diagnosed with COVID-19. No Known allergies. Concomitant medications the patient received within 2 weeks of vaccination included atorvastatin, prednisone, lisinopril, allopurinol, famotidine (PEPCID). The patient experienced 1.5 hours after the vaccine, one eye vision was down to light perception only. The event lasted 15 minutes and resolved completely. ER eval and Ophthololgy eval did not find a cause for the event. CT and labs done. Event onset date was on 17Dec2020 14:00. The patient not received any other vaccines within 4 weeks prior to the COVID vaccine. Since the vaccination, the patient has not been tested for COVID-19. No treatment received for the adverse event. Case was non-serious. Facility where the most recent COVID-19 vaccine was administered at Hospital. The adverse event result in the following: Doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care. The outcome of event was recovered on 17Dec2020 14:15. Information on the Batch/Lot number has been requested.

Mild injection site reaction- red, firm, swollen, tender; Mild injection site reaction- red, firm, swollen, tender; Mild injection site reaction- red, firm, swollen, tender; Mild injection site reaction- red, firm, swollen, tender. Most noticeable day 3 after injection. Note that I had COVID dx 21Apr; This is a spontaneous report from a contactable consumer reporting for herself. This 33-year-old female patient (non-pregnant) received the first single dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot EJ1685) on 17Dec2020 at 07:45, in left arm, for COVID-19 immunization. No other vaccine was given within 4 weeks prior to the COVID vaccine. Medical history included immune thrombocytopenia 2/2, COVID from 21Apr2020, chronic B12 deficiency, ADHD, depression, anxiety and migraine. Allergies to medications, food, or other products: none. Concomitant medications included sertraline HCl (ZOLOFT), lisdexamfetamine mesilate (VYVANSE), lorazepam (ATIVAN), ondansetron (ZOFRAN) and sumatriptan succinate (IMITREX). On 17Dec2020 the patient experienced mild injection site reaction- red, firm, swollen, tender. It was most noticeable on day 3 after injection. No treatment was given. COVID was not tested after vaccination. The events were resolving.

"experienced severe insomnia/some serious felt of insomnia, he did not get a lot of sleep/ tossing and turning all night; This is a spontaneous report from a contactable consumer (patient). A 63-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, lot

number and expiration date not provided), via an unspecified route of administration on 17Dec2020 at single dose for COVID-19 immunization. Medical history included bipolar disorder. Concomitant medication included quetiapine fumarate (SEROQUEL) for bipolar disorder, levothyroxine. The patient received the first dose of the vaccine 17Dec2020 and then last night on 19Dec2020 he experienced severe insomnia. Specifically, it was reported that the patient worked at the front desk and on the Thursday of the 17Dec2020, he received the vaccine from the company and he was fine, he had no real side effects until last night on 19Dec2020 and he was not sure whether it's due to vaccine or not but he did experience some serious felt of insomnia, he did not get a lot of sleep. After about 1'oclock in the morning when he was unable to achieve sleep, he took a ""cup"" ZzzQuil and that usually helps to go sleep but it did not work yesterday (19Dec2020) and the patient was tossing and turning all night. The patient wondering whether it is due to vaccine or not. The patient also tried 10 mg Melatonin and both of the medications didn't work. The patient didn't take them together. He took them separate. He took the Melatonin first and it did not work and then he took ZzzQuil by an hour later and the ZzzQuil did not work either. Neither of them worked. Therapeutic measures were taken as a result of insomnia. The outcome of the event was recovering. Information on the Lot/Batch number has been requested."

muscle aches, pain, and chills that were minor but not fever. He is now experiencing loss of muscle tone in his left foot and feels as if his foot is dropping.; it's hard to walk; muscle aches, pain, and chills that were minor but not fever. He is now experiencing loss of muscle tone in his left foot and feels as if his foot is dropping.; muscle aches, pain, and chills that were minor but not fever. He is now experiencing loss of muscle tone in his left foot and feels as if his foot is dropping.; muscle aches, pain, and chills that were minor but not fever. He is now experiencing loss of muscle tone in his left foot and feels as if his foot is dropping.; This is a spontaneous report from a contactable consumer (patient). A 62-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 18Dec2020 at single dose for covid-19 immunization, carbamazepine (TEGRETOL), via an unspecified route of administration from an unspecified date to an unspecified date at unknown dose and frequency for an unspecified indication. Medical history included ongoing diabetes; ongoing congestive heart problems; ongoing blood pressure high; ongoing mild kidney disease; ongoing gastroparesis; peripheral neuropathy, pain. Concomitant medication included hydrocodone bitartrate, paracetamol (NORCO) for pain, insulin glargine (LANTUS) for diabetes, insulin lispro (HUMALOG) for diabetes, carvedilol (COREG) for congestive heart problem, lisinopril for high blood pressure, spironolactone for high blood pressure, furosemide for high blood pressure, insulin for diabetes. The patient received the Covid-19 vaccine on 18Dec2020. After receiving the vaccine he had muscle aches, pain, and chills on 18Dec2020 that were minor but not fever. He was now experiencing loss of muscle tone in his left foot and feels as if his foot is dropping. The patient noticed on 20Dec2020 that his left foot it's not muscle tone it's kind of flopping there, it's hard to walk. The patient just took Tylenol and took his normal Narcan and Tylenol nothing in addition and one hot shower but it was more of nuisance. The patient stated that the main thing was that the loss of muscle tone in his left foot, that's what bothers him more than chills and everything like that because it was making difficult to walk and he want to walk around. The patient also stated that one of his health problems was peripheral neuropathy and that was what it just seem to make it why he can't feel his foot at all or he can do was move his big toe just a little bit and it was just kind of due to that. The patient just concerned whether that was

supposed to go away in a couple of days. The outcome of the events was unknown. Information on the lot/batch number has been requested.

nausea/sick to stomach; vomiting; sore arm; might be having a Gall bladder issue; This is a spontaneous report from a contactable consumer (patient). A 53-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EJ1685, Expiry Date: Mar2021), via an unspecified route of administration on 19Dec2020 at single dose for COVID-19 immunization. There was no medical history. There were no concomitant medications. The patient experienced nausea, vomiting, sore arm on 19Dec2020. She was feeling better today. She might be having a gall bladder issue, she started feeling sick to stomach yesterday evening (19Dec2020). It had been several hours after she got the vaccine. No treatment received for events. The outcome of events was recovering.

"headaches, weakness, and ""some coughing.""; headaches, weakness, and ""some coughing.""; headaches, weakness, and ""some coughing.""; This is a spontaneous report from a contactable other hcp. A 56-year-old female patient (wife) received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EK5730), via an unspecified route of administration on 17Dec2020 at single dose for covid-19 immunization. The patient was working in hospital, they provided the vaccine and the nurse gave her the vaccine. Next shot will be 3 weeks after that on 07Jan2021. The reporter thought that the patient was the height of the patient was 5 (feet) 6 (inches) and the weight was 68 kg. The patient had no other medical condition or concomitant medication. On the 2nd day on 18Dec2020, the patient experienced headaches, weakness, and ""some coughing."" The patient was taking acetaminophen (Tylenol) 500 mg every 6/8 hours as treatment. The reporter wanted to know if there was anything his wife can do to get rid of these side effects, how long it would last, and what kind of precautions she has to do. The patient was still have them. Just not getting worst or not getting better somehow. She had test for COVID 19 around 09Dec2020 and she was negative. The outcome of the events was not recovered."

Day after the vaccine, I started experiencing throbbing pain on shoulder/arm opposite to the vaccinated arm. Pain became more intense at night and after 48 hours, started experiencing decreased range; Day after the vaccine, I started experiencing throbbing pain on shoulder/arm opposite to the vaccinated arm. Pain became more intense at night and after 48 hours, started experiencing decreased range; decreased range of motion; heaviness on shoulder/arm area all the way to the elbow; This is a spontaneous report from a contactable pharmacist (patient). A 51-years-old non-pregnant female patient the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, lot number=EK5730, intramuscular in left arm on 17Dec2020 at 17:15 (at the age of 51 years-old) as a single dose for COVID-19 immunization. The patient received the vaccine in a hospital. Prior to the vaccination, the patient was not diagnosed with COVID-19 nor was tested. There were no other vaccines within four weeks. Medical history included: hypothyroid, endometriosis, low blood pressure history, anxiety and H pylori. Concomitant medication included sarecycline (SARECYCLINE) for acne, take for 3 days levothyroxine (LEVOTHYROXINE), vitamin c [ascorbic acid] (VITAMIN C [ASCORBIC ACID]), colecalciferol (VITAMIN D [COLECALCIFEROL]), ginkgo biloba (GINGKO BILOBA), and camellia sinensis extract (GREEN TEA [CAMELLIA SINENSIS EXTRACT]). On 18Dec2020 at 0700, the patient experience throbbing pain on shoulder/arm opposite to the vaccinated arm. The clinical course as follows: At 0700, the day after

receiving the vaccine, she started experiencing throbbing pain on shoulder/arm opposite to the vaccinated arm. The pain became more intense at night and after 48 hours, started experiencing decreased range of motion and heaviness on shoulder/arm area all the way to the elbow. The patient was not hospitalized for the events. The patient was treated with OTC obuprofen 400 mg and acetaminophen (TYLENOL). The clinical outcomes of throbbing pain on shoulder/arm opposite to the vaccinated are, decreased range of motion and heaviness on shoulder/arm area all the way to the elbow was not recovered.

24 hours after I received the vaccine I began experiencing terrible body aches all over (muscle aches in my limbs, back, feet, hands, everywhere); 24 hours after I received the vaccine I began experiencing terrible body aches all over (muscle aches in my limbs, back, feet, hands, everywhere); 24 hours after I received the vaccine I began experiencing terrible body aches all over (muscle aches in my limbs, back, feet, hands, everywhere); 24 hours after I received the vaccine I began experiencing terrible body aches all over (muscle aches in my limbs, back, feet, hands, everywhere); fever that reached 101.1 degrees F; chills followed by waking up in a pool of sweat at 6AM on 12/20/20; chills followed by waking up in a pool of sweat at 6AM on 12/20/20; This is a spontaneous report from a contactable health care professional. A 26-years-old non-pregnant female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), lot number-EH9899, intramuscular in left arm on 18Dec2020 at 19:30 (at the age of 26 years-old) as a single dose for COVID-19 immunization. There was no medical history nor concomitant medications. The patient received the vaccine in a hospital. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. There were no other medications received within 2 weeks of the vaccination. On 19Dec2020 24 hours after receiving the vaccination, the patient experienced terrible body aches all over (muscle aches in limbs, back, feet, hands, everywhere), a fever that reached 101.1 degrees F and eventually, chills followed by waking up in a pool of sweat at 0600 on 20Dec2020. She mentioned that she hadn't felt this ill since she was very little. She was a very healthy person, normal BMI, work out every day, eat healthy, have no health conditions. The patient had not been tested for COVID-19 prior to the vaccine and has not been tested after vaccination. The clinical outcomes for experienced terrible body aches all over (muscle aches in limbs, back, feet, hands, everywhere), a fever that reached 101.1 degrees F and eventually, chills followed by waking up in a pool of sweat, was recovering. The patient was not hospitalized for the events. It was noted that the patient had not been tested for COVID-29 prior to vaccination nor after vaccination. The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up.

"Soreness; redness; tenderness just outside of the injection site (not at the site); On my anterior shoulder next to where my arm sits by my armpit. A large red and swollen mark approx 2 on in height, 1 1/2in wide; This is a spontaneous report from a contactable consumer (patient). This 35-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Lot number EH9899) via an unspecified route of administration in the left arm on 19Dec2020 at 11:45 at single dose for COVID-19 immunisation. Vaccination facility type was hospital. The patient did not receive other vaccines in four weeks. Relevant medical history included Graves' disease, hyperthyroidism and chronic spine pain. Concomitant medications included pregabalin (LYRICA), hydroxyzine and buprenorphine hydrochloride/naloxone hydrochloride (SUBOXONE). On 20Dec2020 at 08:00, the patient experienced

soreness, redness, tenderness just outside of the injection site (not at the site). ""On her anterior shoulder, next to where her arm sits by her armpit, a large red and swollen mark approximately 2 on in height, 1 1/2 in wide"" appeared. The events resulted in Doctor or other healthcare professional office/clinic visit. The patient did not receive corrective treatments. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, she had not been tested for COVID-19. The patient had not recovered from the events."

"the rash on her back, more on the flank area/ the upper arms, she got this rash too; had fever, a low grade fever; 24 hour chills; chills was off and on; This is a spontaneous report from a contactable nurse (patient). A 48-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899), via an unspecified route of administration on 17Dec2020 03:40 at single dose for COVID-19 immunization. Medical history (Other medications and other medical conditions) reported as no. The patient's concomitant medications were not reported. Caller initially called to ""report some side effects after getting covid."" Investigation Assessment was No. Consumer (Registered Nurse) further stated Just calling to report side effects because she guessed the data might be needed for study and everything. She went for the vaccine last Thursday (17Dec2020) around 3:40. The first night was the day that she had 24 hour chills (Dec2020). So, just round the clock, Tylenol was taken for that. Then she knew, the rash on her back, more on the flank area that was less than 24 hours that was Friday. And that's in her lower back and now she had more on that lower back and the upper arms, she got this rash too. Chills was off and on. The date when started experiencing rashes was 18Dec2020 and was still experiencing. The patient experienced chills and had fever, a low grade fever (Dec2020), and for chills she took Tylenol. For lab text, the patient stated ""About 2 weeks no, after the COVID vaccine no"". Due date for the next vaccine shot: Consumer believed the due date for the next vaccine shot was 07Jan2021. The outcome of the event ""the rash on her back, more on the flank area/ the upper arms, she got this rash too"" was not recovered, of the other events was unknown."

allergic reaction; dizzy/lightheaded; blood pressure and heart rate skyrocketed; blood pressure and heart rate skyrocketed; fever; sweats; This is a spontaneous report from a contactable consumer reporting for him/herself. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for covid-19 immunisation. The patient medical history and concomitant medications were not reported. On unknown date the patient experienced a mild allergic reaction with unknown outcome. About an hour after getting the shot the patient got dizzy, lightheaded, and her blood pressure and heart rate skyrocketed. She was given 50mg of diphenhydramine hydrochloride (BENADRYL) in the ED and still felt bad. On unspecified date the patient had a fever and sweats but the day after she was feeling good. The patient wanted to know if she could get the second dose. Information on the lot/batch number has been requested.

vomiting; diarrhea; myalgia; headache; face swelling; pain at the injection site; This is a spontaneous report from a contactable physician reporting for one of her patients. A 43-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), lot number: Unknown via an unspecified route of administration on 19Dec2020 at single dose for COVID-19 immunisation. The patient medical history and concomitant medications were not reported. The patient received the COVID-19 vaccine

yesterday (on 19Dec2020) and was experiencing vomiting, diarrhea, face swelling, myalgia, headache, and pain at the injection site on an unspecified date. Expressed being concerned about an anaphylactic reaction and wanted to know how her patient's symptoms compare to it. Then the physician asked for the timing of the anaphylactic symptoms onsets reported in the clinical trials. The event outcome was unknown. Information on the lot/batch number has been requested.

fever; headache; body aches; chills; This is a spontaneous report from a contactable consumer (patient). A 56-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK5730 and expiration date: Mar2021), via an unspecified route of administration on 19Dec2020 at single dose for covid-19 immunization. It was the first dose. Medical history included the patient was Cancer survivor and the patient was not taking any chemo or any radiation. In 2003 the patient took chemo radiation. Concomitant medications included anastrozole, citalopram, alendronate sodium (ALENDRONATE). The patient stated she was having a couple symptoms including fever, headache, body aches, and chills on an unknown date in Dec2020. Treatment included the patient had been taking Excedrin, It had aspirin in it and Tylenol in it and Tylenol is 250 mg and Aspirin is 250 (unit was not specified). The patient was wondering how long her symptoms are going to last. The patient thought the lab test has been about a month. The outcome of the events was unknown.

I felt my left ear become hot and then felt paresthesia of my left ear, side of cheek and jaw, and down side of neck; Felt like numbness after dental procedure; left ear become hot; This is a spontaneous report from a contactable consumer (patient). This 37-year-old female consumer received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) Lot number EH9899, at single dose on 20Dec2020 18:45 on left arm for COVID-19 immunisation. Medical history was none. Concomitant medication was not reported. The consumer had no other vaccine in four weeks. The consumer had no covid prior vaccination. The consumer had no covid tested post vaccination. The consumer had no known allergies. The consumer was not diagnosed with COVID-19 Prior to vaccination. The consumer had not been tested for COVID-19 since the vaccination. Approx 12-15 min after injection (20Dec2020 19:00) the consumer felt her left ear become hot and then felt paresthesia of her left ear, side of cheek and jaw, and down side of neck. She felt like numbness after dental procedure. Waxed and waned over the course of 30-45 minutes. She had mostly resolved after 1.75 hours, though slight abnormal feeling still remained. No treatment was received for all events. The outcome of the events was resolving.

Headache, chills and body was warm; Headache, chills and body was warm; Headache, chills and body was warm; This is a spontaneous report from a contactable consumer reporting for himself. A 37-years-old male patient received bnt162b2 (BNT162B2) , via an unspecified route of administration on 17Dec2020 13:15 at single dose for COVID 19 immunisation. The patient medical history included pre-diabetes. There were no concomitant medications. On 18Dec2020 early in the morning (at about 6-7a.m.) the patient experienced headache, with outcome of not recovered , chills with outcome of recovered and body was warm with outcome of recovered. The patient underwent lab tests and procedures which included blood cholesterol: unknown results on Dec2020 , blood glucose: pre-diabetic but not yet on Dec2020 , body temperature: his body was warm but he did not measure his fever, glycosylated haemoglobin: 5. something, not even 6. on Dec2020 , weight: between 180-190. Information about Lot/batch no has been requested.

felt her heart pounding and took her pulse and it was 158; took her pulse and it was 158; feels fatigued currently; took her blood pressure (BP) and it was 151/113; This is a spontaneous report from a contactable other healthcare professional. A 64-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot# EH9899), intramuscularly in right arm on 18Dec2020 14:05 at single dose for Covid-19 immunisation. Medical history included allergies to penicillin, allergy to mussels (bronco constriction and itch), figs allergy (nausea, vomiting, dizziness, elevated heart rate), allergy to grass (welts), ongoing asthma (asthma environmental triggers (Flowers, perfume, chemicals, soil, grass)), breast cancer left (had radiation and tamoxifen) from 2005 and ongoing, radiotherapy from an unknown date and unknown if ongoing. Concomitant medication included vitamin b complex (VITAMIN B), vitamin C, calcium (CA), Zinc, albuterol [salbutamol] and multivatamins. The patient previously took ampicillin and experienced allergy-rash, previously vaccinated with influenza and experienced weakness in 2010, and previously received tamoxifen for breast cancer female. After one hour later (18Dec2020 15:00), she felt her heart pounding and took her pulse and it was 158 and no other symptoms. Denies chest pain. Staff took her blood pressure (BP) and it was 151/113 on a machine. Recheck 10 minutes later BP 151/112, P 126. EE was brought to the Occupational Medicine Dept, Recheck at 20 min BP 125/68 and an apical pulse of 88. Heart rate (HR) regular, rate and rhythm. Employee states she feels fatigued currently, denies shortness of breath, chest pain, itching, swelling on oral cavity. The outcome of events was recovered on 18Dec2020.

low grade temperature (not fever) within first 24 hours of vaccine; Myalgia resolved with medication; This is a spontaneous report from a contactable consumer (patient). A patient of unspecified age (reported as 28) and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced myalgia resolved with medication, low grade temperature (not fever) within first 24 hours of vaccine on an unspecified date. The outcome of the event myalgia was resolved on an unspecified date, outcome of the other event was unknown. No follow-up attempts are possible. Information about lot/Batch number cannot be obtained. No further information is expected.

itching all over/bottom of his feet were itching too/he was scratching all over, his back, legs everywhere; This is a spontaneous report from a contactable consumer (patient). A 53-year-old male patient received 1st dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot# EK5730), intramuscular in left arm on 18Dec2020 12:45 at single dose for Covid-19 immunisation. Medical history included hypertension and anemia (he only has anemia and hypertension) from 2018 to an unknown date. Concomitant drug included other medications, but he didn't have the list in front of him. Prior vaccinations within 4 weeks was none. He just got the COVID vaccine today (18Dec2020). He started itching about 2 hours ago, once he got home. He was just itching all over. He had a hairbrush just scratching himself because he was itching all over, he was scratching all over, his back, legs everywhere. He confirmed this was his first dose of the COVID vaccine. He was supposed to go back in three weeks to get the second dose. He had not been to an emergency room or physician office yet, but he's getting ready to go. The bottom of his feet were itching too. The itching was everywhere. That was the only symptoms that he had his body was itching. He worked at a hospital, supply them with mask, he was supply technician. He worked

closely with may not be the patient everyday. He was on an esophagogastroduodenoscopy (EGD) done where they put tube down through throat and colonoscopy and EGD, they found some information and they removed it, about a month ago. The outcome of event was not recovered.

Dazed look with nausea; Dazed look with nausea; dry heaving; she looked green; This is a spontaneous report from a contactable consumer. A 61-years-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot Number: EH9899), intramuscular in the left arm on 18Dec2020 07:00 at single dose for covid-19 immunisation. The patient was not pregnant at time of vaccination. Medical history included some metals cause rash, ongoing rheumatoid arthritis and ongoing hypertension. The patient's concomitant medications were not reported. On 18Dec2020 at 08:00 the patient experienced dazed look with nausea and dry heaving: staff standing near her said she looked green. The patient Went to ER at the hospital; EKG done and result normal; seen by ER MD given ondansetron (ZOFRAN); Cleared to return to work same day. The patient recovered from the adverse events.

Numbness in left thumb; Left arm felt heavy and slightly numb; Left arm felt heavy and slightly numb; This is a spontaneous report from a contactable consumer. A 50-year-old female patient received the 1st dose of bnt162b2 (BNT162B2, Manufacturer Pfizer-BionTech) (lot# EH9899), intramuscular in the left arm, on 17Dec2020 at 02:00 PM, at single dose, for Covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient hasn't ever had an adverse event following any previous vaccine administered for immunization. The patient experienced numbness in left thumb on 17Dec2020 at 02:05 PM with outcome of recovered within 30 minutes and left arm felt heavy and slightly numb on 17Dec2020 at 02:05 PM with outcome of recovered within 30 minutes.

joint pain; Dizzy; tired; weak; nausea; This is a spontaneous report from a contactable Other HCP. A 28-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number # EJ1685) on 18Dec2020 at 08:30 AM at single dose via intramuscular on left arm for COVID-19 immunization. Relevant medical history included cancer in 2018 and allergy reaction to bee sting. Concomitant medications were not reported. Prior to vaccination patient wasn't diagnosed with COVID-19 and was not already tested for COVID-19. On 18Dec2020 at 08:45 AM patient experienced dizzy, tired, weak, nausea, and joint pain. At the time of the reporting the patient was recovering. No follow-up attempts are needed. No further information expected.

Sore arm; loss of appetite; nausea; headache; fatigue; This is a spontaneous report from a contactable other health care professional (Other HCP, patient herself). A female patient of unspecified age (reported as 31 also reported as 61) received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) (Lot number EH9899) on 16Dec2020 at single dose for COVID-19 immunization. Medical history and concomitant medications were not reported. Patient experienced side effects reported as sore arm, loss of appetite, nausea, headache, fatigue. All side effects occurred two days after first dose of vaccine (18Dec2020). The outcome of the events was unknown.

Severe pain at site in left arm extending to whole arm, unable to lift arm or do things.; Severe pain at site in left arm extending to whole arm, unable to lift arm or do things.; Severe pain at site in left arm

extending to whole arm, unable to lift arm or do things.; This is a spontaneous report from a contactable nurse (patient herself). A 39-year-old female patient (no pregnancy) received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration at site of right arm at 16:00 on 19Dec2020 at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced severe pain at site in left arm extending to whole arm, unable to lift arm or do things on 20Dec2020. No treatment received for events. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. The outcome of events was not recovered. Information on Lot/Batch number has been requested.

Dizziness; nausea; dry mouth; felt hot; chest tightness; sour taste in mouth; rapid heart rate; tingling on same arm vaccinated (L arm); some numbness in same arm left arm; felt shaky; Blood pressure elevated; This is a spontaneous report from a contactable healthcare professional. A 39-year-old non-pregnant female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot number: EH9899), intramuscularly in the left arm on 17Dec2020 02:25 at a single dose for COVID-19 immunization. The patient had no significant medical history and no concomitant medications. Other illnesses at the time of vaccination and up to one month prior was none. The patient had no allergies to medications, food or other products. On 17Dec2020 02:32, the patient experienced dizziness, nausea, dry mouth, felt hot, chest tightness, sour taste in mouth, rapid heart rate, tingling on same arm vaccinated (L arm), some numbness in same arm left arm, felt shaky and blood pressure elevated. The patient was taken to emergency department and oxygen was provided. The patient underwent lab tests and procedures on 17Dec2020 which included blood pressure measurement: elevated and heart rate: rapid. Therapeutic measures were taken as a result of the events as aforementioned. The patient was observed and discharged to home after 40 min. The outcome of the events was recovered on 17Dec2020.

panic attacks; This is a spontaneous report from a Non-contactable physician. A 30-year-old female patient received bnt162b2 (BNT162B2) at single dose on an unspecified date for immunisation. Medical history included anaphylactic reaction, panic attack and 12 unspecified comorbid conditions. The patient's concomitant medications were not reported. The patient experienced panic attacks on an unspecified date. The action taken in response to the event for bnt162b2 was not applicable. The outcome of event was unknown. According to MD, they are not sure if was a true adverse reaction or a panic attack. No follow-up attempts are possible, information about lot/batch cannot be obtained.

anaphylactic reactions; throat and lip swelling; throat and lip swelling; mild chest pain; This is a spontaneous report from a non-contactable pharmacist. A 34-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration, on an unspecified date at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient previously took terbinafine (MANUFACTURER UNKNOWN) and experienced allergy. The patient experienced anaphylactic reactions, throat and lip swelling, and mild chest pain on an unspecified date. The patient was observed for five hours. The clinical outcome of anaphylactic reactions, throat and lip swelling, and mild chest pain was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Sender's

Comments: There is a reasonable possibility that the events anaphylactic reactions, throat and lip swelling, and mild chest pain were related to BNT162b2 based on known drug safety profile. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

About 30 mins after injection felt brain fog and had a hard time finding words/ like we were having to concentrate more than usual to do routine stuff; About 30 minutes after injection felt brain fog and had a hard time finding words. Another nurse that got vaccinated at the same time felt the same way. It's like we were having to concentrate more t; About 30 mins after injection felt brain fog and had a hard time finding words/ like we were having to concentrate more than usual to do routine stuff; This is a spontaneous report from a contactable consumer. This consumer reported similar events for 2 patients. This is the 2nd of 2 reports. A patient of unspecified age and gender started to receive (PFIZER-BIONTECH COVID-19 VACCINE, Lot number Ej1685), intramuscularly, as first single dose on 20Dec2020 for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. On 20Dec2020, about 30 minutes after injection felt brain fog and had a hard time finding words. Another nurse that got vaccinated at the same time felt the same way. It's like we were having to concentrate more than usual to do routine stuff. Outcome of the events about 30 mins after injection felt brain fog and had a hard time finding words/ like we were having to concentrate more than usual to do routine stuff was unknown.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2020503261 same drug, same event and different patient

"soreness at the injection site; This is a spontaneous report from a non-contactable consumer. A 59-year-old female patient (reporter's mother) received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) (lot EH9899) on 18Dec2020 at a single dose for COVID-19 immunization. Medical history and concomitant medications were not reported. Patient used to receive unspecified vaccines and experienced pain at the injection site. After 8 hours of taking bnt162b2 and into the next day patient reported soreness at the injection site on 19Dec2020. She described it as ""normal"" and like pain felt after other vaccines she has received. The outcome of the event was unknown."

anaphylactic reaction upon receipt of the vaccine; This is a spontaneous report from contactable pharmacist via a Pfizer Sales Representative. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration, in Dec2020 at a single dose for COVID-19 immunization. The patient was reported as a healthcare worker. Medical history included latex allergy. The patient's concomitant medications were not reported. The patient experienced an anaphylactic reaction upon receipt of the vaccine in Dec2020. The reporter called to confirm to confirm the lack of latex in the vaccine and also to inquire about the latex content of the 0.9% sodium chloride (NaCl) used to dilute the vaccine. The clinical outcome of anaphylactic reaction upon receipt of the vaccine was unknown. The batch/lot number for the vaccine, BNT162B2, was not provided and has been requested during follow up.; Sender's Comments: A possible causal association between administration of BNT162B2 and the onset of anaphylactic reaction cannot be excluded, considering the plausible temporal relationship and the known adverse event profile of the suspect

product. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

rash; itchiness; Severe joint pain; nausea; stomach pain; This is a spontaneous report from a contactable Other HCP reported for herself. This 32-year-old female (no pregnant) patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), intramuscular at left arm on 19Dec2020 18:45 at single dose for COVID-19 immunization. Medical history included Auto immune disorder, high-risk medications, asthma, and allergies: Spectrum hand sanitizer. Concomitant medication included adalimumab (HUMIRA) received within 2 weeks of vaccination. No Covid prior vaccination, No Covid tested post vaccination. No other vaccine in four weeks. On 19Dec2020 11:00 PM, the patient experienced severe joint pain, nausea, stomach pain the same day as vaccine. The next day (on 20Dec2020) patient experienced rash and itchiness. No treatment received for the events. The outcome of events was unknown. Information on the lot/batch number has been requested.

she kept having chills and a mild fever; she kept having chills and a mild fever; really bad headaches; She hasn't been able to sleep because of feel warm yet cold and her body aches.; She hasn't been able to sleep because of feel warm yet cold and her body aches.; She hasn't been able to sleep because of feel warm yet cold and her body aches.; She hasn't been able to sleep because of feel warm yet cold and her body aches.; This is a spontaneous report from a contactable healthcare professional. A 28-year-old female patient received BNT162B2 (Lot# EH9899) via intramuscular on 20Dec2020 08:00 AM (anatomical location: arm left, dose number: 1) at single dose for COVID-19 immunization. Medical history and concomitant medications were none. The patient did not have allergies to medications, food, or other products. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine, and did not have any other medications within 2 weeks of vaccination. The patient was not diagnosed with COVID-19 prior to vaccination. Since the vaccination, the patient has not been tested for COVID-19. It was reported that at around 17:00 on 20Dec2020, patient started having really bad headaches. She took a two-hour nap and when she woke up she kept having chills and a mild fever (on 20Dec2020 19:00). She hasn't been able to sleep because of feel warm yet cold and her body aches. No treatment received for the adverse events. Outcome of events was not recovered.

"Tingling throat; This is a spontaneous report from a contactable physician. This physician reported same event for two patients. This is second of two reports. A patient of unspecified age and gender started to receive bnt162b2 (BNT162B2; also reported as COVID-19 vaccine; unknown lot number, NDC number and expiration date), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. It was reported that it was unknown if other products were received or if an investigation assessment was performed. On 16Dec2020, the patient experienced tingling throat (non-serious). The physician called regarding COVID 19 vaccine since they had two events that happened yesterday (16Dec2020), however, the physician stated that she needs to ask a question before speaking with DSU and reporting the events. the physician mentioned that two patients complained of tingling in their

throat during the observation period after the vaccine was administered. The physician thought ""they just panicked and overreacted "" and she did not think they had a reaction. The patients did go the ER (emergency room) and were discharged the same day. The physician wanted to be able to give the second dose. The physician wants to ask about the side effects of the vaccine. The outcome of the event was unknown. The following information on the lot/batch number has been requested; Sender's Comments: Linked Report(s) : US-PFIZER INC-2020502608 same reporter/event, different patient"

Fever; Chill; whole muscle ache; Headache; Runny nose; This is a spontaneous report from a contactable Other HCP reported for herself. This 32-year-old female (no pregnant) patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number: EH9899), intramuscular at left arm on 20Dec2020 11:00 at single dose for COVID-19 immunization. None medical history reported. The patient's concomitant medications were not reported. No Covid prior vaccination, No Covid tested post vaccination. No other vaccine in four weeks. On 20Dec2020 02:00 PM, the patient experienced fever, chill, whole muscle ache, headache, runny nose. No treatment received for the events. The outcome of events was unknown.

Itchiness and small rash on forehead; Itchiness and small rash on forehead; This is a spontaneous report from a contactable nurse (Patient). A 35-year-old female patient received bnt162b2 (lot number: EJ1685), intramuscularly at left arm, 1st dose on 20Dec2020 08:00 AM, at single dose, for COVID-19 immunization. No COVID prior vaccination, COVID tested post vaccination, known allergies, or other medical history. No other vaccines within 4 weeks prior to the COVID vaccine. No other medications the patient received within 2 weeks of vaccination. The patient was not diagnosed with COVID-19, prior to vaccination and after vaccination. Not pregnant at the time of vaccination. There were no concomitant medications. The patient experienced itchiness and small rash on forehead on 21Dec2020 01:00. The event was reported as non-serious. Therapeutic measures were taken as a result of itchiness and small rash on forehead, treatment included: allergy medicine PO (Oral). The outcome of the events was unknown.

Joint pain; Muscle pain; Headache; Fever (100.7 F); Fatigue; This is a spontaneous report from a non-contactable Other Healthcare professional (HCP). A 61-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot # EK5730), intramuscular, on 18Dec2020 at 12:30 PM at single dose for COVID-19 immunisation. Vaccine location was right arm. The patient was vaccinated at hospital, age at vaccination was 61-years-old. Medical history included the patient diagnosed with COVID 19 before vaccination. On 19Dec2020 at 06:00 PM, the patient experienced joint pain, muscle pain, headache, fever (100.7 F) and fatigue. No treatment was administered for the events. The patient recovered from the events on an unknown date in Dec2020. No follow-up attempts are possible. No further information is expected.

Bitter taste with food and drink for 2 hours post injection; This is a spontaneous report from a contactable other Healthcare Professional (HCP, patient). A 49-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot # ej1685), intramuscular, on 19Dec2020 at single dose for COVID-19 immunisation. Vaccine location was left arm. The patient was vaccinated at hospital, age at vaccination was 49-years-old. No other vaccines were administered within 4 weeks prior

to the COVID vaccine. Medical history included allergies to iodine, migraine, and gastrooesophageal reflux disease (GERD). Concomitant medications included duloxetine, erenumab aooe (AIMOVIG), and ubrogepant (UBRELVY) The patient experienced bitter taste with food and drink for 2 hours post injection on 19Dec2020 at 05:30 PM, reported as non-serious. No treatment was received for the event. The patient recovered from the event on an unknown date in Dec2020.

feeling tingling in my lips & face.& tongue; feeling tingling in my lips & face.& tongue; This is a spontaneous report from a contactable nurse (patient). A 61-year-old female patient received her first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot:EL0140) via an unspecified route of administration at the right arm on 19Dec2020 08:30 at a single dose for covid-19 immunisation. Medical history included allergies to medications: sulfa drugs. Concomitant medication included zinc, magnesium, calcium phosphate, colecalciferol (CALCIUM+D), ascorbic acid (VITAMIN C) and clarithromycin (CLARITIN). On 20Dec2020 21:00, the patient felt tingling in her lips, face and tongue. The patient reported that she took diphenhydramine (BENADRYL) orally, 25mg when she got home as treatment. Outcome of events recovered on an unspecified date in Dec2020.

nausea; Headache; This is a spontaneous report from a contactable Nurse (patient). This 60-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot # EK5730), via an unspecified route of administration, on 17Dec2020 at 09:30 AM at single dose for COVID-19 immunisation. Vaccine location was left arm. The patient was vaccinated at hospital, age at vaccination was 60-years-old. No other vaccine was received in four weeks. Medical history included colorectal cancer in 2008, and idiopathic thrombocytopenic purpura (ITP) in 1991 recovered on an unknown date. Concomitant medications included gabapentin, omeprazole, duloxetine. On 17Dec2020 at 01:00 PM, the patient experienced headache and nausea the first day, severe nausea the second and third day, nausea continuing but not as severe as the second and third day. The patient was treated with Zofran. Outcome was not recovered.

headache on left side of head which was similar to migraine; This is a spontaneous report from a contactable other healthcare professional reported for herself. A 43-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number EJ1685, expiry date unknown) intramuscular on left arm on 19Dec2020 11:30 at single dose for COVID-19 immunization. Medical history included penicillin allergies, allergies to sulfa drugs and allergies to cephalosporins. Concomitant medication included vitamin D3 and amylase, ascorbic acid, cellulase, folic acid, lipase, protease nos (JUICE PLUS); both from unspecified date for unspecified indication. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. On 19Dec2020 13:00, the patient experienced headache on left side of head which was similar to migraine and went away on Dec2020 by taking 2 Aleve. The event was considered non-serious and did not results in death, not life threatening, did not caused/prolonged hospitalization, not disabling/incapacitating, not a congenital anomaly/birth defect.

A large raised whelp (welt) at the injection site painful itchy hard and still there 5 days post injection; A large raised whelp (welt) at the injection site painful itchy hard and still there 5 days post injection; A large raised whelp (welt) at the injection site painful itchy hard and still there 5 days post injection; A

large raised whelp (welt) at the injection site painful itchy hard and still there 5 days post injection; This is a spontaneous report from a contactable other healthcare professional, patient. A 56-year-old female patient (non-pregnant) received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 09Dec2020 16:00 in the right arm at single dose for COVID-19 immunization. Patient medical history included hypertension (htn), obesity, chronic pain, arthritis, and season allergies chronic. Concomitant medications were not reported. The patient previously took tramadol, tizanidine and duloxetine hcl (CYMBALTA) and experienced drug allergies. On 09Dec2020 17:00, the patient developed a large raised whelp (welt) at the injection site, painful, itchy, hard and still there 5 days post injection. The events were assessed as non-serious. Outcome of the events was not recovered. Information on batch number has been requested.

Chilled; headache; blurred vision; This is a spontaneous report from a contactable Other Health Professional (patient). A 64-year-old female patient receivef bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) lot number: EJ1685, intramuscular in the right arm, first dose on 18Dec2020 10:15 at a single dose for immunisation. Medical history included cervical dystonia wherein she takes botox treatments quarterly for this. Concomitant medications included estradiol, rosuvastatin calcium (CRESTOR), gabapentin and montelukast sodium (SINGULAIR). The patient was not pregnant. The patient was not diagnosed with covid 19 prior to vaccination nor been tested since vaccination. The patient experienced chilled, headache, and blurred vision on 18Dec2020 at 12:00 PM with outcome of recovered on an unknown date in Dec2020. The patient did not receive any treatment for the events. The events are considered non-serious by the reporter. No follow-up attempts are possible. No further information is expected.

experienced itchy and tight throat that felt like a tickle in throat; experienced itchy and tight throat that felt like a tickle in throat; This is a spontaneous report from a contactable nurse. A 46-year-old non-pregnant female patient received 1st dose of bnt162b2 (brand = Pfizer, lot number: EJ1685), intramuscular in the left arm on 20Dec2020 09:00 at a single dose for COVID-19 immunization at the hospital. Medical history included atrial septal defect repair in 2011 to an unknown date. The patient has no known allergies. Concomitant medications included hydrocodone bitartrate, paracetamol (VICODIN) and diclofenac. The patient experienced itchy and tight throat that felt like a tickle in throat on 20Dec2020 09:00. Airway remained patent and no rash/hives. The AEs resulted in a visit to emergency room/department or urgent care. Outcome of the events was recovered in Dec2020. No treatment was given for the events. It was unknown if patient had COVID prior to vaccination. The patient was not tested for COVID post vaccination.

Injection site pain level 7 to 8 about 6 hours after injection; Very tired and sleepy 4 hours after injection; Very tired and sleepy 4 hours after injection; This is a spontaneous report from a contactable healthcare professional. A 54-year-old male patient received first dose of BNT162B2 (lot number: Ek5730), intramuscularly at the right arm, on 19Dec2020 09:00 at a single dose for COVID-19 immunization at a public health clinic/veterans administration facility. Medical history included continuous positive airway pressure (CPAP), high cholesterol, and high blood pressure (BP). Patient has no known allergy. The patient was no previously diagnosed with COVID-19 not was tested for it. Also the patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Concomitant medication included

atorvastatin calcium (LIPITOR). The patient was very tired and sleepy 4 hours after injection on 19Dec2020 13:00 and experienced injection site pain level 7 to 8 about 6 hours after injection on the same day of 19Dec2020, 15:00. Therapeutic measures were taken as a result of injection site pain which included acetaminophen (TYLENOL). The patient recovered from the event injection site pain by the next day of 20Dec2020 and from the event tired and sleepy after a nap on the same day of 19Dec2020.

Arm soreness; Fatigue; General malaise; Low grade temp; Headache; This is a spontaneous report from a contactable nurse (patient). A 46-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK5730, expiry date: not provided) solution for injection at a hospital, via an unspecified route of administration (on left arm) on 17Dec2020 14:00 at a single dose for COVID-19 immunisation. Medical history included allergy to Sulfa, and FS (flushing and sweating). Concomitant medication included estrogens esterified, methyltestosterone (ESTRATEST) daily. The patient received the vaccine on left arm, dose number 1. The patient experienced arm soreness, fatigue, general malaise, low grade temp, and headache on 17Dec2020. No treatment was given. The events were reported as non-serious. Patient was not pregnant. The patient did not receive any other vaccines within 4 weeks prior to the Covid-19 vaccine; patient has not been tested or diagnosed of Covid-19. Outcome of the events was recovering. No follow-up attempts needed. No further information was expected.

chills; flulike symptoms; cramping in left leg; fatigue; This is a spontaneous report from a contactable other healthcare professional which is also the patient. A 41-year-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 18Dec2020 at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. In Dec2020, the patient experienced having cramping in left leg that has resolved and fatigue, chills that began last night from the time of report, and flulike symptoms since getting the vaccine. The reporter asked if he should be worried and get a COVID test. He was given paperwork and knows these are possible symptoms of the vaccine. Information on lot/batch number has been requested.

Ear pressure and swelling on same side as vaccine injection; Ear pressure and swelling on same side as vaccine injection; This is a spontaneous report from a contactable nurse (patient). A 27-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE lot/batch number EJ1685), via an unspecified route of administration on the right arm on 21Dec2020 08:30 at SINGLE DOSE as COVID-19 immunization. The patient had allergies to tree nuts. Prior to vaccination, the patient was not diagnosed with COVID-19 and patient had not been tested for COVID-19 since vaccination. The patient's concomitant medications were not reported. On 21Dec2020 08:45, the patient had ear pressure and swelling on same side as vaccine injection resulting to doctor or other healthcare professional office/clinic visit. It was unknown if treatment was received for the adverse event. Outcome of the events were unknown.

nausea; headache; fatigue; muscle pain; feeling unwell; This is a spontaneous report from a contactable nurse who reported for herself. A 51-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), intramuscular in Left arm on 17Dec2020 at 11:30 am at single dose for COVID-19 immunization. Patient was not pregnant. No known allergies. Concomitant medication included

unspecified drug: patient received other unspecified medication in two weeks. No other vaccine in four weeks administered. On 17Dec2020 at 11:45 am, the patient experienced nausea, headache, fatigue ,muscle pain and feeling unwell, all non serious. No treatment given. Outcome of the events was reported as recovered in Dec2020. No follow-up attempts are possible, information about batch number cannot be obtained.

Immediate headache followed by total body itching. Itching began 4-5 hours after dose. Itching lasting overnight into early morning. Felt like hives, but skin did not break out into hives.; Immediate headache followed by total body itching. Itching began 4-5 hours after dose. Itching lasting overnight into early morning. Felt like hives, but skin did not break out into hives.; Immediate headache followed by total body itching. Itching began 4-5 hours after dose. Itching lasting overnight into early morning. Felt like hives, but skin did not break out into hives.; This is a spontaneous report from a contactable consumer. A 62-year-old female patient received first dose of bnt162b2 (BNT162B2; lot number: EK5730), via an unspecified route of administration on 20Dec2020 14:00 on right arm , SINGLE DOSE for COVID-19 immunization. Medical history included Known allergies: Contrast dye, sulfur drugs. The patient's concomitant medications were not reported. The patient previously took erythromycin and experienced Known allergies: Erythromycin. No COVID prior vaccination. The patient has not been tested for COVID-19 since the vaccination. On 20Dec2020 18:30, the patient experienced Immediate headache followed by total body itching. Itching began 4-5 hours after dose. Itching lasting overnight into early morning. Felt like hives, but skin did not break out into hives. The events was assessed as non-serious. The outcome of the events was recovered.

Injection site pain; tiredness; headache; muscle pain; chills; injection site swelling; nausea; swollen lymph nodes; feeling unwell; onset of menstrual cycle; This is a spontaneous report from a contactable nurse (patient). A 29-year-old female patient started received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE lot/batch number not provided), intramuscular on the left arm on 17Dec2020 17:00 at SINGLE DOSE as COVID-19 immunization at the workplace clinic. Medical history included Hashimoto's Thyroiditis & Environmental Allergies. The patient also had allergies to ibuprofen, penicillin, & sulfa. Concomitant medications included levothyroxine (LEVOTHYROXINE), montelukast (MONTELUKAST), ethinylestradiol, norgestimate (TRINESSA) and multivitamins. Prior to vaccination, the patient was not diagnosed with COVID-19 and not tested for COVID-19 since vaccination. On 18Dec2020 12:00, the patient experienced injection site pain, tiredness, headache, muscle pain, chills, injection site swelling, nausea, swollen lymph nodes, feeling unwell, and onset of menstrual cycle (as reported). The patient did not receive any treatments for the events. The patient recovered from the events in Dec2020. Information on the lot/batch number has been requested.

hives, urticaria mostly over torso, face; This is a spontaneous report from a contactable physician (patient). A 29-year-old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number: EK5730), intramuscular on the left arm on 15Dec2020 19:30 at a single dose for covid-19 immunization. The patient's medical history included persistent depressive disorder and known allergic reaction to wood varnish. The patient was not pregnant. Concomitant medications included escitalopram oxalate (LEXAPRO) and bupropion hydrochloride (WELLBUTRIN). The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to

vaccination, the patient was not diagnosed with COVID-19 and had not been tested for COVID-19 since the vaccination. The patient experienced hives, urticaria mostly over torso, face on 17Dec2020 18:00. Therapeutic measures were taken as a result of hives, urticaria mostly over torso, face and included treatment with dexamethasone. Outcome of the event was recovering.

intense arm pain, migraine, nausea w/ vomiting; intense arm pain, migraine, nausea w/ vomiting; intense arm pain, migraine, nausea w/ vomiting; intense arm pain, migraine, nausea w/ vomiting; This is a spontaneous report from a contactable other healthcare professional. A 44-year-old female patient received the first dose of bnt162b2 (Covid-19 vaccine, manufacturer: Pfizer, lot no: EJ1685) intramuscular in left arm on 18Dec2020 13:00 at a single dose for COVID-19 immunization. Medical history included type 2 diabetes mellitus, known allergies to sulfa, penicillin group, tetracycline analogues group. Concomitant medication included metformin, fluoxetine hydrochloride (PROZAC), lisinopril, semaglutide (OZEMPIC), and insulin glargine (TOUJEO). The patient experienced intense arm pain, migraine, nausea w/ vomiting on 19Dec2020 04:00. The patient recovered from the events in Dec2020. The events were reported as non-serious. The patient did not receive treatment for events, had no covid prior to vaccination, and was not covid tested post vaccination.

Severe, watery diarrhea; This is a spontaneous report from a non-contactable other healthcare professional. A 30-year-old female patient received bnt162b2 (BNT162B2, lot no and expiry date was unknown), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. The patient is not pregnant. The patient experienced severe, watery diarrhea on 18Dec2020. No treatment received for the event. The outcome of the event was not recovered. No follow-up attempts are possible, information about batch number cannot be obtained.

Really bad body aches the next day.; Itching at site and then itching went to rest of body. No hives.; Itching at site and then itching went to rest of body. No hives.; This is a spontaneous report from a contactable nurse (reported for herself). A 47-year-old female patient (not pregnant) received bnt162b2 (BNT162B2 also reported as COVID 19 brand Pfizer, lot/batch number and expiry date not reported), intramuscular on 18Dec2020 16:45 at single dose (dose number 1) in the right arm for immunisation. Medical history was none. Patient was allergic to medication sulfa, food, or other products. She had no other vaccine in four weeks, no covid prior vaccination. The patient's concomitant medications included unspecified multivitamins. The patient experienced itching at site and then itching went to rest of body (no hives) on 18Dec2020 16:45. She had really bad body aches the next day (19Dec2020). No treatment was given. No hospitalization reported. The outcome of events was recovered on unknown date in Dec2020. Information on the Lot/Batch number has been requested.

mother received BNT162B2/while the mother was breast feeding this 5-month-old patient; vomiting (throwing up); not eating. Not nursing, Not breastfeeding and not taking her bottle; her 5month old baby is lethargic; all of a sudden took ill; This is a spontaneous report from a contactable consumer (parent). This consumer reported information for both mother and baby. This is baby report. This is a case for a 5-month-old patient of an unspecified gender whose mother of unspecified age received first

dose of BNT162B2 (PFIZER/BNT162 Covid-19 Vaccine), via an unspecified route of administration on 18Dec2020 13:15 at a single dose for COVID-19 immunization, while the mother was breast feeding this 5-month-old patient. The patient's medical history and concomitant medications were not reported. On 19Dec2020, all of a sudden took ill. The patient was lethargic, vomiting (throwing up) and not eating. Not nursing, Not breastfeeding and not taking her bottle. The outcome of events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2020503099 mother/baby case

"Received the vaccine last Friday. Having fever. Temperature high as 101.4F .; I have a body ache; This is a spontaneous report from a contactable nurse. A 60-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, batch/lot number EH9899, Expiry Date: 30Mar2021), via an unspecified route of administration on 18Dec2020 at single dose for covid-19 immunisation. Medical history included blood pressure, cholesterol, covid-19 (Had Covid-19 in March). Concomitant medication included amlodipine for Blood pressure, rosuvastatin calcium (CRESTOR) for Cholesterol. Nurse calling on behalf of herself. 60 years old almost 61. Received the vaccine last Friday. Having fever. Temperature high as 101.4F. Still having it lingering between 99F and 100F. How long will it last? Had Covid-19 in March. Compared with her colleagues and they had no side effects except pain at injection site. Lab test: Nurse stated, ""I did a Covid swab on the 14th its negative."" Treatment: Nurse stated, ""When I had a fever I had something, Yes, I did, I took Tylenol."" Causality: Nurse stated, ""Yes, because I was fine before COVID Vaccine."" Nurse further stated, ""Besides the fever I have like my body is aching, my whole body is aching. I have a body ache."" The outcome of the events was unknown."

doesn't feel good; migraine level headaches; body aches; injection site pain; Tiredness; headache; muscle pain; Chills; Nausea; arm is still a little sore; bottom of the arm hurt; she couldn't move it; This is a spontaneous report from a contactable other healthcare professional (patient). A 46-year-old female patient received first dose of bnt162b2 (Pfizer Biontech COVID 19 vaccine), Lot number: EH9899, intramuscular in the deltoid on 17Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. She works in Urgent Care and has to swab people with COVID all day long. The caller had the injection on 17Dec2020 and still doesn't feel good. The patient is a medical assistant calling because of herself. She did not want to go back to work, she does not feel good, she has a headache that is horrible, migraine level headache and a few body aches. This happened two hours after the injection- she had injection site pain, tiredness, headache, muscle pain, chills, nausea. She also stated that her arm is still a little sore, she got it in the deltoid, and the bottom of the arm hurt, she couldn't move it, but the next day, her arm was fine. The outcome of body aches, tiredness, muscle pain, chills, nausea was recovering; migraine level headaches and headaches was not recovered; doesn't feel good and injection site pain was unknown; arm is still a little sore; bottom of the arm hurt and she couldn't move it recovered on an unspecified date.

"Tenderness and slight swelling in my left neck and left armpit; Tenderness and slight swelling in my left neck and left armpit; This is a spontaneous report from a contactable nurse. A 44-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), lot number: EK5730, first dose via an unspecified route of administration in left arm on 17Dec2020 20:30 at single dose for COVID-19 immunization. Medical history included COVID-19 prior to vaccination and penicillin allergy from an

unknown date and unknown if ongoing. On 19Dec2020, the patient stated, ""tenderness and slight swelling in my left neck and left armpit on day 2 after vaccine. The patient had no other vaccine in four weeks. The patient had taken other unspecified medications in two weeks. No treatment was given to patient for the events. The patient had COVID prior vaccination to vaccination and not had COVID test post vaccination. The events were reported as non serious as it did not result in death, not life threatening, did not cause prolonged hospitalization, not disabling or incapacitating and no congenital anomaly or birth defect. The outcome of the events was not recovered."

"injection site pain; This is a spontaneous report from a contactable pharmacist. An adult (reported as 39, unit unknown) female patient received first dose of BNT162B2 (Pfizer-BioNTech COVID-19 mRNA vaccine, batch/lot number and expiry date were unknown), via an unspecified route of administration on 18Dec2020 at a single dose for COVID-19 immunization. The patient received COVID-19 vaccine in a hospital facility. The patient's medical history and concomitant medications were not reported. The patient previously experienced vaccination site pain from flu vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient had 1st dose of COVID-19 vaccine and experience injection site pain. She described it as ""more painful than any flu vaccine received"". The patient did not receive treatment for the adverse event. The outcome of the event was recovered in Dec2020. No follow-up attempts are possible. Information on lot/batch number cannot be obtained. No further information is expected."

Got hot; flushed; weakness; few minutes of itchy throat and back; few minutes of itchy throat and back; lips tingling; a lump in the throat feeling; This is a spontaneous report from a contactable nurse (patient). A 40-year-old male patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number: ek5730), intramuscular on the left arm on 20Dec2020 12:00 at a single dose for COVID-19 immunization. The patient's medical history included irritable bowel syndrome (IBS), attention deficit hyperactivity disorder (ADD), and lactose intolerance. Concomitant medications included hyoscyamine and amfetamine aspartate, amfetamine sulfate, dexamfetamine saccharate, dexamfetamine sulfate (ADDERALL). The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. On 20Dec2020 12:00, the patient experienced got hot, flushed, weakness, few minutes of itchy throat and back, lips tingling, and a lump in the throat feeling. No treatment received for the adverse events. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, the patient had not been tested for COVID-19. Outcome of the events was recovering. The events were considered non-serious.

Low grade temp; headache; achy; diarrhea; tiredness; This is a spontaneous report from a contactable nurse (patient). A 41-year-old female patient received the first dose of bnt162b2 (Pfizer Biontech COVID 19 vaccine), Lot number: EJ1685, via an unspecified route of administration on the left arm on 19Dec2020 11:30 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient was not pregnant. The patient has no allergies to medications, food, or other products. On 20Dec2020 11:00, the patient experienced low grade temp, headache, achy, diarrhea and tiredness. The patient did not receive any treatment for the events and were reported as non-serious. The vaccine was administered in a hospital. The patient has not received

any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. The outcome of events low grade temp, headache, achy, diarrhea and tiredness was recovered on an unspecified date in Dec2020.

lymphadenopathy; joint pain; muscle pain; chills; fatigued; sore, pain at site normal for vaccine admin; This is a spontaneous report from a contactable pharmacist. An adult female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot: EJ1685) intramuscularly on 17Dec2020 at a single dose for covid-19 immunization. The patient's medical history and concomitant medications were not reported. On 17Dec2020 21:00, the patient was fatigued and had sore pain at the site of vaccine administration. On 18Dec2020, the patient experienced joint pain, muscle pain and chills. On 19Dec2020, the patient developed lymphadenopathy. The events were reported as non-serious. Outcome of events recovered on an unspecified date on Dec2020.

purple discoloration to her right arm and right fingers; chills; redness across her chest and stomach; cap refill was sluggish; This is a spontaneous report from a contactable nurse. A 37-year-old female patient received the first dose of BNT162B2 (Pfizer-BioNTech COVID-19 vaccine, lot# EJ1685), via intramuscular on 18Dec2020 11:00 in right arm at single dose for covid-19 immunization. The patient's medical history and concomitant medications were not reported. The most recent COVID-19 vaccine was administered in hospital. Prior to vaccination, the patient was not diagnosed with COVID-19. Employee reported purple discoloration to her right arm and right fingers. She reported her cap refill was sluggish. She stated she had chills and redness across her chest and stomach on 18Dec2020 at 16:00. The events result in Emergency room/department or urgent care. The patient received the treatment for the events. Outcome of events were unknown.

My arm pit is swollen and a little painful; My arm pit is swollen and a little painful; This is a spontaneous report from a contactable consumer (patient). A male patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 18Dec2020 at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient noticed that his arm pit was swollen and a little painful on 20Dec2020. The outcome of the events was unknown. Information about the lot/batch number has been requested.

not being able to smell anything/Cannot smell anything; Sinus issues; Cough; Congestion; Feels hot; backache; fatgue; headache; This is a spontaneous report received from a contactable other health professional (who is also the patient). A 41-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK5730), via an unspecified route of administration in left arm, on 15Dec2020, at single dose, for COVID-19 immunization. There was no medical history. The patient's concomitant medications were not reported. The patient reported that she got the COVID vaccine last Tuesday, on 15Dec2020. She is a psychologist and works close with patients all the time. She has had symptoms since last Wednesday (16Dec2020). She clarified that her symptoms were back ache shortly after the vaccine, fatigue, headache, sinus issues and cough. Then her backache went away. She also had congestion and felt hot on 16Dec2020. She had an appointment last Friday (18Dec2020) and they took her temperature, but she did not have a fever. And then since yesterday (20Dec2020), she

cannot smell anything. She has a baby and cannot smell the dirty diapers. She cannot smell her perfume. She asked other people who received the vaccine if they experienced this, and they did not. She was wondering if this is the vaccine or does she possibly have some other infection or should she get tested for COVID or is it possible this is from the vaccine? The patient clarified that at first her back ache went away but it is still ongoing now. It has persisted at the same level as well as all of the other symptoms. The outcome of the events was not recovered.

Sore arm at injection site and headache at bedtime.; Sore arm at injection site and headache at bedtime.; This is a spontaneous report from a contactable nurse (patient). A 62-year-old female patient (non-pregnant) received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number: EH9899) via unspecified route of administration on 20Dec2020 at single dose for COVID-19 immunization. Patient medical history and concomitant medications were not reported. The patient experienced sore arm at injection site and headache at bedtime on 20Dec2020. Outcome of the event was recovered on unspecified date in Dec2020. No treatment received for the events. The events were assessed as non-serious.

fever; body malaise; Body aches; muscles hurt; sharp eye pain/If she turns her eyes to the right or to the left; chills; This is a spontaneous report from a contactable consumer. A 24-year-old female patient (daughter) received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899), via an unspecified route of administration at 18:00 on 17Dec2020 at single dose for COVID-19 immunization. Medical history included asthma and anxiety. Concomitant medication included sertraline hydrochloride (ZOLOFT) for anxiety. The patient experienced fever, body malaise, body aches, muscles hurt, sharp eye pain/if she turned her eyes to the right or to the left, and chills on 18Dec2020. At time of reporting, the outcome of events was not recovered.

Rash spreading started at the neck slowly progress to the entire neck, then the scalp, torso, legs and arms. Started within 4 hours over night then at 0830 am started getting worse.; This is a spontaneous report from a contactable nurse reporting for herself. A 40-years-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration in the left arm on 20Dec2020 16:15 at single dose for COVID-19 immunization. Medical history included hyperlipidaemia, antiphospholipid syndrome and migraine. Concomitant medication included metronidazole benzoate (FLAGYL), butalbital, caffeine, paracetamol (FIORICET), iron (IRON) and multivitamin. The patient experienced rash spreading started at the neck slowly progress to the entire neck, then the scalp, torso, legs and arms on 20Dec2020 21:30 with outcome of not recovered. On21Dec2020 at 08:30 am it started getting worse. The outcome of the events was not recovered. The patient took Benadryl as treatment for the events. The patient did not undergo COVID test and did not have COVID prior to vaccination. Information on the lot/batch number has been requested.

tingling on roof of mouth, watery eyes, and itchy throat; tingling on roof of mouth, watery eyes, and itchy throat; tingling on roof of mouth, watery eyes, and itchy throat; This is a spontaneous report from a contactable nurse. A 34-years-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number EJ1685), intramuscular in the left arm at hospital on 18Dec2020 09:00 at single dose for COVID-19 immunization. The patient medical history and

concomitant medications were not reported. On 18Dec2020 at 09:15 the patient experienced tingling on roof of mouth, watery eyes, and itchy throat with outcome of unknown. The events required emergency room visit and the patient received treatment.

sore arm following vaccination; This is a spontaneous report from a Pfizer sponsored program, Pfizer First Connect, received from a contactable consumer (patient). A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot/batch number and expiry date were not provided) solution for injection, via an unspecified route of administration on 20Dec2020 at a single dose for COVID-19 immunisation. Medical history included bone pain and arthritis (patient received a prescription of Prednisone today for bone pain and arthritis). The patient's concomitant medications were not reported. The patient reported receiving the first dose of the COVID-19 vaccine yesterday morning (20Dec2020). She mentioned experiencing a sore arm following vaccination. She then explained receiving a prescription of Prednisone today for bone pain and arthritis, after consulting with her foot doctor. She asked if she should she take this steroid treatment, and also asked if she should receive her second dose of the Shingle vaccine while being on the COVID-19 treatment. Outcome of the event was unknown. Information on lot/batch number has been requested.

Tachycardia, heart rate remained higher than 100 bpm throughout the day at rest. Readings ranged from 110-117; This is a spontaneous report from a contactable Nurse. This 25-years-old female Nurse reported for herself (pregnant: No) received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899) on 18Dec2020 01:00 PM at Right arm at single dose for covid-19 immunization. Medical history was allergy to ham. Concomitant drug was Omeprazole. No other vaccine in four weeks. Adverse event reported as Tachycardia, heart rate remained higher than 100 bpm throughout the day at rest (non-serious). Readings ranged from 110-117 on 19Dec2020 09:00 AM with outcome of Recovered. No treatment. No COVID prior vaccination. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. Follow-up attempts have been completed and no further information is expected.

"elevated heart rate of 113; Itching to roof of her mouth; numbness to right side of her throat; This is a spontaneous report received from a contactable nurse. A 24-year-old female patient received her first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EJ1685), intramuscular in right arm, on 18Dec2020 10:45, at single dose, for COVID-19 immunization. The patient medical history and concomitant medications were not reported. It was unknown if the patient was pregnant. It was reported that the patient experienced itching to roof of her mouth, numbness to right side of her throat and had elevated heart rate of 113 on 18Dec2020 at 11:00. The adverse events resulted in ""Emergency room/department of urgent care"". It was unknown if the patient received treatment for the events. The outcome of the events was unknown."

dizziness; weakness; loss of balance; brain fog; lethargy; Dizziness and loss of balance led to a fall where an injury was sustained (leg weakness, loss of balance led to a fall down a flight of stairs with injury to right shoulder); Dizziness and loss of balance led to a fall where an injury was sustained (leg weakness, loss of balance led to a fall down a flight of stairs with injury to right shoulder); Dizziness and loss of balance led to a fall where an injury was sustained (leg weakness, loss of balance led to a fall down a

flight of stairs with injury to right shoulder); This is a spontaneous report from a contactable nurse. This 41-year-old female nurse (patient) reported for herself that she received the first dose of BNT162B2 (Lot# EH9889) intramuscularly at left arm at single dose for COVID-19 ((PFIZER-BIONTECH COVID-19 VACCINE) immunisation on 17Dec2020. Relevant history was unknown. Relevant concomitant drug included multivitamin and ergocalciferol (VIT D). No known allergies. No allergies to medications, food, or other products. Relevant medical history was none. After receiving first dose, the patient experienced dizziness, weakness, loss of balance, brain fog, lethargy on 18Dec2020, 07:00 AM. The dizziness and loss of balance led to a fall where an injury was sustained (leg weakness, loss of balance led to a fall down a flight of stairs with injury to right shoulder). No treatment was received. The patient resolved with sequel from the events. No covid prior vaccination. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. The events were considered as non-serious.

headache; chills; fatigue; This is a spontaneous report from a non-contactable nurse. This nurse reported for a 32-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number=EK5730) Intramuscularly at Left arm at single dose for COVID-19 immunisation on 19Dec2020 (02:30 PM). Relevant history and concomitant drugs were unknown. The patient experienced had chills, fatigue, headache in the morning of 20Dec2020 at 7:00 am. The patient received Tylenol as treatment and the outcome of events was resolved in unknown date of Dec2020. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. No follow-up attempts are possible. No further information is expected.

"amount of blood on his Band-Aid after the injection; This is a spontaneous report from a contactable pharmacist. A male patient unknown age received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) at single dose for COVID-19 immunisation on 20Dec2020. Relevant history and concomitant drugs were unknown. The patient had a significant (then rephrased to ""small"") amount of blood on his Band-Aid after the injection on 20Dec2020. Outcome of the event was unknown. The information on the lot/batch number has been requested."

feeling kind of bad; low grade fever; chills; muscle aches; Arm is still sore at the injection site. It's sore to touch and can tell it's still sore with movement.; swollen lymph nodes; spontaneous report from a contactable nurse. This 47-year-old nurse reported for self that she received her first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) intramuscularly at right arm at single dose for COVID-19 immunisation on 18Dec2020. Relevant history included gestational diabetes history; Her daughter was 14 years old and she had never had diabetes. No signs of diabetes after birth of daughter. The patient was not a smoker/former smoker. The patient had tested positive with COVID antibodies probably in Apr2020, both she and her husband and both wound up getting symptomatic with COVID symptoms about the 14Mar2020. They were unable to get tested and just kind of figured they had it. Her husband also had pneumonia. They both recovered in Apr and decided to get the antibody test done and it was positive for the antibodies and they had also given blood since then and that was also positive for antibodies. The patient considered wondering with this being the first vaccine dose was considered as a

good immune response. Relevant concomitant drug was unknown. The patient reported having the Pfizer-BioNTech COVID-19 Vaccine 685 on Fri and was having some symptoms. Got it about 12:45 Fri (18Dec2020) and around 11PM that evening she was feeling kind of bad, low grade fever, chills, and muscle aches. This was only the first vaccine she had. The symptoms ended up lasting up to 24 hours and the fever went away the next morning, but she still had chills. Only thing she had was the swollen lymph nodes at right axillary, the same side of the site of the injection. The patient mentioned she didn't feel very good Sat, but at the reporting time she could work today. The patient clarified that her husband did not have the Pfizer-BioNTech COVID19 Vaccine 685 vaccine. And she did not test positive for COVID and didn't have the actual testing done because they didn't have the test available it was only for if someone were hospitalized. The patient's arm was still sore at the injection site. It's sore to touch and could tell it's still sore with movement. There was no pre-existing diseases worsened during the SARS-CoV2 infection. The patient was not treated with immunomodulating or immunosuppressing medications or received any other vaccines around the time of COVID-19 vaccination. The patient did not have a positive test for SARS-CoV2. The patient did not display clinical signs at rest indicative of severe systemic illness. The patient did not taking any medications routinely prior to the event being reported. The outcome of event feeling kind of bad, low grade fever and muscle aches was resolved, the outcome of events swollen lymph nodes, chills and sore at the injection site was not resolved. The events were assessed as non-serious. The patient stated she had been positive with Covid in Mar, which may have caused her to be more symptomatic with the vaccine, but was unsure if that was the case. She also heard a lot of people had the first dose, never exposed to Covid, and had no symptoms after receiving the vaccine. The patient asked if she should still take the second dose even though she has been positive with Covid before. Information on the lot/batch number has been requested.

arm started to feel sore; injection site pain; This is a spontaneous report from a contactable consumer (patient). A 76-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number E9899, expiry date Mar2021) intramuscular on left arm on 17Dec2020 at single dose for COVID-19 immunization. The patient has no prior vaccinations within 4 weeks. Medical history included and concomitant medications were none. The patient got the COVID vaccine on Thursday (17Dec2020), her arm was still really sore (17Dec2020). The patient asked on how long will this last and was referred to healthcare professional. Full EUA PI, discussed incidence of injection site pain. No information on duration after 1st dose. The patient received the Covid vaccine around 10:30 on Thursday morning and her arm started to feel sore Thursday evening. The patient clarified that the vaccine was administered around 10:30AM to 11:00AM. The patient was advised to follow up with healthcare professional. The patient did not receive treatment for the events. The outcome of the events arm started to feel sore and injection site pain was recovering. The reporter informed that the vaccination facility type was a hospital and was not administered at a military facility.

"Making me just kind of loopy too kind of light headed; Weakness; Ringing in ears; Headache; pain at the injection site; I could not even turn onto my other side last night from pain; pain at the injection site; I could not even turn onto my other side last night from pain; Chills; fatigue/Tiredness; low grade temperature; I couldn't even sleep; Extreme muscle and joint pain generalized; Extreme muscle and joint pain generalized; This is a spontaneous report from a contactable nurse. A female patient of an

unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), lot number: EH9899, via an unspecified route of administration on 19Dec2020 at single dose for COVID-19 immunization. Medical history was reported as none. There were no concomitant medications. The patient stated, ""I am a Registered Nurse, an RN here in (city name) and I received your Pfizer vaccine (Covid 19 Vaccine) yesterday morning. I just wanted to report some issues with the vaccine. All through the night in Dec2020, I had the muscle pains, generalized muscle pain all over, even Tylenol (later clarified as Ibuprofen 200 mg, lot number: 9FE3019A and expiry date: Mar2021) wouldn't even work. I have a low grade temperature, headache, and real pain at the site of the injection, some chills earlier yesterday on 19Dec2020. So, I am afraid to get the next Pfizer one because to get some more side effects. This one is making me just kind of loopy too kind of light headed, and I am just really tired, really fatigue on 20Dec2020. With this Pfizer vaccine, I thought it was approved by the certain drug and (Center Name) and according to your message that I just got on another phone number has not been approved. But it was rushed out just for emergency use. Is that correct?"". When informed about the role of Pfizer Medical Information and offered the number, the patient stated, ""Well one number that I got, it was all loopy. I mean it was just all over the page, I couldn't leave a message. They gave me so much information that. So, which number you are talking about?"". The due date for the next shot: 06Jan2021. I am a healthcare provider and I also go into the COVID unit probably in January sometimes. So, I wanted, I am kind of one of your guinea pig. ""When I initially got it on 19Dec2020, of course I had pain at the injection site. I could not even turn onto my other side last night from pain at the injection site. Yesterday on 19Dec2020, I got some chills, I got a low grade temperature, feeling fatigue after a while. At first, I didn't feel that other than injections site. Through the whole night I had low grade temperature, extreme muscle and joint pain generalized, which I couldn't even sleep, I had insomnia. Tylenol wouldn't even help with that. Of course tiredness but I couldn't sleep. So I can't really feel okay, not a very good sleep yesterday. Low grade temp when I got up in the morning and dizziness and weakness this morning definitely and ringing in my ears kind of like.Yes I am generally, but the dizziness and the weakness is kind of new one. I had Tylenol during the night because I couldn't sleep, because I had such muscle and joint pain all over my joint in Dec2020."" The outcome of the events was unknown."

headache; had soreness/pain at the injection site between 24-48 hours; muscle aches; fatigue; malaise; low grade fever; This is a spontaneous report from a contactable consumer (patient). A 28-year-old non-pregnant female patient received first dose of BNT162B2 (Pfizer-BioNTech COVID-19 mRNA vaccine, lot number: 1703), via an unspecified route of administration at left arm on 18Dec2020 10:00 at a single dose for COVID-19 immunization, and second dose of hepatitis b vaccine, via an unspecified route of administration at left arm on 11Dec2020 at unknown dose for an unspecified indication. The patient received COVID-19 vaccine in a hospital facility. Medical history was not reported. The patient has no known allergies. The patient's concomitant medication included birth control. The patient previously received first dose of hepatitis b vaccine on unspecified date. Since the vaccination, the patient has not been tested for COVID-19. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient was fine the morning she received the vaccine (up until the evening). Then she started to feel muscle aches, fatigue, malaise, and had a low grade fever on 18Dec2020 19:00. This persisted for about 48 hours. She also had soreness/pain at the injection site between 24-48 hours

(started on 19Dec2020). The 3rd day (today, 21Dec2020), she had a slight headache, but that could be unrelated. The patient did not receive any treatment for the adverse events. The outcome of the events was recovering. The report was considered non-serious.

fatigue; chills; arm soreness; This is a spontaneous report from a contactable pharmacist. This 34-year-old female pharmacist (patient) reported that she received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK5730), via intramuscular on left arm on 18Dec2020 at 12:45 PM at single dose for COVID-19 immunization. Facility where the most recent COVID-19 vaccine administered was hospital. Prior to vaccination, the patient was not diagnosed with COVID-19. Medical history and concomitant medications were not reported. It was reported patient had no other vaccine in four weeks; she had oral contraceptive in two weeks. Since the vaccination, the patient had not been tested for COVID-19. The patient experienced fatigue, chills, arm soreness on 18Dec2020 at 03:00 PM. No treatment was received. Outcome of events was recovered in Dec2020.

arm pain; low grade fever of 100; This is a spontaneous report from a contactable nurse. A 46-years-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK5730), intramuscularly at the left arm on 20Dec2020 10:30 at a single dose for COVID-19 immunization at a hospital. Medical history included migraine and asthma. Allergy with only certain nausea medications (unspecified). There were concomitant medications but were unspecified which the patient received within 2 weeks of vaccination. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient was not diagnosed with COVID-19 prior to vaccination and was not tested for it since the vaccination. On 20Dec2020, 22:00, after almost 12 hours, patient had a low grade fever of 100 (unit unspecified) and had an arm pain with no treatment while fever responded to acetaminophen (TYLENOL). The patient recovered from the events on an unknown date.

redness and swelling to right wrist; redness and swelling to right wrist; Itching to left side neck and back.; This is a spontaneous report from a contactable nurse. A 25-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), lot number: EJ1685, first dose via intramuscular in left arm on 21Dec2020 09:30 at SINGLE DOSE for covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced redness and swelling to right wrist and itching to left side neck and back on 21Dec2020 09:45. The facility where the most recent COVID-19 vaccine was administered was in the hospital. The events resulted in emergency room or department or urgent care. The case was reported as non serious by the reporter, and did not result in death, not life threatening, did not cause prolonged hospitalization, not disabling or incapacitating and no congenital anomaly or birth defect. The outcome of the events was unknown.

Injection site was very painful and it's blowing and my whole arm was hurting; Injection site was very painful and it's blowing and my whole arm was hurting; I have swelling in my whole arm; Weakness; Muscle soreness; Headache; This is a spontaneous report from a contactable consumer (patient, nurse's assistant). A 48-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on Friday 18Dec2020 at about 09:58 at 0.3 ml, single for covid-19 immunization. This was the first dose. None medical history. There were no concomitant medications. In 2020, the patient stated the injection site itself, was very painful and it's blowing and in fact her whole

arm, the whole arm was hurting and she has swelling in her whole arm and also she had like muscle soreness and weakness. The only other thing she felt was like headache and that's it. The patient was given aspirin for treatment. The action taken in response to the events for bnt162b2 was not applicable. The outcome of events was unknown. Information on the lot/batch number has been requested.

"numbness and tingles in armed or pant in all my fingers; numbness and tingles in armed or pant in all my fingers; This is a spontaneous report from a contactable consumer. A 44-year-old female patient received the bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot Number: EK5730 and Expiration Date: Mar2021), via an unspecified route of administration on 18Dec2020 at 44-years-old at a single dose for COVID-19 immunization. The patient's medical history was reported as none. Concomitant medications included estradiol (MANUFACTURER UNKNOWN), misoprostol (MANUFACTURER UNKNOWN); both taken for an unspecified indication from an unspecified date to an unspecified date. On 19Dec2020, the patient experienced: ""numbness and tingles in armed or pant in all my fingers."" The patient stated, ''I got my shot (COVID Vaccine) at work yesterday around 3 pm. Since 1 O 'clock this morning I have numbness and tingles in armed or pant in all my fingers, can won't go away.'' There was no treatment received. The patient reported that she worked in an emergency department as a technician. The patient underwent lab tests and procedures which included body weight: about 190 on an unspecified date. The clinical outcome of the events was not recovered."

Woke up in middle of night; severe muscle pain entire body; chills/fever; chills/fever; debilitating headache; This is a spontaneous report from a contactable nurse (patient). A 61-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot/batch number and expiry date were not provided) solution for injection, intramuscular (left arm) on 20Dec2020 10:00 at a single dose for COVID-19 immunisation. Medical history was reported as none. Concomitant medication included aspirin [acetylsalicylic acid] (ASPIRIN [ACETYLSALICYLIC ACID]), hydrochlorothiazide, losartan potassium (LOSARTAN HCTZ), metoprolol succinate (METOPROLOL SUCCINATE), and estrogens conjugated (PREMARIN). The patient reported she woke up in middle of night, had severe muscle pain on entire body, chills/fever, and debilitating headache on 21Dec2020 02:00. No treatment was received. The events were reported as non-serious. The patient was not pregnant. The patient has not been diagnosed of Covid-19 prior to vaccination and has not been tested. Outcome of the events was recovering. Information about lot/batch no has been requested.

Back pain radiating down to the L buttocks, down the L leg and ending at the ankle.; Back pain radiating down to the L buttocks, down the L leg and ending at the ankle. Rating 5/10 pain.; Back pain radiating down to the L buttocks, down the L leg and ending at the ankle.; Back pain radiating down to the L buttocks, down the L leg and ending at the ankle.; Back pain radiating down to the L buttocks, down the L leg and ending at the ankle.; This is a spontaneous report from a contactable nurse (patient). A 29-year-old female patient received 1 dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899) intramuscular on right arm on 19Dec2020 10:00 AM, single dose for COVID-19 immunization at 29-year-old. Medical history included: COVID-19 diagnosed prior to vaccination. No known allergies. Concomitant medications included: drospirenone, ethinylestradiol betadex clathrate (YAZ); ibuprofen; cetirizine hydrochloride (ZYRTEC); diphenhydramine hydrochloride (BENADRYL); melatonin. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. On

20Dec2020, 10:00 AM, the patient experienced back pain radiating down to the L buttocks, down the L leg and ending at the ankle, rating 5/10 pain. No treatment received for the adverse events. Lab data included: COVID-19 (positive) diagnosed prior to vaccination; pain 5/10 on 20Dec2020. Since the vaccination, the patient had not been tested for COVID-19. Action taken for BNT162B2 was not applicable. Outcome of the events was not resolved. It was reported as non-serious.

feeling light headed; blotchy spots on neck and chest; tingling to the back of the throat; This is a spontaneous report from a contactable nurse. A 42-year-old female patient received 1 dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EJ1685) intramuscular on left arm on 21Dec2020 10:15 AM, single dose for COVID-19 immunization at 42-year-old. Medical history and concomitant medication were not reported. On 21Dec2020 10:30 AM, the patient was reported feeling light-headed, blotchy spots on neck and chest, and tingling to the back of the throat. Emergency room/department or urgent care visited. Action taken for BNT162B2 was not applicable. Outcome of the events was unknown. It was reported as non-serious.

"lips tingling and ""on fire""/tingling ""8/10"", ""2/10""; lips tingling and ""on fire""/tingling ""8/10"", ""2/10""; This is a spontaneous report from a contactable other healthcare professional. A 39-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), intramuscular on 18Dec2020 at single dose for COVID-19 immunization at hospital. The patient's medical history and concomitant medications were not reported. It was reported that the patient received first dose of Pfizer COVID-19 vaccine. After ""10:00 minutes"" of observation phase, patient complained Of (c/o) lips tingling and ""on fire"". Lips not swollen, denies short of breath (SOB), ""skin WNLs"", denies difficulty swallowing. The Medical Emergency Response Team (MERT) was called. Patient was assessed, stated tingling 8/10, no other symptoms. Patient was given bottle of water and was tolerating that fine. Allegra 60mg was ordered and administered at 8:52 A.M. Patient stated was at a 2/10, 10 minutes after getting the Allegra. Patient was drinking water without difficulties. Patient remained without further symptoms, lips still 2/10 with tingling. Outpatient lab work was ordered. Patient left at 10:00 A.M ambulatory to outpatient lab. MERT educated her to notify administrator of her symptoms prior to her second vaccine. The outcome of the event was reported as recovered (in Dec2020). No follow-up attempts are possible; information about lot/batch number cannot be obtained."

incontinence (urine); Tiredness/ exhausted; woke early; numbness down her arm/ numbness went up to her neck/ numbness on the tip of her fingers; soreness on her neck; both her arms since she was so sore; both her arms since she was so sore/ sore at the injection site; sweats; extremely hot; headache; lightheadedness; This is a spontaneous report from a contactable consumer (patient). A 44-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EJ1685) intramuscular on left arm on 19Dec2020 18:00, single dose for COVID-19 immunization at 44-year-old. Medical history was not reported. Concomitant medications included: meloxicam (15mg tablet) oral 15mg once a day for arthritis. The patient had not taken any other medications today (21Dec2020) or yesterday (20Dec2020). The patient experienced numbness down her arm the first day she received the injection (19Dec2020), stated it was like someone was holding her hand tight, stated she thought this was normal. The numbness went up to her neck on 19Dec2020. By Sunday (20Dec2020) she had the

numbness on the tip of her fingers in both hands. The patient stated she also had soreness on her neck on 19Dec2020. The patient stated that when she woke up it felt like someone pulled down on both her arms since she was so sore on 19Dec2020. Treatment received, the patient took paracetamol (TYLENOL), no visit to emergency room or physician office. Currently (21Dec2020), the patient was still sore at the injection site, but she did not have any pain or numbness. The patient had the sweats on 19Dec2020, stated she was extremely hot (19Dec2020). Her back was so wet. She was warm. The patient woke up incontinent (urine) this morning (21Dec2020). The patient stated it was not that she fully emptied her bladder, but she woke up wet this morning. The patient found it odd she did not wake to use bathroom, when she woke up she still went to empty her bladder. She felt like she had recovered completely from the incontinence, she only had it when she woke up. The first night after she took the vaccine (19Dec2020) the patient woke early, like 6 am which she didn't usually wake up so early. The patient stated for two nights she slept and did not move, she woke up the way she fell asleep laying down. It didn't look she changed position, woke up as if the patient did not sleep at all. The patient stated she must have been exhausted because she did not move at all. The patient started to experience the tiredness by the time she left work around 8 pm on 19Dec2020. The patient stated she was regularly tired, not overly tired but she worked two 12-hour shifts. The tiredness was better today (21Dec2020) than the first two days. The patient had a headache, lightheadedness (in Dec2020). Action taken for BNT162B2 was not applicable. Outcome of the event numbness down her arm/ numbness went up to her neck/ numbness on the tip of her fingers was resolved on 21Dec2020; outcome of the events soreness on her neck, both her arms since she was so sore, sore at the injection site was resolving; outcome of the event sweats was resolved on 19Dec2020; outcome of the event incontinent (urine) was resolved on 21Dec2020; outcome of the event tiredness was resolving; outcome of the other events was unknown.

severe dizziness; horrible nausea and vomiting; horrible nausea and vomiting; muscle soreness; headache; This is a spontaneous report from a contactable nurse (patient). A 40-year-old female nurse received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899) via unspecified route in left lower deltoid on 17Dec2020 10 am, single dose for COVID-19 immunization at 40-year-old. Medical history included: surgery and lipoma removed from upper deltoid in Nov2020. Family medical history included: Her mother had colorectal cancer at age 40. When the patient turned 40, she had colonoscopy earlier this year (2020) and it was negative. Concomitant medication included: levothyroxine 100ug daily from 2001. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. She had pretty severe muscle soreness Thursday night (17Dec2020) and the next two days. On 19Dec2020 it was not as severe. It was mild and it started to dissipate on 19Dec2020. The only thing she had been taking was acetaminophen 650mg that night for the muscle soreness. The patient awoke at 3:00 am on 20Dec2020 out of a dream with severe dizziness that turned into horrible nausea and vomiting. She had vomiting for a little while the third night (20Dec2020) into the fourth day. The patient (nurse) considered the muscle soreness and dizziness was non-serious and not medically significant. She didn't feel the need to go to the hospital because it did improve. After she threw up, the dizziness kind of went way. Even today (21Dec2020) she felt fine and no more nausea, but still felt kind of off and dizziness, lingering dizziness. It wasn't extreme dizziness but when texting she could feel, and it was hard to focus. She was not one hundred percent her normal self. She was not sure if it was related to the

vaccine. She was eating and drinking normally. The night that she received the vaccine, she had one beer and one margarita at dinner. She did have alcoholic beverages, a beer and a margarita. It was nothing excessive with dinner. She was not overly drunk. She didn't know if alcohol could have contributed. She had never had that kind of reaction before from drinking. That was very odd. She just wouldn't drink any alcohol. She took acetaminophen for a headache (in Dec2020) that she was experiencing. She was pretty healthy. All of this was so new with the COVID vaccine. That night into this morning she started her menstrual period as well. She had never had any horrible side effects like migraines or cramping when getting her menstrual cycle. It could have been the alcohol or her period. No visit to emergency room or physician office. Action taken for BNT162B2 was not applicable. Outcome of the event muscle soreness was resolved on 19Dec2020; outcome of the event severe dizziness was resolving; outcome of the other events was unknown. Causality assessment between the event muscle soreness and the suspect product BNT162B2 per the patient was reported as related.

Headache; body aches; chills; low grade fever 100 degrees Fahrenheit; Soreness to the right arm where vaccine was administered.; This is a spontaneous report from a contactable consumer. A 60-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via unspecified route on right arm on 18Dec2020 03:00 PM, single dose for COVID-19 immunization at 60-year-old. Medical history included: COVID-19 diagnosed prior to vaccination. Concomitant medication was not reported. No other vaccine received within 4 weeks prior to the COVID vaccine. On 19Dec2020 12:00 PM, the patient had headache, body aches, chills and low-grade fever 100 degrees Fahrenheit. At the same time (19Dec2020 12:00 PM), the patient had soreness to the right arm where vaccine was administered. No treatment received for above adverse events. Lab data included: COVID-19 (positive) diagnosed prior to vaccination; 100 degrees Fahrenheit low-grade fever on 19Dec2020. Since the vaccination, the patient had not been tested for COVID-19. Action taken for BNT162B2 was not applicable. Outcome of the events was resolved in Dec2020. It was reported as non-serious. Information on the lot/batch number has been requested.

swelling of eyelids and cheeks; swelling of eyelids and cheeks; swelling of hands; This is a spontaneous report from a contactable pharmacist. A 58-year-old female patient received 1 dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK5730) intramuscular on left deltoid on 16Dec2020 11:00 AM, single dose for COVID-19 immunization at 58-year-old. Medical history included: Sulfa allergy; diabetes, hypertension, high cholesterol. Prior to vaccination, the patient was not diagnosed with COVID-19. Concomitant medications included: metformin, valsartan and pantoprazole. No other vaccine received within 4 weeks prior to the COVID vaccine. On 17Dec2020 morning, 06:00 AM, the patient had swelling of hands and then 18Dec2020 morning, the patient had swelling of eyelids and cheeks. Doctor or other healthcare professional office/clinic visit. Treatment received as: Diphenhydramine 50mg and prednisone 40mg orally. Since the vaccination, the patient had not been tested for COVID-19. Action taken for BNT162B2 was not applicable. Outcome of the events was resolved in Dec2020. It was reported as non-serious.

Diarrhea, dizziness, swollen tongue and lips. Sore joints for multiple days, headache; Diarrhea, dizziness, swollen tongue and lips. Sore joints for multiple days, headache; Diarrhea, dizziness, swollen tongue and lips. Sore joints for multiple days, headache; Diarrhea, dizziness, swollen tongue and lips. Sore joints for

multiple days, headache; Diarrhea, dizziness, swollen tongue and lips. Sore joints for multiple days, headache; Diarrhea, dizziness, swollen tongue and lips. Sore joints for multiple days, headache; This is a spontaneous report from a non-contactable consumer (patient). A 34-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date not reported), via an unspecified route of administration on left arm at 08:30 AM.on 18Dec2020 at single dose for COVID-19 immunization. Medical history reported as none, no known allergies. The patient's concomitant medications were not reported. The patient experienced diarrhea, dizziness, swollen tongue and lips. Sore joints for multiple days and headache in Dec2020 (reported as 11Dec2020 at time 08:45 AM). All events were reported as non-serious. The patient self administered Benadryl. Acetaminophen and ibup (ibuprofen) as treatment. The outcome of events was resolved with sequel. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. No follow-up attempts are possible. information about lot/batch number cannot be obtained.

urticaria on inside of both arms; This is a spontaneous report from a contactable Physician. This physician reported for a female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) at single dose for covid-19 immunization. Medical history was urticaria. Physician stated that I have a female patient in good health with a history of urticaria. She got the vaccine and developed urticaria on inside of both arms - looking for information on whether this patient should receive the 2nd dose. Outcome of the event was unknown. Information about batch/lot number has been requested.

"I woke up and my left eye is swollen and my face is kind of swollen; I woke up and my left eye is swollen and my face is kind of swollen; rash/ rash on and off on my back and on my arm and around my face; allergic symptoms; kind of like itchiness on my ears and my scalp and also like on and off on my back and also on both of my arms like my wrist area on both arms/All night I was up with scratching my face; The initial case was missing the following minimum criteria: unspecified product. Upon receipt of followup information on 20Dec2020, this case now contains all required information to be considered valid. This is a spontaneous report from a contactable physician (patient). A 30-years-old female patient received first dose bnt162b2 (BNT162B2), intramuscular on 2020 at single dose for covid-19 immunisation. Medical history included On nose, had prior to getting the vaccine, was experiencing some kind of she got through the contact dermatitis rash like her arms and behind her ears and it was all over her neck (she thought it was related to mat because she was getting it on neck and ears taking medication for that it just allergy medication and it had gotten better). There were no concomitant medications. The physician reported she have been experiencing some allergic symptoms following it since Dec2020, she had itchiness, it was like a rash on and off on back and on arm and around face and itchiness on calp and face/ experiencing kind of like itchiness on ears and scalp and also like on and off on back and also on both of arms like wrist area on both arms and then in the morning like 20Dec2020, it was kind of all night she was up with scratching face,; In the morning 20Dec2020, she woke up with some mild facial swelling, noticed like eyes swollen and little bit droopy. The events were still going on, she just took medicine for it. It's kind of persistent. Physician stated, ""I guess I can report the worsening of my symptoms that was in the morning of reporting date like 8 AM."" Treatment included just took medicine, Prednisone, Benadryl and Zyrtec. Weight: About 103. The event outcome was not recovered. Information on lot/batch number has been requested."

flushed; warm face and ears; This is a spontaneous report from a non-contactable other health care professional. A 57-year-old female patient received bnt162b2 (BNT162B2; lot number: HE9899), intramuscular on arm (reported as left arm) dose number 1 on 17Dec2020, SINGLE DOSE for COVID-19 immunization. Medical history included mild history of anxiety, and panic attack. She has medication to treat this at home if needed. The patient's concomitant medications were not reported. She was given the Pfizer vaccination in the right deltoid muscle (pending clarification). During her 15 minute waiting period after the injection, the patient began to experience flushed, warm face and ears. She denied rash, difficulty breathing, difficulty swallowing, wheezing, throat tightness, lightheadedness, lip swelling and tongue swelling. This APP was notified of patient reaction and she was then assessed in the emergency bay area. (Name withheld) was observed x 35 minutes after receiving vaccination. All symptoms resolved within 20 minutes. No treatment was required. The outcome of the events was recovered. No follow-up attempts are possible. No further information is expected.

feeling nauseated, hot; feeling nauseated, hot; headache; difficulty breathing; itchy all over the body, with redness and blotchiness in the face, neck and arms; itchy all over the body, with redness and blotchiness in the face, neck and arms; itchy all over the body, with redness and blotchiness in the face, neck and arms; Blood pressure elevated along with heart rate.; Blood pressure elevated along with heart rate.; This is a spontaneous report from a contactable other healthcare professional (HCP), who is also the patient. This 34-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 19Dec2020 at single dose for COVID-19 immunisation. Vaccination facility type was hospital. Relevant medical history included polycystic ovaries, gastrooesophageal reflux disease, Hashimoto's disease and allergy to sulfa, penicillin, latex and hornets. Concomitant medications included thyroid (ARMOUR THYROID), omeprazole and vitamin D3. On 19Dec2020 at 12:15, 10 minutes after the injection, the patient started feeling nauseated, hot and developed a headache. A couple of minutes after that, she started experiencing difficulty breathing and itchy all over the body, with redness and blotchiness in the face, neck and arms and blood pressure elevated along with heart rate. The events resulted in emergency room/department visit or urgent care. Corrective treatments taken as a result of the events included methylprednisolone sodium succinate (Solu-medrol), diphenhydramine hydrochloride (BENADRYL) and famotadine along with intravenous (IV) fluids. The patient recovered with sequel from the events on an unspecified date. The information on the lot/ batch number has been requested.

Soreness at the injection site; This is a spontaneous report from a contactable nurse (patient). A 62-year-old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number: EJ1685), intramuscular on the left arm on 18Dec2020 13:00 at a single dose for covid-19 immunization. The patient's medical history included hypertension (HTN) and elevated triglycerides. The patient was not pregnant. The patient have no allergies to medications, food, or other products. It was unknown if the patient was diagnosed with COVID-19 prior to vaccination. The patient had not been tested for COVID-19 since the vaccination. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Concomitant medications included metoprolol and fenofibric acid. The patient experienced soreness at the injection site on 19Dec2020 05:00. No treatment was received for the adverse event. Outcome of the event was recovered on Dec2020.

Minor headache; chills; This is a spontaneous report from a contactable other healthcare professional (patient). A 31-year-old male patient received the first dose of bnt162b2 (BNT162B2, lot no. and expiration date were unknown), via an unspecified route of administration on 18Dec2020 23:45 on the left arm at single dose for COVID-19 immunization. Medical history included heart stent. The patient had no known drug allergies. The patient's concomitant medications were not reported. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. On 19Dec2020 01:00 AM, the patient experienced minor headache and chills. No treatment received for the events. The events recovered on unspecified date in Dec2020. Information on the lot/batch number has been requested.

"When they put the shot it's been hurting me ever since then; This is a spontaneous report from a contactable consumer. A 40-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), via an unspecified route of administration on an unspecified date as single dose for COVID-19 immunization. Medical history included diabetes and headache from an unknown date. Concomitant medication included metformin (MANUFACTURER UNKNOWN) for diabetes. On an unspecified date, the patient reported that "" when they put the shot it's been hurting me ever since then "" with outcome of unknown. Details were as follows: Patient indicated that when he got the shot, everything was good but when they put the shot it's been hurting ever since then. There were no lab tests, or treatment given for the event. The outcome of "" when they put the shot it's been hurting me ever since then "" was unknown. The batch/lot number for the vaccine, BNT162B2, was not provided and will be requested during follow-up ."

Heart palpitations and severe fatigue for 48 hours; Heart palpitations and severe fatigue for 48 hours; This is a spontaneous report from a contactable other healthcare professional (patient herself). A 37-year-old female patient received bnt162b2 (BNT162B2 also reported as COVID 19 brand Pfizer, lot EK5730), intramuscularly in the left arm on 18Dec2020 10:30 at single dose (dose number 1) for immunisation. Medical history was none. There were no concomitant medications. The patient experienced heart palpitations and severe fatigue for 48 hours on 18Dec2020 18:00. The events were reported as non-serious. No treatment was given. The outcome of events was recovered on unknown date in Dec2020.

my arm hurt for 4 Hours later and peaked that evening; headache; tiredness; lethargic/pretty lethargic.; This is a spontaneous report from a Pfizer-sponsored program IBCC (Inbound Call Center for HCPs). Contactable Physicians (one was patient) reported that a 72-years-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EH9899, Expiry Date: Mar2021) on 18Dec2020 at single dose for covid-19 immunization. Medical history and concomitant drug were not reported. The caller is a MD. He had the vaccine on Friday. His arm hurt 4 hours later, and then peaked that evening. It was very painful. It hurt and was painful. By Sunday it was 95 % gone. Today (21Dec2020) the pain is completely gone. He received the vaccine Friday. He is supposed to get an MRI Wednesday morning. He will be getting Gadolinun. He wanted to know if there was any adverse reaction with that. Will this material interfere with the immune response of COVID vaccine? He is considering canceling his MRI. The caller confirmed the details provided by the transferring agent. He

doesn't have a prescribing doctor. He was looking at his CDC vaccination record log. He was given 0.3cc. He received the injection, and the pain started 4 hours later. It peaked in the evening. It was the worst arm pain he has ever had from a shot. He couldn't elevate his arm from pain. It was interesting because there was very little heat at the injection site. The amount of arm pain was not proportionate to a local reaction. He did take Tylenol that night. He got up the next day, Saturday, and it was painful but a little less painful. Then on Sunday 20Dec2020, it was 95% essentially. He started to get lethargic that Friday at about 9-12 hours later. Then he had a headache about 11 hours later that lasted 5-10 minutes. He was surprised but it went away. Saturday, he was pretty lethargic. He felt more lethargic from the shingles shot. No details on the shingles shot provided by the caller. He said the tiredness may have been a placebo effect because everyone says you will get tired. He was fine yesterday and today. He is glad he got it. He has recovered completely from all side effects he had. He never had a fever. His question about the MRI was escalated by the Medical information associate. Follow-up attempts have been completed and no further information is expected.

left eye was irritated; left eye was sensitive to light; left eye was painful weeping and red.; left eye was red; left eye weepy; entire left side was sore, achy, including her jaw and stuff; entire left side was sore, achy, including her jaw and stuff; This is a spontaneous report from a contactable consumer. A female patient of unspecified age (reported as 59 with no unit) received BNT162B2 (Pfizer-Biontech COVID-19 Vaccine), via an unspecified route of administration on right arm on 16Dec2020 at single dose for COVID-19 immunization. Medical history and concomitant medications were not reported. It was painless on 16Dec2020. On 17Dec2020, her entire left side was sore, achy, including her jaw and stuff, 18Dec2020 evening, her left eye was irritated, sensitive to light, painful weeping and red (left eye was painful, red, and weepy). She called her doctor on 19Dec2020 and he gave her some eye drops. On 20Dec2020, the eye drops seemed to irritate her eye more. She woke up in the morning and it was seeming to get better as she had been taking Excedrin. She was supposed to wait 6 hours between drops, then her eye again was sensitive to light and painful, so she took another Excedrin, which helped again. She was trying to see an eye specialist the day after the time of the report. She had asked around at work and nobody else had any issues. She was wondering if this was vaccine related. She wanted to get tested for COVID, not that she thought she had it now, but might be she had it before she got the vaccine. She had not even talked to her workplace about this or anything. They asked everyone the first day after, if there were any issues and to report them to HR/Employee Health. She had not done so yet, so she wanted to do that first. Outcome of the events left eye was irritated, sensitive to light, painful weeping and red, and left eye weepy was resolving, and of other events was unknown. Lot/batch number has been requested.

Nausea; headache; fatigue; This is a spontaneous report from a contactable healthcare professional. A 31-year-old male patient received BNT162B2 (Lot number: EJ1685), intramuscularly on right arm on 20Dec2020 07:00 at single dose for COVID-19 immunization. Medical history was not reported. Concomitant medications in two weeks included emtricitabine/tenofovir disoproxil fumarate (TRUVADA), bupropion hydrochloride (WELLBUTRIN), lamotrigine (LAMICTAL), and valaciclovir (VALACYCLOVIR). Patient experienced nausea, headache, and fatigue on 21Dec2020 07:00. No treatment received for these events. Outcome of the events was not resolved.

headache; take BP. My usual normal is 125/80. 164/93 just mow; This is a spontaneous report from two contactable pharmacists. A 53-year-old female patient received BNT162B2 (lot number: EJ1685), via an unspecified route of administration on left arm on 21Dec2020 07:00 at single dose for COVID-19 immunization. Medical history and concomitant medications were not reported. Patient began getting a headache (H) on 21Dec2020 09:00 (around 9:30), felt like a different kind of headache that progressed. At 2:30, patient went back to monitoring area and asked them to take blood pressure (BP). Her usual normal was 125/80, but 164/93 just now (21Dec2020 09:00). COVID-19 vaccine was administered in the hospital. Patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Outcome of the events was resolving.

anaphylaxis; This is a spontaneous report from a non-contactable consumer. This consumer reported similar events for six patients. This is the first of six reports. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot number: AK 5730, EG 1685), via an unspecified route of administration in Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced anaphylaxis in Dec2020. The clinical outcome of anaphylaxis was unknown. No follow-up attempts are possible. No further information is expected.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2020505821 different patient/same drug/event;US-PFIZER INC-2020505822 different patient/same drug/event;US-PFIZER INC-2020505823 different patient/same drug/event;US-PFIZER INC-2020505824 different patient/same drug/event;US-PFIZER INC-2020505825 different patient/same drug/event

anaphylaxis; This is a spontaneous report from a non-contactable consumer. This consumer reported similar events for six patients. This is the second of six reports. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot number: AK 5730, EG 1685), via an unspecified route of administration in Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced anaphylaxis in Dec2020. The clinical outcome of anaphylaxis was unknown. No follow-up attempts are possible. No further information is expected.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2020505820 different patient/same drug/event

anaphylaxis; This is a spontaneous report from a non-contactable consumer. This consumer reported similar events for six patients. This is the third of six reports. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot number: AK 5730, EG 1685), via an unspecified route of administration in Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced anaphylaxis in Dec2020. The clinical outcome of anaphylaxis was unknown. No follow-up attempts are possible. No further information is expected.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2020505820 different patient/same drug/event

anaphylaxis; This is a spontaneous report from a non-contactable consumer. This consumer reported similar events for six patients. This is the fourth of six reports. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot number: AK 5730, EG 1685), via an unspecified route of administration in Dec2020 at a single dose for COVID-19 immunization. The

patient's medical history and concomitant medications were not reported. The patient experienced anaphylaxis in Dec2020. The clinical outcome of anaphylaxis was unknown. No follow-up attempts are possible. No further information is expected.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2020505820 different patient/same drug/event

anaphylaxis; This is a spontaneous report from a non-contactable consumer. This consumer reported similar events for six patients. This is the fifth of six reports. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot number: AK 5730, EG 1685), via an unspecified route of administration in Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced anaphylaxis in Dec2020. Therapeutic measures were taken as a result of the event and included administration of epinephrine (MANUFACTURER UNKNOWN). The clinical outcome of anaphylaxis was unknown. No follow-up attempts are possible. No further information is expected.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2020505820 different patient/same drug/event

anaphylaxis; This is a spontaneous report from a non-contactable consumer. This consumer reported similar events for six patients. This is the sixth of six reports. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot number: AK 5730, EG 1685), via an unspecified route of administration in Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced anaphylaxis in Dec2020. Therapeutic measures were taken as a result of the event and included administration of epinephrine (MANUFACTURER UNKNOWN). The clinical outcome of anaphylaxis was unknown. No follow-up attempts are possible. No further information is expected.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2020505820 different patient/same drug/event

Rash on throat, chest, back and legs; This is a spontaneous report from a contactable healthcare professional. A 38-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899), intramuscular on the left arm on 19Dec2020 07:45 at single dose for COVID-19 immunisation. Medical history included known allergies: penicillin. The patient's concomitant medications were not reported. The patient experienced rash on throat, chest, back and legs on 19Dec2020 11:30. Patient does not receive any treatment. The outcome of the events was recovering.

gut pain; headache; cramping; diarrhea/7 bouts of diarrhea over 3 hours; facial flushing; This is a spontaneous report from contactable nurse. A 58-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK5730), via an unspecified route of administration, at the left arm on 19Dec2020 10:30 at a single dose for COVID-19 immunization at a hospital. Medical history included hypertension and obesity. The patient has no known allergies. The patient was not tested for it since the vaccination. The patient's concomitant medications were not reported. Adverse event: On 21Dec2020, 12:00, patient experienced gut pain, headache, cramping, 7 bouts of diarrhea over 3 hours, and 3/7 also coincided with facial flushing with no treatment. The patient did not recover from the events.

itching on back; hives in a small area; This is a spontaneous report from two contactable consumers (patient and patient's mother). A 22-year-old female patient received BNT162B2 (Pfizer-BioNTech COVID-19 mRNA vaccine, lot number: EH9899, expiry date: 31Mar2021), intramuscular in left arm on 21Dec2020 (about 9:45 -09:50 a.m. this morning) at a single dose for COVID-19 immunization. The patient has no other patient history, no concomitant medications, and no investigation assessment provided. The patient has no previous immunizations. The patient received the COVID vaccine about 9:45 -09:50 a.m. this morning (21Dec2020). She noticed just recently that she was starting to itch on her back and has hives and did not know if it was a side effect. Time of onset of itching on back was around 15:00-15:30 (estimated at within past 30 minutes), while the hives started around 5 minutes later than the itching. No ER or physician's office required. She is a nursing student, so it was recommended she receive the vaccine by the college of nursing. She received it at the hospital. They put Neosporin on her back, and it helped. She does not feel the itching. When asked to provide outcome of the hives, she stated it looks like the hives are getting smaller, but they are still there. The outcome of the events was recovering.

Nasal swab for COVID 19 test; Sore throat. First noticed Saturday morning and not to the point where it's painful to swallow.; Burning from the back of left nostril and down throat; This is a spontaneous report from a contactable healthcare professional (patient). A 40-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK5730, expiry date was not provided) solution for injection, via an unspecified route of administration (on left arm) on 17Dec2020 17:00 at a single dose for Covid-19 immunisation. Medical history was reported as none. Patient had no known allergies. Concomitant medication included ibuprofen. The patient experienced sore throat, he first noticed it Saturday morning (19Dec2020 04:45) and not to the point where it's painful to swallow. Patient reported there was burning from the back of left nostril and down the throat (19Dec2020 04:45). No treatment was administered. The patient underwent nasal swab for Covid 19 test on 21Dec2020 with pending result. Outcome of the event Suspected COVID-19 was unknown while for the other events was recovering.; Sender's Comments: The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

I felt slight dizziness immediately after injection/dizziness increased; feel my heart beating quickly; achiness in my joints; soreness at the injection site; feeling strange; remain uncomfortable; This is a spontaneous report from a nurse (patient herself). A 57-year-old female patient (not pregnant) received bnt162b2 (BNT162B2 also reported as COVID 19 brand Pfizer, lot EH9899), via an unspecified route of administration in the left arm on 21Dec2020 14:45 at single dose, for immunisation. Medical history included rheumatoid arthritis, osteoarthritis, anaemia, bipolar disorder II, hypertension, and GERD. She had no Covid/ Covid test prior to vaccination. She had other medications in two weeks. The patient previously took hydrocodone and experienced drug allergy. The patient felt slight dizziness immediately after injection. When she walked to the 15 min. waiting area, the dizziness increased and she began to feel her heart beating quickly. She drank 8 oz. of water and told the attendant she was feeling strange.

She took a pulse and oximetry reading - 110 and 95%. A nurse came over to check on her. The patient wanted to sit where the patient was for a few minutes longer. After about 20 mins. the dizziness immediately subsided and patient felt her pulse decreased. She got her things and left. After a few minutes, the patient began to feel achiness in her joints and felt soreness at the injection site. She had taken two Acetaminophen and remain uncomfortable. She planned to go home and rest. The events were reported as non-serious. No treatment was reported for dizziness and increased heart rate. The outcome of events Dizziness, Heart rate increased was recovered on 21Dec2020; for other events was unknown.

Employee reported thickness of tongue and dry mouth.; Employee reported thickness of tongue and dry mouth.; This is a spontaneous report from a contactable nurse. A 55-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), Batch/lot number: EJ1685, intramuscular in the right arm on 21Dec2020 12:30 at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The employee reported thickness of tongue and dry mouth on 21Dec2020 12:30. The events resulted in emergency room/department or urgent care. The outcome of the events was unknown.

hypoglycemia; dizziness; This is a spontaneous report from a non-contactable Other HCP. A 33-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) lot number HE9899, intramuscularly in the left arm on unspecified date at single dose for COVID-19 immunization. Patient medical history and concomitant medications were not reported. The patient previously took spironolactone and experienced drug allergy. During her 15-minute waiting period after the vaccination, the patient began to experience feelings of hypoglycemia. She checked her blood glucose with her own monitor and had 77 at 11:04. She chewed 1 glucose tab that she had in her purse. She noted some difficulty with swallowing it and notified clinic staff. The patient also experienced dizziness and was escorted by clinic staff to the emergency bay. This provider was notified of patient reaction and she was then assessed in the emergency bay area. She denied difficulty breathing and chest pain, history of adverse reactions with prior vaccinations or allergies to medications with the exception of spironolactone. Patient had already been given a bottle of water by clinic staff and reported that the glucose tablet went down easier following the water. She took a second glucose tab sometime before 11:13. The event was assessed as non-serious. Outcome of the events hypoglycemia and dizziness was unknown. No follow-up attempts are possible. No further information is expected.

thin red line on back of neck/redness at her right eyebrow and in the midline of her forehead/reddened area above eyebrow along with puffiness, redness on nose, cheeks and left hand; Rash; dot markings on her left hand and redness which is where she received vaccine in her left arm; dot markings on her left hand and redness which is where she received vaccine in her left arm; reddened area above eyebrow along with puffiness, redness on nose, cheeks; This is a spontaneous report from a contactable nurse (patient). A 62-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), lot number: EK5730, via intramuscular in left deltoid on 19Dec2020 10:30 at single dose for COVID-19 immunization. Medical history included hypertension diagnosed when she was 47, hypothyroidism diagnosed 20 years ago and allergic to penicillin and sulfur; all ongoing. Concomitant medication included ongoing metoprolol succinate for hypertension. The patient received her first dose of vaccine

on Friday 19Dec2020 at her job. Stated that she woke up Saturday with redness at her right eyebrow and in the midline of her forehead between her eyebrows and nose. Stated that she had dot markings on her left hand and redness which is where she received vaccine in her left arm. Stated that she had went to ER and was put on Prednisone 60mg for 5 days and Benadryl 50mg prn. Stated that a few people said few different things. Stated that she is allergic to penicillin and sulfur. No further details provided. The patient wanted to know if sulfur is in the vaccine to know if in three weeks should she take the second vaccine. On 19Dec2020, states she had a rash when she woke up. The patient had reddened area above eyebrow along with puffiness, redness on nose, cheeks and left hand. The patient went to the emergency department and an HCP saw a thin red line on back of neck. The patient was prescribed prednisone and benadryl and now symptoms have resolved. The patient was asking about more information regarding this type of reaction. The outcome of the event rash was recovered on unspecified date and the remaining events was recovered on 20Dec2020. The events were reported as non serious.

"a funny metallic taste in her mouth; she felt like she had cotton mouth; This is a spontaneous report from a contactable consumer (patient). A 62-year-old female patient received the first dose of bnt162b2 (COVID 19 vaccine) lot no: EH9899, via an unspecified route of administration in left arm on 21Dec2020 08:00 at a single dose for COVID-19 immunization. Medical history included diabetic type 2 and allergic to metal, both from an unknown date and unknown if ongoing. Concomitant medication included ongoing metformin hydrochloride (METFORMIN ER) for diabetes, taking for a couple of years. The patient received the vaccine on 21Dec2020 8am at her hospital, and by 10:30AM or 11:00AM she noticed ""a funny metallic taste in her mouth."" She stated it was like a metal cup a tin taste like that and she wanted ice water. The patient is a phlebotomist, she continued with her patients and asked a co-worker did you taste/experience that, coworker stated ""I've had covid""; she didn't get the vaccine taste metal in your mouth. The reported wanted to know if that is an expected side effect of the vaccine. She can smell everything. She still has taste buds. It was still there but not as strong. She stated that she felt fine, and doesn't feel anything. She doesn't feel bad. She was just wondering about the side effects. She drank a lot of water. The patient added that all of the sudden her mouth was tasting funny like nickel. She added that she is allergic to metal; stated she can taste the tin in a tin can. She was working in the ER after having received the first dose injection at 8:00AM on 21Dec2020. She started to taste the funny taste about two hours later, 10:30AM or 11:00AM. She drank some ice water and it kind of rinsed her mouth out then she only tasted it a tiny bit. Then she felt like she had cotton mouth. It has improved but not gone away. She received the injection in her left arm. She is scheduled 11Jan2021 for the next dose. The patient was recovering from the events. The sample of the product is not available to be returned."

she started with ringing in her ears and it has not gone away; This is a spontaneous report from a contactable nurse (patient). A 57-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot/batch number and expiry date were not provided) solution for injection, intramuscular (left deltoid) on 19Dec2020 18:00 at a single dose for COVID-19 immunisation. Medical history was reported as none. There were no concomitant medications. The patient reported it was nothing severe, but she had the first dose of the vaccine on Saturday evening at 6pm and about 6 hours after, she

started with ringing in her ears and it has not gone away. She would like to know if that was one of the side effects. It was not listed on the sheet that was given to her; will it go away and should. She was just concerned. She does not want it to progress. It was like a ringing. It was not like a headache but was a steady discomfort from ear to temple. She works at a hospital and got invited to take it. It was just an annoyance since it was still there. Outcome of the event was not recovered. Information on Lot/Batch has been requested.

she started getting really bad body aches; she got really dizzy; nauseous; throw it up; her arm was sore where they gave the vaccination; The initial case was missing the following minimum criteria: no adverse effect. Upon receipt of follow-up information on (21Dec2020), this case now contains all required information to be considered valid. This is a spontaneous report from a contactable nurse (patient reporting for herself). A 21-year-old female patient received bnt162b2 (also reported as PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899), via an unspecified route of administration on 19Dec2020 18:00 on the left arm at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient stated that she got the vaccine, the Covid-19 vaccine, Saturday 19Dec2020 around 6PM. On Sunday 20Dec2020, she went about her day and around mid day, about 5PM she started getting really bad body aches and then after she showered she got really dizzy, states she would try to eat and she would get nauseous and throw it up. She wanted to know how fast the symptoms are showing after vaccination. She went to get a COVID test today as well because she is not sure if this is due to the vaccine or what. She took Ibuprofen 400mg around 10PM last night 20Dec2020 because the body aches are so bad. States she took a shower last night and got really dizzy but that has resolved and has not happened since. On 21Dec2020, she ate some breakfast and at 11AM she got very nauseous and threw up. Initially (in Dec2020), her arm was sore where they gave the vaccination which she was expecting and then it started going all over her body, states it is like menstrual cramps but like all over. The events did not require a visit to Emergency Room and Physician Office. The event dizzy recovered on 20Dec2020. The outcome of her arm was sore where they gave the vaccination was unknown and the rest of the events was not recovered.

aching/he is feeling a little achy/ he feels achy; he has not slept well; he is just tired; His arm did hurt for 2 days after; This is a spontaneous report received from a contactable consumer (patient). A 50-year-old male patient started received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK5730, expiry date: 31Mar2021), via an unspecified route of administration in left arm, on 16Dec2020, at single dose, for COVID-19 immunization. There were no medical history and concomitant medications. The patient reported he got the COVID Vaccine on 16Dec2020 (Wednesday) and now he is feeling a little achy. He is wondering if that is a side effect. He said it is not a big deal and that maybe he is just tired. He also reported he has not slept well so maybe he could just be tired. Although it could be a side effect. He clarified he did not start feeling achy until 21Dec2020 (today). He reported his arm did hurt after for 2 days. The outcome of the event vaccination site pain was recovered on an unspecified date in Dec2020, pain was not recovered, and the remaining events was unknown.

Cough; congestion/stuffed nose; runny nose; chills; sore arm; decreased sense of smell; decreased sense of taste; This is a spontaneous report from a contactable physician. A 49-year-old female patient receive first dose of bnt162b2 (BNT162B2), intramuscular on left arm on 17Dec2020 10:15 SINGLE DOSE for

COVID-19 immunization. Medical history included Cough variant of asthma, prediabetes. The patient's concomitant medications were not reported. On 18Dec2020 10:00, the patient experienced Cough, congestion, runny nose, chills, sore arm, stuffed nose, decreased sense of smell, decreased sense of taste. No COVID prior vaccination. The patient has been tested for COVID-19 post vaccination. The patient underwent lab tests and procedures which included nasal swab test: pending on 21Dec2020. The outcome of the events was recovering.

broke out in hives on my chest and upper back.; This is a spontaneous report from a contactable other healthcare professional (patient). A 25-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot: EJ1685) intramuscularly on 18Dec2020 10:45 at a single dose for covid-19 immunisation. Medical history included moyamoya disease, asthma and allergies to crustaceans. Concomitant medication included acetylsalicylic acid (ASPIRIN (E.C.) and azithromycin. The patient previously took prochlorperazine maleate (COMPAZINE) and experienced drug allergy. On 18Dec2020 23:59, the patient reportedly broke out in hives on the chest and upper back. Outcome of the event recovered on an unspecified date on Dec2020.

102.5 F fever; Chills; Headache; Dizziness; Body aches; Fatigue; Nausea; This is a spontaneous report from a contactable Other HCP (patient). This 24-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 19Dec2020 12:00 at single dose on left arm for COVID-19 immunization. Medical history was not reported. Concomitant medications included vortioxetine hydrobromide (TRINTELLIX) and levothyroxine, both received within 2 weeks of vaccination. Facility that the most recent COVID-19 vaccine was administered in Hospital. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient hasn't been tested for COVID-19. The patient experienced 102.5 F fever, chills, headache, dizziness, body aches, fatigue, nausea on 19Dec2020 23:00. The outcome of 102.5 F fever, chills, headache, dizziness, body aches, fatigue was recovering, of nausea was unknown. No treatment received for the adverse event. The events were assessed non-serious. Information about lot/batch number has been requested.

arm pain; Fever; body aches; fatigue; This is a spontaneous report from a contactable other HCP (patient). This 29-years-old female patient started to receive BNT162B2, on 17Dec2020 09:15 at single dose for COVID-19 immunisation. The patient medical history and the concomitant medications were not reported. Multi vitamins received in in two weeks. Prior to vaccination, the patient was not diagnosed with COVID-19. Facility that the most recent COVID-19 vaccine was administered is Hospital. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient experienced Fever, body aches, fatigue, arm pain on 18Dec2020. The outcome was not recovered. The patient underwent lab tests and procedures which included sars-cov-2 test (Nasal Swab): negative on 11Dec2020. The events were assessed non-serious. No treatment received for the adverse event. Information on the Lot/Batch number has been requested.

Flushing and Dizziness within 10 minutes of administration that resolved after drinking water.; Flushing and Dizziness within 10 minutes of administration that resolved after drinking water.; Injection site tenderness; Tiredness; headaches/headaches were markedly increased; muscle aches; fever to 101.1;

Slight chest discomfort; chest pain/chest pain and headaches were markedly increased; This is a spontaneous report from a contactable nurse. This nurse reported for a 35-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), (Lot number: EK5730) via intramuscular route on 20Dec2020 10:30 at single dose on the right arm for COVID-19 immunization. Medical history included COVID in Apr2020, post COVID syndrome and migraines. No allergies to medications, food, or other products. Concomitant medications included topiramate (TOPAMAX), topiramate (TROKENDI), gabapentin, magnesium, vitamin b complex (VITAMIN B), all received within 2 weeks of vaccination. Facility that the most recent COVID-19 vaccine was administered in Hospital. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was diagnosed with COVID-19. Since the vaccination, the patient hasn't been tested for COVID-19. On 20Dec2020 10:30, the patient experienced flushing and dizziness within 10 minutes of administration that resolved after drinking water. Injection site tenderness. Tiredness, headaches, muscle aches, fever to 101.1. Slight chest discomfort (patient had COVID in April 2020. She had all these symptoms with in the acute phase and still have intermittent chest pain/headaches. With the vaccine, the chest pain and headaches were markedly increased on the day after receiving it). Outcome of the events was recovered in Dec2020. No treatment received for the adverse events. The events were assessed non-serious.

sore at site of injection; had a knot there where it was given; This is a spontaneous report from a contactable consumer (patient). This 67-years-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), on unknown date in Dec2020 at single dose for COVID-19 immunisation. The patient medical history and the concomitant medications were not reported. The patient received vaccine last Wednesday, didn't have any side effects. It was sore at site of injection. Same day, it had a knot there where it was given. The outcome was unknown. Information on the lot/ batch number has been requested.

sore throat; runny nose; This is a spontaneous report from a contactable consumer (patient). A 20-years-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (lot number: EL0140) via an unspecified route of administration on left arm on 18Dec2020 at single dose for COVID-19 vaccination. There was no medical history. There were no concomitant medications. The patient is asking if this is part of the documented side effects of the vaccine. She received the Covid19 vaccine last Friday (18Dec2020), at noon, the first in the series of two. She says on Saturday (19Dec2020) she woke up with a runny nose, and then on Sunday night (20Dec2020) she had a sore throat. She says she would like to know if her body fighting is fighting something off or building antibodies. She received the vaccine from work and it was optional, not prescribed. She has her vaccine card and all it has on the back is the name Pfizer and the LOT. She didn't take any new medications or receive any other injections at the time of the COVID-19 vaccine. She didn't do any treatments for the sore throat and runny nose. Events outcome was unknown.

nodule formed at the injection site; the injection along with localized pain; reddened, warm area remained around the injection site; reddened, warm area remained around the injection site; This is a spontaneous report from a contactable nurse (patient). A 42-years-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (lot number: EH9899) intramuscular on right arm

on 18Dec2020 17:30 at single dose for COVID-19 immunization. Medical history included hypertension. Concomitant medication included the medications the patient received within 2 weeks of vaccination: Amlodipine, hydochlorathiazide, bupropion hydrochloride (WELLBUTRIN), zolpidem tartrate (AMBIEN). The patient previously took albuterol sulfate and experienced drug hypersensitivity. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. On 19Dec2020, a nodule formed at the injection site about 12 hours after the injection along with localized pain. The nodule started to disappear, but a reddened, warm area remained around the injection site. The reddened area is about the diameter of an egg. It has been about 72 hours since the injection. No treatment was received for the adverse event. Events outcome was not recovered.

test positive post vaccination; test positive post vaccination; This is a spontaneous report from a contactable Nurse (patient). A male patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 17Dec2020 at single dose for COVID-19 immunization. The patient medical history was not reported. The patient's concomitant medications were not reported. The patient got the Pfizer Covid-19 vaccine on the 17Dec2020. He would like to how likely is he to test positive post vaccination. He wants to know if the test results would be a false positive post vaccination. He is going to get tested at two different facility. Event outcome was unknown.; Sender's Comments: Based on the current available information and the consistency with the known safety profile of the suspect product BNT162B2, a possible contributory role of the suspect product to the development of Drug ineffective and COVID-19 cannot be excluded. The case will be reassessed if additional information becomes available.

sweating; itching palms; elevated HR; headache that lasted 24 hrs; fatigue; foggy feeling that also lasted 24 hrs; This is a spontaneous report from a contactable nurse (patient). A 39-year-old female patient received the first dose of BNT162B2 (lot number: EJ1685) intramuscular on right arm on 19Dec2020 14:45 at single dose for COVID-19 immunization. Medical history included DM type 2, irritable bowel syndrome, restless legs syndrome, insomnia. Other unspecified concomitant medications received in two weeks. The patient previously took thiomersal and experienced drug hypersensitivity. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. On 19Dec2020, within 10 minutes of the reaction she experienced sweating and itching palms with elevated HR. Within 1 hr of the vaccine she had a headache that lasted 24 hrs with fatigue and a foggy feeling that also lasted 24 hrs. No treatment received for events. Events outcome was recovered. No follow-up attempts are possible. No further information is expected.

felt hot; felt achy; Chills; generalized myalgias; high fever/her highest recorded temperature was 102.5; Deltoid soreness; This is a spontaneous report from a contactable Other HCP. This other hcp (patient) reported for herself that the 32-year-old female patient received bnt162b2 (BNT162B2, Solution for injection, Covid-19 Vaccine manufacturer: Pfizer BioNTech), intramuscular into her left deltoid on 17Dec2020 07:30 at single dose for covid-19 immunisation (Prophylaxis). Medical history included Hypothyroidism, mood and sleep. Concomitant medications included Levothyroxine at 100mcg daily by mouth ongoing for Hypothyroidism started taking at 19 years old, escitalopram oxalate (LEXAPRO) at 10mg once a day by mouth from Dec2020 started it about 2 weeks ago ongoing for mood, zolpidem tartrate (AMBIEN) at 10mg as needed by mouth for sleep and was not taking this at the time. The

patient experienced Deltoid soreness from 17Dec2020 to 18Dec2020, Chills from 20Dec2020 to 21Dec2020, generalized myalgias from 20Dec2020 to 21Dec2020, high fever from 20Dec2020 to 21Dec2020. The outcome of the events was recovered. Her vaccination cared is at her house. She received the product at the hospital she works at. The causality of the events Deltoid soreness, Chills, generalized myalgias and high fever was related. Caller is a nurse practitioner that reported that she wanted to report a possible side effect for herself with the Covid-19 vaccine. She said that she herself got vaccinated on Thursday 17Dec2020. She was doing fine except for the deltoid soreness that showed up about 12 hours after receiving the vaccine and lasted for about 12 hours and then it went away. On Sunday, she had sudden onset of chills, generalized myalgias, and a high fever. Caller said that her highest recorded temperature was 102.5. Her symptoms started at about 1430 and she said she had no other symptoms aside from what she reported. She said that her chills went away after about 3 hours and then she felt hot, and then she just felt achy and had the generalized myalgias. All were subsided by 0900 this morning. She said that she also had a low grade fever of 99.8 this morning, but it was all gone by 0900. Caller said that she is a emergency room employee and was given the vaccine at the hospital and they was no prescribing physician. Caller said that she has never had a reaction like this to a vaccine before. Vaccination Facility Type was hospital. Vaccine Administered at Military Facility was No. Additional Vaccines Administered on Same Date of the Pfizer Suspect was none. No AE(s) was require a visit to ER or physician office. Prior Vaccinations (within 4 weeks) was none. AE(s) following prior vaccinations was none. Family Medical History Relevant to AE(s) was none. Relevant Tests was None. Information on the lot/ batch number has been requested.

Headache, muscle and joint pain,Chills and Fever-102.9 day after; Headache, muscle and joint pain,Chills and Fever-102.9 day after; Headache, muscle and joint pain,Chills and Fever-102.9 day after; Headache, muscle and joint pain,Chills and Fever-102.9 day after; Headache, muscle and joint pain,Chills and Fever-102.9 day after; This is a spontaneous report from a contactable Nurse (patient). A 66-years-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (lot number: EJ1685) intramuscular on arm left on 18Dec2020 12:45 at single dose for COVID-19 immunization. Medical history included osteoarthritis. The patient was not allergic to medications, food, or other products. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Concomitant medication received within 2 weeks of vaccination included Atorvastatin, Ibuprofen, sambucus nigra (ELDERBERRY), Krill Oil, One A Day VitaCraves Women's, ergocalciferol (VITAMIN D), ascorbic acid (VITAMIN C). On 19Dec2020 08:00, the patient experienced headache, muscle and joint pain, chills and Fever-102.9 day after, gradually went down over night. No treatment received for the adverse event. There was no Covid prior vaccination, received COVID tested post vaccination via nasal swab on 20Dec2020 with result of negative. Events outcome was recovered.

tested (nasal swab done) on Sunday; received positive test result; Patient had COVID, did not know she had COVID and got the vaccine; This is a spontaneous report from a Pfizer-sponsored program Pfizer First Connect via a contactable pharmacist (patient). This 41-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), (lot number: EH9899) via an unspecified route of administration on 19Dec2020 at single dose for COVID-19 immunization. There were no medical history and concomitant medications. Patient had COVID, did not know she had COVID and got the vaccine. Patient

received vaccine on Saturday, tested (nasal swab done) on Sunday. Patient received positive test result on 21Dec2020. Outcome of the event was unknown.; Sender's Comments: Based on the information currently available, a lack of efficacy with BNT162B2 in this patient might not be completely excluded.

R sided facial numbness; tingling; muscle weakness; This is a spontaneous report from a contactable pharmacist reporting for herself. This 32-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via intramuscular route at right arm on 21Dec2020 at single dose (lot number: EJ1685) for COVID-19 immunization. Medical history and concomitant medications were unknown. The patient reported R sided facial numbness, tingling, and muscle weakness roughly 20 minutes after receiving the COVID-19 vaccine on 21Dec2020. The sensation was improving over the next 10-15 minutes. The patient was asked to monitor her signs and symptoms and report to her doctor if no improvement/worsening. Events were reported as non-serious. No treatment was received for events. Outcome of the events was recovering. Information about lot/batch number has been requested.

Having a lot of bone pain in the arm that I got the injection at; Having a lot of bone pain in the arm that I got the injection at; This is a spontaneous report from a contactable consumer (patient). This patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose in the arm for COVID-19 immunization. Medical history and concomitant medications were not reported. Patient stated it was the COVID-19 Vaccine. Patient was having a lot of bone pain in the arm that patient got the injection at. It was not 'muscle' (not clarified). The outcome of events having a lot of bone pain in the arm that patient got the injection at was unknown. Information on the Lot/Batch number has been requested.

"bleeding coming from the injection site after the needle was removed his arm; This is a spontaneous report from a contactable other HCP (anesthesiologist) reported for himself. This male patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose on the arm for COVID-19 immunization. Medical history and concomitant medications were not reported. Patient stated after receiving COVID vaccine on an unspecified date (reported as ""today"") he noticed bleeding coming from the injection site after the needle was removed his arm. Patient said he had the vaccine he took the needle out he bleed a little bit he said he was afraid he was injected wrong possible into a vein nothing was swollen nothing was bruised red. Patient stated he was unsure if the vaccine was administered intravenously or intramuscularly. Outcome of the event was unknown. The report was assessed as non-serious. Information on the Lot/Batch number has been requested."

patient received BNT162B2 vaccine that had been through a temperature excursion; patient received BNT162B2 vaccine that had been through a temperature excursion; This is a spontaneous report from a contactable healthcare professional. This healthcare professional reported similar events for ninety patients. This is one of ninety reports. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), via an unspecified route of administration in Dec2020 as a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. In Dec2020, the patient received BNT162B2 vaccine that had been through a temperature excursion. This was further elaborated as the patient received the vaccine that had been

exposed to -50 degrees Celsius for about 20 minutes before being transferred to the refrigerator and then administered within 5 days. The clinical outcome of patient received BNT162B2 vaccine that had been through a temperature excursion was unknown.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2020502898 same reporter reporting similar events in different patients with the same vaccine

severe headache with nausea; severe headache with nausea; This is a spontaneous report from a contactable nurse (patient) who reported for herself that a 56-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EH9899) via an unspecified route of administration on 17Dec2020 at single dose for COVID-19 immunization. Medical history included pulmonary sarcoidosis, thyroid, mild depression. Concomitant medication included famotidine, ibuprofen (DUEXIS). Nurse called in to report side effects, she got her shot on 17Dec2020 and she had a severe headache with nausea about 45 minutes after getting the shot. When probed if still experiencing the event, nurse stated, about 15 minutes it was gone on 17Dec2020. She just took Ibuprofen (MOTRIN) for treatment. Outcome of severe headache with nausea was recovered on 17Dec2020.; Sender's Comments: The reported information is limited. Based on the close temporal relationship and the description of the events,headache with nausea, there is a reasonable possibility that the events are related to BNT162 vaccine. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

Headache; malaise; diarrhea; This is a spontaneous report from a contactable nurse (patient). A 38-year-old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number: Ek5730), intramuscular on the right arm on 19Dec2020 16:15 at a single dose for covid-19 immunization. The patient's medical history included reflux and anxiety. The patient had no known allergies to medications, food, or other products. Concomitant medications included sertraline hydrochloride (ZOLOFT), spironolactone, loratadine (CLARITIN), ascorbic acid, betacarotene, calcium sulfate, colecalciferol, cyanocobalamin, ferrous fumarate, folic acid, nicotinamide, pyridoxine hydrochloride, retinol acetate, riboflavin, thiamine mononitrate, tocopheryl acetate, zinc oxide (PRENATAL VITAMINS), vitamin d3, and famotidine (PEPCID). The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient was not diagnosed with COVID-19 prior to vaccination and had not been tested for COVID-19 since the vaccination. The patient experienced headache, malaise, and diarrhea on Dec2020 (reported as 18Dec2020 19:00, pending clarification). No treatment was received for the adverse events. Outcome of the events was recovered on Dec2020.

He has a temperature of 100.1 but a lot of muscles aches and pain; He has a temperature of 100.1 but a lot of muscles aches and pain; He has a temperature of 100.1 but a lot of muscles aches and pain; This is a spontaneous report from a non-contactable Nurse. This Nurse reported for a male patient (Son) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 19Dec2020 at 08:20 at single dose for covid-19 immunisation. Medical history was not provided Concomitant medications included Lisinopril for a little hypertensive. He received a shot (COVID Vaccine) yesterday (19Dec2020 at 08:20), today he called on for work, and he says that he has a temperature of 100.1 but a lot of muscles

aches and pain. Outcome of the events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

Tiredness; Pain injection site; Headache; muscle pain; Joint pain; Nausea; just isn't feeling good; feels like face and around eyes are swollen; feels like face and around eyes are swollen; This is a spontaneous report from a contactable consumer reported for self. This 53-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 17Dec2020 in her right arm at single dose for required to at work. None medical history and concomitant medications. She is at work right now. She doesn't have a prescribing doctor. She works at the ER, and they were provided to employees. There is pain at the injection site, which she expected. She has had tiredness, headache, muscle, and joint pain. No chills. She has had nausea. She just wasn't feeling good. She feels like her face is swollen. Like around her eye lids is swollen, but she asked her kids, and they said it doesn't look swollen. She can feel it, but not see it. She got the vaccine on 17Dec2020. She started having all the side effects on the 18Dec2020. They have just persisted. She took something for nausea. She took Ibuprofen for pain, Headache, muscle pain, Joint pain. Outcome of the events was not recovered. Information on the lot/batch number has been requested.

She does have a significant muscle ache and joint ache; She does have a significant muscle ache and joint ache; This is a spontaneous report from a contactable physician (Patient's husband). A female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 19Dec2020 at single dose (Lot # EH9899) for covid-19 immunisation. Medical history, concomitant medications or past drug history were not provided. She has received the first injection of the Covid 19 Vaccination, she received it 24 hours ago (19Dec2020) and she doesn't have a fever but she does have a significant muscle ache and joint ache. So the question if it is okay for the patient to take anti-inflammatory medication like non-steroidal. Outcome of the event was unknown.

tested positive for Corona Virus/ symptomatic and has been sick; tested positive for Corona Virus/ symptomatic and has been sick; This is a spontaneous report from a Pfizer-sponsored program by a contactable other HCP reported for self. This 35-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on an 18Dec2020 10:45 am on left arm at single dose (Lot # EK5730) for routine vaccination. No additional vaccines received on the same date. Vaccination facility type was hospital. None medical history, concomitant medications or past drug history. She has a patient on the line who got the COVID vaccine on Friday (18Dec2020 10:45), and on Sunday (20Dec2020) she tested positive for the Corona Virus. The main reason she called is to figure out what to do about the booster. There is not really enough data to determine this at this point. There was no prescriber. She just received it at the hospital. She is symptomatic and has been sick on 18Dec2020 all weekend. Saturday (19Dec2020) is when she began to have more significant symptoms and on Sunday (20Dec2020) as well. Today, she is better, but still symptomatic. She became symptomatic on Friday night 18Dec2020, and experienced loss of smell, extreme fatigue, mild cough, nasal congestion. She states all were related to COVID. This all started around 7:30 pm. Relevant test included Positive for Corona Virus on Sunday, 20Dec2020. Relevant test included Positive for COVID test (Corona Virus) on Sunday, 20Dec2020. Outcome of the events was unknown.; Sender's Comments: Based on the information currently available, a lack of efficacy with BNT162B2 in this patient might not be completely excluded.

arm tingled; a little pain around the injection site; This is a spontaneous report from a contactable consumer. This female consumer (patient) of an unspecified age received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), intramuscular on 20Dec2020 at 4:00 pm at single dose for COVID-19 immunisation in her left arm. The medical history and concomitant medications were not reported. At 4:00 pm a nurse placed the vaccine in her left arm. When she placed the medication the patient felt a zing and a burning sensation with a tingle down her arm. She didn't say anything, she thought maybe the medication was just a thicker consistency like Betamethasone, which can sometimes burn when injected in the muscle. The patient's arm tingled for about 3 to 5 minutes and then it stopped. The patient felt the medication go in and felt burning and tingling. It's 6pm and the patient feel fine, just a little pain around the injection site. The skin surrounding the injection site was normal in color and cool to the touch. No visible swelling. She personally think she placed the vaccine a little too high and hit a nerve. The outcome of the events was recovered on 20Dec2020 6pm. Information about Lot/Batch number has been requested.

Muscle ache; Fatigue; Headache; feels Achy; This is a spontaneous report from a contactable Physician. A female patient started to receive started to receive BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 17Dec2020 at single dose for covid-19 immunisation. This is unknown to her, but she would imagine the second dose is around 07Jan2021. Medical history, concomitant medications or past drug history were not provided. The patient was experiencing that she was referring to is muscle aches, fatigue, and headache. She doesn't feel sickly but feels achy. It is unknown if the patient ever test positive for Covid, or had antibodies prior to the vaccine. Outcome of the events was unknown. Information about Batch/Lot number has been requested.

entire tongue began to itch; entientire tongue began to itch, tingle; A small bruise-like spot appeared on the tip of her tongue; This is a spontaneous report from a contactable Nurse reported for self. This 65-year-old female patient (not pregnant) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on an 19Dec2020 14:30 on Arm left at single dose (Lot # EKS730) for covid-19 immunisation. Facility where the most recent COVID-19 vaccine was administered: hospital. Medical history included Gastrooesophageal reflux disease. Concomitant medications included omeprazole. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Past drug history included Allergies to medications, food, or other products: Bactrim, Ceftin. On 20Dec20200 8:30 AM, 18 hours after receiving the vaccine her entire tongue began to itch, tingle. No swelling noted. A small bruise-like spot appeared on the tip of her tongue. 5 hours later the itching stopped (20Dec2020 13:30) and the bruise-like spot began to fade. The spot was completely gone the next morning. There was no trauma to the tongue at any point that would account for the spot. Prior to vaccination, was the patient did not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. No treatments were received for the events. Outcome of the event tongue itching was recovered on 20Dec2020 13:30. Outcome of the event a small bruise-like spot appeared on the tip of her tongue was recovered on 21Dec2020. Outcome of the event tingling tongue was recovered in Dec2020. Events assessed as non serious.

developed a slight cough; This is a spontaneous report from a contactable nurse reported for herself. This 25-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an

unspecified route of administration on 19Dec2020 at single dose for COVID-19 immunization. Medical history and concomitant medications were unknown. The patient received the COVID Vaccine on 19Dec2020. The following day she developed a slight cough on 20Dec2020, and she felt completely fine otherwise. Outcome of the event was recovered. Information on the Batch/Lot number has been requested.

feeling ok not perfect; This is spontaneous report from a contactable nurse reporting for herself. This female patient of unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 21Dec2020 at single dose for COVID-19 immunization. Medical history and concomitant medications were unknown. The patient got the Pfizer Covid-19 vaccine on 21Dec2020 and wanted to know if she was contagious. She stated she knew it's not a live vaccine and it's an MRNA vaccine. Her pharmacist told that she was not contagious, but she just wanted to make sure. The patient was feeling ok not perfect. The patient did not state any side effects. Outcome of the event was unknown. Information about lot/batch number has been requested.

heaviness in the chest; trembling of the mouth like teeth went on chatter like it is real cold; This is a spontaneous report from a contactable consumer (patient). This 57-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 17Dec2020 at single dose (lot number: EJ1685) for COVID-19 immunization. Medical history included blood pressure abnormal. Concomitant medications included cetirizine hydrochloride (ZYRTEC) and acetylsalicylic acid (ASPIRIN 81) as blood pressure pills. The patient was informing the side effect that she had when she had got the vaccine (Unspecified vaccine). The patient experienced heaviness in the chest and also trembling of the mouth like teeth went on chatter like it was really cold on 17Dec2020. When probed for the lot number, EJ1685 with Pfizer was reported. The patient worked at the hospital. It was just happened between the first 4 hours after receiving. It was not still experiencing. No treatment received for the problem because they left like within the first 4 hours and after that the patient didn't feel anything. Outcome of both events was recovered in Dec2020.

Some chills, temperature; Some chills, temperature; Soreness in the administration site; This is a spontaneous report from a contactable nurse reported for himself. This 51-year old male patient started to receive BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 20Dec2020 at single dose for COVID-19 immunization. Medical history and concomitant medications were unknown. On 21Dec2020, the patient experienced some chills, temperature, and soreness in the administration site. The patient was vaccinated at 51 years old. The patient wanted to know if he should isolate himself again, and if he will get Covid again after receiving the vaccine. Outcome of the events was unknown. Information about lot/batch number has been requested.

Runny nose; Congestion; Malaise; Fever; Chills; This is a spontaneous report from a Pfizer-sponsored program from a contactable consumer (patient). This male patient of unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 18Dec2020 at single dose for COVID-19 immunization. Medical history and concomitant medications were unknown. The patient received the vaccination on Friday, 18Dec2020. The patient was experiencing fever and chills Friday night on 18Dec2020. Then he proceeded to receive a runny nose and

congestion still at the time of reporting along with a little bit of malaise. He was wondering if he should get tested for COVID-19 due to the symptom or if the symptoms were due to the vaccination. Outcome of the events runny nose, congestion and malaise was not recovered. Outcome of the events fever and chills was unknown. Information on the Lot/batch number has been requested.

left deltoid hurt a lot for a while; got left actual swelling like in his armpit; This is a spontaneous report from a contactable consumer (patient). This 49-year-old male patient received the 1st dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration at left deltoid on 18Dec2020 at single dose for COVID-19 immunization. Medical history and concomitant medications were unknown. The patient received the COVID vaccine Friday morning as part of work. The patient had a lot of, kind of significant actual swelling in the (incomplete sentence). The patient was too much concerned about this, but it was out of the ordinary enough that the patient felt it was worth reporting. So the patient got the vaccine in his left deltoid and the left deltoid hurt a lot for a while but currently the patient got left actual swelling like in his armpit it's, where the lymph nodes were, the patient got a very significant swelling. The patient stated he was experiencing it on 20Dec2020. So his age was 49 years. The patient was assuming it was a normal immune response, but he never had it with the flu vaccine or anything, so the patient wanted to report it. It's a COVID-19 Vaccine. No treatment was received for events. Outcome of the events was unknown. Information about lot/batch number has been requested.

sore and heaviness on the injection site; heaviness on the injection site; This is a spontaneous report from a contactable Nurse (patient) via Pfizer sales representative. This female patient of unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. Medical history and concomitant medications were unknown. The patient posted on Social Media that she was injected with COVID 19 vaccine. As per her comment, after 8 hours she experienced sore and heaviness on the injection site. Outcome of the events was unknown. Information on Lot/Batch number has been requested.

mild COVID symptoms; front line nurse and received it because of that; This is a spontaneous report from a contactable nurse. A female patient of unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on an unspecified date at single dose for treating COVID patients. Medical history included COVID. Concomitant medications were unknown. The patient had COVID previously, received the vaccine, and was currently experiencing mild COVID symptoms. The patient received vaccine from the hospital, so there was no prescriber. Patient was a front line nurse and received it because of that. Outcome of the events was unknown. Information about batch/lot number has been requested.

"Cough; Got a COVID test; positive; 4 hours after, my arm became sore; body aches; Still feel sick but not as sick as I was; shortness of breath; fever; Developed like pretty bad symptoms; This is a spontaneous report from a contactable nurse reported for himself. This 38-year-old male patient received 1st dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration at arm on 16Dec2020 at single dose (lot number: PAA156051) for vaccinated against COVID 19. Medical history included HIV. Concomitant medications included bictegravir sodium/emtricitabine/tenofovir

alafenamide fumarate (BIKTARVY) for HIV. The patient had received the Pfizer vaccine for COVID 19 on 16Dec2020 (Wednesday). And then the patient developed like pretty bad symptoms. Then, when the patient went to get tested because he suddenly started having like a cough at night on 16Dec2020 and got a COVID test and it was positive on Dec2020. The patient was a nurse in the emergency room and just wanted to report that. The patient knew scientifically it couldn't give him the virus. The patient didn't have any symptoms of COVID. So, after the patient got the shot, 4 hours after, his arm became sore and then 12 hours after, he had body aches, fever, cough, shortness of breath on Dec2020. About Lab Work, the patient stated, ""Just the COVID one."" And the patient got positive results for COVID test. Due date for the next shot was 06Jan2021. When asked if he was still experiencing cough, the patient stated he still felt sick but he was not as sick as he was. The first 2 or 3 days were really bad. About treatment, the patient stated, ""Nothing for the cough but I took Tylenol."" Outcome of the events was unknown. Information about batch/lot number has been requested."

Hives; felt itching to her scalp; This is a spontaneous report from a contactable other hcp (patient). This 38-years-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (lot number: EK5730), intramuscularly on 21Dec2020 06:40 at single dose on left deltoid for COVID Prevention. Medical history included Polycystic ovarian syndrome, was diagnosed with this in her early 20's and ongoing, Hypothyroidism from 2015 and ongoing, Corneal abrasion from 2020 and ongoing (Patient got a corneal abrasion to her right eye, about a week ago and is currently using eye drops for prophylaxis against infection), and anaphylaxis. Concomitant medication included metformin tablet oral at 750mg, once daily for Polycystic ovarian syndrome, she has been taking the product on and off since being diagnosed with PCOS and ongoing, thyroid (ARMOUR THYROID) oral at 60 (unsure if the product is MG or MCG) once daily for Hypothyroidism, started product four or five years ago and ongoing, moxifloxacin hydrochloride (VIGAMOX) at 1 drop to right eye, three times daily for Infection prophylaxis from Dec2020 and ongoing, patient got a right corneal abrasion last week and is using the product as infection prophylaxis. The patient was a Physician Assistant, who works in the ER, who just received the COVID vaccine at work. The patient stated that she got hives after her injection. The patient received the vaccine today at about 6:40AM. She stated that she was instructed to wait 30 minutes after receiving the vaccine because she does have a history of anaphylaxis, but not to vaccines. So it was about 5 to 10 minutes before her 30 minute wait time was up, that she started getting the hives on 21Dec2020. She stated that the hives she got started on her left wrist, and then they worked to bilateral upper arms, and then she also felt itching to her scalp but states she did not feel a rash on her scalp. She took 50mg of Benadryl orally for treatment. It was stated that the hives have resolved at this time, but patient was unsure as far as outcome goes, because she took Benadryl and the hives are gone now, but she does not know if they will return or not. She stated that she only had to take Benadryl and she declined checking in to the ER, so she considers this, not serious. The outcome of hives was recovered, of felt itching to her scalp was unknown.

fatigue; This is a spontaneous report from a non-contactable consumer (patient) via Pfizer sales representative. This patient of unspecified age and gender received first dose of BNT162B2, from an unspecified date at single dose for COVID-19 immunisation. The patient medical history and the concomitant medications were not reported. The patient experienced fatigue the day after the first

dose. The outcome was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

body aches; pregnant patient received BNT162B2 for COVID Prevention; pregnant patient received BNT162B2 for COVID Prevention; pregnant patient received BNT162B2 for COVID Prevention; This is a spontaneous report from a contactable physician (patient). This 35-years-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (lot number: EH9899), intramuscularly on 19Dec2020 at single dose in right upper arm for COVID Prevention. Medical history was none. Concomitant drug included unspecify drugs. The patient got the vaccine on 19Dec2020, and then that evening she had body aches. She stated that she took 1000mg of Tylenol by mouth because she was really achy, but she was fine by the next day. She was pregnant. Patient last menstrual period date was 08Sep2020. She does take another medication but she does not think it was associated with the body aches she experienced. The outcome of Body aches was recovered on 20Dec2020, of other events were unknown. Primary Source Reporter assessed Body aches related by Method of assessment.

Weakness; Lightheadedness; fast heart beat/heart rate is 101; coughing a little bit; panic attack; he was not acting well and his blood pressure was 158/98; he feels silly then has nervousness; he feels silly then has nervousness; feeling tired; not feeling well; This is a spontaneous report from a Contactable consumer (patient). This 52-years-old male patient received first dose of BNT162B2(PFIZER-BIONTECH COVID-19 VACCINE) (lot number: AK5730), on 20Dec2020 at single dose on left arm for COVID-19 immunisation. Medical history included Blood pressure high. The patient's concomitant medications were not reported. He had one injection given in his left arm around 08:30 or 08:40 in the morning on 20Dec2020, before 9 o clock. He says that they let him rest for 15 minutes after his injection, and it is a delayed reaction that just started this morning and he tried to go to work and had to go home. The patient got the vaccine on yesterday morning then tried to come to work on this morning but he was feeling weak and having light headedness, and his heart beat is so fast. He did go home to try to relax. He said he experienced a panic attack at some other times where his heart beat fast and he was quite light headed at some other times gone from rest and get up to walk or try to do something, and that's why he had gone home after he reported to work earlier. He says just now also trying to have something to do he is feeling it. He says that he took Tylenol and some cough syrup for feeling lightheaded and weak. He clarifies that he took Tylenol yesterday and then after he took vaccine and this morning the nurse gave him Tylenol also. He says he told them he was not feeling well, he felt silly and weak. They told him to go home because he told them he was not acting well and his blood pressure was 158/98. He has been doing Lisinopril 20mg for his high blood pressure, and he has been on it for a long time. He says that the label says discard after 01Oct2021. He says he takes 20mg once a day by mouth, and he keeps refilling it every 30 days. The patient took the cough syrup because he was coughing a little bit. He says that the EXP date on the Tylenol he took that he has at home is Mar2022. He provides EA013 as LOT and dose strength as 500mg. He says he took this last night and this morning at the facility they gave him the 500mg dose too. He says that he took vitals with his nurse, and his heart rate is 101. The patient asks what can he do since he is worried about reading side effects of vaccine so now he is feeling fine, then some other times it comes like first time this morning at work he feels silly then has nervousness or something and a panic attack, so they let him go home. He says he got home, and was

feeling fine again. He says he tries to go to the bathroom, or tries to do something in his garage, and feels light headed and is feeling tired. He says he would like to know if that is normal, should he take anything. Lab data on 21Dec2020 included Blood pressure was 158/98, Heart rate was 101. The outcome was unknown.

rigors; This is a spontaneous report from contactable physician via Pfizer sales representative. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), on an unspecified date at single dose for COVID-19 immunisation. The patient medical history and the concomitant medications were not reported. The patient had rigors that subsided in 12 hours after receiving the Pfizer-BioNTech COVID vaccine. The outcome was recovering. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

"General weakness; body ache; Muscle ache; Headache; This is a spontaneous report from a contactable Nurse (patient). A 56-years-old female patient received first doe of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (LOT#: EK5730), on 17Dec2020 at single dose for COVID-19 immunisation. Medical history was none. There were no concomitant medications. The patient received a Pfizer's Covid vaccine on 17Dec2020 and have got some side effects which is general weakness, headache and it just started second day after received the Vaccine on 18Dec2020. The patient had done Covid test several times and all the time it was negative. The patient stated, ""You mean is it worsened from the start date, it's the same when it started on the second day it continued with the headache and body ache, muscle ache and I am taking some Tylenol 500 every 6 hour but not all the time after that."" The outcome was not recovered.P rimary Source Reporter assessed General weakness; body ache, Muscle ache, Headache were related."

"she has almost a sinus headache; the injection site was very, very sore; Chills/She couldn't get warm; cold; body aches; This is a spontaneous report from a contactable consumer (patient). This 64-years-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (lot number: EK5730) on 19Dec2020 15:15 at single dose on Left Arm for COVID-19 immunisation. Medical history included She had COVID on 10Nov2020. There were no concomitant medications. The patient received the COVID vaccine on 19Dec2020, the first dose. She didn't have much side effects or feel symptoms except the next morning on 20Dec2020, the injection site was very, very sore. As the day progressed, she had chills. No fever, but chills. She couldn't get warm. This morning when she woke up she has almost a sinus headache on 21Dec2020. It's not really a headache, but around her eyes. ""Injection site was very, very sore"" didn't really start until yesterday after lunch. She has not had chills this morning, just body aches. She feels like she is about to get a cold. She had COVID on 10Nov2020. She wasn't as cold this morning like she was when she went to bed last night. She thinks the chills stopped some time in the night. When she went to get in the shower this morning she felt the headache. She still has the sensation around the eyes. She took some Tylenol about 11AM on 19Dec2020. The outcome of the injection site was very, very sore was recovering, of other events were unknown."

tachycardiac; Low grade like a 99.8; This is a spontaneous report from a contactable nurse (patient). A 32-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EH9899), via an unspecified route of administration on 17Dec2020 at single dose at the left deltoid for

immunization. Medical history included tachycardia heart condition (had an underline heart condition that was a tachycardia heart condition). There were no concomitant medications. Patient got Pfizer vaccine on 17Dec2020. Patient really had not had any side effects except had a low grade like a 99.8 yesterday (in Dec2020). Which was probably just the vaccine patient was assuming probably just the vaccine had to do like kid when they get in then they get a little fever. On 19Dec2020, though however patient had tachycardia. Like right now patient was in 130 and blood pressure didn't read when went to stand. And patient had drink plenty fluids all day on 18Dec2020. Patient previously did have an underline heart condition that was a tachycardia heart condition. Patient had not had any issues with heart for about. Because the last time had it was about 2 years ago. Patient had a cardiac condition that caused her to be tachy-cardiac. But it was usually only when she was pregnant. But patient was not pregnant and it had been about 2 years since last episode of this. And the only this that changed was this on 17Dec2020. So, this was the first time patient had had anything that changed after getting that vaccine. Patient did not take any medication. She used to be on a beta blocked but she was recently taken off of that (She don't know 3 months ago). Outcome of events was unknown.

Tingling down entire left side of body, from face to foot.; Numbness and tingling of left side of face.; Had headache temporarily (resolved). Mostly on right side behind eye; This is a spontaneous report from a contactable Other HCP. This Other HCP reported for herself that the 48-year-old female patient received fist dose of bnt162b2 (BNT162B2, Batch/lot number: EK5730), via unknown route of administration in left arm on 21Dec2020 07:45 PM at single dose for covid-19 immunisation. She is not pregnant at the time of vaccination. Medical history included History of breast cancer. Past drug event included Known Allergies to medications, food, or other products: Codeine. Concomitant medications included tamoxifen. Facility type vaccine Hospital. No other vaccine in four weeks. Other medications the patient received within 2 weeks of vaccination included Tamoxifen, multi-vitamins, hair, skin and nails. The patient experienced Tingling down entire left side of body, from face to foot. Numbness and tingling of left side of face. Feel like I got Novocain shot in face. Had headache temporarily (resolved). Mostly on right side behind eye from 21Dec2020 08:00 PM. Outcome of the events was not recovered. No covid prior vaccination. No covid tested post vaccination. Facility where the most recent COVID-19 vaccine was administered was Hospital. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. No treatment was received for the adverse event. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, has the patient has not been tested for COVID-19. Vaccine Facility information available. Location of injection information is available for all vaccines received on the same date.

"I have had an excruciating back and hip pain; I have had an excruciating back and hip pain; I can barely walk around; This is a spontaneous report from a contactable consumer. This consumer (Respiratory therapist) reported that the 64-year-old male patient received bnt162b2 (BNT162B2, Pfizer BioNTech Covid 19 Vaccine), via unknown route of administration on 16Dec2020 at single dose for covid-19 immunisation (""It helps so that I won't get Covid.""). Medical history included Blood pressure. Consumer stated, ""I need it to report that I have had an excruciating back and hip pain. This is the fifth day and I still have pain but its slightly better but I don't think I am going to work today or tomorrow. I can barely walk around."" Consumer stated, ""It was given to me by a nurse at hospital."" Consumer

stated, ""I take a high blood pressure medicine."" Consumer stated, ""I didn't take any Lab work."" Treatment was received and consumer stated, ""Yes I tried Ibuprofen."" The outcome of the events was unknown. Information about lot/batch number has been requested."

arm pain; fatigue; severe nausea; This is a spontaneous report from contactable Physician via Pfizer Sales Representative. This Physician (patient) reported that the patient of unknown age and gender received bnt162b2 (BNT162B2, reported as Pfizer-BioNTech COVID vaccine), via unspecified route of administration on arm on unknown date at single dose for covid-19 immunisation. Medical history was none. Concomitant medications were unknown. Physician reported arm pain, fatigue and severe nausea after receiving the Pfizer-BioNTech COVID vaccine. Patient is a HCP with no prior medical history. The outcome of the events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

"Headache; shivers; coldness; body aches; mouth hurts; feel very weak; This is a spontaneous report from a Pfizer-sponsored program Pfizer First Connect. A contactable consumer reported for self that the female patient of unknown age received bnt162b2 (BNT162B2, reported as PFIZER-BIONTECH COVID-19 VACCINE), via unspecified route of administration on 18Dec2020 at single dose for covid-19 immunisation. Medical history and concomitant medications were unknown. She had a COVID vaccine shot on Friday, on 18Dec2020, now she is experiencing a headache. She would like to know if headache is normal or if she should go to a doctor. Upon callback, consumer states she received the Covid19 vaccine on Friday 18Dec2020, and is experiencing ""shivers, coldness, body aches, headache, mouth hurts, I feel very weak"". Consumer wants to know if these things are normal, and if she needs the second dose. She wants to ""make sure she's not dying"". ""Can I use antipyretics before or after vaccination with the Pfizer-BioNTech COVID-19 vaccine?"" Response: The interim ACIP guidelines note that, "" Antipyretic or analgesic medications (e.g., acetaminophen, nonsteroidal anti-inflammatory drugs) may be taken for the treatment of post-vaccination local or systemic symptoms, if medically appropriate. However, routine prophylactic administration of these medications for the purpose of preventing post-vaccination symptoms is not currently recommended, as information on the impact of such use on Pfizer-BioNTech COVID-19 vaccine-induced antibody responses is not available at this time.& quot; If you are a patient, you should discuss this with your healthcare provider. The outcome of the events was unknown. Information about Batch/Lot number has been requested."

She woke up miserable and is still miserable now; she has had a fever of 101.6/It spiked to 103.1; Dry cough; neck pain; swollen lymph node and glands; headache; napped a lot; hot flash; sweaty; off balance and shaky; felt tired all day; joints felt a bit achy/achy joints/shoulder pain; This is a spontaneous report from a contactable Nurse (patient). A 43-years-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (lot number: E10140) intramuscular in her left deltoid on 20Dec2020 08:25 at single dose for COVID-19 immunization. There was no other additional vaccines administered on same date of the pfizer suspect. Medical history included had COVID from Aug2020 to an unknown date and had a pulse-ox. The patient did not have any other medical history. She has had no reactions to any other vaccines before. Her father died of heart attack but with no other medical history prior to that. Her mom died of a brain tumor. In her extended family there is high blood pressure and high cholesterol. She has not personally be diagnosed with any of these conditions. She is healthy.

She has no history of any allergies and again repeats she has never had this side effect with anything. Concomitant medications included over the counter vitamins regularly. The patient has had a fever of 101.6 about 24 hours after getting the shot. It spiked to 103.1. She has had a dry cough and all the other common sides effects reported with the vaccine. There is nothing to do but treat the symptoms. She has let her primary care doctor know via email but he is out of the office through today so she hasn't heard back. She had a Fever of 101.6 that was noticed at 2am after the shot, on 21Dec2020. When she woke up about 10 minutes ago is when she noticed a fever that spiked to 103.1, it is about 1:20pm where she is located. The dry cough started around 8am 21Dec2020, she took cough medication and has used her inhaler to stay on top of the cough. Her pulse-ox readings have been fine and she is at 97-98%. She has a pulse-ox because she had COVID Aug2020 and was out of work 6 weeks and on home oxygen. She felt if she got COVID again she would die so she would rather have the vaccine. She notes that about 15 minutes after getting the shot while they were monitoring her, she was joking with the nurse, she experienced what felt like a hot flash and was sweaty on 20Dec2020. She was off balance and shaky on 20Dec2020. This lasted about 15- 20 minutes and then she was fine. Afterward, she did notice she felt tired all day on 20Dec2020 and napped a lot. Also it was reported that her joints felt a bit achy throughout the day. She has never had a reaction to a vaccine before. Other events experienced were neck pain, swollen lymph node and glands, neck and shoulder pain, headache on 21Dec2020, and achy joints on 20Dec2020. All the events have gotten worse since starting. The fever, neck pain, swollen lymph node and glands, neck and shoulder pain, and headache were noticed about 2am. She woke up miserable and is still miserable now. The patient received Tylenol, Benadryl, Advil, cough medication and an inhaler as treatment for events. No any event required a visit to emergency room or physician office. Seriousness criterial for events fever, dry cough, neck pain, swollen lymph node and glands, Aching joints, Headache, felt tired all day, hot flash and was sweaty, off balance and shaky was medically significant. Events outcome of fever, dry cough, neck pain, swollen lymph node and glands, aching joints, headache, felt tired all day was not recovered (reported as worsened), events outcome for hot flash and was sweaty, off balance and shaky was recovered on 20dec2020, while for other events was unknown. Relatedness of drug to reactions for fever, dry cough, neck pain, swollen lymph node and glands, aching joints, headache, felt tired all day was related per primary source reporter.

Arm is getting redder today and sore. Was not red or sore yesterday after the injection.; Arm is getting redder today and sore. Was not red or sore yesterday after the injection.; This is a spontaneous report from a contactable Nurse. This Nurse reported for self that the 59-year-old female patient received first dose of bnt162b2 (BNT162B2), via unspecified route of administration on Left arm on 20Dec2020 07:45 AM at single dose for covid-19 immunisation. She is not pregnant at the time of vaccination. Medical history included known allergies to medications, food, or other products: PCN, cedar, mold and Hashimotos disease. Concomitant medications included other medications the patient received within 2 weeks of vaccination:ibuprofen (ADVIL [IBUPROFEN]), Levothyroxine and ergocalciferol (VIT D). Facility type vaccine was Hospital. No other vaccine in four weeks. The patient experienced Arm is getting redder today and sore. Was not red or sore yesterday after the injection from 20Dec2020 07:45 AM. The outcome of the event was not recovered. No treatment received. No Covid prior vaccination. Covid tested post vaccination. Covid test type post vaccination was Nasal Swab on 15Dec2020 with result of Negative. Facility where the most recent COVID-19 vaccine was administered was Hospital. The patient

did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has been tested for COVID-19. Vaccine Facility information available. Information on the lot/batch number has been requested.

"I was achy and tired; I was achy and tired; I was really, severely dizzy, like vertigo. My head was swimming; I was really, severely dizzy, like vertigo. My head was swimming; This is a spontaneous report from a contactable consumer. This consumer reported for self that the 56-year-old female patient received bnt162b2 (BNT162B2, reported as Pfizer-Biontech Covid-19 Vaccine, Batch/lot number: EJ1685, Expiry Date of COVID Vaccine: Mar2021), via unspecified route of administration on 18Dec2020 12:30 at single dose for covid-19 immunisation. Medical history was none. Concomitant medications included cyanocobalamin (VITAMIN B12 [CYANOCOBALAMIN]) Injections. She is a respiratory therapist. She states she got the vaccine on 12:30 PM on Friday. She states that Friday night by 09:30 pm was really bad. Her head was swimming. She said by Saturday she was achy, tired. Also, on Friday night she was severely dizzy and felt like she has vertigo. She is better now."" Consumer stated, ""It was just a shot."" Th outcome of the events was recovering. Treatment was received and consumer stated, ""The only thing I took was 800 mg Ibuprofen Friday evening."" Consumer further added, ""I was, just like in chart second vaccination I guess I am okay to take it. I talked to my doctor."" Consumer stated ""I got the covid vaccine on Friday and it was a bad night. I was really, severely dizzy, like vertigo. My head was swimming. I got the shot at 12:30 that day, but the symptoms didn't start until 9:30 that night. On Saturday I was achy and tired. But I'm better now."" Consumer questioned if dizziness was a reported side effect."

"My arm is sore; I have really weird red like bump blister that formed on my right hand on my index finger; This is a spontaneous report from a contactable Physician. This Physician(patient) reported that the 48-year-old female patient received bnt162b2 (BNT162B2, Batch/lot number: EJ1685), via unknown route of administration on arm on 19Dec2020 01:30 at single dose for covid-19 immunisation. Medical history was none. Concomitant medications were unknown. Physician stated, ""I took the Pfizer Vaccine (COVID Vaccine) yesterday at 1:30 and I am fine. My arm is sore, but I have really weird red like bump blister that formed on my right hand on my finger, on my index finger. I don't have any 'trauma to it'. I don't why it's there? I haven't seen it but its unusual looking."" No treatment received. The causality was assessed by Physician stated, ""No, I don't know. I have no idea if this it is just a rare coincidence."" The outcome of the events was unknown."

"felt more like a burning especially in my neck; Minutes after shot some sweating, first thought perhaps it is some anxiety related to having a vaccination. After monitoring period went back to the office. Started to get severe nausea; Minutes after shot some sweating, first thought perhaps it is some anxiety related to having a vaccination. After monitoring period went back to the office. Started to get severe nausea; Minutes after shot some sweating, first thought perhaps it is some anxiety related to having a vaccination. After monitoring period went back to the office. Started to get severe nausea; muscle pain that started in my neck, shoulder and then moved on to both legs; felt weak and had to go home; pain in my neck; leg pain; arm pain; This is a spontaneous report from a contactable Nurse. This Nurse reported for self that the 50-year-old female patient received first dose of bnt162b2 (BNT162B2, reported as PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EK5730), via Intramuscular on left arm on

18Dec2020 03:15 PM at single dose for covid-19 immunisation. She is not Pregnant at the time of vaccination. Medical history included Known allergies to medications, food, or other products: Dust mites, nickel and recent iron deficiency anemia, esophageal ulceration, reactive airway disease. Concomitant medications included other medications the patient received within 2 weeks of vaccination included Omeprazole 40 mg BID (Twice a day), colecalciferol (VITAMIN D [COLECALCIFEROL]) and Albuterol. Facility type vaccine was Hospital. No other vaccine in four weeks. No other vaccine in two weeks. The patient experienced ""Minutes after shot some sweating, first thought perhaps it is some anxiety related to having a vaccination. After monitoring period went back to the office. Started to get severe nausea and muscle pain that started in my neck, shoulder and then moved on to both legs. I felt weak and had to go home. The muscle pain was not like exercise pain - it felt more like a burning especially in my neck. The pain in my neck got better after Tylenol , the leg pain continued until 10 pm. The nausea was severe until 7:30 and was gone by 10 pm. I had to leave work 2 hours early because of side effects. The arm pain continued for two days, locally, minor and was gone on day three (21Dec2020)"". The event started from 18Dec2020 03:30 PM. The outcome of the events was recovered. No treatment received. No covid prior vaccination. No covid tested post vaccination. Facility where the most recent COVID-19 vaccine was administered was Hospital. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. The events were assessed non-serious."

left arm started to feel numb first, and then she started to feel it in her face/numbness on the side of her face; worried; This is spontaneous report from a contactable other healthcare professional (patient). A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection) via an unspecified route of administration on 21Dec2020 at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient was having a side effect after taking the COVID vaccine today (21Dec2020). The patient experienced numbness on the side of her face on 21Dec2020. The patient added that she had to wait for 15 minutes and didn't have anything. The patient when driving on the way home, she started to feel numbness on her face. The patient clarified within 20 minutes of receiving the vaccine her left arm started to feel numb first, and then she started to feel it in her face. The patient has been trying to exercise it and move it because she was worried it would become weak. The patient was unsure what to do or if this is expected. The patient, while providing contact information she stated she was really worried (21Dec2020), and she can't finish the report at this time. The full report details were unable to be obtained. The outcome of the events was unknown. Follow-up activities are possible, information on the batch number has been requested.

moderate myalgia; This is a spontaneous report from a non-contactable consumer. A 30-year-old female patient (daughter of a friend) received bnt162b2 ((Pfizer-BioNTech COVID-19 mRNA vaccine) lot number and expiration date were not reported, via an unspecified route of administration on 17Dec2020 at a single dose for COVID vaccination. The patient's medical history and concomitant medications were not reported. The patient experienced moderate myalgia following her COVID vaccination last Thursday on

17Dec2020 with outcome of recovering. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

"Injection site pain; Tiredness; Headache; Muscle pain; Chills; I have fever 100.3; Injection site is swelling; injection site have redness; feeling unwell; This is a spontaneous report from a contactable Nurse (patient). The patient received first dose of bnt162b2 (BNT162B2, lot number: EH9899, Expiry Date: Mar2021), unknown on 19Dec2020 18:00 at single dose for covid-19 immunisation. Medical history was reported as Patient History: No. There were no concomitant medications. Nurse stated, ""I have received the vaccine, the Pfizer COVID vaccine yesterday at 06:00 PM. I have side effects is injection site pain, tiredness, headache, muscle pain, chills and I have fever 100.3 (I got the fever after 24 hours of receiving the vaccine) and injection site is swelling, injection site have redness and feeling unwell. I would like to know how long it takes to, the side effects is going to be gone."" The outcome of the events was unknown."

"Dizzy; I felt really weak; Shortness of breath in getting up the stairs; The shortness of breath freaks me out, I think that's where the anxiety comes in; I think the midsternal chest pain was my anxiety but like a little bit; started feeling very like flu; Headache; Weakness; Fatigue; Muscle ache; I also have like really swollen lymph nodes, my lymph nodes feels like draining right now; The shortness of breath must have pain and issue for me; This is a spontaneous report from a contactable nurse (patient). A 32-years-old female patient received bnt162b2 (BNT162B2), via an unspecified route of administration on 19-DEC-2020 07:30 at single dose for covid-19 immunisation. The patient medical history was not reported. Concomitant medication included buspirone hydrochloride (BUSPAR), omeprazole (OMEPRAZOLE), lithium (LITHIUM), doxycycline (DOXYCYCLINE) for infection right now in her toe. The lithium cause 'sinus' reflux asthma. Nurse reported an adverse effect, was kind of confuse if it is related or not. She felt good for first 15 minutes and when she was about to leave. she was not afraid of shot. she felt dizzy and then she had to go upstairs and she felt really weak and Shortness of breath getting up the stairs, to get to her car. The shortness of breath freaks her out, she think that's where the anxiety comes in. she started driving home and she had bad shortness of breath. she think the midsternal chest pain was her anxiety but like a little bit. she am not sure. In '12' hours later she went to work she started feeling very like flu, she started flu like with headache, weakness, fatigue, muscle ache. she was working in ER and it is hard to work and then 20Dec2020 she was still feeling bad but little bit better than first day and shortness of breath that was still there like all day the day before. she also had like really swollen lymph nodes, her lymph nodes feels like draining right now. Nurse stated she was taking Omeprazole. That was wired because she have 'sinus' (Further not clarified, hence not captured in tab) reflux asthma, so the shortness of breath must have pain and issue for her but Omeprazole have stopped it, so before taking the vaccine she thought she was completely fine but then after taking the vaccine, it was like she have the issue again like it was controlled before the vaccine. Result of lab test: TSH was 8. So it was elevated but that was because of lithium and then she reduced the dose so it should be better now. So every result was normal."" Results of tests and procedures for investigation of the patient: Test: CBC, CMP, Lithium level, TSH: Thyroid panel unknown result."

generalized weakness; headache; right sides numbness/bilateral hand numbness/bilateral face numbness; This is a spontaneous report from a contactable other healthcare professional reported for

herself. A 43-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number EH9899, expiry date unknown) via an unspecified route of administration at the right arm on 18Dec2020 10:00 at single dose for COVID-19 immunization. The patient medical history was none. The patient was not diagnosed with COVID-19 prior vaccination. Concomitant medication included influenza vaccine inact split 3v (FLULAVAL, lot number 542MY, expiry date unknown) on 20Nov2020 for immunization. On 18Dec2020 at 16:00 (day 1), the patient experienced headache and right sides numbness. On day 2 (19Dec2020), patient has headache. On day 3 (20Dec2020), the patient has overall improvement. On day 4 (21Dec2020), the patient experienced generalized weakness, at 1300 bilateral hand numbness, at 1540 bilateral face numbness that has persisted into the afternoon (pm). The outcome of the events headache, right sides numbness/bilateral hand numbness/bilateral face numbness and generalized weakness was not recovered.

Headache; Chills; Body ache and little bit congested; Body ache and little bit congested; This is a spontaneous report from a contactable consumer (patient). A 50-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for immunization. Medical history included high blood pressure, seizure disorder. Concomitant medication included metoprolol, aripiprazole (ABILIFY). The patient experienced headache, chills, body ache and little bit congested on an unspecified date with outcome of unknown. No treatment was received for events. Information about Lot/Batch number has been requested.

a little bit of chill; like a slight bit of dizziness; This is a spontaneous report from a contactable consumer. A patient of unspecified age and gender received bnt162b2 (BNT162B2, Batch/lot number: EH9899), via an unspecified route of administration on 18Dec2020 at single dose for covid-19 immunisation. The patient medical history was not reported. The patient's concomitant medications were not reported. The patient experienced a little bit of chill and like a slight bit of dizziness on Dec2020 with outcome of unknown.

really uncomfortable, my stomach is alarming; This is a spontaneous report from a contactable consumer (patient). A 57-year-old female patient received BNT162B2 (COVID Vaccine, manufacturer not clarified), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunisation. Medical history included hypertension, diabetes, atrial fibrillation. The patient had some concomitant medications. When probed for any concomitant, patient stated, that was her other concern. She was seeing there was an issue with if you won't blood thinner (further not clarified). Patient stated, she got her own injection (COVID Vaccine) on Friday and It was not been major but she had been to the bathroom since Friday and she was change her diet or anything. This was really uncomfortable, her stomach was alarming. Patient asked if that was normal. Outcome of the event was not reported. Pfizer is a marketing authorization holder of COVID Vaccine in the country of incidence or the country where the product was purchased (if different). This may be a duplicate report if another marketing authorization holder of COVID Vaccine has submitted the same report to the regulatory authorities. Information on the lot/batch number has been requested.

fatigue, nasal congestion and body aches/tested positive with infection; fatigue, nasal congestion and body aches/tested positive with infection; This is a spontaneous report from a contactable physician. A

male patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 16Dec2020 at single dose for COVID-19 immunisation. The patient medical history and concomitant medications were not reported. On 15Dec2020, the patient reported possible personal exposure (close contact / dinner with friend who tested positive on 18Dec2020, both unmasked) and received Covid vaccine on 16Dec2020. The patient reported fatigue on 17Dec2020, nasal congestion and body aches on 18Dec2020. He tested positive with infection control MD and had monoclonal Ab administered same day (18Dec2020). He wanted to know, what this means for his scheduled second vaccine and if needs to wait 90 days from positive Covid. The outcome of the events was unknown. Information on the lot/ batch number has been requested.; Sender's Comments: The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

"Arm was a little sore; a little dizziness; This is a spontaneous report from a non-contactable consumer (sister). A female patient of an unspecified age received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration from Dec2020, at an unknown single dose for an unspecified immunization. The patient's medical history and concomitant medications were not reported. The patient works as an RN in (Place name), received the Pfizer vaccines (COVID-19 vaccine) on Saturday; she stated that her arm was a little sore and experienced a little dizziness ""but otherwise just fine"". Outcome of events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained."

I have good and bad side effects, first of all I have trouble, pain in my knees and today I relieved from much pain in knees,; Pain in the arm; Headache; Diarrhea; started with a feel and now it was more, it was a pain, it was like a crack in her abdominal; This is a spontaneous report from a contactable consumer (patient). A 52-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 17Dec2020 08:15 at single dose for COVID-19 immunization. The relevant medical history included thyroid disease and arthritis (have problem with her knees and they said it arthritis). Concomitant medications included vitamin c, vitamin d3 and vitamin e, all from an unspecified date for thyroid disease. The patient stated that first moment it was okay, not feeling much just the pain in the arm on 17Dec2020 and in the next day she had good and bad side effects, first of all she had trouble, pain in her knees on 18Dec2020 and at the time of the report she relieved much from pain in knees, they came back but that was okay. She had a little headache, not much on 17Dec2020. But at the time of the report like an hour prior to the report she started with diarrhea in Dec2020. Diarrhea was getting worse, it started with a feel and now it was more, it was a pain, it was like a crack in her abdominal, she had gone to the bathroom few minutes prior to the report and almost she felt like she had to go again. The patient did not ask the dose and stated that they were supposed to give her a one dose, it was her first dose, her second dose coming on 07Jan. The outcome of the event pain in the arm was unknown, for event arthralgia was recovering, while the other events were not recovered. Information about Lot/Batch number has been requested.

"Lost weight; Achiness; Tired; Headache; her daughter was tested positive for COVID/ she was around her daughter; Blurriness; I could hardly see; A little bit of vision changes; eyes, both days, yesterday they were swollen, 'puffy' and draining a little bit; eyes, both days, yesterday they were swollen, 'puffy' and draining a little bit; eyes, both days, yesterday they were swollen, 'puffy' and draining a little bit; Nauseous; This is a spontaneous report from a contactable Nurse (patient). A 54-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 17Dec2020 at single dose for COVID-19 immunization. The relevant medical history included blood cholesterol and sinus problem. Concomitant medications included pravastatin for cholesterol. The patient stated that she received the immunization on Thursday at the hospital that she worked at and Saturday and then at the time of the report her eyes, both days, yesterday they were swollen, 'puffy' and draining a little bit on 19Dec2020. Today they were too this morning. So, that got better than yesterday because she cold compresses on them. For the next shot, the patient stated that she was not so sure, it was within 21 days. An appointment was set-up, she just had to look. It was during work, so she was working. She went downstairs, she got the show. She sat there while they watch her for several hour, observation time and she got on her phone and scanned in something. Maybe appointment but she got to work. She didn't write it down. The patient stated that her daughter was tested positive for COVID on Monday. And they said her to get test it because she was around her daughter. And then they weren't so sure whether or not to give her the vaccine. But they said it was okay so they did. She was negative at that time. The patient stated Friday at work, she didn't feel anything because she was working around, almost 3:30 or 4 O' clock on Thursday. She was nauseous all day at work on 18Dec2020. And just the minor ones that they had. That was to be expected, the achiness, felt a little swollen, tired, headache. But she was okay to work. But then at the time of the report after her eyes been swollen yesterday. She got up to get ready for work but her eyes were like. At that time in the morning on 19Dec2020 she could hardly see out of them. But they were much better at the time of the report. The patient had this mask that was a gel pack. So, it was bit of like a cold compress. And put Vaseline and they told her to get another COVID test. The patient had some vision. Some blurriness and just a little bit of vision changes on 19Dec2020. That she had not noticed at the time of the report. So that was resolved she thought. The patient underwent lab test included COVID test on an unspecified date which showed negative; weight on an unspecified date which showed about 186 pounds (she lost weight, so she might be a little more, she just hadn't checked). Therapeutic measures were taken as a result of the events ""eyes, both days, yesterday they were swollen, 'puffy' and draining a little bit"". The outcome of the events ""eyes, both days, yesterday they were swollen, 'puffy' and draining a little bit"" was recovering, for the event ""Blurriness; I could hardly see; A little bit of vision changes"" was recovered on an unspecified date, the other events were unknown. Information on Lot /Batch Number has been requested."

"I was not feeling well and I actually was like feeling really sick; I was feeling really like weak; I was not feeling well and I actually was like feeling really sick; I was feeling really like weak; I was not feeling well and I actually was like feeling really sick; I was feeling really like weak; I had to throw up; I ended up falling on floor; Arm started hurting; I was getting like crampy; I had to throw up; I ended up falling on floor; This is a spontaneous report from a Contactable consumer. This consumer (patient) reported that the 59-year-old female patient received (BNT162B2), via an unspecified route of administration on

18Dec2020 (yesterday morning about 6:30) at single dose for covid-19 immunization. Medical history included Allergy and consumer stated, ""No, I take Zyrtec D for my allergies. But I have not taken any because I was feeling better from it. So, my doctor said you don't need to take it all the time, just take as you needed."" Concomitant medications included cetirizine hydrochloride/pseudoephedrine hydrochloride (ZYRTEC-D) for Allergy. The patient experienced ""I was not feeling well and I actually was like feeling really sick, I had to throw up, I was getting like crampy. And usually when I throw away I lie down but I didn't and I ended up falling on floor, I was feeling really like weak, Arm started hurting, I was getting like crampy"". No Investigation Assessment. Consumer stated, ""Actually I was just calling to report because I have taken the COVID shot, yesterday morning about 6:30 and I got some side effects from it. So, I was just calling, I guess it is just pamphlet and stuff."" Consumer stated, ""Yes I called off my work because I rescheduled my job today but I couldn't go because I was not feeling well and I actually was like feeling really sick. And I had to throw up. And then I was getting like crampy. And usually when I throw away I lie down but I didn't and I ended up falling on floor. So, I am okay but I didn't go to work because I was feeling really like weak."" Consumer stated, ""Actually they had it done it with the hospital. So, I didn't go to the doctor. They just had a, had to just go on the computer and go to that setup. And then I had an appointment yesterday at 6:30, that's when I got the shot taken at 6:30 in the morning. Consumer stated, ""What is that for? They gave me an envelope, I don't know they gave me a card too. Is that on that card? They schedule me my other appointment, I mean to get my other shot. When I have to get the other one I guess. I don't know why I can't find it. We found the card. It says dose COVID-19, it's Pfizer and then it's looks like E and then it's a J or a T, looks like a J or a T the way wrote it, we'll just go ET1685, I guess. Due date for next shot is 08Jan2021 at 9:15 am."" Consumer stated, ""That's the vaccine because I work around, I work in Intensive Care Unit. And it is pretty much second floor and in COVID unit. So, that's why I wanted to get it for my safety. Consumer stated, I did get them like 2 O' Clock this morning. My arm started hurting towards later in this evening and then I woke up and it didn't help me."" Consumer stated, ""No I feel better when I got up because I didn't go to work because I was a little not, you know weak and kind of. So, I called off my job because I don't want to be going over there and. Yeah I feel better, my stay close to bed because I fell."" No treatment was received. The outcome of the events was unknown. Information on the Batch/Lot number has been requested."

Hives around the injection site; This is a spontaneous report from a contactable consumer (patient). A 38-year-old male patient received the 1st dose of bnt162b2, Pfizer vaccine, lot number: EK5730, expiry date: Mar2021, via an unspecified route of administration in the right arm (deltoid) on 20Dec2020 11:10 at a single dose for COVID-19 immunization. Medical history included hypertension and diabetes mellitus. Concomitant medications included metformin since diabetic, aspirin [acetylsalicylic acid] on 20Dec2020, and ongoing zinc. The patient experienced hives around the injection site on 21Dec2020 05:30. The event was described as follows: after getting the vaccine, he woke up with hives around the injection site. It is itchy, crater-ish like. If you touch it is tough and it feels like one was bit by ants. This on the arm and head. It is bigger on the head. It is like huge bumps. He has been calling his HCP all morning, but has not heard anything back from the doctor. He is calling to see if there were any recommendations, ointments, or anything he can take. He mentioned he took Benadryl this morning for it. He went on to further explain when he woke up 5:30 am this morning he had a bunch of bumps that

were itchy, like ants or mosquitoes biting. They were pretty big. He has one on his collar bone. It is stiff and hard. The bumps are spreading towards the back of his back. He also has it on his left shoulder as well. He provided the hives as the same to worse. He added on his arm near the injection site is a lot worse compared to his forearm. Near the injection site it is also warm to touch. He stated this was typical symptom from what he read. He received the vaccine at 11:10 am. The patient is scheduled to get the second dose on 10Jan2021. The event did not require patient to visit the Emergency Room and the Physician Office. The reporter stated he has been trying to contact his physician to determine if his events are severe enough to go to the ER. He was informed that his doctor has been booked all day. He may have to go to the night clinic if does not get better. Outcome of the event was not recovered.

urticaria to bilateral upper extremity (BUE); This is a spontaneous report from a contactable nurse (patient). A 33-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE lot/batch number not provided), via an unspecified route of administration on 19Dec2020 21:00 at SINGLE DOSE for COVID-19 immunization at the hospital. Medical history included diabetes mellitus (DM), hypertension (HTN), depression, obesity, hyperlipidaemia (HLD), migraines, and degenerative disk disease (IDD). The patient also had allergies with sulfa, oyesters, and adhesives. Concomitant medication included insulin aspart (NOVOLOG), bupropion hydrochloride (WELLBUTRIN), metformin (METFORMIN), sumatriptan (SUMATRIPTAN), and losartan potassium (LOSAR) for unknown dates and indications. Prior to vaccination, the patient was not diagnosed with COVID-19 and had not been tested for COVID-19 since vaccination. On 19Dec2020 17:00, the patient experienced urticaria to bilateral upper extremity (BUE). The patient did not received any treatment for the event. The patient was recovering from the event. Information on the Lot/batch number has been requested.

Soreness in left upper arm; This is a spontaneous report from a non-contactable consumer. A 28-year-old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number and expiration date were not reported), via an unspecified route of administration on the left arm on 20Dec2020 at a single dose for covid-19 immunization. There were no medical history and concomitant medications. The patient had no known allergies to medications, food, or other products. The patient was not pregnant. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient was not diagnosed with COVID-19 prior to vaccination and had not been tested for COVID-19 since the vaccination. The patient experienced soreness in left upper arm starting several hours after administration on 20Dec2020. Soreness was worst the next morning. No treatment was received for the adverse event. However, the outcome of the event was recovering. The event was considered non-serious. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

lightheadedness for 2 hours after vaccine; Flushing and tongue numbness within 2-3 minutes of vaccine administration; Flushing and tongue numbness within 2-3 minutes of vaccine administration; This is a spontaneous report from a contactable Physician (patient) A 42-year-old female patient received,at hospital, the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) intramuscular on arm left on 17Dec2020 (reported as at 01:15 PM) at a single dose for COVID-19 immunization .Medical history prior history of allergies requiring allergy shots, GERD , GERD and Sulfa and environmental/food allergies , food allergy .Concomitant medication included ibuprofen and cetirizine hydrochloride (ZYRTEC). No

Covid prior vaccination and no covid test vaccination provided . On17Dec2020 at 01:15 PM , the patient experienced Flushing and tongue numbness within 2-3 minutes of vaccine administration and lightheadedness for 2 hours after vaccine.All events were reported as non-serious. Patient received treatment with Benadryl 25 mg PO (per oral).The outcome of the events was recovered in Dec2020. Information on the lot/batch number has been requested.

a few blisters near the injection site; Arm soreness; This is a spontaneous report from a contactable consumer. A 29-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 19Dec2020 at single dose for immunization. The patient medical history was not reported. The patient's concomitant medications were not reported. The patient experienced a few blisters near the injection site in addition to arm soreness on 20Dec2020. Outcome of events was unknown. information about lot/batch number has been requested.

Dizziness; Fatigue; got the injection his left arm was a little sore/Severe left arm pain, soreness, throbbing; intermittent kind of dyslexia; This is a spontaneous report from a contactable consumer (respiratory therapist - patient himself). A 52-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE lot/batch number EK5730) via an unspecified route of administration on the left arm on 17Dec2020 at SINGLE DOSE for COVID-19 immunization (also reported as vaccination). Ongoing medical history included type 2 diabetes mellitus since Dec2003, renal disorder (reported as kidney prevention) and blood cholesterol abnormal (cholesterol was not high, but because of Type II Diabetes his doctor wanted to keep it at bay). Ongoing concomitant medications included metformin (METFORMIN) since Jan2004 for type II Diabetes, lisinopril (LISINOPRIL) since May2020 for kidney prevention and atorvastatin (ATORVASTATIN) since May2020 for cholesterol. On 17Dec2020, the patient had first dose administered of BNT162B2. When he got the injection, his left arm was a little sore (like if he leaned against his left arm or rubbed it he would notice the soreness). About mid-morning on 20Dec2020, his left arm just started throbbing like he had just blocked a lacrosse ball shot, severe left arm pain, and soreness. He also had onset of dizziness and fatigue as well on 20Dec2020. He went on, did a heating pad and ibuprofen and all that stuff and all that went on. He found it odd because these events did not start until around like 3 days after the injection was administered though the paperwork showed that these kind of events are expected in the first couple of days after product administered. On 21Dec2020 when he woke up around 11:30am, the throbbing went away, he was not as dizzy as before but still super fatigued and tired (then further stated that maybe a little bit better because he does not have that constant pain constantly draining him). The patient also mentioned that he wondered if there was an intermittent kind of dyslexia that he has because he will transpose words and just last week learned how to spell received without having to tell himself 'i before e except after c'. He also mentioned that he was tested like 4 times for COVID-19 and was negative every time in 2020. The outcome of the event of dyslexia was unknown while recovering for the remaining events.

Tiredness throughout the day; slight lightheadedness; slight headache; This is a spontaneous report from a contactable pharmacist (reporting for himself). A 38-year-old male patient received the first dose of bnt162b2 (BNT162B2, lot number and expiry date were unknown), intramuscular on 21Dec2020 09:30 on the left arm at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. Prior to vaccination, the patient was not diagnosed with

COVID-19. Since the vaccination, the patient has not been tested for COVID-19. On 21Dec2020, the patient experienced tiredness throughout the day, slight lightheadedness and slight headache. There was no treatment that was received for the events. The events were considered non-serious. The most recent COVID-19 vaccine was administered in the hospital. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The outcome of the events was recovering. Information about Batch/Lot number has been requested.

Soreness in the arm more than any other vaccine in the past; This is a spontaneous report from a contactable Other Health Professional (patient). A 31-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) lot number: EJ1685, via an unspecified route of administration in the left arm, first dose on 19Dec2020 14:15 at a single dose for immunisation. The patient's medical history and concomitant medications were not reported. The patient is not pregnant. She had not had other vaccines within four weeks prior to vaccine and she had no other medications in 2 weeks. Adverse event reported was soreness in the arm more than any other vaccine in the past. The onset was on 20Dec2020 with outcome of recovered in Dec2020. She took an over the counter ADVIL. She did not have covid prior vaccination nor had she tested post vaccination. The event was reported as non-serious.

"Chills; I felt like I am getting a fever; like flu like symptoms; nausea and that is why my voice is like this; nausea and that is why my voice is like this; felt like fatigued and tired; Numbness; This is a spontaneous report received from a contactable consumer (patient). A 41-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK5730), via an unspecified route of administration, on 18Dec2020, at single dose, for COVID-19 immunization. Medical history included hypertension (also reported as borderline hypertension, which was before, and the patient got better). The patient reported exercising, he was heavier, but he is losing weight now. There were no concomitant medications. The patient reported, ""I got my COVID vaccine last Friday, that would be on the 18Dec2020. So I feel like I see the side effect of having it, (voice incomprehensible). The day that I got it, when I got back, on 18Dec2020, I felt like fatigued and tired. And then on Saturday (19Dec2020), which I was off, I felt a little better. But then, you know, I had a little numbness (Dec2020) but it disappeared. And then on Sunday, I went to work and last night (20Dec2020), I just woke up and I had chills and I felt like I am getting a fever, like flu like symptoms like nausea and that is why my voice is like this. Is it normal to feel after 3 days this side effect? I mean actually I was reading the paper that I got it because I need to, because I have work today, I need to inform my manager that I cannot go to work because I am feeling this side effect and I don't want him to think that you know."" The patient did not have lab work done and did not receive treatment for the events. The outcome of fatigue was recovering, numbness was recovered on an unspecified date in Dec2020, and the outcome of the remaining events was unknown."

"Woke up 2 days later with painful swelling under both eyes and pain around my chin. these are all areas, and the only areas that I have had dermal filler injections; Woke up 2 days later with painful swelling under both eyes and pain around my chin. these are all areas, and the only areas that I have had dermal filler injections; Woke up 2 days later with painful swelling under both eyes and pain around my chin. these are all areas, and the only areas that I have had dermal filler injections; This is a

spontaneous report from a contactable physician. A 45-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899), intramuscular on the left arm on 16Dec2020 10:45 at single dose for COVID-19 immunisation. Medical history included hypertension and dermal filler injections. Concomitant medication included losartan. The patient stated, ""woke up 2 days later with painful swelling under both eyes and pain around my chin. These are all areas, and the only areas that I have had dermal filler injections. I started steroids and pain and swelling resolved in 3 days"". The outcome of the events was recovered on Dec2020."

she was running a temperature of 100.3 degrees Fahrenheit/highest her temperature got up to last night was 101.9 degrees Fahrenheit; Left arm sore; Left arm was just a little swollen; A little swollen in her left underarm and armpit; Started getting hot and cold and hot and cold; Achy; Nauseous/Feeling like she was going to throw up; This is a spontaneous report from a contactable consumer (patient). A 50-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) lot number and expiration date were not reported, via an unspecified route of administration in the left arm, first dose on 19Dec2020 07:30 at a single dose for vaccination. Medical history included ongoing colitis ulcerative when she was 23 years old (1993), POTS (Postural Orthostatic Tachycardia Syndrome) from 2017 and ongoing, had thyroid problem, with heart medication. Concomitant medication included prednisone, levothyroxine sodium (SYNTHROID), irbesartan, bisoprolol fumarate, fluticasone and potassium. The patient stopped prednisone about 4-5 days before COVID-19 Vaccine administered. She talked to her doctor about prednisone use and getting COVID-19 Vaccine, doctor told her to go ahead and get COVID-19 Vaccine. The patient is a Certified Nursing Assistant who received the Pfizer COVID-19 Vaccine at her place of employment on 19Dec2020. This was her first dose of 2 dose series of the vaccine. She reported after she received the vaccine injection, she had onset of 'achy, nauseous, left arm sore, left arm was just a little swollen, a little swollen in her left underarm and armpit, she started getting hot and cold and hot and cold, feeling like she was going to throw up and was running a temperature. She added that at the night of 19Dec2020 she felt achy and a little nauseous but it was not bad so she took some TYLENOL and she was feeling fine. She stayed at work Saturday. Starting morning of 20Dec2020 she woke up and her left arm felt like she had gotten a tetanus shot, left arm was sore and just a little swollen and she was a little swollen in her left underarm and armpit; she felt achy all over again; so she took some more TYLENOL and went to work and was feeling fine until about lunch time on 20Dec2020. Around lunch time on 20Dec2020, she started getting hot and cold and hot and cold, feeling like she was going to throw up; by about 4:30pm on 20Dec2020 she was running a temperature of 100.3 degrees Fahrenheit. The highest her temperature got up to last night was 101.9 degrees Fahrenheit. She took a Tylenol PM to knock her out to sleep because she was achy. The outcome of the events achy, nauseous, left arm sore, left arm was just a little swollen, a little swollen in her left underarm and armpit, started getting hot and cold and hot and cold, feeling like she was going to throw up, and she was running a temperature of 100.3 degrees Fahrenheit/highest her temperature got up to last night was 101.9 degrees Fahrenheit was recovering. Information about Batch/Lot number has been requested.

headache; fever of 100/mild fever 99.5; fatigue; non productive cough; tested Covid 19 positive; tested Covid 19 positive; This is a spontaneous report from contactable consumer. A 23-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via unspecified route of administration on

unspecified date at single dose for COVID-19 immunization. Medical history and concomitant medications were not reported. It was reported that the patient was a 23 years old nurse and received the Covid 29 vaccine on Saturday morning. Sunday she developed a headache fever of 100 and fatigue. Monday she developed a non productive cough as well as mild fever 99.5, fatigue, and the headache was reduced. It was also reported that the patient was tested Covid 19 positive on 22Dec2020. The outcome of the events were unknown. Information on the lot/batch number has been requested.

Diarrhea; she could feel her stomach again; This is a spontaneous report from a contactable consumer. A 64-year-old female patient received the first dose of BNT162B2 (Pfizer-BioNTech COVID-19 mRNA Vaccine BNT162B2; lot number: EH9899), via an unspecified route of administration on 17Dec2020 at a single dose by injection once so she doesn't get COVID. The patient's medical history was not reported. There were no concomitant medications. The patient experienced diarrhea on 19Dec2020. The patient just thought about it, she had diarrhea, she had said everything is good, but she didn't think about it when answering the questions, when she eats the food, she notices, she got the COVID vaccine. She doesn't know how to change responses to the questions. She answered no to them, but this could be tied together. Every time she eats, she gets diarrhea. Patient got the COVID test. She wanted to change answers, but it wouldn't let her. Patient could feel her stomach again in Dec2019, but she hasn't eaten. This was the first time she received the vaccine. The outcome of the events was unknown.

mild rash around the injection site; This is a spontaneous report from a non-contactable consumer. A 50-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE lot/batch number not provided), via an unspecified route of administration in 2020 at SINGLE DOSE for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. In 2020 (five days after vaccination), the patient experienced mild rash around the injection site. Outcome of the event as unknown. Information about lot/batch number cannot be obtained. No further information is expected.

Rash/rash did have a pretty discreet or distinct area around the injection site; She says it was pretty red and you could tell the area was swollen at first, and it has faded; She says it was pretty red and you could tell the area was swollen at first, and it has faded; She says that the rash this morning has spread to her left chest wall and breast area, and she was looking at her body in other places and saw the reaction was on the rest of her body too/rash had maybe a little mild itch; injection site may bleed longer which was the only thing notable; This is a spontaneous report from a contactable physician (patient). A 28-year-old female patient received single dose of BNT162B2 (lot number: EK5730, exp date not reported), via an unspecified route of administration (one injection to left deltoid) on 18Dec2020 07:00 for primary prevention. Medical history included rare bleeding disorder from 2016, and seasonal allergies. She says she had no effects from it but knows of it from genetic testing. Patient did not receive any other vaccines at the same time as this one, or any other medications. Patient was a resident doctor at the hospital and was calling as consumer. She received her first dose of the Pfizer BioNTech COVID-19 vaccine on 18Dec2020 (Friday morning at 07:00AM). She had gotten sort of a whole body generalized rash which the morning of reporting was worse nearer the site and left chest wall area. She says she would like to see if this has happened to and been reported by others. The vaccine was offered by her employer to any staff who wanted to get it, and she was in phase one. She says that there wasn't a

specific provider who prescribed it. She has the card that they gave her following the injection and says that it doesn't have an expiration date on it, just the date given and the name of the clinic site. She says it just says Pfizer on this part, on the card. She says on the other form it says Pfizer BioNTech COVID-19 vaccine. She says that there was no dose information provided for the injection. Patient further reported that the rash did have a pretty discreet or distinct area around the injection site up through probably the day before reporting (onset date: Dec2020). It was pretty red, and you could tell the area was swollen at first, and it has faded. She says that the rash the morning of reporting had spread to her left chest wall and breast area, and she was looking at her body in other places and saw the reaction was on the rest of her body too. She says that the rash had maybe a little mild itch, she hadn't noticed if there was anything, just a mild itch, not significant. She didn't do any treatment for the rash specifically, she did take loratadine (CLARITIN) the morning of reporting, but not for that reason, as it was for seasonal allergies, not because of the rash. She provides potential LOT 9HE36498, and says there was no UPC, she got the loratadine and it could have been in original package as one of two, there was no bar code on the label. She provides a second potential LOT 61282ZYF3, and EXP May2021. She says she was told the injection site may bleed longer, due to rare bleeding disorder, which was the only thing notable. No investigation assessment performed. The patient recovered from site swollen on Dec2020. The outcome of other events was unknown.

Fever of 102.4; chills; full body muscle aches; fatigue; nausea; injection site pain; swollen lymph nodes; This is a spontaneous report from a contactable healthcare professional. A 21-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), Batch/lot number: ek5730, intramuscular in the left arm on 21Dec2020 08:45 at single dose for COVID-19 immunization. Medical history included COVID-19 diagnosed prior vaccination. The patient has no known allergies. The patient was not pregnant at the time of vaccination. The patient's concomitant medications were not reported. The patient experienced fever of 102.4, chills, full body muscle aches, fatigue, nausea, injection site pain, and swollen lymph nodes on 21Dec2020 at 19:00. No treatment was given for the events. The vaccine was administered at the hospital. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine and no other medications was received within 2 weeks of vaccination. Since the vaccination, the patient has not been tested for COVID-19. The outcome of the events was not recovered.

"Cold sensation down her right arm; Began ""seeing stars""; Metallic taste in her mouth; This is a spontaneous report from a contactable pharmacist. A 40-year-old female patient received the first dose of bnt162b2 (Pfizer Biontech COVID 19 vaccine), Lot number: EJ1685, intramuscular at the right arm on 21Dec2020 09:00 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient was not pregnant at the time of vaccination. On 21Dec2020 09:00, the patient experienced cold sensation down her right arm, began ""seeing stars"", followed by a metallic taste in her mouth. The patient was not hospitalized for the events but required emergency room/department or urgent care visit. The patient did not receive any treatment for the events. The events were reported as non-serious. The vaccine was administered in a workplace clinic. It was unknown if the patient has received any other vaccines within 4 weeks prior to the COVID

vaccine. Prior to the vaccination the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. The outcome of the events was unknown."

Severe ear and eye pain; Severe ear and eye pain; This is a spontaneous report received from a contactable nurse. A 51-year-old female patient received her first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiry date not reported), intramuscular in left arm, on 21Dec2020 15:15, at single dose, for COVID-19 immunization. Medical history included hypertension, depression, and known allergies to eggs, latex, nuts and codeine. The patient is not pregnant. Concomitant medication included aspirin (ASPIRIN), ascorbic acid (VITAMIN-C), hydrochlorothiazide, lisinopril (ZESTORETIC), venlafaxine and zinc. The patient previously took codeine and experienced allergy. The patient experienced severe ear and eye pain on 21Dec2020 at 18:30. It was also reported that the patient did not receive any vaccines within 4 weeks prior to BNT162B2. The patient was not diagnosed with COVID-19 prior to vaccination. The patient has not been tested for COVID-19 since vaccination. Treatment included ibuprofen and rest. The outcome of the events was recovering. Information on the Batch/Lot number has been requested.

was up and down all night; Nausea; so out of breath/was having some shortness of breath; feeling bad; low grade fever, with the highest temperature being 99.8 degrees; Abdominal cramping; pooped in her pants/did another poo right after/a little more diarrhea; This is a spontaneous report from two contactable nurses (patient and daughter). A 65-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number EH9899, expiry date unknown) intramuscular at right deltoid on 17Dec2020 (10:30) at single dose for COVID-19 immunization. The patient did not have any other vaccines on the same day as receiving the COVID vaccine. Medical history was none. The patient's concomitant medications were not reported. The patient on this past Thursday (17Dec2020), around 10:30 AM, the caller had her COVID vaccine. The patient informed that she lives 20 minutes (address), and on the way home after getting the vaccine that morning, the patient started having abdominal cramping (17Dec2020 17:15) like she needed to go to the bathroom. Due to construction and traffic, she was unable to stop to use the bathroom anywhere and by the time she got home, she had pooped in her pants and when she got inside the house and looked, it looked like a cow patty. The patient got the bathroom and did another poo right after that. The patient that night, she had a little more diarrhea, but then she was okay on Friday and went to work. The patient informed that on Saturday (19Dec2020), after lunch, she started feeling bad and was having diarrhea again, but it was sporadic. The patient informed that yesterday (21Dec2020) afternoon, she got diarrhea again. The patient informed that last night (20Dec2020) she was up and down all night, and also had associated nausea and a low grade fever, with the highest temperature being 99.8 degrees. The patient's daughter informed that the low grade fever started Saturday (19Dec2020) and was on Saturday and Sunday evenings, but daughter informed that the patient has not had fever this morning so far. The patient did not go to work today (21Dec2020). The patient informed that over the weekend (20Dec2020), she had gotten a ham into her daughter's (nurse too) refrigerator, and the daughter asked the patient why she was so out of breath. The patient informed that she was having some shortness of breath as well. The patient would say it was not ongoing but she also was still in bed at this time so she was unsure. The reporter informed that the patient was not specifically prescribed the vaccine, but was given the

product as part of a hospital policy. The patient did provide her Primary Care's name and phone number but did not have address or email address to provide at this time. The outcome of the events abdominal cramping was recovering, pooped in her pants/did another poo right after/a little more diarrhea and Nausea was not recovered, feeling bad, was up and down all night, so out of breath/was having some shortness of breath was unknown, low grade fever, with the highest temperature being 99.8 degrees was recovered on Dec2020.

sore throat before she got the shot, but it made it worse; sore throat before she got the shot, but it made it worse; Body aches; She couldn't swallow; This is a spontaneous report from a non-contactable consumer (patient's coworker). A female patient of an unspecified age received bnt162b2 (BNT162B2, lot no. and expiry date were not reported), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient medical history included sore throat. The patient's concomitant medications were not reported. The patient got the shot on Tuesday and on Thursday (unspecified date) she got sore throat and body aches. She gargled with salt water and drank tea and felt better the next day. It was clarified that the patient had the sore throat before she got the shot, but it made it worse. She said she couldn't swallow. The outcome of the events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

she felt a little more local soreness than she did with the regular seasonal influenza shot; This is a spontaneous report from a non-contactable consumer (patient's husband). A female patient in her mid 30s received her first BNT162B2 (Pfizer-BioNTech COVID-19 mRNA vaccine), via an unspecified route of administration on 20Dec2020 at a single dose for COVID-19 immunization. The patient's medical history was not reported. The patient's concomitant medications were not reported. The patient noted that she felt a little more local soreness than she did with the regular seasonal influenza shot on an unknown date in Dec2020. The outcome of the event was unknown. No follow-up attempts are possible, information about lot/batch cannot be obtained. No further information is expected.

"hot flash; itchy throat; This is a spontaneous report from a non-contactable pharmacist. A female patient of an unspecified age received first dose of BNT162B2 (COVID-19 mRNA Vaccine BNT162B2), via an unspecified route of administration on an unspecified date at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced a ""hot flash"" 5 minutes after COVID-19 vaccination and then ""itchy throat"" 30 minutes after vaccination on an unspecified date. They would liked to know if patient should receive the second dose. She is otherwise fine with all symptoms resolved and never had respiratory distress of any kind. The outcome of the events was recovered on an unknown date. No follow-up attempts are possible; information about lot/batch number cannot be obtained."

she felt dizzy; This is a spontaneous report from a contactable Nurse (patient). A 50-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), on unknown date via unknown route of administration at unknown dose for unknown indication. Medical history and concomitant medications were not reported. Patient received the COVID vaccine. Later in the day she felt dizzy. The outcome of the event was unknown. Information on the lot/batch number has been requested.

"Pain in upper two shoulders and neck/upper body joint pain, both sides; Generalized weakness; Pain in upper two shoulders and neck; This is a spontaneous report from a contactable physician reporting for herself. This 63-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (lot/batch number not provided) on the morning of 20Dec2020, intramuscularly in the left arm at a single dose, for COVID-19 immunization. The patient's medical history included arthritis, esophagitis and esophageal ulcer, from unspecified date and unspecified if ongoing. The patient's concomitant medications were not reported. On 20Dec2020, the patient (physician) called to report two side effects: pain in upper two shoulders and neck, generalized weakness. She developed an upper body joint pain, both sides. She got the injection on the left but both her shoulders had joint pain and weakness. She did not receive treatment for the events. She had the COVID test on 19Dec2020 or 18Dec2020 (reported as ""yesterday"" and ""2 days ago"") but the results were not back as of 20Dec2020. The outcome of the events was unknown. The reporter assessed the events as related to the vaccine. Information on the lot/batch number has been requested."

Facial swelling; Low grade fever around a 100; Got my eye supposedly my eye lids like little swelling and they looks like they are bruised and they itch like crazy; Got my eye supposedly my eye lids like little swelling and they looks like they are bruised and they itch like crazy; I have swelling in both of my eyes; It is getting pretty bad actually, it has got worse; This is a spontaneous report from a contactable nurse (reporting for herself). A 41-year-old female patient received bnt162b2 (BNT162B2 also reported as Covid vaccine by Pfizer, lot EJ1685), via an unspecified route of administration on 17Dec2020 at single dose for immunisation. Medical history included depression and anxiety. The patient's concomitant medications were not reported. The patient got the COVID vaccine on Thursday of last week (17Dec2020) and had low grade fever around a 100. On Friday (18Dec2020) she started getting little bit of facial swelling not a whole bunch. After the weekend, her eye lids had little swelling and they look like they were bruised and they itch like crazy. She does not have any drainage like conjunctivitis or anything like that but it looks like she have swelling in both of my eyes and that doesn't happens to her. She does not have any but was probably going in today because it was getting pretty bad actually, it has got worse. The outcome of events was not recovered.

Headache- lasted 12 hours; 24hrs after injection Tachycardia at rest (hr 106); chest pain; flushing/feeling very warm; flushing/feeling very warm; elevated BP 136/96; This is a spontaneous report from a contactable Nurse reporting for himself. A 52-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899), intramuscular on 17Dec2020 10:45 AM at single dose for covid-19 immunization. Vaccine location was Right arm and it was the first dose. The COVID-19 vaccine was administered at Hospital. Medical history included mild coronary artery disease (CAD), Migraine, Psoriasis, and allergy to Sulfa Medications. Concomitant medication included atorvastatin (LIPITOR), finasteride, cetirizine hydrochloride (ZYRTEC]), aspirin, melatonin, biotin, zinc, ergocalciferol (VIT D), ascorbic acid (VIT C), ubidecarenone (COQ10), fremanezumab (AJOVY), and adalimumab (HUMIRA). The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient experienced headache- lasted 12 hours, 24hrs after injection tachycardia at rest (heart rate (HR) 106), chest pain, flushing/feeling very warm, elevated blood pressure (BP) 136/96 on 18Dec2020 10:30. Symptoms lasted for about 2 hours. No treatment received for the events. Prior to vaccination,

the patient was not diagnosed with COVID-19 and since the vaccination, the patient was not been tested for COVID-19. The outcome of the event headache was recovered on 18Dec2020 22:30 (lasted 12 hours), the outcome of the other events tachycardia at rest (heart rate (HR) 106), chest pain, flushing/feeling very warm, elevated blood pressure (BP) 136/96 was recovered on 18Dec2020 (lasted about 2 hours).

Severe rigors and fevers; Severe rigors and fevers; other vaccine same date product; other vaccine same date product; This is a spontaneous report from a contactable physician (patient). An adult male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration in arm left on 21Dec2020 08:00 at single dose for COVID-19 immunisation. Facility where the most recent COVID-19 vaccine was administered was hospital. Medical history included covid (if Covid prior vaccination: Yes/Prior to vaccination, was the patient diagnosed with COVID-19?: Yes). No allergies to medications, food, or other products. Concomitant medications the patient received within 2 weeks of vaccination included gabapentin (NEURONTIN), ibuprofen (MOTRIN), other vaccine same date product=Pfizer, other vaccine same date vaccine location was left arm. The patient experienced severe rigors and fevers on 22Dec2020 02:00. The patient not received any other vaccines within 4 weeks prior to the COVID vaccine. Since the vaccination, the patient has not been tested for COVID-19. Therapeutic measures were taken as a result of severe rigors and fevers (Tylenol). This case was non-serious. The outcome of events severe rigors and fevers was not recovered. The outcome of other events was unknown. Information on the lot/batch number has been requested.

I had severe body rigors/Chills; I threw up; I had a 101.8 fever; I was pretty much out all day yesterday, like I was out sleeping with a fever; pretty much out; This is a spontaneous report from a contactable Nurse. A 59-year-old female patient started to receive first dose of BNT162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot/batch number: EJ1685, Expiry Date: 31Mar2021) intramuscular on 19Dec2020 at 0.3 mL, single for covid-19 immunization from her work. Patient history was reported as no. The patient didn't have really anything. Concomitant medication included paracetamol (TYLENOL), the patient had been taking some Tylenol. The patient had a vaccination Saturday morning on 19Dec2020 and had a very bad reaction during the night. The patient had severe body rigors and chills. She threw up. She had a 101.8 fever. She was pretty much out all day yesterday, like was out sleeping with a fever. Investigation assessment was no. The patient just would like to know if she can get the second injection. Outcome of the events was unknown. The events were considered as related by the reporter via global introspection (Method of assessment).

anaphylactic reaction; This is a spontaneous report from a contactable physician via a sales representative. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot/batch number and expiration date not provided), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced an anaphylactic reaction 8 hours after receiving the Covid-19 vaccine. The outcome of the event was unknown. Information about Batch/Lot number has been requested.; Sender's Comments: Based on the compatible temporal association and the drug's known safety profile, the Company considers the anaphylactic reaction is possibly related to BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE)

vaccination. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

"Runny nose; Headache; Joint pain I guess kind of, small moderate pain; Really bad sore throat; This is a spontaneous report from a contactable consumer (patient). A 31-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number EKS730), intramuscular on 17Dec2020 at single dose for COVID-19 immunization at hospital. The patient's medical history included seasonal allergy (Seasonal allergies he guess, that's it). Concomitant medications were not reported. The patient previously took cetirizine hydrochloride (ZYRTEC) from an unspecified date to Sep2020, not currently, he had not been taken it since summer but he had not currently taken it, he have stopped taking it, three months before the vaccine. The patient was a paramedic (further not clarified) and received the vaccination at a hospital, not a pharmacy. Patient guessed that they vaccinated there whole front line staff. The patient got the vaccine on Thursday (17Dec2020), Pfizer vaccine, Covid 19 vaccine and he was just having side effects mostly sore throat, he was having a really bad sore throat and he was expecting. He knew they said fever, chills, headache, joint pain was normal and things like that they are normal. But he just wasn't sure of this sore throat part of it and was also wondering if he was able to take like, anything to help with the symptoms. He also had other symptoms, on 20Dec2020 (started yesterday by the time of reporting), he experienced runny nose, headache, ""joint pain he guessed kind of, small moderate pain"" and really bad sore throat. As a treatment to the events, he took DayQuil on 20Dec2020 and was not sure what that dosage was. The events were quite persisting, which started yesterday. The patient had general lab work of Cholesterol on date that he didn't remember and did not know the result of it. The outcome of the events was not recovered."

Pain at injection site; Tachycardia like 120 heart rate; Dizziness; Fatigue; Fever; Stressing; Threw up; This is a spontaneous report from a contactable Other healthcare professional (Nurse Practitioner, also the patient). A 32-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, lot number: EK5730), intramuscularly on 20Dec2020 at single dose on right deltoid for COVID-19 immunization. Medical history reported as none. There were no concomitant medications. The patient experienced tachycardia, dizziness, fatigue, fever, stressing, threw up on an unspecified date in Dec2020, and pain at injection site on 20Dec2020. The patient received Covid vaccine yesterday on 20Dec2020 and he woke up and he threw up twice and he have fever 102 and tachycardia like 120 heart rate and some dizziness and he took some Tylenol (taken as treatment) and just drinking water. Feeling a little better right now. Tylenol was taken this morning as a treatment for fever of 102. For Causality, consumer stated, he believed so, because like he hasn't been around, he obviously worked around people who were sick, but he was fully gown and fully PPE. He was fine until this morning. Last night the only symptom he was having was pain at injection site which was expected. Of course, he can expect a low grade fever or maybe just some fatigue, he thought he was just stressing, he had fever went to 102 and he developed tachycardia and dizziness which was getting better after medicine and drinking fluid.

Therapeutic measures were taken as a result of tachycardia, dizziness, fever. The outcome of the events tachycardia, dizziness, fever was recovering, the outcome of the other events was unknown.

Left arm soreness, myalagias and low grade temp 100.5 the morning after the dose.; Left arm soreness, myalagias and low grade temp 100.5 the morning after the dose.; Left arm soreness, myalagias and low grade temp 100.5 the morning after the dose.; This is a spontaneous report from a contactable physician (patient). A 44-year-old female patient received the first single dose of BNT162B2 (Lot number: EH9899, exp date not reported), intramuscular (Anatomical Location: Arm Left) on 21Dec2020 13:45 for immunization. The COVID-19 vaccine was administered at the hospital. The patient was diagnosed with COVID-19 prior to vaccination. The patient had no known drug allergies (NKDA). The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. There were no other medications the patient received within 2 weeks of vaccination. The patient experienced left arm soreness, myalagias and low grade temp 100.5 the morning after the doses (22Dec2020, 04:30 AM). Treatment received for the adverse events included paracetamol (TYLENOL) and naproxen (ALLEVE). The event was considered as non-serious by the reporter. Since the vaccination, the patient had not been tested for COVID-19. The outcome of the events was not recovered.

""""sweaty feeling""; Developed headache; flushing after injection; redness; This is a spontaneous report from a contactable nurse. A 24-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number=EJ1685), intramuscularly on left arm at 12:00 PM on 21Dec2020 at single dose for COVID-19 immunization. Medical history included exercise-induced asthma. The patient's concomitant medications were not reported. The patient experienced headache, redness and flushing after injection, also reported ""sweaty feeling"" at 12:15 PM on 21Dec2020. Ae resulted in: Emergency room/department or urgent care. All events were reported as non-serious. The outcome of events was unknown."

Soreness at injection site; Soreness at injection site The night of vaccine being given, noted fever, chills, malaise, and fatigue. Resolved next morning.; Soreness at injection site The night of vaccine being given, noted fever, chills, malaise, and fatigue. Resolved next morning.; Soreness at injection site The night of vaccine being given, noted fever, chills, malaise, and fatigue. Resolved next morning.; Soreness at injection site The night of vaccine being given, noted fever, chills, malaise, and fatigue. Resolved next morning.; This is a spontaneous report from a non-contactable Physician. A 25-years-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number:9899), intramuscularly on 21Dec2020 12:00 PM at left arm, single dose for covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced fever, chills, malaise, and fatigue from 21Dec2020 16:00. Resolved next morning on 22Dec2020. No treatment was received for the adverse event. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. No seriousness criteria: no Results in death, no Life threatening, no Caused/prolonged hospitalization, no Disabling/Incapacitating, no Congenital anomaly/birth defect. No follow-up attempts are possible. No further information is expected.

Moderate left arm pain, radiating into upper back; Moderate left arm pain; This is a spontaneous report from a non-contactable nurse (patient). A 36-year-old male patient received first dose BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EH9899), via an unspecified route of administration at left arm on 21Dec2020 10:45 at single dose for covid-19 immunization at hospital. Medical history included allergy to penicillin (PCN). Concomitant medication included fish oil, cetirizine hydrochloride (ZYRTEC), fluticasone propionate within 2 weeks of vaccination. The patient experienced moderate left arm pain, radiating into upper back on day 2 (22Dec2020), the adverse event start time was 21Dec2020 08:00 PM. No treatment received for the adverse event. No COVID prior vaccination, no COVID tested post vaccination. The event outcome was not recovered. The was not reported as a serious report. No follow-up attempts are possible. No further information is expected.

Mild soreness left arm at injection site for 1 day, no redness or swelling; This is a spontaneous report from a contactable other healthcare professional (patient). A 56-year-old male patient received the first dose of bnt162b2 (Pfizer Biontech COVID 19 vaccine), Lot number: EH9899, intramuscular in the left arm on 18Dec2020 14:15 at a single dose for COVID-19 immunization. Medical history included Psoriatic Arthritis, HTN, HLD and known allergies: Sulfa. Concomitant medication included losartan and gabapentin. On 18Dec2020 14:15, the patient experienced mild soreness left arm at injection site for 1 day, no redness or swelling. The patient was not hospitalized for the event and did not receive any treatment for the event. The event was reported as non-serious. The vaccine was administered in a hospital. The patient has not received any other vaccines within 4 weeks prior to the COVID vaccine. Since the vaccination, the patient has not been tested for COVID-19. The event recovered on an unspecified date in Dec2020.

Headache; Soreness; Exhaustion; This is a spontaneous report from a contactable healthcare professional. A 45-years-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899), via an unspecified route of administration at the right arm on 21Dec2020 08:15 at a single dose for COVID-19 immunization at a hospital. Medical history included breast cancer, blood pressure abnormal, blood cholesterol abnormal. Concomitant medication included hydrochlorothiazide (HCTZ) and unspecified medications for blood pressure, cholesterol. The patient experienced headache, soreness, and exhaustion on 21Dec2020, 10:15. with no treatment The patient was recovering from the events.

started getting severe abdominal cramping; This lead to diarrhea, nausea with vomiting; This lead to diarrhea, nausea with vomiting; This lead to diarrhea, nausea with vomiting; Afterwards, was feeling tired, but ok.; This is a spontaneous report from a contactable Pharmacist reported for herself. A 51-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EJ1685), intramuscular on 21Dec2020 15:45 at single dose for covid-19 immunization. Vaccine location was Arm Right and it was the first dose. The COVID-19 vaccine was administered at Hospital. Medical history included Hypertension, asthma, obesity and Seasonal allergies - mold/dust etc.. Concomitant medications included losartan, indapamide, omeprazole, montelukast. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. About 9pm on 21Dec2020, the patient started getting severe abdominal cramping. This lead to diarrhea, nausea with vomiting. This lasted about 60-90 minutes of not being able to leave the restroom. Afterwards, she was feeling tired, but ok. No lingering

effects this morning (22Dec2020). No treatment was received for the adverse events. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, the patient was not been tested for COVID-19. The outcome of the events was recovered on 22Dec2020.

Fever, nausea/covid test result= Positive; Fever, nausea/covid test result= Positive; This is a spontaneous report from a contactable nurse (patient). A 24-year-old female (no pregnant) patient received first dose bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot/batch number and expiry date were not provided), via an unspecified route of administration in arm Left on 17Dec2020 02:30 at single dose for COVID-19 immunisation. Facility where the most recent COVID-19 vaccine was administered was hospital. The patient's medical history and concomitant medications were not reported. Prior to vaccination, the patient was not diagnosed with COVID-19. The patient experienced fever, nausea on 20Dec2020 12:00. Since the vaccination, has the patient been tested for COVID-19. The patient underwent lab tests and procedures which included PCR: positive on 21Dec2020, POCT: positive on 21Dec2020, Nasal Swab: positive on 21Dec2020. (reported as '[{covid test type post vaccination= Nasal Swab, covid test name post vaccination= PCR, covid test date= 21Dec2020, covid test result= Positive}, {covid test date= 21Dec2020, covid test type post vaccination= Nasal Swab, covid test name post vaccination= POCT, covid test result= Positive}]'). No treatment received for the adverse event. The patient not received any other vaccines within 4 weeks prior to the COVID vaccine. The outcome of events was not recovered. Information on the Batch/Lot number has been requested.; Sender's Comments: Based on the information currently available, a lack of efficacy with BNT162B2 in this patient might not be completely excluded.

Fever 99.9f, arm soreness, malaise; Fever 99.9f, arm soreness, malaise; Fever 99.9f, arm soreness, malaise; This is a spontaneous report from a contactable nurse (patient). A 32-year-old female patient (not pregnant) received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899), Intramuscularly on 21Dec2020 11:45 AM in left arm at single dose for COVID-19 immunization. The COVID-19 vaccine was administered at hospital. Medical history included COVID prior vaccination. Concomitant medication in two weeks included minerals nos, vitamins nos (PRENATAL VITAMINS), probiotics, levothyroxine. It was unknown if the patient received any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. The patient experienced fever 99.9f, arm soreness, malaise on 22Dec2020 04:00 AM. The patient received paracetamol (TYLENOL) as treatment. The outcome of events was unknown.

Arm soreness for 48 hour; Fatigue; muscle aches; chills; This is a spontaneous report from a contactable physician (patient). A 62-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number:20201216-830), via an unspecified route of administration on 16Dec2020 15:00 at arm left at single dose for covid-19 immunization. The COVID-19 vaccine was administered at Hospital. No other vaccine in four weeks. Medical history included hypothyroidism and hyperlipidaemia. The patient had no known allergies. Concomitant medication included levothyroxine, atorvastatin, ergocalciferol (Vitamin D) for an unspecified indication. The patient experienced arm soreness for 48 hour then fatigue, muscle aches and chills on 3rd and 4th days after vaccination on 19Dec2020 at 08:00 AM. No treatment was received for the event. Prior to vaccination, the patient was

not diagnosed with COVID-19 and since the vaccination, the patient was not been tested for COVID-19. Outcome of the event was recovered.

muscle aches; Chills; This is a spontaneous report from a contactable other health professional (reported for himself). A 56-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number not provided) (Pfizer EH 9899), intramuscularly on 21Dec2020 10:30 at single dose on right arm for COVID-19 immunization. Medical history included hypertension (HTN) and No known drug allergies (NKDA). The patient's concomitant medications were not reported. The most recent COVID-19 vaccine was administered at Hospital. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient experienced chills and muscle aches on 22Dec2020 02:30. The events were non-serious and no treatment received per the reporter. The outcome of the events was recovered on 22Dec2020. Information on the Batch/Lot number has been requested.

Arm pain; This is a spontaneous report from a contactable other health care professional. A 38-year-old female patient received bnt162b2 (BNT162B2; lot number: EJ1685), via an unspecified route of administration on 22Dec2020 09:15 in left arm for COVID-19 immunization. Medical history included allergic rhinitis. Concomitant medication included oseltamivir phosphate (TAMIFLU), meloxicam (MOBIC). The patient previously took dexilant and experienced drug hypersensitivity. No COVID prior vaccination. The patient has not been tested for COVID-19 post vaccination. On 22Dec2020 09:30, the patient experienced arm pain. The event was assessed as non-serious. The outcome of the event was recovering.

Neck also sore muscles; Neck also sore muscles; nausea; very bad HA, almost migraine; This is a spontaneous report from a contactable nurse (patient). A 45-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number=EL0140), intramuscularly on left arm at 05:30 AM on 21Dec2020 at single dose for COVID-19 immunization. Medical history reported as none. There were no concomitant medications (No other-vaccine-in-four weeks, no other-medications-in-two weeks). 21 hours post injection (02:45 AM) on 22Dec2020, the patient experienced very bad HA (headache), almost migraine. Then added nausea. HA was bad for 3 hours, then slowly better. Neck also sore muscles. All events were reported as non-serious. Excedrine and advil taken intermittently. Slept/rested in dark for 8 hours. Prior to vaccination, it was unknown if the patient was diagnosed with COVID-19. Since the vaccination, the patient had been tested for COVID-19. The outcome of events was recovering.

PVCs developed about 20 mins after administration of vaccine; This is a spontaneous report from a contactable Pharmacist. A 35-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, batch/ lot number: EL0140), intramuscularly on 21Dec2020 13:45 at right arm, at SINGLE DOSE for covid-19 immunization. Medical history included ongoing chronic back pain. Concomitant medication included escitalopram oxalate (LEXAPRO), amfetamine aspartate, amfetamine sulfate, dexamfetamine saccharate, dexamfetamine sulfate (ADDERALL). The patient was not pregnant at the time of vaccination. The patient experienced PVCs about 20 mins after administration of vaccine. Placed on Zoll cardiac monitor on 21Dec2020. Vitals to include BP, heart rate, respiratory, pulse ox

several times during additional monitoring period. No respiratory distress or other issues during this monitoring period. No treatment was received for the adverse event. It was unknown if the patient was diagnosed with COVID-19 prior to vaccination. Since the vaccination, the patient had not been tested for COVID-19. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The outcome of the event was recovered in Dec2020.No seriousness criteria: no Results in death, no Life threatening, no Caused/prolonged hospitalization, no Disabling/Incapacitating, no Congenital anomaly/birth defect.

feeling hot and diaphoretic; diaphoretic/ sweaty; massive headache; sleep 13 hours; swollen face; joint pain; chills; start wheezing with a dry cough; start wheezing with a dry cough; 101.8 fever/ mild fever 99.6; swelling in my lymph nodes happened immediately/ swelling; some chest tightness; hard to breathe it was like breathing through a straw; Unable to go to work; uncomfortable; Never shown allergic reaction to vaccines before this; This is a spontaneous report from a contactable other Health Professional (Patient). A 26-years-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 17Dec2020 08:00 at single dose for covid-19 immunization in hospital. Medical history included polycystic ovary syndrome (PCOS) and possibly rheumatoid arthritis. No Known Drug Allergies. Concomitant medications in two weeks included birth control and iron supplements. The patient got the vaccine at 8:00 am on 17Dec2020 Thursday and experienced swelling in her lymph nodes happened immediately and some chest tightness. It was never hard to breathe it was like breathing through a straw. At 10:00 am hits and she got joint pain, chills, start wheezing with a dry cough and a 101.8 fever. Unable to go to work. She sleep and wake up 18Dec2020 Friday with a mild fever 99.6 and some chest tightness/swollen Lymphnodes but nothing else. On 19Dec2020 Saturday she took antihistamines to see if that would help her swelling and go to bed. The patient wake up with a swollen face which was a new reaction to this medicine I've taken before. Chest tightness was gone/ lympnodes still swollen. On 20Dec2020 Sunday she sleep 13 hours. On 21Dec2020 Monday happened and she awake to feeling hot and diaphoretic. She drank water and remove clothes/blankets go back to sleep. Wake up still sweaty with a massive headache but no fever. Lymphnodes still swollen and uncomfortable currently. Never shown allergic reaction to vaccines before this. No COVID prior vaccination, no COVID tested post vaccination. Therapeutic measures were taken as a result of swelling in lymph nodes and included antihistamines, no treatment received for the other adverse event. The outcome of the event fever was recovered in Dec2020; of the event sweaty was not recovered; of unable to work, swollen face, headache, sleep 13 hours, uncomfortable, shown allergic reaction was unknown; of the other events was recovered/resolved with sequel. The seriousness was reported as no. The information on the batch number has been requested.

Pink eye,eye drainage; Pink eye,eye drainage; Chills; Muscle Aches; This is a spontaneous report from a contactable nurse reported for herself. A 50-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: Ek5230), intramuscular on 17Dec2020 16:00 at single dose for covid-19 immunization. Vaccine location was at Right arm and it was the first dose number. The COVID-19 vaccine was administered at Workplace clinic. The patient's medical history was not reported. Concomitant medications included fluoxetine hydrochloride (PROZAC), atorvastatin, buspirone hydrochloride (BUSPAR). The patient did not receive any other vaccines within 4 weeks prior to the

COVID vaccine. Patient's known allergies included Erythromycin. The patient experienced Chills, Muscle Aches, pink eye, eye drainage on 21Dec2020 19:00. Adverse event result in Doctor or other healthcare professional office/clinic visit. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, the patient was not been tested for COVID-19. The outcome of the events was unknown.

I experienced slight heaviness and then a tingling parasthesia in the feet that traveled up to my knees. I stayed for one hour, it began to feel like a cold sensation. I was able to walk and did not f; I experienced slight heaviness and then a tingling parasthesia in the feet that traveled up to my knees. I stayed for one hour, it began to feel like a cold sensation. I was able to walk and did not f; I experienced slight heaviness and then a tingling parasthesia in the feet that traveled up to my knees. I stayed for one hour, it began to feel like a cold sensation. I was able to walk and did not f; anxiety; This is a spontaneous report from a contactable nurse (patient). A 32-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (lot number EK5730), intramuscularly on 15Dec2020 07:45 at single dose for covid-19 immunization. Vaccine location was left arm and it was the first dose. None medical history. No known allergies. Patient was not diagnosed with COVID-19 prior to vaccination nor tested for COVID-19 since the vaccination. There were no concomitant medications. The patient didn't receive any other vaccines within 4 weeks prior to the COVID vaccine nor received any other medications within 2 weeks of vaccination. At 22Dec2020 07:45 am, the patient experienced slight heaviness and then a tingling parasthesia in the feet that traveled up to her knees. She stayed for one hour, it began to feel like a cold sensation. She was able to walk and did not feel dizzy and left work. The patient reported them to the MD who said it could be a coincidence and anxiety. Patient didn't receive any treatment for the adverse events. The action taken in response to the events for BNT162B2 was not applicable. The outcome of events was unknown. The events were non-serious.

had a sudden lightheadedness/a bit lightheaded; slurred speech; extreme sleepiness; feeling like was under anesthesia and unable to move the legs; unable to move the legs; Blood pressure dropped to 80/60mmHg and pulse was at 50; Blood pressure dropped to 80/60mmHg and pulse was at 50; This is a spontaneous report from a contactable pharmacist. A patient of unspecified age and gender received a dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization in their facility. The patient's medical history and concomitant medications were not reported. It was reported that patient (doctor) in their facility received the vaccine and had a sudden lightheadedness, slurred speech and extreme sleepiness. Feeling like was under anesthesia and unable to move the legs. Blood pressure dropped to 80/60 mmHg and pulse was at 50. The episode lasted 2h and then became alert but a bit lightheaded and was normal next day. The outcome of the events was recovered. Information on the lot/batch number has been requested.

migraine; Vomiting; low grade fever and headache; headache; chills; light sensitivity; This is a spontaneous report from a contactable Nurse (patient). A 54-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK5730), via an unspecified route of administration on 18Dec2020 around 07:45 at single dose for COVID-19 immunization. Anatomical location of administration provided as left upper arm; deltoid. Medical history included migraines

(Hasn't had one in a while). There were no concomitant medications. There were no prior vaccinations within 4 weeks. The patient previously took FLU VACCINE and had a low grade fever. The patient experienced low grade fever and chills on 19Dec2020, Headache with Light sensitivity: Woke up in the night with the headache after going to bed on Saturday, 19Dec2020. The patient has been vomiting off and on since Sunday, 20Dec2020. Caller stated she got the vaccine on Friday the 18Dec2020 and now has a low grade fever and headache and asked if she can take Tylenol or Ibuprofen for her symptoms. She also asked if she is allowed to take these before her next dose. Caller asked since she was experiencing symptoms with first dose is it likely she will experience them for second dose or it would be worse. Specifically, it was reported that late Saturday, the patient started running a fever and chills between 4PM and 5PM on 19Dec2020. She knew it was a potential side effect and minor. Got a headache since then and with light sensitivity. She wasn't sure what she could do to break it. Turned into a migraine on an unspecified date and has had vomiting. Vomiting occurs with her migraines, but hasn't had a migraine in a long time. The patient wasn't sure if she could take Ibuprofen or Tylenol with the vaccine. The light fever and chills is listed on the potential side effects she received. She can't focus with the headache she has. Called in to work. The patient knew COVID Vaccine could cause headaches. Think the headache started and ballooned into a migraine. Has been vomiting off and on since Sunday, 20Dec2020. Thinks the vomiting is from the headache and not the vaccine. Not due for next dose of COVID Vaccine until 08Jan2021. Wants to know if she is likely to experience the same symptoms with the second dose. Or if the symptoms will worsen. The outcome of the events was unknown. The seriousness provided as between not serious and medically significant. The causality assessment for events fever and chills, headache with light sensitivity with suspect vaccine provided as Related by Primary Source Reporter via Method of assessment Global Introspection.

Joint pain and swelling 3 days after the first dose. Affected joints: right elbow, right wrist and right third interdigital joint; Joint pain and swelling 3 days after the first dose. Affected joints: right elbow, right wrist and right third interdigital joint; This is a spontaneous report from a contactable consumer (patient). A 60-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number=EK5730), via an unspecified route of administration on left arm on 17Dec2020 at single dose for COVID-19 immunization. Medical history included wasp venom with anaphylaxis. There were no concomitant medications (No other-vaccine-in-four weeks, no other-medications-in-two weeks). The patient previously Stage 4 breast cancer in remission on Xeloda. The patient experienced joint pain and swelling 3 days after the first dose. Affected joints: right elbow, right wrist and right third interdigital joint on 20Dec2020. All events were reported as non-serious. The patient did not receive treatment for the adverse events. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. The outcome of events was not recovered.

dizziness/lightheadedness; severe nausea; rash/hives on chest and back and forearms; rash/hives on chest and back and forearms; severe chills/shivering; This is a spontaneous report from a contactable nurse (patient). A 28-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), intramuscularly on 18Dec2020 11:30 AM at Left arm, at SINGLE DOSE for covid-19 immunization. The patient's medical history and concomitant medications were not reported. The

patient was not pregnant at the time of vaccination. The patient experienced dizziness, lightheadedness, severe nausea, rash/hives on chest and back and forearms, severe chills/shivering on 18Dec2020 11:45 AM. The patient received treatment fluids, pepcid, Benadryl for these events. There events resulted in: Emergency room. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The outcome of the events was recovered in Dec2020. No seriousness criteria: no Results in death, no Life threatening, no Caused/prolonged hospitalization, no Disabling/Incapacitating, no Congenital anomaly/birth defect. Information on the lot/batch number has been requested.

maculo-papular rash on neck and trunk with itchy skin; maculo-papular rash on neck and trunk with itchy skin; This is a spontaneous report from a contactable physician reported for herself. A 52-years-old female patient received first dose BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EH9899), via an unspecified route of administration at left arm on 18Dec2020 20:00 at single dose for covid-19 immunzation at workplace clinic. Medical history included seasonal and dust allergies, allergies to medications doxycycline and erythromycin. Concomitant medication included acetaminophen and ibuprofen. The patient experienced maculo-papular rash on neck and trunk with itchy skin on 19Dec2020 10:00 with outcome of recovered in Dec2020. No treatment received for the adverse events. No COVID prior vaccination, no COVID tested post vaccination. The was seriousness was reported as no.

reports getting the vaccine on Friday and then tested positive for for covid infection on the following Monday; reports getting the vaccine on Friday and then tested positive for for covid infection on the following Monday; This is a spontaneous report from a contactable other healthcare professional (HCP) reported for herself. A 60-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 18Dec2020 (Friday) at single dose for covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient got the vaccine on Friday (18Dec2020) and then tested positive for covid infection on the following Monday (21Dec2020). She asked if this would interfere with getting the second dose and if she should or could get the second dose of the covid vaccine after testing positive for covid infection. The outcome of the events was unknown. Information about lot/batch number has been requested.; Sender's Comments: Based on the current available information and the consistency with the known safety profile of the suspect product BNT162B2, a possible contributory role of the suspect product to the development of Drug ineffective and COVID-19 cannot be excluded. The case will be reassessed if additional information becomes available.

Patient felt lethargic and lightheaded (starting 18Dec, more significant 19Dec-20Dec) post-vaccine administration; Patient felt lethargic and lightheaded (starting 18Dec, more significant 19Dec-20Dec) post-vaccine administration; This is a spontaneous report from a non-contactable pharmacist. A 52-year-old male patient received first dose bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EK5730), intramuscular on 17Dec2020 14:30 at single dose for COVID-19 immunisation. Facility where the most recent COVID-19 vaccine was administered was hospital. The patient medical history was not reported. Concomitant medications the patient received within 2 weeks of vaccination included budesonide (PULMICORT), cetirizine hydrochloride (ZYRTEC). The patient experienced 'Patient felt

lethargic and lightheaded (starting 18Dec, more significant 19Dec-20Dec) post-vaccine administration' on 18Dec2020. It was unknown if the patient received any other vaccines within 4 weeks prior to the COVID vaccine. It was reported unknown whether treatment received for the adverse event. The case was non-serious. The outcome of the events was reported as unknown. No follow-up attempts are possible. No further information is expected.

Dry mouth and throat; Dry mouth and throat; This is a spontaneous report from a contactable nurse (patient). A 24-year-old female patient (not pregnant) received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number: EJ1685), via an unspecified route of administration on 22Dec2020 08:15 in left arm at single dose for COVID-19 immunization. The patient medical history was not reported. Concomitant medication in two weeks included venlafaxine, famotidine. There was no other vaccine in four weeks. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. Facility type vaccine was hospital. The patient experienced dry mouth and throat on 22Dec2020 at time of 08:30 AM. No treatment received for the adverse event. The outcome of event was recovering. No follow-up attempts are possible. No further information is expected.

itching skin; injection site immediately red and hot; injection site immediately red and hot; could not locate hives or welts; This is a spontaneous report from a contactable pharmacist. A 36-year-old female patient (pregnant at the time of vaccination) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK5730), intramuscularly on 21Dec2020 13:15 at single dose on left arm for COVID-19 immunization. Medical history included anaphylactic reaction to food, Anaphylaxis to sesame and lidocaine, had never had anaphylactic reaction to vaccines in past. The patient's concomitant medications were not reported. The most recent COVID-19 vaccine was administered at Hospital. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. On 21Dec2020 13:15 (01:15 PM), the patient experienced itching skin, could not locate hives or welts, injection site immediately red and hot, no wheezing observed, no tachycardia observed. Treatment included observed for an hour, ice pack on injection site x2, 50mg diphenhydramine hydrochloride (BENADRYL), 1 10mg cetirizine hydrochloride (ZYRTEC), 20mg famotidine (PEPCID). Advised to pre-medication prior to booster dose and alert vaccinator of this reaction to be prepared. The events were non-serious. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient hadn't been tested for COVID-19. The outcome of the events was recovered in Dec2020.

"congestion; throat hurts, she has a sore throat; a sore arm where it was administered. It is not swollen or red but hurts to the touch; diarrhea and has gotten a little worse since starting/having to get up and go to the bathroom often; uncomfortable; This is a spontaneous report from a contactable consumer (patient). A 25-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (lot number unknown because the patient was sent a picture of the paper provided for vaccine administration but it did not include any product details), via an unspecified route of administration at arm on 21Dec2020 at single dose for COVID-19 immunization at hospital. The patient's medical history included seasonal allergy, she had no allergies other than season allergies. She had no reactions to any vaccines previously. Prior Vaccinations within 4 weeks was reported as none, and no events following prior vaccinations. Concomitant medications included unspecified medication for birth control daily and

has been on this for a couple months. No additional vaccines administered on same date of the Pfizer suspect. The patient is a medical assistant, an employee at a hospital. She received the vaccine at work yesterday (21Dec2020) around 10 or 10:30 and she was having side effects. She had contacted her employer but wanted to know if it is ok to go to work or should she stay home and treat the symptoms. Afterward she experienced diarrhea which started last night and has gotten a little worse since starting. She also has congestion and her throat hurts, she has a sore throat, that started this morning, on 22Dec2020. There had been no treatment for above symptoms. After getting the shot she had a sore arm where it was administered. It is not swollen or red but hurts to the touch. This started 30 minutes after administration and she had to take pain medication. It was worse on 22Dec2020 (today). She did not require a visit to the doctor at the point when reporting, it was just uncomfortable having to get up and go to the bathroom often. No emergency room or physician visit due to the event. No relevant tests. The outcome of the event ""uncomfortable"" was unknown, and for the rest of events was not recovered. Information on the lot/batch number has been requested."

Increased heart rate; Increased heart rate and blood pressure; Feeling hot; Cold fingers; This is a spontaneous report from a contactable nurse (patient). A 48-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE lot/batch number EH9899), intramuscular on the left arm on 22Dec2020 08:00 at SINGLE DOSE as COVID-19 immunization at the workplace clinic. The patient had no medical history and no allergies to medications, food, or other products. The patient previously had COVID-19 test on 24Aug2020 and showed negative. Concomitant medication included levothyroxine (LEVOTHYROXINE). On 22Dec2020 08:00, the patient experienced increased heart rate and blood pressure, feeling hot and cold. Since the vaccination, the patient had been tested for COVID-19 in Dec2020 with unknown results. The patient did not receive any treatments for the events. The patient was recovering from the events.

tingling in hands and feet; This is a spontaneous report from a non-contactable other healthcare professional. A 48-year-old female patient receives first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: HE9899), intramuscularly on 18Dec2020 12:45 at single dose for immunization. vaccine location provided as Right arm. Medical history included fibromyalgia, rheumatoid arthritis. The patient's concomitant medications were not reported. No history of vaccine or medication reaction previously. During her 15-minute waiting period after the injection, the patient began to experience tingling in hands and feet on 18Dec2020. She denied rash, hives, difficulty breathing, difficulty swallowing, wheezing, throat tightness, hoarseness, lightheadedness, dizziness and tongue swelling This provider was notified of patient reaction and she was then assessed in the emergency bay area. Review of Systems included: Constitutional: Negative for chills and fatigue. HENT: Negative for congestion, facial swelling, rhinorrhea, sinus pain, sneezing, sore throat and trouble swallowing. Respiratory: Negative for cough and shortness of breath. Musculoskeletal: Negative for back pain, myalgias and neck stiffness. Skin: Negative for rash. Neurological: Tingling in hands and feet bilaterally. The outcome of the event was unknown. All events reported as non-serious. No follow-up attempts are possible. No further information is expected.

"Feeling under the weather; Nausea; Headache; Muscle ache; This is a spontaneous report from a contactable other healthcare professional (HCP), who is also the patient. This 63-year-old female patient

received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Lot number EL0140) via an unspecified route of administration on 19Dec2020 at single dose for COVID-19 immunisation. Relevant medical history included hypertension (hypertensive for years and takes medication for that), muscle aches (she got muscle aches once in a while) and headaches (she got some headaches from wearing a mask). Concomitant medications included unspecified drugs for hypertension. On 21Dec2020, the patient experienced nausea; in Dec2020 she experienced headache and muscle ache and on 22Dec2020 she experienced feeling under the weather. The patient specified that she has had light symptoms of nausea, headache, and muscle ache. Nausea was the most prevalent symptom. She said she got some headaches from wearing a mask, and the headaches she has experienced since receiving the COVID-19 Vaccine could be related to her mask wearing, and not the vaccine. She said she was at the age where muscle aches are not uncommon, and she got muscle aches once in a while, so she was unsure if her muscle aches were from receiving the COVID-19 Vaccine. She further specified that the she had a little nausea, saying the nausea was not very noticeable. The nausea was a little heavier at the time of the report, and she had some toast and some things to help settle her stomach. She said she was feeling ""blah."" She clarified she was feeling under the weather, like she just wanted to get in bed and sleep. The patient reported that the symptoms she was experiencing could be stress, and she just wanted to get the rapid COVID test to make sure she doesn't have the virus. She would take the rapid test as a requirement for travel. Treatment: the patient took 2 Extra Strength Tylenol 500mg (Lot Number: SHA086, and Expiration Date: Jun2024). The patient had not recovered from nausea and feeling unwell; the outcome of the headache and muscle ache was unknown."

"Day after vaccine, developed itchiness; Then I began breaking out in hives throughout my body; Also suffered from bouts of nausea and have trouble keeping things down; This is a spontaneous report from a contactable other HCP (patient) . This 24-year-old female patient received,at hospital, the first dose of BNT162B2 (also reported as Pfizer-BioNTech COVID-19) intramuscular on arm left on 20Dec2020 (reported as at 02:30 PM) at a single dose for COVID-19 immunization.No Allergies to medications, food, or other products; No other Medical history Concomitant medication Omeprazole, Terbinafine. No Covid prior vaccination and no covid test vaccination provided . Day after vaccine, on 21Dec2020 at 12:00 PM, the patient developed itchiness. Then she reported ""I began breaking out in hives throughout my body. Also suffered from bouts of nausea and have trouble keeping things down"". The adverse events resulted in Doctor or other healthcare professional office/clinic visit. The patient was tretated with Steroid shot and was prescribed with medication for nausea.All events were reproted as non serious.The outcome of the events was recovering at the time of the report. Information about lot/batch number has been requested."

Bloody nose; Blood in urine (slight tinged); This is a spontaneous report from a contactable pharmacist. A 48-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), lot number: EK5730, first dose via intramuscular in left arm on 17Dec2020 10:30 at single dose for COVID-19 immunisation. Medical history was reported as none. Concomitant medication included atorvastatin (LIPITOR) and estradiol (ESTROGEN). On 18Dec2020 07:00 AM, the patient experienced bloody nose and blood in urine this morning (slight tinge) and has not exhibited any other side effects at the time of this report. Noted in afternoon on 18Dec2020, the patient urinated and no blood present. It was unknown if

patient received treatment for the events. It was unknown if patient had COVID and tested COVID prior vaccination. The patient had no known allergies. The case was reported as non serious as it did not resulted in death, not life threatening, no prolonged hospitalization, not disabling/Incapacitating and no congenital anomaly/birth defect. The outcome of the events was unknown.

Headache fever 100.0 body aches fatigue nausea; Headache fever 100.0 body aches fatigue nausea; Headache fever 100.0 body aches fatigue nausea; Headache fever 100.0 body aches fatigue nausea; Headache fever 100.0 body aches fatigue nausea; This is a spontaneous report from a contactable nurse reported that a 46-year-old female patient received bnt162b2 (BNT162B2 also reported as Covid 19 vaccine), intramuscular in the right arm on 17Dec2020 12:00 at single dose for immunisation. It was in the hospital where the most recent COVID-19 vaccine was administered. Medical history included Hep B chronic carrier. She had no other vaccine/ medications in four weeks, no covid tested post vaccination, no known allergies. The patient's concomitant medications were not reported. The patient experienced headache, fever 100.0, body aches, fatigue and nausea on 20Dec2020. No treatment was given. The outcome of events was recovered on unknown date in Dec2020. Information on the Lot/Batch has been requested.

Feeling tiredness/unwell; Feeling tiredness/unwell; Arm pain/soreness at injection site (expected); Arm pain/soreness at injection site (expected); This is a spontaneous report from a contactable nurse, who is also the patient. A 31-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration in the left arm on 21Dec2020 at 10:30 at single dose for COVID-19 immunisation. Vaccination facility type was hospital. The patient had no relevant medical history. Concomitant medications were not reported. On 22Dec2020, the patient experienced feeling tiredness/unwell and arm pain/soreness at injection site (expected). The patient did not receive corrective treatments. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination she has not been tested for COVID-19. The outcome of the events was unknown. The information on the lot/batch number has been requested.

Headache; Nausea; Ear ache; Injection site pain that started 7 hours after injection and has continued to now; This is a spontaneous report from a contactable nurse (patient herself). A 26-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on right arm on 21Dec2020 at 10:45 AM at single dose for COVID-19 immunization. The patient medical history was not reported. Concomitant medication included vitamin D3 and progesterone, both listed as other medications the patient received within 2 weeks of vaccination. The patient experienced injection site pain that started 7 hours (onset on 22Dec2020 at 17:45 AM) after injection and has continued to now. Pain was lessening as time went on. Tylenol had helped. Headache, nausea and ear ache all started this morning on 22Dec2020 at 07:00 AM. Headache was continuous; nausea and ear ache were intermittent. The patient did not receive any treatment for these events. All events were reported as non-serious. The outcome of event vaccination site pain was recovering. The outcome of rest events was not recovered. Information on the lot/batch number has been requested.

dizziness; tachycardia; fatigue; This is a spontaneous report from a contactable other health professional (patient). A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19

VACCINE), via an unspecified route of administration on an unspecified date at SINGLE DOSE for covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced reported dizziness, tachycardia, and fatigue after taking the COVID vaccine on an unspecified date. The patient's symptoms didn't seem severe. Information on the lot/batch number has been requested.

Redness of skin, especially on face; itching of head and arms; some swelling in feet; This is a spontaneous report from a contactable nurse (patient). A 58-year-old non-pregnant female patient received first dose of BNT162B2 (Pfizer-BioNTech COVID-19 mRNA vaccine, lot number: EH9899), intramuscular at arm left on 21Dec2020 at 12:30 at a single dose for COVID-19 immunization. The patient received COVID-19 vaccine in a hospital facility. The patient has allergies to medications, food, or other products. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. The patient is receiving unspecified concomitant medications within 2 weeks of vaccination. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. On 21Dec2020 at 01:00 PM, the patient experienced redness of skin, especially on face, itching of head and arms, some swelling in feet. The patient received Benadryl 50 mg PO as treatment. The outcome of the events was recovering.

Nauseous; I got a really strong headache; Really intense headache right no/ headache was on her left side of her head; something weird going on with right eye/ very blurry for like 3 minutes/ really blurred up/ blurriness was the right corner of her right eye; This is a spontaneous report from a contactable consumer (patient). A 57-years-old female patient started to receive BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 18Dec2020 at single dose for COVID-19 immunization. The patient medical history and concomitant medications were not reported. On Saturday 19Dec2020, the patient had something weird going on with her right eye. It was very blurry for like 3 minutes, she kind of let it go. But she got a headache afterwards on 19Dec2020. And it happened again at night, same night around 10 o' clock. Not on 20Dec2020, but 21Dec2020, she just got it really blurred up again and she got a really strong headache. But the headache was on her left side of her head whereas the blurriness was the right corner of her right eye. And she just came on very hard headache and she was just very nauseous on an unspecified date. The patient just was in a really intense, she didn't know why she was having such trouble. She just had a little trouble. The patient just wanted to know if this was something normal to get a bad headache like this. The headache outcome was not recovered, of the other evens was unknown. The information on the batch number has been requested.

body aches; fever; This is a spontaneous report from a contactable Other Healthcare Professional (HCP, an x-ray tech who is the patient). A male patient of unknown age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, on 21Dec2020 (reported as ''yesterday'') at single dose for COVID-19 immunisation. Medical history included he had coronavirus in May2020, treated with plasma infusion, and still had detectable antibodies in his system based on lab test administered last month. Concomitant medications were unknown. On 21Dec2020, the patient received the vaccine and has had body aches and a fever. He wanted to know if this was expected after being vaccinated. The reporter asked if there are precautions in patients getting the vaccine who have had

coronavirus previously and been treated with plasma infusions. Outcome was unknown. Information on the Lot/Batch number has been requested.

general malaise; Ringing in both ears; headache; dizziness; nausea; This is a spontaneous report from a contactable Nurse (patient). This 62-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot # EH9899), intramuscular, on 18Dec2020 07:30 AM at single dose for COVID-19 immunisation. Vaccine location was left arm. The patient was vaccinated at hospital, age at vaccination was 62-years-old. No other vaccine was received in four weeks. Medical history included hyperlipidemia, Coronary artery disease (CAD), Barrett's Esophagus. Concomitant medications included unspecified medications the patient received within two weeks of vaccination. On 18Dec2002 at 02:00 PM, the patient experienced ringing in both ears, headache, dizziness, nausea, general malaise, started 5 hours after injection, it still continues 4 days post injection, all reported as non-serious. The adverse event resulted in Doctor or other healthcare professional office/clinic visit. No treatment was received for the events. Outcome of the events was not recovered.

Chills; Muscle aches and pain; joints hurt (her body aching); Muscle aches and pain; joints hurt (her body aching); Muscle aches and pain; joints hurt (her body aching); She has a headache; Sleeping the whole morning. She didn't get up; Doesn't want to eat; Fever; Temperature of 100.4; Doesn't feel good; Little soreness at injection site; This is a spontaneous report from a contactable nurse (patient). A 52-year-old female patient started to received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE lot/batch number not provided), via an unspecified route of administration on the right arm on 21Dec2020 15:00 at SINGLE DOSE as COVID-19 vaccination at the hospital. It was reported that the patient had COVID-19 in May2020 (until 2020). Then had COVID-19 test again in Jul2020 and still tested positive. The patient did have COVID-19 test last week (Dec2020) and it was negative. The patient also had the flu shot every year as immunization and never has a side effect. The patient was also on unspecified supplement. On 21Dec2020 at 15:00, the patient received COVID-19 vaccine. Around 20:00-21:00 (8-9 o'clock), she felt nothing and perfectly fine. Didn't feel anything until 23:00-24:00 (11-12 o'clock), she felt injection site hurting and started to have fever up to 100.4. She doesn't feel good. She was also was afraid to touch the injection site hard or rub it. On 22Dec2020 (that morning), she has chills, muscle aches and pains, and her joints were hurting (her body aching). The patient also had headache this morning and was sleeping the whole morning. She didn't get up. The patient also doesn't want to eat but was drinking water. The patient wanted to know if other people reported side effects like she has. She mentioned that she had 2-3 coworkers, but these coworkers did not have symptoms after COVID-19 vaccination. Outcome of the events were unknown. Information on the Lot/batch number has been requested.

developed congestion in nose; joint aches; This is a spontaneous report from a contactable physician (patient). A male patient of an unspecified age received BNT162B2 (Pfizer-BIONTECH Covid-19 Vaccine), via an unspecified route of administration on 18Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. On an unspecified date in Dec2020, within the next 18 hours, the patient developed congestion in nose, over the next 72 hours the patient developed joint aches and the symptoms have lasted for 96 hours. The outcome of events was unknown.

feeling dizzy/dizziness; tachycardic/tachycardia; This is a spontaneous report from a non-contactable Nurse. A female patient of an unspecified age received bnt162b2 (BNT162B2) vaccine , via an unspecified route of administration on 22Dec2020 at single dose for covid-19 immunisation . The patient medical history was not reported. There were no concomitant medications. After receiving the vaccine on 22Dec2020, after 15 minutes of sitting and waiting, the patient started feeling dizzy and tachycardic which lasted for 1 minute and 30 seconds, then it subsided. No follow-up attempts are possible. Information about lot/batch number cannot be obtained.

Nausea and Headache 1.5-2 hours administration; Nausea and Headache 1.5-2 hours administration; This is a spontaneous report from a contactable other healthcare professional (HCP) reported for herself. A 31-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL0140), via an unspecified route of administration on 22Dec2020 11:30 at single dose for covid-19 immunization. Vaccine location was Left arm and it was the first dose. The COVID-19 vaccine was administered at Nursing Home/Senior Living Facility. Medical history included hypertension (HTN), bipolar disorder, Known allergies included PCN and cefixime (BIOXIN). Concomitant medications included metoprolol, celecoxib (CELEXA), and Multivitamin one a day. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient experienced nausea and headache 1.5-2 hours administration on 22Dec2020 13:00. No treatment received for the events. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, the patient was not been tested for COVID-19. The outcome of the events was unknown.

"Headache only; This is a spontaneous report from a contactable healthcare professional. A 61-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, lot number: EK5730 and expiry date not reported), intramuscular on the right arm on 22Dec2020 07:30 at single dose for COVID-19 immunisation. Medical history included diabetes mellitus (reported as ""diabetic""), gastrooesophageal reflux disease (GERD), and neuropathy peripheral. Concomitant medications included tramadol, alprazolam, cyclobenzaprine, celecoxib, losartan, ropinirole, oxybutynin, gabapentin, metformin hydrochloride (METFORMIN ER), pantoprazole, cetirizine, hydrochlorothiazide, calcium, magnesium, and iron. The patient previously took erythromycin and experienced drug allergy. The patient experienced headache only on 22Dec2020 10:00. Clinical outcome of the event was recovering."

Fever 102, shakes, chills, headache and nausea; Fever 102, shakes, chills, headache and nausea; Fever 102, shakes, chills, headache and nausea; Fever 102, shakes, chills, headache and nausea; Fever 102, shakes, chills, headache and nausea; This is a spontaneous report from a contactable Nurse reporting for herself. A 55-years-old female patient received bnt162b2 (BNT162B2; Lot # EJ1685) vaccine , via an unspecified route of administration in the left arm on 18Dec2020 09:15 at single dose for covid-19 immunisation . Medical history included , coeliac disease from an unknown date and hypertension from an unknown date. Concomitant medication included progesterone (PROGESTERONE), nebivolol hydrochloride (BYSTOLIC), vitamin d3 (VITAMIN D3). The patient previously took codeine and experienced drug hypersensitivity. The patient experienced fever 102¦F, shakes, chills, headache and nausea on 18Dec2020 19:15 with outcome of recovered.

Fatigue beginning the night of the vaccine into early morning. Severe fatigue inability to get out of bed in the morning.; This is a spontaneous report from a contactable Nurse. A 25-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot # EL0140) on 21Dec2020 at 10:00 via intramuscular on left arm for COVID-19 immunization. The patient hd no relevant history. Concomitant medications included unspecified vitamins. The patient reported fatigue beginning the night of the vaccine (about 11:45) into early morning, described as severe fatigue inability to get out of bed in the morning. The patient was recovering from the event.

her throat hurts; She reported that her mouth is raw.; her chest is a little heavy/feels like a chest cold is coming on in her chest; She has a little bit more of a cough; severe joint; achiness; felt a little bit tired, but reported that she has felt increasingly tired and out of it/more fatigue; got possibly exposed to covid from a patient who tested positive after getting random swabbed; like all of her lymph nodes are swollen; she felt like she was getting the flu; the throat pain is throwing her though; The throat pain is up to her ears; She stated her mouth is a little red.; This is a spontaneous report from a contactable nurse, who is also the patient. This 56-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number EK5730; expiration date 01Mar2021) intramuscular in the left deltoid on 19Dec2020 at 15:00 at 0.3 mL single for COVID-19 immunisation. Vaccination facility type was hospital. Relevant medical history included hypertension, breast cancer, obesity, high cholesterol and ex-tobacco user (former, quit over 10 years ago). Concomitant medications included atorvastatin calcium (LIPITOR), amlodipine, losartan and ubidecarenone (CO Q10). The patient got possibly exposed to COVID from a patient who tested positive after getting random swabbed in Dec2020 with outcome of unknown; she also experienced felt a little bit tired, but reported that she has felt increasingly tired and out of it/more fatigue on 20Dec2020 with outcome of not recovered, severe joint (arthralgia) on 21Dec2020 with outcome of not recovered, achiness on 21Dec2020 with outcome of not recovered, her throat hurts on 22Dec2020 with outcome of not recovered, like all of her lymph nodes were swollen on Dec2020 with outcome of unknown, she reported that her mouth was raw on 22Dec2020 with outcome of not recovered, she has a little bit more of a cough on 21Dec2020 with outcome of not recovered, her chest was a little heavy/feels like a chest cold was coming on in her chest on 22Dec2020 with outcome of not recovered, she felt like she was getting the flu on Dec2020 with outcome of unknown, the throat pain was throwing her though on Dec2020 with outcome of unknown, the throat pain was up to her ears on Dec2020 with outcome of unknown and she stated her mouth was a little red on Dec2020 with outcome of unknown. She said that the vaccine was administered on Saturday 19Dec2020. She was at work the next day and felt a little bit tired, but reported that she has felt increasingly tired and out of it. On Monday, she felt very tired and took it easy. She said that she woke up with no fever, but had severe joint and achiness, more fatigue, and her throat hurts, like all of her lymph nodes are swollen. She reported that her mouth was raw. She had a little bit more of a cough and said that her chest was a little heavy. She did not feel like herself. Just spoke to a colleague and one of the people she was working with tested positive for COVID. She was working with her on Sunday 20Dec2020. Caller said that she received the vaccine at the hospital. She was able to work, but felt disconnected and tired. She said that she slept great the night before. Attributed the way she was feeling to the shot or maybe working. She said that she felt like she was getting the flu. She felt like she was hit by a bus. She said that the throat pain was throwing her though. It was throat pain right side. The throat pain was up to her ears. She said

that she was taking 1 gram Tylenol every 6 hours with a lot of water. She stated her mouth was a little red. She said that it was like a thrushy feeling like when you take antibiotics. It was that kind of sensation. She said that she almost felt like a chest cold was coming on in her chest. She had no shortness of breath, just an awareness when you get a chest cold. She used to get bronchitis all of the time. She said that she was speaking to a friend from work and a girl that she works with tested positive on a random swab for COVID-19. Caller said that the girl was asymptomatic and she did not receive the vaccine.

vertigo; dizziness; nausea; This is a spontaneous report from a contactable physician. A 41-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), intramuscular, on 21Dec2020 at 10:00 AM at single dose for COVID-19 immunisation. Vaccine location was left arm. The patient was vaccinated at hospital, age at vaccination was 41-years-old. Medical history and concomitant medications were unknown. On 22Dec2020 at 12:30 PM, the patient experienced abrupt onset vertigo, dizziness nausea - self resolved but then second wave of similar symptoms also self resolved. Th events were reported as non-serious. No treatment was received for the events. Information on the lot/batch number has been requested.

Headache over the front of the head; This is a spontaneous report from a contactable unspecified healthcare professional reporting for herself. This 60-year-old female patient received on 22Dec2020 11:15 first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot EH9899) at single dose intramuscular in the right arm for COVID-19 immunization. Medical history and concomitant medications were not reported. She denied any history of previous adverse reactions to vaccines. On 22Dec2020, during her 15 minutes waiting period after the injection, the patient began to experience headache over the front of the head. The event required an emergency room visit. Outcome was unknown. Neurogical examination was positive on an unknown date. No follow-up attempts are possible. No further information is expected.

Headache; This is a spontaneous report from a contactable nurse. A 38-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, lot number: EK5730), via an unspecified route of administration the right arm on 22Dec2020 12:30 at a single dose for COVID-19 immunisation. Medical history was not reported. Concomitant medications included amfetamine aspartate, amfetamine sulfate, dexamfetamine saccharate, dexamfetamine sulfate (ADDERALL). The patient experienced headache on 22Dec2020 14:30. No therapeutic measure was taken as a result of the event. Clinical outcome of the event was recovered on an unspecified date.

slight nasal congestion; This is a spontaneous report from a contactable other healthcare professional (patient). A 53-year-old male patient received 1st dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot# EJI685), intramuscularly in left arm on 22Dec2020 13:45 at single dose for Covid-19 immunisation. The patient's medical history and concomitant medications were not reported. No Covid prior vaccination. No Covid tested post vaccination. No known allergies. The patient experienced slight nasal congestion (non-serious) on 22Dec2020 14:30 with outcome of recovering. No treatment received for the event.

Fever of approx 101 F; body chills; injection site pain; This is a spontaneous report from a contactable unspecified healthcare professional reporting for himself. This 45-year-old male patient received on 21Dec2020 13:00 first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) at single dose in the left arm for COVID-19 immunization. Medical history included allergies to penicillin and sulfa drugs and hypertension. Prior to vaccination, the patient was diagnosed with COVID 19. Concomitant medications were not reported. On 22Dec2020 03:00 am, the patient had fever of approximately 101 F, body chills, injection site pain. No treatment was provided. Outcome was not recovered. Information on the batch number has been requested.

headache; pain in arm; dizziness; This is a spontaneous report from a contactable consumer. A female patient (wife) of unknown age received on 21Dec2020 11:15 BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) at single dose for COVID-19 immunization. Medical history and concomitant medications were not reported. In Dec2020, she reported headache, pain in arm and dizziness. Outcome was unknown. Information on the batch number has been requested.

Severe crushing headache in bilateral temporal lobes; Severe fatigue day after; This is a spontaneous report from a contactable nurse which is also the patient. A 36-year-old non-pregnant female patient received 1st dose of bnt162b2, intramuscular in the left arm on 18Dec2020 12:00 at a single dose for COVID-19 immunization at the hospital. Medical history included polycystic ovaries (PCOS), anxiety, depression and attention deficit hyperactivity disorder (ADHD). The patient has no known allergies. Concomitant medications included amfetamine aspartate, amfetamine sulfate, dexamfetamine saccharate, dexamfetamine sulfate (ADDERALL), bupropion hydrochloride (WELLBUTRIN), and escitalopram oxalate (LEXAPRO). It was reported that the morning after vaccine, 19Dec2020 08:00, the patient awoke with severe crushing headache in bilateral temporal lobes that resolved in a couple hours with acetaminophen (TYLENOL) and rest. The patient also had severe fatigue day after. Added that there's also fatigue on 2nd day after vaccine but much more mild than 1st day. All symptoms resolved at 48hrs. The patient was not diagnosed with COVID-19 prior to vaccination and since the vaccination. The events were assessed as non-serious. Therapeutic measures were given for the events. Outcome of the events was recovered in Dec2020 after 48hrs. Information on the lot/batch number has been requested.

Tingling in lower arm and hand that lasted from time of vaccine until the following morning.; This is a spontaneous report from a non-contactable other health care professional. A 30-year-old female patient received bnt162b2 (BNT162B2), via an unspecified route of administration on 20Dec2020 13:00 at SINGLE DOSE at right arm for COVID 19 immunization. Medical history included allergies: sulfa drugs. The patient's concomitant medications were not reported. On 20Dec2020 13:00, the patient experienced Tingling in lower arm and hand that lasted from time of vaccine until the following morning. The patient did not receive treatment. No COVID prior vaccination. The patient has not been tested for COVID-19 since the vaccination. The event was assessed as non-serious. The outcome of the event was recovered. No follow-up attempts are possible. Information about lot/batch number cannot be obtained.

Injection site pain; headache; body aches; feeling generally unwell; joint pain; This is a spontaneous report from a contactable other-hcp reporting for herself. A 35-years-old non-pregnant female patient

received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number EH 9899), via an unspecified route of administration in the left arm on 21Dec2020 14:00 at single dose for covid-19 immunisation. The patient medical history was not reported. Concomitant medication included celecoxib (CELEXA, 20mg). The patient previously took thimerosal and experienced drug hypersensitivity. The patient experienced injection site pain, headache, body aches, feeling generally unwell and joint pain all on 22Dec2020 03:00 with outcome of recovering. No treatment was performed. The patient did not have COVID prior to vaccination nor COVID test post vaccination.

"Strange brain fog; forgotten her medications at home, she forgot to do something with her dogs that she usually does; was pretty sure she forgot to brush her teeth; Right arm soreness; This is a spontaneous report from a contactable nurse (patient). A 31-year-old female patient received 1st dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot# EJ1685), intramuscularly in right arm on 18Dec2020 11:00 at single dose for Covid-19 immunisation. Medical history included ulcerative colitis from 2018 and ongoing, birth control from 2018 and ongoing, seasonal allergies from an unknown date and unknown if ongoing, multivitamin (supplementation therapy) from an unknown date and unknown if ongoing. Concomitant medication included HPV vaccine on 11Dec2020, mesalazine (LIALDA, exp: 29Sep2021, Manufacturer: Zydus) from 2018 and ongoing for ulcerative colitis, cetirizine hydrochloride (WAL ZYR, exp: Dec2021, NDC: 0363049547) from 2018 and ongoing for seasonal allergies, probiotics (lot# 20540N0, exp: Apr2022, Company: Seed.) from 2018 and ongoing, fluticasone propionate (Nasal spray, strength: 50 ug, lot# RR7350, exp: Apr2022) from 2018 and onoging for seasonal allergies, ascorbic acid, biotin, calcium pantothenate, calcium phosphate dibasic, colecalciferol, cupric oxide, cyanocobalamin, ferrous fumarate, folic acid, manganese sulfate, nicotinamide, phytomenadione, potassium iodide, pyridoxine hydrochloride, retinol acetate, riboflavin, selenium, thiamine mononitrate, tocopheryl acetate, zinc oxide (FORVIA, tablet, lot# B0115, exp: May2023, UPC: 835134000202) from 2018 and ongoing for multivitamin, ethinylestradiol, ferrous fumarate, norethisterone acetate (LO LOESTRIN FE, exp: Nov2021, barcode:04300420149) from 2018 and ongoing for birth control, and turmeric (exp: Feb2023, barcode #:074312803673) at 1000 mg daily from 2018 and ongoing. The patient previously received tetanus vaccine 10 years ago. The patient experienced right arm soreness on 18Dec2020,""strange brain fog"" on 21Dec2020, she was not sure if it was a reaction to the vaccine, because it was not in the packet that it has been reported; but she wanted to ask if brain fog had been reported. She further described that the brain fog included having forgotten her medications at home, having had a really weird day, she forgot to do something with her dogs that she usually does; was pretty sure she forgot to brush her teeth; and she had a needle stick at work with Heparin after administration of Heparin to patient (little mark on her left middle finger from the needle stick). She had already given the patient the Heparin, then the needle stick to her left middle finger happened after dose to patient was administered the full dose on 21Dec2020. She did not think there was any Heparin left when she got the needle stick; if so it was very very small amount. She washed the needle stick site out really vigorously for 5 minutes, wrapped the site, it was not bleeding or anything; She reported having recovered completely from this event probably 21Dec2020; but clarified that the only lasting effect she has had from this event was since yesterday there is a little mark on her left middle finger from the needle stick; but there is no pain, no swelling and no redness. The hospital drew her blood and the Heparin patient's blood 21Dec2020. She did not notice any of the brain fog or related events on

20Dec2020, not until onset on 21Dec2020. She did not know if these brain fog related events were a side effect of the COVID-19 Vaccine. She felt fine otherwise. She knew that the actual COVID-19 virus had brain fog. She received the tetanus vaccine 10 years ago. The patient received the HPV vaccine a week before the COVID one. She planned on getting the second dose as scheduled, no changes made. Brain fog: She thought she recovered completely by about 21Dec2020. It was better. She had not really done much as of report date. Forgotten her medications at home: These medications were her concomitant products. The outcome of right arm soreness was recovered on 20Dec2020, the other events was recovered on 21Dec2020."

Nausea and diarrhea; Nausea and diarrhea; This is a spontaneous report from a contactable nurse (patient). A 36-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 19Dec2020 at 08:45am at single dose in left arm for COVID-19 immunization. No known allergy to medications, food or other products. Concomitant medications included Multivitamin (unspecified) received within 2 weeks of vaccination. On 21Dec2020 at 02:00 am the patient experienced nausea and diarrhea. Patient was treated with unspecified medication.The outcome of the events was recovering. Information about lot/batch number are requested.

positive test to the COVID-19 infection; This is a spontaneous report from a contactable Other HCP reporting for herself. A 35-years-old female patient received bnt162b2 (BNT162B2; Lot# EL0140) vaccine , via an unspecified route of administration in the left upper arm on 21Dec2020 at single dose for covid-19 immunisation . The patient medical history and concomitant medications were not reported. The patient resulted positive to the test to the Covid-19 infection on the same day she got the vaccine 21Dec2020 with outcome of unknown. The patient was wondering if her symptoms could worsened and if she could receive the second shot as scheduled.

have a really bad headache; This is a spontaneous report from a contactable consumer (patient). A 22-year-old female patient received the first dose BNT162B2 (Pfizer-BioNTech COVID-19 Vaccine, Batch/lot number: EL1284), via an unspecified route of administration on 21Dec2020 at single dose for covid-19 immunization. Medical history included GERD (Gastrooesophageal reflux disease), obsessive-compulsive disorder. Concomitant medication included omeprazole at 40 mg for GERD, fluoxetine at 40 mg for obsessive-compulsive disorder. The patient had a really bad headache in Dec2020. The reporter stated she was a 22 years old pharmacy intern working in a hospital. She received the covid vaccine yesterday (21Dec2020) and she had a really bad headache. The patient further described this as a 'very, very bad headache.' The patient didn't receive treatment for headache. She was wondering if she could take Tylenol for headache. The outcome was unknown.

COVID-19 confirmed by positive COVID-19 test; COVID-19 confirmed by positive COVID-19 test; This is a spontaneous report from a contactable other health professional (reported for himself). A 30-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899), via an unspecified route of administration on 17Dec2020 10:00 at single dose on left arm for COVID-19 immunization. Medical history known allergies: PCN (Penicillin). The patient's concomitant medications were not reported. The most recent COVID-19 vaccine was administered at Hospital. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to

vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has been tested for COVID-19 via Nasal Swab and the test name was PCR with the result of positive on 22Dec2020 (12:00). This wasn't really an adverse event but the reporter thought it may be useful for studies taking place. On 22Dec2020 12:00 PM, the patient was diagnosed with COVID-19 5 days after vaccination and was currently self-isolating. The adverse event result in Emergency room/department or urgent care. No treatment was received for the adverse events. The events were considered as non-serious by the reporter. The outcome of the events was recovering.; Sender's Comments: Based on the current available information and the consistency with the known safety profile of the suspect product BNT162B2, a possible contributory role of the suspect product to the development of Drug ineffective and COVID-19 cannot be excluded.

substantial back pain in her mid back and spine; substantial back pain in her mid back and spine; This is a spontaneous report from a non-contactable Nurse (patient). A female patient of an unspecified age received bnt162b2 (BNT162B2) at single dose on 21Dec2020 for immunisation. The patient medical history and concomitant medications were not reported. The patient experienced substantial back pain in her mid back and spine on an unspecified date. The outcome of events was unknown. No follow up attempts are possible; information about lot/batch number cannot be obtained.

Severe headache; This is a spontaneous report from a contactable pharmacist, who is also the patient. This 37-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number EK 5730; expiration date Mar2021) intramuscular in the left arm on 21Dec2020 at 17:30 at the age of 37 years at single dose for COVID-19 immunisation. Vaccination facility type was hospital. Relevant medical history included Major Depressive Disorder (MDD), anxiety and foramen ovale patent. Concomitant medications were not reported. Past drug history included allergy with sulfamethoxazole/trimethoprim (BACTRIM) and aripiprazole (ABILIFY). On 22Dec2020 at 06:00, the patient experienced severe headache resistant to butalbital/caffeine/paracetamol (FIORICET) and ibuprofen, which were taken as treatments. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, she had not been tested for COVID-19. The patient was recovering from the event.

Diarrhea; Body ache; Spike fever of 99; not a low grade fever; Headache; This is a spontaneous report from a contactable consumer (patient). A 58-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EH9899), via an unspecified route of administration on 18Dec2020 at single dose for immunization. When probed for the due date for the next shot, consumer stated it was on 08Jan2021. Medical history included anxiety, acid reflux and eyes just not really great. Concomitant medication included topiramate (TOPAMAX) at 25 mg, daily for weight loss, fluoxetine for anxiety, omeprazole (PRILOSEC) for acid reflux. The patient experienced body aches, spikes fever of 99, it was not a low grade fever, headache on 18Dec2020, and diarrhea on 19Dec2020. Patient received acetylsalicylic acid (EQUATE, lot number: think it was 0B3076C, Expiry Date of Equate: Dec2022, NDC# 4903552378) for events body aches and the headache and the spike fever. It's Equate pain reliever, a (Company name) brand and it was 325 mg. Outcome of events body ache and headache was not recovered, and outcome of other events was unknown.

Nausea; Chills; This is a spontaneous report from a contactable consumer via a Pfizer-sponsored program,. A female patient of an unspecified age received bnt162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), via an unspecified route of administration on 19Dec2020 at a single dose for COVID-19 immunisation. Medical history and concomitant medications were not reported. The patient experienced nausea and chills on an unspecified date. Clinical outcome of the events was unknown. Information about lot/batch number has been requested.

she is better but still not good; not to be able to breath; sore right arm; This is a spontaneous report from a contactable nurse (patient herself). A 62-year-old female patient received bnt162b2 (BNT162B2, lot EK5730), intramuscular on 18Dec2020 at single dose for immunisation. Medical history included asthma (hospitalized on Jan2020 and has not had any issues since that time, referring to her asthma) diabetes, high blood pressure, swelling, sciatica, blood cholesterol abnormal, rosacea, reflux, allergies, sinus congestion, shingles and post carpal tunnel surgery. Concomitant medications included lisinopril, hydrochlorothiazide, gabapentin, rosuvastatin, metformin, glipizide, doxycycline, sucralfate, cetirizine hydrochloride (ZYRTEC), pseudoephedrine, ascorbic acid, ergocalciferol, nicotinamide, retinol, riboflavin, thiamine hydrochloride (VITAMINS) and tramadol. The patient reported that she not to be able to breath (seriousness criteria-life threatening) on 22Dec2020. She woke up this morning and could not breathe and there was no reason for her to not be able to breath. She thought she may have had a reaction to the COVID vaccine. It was the only thing she could think of that might have caused her not to be able to breathe this morning. As treatment for not to be able to breath, she used Budesonide and Levosalbutamol in her nebulizer. She had sore right arm on 18Dec2020. She informed that she had done everything she can and she was better but still not good. She planned to take the second dose of the COVID Vaccine because she thought it was more important to be protected. She suspected that the vaccine was related to the events sore right arm and could not breathe. The outcome of the event not to be able to breath was recovering; for sore right arm was recovered on unknown date in Dec2020; for she is better but still not good was unknown.; Sender's Comments: Severe allergic reaction including anaphylaxis is the known risk factor; a possible causal association between administration of BNT162B2 and the onset of not being able to breath cannot be excluded, considering the plausible temporal relationship and the known adverse event profile of the suspect product. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Headache; pain in her arm; Dizziness; This is a spontaneous report from a contactable consumer (patient's husband). A 45-year-old female patient started to receive bnt162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, lot number: N9899, expiry date: 01Jan2021), via an unspecified route of administration on the right arm on 21Dec2020 at a single dose for COVID-19 immunisation. Medical history included ongoing high blood pressure. Concomitant medication included ongoing alprazolam for high blood pressure. On 22Dec2020, the patient experienced headache, pain in her arm and dizziness. Clinical outcome of the events was not recovered.

positive COVID-19 test with symptoms; positive COVID-19 test with symptoms; Soreness at injection site; This is a spontaneous report from a contactable nurse (patient). A 40-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 18Dec2020 17:30 in the left arm at single dose for COVID-19 immunization. There was no medical history or concomitant medications. The patient experienced soreness at injection site, cough, body aches on 19Dec2020; sore throat, voice changes from coughing on 20Dec2020; tested positive for covid on 21Dec2020; mild low congestion, loss of taste and smell on 22Dec2020. The nurse stated that he got the vaccine on Friday (18Dec2020). The next day (19Dec2020) he had common side effects: Soreness at the injection site and body aches, which were expected. He also had a cough on top of that, which progressed to the next day. His body aches and coughing were infrequent. The afternoon of Sunday (20Dec2020), he developed sore throat. Yesterday(21Dec2020), he said he could not work because he was still coughing and had a sore throat. His voice was also changing due to the coughing. He was getting better now. The doctor from Employee Heath said that the cough was concerning so he got a COVID swab test yesterday(21Dec2020), and today (22Dec2020) it came back positive. This morning (22Dec2020) he had loss of taste and smell. He no longer had sore throat or cough. He had the vaccine before the test. He wanted to know where they were at with information on this. Was this being monitored? How did this happen? Was it possible that the test was a false positive because he had the vaccine prior? He would like someone to give him an answer, if the test was a false positive due to the vaccine? His doctor could not tell if the test was legit a positive because of the vaccine. He was not able to work right now. He did not even know if the COVID was from the vaccine or not. Will he get compensation for this? Will his workplace cover his absences? In the case he went to the hospital, will this be considered a work related or vaccine related issue? The outcome of event soreness at injection site was recovered on 21Dec2020. The outcome of event tested positive for COVID was not recovered. The nurse considered the cough was disabling as this was not part of the symptoms to watch for after getting the vaccine. All of the symptoms currently besides the cough are not serious as of now, but it has put him out of work. The nurse considered all other events as non-serious except for cough (disabling). Information on the lot/batch number has been requested.; Sender's Comments: Based on the information currently available, a lack of efficacy with BNT162B2 in this patient might not be completely excluded.

hands were tingly and both hands were tingly; lips got numb; both hands were tingly and kind of numb feeling; both hands were tingly and kind of numb feeling and then became itchy; This is a spontaneous report from a contactable nurse (patient). A 58-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot/batch number and expiry date unknown), via an unspecified route of administration on 18Dec2020 17:13 at single dose for covid-19 immunization. Patient history was no. There were no concomitant medications. The patient didn't notice anything until the Saturday on 19Dec2020, at about the same time at 24 hours later, it was noticed that hands were tingly and both hands were tingly and kind of numb feeling and then became itchy and lips got numb during that time frame, the patient just took anti-histamines, only one dose Loratadine on 20Dec2020. Issue still persisting, it's not as bad on 21Dec2020 but it still as numb, fingers were especially numb. The outcome of the events was not recovered. No investigation assessment. When asking the causality, the patient

said it was fine until, that's what she was presuming, the Covid shot. Information on Lot/Batch number has been requested.

Severe headache; photophobia; eye pain; myalgia; diarrhea; skin sensitivity; lesions and blisters around mouth and lips, oral lesions; lesions and blisters around mouth and lips, oral lesions/intra-oral lesions/Buccal lesion; inflammation; pharyngitis; lymph node inflammation in neck; BL earache; nausea; diaphoresis; fatigue; This is a spontaneous report from a contactable consumer (patient). A 50-years-old female patient received first dose of BNT162B2 (Lot# EH9899), via an unspecified route of administration, in right arm, on 18Dec2020 15:00 at single dose for COVID -19 immunization. The patient was not pregnant at the time of vaccination. Facility where the most recent COVID-19 vaccine was administered was workplace clinic. Medical history was none, good health. No allergies to medications, food, or other products. Prior to vaccination, patient was not diagnosed with COVID-19. Since the vaccination, patient had not been tested for COVID-19. No other vaccines was received within 4 weeks prior to the COVID vaccine. The other medication that the patient received within 2 weeks of vaccination was amfetamine aspartate, amfetamine sulfate, dexamfetamine saccharate, dexamfetamine sulfate (ADDERALL) at 30 mg orally daily. The patient experienced severe headache, photophobia and eye pain, myalgia, diarrhea, skin sensitivity, lesions and blisters around mouth and lips, oral lesions and inflammation, intra-oral lesions, buccal lesions, pharyngitis, lymph node inflammation in neck, BL earache, nausea, diaphoresis, fatigue, all on 19Dec2020 05:00 AM. The events were reported as non-serious. No treatment was received for the events. The outcome of the events was recovering.

Hives all over his body, on his tummy, his legs, his wrist; did a cold compress, it seemed to work but it came back again; This is a spontaneous report from a contactable consumer (patient's wife). A 47-year-old male patient received BNT162B2 (Lot# EK5730), via an unspecified route of administration on an unspecified date at single dose for COVID -19 immunization. Medical history included type 1 diabetic, blood pressure high and cholesterol. Concomitant medication included insulin. The patient got the vaccine on Friday. On 21Dec2020, the patient had hives all over his body, on his tummy, his legs, his wrist. He started getting it at midnight and the reporter wondering do she need to take him in or can she just give him Benadryl. she was looking at the documents trying to find a number to call. He got the COVID Vaccine on Friday and no trouble till this morning, now at midnight. The treatment included he did a cold compress on it, it seemed to work but it came back again. It's still the same. Cold compress last night or this morning, it seemed to help. The outcome of the event was not recovered.

"Soreness at the site for the first 24 hours; Swelling underneath my right arm; Inflammatory response or immune response from the vaccine; Right breast had swollen areas in it almost being at lymph nodes; Right breast had swollen areas in it almost being at lymph nodes; Around nipple was very swollen and had about three knots; This is a spontaneous report from a contactable Nurse (patient). A 34-year-old female patient received first dose of BNT162B2 (lot number not provided), via an unspecified route of administration on an unspecified date at single dose for COVID -19 immunization. Medical history and concomitant medication were reported as none. The nurse stated she had received the first dose of the Pfizer Covid Vaccine on Thursday. It didn't really had anything other than some soreness at the site for the first 24 hours but on the Saturday, she started noticing a bit of swelling like underneath her right arm. She didn't think anything of like that was probably just the inflammatory response or immune

response from the vaccine. So, she thought it was all a normal side effect. The next morning, next Sunday morning, she woke up and her right breast had swollen areas in it almost being at lymph nodes and that's kind of where she just thought - Okay the breasts have lymph drainage and vessels and all these things. And she could palpate it like from her arm pits, she could palpate and can find out another one that was the area but it was around her nipple that was the concern because it was very swollen and had about three knots and again she was like probably it's just the lymph nodes. She reported ""But they wanted us to report anything. You are at Hospital, like little health area and I was told that you need to call Pfizer too. I am saying that is something out of the ordinary because I am like they are not ordinary, they are in the breast area. don't want to call it as nothing, it might be something else as it is kind of hard to tell if it related to the vaccine or is it not or something I need to talk to my OB-GYN about. I didn't know if that was something else did anybody else is experiencing"". The event onset date was unspecified. The treatment of the events included Motrin. The outcome of the events was unknown. Information on the Batch/Lot number has been requested."

Severe headache; headache was very bad; it was so much that I am scared to take the second dose; Muscle pain; joint pain; This is a spontaneous report from a contactable nurse (patient). A 55-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EK5730, Expiry Date: 31Mar2021) via an unspecified route of administration on 18Dec2020 at single dose to prevent Covid 19, to get antibodies; folic acid via an unspecified route of administration from an unspecified date at 1 mg, daily for Thalassaemia minor; levothyroxine sodium via an unspecified route of administration from an unspecified date at 50 mg, daily for an unspecified indication; zinc oxide via an unspecified route of administration from an unspecified date at 50 mg, daily for an unspecified indication; nifedipine (NIFEDIPINE XL) via an unspecified route of administration from an unspecified date at 60 mg, daily for blood pressure high; valsartan via an unspecified route of administration from an unspecified date at 80 mg, daily (one morning one in the evening) for blood pressure high; paroxetine via an unspecified route of administration from an unspecified date at 10 mg, daily for an unspecified indication; cyanocobalamin (VIT B12) via an unspecified route of administration from an unspecified date at 1000 mg, daily for an unspecified indication; ascorbic acid (VIT C) via an unspecified route of administration from an unspecified date at 1000 daily for an unspecified indication; acetylsalicylic acid (ASPIRIN) via an unspecified route of administration from an unspecified date at 81 mg (once in week or every other day) for an unspecified indication. Medical history included hyperthyroidism; anxiety; Thalassaemia minor; Blood pressure high; patient was diagnosed with Covid-19 earlier, she stated she was a survivor, she recovered on 06Apr2020, she was sick on 21Mar2020 and she was ruled out positive on 25Mar2020 when they bought out the test first time, she said she might have been positive before but they did not have the test. The patient's concomitant medications were not reported. Patient stated she took the vaccination (Pfizer Covid 19 vaccine) in the hospital, she worked there she was a nurse, and she got the side effect, she got severe headache. She had headache but her mistake she did not take Tylenol that time but it got eased after may be 5 hours but the problem was (statement incomplete), and then she started having muscle pain, joint pain and that was okay but headache was very bad, out of all this. Her question was she was a survivor Covid-19 but this one took on her, the headache and she was on blood pressure medications too (further not appropriately paraphrased and clarified hence captured as unspecified medications) so she didn't know what were the ingredients which caused her

such a severe headache. So now her question was that was it okay for her to take the second dose after 3 weeks. The start date of headache was not even half an hour within 15 minutes of taking vaccine. For headache, patient was okay now, that time it was so much that she was scared to take the second dose, the booster dose, so that was why she want to check with them that it was okay or not because she had severe headache. After 5 hour it was improved without taking anything, it subsided on it's on. No treatment received. The action taken in response to the events for folic acid, levothyroxine sodium, zinc oxide was unknown. The outcome of the event Headache was recovered on 18Dec2020, of the other events was recovering. Pfizer is a marketing authorization holder of [folic acid, levothyroxine sodium, zinc oxide] in the country of incidence or the country where the product was purchased (if different). This may be a duplicate report if another marketing authorization holder of [folic acid, levothyroxine sodium, zinc oxide] has submitted the same report to the regulatory authorities.

Fever; injection site mild pain; This is a spontaneous report from a non-contactable other healthcare professional (patient) via a Pfizer sales representative. A 51-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number and expiration date were not reported), via an unspecified route of administration on an unspecified date at a single dose for covid-19 immunization. There were no medical history. Concomitant medications were not reported. The patient experienced fever and injection site mild pain on an unspecified date. Outcome of the events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

rash; This is a spontaneous report from a Pfizer-sponsored program IBCC (Inbound Call Center for HCPs). A contactable consumer (patient) reported that a 64-years-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number EJ1685) , via an unspecified route of administration on 20Dec2020 at single dose for covid-19 immunisation . Medical history reported as none. There were no concomitant medications. The patient experienced rash on 20Dec2020 about an hour after receiving the vaccine. The patient did put some lotion on rash. The outcome of event was not recovered.

headache; soreness on injection site; hives; This is a spontaneous report from a contactable nurse (patient). A 47-year-old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number: EK5730), intramuscular on the left arm on 20Dec2020 10:30 at a single dose for covid-19 immunization. The patient's medical history included chronic cough, post nasal drip, asthma, sinusitis, and allergies to sulfa. The patient was not pregnant. Concomitant medications included levocetirizine dihydrochloride (XYZAL), amoxicillin, clavulanic acid (AUGMENTIN), omeprazole (PROTONIX), fluticasone propionate, salmeterol xinafoate (ADVAIR), budesonide (PULMICORT), albuterol [salbutamol] (ALBUTEROL [SALBUTAMOL]), and guaifenesin. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. On 20Dec2020 16:00, the patient experienced headache, soreness on injection site, hives started on the day of injection in the afternoon until current day. The patient underwent lab tests and procedures which included COVID-19 Nasal Swab was negative on 13Nov2020. The patient was not diagnosed with COVID-19 prior to vaccination and had been tested for COVID-19 on Dec2020 since the vaccination. No treatment was received for the adverse events. Outcome of the events was recovering. The events was considered non-serious.

coughing; chills; cold; This is a spontaneous report from a contactable consumer (patient). A 76-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), lot EJ1685, Expiration Date 31Mar2021, via unspecified route of administration, on unspecified date, at single dose for COVID-19 immunization. The patient medical history included blood pressure high. Concomitant medications included unspecified medication for high blood pressure. The patient experienced coughing, chills, and cold on 20Dec2020. The events were non serious. The outcome of the event coughing was unknown. The outcome of the events chills, and cold was not resolved.

"muscle soreness; This is a spontaneous report from a contactable physician. A male patient of an unspecified age (age: 43; Unit: unknown) received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 16Dec2020 at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient had muscle soreness for about 24 hours after the shot. The patient stated, ""I received the Pfizer vaccine on 16Dec at my hospital, (Institute Name Withheld). I think our hospital management wanted to first vaccinate some key clinicians who felt very comfortable with it - I personally wanted it as soon as possible since I see patients with COVID-19 every day. Twelve hours before I received the vaccine, I took information survey and signed the consent form. At my appointment, I was asked to confirm that I was feeling OK, was given the injection, and then waited about 15 minutes to make sure I didn't experience any side effects. I had a little muscle soreness, sort of like a punch to the arm, for about 24 hours. Other than a little muscle soreness that felt similar to a punch, I felt perfectly fine. The hospital administrator said they'd be in touch to schedule the second dose, which will be within a 96-hour window about three weeks later. I believe the science behind this type of vaccine - the messenger RNA platform - is strong. Understanding the basic science of it, I have very few concerns about the efficacy of the vaccine or the long-term complications. As a mechanism, there is no live COVID -19 virus in the vaccine: It's just giving you the code for spike protein so that your immune system will be able to make antibodies. To me, it's an even safer platform than many previous types of vaccines. Many infectious diseases are managed through vaccines. Infectious diseases that we don't think of as being a big issue anymore, like polio, even chickenpox, have been all but wiped out in the US thanks to vaccines that most people now get as babies. One or two people are not going to stop the COVID-19 pandemic. It's really when we get a good majority of the population fully vaccinated that we'll start to see a major effect. Until then, I plan to still wear my face mask, practice social distancing, and observe safety and sanitary precautions. The outcome of the event was unknown. Information on the lot/batch number has been requested."

Fatigue; Dizziness; Tachycardia/heart rate is 115 laying down and her heart rate is 123 walking around; patient may be having an allergic reaction; This is a spontaneous report from a contactable other healthcare professional (hcp). A 31-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 Vaccine, lot number: EL0140, NDC number: 59267-1000-1, Expiry Date: 31Mar2021), via intramuscular on 21Dec2020 09:15 at 0.3 mL, single (0.3ml intramuscular injection in arm) for preventative (COVID-19 immunization). There were no medical history or concomitant medications. The patient did not receive any other vaccines prior vaccinations (within 4 weeks) or on the same date. The reporter worried the patient may be having an allergic reaction. The patient experienced dizziness, tachycardia, and fatigue, all on 21Dec2020, started about 45 minutes after receiving the injection

around 10:00 am. The patient's heart rate is 115 laying down and her heart rate is 123 walking around on 21Dec2020. It is not life threatening and is kind of minor. The patient does get motion sickness easily. The reporter also received an injection from the same lot number. The patient she was reporting on is the only patient she has had that had an adverse reaction. There had not been any issues with any of her other patients. Treatment: The patient took Advil pm last night and it did not help, states Advil PM has benadryl in it. States it did not help. The outcome of events was not recovered. The causality between events dizziness, fatigue, tachycardia and BNT162B2 is considered related by Primary Source Reporter per Global Introspection.

hives all over her body; Itching; This is a spontaneous report from a contactable Pharmacist. A 32-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), lot EH9899, Expiration Date Mar2021, via intramuscular route of administration in right arm, on 18Dec2020 15:55, at single dose for COVID-19 immunization. The vaccine was administered at Hospital Facility. The patient medical history and concomitant medications were not reported. The patient experienced hives all over her body and itching on 18Dec2020 at 19:00. The events required visit to Emergency Room. The patient was treated with Benadryl PO and Prednisone 60mg PO. The patient did not have any respiratory distress or anything. They said this was related to the vaccine. The events were non serious. The outcome of the events was unknown.

tingling in her arm at the injection site; hand turned red; soon after had tingling up and down her entire arm; This is a spontaneous report from a contactable consumer. A 27-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration, on 24Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced tingling in her arm at the injection site, hand turned red, and soon after had tingling up and down her entire arm. Therapeutic measures were taken as a result of the events, which included diphenhydramine hydrochloride (BENADRYL). The clinical outcome of tingling in her arm at the injection site, hand turned red, and tingling up and down her entire arm was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

migraine; This is a spontaneous report from a contactable consumer. An adult female patient (middle-aged) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration in Dec2020, at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced migraine in Dec2020. The patient was not responding to their usual migraine medicines. The clinical outcome of migraine was unknown. No follow-up attempts are possible; information about batch/lot number cannot be obtained.

he felt very achy and tired with a sore arm; he felt very achy and tired with a sore arm; he felt very achy and tired with a sore arm; This is a spontaneous report from a contactable physician (patient) via Pfizer Sales Representative. A male patient of an unspecified age received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) Batch/Lot number unknown, via an unspecified route of administration on 21Dec2020 at single dose for COVID-19 immunisation. The patient medical history and concomitant

medications were not reported. The patient reported he felt very achy and tired with a sore arm on 21Dec2020. The events were non serious and the patient completely recovered from the events on 22Dec2020. Information about batch/lot number has been requested.

Sore left arm at injection site. Pain started 8-10 hours after injection; resolved by 3 days after injection; This is a spontaneous report from a contactable physician (patient). A 49-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Lot EH9899) intramuscular in left arm on 18Dec2020 at 07:45 am at single dose for COVID-19 immunization. Medical history included Cluster headaches, Osteoarthritis of right shoulder and gastrooesophageal reflux disease (GER). No Known allergies to medications, food or other products. Concomitant medication included ascorbic acid (VITAMIN-C), omeprazole and fish oil. The patient experienced sore left arm at injection site on 18Dec2020 at 04:00 pm; pain started 8-10 hours after injection and resolved by 3 days after injection. Patient was treated with ibuprofen and recovered from the event in Dec2020. Case is non serious.

Mild arm soreness; This is a spontaneous report from a contactable physician. A 34-years-old female patient started to the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), lot number: EJ1685, intramuscularly on 22Dec2020 14:00 (at the age of 34-years-old) as a single dose in the left arm for COVID-19 immunization. Medical history included allergies to medications, food, or other products: shellfish from an unknown date and unknown if ongoing. Concomitant medication included clomifene citrate (CLOMID), folic acid (FOLATE). The most recent COVID-19 vaccine was administered in the hospital. It was unknown if the patient was pregnant at the time of vaccination. On 23Dec2020, the patient experienced mild arm soreness. The event mild arm soreness did not result in death, was not life-threatening, did not cause/prolonged hospitalization, was not disabling/incapacitating and did not cause congenital anomaly/birth defect. No treatment was received for the event. Outcome of the event mild arm soreness was recovering. Since the vaccination, the patient has not been tested for COVID-19.

He is sleeping a lot of side effect, I mean all day; This is a spontaneous report from a contactable consumer (patient's wife). A 52-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: AJ1685), via an unspecified route of administration on 17Dec2020 at single dose for covid-19 immunization. Medical history was none. There were no concomitant medications. The patient got his first shot on 17Dec2020 and he was sleeping a lot of side effect, all day. No treatment received and he just slept all day. Due date of next short was 08Jan2021 to 10Jan2021. The outcome of the event was unknown.

throat tightness; sore throat; This is a spontaneous report from a contactable consumer (patient herself). A 61-year-old female patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration in Dec2020 at single dose for immunization. The patient's medical history and concomitant medications were not reported. The patient reported that 4 hours later she started to have throat tightness that lasted through the night. Caller reported during the call that the tightness was no longer present but she now had a sore throat. Outcome of event throat tightness was recovered in Dec2020, and outcome of event sore throat was unknown. Information on the lot/batch number has been requested.

"basically thought she had COVID all over again; basically thought she had COVID all over again; Pain at the injection site; Joint pain; Feeling unwell; This is a spontaneous report from a contactable physician (patient). A 45-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EK5730), via an unspecified route of administration on an unspecified date in Dec2020 at single dose for COVID-19 immunization. Medical history included COVID a month ago in 2020. There were no concomitant medications. The patient experienced pain at the injection site, headache, myalgia, joint pain, chills, nausea, feeling unwell, fatigue in Dec2020. The patient basically thought she had COVID all over again. The patient stated, ""I was calling because I just had the COVID vaccine which has caused so many adverse reactions which is the side effects? I am experiencing all the side effects but it is calming down because today is day three. Pain at the injection site, headache, myalgia, joint pain, fatigue, chills, nausea, feeling unwell. Basically I had COVID a month ago and I had vaccine three days ago (Dec2020) and I basically thought I have COVID all over again. I took the vaccine on Friday started with the symptoms pretty much on Saturday."" The patient received ibuprofen (ADVIL) as treatment. The outcome of events was unknown. The physician assessed events pain at the injection site, headache, myalgia, chills, nausea, feeling unwell, fatigue was related with vaccine.; Sender's Comments: Based on the information currently available, a lack of efficacy with BNT162B2 in this patient cannot be completely excluded."

I have like muscle pain; I am having like chest pain, pain in my chest; This is a spontaneous report from a contactable consumer (patient). A 47-year-old female patient received BNT162B2 (Pfizer-BioNTech COVID-19 Vaccine, lot number EJ1685) on 21Dec2020 for COVID-19 immunization. The patient's medical history included high blood pressure and asthma. Concomitant medications were not reported. On 21Dec2020, the patient reported that she had like muscle pain, and had like chest pain/ pain in her chest. The outcome of the events was unknown.

chronic cough; Itchy welt in the lower of my back, its more like swell; whelps; This is a spontaneous report from a contactable nurse reported for herself. This 66-years-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (Lot number: EJ1685, Expiry Date: 31Mar2021) via an unspecified route of administration at single dose in the right deltoid on 22Dec2020 08:00am for Covid-19 immunisation. Medical history included stage 0 breast cancer, she had a lumpectomy and radiation in 2016, she also just her Zyrtec for her seasonal allergies a few minutes. Concomitant medications were not reported. The patient experienced whelps on 22Dec2020 02:00pm with outcome of not recovered, chronic cough on an unspecified date with outcome of unknown, itchy welt in the lower of my back, its more like swell on an unspecified date with outcome of unknown. The events were described as follows: After getting the vaccine she noticed raised whelps on her lower back. They are about 1-2 cm in length and that was the largest and the smaller ones are about 1/2 a centimeter long. There are 4-5 on her lower back and there is one right around her upper scapula area. She describes them as itchy, red, and raised. She has never had this happen to her before and so she immediately took Benadryl. The patient also reported that she has a chronic cough which has been described as a combination of things. It is an asthma variant cough, she has drainage and a hyper-reactive airway but doesn't not have asthma technically. The vaccine was administered at Hospital Facility. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine.

left arm soreness; extreme fatigue for 4 days; severe headache day 3,4; This is a spontaneous report from a contactable physician, who is also the patient. This 44-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration in the left arm on 18Dec2020 at 07:00 at single dose for COVID-19 immunisation. Vaccination facility type: hospital. Relevant medical history included penicillin allergy. There were no concomitant medications. On 18Dec2020 at 15:00, the patient experienced left arm soreness and extreme fatigue for 4 days and in Dec2020 she experienced severe headache day 3, 4. The patient did not receive corrective treatments. She recovered from the events in Dec2020. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, she had not been tested for COVID-19. No follow-up attempts are possible, information about batch number cannot be obtained.

I had a fever last night; This is a spontaneous report from a contactable consumer (patient). A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), via an unspecified route of administration on 21Dec2020 at a single dose for Covid-19 immunization. The patient's medical history was and concomitant medications were not reported. The patient had the Pfizer vaccine yesterday (on 21Dec2020) and had a fever at night. The patient asked if patient has to quarantine because of that. The outcome of the event was unknown. Information on the lot/ batch number has been requested.

severe headache; This is a spontaneous report from a non-contactable consumer (patient husband). A female patient of an unspecified age received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for immunization. The patient's medical history and concomitant medications were not reported. The patient experienced severe headache on an unspecified date with outcome of unknown. No follow-up attempts are possible, information about lot/batch cannot be obtained.

she woke up this morning with vomiting, loose stool and her chest wall muscles are extremely painful; she woke up this morning with vomiting, loose stool and her chest wall muscles are extremely painful; she woke up this morning with vomiting, loose stool and her chest wall muscles are extremely painful; nausea; This is a spontaneous report from a contactable consumer (patient). A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient wanted to know about her symptoms after receiving the covid 19 vaccine. The patient reported that she woke up this morning (an unspecified date) with vomiting, loose stool and her chest wall muscles were extremely painful, and she wanted advice on what to do about her nausea. The outcome of the events was unknown. Information on the lot/batch number has been requested.

metallic taste in mouth; general malaise; This is a spontaneous report from a contactable other HCP (Nurse anesthetist) reporting for himself. A 42-year-old male patient received bnt162b2 (BNT162B2, Batch/lot # EL0140) at single dose at left deltoid on 21Dec2020 08:30 for immunisation. Medical history and concomitant medications were none. On 22Dec2020 he was feeling just some general malaise that has since improved. On 23Dec2020, he woke up with a metallic taste in his mouth around 6:30 am and it

is persisting. The patient stated he felt fine, he was afebrile, could still smell, went for a 7 mile run, but still had this metallic taste in his mouth. The outcome of malaise was recovering, of metallic taste in mouth was not recovered.

intractable vomiting; This is a spontaneous report from a contactable physician (patient). A 38-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number EK5730), intramuscular on 22Dec2020 at 13:00 at single dose in right deltoid for covid-19 immunization. There were no medical history or concomitant medications. The patient experienced intractable vomiting on 22Dec2020. The reporter was a physician, she received the Covid-19 vaccine on 22Dec2020 at 1:00 pm. At night on 22Dec2020, she started experiencing intractable vomiting, it was less frequent at time reporting, happening every 2-3 hours. The outcome of the event was resolving.

"dry throat; arm feeling sore; This is a spontaneous report from a contactable consumer. This consumer reported similar events for two patients. This is the first of two reports. A 43-year-old female patient received bnt162b2 (BNT162B2; lot number: EH9899), via an unspecified route of administration on 21Dec2020 at SINGLE DOSE for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. On 21Dec2020, it was reported that she had a ""weird very dry throat 3 hours after the vaccine at the same time that my arm started feeling sore."" She also commented that her coworker also had a dry throat 2-3 hours after the shot and thought it was just talking to his student too much. The outcome of the event was unknown.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2020510803 same reporter, suspect drug, event, different patient"

"dry throat; This is a spontaneous report from a contactable consumer. This consumer reported similar events for two patients. This is the second of two reports. A male patient of an unspecified age received bnt162b2 (BNT162B2), via an unspecified route of administration on an unspecified date at SINGLE DOSE for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. On an unspecified date, it was reported that the patient experienced dry throat 2-3 hours after the shot and thought it was just talking to his student too much. The outcome of the event was unknown. Information on the lot/ batch number has been requested.; Sender's Comments: Agree with the reporting consumer, the reported dry throat reported as "" just talking to his student too much"" is considered unrelated to the administration of BNT162B2 for COVID-19 immunization,Linked Report(s) : US-PFIZER INC-2020510790 same reporter, suspect drug, event, different patient"

fatigue; headache; sore throat; feeling crummy; This is a spontaneous report from a contactable physician (patient). A 32-year-old male patient received first dose of BNT162B2, via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced fatigue, headache, sore throat, feeling crummy all on an unspecified date with outcome of unknown. Caller stated that he got the COVID vaccine on Saturday, got fatigue, headache and sore throat, kind of feeling crummy. Wanted to know if this was a side effect of the vaccine. Wanted to know if it was worth getting a test. Wanted to know will the test come up positive due to the vaccine. Wanted to know if he needed to quarantined. Wanted to know if what he got was good. Stated that this was his first dose. Information on lot/batch number has been requested.

chills; body aches; runny nose; This is a spontaneous report from a contactable consumer (patient himself). A male patient of an unspecified age received BNT162B2 (Pfizer-BioNTech COVID-19 vaccine), via an unspecified route of administration on an unspecified date at single dose for covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced chills, body aches and runny nose on an unspecified date. All events were reported as non-serious. Outcome of events were unknown. Information on the lot/batch number has been requested.

Feeling a bit unwell/I am not feeling good; Chills; little weak; Little bit tired; This is a spontaneous report from a contactable consumer (patient herself). A 56-year-old female patient received the first dose of (Pfizer-BioNTech COVID-19 vaccine, lot# EK5730), via an unspecified route of administration on 20Dec2020 at single dose for covid-19 immunization. Medical history included allergy. Consumer stated, she guessed its environmental allergies. Concomitant medication included cetirizine hydrochloride (ZYRTEC) for allergy. Patient had the vaccine on Sunday and was feeling a bit unwell on 22Dec2020. Consumer further stated, because she had the vaccine the first shot on Sunday and today (22Dec2020) she was not feeling good, she was wondering it could be a side effect. When probed for the adverse events, Consumer stated, she was feeling like little bit like chills, little bit tired and a little weak. Consumer stated she got it from work at the hospital. Outcome of events were unknown.

"Developed sore muscle pain after the injection; Little more tired than normal/had to go to bed earlier than usual, around 10-10:30pm instead of midnight to 1am; This is a spontaneous report from a contactable other healthcare professional. A 46-year-old female patient received bnt162b2, via an unspecified route of administration on 21Dec2020 at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. It was asked that if patients develop sore muscle pain at site of injection, did that mean the body was mounting an immune response to the vaccine? The patient developed sore muscle pain after the injection on 21Dec2020, it continued 22Dec2020, but it is gone and better on 23Dec2020. It was also reported that the last few nights, she had been a ""little more tired than normal"". She had to go to bed earlier than usual, around 10-10:30 pm instead of midnight to 1am. The outcome of event tiredness was unknown; of another event was recovered on 23Dec2020. Information on the lot/batch number has been requested. ."

back pain has been getting worse; This is a spontaneous report from a contactable other healthcare professional (patient herself). A female patient of an unspecified age received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 18Dec2020 at single dose for COVID-19 immunization. Medical history included back pain. The patient's concomitant medications were not reported. The patient back pain had been getting worse on 20Dec2020. The outcome of event was unknown. Information on the lot/batch number has been requested.

he felt weakness; fever/100.1 degrees; chills; nausea; tiredness; headache; This is a spontaneous report from a contactable consumer (patient himself). A 25-year-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL0140), via an unspecified route of administration at site of left arm (reported left shoulder) at 11:00 on 22Dec2020 at single dose for COVID-19 immunization. Before vaccination, patient was recently COVID-19 positive by a nasal swab COVID-19 test and had

ended his quarantine period a few days before receiving the COVID-19 vaccine. There were no concomitant medications. After vaccination, he had chills, fever, nausea, tiredness, and headache around 10:00 PM on 22Dec2020, and throughout today, he had been experiencing these side effects. The side effects all hit at once. He felt weakness this morning on 23Dec2020, and then had a severe headache and chills. He had a headache and fever of 100.1 degrees. he had taken a generic dextromethorphan hydrobromide guaifenesin paracetamol pseudoephedrine hydrochloride (DAYQUIL, liqui-gels for his symptoms. and about 30 minutes later, his symptoms dissipated, and he was good for 3 hours until the symptoms came back. The outcome of event 'felt weakness' was unknown, of rest events was not recovered.

sore throat and L ear pain about 22 hours after vaccination; sore throat and L ear pain about 22 hours after vaccination; This is a spontaneous report from a contactable pharmacist. A 48-year-old female patient started to receive BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot# eL1284), intramuscular from 22Dec2020 15:45 to 22Dec2020 15:45, single for COVID-19 immunisation. Medical history was none. The patient's concomitant medications were not reported. Vaccine location was left arm. No other vaccine was received in four weeks. The patient experienced sore throat and left ear pain about 22 hours after vaccination on 23Dec2020 13:30. No treatment was administered. The action taken in response to the events for bnt162b2 was not applicable. The events outcome was unknown.

Muscle aches; Chills; Fever little over 100; This is a spontaneous report from a contactable nurse. A female patient of an unspecified age received bnt162b2 (BNT162B2, lot number and expiry date were not reported), via an unspecified route of administration on Dec2020 at a single dose for immunization. The patient's medical history and concomitant medications were not reported. The patient experienced muscle aches, chills and fever little over 100 on Dec2020 with outcome of unknown. Information on the lot/batch number has been requested.

"metallic taste in my mouth; tongue feels like it's being coated with something; This is a spontaneous report from a contactable consumer reported for himself. This 52-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (Lot number: EL0140), via an unspecified route of administration at single dose on 22Dec2020 for Covid-19 immunisation. Medical history included cholesterol. Concomitant medication included colecalciferol (VITAMIN D [COLECALCIFEROL]). The patient stated, ""I get the vaccine about an hour ago and I didn't see anything stating with the side effects but I have got the metallic taste in my mouth and now my tongue feels like it's being coated with something"" on 22Dec2020 with outcome of unknown. No treatment was performed."

fatigued; disoriented; This is a spontaneous report from a contactable physician (patient) via a Pfizer sales representative. A male patient of an unspecified age received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number and expiration date were not reported), via an unspecified route of administration on Dec2020 at a single dose for covid-19 immunization. The patient's medical history and concomitant medications were not reported. On Dec2020, the patient was fatigued and disoriented for 3 days. He felt fine now. Outcome of the event was recovered on Dec2020. Information on the lot/batch number has been requested.

when they were drawing the needle back out of her arm there was unusual amount of blood that came out; This is a spontaneous report from a Pfizer-sponsored program IBCC (Inbound Call Center for HCPs), by a contactable pharmacist. A male patient of an unspecified age received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration at 0.3 mL, single on 22Dec2020 for Covid-19 immunisation. The patient medical history and concomitant medications were not reported. The patient experienced that when they were drawing the needle back out of her arm there was unusual amount of blood that came out on 22Dec2020 with outcome of unknown. We don't know if we needed to re-dose or revaccinate her since it was unusual amount that came out. Information on the Lot/Batch number has been requested.

Headache; Muscle pain; Chills; This is a spontaneous report from a contactable consumer (healthcare medical assistant) reporting for herself. This 39 years old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot EK5730, expiry date 03Jan2021) on 21Dec2020, at single dose, for COVID-19 immunization. Medical history included thyroid (no other information reported). The patient was exposing herself to patients with COVID, she worked in a health care. Concomitant medication included an unspecified thyroid medication. The patient experienced headache, muscle pain and chills on an unspecified date in Dec2020. The reporter asked if she could take like paracetamol (TYLENOL). Events outcome was unknown.

general body aches; discomfort; This is a spontaneous report from a contactable physician reporting for himself, received via a Pfizer sales representative. This healthy 31-year-old male patient received the first single dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 19Dec2020, for COVID-19 immunization. Medical history and concomitant medications were not reported. On 22Dec2020 the patient experienced general body aches during the day. Aches may have begun a day or two before 22Dec2020. Aches caused discomfort but did not interfere with ability to perform normal tasks / activities. Events outcome was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

her tongue felt a little weird; she got nervous; her arm was really sore; something about her tongue was like feeling lazy or heavy or something like that; she had like a taste of metal, like a lingering taste of metal; she was starting to feel a little weird, overall she was getting weird; This is a spontaneous report from a non-contactable consumer. An approximately 47 years old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on an unspecified date in Dec2020, at single dose, for COVID-19 immunization. Medical history and concomitant medications were not reported. On an unspecified date in Dec2020 the patient experienced her tongue felt a little weird, she got nervous, her arm was really sore, something about her tongue was like feeling lazy or heavy or something like that, she had like a taste of metal, like a lingering taste of metal and she was starting to feel a little weird, she just said overall she was getting weird. Last night, on 21Dec2020, the reporter was speaking to her sister who took the COVID vaccine and she said her tongue felt a little weird and she was starting to feel a little weird and she got nervous and she got up and started walking around just to like clear herself and just to make sure there was nothing going on. She said it took about half an hour, it happened about half an hour but sure went ahead. No treatment was given. Events outcome was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

sinus infection; This is a spontaneous report from a non-contactable consumer. A 52-years-old female patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 17Dec2020 at single dose for covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced sinus infection in Dec2020. The patient wanted to know the efficacy of the covid vaccine after getting the first dose. The outcome of the event was unknown. No follow-up attempts are possible. Information about lot/batch number cannot be obtained. No further information is expected.

anaphylaxis; This is a spontaneous report from a contactable physician reporting on behalf of patient. A patient of unspecified age and gender received single dose of BNT162B2 (batch/lot number and exp date not reported), via an unspecified route of administration on an unspecified date for immunisation. The patient's medical history and concomitant medications were not reported. On an unspecified date, the patient experienced anaphylaxis with a very protracted course requiring an epi dose for 4.5 days and was still in the ICU (date/s unspecified) following administration of the COVID vaccine. The physician would like to use a drop of leftover vaccine from one of the vials to do a future skin test after the patient is stable. They were unsure if they needed permission as this was standard practice in allergy to test afterwards but wanted to check in with the company. The outcome of event was unknown. Information about batch/lot number has been requested.; Sender's Comments: A possible causal association between administration of BNT162B2 and the onset of anaphylaxis cannot be excluded, considering the plausible temporal relationship and the known adverse event profile of the suspect product. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Had a sore arm after receiving Pfizer's Covid 19 vaccine; This is a spontaneous report from contactable consumer received via a sales representative. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient medical history and concomitant medications were not reported. The patient experienced sore arm after receiving Pfizer's COVID-19 VACCINE. The patient outcome of the event was unknown. No follow-up attempts are possible, information about batch number cannot be obtained.

mild injection site soreness; This is a spontaneous report from a contactable nurse received via a Pfizer sales representative. A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 22Dec2020 at single dose for COVID-19 immunization. The patient medical history and concomitant medications were not reported. The patient experienced mild injection site soreness on Dec2020. The patient outcome of the event was unknown. Information about Lot/Batch number has been requested.

Sense of taste is gone; This is a spontaneous report from a contactable nurse reporting for himself. A 49-year-old male patient received the 1st dose of bnt162b2 (BNT162B2, Manufacturer Pfizer-BionTech), via an unspecified route of administration, on 20Dec2020, at single dose, for COVID-19 immunisation.

Medical history included asthma from an unknown date and unknown if ongoing. Concomitant medication included procaterol hydrochloride (PRO-AIR) as needed (inhaler) for asthma. The patient experienced sense of taste is gone on 21Dec2020 with outcome of unknown. The information on the lot/batch number has been requested.

Tongue feel tingly; This is a spontaneous report from a contactable consumer reporting for herself. A 27-year-old female patient received bnt162b2 (BNT162B2) (lot# EK5730), via an unspecified route of administration, on 22Dec2020, at single dose, for COVID-19 immunisation. Medical history and concomitant medications were none. The patient experienced tongue feel tingly on 22Dec2020 1 hour after vaccination with outcome of unknown. Therapeutic measures were taken as a result of the event and included treatment with Tylenol.

Sore throat; Headache; Left arm pain; This is a spontaneous report from a contactable nurse. A 39-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK5730), intramuscular on the left arm on 22Dec2020 18:15 at single dose for COVID-19 immunisation. Medical history included she was COVID positive a few months ago. There were no concomitant medications. The patient previously got flu vaccine in Oct2020 for immunisation. The patient experienced sore throat and headache on 23Dec2020 and left arm pain on 22Dec2020. The outcome of sore throat and headache were recovering and left arm pain was not recovered.

Substantial back pain; This is a spontaneous report from a contactable consumer (the patient) A patient of unspecified age and gender received bnt162b2 (BNT162B2; Lot # EK5730) vaccine , via an unspecified route of administration on 21Dec2020 at single dose for Covid-19 immunisation . The patient medical history and concomitant medications were not reported. The patient experienced substantial back pain on an unspecified date with outcome of unknown.

experienced loss of taste; Cannot taste or smell red wine vinegar or bleach respectively.; This is a spontaneous report from a contactable other healthcare professional. A male patient of an unspecified age received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 20Dec2020 at a single dose for COVID-19 immunization. The patient's medical history includes wears a CPAP (ongoing). Concomitant medications were not reported. The patient received vaccine 20Dec2020 and experienced loss of taste. He wears a CPAP. He went to the doctor on 21Dec2020 and was prescribed amoxicillin. The patient cannot taste or smell red wine vinegar or bleach respectivel. Outcome of the events was unknown. Information on Lot/Batch has been requested.

"threw up about 3 hours ago; fever which started last night; This is a spontaneous report from a contactable other healthcare professional (reporting for herself). A female patient (Age: 22; Units: unknown) received bnt162b2 (also reported as PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiry date were unknown), via an unspecified route of administration on 23Dec2020 11:30 at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient got Covid vaccine yesterday at around 1130 am and had fever which started last night (23Dec2020) and ""threw up"" about 3 hours ago this morning (24Dec2020) and mentioned that it

was just on 1 occasion, but it was a lot. She wanted to know if it's normal. The outcome of the events was unknown. Information on the lot/batch number has been requested."

I had a headache quite severe and arm pain; I had a headache quite severe and arm pain; Dizziness; Hot flashes; This is a spontaneous report from a contactable consumer for herself. A 55-years-old female patient started to receive bnt162b2 (BNT162B2; Lot # EJ1685) vaccine , via an unspecified route of administration on 18Dec2020 at single dose for covid-19 immunisation . The patient medical history was not reported. Concomitant medication included liraglutide (VICTOZA). The patient had a headache quite severe, arm pain, dizziness and hot flashes on 19Dec2020 with outcome of recovered. The patient also stated that everything was fine by Sunday.

fever; This is a spontaneous report from a contactable other health professional received via Medical Information Team. A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 23Dec2020 at 09:00 at single dose for COVID-19 immunization. The patient medical history and concomitant medications were not reported. The patient experienced fever on 23Dec2020. The patient outcome of the event was unknown. Information about Lot/Batch number has been requested.

lymphadenopathy in her cervical area; This is a spontaneous report from a contactable consumer (parent). A female patient of an unspecified age (reported as 59, unit unknown) received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 22Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. It was reported that patient noticed lymphadenopathy in her cervical area yesterday (23Dec2020). Outcome of event was unknown. Follow-up attempts are completed. The following information on the batch number has been requested.

slight fever; cold; This is a spontaneous report from a contactable other health professional received via Medical Information Team. A 24-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 23Dec2020 at single dose for COVID-19 immunization. The patient medical history and concomitant medications were not reported. The patient experienced slight fever and cold on Dec2020. The patient outcome of the events was unknown. Information on the lot/batch number has been requested.

Flushing after an hour of receiving the vaccine; This is a spontaneous report from a contactable consumer (patient). A patient of an unspecified age and gender received BNT162B2 (Pfizer-Biontech Covid-19 Vaccine) on 21Dec2020, at single dose, for COVID-19 immunisation. Relevant medical history and concomitant medications were unknown. On 21Dec2020, the patient experienced flushing after an hour of receiving the vaccine and on 22Dec2020, the episode was lasting quite a bit longer. Clinical outcome of the adverse event was unknown at time of this report. Information on the lot/batch number has been requested.

the injection site is extremely painful; bleed a lot; there was lot of blood, it was more than usual; I could barely move; Rest of the arm feels cold like really cold; This is a spontaneous report from a contactable nurse (patient). This 48-year-old female patient (weight 68.04 kg, height 160 cm) received BNT162B2

(Pfizer-Biontech Covid-19 Vaccine) on 22Dec2020, at single dose, for COVID-19 immunisation. Relevant medical history included asthma and allergy from an unspecified date and ongoing. Concomitant medications were none. On 22Dec2020, the injection site was extremely painful and bleed a lot; there was lot of blood, it was more than usual. She could barely move and rest of the arm felt cold like really cold. Patient put 3 band aids on injection site. Clinical outcome of the events was unknown at time of this report. Information on the lot/batch number has been requested.

Swelling reported around mouth and eyes; Swelling reported around mouth and eyes; rash; This is a spontaneous report from a contactable consumer (patient). A female patient of an unspecified age received bnt162b2 (Pfizer-BIONTECH COVID-19 vaccine), via an unspecified route of administration on 22Dec2020 16:30 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient previously took doxycycline in 2019 and experienced swelling reported around mouth and eyes and rash. On an unspecified date in Dec2020, the patient experienced swelling reported around mouth and eyes and rash. The outcome of the events was unknown. Information on the lot/Batch number has been requested.

"Armpit is swollen; This is a spontaneous report received from a contactable consumer (patient). A 45-year-old male patient (also reported as female, pending clarification) received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number reported as ""It is hard to read this handwriting EIP5730. This one it might be A or K, EK5730"" (clarification pending), expiry date not reported), via an unspecified route of administration in gluteus, on 18Dec2020, at single dose, for COVID-19 immunization. Medical history included sexually transmitted disease (STD). There were no concomitant medications. The patient reported, ""I took vaccine shot (COVIDvaccine) on 18th and I noticed my, yesterday (20Dec2020), my armpit is swollen is like big hill, it is like swollen."" The patient stated, ""Armpits, under my arm is swollen."" The patient underwent lab tests and procedures which included blood work (unspecified date) with unknown results, the patient reported that this was for his STD. The outcome of the event was unknown. Information about lot/batch number has been requested."

body aches and fever; body aches and fever; This is a spontaneous report from a contactable nurse. A patient of unspecified age and gender received bnt162b2 (BNT162B2), via an unspecified route of administration on an unspecified date at SINGLE DOSE for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. On an unspecified date, it was reported that the patient was having body aches and fever. The outcome of the events was unknown. Information on the batch/lot number has been requested.

"ear ringing; This is a spontaneous report from a contactable consumer. A male patient of an unspecified age (age: 63; Unit: unknown) received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 20Dec2020 at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient received vaccine on Sunday 20Dec2020 and indicated experiencing ear ringing started Monday 21Dec2020 that has been persistent. The patient's blood pressure was ""fine"". The outcome of the event was not recovered. Information on lot/batch number has been requested."

I had body hives for 24 hours; This is a spontaneous report from contactable nurse (patient). A female patient of an unspecified age received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 16Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. On an unspecified date in Dec2020, the patient had body hives for 24 hours. The patient recovered from the event on an unspecified date in Dec2020. Information on the lot/Batch number has been requested.

headache; nausea; cough; fatigue; This is a spontaneous report from a contactable nurse. A male patient of an unspecified age received bnt162b2 (BNT162B2, lot number and expiry date were not reported), via an unspecified route of administration on 18Dec2020 at a single dose for immunization. The patient's medical history and patient's concomitant medications were not reported. On 22Dec2020, the patient experienced cough and fatigue. On 23Dec2020, the patient got severe nausea, severe headache that continued through the night. The outcome of the events was recovering. Information on the lot/batch number has been requested.

"sore throat; This is a spontaneous report received from a contactable other healthcare professional (who is also the patient). A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiry date not reported), via an unspecified route of administration, on 21Dec2020, at single dose, for COVID-19 immunization. The patient medical history and concomitant medications were not reported. The patient reported, ""I received my vaccine on Monday the 21st and on Tuesday (22Dec2020) I had a sore throat. I don't see on the fact sheet this as a commonly reported side effect. Should I get tested?"" The outcome of the event was unknown. Information about Lot/Batch number has been requested."

hurts to breathe or move; severe pleuritic pain at the right ribcage; abdominal pain; This is a spontaneous report from a contactable consumer. A female patient of an unspecified age received bnt162b2 (BNT162B2), via an unspecified route of administration on left arm on an unspecified date at SINGLE DOSE for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. She experienced abdominal pain 14 hours after receiving the vaccine (went away after 6 hours). At 26 hours after she experienced severe pleuritic pain at the right ribcage (vaccine was injected on her left arm), saturation is at mid 90s, and it hurts to breathe or move. The outcome of the event abdominal pain was recovered, while unknown for the other events. Information about lot/batch number has been requested.

"flu like symptoms; fever 99.5 this morning; feel weak; fatigue; injection site pain; upper arm pain; breathing heavier now; This is a spontaneous report from a contactable consumer (patient). A 27-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on an unspecified date at a single dose for covid-19 immunization. Medical history included COVID-19 in Jul2020. The patient's concomitant medications were not reported. On 24Dec2020, the patient experienced flu like symptoms, fever 99.5 this morning, feel weak, fatigue, injection site pain, upper arm pain and was breathing heavier. The patient took paracetamol (TYLENOL) for the events injection site pain and upper arm pain. Outcome of the events ""upper arm pain"" and ""injection site pain"" was recovering while the outcome of the events ""flu like symptoms"", ""fever

99.5 this morning"", ""feel weak"", ""fatigue"" and ""breathing heavier"" was unknown. Information on the lot/batch number has been requested."

Sore arm; This is a spontaneous report from a contactable nurse, the patient. A 39-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, lot number El0140), via an unspecified route of administration in the left arm on 23Dec2020 at 19:15 (at the age of 39-years-old) as a single dose for Covid-19 vaccination. Medical history included Fibromyalgia from an unknown date. The patient did not have any allergies to medications, or other products, was allergic to milk. The patient was not pregnant at the time of vaccination. Prior to the vaccination, the patient was not diagnosed with COVID-19. The patient was not tested for COVID-19 post vaccination. The patient's concomitant medications were not reported. The patient did not receive any other vaccines within four weeks prior to the vaccination. On 24Dec2020 at 09:30, the patient experienced sore arm. Therapeutic measures were not taken for the sore arm. The clinical outcome of the event sore arm was recovering.

Swollen painful axillary lymph node, malaise, constant headache, nausea for several days; Swollen painful axillary lymph node, malaise, constant headache, nausea for several days; Swollen painful axillary lymph node, malaise, constant headache, nausea for several days; Swollen painful axillary lymph node, malaise, constant headache, nausea for several days; Swollen painful axillary lymph node, malaise, constant headache, nausea for several days; This is a spontaneous report from a contactable consumer, the patient. A 50-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE) solution for injection in the left arm on 18Dec2020 at 09:00 (at the age of 50-years-old) as a single dose for COVID-19 vaccination. The patient was not pregnant at the time of vaccination. Medical history included celiac disease and hypothyroidism. Concomitant medications included levothyroxine sodium (SYNTHROID) and paroxetine hydrochloride (PAXIL). Past drug history included known allergies: minocycle, tetracycline and acetylsalicylic acid (ASPIRIN). The patient did not receive any other vaccine within 4 weeks prior to the vaccine. Prior to the vaccination, the patient was not diagnosed with COVID-19. On 22Dec2020, the patient experienced swollen painful axillary lymph node, malaise, constant headache, nausea for several days. No treatment was provided for the events swollen painful axillary lymph node, malaise, constant headache, nausea. The outcome of the events swollen painful axillary lymph node, malaise, constant headache, nausea was not recovered. Since the vaccination, the patient has not been tested for COVID-19. The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up.

get hot with a feeling of an elevated heart rate /she also experienced similar reactions to her vaccine; get hot with a feeling of an elevated heart rate/she also experienced similar reactions to her vaccine; This is a spontaneous report from a contactable consumer (nephew of the patient). A female patient of unknown age received BNT162B2 on unknown date at single dose for COVID-19 immunisation. Medical history and concomitant medications were unknown. Approximately 3 to 4 minutes after injection site, the patient started to get hot with a feeling of an elevated heart rate. The action taken with BNT162B2 was not applicable. The outcome of the event swas unknown. Information for Lot/Batch number has been requested.

Diarrhea; Nausea; This is a spontaneous report from a contactable Other health care professional (HCP) (patient). A 20-year-old female patient, not pregnant, received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 23Dec2020 at 06:00 PM at single dose in Right arm for COVID-19 immunization, Lot number: EK9231. Medical history included covid. No known allergy to medications, food or other products. Concomitant medications included amfetamine aspartate, amfetamine sulfate, dexamfetamine saccharate, dexamfetamine sulfate (ADDERALL) and trazodone. On 23Dec2020 patient experienced diarrhea and nausea. Patient received anti diarrheal as treatment. Since the vaccination patient had not been tested for COVID-19. Patient was recovering from the events.

hives all over her arms and legs; This is a spontaneous report from a contactable nurse. A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 21Dec2020 at single dose COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient reported on Monday 21Dec2020 that she got the COVID-19 vaccine. Last night 23Dec2020, she got hives all over her arms and legs. The doctor was thinking of putting her on Prednisone and she wants to check to make sure that won't decrease the effectiveness of the vaccine. It was not provided if a sample of the product was available to be returned, if requested and if packaging was sealed and intact. The outcome of the event was unknown. Information on lot/batch number has been requested.

Right lower quadrant pain; back of throat tight and full and moved to tongue; fullness in ears; some itching and fullness on the right side near the back of her tongue; This is a spontaneous report from a contactable nurse (patient). A 50 years old female patient (weight 81.65 kg and height 173 cm) received BNT162B2 (Pfizer-Biontech covid-19 vaccine, Lot. EL1284) on 22Dec2020, at single dose, for COVID-19 immunisation. Relevant medical history and concomitant medications were none. It was reported that she had no allergies to anything. On 22Dec2020, the patient experienced a sharp pain in her lower right quadrant of her abdomen, then her ears started getting full, then the back of her throat started getting tight and full and moved to her tongue. It was also reported that she started feeling some itching and fullness on the right side near the back of her tongue. Her airway was intact. Nurse clarified that her reaction last night after the vaccination all happened within 12 minutes of receiving the shot. She went to the emergency room for observation and was treated with epi and Benedryl. She went home after a couple of hours. Clinical outcome of the events was recovering at time of this report. The adverse event, right lower quadrant pain, was assessed as serious (medically significant).; Sender's Comments: By close temporal relationship ('within 12 minutes of receiving the shot') and absence of factors which may provide an alternative cause, the company cannot exclude a contributory role of the BNT162B2 administration in the development of the serious event reported as 'sharp pain in her lower right quadrant of her abdomen'. The impacts of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Itching - injection site and left side of body, throat, back and neck Slight soreness off & on - inj site. Sore body, tired, headache

Fatigue x 3 days, SOB x 4 days (history of asthma; used inhaler multiple time daily). Headache - motrin/Tylenol x 7 days. Upset stomach x couple of days. Arm, red swollen, hard, painful with some itching x 1 wek.

Started feeling unwell Monday night and sick by Tuesday night. Extreme fatigue Tuesday AM, nausea & fatigue & headache. By Tuesday night, very sore throat and extreme fatigue. Wednesday very congested, sore throat, swollen and painful lymph nodes. Went to urgent care & swabbed for COVID and strep. Both negative (tests were rapid and PCR). Since Wednesday continuing through today 12-28-20 - congestion, sore throat, coughm, swollen painful lymph nodes, some GI issues, headache, and fatigue. Return to PCP on 12-29-20

- light headedness, headache started later Some itchiness but did not last BP - 118/84 Headache not resolved

itchiness around vaccine 5-10 mins - resolved with cold compress intermittent dizziness (did resolve) + headache (did not resolve) at 15 mins - 60 mins

On December 23rd, around 5:30-6:00 p.m. I received the Moderna COVID-19 Vaccine EUA at the Vaccination Site. I did not have any adverse symptoms until the night of December 24th around 11:30 p.m. It started that night with nausea. I initially thought it was something I had eaten. I went to bed feeling nauseous but fell asleep. I slept through the night, and work up the next morning, December 25th, still nauseous. I did not ever vomit, even though I very much thought I would. As the day progressed, I developed chills and a low-grade fever. This continued through the day. The nausea was terrible! I could not eat anything because the mere thought of food made me feel sicker. I drank very little as well. I also developed flu like symptoms. I could not stand to be touched, as my skin was highly sensitive to touch. (The same feeling you get if you have a bad case of the flu.) I used a cold wet washcloth all day, as I felt hot, but my fever never went over 99.7 degrees. I eventually fell asleep that night, but I was restless. I woke up several times to noises in my home. Each time it felt like my body was trembling or my heart was racing or fluttering, but these episodes did not last long, nor could I tell you for sure that was exactly what it was. I just felt shaky. Each time I fell back asleep. The next morning, December 26th, I awoke, and the nausea was gone, but the chills and the fever were still hanging on. I just felt bad! I used a cold wet washcloth on my forehead, face, and neck all day. I did eat maybe 5-10 dry saltine crackers and drank a glass or two of sprite. As the day progressed, I felt worse!! The nausea came and went all afternoon and into the night. I eventually fell asleep around 10-11:00 p.m. I slept all night. I awoke the next morning, December 27th, initially feeling nauseous again. I made it a point to drink a lot of Gatorade and sprite throughout the day. I found that I felt some better when I sat up but felt worse when I laid down. So, I sat for about an hour on the side of my bed. I eventually got up and walked around my house. I began to feel better and thought I might be able to shower and possibly eat. So, I did? and it was like my body did a 180! I quickly felt so much better. I ate some soup and drank some sprite. I didn?t completely go back to my normal routine, but I did stay up the remainder of the day and did not get sick. The next day, December 28th, I felt like myself again and pretty much went back to my normal routine. The most interesting side effects that I had that are not mentioned in the CDC COVID-19 Vaccine common side effects are: *My feet were ice cold, but they were wet with sweat

(I put on socks to try to warm them up, but it did not help as my socks would get damp thus making my feet colder) *My tongue became coated white (I did not lose my sense of taste or smell) *My skin felt hot to me, even though it was not hot to the touch (I used a cold wet washcloth for 2-3 days straight)

1 hour after vaccination, itchy eyes, swollen lip, tickle/scratchy throat. Went to ED. Took 25mg benadryl. Observed x 5 hours. Symptoms improved.

Headache the evening after , migraine overnight, soreness at the injection site, fatigue the next day, mild myalgia

Dizziness, itching of entire arm for days, migraine and nausea, sore muscles and fatigue for days, sinus pressure and pain, small rash at site

Started with lower back pain in the morning when I woke up. Then my back and hamstring muscles tighten up. All that went away as the day went on. Just a lingering discomfort remained. That night I was awaken by 10/10 dull pain in both my hips. I don?t have arthritis, but I imagine that is what the pain must feel like. That eventually subsided over the course of the night and then the following morning I woke up with a stronger lower back pain and major stiffness in my hamstrings, but the hip pain was gone. Throughout the day the pain would come and go and move up and down my back and along my spine. It was the strongest on the night of the 22 and has since gotten weaker and the tightens in my back and hamstrings has since left. Now I just get random aches throughout my back that come and go during the day. Yesterday, the 27th, I was hiking down a hill and the impact from that caused instant discomfort in my spine, it felt like it was compressing like an accordion. Never had this happen before. After that my back was sore for hours. Today, the 28th, I tried jogging and the spinal discomfort was instantly there. Went about thirty yards before I stopped and my back has been aching down my spine for hours. Also been experiencing a couple mild headaches through the day since the 22nd. This also has fired up the endothelial dysfunction in my heart which causes some strong chest pain throughout the day. I?ve gone back in my heart medication, so hopefully that will fix that issue. I will be contacting my cardiologist in regards to this and seeing if the vaccine can affect that.

Fever, chills, bodyaches

Burning eyes bilateral one hour after injection. Sore throat 4hours after injection.

Hives on neck. Swollen throat. Nausea.

Numbness and tingling all the way from injection site to the pinky and ring fingers foe few days. Nausea since injection off and on.

Fever and body aches. It feels like when I had covid a month and a half ago.

About 24 hours after the vaccine moderate soreness/pain in the area of the injection on the left upper arm. It disappeared 48 later without treatment. Also, 48 hours after the vaccine, a slight pain in the right ear/upper right mandible, especially when chewing, presented itself. it disappeared without treatment three days later, about five days after the vaccination.

I recieved vaccine on 12/22 at 1500 and awoke 12/24 at 0500 with a broken blood vessel in my R eye that did not involve pain, blurred vision or irritation.

headaches, severe myalgia, fatigue for over 24 hours

fever, nausea, vomiting fatigue starting 12/25 2 hrs after vaccination, fever 100.8 starting 12/26 at 2 pm, improved with acetaminophen, emesis x 1 around 9 pm, symptoms resolved by 12/27 9 am

Headache, lightheadedness, nausea, pain at injection site

Tiredness first thru day 5 Injection site soreness next for 24 hours Fever and chills at 12 hours thru day 6, highest fever 101.5 at day 5. Sweating and skin paleness day 4 thru 5. Headache at 12 hours thru currently, piercing behind right eye day 3 thru 6, eye watering on day 5 during worst fever, occasional nausea when headache is worst. Fatigue at 12 hours thru day 6.

Malaise, persistent fever 99.3-101.8 defF. Chills, diarrhea, body aches. All since the vaccination day to present.

The day after getting the vaccine I started having an intermittent tremor in my lower lip. This has continued through 12/29/20.

Within minutes of receiving my first vaccination, I developed a metallic type taste in my mouth. Currently experiencing altered smell and greatly reduced or altered taste.

Numbness and swelling of left upper lip

Fever 101 the first night , achy muscles and occasional dry cough

Woke up from being asleep with moderate pain in injection site, mild headache that has rapidly intensified into a moderate headache, body aches and chills began around 130 am and have continued. Took advil around 1 am for headache and has not helped. Low grade temp was recorded at 150 am of 99.9.

Presyncopal with hypertension and tachycardia . Resolved after observation . Was given oral Benadryl

Mild Bell's Palsy affecting right side of face. Mild assymetry noted, mild decreased muscle strength and tone, and slight right eye irritation. Symptoms with minimal progression by day 2. Started course of Prednisone on day 3 (12/28/20.) Currently symptoms persist but early in treatment course.

Left arm soreness, Chills since around 1:30pm on 12/28/2020, nausea around 4:00 am, low temp fever 99.1

Patient experienced a syncopal episode after receiving the COVID-19 vaccine. Patient transferred to the emergency department. Upon arrival to the emergency department, patient was awake and alert with GCS of 15. Patient did state she felt a little dizzy. Patient denied any nausea, vomiting, or abdominal pain. Patient received IV fluids. Patient was reassessed and stated she felt significantly improved. Patient discharged at 1300 on 12/23/2020.

Moderna COVID?19 Vaccine EUA 10 minutes after vaccine : injection site pain, feeling warming of entire body. 1 hour after vaccine: fatigue, worsening injection site pain. 15 hours after vaccine: woken up to mild head ache, mild body ache, moderate chills, restlessness. General malaise. Worse injection site pain

Within a couple minutes I had a metallic taste. Within about 15 minutes of vaccine my lips started feeling tingly and numb, after 20 minutes it spread to my mouth, nose area and eventually my whole face. My face felt numb. My eyelids felt like they were turning in. I was advised to take a Benadryl. I took one and within 20mins symptoms improved. After about 40mins the numbess started to come back. I then realized my Benadryl had expired in July 2020. I went back to vaccine site and they gave me pepcid & advised to take more Benadryl. I took pepicid & went to pharmacy & got new Benadryl. Within about 20 mins my symptoms improved. I was advised to take another pecid and did so that evening. I stayed with the metallic taste for another day. Symptoms have not returned.

Slurred speech, crooked walking, slow thought process, unable to spell words that I've never had a problem with before.

Patient reported flushing in the face, tingling on the left side down the left arm and then began to break out into hives on their chest. The individual also had a rapid heart rate and needed a wheel chair due to feeling slightly faint.

start time 03:00 am 12/29/2020: headache, neck pain, fatigue, injection site pain - treating with over the counter ibuprofen and rest

Headache, body aches, chills

Cold sore

Generalized Warm sensation x 3 min

"5 to 10 minutes after receiving vaccine started feeling ""drunk"", anxious, paranoid. Muscles became mildly tense and teeth clenched. The physical aspects only lasted a short time (10-15 minutes)the anxiousness paranoia and ""drunk"" feeling lasted approximately another hour. An hour after receiving vaccine started experiencing nausea and vomiting with extreme muscle soreness that was generalized and fatigue. After napping the nausea and vomiting resolved. Woke up shivering in cold sweats and shivering. Began experiencing forgetfulness and having problems thinking correctly. Issues with finding words, conversing and conveying information to other people. Shortly after waking up began experiencing severe back pain in lower to mid left back. Pain was shooting and it did not seem to matter on positioning. Back pain has resolved. Day 2 still experiencing severe fatigue, extreme muscle soreness, forgetfulness and not thinking correctly. Having issues finding words to use and communicate. Thinking process seems slow. Occasional cold sweats and shivering. Day 3 still feeling of forgetfulness, unable to find words and communicate correctly, slow thinking process, occasional cold sweats and shivering, occasional bouts of anxiety (lasts only 2-3 minutes at a time), short bouts of shortness of breath with exertion resolved quickly. Some muscle soreness seems to be resolving."

shanking chills (fever taken = 101.9), body aches, fatigue, nausea & vomiting

very bad palpitations for a short time frame

Parathesia in left foot. Did not seek medical treatment yet.

swelling and tingling sensation of left eyelid

Injection sight began to become sore around 6:30pm on 12/28, which kept me up all night with the soreness worsening. Throughout the night, I had severe chills, which is not normal for me.

3 Hours after injection left arm swollen from shoulder to elbow. 2 days after injection arm still swollen and rash on 20 percent of left arm

Pt c/o mottling of palms, tingle in arm; pt became hypertensive with headache within 15 minutes of vaccine; symptoms resolved and pt dc from ED

12/24 @3pm - tingling and heat sensations throughout body, tingling in mouth. Sore arm. 12/25 @5am - total body aches, joints, bone pain , mild headache, increased heat and tingling sensation to face, bright red cheeks. Body temp normal to low-grade 99F. Fatigue. Self-treated with Tylenol x3 doses. 12/26 - body pain resolved, heat and tingling sensation continued until late morning. Arm was red/hard/itchy 12/24 through 12/26.

40 min after vaccine was given my face turned red and tight on left side. Then something happened next day. Face on left side felt weird like tight skin and a little numbness on left side that comes and goes on left side since and a little swelling on left side of face.

Feels extremely fatigued, body weakness, and a migraine.

Lumbar back pain for 12-14 hours

Pt experience leg cramps post vaccination.

loss of smell

Pt became diaphoretic, tachycardic, nauseous 10 minutes after vaccination; juice given; symptoms resolved

Around 2pm, developed itchy, blotchy, red rash on left elbow, spreading to neck and face, lips began to tingle, went to ED, ED provide PO Benadryl, discharged home, symptoms resolved.

C/O of right sided numbness and tingling. No SOB, NO Diaphoresis, No Chest pain. Pt transferred to the ED in no distress.

HEADACHE, NAUSEA, VOMITING, FATIGUE

Pt had tachycardia later in the evening after vaccination and tachycardia next morning

Worsening itchy rash on the belly (20cm x 13cm). loratadine 10mg Bid, triamcinolone 0.1% cream applied QID. Limited efficacy. Affecting sleep and daily activities.

Lightheadedness and fatigue. The following afternoon nausea, chills, body aches, severe headache and fever of 101F which lasted till Sunday night 12/20/2020. Monday 12/21/2020 the patient started experiencing hot rash all over the body, and burning Itching two days afterwards and lasted Friday 12/25/2020

DIZZINESS

At 30 minutes after vaccination patient informs she felt palpitations, blurry vision and headache. The day after she noticed a lump on her left supraclavicular area, no other swelling noted.

1 hour after administration the left side of my face is numb, specifically my cheek

Patient stated she felt tingling/scratchiness in throat. BP 96/65, Pulse 71 , Pulse Ox 99%. Shortly afterwards, patient stated that her throat was feeling a little more swollen but that she did not want to go to convenient care. Patient stated she was fine and she didn't want conveneint care doctor to come see her. Patient was talking and no dyspnea noted throughout. Kept for 30 minutes to monitor. At end of 30 minutes, patient started to itch and wanted to go to convenient care. Went to convenient care, received methylprednisolone 125 mg IM x 1 and diphenhydramine 50 mg PO x 1. Stayed for 20 minutes and reprted relief from treatment. Discharged to home.

Pfizer-BioNTech COVID-19 Vaccine Soreness at injection site, generalized body aches and malaise, headache/neck ache, low grade fever (99.3), mild chills.

Awoke with Flu-like symptoms: nausea, vomitting, fatigue, muscle soreness

Received SARS-CoV-2 Moderna vaccine in left deltoid. Pain at injection site and developed stiff/sore trapezius about 12 hours after injection. Got worse for about 12 hours after that before starting to get better. Fully recovered after 3 days.

localized reaction at site of injection redness and itching

On 12/26, I woke up with a headache, nausea, and feverish without a temp. They resolved by 12/28. I was tested for Covid on 12/26, results pending

throat tightness

Pain, burning, redness and heat at injection side and upper arm to shoulder

Extreme fatigue, headaches, and body aches since day of vaccination given. Taken Tylenol. Symptoms go away for couple hours and then come back.

"I had tingling/swelling in tongue and body itching for 30 minutes post vaccine, then felt light headed/dizzy and almost passed out. Then about 8 hours later I noticed my arm was swollen, hard, red, puffy and hot at injection site. It continued to get worse the next day. I was extremely tired and felt "" like I was hit by a truck "" for almost 2 days later. Pain in arm continued for a couple days later."

After having covid 4 weeks ago, I got the covid vax. After an hour, arm was sore. I went through my work day. Got home and was tired, showered, and was tired. I woke up at 1am and was shivering and shaking . It was intense. I had a better reaction with the actual virus. The CDC stated that I should be 10 days out from having covid, to get the vaccine, and I did so. My arm is swollen, there is a lump where the injection was. I did not take any thing for pain or symptoms.

Extreme fatigue. I slept close to 24 hours, woke for about 10 min and had horrible muscle/joint aches. Returned to bed for another 5 hours. Had a lingering headache (pain behind my eyes) for about 2 days afterwards.

Received vaccine on 12/28/2020 at 12:30 PM. Experienced injection site soreness by 6:00 PM. Experienced fever and chills in the night at 02:00 AM. On 12/29/2020 @ 06:00 AM I experienced perfuse sweating. At that time I took (2) Tylenol 500 mg tablets PO. Shortly thereafter the symptoms resolved.

Pt received injection in left arm. Pt had no initial pain. Approximately 5 minutes after injection became flushed, started seeing spots, felt like he may black out, felt numbness and tingling in the left arm that radiated up into the left side of the face and jaw.

Began with feeling fatigued around 6pm, had chills, palpitations and severe body aches with 101.3 fever. Fever resolved with Tylenol . Woke up then next morning (24 hours later) still with low grade 99 fever with weakness and fatigue. Fever spike again at 1pm 101F. Tylenol resolved fever again. The next day (48 hours after) fever free still with general aches and fatigue.

About 9 hours post vaccine, started to get extreme fat. 12 hours post vaccine, started getting chills and body aches. About 15 hours post vaccine, woke up with worsening body aches, headache, chills, nausea and a fever of 101.4. Took 600mg Ibuprofen at this time. 22 hours post vaccine, still having body aches, headache, nausea and temp 100.2. Took another 600mg Ibuprofen. 23 hours post vaccine, I feel exactly how I felt when I was infected with Covid-19 a few weeks ago. Temp 100.5.

dry cough, headache, body ache, feverish the following morning

rash all over chest to neck and lower face, started resolving on own, but took allergy med before bed. Mostly gone in am

Employee reported feeling shortness of breath and chest discomfort. Employee was taken to ED for evaluation.

Noted to have difficulty swallowing approximately 1-2 minutes after injection. Palpitations noted as well as being shaky. This lasted about 1-2 hours after. Difficulty swallowing did not worsen. Became light headed for about 1/2 hr after above symptoms subsided. Then all symptoms disappeared. Towards evening soreness in right arm started... throughout night soreness increased to the point of alternating Tylenol and naproxen. Soreness continue to increase throughout 2nd day... 3rd day soreness lessened and today(day4) almost nonexistent

I received my vaccine on 12/22 around noon. I woke up at 4am this morning 12/25 with tingling in my lips and tongue, in addition to the left side of my face being swollen. Not entirely sure what these side effects are from exactly but thought it best to report my experiences I was hospitalized on 12/25 to 12/26 because my reaction did get worse. I was experiencing numbness on the left side of my body and swelling, numbness, and redness on the left side of my face as well. The hospital didn?t really give any explanations but I?m only now have mild swelling and numbness on the left side of my face. Everything else has resolved at this point in time.

Slight lip swelling sensation, scratchy throat, her skin felt itchy (no visible hives).

muscle pain in both arms, R worse than L. Slight dizziness for first 4 hours after vaccine. On and off minor headaches for the first 48 hours post vaccine

tiredness, extreme nausea, pain in arm of injection, horrible headache

At 1234 am I developed fever, chills, severe night sweats and whole body aches. It lasted approx. 6-630 hours. I also have had increase in GERD/acid reflux since about 2 hours after the injection.

Achy body Extreme tachycardia (HR in the 180s). Unable to get below 90. Uncontrollable shaking Migraine

whole body hives, responsive to diphenhydramine

Became diaphoretic a few minutes after receiving the vaccine. Said his throat was 'scratchy' and was dizzy when he stood up. Sent to ED for evaluation. Discharged from ED without incident.

chills, achiness, diarrhea, fatigue

Moderna COVID-19 Vaccine EUA Experienced injection site soreness, Body and Joint aches, Fatigue, Sleeplesness

"Two minutes after vaccine was give to left arm was painful and swelled about 1"" diameter at injection site 2-3 mm out from skin. No redness present."

body hives

Left upper additional pain and left shoulder pain. Palpable mass under left anterior ribs. Tiredness.

Patient experienced episode of severe leg cramping on 12/22/2020 that began in early AM and lasted until noon. Patient experienced another episode on 12/24/4040 of cramping that began in the legs and went up to the head that felt like muscle tension. This episode also began in the early AM and lasted until noon. However, patient did have residual minor leg cramping. Patient did follow-up with his PCP, who obtained bloodwork on patient. On 12/28/2020, patient states all symptoms have been resolved.

58 y/o female with history of severe seafood allergy presented to ED on 12/24 at 933am with hoarseness, sensation of throat closing. Stated received Covid vaccine at 0730 this morning. Patient took claritin and prednisone prior to vaccine and 20 minutes prior to arrival to ED took benadryl. Symptoms

have improved since arrival to ED. Presenting with symptoms of difficulty swallowing. No difficulty breathing, no itching, no rash, no swelling and no wheezing. One dose of Prednisone 40mg tablet given orally at 0955am. Patient monitored and then discharged to home at 1027am with prescription for Prednisone 20 mg by mouth daily for 4 days and to follow-up with primary physician.

waited 20min. got up to leave and while walking out had a little side step/unbalance moment. thought nothing of it and got to car. waiting in car for an extra 10 min. left hand started tingling. same tingling like if it was asleep and was waking up. started to drive home, on the way home, noticed tingling in left foot and left side of face. neck on left side felt like someone had hit it. about 50 min after receiving injection, was at home, injection site and whole deltoid was numb. left side of face, left foot and left ear all felt numb but with tingles. I had stopped timer after 2 hours. tingling and numbness subsided sometime after 2 hour of receiving vaccine. Today, everything feels fine. Injection site just feels like I got a shot, can barely notice it.

Pain at time of administration, right upper arm, continued throughout day. Nauseated appprox, 0100 29 December. Still Nauseated at 0815, Pain in upper arm increased.

Cold Chills Muscle aches Heart rate 110-150BPM for 5-6 hours that started approx 36hrs after the vaccine was administered Axillary swelling the size a baseball, swelling was also noted in left pectoral muscle and in left shoulder blade

Dose given was 1mL vs. 0.5mL

Pain at injection site, trouble sleeping.

"Tingling tongue and numbness and tingling on R cheek and jaw; R jaw line pain and R sided teeth pain--pain rated 8/10 initially; Provided 50 mg of Benadryl orally; tingling tongue symptom resolved; after 45 minutes pain 2/10 with ""mild"" jaw and teeth pain and R-cheek numbness and tingling"

headache, lower back pain, inject local site achiness.

I received the covid vaccine on 12/23. Since then I have had a fever, chills, body aches, sore throat, headaches, sinus pressure and have been very fatigued. My symptoms seem to come and go, they are currently less severe, but last night a had a fever of 103.2 with chills and shakes.

Patient became dizzy / weak a few minutes after getting the dose. Had slight flushing on chest and rapid heart rate. ER physician feels it is likely vaso vagal response and not a medication reaction. Patient recovered quickly.

The employee's primary care provider's office contacted our office this morning saying that she received the vaccine on 12/22/2020, on 12/26/2020 she began experiencing facial drooping, came into their office on 12/28/2020, had MRI performed (that was negative), and was diagnosed with Bell's Palsy.

Intermittent Fever, cold sweat, cough, congestion, fatigue, stomach upset, loss of appetite, and diarrhea resolved with Tylenol, PO fluids, and light diet of soup and saltine crackers

Already did: 2:30 p.m. until about 6:30 p.m., leg cramps and unusual joint pain in hip and knees. Subsided. From about 10 pm to 8 am, localized discomfort at injection site, on upper left arm.

1mL was given instead of 0.5mL

headache feeling unwell pain and swelling at injection site muscle pain fatigue fatigue

Patient presented to the ED ~ 14 hours post dose. Chest discomfort, dyspnea, fatigue, and malaise. Had prolonged covid hospitalization April-May. Had some sinus tachycardia between 110 and 117. Administered methylprednisolone 40 mg IV. Was discharged from the ED with no outpatient prescriptions.

pt was given 1mL instead of 0.5mL

Vomiting and diarrhea for 2 days. Chills, body aches, sore throat on left side only, ear ache left side only, low grade temps up to 99.9 F taken temporal, lasting 4 days.

Around 4:30 pm on day if vaccination I started feeling nauseous and had the chills. Then around 8 pm my arm became extremely sore to the point where I could not lift it without 10/10 pain and when I touched it my pain was also 10/10. As the night progressed my body not only had the chills but I got a temperature of 102 and I was on fire. I could not cool down until my significant other put cold compresses on my forehead chest and arm. I felt all of those symptoms until about 5am when my fever finally broke. The next day I continued to have a headache and mild soreness in my arm. Then that night I had mild chills and night sweats and a mild temperature. I was therefore out of work for two days following the vaccine.

Alergi

Throat tightness and tingling , itchy mouth within 15 minutes post-vaccination. Received diphenhydramine 50 mg PO and hydrocortisone 20mg PO. VS stable throughout observation period with O2 Sat at 99%. D/C'd in stable condition. Will be evaluated by Allergy Clinic for Dose #2 recommendations.

Extreme fatigue; intermittent episodes of vertigo; intermittent episodes of tachycardia - all started on 12/28 at approximately 7 p.m. The tachycardia appears to be resolving today; the vertigo remains and the fatigue continues. Localized reaction has lessened.

MUSCLE PAIN, CHILLS, LOW GRADE TEMPERATURE, TIREDNESS, HEADACHE

Ibuprofen

Ibuprofen

Patient woke up in the night, walked downstairs to get water, walked back upstairs and became nauseous, laid down and became unresponsive. Eyes were open but not focused, breathing was irregular and snoring-like. this lasted less than a minute and he regained consciousness.

red, raised, hard, swollen. painful area at the site of injection. Area of swelling was approximately 3 inch circular shape. Treated with ice pack and Tylenol for pain After about 2 days, the pain and swelling gradually subsided

I received the injection at 11:00am and around 4:00p, I began to feel like my heart was racing. It continued until about 7p. At one point I thought I should go to the Emergency room but I began to feel better. That was about an hour and a half later but then it started again increasing but by 7p, it went away.

Swollen and discomfort left armpit lymph nodes

Day of injection uncontrollable diarrhea for 36 hours Saturday and Sunday night- nausea , abdominal pain, Sunday I starting vomiting Monday went to the hospital

Day 1: Arm pain 5/10, neck stiffness, tension headache 5/10 (occipital and temporal) Day 2: Arm pain 5/10, neck stiffness, throbbing headache 5/10 (occipital and temporal) Day 3: Arm pain 1/10 Day 4: no symptoms

I broke out in hives Sunday morning. The convenient Care would not see me and sent me to the ED. I was given a muscle relaxer and benadryl. I was prescribed prednisone and benadryl. It took 3 days for the hives to go away. I still have spots and swelling.

Moderate muscle pain/soreness of left arm- started approximately 6 hours post injection and present even after 24 hours

Nurse at vaccine clinic injected subcutaneously and did not reach the muscle. Did not have information to know what to do. Observed patient who was asymptomatic.

Panic attack following, both cheeks red. symptoms left. 6 hours after L side of face started swelling, pain at cheek bone followed by numbness of entire left side of face. numbness lasted for 5 hours. Today face is still swollen. I went to the ER and was kept for two hours for observation, no intervention

After I received the vaccine. Approx 24 hours after the shot, I started having a headache. As my headache got worse, the ache muscle and joint pain came. When the headache started, I started feeling really tired. I was feeling like I was having flu symptoms. I started taking IB prophen on Wednesday morning. It lasted aprox 2 days, and I started feeling better on Saturday morning. Symptoms lasted about 3 days. Symptoms got better with IBprophen.

12/24- fatigue, joint aches, cough, diarrhea, headache 12/25- fatigue, less cough and aches, headache, some diarrhea 12/26- same 12/27 slightly better 12/28 loss of taste and smell. Positive Covid nasal swab test 12/29 headache, cough, fatigue, diarrhea

7:48 am hot, difficulty swallowing, numbness/tingling lips, raspy/hoarse, 50mg benadryl given- symptoms did not resolve so sent to ER, Initial Blood pressure 166/117 Given 50mg IV benadryl, IV dexa

methasone, and IV pepcid Difficulty swallowing resolved in about 1 1/2 hours, numbness and tingling lips resolved approximately 8 pm 12/28/2020 continued raspy/hoarse and day 2

30 minutes after receiving the vaccine I developed pain in my left upper gumline, swelling started and over the next 12 hours included my entire left cheek. I sought medical treatment and 12/24/2020 was prescribed prednisone 50mg PO daily for five days. The swelling has decreased but not resolved, the pain has resolved.

Dizziness/Headache Swollen right elbow (tender to touch) Fatigue High Temperature

Patient reported numbness and tingling to bilateral hands. Patient was transported to ED for evaluation.

I am Health Care worker (Security Officer) at Hospital. On 12/28/2020 around 9am I received my Covid Vaccine (1st) After the shot, I sat the required 15 minutes and felt no ill effects Around 530 pm. I was out shopping after work and almost passed out. It was not a gradual feeling -It felt more like someone had punched me in the head. I was too dizzy to walk for 30 seconds or so. After about 5 minutes I felt okay and drove home. I feel absolutely fine today (12/29/2020)

Chills, Aches, Fever of 101, HA

Extreme soreness at injection site, hard to lift arm above shoulder. Chills, low grade fever, nausea

Muscle soreness, chills, fever, body aches

Diarrhea, headache, chills, body aches, chest pain, shortness of breath, finger on hands and toes get cold. All the symptoms happened at 4:30pm.

Employee reported numbness and tingling to left arm, fingertips and both feet. Left hand is shaky. Employee was transported to ED for evaluation.

For the first day after vaccination I was so fatigued I couldn't get out of bed. My arm was too sore to use for about 48 hours, and I had a headache starting 12/23 and lasting through 12/25. Both arms were very sore then on 12/25. Nausea started 12/26.

Vaccine receieved 12/21/20 at 10 am. Glucose in evenening 12/21/2020 120. Patient reports hypoglycemic event at 8 am 12/22/2021 - glucose of 80 followed by 3 hours of glucose of 40. Glucose then stabilized for remainder of week with no repeat events.

Hives and itching developed about 230pm on 12/28/20. patient self treated with oral Benadryl. presented to clinic about 830 am on 12/29/20 with continued c/o hives and itching . She was sent to ED at Hospital for evaluation. patient denied any other symptoms

102 fever that wouldn't break until about 10 hrs later, severe nausea and headaches, dizziness, extreme body pain

Patient became dizzy, lightheaded, pale, diaphoretic and hypotensive approx. 5 minutes after receiving vaccine. Also c/o nausea without vomiting.

Heat flash Elevated BP

"At 8:50 AM she developed nausea, diffuse headache, malaise, tingling of her hands, elevated blood pressure and metal taste in mouth. She denied any trouble breathing. No swallowing difficulty, swelling of the tongue or lips observed. Subject stated she did not feel safe driving and was brought to ED by EMS. She has a history of fibromuscular dysplasia and is on aspirin and Plavix. Emergency Department ASSESSMENT and PLAN This is a 58 y.o. female who presents with vaccination side effects. She is well-appearing on exam. There is no evidence of airway swelling or anaphylaxis. Will observe. 11:34 AM Has been observed for 2 hours and her symptoms have not worsened. She did take her own dose of Tylenol for headache. She is comfortable returning home. She does have the Moderna fact sheet and we discussed signs and symptoms of when to return. She is comfortable with plan. All questions were answered."""

Itching, redness, rash, difficulty breathing

I received COVID vaccine on December 23rd and had tongue swelling one hour later. I took Tylenol and benedryl and swelling went away

Employee became dizzy at time of check out from observation area. Employee was taken to ED for evaluation.

fever 102.7 in the evening of 12/28, in the morning 99.6 with stuffy nose/chills, soreness at injection site, COVID + 12/14

Employee received the Pfizer covid vaccine @ 0752. @ 0800 employee began to feel flushed, SOB, increased HR. Patient also had some throat tightness and itchiness. BP 147/95. O2 100% HR 149 @ 0755. Symptoms worsened by 0805 and EPI pen given at this time. By 0807 patient was feeling much better- HR 81, BP 134/75, no SOB. Patient chest and face flushed. Taken to ED at 0812.

Chills, fatigue and L shoulder soreness at injection site

Acute headache for 48 hours Acute lethargy for 48 hours Minor pain at injection site for 36 hours

Soreness of left arm radiating to left upper neck and numbness of left hand, pulling sensation of left side of neck

called to observation area at 1020. 98/60 p 100. stated felt shaky, tongue feels thick and not changing, skin warm, hands, face, neck mottled. respirations not labored. oriented. rapid response called and arrived at 1025. transported to ER per wc as stated throat getting tighter.

Severe nausea Esophageal spasm. Could not swallow

Nausea and lightheadedness on day of the vaccine. By that night, fever, chills, headache, shaking, body aches and local pain at site of injection. Nausea gone the next morning. Fever lasted 36 hrs. Body aches and headache lasted 48 hrs. Fatigue lasted 3 days. Side effects resolved by 4 days.

Facial Flushing, throat constriction, feeling faint

12/27/2020 joint pain, body aches, sinus congestion, chest and throat soreness; . l cheek numb, sluggish.; left eyelid more raised and sluggish than other 12/28/2020; l armpit swollen armpit.

Nausea; vomiting; diarrhea; fatigue; headache

She was vaccinated 12/23. Initially she had some soreness, nausea, diarrhea, extreme fatigue, but no fever. Two days later, she developed a diffuse erythematous rash on her bilateral arms, chest and neck with sharply delineated white patches. She also describes that her hands were purple, almost cyanotic appearing. The rash was not itchy or painful and lasted about 6 hours before going away completely.

Vaccine administered via SubQ pinching technique in upper left posterior arm, midway between shoulder and elbow. NOT an IM injection. Site red, swollen and tender. Concern raised for less immune response. No training given to administration staff by hospital clinic.

paresthesia along ipsilateral arm (ulnar nerve distribution) a few minutes after vaccination soreness at injection site, mild headache, & lightheadedness 1-2 hours after vaccination chills 4 hours after vaccination (but no fever) * most symptoms improved/resolved 8 hours after vaccination

Moderna COvid-19 vaccine eua

6 days after receiving my initial covid vaccine, I began to develop an itchy rash. The rash started in the morning of 12/28/2020, beginning with itchy, red ankles. Progressed over the next 8 hours over my whole body. Red, raised, itchy patches. No other associated symptoms and no other means of explaining allergic reaction (no new meds, foods, clothing, detergents). Left work, took Benadryl and a shower. Rash subsided. I feel fine today.

Developed headache rated 9/10, feeling hot and light headed.

Pain both right and left arms and left side of neck with tingling of the lips, palms of hand and soles of the feet. Mild headache. Mild chest pains at 1900 same day. Performed breathing exercises and yoga. Took a 1.5 mile walk. Took 1000mg of Tylenol and 12.5mg of Benadryl at 1900. Pain was relieved but tingling around the mouth persist even today 12/29/20 with leg muscle tingling and stiffness in the left neck . I had to take off work 12/28/20 due to severe pain left neck. Same symptoms I have when I take the tetany vaccine.

Moderate arm pain and swelling at site of injection.

Patient reports freezing and sweating for 2 days after immunization 12 days ago. Body aches and headaches have persisted since then. Also reports numbness going down left arm to all fingertips since vaccine.

2-3 minutes after injection, experienced what felt like a drop in blood pressure, tachycardia, tongue tingling and taste, and for a few seconds, my nose stuffed up but then all symptoms went away within a few minutes. I felt completely fine 5 minutes later.

Went to hair appointment and water aerobics after vaccination. Arm started to hurt a lot. Went to bed at 10pm and at 12am was feeling really hot with a headache, chills, and shivering. Temp was 99.4.

trouble breathing

ON THE THIRD DAY I FEEL LIKE PINS ON MY BACK AND A SLOPE CAME OUT OF MY NOSE AND ON MY LIP. I TAKE BENADRYL TABLETS 50MG TWO TIMES.

muscle pains, shakes, 100.3 temp, headache, nausea

Fever, body weakness, headache, sinus drainage

Drooping of the Right side of her face. Started 12/26/20. MRI to rule out Stroke negative. Diagnosed with Bell's Palsy. RX with a Prednisone taper and Valtrex.

called to observation area 10:50 - report that patient passed out, was on stretcher, reported did not fall, 'came to' in less than 1 minute. 108/68, P 70 and strong, alert and oriented. states feels anxious about flu shots. felt lightheaded, hot, sweaty, skin pale and warm. at 1052 rapid response arrived. states feeling better, had had food/fluids today. assessed that not allergic response - vaso/vagel. 1055 sat up and feeling good, skin pink. 1100 to chair. 1115 left area walking.

Patient felt lightheaded, flushed and nauseous.

Approximately 1 and 1/2 hours after the injection, her tongue became thick, lips swelled, chest pain, short of breath and headache. Injections site was red and swollen. She was traveling out of town and called an urgent care and was advised to take 50 mg of Benadryl q 4 hours till swelling was gone. She took it for 4 days. She saw here PCP on 12/21/2020.

Didnt feel good, soreness on arm Monday I had chills , Unconformable at work Took Antibiotics Chills Possible UTI the following Wednesday I discovered a cold sore on lip

Called and spoke with patient, the received her COVID vaccine yesterday. Since the vaccine she had a temp of 99.9 last night, has not checked today, feeling a little warm today but not as warm as last night. The area is hot and red and swollen in the size of a golf ball, was bigger yesterday. Her entire body feels itchy. She did take benadryl approx 5 hours ago, it helped a little bit right away but now she feels no relief again. She states she has small little bumps that have slowly been spreading from the arm of injection to back and now onto other arm. á Does report she felt like she needed her inhalers, now denies and swelling or itching of mouth throat or tongue. No difficulty breathing at this point.

RASH AND HIVES TO NECK. BENEDRYL AND PREDNISONE. SYMPTOMS STARTED AT 4:00 VACCINE ADMINISTERED AT 1:00

5 hours after injection my legs from the knee to the ankle joint became very itchy, I wrapped them both in a cool wet towel to keep the itching down. This lasted for 48 hours and then went away.

5 hours after injection my legs from the knee to the ankle joint became very itchy, I wrapped them both in a cool wet towel to keep the itching down. This lasted for 48 hours and then went away.

During first few minutes after the vaccination, the client began to cough repeatedly. She stated that her throat was tingling and she was noted to be diaphoretic, with Shortness of breath, an increased heart rate and hives. Epinephrine 0.3 mg IM given to client. Client responded with less diaphoresis and cough subsided. However, noted in 5 more minutes that the symptoms progressed. (As we were in a hospital area administering the vaccine), a rapid response team was activated and she was sent to the ER for further evaluation monitoring and treatment.

intermittent itching, some blotchy rednesss no hives or raised rash that lasted about 3 hours, went away on its own without any treatment

Employee reported numbness and tingling in upper lip 10 minutes after receiving vaccine. Employee was transported to Emergency Department for evaluation.

low grade fever- 99.9 sore arm

Hot flush Dull headache

Day 1-after immunization covid 19 moderna vaccine-headache, sneezing, low grade temp 99 when she arrived home Day 2-102F-took tylenol as needed, she continue to experience headaches, body aches Day 3- No signs or symptoms, temp 97.6F with out tylenol

Local reaction: Pain and swollen arm in the injection spot for over 2 days

14 hours after injection woke up with swollen upper lip and extreme systemc itching. Took 50 mg Benadryl. 12/26/2020 at 0900 continued itching took claritin 10mg and 25 mg Benadryl lip still swollen.12/26/2020 @2000 took 25mg benadryl for itching lip no longer swollen. 12/27/2020 itching has now become burning sensation systemically took 25 mg benadryl and 10mg Claritin. Upper lip swollen 12/27/2020 @ 2000 took 25 mg benadryl for continue burning and itching Lip no longer swollen. 12/28/2020 @ 0600 took 10 mg claritin till itching no burning. 12/28/2020 at 2100 took benadryl 25 mg for continued itching. 12/29/2020 0600 took claritin 10 mg for itching.

Vomiting within 15 minutes Fever 1 hr post vaccination Continued vomiting

Rash on chest

Scratchy throat within minutes. Left thigh pain and spasms, left arm pain. The next morning I can't lift my arm above shoulder, thigh pain not as bad, diarrhea at 9:30 am.

Erythematous rash over anterior torso, groin, flexor aspect of elbows/knees/hips

12/28/2020 weakness, fatigue, chills, tongue swollen, left arm pain at injection site 12/29/2020 fever 101.00 headache, loss of appetite, weakness, fatigue, dizziness, throat swollen

Injection site swelling (~6 cm across), redness, and tenderness beginning 12/28, resolved when patient took benadryl

developed raised red bumps on arms and legs several hours after receiving vaccine.

Debilitating, severe neck and shoulder pain the next day that continued for a week Stiff neck, spread to back pain Unable to work/left work early Still have stiff neck and feel strain doing my normal day-to-day tasks

Day 1-after Covid 19-Moderna injection-employee experienced an extreme pounding headache, her blood pressure was elevated 161/93. Evening hours employee reported fatigue, rash to chest/back no itching, along with fever 102F Day 2-Employee continued with fever 100.2 F and rash to chest/back no itching-taking Motrin and Tylenol Day 3-No fever, no rash, pain to injection site and generalized body aches Day 4-No symptoms

38 y.o. female who arrived by Clinic/physician office presented to the emergency department for Concern for possible allergic reaction. Patient was receiving the Covid vaccine today and while waiting during the observation. She felt some palpitations and was found to have some tachycardia. She was sent here for further evaluation. Currently she says she feels fine and denies any swelling, rashes, difficulty breathing or wheezing. She has not had any allergic reactions in the past and has never had any issues with shots or vaccinations before. She does not have any pain or swelling at the injection site. She was initially heart rate in the 120s but during exam is 100-105. She denies any shortness of breath, chest pain, lightheadedness and does not think she is feeling anxious at all. o ECG (My read): Sinus tachycardia, normal intervals, no ST elevations or depressions and no T wave inversions or signs of right heart strain o Patient did start to feel palpitations again, her heart rate periodically drops into the 90s and then jumps back up into the 1 teens. Considering this, did obtain basic labs all of which were completely normal. Her heart rate has improved, did order Zio patch for monitoring over the next 7 days and recommend she follow-up with her PCP for results on this. Otherwise appears well with no signs of allergic reactions or other emergent concerns. Discharged in stable condition with return precautions given

Developed a severe headache around 1 PM of the day she received her vaccine, some general tingling non-specific; sever headache lasted until 9 PM that evening, relieved with medication but in the morning continued to have headache although more mild then previously. Was better by the 3rd day.

Pain at injection site

Numbness in nose tip of tongue; earlobes warm

Severe right arm soreness inability to have range of motion cannot pick up items over 5 lbs numbness and tingling and cooler fingers in rt hand

Fatigue, chills, body aches, mild cough, headache, sweats for 36 hours Arm soreness for 5 days

Injection site pain

Approximately 5 minutes after administration of vaccine, patient felt nauseated and vomited with some relief. Blood pressure was checked (171/94). Approximately 50 minutes @09:20am after administration of vaccine, patient complained of mild headache. Blood pressure was checked (148/96). At 09:35am, patient reports no nausea. Continues with mild headache. Patient clinically stable. No medications administered. At 10:05am patient reports headache still present but is gradually subsiding. Patient was released at 10:10am.

2 minutes after injection patient c/o head heaviness, nose tightness. VS: BP 159/88, HR 101, O2 SAT 99%, RR 24

Approximately 15 minutes after administration of vaccine, patient experienced twitching on left upper eyelid off-and-on for approximately 10 minutes. Twitching resolved. Blood pressure was checked at 09:50am (161/109). HR=76. Patient clinically stable. No medications were administered. Patient was advised to follow-up with PCP regarding blood pressure concerns and released at 10:10am.

Injection Site Pain

Experienced fever, chills, sweats, joint pain and soreness in Right arm

Fever, chills, headache, arm soreness

After receiving the vaccination, I experienced slight soreness at the site of the injection and a mild headache every day until Friday 12/25. Starting Friday evening 12/25 I started to experience tingling around my jaw after flossing my teeth. It continued when I woke up the next day and spread to my chin and around my lips. I now feel the sensation on my forehead as well. In addition to this I have been having chills, runny nose, pressure in my face, head, and ears, had diarrhea X1 and have been nauseous . I tested COVID negative on 12/28 and had my electrolytes checked along with CBC which all came back normal. Today 12/29 I took 2 Benadryl in the event it could help an allergic reaction.

Patient began with muscle/body aches and chills on 12/24. Highest temperature recorded was 99.8, took ibuprofen. On 12/25, lymph nodes near right clavicle and right axilla swollen and stiffness in neck and shoulder. Right foot also became swollen. On 12/27, developed pain behind eyes, swelling began decreasing on 12/27. Began having headache on 12/28.

Nausea, Headache, arm pain, Neck pain, Swelling, Headache

Swollen, tender lymph node under left armpit

Loss of taste

Resident found unresponsive in her room. Note from earlier: Resident appears to be weak today. Resident ate a few bites of dinner before refusing the tray. Writer encouraged fluids. Vitals 123/72 80HR BS 166. Will log for Doctor and continue to monitor. Was sent out 911.

Flush and dizziness ,Increased heart rate and elevated BP 8 mins after the shot. Evening of the shot 12/18/20,patient c/o blurry vision and joint pains.

First symptom was body ache, headache, fatigue, loss of taste

Runny Nose, Sore Throat, and Fatigue

Patient with tongue and throat swelling, some shortness of breath

developed fever,chills, shaking and body aches. Very sore arm

Dizzy/lightheaded at 8pm 12/28, nauseous. 12/29 6:30am dizzy, lightheaded, fainted in shower

Chills, back pain, severe headache, muscle pains

no symptoms

Started with mild headache the evening of vaccine administration. 12/27/20 woke up with severe body aches, severe chills, sorethroat, sinus congestion and sinus discomfort, and extreme fatigue. Took temp once and it was 99.5 oral. Symptoms were gone within 28 hours of onset. Minor discomfort at vaccine site as expected.

Injection site soreness

When leaving post vaccine, numbness and tingling of right foot, over the next 7 days spread numbness to both lower extremity extending into calf?s. Burning nerve sensation started at day 7 increased up legs into hips. Numbness and burning sensation bilateral from feet to hip

One week following the COVID 19 vaccine, patient developed a psoriatic arthritis flare up. She has history of psoriatic arthritis; however reports it has been well controlled. She had a change in her medication in 11/2020 and was started on Ixekizumab. She is also taking Hydroxychloroquine. States psoriasis rash under her nails is severe. She also reports bilateral shoulder pain. Taking Tylenol.

Right arm and neck are very sore and has a headache.

muscle pain in arm, headache, fatigue

Injection Site Pain, Fatigue

After i received my vaccine 11:00am, i was ok until 8:30 PM, i started to unusual to my body, particularly in my stomach. I didn?t hqve the appetite to eat. By 2am, i woke up with chills and my body was shivering. Temperature 98.3, i took tylenol ES. After an hour, my chills went away. I feel lack of energy. This morning, i still have feelings of being cold, body malaise and mild headache and still no energy to do house chores.

Pt was experiencing shortness of breath, sweating, and racing heart, and dizziness. Code A was called and RN and MD came to attend. Vitals 1st set 90/41, pulse was 50, and O2 was 100%. Vitals 2nd set, 10 min later 100/60, pulse was 60, and O2 was 100%. Pt was given apple juice and given the okay to discharge home after waiting 10 more minute for observation.

Extreme dizziness with nausea and vomiting that starting on 12-26-2020 after receiving the vaccine on 12-24-2020

Lip swelling, left 4th digit swelling, pruritic palms, headache

I received the vaccine shot on 12/23/20 at 3 pm. By 12/24/20, I had pain in my left arm that radiated to my neck and back on the left side. Over the past 4/5 days, I continue to have pain in my left arm, back and neck

soreness on injection site, headache, fatigue, muscle pain, joint pain, chills

Fever, Body aches, fatigue, Nausea

On monday 12/28 i started to feel fatigue/ weakness Body ache Headache Slight feverish On tuesday morning between 1-5am i had Fever Body ache Chills

Nausea, extreme fatigue, headache, swelling left arm

within 15 minute waiting period after vaccine, employee felt like she was going to black out, no LOC. Increased BP 180/130 and tachycardia, HR 120's. After sitting/resting, VS returned to normal and employee felt weak but better. On 12/29 called employee and she had called in ill to work today for h/a, vomiting and is now reporting severe dizziness that she cannot stand up, chills with the h/a and vomiting. She is taking Tylenol/ibuprofen.

I received the Moderna COVID-19 Vaccine EUA on December 28 at 3:30 PM. Starting at 4:30 AM today (December 29), I started to have chills, followed by fatigue, headaches, muscle pain, joint pain, chills, nausea and vomiting. I vomited twice.

Nausea, Injection Site Pain, Vomiting, Diarrhea

Severe myalgia, chills, fever, nausea, vomiting

"Employee reported ""racing heart and ""feeling like passing out"". Employee was transported to Emergency Department for evaluation."

Pfizer-biontech covid-19 vaccine eua 15 minutes after receiving shot my head became itchy. that resolved within 15 minutes. around 1430 that day i developed nausea and diarrhea, which lasted until 12/25/20 at 2130.

It started with a cough that night went to work. The cough was consistent at work the coworkers asked me to call employee health. I was informed to get Covid test at 11:00 am when I got home took a nap. Upon waking had a fever, cough had gotten worse, exp breathing problems, abdominal pain, muscle ache and joint in knee/wrists swelling. I took Tylenol for fever went away and still feel exhausted. On this morning my fever was 99.7,still have cough, and trouble breathing after Nebulizer treatments. I have missed over 5 days of work.

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Severe Headache x4 days Sinus pressure x3 days Nausea and vomiting x 2 days

Hives, Benadryl 25 mg given, itching has decreased, but is moving from original area.

Patient is four months pregnant. She received the vaccine at an employee immunization clinic. Ten minutes post-vaccination, she reported feeling lightheaded and dizzy, HR of 121. She was provided an area to rest and given juice and peanut butter crackers. At 30 minutes post vaccination, she continued to feel lightheaded and dizzy. Vitals: BP 122/64, P 71. Continued rest, juice, and crackers provided. EMS and RN observation at bedside. 1 hour post vaccination, she reported feeling much better and feels safe to drive home. Discharge vitals: 120/66, HR 75.

Pt complaint of mild symptoms ie. itchy mouth. Interview and vs taken as noted. Pt given Benadryl 25mg PO x1. Per standing order. Emergency medication management of vaccine reactions. Symptoms Remain present after 10 min of observation. Pt taken to urgent care and checked in. She stated that her face was starting to feel itchy while being checked into UC. Report given to Urgent care RN.

Fever, Injection Site pain

"vaccine. She was waiting about 15 min after vaccination when closer to 4:45 complained of headache, cold and chills. She was asked to lay down on stretcher where her BP was checked 134/94,P=74 Pulse OX 100% on room air. She drank two small juice box and continued laying down. Raised her feet up and while she was resting she felt increased heart rate BP=143/104, P 97, Pulse OX 100%. Pt has no medical history, denies any environmental, food or vaccine allergies previous to this vaccine. She was alert, awake and oriented through the process yet escalated to transfer to ED since her BP remained elevated above her normal level of 120/80. Paramedic arrived at 17""35 and she was transferred to ED. BP 144/93 P=80, T=99.2(tympanic), Pulse Ox=100% at the time of transfer. Her chest was clear to auscultation and heart is regular with occasional iregular heart beat on auscultation. Her headache decreased yet still had mild headache."

1. soreness on my right arm beginning at injection site and expanding to the entire area from the shoulder down to the elbow 2. I am feeling extremely tired 3. sore/stiff muscles

Severe hives and itching to lower abdomen, lower back,buttocks and left hip.

Fever, Chills, lasted 24 hrs

Fever, Chills, lasted 24 hrs

Neck/shoulder stiffness; all over body aches; severe fatigue; nausea; chills; high temperature; migraine, and loss of appetite.

dejavu symptoms throughout the week after the dose. On Thursday Morning approximately 2.5 days after the dose, I had a seizure in my sleep at approximately 4am.

Day after receiving the vaccine - Headaches, heart palpitations, chills, loss of appetite, severe nausea, and fatigue.

Patient called after events occurred. She was administered the shot on 12/21. She stated that evening, she became short of breath however did not seek medical treatment. She stated she instead went to sleep and Tuesday 12/22 she was experiencing a back ache but also had a dull ache in her neck and forehead. I suggested patient be seen by their PCP. Whether or not patient followed up with medical care is unknown. I also encouraged her to call back if symptoms do not improve or if any new symptoms occur. Have not heard back from individual.

Patient called after events occurred. She was administered the shot on 12/21. She stated that evening, she became short of breath however did not seek medical treatment. She stated she instead went to sleep and Tuesday 12/22 she was experiencing a back ache but also had a dull ache in her neck and forehead. I suggested patient be seen by their PCP. Whether or not patient followed up with medical care is unknown. I also encouraged her to call back if symptoms do not improve or if any new symptoms occur. Have not heard back from individual.

Employee received vaccine, c/o shortness of breath, throat tightness, difficulty swallowing, difficulty breathing and hoarseness. METS team called and Employee taken to Emergency Room.

about an hour afterward began experiencing diarrhea up to 6 times that day. around 11:30PM at work I began feeling a whole body tingling/pins and needles sensation along with muscle/joint pain in my back, neck, and hands. The tingling lasted about 3 hours then subsided, on the 19th night again I felt the tingling for about an hour. patient replied yes, she had MIS as result of Covid vaccine.

Injection site redness and increase skin temp at site which occurred 8 days after 1st dose of vaccination. No itching present. Slightly tender and no swelling at this time.

Headache Fever Body aches Fatigue

I had three days of fatigue, chills, aches, and intermittent night sweats. 1 day after the vaccine was administered I developed a rash (red bumps/itchy) over my chest, back, and inner ankles. The chest rash was relieved with Benadryl administration and lasted 2 days, I still have a very mild rash within my inner ankles 6 days later (tiny red itchy bumps).

Fatigue, Body aches

Vaccine error: Vaccinator administered COVID 19 vaccine however some of the liquid of vaccine splashed onto the patients arm and thus the patient did not receive full first dose. The vaccinator likely

did not secure the needle to the syringe well enough. Incident was filed on the date of occurence. Patient did not have any symptoms.

throat tightening and scratchy

Modern a COVID-19 Vaccine. Swelling in the right eye lid. Muscle pain. Headache. Injection site throbbing in pain. Labored breathing (with burning discomfort). Fatigued.

Hives and itching to left bicep on Morning of 12/28, Hives spreadin to all four extremeties by 0500 on 12/29. Mild Shortness of breath

states she had nausea and diarrhea afternoon that she received the vaccine and into the following day with lack of appetite; had not eaten anything

Severe Headache

Moderna COVID-19 Vaccine EUA Fever (99.8 - 100.4 F over course), body aches, chills - took 2 tylenol (650mg each) about 1-2 hours after onset, symptoms resolved within 2 hours, temperature back down to 98.6F.

Tuesday, rash started on Wed with no new meds/food/lotion/soap/detergent. Rash is raised, wide-spread to left arm, abdomen and upper back/shoulders. + Itching/irritation. Denies blistering, SOB, cough, fever, chills. Using topical triamcinolone which helps with itching START ON Prednisone for 9 days, Claritin 10mg AM for 7 days,Benadryl 25-50mg PM for 7 days.

After injection, within 1 hour, started having left arm muscle tightening, up to left shoulder. Following morning: facial numbnes/decreased sensation; mild facial droop. Onset 9am on 12/28/2020. Went to ED for evaluation. Sensation started to resolve, continues to be slightly diminished on left side of face. Droop has since resolved.

Pt came in for vaccination for COVID-19 at 4:03 . She received Moderna vaccine at 4:15. She experienced palpitation, worsening chills, headache, and presyncope. No loss of consciousness. Denies chest pain, shortness of breath but feels heavy to push air in and pulse OX 100%, No angioedema, No rash, No pruritus, No throat swelling, denies hoarse voice, or difficulty breathing. She traveled to MD on 12/14/20 to receive antibiotics. She was treated with Erythromycin dose for 6 days from MD. á The patient was +COVID19 on 12/11/20 with fever, scratchy throat, congestion, cough, and SOB and was seen in urgent care on 12/13/20 where was DX + for COVID19. She was quarantine for 10 days when she was returned to work on 12/22/20. Her Chest X-ray was negative on 12/13/20. She was negative for nausea, vomiting, diarrhea. She denies any recent vaginal bleeding, or abdominal pain. Denies any history of cardiac disease, or history of arrhythmias. Denies any history of prolonged immobility, or history of clots.

Headache for 48 hours, fever x 12 hours, fatigue x 5 days, severely enlarged lymph nodes to left arm started Monday 12/28, continues today 12/29

Employee reported by bedtime of 12/28/2020 which was the date she received her 1st dose of the COVID-19 vaccine she had the following symptoms: Arm was sore as a boil and she had upper respiratory symptoms similar to a cold, drainage, nasopharyngeal irritation and cough lasting a good while.

Pt. received vaccine, at 640pm... at 705 pm, c/o throat tightness, nausea, mouth tasting like chemical. METS team called, taken to Emergency Room

Pfizer-BioNTech COVID-1 Vaccine Patient presented to ED 10 minutes after receiving COVID vaccine with mild redness around injection site and some chest tightness that may be attributed to being nervous and anxious over vaccination. no erythema or swelling noted around injection site. Patient had just worked 14 hours night shift. 0823 redness improved along with chest tightness. IM dexamethasone 8 mg given in ED 0837 significantly improved after ED observation and stable for discharge Prescription for hydroxyzine 50 mg po TID x 7 days Follow up with PCP

Sore Throat, Coughing, started 16hrs after injection

Uterine/pelvic cramping, nausea. Third pregnancy, EDD 6/8/21, 16 weeks pregnant

Hives, angioedema, and periorbital edema.

hand tingling, itching all over, chest feels hot or flushed, nausea, rash Went to the ER after advised by staff -treated with benadryl 50 mg IV solu medrol 125 mg IV/zofran 4mg IV/Pepcid 20 mg IV/Tylenol 975 mg po stable after IV meds, discharged home with epi pen and steroid dose pack

"Woke up the morning after vaccination and had ""blisters"" in mouth and itching all over. States wife saw some ""red spots"" on his back but no other place. Also immediately after injection felt the need to take inhaler. Itching to hands and ""all over"" continues as of 12/28/2020 without evidence of hives or rash."

Vomiting at 10:30. Watery diarrhea until about 1:00 am

Injected into tricep instead of deltoid

Runny Nose, No smell

Patient c/co - lightheadedness, tingling on L side of jaw, w/ peripheral tingling in bilateral feet. Pt given water for hydration, VS taken: 121/75 BG of 105 HR of 85 w/ O2 sat. of 98%. ED (Dr.) contacted, assessed for anaphylactic events - none noted. After 20 mins, patient reported relief w/ only dry mouth remaining. Pt believes it may have been an anxiety attack. Continuous monitoring applied. Patient washed face w/ water and relayed he was feeling fine and will now get something to eat. Pt released w/ no s/s reported.

headache backache neck ache dizzy about 30 min. after vaccine

heart rate of 40; dizzy; really tired; This is a spontaneous report from a non-contactable consumer (patient's friend). A male patient of an unspecified age received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date were not reported), via an unspecified route of administration on 16Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient was having some symptoms that wanted to check out. On Dec2020, he was really dizzy, he was really tired, and he had a heart rate of 40. No questions, they just want to make sure that he was not going to die. Outcome of the events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

immediate chills, shaking, low BP (82/60), low grade fever (99.8) when covered with blanket in following 48 hrs - fever 102.7 before meds. chills, shaking, severe diarrhea, abdominal cramping, nausea

Chills, body aches, dizzy, migraine, vomiting, low grade fever, neck pain. Took Tylenol and Advil to relieve the pain.

Diaphoretic, felt like she was going to pass out. Lost pulse momentarily, stopped breathing momentarily. Spontaneously recovered.

Left side of face Numbness, Gone after 24 hrs

Injection into tricep instead of deltoid. Discovered next day by patient based upon pain location.

I was being monitored for 30 minutes. At 20 minutes after the vaccination, I began having difficulty swallowing and within minutes of that began experiencing numbness around my mouth, including my lips, with minimal swelling wound my lips and mouth. Then I had a tingling sensation as if pins were sticking me in my face, especially around my eyes and forehead. I immediately ported my symptoms to the nurse standing next to me for observation. My entire body felt as if it was on fire, with a burning and itching sensation. I was administered 25 mg of Benadryl IM and was transported to the Emergency Department, where I was given oral prednisone. I left the Emergency Department is about 2 hours. At 24 hours after the, I still have itching around my scalp, back and lips.

7:30PM flu like symptoms with severe shaking and fever ranging from 102 to 104 the first night. At approximately the same time for the next two nights fever ranging from 101 to 103 and flu like symptoms . These symptoms lasted 3 days during the evening hours only.

Sore arm, Joint Aches

Sore arm, Joint Aches

The vaccine was administered on the following date: 12/28/20áand at approximately the following time: 12:20pm á The symptoms began 5 min after administration of the vaccine.á The symptoms were: 5 min after vaccine had hives, felt itchy and warm. Symptoms were on chest, face and scalp. Tingling in her arm and left jaw tingling. She did not have swelling, wheezing, SOB, dysphagia, GI symptoms. She went to the ER- given IV benadryl, pepcid, solumedrol. 30 min it felt much better By the time she left 2 h later, she felt much better. She had some blotchiness and itcihng on her skin this AM (24h later) so she took

allegra. She was prescribed prednisone but has not yet picked it up. The treatment of the reaction was:áá o Antihistamines:ábenadryl 25mg, famotidine 20mg o Steroids:ámethylprednisolone 125mg in the ER o Epinephrine:ánone á Other medications taken on day of reaction:áázoloft and MVI- taken for years. Other possible exposures (e.g.áfoods):ánone Was this the first dose of the vaccine?: yes Location of injection site:áLeft upper arm Other pertinent past medical history: noneá History of COVID infection: no History of systemic allergic reactions to drugs, foods, vaccine:ánone Other pertinent medications:ánone

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Extreme arm soreness, pain with any/all arm movement > 24 hours

First I had a really bad muscle ache , chills, fatigue headache, fever, ear ache , sore throat

Chills,Lightheaded, Nauseated, Left leg pain and body aches.

Soreness of Arm, cold like symptoms for 3hrs day after, joint pain

Developed hives on face and both arms. Released after 30 minutes of monitoring with no further progression of symptoms. Returned one hour later reporting scratchy throat and feeling of being swollen all over. Also presented with increased redness on face (blushing). No difficulty with shortness of breath. Escorted to ER for monitoring.

Moderna Covid-19 Vaccine EUA Swollen lymph node in right arm pit: starting 12/27/20 at 11:00 pm

severe vertigo

When I got the vaccine, I observed redness on both arms immediately and severe itching all over my body. I had nausea, I vomitted, I felt like I was drowning, I had tightness left side of my body from neck to foot, The Director of Nursing observed that rashes reached up to my neck, BP was elevated as well

Became hot, flushed and felt dizzy,. Had slight weakness in rt face

Hives 4 hours post-vaccine. Improved with diphenhydramine. Resolved by the following day

Adverse reaction post Covid vaccine. Waited for 20 min post vaccine. Experienced S/S Heart palpitations, shortness of breath, tingling in extremities, diaphoretic after leaving clinic observation. Drove back to hospital, escorted by pre surgical testing hospital staff and taken by wheelchair to ED.

Body Chills, Joint pain

major confusion 9 hours after first administration continuing on to the next day, pain at wound site, itchy feeling

"Patient reported developing a ""butterfly rash"" across the bridge of nose and cheeks approximately 24 hours after COVID-19 vaccine. Rash resolved without treatment within 10 days. Also experienced some fatigue."

Within 1 hr of receiving shot felt heaviness and pain in lungs, gradually getting worse then swollen face and clearing of throat constantly by hr 4. By hr 7 gradual lung pain and face swelling reduced. Today 12/29 still have some lung pain little face swelling but still have trouble breathing while walking and talking.

Throbbing, constant pain with burning from L) shoulder joint to fingertips plus shoulder joint up to left neck; nausea, dizziness, headache, joint pain (all body), muscle aches, throwing up, loss of appetite

headache

Achiness, chills and fatigue for 2 days. Better for 1 day, worked and went for a run, then woke up in middle of night going into 4th day post vaccine with severe aches. Got Covid tested on day 4, came back negative on day 5. I am now on day 11 post vaccine and am still having aches in my hip joints. I?m unsure if it?s related to the vaccine but I haven?t been able to run (I am a regular runner) without pain. I did not have any pain from running prior to the vaccine.

Injection site soreness in the AM 12/23. Later in the day on 12/23, body aches and general malaise. On 12/24 continued malaise and painful headache.

Low grade fever and body aches onset approx 14-16 hours post vaccine

Lightheaded, body aches, hot flashes, chills, developed a 101 fever, shortness of breath

Almost a week later after the first dose, still experiencing intense shaking / chills at night. Fatigue during the day with headaches.

The patient was given the Moderna vaccine. She then felt very hot around 15 min post vaccine, felt anxious. Felt her HR was racing, so she looked at her Apple Watch, which said it was 103bpm. She let the RN know and it went up to 125 bpm. BP was 140 which is high for the patient, baseline is around 100 systolic. She then felt shaky. The RN said she saw a few hives on her chest and it was a bit itchy. They gave her some water and juice. She felt better and the hives resolved on their own. She then was given

Zyrtec 10mg. About 30 min post-vaccine, her HR was 85 and BP was 130 systolic. No wheezing, no SOB, O2 sat was normal the entire time. She still feels shaky and anxious. 2 h later she felt asymptomatic.

Low grade fever to 100.1 the morning after receiving the vaccine, mild body aches and headache. Symptoms dramatically improved within 12hrs and by the following morning (48hrs post receipt of vaccine), I was symptom free.

Experienced numbing of right face and jaw for half a day 2 days post vaccination. Took ibuprofen 400mg and symptoms eventually resolved.

Arm soreness Feverish Chills Body Aches

Pt felt lightheaded. Pt did not eat breakfast or lunch prior to vaccine. Pt commonly becomes nauseated after flu shots with no additional adverse effects. Pt was positioned in supine and given Sprite and crackers. After eating, symptoms resolved.

Red itchy spots/hives across abdomen and chest. Have used topical anti-itch cream, taken over the counter benadryl and zyrtec. Topical cream and benadryl did not seem to have any effect. Just took zyrtec this morning so results tbd.

within 2 minutes after receiving vaccine I became flush, tightness in base of my throat and chest and heart starting racing faster and faster. A few nurses came over and saw my fit bit heart rate going higher (max 136 BPM) my fingertips started to get numb. They quickly injected me with .05 epinephrine. They brought me up to the emergency room and put me on a heart monitor. The racing heart subsided after approx. 7 min then started again. It happened 3 times in the emergency room. They ran a few EKG's to try to catch the tachycardia episodes. They started an IV and ran fluids. After 2 hours the symptoms stopped and they released me from the hospital.

Mild rash all over the body the evening post-vaccination. Alleviated by diphenhydramine. Heart palpitations for 2 days post-vaccination

Sore arm, body aches that are as bad as when I had covid, chills, stomach ache.

12am I woke up with a headache chills body aches and sore arm

Sore arm, Heart skipping Beats, Body pain

Itching, redness, hives to right side of face and neck, abd pain. Right upper back pain started almost immediately after vaccination. Continued through the night. Itching, redness, and hives resolved in approximately 2 hours with administration of dexamethasone. Abd pain continues today. Right upper back pain is full today, instead of sharp, and is intermittent today.

The employee reported difficulty breathing. She transferred to the Emergency Department for elevated heart rate and possible syncopal episode. Symptoms self resolve with no medications required.

Received vaccine on 12/28/2020 @ 930am. By 7:00pm left deltoid was tender to touch. Redness , swelling at site. on 12/29/2020 the redness and swelling had increased to 1 inch wide x 3 inch like a band across my deltoid , It is tender to touch and itchy.

Facial numbness,redness

terrible headache, pain in the joints, chest tightness.

Sweating then chills. Back to back. Two days.

Swelling redness and soreness at injection site

Swelling redness and soreness at injection site

Soreness in arm immediately. 13 hours after injection- sweats, chills, increased arm pain, body aches, extremity pain, palm sensitivity, nausea, trouble sleeping. 14 hours after injection- fever, shortness of breath, fatigue, redness in arm, swelling in injection site. 18 hours after injection- stiffness in injection site, extreme fatigue, increased nausea.

6 hours post vaccine: sore arm, chills 24 hours post vaccine: fever (101-102), chills, myalgias, headache, severe soreness at injection site (no other symptoms). All symptoms resolved by 48 hours post vaccine.

cough and a little difficulty breathing rash in the torso (of abdomen and back

Red circle about 3 inches wide and 3 inches long bruising itching, swelling, dizzy headache

Headache and injection site pain, Nausea

shingles

Moderna has an EUA from the FDA for patients aged 18 and older. This vaccine was used inappropriately to vaccinate a 17 year old staff member at a clinic hosted by Pharmacy. Patient experienced no adverse effects, but this improper usage of the vaccination requires reporting to VAERS.

hives down bilateral exposed skin - Benadryl oral tab provided with relief. Hives disappeared by 12:45PM

elevated blood pressure to 156/92 following injections. Experienced dizziness. BP checked 5 hours after vaccine: 143/88.

lightheaded, left lower arm pain chest pain with burning sensation , increase heart rate to over 190 and High blood pressure lasting for 2-3 hours

Fever, Nausea, Diarrhea, covid test was negative

On December 27th I began to have uticaria on my chest, back, legs and neck that respond to oral diphenhydramine but return after 6-8 hours. This is ongoing for three days so far.

Anaphylaxis requiring epinephrine

Body aches, low grade fever 99.5

Injection sight soreness

Body aches, chills, slight fever

a couple days after the vaccine, I developed a rash on the bottom of my abdomen, my neck, and my elbow creases. The rash was worst along my abdomen especially the right hip. The rash is red and looks like tiny red circles.

Patient presented five days after first COVID vaccine with complaints of tingling running down her arm (peripheral paresthesias per MD report) and also swelling and redness at injection site. She does also complain of feeling a little achy the day following her vaccination. She was given prednisone and diphenyhdramine while in the ED. She was prescribed prednisone (20 mg x 3 days) upon discharge.

Fatigue, joint pain, muscle aches, headache, nausea and vomiting for three days. Treated at home with over the counter pain relievers.

Neck swelling, labored breathing

Fatigue, Muscle pain and redness at injection site

moderate rash to left arm, mild to right arm. Also rash to trunk and legs. Benadryl was taken

Hives to face for 1.5 hours - improved after 1 course of Benadryl

5 minutes after the injection I developed tinnitus in both ears. This has continued on since the injection. It varies in intensity but is constantly there. I had never experienced tinnitus prior to the shot.

Vaccine recipient received vaccine on 12/17/2020. Reported that they felt tired the next day. Three days after receiving the vaccine, reported to develop headache and neck/should pain. This was still bothering the vaccine recipient. Directed to follow-up with occupation health.

Rapid heart rate, achy, fever 101, flu like symptoms started about 7 hours after vaccine. She did have Covid on 11/1/2020. She is going to give it today and see how she feels and will let me know if she goes to the DR or ER.

Pain at injection site, muscle pain, redness around injection site

Fever, shortness of breath, headache, myalgias

itching, face and eye swelling, wheezing, H/A. Treated successfully with Epi X 2 and Benadryl.

Anaphylaxis requiring epinephrine

tenderness in armpit, specifically upon touch

Patient received the covid vaccine on 12/20/2020. She reported that she started to have chills (temp reading were in 98.0s), headache, bodyaches, and swelling of the Right groin on 12/21/2020. She was evaluated by her PCP (in person) and treated with Ampicillin x 7 days . She did NOT inform her PCP about her covid vaccination status. HAs, bodyaches, chills, and R groin swelling resolved by 12/26/2020. On 12/28/2020 she c/o new onset of nasal congestion. Denies fevers or cough. She tested positive for covid on 12/28/2020 at Employee Health. Has FU appt with PCP in one week and EH on on 1/7/2021.

Hives on abdomen, back, and ankles; associate reports taking loratadine 10 mg PO from personal stock

Fell light headed, muffled hearing, flush, warm.

Jittery, Increase heart rate with 20 min after shot.

Light Headed, Cold, burning sensation inside, nausea, felt like she was going to pass out, rash on chest/neck, she could hear people talking but felt she didn't feel like she was present - elevated BP 200/110. Staff member took Metoprolol 25mg. 1/2 hour took medication feels better but feels foggy

Rash on the upper chest and neck

Increased heart rate and blood pressure, syncope, nausea, sore throat, fever

I received the Pfizer EK5730 shot at about 11:30 am on 12/28/2020. When I walked out of the office from getting the shot I started feeling like I had walked mile but I was ok. At about 4:00 PM I started feeling some tightness on my chest and some aching like a pulsing aching on my chest. I felt like I had some energy but I also felt I was paying to mush attention to my symptoms. I lay down at 8:30 PM and I fallen to sleep on the couch. When I got up this morning as stood up from my bed my legs were hurting and I feel exhausted. I just want to cuddle and go back to sleep. I force myself to make it to work but I am dealing with leg pain and very very tired with a slight headache and chills.

"My temperature, it is 100.6; I was feeling chills; I am having body aches/full blown body aches; I was starting to feel achiness/achiness was not going away; I am congested all of a sudden; I felt like I was developing a headache that just got worse as the day progressed/now I woke up this morning and my head is hurting; I was not feeling well; This is a spontaneous report from a contactable nurse who reported for herself. A 56-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot #: EH9899; Expiry Date: Mar2021) via an unspecified route of administration on 18Dec2020 at 09:59 (at the age of 56-years-old) as a single dose for COVID-19 vaccination. Medical history was reported as none. The patient reported ""no, I do not have any health issues."" Concomitant medications included estradiol taken as hormone therapy from an unspecified date at 0.1 mg, once daily. The patient experienced ""I felt like I was developing a headache that just got worse as the day progressed/now I woke up this morning and my head is hurting"" and ""I was not feeling well"" on 18Dec2020, ""I was starting to feel achiness/achiness was not going away"" on 18Dec2020 at 18:00, ""I was feeling chills"" and ""I am having body aches/full blown body aches"" on 18Dec2020 at 19:00, ""I am congested all of a sudden"" on 18Dec2020 and ""my temperature, it is 100.6"" on 19Dec2020. It was reported that the ""symptomatology began immediately after I got the vaccine (COVID Vaccine)"". The

clinical course was reported as follows: ""I received a vaccine (COVID Vaccine) at work. I am a nurse, I received a vaccine at 09:59 today morning and within probably 5 or 10 minutes, I felt like I was developing a headache that just got worse as the day progressed. By the time, I got home, I get off at 6 O'clock, I started to feel achiness and then eventually I was feeling chills and I was congested all of a sudden as well. So, I took a 1000 mg of acetaminophen last night probably around 9 PM. Initially, I thought it was just side effects from the shot and I would ride it out, but the achiness was not going away. So, I took the acetaminophen and went to bed. When I took the acetaminophen within about two hours the symptoms improved, the achiness had diminished, but I woke up this morning and my head was hurting, I am having chills, I am having body aches. I just took my temperature, it was 100.6."" The nurse stated that she took acetaminophen as treatment for the side effects. When asked about the primary/prescribing Healthcare Professional details the patient stated ""well, it was not a doctor it was a nurse at our hospital, it was a room full of people giving the shot."" The patient also stated ""I read correctly under side effects that the vaccine cannot cause you to contract COVID. Is that true?"" The nurse was informed about Pfizer Medical Information department. When asked about the dosage, the patient stated ""No, I don't think that is on here."" When asked about the causality, the patient stated ""I think it is possible, but it is also possible I mean I just got the vaccine yesterday, I mean we test patients for COVID in my department. My department is responsible for testing all procedures on surgical patients at the hospital and there is always a chance that I have contact with COVID but it is odd that the symptomatology began immediately after I got the vaccine (COVID vaccine), I mean within 10 minutes, I was not feeling well. When I woke up yesterday I was having no symptoms whatsoever and then almost immediately after I took the vaccine it seemed that I had a headache again and it just lasted the entire day, all day until I got home it was so bad and I still have not taken anything because I thought it was just the side effects and like 7 O'clock I was having full blown body aches and chills."" (as reported). The clinical outcome of the event ""I felt like I was developing a headache that just got worse as the day progressed/now I woke up this morning and my head is hurting"" was not recovered/not resolved; the outcome of the event ""I was starting to feel achiness/achiness was not going away"" was recovering/resolving; while the outcomes of the events ""I was feeling chills"", ""I am congested all of a sudden"", ""my temperature, it is 100.6"", ""I was not feeling well"" and ""I am having body aches/full blown body aches"" were all unknown."

parasthesia in injected arm including ring and pinky fingers; parasthesia in injected arm including ring and pinky fingers; weakness in injection arm up to the tricep muscle; He also experienced mild weakness; This is a spontaneous report from a contactable nurse (patient). A 33-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number: EK5930), via an unspecified route of administration in left arm on 21Dec2020 09:00 at a single dose in TB size syringe for COVID-19 immunization. The patient has no medical history. There were no concomitant medications. The patient is a nurse anesthetist calling about himself, stating that he thinks he has had a reaction to the Pfizer COVID Vaccine. He took a dose about 9am this morning and about 2.5 hours later he experienced paresthesia in his injected arm including his ring and pinky fingers. He also experienced mild weakness. The symptoms lasted about 45 minutes. Stated that the symptoms lasted about 45 minutes and has completely resolved thus far; however, he cannot attest if these symptoms will return or not. Stated that it was given with a TB size syringe and so assumes that it was the standard dose that

he received, but does not know for sure. No treatment was received for the symptoms. He just monitored himself. Caller wants to know if he should move forward with the second dose. He heard about Bells Palsy. If he had paresthesia with his first dose in the injected arm, could the paresthesia come to his face next? He wants to know if he is in the normal category to advance with the second dose. The events were reported as not serious. The events recovered on 21Dec2020.

Severe heartburn; abdominal pain; Agita; swelling; chest tightness; generalized redness; itching; sore throat; severe weakness; fatigue; headache; muscle pain; nausea; malaise/feeling unwell; increased temp but not febrile; This is a spontaneous report from a contactable nurse, the patient. A 63-year-old non-pregnant female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), intramuscular in the left arm on 18Dec2020 at 14:15 (at the age of 63-years-old) as a single dose for COVID-19 immunization. Medical history included chronic pain, hypertension, diabetes, depression, and broken vertebra. The patient was allergic to many antibiotics and benzodiazepines which caused dystonia. The patient also had an allergy to all anti-emetics except ondansetron (ZOFRAN) in the form of dystonia. Prior to the vaccination, the patient was not diagnosed with COVID-19. Ongoing concomitant medications included diclofenac (MANUFACTURER UNKNOWN) from an unknown date for an unknown indication, esomeprazole magnesium (MANUFACTURER UNKNOWN) from an unknown date for an unknown indication, fentanyl (MANUFACTURER UNKNOWN) for a broken vertebra from an unknown date, gabapentin (MANUFACTURER UNKNOWN) from 2019 for an unknown indication, misoprostol (MANUFACTURER UNKNOWN) from an unknown date for an unknown indication, oxycodone hydrochloride/paracetamol (PERCOCET) from an unknown date for an unknown indication, and fentanyl (FENTANYL PATCH) from an unknown date for an unknown indication. The patient did not receive any other vaccines within four weeks prior to the vaccination. On 18Dec2020 at 14:30, the patient experienced generalized redness, itching, swelling, and chest tightness; which required her to go the emergency room for 6 hours and was treated with epinephrine (MANUFACTURER UNKNOWN), diphenhydramine hydrochloride (BENADRYL), and fluids. On an unknown date in Dec2020 (reported as later), the patient had sore throat, severe weakness, fatigue, headache, muscle pain, nausea, malaise/feeling unwell, and increased temperature but not febrile. On 22Dec2020, the patient had severe heartburn, abdominal pain, and agita. Since the vaccination, the patient had not been tested for COVID-19. The clinical outcomes of generalized redness, itching, swelling, chest tightness, sore throat, severe weakness, fatigue, muscle pain, nausea, malaise/feeling unwell, and increased temperature but not febrile were recovering; while that of the headache, severe heartburn, abdominal pain, and agita were not recovered. The events were reported as non-serious and assessed as possibly related to the vaccine. The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up.; Sender's Comments: The patient was allergic to many antibiotics and benzodiazepines and had an allergy to all anti-emetics except ondansetron (ZOFRAN) in the form of dystonia. Based on information available, the reported chest tightness and swelling together with generalized redness and itching were possibly related to the BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), considering temporal relationship and clinical course. This case will be reassessed should additional information become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any

appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Severe headache woke me from sleep approx. 6 hrs later, continued till the next day; Severe headache woke me from sleep approx. 6 hrs later, continued till the next day; severe neck and back stiffness, just did not feel well; severe neck and back stiffness, just did not feel well; This is a spontaneous report from a contactable nurse (patient). A 47-year-old female patient received bnt162b2 (Pfizer Biontech COVID 19 vaccine), lot number: EJ1685, via an unspecified route of administration at the left arm on 20Dec2020 06:30 at a single for COVID-19 immunization. Prior to vaccination the patient was diagnosed with COVID-19. Concomitant medication included levothyroxine sodium (SYNTHROID), carvedilol (COREG), ergocalciferol (VIT D), vitamin b complex (VIT B COMPLEX) and bupropion hydrochloride (WELLBUTRIN). On 20Dec2020, the patient experienced severe headache that woke her from sleep approximately 6 hours later and continued till the next day. She started having severe neck and back stiffness and just did not feel well. The patient was not hospitalized for the events and did not receive any treatment for the events. The events were reported as non-serious. The vaccine was administered in a hospital. The patient has not received any other vaccines within 4 weeks prior to the COVID vaccine. Since the vaccination, the patient has not been tested for COVID-19. The events recovered on an unspecified date in Dec2020.

Her BP went down to 80/60 with a pulse of 50.; sudden light headiness/light headedness; pulse of 50; Slurred speech; extreme sleepiness/sleepiness that there was no other focal deficit; felt like she was under anesthesia, was unable to move her legs/felt like she was under general anesthesia trying to wake up but unable to open her eyes or move her arms or legs; This is a spontaneous report from a contactable pharmacist. A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) lot number and expiration date were not reported, via an unspecified route of administration on unspecified date at a single dose for immunization. Medical history was none. The patient's concomitant medications were not reported. It was reported that the patient (a doctor) received the vaccine and had a sudden light headiness, slurred speech, and extreme sleepiness with outcome of recovered. She felt like she was under anesthesia, and was unable to move her legs. Her BP went down to 80/60 with a pulse of 50. All of these episode lasted about 2 hours. The patient became alert, but she still felt a bit light headed. She felt normal the next day. The patient said that at the sudden onset of the side effects: light headedness, slurred speech, and sleepiness that there was no other focal deficit. She felt like she was under general anesthesia trying to wake up but unable to open her eyes or move her arms or legs. The outcome of the events Her BP went down to 80/60 with a pulse of 50, sudden light headiness/light headedness, Slurred speech, extreme sleepiness/sleepiness that there was no other focal deficit and felt like she was under anesthesia, was unable to move her legs/felt like she was under general anesthesia trying to wake up but unable to open her eyes or move her arms or legs was recovered on an unknown date. Information about lot/batch number has been requested.; Sender's Comments: A possible causal association between administration of BNT162B2 and the onset of low blood pressure/ low pulse with dizziness cannot be excluded, considering the plausible temporal relationship. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for

adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate

Midbottom of foot to toes is completely numb; tingling in toes of both feet; paresthesias (numbness, tingling) right arm; paresthesias (numbness, tingling) right arm; This is a spontaneous report from a contactable nurse practitioner, the patient. A 56-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot Number: EK5730), intramuscular in the left arm on 18Dec2020 (at the age of 56-years-old) as a single dose for COVID-19 immunization. The patient did not have any relevant medical history. Ongoing concomitant medications included levothyroxine sodium (SYNTHROID) and unspecified vitamins. On 18Dec2020, the patent experienced paresthesia (numbness, tingling) in right arm. On 19Dec2020, the patient had tingling in the toes of both feet. On 21Dec2020, the mid bottom of foot to toes was completely numb. The clinical course was as follows: The patient received the vaccine in the left arm on 18Dec2020 and 9 hours later, she had paresthesias (tingling/numbness) in right arm. It was stemming from her shoulder down her arm. Around mid-morning on 19Dec2020, she had started having tingling in the toes of both feet. On 21Dec2020, the mid bottom of foot to toes was completely numb. The patient reported that the paresthesias (tingling/numbness) in right arm was getting better and was more intermittent and the tingling in the toes was only in the left foot as of 22Dec2020. The clinical outcome of the paresthesia (numbness/tingling) in the right arm was recovering; while that of the numbness in mid foot to toes and tingling in the toes were not recovered. The reporter assessed the events as serious for being medically significant and assessed the events as related to the suspect vaccine.; Sender's Comments: The Company cannot completely exclude the possible causality between the reported paresthesia (numbness, tingling) in right arm, tingling in the toes of both feet, the mid bottom of foot to toes was completely numb, and the administration of the BNT162B2 for COVID-19 immunization, based on the plausible temporal association. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified, as appropriate.

Hypotensive (diastolic 43, sistolic 103); neurological tingling -upper spine/between shoulder blades; felt crummy; This is a spontaneous report from a contactable consumer. A female patient of an unspecified age received 1st dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration in left arm on 21Dec2020 15:45 at single dose for Covid-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient experienced hypotensive (diastolic 43,sistolic 103), neurological tingling - upper spine/between shoulder blades and generally felt crummy on 21Dec2020 at 15:45 (also reported as occurred within 5 minutes of shot). The patient underwent lab tests and procedures which included blood pressure measurement: 103/43 on 21Dec2020. Event resulted in emergency room and physician's room visit. Treatment received intravenous (IV) fluid replacement, lab tests (unspecified), 6 hour observation. The outcome of events was unknown. Information on the lot/batch number has been requested.

"Immunocompromised; Flushing; This is a spontaneous report from a contactable other healthcare professional which is also the patient. A 37-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration not provided), via an unspecified route of administration on 21Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient received the COVID-19 vaccine yesterday (21Dec2020) and experienced flushing since Dec2020. Added that patient was also immunocompromised. The events were reported as non-serious. Outcome of the events was unknown. Information on the Batch/Lot number has been requested.; Sender's Comments: Limited information was provided for the mentioned ""immunocompromised"". Based on the information currently available, pending further clarification, the Company deems the reported ""immunocompromised"" unlikely related to the administration of BNT162B2. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RA, IEC, as appropriate."

chills all night and syncope; chills all night and syncope; This is a spontaneous report from a contactable other health professional (patient). A 39-year-old male patient received the first dose of the bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot Number and Expiration Date: Unknown), intramuscularly in the left arm (also reported as the right arm) on 22Dec2020 at 15:00 at 39-years-old at a single dose for COVID-19 immunization. The facility where the most recent COVID-19 vaccine was administered was reported as: other. Medical history included Penicillin allergy from an unknown date and unknown if ongoing. Concomitant medications included estrogens conjugated (PREMARIN), progesterone (MANUFACTURER UNKNOWN), estradiol (MANUFACTURER UNKNOWN), montelukast (MANUFACTURER UNKNOWN); all taken for an unspecified indication from an unspecified date to an unspecified date (all of which were received within two weeks of vaccination). The patient did not receive any other vaccines within four weeks prior to the COVID vaccine. On 23Dec2020 at 00:00, the patient experienced: chills all night and syncope. The event syncope was considered medically significant; and the event chills was non-serious. There was no treatment received due to the adverse events. It was reported that prior to vaccination, the patient was not diagnosed with COVID-19; and since the vaccination, the patient had not been tested for COVID-19. The clinical outcome of the events, chills all night and syncope, was recovering. The batch/lot numbers for the vaccine, bnt162b2, were not provided and will be requested during follow up.; Sender's Comments: Based on temporal association, a possible contributory role of suspect BNT162B2 vaccine cannot be excluded for reported event syncope. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

"vomiting; nausea/felt like she was going to vomit; headache/bad headache was reported as worsened; arm and joint pain in injection arm/Joint pain; arm and joint pain in injection arm; arm and joint pain, mostly in the left arm where she received the COVID vaccine/left arm pain at injection site; had a history of a pain conditions in her back/ but got worse after the shot""; This is a spontaneous report from a

contactable nurse (reported for herself). A 26-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899), via an unspecified route of administration on 22Dec2020 11:30 at single dose at arm for COVID-19 immunization. Medical history included complex regional pain syndrome from Dec2019 and ongoing, back pain ongoing. Concomitant medications included naproxen sodium (ALEVE) ongoing, duloxetine hydrochloride (CYMBALTA) from 20Dec2020 and ongoing. Caller wanted to know if she should receive the second dose of the Covid vaccine. She received the vaccine yesterday (22Dec2020) at 11:30 (11:30 a.m.) by 21:30 (9:30 p.m.) she was experiencing side effects of vomiting, nausea, headache, arm and joint pain in injection arm, and continued to feel as if she was going to throw up. HCP was called to get Zofran prescribed. Caller further reported that she got the COVID Vaccine yesterday, 22Dec2020, at 11:30 (11:30am). At 21:30 (9:30 pm) last night (22Dec2020), she started vomiting and has had nausea since that time. Caller also stated that she had a really bad headache. Caller stated that she also had arm and joint pain, mostly in the left arm where she received the COVID vaccine. She went to sleep at 8:30 last night and woke up vomiting at 9:30pm and then had had nausea and a headache since then. If she tried to get up, she felt like she was going to vomit. She had a history of a pain conditions in her back and ""let"" (as reported, pending clarification). Stated that she cannot say that this was entirely due to the shot, but got worse after the shot (Dec2020). Caller reported that last night, she took Zofran which help the vomiting. The vomiting stopped around 3 o'clock this morning (23Dec2020 03:00), but she was still having nausea that made her feel like she was going to throw up. She could not stop vomiting for a few hours during the night. Caller asked how she know if she should be taking the 2nd dose of the COVID vaccine. Events Vomiting, Nausea, bad headache, left arm pain at injection site, Joint pain all reported as started from 22Dec2020 (21:30). Patient recovered from vomiting with lasting effects of nausea which made her feel like she was going to vomit, started on 23Dec2020. Reporter seriousness for Vomiting, Nausea, bad headache was Medically significant and bad headache was reported as worsened. Reporter seriousness for left arm pain at injection site and Joint pain was not serious. No Investigation Assessment. The reporter considered events Vomiting, Nausea, bad headache, left arm pain at injection site, Joint pain were related to the suspect product. The outcome of the event vomiting was recovered on 23Dec2020 03:00. The outcome of ""had a history of a pain conditions in her back/ but got worse after the shot"" was unknown. The outcome of the other events was not recovered.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the vomiting, nausea, headache and other reported events due to temporal relationship. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate."

hypertensive emergency; felt like the swelling was progressing into the back of her throat; swallowed harder; she felt like she was hot in her face and felt like something was squeezing her neck like a tight collar on her shirt; she felt like she was hot in her face and felt like something was squeezing her neck

like a tight collar on her shirt; shivering on and off; This is a spontaneous report from a contactable pharmacist. This pharmacist reported similar events for two patients. This is the first of two reports. A 67-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot number: EH9899), intramuscularly in an unspecified arm on 21Dec2020 14:30 at 0.3 mL single for COVID-19 immunization. Medical history included sulfa allergy. The patient's concomitant medications were not reported. There were no prior vaccinations within 4 weeks prior to the first administration of the suspect vaccine. The patient did not have a history of reactions to any other vaccines. On 21Dec2020, the patient experienced hypertensive emergency, which was reported as being medically significant. On 21Dec2020, the patient also felt like she was hot in her face and felt like something was squeezing her neck like a tight collar on her shirt, shivering on and off, felt like the swelling was progressing into the back of her throat and she swallowed harder. Clinical details were reported as follows: the patient received the vaccine on 21Dec2020 at 14:30 and fairly quickly the patient started saying she felt like she was hot in her face and felt like something was squeezing her neck like a tight collar on her shirt. She was given 25mg of diphenhydramine hydrochloride (BENADRYL), orally. The patient was shivering on and off and patient said she felt like the swelling was progressing into the back of her throat. She was having to clear her throat and swallow harder. She was taken to the emergency department around 15:11 and given intravenous (IV) famotidine (PEPCID) 20mg at 15:27. The patient did not have issues oxygenating. It was noticed that the patient's blood pressure was 232/100 on 21Dec2020 and they started treating her for the hypertensive emergency with amlodipine (MANUFACTURER UNKNOWN) 5mg orally, one time of IV labetalol (MANUFACTURER UNKNOWN), 10mg , IV labetalol (MANUFACTURER UNKNOWN) 20mg once, Clonidine (MANUFACTURER UNKNOWN) 0.1mg, orally. The patient was sent home around midnight and was not admitted to the hospital. The outcome of hypertensive emergency was recovering and of patient also felt like she was hot in her face and felt like something was squeezing her neck like a tight collar on her shirt, shivering on and off, felt like the swelling was progressing into the back of her throat and she swallowed harder was unknown. When querying causality, the reporter stated this patient did not have a history of hypertension, so she thinks it is suspicious.; Sender's Comments: The 67-year-old female patient had sulfa allergy medical history. Throat swelling and hypertensive emergency were possibly related to the BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), considering temporal relationship and clinical course. This case will be reassessed should additional information become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.,Linked Report(s) : US-PFIZER INC-2020510772 Same reporter/different patient/similar events

had a patient receive COVID vaccine and 3 days later developed bilateral pulmonary embolisms; This is a spontaneous report from a contactable physician. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration at single dose on an unspecified date for COVID-19 immunisation. The patient medical history and concomitant medications were not reported. The physician had a patient receive COVID vaccine and 3 days later developed bilateral pulmonary embolisms on an unspecified date with outcome of unknown. Have there

been any similar reports of such events within short time frame of receiving the vaccine? Information about lot/batch number has been requested.; Sender's Comments: The information provided is limited and doesnot allow a full medically meaningful assessment. This case will be reassessed should additional information, especially patient age, relevant medical history, concomitant drugs and clinical course, become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

facial itching; throat swelling; lump in throat; hoarse voice; This is a spontaneous report from a contactable nurse. A 37-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: ELO140), via intramuscular on left arm on 23Dec2020 at 09:45 at single dose for COVID-19 immunization. The relevant medical history and concomitant medications were not reported. The patient experienced facial itching, throat swelling, lump in throat and hoarse voice, all at 11:30 on 23Dec2020. The most recent COVID-19 vaccine was administered at hospital. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The events resulted in doctor or other healthcare professional office/clinic visit for the patient. The patient received IV benadryl and Epi pen as the treatment for the events. Prior to vaccination, the patient was unknown if diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. The outcome of the events was recovered on an unspecified date in Dec2020.; Sender's Comments: Based on temporal association, the causal relationship between BNT162B2 and the events pruritus, pharyngeal swelling, sensation of foreign body and dysphonia cannot be excluded. This case will be reassessed once additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate.

Exaggerated immune response and rigors; Exaggerated immune response and rigors; Fever and night sweats; Fever and night sweats; Sustained tachycardia between 100-105; This is a spontaneous report from a Pfizer sponsored program. A contactable 31-year-old male physician reported that he received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Lot number EH9899) via an unspecified route of administration in the right deltoid on 19Dec2020 at 10:30 at single dose for COVID-19 immunisation. Vaccination facility type: hospital. Relevant medical history included COVID-19 (recently had COVID prior to receiving the COVID-19 Vaccine). There were no concomitant medications. Five minutes after the COVID-19 Vaccine, on 19Dec2020, the patient experienced sustained tachycardia between 100-105 that lasted about 40 minutes and then dissipated by itself; the patient recovered from tachycardia on 19Dec2020. Early morning on 20Dec2020 at 03:30, he had an exaggerated immune response and rigors, which lasted about 30minutes to 40minutes, followed by fever and night sweats, which continued for 30 minutes and then it was all over. Reactions were spontaneously over. The patient recovered from the events exaggerated immune response and rigors, fever and night sweats on

20Dec2020. The physician believed that it was a hyper immune response. Recently, he had COVID prior to receiving the COVID-19 Vaccine and he wanted to know whether he should have waited after experiencing COVID to have received the first dosage of the COVID-19 Vaccine. The physician considered the reported events related to the COVID-19 Vaccine.; Sender's Comments: Based on available information, a possible contributory role of the subject product cannot be excluded for the tachycardia and other reported events due to temporal relationship. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics including EKG at baseline and during subject drug therapy, echocardiogram, electrolytes, chemistry panel, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

patient's anaphylactic reaction persisted longer than expected; This is a spontaneous report from a contactable pharmacist. A 45-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration in Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient's anaphylactic reaction persisted longer than expected in Dec2020. The outcome of the event was unknown. The batch/lot number for the vaccine, BNT162B2, was not provided and will be requested during follow-up.; Sender's Comments: The causal relationship between BNT162B2 and the event anaphylactic reaction cannot be excluded as the information available in this report is limited and does not allow a medically meaningful assessment. This case will be reassessed once additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate.

heart racing/her heart beat was 140 BPM; felt flush, hot; tired; soreness at the injection site; This is a spontaneous report from a contactable consumer. An adult female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 22Dec2020 at single dose for COVID-19 immunization. The patient medical history was not reported. The patient's concomitant medications were not reported. The patient received the vaccine and with 10 minutes felt flush, hot, and her heart racing on 22Dec2020. At one point she looked at her watch and her heart beat was 140 BPM. She was sent immediately to the ER (emergency room). Since then she was tired and had soreness at the injection site. She would have to see an allergist before getting the 2nd shot. The outcome of the events was recovered on unspecified date in Dec2020. Information about batch/lot number has been requested.

tunnel vision; Shortness of breath; headache; couldn't move arms/legs; This is a spontaneous report from a contactable other health professional via a Pfizer sales representative. A patient of unspecified

age and gender received bnt162b2 (BNT162B2), via an unspecified route of administration, on an unspecified date, at single dose, for Covid-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient experienced tunnel vision, shortness of breath, headache and couldn't move arms/legs all on an unspecified date with outcome of unknown. The information on the lot/batch number has been requested.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the reported events of tunnel vision, shortness of breath, headache and couldn't move arms/legs due to temporal relationship. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics including eye examination at baseline and during subject drug therapy, Head CT/MRI, chemistry panel and chest x-ray , counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

hallucinations; pain in right arm; headache; fever; chills; This is a spontaneous report from a contactable pharmacist via Regulatory Authority (Regulatory Authority report number not provided). A 35-year-old female received the 1st dose of bnt162b2 (BNT162B2, Manufacturer Pfizer-BionTech), intramuscular, on 18Dec2020 morning, at single dose, for Covid-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient has never had an adverse event following any previous vaccine. On 18Dec2020 afternoon, 12 hours after receiving vaccine, the patient experienced hallucinations, pain in right arm, headache, fever and chills. The patient underwent lab tests and procedures which included body temperature: fever (18Dec2020). The events recovered in Dec2020, 36 hours after. The information on the lot/batch number has been requested.

She woke up with a burst blood vessel in her eye; This is a spontaneous report from a contactable other healthcare professional (hcp) (patient). A 35-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 Vaccine), via an unspecified route of administration on an unspecified date in 2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. After receiving the Covid-19 vaccine in 2020, she woke up with a burst blood vessel in her eye. There was blood throughout the white portion of her left eye. The outcome of event was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Based on available information, a possible contributory role of the subject vaccine cannot be excluded for the reported event of eye hemorrhage due to temporal relationship. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics including including eye examination at baseline and during subject drug therapy, Head CT/MRI, chemistry panel, CBC and coagulation panel, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events.

Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

tenderness when pressure applied under left arm pit

Elevated temp 1?.2, chills, aches, nausea

Throat tightness, hoarse voice

Patient stated her throat felt tight and she was having trouble swallowing and her heart was racing. She was given diphenhydramine 50 mg IM and taken to the emergency room for observation. She was not given any additional medication in the emergency room and was discharged to home approximately 3 hours later.

nausea, headache, pain and swelling in arm, and weakness

Felt dizzy/faint and heart pounding. Given ice water and cool wash cloth, rest. Monitored, blood pressure 102/76. After 30 minutes continued to feel faint and dizzy with heart pounding feeling. Brought to Emergency Department for further evaluation.

Mild generalized, erythematous rash noted on patient's abdomen and back. The rash is pruritus.

Near Syncope

swollen gland in left armpit? tenderness to touch

Dry Cough

Client complained of numbness in arm, SOB, throat closing per onsite party, medical rendered by ambulance service, client given a Benadryl, condition improved, client released to self and drove self from the waiting parking lot.

Chills, body aches. He did have Covid on 11/11/2020

When rec'd injection on 12/23, it hurt more than any I've ever had and expected discomfort for several hours. By evening on 23rd my upper arm and shoulder were very painful and deltoid area swollen. By 24th, the pain was affecting entire left arm, shoulder, left back and neck. Then had pain/discomfort throughout body through the 25th, Ibuprofen taken as needed, by end of 26th I was feeling a bit better, and the 27th near all symptoms resolved. I do still have a good sized bruise around injection site.

7 AM - severe arm pain and swelling (for about 24 hours) 12:00 PM - 10 PM: chills, fever, fatigue, malaise

Patient reports elevated heart rate of 147 (normal: 70-120) and dizziness about 20 minutes after receiving vaccine.

shoulder pain with movement.

Patient was vaccinated for COVID-19 on 12/27/20 at 11am. 2 days later, upon waking up she developed pain at the injection site (left deltoid), and a rash on her right hand and right side of her stomach, not itching reported. The patient reported to employee health the reaction, she was seen in urgent care and given prednisone, benadryl, and famotidine.

Golf ball size swelling lymph nodes. Swelling in shoulder, chest, N/V.

Throat swelling, hard to breath, wheezing, went to employer ER. Prescribe a steroid and antihistamine.

"Patient reports that at about 30 minutes after she received her vaccine, her lips began feeling numb and tingling, mouth dry. She reports her face starting itching and developed a red rash, her face felt like it was ""on fire"". She denied any shortness of breath or difficulty breathing. She walked back into the clinic office at 1240, a set of vitals were taken and at 1250 25mg of PO benadryl was administered. Patient was held for observation and at 1325 she reported that the itching had improved. She did have an itching sensation in her through but no feelins of constriction or difficulty breathing. She stated that she did not feel drowsy and was okay to drive herself home. Her husband would be at home with her for the remainder of the day and she was told that if she developed any new or worsening symptoms to report to the ED immediatley."

Vaccine recipient received vaccine on 12/18/2020 at 7:30 am and at 9:00 am reported their bottom lip had swelling and around the chin had tingling that lasted 1.5 hours. At the occupational health follow-up visit on 12/28/20, the vaccine recipient reported that the injection site has been soar with occasional numbness and weakness that has not changed in intensity. Pfizer-BioNTech COVID-19 Vaccine

Received vaccination 12/23/20. On 12/28/20 began having fever 102+ and shortness of breath. Decided to go to ED for evaluation and COVID tested. Discharged from ED.

Back started itching, noticed huge red spot warm to the touch, hives. Neck and face become blotchy looking. Called NP, took 50mg of diphenhydramine. The hives and rash subsided by the end of the day on December 24th.

minutes after had flushed feeling all over body (similar to when I had dye injected for a cat scan).. felt lightheaded and extreme dry mouth.. lasted for about an hour. blood pressure when check on floor had a high diastolic number (120/94)

Approx 25 minutes after vaccination, client developed mild, red, raised rash with itching on lateral left wrist distal to injection site. Client denies any other adverse signs/symptoms of angioedema or anaphylaxis 1 hour after administration of vaccine.

Fever (102): body aches, chills, nausea, lightheaded (vertigo) All symptoms have subsided EXCEPT Vertigo/dizziness

Severe arm pain the following day. Resolved after about one day.

"Dizziness, warmth, ""just not normal"", scratchy throat. Resolved in about 1 hour."

Dizziness and nausea 10 minutes after injection, continued to wax and wane over approx 90 minutes. No vitals taken. Patient ambulated back to work at 1800.

tenderness to touch under right arm/armpit area. pain pressure felt when running.

Swelling of palate approx. 5 minutes post COVID Vaccine Dose #1. VS normal and stable. Received diphenhydramine 50mg PO with symptom resolution within 20 minutes. Observed for 40 minutes and D/C'd in stable condition with no sxs present.

Rash developed on forehead. Felt itch on other part of body. Felt hot and prickly. Took diphenhydramine and subsided within 45 minutes.

Weird rash to both lower legs, chest and neck area about 2 hours after administration.

Patient describes a tingling feeling all over the body, especially in the hands in face and it came in 2 waves lasting not more than a few seconds. She no longer is having these symptoms

Symptoms started 2 days after I got my injection. I had a massive migraine, body aches, chills, fever with temperature reaching 102. Symptoms lasted 24 hours. The following day I felt fine again.

Soreness in the arm achness around injection site itchy around the ears, in ears and itchy spots in throat around lips and face body felt numb

Near Syncope, dizziness

Near Syncope, dizziness

While, receiving the Covid vaccine with the needle still inserted, felt a significant amount of liquid drip down my arm and unsure how much of vaccine was administered.

Extremely stiff joints and joint pain.

Ipsilateral (to side of vaccination, i.e. left) supraclavicular adenopathy (painful, swollen, very tender to palpation for 3 days) Itchy throat Congestion Left arm soreness (this was immediately after, resolved after 3 days around the time the adenopathy began)

On December 25th developed a rash that started on the stomach, spread down legs then up the back on December 26th, all over body by the December 28th. Started off as a blistery area then turned to dry flakey skin, on the 28th started itching. by December 29th the itching had started to subside. Rash did not occur on the face but was in the scalp area. Patient took diphenhydramine but it die not help. As of the time this report is being filed has not contacted any healthcare provider.

facial swelling and hives; hives to right arm - zyrtec and prilosec taken. Ice administered. subsided by next day.

About 7 hrs after the vaccination I've experienced the side effect of tense pain on neck, lower back, thighs, calves and got more intense with time throughout the night and in the morning, daytime (now

12:34pm). Hard to sleep, kept waking up at night. I took Advil and Tylenol and couldn't tell if one was helpful then the other. The pain was still there but not as intense.

metallic taste in mouth

sore arm, chills, body aches; lasted 2 days after the vaccine date

Chills, joint pain, and headache starting 4 hours after the covid vaccine. S/S have yet to subside.

Patient received the covid vaccine on 12/19/2020. C/O new onset on sore throat and diarrhea on 12/28/2020. Sore throat is worsening. Hx of colitis by well controlled with Xeljanz. Diarrhea is unusual this time. Last diarrhea was almost 1 year ago. Denies fever, cough, loss of smell, rhinorrhea, nasal congestion, abdominal pain Awaiting PCP at medical center for evaluation and testing. Declined Employee Health Service

Systemic reaction. 3 days after injection. Severe, worsening macular-papular rash. Started on Abdomen and groin area. Now diffuse and encompasses chest, neck, and both legs. Very pruritic/itchy. Been taking daily Claritin and Benadryl. Not improving after >4 days.

Severe, disabling myalgias of lower back, flank, then lower abdomen resulting in extreme difficulty with standing and ambulatory.

"tingling in fingers approx 5 minutes after injection which resolved approximately 2 minutes later. At 0954, complaint of feeling ""clammy"", 1001 states feeling ""weak"" overall, denies lightheadedness, dizziness while sitting up on cart with HOB elevated. At 1011 no complaints and discharged from care."

Recipient reported to Employee Health Nurse: Pain at injection site, severe fatigue, headache, muscle pain, severe chills, joint pain, fever exceeding 101.0 for 2 days, increased heart rate, rash, dizziness, weakness, tightness in throat, difficulty breathing, nausea, swelling of face/lips.

8PM: Extremely nauseous 4AM: 101.5 fever 11AM: 100.3 fever 11AM: extreme body pain

12/29 c/o fatigue, heavy eyes, and numbness, tingling and swelling to left arm. Also numbness, tingling to left leg and foot. She was seen in ED , prescribed naproxen and sent home.

24 hours after receiving vaccine, Patient started to experience fever, tachycardia, chest pressure, excessive sweating, cough. Patient presented to ER for evaluation. Patient received EKG, blood tests and Covid Rapid antigen test. Patient tested positive for Covid on Rapid Antigen test in ER. Patient was having no symptoms of covid and reported no exposure to covid on pre-vaccine questionnaire the day prior. Patient released from ER to home in stable condition with instructions to call physician immediately if condition worsens.

On 12/28, start getting a really bad headache. Within two hours, I started developing aches all over my body. Developed chills for a few hours. Chills were gone by morning, but headache and some of the aches remained by noon.

Was given the vaccine and about 5 minutes later started having swelling and my eyes and face. It was watched for a few minutes and was assessed by EMS and taken to the emergency department. I was given epinephrine, Benadryl, Solu-Medrol, Pepcid, IV fluids, DuoNebs and observed overnight. I was given multiple rounds of Benadryl, steroids, Pepcid, DuoNebs

She arrived at 12:30 and was vaccinated shortly after while waiting 15 for observation within the 1st 10 min she C/O tingling of her throat and lower lips, felt palpitation. No chills, No headache, + palpitations, and No presyncope. Tells me that she did not experience any loss of consciousness. Never had any chest pain, shortness of breath, or angioedema, rash, pruritus, throat swelling, hoarse voice, or difficulty breathing. The patient has had no recent illnesses, fevers, chills, nausea, vomiting, diarrhea, or flu-like illnesses. She has had no cough, rhinorrhea, or congestion. She denies any recent vaginal bleeding, or abdominal pain. Denies any history of cardiac disease, or history of arrhythmias. Denies any history of prolonged immobility, recent travels, or history of clots. In ED:32 year old female with PMHx as listed in HPI presents with concern for allergic reaction to mod chair and a COVID-19 vaccine, felt tingling in the back of her throat and lower lip, no swelling, wheezing, shortness of breath, throat tightening, rash, nausea vomit or dizziness. Vitals reviewed found to be within normal limit. Physical exam as per above, no signs of mucosal or oral swelling, no hives or rash and no wheezing on exam. Given above findings, low suspicion for allergic reaction this time but plan to observe patient in the ED for any delayed reaction. á

Nausea 10-15 mins after dose. Pain at injection site ~10 hours later. Generalized severe myalgia (thighs and buttocks), chills & rigors ~12 hours after. Headaches, mild nasal congestion and persistent myalgia 24 hours post vaccine with fevers of 38.7 C max 36 h post vaccine. Now ~48h post vaccine and continue with headaches and myalgia especially of lower limbs. However, now also feeling fatigued.

C/o itching and redness to arms and face approx. 20 minutes post vaccine administration.á Admin Benadryl 25mg po x1 per S.O.á 1400-Pt reports itching is nearly resolved; redness improving.

extreme arm soreness, extreme body ache

Fever, chills, recently was positive for Covid on 11/29/2020

Myalgia Dizziness Nausea Fatigue Fever

Pressure in ears that started approximately 3 hours and 40 minutes after vaccination. Pressure is reported in both ears but more prominent in the left ear. Patient came back to immunization clinic under direct observation for additional 30 minutes after symptoms started. Symptoms still present.

Tachycardic, flushing

"Dizzy, nausea at 1 hour Throat tightness, felt ""swollen"" Worked x 2 1/2 hours then reported to nurse, sent to ER"

Around 4am exactly a week after getting the vaccine; I woke up in a sweat, went to the bathroom with extreme nausea thought I may throw up. No throw up came but severe nausea persisted. Along with a

lot of dizziness and light headedness. My balance feels off. My body feels strange, very sensitive to touch. Extreme exhaustion. No motivation. Head ache that seems to not go away with Tylenol. Stomach pain. And my body hurts on the inside my joints. I have metal in my back and it seems to be increased in pain. I had to take the day off and could not work. I feel miserable. Very flu like.

12hours after shot -mild to moderate pain at injection site (no redness or swelling). 12/27/20 (day 5) Skin reaction to few mosquito bite (1 inch red spot around bites). Its the first time I react to mosquito bites. Resolved overnight. 12/28/20 (day 6) Dark reddening around both eyes (specially in eyelids) when removing my makeup. Same routine/products as always. Also resolved overnight.

Dizziness. Light-headed. Given water & mint candy. Took blood pressure. Reading normal. Offered opportunity to lie down. Refused. Sat in chair until about 11:00 AM when felt better to drive.

Dizziness. Light-headed. Given water & mint candy. Took blood pressure. Reading normal. Offered opportunity to lie down. Refused. Sat in chair until about 11:00 AM when felt better to drive.

Dizziness. Light-headed. Given water & mint candy. Took blood pressure. Reading normal. Offered opportunity to lie down. Refused. Sat in chair until about 11:00 AM when felt better to drive.

12 hours after vaccination I started chilling and had intense body aches, terrible joint pain. I do have arm soreness but nothing worse than with other vaccinations. These symptoms have continued for 24 hours after the injection

"Vasovagal response. Pt requested to lie down following vaccination. Reported feeling faint, nauseous and ""seeing stars."" Team applied cool compresses, patient instructed to lie on the floor with feet on a chair. Vitals were BP: 124/82, hr 53, o2 97% at 1200. Pt moved to sitting shortly thereafter. Then, at approximately 1210 requested to lie down 2/2 ringing in ears, sweating, and feeling nauseous again. At 1212 vitals were bp 124/78, hr 58, o2 97%. At approximately 12:25 symptoms abated, pt moved to sitting. Continued to monitor until 12:50 with no recurrence of symptoms."

12/23/2020 - VACCINATION 12/24/2020 - WOKE UP AT 6AM WITH HEADACHE. LASTED 12 HOURS; NO RELIEF WITH TYLENOL (TOOK 2 BRANDS); NAUSEOUS. 'WAS NOT THE NORM'. FELT BETTER AFTER THE 12 HOURS. PREGNANCY HISTORY; 12 WEEKS,; DUE DATE JULY 11/12TH 2021.

About 45 minutes post injection I experiences the sensation of heat all over my body, my heart rate increased rapidly and I had tingling in my mouth. This passed after about 10 minutes, since then I have been experiencing exhaustion and feeling foggy. No additional reactions at this time.

Feeling of wanting to pass out, dizziness and fell at home, severe headache, body aches, scratchy throat and SOB.

Localized urticaria on day 7 post vaccine with generalized swelling, itching, and tenderness. No prior reaction until day 7.

"She arrive at 3:43 and she was nervous before the vaccination for COVID19 (Morena) because has had anaphylactic reactions to Flonase. She was feeling well up to 15 min post vaccination when she felt she is going to pass out w/o loosing consciousness. She felt weak and feeling fainted when we transferred her to the stretcher. Her BP was 163/106 P=112, Pulse Ox 100% at 16:09. She was resting, received O2 lit per min, she was feeling chest tightness when she used her inhaler Albuterol 2 puffs X2 within 5 min. She was feeling weak and stating ""I am going to pass out."" Her repeat BP=152/110, P=94 with pulse Ox 100% at 16:12 repeat at 16:30 BP=139/100, P=99 pulse OX 100% She then C/O chills later. Paramedics were called and transferred in to ED. She takes AMLODIPINE 5 MG DAILY FOR HTN. She has family HX of HTN. Negative for headache, + palpitations, + presyncope, + shortness of breath, slight difficulty brathing. She did not experience any loss of consciousness. Never had any chest pain, angioedema, rash, pruritus, throat swelling, hoarse voice. The patient has had no recent illnesses, fevers, chills, nausea, vomiting, diarrhea, or flu-like illnesses. She has had no cough, rhinorrhea, or congestion. She denies any recent vaginal bleeding, or abdominal pain. Denies any history of cardiac disease, or history of arrhythmias. Denies any history of prolonged immobility, recent travels, or history of clots. á In ED: 36 year old female presents with dizziness and presyncopal like symptoms approximately 15 minutes after receiving the Medina vaccine at this hospital the patient who is mildly tachycardic mildly hypertensive but otherwise normal and stable vital signs and is overall nontoxic appearing. Of note the patient's oxygen saturation was 97% while I was in the room and not the 2% that is documented here. á EKG notable for a rate of 87 normal axis normal sinus rhythm T-wave inversion in V1 otherwise no evidence of Brugada interval abnormality or evidence of electrolyte abnormality that would require further workup at this time. Patient counseled to follow up with her primary care. Patient given EpiPen given her EpiPen has expired. Patient requested to go back to work I feel this is fair given patient will be on campus and can return to the emergency department should she develop any further symptoms. á Patient states her symptoms have completely resolved and she has normal vital signs currently heart rate in the 80s blood pressure 138 systolic feeling well and requesting to be discharged."

Upon registration, pt informed staff she normally gets hives and itching with flu vaccine. Pt received COVID vaccine at 1205. Pt sat down in monitor area at 1209. At 1221, pt stated she started to feel slight itching. At 1230, pt stated itching had increased. RN also noted redness to neck. Pt denied any SOB, difficulty breathing, tingling in mouth, or any other anaphylactic symptoms. At 1234, RN gave 25mg Benadryl orally. Pt requested to receive smaller dose instead of the entire 50mg. Pt stayed to be monitored until 1255. No other symptoms noted. Pt educated to monitor for further signs of anaphylaxis.

Immediately injection site was itchy, but no distress. within 10 minutes, throat became very dry; back of tongue started to tingle and feel as if it were swelling. No shortness of breath noted.

Full body hives approximately 12 hours after injection, resolved with oral diphenhydramine

Shortness of breath, wheezing, throat tighness, body aches without fever beginning 3 days ago lasting 2 days resolved spontaneously overnight

reported throat closing

She stated she had hives appear on her face and had to take Benadryl.

Large red lump that was very sore to the touch, the site is warm and 7 days later a bruise has formed. Lump appears to be very slowly getting smaller.

I woke up on the morning of Dec 26th with significant eye swelling. It was somewhat relieved with loratidine anithistimine 10 mg po daily x 3 days . The swelling was bilateral, symmetrical and was not accompanied by significant reddening of the eyes. Swelling was above and below the eyes. Swelling is slowly resolving but still present today 12/29. A small amount of skin sloughing occurred below the eyes and on the eyelids. Swelling was accompanied by watery eyes, itching with foreign body sensation.

Fever- Started in the middle of the night around 1:00 am and dizziness felt like I was going to pass out. Woke up at 8 with a slight cough, dizziness and faint feeling.

Patient felt lightheaded and dizzy about 5-10 minutes after receiving his first COVID vaccine. His blood pressure was elevated (160/96 mmHg) and he was tachycardic (143 bpm). He said he felt some tingling in his arm. The injection site appeared normal. The patient sat for 30 minutes and his blood pressure and pulse normalized (134/86 mmHg and 84 bpm). He said he began to feel better and eventually left the building.

Approximately 2 and a half hours after vaccine administration, I had the sudden onset of abdominal cramping, multiple episodes of diarrhea, nausea, and tingling in my hands and lips. I recognized these symptoms as a potential allergic reaction and took cetirizine 20 mg and famotidine 20 mg. These symptoms subsided approximately one hour after onset. Approximately 4 hours later, I experienced moderate fatigue and mild muscle soreness of my left arm (where the vaccine was administered). The fatigue and soreness persisted into the next day and gradually subsided.

Sudden onset. Chills, low-grade fever. Myalgia, arthralgia I did have the Covid virus in June. I still have adequate IgG. This began while I was seeing patients today. I do not feel very good. No cough, nasal congestion, no fear of contamination.

Redness of both arms, mild cough, temp 99F

12/22/2020 Received vaccination at approximately 1000 in left deltiod area. Approximately 1700 12/22/2020 developed parethesia 3rd, 4th and 5th fingers diagonally to ulnar area of left palmar surface. 12/23/2020 noted paresthesia alone vertebrea with outward extension to all areas of back.

None stated.

c/o tingling in nose/throat, dizziness, Chills administered 25mg Benedryl PO @ 1225 v/s 98% RA HR 81 126/82 c/o Cough and itching of throat @ 1246 93% RA, 124/84, HR 83 c/o Tightness in R/chest, symmetrical chest, diminished throughout, with wheezes and faint crackes on RUL clears with cough. 1306 1306 called EMS - sent to ER for Eval

Very tired the first day; pain in my arm for two days; sporadic palpitations; This is a spontaneous report from a contactable nurse (patient). A 28-year-old female received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) lot number: Ek5730, via an unspecified route of administration in the left arm, first dose on 18Dec2020 08:15 at a single dose for immunization. Medical history included hypothyroidism. Concomitant medication included levothyroxine sodium (SYNTHROID). The patient previously took oral aspirin but had intolerance. The patient was not pregnant. The patient did not receive any other vaccines within 4 weeks prior to the vaccine. The patient was not diagnosed with covid-19 prior to vaccination and she has not been tested since the vaccination. The patient was very tired the first day, she had pain in her arm for two days and sporadic palpitations that continued. The events started on 18Dec2020 at 10:30 AM. The outcome of the events 'very tired the first day, she had pain in her arm for two days and sporadic palpitations' was unknown. The patient did not receive any treatment for the events.

Numbness and swelling of the right side of the face; Numbness and swelling of the right side of the face; This is a spontaneous report from a contactable pharmacist. A 39-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899) via intramuscular on 15Dec2020 12:45 on left arm at a single dose for COVID-19 immunization. The patient has no medical history and not allergy to medications, food, or other products. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine and did not receive any other medications within 2 weeks of vaccination. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, the patient has not been tested for COVID-19. The patient experienced numbness and swelling of the right side of the face on 22Dec2020 12:30. The adverse events result in emergency room/department or urgent care. There is unknown whether treatment received for the adverse events. The outcome of the events was unknown.

High Blood pressure; tachycardia; This is a spontaneous report from a contactable nurse (patient). A 36-year-old male patient received first dose of BNT162B2 (Pfizer-BioNTech COVID-19 mRNA vaccine, lot number: EK 5730) intramuscular in the left arm on 18Dec2020 17:00 at a single dose for COVID-19 immunization. The patient received COVID-19 vaccine in a hospital facility. Medical history included asthma, high blood pressure, and allergy to seafood. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. The patient is taking unspecified concomitant medications. The patient previously had allergies to acetylsalicylic acid (ASPIRIN) and iodine (IODO). The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient experienced high blood pressure and tachycardia then 2 minutes after receiving the vaccine. The patient did not receive treatment for the adverse events. The outcome of the events was recovered in Dec2020. The report is considered non-serious.

Pain and numbness in the left arm, from the shoulder to the fingers.; Pain and numbness in the left arm, from the shoulder to the fingers.; Pain and numbness in the left arm, from the shoulder to the fingers.; Cannot raise arm, nor leave it down.; This is a spontaneous report from a contactable pharmacist. A 55-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK5730), intramuscular on 17Dec2020 14:15 at single dose for covid-19 immunization. Vaccine location was left arm and it was the first dose. The COVID-19 vaccine was administered at Hospital. Medical

history included Right breast cancer. Concomitant medication included vitamin Vitamin C, Vitamin D, anastrozole (ARIMIDEX). The patient experienced pain and numbness in the left arm, from the shoulder to the fingers. Can not raise arm, nor leave it down on 19Dec2020. Relief with a sling. Also, to manage pain she was taking Tylenol every four hours. By medical order she started diclofenac potassium 50 mg tablet. Adverse events resulted in: Doctor or other healthcare professional office/clinic visit. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, it was unknown if the patient was been tested for COVID-19. The outcome of the events was unknown.

Nausea; colic; diarrhea; This is a spontaneous report from a contactable pharmacist. A 51-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number EK5730), intramuscular at left arm on 21Dec2020 11:15 at single dose for COVID-19 immunization at a hospital. The patient's medical history and concurrent conditions was reporter as none. The patient had no known allergy (NKA) to medications, food, or other products. There were no concomitant medications (no any other vaccines within 4 weeks prior to the COVID vaccine, no any other medications received within 2 weeks of vaccination). The patient was not diagnosed with COVID-19 prior to vaccination, and had not been tested for COVID-19 since the vaccination. On 21Dec2020 15:00, the patient experienced nausea, colic, and diarrhea. The events lead to doctor or other healthcare professional office/clinic visit. No treatment was received for the events. The outcome of the events was recovered in Dec2020.

joint pain in both knees and elbows/pain in both hips/some joint pain on the right knee and hip; This is a spontaneous report from a contactable physician(patient). A 35-year-old male patient received the first dose of BNT162B2 (lot number: EKS730), via intramuscular in left arm, on 18Dec2020 09:45 AM at single dose for COVID-19 immunization. Facility where the most recent COVID-19 vaccine was administered was hospital. The patient was not diagnosed with COVID-19 prior to vaccination. Since the vaccination, the patient was not tested for COVID-19. Relevant medical history was none. No allergies to medications, food, or other products. No other vaccines were received within 4 weeks prior to the COVID vaccine. The medications received within 2 weeks of vaccination included CBD oil drops. On Monday 21Dec2020 06:00 AM the patient started experiencing joint pain in both knees and elbows. Pain was moderate and fluctuating, the patient took some Tylenol and intensity of pain improved. On Tuesday, 22Dec2020 pain intensity decreased, however at night time the patient started experiencing pain in both hips, mostly on the right side. Today 23Dec2020 pain has disappeared from both elbows, left hip and left knee. The patient was still experiencing some joint pain on the right knee and hip, mostly when he was walking, if he was sitting down or not moving at all, pain is not present. Treatment Tylenol 500 mg P.O. (oral) q (every) 8 hours and CBD oil was received for the events. The outcome of the event was recovering.

Bell's Palsy; This case has been considered invalid as non-serious event was not reportable in clinical study. This is a report from an interventional study. A 51-year-old female non-pregnant subject received blinded therapy (BNT162; PLACEBO) first dose on 24Aug2020 at 13:15 and second dose on 15Sep2020, via an unspecified route of administration on left arm at single dose for COVID-19 immunization. Medical history included allergy to some foods. No other vaccine in four weeks and no other medications in two weeks. The subject experienced bell's palsy on 03Dec2020 which considered as non-

serious by investigator. Clinical course was as follows: on 03Dec2020, the subject had a diagnosis of bell's palsy post 2nd vaccine. The subject had no COVID prior vaccination. A nasal swab post vaccination on 30Nov2020 was negative. After visit 3 (13Oct2020), the subject reported the Bell's Palsy. She went to her doctor, but mot hospitalized. The investigator did not think this was an SAE and was not considered life threatening. The action taken in response to the event for blinded therapy was not applicable. Event treatment included an unspecified medication. The outcome of the event was not recovered. The investigator assessment with blinded therapy, concomitant drugs and clinical trial procedure not reported. Follow-up (21Dec2020): New information received from site included: updated report type, patient ID, event seriousness (non-serious).

Headache for 4 days now; 10 hours post vaccination, patient's entire arm (not injection site) hurt horribly, unable to lift; 10 hours post vaccination, patient's entire arm (not injection site) hurt horribly, unable to lift; At times her face will feel tight; 30 min post starting itching very bad; Have experienced insomnia since the injection, followed by exhaustion; Have experienced insomnia since the injection, followed by exhaustion; eyes itch and have been red; eyes itch and have been red; This is a spontaneous report from a contactable nurse. A 45-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK5730), via an unspecified route of administration (left arm) from 18Dec2020 09:45 at a single dose for COVID-19 immunization. Medical history included migraine, depression, anxiety, allergies, poly cystic ovary syndrome, asthma, different food allergy and sensitivity to all antibiotics. It was reported that 30 min post vaccination, patient started itching very bad and none of her allergy meds would calm it. Have experienced insomnia since the injection, followed by exhaustion. The itching decreases daily but even 10 hours post vaccination, patient's entire arm (not injection site) hurt horribly, unable to lift. She had headache for 4 days now. At times her face will feel tight. She added that she has allergies and sensitivity to many medications/ environmental/ scents. Outcome of events was recovering. No treatment was received due to events. Follow-up attempts are completed. The following information on the batch/lot number has been obtained.

Muscle aches in legs; This is a spontaneous report from a contactable nurse. A 50-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), intramuscular from 18Dec2020 07:45 to 18Dec2020 07:45 at a single dose for COVID-19 immunisation. Medical history included sinusitis, HLD, and penicillin (PCN) allergy. Concomitant medication included vitamin c [ascorbic acid], tocopheryl acetate (VITAMIN-E), ergocalciferol (VIT D), magnesium and calcium. The patient experienced muscle aches in legs from 2 to 12 hours post vaccine administration (18Dec2020 10:00). Outcome of event was reported as recovered. No treatment was received due to the event.

redness above eyebrow, nose and cheek and left hand had few reddened marks on skin, neck had a thin red line; right eyebrow was swollen and neck had a thin red line; The initial case was missing the following minimum criteria: unspecified event. Upon receipt of follow-up information on 23Dec2020, this case now contains all required information to be considered valid. This is a spontaneous report from a contactable nurse. A 62-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot number: EK5730), intramuscularly in the left deltoid on 18Dec2020 10:30 at a single dose for COVID-19 immunization. Medical history included hypertension (diagnosed at 47 years old), hypothyroidism, Hashimoto's disease from 2000 to an unknown date (diagnosed 20 years ago), anxious

person and weight loss. Concomitant medication included hydrochlorothiazide (MANUFACTURER UNKNOWN), taken for blood pressure from 2000 to an unspecified date, levothyroxine sodium (SYNTHROID), taken for hypothyroidism and Hashimoto's disease from 2015 to an unspecified date, rosuvastatin calcium (CRESTOR), taken prophylactically from 2010 to an unspecified date and semaglutide (OZEMPIC) taken for weight loss from May2020 to an unspecified date. Family history included; the patients mother had an allergy to Sulfa and allergy to penicillin and the patients father had unspecified allergies and hay fever. There were no prior vaccinations within 4 weeks. On 19Dec2020, the patient experienced redness above eyebrow, nose and cheek and left hand had few reddened marks on skin, neck had a thin red line and right eyebrow was swollen. The reporter considered the events to be non-serious. The patient was worried about anaphylaxis, so they went to the emergency room (ER) for the reported events but was not admitted. The patient was treated in the ER for the events with diphenhydramine hydrochloride (BENADRYL), prednisone (MANUFACTURER UNKNOWN) and famotidine (PEPCID). Relevant tests were none. The outcome of the events was recovering. The reporter stated that there was a reasonable possibility that the events were related to the suspect product.

left arm began having generalized weakness and difficulty holding pen.; Mild tremors of left hand and fingers.; This is a spontaneous report from a contactable pharmacist. An adult female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number: EJ1685), intramuscular on 18Dec2020 at a single dose for COVID-19 immunization. The vaccine was administered in the hospital. The patient's medical history and concomitant medications were not reported. Around 6 hours post-administration on 18Dec2020, patient's left arm began having generalized weakness and difficulty holding pen. Mild tremors of left hand and fingers. Lasted approximately 2-3 hours and resolved spontaneously. No other symptoms. No treatment was given. The events were reported as non-serious. Outcome of the events was recovered in Dec2020.

Was exposed to someone positive and then 2 days later tested positive; Was exposed to someone positive and then 2 days later tested positive; Was exposed to someone positive and then 2 days later tested positive; This is a spontaneous report from a contactable pharmacist. A male patient of an unspecified age received the first dose of BNT162B2 (Pfizer-BioNTech COVID-19 mRNA vaccine), via an unspecified route of administration in Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient received the first COVID-19 vaccine last week in Dec2020, then was exposed to someone positive and then 2 days later, patient tested positive. Reporter inquired whether they can vaccinate patient on schedule 3 weeks after the first dose or if they have to wait 90 days. The outcome of the events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

Extreme dizziness that is still ongoing; This is a spontaneous report from a contactable nurse (patient). A 54-year-old female patient received the first dose of bnt162b2 (Pfizer Biontech COVID 19 vaccine), Lot number: EK5730, via an unspecified route of administration at the left arm on 18Dec2020 15:15 at a

single dose for COVID-19 immunization. The patient medical history includes migraine and known allergies to Latex and sulfa drugs. Concomitant medication included levothyroxine, gabapentin, calcium, colecalciferol (CALCIUM & VITAMIN D). On 05Dec2020 03:00 (pending clarification), the patient experienced extreme dizziness that is still ongoing. The patient was not hospitalized for the event, did not receive any treatment for the event and event was reported as non-serious. The vaccine was administered in the workplace clinic. The patient has not received any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination the patient was not diagnosed with COVID-19. Since the vaccination, the patient has been tested for COVID-19 (Dec2020-unknown results). On 14Dec2020, Nasal Swab (COVID 19) Result was Negative. The outcome of the event was not recovered.

tightness in throat; This is a spontaneous report from a non-contactable Other Health Professional. A 51-year-old female patient started to receive bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) lot number: HE9899, intramuscular in the right arm, first dose on 16Dec2020 10:21 at a single dose for immunisation. The patient's medical history and concomitant medications were not reported. The patient is not pregnant. The patient had been escorted from observation area to emergency area with complaints of tightness in throat. The patient was eupneic, p/w/d, ambulatory, NAD. Vitals #: P72, 100% pulse ox, RA Vitals #: P72, 98% pulse ox on RA, 112/78 seated. She was administered with 25mg diphenhydramine PO per verbal order (VO)/D. (Name) PA #, pt swallowed with water. Vitals #: 98% pulse ox on RA, P74, denies shortness of breath or pain. She was presented to vaccination clinic. Patient received her vaccination at approximately 1021. Patient reported symptoms onset at approximately 1038 with tightness of the throat. The outcome of tightness in throat was recovered on an unknown date. No follow-up attempts are possible. Information about lot/batch number cannot be obtained. No further information is expected.

tongue tingling and swelling specific to the left side of her tongue; tongue tingling and swelling specific to the left side of her tongue; This is a spontaneous report from a non-contactable other hcp. A 57-year-old female patient received 1st dose of bnt162b2, lot number: HE9899, intramuscular in the right deltoid muscle on 16Dec2020 13:30 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient was seen at the clinic today for her first dose of the COVID 19 vaccination. She denied any history of previous adverse reactions to vaccines. She reports that she also had shingles and pneumonia vaccination on Monday, 14Dec2020. She was given the Pfizer vaccination in the right deltoid muscle. During her 15 minute waiting period after the injection, the patient began to experience tongue tingling and swelling specific to the left side of her tongue. She denied rash, difficulty breathing, difficulty swallowing, wheezing, throat tightness, dizziness and lip swelling. She reports similar reactions after receiving other vaccinations. States that those symptoms always resolved with time and never required any treatment. Outcome of the events was recovered. The events was assessed as non-serious. No follow up attempts are possible. No further information is expected.

Red itchy rash around injection site; Red itchy rash around injection site; Red itchy rash around injection site; This is a spontaneous report from a contactable nurse. A 38-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: Eh9899), intramuscular (Arm Left) from 18Dec2020 18:45 at a single dose for COVID-19 immunisation. Medical history included hypothyroidism

and pre diabetes. Patient had no known drug allergies (NKDA). Concomitant medication included levothyroxine. On 20Dec2020 23:45, the patient experienced red itchy rash around injection site. The patient underwent lab tests and procedures on 16Dec2020 which included nasal swab with negative result. Outcome of events was recovered. No treatment was required/involved. Follow-up attempts are completed. Information on the batch/lot number has been obtained.

lymphadenopathy/I was having reaction of lymphedema; This is a spontaneous report from a contactable consumer (medical dosimetrist and patient herself - pending clarification). A female patient of an unspecified age received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE lot/batch number EJ1685), via an unspecified route of administration in Dec2020 at SINGLE DOSE for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. In Dec2020, the patient was having reaction of lymphedema/ lymphadenopathy and was wondering how long it last generally. The patient also inquired if she would get the next vaccine in different arm. Outcome of the event was unknown. No follow-up attempts are possible. No further information is expected.

Left sided lip numbness; Left hand and foot tingling; This is spontaneous report from a contactable physician (patient). A 29-years-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (lot number EH9899) intramuscular in left arm on 20Dec2020 17:45 at single dose for COVID-19 immunization. There was no medical history. The patient was not allergic to medications, food, or other products. There were no concomitant medications. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient experienced left sided lip numbness, left hand and foot tingling on 20Dec2020 18:00. No treatment was received for the adverse events. Events outcome was not recovered.

Itching and tingling to right arm that traveled to elbow; Itching and tingling to right arm that traveled to elbow/itching to flank area; Itching and tingling to right arm that traveled to elbow; Itching and tingling to right arm that traveled to elbow; This is a spontaneous report from a contactable nurse. A 30-year-old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EJ1685), intramuscular at the right arm on 22Dec2020 07:45 to 22Dec2020 07:45 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. On 22Dec2020 8AM, the patient experienced itching and tingling to right arm that traveled to elbow, employee reported sensation was 'easing up' 5 minutes after it started. She also reported itching to flank area, no rash was noted. The patient was not hospitalized for the events but had an emergency room/department or urgent care visit because of the events. The events were reported as non-serious. The vaccine was administered in a hospital. The outcome of the events was recovering.

throat tightness; This is a spontaneous report from a non-contactable other healthcare professional. A 36-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), lot number HE9899, intramuscular Right arm (right deltoid muscle) from 18Dec2020 12:45 to 18Dec2020 12:45 as single dose for COVID-19 immunization. Medical history included mild anxiety. The patient's concomitant medications were not reported. Patient was given the Pfizer vaccination in the right deltoid muscle. During her 15-minute waiting period after the injection, the patient began to experience throat

tightness. She denied rash, hives, difficulty breathing, hoarseness, lightheadedness, dizziness, facial swelling, lip swelling and tongue swelling. Review of Systems Constitutional: Negative for activity change, appetite change and fever. HENT: Negative for congestion, facial swelling, rhinorrhea and trouble swallowing. Initially with some throat tightness. Resolved within 10 min Respiratory: Negative for cough and shortness of breath. Neurological: Negative for dizziness, weakness, light-headedness and headaches. The outcome of the event was recovered on 18Dec2020. No follow-up attempts are possible, information about batch number cannot be obtained.

bumps; This is a spontaneous report from a contactable consumer. A 58-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EJ1685 & expiration date: 30Dec2069), via an unspecified route of administration at the left arm on 17Dec2020 15:30 at a single dose for COVID-19 immunization. Medical history included border line diabetic, ovarian cancer over 25 years ago, high blood pressure, depression, all under control. The patient has no known allergies. Concomitant medications included metformin, sertraline, lisinopril, ibuprofen, vitamin c, and ergocalciferol (VITAMIN D). Sunday of 20Dec2020, around 16:00, patient noticed bumps on her arms, then the next day more came out and some on her upper legs, which were not painful or red, just bumps. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient was not diagnosed with COVID-19 prior to vaccination and was not tested for it since the vaccination. The patient has not recovered from the event.

tachycardia; This is a spontaneous report from a contactable nurse. A 25-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number: EL0140, expiry date: 31Mar2021), intramuscular on the left deltoid on 17Dec2020 13:22 at 0.3 mL, single for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient had tachycardia on 17Dec2020 13:25, post vaccine but it went away quickly. Reporter stated that she didn't know if patient was anxious. Outcome of the event of tachycardia was recovered on 17Dec2020. The reporter assessed the event as non-serious.

diarrhea; shortness of breath; tachycardia; elevated blood pressure; flushing; chills; 101F fever; weakness; fatigue; muscle aches; This is a spontaneous report from a contactable nurse. A 24-year-old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EJ1685, expiration date unknown) via an unspecified route of administration on 19Dec2020 ast 14:15 at a single dose for COVID-19 immunization in the hospital. The patient has no medical history. There are no known allergies. Concomitant medication included ethinylestradiol, ferrous fumarate, norethisterone acetate (JUNEL FE) for birth control. The patient was not diagnosed with COVID-19 prior to vaccination. The patient experienced diarrhea, shortness of breath, tachycardia, elevated blood pressure, flushing, chills, 101F fever, weakness, fatigue, muscle aches all on 20Dec2020 at 10:00. No treatment was received in response to the events. The patient has not been tested for COVID-19 since vaccination. The patient recovered from diarrhea, shortness of breath, tachycardia, elevated blood pressure, flushing, chills, 101F fever, weakness, fatigue, muscle aches all on an unspecified date.

diagnosed with COVID-19; diagnosed with COVID-19; This is a spontaneous report from a contactable physician, the patient. A male patient of an unspecified age received the first dose of BNT162B2 (PFIZER-

BIONTECH COVID-19 mRNA VACCINE), via an unspecified route of administration on 21Dec2020 as single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. On 22Dec2020, the patient was diagnosed with COVID-19. The clinical outcome of diagnosed with COVID-19 was unknown. The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up.; Sender's Comments: The patient was diagnosed with COVID-19 one day after he received vaccination with BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE). There was not a reasonable possibly that the event was related to vaccination considering the temporal gap between the vaccination and the event onset.

hives; she had an achy left arm (injection arm); fatigue; This is a spontaneous report from a contactable nurse (patient). A 67-years-old female patient started to the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), Batch/lot number was not provided, unspecified route on 17Dec2020 (at the age of 67-years-old) as a single dose in the left arm for COVID-19 vaccination. Medical history and concomitant medication were not reported. On unspecified date in Dec2020, the patient experienced she had an achy left arm (injection arm) and fatigue which she states that she expected. On 22Dec2020, the patient experienced hives. She woke up and had hives. Outcome of the event fatigue was recovered in Dec2020. Outcome of the events hives and she had an achy left arm (injection arm) were unknown.

rash to both forearms, thigh and private area/developed a rash on both arms, thighs, and kind of near the private area. Areas are red and bumpy/rash now is flat, red, and pinkish; rash to both forearms, thigh and private area/developed a rash on both arms, thighs, and kind of near the private area. Areas are red and bumpy/rash now is flat, red, and pinkish; rash to both forearms, thigh and private area/developed a rash on both arms, thighs, and kind of near the private area. Areas are red and bumpy/rash now is flat, red, and pinkish; This is a spontaneous report received from a contactable nurse (who is also the patient). A 62-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EJ1685, expiry date unknown), intramuscular in left deltoid, on 19Dec2020 at single dose for COVID-19 immunization. The patient medical history and concomitant medications were not reported. The patient reported she received the COVID-19 vaccine on Saturday (19Dec2020). Everything was fine all day on Saturday and when she took a shower on Sunday morning (20Dec2020), she noticed she developed a rash on both arms, thighs, and kind of near the private area. Areas are red and bumpy, and she still has the rash on the arms. She called her primary care provider and was instructed to use Benadryl at bedtime and Zyrtec in the morning to help. She was wondering because in 20 some odd days she is to get the second shot and wants to know if she should expect this type of adverse reaction. She mentioned that the rash now is flat, red, and pinkish. She stated she has never had COVID-19 testing or symptoms. Just this rash from the vaccine. The reporter assessed the events as non-serious. The outcome of the events was not recovered (reported as ongoing).

Patient woke up with forehead and back of hand rash; she had swelling in the morning after being vaccinated; This is a spontaneous report from a contactable pharmacist. A 29-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) lot number: unknown, via an unspecified route of administration on 21Dec2020 at a single dose for immunization. The patient's medical history and concomitant medications were not reported. It was reported that the patient woke up with forehead and back of hand rash and she had swelling in the morning after being vaccinated. She took a

BENADRYL and went to the ED (Emergency Department). Event onset date was on 22Dec2020. The event was reported as non-serious. The outcome of forehead and back of hand rash and she had swelling was unknown. Information on Lot/Batch number has been requested.

my lt. arm felt like lead , so heavy and very sore; my lt. arm felt like lead , so heavy and very sore/felt soreness if she lifted up her arm; This is a spontaneous report from a contactable healthcare professional (patient). A 58-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EUA), intramuscular in the left arm on 21Dec2020 16:45 at single dose for COVID-19 immunization. Medical history included the patient being pre-diabetic. The patient's concomitant medications were not reported. The patient previously took epinephrine, norethindrone, and comtrex cold medicine and experienced drug allergy. The patient didn't have anything until around 2:00am on 22Dec2020 - her lt. arm felt like lead, so heavy and very sore. Her arm felt better after getting up - having shower around 6:30am. By 2 pm she only felt soreness if she lifted up her arm. No treatment was given for the events. The patient was not diagnosed with COVID-19 prior to vaccination and was not tested for COVID-19 post vaccination. The patient also did not receive any other vaccines within 4 weeks prior to the COVID vaccine and have not received any other medication within 2 weeks of vaccination. The outcome of the events was recovering. Information on the Lot/batch number has been requested.

achiness; Fatigue; patient was administered 0.3ml of undiluted covid vaccine intramuscularly.; patient was administered 0.3ml of undiluted covid vaccine intramuscularly.; This is a spontaneous report from a Pfizer-sponsored program, IBCC (Inbound Call Center for HCPs). A contactable pharmacist reported that a 28-year-old female patient received bnt162b2 (BNT162B2; lot number: EH9899; NDC number of Covid vaccine: 59267-1000-1 Expiry Date of Covid vaccine: Mar2021), intramuscular on right deltoid on 18Dec2020 at 0.3 mL for COVID-19 immunization. There were no medical history and concomitant medications. On 18Dec2020, a patient was administered 0.3ml of undiluted covid vaccine intramuscularly. The patient experienced achiness, fatigue. The patient received the covid vaccine injection Friday afternoon. When querying seriousness regarding the patient receiving the undiluted dose, he states she has not had very many side effects from it thus far. Clarifies that achiness and fatigue were her main side effects which started Friday night and continued into Saturday. Treatment: She received IV fluids this weekend in the ER as a precautionary measure He does not have time to continue with report and requested to be transferred. No further details. The outcome of the events was unknown.

localized tingling at the injection site that radiated into her 4th and 5th digits and proximally along the sternomastoid muscle; localized tingling at the injection site that radiated into her 4th and 5th digits and proximally along the sternomastoid muscle; This is a spontaneous report from a non-contactable healthcare professional. A 45-year-old female patient received bnt162b2 (BNT162B2; lot number: EH9899; expiration date: unknown), intramuscularly left arm on 22Dec2020 11:15 at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. During her 15-minute (22Dec2020 11:30) waiting period after the injection, the patient began to experience localized tingling at the injection site that radiated into her 4th and 5th digits and proximally along the sternomastoid muscle. The patient denied rash, hives, difficulty breathing, difficulty

swallowing, wheezing, throat tightness, hoarseness, stridor, itching, dizziness, facial swelling, lip swelling and tongue swelling. This reporter was notified of patient reaction and she was then assessed in the emergency bay area. Monitored patient for severe reaction symptoms, including rapid progression of symptoms, vomiting, hypotension and chest pain. The patient was observed for approximately 30 minutes post injection with no evolution of symptom. Injection site tingling that extended along the ulnar nerve distribution was improving at the time of discharge. The outcome of the events was recovering. No follow-up attempts are possible, information about batch number cannot be obtained. No further information is expected.

Hives torso, abdomen, neck and leg; This is a spontaneous report from a contactable nurse. A 50-year-old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number: EH9899), intramuscular on the right arm on 22Dec2020 08:30 at a single dose for COVID-19 immunization. The patient's medical history included penicillin allergy. The patient was not pregnant. There were no concomitant medications. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient was not diagnosed with COVID-19 prior to vaccination and had not been tested for COVID-19 since the vaccination. The patient experienced hives torso, abdomen, neck and leg on 22Dec2020 12:00. Therapeutic measures were taken as a result of hives and included treatment with oral antihistamine. Outcome of the event was recovered on 22Dec2020. The event was considered non-serious.

Severely swollen, hard and painful lymph nodes in the L axillary region. / other swollen glands; fever; muscle aches; chills; headache; This is a spontaneous report from a contactable nurse (patient). A 52-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EJ 1685, expiry date was not provided) solution for injection, via an unspecified route of administration on left arm on 17Dec2020 12:00 at a single dose for Covid-19 immunisation. Medical history included Covid-19. Concomitant medication included sertraline hydrochloride (ZOLOFT). Prior to vaccination, patient was diagnosed with COVID-19. The patient received the vaccine at a workplace clinic and experienced severely swollen, hard and painful lymph nodes in the L axillary region, other swollen glands; fever; muscle aches; chills; and headache, all on 18Dec2020 12:00. It was unknown if patient received treatment for the events. The events were reported as non-serious. Outcome of the events was not recovered. No follow-up activities are needed. No further information is expected.

"BNT162B2 was given to the patient subcutaneously instead of intramuscular; upset; crying; This is a spontaneous report from a contactable nurse via medical information team. A 42-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via subcutaneous on 19Dec2020 at single dose for COVID-19 immunization. Medical history included deep vein thrombosis (DVT) from 3 years ago and unknown if ongoing. Concomitant medication included acetylsalicylic acid (ASPIRIN (E.C.) for DVT and multivitamins. The patient stated ""BNT162B2 was given to me subcutaneously instead of intramuscular (IM)."" She stated she works at (Name withheld) and it was administered by an employee and her hospital employee health will not talk to her and she was being brushed off. The patient asked what's needed to do moving forward. She stated she does not know the efficacy for subcutaneous administration. After providing information in attached document the patient asked what should her next steps be since the hospital will not answer do anything about this incorrect administration.

BNT162B2 was administered her incorrectly. The patient was little upset and was crying about it in Dec2020. The outcome of the events was unknown. Information on the lot number/batch number has been requested."

Having some raised bumps in the back of the hand, multiple small bumps very very small/The bumps are very very small, like an 8th of a centimeter; almost like hives and chicken pox; almost like hives and chicken pox; This is a spontaneous report from a contactable nurse (patient). A female patient of an unspecified age received BNT162B2 (Pfizer-BioNTech COVID-19 mRNA vaccine, lot number: EJ1685, expiry date: Mar2021), intramuscular in the left deltoid on 21Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced a mild side effect after receiving the COVID Vaccine yesterday on 21Dec2020. The patient is having multiple raised bumps, almost like hives and chicken pox, on the back of her hand. The bumps are very very small, like an 8th of a centimeter. The outcome of the events was unknown.

dizziness; throat dryness; nausea; This is a spontaneous report from a non-contactable healthcare professional . A 23-year-old male patient received bnt162b2 (BNT162B2, lot number:EH9899), intramuscularly in his left arm on 22Dec2020 11:00 at a single dose for covid-19 immunization (reported as covid-19 vaccination). The patient's medical history included GI symptoms that he was currently being worked up for. Patient reported onset of similar signs around time of vaccine injection. The patient's concomitant medications were not reported. During his 15 minute waiting period after the injection, the patient began to experience dizziness, throat dryness, and nausea. He denied rash, hives, difficulty breathing, difficulty swallowing, throat tightness, hoarseness, stridor, itching, facial swelling, lip swelling and tongue swelling. The provider was notified of patient reaction and he was then assessed in the emergency bay area. Monitored patient for severe reaction symptoms, including rapid progression of symptoms, respiratory distress with stridor, vomiting, abdominal pain and hypotension. Outcome of the events was unknown. No follow-up attempts are possible; information about batch number cannot be obtained.

I feel weird, kind of spacey; metallic taste; Blood pressure 133/90.; This is a spontaneous report from a contactable nurse. A 53-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE lot/batch number: EJ1685), intramuscular on the left arm on 22Dec2020 14:15 at SINGLE DOSE as COVID-19 vaccination at the hospital. Medical history included reactive airway disease, attention deficit hyperactivity disorder (ADD) and asthma. The patient also had allergies to sulfa. Concomitant medications included losartan potassium (LOSARTA), methylphenidate hydrochloride (CONCERTA) and unspecified inhaler for asthma. On 22Dec2020 14:25 (10 minutes after injection), the patient felt weird, kind of spacey and had metallic taste. The patient also had blood pressure of 133/90 (unit of measure not reported) on 22Dec2020 but denies urticaria, itching, pain, shortness of breath, and chest pain. The patient was brought to the emergency room/department or urgent care further evaluation due to the events. It was unknown if treatments were received for the events. Outcome of the events were unknown. No follow-up attempts are possible. No further information is expected.

Fatigue; The initial case was missing the following minimum criteria: No adverse effect. Upon receipt of follow-up information on (23Dec2020), this case now contains all required information to be considered

valid. This is a spontaneous report from a contactable healthcare professional. A 23-year-old female patient started to receive BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EJ1685), first dose via intramuscular on 22Dec2020 15:00 in left arm at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The facility where the most recent COVID-19 vaccine was administered in a hospital. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. The patient experienced fatigue on 22Dec2020 18:00. The outcome of the event was unknown. The event was considered non serious as it did not results in death, was not life threatening, did not cause/prolonged hospitalization, was not disabling/Incapacitating and had no congenital anomaly/birth defect.

now COVID positive with symptoms; now COVID positive with symptoms; This is a spontaneous report from a contactable consumer(patient). A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 16Dec2020 at single dose for COVID-19 immunization. The patient medical history and concomitant medications were not reported. The patient received the vaccine on 16Dec2020 and now COVID positive with symptoms as of 19Dec2020. The patient asked that should he (she) still get the second vaccine. The outcome of event was unknown. Information on lot/batch number has been requested.

my lymph node is really swollen/and it hurts; headache/a mild headache; had a little bit of dizziness; sick for a little bit; had a little bit of chills; soreness in my arm; This is a spontaneous report from a contactable other hcp (patient). A 40-year-old female patient received 1st dose of bnt162b2 (Pfizer-Biontech Covid-19 Vaccine, lot number: EH9899), via an unspecified route of administration into the left arm on 19Dec2020 at a single dose for COVID-19 immunization. Medical history included high cholesterol diagnosed in maybe 2016 or 2017, but stated that she has the hereditary type, so she can never get rid of it. Concomitant medication included acetylsalicylic acid (BABY ASPIRIN) for high cholesterol; the patient started taking this last year, but then she stopped for a while because her cholesterol was ok, and then her cholesterol went back up and she started taking this again 3-4 months ago. The patient had the COVID vaccine on Saturday and 20 min in, she had a headache and didn't think much of it, had a little bit of dizziness and they gave her Tylenol and she was fine. She was sick for a little bit and just a mild headache. She had a little bit of chills and soreness in her arm. The next day she woke up and notice her neck, between her shoulder and collar bone and woke up and said 'oh that hurts me' and looked and her lymph node was really swollen. It does not bother her but she took a Tylenol and that seems to help with the swelling and it swells up again after the Tylenol. The caller asked if that was a normal side effect or adverse side effect and should she take the next dose 09Jan2021. She also asked if this is a serious adverse reaction or just a side effect. The patient has an appointment today at the time of report with her doctor. The reporter further added that she is a healthcare worker and she took the COVID vaccine this last Saturday; she received the vaccine in her left arm, and on the left side of her body, where she got the vaccine, she is having a reaction. She was fine right after she got the vaccine, like maybe within 20 minutes of getting it she had a headache a little bit of dizziness, and so she was kept in observation for an hour, but she took some Tylenol and was fine. Then, the next day, the caller woke up and on the left side of her body, she has a lymph node that is swollen, and still has not gone

down, and she is wondering if that is normal for the product. She does not really have the headache anymore, but the dizziness is still coming and going, not as bad as it was on that first day, but it comes and goes. She also did have the chills for a bit the day she got the vaccine, but it was just for a few hours and then it went away. The headache she had, was a different type of headache, it was not severe, but it was like a wave where it would come on strong, but not where she couldn't tolerate it, and then the dizziness would come at the same time, and then it would all just go away, and then come back like a wave; caller states that it was weird. The swollen lymph node started the next day, and it hurts. It was pretty swollen when she found it, but she took Tylenol and with the Tylenol, the swelling went down a little bit, but when the Tylenol works its way out of her system, the lymph node swells back up. The patient stated that the lymph node hurts and is painful. The patient does not know the actual dosage amount she received, she just knows it was the first dose in the series. The patient confirms that she did not take any other vaccines on the same day as the COVID vaccine. The patient is due for her second dose of the COVID vaccine next month, and she is wondering if the swollen lymph node would be something that would disqualify her from getting the second dose. Therapeutic measures were taken as a result of headache, dizziness, lymph node is really swollen and it hurts. Outcome of the events headache and chills recovered in Dec2020, for the events dizziness, sick, and soreness in arm was unknown; and for the event node is really swollen/and it hurts was not recovered.

Diarrhea; This is a spontaneous report from a contactable other healthcare professional (patient). A 46-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number EL0140, expiry date unknown) intramuscular at the left arm on 21Dec2020 13:30 at single dose for COVID-19 immunization. The patient received Covid vaccine in a hospital. Medical history included high blood pressure, penicillin allergies. Concomitant medications included clonidine, bupropion hydrochloride (WELLBUTRIN XL), pantoprazole, topiramate, alprazolam (XANAX), cetirizine hydrochloride (ZYRTEC [CETIRIZINE HYDROCHLORIDE]), ascorbic acid (VIT C), fish oil, lactobacillus nos (CULTURELLE), ox bile; all from unspecified date for unspecified indication. The patient previously took ceftriaxone and experienced allergies. The patient did not receive other vaccine in four weeks. The patient has no diagnosis of Covid-19 prior to vaccination. On 22Dec2020 07:00 AM, the patient experienced diarrhea. The patient was not Covid tested post vaccination. No treatment was administered due to diarrhea. The outcome of the event diarrhea was not recovered. The reporter considered the event non-serious.

Allergic reaction; full body rash; fatigue; This is a spontaneous report from a contactable nurse. A 48-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) lot number: EK5730, intramuscular, first dose on 20Dec2020 at a single dose for immunization. Medical history included diabetes mellitus (DM), depression, gastrooesophageal reflux disease (GERD) and hypercholesterolaemia. The patient had no known allergies. The patient have unspecified concomitant medications. She had other vaccines in two weeks (unspecified). The patient experienced allergic reaction- full body rash, fatigue on 21Dec2020 with outcome of not recovered. Treatment received for the events included steroid and antihistamines. The events are reported as non-serious. The patient had doctor or other healthcare professional office/clinic visit. She had no covid prior vaccination. She was tested for covid post vaccination through nasal swab on 21Dec2020 with negative result.

Body aches; fatigue; headache; not feeling well; Muscle aches; elevated temperature; This is a spontaneous report from a contactable nurse (patient herself). A 43-year-old female patient received the first dose of bnt162b2 (BNT162B2 also reported as Covid-19 vaccine by Pfizer, lot EK5730), intramuscular 20Dec2020 15:15 at single dose in left arm for Covid-19 immunisation. Medical history included High blood pressure and interstitial cystitis interstitial. Concomitant medications included losartan and hyoscyamine sulfate, methenamine, methylthioninium chloride, phenyl salicylate, phosphoric acid sodium (URIBEL). The patient previously took doxycycline and experienced drug allergy. The patient experienced body aches, fatigue, headache, was not feeling well, muscle aches, elevated temperature, all on 21Dec2020 12:00. The events were reported as non-serious. Prior to vaccination, patient was not diagnosed with COVID-19 and since the vaccination, the patient was been tested for COVID-19 via nasal swab on 22Dec2020 with pending results. The outcome of events was unknown. No follow-up attempts are possible. No further information is expected.

headache; body aches; chills; fatigue; fever of 102; This is a spontaneous report from a contactable nurse (patient). A 28-year-old male patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE; lot/batch number unknown), via an unspecified route of administration on the left arm on 21Dec2020 07:30 at a single dose for covid-19 immunization. Medical history included anxiety and Covid-19. Prior to vaccination (covid-19 vaccine), patient was diagnosed with COVID-19 (Covid prior vaccination: Yes). The patient has no known allergies. No allergies to medications, food, or other products. Concomitant medications received within 2 weeks of vaccination included sertraline hydrochloride (ZOLOFT), ascorbic acid (VITAMIN C), zinc and colecalciferol (VITAMIN D). The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. On 21Dec2020 at 18:00 hour, the patient experienced headache, body aches, chills, fatigue and fever of 102 around 6pm the same day receiving vaccine. The events were considered non-serious by the reporter. Since the vaccination, the patient has not been tested for COVID-19 (Covid tested post vaccination: No). No treatment was received for the events. The outcome of the events was recovering. Information on the lot/batch number has been requested.

Moderate to severe lower back pain; This is a spontaneous report from a contactable physician (patient). A 38-year-old male patient started to receive BNT162B2 (Solution for injection, lot number and expiry date unknown), via an unspecified route of administration on 18Dec2020 08:30 at single dose in the left arm for COVID-19 immunization. The patient's medical history was not reported. Concomitant medication included vitamin C and multivitamins. The patient was not diagnosed with COVID-19 prior to vaccination and since the vaccination, the patient has not been tested for COVID-19. On 18Dec2020 19:00, the patient experienced moderate to severe lower back pain approximately 9-10 hours after receiving vaccine. He was feeling well prior to that, no strenuous activity. Symptoms progressed over 1-2 hours, then resolved over 4 days with tylenol/motrin use. Therapeutic measures were taken as a result of moderate to severe lower back pain. The outcome of the event was recovered on an unspecified date. The following information on the batch number has been requested.

runny nose; sore throat; This is a spontaneous report from a Pfizer-sponsored program. A contactable consumer (patient) reported that a 44-year-old male patient started to receive BNT162B2 (Solution for injection, lot number and expiry date unknown), intramuscular on 18Dec2020 at single dose in the left

deltoid for COVID Prevention. There were no medical history and concomitant medications. The patient called and stated that he took the COVID vaccine first dose, on Monday, and now he is getting the side effects of running nose and sore throat. Stated that the running nose and sore throat starting this morning on 22Dec2020, right as he woke up, and then it went away, and now it just seems to have gotten worse. He wondered if those are common side effects because he couldn't find them on the facts sheet. He stated that he is just trying to gather more information because he knows that it is currently cold and flu season, and it could also just be allergies. Also he wanted to make sure this is a common side effect, because if not, he has family coming to town to visit him for the holiday and he wants to be safe if he is sick. The outcome of the events was not recovered. The following information on the batch number has been requested.

Tachycardia; This is a spontaneous report from a contactable physician (patient). A 41-year-old male patient started to receive BNT162B2 (Solution for injection, lot number and expiry date unknown), via an unspecified route of administration on 21Dec2020 12:30 at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient was not diagnosed with COVID-19 prior to vaccination and since the vaccination, the patient has not been tested for COVID-19. The patient experienced tachycardia on 22Dec2020 02:30. No treatment received for the event. The outcome of the event was not recovered. The following information on the batch number has been requested.

Fever (39.1 C); chills; headache; body aches; nausea; This is a spontaneous report from a non-contactable nurse. A 37-years-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899), intramuscular at the left arm on 21Dec2020 10:45 at a single dose for COVID-19 immunization. Medical history included COVID-19 prior to vaccination. The patient has no known allergies. There were no concomitant medications. The patient experienced fever (39.1 C), chills, headache, body aches, nausea on 21Dec2020 20:00 with no treatment. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient was not tested for it since the vaccination. The patient recovered from the events on an unknown date. No follow up attempts are possible. No further information is expected.

Nausea; body aches; night sweats; headache; tired; This is a spontaneous report from a contactable other healthcare professional (patient). A 37-year-old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number: EJI685), intramuscular on the arm (reported as location was in the left and right arm, pending clarification) on 21Dec2020 15:30 at a single dose for COVID-19 immunization. The patient's medical history included celiac disease and wheat, gluten, chicken, nightshades, yeast allergy. The patient was not pregnant. Concomitant medication included vortioxetine hydrobromide (TRINTELLIX). The patient previously took chlorhexidine (CHLORAPREP) and experienced allergies to chlorhexidine. The patient was not diagnosed with COVID-19 prior to vaccination and had not been tested for COVID-19 since the vaccination. On 21Dec2020 17:00, the patient experienced nausea, body aches, night sweats, headache, and tired. Therapeutic measures were taken as a result of the events and included treatment with ondansetron (ZOFRAN) and paracetamol (TYLENOL). Outcome of the events was not recovered.

Diarrhea; Vomiting; dry heaves; This is a spontaneous report from a contactable nurse (patient). A 48-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK5730), intramuscular (left arm) on 21Dec2020 17:00 at single dose for Covid-19 immunization. The patient's medical history included high blood pressure. Concomitant medications were not reported. The patient was not diagnosed with COVID-19 prior to vaccination. The patient has no allergies to medications, food, or other products. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient experienced diarrhea, vomiting, and dry heaves on 22Dec2020 (06:00 AM). There was no treatment received for the adverse events. The patient has been tested with COVID-19 since the vaccination. The patient had nasal swab (test) on 22Dec2020 with pending result. The outcome of events was unknown.

"positive COVID-19 test with symptoms; positive COVID-19 test with symptoms; This is a spontaneous report from a contactable physician (patient). A male patient of an unspecified age received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration in Dec2020 at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced tested positive for COVID in Dec2020. The patient got the first dose of the vaccine on the day before the date of this report, started coughing on the day before the date of this report and tested positive for COVID on the date of this report. Caller requested guidance regarding whether he should receive the second vaccine dose, specifically will it be effective. Caller stated that he was ""an ER doc"" and understand that he did not get COVID from the vaccine. The patient underwent lab tests and procedures which included tested positive for COVID in Dec2020. The outcome of events was unknown. Information about lot/batch number has been requested.; Sender's Comments: Considering the temporal gap between the vaccination and the event onset, there was not a reasonable possibility that the COVID-19 infection was related to vaccination with BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE)."

"""pins and needles type tingling"" of the face; Chills; malaise; fever (101F); scratchy throat; headache; lack of appetite; pain of entire body; my feet hurt as soon as they hit the ground; This is a spontaneous report from a Pfizer Sponsored Program IBCC (Inbound Call Center for HCPs) from a contactable physician reported for herself. A female patient of unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via unspecified route of administration on 21Dec2020 at single dose for COVID-19 immunization. Patient medical history and concomitant medications were not reported. Patient reported that she received vaccine yesterday, 21Dec2020. Approximately 24 hours later, on 22Dec2020, she started experiencing ""pins and needles type tingling"" of the face, chills, malaise, fever (101F), ""scratchy throat"", headache, lack of appetite, ""pain of entire body"" and feet also hurt as soon as they hit the ground. She asked with the reaction that she was having, when do she seeks help and how long does it lasts. ""With the reaction that I'm having, when do I seek help? How long does this last? Are there any reports of fever? Are these common side effects?"" Outcome of the events was unknown. Information about lot/batch number has been requested."

Sore arm within an hour; Chills; body aches; fatigue overnight and throughout the next day; slight headache; This is a spontaneous report from a contactable nurse (patient). A 24-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) lot number: Eh9899, via intramuscular route

in the right arm, first dose on 21Dec2020 11:00 at a single dose for immunization. Medical history was none. The patient's concomitant medications were not reported. The patient is not pregnant. She has no known allergies. The patient did not have Covid prior vaccination and was not tested post vaccination. She did not receive other vaccines with 4 weeks prior to covid vaccine. The patient experienced sore arm within an hour on 21Dec2020 with outcome of recovering. She also had chills, body aches, fatigue overnight and throughout the next day with outcome of recovering. Almond with slight headache which was recovering. No treatment received for the events. The seriousness of the events was reported as non-serious.

12 minutes after vaccination, pt experienced jaw discomfort on left side and sharp intermittent pain in L ear.; 12 minutes after vaccination, pt experienced jaw discomfort on left side and sharp intermittent pain in L ear.; This is a spontaneous report from a contactable pharmacist. A 44-year-old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number: EL0140), intramuscular at the left arm on 22Dec2020 at a single dose for COVID-19 immunization. The patient medical history was not reported. The patient was not pregnant at the time of vaccination. Concomitant medications included baclofen, vitamin d3 and pitavastatin. The patient previously took tramadol and experienced drug allergies. On 22Dec2020, 12 minutes after vaccination, the patient experienced jaw discomfort on left side and sharp intermittent pain in L ear. The patient was not hospitalized for the events. It was unknown if patient receive any treatment for the events. The events were reported as non-serious. The patient has not received any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination the patient was not diagnosed with COVID-19. Since the vaccination, it was unknown if the patient has been tested for COVID-19. The outcome of the events was unknown.

pain in the arm of injection site; numbness and pins and needle tingling in the lower arm and hand; numbness and pins and needle tingling in the lower arm and hand; loss of feeling in hand and loss of sensation and strength; difficulty holding onto objects; loss of feeling in hand and loss of sensation and strength; difficulty holding onto objects/weakness; loss of feeling in hand and loss of sensation and strength; difficulty holding onto objects; dizziness; severe joint pain; throbbing headache; This is a spontaneous report from a contactable other healthcare professional (patient). A 41-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number EJ 1685, expiry date unknown) via unspecified route of administration at left arm on 19Dec2020 07:30 at single dose for COVID-19 immunization. The reporter informed that the covid-19 vaccine was administered in a hospital. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient was not diagnosed with COVID-19 prior to vaccination. Medical history included asthma, allergies to penicillin, allergies to milk, seasonal allergy, allergies to bees, allergies to latex. Concomitant medications included montelukast, fluticasone, budesonide, formoterol fumarate (SYMBICORT) and cetirizine; all from unspecified date for unspecified indication. The patient previously took Bactrim and experienced allergies. On 19Dec2020 15:00, the patient experienced pain in the arm of injection site including numbness and pins and needle tingling in the lower arm and hand, loss of feeling in hand and loss of sensation and strength; difficulty holding onto objects, dizziness and weakness, severe joint pain and throbbing headache. The patient underwent lab test and procedures post vaccination which included nasal swab/Covid-19 RNA rapid: negative on 22Dec2020. No treatment was

received due to the events. The outcome of the events pain in the arm of injection site, numbness and pins and needle tingling in the lower arm and hand, loss of feeling in hand and loss of sensation and strength; difficulty holding onto objects, dizziness, weakness, severe joint pain, throbbing headache was not recovered. The events were assessed as non-serious which did not results in death, not Life threatening, did not cause/prolong hospitalization, was not disabling/incapacitating, and not a congenital anomaly/birth defect.

Fever/ got up to 102 degrees Fahrenheit; Body aches; Sore throat; Feels like she has got just a regular cold; This is a spontaneous report from a contactable other hcp (patient). A 59-year-old female patient started to receive BNT162B2 (Solution for injection, lot number and expiry date unknown), intramuscular on 21Dec2020 19:00 to an unspecified date at single dose in the right arm for vaccination. Medical history included menopause from an unknown date. Concomitant medication included levothyroxine sodium (SYNTHROID), fenofibric acid, metformin, escitalopram and unspecified hormones for menopause. The nurse practitioner called to report on herself as the patient. She received her first dose of COVID-19 Vaccine on 21Dec2020 around 7:00pm. Starting about 10:00 am today, 22Dec2020, she had onset of fever, body aches and sore throat. She is hoping that this is all a normal part of the COVID-19 Vaccine; but she called to verify if that is all normal because she has to work tomorrow. Stated that her fever got up to 102 degrees Fahrenheit. She mentioned regarding seriousness criteria of all events that they are not serious, that she feels like she has just got a regular cold. She is scheduled to get the second dose of this vaccine 21 days after first dose. Causality of all events reported as yes, she really believes it is related to product. The outcome of the events was not recovered. The following information on the batch number has been requested.

Sore arm at injection site; This is a spontaneous report from a contactable healthcare professional reported for himself. A 41-year-old male patient started to receive BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number: EJ1685, expiry date: unknown), intramuscular on the left arm on 22Dec2020 01:30 at a single dose for COVID-19 immunization. There was no medical history. The patient's concomitant medications were not reported. The patient experienced sore arm at injection site on 22Dec2020 02:00. Outcome of the event was not recovered. No treatment was given. Patient had no COVID prior to vaccination and was not tested for COVID post vaccination. The event was considered non-serious.

back is achy; Injection site pain; Body achy; body feels like after you have a workout; Muscles are sore; My close coworker who works with me in the same company cubicle as me when we document, tested positive for COVID; This is a spontaneous report from a contactable other health professional (patient). A female patient (Age: 35; unit unknown) received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EH9899), via an unspecified route of administration on 21Dec2020 at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient received COVID vaccine on 21Dec2020 and experienced side effect of the vaccine. Stated 'achy feeling. The patient's abdomen and trunk like after a workout.' She move suddenly her back was achy. She had injection site pain. Consumer stated, her close coworker who worked with her in the same company cubicle as she, tested positive for COVID and he had been having symptoms since Saturday. And she was body achy at the time of this report, like she kind of feel like, her body felt like after she

had a workout and her muscles are sore. So, she did not know what to do because she do not know if this body achiness is a symptom of COVID or a symptom of the vaccine. And if she went get tested, whether she will show like a positive because she had the vaccine. The outcome of events was unknown.

she was freezing one minute, and then she was hot the next minute; dizzy; soreness throughout body/achy; stated her eyes feel heavy; Chills; This is a spontaneous report from a contactable consumer (patient herself). A 50-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), lot number: EK5730, expiration date: Mar2021, intramuscular in left upper arm from 21Dec2020 10:00 to 21Dec2020 10:00 at 0.3 mL for Covid-19 immunization. Medical history included COVID-19 in Jul2020. She said she had a real bad case of COVID-19, and didn't get over it until Oct2020. The patient's concomitant medications were not reported. The patient stated she received the COVID-19 Vaccine yesterday at her employer, which is a hospital. She said she got the COVID-19 Vaccine at around 10:00AM on 21Dec2020. She said she had a few chills not too long after receiving the COVID-19 Vaccine. She said last night the chills got worse, saying she had chills all night. She said the chills are not as bad now. Reported she is sore and achy, clarifying she has more of a soreness throughout her body. She stated her eyes feel heavy too. Caller asked if what she was experiencing were side effects of the COVID-19 Vaccine and how long were the symptoms going to last. The reporter stated she is not a healthcare professional. She said she works in the surgery area at the hospital, and the hospital was offering the COVID-19 Vaccine yesterday, so she got the vaccine. Reported after receiving the COVID-19 Vaccine, she noticed she felt cool at work. She said last night she felt like she was freezing one minute, and then she was hot the next minute, and kept going back and forth between freezing and hot. She said she woke up at 1:00AM and felt really hot. She said she wished she had a thermometer at the time to check her temperature because she thought she had a fever. She said her husband told her what she was experiencing was part of having the chills. She said when she woke at 1:00AM, she got out of bed to go to the bathroom, and her eyes felt heavy, and she thought she may have been a little dizzy. She said now she doesn't think she was dizzy at the time, but maybe it was because she just woke up and got out of bed. She said she hasn't had any dizziness today. Treatment: Reported she took an Ibuprofen 200mg at 2:00AM and another Ibuprofen 200mg at 8:30AM. She clarified it was Equate Brand Ibuprofen 200mg. The event chills with outcome of recovering; the rest of the events was unknown. Therapeutic measure has been given as a result of the events. Information about the lot/batch number and expiration date has been requested.

Dry mouth; rapid heart rate; fuzzy feeling in middle of forehead; This is a spontaneous report from a non-contactable other healthcare professional (patient). A 23-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899, expiry date was not provided) solution for injection, intramuscular from 21Dec2020 11:15 at a single dose for Covid-19 immunisation. Medical history included PVC's (Premature ventricular contractions). Concomitant medication included ibuprofen. The patient received the dose number 1 of the vaccine at a hospital and experienced dry mouth, rapid heart rate, and fuzzy feeling in middle of forehead on 21Dec2020 11:15. No treatment was administered. The events were reported as non-serious. Patient was not pregnant. Patient was not

diagnosed with Covid-19 prior to vaccination and has not been tested. Outcome of the events was recovering. No follow-up activities are needed. No further information is expected.

4 days after first vaccine started to get left cheek and left arm numbness without weakness. Also had left vision spotting. Different pattern than pts usual migraine

Left arm pain on first 2 days; extreme fatigue; chills/ All night chills; flu like illness; This is a spontaneous report from a contactable Physician (patient himself). A 40-year-old male patient received his first dose of bnt162b2 (BNT162B2 also reported as COVID 19 vaccine brand Pfizer, lot/batch number and expiry date were not reported), via an unspecified route of administration in left arm on 18Dec2020 11:45 at single dose for Covid-19 immunisation in a hospital. Medical history included High cholesterol. Concomitant medication included influenza vaccine (FLU). Prior to vaccination the patient was not diagnosed with COVID-19 and had not been tested for COVID-19 post vaccination. The patient experienced left arm pain on first 2 days (21Dec2020) 12:00, had extreme fatigue, chills described as all night chills and flu like illness on 21Dec2020 12:00. The patient took Tylenol as treatment. The outcome of events was not recovered. Information on the Lot/batch number has been requested.

Nausea; injection site soreness; fatigue; chills; general feeling unwell; This is a spontaneous report from a non-contactable healthcare professional. A 33-year-old female patient received bnt162b2 (BNT162B2; reported as COVID-19 vaccine; solution for injection; unknown lot number and expiration date), intramuscular right arm on 21Dec2020 04:30 at single dose for COVID-19 immunization. The patient had no medical history and concomitant medications. The patient was not pregnant at the time of vaccination. The patient has no allergies to medications, food, or other products. On 21Dec2020 at 08:30 PM, the patient experienced nausea, injection site soreness, fatigue, chills and general feeling unwell. The patient did not treatment for the adverse event. The patient had her most recent COVID-19 vaccine was administered in a hospital. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient had no other medications the patient received within 2 weeks of vaccination. The patient was not diagnosed with COVID-19 prior to vaccination and has not been tested for COVID-19 since the vaccination. The outcome of the events was not recovered. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

Cold/Flu/COVID symptoms, skin rash around injection site and left side of back

Injection site pain; myalgia; abdominal pain; This is a spontaneous report from a contactable physician. A 40-year-old male patient (not pregnant) received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, batch/lot number: unknown), via an unspecified route of administration on 21Dec2020 (19:15 PM) at single dose for COVID-19 immunization. There was no medical history. Concomitant medications were not reported. The patient has not been diagnosed with Covid-19 prior to vaccination. No know allergies. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. There was no other vaccine in four weeks and other medications in two weeks. The patient experienced injection site pain, myalgia, and abdominal pain on 22Dec2020 (09:00 AM). There was no treatment received for the adverse event. The patient was not tested for Covid-19 post vaccination. The outcome of events was

recovering. This case is reported as non-serious. Information on the lot/batch number has been requested.

Soreness at the injection site, Joint pain, including hip, leg soreness with a change in mobility.

aches; chills/shivering; generally not feeling well.; don't fall asleep; I have been feeling tired and like funny like a you have a cold or something/fatigue; I have been feeling tired and like funny like a you have a cold or something/cold; The initial case was missing the following minimum criteria: Unspecified product. Upon receipt of follow-up information on 23Dec2020, this case now contains all required information to be considered valid. This is a spontaneous report from two contactable consumers (including the patient). A 70-year-old female patient received BNT162B2 (Pfizer-BioNTech COVID-19 mRNA vaccine, Solution for injection; lot number and expiration date were not provided), via an unspecified route of administration on 20Dec2020 at single dose for immunization. Medical history included hot flashes. There were no concomitant medications. The patient stated that she just got the shot yesterday (20Dec2020) at the hospital she just went. Today (21Dec2020), she was feeling like a kind of funny and further described she had been feeling tired and like funny like she had a cold or something. She had a shot in the arm. It was further reported that she received the vaccine on Sunday (20Dec2020) at the hospital she works at; reported side effects of aches, chills, and generally not feeling well. She also stated tiredness and fatigue, she didn't fall asleep even if she did a night shift. For 2 days, she felt achy, chills were bad, she was cold, and was shivering, then they went away. The patient had hot flashes before, but it wasn't like that. She was having cold. Then it would go away, took a while. She had them (feeling tired, feeling cold, generally not feeling well, didn't fall asleep) since Monday (21Dec2020), then yesterday (22Dec2020), she felt the chills, aches and fatigue. The patient wanted to know how long to expect the side effects to last. The outcome of the events was not recovered. Information about lot/batch number has been requested.

shingles; This is a spontaneous report from a contactable Nurse. A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), via an unspecified route of administration in Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient was vaccinated with the Pfizer-BioNTech COVID-19 Vaccine last week (in Dec2020). She claimed being diagnosed with shingles and has asked the nurse if it could be related to the vaccine. The outcome of the event was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.

left hip pain; This is a spontaneous report from a contactable physician. A 71-year-old male patient received bnt162b2 (BNT162B2), via an unspecified route of administration on 17Dec2020 at, SINGLE DOSE for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. Caller stated that he got the coronavirus vaccine last Thursday and on midday Saturday that he got left hip pain. reported that he has sticky hips. Stated that he does not experience pain normally. Stated that the day before on Wednesday that he did yoga at home. Stated that he has done yoga for years. Stated that every time that he does it the he could strain something. Stated that the pain was bad enough that he took 3 doses of Advil over the next 24 hours and it went away. Stated that it did not

cause any major limping. Stated that he took 75 minutes walks on Saturday and Sunday and did yoga that evening. Stated that he is not sure that it is not related to the vaccine. Stated that this is his first dose of the vaccine. Stated that he is happy that he got the vaccine. Stated that he would get it again in a heartbeat. The outcome of the event was recovered. Information on Lot /Batch Number has been requested.

I am diabetic on a CGM and insulin pump. My blood sugar started to rise mid-afternoon and I couldn't get it below 200 despite giving myself increased amounts of insulin. It was up to 289 at bedtime. I count carbs and was very careful about what I ate yesterday. This morning I was back down to 169 when I got up, but I had increased my basal rates during the night. Second event that I'm not sure is related, but FYI, last evening I got some sharp pains in my left hip and continual aching in my left buttock while sitting watching TV. It continued until after I went to bed. It's back to normal this morning.

injection site pain-minor; tiredness-moderate/fatigue; headache-mild to moderate; muscle pain-minor/muscle aches; chills; fever-low grade; injection site redness light pink; nausea-comes and goes; feeling unwell-mild to moderate; muscle weakness; weak; This is a spontaneous report from a contactable consumer (patient). A 49-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899), via an unspecified route of administration on 18Dec2020 12:15 on the right arm at a single dose for COVID-19 immunization. Medical history included allergies to anxiety medication. The patient's concomitant medications were not reported. On 18Dec2020 20:00, the patient experienced mild to moderate side effects: injection site pain (minor), tiredness (moderate), headache (mild to moderate), muscle pain (minor muscle aches), chills (sometimes), fever (low grade), injection site redness (light pink), nausea- (comes and goes), feeling unwell (mild to moderate), muscle weakness and feeling fatigue which were moderate Friday, Saturday, and Sunday and Monday. If patient was active, for example Christmas shopping for about an hour, she was very fatigue, weak and the nausea was strongly moderate and it would come and go. Outcome of the events was recovering. No treatment was received for the events. The events were considered non-serious. The patient was not diagnosed with COVID-19 prior to vaccination and had not been tested post vaccination.

dry mouth; peculiar sensations running through extremities/trunk/abdomen (akin to IV contrast administration); elevated BP; tachycardia; lower abdominal cramping; This is a spontaneous report from a contactable physician (patient). A 46-year-old male patient received the first single dose of BNT162B2 (Lot number: EH9899, exp date not reported), intramuscular (vaccine location: left arm) on 21Dec2020 15:00 for Covid-19 immunisation. Medical history included hyperlipidaemia. The patient had no known allergies. Concomitant medication included atorvastatin (LIPITOR), and omeprazole (PRILOSEC). The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The COVID-19 vaccine was administered at a Hospital. On 21Dec2020 at 3:00 pm (also reported as within minutes of receiving vaccine), the patient developed dry mouth, peculiar sensations running through extremities/trunk/abdomen (akin to IV contrast administration), elevated BP, tachycardia, and lower abdominal cramping. The patient considered the events as non-serious. AEs resulted in doctor or other healthcare professional office/clinic visit. No treatment was given for the events. The patient had no

prior COVID vaccination and did not undergo COVID testing post vaccination. The patient recovered from the events on an unspecified date Dec2020.

Patient with a nut allergy, tongue became tingly 20-30 minutes following vaccine. Patient was given 50 mg of diphenhydramine and was able to transport home with his wife.

is 'fibril' until today/ fever; This is a spontaneous report from a contactable pharmacist. A patient of unspecified age and gender received BNT162B2, via an unspecified route of administration on 18Dec2020 at single dose for COVID -19 immunization. The patient medical history and concomitant medications were not reported. The reporter asked to just call her back to give info Covid vaccine was administered to a physician last 18Dec2020 and was 'fibril' until today (pending clarification). Asking if there is info on the duration of the fever that occurs. The outcome of the event was not recovered. Information on the Batch/Lot number has been requested.

Sore throat, mild bronchial congestion, mild muscle aches, soreness in left arm; Sore throat, mild bronchial congestion, mild muscle aches, soreness in left arm; Sore throat, mild bronchial congestion, mild muscle aches, soreness in left arm; Sore throat, mild bronchial congestion, mild muscle aches, soreness in left arm; This is a spontaneous report from a contactable nurse (reported for herself). A 62-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899), via an unspecified route of administration on left arm on 21Dec2020 08:45 at a single dose for immunization. Medical history included rosacea, primary hypertension, Hashimoto's Thyroiditis and penicillin allergy. The patient's concomitant medications were not reported. The patient experienced sore throat, mild bronchial congestion, mild muscle aches, and soreness in left arm; all on 22Dec2020 at 06:30. The patient did not receive treatment for the events. Outcome of the events was recovering.

patient called to report nausea, vomiting headache low grade fever abd pain

Extreme fatigue; nausea; lightheadedness; diarrhea; muscle ache; inability to sleep; sickness; This is a spontaneous report from a contactable physician (patient). A 41-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, batch/lot number: unknown), intramuscular (left arm) on 21Dec2020 16:00 at single dose for COVID-19 immunization. The patient has no medical history. No known allergies. The patient has no allergies to medications, food, or other products. Concomitant medications were not reported. The patient has received other medications (unspecified) within 2 weeks of vaccination. The patient was not diagnosed with COVID-19 prior to vaccination. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. On 21Dec2020 (18:00), the patient experienced extreme fatigue, nausea, lightheadedness, diarrhea, muscle ache, inability to sleep, and worst sickness of entire life (as reported). The patient received over the counter medication as treatment for the adverse events. The patient has not been tested for COVID-19 since the vaccination. The outcome of events was not recovered. This case is non-serious (as reported). Information on the lot/batch number has been requested.

"arm stiff and sore two hours after getting vaccine/muscle is stiff in her right arm; arm stiff and sore two hours after getting vaccine, at right arm; she didn't get to sleep last night since it felt heavy and stiff with

discomfort; she didn't get to sleep last night since it felt heavy and stiff with discomfort; Couldn't raise her right arm/couldn't lift her right arm/ farthest she can lift her right arm from her side is 2 inches; she didn't have strength to open the bottle it was new and she cannot open it; This is a spontaneous report from a contactable consumer. A 69-year-old female patient started to receive BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 21Dec2020 15:00 at single dose, at right arm for COVID-19 immunization. Medical history included ongoing hypertension (controlled), ongoing prediabetes (controlled), blood thinner, stroke (it was a very mild trace of a very mild stroke) and MRI on 2015. Historical vaccine included flu vaccine on an unspecified date. Concomitant medication included clopidogrel bisulfate (PLAVIX) from 2015 as blood thinner. After the patient got the vaccine on 21Dec2020, she was instructed to sit for 15 minutes and was given flyers and the card that stated the next scheduled dose is on 11Jan2020. She mentioned that the card she was given is the COVID-19 appointment card with a return flyer attached regarding Pfizer vaccine recipients and care givers. She reported that all that she can see on there is that, there was no lot, batch or serial number, just the name of the vaccine. She stated that the vaccine was shipped in the morning and they started giving it around noon and she got hers at three o'clock in the afternoon. She stated this is their facility's second batch, and the first was consumed last week. She stated she made a mistake, and that she should have requested they inject her left arm because she is right handed. The patient reported that she experienced arm stiff and sore two hours after getting vaccine (17:00). It was tolerable at first, but when she got home, she couldn't raise her right arm. She thought it would just be like the Flu vaccine and tolerable but she couldn't lift her right arm. The farthest she can lift her right arm from her side is 2 inches. She tried putting a cold compress on it but it was not working. She doesn't know if she can take TYLENOL. She would like to know if she can take TYLENOL for the pain since it was the only medication she has. Her supervisor advised her to take Advil, but she only has TYLENOL. She says she does feel better and that she was fine, there was nothing else, just her arm is so sore. She has nothing negative, no other side effect, no redness, just her muscle is stiff in her right arm and it feels sore. She stated maybe if she had taken TYLENOL the night before, but last night or today she didn't have strength to open the bottle it was new and she cannot open it. She stated at least the pain is lesser than last night, she didn't get to sleep last night since it felt heavy and stiff with discomfort. She was supposed to get a mammogram on reporting time, but since she couldn't raise her arm she was trying to reschedule. She is supposed to have a blood test the following day. Therapeutic measures were taken which includes cold compress. Outcome of the event ""arm stiff and sore two hours after getting vaccine, at right arm"" was recovering while outcome of all other events was unknown. Information on the lot/batch number has been requested."

Subject received vaccination Wednesday Dec 16th in the afternoon. He became symptomatic (shortness of breath, low grade fever) the next day. Went to the Emergency room on Saturday Dec. 26th, 2020 due to shortness of breath, had an 02 Sat of 60%, and was hospitalized in the ICU at another hospital (due to bed unavailability).

Brown spots in the shape of a circle at different locations in the body all appearing within a few hours; This is a spontaneous report from a contactable nurse (patient). A 29-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE lot/batch number: EH9899), via an

unspecified route of administration on the right arm on 22Dec2020 07:45 at SINGLE DOSE for COVID-19 immunization at the hospital. The patient had allergies with detergent and soap products. Concomitant medications included fenofibrate (FENOFIBRATE) and vitamin D from unknown dates and indications. Prior to vaccination, the patient was not diagnosed with COVID-19 and has not been tested for COVID-19 since vaccination. On 22Dec2020, the patient experienced brown spots in the shape of a circle at different locations in the body all appearing within a few hours. No treatment was received for the event. Outcome of the event was not recovered. No follow-up attempts are possible. No further information is expected.

Fever; Chills/rigors; Nausea; Vomiting (one episode); Headache; Myalgia; Change in taste; Generalized weakness; This is a spontaneous report from a non-contactable physician (patient). A 44-year-old male patient received one dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number: 1647, expiration date not reported), via an unspecified route of administration (left arm), on 21Dec2020 at 12:30 at a single dose, for COVID-19 immunization. Medical history included hypertension and COVID-19 from an unknown date. Concomitant medication included lisinopril and amlodipine. On 22Dec2020 at 04:30, the patient experienced 8 hours of severe symptoms: fever, chills/rigors, nausea/vomiting (one episode), headache, myalgia, change in taste, generalized weakness. The patient took Tylenol and naproxen as treatment. The patient was recovering from the events. No follow-up attempts are possible. No further information is expected.

"Patient became visibly flushed within five minutes after inoculation, and she reported having ""waves of nausea."" A cool compress was applied to her neck. While she was closely being monitored, she admitted feeling ""dizzy right after the shot bit didn't want to tell anyone because she [ic] was embarrased."" At 1532, patient denied that she was allergic to Benadryl, so Benadryl 50 mg/mL IM was injected into her right deltoid. At 1545, patient reported an alleviation of symptoms. She was advised to go home to rest, but to immediately contact 911 or go to the ER if symptoms worsened. Patient voiced understanding and left the facility with coordinated ambulation and in stable condition. RN 12/29/2020 @ 1318"

"tingling in injection arm, left arm, left neck, around the lips/tingling through arms, hands, fingers, and legs/worsened by sitting on legs/dense tingling in anterior shins upon standing; tingling in injection arm, left arm, left neck, around the lips/tingling through arms, hands, fingers, and legs/worsened by sitting on legs/dense tingling in anterior shins upon standing; tingling in injection arm, left arm, left neck, around the lips/tingling through arms, hands, fingers, and legs/worsened by sitting on legs/dense tingling in anterior shins upon standing; This is a spontaneous report from a contactable physician (who is also the patient). A 37-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK5730, expiry date not reported), via an unspecified route of administration in left arm, on 19Dec2020 09:30, at single dose, for COVID-19 immunization. There were no medical history and no known allergies. The patient's concomitant medications were not reported. The patient reported that about 30 minutes after vaccination on 19Dec2020 at 10:00, while driving home, tingling was noted in injection arm, traveling up the left arm into the left neck and around the lips. Tingling resolved but the next day, tingling was noted to be diffuse, light and scattered through arms, hands, fingers, and legs equally and bilaterally. No dermatomal or distinct nerve distribution. Tingling worsened by sitting on

legs, became dense tingling in the anterior shins upon standing, but then resolved a few minutes later to the more diffuse light tingling. No notable difference in strength (able to hike and cook) and no notable numbness. No rashes, no shortness of breath, no changes in heart rate. The events resulted in ""doctor or other healthcare professional office/clinic visit"". No treatment was received for the events. The patient was not diagnosed with COVID-19 prior to vaccination. The patient has not been tested for COVID-19 since vaccination. The patient did not receive any other vaccines within 4 weeks prior to BNT162B2. The reporter assessed the case as non-serious. The outcome of the events was recovered (as reported)."

"light headache; Low grade fever; Muscle ache; Pain; This is a spontaneous report from a contactable consumer (parent) reported that a 49-year-old female patient received single dose of (BNT162B2, Solution for injection, lot number was not provided), via an unspecified route of administration on the left arm on 18Dec2020 for covid-19 immunization. Medical history included ongoing hypertension that was diagnosed when she was 32-years-old, after she gave birth to her second child; she was diagnosed with COVID-19 on 25Aug2020, and now was 4 months out from having COVID-19; reportedly she was tired and had a lot of ""nervously"" feeling, like heart palpitations before she took the COVID-19 vaccine. There were no concomitant medications. On 19Dec2020, the patient experienced light headache, low grade fever, muscle ache and pain. The patient underwent lab tests and procedures which included weight: 212-213 lbs on an unspecified date. The outcome of the events was recovered on 19Dec2020. Information about lot/batch number has been requested."

Raspy voice, body and joint pain, pain at injection site, fatigue, headache

myalgia; chills; headache; fatigue; Loss of appetite; This is a spontaneous report from a non-contactable physician. A 44-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899), via an unspecified route of administration on 21Dec2020 14:30 in left arm at single dose for COVID-19 immunization. Medical history included COVID-19 from an unknown date and unknown if ongoing. Concomitant medication included omeprazole. After vaccination, 12-15 hours later, the patient pronounced myalgia joined 18 hours later with chills, headache, fatigue and loss of appetite. The patient experienced myalgia on 22Dec2020 05:00; chills, headache, loss of appetite and fatigue on 22Dec2020. Treatment such as acetaminophen and rest was given to patient for the events. The facility where the most recent COVID-19 vaccine was administered was in the hospital. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. The patient had no allergies to medications, food, or other products. The events were considered non serious as it did not results in death, was not life threatening, did not cause/prolonged hospitalization, was not disabling/Incapacitating and had no congenital anomaly/birth defect. The outcome of the events was not recovered. No follow up attempts are possible. No further information is expected.

Metallic taste in mouth.

Headache; nausea; mild body aches; hot flashes; This is a spontaneous report from a contactable nurse (patient). A 39-year-old female patient (not pregnant) received the first dose of BNT162B2 (PFIZER-

BIONTECH COVID-19 VACCINE, lot number EJ1685), intramuscular at right arm on 21Dec2020 17:45 at single dose for COVID-19 immunization at a hospital. The patient's medical history included migraines, bipolar II, anxiety, attention deficit hyperactivity disorder (ADHD) and insomnia. No allergies to medications, food, or other products. No other vaccines within 4 weeks prior to the COVID vaccine. Concomitant medication received within 2 weeks of vaccination included amfetamine aspartate, amfetamine sulfate, dexamfetamine saccharate, dexamfetamine sulfate (ADDERALL), diphenhydramine hydrochloride (BENADRYL), lamotrigine (LAMICTAL), nortriptyline, alprazolam (XANAX) and multivitamin. The patient was not diagnosed with COVID-19 prior to vaccination, and since the vaccination, the patient been had not tested for COVID-19. It was reported that on 22Dec2020 17:45, the patient experienced headache, nausea, mild body aches, and hot flashes. Treatment for the reported events included that the patient took ondansetron (ZOFRAN) and acetaminophen (Tylenol) that she had at home. She took them on her own. No doctor needed. The outcome of the events was recovered in Dec2020.

Arm pain/Pain in arm was so severe; Pain in arm was so severe I could not sleep; Extreme body aches the aches intensified throughout the day; Headaches; sore throat; head and chest congestion; head and chest congestion; This is a spontaneous report from a contactable other hcp (patient). A 49-year-old female patient received bnt162b2 via an unspecified route of administration on arm left, first dose on 16Dec2020 12:45 at single dose for COVID-19 immunization. Other vaccine same date product included Pfizer-Biontech first dose on 16Dec2020 on left arm (pending clarification). Medical history included COVID-19 prior vaccination from an unknown date. Not pregnant at the time of vaccination. No known allergies. No other medical history. Concomitant medication included bupropion from 2020. No other vaccines within 4 weeks prior to the COVID vaccine. The patient experienced arm pain. Pain in arm was so severe she could not sleep. Applied an ice pack throughout the night. Extreme body aches the aches intensified throughout the day. Headaches, sore throat, head and chest congestion. Adverse event start date was on 16Dec2020. The event was reported as non-serious. Therapeutic measures were taken as a result of arm pain/pain in arm was so severe, treatment included ice pack. No treatment was received for other events. The outcome of the events was recovering. Information about Lot/batch no has been requested.

Significant arm soreness, headache.

"muscle soreness; This is a spontaneous report from a contactable physician (patient). A patient of an unspecified age (reported as 35, unit unknown) and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration from 15Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient reported that after he got the shot (Dec2020), he had experienced ""just a little muscle soreness"". The outcome of event was unknown. Follow-up attempts are completed. The following information on the batch number has been requested."

muscle soreness; This is a spontaneous report from a contactable physician (patient). An adult patient (Age: 44; Unit: Unknown) of an unspecified gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE lot/batch number: not provided), via an unspecified route of administration on 14Dec2020 at

SINGLE DOSE for COVID-19 immunization. Medical history and concomitant medications were not reported. It was reported that the patient had side effects that were minimal - muscle soreness in Dec2020 for 24 hours, that's about it. The patient recovered from the event in Dec2020. No follow-up attempts are possible, information about batch number cannot be obtained.

I started getting profused rhinitis; I am got a little hoarse and it lasted all night long; I started getting profused rhinitis; I am got a little hoarse and it lasted all night long; I had enough Postnasal drip that I got a little bit of cough and no fever and didn't know if this was related to the vaccine; I had enough Postnasal drip that I got a little bit of cough and no fever and didn't know if this was related to the vaccine; This is a spontaneous report from a contactable physician who was also the patient. A 71-year-old male patient received bnt162b2 (BNT162B2 lot: EK5730, expiry: Mar2021), intramuscular in left arm on 17Dec2020 at a singe dose for covid-19 immunisation. The patient's medical history included hypertension from an unknown date and unknown if ongoing. Concomitant medications included olmesartan medoxomil (BENICAR) for hypertension and unspecified vitamins. On a unspecified date, the patient started getting profused rhinitis, he got a little hoarse and it lasted all night long. Patient actually had enough Postnasal drip (Captured as suspect conservatively) that got a little bit of cough and no fever and didn't know if this was related to the vaccine or not and needed to find out if that's the case. It was also reported that the patient took a rapid Covid test in the morning and whould like to know if that would to be 'false' positive because of taking the virus shot or Covid shot. It was reported that an RN administered the vaccine. The outcome of the events was unknown.

"Pain in arm; Kind of allergy you know like sneezing a lot, the whole day I have been sneezing; Kind of allergy you know like sneezing a lot, the whole day I have been sneezing; This is a spontaneous report from a contactable consumer. A patient of unspecified age and gender received bnt162b2 (BNT162B2), via an unspecified route of administration on 18Dec2020 at SINGLE DOSE for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. Consumer stated, ""I have a question about, I just had Pfizer on last Friday so I didn't have any symptom anything, the next day on 19Dec2020 I have like my arm pain, not swollen just pain and then I have kind of allergy you know like sneezing a lot, it is the whole day I have been sneezing and just like the whole day. Is it allergy to the Pfizer or should I just have another like second shot should I have it or is it the allergic reaction or what is that? It is the COVID the one COVID I had from Pfizer (COVID Vaccine). Because of I am afraid to have second shot if I have like more allergy or."" The outcome of the events unknown. Information on the Batch/Lot number has been requested."

Spiked the temperature during the night; Body ache; Fatigue; This is a spontaneous report from a contactable nurse (patient). A 58-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number EH9899), via an unspecified route of administration on 21Dec2020 at a single dose for COVID-19 immunization. There were no medical history and no concomitant medications. The patient was not having any serious side effects but she was having like probably spiked temperature during the night, body ache, and fatigue on 22Dec2020. The patient want to make sure if it is okay to take paracetamol (TYLENOL) or ibuprofen (MOTRIN) generally. Outcome of the events was unknown. The reporter assessed that the events were related to the suspect drug.

bad headache; This is a spontaneous report from a contactable consumer. A male patient of an unspecified age received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), via an unspecified route of administration on 22Dec2020 as a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. On 22Dec2020, the patient experienced bad headache. The clinical outcome of the bad headache was unknown. No follow-up attempts are possible; information about lot number cannot be obtained.

I have COVID after getting the vaccine. Fever, chills, and I feel very bad.

Respiratory: Laryngeal stridor going into the trachea and the central bronchial tubes. No wheeze out on the periphery. , Respirations: Tachypneic, Breath sounds: Stridor.

lightheaded/dizzy; This is a spontaneous report from a contactable consumer. A 35-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK5730), first dose via an unspecified route of administration on 21Dec2020 at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient was vaccinated yesterday with the Pfizer COVID-19. The patient felt lightheaded/dizzy after the injection and for many hours after in Dec2020. The patient felt these events before with other vaccines. The outcome of the event was unknown.

chills; malaise; raynauds in left fingers cold,blue; tingling; This is a spontaneous report from a contactable physician (patient). A 42-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EH9899), via an unspecified route of administration on 21Dec2020 06:15PM, at right arm, at single dose for covid-19 immunization. Medical history included Guillain barre after flu vaccine in 2010, covid-19 prior vaccination. The patient's concomitant medications were not reported. The patient previously received flu vaccine in 2010. The patient experienced chills, malaise, raynauds in left fingers cold, blue, tingling on 22Dec2020 08:00 AM. No treatment received for all events. The outcome of events was recovering. Patient had not tested for COVID-19 post vaccination. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. No seriousness criteria: no Results in death, no Life threatening, no Caused/prolonged hospitalization, no Disabling/Incapacitating, no Congenital anomaly/birth defect.

Headache Fever (101.3) with chills body aches/malaise nausea/decreased appetite site injection-arm pain

headache; Tachycardia; chills; body aches; This is a spontaneous report from a contactable nurse (patient). A 25-year-old female patient received her first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number: EH9899), intramuscularly on right arm at 07:30 AM on 18Dec2020 at single dose for COVID-19 immunization. The patient medical history was not reported. Concomitant medication included ethinylestradiol, ferrous fumarate, norethisterone acetate (LO LOESTRIN FE). The patient experienced tachycardia, chills, body aches, headache at 12:00 AM on 19Dec2020, events resulted in: Emergency room/department or urgent care], events were reported as non-serious. Prior to vaccination, the patient was not diagnosed with COVID-19. The patient was tested COVID post vaccination on

19Dec2020; COVID test type: Nasal Swab, COVID test name : Covid PCR, Covid test result: Negative. The patient did not receive any treatment for events. The outcome of events was recovered in Dec2020.

Episode of nausea; Right-sided preauricular and superficial cervical lymphadenopathy; This is a spontaneous report from a contactable physician (patient herself). This 36-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number EJ1685), via an unspecified route of administration, at single dose on 19Dec2020 at 08:45 AM for COVID-19 immunisation. Vaccine location was left arm. The patient was vaccinated at hospital, age at vaccination was 36-year-old. No other vaccine was received in four weeks. The patient was not pregnant. The patient did not have a relevant medical history. Relevant concomitant medications included ibuprofen and 20 Ethinyl Estradiol-3 Drospirenone. On 21Dec2020, the patient developed right-sided preauricular and superficial cervical lymphadenopathy. On 22Dec2020, the patient had an episode of nausea. The patient did not perform COVID test before and after vaccination. No therapeutic measures were taken as result of the events. The outcome of the events was unknown.

On day to the left arm had some redness at the injection site and was sore. This was listed as unknown possible side effect. On the days following a became increasingly red and itchy. I took Benadryl to help resolve the itching. Redness and itching continued and then on Sunday 12/27/20 The site became increasingly read painful to touch and warm to touch. On Monday morning I contacted my immediate supervisor advised her that I was having something outside of what I believed to be a ?normal? reaction or side effect. I went to urgent care to see occupational health. I was given prescriptions for keflex and naproxen for cellulitis. My arm is extremely painful to touch. I was advised if the area worsens or spreads to see the ER because I may need IV antibiotics.

Sore arm; This is a spontaneous report from a contactable nurse (patient). A 24-year-old female patient (no pregnant at the time of vaccination) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EH9899) via intramuscularly on 22Dec2020 06:15 AM on left arm at single dose for COVID-19 immunization. The patient's medical history included hyperthyroidism/goiter and not allergy to medications, food, or other products. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine and did not receive any other medications within 2 weeks of vaccination. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, the patient has not been tested for COVID-19. The concomitant drug included vitamins within 2 weeks of vaccination. The patient experienced sore arm on 22Dec2020 06:15 AM. No treatment for sore arm. The outcome of the events was recovering.

"In Clinic: Pt received Moderna vaccine on right arm. She immediately felt numbness and tingling sensation on both shoulders and right neck. Neck felt tight, pain and + weakness on left wrist and 4th / 5th digit. BP was 149/ 78, O2 sat 99%, pulse 82. Pt then felt nausea, dizziness, burning sensation of left thigh, ""not feeling well"". Pt abvle to move all extremities, denies SOB. Hx of allergic reaction to Reglan and compazine. Repeat Vitals: 160/74, pulse,83,O2sat 100%, 2 pm: 135/85, pulse 75, O2 sat 99% Paramedics was called and arrived at 2:11 pm. Pt to be further evaluated in ER. In ED: Gen: Patient is in NAD, non-toxic appearing, cooperative HEENT: NC/AT, MMM, no conjunctival injection, b/l sclera anicteric. Mallampati 1 oropharynx clear, no exudates, tonsils within normal limits. No edema or

erythema. Neck: Supple. Cardiovascular: RRR Pulmonary/Chest: CTAB, no increased WOB, no respiratory distress, no wheezes/rhonchi/rales, chest wall tenderness. Abdominal: Soft. NT/ND, no r/g, no masses Extr/MSK: Well perfused, distal pulses intact. No tenderness. No LE edema. Back: No CVAT Neuro: No evidence of facial droop, normal speech, mentation appropriate, steady gait. Sensation intact to light touch to upper lower extremities. Cranial nerves 2-12 within normal limits. Psychiatric: Normal affect. Mood not labile nor depressed. Skin: No rashes, lesions, or wounds appreciated on exposed skin. á ED Course & Clinical Decision Making: 43 year old female with PMHx as listed in HPI presents with intermittent numbness after receiving the coronavirus vaccination. á - History of present illness also notable for symptoms started 20-30 minutes after receiving the coronavirus vaccination. á - Vitals reviewed and all wnl á - Physical exam notable for neurologically intact, no rashes, no airway abnormalities, otherwise unremakrable. á - Given above findings, presentation is concerning for side effects from the coronavirus vaccination, electrolyte abnormality. Will check basic lab work here in the emergency department. Will give symptomatic control with 1 L of IV fluids and Zofran for the nausea. Will monitor here in the emergency department. Disposition pending clinical improvement. á Lab work grossly unremarkable here in the emergency department. Mild hypo phos of 2.6. Electrolytes otherwise within normal limits. No leukocytosis. Hemoglobin of 10.2, no baseline but the patient does have a history of chronic anemia given uterine fibroids. á The patient was able to ambulate with steady gait. She continues to have burning sensation to her left leg and her right arm. She will be given lidocaine patches for symptomatic control. She also be given ibuprofen 600 mg. á Return precautions returning to the patient. At this time presentation does not appear consistent with anaphylaxis. Min presentation most consistent with side effects from coronavirus vaccination. á Patient tolerated p.o. here in the emergency department. She was able to ambulate with steady gait. Symptoms mildly improved after lidocaine patch and ibuprofen. Return precautions given. á Patient re-evaluated and is stable for discharge. á At this time, suspicion is low for acute injury/illness requiring hospital admission or emergent intervention. No indication for inpatient management; No medical or surgical emergent care needed at this time. á However, it was stressed to the patient that symptoms may persist or worsen, in which case she should be reevaluated. Patient should also get appropriate and timely follow up for further evaluation and continuation of care. The patient indicates understanding of these issues. Patient is ready for discharge. Return precautions (advised to return to ER if their symptoms persist, change, or worsen) and follow up plan reviewed with patient and understood. á á"

Left deltoid soreness; This is a spontaneous report from a non-contactable physician (patient). A 28-year-old female (not pregnant) patient received first dose bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EJ1685), intramuscular in left arm on 22Dec2020 08:15 at single dose for COVID-19 immunisation. Facility where the most recent COVID-19 vaccine was administered was Hospital. Medical history included asthma (Prior history of asthma). No allergies to medications, food, or other products. Prior to vaccination, the patient was not diagnosed with COVID-19. Concomitant medications included ethinylestradiol, norethisterone acetate (JUNEL), ascorbic acid, betacarotene, biotin, capsicum annuum fruit, colecalciferol, collagen marine, curcuma longa, cysteine hydrochloride, equisetum arvense, fallopia japonica, hyaluronic acid, iodine, keratin, lysine, methionine, piper nigrum, selenium, serenoa repens, tocotrienols nos, withania somnifera, zinc (NUTRAFOL). The patient not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient experienced left

deltoid soreness (non-serious) on 22Dec2020 10:00. No treatment received for the adverse event. Since the vaccination, the patient has not been tested for COVID-19. The outcome of the event was not recovered. No follow up attempts are possible. No further information is expected.

""""whole body aches everywhere.""/whole body is so sore today, my breast, my back, shoulders, my neck; My throat gets a little sore; I just threw up everywhere; This is a spontaneous report from a contactable consumer (patient). A 65-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK5730), via an unspecified route of administration on 22Dec2020 08:20 at single dose for COVID-19 immunization. The patient medical history was not reported. There were no concomitant medications. The patient reported that her ""whole body aches everywhere/her whole body hurts."" Healthcare professional (HCP) had not been made aware of this at time of call. The patient further reported that her whole body was so sore today (23Dec2020), my breast, my back, shoulders, my neck. Also, her throat gets a little sore and she just threw up everywhere on an unspecified date in Dec2020. The patient was working in a nursing home. No treatment was given for the events. ""Lab test: Consumer stated, ""No, just the Covid test but I passed it so (sentence incomplete)."" The outcome of the events was unknown."

Anxious, dizzy, hypertensive, lightheaded for 30 min-- monitored throughout -- resolved without intervention -- discharged home

"Facial Tingling 25 minutes after injection. Still with mild tingling.; Face and ears felt very warm; This is a spontaneous report from a contactable nurse (patient). A 55-year-old non-pregnant female patient received her first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899), via an unspecified route of administration on 21Dec2020 13:30 at single dose on her left arm for covid-19 immunization. Medical history included gastrooesophageal reflux disease (GERD) and known allergies included Latex, epinephrine (""epi""), shell fish. Concomitant medication in two weeks included fexofenadine hydrochloride (ALLEGRA), lansoprazole (PREVACID), plantago ovata (METAMUCIL), dextran sulfate sodium (DSS). The patient previously took epinephrine and experienced drug hypersensitivity. The patient experienced face and ears felt very warm. Facial Tingling 25 minutes after injection on 21Dec2020 14:00. No treatment was received. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, the patient has not been tested for COVID-19. The outcome of the events was recovering."

2 inch diameter at injection site; swelling, redness, tender for 3 days after; 2 inch diameter at injection site; swelling, redness, tender for 3 days after; 2 inch diameter at injection site; swelling, redness, tender for 3 days after; This is a spontaneous report from a contactable other health professional (patient). A 40-years-old female patient (not pregnant at the time of vaccination) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), intramuscularly on 17Dec2020 16: 30 at single dose on left arm for COVID-19 immunization in hospital. Medical history included attention deficit hyperactivity disorder (ADHD), idiopathic retinitis. Concomitant medication included amfetamine aspartate, amfetamine sulfate, dexamfetamine saccharate, dexamfetamine sulfate (ADDERALL), gabapentin, naproxen sodium (ALEVE), ergocalciferol (VIT D), magnesium supplement and multivitamin.

The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient experienced 2 inch diameter at injection site; swelling, redness, tender for 3 days after, stated from 18Dec2020 12:00 PM. Then gone. No treatment received for the adverse events. The events outcome was recovered in Dec2020. No COVID prior vaccination, since the vaccination, the patient hadn't been tested for COVID-19. The seriousness was reported as no. The information on the batch number has been requested.

Tachycardia up to 160 with exertion. Some shortness of breath noted. Returns to normal heart rate with rest. Cardiac monitor, CXR, CBC, TSH, CMP in the Emergency Department and physician evaluation. Returned to work same day without restrictions. Will follow up with personal provider.

left arm soreness a little; This is a spontaneous report from a contactable nurse (patient). A 55-year-old female patient (not pregnant at the time of vaccination) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK5730), intramuscularly on 22Dec2020 16:30 at single dose at left arm for COVID-19 immunization. Medical history was none. The patient's concomitant medications were not reported. The most recent COVID-19 vaccine was administered at Hospital. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient did not receive any other medications within 2 weeks of vaccination. The patient experienced left arm soreness a little on 22Dec2020 16:30. There was no any treatment received for the adverse event. The case safety report was non-serious per the reporter. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient hadn't been tested for COVID-19. The outcome of the event was recovering.

joint pain; fatigue; headache; sore arm; This is a spontaneous report from a contactable pharmacist (patient). A 27-year-old female patient (not pregnant) received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number= EH9899), via an unknown route of administration on 22Dec2020 09:00 AM in left arm at single dose for COVID-19 immunization. The COVID-19 vaccine was administered at hospital. The patient's medical history and concomitant medications were unknown. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient experienced joint pain, fatigue, headache, sore arm on 23Dec2020 09:00 AM. The patient received Ibuprofen as treatment. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, the patient was not been tested for COVID-19. The outcome of events was unknown.

oral lesions; This is a spontaneous report from a contactable nurse. A 48-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (lot number EH9899), via an unspecified route of administration on 21Dec2020 at single dose for covid-19 immunization. Vaccine location was right arm and it was the first dose. The facility type vaccine was hospital. None medical history. No known allergies. Patient was not diagnosed with COVID-19 prior to vaccination nor tested for COVID-19 since the vaccination. Concomitant medication included acetylsalicylic acid, caffeine, paracetamol (EXCEDRIN MIGRAINE) within 2 weeks of vaccination. The patient didn't receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient experienced oral lesions on 22Dec2020 with outcome of not recovered. Patient didn't receive treatment for the adverse event. The action taken in

response to the events for BNT162B2 was not applicable. The date report was first received from source was 23Dec2020. The event was reported as non-serious.

I woke up in the middle of the night after my vaccine; experienced a rapid heartbeat; This is a spontaneous report from a contactable healthcare professional. A 50-year-old female patient received BNT162B2 (Pfizer-BIONTECH Covid-19 Vaccine), via an unspecified route of administration on an unspecified date at a single dose for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient stated that she received the first injection of the vaccine on Monday and experienced a rapid heartbeat on Monday night (unspecified dates). She further stated that she woke up in the middle of the night after her vaccine with her heart rate at 127. She wanted to know about this side effect if it was the true side effect and if it could happen again after receiving the second dose of the vaccine. Outcome of the events was unknown. Information on the lot/batch number has been requested.

chills, muscle soreness, left arm pain/injection site pain. injection site hard started around 7pm 12/28/20, currently 12/29/20 no longer have chills still have generalized muscle soreness, left arm pain/injection site pain, injection site hard

fever accompanied by severe chills for 12 hours; fever accompanied by severe chills for 12 hours; This is a spontaneous report from a non-contactable Other healthcare professional (HCP) reporting for herself. A 25-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 22Dec2020 at single dose for covid-19 immunization. Vaccine location was Right arm and it was the first dose. The COVID-19 vaccine was administered at Hospital. Medical history included the patient was diagnosed with COVID-19 Prior to vaccination. Concomitant medications included escitalopram oxalate (LEXAPRO), trazodone, acetylsalicylic acid (BABY ASPIRIN), ibuprofen. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient experienced fever accompanied by severe chills for 12 hours on 22Dec2020 07:00 PM. Since the vaccination, the patient was not been tested for COVID-19. No treatment received for the events. The outcome of the event was recovering. No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.

drop in platelets; This is a spontaneous report from a Pfizer-sponsored program. A contactable pharmacist reported that a patient of unspecified age and gender started to receive bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE; lot/batch number not reported), via an unspecified route of administration on an unspecified date at a single dose for covid-19 immunization. The patient's medical history and concomitant medications were not reported. Pharmacist on the line calling about COVID 19 Vaccine. He was doing some administrative work and noticed they have patient who received the COVID 19 vaccine and has since experienced a drop in platelets. He wanted to know if we have any information about any other reports of this occurring. The COVID 19 vaccine was given and then noticed patient had a drop in platelets. The reporter stated he does not know when the patient experienced the drop in platelets. He was provided with this question yesterday, so it's possible the drop occurred yesterday, but he does not know. It was unknown to the caller if the drop in platelets is still ongoing or has resolved. The outcome of the event was unknown. Information on the lot/batch number has been requested.

Pain at injection site

nausea; Headache; fever; chills; body aches; This is a spontaneous report from a contactable Nurse (patient). A 42-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number E12573C) , intramuscular in Left arm on 21Dec2020 at 19:00 at single dose for COVID-19 immunization. Medical history included COVID-19 (the patient diagnosed with COVID-19 prior to vaccination); since the vaccination, the patient has not been tested for COVID-19. No known allergies to medications, food or other products.Concomitant medication included cetirizine hydrochloride (ZYRTEC) and ibuprofen, received within 2 weeks of vaccination. On 22Dec2020 at 17:00, the patient experienced nausea, headache, fever, chills and body aches, all non serious. No treatment was given and patient recovered from all the events in Dec2020.

"Urgency, repeated episodes of diarrhea; GI symptoms; Cramping; This is a spontaneous report from a contactable physician (patient). A 58-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number EJ1685), via an unspecified route of administration at right arm on 19Dec2020 07:15 at single dose for COVID-19 immunization at a hospital. The patient's medical history included hypertension (HTN), obesity, had hx of stroke 2007 and COVID-19 (diagnosed prior to vaccination). No allergies to medications, food, or other products. No other vaccines within 4 weeks prior to the COVID vaccine. Concomitant medication received within 2 weeks of vaccination included hydrochlorothiazide, valsartan (VALSARTAN HCTZ), rosuvastatin calcium (CRESTOR), acetylsalicylic acid (ASA 81) and multivitamin. Since the vaccination, the patient had not been tested for COVID-19. It was reported that on 20Dec2020 09:00, the patient experienced gastrointestinal (GI) symptoms, cramping, and ""urgency, repeated episodes of diarrhea"". No fever. No treatment was taken as a result of the events. The outcome of the events was recovering."

Severe fatigue/malaise.; Severe fatigue/malaise.; This is a spontaneous report from a contactable Other Health Professional (patient). A 32 years old male patient received the 1st dose BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, lot EH9899), intramuscular at 21Dec2020 11:00 AM at single dose in left arm for COVID-19 immunisation. Medical history included Asthma, ADHD and Known allergies: Sulfa. Concomitant medications included salbutamol sulfate (PROAIR), fluticasone propionate, salmeterol xinafoate(ADVAIR), montelukast sodium (SINGULAIR) and amfetamine aspartate, amfetamine sulfate, dexamfetamine saccharate, dexamfetamine sulfate (ADDERALL). The patient experienced Severe fatigue/malaise on 22Dec2020 06:00 AM. Remained afebrile during symptoms. The patient did not receive any treatment. Outcome of events was recovering.

Sore/tender arm; headache; This is a spontaneous report from a contactable other hcp (patient). A 67-year-old female patient received bnt162b2 (lot number: ek5730), intramuscularly at left arm, first dose on 18Dec2020 13:45, at single dose, for COVID-19 immunization. Medical history included high blood pressure from an unknown date. No known allergies. The patient is not pregnant at the time of vaccination. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Concomitant medication included blood pressure medication. The patient experienced Sore/tender arm and headache the day after the vaccine on 19Dec2020 01:00. The event was reported as non-serious. No treatment received for the

adverse event. The patient underwent lab tests and procedures which included blood pressure measurement: high on an unspecified date. The outcome of the events was recovered.

Symptoms started the morning after (12/29/2020), the injection site is very sore. Sudden onset of headache.

Initial flushing in face and slight metallic taste in mouth lasting less than 5 min; Initial flushing in face and slight metallic taste in mouth lasting <5 min; tiredness; mild nausea; Next 1-2 days bruising more than my normal at site of injection; This is a spontaneous report from a contactable Other healthcare professional(patient). A 39-year-old female patient received first dose BNT162B2 via Intramuscular at Arm Left on 20Dec2020 11:00 at the 39-year-old at single dose for COVID-19 immunization. The medical history included Sulfonamide allergy, Varicose veins, 1/2 thyroid removed no meds, chronic sinuses take nasacort for and COVID-19. The concomitant medication was Vitamins. The patient previous took levaquin, chloraprep and both Allergies to them. On 20Dec2020 11:15 the patient Initial flushing in face and slight metallic taste in mouth lasting less than 5 min. Then tiredness for 12-24 hours as well as mild nausea and in well feeling. Next 1-2 days bruising more than my normal at site of injection. After that fine. Over all fairly mild symptoms. There was no treatment received for the adverse events. The outcome of the events Initial flushing in face and slight metallic taste in mouth was recovered on 20Dec2020 11:20, the other events was recovered in Dec2020. Information on the lot/batch number has been requested.

mild injection site soreness; mild light headed; tiredness; This is a spontaneous report from a non-contactable nurse (patient). A 39-year-old female patient the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EK5730), intramuscularly on 22Dec2020 at left arm, at single dose for covid-19 immunization. Medical history included hypothyroid, migraine and known allergies: Penicillin. The patient's concomitant medications were not reported. The patient was not pregnant at the time of vaccination. The patient experienced mild injection site soreness, mild light headed, tiredness on 22Dec2020. No treatment received for all events. The outcome of the events was recovered in Dec2020. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. No seriousness criteria: no Results in death, no Life threatening, no Caused/prolonged hospitalization, no Disabling/Incapacitating, no Congenital anomaly/birth defect. No follow-up attempts are possible. No further information is expected.

Fever, chills, body aches, low back pain, pain at injection site

"feeling her face numb; funny; flushed; Also felt 'a little bit' of nausea; tired; low joint pain the next morning; This is a spontaneous report from a contactable other health professional (patient). A female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications was not reported. The patient experienced after 30 minutes to 1 hour of receiving the injection she described ""feeling her face numb, funny, flushed, but then that kind of went away an hour or 2, less and less and less."" Also felt 'a little bit' of nausea and

tired, low joint pain the next morning, that went away in one and a half days. The outcome of the events was recovered on an unknown date. Information on the batch number has been requested."

"Patient with HA / ""Mucous"" sensation in throat. Progressed to patient frequently coughing / clearing throat. Felt like something in throat, difficult to swallow water ICC called for ER MD to eval. IV started. Benadryl, Pepcid, and Solumedrol given as per protocol. Pt taken to ICC for monitoring."

Headache; tinnitus; This is a spontaneous report from a contactable physician (reported for herself). A 41-year-old female patient (not pregnant at the time of vaccination) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK5730), via an unspecified route of administration on 21Dec2020 12:15 at single dose at left arm for COVID-19 immunization. Medical history included endometriosis, sinus disease, allergies, and known allergies: NSAID. Concomitant medications received within 2 weeks of vaccination included cyclobenzaprine, doxepin, ergocalciferol (VIT D), cetirizine hydrochloride (ZYRTEC [CETIRIZINE HYDROCHLORIDE]), Ocp. The most recent COVID-19 vaccine was administered in Hospital. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. It was reported that headache developed at 48 hours with tinnitus on 23Dec2020 11:00. Treatment received for the adverse event included Tylenol. The events were non-serious per the reporter. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient hadn't been tested for COVID-19. The outcome of the events was not recovered.

Rash swelling primarily to arm injected.; Rash swelling primarily to arm injected.; Chills; fatigue; mild nausea; This is a spontaneous report from a contactable nurse. A 50-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number= EH9899), Intramuscularly on 17Dec2020 08:15 AM in left arm at single dose for COVID-19 immunization. The COVID-19 vaccine was administered at hospital. Medical history was not reported. The patient had unknown allergies. Concomitant drugs in two weeks included Glucosamine, curcuma longa rhizome (TURMERIC). The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient experienced rash swelling primarily to arm injected, chills, fatigue, mild nausea on 18Dec2020 08:00 AM. No treatment received for the events. The adverse events resulted in doctor or other healthcare professional office/clinic visit. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, the patient was not been tested for COVID-19. The outcome of events was recovering. No follow up attempts are possible. No further information is expected.

Tachycardia, ?hot?, ?jittery? and chest tightness. Lasted ~45 minutes.

Body aches; Joint Pain; low grade fever; This is a spontaneous report from a contactable nurse (patient). A 37-year-old female patient received the first dose of BNT162B2 (Lot number: EJ1685), via intramuscular, in arm left, on 21Dec2020 15:00 at single dose for COVID-19 immunization. Facility where the most recent COVID-19 vaccine was administered was hospital. Medical history included HTN(Hypertension). Prior to vaccination, the patient was diagnosed with COVID-19. Since the vaccination, patient was not tested for COVID-19. Known allergies included PCN. No other vaccines were received within 4 weeks prior to the COVID vaccine. The other medication that the patient received within 2 weeks of vaccination was HCTZ, alprazolam(XANAX), paracetamol(TYLENOL),

colecalciferol(VITAMIN D), Ibuprofen, naproxen sodium(ALEVE). The patient experienced body aches, joint pain, low grade fever on 22Dec2020 09:00 AM. The events were reported as non-serious. No treatment was received for the events. The outcome of the events was recovering.

Client was leaving the building after her 15 min wait. She became dizzy and got a headache. She returned to the monitoring room. B\P 142/80 Respirations even and unlabored. Skin pink warm and dry. Reported dizziness and a headache. Client monitored an additional 15 min. No further headache or dizziness. B]P 138/78 pulse 60. Respirations even and unlabored. Skin pink, warm and dry. Released informed to report to V-safe and to seek medical advise if in symptoms reoccurred.

Headache; Runny nose; Sore throat; mild fever; fatigue; This is a spontaneous report from a contactable other hcp (patient) from a Pfizer Sponsored Program. A female patient of an unspecified age received bnt162b2 (lot/batch number and expiration date not provided) via an unspecified route of administration, first dose on 16Dec2020 (reported as last wednesday of 23Dec2020), at single dose, for COVID-19 immunization. The patient medical history and concomitant medications were not reported. Stated that she got her first dose COVID vaccine last wednesday and experienced mild fever and fatigue on 16Dec2020. Stated that this morning (23Dec2020) she woke with a headache, runny nose and sore throat. Stated that she had wanted to know if the side effects are normal for the time frame and if she would have to be tested. The patient underwent lab tests and procedures which included body temperature: mild fever on 16Dec2020. The outcome of the events mild fever, fatigue was unknown, of the other events are not recovered. Information on the lot/batch number has been requested.

joint pain; fever; nausea; stomach pain; This is a spontaneous report from a contactable physician (patient). A 76-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 22Dec2020 at left arm, at single dose for vaccination. Medical history included ongoing diabetes. Concomitant medication included dulaglutide (TRULICITY) for diabetes. The patient the vaccine on 22Dec2020 and had developed joint pain, fever, nausea, and stomach pain on 22Dec2020. The patient had taken Pepto bismol and Tylenol in response to these events and what to know if these medications are safe to take or what recommendations to treat side effects. He called to ask if those products were safe to take relative to having gotten the COVID-19 Vaccine; and if there are any recommendations on medications to or not to take relative to having gotten the COVID-19 Vaccine. The patient stated his was also on Trulicity for diabetes and that medication can cause stomach pain too. He stated the pain is in the center of his abdomen. COVID-19 Vaccine next dose is scheduled in 3 weeks, no dose change made. The patient specified that there is no relevant information to provide regarding concomitant products or medications or other medical conditions. He took medication for diabetes but that was not relevant. The outcome of the events was not recovered. Information about Lot/Batch number has been requested.

Heart Racing, lump in the throat, facial swelling

Fever; chills; nausea; injection site pain; body aches; This is a spontaneous report from a contactable nurse (patient). A 33-year-old female patient (no pregnant at the time of vaccination) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: Ek5730) via an unspecified

route of administration on 22Dec2020 06:45 PM on left arm at single dose for COVID-19 immunization. The patient's medical history included chronic low back pain and not allergy to medications, food, or other products. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine and did not receive any other medications within 2 weeks of vaccination. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, the patient has not been tested for COVID-19. The concomitant drug was not reported. The patient experienced fever, chills, body aches, nausea, injection site pain on 23Dec2020 11:30 AM. No treatment for adverse events. The outcome of the events was recovering.

Headache; soreness to the injection site; This is a spontaneous report from a contactable nurse. A 55-year-old female non-pregnant patient received her first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK5730), via intramuscular on 21Dec2020 07:30 at single dose on her left arm for covid-19 immunization. Medical history included hypertension. No allergies to medications, food, or other products. Concomitant medication was received within 2 weeks of vaccination included lisinopril. The patient experienced headache and soreness to the injection site on 21Dec2020 10:00. Treatment included Tylenol 500mg. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19, since the vaccination, the patient had not been tested for COVID-19. The outcome of the events was recovered in Dec2020. No follow-up attempts are possible. No further information is expected.

fever, headache, nausea, extreme fatigue lasting 24 hours No treatment besides ibuprofen. Symptoms began aboue 20 hours after injection and gone 26 hours later

12-26-2020 uncomfortable heart palpitations, tired and disruption of sleep x 2 days.

Extreme body aches, has to stay in be, severe headache, eyes hurt, swollen lymph nodes under right arm, fever to 99.2

Moderate/severe fatigue; muscle discomfort at injection site; muscle discomfort at injection site; This is a spontaneous report from a non-contactable other health professional (patient). A 25-years-old female patient (not pregnant) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number: EH9899), intramuscularly on 22Dec2020 08:00 at single dose on left arm for COVID-19 immunization. Medical history included polycystic ovarian syndrome (PCOS), sinus tachycardia, anxiety. Concomitant medication included propranolol, fluoxetine hydrochloride (PROZAC), spironolactone (ALDACTONE A), all from Dec2020. The known allergy included metoclopramide (REGLAN). The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient experienced moderate/severe fatigue, muscle discomfort at injection site on 23Dec2020 05:45 AM. No treatment received for the adverse events. The events outcome was not recovered. No COVID prior vaccination, since the vaccination the patient hadn't been tested for COVID-19. It was not reported as serious. No follow-up attempts are possible. No further information is expected.

she felt cold, then hot; she felt tired and weak; feel hot; she felt tired and weak/weakness; she felt cold/cold sensation; chills; headache; have a temperature of like 99 to 99.1/temperature went to 99.1; This is a spontaneous report from a contactable physician (patient). A 41-year-old female patient

received first dose bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EK5730, Expiry Date: Mar2021), intramuscular in left deltoid on 16Dec2020 around 2:00 or 2:30 in the afternoon at single dose for COVID-19 immunisation. Medical history included none. Concomitant medications included colecalciferol (VITAMIN D), ascorbic acid, ergocalciferol, nicotinamide, retinol, riboflavin, thiamine hydrochloride (VITAMINS [ASCORBIC ACID;ERGOCALCIFEROL;NICOTINAMIDE;RETINOL;RIBOFLAVIN;THIAMINE HYDROCHLORIDE]). The patient previously took flu shot on 16Oct2020 at age of 41-year-old for immunization. Caller asking if is possible to see side effects days later after getting the vaccine. Caller report her symptoms which the caller reports started 4-5 days after receiving the vaccine. Symptoms included were chills, weakness, headache and temp. Caller on the line a doctor, MD, calling about the COVID Vaccine. She mentioned she got the shot last week, 16Dec2020. Almost like the fourth day after getting the vaccine, that Sunday (20Dec2020), she started to experience chills and have a temperature of like 99 to 99.1. She did not get the vaccine through her doctor. She got the vaccine at the hospital she works at. She explained on Sunday (20Dec2020) night, she felt cold. She had to use a couple of blankets and wear a sweatshirt which was not usual for her. On Monday 21Dec2020, she felt tired and weak. That afternoon and evening she felt chills as well. It was like all of a sudden she had a cold sensation. She commented her normal temperature always runs like 97.6 to 98. Her temperature went to 99.1, something like that. However, she confirmed it did not go above that. She would feel hot at times and chilly at times. She also mentioned she experienced headaches. Yesterday (22Dec2020) morning she felt better. Last evening it was not that bad. She mentioned with chills she felt cold, then hot. She checked her temperature and it was 98.8 something like that. Just a little higher than her normal. Outcome of chills: Stated this morning she was fine, but in the evening it is worse. Felt weak: She mentioned there was time where she was fixing lunch and after it was cooked she felt weak and like she had to sit right away. Headache: Had an episode Sunday (20Dec2020) night and it happened again yesterday. The headaches for short periods. Caller confirmed this was the first dose received of the COVID vaccine. She confirmed she does not know if the chills, feeling weak, headache, or temperature is related to the COVID vaccine. She mentioned she has no other symptoms like cough. She also added she was tested for COVID and it was negative. She had the test done on 22Dec2020. At end of call, caller questioned, it was asked if it is possible to have side effects days later after getting the COVID vaccine and it be related to the vaccine. She stated she's read it's common for it to occur like two days after, but not this long afterwards. Vaccination Facility Type was Hospital. Vaccine Administered at a Military Facility was No. Additional Vaccines Administered the Same date of the Pfizer Suspect was None. No AE(s) require a visit to the Emergency Room or Physician Office. The outcome of the event weakness was not recovered. The outcome of the event have a temperature of like 99 to 99.1/ temperature went to 99.1 was recovering. The outcome of other events was unknown.

lump in armpit and sore; sore collar bone swollen on side that received vaccine; lymph node and collar bone swollen; collar bone swollen; fever; chills; shakes; This is a spontaneous report from a contactable nurse. A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 21Dec2020 at single dose for covid-19 immunization. The patient medical history and concomitant medications were not reported. The patient stated she was noticing possible side effects in Dec2020, with lymph node and collar bone swollen,

fever, chills, shakes, this morning (23Dec2020) lump in armpit and sore collar bone swollen on side that received vaccine. The action taken in response to the events for bnt162b2 was not applicable. The outcome of events was unknown. Information on the lot/batch number has been requested.

Moderna COVID-19 vaccine EUA

Sore arms; light headed; This is a spontaneous report from a contactable Other Healthcare professional (HCP) reported for himself. A 55-year-old male patient received (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK5730), intramuscular on 22Dec2020 18:30 at single dose for covid-19 immunization. Vaccine location was Right arm and it was the first dose. The COVID-19 vaccine was administered at Doctor's office/urgent care. Medical history reported as none. The patient's concomitant medications were not reported. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient experienced sore arms, light headed on 22Dec2020. No treatment received for the events. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, the patient was not been tested for COVID-19. The outcome of the events was recovered on an unknown date in Dec2020.

I hard time swallowing Tingling in my face

SEVERE chills/shivering; significant nausea; tachycardia- mid to upper 120's; dizziness; fatique; headache; body aches; This is a spontaneous report from a contactable nurse (patient). This 50-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: Not available/provided to reporter at the time of report completion) via an unspecified route of administration on 21Dec2020 06:30 on right arm at a single dose for COVID-19 immunization. The patient no known allergy and no medical history. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Concomitant medications received within two weeks included methyprednisolone, azithromycin, celecoxib (CELEXA) and fish oil. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, the patient has not been tested for COVID-19. The patient experienced severe chills/shivering, significant nausea, tachycardia- mid to upper 120's, dizziness, fatigue, headache, body aches on 21Dec2020 08:00. The patient received Zofran to treat nausea. The outcome of the events was recovering. Information on Lot/Batch number has been requested.

Patient reported chest pain and tingling/numbness to face. HR 60 Respirations 18. Monitored and chest pain resolved - did have evaluated n Emergency Room and was discharged home and advised to return if symptoms worsen. 12/29/2020 spoke with patient and feeling good, no symptoms at all.

"Left armpit 7.5centimeter long x 4.5 centimeter tender mass; This is a spontaneous report from a contactable nurse (patient). A 55-year-old female patient (not pregnant) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number EH 9899), via an unspecified route of administration at left arm on 21Dec2020 15:15 at single dose for COVID-19 immunization at a hospital. The patient's medical history included arthritis, known allergies: Penicillin (Pcn) and COVID-19 (diagnosed prior to vaccination). Concomitant medication received within 2 weeks of vaccination included golimumab (SIMPONI), methotrexate and meloxicam (MOBIC). No other vaccines within 4

weeks prior to the COVID vaccine. It was reported that on 23Dec2020 09:00, the patient experienced ""left armpit 7.5centimeter long x 4.5 centimeter tender mass"". The event led to doctor or other healthcare professional office/clinic visit and patient consulted the event. The outcome of the events was unknown."

arm soreness starting seven or eight hours after injection; Pregnant at the time of vaccination?: Yes; Pregnant at the time of vaccination?: Yes; Pregnant at the time of vaccination?: Yes; This is a spontaneous report from a contactable consumer (patient). This consume reported information for both mother and fetus/baby. This is a mother report. A 39-year-old female patient received bnt162b2 (lot number: EJ1685), intramuscularly at left arm, on 22Dec2020 11:00 at single dose for COVID-19 immunization. Medical history included asthma, migraines from an unknown date. The patient is pregnant at the time of vaccination. The patient date of LMP is 09Oct2020. The mother was 10 weeks pregnant at the onset of the event. The mother was due to deliver on 16Jul2021. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. No allergies to medications, food, or other products. Concomitant medication included ascorbic acid, betacarotene, calcium sulfate, colecalciferol, cyanocobalamin, ferrous fumarate, folic acid, nicotinamide, pyridoxine hydrochloride, retinol acetate, riboflavin, thiamine mononitrate, tocopheryl acetate, zinc oxide (PRENATAL VITAMINS). The patient experienced arm soreness starting seven or eight hours after injection on 22Dec2020 21:00. The event was reported as non-serious. No treatment received. The outcome of the event was recovering.

rash on upper chest, itching in both arms, pt reported she felt short of breath

Fever up to 100; myalgias; chills; wheezing; coughing; some shortness of breath; This is a spontaneous report from a contactable Other Healthcare professional. A 41-year-old female patient received first dose BNT162B2 via Intramuscular at Arm Left on 18Dec2020 15:00 at the 41-year-old at single dose for COVID-19 immunization. The medical history included Asthma, GERD, insomnia, bladder pain syndrome and COVID-19(Prior to vaccination, was the patient diagnosed with COVID-19). The concomitant medications were Amitriptyline, Trazodone, diphenhydramine hydrochloride (BENADRYL), Omeprazole, macrogol 3350(MIRALAX), mometasone furoate (ASMANEX), Naproxen. Symptoms started 7 days after injection. On18Dec2020 12:00 the patient experienced Fever up to 100, myalgias, chills, wheezing, coughing, some shortness of breath. The patient received treatment Naproxen for the adverse events. The outcome of the events was recovering. Information on the lot/batch number has been requested.

Patient left eye felt like sand was in it, she tried eye drops and eye wash and nothing worked. She also reports left leg pain

None, just a sore arm; This is a spontaneous report from a contactable nurse (patient herself). A 43-year-old female patient started to receive her first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot Number: EJ1685), intramuscularly on right arm at 14:45 on 22Dec2020 at single dose for COVID-19 immunization. Medical history included hypothyroidism and psoriasis, no allergies to medications, food, or other products. Concomitant medication included ibuprofen (MOTRIN). The patient experienced sore arm on 23Dec2020, event reported as non-serious. Prior to vaccination, it was

unknown if the patient was diagnosed with COVID-19; Since the vaccination, the patient had not been tested for COVID-19. The patient did not receive any treatment for events. The outcome of event was unknown.

Headache; This is a spontaneous report from a contactable Other Health Professional (patient). A 38-year-old female patient (no pregnant at the time of vaccination) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899) via intramuscular on 22Dec2020 10:00 AM on left arm at single dose for COVID-19 immunization. The patient's medical history included allergy to cefdiner and augmentin and no other medical history. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine and did not receive any other medications within 2 weeks of vaccination. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, the patient has not been tested for COVID-19. The concomitant drug was not reported. The patient experienced headache on 23Dec2020 05:00 AM. No treatment for adverse event. The outcome of the events was recovered in Dec2020.

tiredness, headache, hot flashes, chills, reduced appetite. Conditions started approx 22 hours after inoculation and lasted for 15 hours. After that just minor hot and cold spells on the second day, today.

5 days post-vaccination, temperature ranging from 99.0-99.6F.; 4 days post-vaccination noticed lymphadenopathy behind right ear.; Mild swelling; sensitive to touch; This is a spontaneous report from a contactable nurse (patient). A 22-year-old female (not pregnant) patient received first dose bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: Unknown), intramuscular in arm left on 17Dec2020 17:30 at single dose for COVID-19 immunisation. Facility where the most recent COVID-19 vaccine was administered was hospital. Medical history included none. No allergies to medications, food, or other products. Prior to vaccination, the patient was not diagnosed with COVID-19. The patient's concomitant medications were not reported. The patient experienced 4 days post-vaccination (21Dec2020) noticed lymphadenopathy behind right ear. Mild swelling, sensitive to touch. 5 days post-vaccination (22Dec2020), temperature ranging from 99.0-99.6F. No treatment received for the adverse event. Since the vaccination, the patient has not been tested for COVID-19. The patient not receive any other vaccines within 4 weeks prior to the COVID vaccine. The case was non-serious. The outcome of events was recovering. Information on the Lot/batch number has been requested.

can't smell or taste anything; can't smell or taste anything; Head cold; This is a spontaneous report from a contactable nurse (patient). A 63-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EK5730), via an unspecified route of administration on 18Dec2020 at single dose for immunization. Medical history and concomitant medications were no. Patient got the Covid vaccine on 18Dec2020, towards the end of her shift around 1800 on 22Dec2020, she felt like she was getting a head cold. On 23Dec2020 morning, patient stated she cannot smell or taste anything. Outcome of all events was not recovered. Reporter seriousness for cannot smell or taste as not serious.

Feeling tired after the vaccine; This is a spontaneous report from a contactable consumer (Patient). A 34-year-old male patient received (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK9231), via an

unspecified route of administration on 23Dec2020 09:00 at single dose for covid-19 immunization (Front line health care worker). Vaccine location was left arm and it was the first dose. He was scheduled to get the second dose in Jan2021. The COVID-19 vaccine was administered at Hospital. Medical history included attention deficit hyperactivity disorder (ADHD). Concomitant medication included ongoing methylphenidate hydrochloride (CONCERTA) for ADHD taking for five years. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient was feeling tired after the vaccine on 23Dec2020, Stated he just got the vaccine and he was now just really tired, not sick or anything and he was at work. He was considering going home from work and they told him he had to call Pfizer. Reported he received the COVID 19 vaccine today at work at the at 0900 23Dec2020 in the left arm. About 20 minutes after the injection he started to feel tired and like he wanted to go home from work. His feeling was staying the same. The outcome of the event was not recovered.

I started feeling a lump in my throat, not really bad but it got worse it did not affect my speech or my breathing. But after a while I realized I was having a hard time swalowing, I asked the nurse for Benadryl and it took about 10 min to receive, they took my vitals, they watched for about 45 min and once I told them my throat was feeling better I was realized to go back to work.

Sore arm only; This is a spontaneous report from a non-contactable other HCP (patient). A 39-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EJ1685) via intramuscular on 22Dec2020 08:30 on left arm at a single dose for COVID-19 immunization. The patient allergy to Percocet and medical history included hypothyroidism. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine and did not receive any other medications within 2 weeks of vaccination. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, the patient has not been tested for COVID-19. The patient experienced sore arm only on 23Dec2020 18:00 and no treatment received. The outcome of the event was recovered in Dec2020. No follow-up attempts are possible. No further information is expected.

Difficulty breathing, itchy mouth rash, very bad cough, fever (103)

chills; fatigue; headache; arm pain; body aches; Fever; This is a spontaneous report from a contactable nurse(patient). A 29-year-old female patient received the first dose of BNT162B2 (Lot number: EL0140), via intramuscular, in arm left, on 22Dec2020 18:15 at single dose for COVID-19 immunization. Facility where the most recent COVID-19 vaccine was administered was hospital. Medical history included Covid 19, pneumonia, anxiety/depression. Prior to vaccination, the patient was diagnosed with COVID-19. Since the vaccination, patient was not tested for COVID-19. No allergies to medications, food, or other products. No other vaccines were received within 4 weeks prior to the COVID vaccine. The other medication that the patient received within 2 weeks of vaccination was MULTIVITAMIN, sertraline hydrochloride(ZOLOFT), VITAMIN D3, ZINC, VITAMIN C. The patient experienced fever, chills, arm pain, body aches, headache, fatigue on 23Dec2020 09:00 AM. No treatment was received for the events. The outcome of the events was not recovered.

"Chills; sweats; aches and pain; Reports she was up all night opening the window and tuning on the heating blanket during the night; This is a spontaneous report from a contactable consumer (patient). A

67-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number ""CJ1685 and 228255"" pending clarify), via an unspecified route of administration on 22Dec2020 08:30 at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. It was reported that she got the covid-19 vaccine yesterday (22Dec2020) at 08:30 A.M. Reported that all night long (22Dec2020) she had chills, sweats, aches and pains. She was told that she should be fine by Christmas. She was up all night opening the window and tuning on the heating blanket during the night. She was wrapped in blankets. Patient was advised to contact healthcare professional for treatment recommendations. Patient declined any treatment to the events. Patient also mentioned that her doctor did not want her to get the vaccine. She works as a certified nurse assistant (CNA) in the hospital. For the lot number, NDC number, and expiration date, she provided details from the card she was given for the vaccine. She read first dose COVID-19: ""CJ1685 and 228255"". She put her glasses on to read the card. The patient she wanted to lay down. The outcome of the event chills, aches and pains was not recovered, for event sweats was recovering, for the rest of event was unknown."

At about 15 minutes the patient experienced nausea, headache, then face flushing.

fever/steady fever/Caller says his fever got as high as 101.5 degrees Fahrenheit; This is a spontaneous report from a contactable Other Health Professional (patient) from a Pfizer-sponsored program IBCC (Inbound Call Center for HCPs). An 82 years old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, lot EL0140) via an unspecified route of administration on 21Dec2020 at single dose in left arm for COVID-19 immunisation. Medical history and concomitant medications were none. Warm transfer in regards to the COVID vaccine which he received Monday morning. Agent reports caller said since then he has had a steady fever and has questions in regards to side effects. As for Height: Caller says he is shrinking, he is about 5 feet 9 inches tall. No further details provided about shrinking. Caller clarifies his doctor title and says that he is not a physician or medical doctor, he has a PhD in psychology. Caller says he doesn't have a prescribing provider, he got the vaccine at a retirement home called (facility name and location). Caller says that his fever started the day he got the shot. He says he got the shot that morning, clarified to being about noon, and had a fever that evening. Caller clarifies that he takes Advil, not Aspirin for his fever. He says when he takes the Advil it goes away, it gets rid of it, but when the Advil wears off the fever comes back again. He says he has no idea what side effects of this drug are, so he thought he would give a call because others were worried about it and pressured him to ask. Caller says the only information he has is the card, the COVID-19 Vaccine Record Card, which says Pfizer, then below it EL0140, which could be either 0 or letter O, probably 0. He says it has the date 21Dec2020 on it from when he got it and he got it in his left arm, it was his first injection of it, he has another to come. Caller says his fever got as high as 101.5 degrees Fahrenheit on 22Dec2020, and he also has a fever right now. Therapeutic measures were taken as a result of fever and included treatment with Advil. Outcome of event was not recovered.

after 2 hours headache lasted for 3-4 hours; left arm injection site soreness worse at night unable to raise arm due to pain lasted up to 48 hours from time of injection; unable to raise arm due to pain; This is a spontaneous report from a contactable other hcp (patient). A 64-year-old male patient received bnt162b2 (Lot: EK5730), via an unspecified route of administration at Left arm, first dose on 20Dec2020

10:30 at single dose, for COVID-19 immunization. Medical history included diabetes, high cholesterol and hypertension (HTN) from an unknown date. Prior to vaccination, the patient was not diagnosed with COVID-19. No Known allergies. Concomitant medication included metformine, lisinopril, atorvastatin and finasteride. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. It was reported that after 2 hours headache lasted for 3-4 hours left arm injection site soreness worse at night unable to raise arm due to pain lasted up to 48 hours from time of injection. The adverse event start on 20Dec2020, at 12:15 PM. The events are reported as non-serious. Therapeutic measures were taken as a result of after 2 hours headache lasted for 3-4 hours left arm injection site soreness worse at night unable to raise arm due to pain lasted up to 48 hours from time of injection, treatment included ibuprofen. The outcome of the event was recovering.

After a few minutes started experiencing a headache pressure feeling and dry mouth

redness at the site that was more noticeable; some tenderness; This is a spontaneous report from a contactable nurse (patient herself). A female patient of an unspecified age received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot #: EH9899), via an unspecified route of administration on 21Dec2020 at single dose for immunization. The patient's medical history and concomitant medications were not reported. The patient experienced redness at the site that was more noticeable, and some tenderness in Dec2020 with outcome of unknown.

Patient woke up with nausea, vomiting, and a headache this morning. OTC treatment, not see by physician.

Groggy/sleepy; mild cognitive impairment; mild unsteady gait; light headed; malaise; tired; This is a spontaneous report from a contactable other health professional (patient). A 55-year-old female patient received the first of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot/batch number: EJ1685), intramuscularly on 22Dec2020 06:30 AM at left arm, at single dose for covid-19 immunization. Medical history included Rheumatoid arthritis, hypothyroid and remission of DM2, known allergies: Penicillin. Concomitant medication included arginine hydrochloride, ascorbic acid, calcium, calcium pantothenate, cyanocobalamin, ferrous fumarate, folic acid, magnesium, methionine, nicotinic acid, phosphorus, potassium, pyridoxine hydrochloride, retinol, riboflavin, selenium, thiamine hydrochloride, tocopheryl acetate, triticum aestivum, zinc (MULTI VITAMIN), methotrexate, thyroid, sertraline. The patient previously took tramadol and experienced drug hypersensitivity. The patient was not pregnant at the time of vaccination. The patient experienced Groggy, mild cognitive impairment, mild unsteady gait, light headed, malaise, tired, sleepy on 22Dec2020 11:00 AM. No treatment was received for all events. The patient underwent lab tests and procedures which included covid test: negative on 21Dec2020 (Nasal Swab). The outcome of the events was recovering. Prior to vaccination, the patient was not diagnosed with COVID-19. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. No seriousness criteria: no Results in death, no Life threatening, no Caused/prolonged hospitalization, no Disabling/Incapacitating, no Congenital anomaly/birth defect.

Sore injection site; This is a spontaneous report from a contactable other HCP. A 45-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), Intramuscularly on 22Dec2020

02:45 PM in left arm at single dose for covid-19 immunization. The COVID-19 vaccine was administered at hospital. Medical history included diabetes. The concomitant drugs were not reported. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient experienced sore injection site on 23Dec2020 05:00 AM. No treatment received for the event. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, the patient was not been tested for COVID-19. The outcome of event was recovering. No follow-up attempts are possible. Information on Lot/Batch number cannot be obtained.

Extreme headache, as bad as I has while sick with covid. Exhaustion, shortness of breath while talking

Slightly elevated heart rate - most of that afternoon through early morning Slightly elevated blood pressure - most of that afternoon through early morning Palpitations at night - when I went to bed that's when I noticed it up until 1:30'ish in the morning I took one (1) 500 mg tylenol at around 1:00 am and felt a bit better; that was it

headache; ear neck back pain; ear neck back pain; ear neck back pain; chills/shivers; sweaty; nausea; vomiting; diarrhea; dizzy; weak; sore muscles; heavy feeling in both arms; tingling in lower legs; This is a spontaneous report from a contactable Nurse reported for herself. A 62-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, EK5730), intramuscular on 21Dec2020 08:30 AM at single dose for covid-19 immunization. Vaccine location was Right arm and it was the first dose. The COVID-19 vaccine was administered at Hospital. Medical history included rheumatoid arthritis and high blood pressure. Concomitant medication included quetiapine, metoprolol succinate, cyclobenzaprine, levothyroxine, omeprazole, tofacitinib citrate (XELJANZ). The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient's Known allergies included Iodine, Morphine. The patient experienced headache, ear neck back pain, chills, shivers, sweaty, nausea, vomiting, diarrhea, dizzy, weak, sore muscles, heavy feeling in both arms, tingling in lower legs on 21Dec2020 11:00 AM. No treatment received for the events. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, the patient was not been tested for COVID-19. The outcome of the events was recovered on an unknown date in Dec2020.

Headache; felling warm; This is a spontaneous report from a non-contactable other HCP. A 23-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899) via intramuscular on 22Dec2020 15:30 on left deltoid at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient denied any history of previous adverse reactions to vaccines. The patient was given the Pfizer vaccination in the left deltoid muscle. During her 15 minutes waiting period after the injection, the patient began to experience headache and felling warm. She denied rash, hives, welts, difficulty breathing, difficulty swallowing, wheezing, throat tightness, hoarseness, stridor, itching, lightheadedness, dizziness, facial swelling, lip swelling and tongue swelling. This provider was notified of patient reaction and she was then assessed in the emergency bay area. Monitored patient for severe reaction symptoms, including respiratory distress with stridor, wheezing, dyspnea, increased work of breathing, persistent cough and cyanosis. The patient was told to receive Tylenol and no side effects.

The patient was stable to go home and follow up with PCP. The outcome of the events was unknown. No follow-up attempts are possible. No further information is expected.

heart rate increased to 100BPM; This is a spontaneous report from a contactable Other Health Professional (patient). A 47-year-old female patient received 1st dose BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, lot EJ1685) via an unspecified route of administration on 18Dec2020 04:30 PM at single dose in left arm for COVID-19 immunisation. Medical history included Asthma, Known allergies: Sulfa, Peanuts, Shell Fish and Peas. Concomitant medications included cetirizine hydrochloride (ALEGRA), montelukast sodium (SINGULAIR), fluticasone propionate (FLOVENT) and ascorbic acid, tocopheryl acetate, xantofyl, zeaxanthin, zinc (AREDS) and Probiotics. The patient previously took Iodine and Erythromycin and experienced known allergies. At 18Dec2020 04:45 PM, her heart rate increased to 100BPM and continued for 45 min, and this result in Emergency room/department or urgent care. The patient underwent lab test and included EKG and heart rate count. Therapeutic measures were taken as a result of event and included treatment with Pepcid, Benadryl, EKG and Monitored her heart rate. Outcome of event was recovered on Dec2020.

3 hours after patient received vaccine on 12/27/2020 @ 2pm she started to feel flushed in the face and hands. She also started to get blisters on both hands. Pt. took a 25mg tab of Benadryl by mouth and symptoms resolved. She awoke at 3:30 am and felt that her carotid artery was pulsating. Patient informed Primary Care Physician's office on 12/28/2020 of symptoms who then prescribed patient an Epi-pen. Advised to receive emergency medical service if symptoms worsened. On 12/29/2020 patient feels good and all symptoms have subsided.

her upper face was swollen, clarifying more on the left side, and mostly around her eyes.; her upper face was swollen, clarifying more on the left side, and mostly around her eyes.; her eyes are a little red; This is a spontaneous report from a contactable consumer(patient). A 61-year-old female patient received BNT162B2 via an unspecified route of administration at Deltoid Right on 22Dec2020 14:00 at the 61 years old at single dose for COVID-19 immunization. The medical history included Type 2 diabetes mellitus from 1995 and ongoing(diagnosed about 25 years ago, controlled diabetic with a Hemoglobin A1C of 5) and Blood pressure high from 1995 and ongoing (diagnosed with high blood pressure about the same time as her diabetes, clarified as 25 years ago. She stated she has controlled blood pressure). The concomitant medications were not reported. The patient previously received a flu shot in Oct2020. On 23Dec2020 the patient reported her upper face was swollen, clarifying more on the left side, and mostly around her eyes. She said her eyes were a little red, too. She said she does not have any swelling around her mouth. The patient reported the facial swelling had slightly improved. She said she keeps looking at her face, so it was hard for her to tell, but her boss said her face was swollen. The patient reported she took a generic Benadryl 30 mg tablet this morning. She said she normally takes a Benadryl 30 mg tablet every night along with Melatonin for sleep. She said she has a big bottle of the generic Benadryl 30 mg at home and the bottle is almost empty. She said she rather take the Benadryl and Melatonin. The outcome of the events upper face was swollen and mostly around her eyes was Recovering, the event eyes were a little red was Not Recovered. Information about batch/lot number has been requested.

Employee c/o of sudden loss of vision and fell forward on the floor. Employee states he did not have any lunch yet. Emergency team called and assess the employee. Client refused to be taken to the ER for further evaluation. VS monitored and stable . No SOB, no difficulty of breathing. No Taking po fluids. Client d/c with steady gait and no c/o.

Anxiety; Anxiety; dizziness; rapid breathing; This is a spontaneous report from a non-contactable other health professional. A 34-year-old female patient received the first of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EH9899) intramuscularly on 22Dec2020 14:00 at left arm, at single dose for covid-19 immunization. Medical history included anxiety and took Hydralazine prn (As needed). The patient's concomitant medications were not reported. The patient denied any history of previous adverse reactions to vaccines. The patient was given the vaccination in the left deltoid muscle. During her 15 minute waiting period after the injection, the patient began to experience dizziness on 22Dec2020. She denied rash, hives, welts, difficulty breathing, difficulty swallowing, wheezing, throat tightness, hoarseness, stridor, itching, facial swelling, lip swelling and tongue swelling. This reporter was notified of patient reaction and she was then assessed in the emergency bay area. The patient presented with rapid breathing and anxiety. Monitored patient for severe reaction symptoms, including respiratory distress with stridor, wheezing, dyspnea, increased work of breathing, persistent cough and cyanosis. The patient's breathing slowed and felt less anxious by the time she left. The outcome of the events rapid breathing and anxiety was recovering, the outcome of the other event was unknown. No seriousness criteria: no Results in death, no Life threatening, no Caused/prolonged hospitalization, no Disabling/Incapacitating, no Congenital anomaly/birth defect. No follow-up attempts are possible. No further information is expected.

The day after on 12/18 soreness at at the injection site. On 12/19 symptoms exp headache and fatigue. Then on 12/20 started chills, fever and headache. I went to see the doctor on 12/21 and got several test Covid ,Flu and Strep results positive for all. Since then symptoms has continued. I have had to miss 6 days of work.

muscle aches; chills; Fatigue; This is a spontaneous report from a contactable nurse (patient). A 51-year-old female patient received 1st dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, expiration date: 31Mar2021), via an unspecified route of administration on 19Dec2020 19:30 at single dose to prevent Covid. Medical history included COVID-19 from 30Oct2020 to 24Nov2020. There were no concomitant medications. Eight hours after getting the vaccine (20Dec2020 03:30), she had muscle aches and chills, she also had fatigue on 20Dec2020. She was worried. She was concerned that she had done something crazy. She was through Covid for sure. She wasn't able too much. She was off work that day and didn't have to do anything. She would not have been able to work. The muscle aches were rivaling the worst days of Covid. She had Covid for 3 weeks. Then she had to wait another 10 days to get over the symptoms. She never had to go to the hospital. These muscle aches that she experienced after the injection were as intense as when she had Covid. The Lot on the patient card was difficult read. The information was hand written and squished in. She was unsure if it was EK5B30 or EK5030 or EK5730. The patient underwent lab tests and procedures which included COVID test: positive on 30Oct2020, negative on 24Nov2020. The outcome of muscle aches and chills was recovered on 21Dec2020, fatigue was recovering. The event muscle ache reported as serious, with serious criteria medically significant.

Information about lot/batch number has been requested.; Sender's Comments: The Company considers there is a reasonable possibility that the reported muscle ache is related to the administration of BNT162B2, based on the plausible temporal association and the known safety profile of the suspect. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RA, IEC, as appropriate.

Low-grade fever and chills (99.5 Fahrenheit); Low-grade fever and chills (99.5 Fahrenheit); headache; This is a spontaneous report from a contactable nurse (patient). A 29-year-old female patient received her fist dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number not provide), intramuscularly on right arm at 09:30 AM on 21Dec2020 at single dose for COVID-19 immunization. Medical history included deep vein thrombosis (DVT), covid-19 prior vaccination. Concomitant medication included escitalopram oxalate (LEXAPRO), rivaroxaban (XARELTO), atenolol, multivitamins. The patient experienced severe headache at 18:00 on 21Dec2020. Low-grade fever and chills (99.5 Fahrenheit) Q (every) 90 mins from 22:00 21Dec2020 till 04:00 22Dec2020. The events were assessed as non-serious. Since the vaccination, the patient had not been tested for COVID-19. The outcome of event headache was recovered in Dec2020, the outcome of events chills and low grade fever was recovered at 04:00 on 22Dec2020. Information on the Lot/Batch number has been requested.

dizziness; This is a spontaneous report from a non-contactable healthcare professional. A 21-year-old male patient started to receive bnt162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, lot number: EH9899, expiry date not reported), intramuscular on the right arm (right deltoid muscle) on 22Dec2020 18:15 at a single dose for COVID-19 immunisation. Medical history and concomitant medications were not reported. The patient experienced dizziness on 22Dec2020. He denied rash, hives, welts, difficulty breathing, difficulty swallowing, wheezing, throat tightness, hoarseness, stridor, itching, facial swelling, lip swelling and tongue swelling. The provider was notified of patient's reaction and he was then assessed in the emergency bay area. The patient was monitored for severe reaction symptoms, including rapid progression of symptoms, respiratory distress with stridor, wheezing, dyspnea, increased work of breathing, persistent cough and cyanosis, vomiting, abdominal pain, hypotension, dysrhythmia, chest pain and collapse. Therapeutic measures were taken as a result of dizziness that included water and rest. The patient was stable to go home. Clinical outcome of the event was unknown. No follow-up attempts are possible. No further information is expected.

I felt a little flushed; My heart is breathing; This is a spontaneous report from a contactable consumer (patient). This female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration at single dose on 21Dec2020 for Covid-19 immunisation. The patient medical history and concomitant medications were not reported. The patient stated: I felt a little flushed and my heart is breathing on an unspecified date with outcome of unknown. Information on the lot/batch number has been requested.

dizziness; This is a spontaneous report from a non-contactable healthcare professional. A 72 year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, lot number: EH9899),

intramuscular on the right leg (right deltoid muscle) on 22Dec2020 17:30 at a single dose for COVID-19 immunisation. Medical history and concomitant medications were not reported. The patient experienced dizziness on 22Dec2020 17:45, during her 15 minute waiting period after the injection. She denied rash, hives, welts, difficulty breathing, difficulty swallowing, wheezing, throat tightness, hoarseness, stridor, itching, facial swelling, lip swelling and tongue swelling. This provider was notified of patient reaction and she was then assessed in the emergency bay area. The patient was monitired for severe reaction symptoms, including rapid progression of symptoms, respiratory distress with wheezing and dyspnea, vomiting, abdominal pain, hypotension, dysrhythmia, chest pain and collapse. On an unspecified date, the patient underwent lab tests and procedures which included blood sugar: 108 and vital signs measurement: normal. No therapeutic measure was taken as a result of the event. Clinical outcome of the event was unknown. No follow-up attempts are possible. No further information is expected.

About 10 minutes after vaccine a red injection site appeared and then also was red further up around the shoulder (noticed because shoulder was itchy). I also felt warm. I have been diagnosed in the past with exercise induced asthma. Asthma started to flare up shortly after but did not require intervention. Was monitored by a doctor at facility where vaccine was given and symptoms did not worsen. No medication required. I noticed unusual muscle aches starting the next morning and persisted for a week after vaccine. Left arm where vaccine was given did not hurt, but other right arm, shoulders and thighs were aching. Hands seemed arthritic with movement at work. Feet occasionally felt tingly when walking for 5 days after vaccine. Asthma flare-ups continued after vaccine. Had to stop and rest after climbing stairs which is unusual for me. The worst asthma flare-ups persisted for up to 5 days. After 10 days at time of reporting adverse effects, asthma is still triggered but to a lesser extent. Can climb stairs without pause now. Airways have not fully recovered yet and I have a residual cough. Started self treating with albuterol rescue inhaler if needed.

Developed swollen lymph node under right arm; This is a spontaneous report from a contactable nurse (patient). A 35-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number: EK5730) intramuscularly at right arm on 20Dec2020 at 10:15 a.m. at a single dose (dose number=1) for COVID-19 immunization. Medical history and concomitant medications were not reported. The patient was not pregnant. Facility type vaccine was at hospital. No other vaccine in four weeks. The patient developed swollen lymph node under right arm on 21Dec2020 at 11:00 a.m. The event was reported as non-serious. with outcome of recovering. No treatment received for the event. No COVID-19 diagnosed prior vaccination and no COVID-19 tested post vaccination. No known allergies (no allergies to medications, food, or other products). No follow-up attempts are possible. No further information is expected.

Chills and body aches

Headache; nausea; This is a spontaneous report from a contactable other health professional (other HCP) (patient). A 60-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK5730) via an unspecified route of administration at right arm on 21Dec2020 at 10:00 a.m. at a single dose (dose number: 1) for COVID-19 immunization. Medical history included hypothyroid and

hyperlipidemia. Concomitant medications in two weeks included levothyroxine, simvastatin (ZOCOR), ergocalciferol (VITAMIN D), ascorbic acid (VITAMIN C) and calcium (reported as calcium mul, to be clarified). No other vaccine in four weeks. The patient was not pregnant. Facility type vaccine was hospital. No COVID-19 diagnosed prior vaccination and no COVID-19 tested post vaccination. No known allergies (no allergies to medications, food, or other products). The patient experienced headache, nausea on 22Dec2020 at 12:00 p.m. with outcome of resolved in Dec2020. The events were reported as non-serious. No treatment received for events.

Bilateral parasthesia to fingers 4 hours post injection. This passed in 15 minutes, About 7 Pm on 12/28/20, bilateral parasthesia to hands & feet. On 12/29/20 (AM) foot pain--painful to walk, went away in about 5 minutes, but still felt tingling to both feet. Still having tingling sensation to both feet (constant) and both hands (intermittent)

Pain injection site; numbness in both hands; This is a spontaneous report from a contactable consumer (patient). A 30-years-old male patient started to receive first dose bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, Lot number: EK5730), via an unspecified route of administration on 22Dec2020 14:00 at single dose (Anatomical Location of Administration: right shoulder) for COVID-19 immunization. Medical history included ongoing allergy, allergic to Sulfa drugs, Clindamycin, and Vancomycin. Concomitant medication included ongoing fluticasone propionate (FLONASE [FLUTICASONE PROPIONATE]) for Allergy and ongoing loratadine for Allergy. Prior vaccinations within 4 weeks was none. The patient experienced numbness in both hands on 22Dec2020 about ten minutes after the injection, pain injection site on 23Dec2020 09:00. He had an interesting side effect that was not listed on the fact sheet. He mentioned he did not want his information going to any third parties. He clarified the interesting side effect that he did not see listed on the fact sheet as, received the COVID 19 vaccine yesterday (22Dec2020) around 2 pm, after getting the shot he felt fine initially, but then he started to experience both of his hands go numb. He was not sure if had any effect on the nerves, but it effected his hands. Then he noticed today (23Dec2020) he had some pain at injection site. He stated that was normal and saw it listed. It was the numbing of his hands that was weird to him. His left hand felt better, but right hand felt the same. He was calling to see if due to this if he should still take the booster shot or not. He also wanted to see if these details had been reported before. Pain at injection still hurts a good amount and unable to provide outcome. He mentioned the card he received with the lot number the person who wrote on it had terrible hand writing, so he was not sure of the lot number. He stated these reactions are not severe, it is kind of annoying. The action taken in response to the events for bnt162b2 was not applicable. Relevant Test was None. The outcome of the events was not recovered.

anxiety; chills; generalized feelings of not feeling quite right; nausea; nervousness; This is a spontaneous report from a non-contactable other hcp. A 34-years-old female patient received first dose bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, Lot number: EH9899), intramuscular on 22Dec2020 13:45 (vaccine location: Right arm) at single dose for covid-19 Vaccination. Past medical history includes anxiety for which she took venlafaxine (Effexor) on a daily basis as well as type 2 diabetes, diagnosed approximately seven or 8 years ago during a pregnancy, she was on oral medication during the day and insulin at nighttime. Concomitant medications were not reported. She did take her oral medication today (22Dec2020) and last ate a pasta lunch right before arriving to the vaccine clinic. Last A1c was 6.

During her 15-minute waiting period after the injection, the patient began to experience generalized feelings of not feeling quite right as well as anxiety/nervousness, nausea and chills. She denied difficulty breathing, throat tightness, dizziness, chest pain, or other GI complaints. This provider noticed her raising her hand from across the waiting area and tended to her where she noted the above complaints. she was then assessed in the emergency bay area. She was monitored for severe reaction symptoms, including rapid progression of symptoms, vomiting, hypotension, chest pain, collapse and Respiratory distress. The action taken in response to the events for bnt162b2 was not applicable. The outcome of the events was unknown. No follow-up attempts are possible. No further information is expected.

Upset stomach; Nausea; Mild headache; This is a spontaneous report from a contactable nurse reporting for herself. This 26-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (lot number: EJ1685) on 22Dec2020 14:25 at a single dose intramuscularly in the left arm for COVID-19 immunization. The patient medical history was not reported. Concomitant medication included sertraline hydrochloride (ZOLOFT). Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. The patient experienced upset stomach, nausea and mild headache on 23Dec2020. The events were non-serious, no treatment received for the events. The patient was recovering from the events.

Patient was under the age of 18 when Covid-19 vaccine was administered

dizziness; This is a spontaneous report from a non-contactable healthcare professional (HCP). A 63-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (lot number EH9899) on 22Dec2020 17:30 intramuscularly at a single dose in the left arm (in the left deltoid muscle) for COVID-19 vaccination. No relevant medical history. The patient denied any history of previous adverse reactions to vaccines. The patient's concomitant medications were not reported. During her 15 minute waiting period after the injection, the patient began to experience dizziness. She denied rash, hives, welts, difficulty breathing, difficulty swallowing, wheezing, throat tightness, hoarseness, stridor, itching, facial swelling, lip swelling and tongue swelling. She was then assessed in the emergency bay area, monitored for severe reaction symptoms, including rapid progression of symptoms, respiratory distress with stridor, wheezing, dyspnea, increased work of breathing, persistent cough and cyanosis, vomiting, abdominal pain, hypotension, dysrhythmia, chest pain and collapse. Vitals were normal, glucose was 100. The event dizziness was non-serious. The outcome of the event was unknown. No follow-up attempts are possible. No further information is expected.

Swollen lymph nodes; Injection site pain; Tiredness; This is a spontaneous report from a contactable Nurse(patient). A 31-year-old female patient received first dose of BNT162B2(PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL0140), via an unspecified route of administration on 22Dec2020 20:45 at single dose at left arm for COVID-19 immunization. The patient was not pregnant. There were no known allergies or other medical history. There were no other vaccine in four weeks. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. Concomitant medication included ascorbic acid (VITAMIIN C), ergocalciferol (VIT D), vitamin b complex (SUPER B COMPL); reported as prenatal. The patient experienced swollen lymph nodes,

injection site pain, tiredness; all on 23Dec2020 14:00 with outcome of not recovered. The events were non-serious. No treatment received for the events.

Moderna COVID-19 Vaccine EUA Day1- none Day2- Injection site: soreness, firmness, and weakness. General symptoms: none Day3- Injection site: bruising, tenderness. General symptoms: fatigue Day4- Injection site: bruising, tenderness. General symptoms: fatigue, body aches, joint pains, difficulty waking in the morning Day5- Injection site: bruising, tenderness. General symptoms: fatigue, body aches, joint pains, difficulty waking in the morning Day6- Injection site: bruising, tenderness. General symptoms: fatigue, body aches, joint pains, difficulty waking in the morning I am currently on day 6 from getting the Moderna COVID-19 Vaccine and the injection side bruising and tenderness still persist along with the general symptoms of fatigue, body aches, joint pains, and difficulty waking up in the morning.

had only a sore arm; muscles were sore.; This is a spontaneous report from a contactable physician (patient, psychologist, work as a healthcare provider in a prison system). A 69-year-old male patient received a single dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (Lot number reported as: E316, either 05 or 85) via an unspecified route of administration on 21Dec2020 (between 13:15 and 13:30) in the right arm for COVID-19 immunization. Medical history included flu, not recently, several weeks ago. Concomitant medications were reported as none. The patient had only a sore arm on 21Dec2020 as a side effect. The patient also reported muscles were sore on 21Dec2020. The outcome of the events was unknown. Caller stated he wanted to check and make sure he wasn't supposed to have side effects. He had seen on TV people complaining of chills, fever and headache. As he was looking at the document he was given, he may have called the wrong number for the question to ask: he was lucky enough as a healthcare professional to be administered his first shot of Pfizer's COVID vaccine, and with the exception of where the site where it was injected, his right arm being a little sore, like with any shot, he had not experienced side effects, like headaches or nothing, and today he noticed he didn't get a check in, he got texts. But his question was: if he didn't feel side effects, did it mean the vaccine was not necessarily taking, if no side effects, did it mean it will not be effective? Stated it was just minor, like any other shot. He did not mind participating in this study, for information, since Pfizer may be counting soreness in the arm, but he did not perceive this as a problem. He got the vaccine on Monday 21Dec2020, between 13:15 and 13:30, and then it was just like, he had a flu shot, not recently, several weeks ago, and to the same point. No further details provided. Like within a couple, three hours, it started, and it was difficult to sleep on it, just sore, no redness/inflammation, he could not tell where the skin was punctured, just his muscles were sore. He called the number on the sheet, he was just real curious, he did not feel bad, like he hears on TV, and he knew personally people who got symptoms and he no symptoms, that he can ascertain. No further details provided. His appointment was 1:15, it may have been in his arm at 13:25, or 13:30 or something, he went and sat for his 15 minute wait time, at 1:30, so it was between 13:15 and 13:30. Outcome reported as it was OK during the daytime, but to sleep on that side, it can feel sore, and he turned to the other side, it did not keep him from typing, lifting, writing, working, emptying the dishwasher. He had a registration code, was given a card. Read from his vaccination card: provided date of vaccination 21Dec2020, vaccine name Pfizer COVID 19, stated lot was written in ink, looked like it was E316, stated he can't read, it was smeared, but then said next dose is 11Jan2021. States it was E316, either 05 or 85. He didn't have the sore arm before he got it,

and it is going away now, or it would go away. Information on the lot/batch number has been requested.

she broke out in hives 4 hours after she received the vaccine; This is a spontaneous report from a contactable other-healthcare professional (HCP) (patient). A 34-year-old female patient received a single dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (Lot #: EL1284) as the first dose via intramuscular on 23Dec2020 13:00 in the right arm for COVID-19 immunization. The patient medical history and concomitant medications were not reported. The patient did not receive any other vaccines within 4 weeks prior to the vaccine BNT162B2. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. The patient reported that she broke out in hives 4 hours after she received the vaccine on 23Dec2020 (also reported as at 16:00). The event was reported as non-serious. No treatment was received for the event. The outcome of the event was recovering. No follow-up attempts are possible. No further information is expected.

"This is a spontaneous report from a contactable nurse (patient). A 33-year-old female patient received BNT162B2 (Pfizer-BioNTech Covid-19 vaccine) on 22Dec2020 11:30AM at left arm for COVID-19 immunization. The patient had known allergies to sulfa and was currently breastfeeding. The patient had concomitantly received ascorbic acid, honey, melatonin, zinc gluconate (ZARBEE'S ALL NATURAL COUGH SYRUP NIGHTTIME) (reported as "" Zarbees elderberry immune syrup"") in two weeks. The patient experienced fatigue, myalgias, headache, arm soreness, brain fog at 3:00PM on 22Dec2020. Patient received ibuprofen 400 mg as treatment for the adverse events. The outcome of the events was resolving at the time of reporting. Information on the lot/batch number has been requested."

headache; fatigued; lightheaded/dizzy(the room was spinning); nauseous; chills; hot flashes; This is a spontaneous report from a contactable nurse reported for herself. A 24-year-old adult female patient (pregnant: no) was received the first dose BNT162B2 (brand: Pfizer, Batch/lot number: EK5730) via unspecified rout of administration on left arm on 23Dec2020 13:00 at single dose for COVID-19 immunization. Medical history included asthma, Bipolar Disorder, known allergies: Latex, milk, bananas, blue dye 2&, COVID-19 (Prior to vaccination, was the patient diagnosed with COVID-19? :Yes). Concomitant medication in two weeks included lamotrigine (LAMICTAL), fluoxetine hydrochloride (PROZAC), cetirizine hydrochloride (ZYRTEC [CETIRIZINE HYDROCHLORIDE]) and ascorbic acid, ferrous fumarate, folic acid, retinol (PRENATAL [ASCORBIC ACID;FERROUS FUMARATE;FOLIC ACID;RETINOL]). No other vaccine in four weeks. After the vaccination patient became lightheaded, dizzy (the room was spinning), nauseous and got chills and hot flashes. After 30minutes or so she began to get a headache while the other symptoms wore off and then became fatigued. Adverse event start date was 23Dec2020 01:00 PM. the most recent COVID-19 vaccine was administered in Hospital. Since the vaccination, the patient has not been tested for COVID-19. Treatment received for the events included ibuprofen (MOTRIN), Meclizine, ondansetron (ZOFRAN) and paracetamol (TYLENOL). Patient was recovering from the events. It was reported as non-serious. No results in death, life threatening, caused/prolonged hospitalization, disabling/Incapacitating nor congenital anomaly/birth defect.

woke up with mild fever, and severe headache, lasted through the day, was gone upon waking next morning.

Joint ache and tiredness on the next day after vaccination; Joint ache and tiredness on the next day after vaccination; This is a spontaneous report from a contactable other healthcare professional (patient). A 27-years-old female patient (not pregnant) received BNT162B2 (lot number: EK5730) first dose on 18Dec2020 12:45 PM intramuscularly on Left arm at single dose for COVID-19 immunization. Medical history and concomitant medications were not reported. No Known allergies to medications, food, or other products. Facility type vaccine was Hospital. Other medications in two weeks was No. Patient experienced Joint ache and tiredness on the next day after vaccination (19Dec2020). Patient had no covid prior vaccination. Patient had covid tested post vaccination on 21Dec2020, Nasal Swab, the result was negative. Patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. No treatment received for the events. The outcome of the events was recovering. The seriousness was reported as no.

soreness at site of injection; This is a spontaneous report from a contactable nurse (patient). A 39-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 17Dec2020 intramuscularly on right arm at single dose for COVID-19 immunization. Medical history included ongoing Psoriatic arthritis, patient received allergy shots (Unable to provide the names, NDC. Lot, or expiry for the allergy injections she received. It's the regular one for pets (cat and dog dander), trees, mold and dust. No food allergy. Mentions having an allergy to sulfur), unspecified sulfur products-wheezing, rash, itching. Concomitant medications included adalimumab (HUMIRA) and methotrexate, both ongoing for Psoriatic arthritis. She Is having soreness in her arm where she received it and she got it last Thurday (17Dec2020). Today (23Dec2020), she went to get her allergy shots and not sure if she should have waited or if she is missing something in the literature about doing the allergy shots after. It didn't say. She knows that it is the same when she has to get a flu shot she waits about a week to get her allergy shots. Received the vaccine early last Thurday evening and the allergy shots today at 2pm. Received the vaccine through her workplace. The soreness started on Friday morning (18Dec2020) and by Monday afternoon (21Dec2020) and it had gone away. She is just worried because she got the allergy injection today in the same arm that the vaccine was given. Clarifies that the soreness is around the injection site of where the vaccine was given, not where the allergy shots given. Worried that she should have waited and doesn't want to go to bed and wake up with something wrong. States this is her first shot. Unable to provide the names, NDC. Lot, or expiry for the allergy injections she received. It's the regular one for pets (cat and dog dander), trees, mold and dust. No food allergy. Mentions having an allergy to sulfur. Has wheezing airway and the first time was when she was a kid and she got a rash, redness, and itching. The doctor now knows not to prescribe anything with sulfur because the second time was when she was 20 something she had the wheezing. Vaccination Facility Type was Hospital. Vaccine Administered at Military Facility was No. History of all previous immunization with the Pfizer vaccine considered as suspect (or patient age at first and subsequent immunizations if dates of birth or immunizations are not available) was none. Additional Vaccines Administered on Same Date of the Pfizer Suspect was none. No AE(s) require a visit to Emergency Room or physician office. Prior Vaccinations (within 4 weeks prior to the first administration date of the suspect vaccine(s)) was none. The outcome of the event was recovered on 21Dec2020. The seriousness was reported as no. Information on the Batch/Lot number has been requested.

woke up with mild fever, and severe headache, lasted through the day, was gone upon waking next morning.

Severe body aches; chills; low grade fever 100.7; fatigue; muscle pain; This is a spontaneous report from a contactable nurse (patient). A 34-year-old female patient (pregnant: no) was received first dose BNT162B2 (brand: Pfizer BioNtech, lot number: EJ1685), via unspecified route of administration at arm right on 17Dec2020 12:30 PM at single dose for COVID-19 immunization. Medical history included Complex Migraines, prior to vaccination, the patient was diagnosed with COVID-19. Concomitant medication in two weeks included verapamil, amitriptyline, fish oil, magnesium, vitamin b2 [riboflavin], no other vaccine in four weeks. Patient previous took amoxicillin clavulanic acid (AUGMENTIN), butalbital caffeine paracetamol (FIORICET) and eletriptan hydrobromide (RELPAX) and had allergies to them. Patient experienced severe body aches, chills, low grade fever 100.7, fatigue, muscle pain on 18Dec2020 03:00 AM. the most recent COVID-19 vaccine was administered in Hospital. Since the vaccination, the patient has not been tested for COVID-19. No treatment received for the events. Patient was recovered from the events. It was reported as non-serious. No results in death, life threatening, caused/prolonged hospitalization, disabling/Incapacitating nor congenital anomaly/birth defect.

soreness at site of injectio and droziness

"Fever up to 100.4; Headache; Chills; Muscle pains; This is a spontaneous report from a contactable physician (patient). A 57-year-old male patient was received first dose BNT162B2 (reported ""Active Drug substance names: COVID 19"", lot number: EJ1685), via unspecified route of administration at left arm on 18Dec2020 05:15 PM at single dose for COVID-19 immunization. Medical history included hyperlipidaemia and COVID-19 (Prior to vaccination, was the patient diagnosed with COVID-19?:Yes), No known allergies. There are no other medications in two weeks and no other vaccine in four weeks. Patient experienced fever up to 100.4, headache, chills, muscle pains on 19Dec2020 12:00 PM (20Dec2020 00:00). the most recent COVID-19 vaccine was administered in Hospital. Since the vaccination, the patient has not been tested for COVID-19 (COVID was not tested post vaccination). Treatment for the event included paracetamol (TYLENOL). Patient was recovered from the events. It was reported as non-serious. No results in death, life threatening, caused/prolonged hospitalization, disabling/Incapacitating nor congenital anomaly/birth defect. Pfizer is a marketing authorization holder of COVID 19 vaccine in the country of incidence or the country where the product was purchased (if different). This may be a duplicate report if another marketing authorization holder of COVID 19 vaccine has submitted the same report to the regulatory authorities."

Patient reports that about 25 minutes after receiving the vaccine she began to feel like her throat was swollen and the her voice was changed and she had a feeling of pressure on her vocal chords. She also noted that she seemed to have an increase in heart rate. She took a dose of Benadryl and no further symptoms were experienced. She reports that these symptoms resolved by next day but she felt extreme fatigue for the next few days.

fever; Headache; fatigue; This is a spontaneous report from a contactable Other healthcare professional (patient). A 59-year-old male patient received BNT162B2 (lot number: EJ1685) first dose on 22Dec2020 07:30 AM on left arm at single dose for COVID-19 immunization. Medical history included HTN (Hypertension) and Allergies to PCN (Penicillin) and Sensitive to morphine. Concomitant medications included venlafaxine hydrochloride (EFFEXOR), atenolol, ergocalciferol (VIT D) and multivitamin. Facility type vaccine was Hospital. Patient had other vaccine (Trial) in four weeks, patient had it on 02Dec2020 first dose on Left Arm. Patient had other medications in two weeks: Effexor, atenolol, multivitamin, vit D. About 16 hrs (22Dec2020 11:00 PM) after injection patient began fever 100-101. Lasted about 20 hours. Relieved with ibuprofen. Headache and fatigue also. All resolved about 36 hours after injection. Patient did not have covid prior vaccination and no covid tested post vaccination. No treatment received for the adverse event. The outcome of the events was recovered. The seriousness was reported as no.

Patient received the vaccine, waited 15 minutes and had no difficulties. He presented back to the injection area with complaints of dizziness, slight chest and neck tightness. BP was slightly elevated. He was given 2 benadryl an taken to the ED where they monitored him. No further medication intervention needed.

Felt a little achey and a sore arm; This is a spontaneous report from a contactable consumer. An adult female patient of unspecified age was received first dose of BNT162B2 (Brand: Pfizer/BioNTech, lot number: unknown) via unspecified route of administration at single dose for COVID-19 immunization. Medical history and concomitant medication were unknown. It was unknown if other vaccine in four weeks. Patient felt a little achey and a sore arm on 21Dec2020. It was unknown if the patient diagnosed with COVID-19 prior to vaccination, it was unknown if the patient been tested for COVID-19 since the vaccination (unknown covid tested post vaccination). It was unknown if treatment received for the event. Outcome of the events was unknown. It was reported as non-serious. No results in death, life threatening, caused/prolonged hospitalization, disabling/Incapacitating nor congenital anomaly/birth defect. Information on the Batch/Lot number has been requested.

"Vertigo; Dizziness; Sore arm; This is a spontaneous report from a contactable Other healthcare professional (patient). A 63-year-old female patient received BNT162B2 (lot number EL0140) on 21Dec2020 2:30""pm on arm left at single dose for COVID-19 immunization. Medical history was none. Concomitant medications included multivitamin. She doesn't know if it is a side effect but today she has had vertigo that she has never had before, and a little bit of dizziness on and off. The vertigo started about 4:30am this morning (23Dec2020) when she got up to go to the bathroom. Everything was just spinning so she didn't go to the bathroom, she just laid down. She had it 2 more times but not anymore after that. Now she is just having some dizziness from time to time (Dec2020). She also specified that soreness is ""normal"" for her to experience ""after injection"". She has takes multivitamin but nothing that would be related to this event. She has just never had this happen before. It was given in his left upper biceps area. With previous vaccines she has had a sore arm but with this vaccine the sore arm wasn't that bad. It was sore that day (21Dec2020) and yesterday but today there is nothing, no soreness. She received no other vaccines that day or within 4 weeks of the vaccine. There is no significant family history. There have been no treatments for the events. The outcome of event vertigo and sore arm recovered on 23Dec2020. The outcome of event Dizziness was not recovered."

Shaking chills; body aches; nausea; vomiting; vertigo; This is a spontaneous report from a contactable Other-healthcare professional (patient). A 57-year-old female (not pregnant) patient received BNT162B2 (lot number: EH9899) first dose on 17Dec2020 02:00 PM intramuscularly on left arm at single dose for COVID-19 immunization. Medical history included Colon Cancer, Hypothyroidism, Allergic Rhinitis, Weight Loss Surgery, GERD, BPPV. Concomitant medications in two weeks included Levothyroxine, cetirizine hydrochloride (ZYRTEC), Escitalopram, MVI, Calcium, colecalciferol (VIT D3), cyanocobalamin (VIT B12). No Known allergies to medications, food, or other products. Facility type vaccine was Other. No other vaccine in four weeks. Patient experienced Shaking chills, body aches, nausea, vomiting and vertigo on 18Dec2020 03:30 AM. Patient received Zofran, Meclizine, Phenerga as treatment. Patient did not have covid prior vaccination and no covid tested post vaccination. The outcome of the events was recovering. The seriousness was reported as no.

Within two days of vaccine, shortness of breath on light exertion (talking, walking), ?revved up? like on steroid or medrol. Anxiety, increased resting HR, abdominal cramping, diarrhea, agitation, palpitations, fatigue, dazed, premenstrual spotting.

Temp 103, and very sore arm for 3 days; Temp 103, and very sore arm for 3 days; This is a spontaneous report from a contactable nurse reported for herself (patient). A 57-year-old female patient (pregnant: no) was received BNT162B2 (brand: Pfizer, Lot number: unknown) via unspecified route of administration on 19Dec2020 10:30 AM at single dose for COVID-19 immunization. Medical history included COVID-19 (Prior to vaccination, was the patient diagnosed with COVID-19?:Yes). Concomitant medication in two weeks of vaccination included simvastatin, acetylsalicylic acid (BABY ASPIRIN), docusate sodium (COLACE) and fish oil (FISH OIL OMEGA 3). no other vaccine within 4 weeks prior to the COVID vaccine. Patient used took ciprofloxacin (CIPRO) and had allergy. Patient experienced temp 103, and very sore arm for 3 days on 20Dec2020 02:00 AM. the most recent COVID-19 vaccine was administered in Hospital. Since the vaccination, the patient has not been tested for COVID-19. Since the vaccination, the patient has not been tested for COVID-19. Treatment received for the events included ibuprofen. Patient was recovered from the events in Dec2020. It was reported as non-serious. No results in death, life threatening, caused/prolonged hospitalization, disabling/Incapacitating nor congenital anomaly/birth defect. Information on the lot/batch number has been requested.

"12/28/20 called to observation area at 12:05. she had already waited 15 minutes after vaccine. reports tingling top of tongue, tingling ums, back of mouth/throat scratchy. 12:10 states no change, 12:12 rapid response and supervisor arrived - talked with her. decided to not go to ER unless worse, agreed will not go back to work or leave for home until sx resolved. 12:20 states gum tingling decreasing. 12:30 states sx resolved - left observation with instruction to return if sx. 12/29/20 came to vaccine area at 1045 to report injection site with 1"" redness, firm to touch. blanches, tender w/ pressing outer edge redness. arm size unchanged, noted when got up this morning. states sore, able to move arm. 1050 evaluated by rapid response and nursing supervisor. states otherwise feeling ok, no sx. supervisor drew circle around redness. suggested ice/anti-histamine. talked with her - to wait 30 minutes, to contact PCP if spreads. 1130 states no change, decided to RTW"

Severe arm pain at injection site.; No swelling but can barely move arm; Chills; fatigue; moderate headache; This is a spontaneous report from a non-contactable nurse (patient). A 27-year-old non-pregnant female patient receive first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EH9899), via an unspecified route of administration at left arm on 22Dec2020 at 10:00 AM at single dose for COVID-19 immunization at pharmacy or drug store. Medical history was none and there was no known allergies. Concomitant medication included oxybutynin hydrochloride (OXYBUTYNIN) and birth control received within 2 weeks of vaccination. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient experienced severe arm pain at injection site, there was no swelling but can barely move arm, chills and fatigue and moderate headache, all on 22Dec2020 at 09:00 PM. There was no treatment for the events. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. The outcome of the events was not resolved. No follow-up attempts are possible. No further information is expected.

He was diagnosed with COVID 19; He was diagnosed with COVID 19; This is a spontaneous report from a contactable consumer (front line hospital worker) reporting for himself, received via a Pfizer sales representative. This male patient of unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on an unspecified date in Dec2020, at single dose, for COVID-19 immunization. Medical history and concomitant medications were not reported. On an unspecified date in Dec2020, after vaccination, the patient was diagnosed with COVID 19 with unknown outcome. Information on the lot/batch number has been requested.

Pain at the injection site; This is a spontaneous report from a contactable Other Health Professional (patient) via Pfizer sales representative. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced pain at the injection site after Covid 19 vaccine on an unspecified date with outcome of unknown. Information on the Batch/Lot number has been requested.

Lightheadedness; This is a spontaneous report from a contactable Nurse (patient). A 60-year-old female patient (not pregnant at the time of vaccination) received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EL1284), intramuscularly in arm left on 23Dec2020 16:30 at single dose for COVID-19 immunization. The patient medical history was not reported. Concomitant medication the patient received within 2 weeks of vaccination included colecalciferol (VIT D3), smilax aristolochiifolia (SARSAPARILLA), ascorbic acid (VIT C), dioscorea villosa (WILD YAM), multi collagen protein. The patient previously took codeine and experienced allergies: Codeine. The patient experienced lightheadedness on 23Dec2020 17:15 with outcome of recovered in Dec2020. Facility where the most recent COVID-19 vaccine was administered: Hospital. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. No treatment received for the adverse event. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. Identification of the case safety report: Serious: No; Seriousness criteria-Results in death: No; Seriousness criteria-Life threatening: No; Seriousness criteria-Caused/prolonged hospitalization: No;

Seriousness criteria-Disabling/Incapacitating: No; Seriousness criteria-Congenital anomaly/birth defect: No.

I begin chilling the next day after I received the vaccine and started running a low grade fever of 100.5-body aches, headache, fatigue and pain in the arm where I received vaccine x 2 days.

Tiredness; Chills; mild joint pain; Nausea; feeling unwell; he hasn't eaten; threw up; This is a spontaneous report from a contactable consumer (patient). A 28-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration by injection once in the left arm, near shoulder on 18Dec2020 at single dose for COVID-19 immunization. Medical history included asthma from 2009 and ongoing (Has asthma but he has no breathing symptoms, no runny nose, no dry cough, no shortness of breath, no COVID symptoms). There were no concomitant medications. The patient experienced tiredness on 20Dec2020 with outcome of not recovered, chills on 20Dec2020 with outcome of recovered on 20Dec2020, mild joint pain on 20Dec2020 with outcome of recovered on 20Dec2020, nausea on 20Dec2020 with outcome of not recovered, feeling unwell on 20Dec2020 with outcome of not recovered, he hasn't eaten in Dec2020 with outcome of unknown, threw up in Dec2020 with outcome of unknown. No runny nose, cough or anything. Investigation Assessment: No. The patient took the COVID vaccine and was having mild symptoms, which he wished to report, and he was seeking recommendations. He had the print out thing given with all the symptoms that may happen, he had tiredness, chills, mild joint pain, nausea, and feeling unwell. He was a COVD tester, which is why he got it last week. This is not his first date of symptoms. Nausea: He threw up Sunday and Monday, was nauseous on Tuesday, is nauseous now but feels better, he missed work on Monday, he went for 2 hours yesterday and was sent home, he didn't go in today, but is feeling more normal, but has been perpetually nauseous since Sunday, like 24/7, in the middle of the night, middle of day, for no reason. He ate yesterday, he hasn't eaten today, because he feels nauseous. States feeling unwell goes along with nausea, he can't separate the two. What kind of medicine should he take, like over the counter or Pedialyte. What would a person potentially take if they were nauseous. Pedialyte, fluid or something. States this is Pfizer, he guesses any guidance is medical. Information on the Lot/batch number has been requested.

"positive rapid COVID testing positive/COVID-19 PCR test positive; positive rapid COVID testing positive/COVID-19 PCR test positive; This is a spontaneous report from a contactable nurse (patient herself). A 42-year-old female patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899, Expiration date: Mar2021), intramuscularly at site of right deltoid at 08:00 on 16Dec2020 at single dose for COVID-19 immunization. Medical history included ongoing high blood pressure. The patient received a flu shot in Oct2020. The patient's concomitant medications were not reported. The patient was tested positive for rapid COVID-19 testing on 21Dec2020 and was also positive for COVID-19 PCR test on 22Dec2020. No treatments after positive testing and patient was not hospitalized. The outcome of events was not recovered.; Sender's Comments: The reported ""tested positive for rapid COVID-19 testing"" after 4 days of immunization with BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) is considered related to BNT162B2 administration."

soreness at the injection site; slight fever; tiredness; This is a spontaneous report from a non-contactable consumer. A female patient of an unspecified age received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 22Dec2020 at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced soreness at the injection site, slight fever and tiredness on 22Dec2020. The outcome of events was recovered in Dec2020. No follow-up attempts are possible; information about batch/ lot number cannot be obtained.

Mild symptoms such as muscle soreness; This is a spontaneous report from a Pfizer-sponsored program. A contactable physician (patient himself) reported that a 31-year-old male patient received the first dose of BNT162B2 (Pfizer-BioNTech COVID-19 vaccine, lot# EJ1685), via intramuscular on 17Dec2020 20:00 in right arm at single dose for routine vaccination. There were no medical history and concomitant medications. Vaccination facility type was hospital, not a military facility. No additional vaccines were administered on same date of the Pfizer suspect. Prior Vaccinations (within 4 weeks) was none. Event following prior vaccinations was none. Relevant test was not tested. Patient was calling about COVID vaccine. He got the vaccine last Thursday and experienced mild symptoms such as muscle soreness around 6 am on Friday, 18Dec2020. On Sunday, his family became symptomatic and got tested for COVID and tested positive. He wanted to know if the COVID vaccine could produce false positive and if he can get the second dose. Caller did provide medical information's number and patient would need to be transferred over. There was no prescriber. It was given as routine from the hospital that he worked at. ER (emergency room) or physician's office required was none. Outcome of event was recovering.

Just letting you know it felt like a bad flu shot, sore enough to avoid sleeping on, but it went away after a few days :) thank you for your hard work, let?s hope after Jan 20 you can do your jobs without restriction.

felt weak; Nauseated; unable to sleep; was sick for about 2 hours; got so cold and couldn't get warm/felt cold to her bones; This is a spontaneous report from a contactable consumer (patient herself). A 64-year-old female patient received BNT162B2 (Pfizer-BioNTech COVID-19 vaccine), via an unspecified route of administration on 21Dec2020 at single dose for covid-19 immunisation. There were no medical history and concomitant medications. Investigation assessment was no. Caller received the Covid-19 vaccine Monday (21Dec2020). She was sick for 2 hours yesterday (22Dec2020). She got so cold and couldn't get warm, after a while she felt better. She felt cold to her bones. Today (23Dec2020) she felt weak and was nauseated. She worked at hospital. She was a tech at the hospital. She was a frontline worker. When a vial became available, she was given the vaccine. She was also unable to sleep last night (22Dec2020). She was up most of the night. She clarified that when she said she was sick for about 2 hours she was referring to being cold. Outcome of cold was recovered on 22Dec2020, and outcome of other events were unknown. Information on the lot/batch number has been requested.

Lymphadenopathy; Injection site pain/pain and tenderness under her arm; Lethargy; tired/did not feel like getting out of bed; Headache; arm was swollen/her sleeve was tighter, 1.5-2 inches bigger than her other arm; This is a spontaneous report from a contactable nurse reporting on behalf of herself. This 50 years old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot EJ1685) on

19Dec2020 at 11:15, at single dose, in right deltoid, for COVID-19 immunization. No other vaccine was given on the same date or within 4 weeks before. Medical history included ongoing epilepsy, ongoing depression and anxiety, COVID in late Oct2020 early Nov2020 (so her manager advised her to get the vaccine), allergies as a child, ongoing allergy to penicillin that showed up on an allergy test, ongoing allergy to house dust and trees, things like that. She previously received influenza vaccine in Oct2020, for immunization. AE(s) following prior vaccinations: none. Family medical history relevant to AE(s): none. Concomitant medications included topiramate (TOPAMAX) and brivaracetam (BRIVIACT), both for years, for epilepsy and duloxetine HCl (CYMBALTA) from Aug2020, for depression and anxiety. The reporter related Cymbalta use to COVID. The patient experienced lymphadenopathy on 21Dec2020, headache on 20Dec2020, injection site pain on 20Dec2020 at 03:00, lethargy on 20Dec2020, tired on 20Dec2020, arm was swollen on an unspecified date in Dec2020. Lymphadenopathy was reported as medically significant. The other events were reported as non-serious. The reporter stated it was painful but everyone told her it would be so she expected that. At about 3 A.M. on 20Sun2020 she woke up to her arm hurting when she tried to turn on her right side. She had taken 2 of the arthritis strength paracetamol (TYLENOL) the night before because she was told it was going to hurt, that might have been the reason she did not notice it before then. This was just injection site pain. At this point, she still had some injections site pain and it was tender if bumped but it was better than before. On 20Dec2020 she did not go to church because she felt tired and did not feel like getting out of bed, she also had a headache but these things were expected by her. She stayed in bed till noon. She went to work on 21Dec2020 and in that morning when she went to apply deodorant she noticed pain and tenderness under her arm. Her arm was swollen and she noticed that her sleeve was tighter so she had her husband measured her arm and it was 1.5-2 inches bigger than her other arm. It was tight and tender, actually at this point it was more than tender when she put her deodorant on. She was also giving the vaccine. No other treatments were given and she had not called her doctor about this. No emergency room or physician office visit were not required. Relevant tests: none. Headache and lethargy resolved on 20Dec2020. Injection site pain was resolving. Lymphadenopathy had not yet resolved and was reported as aggravated. The outcome of the other events was unknown. The reporter considered there was a reasonable possibility that headache, injection site pain, lymphadenopathy, lethargy were related to BNT162B2 vaccine.; Sender's Comments: Based on available information, a possible contributory role of the subject drug cannot be excluded for the lymphadenopathy and the other reported events due to temporal relationship. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Tachycardia

was tired and slept more than usual; was tired and slept more than usual; Soreness in left arm; This is a spontaneous report from a contactable consumer reported for himself. A 71-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration in left arm on 22Dec2020 13:50 at single dose for covid-19 immunisation. There were no medical history or concomitant medications. The patient got it at 1:50 pm, and got home and was really tired, so he said he was going to bed at 6pm and woke up at 7:30 feeling pretty refreshed. He then told himself, if he didn't get up, he wouldn't sleep at night, so he got up until 11:00 and slept until 8am. The patient was tired and slept more than usual on 22Dec2020 at 16:00. The only side effect was that he got a little bit more rest than normal. The other side effect is he got soreness in left arm and it was pretty sore unspecified date in Dec2020. He did not have any headaches or anything else. He was pretty satisfied. The outcome of the events was tired and slept more than usual was recovering while for other event was unknown. Information on lot/batch number has been requested.

rash on his forearm by his elbow/He said that the rash is also on the back of his of calf; injection site soreness; a little achy; tired; itching; could not sleep well; This is a spontaneous report from a contactable consumer (reporter). A 50-year-old male patient received bnt162b2 (BNT162B2, lot number EK5734), via an unspecified route of administration on 18Dec2020 18:30 at single dose for COVID-19 immunization. Medical history included asthma. He said that he took no other medication except for a multivitamin and his asthma medication. The patient said that within 5 hours of receiving the vaccine, he was a little achy and had injection site soreness. He said that he felt a little tired on Friday (18Dec2020) and Saturday (19Dec2020), but by Sunday (20Dec2020) it was gone. He said that starting Monday (21Dec2020), he noticed a rash on his forearm by his elbow. He said that his skins was normally sensitive and dry. He thought maybe it was not the vaccine and said that he used hand sanitizer that may have bothered it. He said that the rash was on the back of his tricep now though. He said that the rash was also on the back of his of calf. He said that it was itching. He stated that he treated it with triamcinolone cream for rash from his kid and it did not do anything. He said that he was following up with this primary care physician about this. He stated that it was so itchy and he could not sleep well. The outcome of the event tired was recovered on 20Dec2020 while for other events was unknown.

test positive for COVID-19; test positive for COVID-19; This is a spontaneous report from a contactable consumer (patient). A 26-year-old female patient received the first dose BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 20Dec2020 at single dose in left arm for covid-19 immunization. There was none medical history or concomitant medications. The reporter reported that she got the vaccine on the 20Dec2020 and found out Monday (21Dec2020) that she was exposed to someone who was positive so they used a rapid test post exposure on the 22Dec2020 that the result was positive for COVID-19. She reported she knew that the vaccine would not have given her COVID, and it was likely she had it before she got the vaccine and didn't know she had it because she didn't have symptoms. The outcome was unknown. Information about lot/batch number has been requested.

Sore left arm the day of the vaccination near the site. Throughout the next morning I felt a progressively worsening sore neck, that evolved into a stiff neck by early afternoon. My neck is a bit swollen, on the same side I received the vaccination (Left).

arm feels sore and heavy; arm feels sore and heavy; This is a spontaneous report from a contactable nurse (patient). A 36-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient reported that arm felt sore and heavy on an unspecified date after vaccination. The outcome was unknown. No follow up attempts are possible; information about lot/batch number cannot be obtained.

the arm was quite sore; This is a spontaneous report from a contactable consumer (patient's friend). A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK5730, expiration date: Mar2021), via an unspecified route of administration on an unspecified date at single dose in arm for covid-19 immunization. The patient's medical history was and concomitant medications were not reported. The patient was a frontline healthcare worker, the patient said the arm was quite sore (far more than expected) after vaccination, but no problem after an hour or so. The outcome of the event was resolved.

head ache; sore arm; This is spontaneous report from a contactable nurse (patient). A 43-year-old female patient (non-pregnant) received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot #: lot number Eh9899), via an unspecified route of administration on 22Dec2020 at single dose for immunization. Medical history was none. The patient's concomitant medications were not reported. Patient didn't receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, patient was not diagnosed with COVID-19. Since the vaccination, patient has not been tested for COVID-19. The patient experienced head ache after 24 hours, sore arm on 23Dec2020 18:00 with outcome of unknown. Patient didn't receive treatment for events. The report is considered non-serious. Information on Lot/ Batch number has been requested.

Slight alteration in smell. Smells are not as pungent and some smells are different then what they should be.

lymphadenopathy in left lower neck area above clavicle/swelling of lymph nodes; sick; sore throat; This is spontaneous report from a contactable other-healthcare professional (patient). A 45-year-old female patient (non-pregnant) received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot #: lot number Eh9899), via an unspecified route of administration on 16Dec2020 19:00 at single dose at left arm for immunization. Medical history included known allergies/shellfish. The patient's concomitant medications were not reported. Patient didn't receive any other vaccines within 4 weeks prior to the COVID vaccine, patient didn't receive other medication within 2 weeks of vaccination. Prior to vaccination, patient was not diagnosed with COVID-19. Since the vaccination, patient has not been tested for COVID-19. On 21Dec2020 07:00 AM, the patient experienced lymphadenopathy in left lower neck area above clavicle. Patient had never had this before but had felt sick since patient took the vaccine mainly the first day but sore throat not sure if related, then the swelling of lymph nodes. Patient didn't receive treatment for events. Outcome of events was not recovered. The report is considered non-serious.

Arm soreness; slight aches; slight fatigue; Large lump (lymph node maybe) under arm pit left arm; This is a spontaneous report from a contactable other health professional (patient). A 47-year-old male patient received first dose of BNT162B2 (Lot number: Eh9899) intramuscularly in left arm on 21Dec2020 10:00 at single dose for COVID-19 immunization. Medical history included COVID-19 from an unknown date and unknown if ongoing (COVID prior vaccination: Yes). There were no concomitant medications. The patient experienced arm soreness, slight aches, slight fatigue, large lump (lymph node maybe) under arm pit left arm all on 23Dec2020 03:00 AM. Treatment was not received. The patient underwent lab tests and procedures which included COVID test: COVID on an unspecified date. The outcome of events was not resolved. Facility where the most recent COVID-19 vaccine was administered in hospital. Prior to vaccination, the patient was diagnosed with COVID-19.

pain that worsened at injection site; pain that worsened at injection site; This is a spontaneous report from a non-contactable consumer (patient). A 43-year-old patient of an unspecified gender received BNT162B2 via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced pain that worsened at injection site over time on an unspecified date with outcome of unknown. No follow up attempts are possible; information about lot/batch number cannot be obtained.

dry mouth; my arm is sore at the injection site; my temperature is also slightly above baseline; It feels like I am dehydrated; my arm is sore at the injection site; This is spontaneous report from a contactable other health professional (Patient). A 32-year-old male patient received first dose of BNT162B2 (lot number: EJ1685), via an unspecified route of administration in left arm on 22Dec2020 17:45 at single dose for COVID-19 immunization. Medical history included psychiatric history, partially empty selle tursica, no other major Illnesses. Concomitant medication included testosterone, emtricitabine, tenofovir disoproxil fumarate (TRUVADA) for prevention. On 23Dec2020 09:00 AM, the patient was experiencing a dry mouth. This was unique because he never had this problem but his arm is sore at the injection site and he had a dry mouth, his temperature is also slightly above baseline, but not significantly. It felt like he was dehydrated but he was drinking lots of water. He had about 3/4 of a gallon today and his mouth was still dry. Almost like a cotton mouth feeling but very mild. It was only 3/10 on how bad it's bothering him. Treatment was not received. The patient underwent lab tests and procedures which included body temperature: slightly above baseline on an unspecified date. The outcome of events was not resolved.

--- 12/29/2020 11:02 AM by NOT AUTHENTICATED--- 1809: Patient is a 54 year old female presents requesting vaccination for COVID-19. Patient's identity was verified utilizing two patient identifiers. Allergies reviewed and patient has no history of severe allergic reactions. Patient reviewed vaccine information and given opportunity to ask questions: Yes Patient wants vaccine: Yes Pfizer-BioNTech COVID-19 vaccine # 1 in series administered, see Immunizations activity for vaccine details. Patient tolerated well and will remain for observation period to monitor. 1815: Patient is a 54 year old female COMPLAINED OF NO FEELING STRANGE, WITH TINGLING IN NECK ON BOTH SIDES. ADULT EMERGENCY WAS CALLED AND WATER WAS OFFERED TO PATIENT. RADIAL PULSE READ 110 BPM. SHE WAS TRANSFERRED TO HOSPITAL FOR EXTENSIVE OBSERVATION. NO APPOINTMENT WAS MADE FOR

SECOND VACCINE. 1817: Staff present and transported via w/c for eval. Pt. treated as noted below. Triage Note: C/O feeling ? Strange?. Tingling in neck. Pulse:110 Upon arrival, (Triage Note) Member received COVID vaccine, and shortly thereafter began to experience SOB, tingling in bilateral hand and back of neck and head, and elevated heart rate. Feels like symptoms have improved. Pt speaking in complete sentences, in no acute distress. Given Benadryl 25mg IV, Famotidine 40mg PO. Improved, Observed. D/C home at 2242.

area of swelling, erythema, induration, one inch by 2.5 inches from the injection site and downwards, noted 24 hours after injection; area of swelling, erythema, induration, one inch by 2.5 inches from the injection site and downwards, noted 24 hours after injection; area of swelling, erythema, induration, one inch by 2.5 inches from the injection site and downwards, noted 24 hours after injection; This is a spontaneous report from a non-contactable physician (patient). A 31-year-old female patient received BNT162B2 (lot number: e51685), via an unspecified route of administration in left arm on 22Dec2020 at single dose for covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced area of swelling, erythema, induration, one inch by 2.5 inches from the injection site and downwards, noted 24 hours after injection in Dec2020. The outcome of events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

muscle soreness; fatigue; This is a spontaneous report from a contactable nurse (patient herself). A 42-year-old female patient (non-pregnant) received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number: EK5730), intramuscular on 22Dec2020 07:30 at single dose at left arm for immunization. Medical history included PCOS, allergy to ragweed, grass. The patient's concomitant medications were not reported. Patient didn't receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, patient was not diagnosed with COVID-19. Since the vaccination, patient has not been tested for COVID-19. On 22Dec2020 10:00 AM, the patient experienced muscle soreness and fatigue. Patient was unsure if the fatigue was from lack of sleep before working 12 hours and then getting the vaccine, or from the vaccine itself. Patient was recovered from all events in Dec2020, and didn't receive treatment. The report is assessed as non-serious. Information on the lot/batch number has been requested.

Woke up next morning after vaccine with chills and sweats and bodyaches. He has been fatigued. He has been nauseated and headache as well. Fever of 102.4 degrees and chills and sweats back and forth.

Headache; muscle aches; fatigue; possible fever; This is a spontaneous report from a contactable other healthcare professional (hcp) (patient). A 26-year-old female non-pregnant patient received first dose of BNT162B2 (Pfizer-BIONTECH Covid-19 Vaccine, lot number: EH9833), intramuscularly on 22Dec2020 10:30 at a single dose in left arm for COVID-19 immunization. There was no medical history. Concomitant medication included fluoxetine received within 2 weeks of vaccination. There were no other vaccines received in four weeks. No known allergy. The patient experienced headache, muscle aches, fatigue, and possible fever, all on 23Dec2020 18:30. No treatment received for these events. The patient did not have COVID prior vaccination. Since the vaccination, the patient had not been tested for COVID-19. The outcome of events was unknown.

severe myalgias, fever of 100.6*F, malaise, fatigue for the past 12 hours (approximately 12-18 hours after receiving the vaccine). Patient of note, had COVID19 infection in July 2020. She tested negative for COVID19 this morning (screening done/ordered after reporting her initial symptoms).

skin reaction of circles on forearm and trunk; This is a spontaneous report from a contactable nurse (patient). A 46-year-old male patient received BNT162B2 (Pfizer-BIONTECH Covid-19 Vaccine), via an unspecified route of administration on 22Dec2020 09:15 at a single dose for COVID-19 immunization. He is fair skinned. There were no medical history or concomitant medications. The patient experienced skin reaction of circles on forearm and trunk on 23Dec2020. The outcome of event was unknown. This case is reported as non-serious by reporter. The causality between event skin reaction of circles on forearm and trunk and BNT162B2 is related by Primary Source Reporter per Global Introspection. Information on the lot/batch number has been requested.

Cough; voice sounded different; not feeling great; Chest congestion; Nasal congestion; sore arm; Fatigue; body ache; This is a spontaneous report from a contactable consumer, the patient. A 27-year-old non-pregnant female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot Number: EK5730), via an unspecified route of administration in the left arm on 20Dec2020 (at the age of 27-years-old) as a single dose for COVID-19 immunisation. The patient did not have any relevant medical history. She never had any reactions to any vaccines prior. Prior to this vaccination, the patient was not diagnosed with COVID-19. The patient's concomitant medications included loratadine (CLARITIN) and unspecified birth control. The patient did not receive any other vaccines within four weeks prior to the vaccination. On 21Dec2020, the patient experienced sore arm, fatigue, and body ache. On 22Dec2020, the patient developed nasal congestion and chest congestion. On 23Dec2020, the patient had a cough, her voice sounded different, and was not feeling great. Since the vaccination, the patient had not been tested for COVID-19. However, in May2020, she was tested for COVID-19 antibodies and was negative. The clinical outcomes of fatigue, body ache, nasal congestion, chest congestion, cough, voice sounded different, and not feeling great were not recovered; while that of the sore arm was recovered on 22Dec2020.

Employee started exhibiting sx 10 minutes after vaccine administration. She started having chest heaviness, difficulty breathing and became tachycardic. Employee was sent to the emergency room.

Fever 100; cough; fatigue; This is a spontaneous report from a contactable Nurse (patient). A 33-year-old female patient (not pregnant) received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot# EJ1685), intramuscularly in right arm on 20Dec2020 16:15 at single dose for COVID-19 immunization. Medical history included Hashimotos, PCOS, hyperlipidemia. Concomitant medication the patient received within 2 weeks of vaccination included levothyroxine sodium (LEVOTHYROXIN), neomycin hydrochloride;polymyxin b sulfate (neomycin and polymyxin b sulfates otic solution). The patient previously took ciprofloxacin hydrochloride (CIPRO) and experienced drug allergy. Facility where the most recent COVID-19 vaccine was administered: Hospital. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. The patient experienced fever 100, cough, fatigue, all on 22Dec2020 13:00 with outcome of not recovered. The

patient underwent lab tests and procedures which included pyrexia: fever 100. AE resulted in: None of the above. It was unknown if treatment received for the adverse event. Serious (NO). Seriousness criteria-Results in death (NO). Seriousness criteria-Life threatening (NO). Seriousness criteria-Caused/prolonged hospitalization (NO). Seriousness criteria-Disabling/Incapacitating (NO). Seriousness criteria-Congenital anomaly/birth defect (NO).

Symptoms clarified as body aches and pains like her bones aching; Symptoms clarified as body aches and pains like her bones aching; This is a spontaneous report from two contactable consumers (one was patient herself). A 54-year-old female patient received the first dose of NT162B2 (Pfizer-BioNTech COVID-19 vaccine, lot# EJ1685), via an unspecified route of administration on 21Dec2020 in right arm at single dose for vaccination. Medical history included hypertension. Concomitant medication included lisinopril from 2017 and ongoing for hypertension. This Medical Assistant called to report on behalf of herself, not a healthcare professional. She had her first dose of Pfizer COVID-19 Vaccine on 21Dec2020. She reported she developed symptoms which she clarified to be body aches and pains like her bones aching. Symptoms clarified as body aches and pains like her bones aching: onset 22Dec2020 around 10:00am. By around 8:00pm on 22Dec2020 this event pretty much went away, but she can still feel the body aches and pains like her bones aching on and off; event had improved now. She was taking paracetamol (TYLENOL) 1000mg every 6 hours for this event. She was scared she was gonna not be alive after getting this vaccine; because she was very sensitive with flu shots. She clarified that she got flu shot on 30Oct2020 at the institution where she worked and did not get sick with that flu shot. Second dose in series scheduled for 11Jan2020-she did not plan to change dose at this time. Outcome of events were recovering.

Myalgias; Left leg sensitivity; Fatigue; This is a spontaneous report from a non-contactable Other Health Professional. A 38-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot# EJ1685), intramuscularly on 21Dec2020 at single dose for COVID-19 immunization. Medical history included COVID from an unknown date and unknown if ongoing (Prior to vaccination, was the patient diagnosed with COVID-19: Yes). The patient's concomitant medications were not reported. Facility where the most recent COVID-19 vaccine was administered: Hospital. Did the patient receive any other vaccines within 4 weeks prior to the COVID vaccine: No. Was treatment received for the adverse event: No. Since the vaccination, has the patient been tested for COVID-19: No. The patient experienced myalgias, left leg sensitivity, fatigue on 21Dec2020 with outcome of recovered in Dec2020. AE resulted in none. Serious: No: Seriousness criteria-Results in death: No. Seriousness criteria-Life threatening: No. Seriousness criteria-Caused/prolonged hospitalization: No. Seriousness criteria-Disabling/Incapacitating: No. Seriousness criteria-Congenital anomaly/birth defect: No. No follow-up attempts are possible. No further information is expected.

Pt reports approximately 5-6 hours after waking he begins to feel very flushed and hot. After that, he begins to have severe dizziness, to the point that he is unable to ambulate, instead having to crawl across the floor. He checked his blood pressure and blood sugar, both of which were within normal limits. The dizziness can last several hours and is only resolved if he goes to sleep.

Injection site soreness; This is a spontaneous report from a contactable other healthcare profession (hcp) (patient). A 54-year-old non-pregnant female patient received first dose of BNT162B2 (Pfizer-BIONTECH Covid-19 Vaccine, lot number: EJ1685), intramuscularly on 21Dec2020 16:30 at a single dose in left arm for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. No known allergies. The patient experienced injection site soreness on 21Dec2020 17:00. No treatment received for this event. The patient underwent lab tests and procedures which included COVID test type post vaccination (Nasal Swab): negative on 14Dec2020. Prior to vaccination, the patient was not diagnosed with COVID-19. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. This is a non-serious report. The outcome of event was recovering.

Dizziness for about 1 hour; This is a spontaneous report from a contactable other health professional (patient herself). A 43-year-old female patient (non-pregnant) received the first dose of BNT162B2 (Pfizer-BioNTech COVID-19 vaccine, lot# EJ1685), via an unspecified route of administration at 23Dec2020 01:00 in left arm at single dose for covid-19 immunization. Medical history included slightly elevated BP (blood pressure) and gastrooesophageal reflux disease (GERD). Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. Concomitant medication included omeprazole (PROTONIX) and lisinopril. The patient experienced dizziness for about 1 hour on 23Dec2020 01:30 with outcome of recovering. No treatment was received for the event.

rash; This is a spontaneous report from a contactable pharmacist. A patient of unspecified age and gender received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for immunization. The patient's medical history and concomitant medications were not reported. The patient experienced rash after first vaccine on an unspecified date with outcome of unknown. Information on the lot/batch number has been requested.

Pt reports approximately 5-6 hours after waking he begins to feel very flushed and hot. After that, he begins to have severe dizziness, to the point that he is unable to ambulate, instead having to crawl across the floor. He checked his blood pressure and blood sugar, both of which were within normal limits. The dizziness can last several hours and is only resolved if he goes to sleep.

Chills; dizziness; high blood pressure; This is a spontaneous report from a contactable nurse (patient). A 50-year-old female patient (not pregnant) received first dose of BNT162B2 (lot number: EJ1685), via an unspecified route of administration in right arm on 22Dec2020 16:45 at single dose for COVID-19 immunization. Medical history included GERD (gastrooesophageal reflux disease) from an unknown date and unknown if ongoing. Concomitant medication included omeprazole (PRILOSEC), cetirizine, ascorbic acid (VIT C), ergocalciferol (VIT D), zinc, magnesium. The patient experienced chills, dizziness, high blood pressure on 22Dec2020 17:30. Treatment fluids was received. The patient underwent lab tests and procedures which included blood pressure: high on 22Dec2020. Facility type vaccine: Hospital. The patient didn't receive any other vaccines within 4 weeks prior to the COVID vaccine. The adverse event result in emergency room/department or urgent care visit, treatment was received for the adverse event (fluids). The outcome of events was resolving.

Experienced right arm tingling and the tingling went up into the right side of her neck. Experienced a few minutes of chills and heart racing.

Dizziness; Headache; chest pain; This is a spontaneous report from a non-contactable physician (patient). A 40-year-old female non-pregnant patient received BNT162B2 (Pfizer-BIONTECH Covid-19 Vaccine), intramuscularly on 23Dec2020 13:00 at a single dose in arm for COVID-19 immunization. Medical history included known allergies: roasted chestnuts. Concomitant medication included ascorbic acid, betacarotene, biotin, calcium carbonate, calcium phosphate, chlorine, colecalciferol, cupric oxide, ferrous fumarate, folic acid, iodine, magnesium oxide, manganese sulfate, molybdenum, nickel sulfate, nicotinamide, pantothenic acid, phosphorus, potassium chloride, pyridoxine hydrochloride, retinol acetate, riboflavin, selenium, silicon, thiamine, tin, tocopherol, vanadium, vitamin b12 nos, zinc oxide (MULTIVITAMINS & MINERALS PLUS LUTEIN) within two weeks of vaccination. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient experienced dizziness, headache, chest pain, all on 23Dec2020 21:30. No treatment received for the event. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. The outcome of events was recovering. This is a non-serious report. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

Swollen, firm, tender infraclavicular lymph node on side ipsilateral to injection site. Swollen to the extent where it is visible without need for palpation.

I had a very mild soreness on my right jaw at about 10 mins about my shot.

Headache; Pain and swelling at the injection site.; Pain and swelling at the injection site.; This is a spontaneous report from a contactable nurse (patient) from a Pfizer sponsored program. A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 19Dec2020 at single dose for COVID-19 immunization. The patient medical history was not reported. The patient's concomitant medications were not reported. The patient experienced pain and swelling at the injection site on 19Dec2020. They told her she could only take paracetamol (TYLENOL). Then she was reporting a headache on 23Dec2020 and was asking if she could take ibuprofen (ADVIL) as well. The outcome of the event was unknown. Information on the lot/batch number has been requested.

Minor headache; This is a spontaneous report from a contactable nurse (patient). A 39-years-old male patient started to receive bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) , intramuscular at 10:30 22Dec2020 at the first single dose for covid-19 immunisation. Vaccine location was Left arm. The patient medical history was not reported. No covid prior vaccination; No covid tested post vaccination. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient's concomitant medications were not reported. The patient experienced minor headache in Dec2020. The outcome of event was unknown. Information on the lot/batch number has been requested.

Mild/moderate nausea starting 24 hrs after vaccine, continuing for 10 hours now and has not subsided. Mild injection site soreness; Mild/moderate nausea starting 24 hrs after vaccine, continuing for 10 hours now and has not subsided. Mild injection site soreness; This is a spontaneous report from a contactable

other health professional reported for herself. A 40-year-old female patient (pregnant at the time of vaccination was reported as No) received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), intramuscularly on 22Dec2020 13:00, on Right arm, at single dose for COVID-19 immunization. Medical history included migraines, anxiety. Concomitant medications included fluoxetine, Vit B complex, ergocalciferol (VIT D), cetirizine hydrochloride (ZYRTEK). The patient previously took Iohexol and experienced allergies. The patient reported mild/moderate nausea starting 24 hrs after vaccine on 23Dec2020 13:00, continuing for 10 hours now and had not subsided. Also reported Mild injection site soreness on 23Dec2020 13:00. No treatment was received for the adverse events. The outcome of the events were not resolved. Information on the lot/batch number has been requested.

Went to the PMD a day later for routine blood work and found I have significantly elevated LFTs with ALT and AST 400s

Within 6-8 minutes of receiving vaccine, looked at cell phone to text husband and could not focus on the keys (Blurred vision), then felt a rush/tingling sensation thru whole body, as if the medication starting/moving from my arm all the way down my legs, some dizziness and heart rate increased - I believe to 120. No increased BP, SOB, itchiness, closed throat feeling, hives. Heart felt like it was racing for about 10 minutes. RN at site checked BP and heart rate 5 times in 40 minutes. Left facility and was able to drive myself home. Later that evening, soreness at injection site for 36 hours. No fever, chills, body aches.

"Fast heart rate, heart rate kept fluctuating went to 120 then 112 then 90 and 80, it went high for like at least half an hour, I kept feeling that palpitation; Sweaty; Tired; Body pain and ache; This is a spontaneous report from a contactable Consumer (patient). The 39-years-old female patient received bnt162b2 (BNT162B2), unknown on unknown date in Dec2020 at single dose for COVID-19 immunisation. Medical history and concomitant medications were none. Consumer stated, ""I am calling because I got the COVID Vaccine yesterday morning and then after I got the vaccine I had a fast heart rate and then my heart rate kept fluctuating, it went to 120 then 112 then 90 and 80 and it kept, it went high for like at least half an hour not more and then I kept feeling that palpitation and then today I am still feeling sweaty, tired, body pain and ache. So, I want to see what should I do regarding that? Is that considered like a severe allergic reaction and I need to do something about it or what should I do? So, I contact my employee health and they told me I need to contact you guys."" The outcome of the event Palpitation was unknown and was not recovered for the rest events. Information on the lot/batch number has been requested"

Moderna COVID-19 Vaccine EUA: injection site soreness for 36 hours

Chills/chills in the night; Headache, very severe headache very painful; Pain at the injection site; Little bit of stomach cramping and pain; probably a fever too; Little pain; This is a spontaneous report from a contactable consumer (patient). A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK5730), via an unspecified route of administration on 22Dec2020 at single dose for Covid-19 immunisation. The medical history and concomitant medications

were not reported. The patient experienced chills, headache, very severe headache very painful, pain at the injection site, little bit of stomach cramping and pain and probably a fever too, little pain and chills in the night in Dec2020. The outcome of the events was unknown.

notable pain at the injection site; This is a spontaneous report from a contactable consumer (patient) via Pfizer Sales Representative. This 40-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 23Dec2020 at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient received the COVID vaccine on 23Dec2020, that evening he was having notable pain at the injection site. The outcome of the event was unknown. Information on the lot/batch number has been requested.

body aches, chills, rigors, headache, fatigue, lymphadenopathy on the side of the injection

"I started getting achy; Headache; Joint pain; I started developing congestion; Cough; Sore throat; Fatigue; This is a spontaneous report from a contactable consumer (patient). A 23-years-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (lot number: EH9899) via an unspecified route of administration in right arm on 17Dec2020 at single dose for COVID-19 immunization. There was no medical history. There were no concomitant medications. The patient got the vaccine (Covid vaccine) on this past Thursday the 17 and he first didn't show any symptom or anything like that and then later at night and then in the beginning of morning of 18Dec2020, he started showing some symptoms. He started getting achy, he guessed little bit joint pain and started to get headache and didn't take too much of it neither of those side effects and as he found out last night apparently he had a positive exposure on the 18th the following day and didn't find out until last night but after the 18th he started showing different symptoms, he can't find better with the vaccine so he started developing congestion, cough, sore throat and a little bit of fatigue (all on Dec2020). He is going to get tested now and they have told him that the test, the vaccine should not affect the test itself. He received a medication for his headache. Treatment reported as the only thing he took was Tylenol. His height was about 5""8 or 5""9. Events outcome was unknown."

Continued fevers after 24 hrs after injection and body aches; Continued fevers after 24 hrs after injection and body aches; This is a spontaneous report from a contactable nurse(patient). The 25-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), intramuscular on 22Dec2020 09:45AM at single dose(dose number was 1) at left arm in workplace Clinic for covid-19 immunisation. Medical history and concomitant medications were none. She was not pregnant, no known allergy to medications, food, or other products. There is no Covid prior vaccination, no covid tested post vaccination. There is no other vaccine received in four weeks, no other medications in two weeks. The patient experienced continued fevers after 24 hours after injection and body aches on 23Dec2020 06:00AM. There is no treatment received. Outcome of events was not recovered. Case considered non-serious. Information on the Batch/Lot number has been requested.

soreness in the injection; headache; This is a spontaneous report from a Non-contactable Nurse reported for herself. This female patient of an unspecified age received the first dose of BNT162B2

(PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for Covid-19 immunisation. The medical history and concomitant medications were not reported. The patient had the first dose of the vaccine and mentioned that she experienced the expected adverse events of soreness in the injection site and headache. She said she felt better after multiple ibuprofen (ADVIL). The outcome of the events was recovering. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

Moderna COVID-19 Vaccine EUA

she felt sleepy and cold; she felt sleepy and cold; a bit dizzy; This is a spontaneous report from a contactable consumer reported for cousin. A female patient of unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 23Dec2020 at single dose (lot number: Ek5730) for COVID-19 immunization. Medical history and concomitant medications were unknown. The patient got the vaccine on the morning of 23Dec2020. She said she felt sleepy and cold. The patient said she felt better this afternoon. A pinch, the patient felt cold and sleepy. She could take a nap. The patient felt a bit dizzy when she got out of her chair just now. Outcome of the events was recovering. No follow-up attempts are possible. Information about lot/batch number cannot be obtained.

Drowsiness; This is a spontaneous report from a contactable pharmacist reported for self. This 43-year-old female patient (not pregnant) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on an 23Dec2020 14:15 on Arm left at single dose for covid-19 immunisation. Medical history included Seasonal allergy. No allergies to medications, food, or other products. Concomitant medications were none. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. No any other medications the patient received within 2 weeks of vaccination. The patient experienced drowsiness on 23Dec2020 16:30. Prior to vaccination, was the patient did not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. No treatments were received for the event. Outcome of the event was Not recovered. Information about lot/batch number has been requested.

"Patient notified me this morning that his clavicle (on the same side as injection) is ""very swollen."" Patient was advised to follow up with his PCP and report event through V-Safe."

Left arm/shoulder pain; Left arm/shoulder pain; Sternal pain; Fatigue; Headache; This is a spontaneous report from a contactable Other HCP (patient). A 33-years-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on left arm on 23Dec2020 16:00 at single dose for COVID-19 immunization. The patient medical history was not reported. There were no known allergies, no allergies to medications, food, or other products. The patient's concomitant medications were not reported. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19, since the vaccination, the patient has not been tested for COVID-19. The patient experienced left arm/shoulder pain, headache, sternal pain, and fatigue on 24Dec2020. No treatment was received

for the adverse events. Events outcome was not recovered. Information on the lot/ batch number has been requested.

Night sweat; Soreness of the thighs; This is a spontaneous report from a contactable Nurse (patient). A 47-years-old female patient received bnt162b2 (Batch/lot number: EJ1685), via an unspecified route of administration on 22Dec2020 16:30 at single dose for covid-19 immunisation. Medical history was none. There were no concomitant medications. The patient experienced night sweat on 22Dec2020 with outcome of unknown, soreness of the thighs on 22Dec2020, which was ok with outcome of recovered on Dec2020.

Onset of body aches 12h after vaccination, lasted for 24h; This is a spontaneous report from a contactable other healthcare professional reporting for a patient. A 26-year-old female patient (no pregnant) received her dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (Batch/lot number: EH9899), via an unspecified route of administration on 21Dec2020 at single dose for COVID-19 immunization. Medical history was not reported. The patient had no allergies to medications, food, or other products. The patient's concomitant medications were not reported. The patient experienced onset of body aches 12h after vaccination on 21Dec2020, lasted for 24h. No treatment received for the event. The event was reported as non-serious. The most recent COVID-19 vaccine was administered in Hospital. The patient had not received any other vaccines within 4 weeks prior to the COVID-19 vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. The outcome of the event was resolved in Dec2020.

Arm soreness lasting 24 hours; This is a spontaneous report from a contactable Nurse reporting for herself. A 48-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) Lot number EK5730, intramuscularly on 15Dec2020 14:00 at the right arm at single dose at workplace clinic for COVID-19 immunisation. There were no medical history and no concomitant medications. There were no allergies to medications, food, or other products. The patient did not receive any other medications within 2 weeks of vaccination. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient had no COVID prior vaccination. The patient did not have COVID tested post vaccination. The patient experienced Arm soreness lasting 24 hours on 15Dec2020 16:00. The event was reported as non-serious. Treatment was not received for the adverse event. The outcome of the events was recovered on an unspecified date in Dec2020.

Tenderness in injection site; This is a spontaneous report from a non-contactable Other HCP (patient). A 34-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) Lot number EJ1685, via Intramuscular route of administration on 23Dec2020 11:15 at single dose on left arm for COVID-19 immunization. Medical history included Gastrooesophageal reflux disease (GERD), Postpartum Depression. Concomitant medication included sertraline. The patient previously received nickel, amoxicillin, penicilline, hepatitis b vaccine and had allergies. The patient had not received other vaccine in four weeks. The patient had no covid prior vaccination. The patient had no covid tested post vaccination. The patient experienced Tenderness in injection site on 24Dec2020. The outcome of the event was resolving. No follow-up attempts are possible. No further information is expected.

105 degree fever, chills, fatigue, pain in injection site that extended to neck, shoulder, right breast, and right leg and thigh. Headache. These symptoms were at there worst for first 48 hours. I am now at day 5 and continue with headache, arm pain and right leg tingling.

Body aches and weakness; Body aches and weakness; Really fatigued; Sore arm; Chills; This is a spontaneous report from a contactable consumer (patient). This 25-years-old female patient (no pregnant) received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number: EH9899) on 23Dec2020 02:15 PM on Right arm for COVID-19 immunization. Medical history and concomitant drug were not reported. Past drug was known allergies with pethidine hydrochloride (DEMEROL). No other vaccine in four weeks, no other medications in two weeks. It was reported that patient experienced really fatigued, sore arm, chills and slight body aches and weakness (all reported as non-serious) on 23Dec2020 08:00 PM with outcome was Recovered in an unspecific date in Dec2020. No treatment. No COVID prior vaccination. No COVID tested post vaccination. Prior to vaccination no diagnosed with COVID-19. No follow-up attempts are possible. No further information expected.

Ten minutes after vaccine administration, employee started feeling very nauseated. She became tachycardic and became very blotchy across her chest and left arm. Employee was sent to the emergency room for evaluation.

Right nipple soreness and swelling; Right nipple soreness and swelling; This is a spontaneous report from a contactable physician (patient). This 73-year-old male patient reported that he received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EK5730), via intramuscular at arm right on 19Dec2020 03:00 PM at single dose for COVID-19 immunization. Medical history was none. Prior to vaccination, the patient was not diagnosed with COVID-19. No allergies to medications, food or other products. Concomitant medication was not reported. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient received no new medications within 2 weeks of vaccination. Since the vaccination, the patient had not been tested for COVID-19. Patient experienced right nipple soreness and swelling on 22Dec2020. No treatment was received for the adverse event. It was reported as non-serious. Outcome of event was not recovered.

swelling right under the arm (mentioned axilla); This is a spontaneous report from a contactable consumer (patient herself). A female patient of an unspecified age received bnt162b2 (BNT162B2 also reported as PFIZER-BIONTECH COVID-19 VACCINE) , via an unspecified route of administration on unspecified date at single dose, for immunisation. The patient's medical history and concomitant medications were not reported. The patient experienced swelling right under the arm (mentioned axilla) on an unspecified date. The outcome was unknown. Information about batch/lot number has been requested.

Sore arm a few hours after injection but very mild on first day. Day 2 arm soreness was worse and throbbed at times and was slightly warm to touch with mild swelling but relieved with ibuprofren. Day 3 arm sore but just barely noticeable. Soreness gone on day 4. No treatment needed other than the ibuprofren.

Arm soreness for 24 hours. Muscles aches and chills in the evening after the vaccine.; Arm soreness for 24 hours. Muscles aches and chills in the evening after the vaccine.; Arm soreness for 24 hours. Muscles aches and chills in the evening after the vaccine.; This is a spontaneous report from a non-contactable physician reported for self. This 26-year-old female patient (not pregnant) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot#: EH 9899) at single dose on 18Dec2020 at 07:00 on arm left for COVID-19 immunization. Medical history and concomitant medication were not reported. There was no allergies to medications, food, or other products. Concomitant medication was not reported. There was no other vaccine in four weeks. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. The patient experienced arm soreness for 24 hours, muscles aches and chills in the evening after the vaccine. Onset was 18Dec2020. There was no treatment for the events. The outcome of events was resolved in Dec2020. No follow-up attempts are possible. No further information is expected.

Shortly after injection started itching. Then when she got home she started a rash on face, chest.

Non productive cough; diarrhea; This is a spontaneous report from a contactable other healthcare professional (HCP). A 36-year-old male patient received 1 dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot Number: EJ1685) intramuscular on right arm on 23Dec2020 03:15PM, single dose for COVID-19 immunization at 36-year-old. Medical history included: allergies: promethazine hydrochloride (PHENERGAN). Prior to vaccination, the patient did not diagnose with COVID-19. Concomitant medication was not reported. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. On 24Dec2020, 05:00AM, the patient experienced non-productive cough, diarrhea. No treatment received. Since the vaccination, the patient had not been tested for COVID-19. Action taken for BNT162B2 was not applicable. Outcome of the events was not resolved. It was reported as non-serious. No follow-up attempts are possible. No further information is expected.

Fever, 100.4, sore arm

Injection site soreness 10 hours post administration; Still sore injection site this morning; Mild headache, muscle achiness and chills also 10 hours post administration of vaccine; Mild headache, muscle achiness and chills also 10 hours post administration of vaccine; Mild headache, muscle achiness and chills also 10 hours post administration of vaccine; This is a spontaneous report from a contactable other HCP. This 47-year-old female other HCP (patient) reported for self that she received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number=EK9231) intramuscularly at the right arm at single dose for COVID-19 immunization on 23Dec2020; 09:45 AM. Relevant medical history included Asthma, Ulcerative Colitis and allergies to Penicillin, Fiorinal with Codeine. The patient received Ibuprofen, Mesalamine, Pantoprazole within 2 weeks of vaccination. The patient experienced injection site soreness 10 hours post administration on 23Dec020, mild headache, muscle achiness and chills also 10 hours post administration of vaccine. The patient felt better in the next morning on 24Dec2020, while she still had sore injection site this morning. No treatment was received. The final outcome of events was resolved. All events were considered as non-serious. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19.

About 5 min after receiving IM Pfizer COVID injection, patient developed flush feeling, dizziness, and sore throat. Taken to ED for evaluation. Monitored for approximately 1 hour with resolution of symptoms.

Received vaccine at 1:30 pm yesterday, noted onset of symptoms at 8:45 pm. Numbness and tingling to mouth and bilateral upper and lower extremities, mild vision change, feeling of some swelling to bilateral eyelids. Also swelling to lips. She also did take zinc gluconate 50 mg last night and this morning. Has never taken zinc 50 mg, but has taken zinc as component of multivitamin/pre-natal vitamins. Patient was prescribed Pepcid 20 mg BID, Medrol 4 mg dose pack 21 pill taper until complete. Also given Benadryl 25 mg - 50 mg every 4 - 6 hours for allergy symptoms. And provided with an Epi-Pen for home.

Tingling in upper body, heat, warm

Medium area of redness, lump, itchy and sore around area of injection.

Headache, body aches, fatigue, injection site pain; Headache, body aches, fatigue, injection site pain; Headache, body aches, fatigue, injection site pain; Headache, body aches, fatigue, injection site pain; This is a spontaneous report from a contactable Nurse (patient). A 55-year-old female patient (No pregnant) received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) Intramuscular on 22Dec2020 10:30 AM on Right arm for COVID-19 immunization. Medical history was diagnosed with COVID-19 prior to vaccination. Concomitant drug was not reported. No other vaccine in four weeks. Adverse event reported as Headache, body aches, fatigue, injection site pain (all was non-serious) on 23Dec2020 12:00 AM with outcome was Recovering. No treatment. No COVID prior vaccination. No COVID tested post vaccination. Since the vaccination, the patient was not been tested for COVID-19. Information about lot/batch number are requested.

went to observation area at 1045. called to observation area 1100. states sx started at 1055: inside ears tingling, itching and warm. sweaty armpits. states has eaten peanutbutter, snacks and coffee for intake today. not lightheaded, dizzy, states no other sx. 1102 seen by, RN from rapid response. decided to wait 10 minutes to see if sx resolve. 1115 still no change in sx, ed called and transported to ED at 1125.

Chills; Fever 101.1¦F; Body Aches; This is a spontaneous report from a contactable physician, the patient. A 34-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE) Lot: EJ1685, via an unspecified route of administration in the left arm on 21Dec2020 (at the age of 34-years-old) as a single dose for COVID-19 immunization. Medical history included a diagnosis of COVID-19 (COVID positive) on 31Aug2020. The patient did not have any allergies to medications, food or other products. Concomitant medications were not reported; however, it was reported that the patient received unspecified medications within 2 weeks of the vaccination. The patient did not receive any other vaccines within 4 weeks prior to the vaccination. On 22Dec2020, the patient experienced a fever of 101.1¦F, body aches and chills. Treatment was not received for the events. Since the vaccination, the patient had not been tested for COVID-19. The clinical outcomes of the fever of 101.1¦F, body aches and chills were recovered on an unspecified date in Dec2020.

Headache; fatigue; nausea; muscle soreness; injection site pain; This is a spontaneous report from a contactable healthcare professional, the patient. A 32-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, Lot EH9899) solution for injection in the left arm on 23Dec2020 at 13:30 (at the age of 32-years-old) as a single dose for COVID-19 vaccination. The patient was not pregnant at the time of vaccination. There was no medical history. Concomitant medications included amfetamine aspartate/amfetamine sulfate/dexamfetamine saccharate/dexamfetamine sulfate (ADDERALL) and sertraline. The patient had no known allergies. The patient did not receive any other vaccine within 4 weeks prior to the vaccine. Prior to the vaccination, the patient was not diagnosed with COVID-19. On 23Dec2020 at 18:00, the patient experienced headache, fatigue, nausea, muscle soreness, and injection site pain. No treatment was provided for the events headache, fatigue, nausea, muscle soreness, and injection site pain. The outcome of the events headache, fatigue, nausea, muscle soreness, and injection site pain was recovering. Since the vaccination, the patient has not been tested for COVID-19.

12/23 @ 2000: severe chills 12/24 @ 0100: severe chills, nausea, vomiting, body aches, fever of 102.4 12/24 @ 0900: body aches, fever of 101.5 12/25 @ 0800: body aches, fever of 100.8

headaches; dehydration; nausea; vomiting; diarrhea; This is a spontaneous report from a contactable healthcare professional, the patient. A 33-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, Lot EJ1685) solution for injection in the right arm on 22Dec2020 at 15:45 (at the age of 33-years-old) as a single dose for COVID-19 vaccination. The patient was not pregnant at the time of vaccination. Medical history was unknown. Concomitant medications included amoxicillin, diphenhydramine hydrochloride (BENADRYL) and birth control. Past drug history included known allergies: cyclobenzaprine. The patient did not receive any other vaccine within 4 weeks prior to the vaccine. Prior to the vaccination, the patient was not diagnosed with COVID-19. On 23Dec2020 at 08:15, the patient experienced headaches, dehydration, nausea, vomiting and diarrhea. No treatment was provided for the events headaches, dehydration, nausea, vomiting and diarrhea. The outcome of the events headaches, dehydration, nausea, vomiting and diarrhea was unknown. Since the vaccination, the patient has not been tested for COVID-19.

Diarrhea , nausea, 'feeling unwell', fatigued began at 9am the next day - it is currently 3pm - continuing to feel symptoms

lightheadedness; confusion; This is a spontaneous report from a non-contactable healthcare professional. A 34-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, Lot EH9899) solution for injection intramuscular in the left arm on 22Dec2020 at 15:45 (at the age of 34-years-old) as a single dose for COVID-19 vaccination. Pregnancy status was not provided at the time of vaccination. Medical history and concomitant medications were unknown. Past drug history was unknown. On 22Dec2020 during her 15 minutes waiting period after the injection, the patient began to experience lightheadedness and confusion. The patient denied rash, hives, welts, difficulty breathing, difficulty swallowing, wheezing, throat tightness, hoarseness, stridor, itching, facial swelling, lip swelling and tongue swelling. The patient was discharged stable to go home and follow up with PCP (primary care physician). The patient was released at 16:39 with no symptoms at that time. No treatment was

provided for the events lightheadedness and confusion. The outcome of the events lightheadedness and confusion was recovered on 22Dec2020. No follow-up attempts are possible. No further information is expected.

Employee developed a severe headache approximately 10 minutes after vaccine administration.

Extreme fatigue and nausea and vomiting; Extreme fatigue and nausea and vomiting; Extreme fatigue and nausea and vomiting; This is a spontaneous report from a contactable nurse. A 40-years-old female patient started to the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), Batch/lot number: Unknown, intramuscularly on 23Dec2020 11:30 (at the age of 40-years-old) as a single dose in the right arm for COVID-19 immunization. The patient did not have allergies to medications, food, or other products. Concomitant medication included metformin, zolpidem tartrate (AMBIEN), venlafaxine hydrochloride (EFFEXOR XR). The most recent COVID-19 vaccine was administered in the hospital. The patient was not pregnant at the time of vaccination. Prior to vaccination, the patient was not diagnosed with COVID-19. On 23Dec2020 14:30, the patient experienced extreme fatigue and nausea and vomiting. The extreme fatigue and nausea and vomiting did not result in death, was not life-threatening, did not cause/prolonged hospitalization, was not disabling/incapacitating and did not cause congenital anomaly/birth defect. No treatment was received for the event. Outcome of the event extreme fatigue and nausea and vomiting was recovering. Since the vaccination, the patient has not been tested for COVID-19. Information on lot/batch number has been requested.

muscle ache, fatigue, hoarse throat, flushed skin, chills

Sore arm; nausea; This is a spontaneous report from a contactable nurse reporting for self. A 43-years-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), Lot# EH9899, via an unspecified route of administration in the right arm on 19Dec2020 at 15:30 (at the age of 43-years-old), as a single dose for COVID-19 immunization. The patient was not pregnant at the time of vaccination. The vaccine was administered in a hospital facility. There was no prior COVID-19 vaccination. The patient was not diagnosed with COVID-19 prior to vaccination & not COVID tested post vaccination. Medical history was none. Concomitant medications were not reported; however, there were no other medications the patient received within 2 weeks of the vaccination. The patient did not receive any other vaccine within 4 weeks prior to the COVID vaccine. There were no known allergies to medication, food, or other products. The patient experienced sore arm for 24 hours, then from about 34-72 hours had nausea. The onset date and time for the events was reported as 19Dec2020 at 15:30. The events were reported as non-serious. There was no treatment for the events. The patient recovered from the sore arm and nausea on an unspecified date.

"hearing in his left ear started sounding muffled; I was given the shot and instantly, within 30 seconds felt a slight numbing feeling radiating up my arm, then to my neck and up the left side of my face.My tongue felt a little numb but not swollen; had that ""metal"" taste in my mouth, but that did not return; This is a spontaneous report from a contactable other HCP. A 58-year-old male patient received BNT162B2 (Pfizer-BioNTech COVID-19 mRNA vaccine) (lot number EL1284), intramuscularly in the left arm on 23Dec2020 at 07:00 (at the age of 58-years-old) as a single dose for COVID-19 immunization.

Medical history included high blood pressure from an unknown date and unknown if ongoing and latex allergy from an unknown date and unknown if ongoing. There were no other vaccines received within 4 weeks of the BNT162B2 vaccination. Prior to the vaccination, the patient was not diagnosed with COVID-19. Concomitant medication included nebivolol hydrochloride (BYSTOLIC), fish oil (FISH OIL), naproxen sodium (ALEVE) and bifidobacterium lactis (PROBIOTIC [BIFIDOBACTERIUM LACTIS]). On 23Dec2020 at 07:00 (within 30 seconds of the vaccination as reported), the patient felt a slight numbing feeling radiating up his arm, then to his neck and up the left side of his face. Then, within 15 minutes, his hearing in his left ear started sounding muffled. His tongue felt a little numb but not swollen. It was reported when he first started feeling the numbing feeling, for about a split second, he had a metal taste in his mouth, but that did not return. It took about 1.5 hours for the numbness to go away. No therapeutic measures were taken as a result of the events. Clinical outcome of the numbness was resolved on 23Dec2020 at 08:30. Clinical outcome of the metal taste in his mouth and hearing in his left ear sounded muffled was unknown. It was also reported that since the vaccination, the patient tested negative for COVID-19 on 23Dec2020."

Headache, body aches and pain, lower back pain, high blood pressure, injection site soreness

severe shoulder pain/injection in left shoulder once, close to shoulder higher up; states it was not on the deltoid, it was given higher than normal; This is a spontaneous report from a contactable consumer (patient). A 61-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) Lot number EJ1685, on 23Dec2020 13:30 at single dose by injection in left shoulder once, close to shoulder higher up for COVID-19 immunization. Medical history and concomitant medication were none. The patient received the shot yesterday, and her only experience she was having was severe shoulder pain, and she was wondering if it was possible to just take Aleve, they mentioned taking Tylenol, but she was wondering if Naprosyn was ok to take. Towards yesterday evening, she noticed the severe shoulder pain, she received it at 1:30 in the afternoon, and noticed probably around 9PM, all night was just pain like as if someone or else you overexert with exercise, that kind of pain. She hadn't taken anything, she wondered if it was ok to take Aleve, no one seemed to know. She stated the dose was not given on the deltoid, it was given higher than normal. The outcome of severe shoulder pain was not resolved.

Weakness in the left side of face; and fatigue. 1112 am went to observe patient in her room. Laying in the bed with left side droopiness to face. Weakness on left side only, nurse taking care of her stated just happened. On observation it appears to be Bells Palsy reaction. No treatment at the time, Hospice nurse is to visit her today and check on her. Staff will check on her every 30 min for the next few hours and do a pulse oximeter check every hour for next few hours. 1205 second check on patient in room prior to staff leaving. Patient squeezed my hand and opened her eyes on command. Pulse saturation was 95 per staff. Patient resting comfortable with no signs of trouble breathing.

"I don't feel so good; This is a spontaneous report from a non-contactable consumer, the patient. A female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration on an unknown date as a single dose for COVID-19 vaccination. Medical history was unknown. The patient's concomitant medications were not reported. On an unknown date, the

patient reported ""I don't feel so good and I don't want to go to the hospital."" The clinical outcome of "" don't feel so good"" was unknown. No follow-up attempts are possible. Information on the lot/batch number cannot be obtained."

pruritic rash in pubic area moving up; This is a spontaneous report from a contactable nurse (patient). A female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, lot number:EH9899), via an unspecified route of administration in the left arm on 21Dec2020 at 11:00 AM as a single dose for COVID-19 vaccination. Medical history included cardiomyopathy and hypothryroid. The patient did not have any allergies to medications, food, or other products. The patient was not pregnant at the time of vaccination. Prior to the vaccination, the patient was not diagnosed with COVID-19. The patient's concomitant medications were not reported; however, there were other medications the patient received within 2 weeks of the vaccination. The patient did not receive any other vaccine within 4 weeks prior to the vaccine. On 22Dec2020 at 08:00 AM, the patient experienced pruritic rash in pubic area moving up. The report was reported as non-serious. The patient was not treated for pruritic rash in pubic area moving up. The clinical outcome of pruritic rash in pubic area moving up was not recovered. It was also reported that since the vaccination, the patient had not been tested for COVID-19.

chills; body aches; fatigue; This is a spontaneous report from a contactable consumer. This consumer reported that a 54-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration in the right arm on 23Dec2020 at 03:00 PM ((at the age of 54 years-old) as a single dose for COVID-19 vaccination. Medical history was unknown. The patient was not pregnant at the time of vaccination. Prior to the vaccination, the patient was not diagnosed with COVID-19. The patient's concomitant medications were not reported. The patient did not receive any other vaccine within 4 weeks prior to the vaccine. On 23Dec2020 at 10:00PM, the patient experienced chills, body aches, fatigue. The report was reported as non-serious. The patient was not treated for chills, body aches, fatigue. The clinical outcome chills, body aches, fatigue was recovered on an unknown date in Dec2020. It was also reported that since the vaccination, the patient had not been tested for COVID-19. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

Fever; Headaches; Chills; Aches and pains; This is a spontaneous report from a contactable consumer (patient herself). This 60-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, on 23Dec2020 at 08:30 AM at single dose for COVID-19 immunisation. Vaccine location was left arm. The patient was vaccinated at hospital, age at vaccination was 60-year-old. She was not pregnant. No other vaccine was received in four weeks. Relevant medical history included diabetic, allergies to eggs, chicken and latex. It was reported that prior to vaccination, she was diagnosed with COVID-19. Relevant concomitant medications included insulin aspart (NOVOLOG) for diabetes. On 24Dec2020, at 02:30 AM, the patient developed fever, headaches, chills, aches and pains. The patient was treated for the events. Nasal swab, COVID test (rapid) was performed on 24Dec2020 and was negative. The outcome of the events was unknown. Information on the lot/batch number has been requested.

I noticed onset of a mild rash down my bilateral arms and along my hips, back and legs. This rash worsened upon inspection on 24Dec2020 with associated itching and warmth along the rash site; warmth along the rash site; I noticed onset of a mild rash down my bilateral arms and along my hips, back and legs. This rash worsened upon inspection on 24Dec2020 with associated itching and warmth along the rash site; This is a spontaneous report from a contactable Other HCP. A 25-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, Batch/lot number: EK5730) via an unspecified route of administration on 22Dec2020 at 18:15 (at the age of 25-years-old) at an unspecified dose in the right arm for COVID-19 vaccination. Medical history was not provided. The patient had no allergies to food or medications but reported having seasonal allergies and it was reported that prior to vaccination the patient was diagnosed with COVID-19 on an unspecified date. The patient was administered the vaccine in the hospital. Concomitant medication included an unspecified oral contraceptive. The patient did not receive any other vaccines within four weeks prior to the vaccination. On 23Dec2020 14:00, the patient noticed the onset of a mild rash down her bilateral arms and along her hips, back and legs. This rash worsened upon inspection on 24Dec2020 with associated itching and warmth along the rash site. The patient did not receive any treatment for the events. The clinical outcomes of the events were reported as not recovered. It was also reported that since the vaccination the patient had not been tested for COVID-19.

Aches; Headache; Fever 102 degrees; This is a spontaneous report from a contactable physician, the patient. A 59-year-old non-pregnant female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot Number: EJ1685), via an unspecified route of administration in the left arm on 23Dec2020 at 08:00 (at the age of 59-years-old) as a single dose for COVID-19 immunization. Medical history included asthma and penicillin allergy. Prior to the vaccination, the patient was not diagnosed with COVID-19. Concomitant medications included naproxen sodium (ALEVE) and unspecified multivitamins (MANUFACTURER UNKNOWN). The patient did not receive any other vaccines within four weeks prior to the vaccination. On 24Dec2020 at 07:00, the patient aches, headache, and fever of 102 degrees Fahrenheit, reported as non-serious. The patient was not treated for the events. Since the vaccination, the patient had not been tested for COVID-19. The clinical outcomes of aches, headache, and fever of 102 degrees Fahrenheit were not recovered.

"Lightheadedness an dyspnea after receiving COVID 19 vaccine. Patient states that 5 minutes after receiving the vaccine, he felt ""out of it."" He felt like he was ""in a dream."" He reported feeling palpitations, shortness of breath, and chest pain. He denies feeling overly anxious. He states that the chest pain is substernal with no radiation. He reports it is pleuritic in nature. He states it is currently a 4/10, feels like a pressure on this chest; He received 50mg Benadryl and 0.3mg epi x2 by EMS and was brought to the ED for further evaluation. Admitted from ED for observation on 12/18/2020 and discharged on 12/20/2020."

"Lymphadenopathy: 0.5 cm left arm tender lymph node and 2 cm left infraclavicular tender lymph node; Lymphadenopathy: 0.5 cm left arm tender lymph node and 2 cm left infraclavicular tender lymph node; This is a spontaneous report from a contactable physician reporting for herself. A 49-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot #: EH9899), via an unspecified route of administration on 16Dec2020 at 09:00 (at the age of 49-years-old)

as a single dose in the left arm for COVID-19 vaccination. Medical history and concurrent conditions were reported as ""none"". The patient was not pregnant at the time of vaccination. Prior to the vaccination, the patient was not diagnosed with COVID-19. Concomitant medications (""other medications in two weeks"") included valaciclovir hydrochloride (VALTREX) taken for an unspecified indication from an unspecified date and unspecified if ongoing. The patient did not receive any other vaccines within four weeks prior to the vaccination. The patient previously received sulfa (sulfonamide) on an unspecified date for an unspecified indication and experienced allergy. On 22Dec2020, the patient experienced lymphadenopathy: 0.5 cm left arm tender lymph node and 2 cm left infraclavicular tender lymph node. It was reported that the event was non-serious and did not require hospitalization. The patient did not receive any treatment for the event. The clinical outcome of the event lymphadenopathy: 0.5 cm left arm tender lymph node and 2 cm left infraclavicular tender lymph node was not recovered/not resolved. It was also reported that since the vaccination, the patient had not been tested for COVID-19."

""" Code called for a 36 YOF complaining of anaphylactic reaction after receiving COVID vaccine. Per staff, patient began to have hives around mouth and a tingling in mouth. RN on scene administered epi pen at 1310. Patient found awake and alert, in no distress. Team took over care of patient to bring down to ER. Pt VS WNL: BP 158/80, HR 122, RR 18 (post epi pen). Skin parameters WNL with vanishing hives. Patient brought to ED 09 for evaluation. """

vomited; muscle pain.; severe flu symptoms for about 4 hours; This is a spontaneous report from a contactable healthcare professional, the patient. A 58-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, Lot# EL1284), via an unspecified route of administration in the right arm on 23Dec2020 at 10:45 (at the age of 58-years-old) as a single dose for Covid-19 vaccination. Medical history was not reported. The patient did not have any allergies to medications, food or other products. The patient was not pregnant at the time of vaccination. Prior to the vaccination, the patient was not diagnosed with COVID-19. The patient was not tested for COVID-19 post vaccination. The patient's concomitant medications were unspecified (had received other medications in two weeks). The patient did not receive any other vaccines within four weeks prior to the vaccination. On 24Dec2020 at 00:00, the patient experienced severe flu symptoms for about 4 hours, vomited and had muscle pain. Therapeutic measures were not taken for the severe flu symptoms for about 4 hours, vomited and had muscle pain. The clinical outcome of the events severe flu symptoms for about 4 hours, vomited and had muscle pain was recovered.

Fever; chills; arm was sore; extreme body aches; This is a spontaneous report from a contactable consumer, the patient. A 51-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), intramuscular in the left upper arm on 21Dec2020 at 11:00 (at the age of 51-years-old) as a single dose for Covid-19 vaccination. Medical history included COVID in May2020 for he knows he has detectable antibody levels; body aches in his shoulder, hip joints, knee joint and elbow joint for the last month and a half after recovering from COVID virus from an unknown date and weight loss of about 27 to 28 pounds since having COVID from an unknown date in 2020. The patient's concomitant medications included vitamin C, oral from an unknown date and ongoing for supplementation; Vitamin D, oral from an unknown date and ongoing for supplementation and aspirin (unspecified) since middle

of Jun2020 after having COVID per recommendation of his doctor. The patient previously received flu shot Flublok Quadrivalent a couple months ago (did not receive any other vaccines within four weeks prior to the vaccination). On 21Dec2020, the patient experienced extreme body aches around 8:30 to 9:00pm (described as more like the ones he experienced when he had COVID virus) and chills around the same time; and arm was sore. The patient experienced fever on an unknown date (in the middle of the night). The patient underwent lab tests which included body temperature which included 99.5 degrees F (last night), up to 100.8 degrees F (this morning) and 98.8 degrees F; and blood tests on an unknown date with unknown results. Therapeutic measures were taken for the events pain, pyrexia, chills and arm was sore which included paracetamol (TYLENOL) in the morning around 8am. The clinical outcome of the events pain, chills, pyrexia and arm was sore was recovering (improved with treatment). Information on the lot/batch number has been requested.

About 12 hours following the vaccine, I suddenly felt like I had the flu - shivers, shakes, nausea, headache, fatigue but no fever. I went to bed and woke up the next morning and felt back to normal. I was fatigued the second day and had a very sore arm.

Severe headache; fever; chills; fatigue; This is a spontaneous report from a contactable nurse, the patient. A 40-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), intramuscularly on 23Dec2020 at 18:15 (at the age of 40-years-old) as a single dose in the left arm for COVID-19 immunization. Medical history included multiple sclerosis and hypothyroidism. The patient had no known allergies. The patient was not pregnant at the time of vaccination. Prior to vaccination, the patient was not diagnosed with COVID-19. Concomitant medication included duloxetine hydrochloride (CYMBALTA), gabapentin, cefixime (FLEXERIL), tolterodine, levothyroxine, liothyronine; all for unknown indications from unknown dates and unknown if ongoing. The patient did not receive any other vaccines within 4 weeks prior to the vaccination. The patient experienced severe headache, fever, chills, and fatigue on 23Dec2020 at 18:30. No treatment was received for the events. Since the vaccination, the patient had not been tested for COVID-19. The clinical outcomes of the severe headache, fever, chills, and fatigue were recovering. Information on the lot/batch number has been requested.

Armpit of injected arm swollen and sore; Armpit of injected arm swollen and sore; This is a spontaneous report from a contactable healthcare professional, the patient. A 29-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, Lot ek5730) solution for injection in the left arm on 19Dec2020 at 14:00 (at the age of 29-years-old) as a single dose for COVID-19 vaccination. The patient was not pregnant at the time of vaccination. Medical history included fibromyalgia, depression, anxiety and ADHD (attention deficit hyperactivity disorder). Concomitant medications were unknown. The patient did not receive any other vaccine within 4 weeks prior to the vaccine. Prior to the vaccination, the patient was not diagnosed with COVID-19. On 20Dec2020, the patient experienced armpit of injected arm swollen and sore. No treatment was provided for the event armpit of injected arm swollen and sore. The outcome of the event armpit of injected arm swollen and sore was recovering. Since the vaccination, the patient has not been tested for COVID-19.

Reported paresthesia on the left side of her face and swelling of the lower part of her mouth an hour after administration of the Moderna COVID-19 vaccine. These symptoms resolved by this morning. She was observed for 15 minutes (as directed) following the vaccine and symptoms were not observed by clinic staff. She was advised to contact her personal physician for recommendations.

Unsure if side effect of vaccine but experiencing sweating, abdominal cramps and diarrhea.; Unsure if side effect of vaccine but experiencing sweating, abdominal cramps and diarrhea.; Unsure if side effect of vaccine but experiencing sweating, abdominal cramps and diarrhea.; This is a spontaneous report from a contactable Nurse. A 41-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, lot and batch number unknown) via an unspecified route of administration at an unknown dose in the right arm on 23Dec2020 at 12:45 (at the age of 41-years-old) for COVID-19 immunization. Medical history included asthma, anxiety, arthritis, fibromyalgia and surgical menopause all from unknown dates and unknown if ongoing. The patient did not have any allergies to medications, food or other products. Prior to the vaccination the patient was not diagnosed with COVID-19. The patient was not pregnant at the time of vaccination. The patient was administered the vaccination in the hospital. Concomitant medication included meloxicam (MELOXICAM), estradiol (ESTRADIOL), gabapentin (GABAPENTIN), phentermine (PHENTERMINE), melatonin (MELATONIN), aminobenzoic acid, biotin, calcium pantothenate, choline bitartrate, cyanocobalamin, folic acid, inositol, nicotinamide, pyridoxine hydrochloride, riboflavin, thiamine mononitrate (B COMPLEX), collagen (COLLAGEN). The patient did not receive any other vaccines within four weeks prior to the vaccination. The patient stated that she was unsure if these were side effect of vaccine but on 25Dec2020 at 10:00 she was experiencing sweating, abdominal cramps and diarrhea. The clinical outcomes of sweating, abdominal cramps and diarrhea were reported as recovering. It was also reported that since the vaccination the patient had not been tested for COVID-19. The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up.

"Describes left face, arm, leg felt numbness/tingling Had first COVID shot on 12/20/2020 19:36 then while driving home felt L face numbness at 20:37 Went to ED, BP 167/107 ""...driving home she states that she developed a strange, difficult to describe sensation when she was swallowing in her car, this started around 8:37 p.m.. She states that her numbness generalized to involve the entire left side of her face on the left side of her body including her left upper and left lower extremity. She denies any weakness. She denies any dysarthria or noticeable facial droop, she does not feel like she is walking differently. She denies any headaches or visual changes, denies any dizziness, chest pain, shortness of breath, palpitations. She states she has never had anything like this before."" ED notes had a normal neuro exam POCT glucose was normal at 83 resolved after minutes to hours in ED"

Vaginitis; This is a spontaneous report from a contactable healthcare professional. A 22-month-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration at the left arm from 23Dec2020 13:00 at a single dose for COVID-19 immunization at a hospital. The patient medical history was not reported. The patient's concomitant medications were not reported. The patient experienced vaginitis on 24Dec2020 13:00 which was reported to be treated with an unspecified OTC. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient was not diagnosed with COVID-19 prior to vaccination

and was not tested for it since the vaccination. The patient was recovering from the event. Information on the batch number has been requested.

Headache; This is a spontaneous report from a contactable consumer (patient). A 61-year-old female patient received the first dose on BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), on 18Dec2020 at single dose for COVID-19 immunization. Medical history was reported as none. Concomitant medications were not provided. Patient stated that she had her COVID shot on 18Dec2020 (reported as last Friday) and she had a headache ever since. Patient was just taking Ibuprofen trying to get rid of the headache. Outcome of the event was unknown. Information on lot/batch number has been requested.

developed some tingling, kind of a shock that comes and goes in her arms and in her back; This is a spontaneous report from a contactable nurse (patient). A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899) via an unspecified route of administration on 23Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient took the vaccine yesterday on 23Dec2020 and she developed some tingling, kind of a shock that comes and goes in her arms and in her back. She watched it for a long time, as nurses like to watch, and she finally feel asleep, so she wanted to tell this, she didn't know if this is any danger to her, she didn't think so, she was breathing well and can talk, but she was concerned because the tingling was almost like a little shock that comes and goes, not permanent. The reporter wanted to know if anyone has reported this. She was about to go out, but decided to call, agent can't say if this is something reported and she need to go to the local hospital. The outcome of the event was unknown. Information on the Lot/batch number has been requested.

UTI; This is a spontaneous report from a contactable consumer. A 65-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899), via an unspecified route of administration, left upper arm on 22Dec2020 12:30 at a single dose for COVID-19 immunization at a hospital. Medical history included urinary tract infection (UTI) in 2018 (2 years ago). There were no concomitant medications as the patient does not take any prescription drugs. Patient thinks her urinary tract infection (UTI) started to develop, 28-29 hours after receiving the vaccine so the onset was 23Dec2020. Patient stated the UTI came on fast and she has an appointment with an urgent care and may need antibiotics to treat the UTI. Patient was drinking a lot of fluids to try to flush the UTI out of her system. She said she doesn't feel as bad and felt like the UTI was getting better, and just woke up a short time ago. Patient also stated that she is concerned the antibiotic will mess up the vaccine, and wanted to know if she can take an antibiotic so soon after receiving the vaccine. The patient was recovering from the event. . .

Rash all over body, very itchy; Rash all over body, very itchy; This is a spontaneous report from a contactable nurse reporting for herself. A 62-year-old female patient received bnt162b2 (BNT162B2, Batch/lot # EJ1685) at single dose at left deltoid on 20Dec2020 in the afternoon around 13:30-13:45 for covid-19 immunisation, administered by a nurse at a tent outside of the hospital. The patient medical history was not reported. There were no concomitant medications. No additional vaccines administered on same date of BNT162B2. No prior vaccinations within 4 weeks. The patient got Flu shot a long time ago for immunisation. No events occurred following prior vaccinations. The patient experienced bad

rash all over body, very itchy on 20Dec2020 in the evening. The rash was driving her crazy.The reporter assessed the events were not really life threatening, not requiring hospitalization. Therapeutic measures were taken as a result of events: patient just bought Benadryl cream. No invesitgations. The outcome of events was unknown. She wanted to know if she has to get the second dose.

Arm pain on the left side, back pain, neck pain, headaches and then a dry cough developed several days later.

Headache; Body ache; Joint pain; This is a spontaneous report from a contactable consumer (patient). A 31-year-old male patient received the first dose BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), intramuscular, on 22Dec2020 at 11:00 AM at single dose for COVID-19 immunisation. Age at vaccination was 31-years-old. Medical history and concomitant medications were reported as none. On 22Dec2020, the patient developed headache, body ache, and joint pain. The patient reported the body ache has gotten worse, headache is still the same. The patient was treated with Advil. Outcome of all events was not recovered. Information on lot/batch number has been requested.

Shortly after vaccination (within 15 min), patient experienced warmth and itching at injection site, some radiating pain. Patient asked to stay longer to be observed, but eventually returned back to work without progress in symptoms. Approximately an hour later, she was prompted by her supervisor to return to vaccine area when she developed a headache and tingly lips. She was given 50mg of diphenhydramine PO. In no apparent distress after dosing

Fatigue, Headache, Nausea, sore throat

Achy pain at injection site; This is a spontaneous report from a non-contactable Other health care professional (HCP) (patient). A patient of an unknown age and gender received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), on unknown date at single dose for COVID-19 immunization. Medical history and concomitant medications were not provided. On unknown date patient experienced achy pain at injection site. Outcome of the event was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

GI problems; This is a spontaneous report from a contactable consumer (patient). A 46-year-old female patient (weight 74.39 Kg) received the first dose of BNT162B2 (Pfizer-Biontech covid-19 vaccine, Lot. EK5730) on 18Dec2020, in the left upper arm, at single dose, for COVID-19 immunisation. Relevant medical history included thyroid disorder. Concomitant medications were unknown. On 18Dec2020, the patient experienced gastrointestinal (GI) problems. Clinical outcome of the adverse event was unknown at time of this report.

Some problem with my arm; that is red; This is a spontaneous report from a non-contactable consumer (patient) This patient of an unknown age and gender received BNT162B2 (Pfizer-BioNTech COVID-19 at a single dose for COVID-19 immunization.Medical isotry and concomitant medication were not provided.The patient stated as follows:I have some problem with my arm that is red .The patient was wondering if it was an allergic reaction.The outcome of the event was unknown at the time of the report. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

Patient experienced dizziness/lightheaded, pale, body wide shaking, face tingly, hypertensive, tachycardic from patient reported baseline.

"Paresthesia in right hand (received covid-19 vaccine in right arm); Numbness; ""pins and needles""; This is a spontaneous report from a non-contactable nurse, who is also the patient. This 25-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration in the right arm on 23Dec2020 at 13:00 at single dose for COVID-19 immunisation. Vaccination facility type: workplace clinic. The patient did not receive other vaccines in four weeks. Relevant medical history included allergy to latex, mango and naproxen. Concomitant medication included unspecified oral contraceptive pill. On 23Dec2020 at 13:30, the patient experienced paresthesia in right hand (received COVID-19 vaccine in right arm), numbness and ""pins and needles"" which continued on and off for 48 hours. The patient did not receive corrective treatments for the reported events. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, she had not been tested for COVID-19. The patient recovered from the events in Dec2020. No follow-up attempts are possible; information about lot/batch number cannot be obtained."

headache; This is a spontaneous report from a contactable consumer received via Medical Information Team. A 61-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 18Dec2020 at single dose for COVID-19 immunization. The patient medical history and concomitant medications were not reported. The patient experienced headache on 23Dec2020. The patient outcome of the event was not recovered. Information about Lot/Batch number has been requested.

The following day had arm pain and fatigue for three and a half days, nasal congestion, dry eyes and itchy throat. Got tested for COVID one week later and is positive.

fever on and off; arm pain; body aches; chills; joint pain; This is a spontaneous report from a contactable nurse who was also the patient. A 55-year-old female patient received bnt162b2, lot:EK9231, via an unspecified route of administration on 23Dec2020 at an single dose for covid-19 immunisation. The patient's medical history was none. The patient's concomitant medications included unspecified vitamins. On 23Dec2020, the got the vaccine and the fever (on and off) started that night and had some arm pain too. The patient also had body aches, some chills and joint pain in Dec2020. The nurse stated that the thing should have gone better. She was just wondering how long she could have that side effects because it's been 3 days. Therapeutic measures were taken as a result of fever on and off pyrexia, body aches pain and chills were Tylenol and Motrin (patient did not clarify the improvement after taking the treatment). The outcome of the events was not recovered at the time of the report.

Feeling nauseous, throwing up; Feeling nauseous, throwing up; don't have the strength to keep talking right now; This is a spontaneous report from a Pfizer-sponsored program. A contactable female consumer, who is also the patient, of an unspecified age reported that she received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 23Dec2020 at single dose for COVID-19 immunisation. Relevant medical history and concomitant medications were not reported. In Dec2020, the patient started been feeling nauseous, throwing up and she wanted to double check if

she needed the second dose of the vaccine. The patient further specified that she didn't have the strength to keep talking. At the time of the report, the outcome of the events was unknown. The information on the lot/batch number has been requested.

"Tingling in her tongue and in her arm; Tingling in her tongue and in her arm; This is a spontaneous report from a contactable other health professional (patient) from Pfizer-sponsored program. A 33-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), intramuscular on Dec2020 at single dose for COVID-19 immunization. The patient medical history and concomitant medications were not reported. On Dec2020, the patient experienced tingling in her tongue and in her arm, the patient reported that: ""after getting the vaccine but it looked like the tingling in my arm was probably within an hour and the tongue was all like that in evening"". The patient outcome of the events was recovered. Information on Lot/Batch number for the product has been requested.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2020516692 same reporter, different patient/drug/event"

Pt woke up morning on 12/23 at0800 with rash on arms, thighs and legs. Called Nurse Manager, and primary doctor. Took 25mg PO Benadryl at 0815. Claritin 10mg PO at 0820. Took Pepcid 20mg at 0915. Had telehealth visit with primary doctor at 1000. Primary doctor informed patient that he believed this was an allergic reaction as the rash was spreading, patient was itching and had trouble swallowing pills in AM (unusual for patient to have that problem, resolved 1 hr post benadryl). MD informed patient to take 25mg PO of benadryl Q4H until rash disappeared. Ordered steroid dose pack if patient felt the benadryl did not help. Rash went away after 5 doses of 25mg PO Benadryl.

24hrs Soreness at injection site; This is a spontaneous report from a contactable consumer. A female patient of unknown age received on an unknown date BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) at single dose for COVID-19 immunization. Medical history and concomitant medications were not reported. On an unknown date the patient had 24hrs soreness at injection site. Outcome was unknown. Information on the batch number has been requested.

Patient received Pfizer vaccine at approximately 12:00 PM and drove to observation area. Observer reviewed safety measures with patient. Observer stated that patient c/o tingling at injection site. At approximately 12:05PM observer stated that she saw patient slightly waving paddle and went to assess patient, upon arrival to patient's car, patient was unresponsive. Emergency measures implemented. Epi administered via IM route, Oxygen applied, vital signs taken and EMS called. Patient remained unresponsive up EMS arrival. Patient was transported to the ER via EMS.

"I started running a fever; This is a spontaneous report from a contactable consumer (patient). A 63-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot EH9899) intramuscular in the arm on 22Dec2020 at single dose for COVID-19 immunization. Medical history included depression, allergy, high cholesterol, asthma, thyroid disorder. Concomitant medication included sertraline, bupropion and atorvastatin for High cholesterol. The patient started running a fever (non-serious) on Dec2020. Patient worked at the day care center that provided care for the Doctor's and Nurses Children. She worked at a healthcare site, she was not a doctor or a pharmacist, so that's how

she got a vaccine.Patient stated she got vaccine on 22Dec2020 and on 26Dec2020 she took her son, he was 24, to the doctor and he tested for Covid, now up to that point she had no side effects or anything, he did not get a vaccine so she wasn't surprised when he came down with it on his own but well she was surprised, last night she started running a fever so she was wondering ""will the vaccine effect a Covid Test?"" (as reported). Patient was treated with paracetamol (TYLENOL) and final outcome of the event was unknown."

Constant headache; This is a spontaneous report from a contactable nurse (patient). A 42-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number: EH9899) on 24Dec2020 at 09:00 at single dose for COVID-19 immunization. Medical history was none. Concomitant medication included multivitamin (unspecified) . The patient experienced constant headache on 24Dec2020 at 15:00. The patient, who was a health care worker front line (nurse), received the vaccine on 24Dec2020. She started having a headache, bad like afternoon around 6 hours after she was given the vaccine. The headache has not gone away. It was not like a terrible headache. It was a constant headache like if she took some paracetamol (TYLENOL) it went away but it came back. Patient stated she did not suffer from headaches and she had been having a constant headache since 24Dec2020, when she received the vaccine. The final outcome of the event was reported as not recovered.

Rushed to ER. Has now been tubed and put into the ICU and has had full-cardiac arrest less than 24 hours after receiving the vaccine.

nausea; chills; This is a spontaneous report from a Pfizer-sponsored program a contactable consumer (patient). This female patient of unknown age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route od administration, on 19Dec2020 at single dose for COVID-19 immunisation. Medical history and concomitant medications were unknown. She's experiencing symptoms like nausea and chills. She wants to know how long the symptoms will be. Outcome was unknown. Information on the lot/batch number has been requested.

Nauseous; I did start throwing up; Headache; This is a spontaneous report from a contactable consumer (patient herself). This 65-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, on 27Dec2020 at 07:30 AM at single dose for COVID-19 immunisation. The patient was vaccinated at hospital, age at vaccination was 65-year-old. Relevant medical history included diabetes, blood pressure abnormal and thyroid disorder. Relevant concomitant medications included insulin for diabetes, levothyroxine for thyroid disorder, and lisinopril for blood pressure abnormal. She was a MRI tech. She stated ''I had COVID Vaccine this morning at 7:30 and a little while ago like about 4'o clock. I work mid night, I got up from bed and I stand little nauseous and I did start throwing up and I have bad headache now but that's it. It is not emergent, but I just want to make sure, I am just checking in because I haven't. I can't get my smart phone to work because it keeps discharging so fast, but I was in bed. I am all right.' She stated ''there is no rash or anything. I just got nauseous which surprised me.'' The second dose is planned for 19Jan2021. No therapeutic measures were taken as result of the events. The outcome of the events was unknown. Information on the lot/batch number has been requested.

Aching in left deltoid hear injection site

Patient received vaccine around noon. She immediately felt numbness and tingling after injection. She reported back to clinic an hour later due to numbness and tingling persisting. She was given oral Benadryl and referred to the emergency department for evaluation.

Pain in left fingers and elbow that occurred within 15 minutes of injection. Numbness in left hand and forearm

0915 Generalized itching walked pt over to EMS Administered 50 mg of diphenhydramine PO

injection site pain, redness around injection site, Fatigue

Pt received first dose of Pfizer Covid 19 vaccine at around 12:45 and within 20 seconds, pt reported feeling sensation of tightness in his throat. Pt was observed for 15 minutes and his symptoms persisted but did not progress. Patient was taken to ED for evaluation. At 30 minutes post injection symptoms resolved. Monitored in ED for approx. 3 hours and discharged.

"Pt began c/o ""not feeling right"" with her tongue ""feeling funny"" and her lips tingling approximately 5 minutes after the administration of the Moderna COVID19 vaccine. Pt was transported to the Emergency Department for care and monitoring and was discharged when symptoms had resolved after approximately one hour."

Severe injection sure pain, jaw pain, hip pain, headache, palpitations, chills, nausea/vomiting, dizziness, fatigue

Left lip, cheek and nare swollen very visible to others. No difficulty breathing or swallowing . She has been taking zertec and this has resolved some but not all of the swelling.

Left eye bloody area lateral from iris, approximately 2cm x 2cm

Peripheral sensation loss

Swollen upper arm. Fever, chills with nausea

Extreme chills, muscle aches, joint pain, headache, fever, fatigue

On 12/28, reported that on 12/25 she had swollen lymph glands in her clavical and neck areas. Also, reported extreme fatigue (slept 16 hours following vaccine on 12/24) and significant arm soreness. Is seeking medical attention.

numbness on my right foot right after the injection (it went away) 30 min after swelling of right side of my face and droopy right eye (swelling went away but my eye is still droopy) little body pain, head ache and body felt warm (took Tylenol and it all went away). I'm just a little worried about my eye. Not sure how long it will take this to go away. I didn't take any allergy med because I'm not sure if I can.

High blood sugars, vision change, hearing issues, anxiety

Chest/arms itchy, tingling tongue

Itchiness after her first dose of COVID-19 vaccine this afternoon. Received vaccine around 2:15 PM and may be 30 minutes later just got diffusely itchy. No rashes not swollen anywhere no nausea or vomiting or belly pain no trouble speaking or swallowing or breathing. She got some oral Benadryl 50 mg prior to ED arrival.

Patient received the vaccine Monday, December 21. Patient started getting flu like symptoms on Thursday including cold, cough and headaches. Patient reports on Saturday the left ear and the left side of the throat began to hurt. Today Monday , December 28th, the patient states to waking up with a sore throat and the left side of the neck was swollen as big as a golf ball and remains swollen.

Patient received the vaccine Monday, December 21. Patient started getting flu like symptoms on Thursday including cold, cough and headaches. Patient reports on Saturday the left ear and the left side of the throat began to hurt. Today Monday , December 28th, the patient states to waking up with a sore throat and the left side of the neck was swollen as big as a golf ball and remains swollen.

Cold Like Symptoms

At 9 PM on December 22 I became absolutely exhausted extreme fatigue I went to bed I was woken around 11 1115 something like that every part of my body hurt it hurt to move my fingers it hurt to move everything every joint hurt and if I did move I felt nauseous then I started to throw up I did that for half an hour or so it was if you need to know it was violent and then I got back into bed with a cool cloth on my head at about 4 AM I got back to sleep I woke up at 6 AM to my alarm for work and I felt absolutely fine except my arm was sore just like it is from any regular inoculation.

area around injections, red, raised, warm, tender to touch

Hospitalized 12/29, has now been tubed and put into the ICU

May be in no relation at all but day after vaccination patient woke up with ankle pain. It was hard for the patient to walk/run. During the evening time he reports possible pulling of muscle/ligament while walking in a parking lot at the store during a snow storm.

Approximately 29 hours after the vaccine I developed fatigue, myalgias and chills. Lasted until I went to bed that night (4 hours or so). Resolved as of when I woke up the next morning.

Approximately 29 hours after the vaccine I developed fatigue, myalgias and chills. Lasted until I went to bed that night (4 hours or so). Resolved as of when I woke up the next morning.

Developed a rash on her face and arms; took Benadryl 50 mg immediately when the rash emerged at 9:15 AM; she notified the Employee Health office of the rash at 9:45 AM and was immediately referred for evaluation by an Employee Health medical provider at 9:50 AM; she took Benadryl 25 mg at 7:00 PM and then went to bed; the rash was gone upon waking at 8:00 AM on 12-29-2020; she had a follow-up

evaluation at 9:00 AM on 12-29-2020 with an Employee Health medical provider and was cleared to return to full duty and was discharged from care.

9:30pm on 12/23/20 i started with a severe headache and then an immediate onset of fatigue, i was unable to stand up and felt like i could not walk. thru at the night i had bodyaches, nightsweats, chills and fever. i had a fever or 101.3 on 12/24/20 for most of the day I rotated tylenol and ibuprofen and was only able to get it too 100.3 . bodyaches and headache continued . 12/25/20 fever and burning of eyes. 12/26/20 -12/27/20 fever and headache. all symptoms subsided on 12/28/20

Moderna COVID-19 Vaccine EUA. Around 25 min after injection I started feeling dizzy then had tachycardia, sweating, numbness and tingling in extremities. Given Oxygen and taken to the ER. Symptoms subsided 5 min after arriving in ER except numbness and tingling in hands. About 30 min later I started having dizziness and tachycardia again which lasted a few minutes. EKG, CHest X-ray and labs all normal. Just feel tired.

Patient observed for 15 minutes in the clinic after vaccine with no issues. Patient is a NP and left clinic. 10 min after leaving, was in physician lounge and had tachycardia, dizziness, flushing. Hospitalist in lounge recorded pulse as 180 normal rhythm. Patient taken to ED. In SVT - heart rate eventually reduced. Patient released on cardiac monitor to home. Later that night, patient had increased heart rate again - 160's - while in bed. Admitted to hospital.

Cough, diaeresis; initially only injection site soreness then other symptoms developed

Patient had tingling and numbness of the mouth and throat 20 minutes after receiving the COVID vaccine

Patient reports 2 hours after getting vaccination that she had difficulty moving left arm. Reports having decreased strength in left arm, and decreased ability to lift any amount of weight with left arm. Reports having numbness in left arm that is ongoing. Pt reports symptoms are improving .

Directly after receiving the vaccine I tasted a metallic taste and my tongue started to tingling. My face flushed. Last about ten minutes.

Lethargy & fever 12/29/2020

12/29/20 came to vaccine clinic to report. states had vaccine 7:10 pm, waited 15 minutes, 'felt edgy' but thought maybe nerves. 7:25 pm walked back to her office, felt slightly lightheaded, had worked 12 hours, sx subsided. 7:45 pm walked to her car felt right side jawline numbness that extended to forehead and whole side of face, able to smile, swallow, drove home (30 min) and sx stayed the same. states lingered over the evening, went away by 10 pm. states eyelid felt heavy, was not puffy. did not keep her awake - did report night sweats. 0700 awoke, states no sx, no residual. states arm slightly sore and general joint aches. 1205 came to clinic to report. states feels pretty good, concern is about next shot. Will contact PCP, did vsafe and will complete report.

Right side tongue numbness, tingling and burning in/around lips, elevated heart rate 136+, Blood pressure spike 165/105. Shortness of breath believed to be r/t elevated heartrate. Within 10 mins of shot. Face flushed, redness worsened with some swelling to ears and tongue skin felt like a sun burn rawness. Throat tugging noted. Dispatched an ambulance, had my husband take me around corner to ER where I was treated for anaphylaxis with 1 dose of Epi IM, IV solumedrol, and two rounds of benadryl IV. I was monitored and sent home on steroids, benadryl, and cimetidine for several days. I was issued an Epi Pen at that time. The rash and redness with feeling of burning has come and gone since as well as the tongue numbness on right side.

Red bump, painful and itchy

Cough and injection site soreness

Patient is a physician. He reported palpitations and tachycardia the evening of vaccination (about 4 hours after vaccination) when he was at home. It did subside within 2-3 hours.

I'm not sure if it was the vaccine, I'm a chaplain at the hospital I didn't eat or drink anything before the vaccine. I had a trauma that day and after the shot my arm was tingling when I was driving home I couldn't focus I had a headache, when I got home I ate and immediately went to bed, I slept for 10 hours and the next day I was getting my son ready and I fell asleep sitting up and by lunch time I felt completely normal again.

Generalized itching

Itching and rash/ hives. Itching started approximately 5 minutes after injection, slight at first then itching increased throughout body. Rash hoed later. Mostly only on areas scratched (face, chest and neck). Rash and itching present for 5 days including day injection given. Used over the counter antihistamines round the clock. Used inhaler once evening of injection day and once 3 days later. (Albuterol)

Deltoid pain with movement of arm.

"Co-worker reported a ""sever headache"" and later at 2:05pm she reported she was ""unable to open her right eye due to the severe pain in her head"". She took Benadryl 25mg by mouth. Her mother came and picked her up to take her home after an hour without any additional symptoms. The co-worker reported she still had a ""headache"" the next day, but it was much better."

12/19/2020 0630 AM WOKE UP AND WENT TO REACH FOR PHONE, COULD BARELY LIFT LEFT ARM. HURT ALL WAY DOWN TO WRIST. WHOLE ARM WAS SWOLLEN, HARD. SEVERE HA. GOT UP TO GO TO BATHROOM; BODY ACHES, CHILLS, DIARRHEA. 12/20/2020 AFTERNOON FELT WORSE. FELT LIKE HAD THE FLU BUT 50 MILLION XS WORSE; BODY DIDN'T 'FEEL RIGHT'. GETTING TO POINT OF FEELING WORSE. CALLED HOSPITAL, PHARMACIST. SCARED. COULDN'T STAY AWAY, COULDN'T STOP SLEEPING. COULDN'T WORK. CALLED PCP. TEMP SLIGHT ; 99.5 12/21/2020 WEDNESDAY MIDDAY ALL SIDE AFFECTS WENT AWAY LIKE SOMEONE FLIPPED A SWITCH. 'NOT A GOOD EXPERIENCE' 'I DON'T THINK I CAN GO THRU THIS AGAIN WITH THE SECOND SHOT'

general body itching

Hives, nausea, headache. Given benadryl. Hives resolved. Residual dull headache. Patient sent home with scheduled Benadryl x 24 hours, has Epipen. Encouraged to use prn and to seek medical attention prn.

Day of vaccine- extreme fatigue, pain at injection site Day 1- scratchy throat, extreme fatigue, muscle pain Day 2 - scratchy throat, extreme fatigue, chest tightness, muscle pain, headache Day 3 all symptoms as above with sore throat and fever

Palpitations, dry eyes, vertigo, rash on chest several hours after receiving vaccine. Resolved within a few hours.

Patient reported on 12/29/2020 that she experienced right hand numbness 15-20 minutes after vaccination and this lasted about 5-10 minutes. About 20 minutes after the vaccination she experienced lip tingling which then progressed to mild swelling and redness of the lips. This has persisted to this day and is gradually improving. She has experienced lip swelling in the past, not triggered by any event, medication, or substance, however has never experienced hand numbness or reactions to vaccines in the past. She has not received fillers.

Woke up with a rash over stomach, back, thighs and arms that were like goosebumps and itchy. They would get red and were painful and that would come and go. on the 25th the rash was constant, The rash was not relived with multiple doses of Zyrtec, Allegra or hydrocortisone cream and has persisted and worsened through the weekend. Prednisone was started on Sunday the 27th which seems to have helped however still itchy and the goosebump like rash is still on stomach, back and thighs.

SOB, Asama attack

Headache, muscle pain, joint pain, fever 100.6, fatigue,chills

Sensation of a racing heart

Employee came and report/showed me a raised rash that is on her face, neck and chest that developed the evening of her vaccine. Has been utilized OTC Benadryl. Able to still work.

low grade fever 99.2 after taking Ibuprofen headache sudden hot feeling and then fast cooling off, almost chilled, but I am fine, very mild

Noticed a rash around mouth and cheeks

5-10 minutes after vaccine got mild numbness/heaviness feeling corner of left side of mouth (very pinpoint without migration) that 1-2 hours after vaccine progressed to similar feeling on lateral left side of face and corner of left eye-no motor weakness in face, facial drooping or clinical change in sensation on palpation of skin, intermittent gritty/sandy feeling on tongue/mouth that started about 30 minutes or so after received the vaccine. Intermittent very mild scratchy/sore throat that start 30+ minutes after vaccine, frontal pressure-like headache-forehead/temples/cheeks on face-started within about 30 mins-

1 hr of getting vaccine-can get extremely strong at times. Approximately 12-14 hrs after vaccine got tingling/burning sensation on tongue with complete 100% loss of taste that was transient and 1-2 hours after started has slowly been improving and taste is slowly returning since then. no loss of smell. no tongue swelling or throat closing up sensation. all symptoms improve with taking over the counter antistamines-Zyrtec or benadryl, but haven't resolved yet. all symptoms overall mild (except headache at time) and are waxing and waning in severity (including headache) the entire time since receiving the vaccine. I feel completely fine otherwise.

Tachycardia and throat tightening

I developed a maculopapular rash over my chest, abdomen, back and proximal extremities but sparing my face, hands and feet. I was otherwise asymptomatic and the rash was not painful or itchy. It resolved on its own after 24 hours.

Patient reports arm tingling down from elbow to hand of left arm. A little numbness in left hand. Few hours later patient reports numbness moving down to arm and hand and up to eye with somewhat lessening on the lip. Patient currently experiencing some tingling on the right arm.

I actually am having a hard time lifting up my arm. Cannot put any pressure on the arm or take off clothes in shower. I cannot carry my son. I cannot lift anything. I cannot put my arm in pocket or jacket. If I get beyond 15-30 degrees abduction, I cannot do very well. Beyond that I can.

Sore arm for a week, redness and bump at injection site

Sore arm for a week, redness and bump at injection site

patient had body aches, head ache and shortness of breath. symptoms resolved on own no treatment necessary.

12/19/20 Employee's written report/description of events: shoulder injection site, left shoulder. Including shooting pain from my left wrist into the left side of my face. I have shooting pain into my chest from the injection site which also has included involuntary muscle movement in my neck and face, involuntary muscle movement is painful and this occurs with dizziness. All the pain stems from the injection site itself and always starts there when the pain happens. 12/23/20 saw OHS RN and was improved: states symptoms are better today & no involuntary muscle movements experienced today. Pain at injection site is less also. Has been using OTC Aleve, 1-2 every 12 hours. CMS left hand intact; all digits both hands have pale nail beds with > 2 sec cap refill; skin temp cool to warm. States has been on a medication that can cause Reynaud's disease; and has been concerned this may be occurring. Work comp MD appt. for 12/30/20; has not confirmed.

2:30 PM vaccine listed above given, 3:02 PM cheeks flushed with slight swelling of lips, Benadryl & Pepcid taken per employee. 4:35 PM symptoms resolved, 6:34 PM employee to ER with rash, itching, and trouble swallowing. Treatment received of Benadryl and Solu-Medrol, symptoms improved and employee DC to home. FU this am, employee states she has a HA and has taken med for, no further problems noted.

Strange taste in mouth, heart felt like it was pounding out of chest, blood pressure 195/100 (elevated), dry/burning mouth Was brought to ED and given Benadryl and Lorazepam

Tachycardia. Fever. Sweat. Body aches. Weakness

After I received the vaccine, after I went upstairs to go back to work (about 30 min later) I felt my hands and feet very cold and numb. I also felt dizzy and my hands and feet kept cold. Kept trying water and coke and I was continuously dizzy, a weird dizzy, like I had taken some kind of drug. My coworkers said I had slurred speech, my BP was 180/120 and my heart rate was 140. They sent me down to the ER. As soon as I laid down at the ER I started feeling better and within one hour my symptoms were gone. I also felt very sleepy throughout, as soon as I started feeling dizzy. I was fighting the sleep.

Fever Chills Rash and hive Fatigue

Noticed redness and swelling to vaccination site upon waking up. Site is warm to the touch and hard now about the size of a quarter.

Swelling redness and bump at injection site

Swelling redness and bump at injection site

Patient reported that his arm is tingling, has nausea, chills (no fever) and vomiting. These events all occurred as the patient woke up the morning after vaccination on 12/29/20.

Headache, light headed, dizziness for about 10 minutes

itchy tongue/throat

Right side of face swollen

Palpitations, tachycardia, anxiety several hours after vaccine while at home after awakening from a nap. Resolved after 2 hours.

Chest pain, short of breath. Morphine, sublingual Nitro, IV Nitro drip & Heparin drip

Severe headache, mild fatigue

Tension headache

Patient developed persistent nausea one day after vaccination with Pfizer COVID-19 vaccine. Nausea is ongoing 7 days post vaccination. Patient has not had any vomiting, diarrhea, myalgias, fever, and endorses no pain or tenderness in her abdomen. She has taken promethazine oral with minimal relief of nausea.

Headache body aches dizziness low back pain sore throat diarrhea

fever, fatigue, cough/dyspnea, muscle aches, headache, dizzy

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12 hrs after vaccine. symptoms runny nose, tenderness on left arm, headache, dry cough

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About 7-10 minutes after receiving covid vaccine, I was just talking with other nurses and suddenly felt a rush came over me. Felt lightheaded and dizzy. My pulse and blood pressure spiked. After about 5 more minutes, my forehead became numb. My pulse and BP had come back down. Later on that evening and into the next day my palms of my hands were bright red and itchy.

Flushing for 5-10 minutes

General Hives, sunburn effect, itching

General Hives, sunburn effect, itching

"Blurry vision, RIGHT arm weakness, shortness of breath, feels ""sick."""

Pain at injection site the night after injection. Swelling, pain, heat in the muscle around the injection site the next day.

12/18/2020 9:00PM Body aches, fatigue, headache and chills; Tylenol dose. Symptoms have not subsided; have continued to today 12/29/2020. 12/28/2020 Swollen lymph nodes left armpit, extremely fatigued and headache. 12/29/2020 Clinic visit with NP, Flu -- negative and COVID 19 test taken -- no results yet. Advised to continue Tylenol for treatment.

Received vaccine in left arm at 7:20 am sat for 15 minutes without any incident. At approximately 7:50 am I felt an intense burning sensation to outer aspect of right eye and eyelid. My eye was burning and watering continuously.Reported back to department where vaccine was administered nurse gave my 25 mg of P.O Benadryl. No other symptoms at that time. At approximately 2:00pm same day right eye partially opens,swelling persists to right eyelid with burning sensation and eye watering.

Loss of appetite/nausea

Vertigo, nausea, altered vision within minutes of receiving vaccine. Observed in clinic for 1 hour. Symptoms resolved. Returned to work. Vaccine received around 1150 am - patient had not had anything to eat that morning.

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stiff and inflamed joints where i have had previous injuries. Also sore throat and hot flashes.

Fever 103.5, body aches, chills, nausea, vomiting

22 mins after , I was light headed, Accelerated heartrate 170/101. I felt weak and shaky . Chills, I was given Iv fluid. In injection of Benadryl Slight Fever of 98.7

After 24 hours. Chills diarrhea and fever

RASH ON NECK AND LEFT HAND BUMP/ITCHYNESS

"Felt ""fine"" initially, then became ""lightheaded and dizzy"", felt like having an asthma attack. This occurred approximately 20 minutes after immunization. Went to ER, given rescue Albuterol inhaler, given Benadryl IV, Pepcid IV , monitored vitals"

Chest pains and short of breath within one hour of vaccine

Low grade temp 99.5

"Mental confusion. Couldn't gather thoughts. Mental ""fog"". Dizziness while sitting."

Patient received the vaccine on 12/23. Patient reports fever and fatigue from 12/24 ? 12/27 and developed hives on 12/26 and a diffuse red rash on 12/28. Patient was treated in the ED 12/28. On 12/28/20 patient was diagnosed with Diverticulitis, Allergic Reaction. Patient discharged with antibiotics and corticosteroid.

Fever this morning of 103 F. Took 1,000mg of Tylenol and fever went down to 101 F. 4 hours later took another 1,000mg of tylenol and fever is currently down to 100 F. Chills Soreness at injection site Fatigue

Patient received Pfizer Vaccine at approximately 1430 and was in observation area. At approximately 1435 observer stated that patient started to c/o dizziness and became pal.. Patient maintained LOC. Emergency measures implemented. Patient was place on oxygen, vital signs taken, EMSA called. EMSA present and evaluated patient. Patient was able to leave clinic site after evaluation.

Hospitalization 12/26 for Covid PNA

generalized edema, facial redness, slow resolution over next 18 hours

After injection developed swelling in cheeks and under eyes -

Moderna covid-19 Vaccine. Moderna was given to pt Im Left Deltoid 2 10:06 am . during her observation period for 15 min @ 10:20 she complained of itching and red spots on left arm and started on her back until 10:30 when 50 mg of Benadryl given in RD Im . started itching and red spots on rt arm noted. no other c/o , no shortness of breath noted, pt alert, oriented x4, sitting in chair talking to husband and drinking water. 11:00 am pt says I am no longer itching, my husband is going to drive me home. Instructed pt if any other symptoms develop go to Hospital ER . Pt walked out to car with husband to go home. I called pt 3:50 no answer at home number. spoke to pt at 4:10 pm , she also vomited X1, Slight headache.

Left arm put swollen and tender, lymph node

injection site pain

Pt called on 12/29 to report she is in pain. Reports at around 9:30 PM on 12/28 she had headache. They woke up at around 4 AM in severe pain. Her head hurt all over as well as the back of her neck down in her legs. Her entire body ached. She felt like she could not get a good breath. Her SaO2 was decreased. Today she is still in pain. Her pulse is 108 lying down and SaO2 88-92%. Will be going to the ER. Her oncologist is concerned about pneumonnia.

Fever-100.3

prolonged pain at the injection site, the pain increased in intensity 72 hours after the vaccine was administered and is persistent after 10 days. no systemic symptoms, evaluated locally, no findings on exam.

Multiple episode of irregular HR for about 7 hours. Severe pain in the left shoulder and joint, with muscles involvement. The pain extended down the arm to the wrist. Muscles were weak and unable to lift arm higher than chest, unable to perform ADL's with left arm as there wasn't any muscle strength to lift a thin blanket covering. Severe pain lasted about 48 hours with continued joint pain, although much less severe, in the left shoulder. Used Benadryl and Motrin. Didn't notice any different outcomes. Arm remained elevated on a pillow for some pain diminishment.

Near syncope, palpitations, tachycardia, elevated blood pressure

received vaccine at 02:30 pm 12/26/20, by 09:30 12/27/20 had chills, muscle aches, headache, sinus pressure, fatigue, and moderate soreness in arm of injection, symptoms resolved as of 12/28/20 09:30

Patient stated she had her Covid Vaccine on Friday 12/18 at 930am. On Friday night she reports she had a terrible migraine, on Saturday she felt very fatigued. She reports Sunday was her worst day and she felt very achy & her body felt like it was on fire. On Monday (12/21) she reports feeling better, but today 12/22 she reports that she has a bad cough and chest tightness.

Loss of appetite/nausea

"Co-worker reported she brought her ""epi pen"" with her to receive vaccine as she has allergies. Pt was given vaccine and waited 30 minutes and did not report any symptoms. Co-worker returned the next day to the vaccine clinic at approximately 11Am and reported that she was having symptoms of a reaction ""(unable to walk), "". She was taken to the emergency room. Co-worker had already taken Benadryl prior to coming to report the adverse reaction. Co-worker was called the next day by co-worker health 12/23/2020 and she reported that she had symptoms the evening of the day she received the vaccine that consisted of hives on her arms, shortness of breath and felt like ""something was coming on"" and she was disoriented. Co-worker was treated and released from the ED the same day."

"Patient stated that 2 hour after shot stated to develop ""brain fog,"" fatigue, and pain/burning in injection arm. In am, was nauseated, slept all day, arm pain improved as did ""brain fog."" Did not feel this was an allergic reaction, but side effects that needed to be reported"

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Night sweats, body aches, temp 100, severe fatigue. Symptom onset approximately 6 hours after vaccine, resolution within 24 hours

Patient is first responder (EMT) did not disclose symptoms of illness at time of vaccination or would have been denied. Reported that he developed headache and sinus issues on 12/26/2020. Developed extreme arm soreness in arm of injection site and night-time onset of extreme chills. Presented at local health department 12/29/2020 9 AM for PCR testing and tested positive for SARS-CoV2 negative for Influenza A&B. Chills have subsided was of short duration - arm remains sore. Patient denies known route of exposure . Was active over the recent holiday - significant other (GF) scheduled for PCR during AM 12/30/2020 currently asymptomatic.

Significant exhaustion, headache, flu like symptoms, body and muscle aches, fever, chills

Swollen supraclavicular lymph nodes (2 bumps) 12/28/2020 7:00 pm 1 week after. None other side effects

EE developed tingling in left arm, tingling of tongue and roof of mouth, started feeling like her tongue/mouth was swelling. Was given 50 mg of Benadryl PO at 1255. Symptoms continued to worsen, to Emergency Dept at 1300. Was given IV solumedrol and Pepcid. Oral Zyrtec and discharged home. OK to RTW with out restrictions. Upon f/u EE did report a hive like rash on the right side of her body but this has since resolved as well.

Numbness, tingling of low lip, tongue, right side of face for 5 minutes. Hours later developed temp, 101.2, headache. Took a Claritin.

Fevers-101.3, 99.3, 99.1

On 12/28/20 at approximately 1700 hours I felt slightly drowsy and warm. I checked my temperature with a tympanic thermometer which read 98.4. At around 1900 hours I began to feel I had a fever and chills. Temperature was checked again and it read 101.2. I went to bed around 2200 hours where I continued to experience moderate fever and chills. At around 0100 hours on 12/29/20 I had profuse sweating, headache. I took tylenol PM and awoke at around 0730 hours on 12/29/20 and found I no longer had any symptoms.

Itchy Hands were red Itchy at injection site 2 days later got a migraine. from her elbows up everything was red, not hot or didn't break out in a rash.

Dizziness, migraine, neck pain, jaw pain? all on the right side

12/28/2020 flushed neck to face and R side face paralysis (duration for 30 minutes). symptoms resolved and pt feeling better No further symptoms to report

Nausea, which started around 1pm on the same day of vaccination.

Nausea, which started around 1pm on the same day of vaccination.

Loss of appetite/nausea

Approximately 35 minutes after the patient received the vaccine, she reported a muscle spasm and tremor in her right arm, numbness in her lower lip, nausea, jaw heaviness; numbness, tingling and weakness bilaterally in legs.

5 days after injection have a red welt around injection site 2 in wide by 1 in up and down

5 days after injection have a red welt around injection site 2 in wide by 1 in up and down

Loss of appetite/nausea

10:05am injection of moderna covid vaccine into left arm 1010am- started with tingling of left fingers 10:15 tingling increasing up arm, pressure feeling on left side of head and tongue 10:20am tongue feeling numb on left side 10:21am Benadryl 50 mg given PO Liquid 1030am Cetirizine 10 mg tablet given PO Physician observation for 30 minutes, symptoms resolved, still felt groggy, sent home

She has an area measuring 3x2 inches of red, warm tissue. The area is itchy, but I am concerned with a possible cellulitis brewing.

Loss of appetite/nausea

Stated she developed itching all over her body and a rash on her left side of her body. Was taken to ER for further evaluation. Reported to ER provider history of anxiety and panic attacks and stated she was unsure if she could possibly having and anxiety attack. Reported also having chest tightness. . Given Benadryl 50mg po, Ativan 1mg po, and Solu-Medrol 125mg IM. Relieve of symptoms

Fever, severe headaches, body aches, fatigue

On 12/19 when I got my vaccine at 5:00 pm. When I woke up tingling feeling fingers, feet, face and scalp of head. The following morning I notice a rash around my hairline. I called my associate health was informed to take Benadryl multiple times throughout the day and was prescribed Ativan. The itching is still occurring in my scalp of the head and feet. I dint have to miss any days of work.

Vaccine scheduled for 6:30 pm on 12/28/20. only new loss of taste and smell the next morning approx. 5:15 am of 12/29/20.

itcing and welp/hive at injection site

Pain in right arm lasting two days, headache lasting two days, dizziness lasting two days, and fatigue lasting three days

Pain in right arm lasting two days, headache lasting two days, dizziness lasting two days, and fatigue lasting three days

Pt presented to COVID Vaccine Clinic for first dose of Pfizer vaccine, which was administered. Pt complained of throat swelling and itching approx. 1 min later. Patient transferred to ED.

"A few minutes after receiving the Moderna vaccine, pt reported feeling ""warm and heavy,"" seeing spots. Felt faint right away. Pt pale and clammy. Does have a hx of anxiety and reports taking propranolol 40 mg prior to vaccination. She had this reaction prior to a Hepatitis A vaccine"

Approximatley 2 hours after injection, after arriving home and starting some housekeeping activities, vertigo started with nausea and sensitivity to light. It is going on 2 hours while lying down with eyes covered and some improvement in that eye motion is no longer sensitive.

Developed high fever of 103.2; body aches, headache at 7:00pm; this morning fever down to 99.7; continues with body aches and fatigue.

Pt described starting to have warm, red, swollen, tingly fingers on both hands and felt that her ears and back of her neck were hot/red. Upon examination - there was no warmth or redness noted on ears or neck; lungs were clear to auscultation. Her hands were a little pink but did not appear swollen. She was able to drink a large cool water and said holding the container in her hands felt good. She also noted her lips were a little tingly. A decision was made to offer her 25 m.g. benadryl p.o. - and she felt some relief within ~ 20 minutes of dose. She was able to return to work but did note she developed a headache and did take excedrin for that. Since this initial episode - she has felt extreme fatigue and body aches and those appear to continue to today (29Dec2020). She also has been experiencing chills and some itching on her torso. She also reported starting to have a bit of a cough and sore throat - so will see if she should go to COVID testing.

severe chills fevers and myalgias.

Diarrhea , 102Temp, Nausea and vomiting

Extreme pain at injection site, fever, headache, nausea, vomiting, metallic taste in mouth, muscle aches

Extreme pain at injection site, fever, headache, nausea, vomiting, metallic taste in mouth, muscle aches

Headache, nausea, stomach cramps, diarrhea

Client was vaccinated approx 10:00am at the Health Dept. Client left after 15min without incident. Client went to report to work and began feeling nauseated, dizzy, and feeling as if was going to faint. Client returned to Health Department approx 12:30. Client was diaphoretic, HR was 140bpm, and BP was 178/120. Client was given 50mg/20mL of diphenhydramine PO and EMS was called and client taken to local ER. Client remained A+Ox3 at time of EMS transport. Spoke with client evening of 12/28/2020. He reports he was transferred to another facility and was told was in a-fib. He reports that he is feeling much better but heart still fluttering. Spoke with client afternoon of 12/29/2020. He reports that he is

being discharged in a few hours and is being sent home on metoprolol and a baby ASA. He reports they had been working on getting his BP down. He reports that he is feeling better and is going to be scheduled for a heart cath outpatient. He reports that he was initially in a-fib, then a-flutter, and then arrhythmia. He reports that he has been seen by Dr. a Cardiologist, while hospitalized.

"Pt presented to COVID vaccine clinic for 1st dose of Pfizer, which was administered at 0739. Pt complained of itchy throat and ""unable to speak."" Pt was transferred to ED"

Rash on both thighs, hypersensitivity to touch, burning pain when walking and thighs touching, chills of feeling like getting sick

828a- covid injection left arm 836a- itchiness at site of injection in left arm 839a-hives at site of injection left arm physician notified 840a-benadryl 50 mg PO liquid given, zyrtec 10 mg given po 852a-symptoms resolving, pt feeling fine, no difficulty breathing or swallowing, no further increase in hives

Throat started to swell. Did not affect my breathing, but made it difficult to swallow. The employee health nurse gave me a Benadryl and monitored me for an additional 30 minutes or so. By the time I left, my throat was starting to feel a bit better. Never got any worse.

Swelling and pain at injection site, nausea, headache, muscle aches, chills but no fever

After 25 minutes started coughing, shortness of breath, wheezing, vitals taken,albuterol inhaler administered, wheezing and shortness of breath improved

Fever spiked at 102.6 then broke after 6am and tylenol 1200 po, blotchy red raised rash to rt side of body(harlequin in nature) only mainly torso and back extending to some anterior upper thigh and neck region went away around 1300 on 29th, severe HA, shakes, N/V, dizziness, severe body aches especially to neck amd ankles, injection site swollen x4 camaraderie to rt arm with heat for 12+ hours.

Patient began with a rash to trunk 20 minutes after vaccine Benadryl IM given as no other symptoms. Within 5 minutes he stated his throat itched and was sractchy Epinephrine 0.3 mg given IM then sent to ER as he needed monitored

Fatigue, chills, fever and now headache.

Employee reports Myalgia and SOB

dizziness, nauseas, dry mouth, Shortness of breath, see light spots Solu-Medrol 125mg IVP slowly Benadryl 50mg IVPB refer to ED

Monitored x 15 min per guidelines. Began to experience SOB and throat swelling, after which pt presented to the ED for tx, dx acute hypertensive urgency with severe hypertension.

Patient presented back at work with a rash on her chest, mouth felt tingly, had red blotches on her arm about an hour after receiving injection. Patient returned to ER and was given Benadryl and monitored for 3.5 hours.

"Pt presented to receive 1st dose of Pfizer COVID Vaccine, which she received at 1130. She emailed hospital leadership to describe a reaction which is as follows: I feel the need to inform you about a likely reaction I had to the COVID vaccine I received yesterday around 11:30 am. I was feeling fine after the immunization, drove home and took some Tylenol in case of any arm pain (of which I have had none). I ate some lunch, was on the phone talking with a friend and developed sudden onset of lightheadedness, slurred speech and extreme sleepiness. No other focal deficit. I actually got up and walked around to try to shake it off. But I suddenly felt so tired that I could not keep my eyes open. I called my husband and asked him to come home immediately. I laid down and tried to reassure my kids that I was fine. I don't remember much thereafter. Just bits and pieces. It felt like I was under general anesthesia, trying to wake up but not able to open my eyes or move my arms/legs. I could hear some things going on but could not talk. There were times I would ""wake up"" in my mind and I would check to make sure I could swallow and I was breathing ok. I remember mumbling to my husband that I could breathe. He says he was checking my vitals throughout this time and monitoring things. He said my Blood pressure was initially 80/60, pulse 50, and as he keep checking it gradually improved. This lasted about 2 hours and then finally I was able to wake up. I felt a little lightheaded and tired for the rest of the day, but I feel essentially normal today. Please note: age not provided in internal system report; unsure of person's age"

Upper lip numbness, bilateral midline. Possibly associated with very minimal swelling to the upper lip. Lasted a few hours. No other associated reaction.

Dizziness, racing heart , short of breath

Fogginess in the head, dry mouth, increased heart rate 120s-140s No treatment Lasted approximately 3 hours

Weakness, Headache, Chills, Fever, Nausea, Vomiting, Diarrhea

dizziness, chills, fever, muscle aches, tachycardia

Body aches, left arm soreness, chills

Received vaccine 12/26/2020, by 4:45 pm 12/27/2020 started feeling a headache. On 12/28/2020 it had become a migraine with nausea. On 12/29/2020 it is still a migraine with some vomiting and nausea.

The symptoms began 20 min after administration of the vaccine. The symptoms were: throat tightening and tongue swelling which self-resolved within 15 min. He did feel that there was difficulty swallowing which persisted. He had a sneezing fit when he got back to the vaccine clinic. He got very anxious. He felt that his hand was swelling and was cold. He felt that he was having itching in his arm where the vaccine was given.He was in his car when the symptoms began so he turned around and went back to hospital. His BP 153/98, HR 128. At this point, he felt that he had no blood in his hands and he felt he needed to do deep breathing. He was observed for 1.5 hours and the symptoms self-resolved with the exception of his HR which has persistently been > 100. He feels very anxious. No treatment was given. He has no symptoms at this moment, 3.5 h after vaccine administration.

Redness about 2 inches diameter swelling after hour Following several hours tenderness and swelling to bicep to lift and move and tenderness in armpit

Hot flash, tightening to throat, tingling to tip of tongue and lips. Mild to moderate. Began 5 minutes post injection. Increased for about 10 minutes, then leveled off but did not resolve. Seen in ER and given Benadryl 50 mg IV and Solu-Medrol IV, dose of Solu-Medrol not listed on ER visit summary. Observed for about an hour and a half symptoms resolved,and discharged. Rx for Prednisone 40 mg po x 4 days and Epi pen given.

Chills, Headache, Cough, Body Aches

Pain to right leg

So that night throughout I felt feverish around 100.9 the highest was 101F. I would break though and then 1-2 hours later again it would come back. Body chest, couldn't move my arm, the pain was severe. Tuesday I could not even sit down I felt so weak, I had rashes in my face, legs, chest. I was so weak, I fainted and hit my head twice while going to the bathroom and kitchen. I felt like I was constipated, ant then I had diarrhea, I did not have appetite but could not hold anything in, I would throw up. My left side was all numb. I could not feel anything. It was like that the while Tuesday. Wednesday body aches, rashes, numbness, but I had a little bit of a body strength and could walk on my own. Thursday I was able to start eating a little bit and constipation were stating to go way. Friday was just body aches. Sunday the rashes finally went away.

After vaccine started with dyspnea \Tx: Pepcid 20mg Benadryl 50mg Atrovent 0.5mg

Arm was very sore for several days. 6 days after injection -- upper left arm broke out in a red, itchy rash (12/28). On 12/29 the rash is more spread out on the left upper arm and is lighter red.

Chest heaviness, chills, headache, fatigue

ask for auscultation before she goes, found with wheezing Solu-Medrol 125mg IVP slowly Refer to ED

PATIENT STATES FEELS LIGHTHEADED AND FLUSH AFTER INITAL 15 MINUTE WAIT TIME. PATIENT HAD NO INCREASE IN HEARTRATE. PATIENT STATES HAS NOT HAD ANYTHING TO EAT TODAY. PATIENT GIVEN WATER AND PEANUT BUTTER CRACKERS AND OBSERVED ADDITIONAL 15 MINS WITH NO OTHER COMPLAINTS AND FEELS BETTER.

Chills, Shortness of Breath, Chest Pain, Arm Pain

Swelling, warmth, redness to left deltoid at injection site started 12/29/2020. Measures 3.5 inches vertical and 2 inches wide. Ice and advil.

After 15 minutes observation I drove home, ate almonds and took a hot shower. My face turned bright red over my cheeks and forehead and broke out in hives all over my face. I never had a reaction like this to nuts before and believe it may be from the vaccine. The redness lasted one hour the hives slowly subsided after a full day.

Within a short period of time my neck became stiff. I developed a headache and became unsteady on my feet. After sitting longer while being observed by our nurse I was allowed to leave. That night I woke up nauseous and vomited. The next day I develped muscle and joint pain. Similar to flu symptoms. Everytime I ate I felt nauseous again. All the symtoms disappeared about 42 hour later. I have had an annaphilatic shock to penicillin as a child.

Patient felt tachycardia, was hypertensive, HR 200, O2 wnl, skin with red blotches throughout shoulders, face and chest and had cold hands and more blotches on shoulder area, transported to ED urgently for further evaluation

Heachache, chills, muscle pain, and temp of 100.9

Nausea, face tingling

Patient received a Hepatitis B booster within 2 weeks of COVID vaccine.

Slight arm soreness, nausea and decreased appetite

TEN MINUTES AFTER VACCINATION, PERSON BECAME LIGHTHEADED, PALE, NAUSEATED AND C/O HEADACHE. SHE ALSO C/O OF BEING HOT AND COLD. HR AND BP ELEVATED AT 157/100 AND 130 BPM. PERSON SITTING WITH LOWER EXTREMITIES ELEVATED, ICE PACK GIVEN TO POSTERIOR NECK, JUICE AND ICE WATER GIVEN TO PT TO DRINK. RAPID RESPONSE TEAM ACTIVATED. PERSON RESTED AND MONITORED AT VACCINE SITE FOR ONE HOUR WITH IMPROVEMENT IN SYMPTOMS. PERSON STABLE AFTER THIS TIME AND ABLE TO GO HOME.

"Immediately Following vaccine: light headed (resolved) & left jaw pain 1 Day following vaccine: nausea, dizziness, headache - all resolved 2nd day following vaccine: fatigue- all resolved 12 days after vaccine: continued left jaw pain- described as consistent dull ache with intermittent ""nerve shock"", weird taste in mouth, left ear pain feeling full with ""crackles"". Patient has not reported symptoms or seen any health care provider since vaccination."

Patient reports having symptoms of nausea headache and Low grade fever.

1237pm- injection of covid vaccine into left deltoid 1240p-hives noted on left arm Benadryl 50 mg given po liquid 1241p-hives spreading rapidly on body physician notified, rapid response called epipen 0.3 mg IM given 1242p tingling of left arm noted 1245- transferred to observation unit on floor with RN/ physician present 1Pm-3pm, itchiness noted, some shakiness due to epipen, hives resolving 145pm 25 ng Benadryl po given one hour post epiepn given itchiness increasing on body, saying throat is itchy 245pm increasing itchiness, discomfort with swallowing solids, taking liquids, says he feels funny, sl lightheaded, did walk to bathroom to void Famotidine given 40 mg PO per Dr 330- remains very itchy, with dysphagia, some hoarsness, breathing comfortably, ambulance called and take to hospital.

CHILLS LIGHT FEVER MUSCLE PAIN ALL OVER MY BODY JOINT PAIN ALL OVER MY BODY GAIT BALANCE

Rash, itching

Itching, cough. Given benadryl 50mg and epinephrine 0.3 in vaccine clinic, and taken to ED for further tx.

Intense arm pain, site redness and swelling, site was warm to touch, increased nausea, decreased appetite, slight shortness of breath, and fatigue

Patient stated she felt experiencing potential angioadema and scratchy back of throat, additionally she was tachycardic and hypertensive

Elevated Blood pressure, dizziness, fatigue, Headache, Light headed , Nausea .

Headache, Fatigue, light chills. taking Tynenol. it is improving slowly.

Headache, Fatigue, light chills. taking Tynenol. it is improving slowly.

With five minutes of vaccine Increased heart rate shot up to 198 bpm. Regular resting heart rate for me is in the 50s. Left pupil dilated completely, right people constricted to pin size. Extremities went numb and ice cold. Went to emergency room Per request of EMTs at vaccination center. Was given high-dose Benadryl and Saline IV. Heart rate return to normal and all other symptoms disappeared after treatment.

Headache, Chills, vomiting

All other symptoms resolved, continued arm redness

Developed chest tightness, slight fever and headaches

Patient experienced hives all around her body she was give benadryl and within 5 minutes the allergic reaction seemed to resolve

After vaccine started with chest pain, dizziness and dry mouth Tx: Solumedrol 125mg Benadryl 50mg

PATIENT FELT LIGHTHEADED AFTER INITIAL 15 MINUTE WAIT TIME. PATIENT WAITED ADDITIONAL 15 MINS UNTIL HE FELT BETTER. PATIENT SYMPTOMS RESOLVED BEFORE HE LEFT.

Swollen lymph node under clavical on left side

Soreness at injection site starting 30 min after the infection.

Itching in hands, head and back of neck, dizziness. Benadryl 25mg given and taken to ED for further tx.

Patient is reporting injection site discomfort, body aches and a tactile fever (unable to measure fever due to no thermometer).

Chills, fever, running nose, fatigue, joint pains, muscle pain, nausea, loss of appetite; lasted two days. Took Tylenol

"Significant redness/rash to chest and back with itching, lips numb, dry mouth, itchy hands, ""feels like I've been hit by a truck"" 2 doses of Benadryl 25 mg IM administered at 11:42 am and at 12:19 pm. 3 hours later, patient still reports feeling like she'd been hit by a truck"

Pt reported feeling of lightheadedness, dizziness and had sweating a few minutes after receiving the injection. Pt is breastfeeding just an FYI.

Right arm pain. Nausea, body and joint aches.

Jaw pain Numb lips Hives over face and neck Hard to breath

Jaw pain Numb lips Hives over face and neck Hard to breath

Tingly lips and around mouth Swollen bottom lip 10 minutes post infusion Right top of mouth tingly

n/v headache T 101 on 12/27/20

soreness in arm of injection, about a 6 inch area

fever of 103F the morning after the vaccine, chills

covid vaccine given at 1030am 12/28/20 bed ridden from pain, dizziness, nausea, and lightheadedness from 2pm 12/28/20 to 4pm 12/29/20. severe muscle pain in L upper pain which peaked around 1230am generalized muscle aches dehydration even though constant fluid drinking nausea, lightheadedness, dizziness if speaking more than one sentence at a time, shortness of breath vitals (taken 5pm 12/29/20) BP 131/87 (normal is usually 116/56) HR 95-105 (normal resting is around 70s-80s)

Client received vaccine,while scheduling next appointment got hot , heart felt like it was pounding, felt like her throat was slightly tight. She immediately took a benadryl from her purse. When writer arrived client's B/P was 150/78 heart rate 98. Respirations even and unlabored. Skin pink,warm and dry. Client was kept for further monitoring. Upon discharge B/P 110/68 no signs or symptoms of distress. Informed to seek medical advice if any further problems.

Metallic taste in the mouth for 10-15 minutes post vaccination; started 10 minutes after vaccination. About 5.5-6 hours after vaccination, experienced rhinorrhea and epiphora for about 1-2 hours, which then progressed to mild nasal congestion and mild chest congestion. Also experienced mild headache and mild fatigue around the time of the congestion. Notable puffiness/swelling of the hands and face set in about 10 hours post vaccination; resolved by the next morning upon waking.

The evening following administration of the vaccine, patient had left-sided rib 2-7 muscoskeletal pain.

Severe cold symptoms beginning 2 days post vaccine, runny nose, cough, shortness of breath leading to ER visit on 12/28, covid test results still pending as of time of this submission

Received COVID vaccine on 12/19/2020. On 12/20, she experienced chills and fever (100.9) and body aches (shoulders, HA). UC visit on 12/21 and doing much better, essentially normal. Clinical Impression: Post-vaccination syndrome. Tested for COVID and flu on 12/21, received negative results on 12/22

Nausea, Fatigue, Minor Chest Pain

I got it on the 21st and ten mins after I had tingling sensation all the way down to my hands, dizzy 190/101 blood pressure, I was sent to Urgent Care and they did a EKG and it was normal I was discharged with BP 180/90, I had cold clammy hands that day, weakness, the next day I was week and fatigued. The 23rd I started having chills and numbness on the left arm. I never had a fever. I'm still not 100% back I'm still tired and I've been having palpitations. I have an appt with my primary Dr today 12/29/20 in the evening.

Patient reports dizziness, hot/flushed, and ears ringing; Patient placed supine x 15 minutes and provided water as requested. BP 128/72 HR 76 O2 sat 100% Patient denies any symptoms after 10 minutes. Observed sitting for another 15 minutes

Patient is a 40 y.o. female with no known past medical history brought to ED with concern for ALOC after getting the COVID vaccination 30-40 minutes PTA. Pt is a nurse and experienced decreased level of consciousness following her COVID vaccinationn. Pt reports h/o anaphylaxis. She was given epinephrine PTA. Denies SOB, oral swelling, CP. BGL within normal limits. Pt denies any other complaints or symptoms at this time.

"got flushed, trying to ""clear"" throat, labored breathing, bp elevated, pulse 120's 15 minutes after vaccine administration. Given 50 mg of po benadryl and at the advice of her physician, 0.3mg epi im in R thigh. After epi, patient breathing slowed, flushing slowed, BP and pulse remained elevated. Pt. expressed feeling better. History of multiple allergies and seen in clinic. Encouraged by physician to receive vaccine."

Strong migraines, fatigue, muscle pain, chills. Pain, tenderness, and swelling at vaccine sight.

Patient received the Moderna Vaccine within 5 minutes complained of throat tightness and not feeling well. The patient was noted to be pale and hypertensive. She was placed on a stretcher, placed on oxygen and a Rapid Response was called. MD responded and initiated IV fluids and administration of Pepcid 20 mg IVP. Patient was transported to the Emergency Department (ED) for further evaluation. In the ED, patient received Methylprednisolone succinate 125 mg IV x 1 dose and Diphenhydramine 25 mg IV x 1 dose. Patient reported relieve of throat tightness and upper chest pressure. Patient was discharged with prescriptions for oral Prednisone x 3 days, Pepcid 20 mg oral twice daily and Benadryl 25 to 50 mg every 6 hours as needed for and recurrent symptoms.

12/29/2020. 0430 I awoke with facial swelling including eyes/nose/lips. Slight wheezing, coughing & my skin felt like I had been sunburnt. I took Benadryl 25mg, Pepcid 20mg, Prednisone 10mg and I did an Albuterol Neb treatment. When I awoke at 0830, the swelling ,wheezing & burning had subsided. I was extremely fatigued & I had a 99 degree fever. The fever subsided ,but I remain fatigued. (12/29/20 @ 1615) It's important to note my past severe allergic reactions have always been delayed by 8-14 days. I do carry an epi-pen.

Body aches & sore left upper and lower arm.

About 28 minutes after receiving I started getting hot, I could feel my heart racing in my chest, my breathing quickened, rapid response was called taken into another room by then my fingers had cramped up to where I couldn't work then arms and legs felt like pins & needles. Sent by ambulance to nearest ER where I was given benadryl and Solu-Medrol by IV, given another dose before being discharged with a prescription for Methprednisolone a few hours later.

Difficultly breathing sweats then passed out

Cloudy vision in left eye

Immediately after getting the vaccine she complained of headache. She had warm feeling at injection site She H/A Thursday, Friday and Saturday at mid-day her boyfriend called and said weakness in Right arm right face droop, no speech she was taken to the ER at 1 pm approximately. She was admitted and was dx was CVA . 2 TIA on left side of brain. Stopped Birth control and physician said it could be a combination of both birth control and vaccine.

26 hours after injection, the person had hives on bilat upper ext, pt's back had some redness

Patient (aRN) felt dizzy was tachycardiac stayed in area for 1 hr symptoms persisted then was taken to ED there was no evidence of Anaphylaxis is. Patient stateds she was given to large of dose RN administering denies states gave 0.5 IM she was monitored for several hours because patient has cardiac history

We requested pt wait 30 min due to her hx of severe allergies. Initially after vaccination, she felt nauseated and looked a little flush. Gave her cold compress and she felt better and wanted to leave. We made her wait and around 20-25 post vaccination, she reported feeling itchy all over and then said her throat felt funny. We were administering the vaccine for a clinic for their hcp staff. Rather than using our benadryl and ER kit, we walked her down to the ER since we were right in the hospital.

Fever, chills, arm pain, horrible body aches and congestion

Headache, chills, vomiting

Difficulty catching my breath, stiff joints in legs

5 minutes post-vaccination, struggled to breathe, felt itchiness in throat, light-headed, dizziness, & tightness in chest.

I have had intermittent numbness in my left hand for about 1 week. The first 2 days were the worse. It is also resolved but still feels different from my right hand. I have not had any weakness.

Pt reported her lip swelling and lip tingling a few minutes after receiving the injection.

Throat numb and swollen metallic taste back of tongue numb chest tightness

Pt c/o nausea and headache. Reported very nervous about getting vaccine. 1013 Vital Signs - 139/80; HR 96, Spo2 99. 1018 reported I may be hungry VS - 129/75; HR 86: SPO2 100. 1025 VS 125/75; HR 86, sp02

100 reported HA, Warm, I am so nervous. At 1030 VS 130/83, HR 97 SPO@ 100 pt reported All I want to do is eat.

Body aches, chills, L arm pain (lasted 2 days-until 12/26) Swollen lymph nodes L arm (lasted at least 5 days, current)- have added warm compress.

"Received the COVID-19 vaccine 12/19/2020 and felt great the next few days with zero symptoms. About 3-4 days later I felt some chest discomfort especially when taking a deep breath in. This occurred on both the front side and back side of chest. This continued for the next 5-7 days. Kept experiencing pain with deep breaths and my exercise tolerance was diminished. When I would hike up a small incline I felt I was not getting enough air and was a bit winded. Finally made an e-visit with my healthcare provider on 12/28/2020 after 5-7 days of symptoms. Knowing I work in healthcare my provider asked if my pain felt like, ""pleuritic chest pain"" and I think that is a spot on description of how it felt. Based on my symptoms he told me the most likely diagnosis is a mild case of pericarditis and prescribed me ibuprofen 400 mg by mouth 3 times daily for a few days. After ~36 hours of ibuprofen I'm feeling 80-90% better but still have some discomfort with deep breaths or exertion."

Soreness in injection site arm, headache, sore throat

Headache, chills, vomiting, temp 100.3

I had my vaccine at 0910 and was instructed to wait 15 minutes post-injection to monitor for any reaction. While seated, at 0920 I felt suddenly extremely lightheaded, dizzy, and nauseous. I had a feeling in my chest like my heart was racing and I check my HR on my watch and it read 120-125 bpm. My baseline HR is 60-70 at rest. I notified staff immediately and was placed onto a stretcher. The rapid response team was called and I was brought to the emergency department on site for evaluation. In my recollection, my heart rate came down to the 70?s/80?s within the hour at which time the feeling like my heart was racing had subsided. The nausea was treated with 4mg IV Zofran. My lightheadedness, dizziness, and nausea resolved with a 1,000 mL NS Bolus. I was discharged home at approximately 1145 with a mild to moderate headache and generalized fatigue.

metallic taste, tongue tingling and numbness began within minutes and numbness took the longest to resolve--hours

patient received a dose of Moderna vaccine after receiving the Pfizer vaccine.

1037 Pt c/o dyspnea, metal taste in mouth and dizziness; 50 mg Benadryl given.. 1039 vs 160/112, HR 123; rr 20; spo2 98 - pt reports metal taste gone. 1044 VS 148/107; hr 94; rr 20; sp02 96; 1052 vs 162/106, 90 sp02 97 - pt said he felt fine and wanted to drive home. no further reports of any s/s first reported.

Started with nausea and racing heart rate on 12/21/20 then lymph node under left arm became swollen, warm and tender on 12/23/20 and continued through 12/28/20

I started on Sunday 12/27/20 with chills, body aches, headache (that was all over) reaction on my arm, felt like my arm was the size of baseball. I figured it was all from the shot because I, myself work in the health field so I knew these were all reactions. However, as the day went along the worse I got to feeling. I kept taking Tylenol (only thing I can take because of not having a spleen and having a bleeding disorder) and my headache would not go away. So, then at midnight I ended up checking my temperature and it was 100.4. As the night went on I still wasn't able to get rid of my headache and I had even started adding Benadryl along with my Tylenol and still wasn't able to get rid of it. I ended up talking to my Hematologist and she had recommended me to go to the ED to be checked out.

Chills and temp of 101

Pfizer-BioNTech COVID-19 Vaccine EUA About 3.5 hours after vaccine was administered pimple like rash appeared on right hand and wrist. Slight itch associated with rash. Rash still present on second day after administration.

"Patient felt a migraine aura that started about 8-10 min post-vaccination. She was experiencing pain around her left eye and some vision disturbance although no nausea which she stated she usually has. Patient was still at clinic waiting since it had not been past her 15 min time yet. We gave her some tylenol and had her move to a room that was a little darker and quieter and kept her for another 30 min (45 min total). Patient said she still felt like it was the ""beginning of a migraine"" and not feeling well. We called someone to come drive her home and sent her home for the rest of the day."

"12/29/20- Spoke to CG. Received Pfizer COVID-19 vaccine, dose #1 on 12/23/20 @ 4pm. Stayed in Observation area for 15 minutes without any problem. Suddenly, on 12/26/20 (3 days after receiving the COVIID vaccine), CG felt ""itching to throat, gum, mouth and body; itching head to toe"", also noticed ""lip, mouth swelling"" as well as ""wheezing"". Stated she has history of ""asthma"". CG then self-medicated with ""Claritin and Albuterol inhaler"" without much improvement on 12/26/20. Then the next day, on 12/27/20, itching to throat and mouth is resolving but still had shortness of breath and itching body. On 12/28/20, CG came to work but still experienced itching body and ""hard to breath"" when wearing surgical mask (required at work). CG was sent home and saw primary care physician (PCP) via virtual visit. Per PCP's evaluation, CG has had ""delayed allergic reaction"" to COVID-19 vaccine. PCP recommended CG to continue with Benadryl and Albuterol inhaler until recheck on January 4 for re-evaluation and discussion on preparation of 2nd dose with steroid and EpiPen. CG would like to complete the vaccination series to receive 2nd dose. As of today, 12/29/20- CG stated she still has shortness of breath and itching and will be off work until re-evaluation by PMD on Jan 4, 2021. Reviewed CG?s consent form of COVID-19 Vaccine- Date received 12/23/20 @3:37pm. Answer of NO to question ?Do you have a history of severe allergic reaction (e.g. anaphylaxis) to another vaccine or injectable medication??"

Fatigue Headaches Muscle pain Joint pain Fever Soreness at injection site

throat discomfort/ irritation

Arm soreness, same day Fever and chills, same day and 1 day after Fatigue, same day and 1 day after

Sore arm at injection site, about 6 hours after injection, ongoing Next morning stiff neck on left side, about 19 hours after injection, ongoing Swollen lymph node in neck area, collar bone, left side about 21 hours after injection, ongoing Tiredness, off and on, about 7 hours after injection, sporadically ongoing

Hot flushes with rash to chest

headache, 100.0 temperature

I got the shot at 115PM I waited and within a couple of mins I tasted metal on the left side of my tongue. the back of my tongue and my left cheek started to go numb and I was taken to the ER, my vitals were taken and was normal and was monitored for a couple hours, triptase was taken and they did bloodwork, the numbness climbed to the left side of my face from my eye to my jaw, they gave me antihistemines for the next 48 hours and was sent home. Saturday morning I went to the gym and felt fine and 24 hours later I felt complete fatigue like I had been hit by a bus, Sunday I had congestion and still numbness on my face. On Monday I got a call from an allergist, they couldn't figure out if it was an allergic or adverse reaction. I was put on a high dose of Allegra to see what it could be. Tuesday the congestion went into my lungs and was out of breath and was having trouble breathing. My PCM called me and asked me to video call and said I looked terrible. my pulse oximeter was 99. Wednesday when I woke up my difficulty breathing was starting to get better. I was tested for covid twice on Wednesday and both were negative. Wednesday to 12/28 I continued to have serious fatigue and I'm very active I feel much better 12/28 and 12/29 I feel better but I've had the numbness on my left side of my face this whole time and it feels like I've had Novocain I can't get rid of it.

PATIENT received the covid vaccine on 12/28/2020. He had two episodes of nausea and vomiting at 2 pm and at 3:30 pm on 12/28/2020 (about 3 hours after vaccination). Nausea and vomiting have resolved. Has bodyaches today. Denies fever, chills, cough, sore throat or HA.

SHORTLY FOLLOWING THE VACCINATION, PATIENT COMPLAINED OF ITCHING, REDNESS ON HER FACE, SCALP AND MOUTH. LEGS AND TORSO ITCHING ALSO.

Patient rec'd first dose of the Pfizer Covid-19 vaccine. About 5 minutes after she reported a hot peppery taste and her tongue felt hot. No other reported symptoms. Had the patient sit in observation for a total of 45 minutes with no worsening or new symptoms. Called patient 2 hours after event and symptoms have resolved.

Client reported dry mouth occasional cough and feeling warm after. Water provided leg elevation cool compress to neck reports feeling much better

sore throat, cough

2 minutes after she received the vaccine, she felt numbness at injection site that radiated across her chest and down her right arm. She was sent to the ED, no treatment needed and symptoms had resolved prior to her leaving the ED.

First day of vaccine, I had a really sore arm. Next day after vaccine, felt very fatigued that continued for 3 days. On 3rd day after vaccine, developed mild cold symptoms/sinus congestion. Day 5 after vaccine, lost taste and smell and tested positive for COVID-19.

1st day - muscle tenderness in injection site. 2nd day - around 11am headache, fatigue, chills, joint pain

Patient was nauseated and warm Ice pack to neck Denies further symptoms

Anxiety, arm soreness and chills

No adverse event. The vaccine was given 22 hours after the vial was punctured. The event was discovered three days later which was a Sunday at 10pm at night. The patient was notified the next day (12-28-20). The patient reported no side effects and was feeling felt great.

Took Benadryl at home before arriving at shot clinic - began to feel tightness & burning sensation in throat shortly after injection - taken to ER for observation and was administered prednisone

Extreme fatigue, fever, chills, headache, body aches and pain at injection site. I know they are all listed I just didn?t know if I needed to report them

headache, chills 100.0 temperature

"Patient was monitored for >15 minutes after vaccination. Patient told a nurse that her knees felt weak. Patient then fainted and was laying on the floor when i arrived. Patient reported she felt like she was ""floating"" and she did not want to ""fall"". She was also nausea and wanted to vomit and did not end up vomiting anything up. Patient fainted several more times. Her BP was around 143/80 and unsure about the pulse. Patient then become unresponsive for 20-30 seconds."

1:00 am to 5:00am the night after vaccine in morning. Chills and shivering severely. Body ache. Headache. No fever. Chills subsided. Mild Headache only symptom for remainder of day.

Moderna COVID-19 Vaccine EUA Approximately 16 hours after receiving the vaccine (8 AM), I was woken to hot flashes, sweating, and fever-like symptoms. My arm was also very sore and slightly bruising had occurred. My temperature at this point was 99 degrees. After taking Tylenol at 4 AM for arm soreness and Motrin at 8 AM, symptoms of aching and soreness subsided. At 2 PM I had not had medicine since 8 AM and symptoms resumed. My temperature was 100 degrees and I experienced chills and body aches. It is currently 6 PM and symptoms have mostly subsided, however, my arm is still sore and I feel faint fatigue and soreness all over.

Developed 2 hive like welts on chest that I thought might be bug bites because they were very painful itchy and swollen with fluid in them. After a few days more of them developed until there were about 22 on my legs, arms and chest. Very painful and inflamed and itchy. They are as painful as shingles but there are none on the midline or abdomen. I saw physician and he determined it was a reaction to the vaccine. I have never had a reaction to a vaccine before nor have I ever had welts as painful or like these. He prescribed prednisone which I am taking now. I have only finished one day of oral prednisone

and the swelling on the site have started to improve but I still have pain itching and have 3 new ones that have come up. One on the lateral breast and the other two on the anterior breast (superior).

headache, chills, temp 100.7

headache, chills, temp 100.7

Within 1-2 minutes: left hand felt numb and my body became very warm. Within 5-10 minutes: a huge headache. Within 30 to 45 minutes: Blood Pressure fluctuated, headache became worse, and chills started to occur. Within 1 hour to 1.5 hours: the headache became a huge migraine and my head felt like a bowling ball (I was still at work at this time.) Eventually, I could not lift my head off the desk. About 2 hours to 2.5 hours later, I felt so bad that I could not continue to work and head to leave work and go home. Upon arrival at home, the chills, aches, pains, migraine, some fever, eyes could barely stay open, and diarrhea started. About 7 hours later, a full blown Lupus flareup seemed to have started and/or it seemed to feel like a full blown case of the flu (if that makes any sense at all.) By the time I wrote this, all the symptoms have remained the same. I have had chicken soup, Gatorade, and bananas and treating this like the flu. I have continued to take my medication except for the Prednisone because I was told not to take the prednisone at the time that I was given the COVID19 shot at 9am this morning. I have stayed at home since I arrived at home around 1:30 or so...

Headache, body aches, chills, nausea and vomiting. Tool Ibuprofen at start of symptoms, and an additional dose later in the day.

Approximately 10 minutes after administration of vaccine, patient reports having dry mouth and some tightness and closure of esophagus (similar to what happens when patient eats shell fish), but not as severe. Patient was offered Benadryl, but declined. Patient drank some water to help relieve dry mouth. Blood pressure @4:30pm was 136/84. At approximately 35 minutes after symptoms started, patient reports being able to produce a little more saliva. Blood pressure @4:55pm was 118/87. Clinically stable. Symptoms are not progressing.

Individual began feeling dizzy and reported feeling painful sensation in her neck within approximately 5 minutes after receiving the vaccine. She was tachycardic in the 120s. She was encouraged to take deep breaths, offered water, and given 50 mg Benadryl IM in the right deltoid. After several minutes post Benadryl administration, her symptoms resolved. She was taken home by a family member.

Approximately 7 minutes after administration of vaccine, patient reports having tingling sensation on head and face. Symptoms lasted for approximately 10 minutes. Blood pressure @4:34pm was 140/87, HR=71. Blood pressure @16:52 was 150/73, HR=105. At 5:10pm, patient clinically stable. Symptoms have completely resolved. Patient released from vaccination clinic at 5:14pm.

headache

Vaccine administered at 7AM on 12/26/20. 12:00 noon, 101 fever, chills, joint and muscle aches same day. Took Ibuprofen to reduce fever, temp down to 99 by 6PM 12/26/20. Next day, 12/27/20, at 5AM temp back up to 101. Took Ibuprofen again and fever was gone by 5PM. Muscle aches and fatigue

continued through 12/28/20. 12/29/20 woke up feeling like I have a minor cold with some congestion. No fever as of 3:20PM on 12/29/20

During the observation time after receiving the vaccine, the employee report that her ears were read and warm. Employee noted to be squeezing her ears at time of concern. Employee evaluated by RN staff, no swelling, SOB or difficulty swallowing noted. Employee then reported onset of itching to her neck and ears. Employee was escorted to the Emergency Room for evaluation. Per ED physician note: 46 yo F c/o R ear redness, swelling and generalized itching. sudden onset just PTA. pt had COVID-19 vaccine approx 20 min ago. denies throat/tongue tingling/swelling or SOB. O2 sat = 100%, no acute distress, lungs clear, respirations non-labored, breath sounds equal, speaking in full sentences, no pharyngeal erythema or exudate.. Treated with diphenhydramine 50mg IV, famotidine 40mgIV, methylprednisolone 125mg IV and NS 1000 ml x 1.

patient experienced dizziness, lightheadedness approx 20 minutes after dosing. VS WNL BP 100/70, HR 80. Pt sat and drank water and put ice on her neck for approx 30 mintues

After administration of vaccine at 1:00 pm, I looked up and saw patient had fainted in chair, that time was maybe around 1:01 pm. When I rushed over to her, she regained consciousness, noticed she was not able to speak well, nurses removed her mask and we noticed her lips were swollen and was having an anaphylactic reaction, I then administered one dose of Epi-pen at 1:04 pm and called 911. We took her BP but it was high due to the Epipen injection, we tested her blood sugar. When the EMT arrived, they took over and took her to the ER.

Hives on neck takes Benadryl and refused to be seen

Loss of taste that evening only, some dizziness at time of vaccination - fatigue, muscle aches, nausea and declined in appetite. Symptoms have cont as of time of generating this report 12/29/2020 but has lessened in severity each day.

DAY ONE 12/22/2020- SORE INJECTION SITE, DAY 2 TOTAL BODY ACHES ON 12/23/20, FELT FINE ON 12/24/2020, 12/27/20 SWOLLEN LYMPH NODES AROUND THE CLAVICAL AREA WITH SORENESS IN THE INJECTION SITE, NUMBNESS AND TINGLING TO THE EXTREMITIES.

received injection at 13:04, went to observation area. reported brief dizzy spell at 13:20. Drank water, BP right arm 184/101, BP left arm 166/90 at 13:25. Patient reported only brief episode of dizziness and no further dizziness. User reports they ate lunch 1.5 hours earlier. BP 173/90 at 13:30. User reports she feels fine and will recheck BP when she gets home and follow up with her PCP. User waited 5 additional minutes before leaving with no further adverse effects. Total time of observation post injection was 30 minutes.

About 15 hours after the injection I developed sudden onset of chills, headache, nausea, dizziness and low back pain. The site of the injection was also throbbing. I had no side effects prior to this. It was severe enough that I had to call off of work. Symptoms resolved about 6 hours later. I have had no further symptoms since that time.

Fever 102.1 Chills Muscle aches Cough Headache

Fever, coughing, tachypnea, tachycardia

Right after vaccine, felt like she was freezing. Got home from work, took Tylenol felt achy, went to bed, woke up about 11:00 pm shivering really bad, breathing heavily, temp was 102.3, took more Tylenol. Up all night off and on with body aches, headaches, chills and fever. Felt the same way as when she had COVID.

Frontal headache, shivers, body aches, fever to 101.6F.

Received vaccine at 13 15. At 1351 c/o mild chest pain. 1353 c/o throat fullness and anxiety; 1354 bp 148/81 HR 99 O2 sat 100% c/o difficulty swallowing, SOB and itching. Rapid response called. Benadryl 50 mg IVP given at 1355. 1356 Solumedrol 125mg given IV; 1357 Epinephrine given; 1358 Pepcid 20 mg given. 1400 Normal saline 250 mg IV; 1415 transported by ambulance to local ER. In waiting area in local ER no attention. Came back to Hospital and admitted to observation

Developed skin reaction (hives). Treated with 25 mg of Diphenhydramine orally and observed for additional 30 minutes. Hives subsided and patient released.

developed headache, body aches and fever - has since resolved

headache/chills/weakness

Patient reported that immediately after receiving the vaccine she felt lightheaded, dizzy, like she might pass out. She felt as though her throat was more swollen and she had difficulty swallowing. She had no hives, shortness of breath, or difficulty breathing. No myalgias, sore throat, cough, or wheezing.

Facial/ arm numbness and tingling

Soon after IM vaccine c/o sore & swollen arm for 2 days. Also felt weak, shaky and tired for those 2 days

About 4 hours after injection, pain at injection site started. 5 hours after injection, fatigue, body aches, and fever and chills occurred. Symptoms subsided for several hours until night time. Severe nausea occurred sometime around 1:30 am, a little 12 hours after injection. Vomiting happened at 5am. The entire next day after injection I experienced nausea, fatigue, sore throat, headache and fever.

High fever to 102 with uncontrollable shivering and chills beginning apx 12 hours after injection, improved with ibuprofen but not resolved, fever continued x 16 hours

18 min after injection. Throarlt began tonitch and feel tight, chest pressure. Light headed. Epi 0.3 given, sent to er, provided with solumedrol, benadryl, pepcid, ativan and 1750 cc of fluid. Released from hospital at 330.

- arm tenderness. Initially felt like routine flu vaccine. After 12 hours, arm started to increase in tenderness, more similar to other vaccines such as TdaP or tetanus. Gradually resolved at 72 hours. - Mild malaise developed at 24 hour mark (1st day post injection). Checked temperature at 28 hour post

injection with 1 degree Fahrenheit higher than normal forehead temperature using Exergen thermometer. Subtle myalgia during the evening. Symptoms resolved after sleeping, which should be at 40 hours after injection. Slightly less than normal physical stamina between 40-50 hours post injection (2nd day post injection). Symptoms have completely resolved after the second night sleep (66 hours post injection or 3rd day post injection). Injection was on Saturday 2:00pm. Completely symptom free on Tuesday.

Next day after the vaccination, the patient(staff member) came back to the vaccination clinic and stated that she felt numbness and tingling along the smile lines of her face and around her lips. She was monitored for about 40 minutes then she reported difficulty of swallowing. At first reported symptom of swallowing difficulty she as administered diphenhydramine 50 mg oral liquid by mouth. After about 30 minutes of continued monitoring, epinephrine 0.3 mg IM was administered. At the same time 911 emergency response was called and the patient was transferred to the acute care hospital.

Four hours later after received vaccination he complaints of tingling sensation in both cheeck with associated edema and redness. Treated with Solumedrol 125 mg IV and Benadryl 50 mg IV. Patient improved and was discharge with instruction .

Sustained slight but rapid muscle twitching in the deltoid muscle of the injection (left) arm. Noticable the afternoon of post injection day #1. Twitching continued for approximately 1 hour then ceased. No other side effects reported other than minimal arm soreness that didn't interfere with daily activity

Received dose @ 1445; 1458 had a cough and itchy throat and flushed; Bp 162/103 HR 86 Sat 99%; At 1459 gave IV push solumedrol 125 mg; 1510 bp 150/93 hr 80; sat 99%; feeling better

Hives on neck, face, upper chest, and back. Increased heart rate. Metal taste in mouth. Zyrtec given and monitoring Relief after about an hour

Onset of herpes zoster (shingles) - right anterior thigh

Moderna COVID- 19 Vaccine: During observation period after receiving the vaccination patient reported headache, nausea, and dizziness. Vital signs: blood pressure: 111/73 mmHg, pulse: 56 beats per minute, oxygen saturation 100%. Patient reports that she is typically hypotensive and does become nauseous somewhat frequently. Patient offered water and snacks. No loss of consciousness or respiratory symptoms reported. Patient observed for at least 30 minutes and left vaccine clinic in stable condition.

fever 102

nauseated; sensitivity to light; sweaty; hypertensive; tachycardic.

Received vaccine on 12/22/20, on 12/25/20 noticed redness, hives, and itching on the left arm where received vaccine. Took Benadryl on 12/25/20 and 12/26/20. Reported on 12/29/20, and feels itching with some redness subsiding, no pain.

12/24 EVENING c/o being so cold causing shivering. Not normal for pt. Also arm pit area swelling for a bit. All symptoms resolved on 12/25/20.

Morning of day after vaccination had headache, fever, chills, joint pain, muscle aches. 2 days after vaccination same symptoms also diarrhea and positive COVID-19 test.

Moderna COVID - 19 VACCINE Sorearm in left arm Chills Severe headaches Nausea and vomiting

flushed and nauseous and anxious and dry cough; dizzy; hypotensive

METALLIC TASTE IN MOUTH ABOUT 10 MINUTES AFTER VACCINE. NO OTHER SX.

Feeling dizzy and light headed 30 mins after injection. One hour later felt nausea and dizzy. BP 177/73, and 156/70-72 w/ repeat. Symptoms improved with Tums.

fever 103'

"Patient received the covid vaccine on 12/22/2020. No problem with the vaccination. Reported new onset of ""dry cough"" and nasal congestion started on 12/29/2020. Denies fever, chills, HA, body aches, or fatigue. Last covid test on 12/17/2020 was negative."

Complains of left arm swelling and pain. She had the COVID-19 vaccine on December 23. The next day she had some mild pain at the injection site. She massaged it and use Tylenol. On December 24 he developed pain down all of her left arm. On the 25th she had complete loss of sensation and feeling in her left hand for about 3 hours. Then the arm seemed to tingle and feeling came back. That night she developed pain down in her wrist. Complains of some swelling in the left forearm. That area is burning and throbbing. Pain is affecting her sleep. She has tenderness to palpation on her wrist area. She also has pain with with wrist movements. . .

Pain in area of inyection (left arm), mild rash in chest area

Approximately 5-7 minutes after receiving vaccine, I experienced a rapid increase in heart rate along with a head rush. I then was shaky and lightheaded and was told extremely pale. I then noticed the back of my tongue was slightly swollen and I had a tightness/itchy feeling so n my throat. My pulse was checked at 120bpm, Approximately 10 minutes later my lips were tingling and numb. I was given Benadryl and prednisone. 1.5 hours later since my symptoms did not go away I was escorted to the ER for epinephrine.

12/28 Difficulty falling asleep, Awake in middle of night w/ achiness - couldn't get comfortable. This morning c/o headache, feeling exhausted and weak.

staff member received his first injection in the left arm. As staff was waiting for his time of observation, he stated he could feel his blood pressure rising. When assessed, his blood pressure was 196/119. Staff member stated to the MD he takes medications for hypertension but was unable to state what that medication was. He says he just takes what he was given. Staff member stated he was having a hard time breathing due to his blood pressure and was given supplemental oxygen at 3L per nasal cannula.

O2 was 98% throughout. 911 was called to assist staff member to ED for evaluation of symptoms. While taking staff member to meet the ambulance, via wheelchair, he stated he believes he forgot to take his medication for the day. Ambulance took staff to ED with no noted complications.

Immediately after receiving the dose, I developed lightheadedness, nausea, sweating. This worsened for 15 minutes, then slowly subsided over several hours. The next day, I was a little fatigued, but returned to baseline by the evening. On the 2nd day after vaccination, I developed uncontrollable violent rigors and PACs, along with fatigue and vertigo. These symptoms improved on days 3-5 after the vaccine, but returned on day 9 with worsening rigors and PACs. I also developed substernal chest pain on day 5. Now, day 9 post vaccination, and I'm feeling unwell. Main symptoms are chest pain, PACs, intermittent rigors, vertigo.

Pfizer-BioNTech COVID 19 Vaccine Starting at 20-minutes post vaccination and lasting for approximately two hours, patient experienced episodic tachycardia (HR 123-200), flushing of face and arms, and tingling sensation in upper body lasting up to 5-minutes per episode. Episodes were 20 minutes apart and decreasing in severity. Patient medicated after second episode with 25mg/Benadryl, 40mg/prednisone, and 20mg/pepcid. Side effects resolved within 40 minutes of medicating.

Pfizer-BioNTech COVID-19 Vaccine: Soon after vaccine administration patient reported dizziness, trouble swallowing, paresthesias in both hands, shortness of breath, anxiety, and one episode of vomiting. Patient was transferred to the emergency department where initial vital signs were: blood pressure 161/84 mmHg, pulse 97 beats per minute, temperature 36.9 degrees Celcius, respiratory rate 16 breaths per minute, and oxygen saturation 98%. The patient presented alert and oriented in no acute distress. On exam no rash, edema of the uvula or tongue, respiratory distress, wheezing, rhonchi, or rales were noted. Patient was administered one dose each of lorazepam and ondansetron and was discharged.

I previously had covid the first 2 weeks of november** Symptoms of adverse reaction included: -severe pain and limited movement of injection site - large amount of redness and swelling at injection site - fever of 101.2 - body aches and chills - headache

drooping OF LEFT EYE, twitching, weeping of left eye. Upper eyelid of left eye puffy and red. Chest tightness

"""Pfizer-BioNTech COVID-19 Vaccine"": left-sided facial bell's palsy; facial drooping mostly resolved, minimal eye drooping on left side; headache; Tylenol taken for headache; headache has resolved;left-sided sensitivity to loud noises; hearing sensitivity resolved"

Mild headache, significant fatigue, runny nose

Severe headache, nausea almost to vomiting, body aches, injection site inflamation/pain,

itching (full body), sore throat, L ear pain

Diarrhea

physician/patient with history of anaphylaxis to shellfish - symptoms of tingling tongue & syncope. no longer carries epi pen sue to ability to avoid food. 10 minutes post vaccination pt/physician experienced tongue tingling similar to prior anaphylactic events. administered 25 mg. Benadryl po. no further issue, vital signs stable throughout & later in evening.

chest tightness, tongue tingling, tachycardia, hives on left arm

Unilateral facial numbness, tingling, and swelling

"Metallic taste in mouth, dizziness, weakness, altered mental status, difficulty raising arms, ""heavy like a slug"", HR 81, BP 112/78. reaction immediately after vaccination. Symptoms did not resolve after an hour. Patient taken to ER for evaluation."

rash, dizziness, neck pain, hypertension, vomiting, mydriasis, diaphoresis: neck pain started within 10 mins, while other symptoms proceeded after about 20-30 mins.

Temporary Numbness of facial muscles

Days 1-4 - low grade fever (100.8) swollen lymph nodes and extreme sore throat and lethargic. Day 5 no fever but swollen lymph nodes and sore throat. Day 6 congestion, no taste or smell.

10 MINUTES FOLLOWING VACCINE - SOB, COUGH, TIGHTNESS IN CHEST, THRAOT SWELLING, DIFFICULTY SWALLOWING, LIGHT HEADEDNESS, AND ELEVATED HEART RATE. ORAL AND IM BENADRYL ADMINISTERED, 2 DOSE OF EPINEPHRINE, 2 NEB TREATMENTS, O2 PLACED. 911 CALLED AND TRANSPORTED TO EMERGENCY FOR FURTHER TREATMENT AND MONITORING. AT HOSPITAL IV STEROID ADMINISTERED. SYMPTOMS SUBSIDED WITH SECOND DOSE OF EPINEPHRINE, HOWEVER RETURNED 3 HOURS LATER AND ANOTHER DOSE OF BENADRYL ADMINISTERED. ELEVATED HEART RATE CONTINUED AND IV FLUIDS ADMINISTERED TO ATTEMPT IN BRINGING DOWN HEART RATE. IV FLUIDS WERE NOT EFFECTIVE. HEART RATE (118-120) REMAINED ELEVATED INTO THE OVERNIGHT HOURS AND SUBSIDED AROUND 1:30A ON 12/29/2020. CONTINUED HEADACHE, NAUSEA ONSET, FATIGUE, DIFFICULTY SWALLOWING AND COUGH ON 12/29/2020.

Shingles outbreak mostly lesser occipital nerve distribution

Got shot on Tuesday. On Sunday night had cough and congestion and little fever. Going to do COVID testing this morning. Is feeling better today.

I received my Moderna vaccine 12/28/2020. First symptom began that day with pain, soreness of injection site. Later throughout the day I began to have chills, and body aches. I had a sleepless night. The following morning 12/29/2020, I still felt chills, body. Then, I felt nausea, and headache. I slept most of the day today since I felt fatigue too, but it's better than going through Covid .

Face turned red,sweating,cold clammy skin, throat constricted

Atrial fibrillation

The morning after getting vaccine, patient had high BP 213/159, 92% on room air, shaking, chills, LCTAB with diminishment at bases, emesis. Admitted to hospital for pneumonia.

Muscle tightness to bilat shoulders and neck. Tension headache. Rash across shoulders and chest.

Sore arm, body aches, mild fevers for 48 hours

Bad Headache, nausea, extreme body aches

Pt had felt little tingling effect in mouth and mentioned about having an allergy shot today.

Hives from Head to toes. Swollen ears, slight lip swollen, fever 101

12/23/2020 developed left ear pain and next day experienced drooping of left side of face, difficulty blinking left eye Bells Palsy

Chills, fever, fatigue, headache

Vaccine administered with no immediate adverse reaction at 11:29am. Vaccine screening questions were completed and resident was not feeling sick and temperature was 98F. At approximately 1:30pm the resident passed away.

Injection site pain 4-36 hours after dose. Headache 12-36 hours after dose. Joint pain 12-36 hours after dose. Fatigue 12-36 hours after dose. Chest tickle 24-36 hours after dose. Tooth ache 4-36 hours after dose.

His wife ended up contracting Alpha-Gal by Ticks; This is a spontaneous report from a Pfizer-sponsored program Pfizer First Connect via contactable consumers (patient's husband, and patient herself). A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient medical history and concomitant medications were not reported. The patient ended up contracting alpha-gal by ticks on an unspecified date. The reporter asked about the ingredients of the COVID-19 vaccine, if it contains mammalian cells, dairy, guinea pig 1 cell, or cholesterol origin. Outcome of the event was unknown. Information on the lot/batch number has been requested.

near syncope episode, orthostatic; feels a little foggy; This is a spontaneous report from a contactable Physician. A 38-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), via an unspecified route of administration on unspecified date in 2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The emergency medicine physician was monitoring a patient that came in from a vaccination event, stated that it was Pfizer BioNTech Covid 19 vaccine. The patient had a near syncopal episode. They did orthostatics (unspecified) and found that she was orthostatic (near syncope episode, orthostatic). There was no anaphylaxis reaction or allergic reaction. She still felt a little foggy. The physician did a blood glucose, labwork and EKG that look good. The physician wanted to know if there was any data for things that they should looking for with the vaccination and will direct the patient to

contact Pfizer to report it. The outcome of the events was unknown. Information on the lot/batch number has been requested.

Sore arm; Dizziness; Tiredness; nausea; fever of 102¦F; severe headache; This is a spontaneous report from a contactable consumer (patient). A 20-year-old female patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899, expiration date unknown) intramuscular at the left arm on 18Dec2020 at a single dose for COVID-19 immunization in the hospital. Medical history included allergy to Sulfa from an unknown date. Concomitant medications included escitalopram and clonazepam. The patient did not receive any other vaccines within 4 weeks prior to the vaccine. It was unknown if the patient was diagnosed with COVID-19 prior to vaccination. The patient experienced sore arm after first 8 hours; dizziness, tiredness, nausea, fever of 102 F and severe headache all on an unspecified date in Dec2020 (reported as 12Dec2020 at 01:15 AM). The patient was tested for COVID post vaccination and had a nasal swab with negative results. The patient recovered from sore arm, dizziness, tiredness, nausea, fever of 102 F and severe headache all on an unspecified date in Dec2020.

Fever of 101.0; sore throat; light headedness; aches; chills; excessive sweating; nasal congestion; This is a spontaneous report from a contactable healthcare professional. A 32-year-old female patient received BNT162B2 (lot number and expiry date unknown) at a hospital, at age 32-year-old, intramuscular, on the left arm on 21Dec2020 19:45, at single dose (dose 1), for COVID-19 immunization. Medical history included anemia, anxiety, and urticaria. Patient was also diagnosed with COVID-19 prior to vaccination. Patient is not pregnant at the time of vaccination. Patient did not receive any other vaccines within 4 weeks prior to the COVID-19 vaccine. Concomitant medication included ethinylestradiol, norgestimate (ORTHO TRI-CYCLEN), lorazepam (ATIVAN), clonazepam (KLONOPIN), and diphenhydramine hydrochloride (BENADRYL) from unspecified dates. The patient previously took hydrocodone/acetaminophen (VICODIN), oxycodone / paracetamol (PERCOCET), pseudoephedrine hydrochloride (SUDAFED) on unspecified dates and had known allergies. On 21Dec2020 at 23:00 , the patient experienced fever of 101.0, sore throat, light headedness, aches, chills, excessive sweating and nasal congestion. No treatment was received for the events. Since the vaccination, has the patient has not been tested for COVID-19. The outcome of the events was recovering. Case is reported as non-serious. Information on the lot/batch number has been requested.

hives and sore throat the day after receiving COVID19 Vaccine; hives and sore throat the day after receiving COVID19 Vaccine; This is a spontaneous report from a contactable Nurse. A 46-year-old female patient started to receive BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Lot number: EL0140, Expiry Date: 31Mar2021), intramuscular (injection left deltoid) on 18Dec2020 (around 1621) at single dose for COVID-19 immunization. The patient medical history and concomitant medications were not reported. The patient has no prior vaccinations. The patient experienced hives/ She had body hives all over and sore throat the day after receiving COVID19 vaccine on 19Dec2020, within 24 hours. The patient took BENADRYL and was fine. Reporter was not sure if the patient would receive the second dose. The adverse event did not require a visit to the emergency room nor physician office. Outcome of the event was recovered on 19Dec2020.

headache; fever/as high as 102.9 degrees Fahrenheit, now (22Dec2020) it's just over 100.0 degrees Fahrenheit; This is a spontaneous report from a contactable nurse. A 31-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), lot number: EK5730, via an unspecified route of administration, at the right arm, from 17Dec2020 18:30 at a single dose for covid-19 immunization. Medical history included attention deficit hyperactivity disorder (ADHD), osteoarthritis (OA); patient already suffer joint pain and her current joint pain is no worse than usual, Raynaud's, palpitations and joint pain. Concomitant medications included amfetamine aspartate monohydrate, amfetamine sulfate, dexamfetamine saccharate, dexamfetamine sulfate (MYDAYIS); amfetamine aspartate, amfetamine sulfate, dexamfetamine saccharate, dexamfetamine sulfate (ADDERALL); and ibuprofen (IBUPRO). It was reported that the patient has had fever daily. Initially on 18Dec2020 at 9:00, it was as high as 102.9 degrees Fahrenheit, now (22Dec2020) it's just over 100.0 degrees Fahrenheit. She also has had a headache daily(reported as started on 18Dec2020 at 9:00), but today's headache is much worse than previous days. The patient underwent lab tests and procedures on 18Dec2020 which included sars-cov-2 test/COVID-19 test/nasal swab with negative result. Outcome of events was reported as not recovered. Therapeutic measures were taken as a result of events headache and fever included OTC medications (unspecified). Follow-up attempts are completed. The information on the batch/lot number was obtained.

Chills; joint pain; muscle pain; This is a spontaneous report from a contactable other healthcare professional (patient). A 21-year-old female patient (not pregnant) received first dose BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899), intramuscular (Left arm) on 22Dec2020 09:30 at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient was not diagnosed with COVID-19 prior to vaccination. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. There were no other medications received within 2 weeks of vaccination. The patient experienced chills, joint pain, and muscle pain on 22Dec2020 (19:00). There was no treatment received for the adverse event. The patient has not been tested for COVID-19 since the vaccination. The outcome of events was recovering. This case is non-serious.

Fever; chills; body aches; headaches; malaise; chest pain in side-lying; cough; diminished appetite; This is a spontaneous report from a contactable healthcare professional. A 30-year-old male (also reported as female) patient received the first dose of BNT162B2 (Pfizer-BIONTECH Covid-19 Vaccine; Lot number: EH9899), intramuscular in the left arm on 17Dec2020 at 15:45 at a single dose for immunization. The patient had no relevant medical history. The patient din not have Covid prior to the vaccination and had no known allergies to medications, food, or other products. The patient's concomitant medications were not reported. It was reported that the patient had no other medications in two weeks and did not receive any other vaccines within four weeks prior to the COVID-19 vaccine. The patient experienced fever, chills, body aches, headaches, malaise, chest pain in side-lying, cough, and diminished appetite starting at 11pm (23:00) on 17Dec2020 and gradually decreasing mild symptoms still present on 22Dec2020. The patient received no treatment for the adverse events and was not tested for COVID-19 after the vaccination. The facility where the most recent COVID-19 vaccine was administered was at the hospital. The outcome of the events was recovering. The case was reported as non-serious (did not

result in death, was not life-threatening, did not cause or require prolonged hospitalization, was not disabling/incapacitating, and did not result to any congenital anomaly/birth defect).

Left arm pain; generalized malaise; i was wiped out and wanted to sleep all day; This is a spontaneous report from a contactable Nurse. A 52-years-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Lot number: EJ1685), via an unspecified route of administration on 22Dec2020 07:15 at a single dose (dose number 1, left arm) for COVID-19 immunization. Medical history included HIV+ and COVID-19 from an unspecified date. Concomitant medication included bupropion hydrochloride (WELLBUTRIN), trazodone, oxazepam (SERAX), valaciclovir hydrochloride (VALTREX), and ibuprofen from an unspecified date for an unspecified indication. The patient has allergies to Tegretol and AZT. The patient was diagnosed with COVID-19 prior to vaccination. The patient had no other vaccine in four weeks. The patient experienced left arm pain, generalized malaise (he was wiped out and wanted to sleep all day) on 22Dec2020 09:00. Treatment was not given. Event outcome was recovering. Since the vaccination, the patient has not been tested for COVID-19. The events were assessed as non-serious.

"vertigo; left facial tingling; lip tingling/tingling in the left corner of the mouth; he feels hazy/Haziness; facial numbness; heaviness and tingling in the left corner of the mouth; This is a spontaneous report from a contactable physician (patient). A 32-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (lot number EL0140), via an unspecified route of administration on 18Dec2020 08:15 am at single dose for covid-19 immunization. Vaccine location was left deltoid and it was the first dose. The facility type vaccine was hospital. Medical history included raynaud from an unknown date. The patient clarified that Raynaud's is not officially diagnosed. When he was in medical school and would take Methylphenidate to study his fingers would get pale and in cold weather he gets it in his hands. No known allergies. Patient didn't do relevant test. There were no concomitant medications. The patient didn't receive any other vaccines within 4 weeks prior to the COVID vaccine. Physician stated that received COVID-19 Vaccine on Friday. A couple of hours later he had left facial tingling and lip tingling that lasted about an hour. The left facial tingling and the lip tingling started between 9AM and 10AM. It felt like facial numbness and heaviness and tingling in the left corner of the mouth. It was less tingling and more of a heaviness. Vertigo started on the second night (19Dec2020). Whenever he sit back in a chair quickly he has vertigo as well as when he laid back in the bed at night. He took no medications. Throughout the day he felt hazy. Haziness that is consistent. The best way to described it is if you drank a lot of alcohol and were well hydrated. The next morning you feel fine, but there is something there and feels off, but you can't put a finger on it. There was no adverse event require a visit to emergency room or physician office. The action taken in response to the events for BNT162B2 was not applicable. The outcome of events ""left facial tingling"" and ""lip tingling"" was recovered on 18Dec2020 and were reported as non-serious. The outcome of event Vertigo was not recovered, it was reported as serious-Medically significant. The outcome of other events was unknown. The drug result of events ""Vertigo"", ""left facial tingling"" and ""lip tingling"" was Related.; Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of event Vertigo cannot be totally excluded. The case will be reassessed if additional information becomes

available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate."

cold tingling sensation in right hand; sore right arm; This is a spontaneous report from a contactable consumer. A 56-years-old female patient receive BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Lot number: EK5730), via an unspecified route of administration on 18Dec2020 at a SINGLE DOSE (injection to right arm one time) for COVID-19 immunization. Medical history included Pencillin allergy, diagnosed with a sulfur allergy in her 20s and developed a rash (ongoing). There were no concomitant medications. The patient experienced cold tingling sensation in right hand in hand in same that had the injection, and sore right arm, few minutes after the injection on 18Dec2020. Treatment for sore right arm included, 24 hours after took ALEVE and did gentle stretching exercises. Event outcome was recovered completely on 18Dec2020. Event outcome was recovered on 18Dec2020.

Head cold; cannot smell or taste anything; cannot smell or taste anything; This is a spontaneous report from a contactable nurse (patient herself, ICU nurse). A female patient of an unspecified age received bnt162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, lot number and expiry date not reported), via an unspecified route of administration on 18Dec2020 at a single dose for COVID-19 immunisation. Medical history and concomitant medications were not reported. After receiving the vaccine on 18Dec2020, she had a head cold, she cannot smell or taste anything. Clinical outcome of the events was unknown. Information about Lot/Batch number has been requested.

hoarseness; throat tightness; flushing; This is a spontaneous report from a contactable consumer. An adult female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, lot number and expiry date not reported), via an unspecified route of administration on 23Dec2020 at a single dose for COVID-19 immunisation. Medical history was none. Concomitant medications were not reported. On 23Dec2020, the patient experienced hoarseness, throat tightness and flushing. Therapeutic measures were taken as a result of the events that included epinephrine, steroid, and Benadryl. Clinical outcome of hoarseness was recovering, while for the other events was unknown. Information on the lot/batch number has been requested.

experiencing tingling sensation in my throat and some tightness; experiencing tingling sensation in my throat and some tightness; This is a spontaneous report from a non-contactable pharmacist. A 41-year-old female patient started to receive BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Lot number: EK5730), via an unspecified route of administration on 22Dec2020 15:30 at SINGLE DOSE (right arm, dose number 1) for COVID-19 immunization. The patient has no medical history. The patient's concomitant medications were not reported. Patient has no known allergies. The patient experienced experiencing tingling sensation in her throat and some tightness on 22Dec2020 15:30, 1 to 2 minutes after vaccine administration. After 10 min symptoms started going away and completely disappeared in 30 minutes. Patient did not had other vaccine in four weeks nor other medications in two weeks. Patient has no prior COVID vaccination and was not tested for COVID post vaccination. Patient is not pregnant.

Treatment was not received. Outcome of the event was recovered on 22Dec2020 16:00. Events were reported as non-serious. No follow-up attempts are possible. No further information is expected.

Fatigue; This is a spontaneous report from a contactable nurse (patient). A 50-year-old male patient received first BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899), intramuscular (left arm) from 21Dec2020 (09:45 AM) to 21Dec2020 at single dose for COVID-19 immunization. The patient's medical history included hypertension, hyperlipidemia, and Type 2 diabetic. No known allergies. Concomitant medications included amlodipine besilate, olmesartan medoxomil (AZOR), atorvastatin calcium (LIPITOR), metformin, insulin glargine, lixisenatide (SOLIQUA), and empagliflozin (JARDIANCE). The patient was not diagnosed with COVID-19 prior to vaccination. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient experienced fatigue on 22Dec2020 12:00 with outcome of recovering. There was no treatment received for the adverse event. The patient has not been tested for COVID-19 since the vaccination. This case is non-serious.

I have some aches which feels like the same I had; This is a spontaneous report from a contactable Other HCP (patient). This 52-year-old female patient reported that she received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via intramuscular at left arm on 23Dec2020 at 12:45 AM at single dose for COVID-19 immunization. Medical history included patient diagnosed with COVID-19 in Oct2020. No allergies to medications, food, or other products. Concomitant medication was none. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient received no other medications within 2 weeks of vaccination. Since the vaccination, the patient had not been tested for COVID-19. After vaccination, patient had some aches on 24Dec2020 07:00 AM, which felt like the same she had since she did have Covid the first part of Oct2020. It was reported as non-serious. No treatment was received. Outcome of event was unknown. Information about Lot/Batch number has been requested.

severe body aches; chills; fatigue; cervical and left axillary lymphadenopathy; left axillary lymphadenopathy; muscle weakness; This is a spontaneous report from a contactable physician reported for herself. A 48-year-old female patient received first dose of BNT162B2 (Pfizer product), intramuscular on 21Dec2020 10:15 at single dose on left arm for COVID-19 immunization. Medical history included High cholesterol, insomnia, ongoing penicillin allergy, covid-19 from 13Nov2020 to an unknown date and pneumonia from an unknown date (the patient was tested positive for covid on 13Nov2020 and was hospitalized on 23Nov2020 with pneumonia). Concomitant medication included atorvastatin calcium (LIPITOR), zolpidem tartrate (AMBIEN), escitalopram oxalate (LEXAPRO), colecalciferol (VITAMIN D), fish oil (FISH OIL OMEGA 3) , zinc (ZINC), ascorbic acid, dexpanthenol, ergocalciferol, nicotinamide, pyridoxine hydrochloride, retinol, riboflavin, thiamine hydrochloride, tocopheryl acetate (MVI) and bifidobacterium lactis (PROBIOTIC). The patient previously took niacin and experienced drug allergy. The patient received injection at 1015 am at 0300 am on the following day (22Dec2020) she experienced chills, severe body aches, fatigue, cervical and left axillary lymphadenopathy and muscle weakness, woke up the next day and was asymptomatic except the left axillary lymphadenopathy which is still present today on 24Dec2020. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. No covid tested post vaccination. No treatment was received for the events. The outcome of the event left axillary lymphadenopathy was not

resolved while of other events was resolving. The reporter assessed the events as non-serious. Information about lot/batch number has been requested.; Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of event severe body aches cannot be totally excluded. The case will be reassessed if additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

back pains; back spasms; This is a spontaneous report from a contactable physician. A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), via an unspecified route of administration on 21Dec2020 as a single dose for COVID-19 immunization. Medical history and concomitant medications were not reported. It was not reported if the patient was pregnant nor if any other vaccines were received 4 weeks prior to the vaccination. The patient reported that she had the COVID-19 vaccine last Monday (22Dec2020) and was told to stop taking NSAIDS. Now, she is experiencing back pains, so she wants to know when she could restart taking NSAIDs. She doesn't think her back spasms are from the COVID-19 vaccine. The clinical outcome of the back pains and back spasms was not reported. It was also not reported if the patient had been tested for COVID-19. The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up.

Tingling sensation in my fifth digit that radiates up to my arm; This is a spontaneous report from a contactable physician, the patient. This 28-year-old female patient received BNT162B2 (Pfizer-BioNTech COVID-19 mRNA vaccine) (lot number: EK5730), intramuscularly in the left arm on 23Dec2020 at 12:00 (at the age of 28-years-old) as a single dose for COVID-19 vaccination. It was unknown whether the patient received any other vaccine within 4 weeks prior to the vaccine. Medical history included asthma from an unknown date and unknown if ongoing. The patient was not pregnant at the time of vaccination. Prior to the vaccination, the patient was not diagnosed with COVID-19. The patient did not have any allergies to medications, food, or other products. The patient did not receive any other vaccines within four weeks prior to the vaccination. Concomitant medication included escitalopram oxalate (LEXAPRO). On 24Dec2020 at 06:00, the patient experienced tingling sensation in her fifth digit that radiates up to her arm. No therapeutic measures were taken as a result of the events. The clinical outcome of the tingling sensation was not resolved. It was also reported that since the vaccination, the patient had not been tested for COVID-19.

"Small itchy blister/zit like bumps. Started on back of legs and back. Now some sporadically showing up on arms, belly, shin.; Small itchy blister/zit like bumps; This is a spontaneous report from a contactable Other Health Care Professional (HCP). A 48-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, Batch/lot number: EJ1685), intramuscularly at an unspecified dose in the left arm on 18Dec2020 at 04:00 (at the age of 48-years-old) for COVID-19 immunization. Medical history included allergy to sulfa drugs from an unknown date and unknown if ongoing. The patient did not have any allergies to medications, food or other products. Prior to the vaccination, the patient was not diagnosed with COVID-19.The patient was not pregnant at the time of

vaccination.The patient was administered the vaccine in the hospital. Concomitant medication included cetirizine hydrochloride cetirizine hydrochloride (ZYRTEC). The patient did not receive any other vaccines within four weeks prior to vaccination. On 21Dec2020 at 20:15,the patient experienced small itchy blister/zit like bumps which started on back of her legs and on her back. Some are sporadically showing ""now"" up on arms, belly and shin.The patient did not receive any treatment for the events.The clinical outcomes of small itchy blister/zit like bumps was not recovered. It was also reported that since the vaccination the patient had not been tested for COVID-19."

woke up with Chills, body/ joint pain, chest pain with mild difficulty to breath; woke up with Chills, body/ joint pain, chest pain with mild difficulty to breath; woke up with Chills, body/ joint pain, chest pain with mild difficulty to breath; woke up with Chills, body/ joint pain, chest pain with mild difficulty to breath; take smaller breaths because Rib cage hurts every time she took a deep breath; An hour after the vaccine developed a headache; woke up with Chills, body/ joint pain, chest pain with mild difficulty to breath/mild body aches; back also had moderate pain.; This is a spontaneous report from a contactable other healthcare professional (HCP) reporting for herself (patient). A 45-years-old female patient started to the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), lot number unknown, intramuscularly on 22DEC2020 13:45 (at the age of 45-years-old) as a single dose in the left arm for COVID-19 immunization. Medical history included drug allergy to vancomycin. Concomitant medication included nebivolol hydrochloride (BYSTOLIC), duloxetine hydrochloride (CYMBALTA), hydrochlorothiazide, levothyroxine. The patient previously took vancomycin and experienced drug allergy. The most recent COVID-19 vaccine was administered in the hospital. The patient was not pregnant at the time of vaccination. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. An hour after the vaccine the patient developed a headache and mild body aches on 22Dec2020 14:45. Two days after (24Dec2020) she woke up with chills, body/ joint pain, chest pain with mild difficulty to breath. She had to take smaller breaths because her rib cage hurts every time she took a deep breath. Her back also had moderate pain on unspecified date in Dec2020. The events an hour after the vaccine developed a headache, woke up with chills, body/ joint pain, chest pain with mild difficulty to breath/mild body aches, take smaller breaths because rib cage hurts every time she took a deep breath and back also had moderate pain did not result in death, were was not life-threatening, did not cause/prolonged hospitalization, was not disabling/incapacitating and did not cause congenital anomaly/birth defect. No treatment was received for the events an hour after the vaccine developed a headache, woke up with chills, body/ joint pain, chest pain with mild difficulty to breath/mild body aches, take smaller breaths because Rib cage hurts every time she took a deep breath and back also had moderate pain. Outcome of the events an hour after the vaccine developed a headache, woke up with chills, body/ joint pain, chest pain with mild difficulty to breath/mild body aches, take smaller breaths because Rib cage hurts every time she took a deep breath and back also had moderate pain were unknown. After the vaccination, the patient has not been tested for COVID-19. Information on the lot/batch number has been requested.

developed a tingling sensation 45 minutes post vaccination. Came on gradually and increased in sensitivity; Lips also had a tingling sensation similar to a sunburn feeling on lips/But lips Continue to have a weird sensation to lips; This is a spontaneous report from a contactable nurse (patient). A 49-

years-old female patient started to the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), lot number EK5730, intramuscularly on 23Dec2020 16:00 (at the age of 49-years-old) as a single dose in the left arm for COVID-19 immunization. Medical history included hyperactive thyroid for which was treated with radioactive iodine thus makes her hypothyroid. Concomitant medication included levothyroxine sodium (SYNTHROID). The patient previously took hydrocodone/acetaminophen (VICODIN) and experienced drug allergy. The patient did not have allergies to food.The most recent COVID-19 vaccine was administered in the hospital. The patient was not pregnant at the time of vaccination. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. On 23Dec2020 16:45 the patient developed a tingling sensation (45 minutes post vaccination). It came on gradually and increased in sensitivity. Her lips also had a tingling sensation similar to a sunburn feeling on lips. Tingling sensation gradually subsided to body lasted 4 hours. Tingling sensation to lips also gradually decreased 6 hours later but lips continue to have a weird sensation to lips. The events developed a tingling sensation 45 minutes post vaccination. Came on gradually and increased in sensitivity, Lips also had a tingling sensation similar to a sunburn feeling on lips/but lips continue to have a weird sensation to lips did not result in death, was not life-threatening, did not cause/prolonged hospitalization, was not disabling/incapacitating and did not cause congenital anomaly/birth defect. No treatment was received for the events tingling sensation 45 minutes post vaccination. Came on gradually and increased in sensitivity, lips also had a tingling sensation similar to a sunburn feeling on lips/but lips continue to have a weird sensation to lips. Outcome of the event developed a tingling sensation 45 minutes post vaccination. Came on gradually and increased in sensitivity was recovered on 23Dec2020 20:45. Outcome of the event lips also had a tingling sensation similar to a sunburn feeling on lips/but lips continue to have a weird sensation to lips was not recovered. Since the vaccination, the patient has not been tested for COVID-19.

left arm pain at injection site throbbing pain; This is a spontaneous report from a contactable other HCP (healthcare professional) who reported for a patient. A 53-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot #: EJ1685) intramuscularly on 23Dec2020 at 15:45 (at the age of 53-years-old) as a single dose in the left arm for COVID-19 vaccination. Medical history included known allergies to shrimp from an unspecified date and unspecified if ongoing. The patient was not pregnant at the time of vaccination. Prior to the vaccination, the patient was not diagnosed with COVID-19. Concomitant medications were not reported; however, there were no other medications the patient received within 2 weeks of the vaccination. The patient did not receive any other vaccines within four weeks prior to the vaccination. On 23Dec2020 at 20:00, the patient experienced left arm pain at injection site throbbing pain. It was reported that the event was non-serious and did not require hospitalization. The patient did not receive any treatment for the event. The clinical outcome of the event left arm pain at injection site throbbing pain was recovering/resolving. It was also reported that since the vaccination, the patient had not been tested for COVID-19.

Minor rash on chest; This is a spontaneous report from a contactable health professional, the patient. A 20-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration in the left arm on 22Dec2020 at 02:00 or 14:00 as

reported, pending clarification (at the age of 20-years-old) as a single dose for COVID-19 immunization. The patient medical history and concomitant medications were not reported. The patient was not pregnant at the time of vaccination. The patient did not have any allergies to medications, food, or other products. Prior to the vaccination, the patient was not diagnosed with COVID-19. On 24Dec2020 at 08:00 the patient experienced a minor rash on chest. The patient did not receive treatment for the event. Since the vaccination, the patient had not been tested for COVID-19. The clinical outcome of the minor rash on chest was resolving. Information about lot/batch number has been requested.

numbness of the lower left face, cheek and area around the mouth (peri-oral and mandibular numbness); numbness of the lower left face, cheek and area around the mouth (peri-oral and mandibular numbness); This is a spontaneous report from a contactable physician reporting for a patient. A 37-years-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), intramuscularly on 19Dec2020 (at the age of 37-years old) as a single dose for COVID-19 vaccination. The facility where the most recent COVID-19 vaccine was administered was a hospital. Prior to vaccination, the patient had not been diagnosed with COVID-19. The patient's medical history and concomitant medications were not reported. It was unknown if the patient received any other vaccines within 4 weeks prior to the COVID-19 vaccine. On 19Dec2020, the patient experienced numbness of the lower left face, cheek and area around the mouth (peri-oral and mandibular numbness). No treatment was received for the adverse events. The patient was recovering from the events.Since the vaccination, has the patient has not been tested for COVID-19. The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up.

"Ongoing fever spikes starting on Day 5 from 101-103 along with moderate to severe chills; Ongoing fever spikes starting on Day 5 from 101-103 along with moderate to severe chills; diarrhea; excess fatigue; This is a spontaneous report from a contactable physician. A 47-years-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), Lot number EJ1685, via an unspecified route of administration on 16Dec2020 12:30 as a single dose (dose 1) in the left arm for COVID-19 vaccination. The facility where the most recent COVID-19 vaccine was administered was a hospital. Prior to vaccination, the patient was not diagnosed with COVID-19. Medical history included type 2 diabetes mellitus and hyperlipidaemia. There were no allergies to medications, food, or other products. Concomitant medication included metformin, eicosapentaenoic acid ethyl ester (VASCEPA), and losartan. The patient did not receive any other vaccines within 4 weeks prior to COVID-19 vaccine. The patient experienced ongoing fever spikes starting on Day 5 from 101-103 along with moderate to severe chills, diarrhea and excess fatigue. The adverse events' start date & time was reported as 21Dec2020 at 12:30. The events were reported as non-serious. ""Today"" (24Dec2020) was day 8 and none of these symptoms have improved. The patient underwent treatment for the adverse event which included paracetamol (TYLENOL) and fluids. The outcome of the events fever spikes, moderate to severe chills, diarrhea, and excess fatigue was not recovered. Since the vaccination, the patient has not been tested for COVID-19."

lost my sense of taste/smell.; lost my sense of taste/smell; This is a spontaneous report from a contactable other hcp, the patient. This 44-year-old female patient received BNT162B2 (Pfizer-BioNTech COVID-19 mRNA vaccine) (Lot number: EH9899), intramuscularly in the right arm on 16Dec2020 at 18:30

(at the age of 44-years-old) as a single dose for COVID-19 vaccination. The patient's medical history was not reported. Prior to the vaccination, the patient was not diagnosed with COVID-19. The patient previously took ceclor for an unknown indication and experienced drug hypersensitivity. The patient did not receive any other vaccines within four weeks prior to the vaccination. The patient was not pregnant at the time of vaccination. Concomitant medication was reported as none and no other medications were received within 2 weeks of the vaccination. On 24Dec2020 at 12:00, the patient experienced losing her sense of taste and smell. It started changing over the course of the day. Things tasted and smelled different or oddly before the senses going away. No therapeutic measures were taken as a result of the events. The clinical outcome of the loss of sense of taste and smell was not resolved. It was also reported that since the vaccination, the patient had not been tested for COVID-19.

headache, chills and muscle pain and a slight dizziness; headache, chills and muscle pain and a slight dizziness; headache, chills and muscle pain and a slight dizziness; headache, chills and muscle pain and a slight dizziness; This is a spontaneous report from a contactable consumer, the patient. A 57-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), Lot: Ek9231 via an unspecified route of administration on 24Dec2020 at 10:00 (at the age of 57-years-old) as a single dose in the left arm for COVID-19 immunization. Medical history included an allergy to sulfa drugs as of an unspecified date and unknown if ongoing; Covid-19 diagnosed prior to the vaccination on 24Nov (year unspecified) and not ongoing (patient had recovered from COVID, was sick and quarantined until 04Dec (year unspecified)). The patient was not pregnant at the time of vaccination. Concomitant medications included calcium carbonate/colecalciferol (CALCIUM & VITAMIN D3), garlic [allium sativum], omeprazole magnesium (PRILOSEC), ascorbic acid (VIT C) and an unspecified multi-vitamin; all for unknown indications from unknown dates and unknown if ongoing. The patient did not receive any other vaccines within 4 weeks prior to the vaccination. The patient previously took meloxicam and doxycycline; all from unknown dates to unknown dates for unknown indications and experienced allergy. On 24Dec2020 at 23:00 (reported as later in the evening), the patient experienced headache, chills, muscle pain and a slight dizziness. The patient did not receive treatment for the events. Since the vaccination, the patient had not been tested for COVID-19. The clinical outcomes of the headache, chills, muscle pain and a slight dizziness were resolving.

Very sore arm for about one day.; Dizzy for one hour, five hours after the vaccine; Chills and body aches for about one hour 10 hours after vaccine with one hour of fatigue also; Chills and body aches for about one hour 10 hours after vaccine with one hour of fatigue also; Chills and body aches for about one hour 10 hours after vaccine with one hour of fatigue also; This is a spontaneous report from a contactable healthcare professional. A non-pregnant 48-year-old female received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration in the left arm on 21Dec2020 09:15 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. There were no other vaccines within four weeks of the suspect product. The patient previously took mefloquine hydrochloride (LARIAM) and experienced allergies. On 21Dec2020 14:15, the patient experienced very sore arm for about one day, dizzy for one hour, five hours after the vaccine. On 21Dec2020, the patient experienced chills and body aches for about one hour 10 hours after vaccine with one hour of fatigue also. There was no treatment received

for the events. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, the patient has not been tested for COVID-19. The outcome of the very sore arm for about one day was recovered in Dec2020 and of dizzy for one hour, five hours after the vaccine and chills and body aches for about one hour 10 hours after vaccine with one hour of fatigue also was recovered on 21Dec2020. The batch/lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up.

can't raise her arm up; pain at the site of the injection; During the night she couldn't sleep; This is a spontaneous report from a contactable nurse (patient herself) via the Pfizer Sponsored Program. A 69-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), lot number: EK9231, via an unspecified route of administration on left arm from 23Dec2020 10:10 to 23Dec2020 10:10 as single dose for COVID-19 immunization. The patient medical history was not reported. There were no concomitant medications. The patient previously took tetanus toxoid and got red and was itching (clarified she had a reaction to a tetanus shot several years ago). Reports she received the first dose of COVID 19 vaccine at the hospital where she works on 23Dec2020 at 10:10AM in left upper arm. She started having pain at the site of the injection in the afternoon at around 3PM or 4PM 23Dec2020. During the night she couldn't sleep because of the pain no matter where she turned. The patient states the pain was probably 8 out of 10 on the pain scale. Adds she had no redness or swelling. The pain today (24Dec2020) is still the same and now she can't raise her arm up. No treatment has been applied. No cold or heat applied. The outcome of the event pain at the site of the injection was not recovered; while the other events was unknown. Information about lot/batch number and expiration date requested.

headache; Had soreness in arm; This is a spontaneous report from a non-contactable consumer. A female patient in her 60s received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), lot/batch number and expiration date not reported, via an unspecified route of administration from 23Dec2020 to 23Dec2020 as single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced had soreness in arm and a headache on 24Dec2020. The outcome of the events was unknown. Information about lot/batch number has been requested.

Fever; Chills; Myalgia; Headache; Feeling weak; anorexia; This is a spontaneous report from a contactable consumer. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot number: EH9899), via an unspecified route of administration on 22Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced fever, myalgia, feeling weak, anorexia and headache in Dec2020. The patient reported that the symptoms lasted over 48 hours. The outcome of the events was unknown.

"Vertigo; Headache; High temperature; Woke up in the morning with vivid nausea and vomiting and threw up constantly; Woke up in the morning with vivid nausea and vomiting and threw up constantly; Body aches; This is a spontaneous report from a contactable consumer (patient). A 70-year-old female patient (weight: 81.65 Kg, height: 173 cm) received BNT162B2 (Pfizer-Biontech covid-19 vaccine, Lot. EL0140) on 21Dec2020, at single dose, for COVID-19 immunisation. Relevant medical history included

pulmonary arterial hypertension. Concomitant medications included furosemide (LASIX) 20 mg, daily and potassium 20 meq, daily. The patient experienced the following reactions: body aches on 22Dec2020; nausea and vomiting on 23Dec2020 at 02:00 described as ""she woke up in the morning with vivid nausea and vomiting and threw up constantly all on the 23rd and most of the day 24th""; headache and high temperature on 24Dec2020 and vertigo on 25Dec2020. The patient recovered from nausea and vomiting on an unspecified date, in Dec2020, while clinical outcome of the other events was unknown."

Resident extremely confused. BP 125/66; Pulse 124, Temp 99.7; 02 at 92% (around 10:00a.m.) BP 138/84; Pulse 125, Temp 99.5, O2 at 95% (around 1:00p.m.)

Increased heart rate majority of day, low bld sugar, nausea and headache late evening of vaccine. Hives appeared Rt arm - elbow, neck to eye. Took Benadryl 50mg at 7:30 pm another dose at 10pm. Awoke 12-29-20 all hives gone but feels hot, fluctuating heart rate, stiff neck, short of breath. Called MD, will monitor symptoms next 24 hours.

In middle of night had strong headache, then day following vaccination was headache-y (mild), light-headed, tired and with body aches. Two days after had mild body aches and mild light headed-ness; day 3 I was clear.

"Patient contacted our pharmacy and noted that ""the day after his Moderna dose, he experienced fever and chills of 100.3 Deg. Pain at the site of injection, and Vomitting."""

Pt experienced Weakness, dizziness, vomiting, headache soreness @ inj. site.

Pt developed a rash about an 30mins to an hour after receiving vaccine. Pt took Loratadine & Benadryl. Next day pt felt better. Soreness @ inj. site.

Patient left hospital and complained of dizziness outside. Patient brought back to vaccine Pod. Patient's blood pressure taken, patient given snack and water and felt better.

Patient felt tingling in left hand. Patient's blood pressure taken. Patient monitored by RN and seen by Resident. As per patient tingling went away

Patient complained of dizziness. Patient's blood pressure taken. Patient given water and snack and felt better.

Bell?s Palsey about 4.5 hours after injection.

10 minutes after receiving vaccine patient complained for being jittery and having an elevated heart rate. monitored BP, heart rate and 02 saturation; patient chose to leave with her friend and drive to Medical Center for evaluation

Starting around 1700 the day I was vaccinated, I started to experience body aches and a sore throat. As the night progressed, I had a fever of 102F. The fever lasted throughout the night until it broke the next

morning. It is currently 2125 the day after vaccination and I still am experiencing body aches and fatigue after sleeping for 18 hours. I have taken Tylenol to help relieve these symptoms.

1 hour after vaccine itching, redness, elevated small bumps in arms. 6.5 hours after the vaccine had flushing and tachycardia up to 130. Had to call FIRE RESCUE .,Took tachycardia meds

headache, nausea, light headed, swelling of the hands Patient was given 1000mg of acetaminophen and 25mg diphenhydramine. Patient was monitored for 60 minutes.

Fevers, chills, night sweats, fatigue, malaise, body aches

Approximately 5 minutes after the injection, I suddenly began experiencing tachycardia (felt like I had way too much coffee). The nurse took my pulse and summoned the attending physician who sat with me for more than 30 minutes. I felt good enough to leave but did experience a somewhat rapid heart rate on and off through the afternoon. Upon leaving, I was told to call my allergist to have my Epi-Pen refilled (my current Epi-Pen had expired), which I did. Eleven hours post injection I'm feeling fine except for the expected arm soreness. In terms of my allergic history, I had previously discontinued allergy shots last year due to repeated systemic reactions to very low dose vials (itchy roof of mouth, swollen throat, etc).

I received my vaccine on 12/18/2020. The side effects I experienced were initially as expected. Mild headache, muscle pain at the injection site. However, the muscle issues have not subsided, and have actually gotten worse. Day 3 I began having a burning sensation in my underarm area radiating back towards my triceps. Muscle spasms continued to increase and spread to include deltoid, trapezius, and SCM muscles. Yesterday I developed a fever and began having a burning sensation down my triceps muscles and radiating into my forearm (radial side). No visible rash noted. Slight weakness in left arm.

On the second day I had a sore arm and I woke up with a headache that lasted 2 hours.

Muscle aches, headaches, chills, vomiting, shakes

Developed metallic taste in mouth within 5 minutes of vaccine administration that persisted for 1 to 2 hours. Developed palpitations and flushing within 10 minutes of vaccine administration that resolved after 1 minute. Palpitations and flushing recurred along with development of burning sensation in distal extremities within 15 to 20 minutes of vaccine administration. Palpitations were forceful and pronounced enough to cause chest tightness, lightheadedness, and weakness. These symptoms resolved without intervention after less than 5 minutes.

Maculopapular Rash beginning not long after vaccine, began with hives and itching on hands, did not speculate vaccine relation until following day, hives appeared on hands and continued non-uniform across forearms, armpits, chest, abdomen, pelvic/thigh crease, buttocks, and behind knees, approx 50-60% of body experienced hives and maculopapular rash within 0-4 days after vaccine, minor swelling occurred where rash was present and was most prevalent 3 days post injection.

Short-term memory loss consistent with Transient Global Amnesia

Had shot at 7:45am and around 3:45pm started having severe itching in mouth , ears and skin. Took oral zyrtec without relief. Was scratching myself raw and bleeding. Went to ER and got solumedrol 125 and 25mg IV Benadryl. Next day had wheezing and rash on chest. Went on prednisone oral taper and albuterol.

One week after vaccine administration I developed lymphadenopathy on the left side - very painful and has lasted 4 days and is ongoing. Antibiotics were started on day 4.

Swollen Lips, throat, foot, sore throat, body aches, chills, head aches, Feeling that can not keep eyes open, pain on administration site, on/off body itching.

Fever within 16 hours of vaccine lasting for 48 hours, general muscle aches lasting under 48 hours, fatigue, non-productive cough persisting more than 3 days

severe chills, hot sweats, muscle and joint pain, headache, fever, vertigo

pt received dose 1 of pfizer/biontech covid-19 vaccine on 12/29/20 at approx 14:04. after 10 minutes of observation pt developed a left upper trunk rash. patient's HR was elevated and BP elevated. pt was nervous. Benadryl 25 mg PO and Pepcid 20 mg PO was given and patient had no other reactions. after 30 additional minutes of observation, pt was able to go home as spouse was driving her home

10:30 AM After receiving the COVID-19 vaccine, the patient experienced an anaphylaxis reaction that included, throat closing and tongue swelling sensation, itchiness, and hives on her bilateral arms and legs. Patient received 65 mg of Benadryl IV, 125 mg SoluMedrol IV, two doses of 0.3 epinephrine IM, 1 mg of Ativan, and 4 mg of Zofran, then taken to the ED for further monitoring. Patient was on 2L NC for comfort, sats in mid 90s off oxygen, and monitored the patient for a few hours. Patient discharged to home with stable vital signs off oxygen and a steady gait.

Unusually high level of fatigue / exhaustion. Feeling ?fluish? Headache Feeling feverish but no actual fever. Has lasted So far from 12/24 to 12/29. Six days. A bit better day 6.

Extreme gas and diarrhea.

Arm started hurting a few hours after injection. A headache and nausea a few hours after that.

Pt. developed tachycardia, hypertension and felt weak with decreased verbal responsiveness, alert but lethargic. She complained of dry throat, took a sip of water then began persistent coughing and wretching also C/O itching of her throat. She denied difficulty breathing, there were no cutaneous signs of edema, tongue enlargement, etc.

Pt. began to feel weak with palpitations about 8-10 minutes after vaccination, her pulse was extremely fast, she then began to complain of lower mid-esophageal burning

LEFT AXILLARY LYMPH NODES TO LEFT ARM SWOLLEN AND PAINFUL. WARM COMPRESS APPLIED. CONTINUE TO MONITOR

Pfizer-BioNTech COVID-19 Vaccine EUA Itching and hives on upper arms, upper legs, and sides of torso x48 hrs thus far, controlled with oral otc Benadryl and pep I'd.

Muscle pain in left deltoid, vomited at 1:22am. No treatment taken

Syncope, severe bradycardia followed by 20+ hours of chills, fatigue, weakness, body aches

Began developing flu-like symptoms about twelve hours after receiving first dose. I started having body aches, chills, fever, and fatigue. Ibuprofen has helped manage symptoms.

About 15 hours after I received the vaccine I started getting body aches and chills. Low grade fever. After 24 hours I was shivering, aches and temp of 102.4. Symptoms lasted a total of 48 hours from first onset of body aches.

On Dec 28th I received the shot & initially didn't feel anything. When I woke up on the morning of Dec 29th I had a really bad headache, felt burning up & cold at the same time. My right arm (shot arm) and my left hip were super soar. I couldn't keep liquids down. I passed out the first time between 6:55 A.M. & 7:05 A.M. Later that morning I passed out a second time for 2 mins. I still plan to get the second dose on Jan 25th 2021. Since I'm a contact tracer I texted my supervisor. I was advised to take the day off & report it just in case it was related to the vaccine.

Started with sudden headache which gradually worsened. Dizziness/light headed followed by progressive foggy thought process, severe arm soreness, and general aches all worsening through the night.

I received the vaccination on Saturday morning. The following day around 10:00a.m., I started feeling weak with a headache and severe left arm pain around the injection site. Around 2:00p.m., I started getting chills and spiked a temperature of 100.6. I was taking ibuprofen and Tylenol interchangeably. The fever and chills resolved that night but still with a headache and weakness. Only the headache remained the following day but the rest of the symptoms subsided.

30 seconds following IM injection, felt warm, flushed, lightheaded, vision dimming., near syncope. Symptoms improved lying supine. Blood pressure measured to be 90's systolic, Heart Rate 60's. NO RASH, NO ANGIOEDEMA, NO Shortness of breath. Symptoms resolved completely within in 3 minutes.

Rig he arm sever pain at elbow. Swelled and painful right axilla lump nodes

mild arm soreness low grade headache

Large lymph node about size of lime in left armpit

lost of taste and smell

Swollen lymph nodes in armpit and side of chest, extreme pain in swollen area Pain at injection site, but not nearly as severe as armpit pain

Large red, swollen area at site of injection Nausea, diarrhea, stomach cramping

"""Increased skeletal pain, Shinbone, back, muscle tightening swelling in back, sharp pains throughout knees and shinbones. These are ongoing medical issues but over the pat week they increased to the point where I stayed in bed with warm compresses and analgesic topic creams from Christmas through Monday the 28th. Currently working and taking 3 advils every six hours to deal with back pain."""

2 days after vaccine had significant back pain. Lower back with excruciating pain. Chest muscles became stiff Was difficult to walk or sit. Then the next day was having breakfast and had an allergic reaction to food that I have eaten regularly. I had an allergic reaction for the first time in September to a different food but it was same reaction. Significant periorbital edema to where my eyes were almost completely swollen shut. No breathing issues.

lethargy chills/sweats pain at injection site for multiple days nausea headache

Moderate myalgia of arms, shoulders, neck and upper back; milder myalgia of lower back and thighs. Treatment is rest, acetaminophen and massage. Outcome to be determined; symptoms still present at 48 hours.

Patient c/o of tingling in the legs about 15 mins after receiving the vaccine. Patient also c/o of warmst in the chest area

My arm was very sore all night and when I woke up I had two raised, red patches on my right arm. One patch was at the injection site, one was slightly below the injection site. The injection site is also still very sore and hard.

Developed a lump in my throat soon after receiving the injection. Feel like I have to keep swallowing and clearing my throat. Some fullness in my ears that resemble having water in your ears when swimming. Some chest tightness, but mild. No shortness of breath. No rashes. Reported this to the nursing staff at the Covid Pod site around 12:15pm. Ate lunch, drank water, and took Benadryl at 1230. Developed chills and fever of 100.1 at 2:30pm.

Fever to 101.5F reported evening of vaccination. No other symptoms reported yet.

Red, raised rash noted to right arm, hands bilaterally, and neck area. Swelling noted to bilateral hands 6 days post injection. Patient given Decadron for symptom relief per PCP.

Patient reported headache immediately after injection. Within 5 minutes, reported headache radiating down neck and arms to elbows with tingling down arms lasting about 10 seconds. 30 minutes after injection, patient declined further care while complaining of persistent sharp frontal headache radiating down neck. Patient was very anxious prior to receiving vaccine.

103.5 fever Vomiting Chills Muscle spasms Headache Difficulty walking

I got the vaccine around 12:35 on 12/29/2020. Around 3 in the morning I started having sever body aches. Now its 12/30/2020 7:32 in the morning, I have sever body pain, Dont have fever but I feel very

warm, My hands are very warm it feels like I have a high fever, chills and very tired with no energy. It feels like I have flu.

Severe Chills, fatigue, blinding headache, pain at ejection site,

Arm pain, chills, headache, fatigue

hives, itching; seen in ED given po Benadryl,, Pepcid with relief discharged on po Benadryl, Rx Decadron if needed Improved and back to work in 2 hours; will follow up with health clinic.

Moderna COVID?19 Vaccine EUA Pain, swelling, warmth to injection site. Chills, body aches and headache onset the next morning.

Fatigue, low grade fever 99.3, chills, muscle and joint pain ,and nausea. At vaccine site bruise and right arm pain

On his drive home, his cheeks started to swell up, throat swelled, the roof of his mouth didn't feel right & he had difficulty swallowing. He went to the ED and his throat closed.

2hours after receiving injection developed a uticarial rash on upper body. Treated with zyrtec 10mg and 25mg of benadryl. Resolved after 30 minutes of receiving benadryl.

Symptoms started on Monday when the test site of my arm was extremely sore and I had a mild headache. Tuesday I started getting additional symptoms of respiratory symptoms with a runny nose and cough, chills, and headache.

Itching to face and legs. Rash to left leg. States she applied Hydrocortisone cream to areas. Side effects have improved.

Fever (100.1 F when first taken), chills, body aches, headache, soreness at injection site. Fever and chill started during the night, woke up about 1am with sweats, chills, and headache. Took 400 mg ibuprofen and headache went away. Low grade fever and chills still persist.

8 hours post injection developed mild injection site/arm pain and soreness 13 hours post injection developed fever, tax 102.7F, chills/rigors, severe body aches

Confused, dizzy, heavy tongue feeling, pale skin, weakness.

Pt developed anaphylaxis, was given IM Benadryl, and was sent to the ED. Pt spent 1 night in the hospital, went home, and has come back and is in the ICU. Pt had hives, itching, chest tightness, swollen lips.

Shortness of breath Hives, Fever, chills joint pains. I was Tx in the ER with Pepcid IV Solumedrol IV, Benadryl IV ,Tylenol and IV fluids. I was discharged on prednisone , Benadryl and Tylenol.

12/29/2020 07:00AM Mild body aches, low grade fever 100.0; 12/29/2020 PM same day-- fever 102.6, severe body aches and fatigue and headache, Tylenol and ibuprofen-- some relief to fever. 12/30/2020 mild headache, left armpit swollen, tender knot -- all other symptoms have resolved.

Approximately 15 minutes after IM injection, patient developed chest tightness. Patient was taken to the Emergency Department for treatment. Was given sublingual nitroglycerin and subsequently admitted to the hospital for observation. Patient discharged home the following morning in good condition.

Several minutes after vaccine started feeling tightness in her throat and a rapid heart rate. Administered epinephrine pen and when to the emergency department. Received oral Benadryl and steroids. Was discharged home later.

My grandmother died a few hours after receiving the moderna covid vaccine booster 1. While I don?t expect that the events are related, the treating hospital did not acknowledge this and I wanted to be sure a report was made.

About 3 am after the injection I woke up with severe chest pains and headache and went to the ER. I was admitted for 2 days and was released with a prescription of Isosorb Monoer, Metroprol, aspirin which is used as a blood thinner. The diagnosis and prognosis was severe migranes and cardioartery disease.

Shortness of breath , Erythema within 30 minutes of vaccine per provider note

Left side of my face went numb. 5 minutes later tongue was dry and tingly. Went back to place of work and went to monitoring room. Went to ER to be checked out. Got better over that day. I was admitted the same day and discharged the next day.

anxiety, tachycardia, flushing, diaphoresis, HTN, SOB

Patient administered Pfizer-BioNtech vaccine, dose #1 in series at 810AM, without notable concerns for 10 minutes. At 10 minutes post vaccination, patient developed itching and some blotching, throat becoming scratchy. No known allergies to components listed in vaccine, though does have a listed allergy to contrast dye, does not carry an epi-pen. Patient was walked to urgent/emergency care in the clinic, where she was seen immediately. Patient was given diphenhydramine 25 mg IV, pantoprazole 40 mg IV, with mild uticaria continuing. Patient notes she feels her 'back is on fire'. Patient was then given methylprednisolone 125 mg IV. At this time, no SOB is noted, uticaria is still present. 0930 patient reports swelling in throat and respiratory difficulties at this time with visible edema in the neck. 0.3 mg Epinephrine given at 0935, epinephrine drip and racemic epinephrine neb given. 1006 Patient on epinephrine drip 2.5 mics/hour. Patient transferred to Medical Center ICU, where she remains at the time of this report.

BP of 176/126mmhg/persistent severe hypertension/continued severe elevation of BP of 178/130mmHg; intermittent chest pains; severe nausea; rash and hives on left side of arm where injection site was, as well as left side of face; rash and hives on left side of arm where injection site was,

as well as left side of face; rash and hives on left side of arm where injection site was, as well as left side of face; rash and hives on left side of arm where injection site was, as well as left side of face; mild progressive headache; body aches; chills; fatigue; fever of 100 degree F; This is a spontaneous report from a contactable Other Health Professional (patient). A 29-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) lot number: unknown, intramuscular in the left arm, first dose on 18Dec2020 12:30 at a single dose for immunisation. Medical history included ongoing gestational hypertension in 2016 that never recovered, with controlled hypertension, asthma/COPD, and seasonal/animal allergies. Concomitant medication included sertraline hydrochloride (ZOLOFT) and losartan. The patient is not pregnant. The patient previously took and had allergies to erythromycin and nitrous oxide. It was reported that within 20-30 minutes of receiving covid vaccine on 18Dec2020, the patient developed mild progressive headache, body aches, chills, fatigue, fever of 100 degree F. At approximately 8:00 p.m. same day of vaccination, she developed rash and hives on left side of arm where injection site was, as well as left side of her face. Immediately following this, she had intermittent chest pains in which she took a BENADRYL 25 mg with some relief. Next day (19Dec2020), progressive headache persisted to a severe headache, severe nausea, persistent chest pains and a BP of 176/126mmhg. Reported to a place for evaluation with persistent severe hypertension and severe headache treated by toradol, compazine, and Benadryl. She was released from the ER with improved blood pressures and reduced headache. The following day Sunday Dec2020, progressive and severe headache occurred with continued severe elevation of BP of 178/130mmHg. Current treatment of losartan 50 mg was increased to 100 mg to attempt control. She was then placed on chlorthalidone/amlodipine. The events resulted in doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care. The outcome of the events mild progressive headache, body aches, chills, fatigue, fever of 100 degree F, rash and hives on left side of arm where injection site was, as well as left side of face, intermittent chest pains, severe nausea, and BP of 176/126mmhg/persistent severe hypertension/continued severe elevation of BP of 178/130mmHg was not recovered (reported as symptoms persist). The patient was not diagnosed with Covid 19 prior to vaccination and she had not been tested since vaccination. Information on the lot/batch number has been requested.; Sender's Comments: Based on the compatible time association, the hypertension aggravated is possibly related to bnt162b2 administration. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

blood pressure was super elevated, in the 190/110 range; It was getting close to stroke level; woke up and felt restlessness and agitation; Headache; felt really restless and anxious; felt really restless and anxious; was not able to sleep/ could not go back to sleep; This is a spontaneous report from a contactable consumer (patient). A 53-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) lot number: EK5730, expiration date: Mar2021 intramuscularly in left deltoid from 17Dec2020 at single dose for COVID-19 immunization. Patient medical history included seasonal allergy. Concomitant medication included mometasone furoate (FLONASE) via nasal from 2018 (about 2 years ago) and ongoing at 1 spray each nostril, 1x/day for seasonal allergy. The patient previously received flu

shot, on Oct2020 (2 months ago) for immunization. Patient was a firefighter and reported that he received the vaccination in the afternoon of 17Dec2020. On that afternoon, he was on duty and felt really restless and anxious and was not able to sleep. He did not sleep at all that night. He maybe got like an hour or 2 on Friday after his shift. Friday night he had the same kind of deal and it continued on into Saturday. He did crash and burn (pending clarification) on Saturday night. On Sunday, he got up and felt normal again. A few hours later on Sunday, it started up again and then it went away. He said that after dinner Sunday evening it started up again, but he was able to get some sleep. He said that Yesterday, 21Dec2020, he was fine. He took off yesterday. This morning on 22Dec2020 at 0200 he woke up and felt restlessness and agitation and he could not go back to sleep. He said that he had a headache and his blood pressure was super elevated, in the 190/110 range on 22Dec2020. It was getting close to stroke level. He said that he thought about going to the ER, but did not experience any stroke or cardiac symptom's, although his blood pressure is still high, but not as high as it was. He has not gotten any sleep since then. He said that he has an appointment to see his physician this afternoon at 1300 22Dec2020. It was reported that all events require physician office visit. Got his flu shot like 2 months ago and nothing like this happened. He said that he heard with the second round there are supposed to me more symptoms like flu like symptoms with the Covid vaccine like fever, muscle aches. Outcome of the events was reported as unknown.

"diagnosed with COVID-19; diagnosed with COVID-19; This is a spontaneous report from a contactable pharmacist. A female patient of an unspecified age (reported as 62 without unit) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot/batch number and expiration date not provided), via an unspecified route of administration on 16Dec2020 at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. Reporter requested information on the administration of the second dose of the COVID-19 vaccine to a patient. The patient received vaccine first dose 16Dec2020; she was diagnosed with COVID-19 on 18Dec2020; started taking the medication ""Bamlanivimab"" on 21Dec2020. The outcome of the events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: There is not a reasonable possibility that reported ""diagnosis with COVID-19"" is related to BNT162B2 vaccine. Event developed 2 days after vaccination. The event is most likely intercurrent medical condition."

Patient had dizziness when she got down to the emergency department.; transient ischemia attack (TIA); Hypertensive emergency; This is a spontaneous report from a contactable pharmacist reporting for two patients. This is the second of two reports. A 53-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (Lot number: EH9899), intramuscular at 0.3 mL, single in the arm on 23Dec2020 for Covid-19 immunisation. Medical history included hypertension, allergies to sulfa, morphine and cipro. There were no concomitant medications. The patient experienced hypertensive emergency on 23Dec2020 with outcome of unknown, patient was getting her blood pressure checked and the patient was in the 170s systolic on an unspecified date with outcome of unknown, patient had dizziness when she got down to the emergency department on an unspecified date with outcome of unknown. The events were described as follows: Patient was getting her blood pressure checked and the patient was in the 170s systolic. She was taken down to the emergency department. She had a blood pressure of 191/105 in the emergency department. Patient had dizziness when she got down to the

emergency department. She does not have further details to provide since the patient is being worked up right now to see if she experienced a transient ischemia attack (TIA). Patient has a history of hypertension. The vaccine was administered at Hospital Facility. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine.; Sender's Comments: While the patient is a known hypertensive and events may be intercurrent events, the causal relationship between BNT162B2 and the events hypertensive emergency, dizziness and transient ischaemic attack cannot be completely excluded due to temporal association. This case will be reassessed once additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate.,Linked Report(s) : US-PFIZER INC-2020510735 Same reporter/different patient/similar events

positive COVID-19 test with no symptoms; positive COVID-19 test with no symptoms; This is a spontaneous report from a contactable other HCP. A 93-year-old male patient received fist dose of BNT162B2(PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 18Dec2020 at single dose by injection at arm for COVID-19 immunization. Medical history and concomitant medications reported as none. The patient was not been treated with immunomodulating or immunosuppressing medications or received any other vaccines around the time of COVID-19 vaccination. The patient, nursing home had turned positive after the getting the vaccine. The patient was tested negative for COVID 19 before getting the vaccine on 18Dec2020, then took his first dose of COVID vaccine. The patient had no reaction to the vaccine. The patient got on the plane on 19Dec2020 and tested positive on 22Dec2020. PCR test for COVID 19 was done on 22Dec2020 and received the results on 23Dec2020 and it was detected(PCR test was positive). Event reported as non-serious. The patient still had had no symptoms before the test and none after the test came back detected. He was pretty healthy. It was unknown if patient would receive the second dose but he was scheduled to receive it. Patient was not admitted to an Intensive Care Unit. Patient did not display clinical signs at rest indicative of severe systemic illness. Patient did not require supplemental oxygen (including high flow or ECMO) or receive mechanical ventilation. Patient had no any new or worsened symptoms/signs during the COVID-19 illness experienced (including date of onset/worsening). The patient did not receive any additional therapies for COVID-19. The event did not require the initiation of new medication or other treatment or procedure. Patient's outcome with COVID-19 reported as not currently ill. The outcome of the event was unknown. Information on the Batch/Lot number has been requested.; Sender's Comments: The patient received BNT162B2 on 18Dec2020 and took plane on 19Dec2020. The patient was tested positive for COVID-19 on 22Dec2020. The event occurred only 4 days after first vaccination and therefore the patient was not under full protection by vaccine.

"patient tested positive for COVID 19 the same day; patient tested positive for COVID 19 the same day; This is a spontaneous report from a non-contactable Nurse. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The relevant medical history and

concomitant medications were not reported. The COVID 19 vaccine was administered to the patient and the patient tested positive for COVID 19 the same day. Patient did not have a fever and reported feeling tired. The nurse wanted to know if the immune response would be affected by having COVID 19 at the time of vaccination and will the symptoms be exacerbated because of receiving the vaccine. The outcome of the events was unknown. No follow up attempts are possible. Information on Lot/Batch could not be requested. No further information is expected.; Sender's Comments: The patient tested positive for COVID-19 on the same day when receiving BNT162B2 vaccine. And therefore there is not a reasonable possibility that reported ""tested positive for COVID 19"" is related to vaccine."

tested positive for COVID; positive for COVID; positive for COVID/asymptomatic; This is a spontaneous report from a contactable nurse reporting for herself. A female patient of an unspecified age received the 1st dose of bnt162b2 (BNT162B2) at single dose on 18Dec2020 for Covid-19 immunisation. The patient medical history and concomitant medications were not reported. She was tested positive for COVID, through the rapid COVID test on 27Dec2020. She stated being asymptomatic and being scheduled for her 2nd dose on 08Jan2021. She asked can she still receive the 2nd dose of the vaccine or should she repeat the vaccination series. The outcome of event was unknown. Information on the Lot/batch number has been requested.; Sender's Comments: Based on the information currently available, a lack of efficacy with suspected vaccine in this patient cannot be completely excluded. Further information like confirmative COVID 19 Nucleic acid/ PCR test are needed for full medical assessment.

10 minutes after receiving vaccination, a significant increase in HR was noted, along with a tingling sensation through out body. Also, scratchy throat was noted. Alert by patient made to staff at vaccination site. Sweating noted and shortness of breath at that time. Epi pen given via L thigh IM. PIV started and benadryl and solumedrol given. Relief of symptoms noted very shortly after Epi administration. Taken to ER for 4 hour observation. Sent home after 4 hours and given prednisone to be taken at home, 50mg daily for 4 days. No further adverse symptoms noted.

decreased range of motion in vaccinated arm: unable to raise left arm above shoulder x 72 hours now due to pain. no associated numbness or swelling. I am a surgeon and this impacts my work and driving. I would not have been able to operate during these last 3 days and while the pain is better 72hrs later, my arm is still out of commission. I think we need to inform healthcare providers who perform procedures that they may want to schedule the vaccine when no planned procedures for at least 72 hrs. Due to this issue I will be unable to proceed with the second dose, unless I can take it a week later than the scheduled January 24, 2021. It is taking too long to regain full function of the arm but i expect it will be back to normal as it is better today 72 hrs later.

Facial numbness radiating down left side of neck to left arm, elbow and chest. Went to ED, admitted for observation overnight.

Bell's palsy; experienced sudden flushing; tachycardia; the left side of my tongue became numb and tight. The numbness and tightness radiated to my left cheek, ear, jaw, and neck; the left side of my tongue became numb and tight. The numbness and tightness radiated to my left cheek, ear, jaw, and

neck; the left side of my tongue became numb and tight. The numbness and tightness radiated to my left cheek, ear, jaw, and neck; The numbness lasted for approximately 45 minutes with resulting jaw and ear pain for 3-4 days after injection; The numbness lasted for approximately 45 minutes with resulting jaw and ear pain for 3-4 days after injection; New lymph node tenderness at day 4.; This is a spontaneous report from a contactable other healthcare professional (patient). A 31-year-old female patient received her first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899), via an unspecified route of administration on left arm at 11:30 AM on 18Dec2020 at single dose for COVID-19 immunization. Medical history included seasonal allergy. Concomitant medication included fluticasone propionate (FLONASE), loratadine (CLARITIN) both for seasonal allergies. The patient had sudden generalized flushing, tachycardia, and the left side of her tongue became numb and tight. The numbness and tightness radiated to her left cheek, ear, jaw, and neck at 11:45 AM on 18Dec2020. She hadn't found any similar reports/reactions documented. Spoke briefly per document below regarding Bell's palsy. The numbness lasted for approximately 45 minutes with resulting jaw and ear pain for 3-4 days after injection. New lymph node tenderness at day 4 in Dec2020. No shortness of breath, dysphagia, or facial drooping associated. All events were reported as non-serious. The patient was not diagnosed with COVID-19 prior to vaccination. Since the vaccination, the patient had not been tested for COVID-19. The patient did not receive any treatment for events. The outcome of events was unknown. Explained that Pfizer would not be able to provide treatment recommendations and referred to her HCP to discuss the 2nd dose.; Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of event Bell's palsy cannot be totally excluded. The case will be reassessed if additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

lips were tingly and swollen; lips were tingly and swollen; fatigued; allergic reaction; passed out; breathing fast; her brain felt like a rock, like she was there but not there; head was so heavy,wouldn't open her eyes; her throat started to tighten up; chest pain; nauseous; headache; felt a little lightheaded, a little wobbly; palpitations; sweaty; This is a spontaneous report from a contactable consumer (patient) via Pfizer Sponsored Program. A 48-year-old female patient (no pregnant at the time of vaccination) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EH9899) via an unspecified route of administrationon 22Dec2020 on left shoulder at single dose for COVID-19 immunization. The patient's medical history included pernicious anemia and She had problems with B12 and Vitamin D like 10 years ago, she had none in her body, everyone said she was deficient and this year with her new primary care, they sent her to do some antibody tests, and found out she has pernicious anemia, allery to MRI and CT contrast. MRI and CT contrast NDC, lot, expiry unknown. Her CT contrast allergy happened when she was 9 and 12 years old. It turns out to be her dad has an allergy the same way, his airways close. Whenever she needs a CT, they do without contrast, if she does need, they prep and give her Benadryl and keep an eye on her. This only happened once, that she needed with contrast, and with prep she was ok. With the MRI, this happened 4 or more years ago, maybe like 5 years ago. She

needed an MRI, they said she would be fine, they injected contrast, she felt pretty hot, then she doesn't know, 20 minutes into it, she couldn't handle her gown, she looked at her chest, her whole chest was red like a burn. They gave her the IV Benadryl, she guesses, and it went away, now she knows, she doesn't know if her dad is allergic to MRI dye, but she knows she got the allergy from him for the CT contrast. The concomitant drugs was not reported. The patient was taken to ER with a severe allergic reaction. She had an allergic reaction on 22Dec2020: she passed out, said her brain felt like a rock, like she was there but not there, she then received an Epi Pen shot, when she got to the ER, her throat started to tighten up, lips were tingly and swollen, she was breathing fast, she had chest pain, she scaled it from a scale of 1-10, as about a 3 to 4 for chest pain, she felt nauseous, sweaty, and had a headache. She went to bed last night, and woke up, feeling better but a little fatigued on 23Dec2020. She is wondering if she should take the second dose, and wants to be in the clinical trial for this type of reaction. She needs transfer to Regulatory Authority. Caller confirmed details. Caller states she works in a hospital, and all this happened at the hospital, and her doctor was not involved. Outcome of allergic reaction: asks what does lasting effects mean? Right now she has a little fatigue and headache, but she knows they are regular symptoms she can have with the vaccine, are those lasting effects? She was discharged from the ER to home. She mentioned to the nurse she has, she went to get the shot, she told the registration nurse, she said she has a severe allergic reaction to CT contrast, her airway closes and she has a severe reaction to MRI contrast, her skin burns, it turns red and feels like a horrible burn, she cannot handle anything to contact her skin, it burns, and she mentioned that to the nurse, she said, instead of staying 15 minutes, said to stay 30 minutes there to observe just in case. She got the vaccine, and 10 minutes after the vaccine, she felt a little lightheaded, a little wobbly, but she didn't think much, it was mild, and on the mark at 30 minutes, the nurse asked her to stand, and that is when she started feeling, like her head was so heavy, the only way to describe, was like her brain was like a rock, she had to lay down, and when they laid her down, she wasn't there, she was there but wasn't, and they didn't wait at all to give her the Epi Pen, she had a feeling of heaviness that got worse, she wouldn't open her eyes, she was able to answer questions, but it was not her there, it was weird, then she didn't have. she breathed fast, had palpitations, chest pain, so they called a Rapid Response team, they were keeping an eye on her breathing, which was super fast, and they rushed her to the ED, and the doctor did what they were doing, giving her IV of whatever medication, and she was also very nauseous, then at one point in the ED, she started feeling, like imagine if fists were on throat, pushing her throat, a little bit, and she tried to tell to the ED doctor, but guessed she was calling everyone to give her things, and didn't catch it, but it didn't last long, at the same time, she started to feel her lips tingly, so she thinks that, because they gave the Epi Pen so quickly, they wasted no time, she didn't have the airways closing like she does when she gets the CT contrast, they were quick. NDC/lot/expiry: She reads from the card they gave her: states first dose COVID-19 EH9899, states it doesn't specify lot, but she can find that out, they just gave her a vaccine record card. EPi Pen: NDC, lot, expiry unknown, states everything happened so quickly, she didn't think to get this information before calling, but she can get it. There at the hospital, she went to see the occupational health doctor, and based on guidelines from the CDC, he read supposedly she cannot get the second dose, but the doctor said because it is so new, and she has to wait the 3 weeks she guesses, things can change, and she wanted to be proactive. The outcome of the events, allergic reaction, passed out, throat started to tighten up, lips were tingly and swollen, chest pain, nauseous,

headache, lightheaded, palpitations, sweaty was recovering. The outcome of other events was unknown.

COVID test positive two times; COVID test positive two times; Pain in bum, back; Pain in bum, back; Last night I was feeling so bad; Skin like a rash; This is a spontaneous report from a non-contactable consumer (patient). This patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot EK5730) on 21Dec2020 at 1:36 P.M., at single dose, for COVID-19 prevention. Medical history and concomitant medications were not reported. On an unspecified date in Dec2020 the patient experienced pain in bum, back, last night was feeling so bad, skin like a rash. On 22Dec2020 the patient did COVID test which was negative. She did another test on 23Dec2020 and it was negative. The patient did not feel any fever. But last night, on an unspecified date in Dec2020, when the patient went to the emergency for work, the lady did COVID test two times and the patient was positive. Events outcome was unknown. No follow-up attempts are possible. No further information is expected.

Tested positive for covid after the first dose of the vaccine; Tested positive for covid after the first dose of the vaccine; This is a spontaneous report from a contactable Pharmacist. A patient of unspecified age and gender received the 1st dose of bnt162b2 (BNT162B2) at single dose on 18Dec2020 at single dose for Covid-19 immunisation. The patient medical history and concomitant medications were not reported. The patient experienced Tested positive for covid after the 1st dose of the vaccine on an unspecified date. The outcome of unknown. Reporter wanted to know if the patient should receive the 2nd dose. Information on the lot/batch number has been requested.; Sender's Comments: The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

Patient presented to the ER on 12/26/2020 with complaints of fever, chills and SOB for about 3 days. Stated it was a gradual onset and has been intermittent. Also reported some nausea and chronic loose stools, mild loss of smell and sinus drainage, non productive cough. Discharged to observation and then home on 12/27/2020. Patient readmitted to hospital on 12/30/2020.

Within 3 minutes of vaccination patient became fully flushed head and neck, with rapid heart rate (112), and feeling like her airways were tightening.. Nurse immediately called for response, administered Epipen, when response arrived applied oxygen and transported to ED. Solumedrol 125 mg, Bendadryl 25 mg, and Famotidine 20 mg, she responded well and was released home with Rx Prednisone 40 mg x 3 days. Only residual effect was a dry/sore throat.

12/30 9:30 am developed angioedema. Swelling of face, lips, tight throat. Also had bright red rash over body trunk and arms. Both palms were red, hot and painful.

Weakness, fatigue, decreased appetite, upper extremity shaking, sternal red blotchy rash, decreased mental status, non-verbal, decreased level of conscious, mottling, left side facial droop, hypertensive, fever, unable to follow commands

headache 15 minutes after receiving vaccine, 3 to 4 hours later broke out in rash on upper extremities, ABD pain, itchy, and arm swelling, throat hurts. SOB

Left sided weakness, fatigue for 3 days post immunization. Patient was seen by health care provider on 12/30/2020. Provider transferred patient to Hospital ER for further evaluation.

At about 6am after receiving the shot I felt very tender at the injection site almost as if it was bruised. Then over the course of the day I started to feel very itchy all over my body but mainly on my right side. 10pm I got up for work, and could barely move, I'm feeling intense back pain on my lower back on the right side. I can walk but its all very limited motion, I can really only manage by putting all my weight on my left side.

I developed severe abdominal pain and was diagnosed with colitis. I was seen in ER. I have no idea if the vaccine called this.

Patient presents with ? Altered Mental Status ? Headache á á HPI Patient presents to ER by EMS ambulance after family called 911 as patient was incomprehensible with slurred speech and moaning on the phone this evening. On arrival of EMS patient was asleep in bed and reportedly unresponsive other that to localize to pain. EMS transferred patient to ER. On arrival to ER patient had GCS 7. Reportedly patient is locum nurse who works in a Nursing Home and patient reportedly received COVID vaccination 2 days ago and that night reportedly began complaining to family on the phone of headache, nasal congestion, sore throat, cough, fever, chills, nausea, emesis, myalgias, and lethargy. Per the medical record patient has history of seizures, migraines, and sciatica. No other information is known on patient arrival to ER. 1. Peripheral IV right dorsal hand placed by EMS in route to ER. 2. On arrival to ER GCS 7 (E1M5V1) and roving eye movements with episodic lateral conjugate and at times disconjugate gaze concerning for seizure activity. Arms and legs with moderately increased tone but no clonic movements and patient able to localize bilaterally. 3. Ativan 1 mg IVP for seizure, then further 2 mg IVP for persistent seizure. 4. Fosphenytoin 1,000 mg IVPB in ER for loading dose of antiseizure medication. 5. Patient had significant improvement following completion of Ativan 3 mg IVP and GCS improved to 14 (E3M6V5) from GCS of 7 (E1M5V1). 6. Patient able to communicate after improvement as above and reports she has had headache or migraine for past several days as well as dysuria with bilateral CVA pain and has significant pain on percussion of bilateral CVA and moderate pain on palpation of bilateral flanks. No nuchal rigidity or pain with ROM of neck. Additionally, she complains of severe headache and diffuse pain of back and abdomen/pelvis. She reports a history of seizures in the past and reports she had one last month and was treated at a hospital in her home state. She denies antiseizure medications. Additionally, patient reports nonproductive cough, sore throat, nasal congestion, fever, chills, myalgias, lethargy, nausea, and episodic emesis over the past 2 days. She has anterograde amnesia following seizure and does not recall events. 7. Normal saline 1,000 mL IV bolus, then 100 mL/hour in ER. 8. CT of head with and without contrast performed and negative for intracranial hemorrhage, lesions, stroke, or other acute pathology. 9. CT of chest/abdomen/pelvis with IV contrast shows no acute pathology or notable abnormalities. 10. Lactic acid drawn and normal. 11. UA and urine microscopy collected by straight catheterization and culture collected and pending. 12. Blood cultures x 2 collected and pending. 12. Rocephin 2 mg IVPB in ER after blood cultures collected. 13. Vancomycin 20 mg/kg (1,500 mg) IVPB

following Rocephin. 14. Dexamethasone 10 mg IVP in ER. 15. Duoneb nebulizer in ER. 16. Called to discuss with patient's daughter and the family's preferred contact who is 23 years old. She reports patient had COVID vaccination 2 days ago and beginning that night patient has complained of headache, fever, chills, nonproductive cough, sore throat, nasal congestion, myalgias, and lethargy. Additionally, she reports patient has history of seizures on at least 1 occasion in the past a few months ago but is not on antiseizure medications. She reports patient had MRI and MRA of her brain at that time and reportedly and intracranial aneurysm was identified at that time. 17. Called to request transfer to another facility and spoke with hospitalist who states there is no neurologist there and suggests transfer to larger tertiary care facility with neurology. 18. Called to request transfer and accepted by ER provider. 19. Transfer by ALS ground ambulance with telemetry, pulse oximetry, O2 to keep > 02%, vitals every 30 minutes, normal saline at 100 mL/hour, Rocephin 2 grams IVPB, vancomycin 20 mg/kg (1,500 mg) IVPB in ER. á DISPOSITION Patient Stabilized and Transferred Data Unavailable Wed Dec 30, 2020 2:12 AM CST

PATIENT WAS OBSERVED FOR 15-20 MINUTES IN THE PHARMACY POST INJECTION, AND HAD NO SYMPTOMS. PATIENT ALSO HAD BROUGHT ALONG HER EPI-PEN TO THE APPOINTMENT AS SHE WOULD BE PREPARED IF SHE HAD ANY PROBLEMS. ON HER WAY HOME, APPROXIMATELY 30 MINUTES AFTER HER VACCINATION, SHE HAD SOME MILD CHEST PAIN AND FELT SOME THROAT TIGHTNESS. SHE DID ADMINISTER 1 DOSE OF HER EPI-PEN 0.3 MG INJECTION AT THAT TIME. SHE EXPERIENCED RELIEF OF HER SYMPTOMS, AND APPROXIMATELY 1 HOUR AND 30 MINUTES LATER WHEN I CALLED HER, SHE WAS STILL FEELING UNUSUAL SENSATION IN HER THROAT, BUT WAS MUCH BETTER. I ENCOURAGED HER TO TAKE SOME HYDROXYZINE , WHICH SHE HAD AVAILABLE AT HOME, AND TO CONTACT THE EMERGENCY ROOM IF HER SYMPTOMS DID NOT RESOLVE COMPLETELY OR SEEM TO BE GETTING WORSE.

Anaphalaxis reaction, stridor an unable to breathe. Happened in 30 seconds

Spouse awoke 12/20 and found spouse dead. Client was not transferred to hospital.

Resident in our long term care facility who received first dose of Moderna COVID-19 Vaccine on 12/22/2020, only documented side effect was mild fatigue after receiving. She passed away on 12/27/2020 of natural causes per report. Has previously been in & out of hospice care, resided in nursing home for 9+ years, elderly with dementia. Due to proximity of vaccination we felt we should report the death, even though it is not believed to be related.

Within 24 hours of receiving the vaccine, fever and respiratory distress, and anxiety developed requiring oxygen, morphine and ativan. My Mom passed away on the evening of 12/26/2020.

Near syncopal episode approximately 2.5 hours after vaccination. Sudden onset of dizziness, nausea, and diaphoresis. Was admitted to ED and observed overnight. Full cardiac work up was done and shown to be within normal limits. I have no pre-existing conditions and considered to be a healthy adult.

On Dec. 20, 2020 around 11:30 PM, 2 days after patient received her COVID-19 vaccination, she was found on the bathroom floor , obtunded, very pale, diaphoretic, nauseous, and complaining of severe chest pain. Paramedics was called and patient was transported to the nearest emergency room.

According to paramedics, on the way to the ER while patient was in the ambulance,she was noted with a sudden drop in heart rate about 19 beats/minute and have to be given Atropine IV Push, oxygen and was connected to transcutaneous pacing which improves her heart rate. In the ER patient continued to have chest pain and she was given Morphine, Oxygen, Nitroglycerine and Aspirin. IM had an EKG which showed Sinus Bradycardia with a Right Bundle Branch Block. She had serial ekgs, a chest x-ray, laboratory testing which included Troponin. Her first Troponin level came back elevated prompting her hospital admission to Telemetry. Her next 2 Troponin level improved and return to normal range and her chest pain has resolved.. She underwent a Stress Test which came back negative. Patient was admitted for a total of 20 hours in the Telemetry unit with Cardiology consultation before being discharged home last . She was re-evaluated by the cardiologist yesterday which diagnosed her a chest pain of unknown origin.

RESIDENT CODED AND EXPIRED

Rash, Itching and swelling of left arm. Progressed to tachycardia in the 150's, hypertension 200/114. Tingling of lips, dizziness

Went to Emergency room on 12/28/20 because he was short of breath. Tested positive for COIVD_19 and was admitted with hypoxia.

Approx 20 min after vaccination patient developed itching at the site and this progressed to include chest, neck. EMS evaluated patient who recommended transport and patient agreed. Benadryl offered by EMS and IV started. Pt with concurrent treatment for valley fever noted. ED administered medications - famotidine 20mg iv, methylprednisolone 125mg iv, NS 1000ml bolus. Prescribed prednisone 20mg po daily x 2 days.

Injection given on 12/28/20 - no adverse events and no issues yesterday; Death today, 12/30/20, approx.. 2am today (unknown if related - Administrator marked as natural causes)

Death by massive heart attack. Pfizer-BioNTech COVID-19 Vaccine EUA

Moderna COVID?19 Vaccine EUA - Metalic taste - Lump in her throat- felt like swelling - Nausea and then vomiting - Shaking and started to become unresponsive.

pt passed away with an hour to hour and 1/2 of receiving vaccine. per nursing home staff they did not expect pt to make it many more days. pt was unresponsive in room when shot was given. per nursing home staff pt was 14 + days post covid

pt was a nursing home pt. pt received first dose of covid vaccine. pt was monitored for 15 minutes after getting shot. staff reported that pt was 15 days post covid. Pt passed away with in 90 minutes of getting vaccine

The patient had COVID19 infection diagnosed 12/14/2020, and he stated 5 to 10 days after this, he developed shortness of breath. Had vaccine on 12/24/2020. Hypoxic and short of breath with COVID19

pneumonia on 12/29/2020. I do not know if this is an adverse effect or temporally related or if the vaccine activated prior infection.

"my left arm and breast were tender with some mild body aches and low grade headache/Arm soreness; my left arm and breast were tender with some mild body aches and low grade headache/ left breast was increasingly painful with swollen palpable lymph nodes; my left arm and breast were tender with some mild body aches and low grade headache/ left breast was increasingly painful with swollen palpable lymph nodes; my left arm and breast were tender with some mild body aches and low grade headache/ left breast was increasingly painful with swollen palpable lymph nodes; my left arm and breast were tender with some mild body aches and low grade headache; body soreness and stiffness; This is a spontaneous report from a contactable healthcare professional. A 34-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899), via an unspecified route of administration on 18Dec2020 at single dose for COVID-19 immunisation. The patient medical history and concomitant medications were not reported. The patient stated, ""the day after the injection, my left arm and breast were tender with some mild body aches and low grade headache. Sunday Arm soreness went away but left breast was increasingly painful with swollen palpable lymph nodes, with body soreness and stiffness. Monday left breast is still remarkably tender with palpable lymph nodes"" on 19Dec2020 (reported as Seriousness criteria-Caused/prolonged hospitalization: Yes, on an unspecified date in Dec2020). The outcome of the event was not recovered.; Sender's Comments: The reported information is limited. Based on the close temporal relationship and the description of the events, there is a reasonable possibility that the events are related to BNT162 vaccine. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate."

got COVID vaccine from Pfizer, next day got COVID tested with mild symptoms and positive; got COVID vaccine from Pfizer, next day got COVID tested with mild symptoms and positive; This is a spontaneous report from a contactable physician (patient). A patient of unspecified age and gender received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on an unspecified date at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient reported that he is a physician and got COVID vaccine from Pfizer, next day got COVID tested with mild symptoms and positive. The patient stated so he got vaccinated probably while having COVID. The patient wanted to know any concerns from the vaccine standpoint efficacy side effects. Outcome of the event was unknown. Information on the lot/batch number has been requested.; Sender's Comments: The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

"asking on how to differentiate between side effects from COVID vs vaccine side effects/also wondered if he needs to quarantine; asking on how to differentiate between side effects from COVID vs vaccine side effects/also wondered if he needs to quarantine; swelling of glands in throat/lymphadenopathy in throat; headache; Feeling a little fluish; This is a spontaneous report from a contactable healthcare professional (patient). A 61-year-old male patient received BNT162B2 (Pfizer-BioNTech COVID-19 mRNA vaccine, batch/lot number and expiry date were unknown), via an unspecified route of administration on 21Dec2020 18:06 at a single dose for COVID-19 vaccination. Medical history included diet controlled Type 2 Diabetic diagnosed 5 years ago in 2015. There were no concomitant medications. The patient previously got Shingles vaccine and it was a two dose vaccine. He felt a little bit like he did now after receiving the second vaccine. He felt fluish for 8-12 hours the day after receiving the vaccine. He has gotten lots of vaccines like Flu and has no responses. The patient does not have prior vaccinations within 4 weeks. The patient received the vaccine yesterday (21Dec2020), and maybe an hour ago on 22Dec2020, he started feeling swelling of the glands in throat or lymphadenopathy in throat and a little bit of headache. He has a question that he cannot find the answer to anywhere. The patient is asking on how to differentiate between side effects from COVID vs vaccine side effects? His temperature was 98.1 on unspecified date. He did not have an exact time frame for when it began. He stated, ""you get swelling in glands and then you notice it."" He noticed about 2 hours ago and it is getting worse. Now he is feeling like he is sick. He has been volunteering and giving the vaccines over the past two days himself. He is feeling now a little fluish. He doesn't know how to say it other than tired and just doesn't feel good. He would go to work like this and does not feel it is medically significant. He does feel like he is deteriorating but that is only a guess. He felt a little worse than an hour ago. He also wondered if he needs to quarantine because he is signed up to give the vaccines and would not want to do that if he should not. No ER or physician's office required. The outcome of the events was not recovered. Information on batch/lot number has been requested.; Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of reported events cannot be totally excluded. The case will be reassessed if additional information becomes available."

tested positive for Covid; tested positive for Covid; This is a spontaneous report from a contactable consumer (patient) from a Pfizer-sponsored Program Pfizer First Connect. A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) Lot number Unknown, via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunisation. The patient medical history and concomitant medications were not reported. The patient was upset. She was part of the COVID Trial in and this past week (in Dec2020) she started to get sick and tested positive for COVID. They gave her a diary which she had to fill out weekly, so she filled it out and put that she had COVID. She never heard from anyone. She stated the testing site people and snarky attitudes and when they went no one was wearing masks. She was told by the testing site, they couldn't make people wear them. Relayed that she could do an escalation and have someone reach out to her in regards to this. The patient underwent lab tests and procedures which included Covid test: positive on unspecified date in Dec2020. The event outcome was unknown. Information on the Batch/Lot number has been requested.

Itchy throat, red eyes after 30 minutes. EMS on site gave IV Benadryl, epi pen shot and took to ER for monitoring. Vitals were good so he was discharged.

Hives/swelling/itchiness/redness at injection site about 5 inches long a week after injection.

"Chills, Fatigue, ""hot"" feeling eyelids when I close eyes, muscle/joint pain, injection site pain. No treatment besides rest and a hot shower."

Pt felt hot and short of breath . Pt recieved EPI in office and EMS was called . Pt was transported to the Hospital

Sore arm-2days , headache -current on and off , light sensitivity 2 days

Currently have shortness of breath, chest pain, fatigue, nausea, body aches, joint pain, and injection site pain.

Dizziness, Equilibrium was off. This started within an hour of the vaccine and lasted 24 hours. Had to take the following day off of work. Also, burning in the chest (like heartburn) lasted 48 hours.

Weakness, headache, high level myalgias, fever, nausea, cold intolerance, shaking

Onset was 10 min post vaccination. Symptoms experienced over an hour, in this order. Went to the ED. Some still continuing within 14 hrs past time of shot. Severe headache. * same night Dizziness and lightheaded. * same night Nauseous Clammy Cheeks flushed Itchy Chills Short of breath / slight wheezing * same night Fatigue * same night

Extreme vertigo occurred suddenly around 9:00 pm. Continuous dizziness continues. Unable to walk straight lines. Wobbling and loss of balance when I walk. I have eaten and been drinking fluids. Side effect still continues.

Normal resting heart rate of 58-61. At 10 PM, heart rate increased to 137 while watching TV, heart rate continues to average at 102 bpm for 120 minutes + and counting. Body feels warmer than usual

About 4 hours after receiving this vaccine I experienced burning down my left arm and up into my chest. I had chest tightness and over the course of the day it became worse. I developed a fever of 100.9 and I woke in the night to SEVERE body aches and a migraine headache. Fever and chills I also had a runny nose earlier that day. It is now the second night after the vaccine and I am still experiencing severe pain in my joints back and kidneys. Also muscle pain If I have a fever in the am, should I wait to go back to work?

Fever of 102 with onset at midnight after vaccination,a long with chills, muscle aches, some nausea,--subsided after a few hours. headache and tiredness the morning after

Raised, hardened, hot bump on arm 24 hrs post injection with pain and swelling

I have an autoimmune disease, psoriatic arthritic and osteoarthritis. This caused my flare up. My knees and ankles swelled to the size of grapefruits. I could not move legs for about 18 hours. From Friday to

Sunday, I could not get out of bed. Monday night, I really started feeling better and was able to take care of my kids again on Tuesday. I went back to my normal shift on Wednesday. I was under the care of my PCP and Rheumatologist.

10 minutes after receiving vaccine, patient reported numbness across upper lip which progressed to her tongue. Felt tingling and dryness of tongue and swelling. No difficulty breathing or swallowing, no chest pain, no wheezing, no rash, no itching. Taken to ED and given methylprednisolone 125mg IV, diphenhydramine 50mg IV, famotidine 20mg PO. Patient improved and monitored x 4 hours with resolution of symptoms. Prescribed prednisone 50mg po x 4 days.

erythema, tachycardia, tachypnea, headache, uncontrolled dystonic shaking

Developed sudden onset of shaking chills and fevers as high as 103.0. She has developed a small circular 5 x 5 area of erythema and firmness at the injection site of her left upper arm.

Dizziness, Hives on entire body

pt received vaccine at covid clinic on 12/30 at approximately 3:30, pt vomited 4 minutes after receiving shot--dark brown vomit, staff reported pt had vomited night before. Per staff report pt became short of breath between 6 and 7 pm that night. Pt had DNR on file. pt passed away at approximately 10pm. Staff reported pt was 14 + days post covid

Sent home from work after receiving vaccine. I immediately developed sore throat. First 3 days I was miserable and then this whole week everything has bad. Outside of ears were burning. Stomach turned immediately. I thought I was going to vomit. Top of my head started spinning. I am still foggy. Breathing was never altered.

Received my vaccine on December 22nd, 2020 at around 830 Am. That afternoon, about 3 PM, I started to have a reaction. It started with tingling/numbness in my right hand which progressed up my arm into my elbow. About 10 minutes later, it then progressed into my right foot, and my left foot. About 10 minutes after that, I started to get flushed and a neck rash (diagnosed from Dr.). I took Benadryl and Ibuprofen 800mg PO every 6 hours for the next 24 hours. The numbness in my right foot and left foot along with the flushness went away a couple hours later. Although, the numbness in my right hand never went away. It came and went for the next 4 days until December 27th and 28th when it started getting worse. On December 28th evening, it got so bad that I was debating going to the emergency room around 1 am. The numbness and tingling was in my right hand and started shooting up my arm. The nerve pain around my wrist was unbearable. I finally fell asleep and the next morning, it was not nearly as bad, but was still there. The numbness and tingling moved from my right hand mainly to right hand, right foot, right leg, left foot and left hand today (12-30-2020).

angiodema. hospitalized overnight. During the hospitalization pt was started on an epi gtt and given MTP 125 mg. He had subsequent hyperglycemia, and increased his rate on his insulin pump to 2 U/hr (from 0.83 U/hr). Pt then decreased his rate to 1.4 U/hr while on the epi gtt, and then to 1.1 U/hr when off of the epi gtt. He also strengthened his carb ratio from 1:12 to 1:10 last night.Pt reports he had

postprandial hyperglycemia overnight after his meal, but then BG corrected overnight. Pt reports fasting this morning is in the 110s. This morning's breakfast on 1:10 CR with well controlled BG.

Resident received vaccine per pharmacy at the facility at 5 pm. Approximately 6:45 resident found unresponsive and EMS contacted. Upon EMS arrival at facility, resident went into cardiac arrest, code initiated by EMS and transported to hospital. Resident expired at hospital at approximately 8 pm

Due Date unknown/6-7 wks pregnant -nausea -Body felt heavy -headache -in & out consciousness -Fatigue, severe -Heart Racing

Patient had an anaphylactic reaction to the vaccine the day after it was given and went to the nearest ER.

Patient stated he stopped his blood pressure medications 3 days prior to vaccination due to a previous reaction to losartan, a medication he was no longer taking. Patient took aspirin and a MVI on day of vaccination and drank lemon water. Patient developed tingling sensation in his mouth after eating dinner around 18:00. Patient stated he ate tacos with apple cider and noticed tingling after dinner. Patient stated he took two benadryl with no relief. His tongue continued to swell and he took two additional benadryl at 22:00. Once he developed difficulty swallowing he went to the emergency department. Patient presented to the ED with tongue swelling and difficulty swallowing. At 23:57 he was adminsitered 0.3mg of epinephrine IM, diphenhydramine 25mg IV, famotidine 40mg IV, dexamethasone 10mg IV at 0114, methylprednisolone 60mg q6hrs started at 0417, diphenhydramine 25mg q6hrs IV started at 0416, albuterol 2.5mg via neb q6hrs started at 0710

Patient died within 12 hours of receiving the vaccine.

Resident received vaccine in am and expired that afternoon.

Started feeling a reaction immediately after the vaccine, felt blurred vision, dizziness, racing heartbeat, chest rash and face, itching all over, difficulty swallowing, tongue tingling and wheezing. Sent to ED. EPI and Benadryl. 1800 Went to see her in the ED, room 33. She has red rash to neck, shaky hands itching to neck and chest. ED Dr to discharge, she stated husband to pick her up and she will follow up with OH tomorrow. ----------RN ED gave her Epinephrine 0.3 mg, Methylprednisolone 125mg, Diphenhydramine HCL 50 mg, Zofran 4mg, Lorazepam 1 mg, Hydroxyzine HCL 50 mg Sumatriptan 6mg , Discharge from ED at 1902 ---------- ---------- RN 12/29/2020 1715 called to check on patient. left voicemail for her to call OH. ???????..? 12/29/2020 1838 left voicemail for patient to call OH. ??????????????????????. 12/30/20 2030 spoke with her. Tuesday 12/29 3pm-4pm dizziness, confusion, sob. Wheezing. Ambulance called. Hospital admitted. Intubated for less than 24 hours. Breathing treatments, epi drip. Now just on steroids and walking around and feeling better. Still admitted at hospital. Hoping discharged tomorrow. ----------RN

Patient received dose 1 of COVID vaccine 12/24. He developed symptoms consistent with COVID infection on 12/25. He was seen in the emergency room at Hospital on 12/27,was diagnosed as COVID positive, and was discharged to home. He returned to the emergency room on 12/29 and was admitted to the hospital for treatment related to COVID infection. He is currently admitted to Hospital.

10 minutes after vaccine numbness and tingling in left foot, hand and left side of face. Spacing out feeling. Feel like i'm going to pass out.

EDD - 4/1/2021 - Contractions at 26 w 3 days sent to L&D to be monitored on 12/28/20. Covid-19 Sars Vaccine given 1st dose 12/27/20. Patient was diagnosed with Fetal Hydrops. Patient Hospitalized 12/28/20 - current MFM consulting in hospital & outpatient

EE has a history of anaphylaxis reaction to Latex. EE states she was intubated in Mexico over this in the past. Pfizer-BioNTech vaccine given, 20 minutes later EE c/o dizziness. EE places on cot and starting wheezing and being short of breath. Lungs sound tight and wheezy throughout. á 1052- Epi 0.3mg IM given in Right Deltoid 1053- Benadryl 50mg IM given in Left Deltoid á 1054- EE getting restless and starts feeling chest tightness. Epi 0.3mg IM given in Right Deltoid á Code Green Team arrived at 1054. á BP 197/126, HR 88, RR 44, blood sugar 109 á 1058- EE getting wheezing and short of breath again. Epi 0.3mg IM given in Right Deltoid and Benadryl 50mg IM given in Left Deltoid. á 1059- EE transferred to ED on stretcher, escorted by ICU RN and ICU MD. In ED- patient given solumedrol, epi, benadryl, phemodidine, ativan, zofran x 2 and ee sent home with medications as well.

Redness about 1 1/2 inches around injection site, edema to right arm, r side of neck, r breast, r shoulder, temp 99.3, increased blood pressure. Patient went to primary care physician. She was then sent to the ER. She was Covid (+) in July 2020

Shortly after receiving the vaccine (within 10 minutes) the patient's tongue swelled, facial redness, gasping for air. This resident was marked for a 30 minute observation due to previous anaphylaxis type reaction. Immediately administered 0.3mg epinephrine x 1 dose. Then administered 50mg IM Diphenhydramine. This treatment course resolved the adverse reaction. Patient was monitored onsite at facility. Her husband came to pick her up and take her home. Tried to reach patient several hours after but was unable to at this time.

I had shortness of breath

approximately 30 minutes after receiving vaccination i began to develop tongue and lip swelling as well as difficulty swallowing and breathing , i then proceeded immediately to the nearest er

Patient complained of a headache, then patient was losing consciousness and gasp for air. EpiPen was utilized due to being unresponsive then began to seizing. Patient started to flatline and an AED was used while a paramedic came. Patient was put on her side then facility gave something for seizures. Lastly, ,ambulance took her to the hospital.

Patient started having myalgia, chills, nausea on the next day of the vaccination. on 2nd day (12/29) patient had chest pressure which made her present to Hospital ED. She had troponin elevation to 1.14.

Cardiac Catheterization was done which was negative. On Trans Thoracic Echocardiogram, patient was found to have hypokinesis of the mid and distal segment with some sparing of apex proving Takotsubo (stress induced) cardiomyopathy. Patient did not have any underlying emotional or physical stress going on in her life or family. Till now extensive infectious as well as inflammatory work up is done to rule out any secondary causes of cardiomyopathy which till date have remained negative. As a diagnosis of exclusion, her presentation seems to be COVID-19 vaccine induced Takotsubo Cardiomyopathy

Pt received 1st dose of Moderna vaccine in am at COVID vaccination clinic. On presentation to clinic he stated he was feeling well. Pt was brought to ER in pm with hypoxic, requiring 15L supplemental O2. Per pt's family, pt was not feeling well for the last couple of days but didn't think it was related to COVID. Abbott COVID + in ER. Possible vaccine reaction, though seems unlikely.

"15-20 mins after receiving the vaccine she reported she had difficulty swallowing and difficulty breathing and was ?shaking."" a PA wrote in her note that when she ran in to help, she found the patient to be tachypneic, diaphoretic, warm with some red blotchy patches on face, chest & neck. Able to speak easily c/o trouble breathing & sensation of throat swelling & extremities feeling abnormal. No stridor. No facial edema noted by that clinician. Administered epi-pen 0.3mg - IV started , Benadryl 50mg IVP and solumedrol 125mg IVP. Patient reports she subsequently arched her back and had rigidity of her arms/legs and tremors. Clinic PA reports that while she was there, pt was never hypotensive. Initially hypertensive after epi as expected with some favorable response after 10-15 min Staff there gave her IM epinephrine, IV Solu-Medrol and 50 mg IV Benadryl. EMS was contacted and transported to the emergency room. She arrived at the ER, was monitored for 2 hours, was started on pepcid and benadryl and discharged from the ER. She had a diffuse itchy rash. The following day she again developed recurrence of throat swelling. Went back to a different ER. Developed dyspnea immediately prior to arrival at ER. There was again given solumedrol and benadryl and pepcid and developed muscle rigidity and arched back for 10 minutes. Symptoms of SOB and dyspnea resolved with epinephrine. Was discharged from the ER with prednisone after being monitored for 5 hours. Is continuing to take prednisone and benadryl. Rash is still present but improving with scheduled benadryl. Has new redness at injection site today. Continues to feel some throat swelling but no tightness today. This information was gathered from talking with pt today for a phone appt and also from her medical chart regarding her vaccination visit and two ER visits."

Acute appendicitis, onset morning of 1/1/2021 (Reporting this because Pfizer covid vaccine had 3-4x higher risk of appendicitis, although data not reported for Moderna covid vaccine)

on dec 22 I felt some myalgias, chills, fatigue, HA --quite normal. That evening, noted small amount swelling R hand --I iced and took acetaminophen. By Dec 25, hand very swollen and painful with decreased ROM all fingers

Within 15 minutes of receiving the vaccine I began to get very itchy and blotchy with a hoarse voice. The paramedic downstairs walked me up to the emergency room. I was treated with medications to help calm the itching and burning feeling. By 940 I went anaphylactic and had several doses of epinephrine to help calm this. I continued to have rashes and the feeling of my throat closing. I was transferred by

ambulance to medical center in the ICU. I am still here and have had two toner anaphylactic episodes since. I have been on a epi drip, steroids, famotidine, Ativan and Benadryl. I also had a picc like placed.

Anaphylaxis. Immediately experienced shortness of breath, rapid heart rate, and rash. I am a Nurse Practitioner in the emergency department. Had went down to the temporary vaccine station to receive my vaccine, immediately returned to the ER and began to experience symptoms of anaphylaxis. Was immediately placed in a treatment room and received treatment by the ER physician, which included oxygen, intravenous Benadryl, Solumedrol, and Normal Saline. Was observed for several hours and then eventually sent home with prescription for Prednisone and Pepcid. I do have a allergy to shellfish, was never asked about my allergies and nothing on the paperwork I was given prior to the injection noted a concern for shellfish allergies.

Vaccine on 12/22/2020 and started feeling bad on 12/27/2020 and tested positive on 12/30/2020 for COVID 19 Was advised to fill this out by my PCP

Flushing, sweating, increased heart rate proceeded to feel difficulty swallowing and clearing my throat. I was taken to the ER. The symptoms progressed to feeling dizziness, difficulty speaking, and chest pressure with increased SBP/DBP. General nausea and feeling very unwell.

CAREGIVER RECEIVED FIRST VACCINE DOSE AND SOON AFTER BEGAN TO FEEL DIZZY AND HER EYES BEGAN TO TWITCH, FOLLOWED BY UNCONTROLLED SHAKING, WITH HIGH FEVER FOLLOWED BY SEVERE SHORTNESS OF BREATH AND GASPING, WITH TIGHTNESS AROUND THE CHEST. TRANSPORTED TO EMERGENCY DEPARTMENT. HAD MULTIPLE EPISODES OF ITEMS LISTED ABOVE WHILE IN ED, INCLUDING HEAVINESS IN HER LEGS AND TINGLING IN ARMS. SHE WAS DISCHARGED FROM ED AT 10:30PM BUT WAS READMITTED ON 12/24 TO ED FOLLOWING SIMILAR ISSUES. TO DATE SHE HAS HAD 5 RAPID RESPONSES IN HOSPITAL DUE TO REPEAT OF SIGNS/SYMPTOMS. CT AND PULMONOLOGY CONSULT SCHEDULED FOR 12/28/2020.

Patient is a 55 year old male with no past medical history who presents with complaint of sudden onset of left-sided nonradiating chest discomfort of sudden onset approximately 1 hour prior to presentation while doing administrative work at rest. He describes the pain as a dull heaviness sensation and approximate 3/10 pain severity. Chest discomfort was associated with a feeling of flushing that was quite transient but chest discomfort was persistent. Patient immediately presented to the ED for further evaluation. He denies experiencing any chest pain upon waking up this morning. Does note that he did have a transient episode of epistaxis on his way to work for which he had to pull over and apply pressure to his nose but this subsequently subsided and he attributed this to dry air as he has experienced epistaxis in the past but with less severity previously. In the ER, vital signs noted for BP 133/76, pulse ranging 91-114, respiratory rate 16-20, 96% on room air. Initial laboratory parameters were completely normal including normal CBC, CMP, LFT, lipase, UA, and normal D-dimer. Initial troponin was negative x1. EKG with sinus tachycardia, heart rate of 115. Noted Q waves inferiorly. No acute ST or T wave changes appreciated. Chest x-ray with mild increased density in the left lower lobe. Given this, patient was tested for rapid Covid which was negative but PCR was positive for COVID. CT of the chest noted for focal subsegmental groundglass infiltrate at the superior segment of the LLL, likely infectious versus

inflammatory. Also noted small nonspecific groundglass attenuation with focal septal thickening at the right upper lobe which could be infectious or inflammatory, bibasilar atelectasis. Patient was treated with aspirin 324 mg in the ED. Of note, patient actually just received the COVID-19 vaccination on 12/24/20. He denies any shortness of breath, no cough, denies any nausea or vomiting, denies any change in taste or smell nor change in appetite. Does note 1 single episode of loose stool but otherwise denies any diarrhea. Does report that he had approximate 48 to 72-hour period of fatigue and soreness at the site of the left deltoid injection following the vaccination but otherwise no further symptoms. It is also noted that he does have a positive family history of coronary artery disease as his dad had an MI at the age of 49. Patient has never undergone a cardiac catheterization in the past but does report having a negative stress test at the age of 42. He is being admitted under the hospitalist service for further management Patient was initially admitted under observation for chest pain obs. However patient's Covid test came back positive and patient also had dynamic EKG changes concerning for possible unstable angina. Patient was treated with aspirin Plavix full-strength Lovenox along with beta-blocker and a cardiology consult. Serial troponins were negative. Echocardiogram revealed normal EF of 55 to 60% with no hemodynamically significant valvular disease. Cardiology felt that patient likely has underlying coronary artery disease have recommended discharge home with aspirin and Plavix with outpatient stress testing given his positive Covid testing. At the time of discharge patient denied any chest pain or shortness of breath. Patient was borderline diabetic with a hemoglobin A1c of 6.1. Patient was discharged home with Metformin along with glucometer, glucose strip, lancets. Given patient's tachycardia patient's Metformin 25 mg twice daily was changed to Toprol 25 mg daily. (Please note clarification in comparison to discharge home med list. Toprol XL 25 mg daily was called to pharmacy in place of the metoprolol.)

The vaccine was received at 1:12 PM, and I felt fairly fine, aside from injection site pain and some tingling in my left arm until I had sudden significant elevation of heart rate, with shortness of breath, and throat swelling/tightening at approximately 1:26PM. I cold compress was applied to my forehead and I was put in a reclining position & then received Epinephrine at 1:28PM. EMS (present onsite) arrived for transport at 1:31PM. 4L of oxygen was applied after O2 sat of 89% noted by EMS. Blood pressure was elevated to >200/100 initially by EMS. Symptoms improved quickly following epinephrine, with some residual feelings of very mild throat fullness, and I developed chills which improved over time. I was transported to emergency department where I was evaluated (symptoms mostly resolved at that time, but ED physician noted a little swelling remaining in my uvula), then IV Benadryl and Decadron were given. Later acetaminophen was also given for headache that developed during my ED stay. My vitals were monitored throughout and observation occurred until I was discharged at approximately 5:00PM, as symptoms had not recurred.

HIVES, SOB, THROAT CLOSING UP, WHEEZING

12/28/2020, Pharmacy staff administered Moderna COVID Vaccine. 12/29/2020, he had not eaten breakfast or lunch but did consume fluids and take his medications. BP =150/70, Temp. = 101.6, Pulse= 102, Respirations= 18 and Oxygen saturation= 97%. Tylenol 650 mg given. It was difficult for him to swallow. Also had no use of right upper extremity and unable to move lower extremity, mouth was drooping and was drooling. Physician in attendance and ordered to send to ER. 1/1/2021, received

information from nurse at hospital that patient received a Peg Tube this afternoon and Clinical indication of a stroke.

I received the vaccine at 6:30pm on 12/27. I worked atb7pm and took lunch at 2:00am. After lunch, I immediately felt sick to my stomache and threw up. I went home after my shift and went to bed. After 5 hours, I woke up and went to the couch to lay down while kids watched TV. Next, I woke to several people in my house. I had a seizure and my son had called 911. I was taken to emergency department. I was admitted and stayed 2 nights in the hospital.

After vaccination, patient tested positive for COVID-19. Patient was very ill and had numerous chronic health issues prior to vaccination. Facility had a number of patients who had already tested positive for COVID-19. Vaccination continued in an effort to prevent this patient from contracting the virus or to mitigate his risk. This was unsuccessful and patient died.

A little over ab hour after receiving the vaccine I noticed a burning sensation in my sinuses. By 130am 1/1/2021 I awoke from my sleep terribly dizzy, shaking violently and experiencing a fever of 101.3 F. I took advil and tylenol and fell asleep about an hour later. I woke up with similar symptoms at approximately 830am on 1/1/2021 took an additional dose of advil and tylenol and slept till 12p. I woke up with a bad headache and coughing fits similar to when I had covid back in March. I went to an urgent care who assessed me and ordered me to the ER. medical center administered IV fluids, an inhaler, steroids, epinephrine and benadryl and a few hours later my symptoms had subsided for the most part and a dose of IV antibiotics was administered. I am currently admitted for observation with likely discharge on 1/2/2021.

30YO F ICU nurse obesity (BMI 35) COVID 19 on Dec 2 symptoms, Dec 3 tested positive for COVID-19. never hospitalized, outpatient only. 12/12 completed isolation 12/21 received vaccine 12/7 developed Fever chills diarrhea SOB cough Urgent care visit. RLL consolidation on CXR given doxycycline 100 mg po bid worse, fever 40 targetoid lesions to LE (started before doxy) WBC 22K tachycardic tachypneic admitted requiring 2-4L oxygen CT angio without clot, diffuse ground glass and RML dense infiltrate DDimer 7.8 LDH 599 CRP 41 procal 0.67 ferritin 500 Viral respiratory PCR negative Sputum cx with oral flora (pending) COVID ag testing neg COVID PCR 1/3 targets positive (called as indeterminate).

Within 5 minutes of the vaccine, patient had wheezing, shortness of breath and chest pain. patient given epi x 4, decadron, fluids with some improvement and then hospitalized. IN the hospital, patient continued to have chest pain and satting well but with protracted course and is still in the hospital.

Vaccine given at 7:05am 12:00noon, 5 hours later, I started experiencing severe chest pain, jaw pain and shortness of breath in which EMS was called and I was taken to the hospital. Since then, I lost feeling in my hands and feet, numbness and tingling. I've improved however, during my recovery suffered with spinal pain, shortness of breath, very winded, muscle pain and loss of appetite to especially meat.

Soreness and weakness of left arm for more than 5 days. Intermittent headaches and runny nose

On 12/29: lightheadedness, flushed, felt like I was going to pass out, numbness/tingling down arms and hands, chest tightness, clammy hands and feet.

Anaphylaxis. The COVID shot was given, no reaction then. After 7 minutes, congestion, severe cough, vomiting phlegm, feeling like throat closing started happening. Code was called, Benadryl was immediately given intramuscular in the left arm, blood pressure, pulse ox was taken, and then was taken to the Emergency Department. In the ED, I was given prednisone, one EPI, anti-nausea medication all through I.V. and many more medications given to me via I.V. that I don't sincerely remember. I was under observation for 4 hours. I was discharged after all symptoms dissipated and was given Prednisone 20 MG (3 tabs a day) to take to help my lungs. Management followed up almost immediately, everyone from the moment I had the anaphylactic reaction was quick and prepared.

Patient with a history of thalassemia and Gilbert's disease, developed severe jaundice three days after vaccination. Had mild headache and sore arm but otherwise felt well. Had labs drawn - found to have highly elevated bilirubin (23) and LFTs in the 700s. Was admitted to the hospital and had CT showing Cholelithiasis, choledocholithiasis and minimal intrahepatic biliary ductal dilatation. Left hospital and was admitted to another facility where plan was for ERCP and cholecystectomy. Ultimately unclear if at all related to the vaccination - may be coincidental.

Pt had vaccination at city site. Waitied 15 min after shot and was cleared to go. Reported to wife that he was very thristy, so they stopped at a convenience store on the way home. While there, he felt worse and asked to go to the Emergency room. They chose Methodist to enter. Pt went to triage and while at triage, had syncopal episode, then full arrest. After short course of CPR and defib, he had ROSC. Was taken to cath lab for intervention (stents) and is now in ICU.

At the time of vaccination, there was an outbreak of residents who had already tested positive for COVID 19 at the nursing home where patient was a resident. About a week later, patient tested positive for COVID 19. She had a number of chronic, underlying health conditions. The vaccine did not have enough time to prevent COVID 19. There is no evidence that the vaccination caused patient's death. It simply didn't have time to save her life.

Prior to the administration of the COVID 19 vaccine, the nursing home had an outbreak of COVID-19. Patient was vaccinated and about a week later she tested positive for COVID-19. She had underlying thyroid and diabetes disease. She died as a result of COVID-19 and her underlying health conditions and not as a result of the vaccine.

Tactile fever ,arm pain, headache and malaise in 24 hrs following injection Next day generalized achiness ,retrosternal chest pain and bilateral forearm tingly pain similar to Nov 2019 and went to Hospital UC,CXR and EKG normal but with short PR interval on EKG ,elevated troponin 3.5 Transferred to hospital troponin 12.1 ng/ml IVIG given SARS IGG positive on admission PCR negative

ON 1/1/21 THE DAY AFTER I RECEIVED THE VACCINE I WAS TAKING A NAP AND MY WATCH KEPT SENDING ME ALERTS. HOWEVER I DID NOT CHECK MY WATCH UNTIL 5:30 WHEN I WOKE UP AND I FELT LIKE I WAS HAVING HEART PALPITATIONS. I WENT TO THE EMERGENCY ROOM WHERE I WAS TREATED. I

WAS TOLD THAT I WAS FEBRILE WITH A TEMPERATURE OF 102. I WAS GIVEN IV FLUIDS, CHEST X-RAY, EKG AND LAB WORK. I WAS RELEASED ON 1/2/21 AT APPROXIMATELY 0030 (MIDNIGHT).

"Patient is hospital employee who completed screening form for COVID-19 vaccine by answering ""no"" to all contraindication questions. Approx 10 minutes after receiving COVID-19 vaccine dose # 1, patient was still in vaccine clinic area and complained of dizziness, palpitations and flushing. I observed patient fanning herself with papers. She was escorted out of the immediate clinic room, and assessed by paramedics present as having an anaphylactic reaction. Epinephrine 0.3 mg IM and diphenhydramine 50 mg IV given in clinic, Rapid Response was called overhead and patient immediately transported down the hall to the Emergency Dept. In ED, pt was noted as having swollen tongue, large areas of erythema on face, arms and chest, shortness of breath, nausea, dizziness (per ED physician notes). Pt reported being hospitalized in ICU with COVID disease more than 3 months ago, including intubation (not treated at this hospital), and has been back at work since August 2020. ED physical exam noted bilateral wheezing and patient in acute distress. In ED, pt administered racemic epinephrine 2.25% 0.5 mL via neb, epinephrine 0.3 mg IM, diphenhydramine 50 mg IV, Solu-Medrol 125 mg IV, famotidine 20 mg IV and epinephrine 5 mg/250 mL IV drip (started at 0.118 mcg/kg/min). Acute symptoms reported to resolve in ED. COVID test was negative. ED physician discovered that pt had history of multiple medications, including previous anaphylactic reaction to radiocontrast dye requiring intubation (which was not disclosed on the vaccine screening form). Pt admitted to Telemetry floor for observation. Overnight course was unremarkable, and patient was discharged the following day with prescription for Prednisone taper and prescription for Epi-pen. Advised not to return for second dose of COVID vaccine. EMR updated to reflect possible anaphylactic reaction to Moderna COVID-19 vaccine."

25 minutes after receiving the injection, there was a sudden onset of facial swelling, hives, itching and airway constriction. I had already left the drive-thru vaccination clinic and was driving to the hospital emergency room where I work. I informed my colleagues of my symptoms and was treated for anaphylaxis with IV diphenhydramine and famotidine over several hours. I was given a prescription for a prednisone taper for the next 6 days.

I suffer from lingering SOB with exertion after COVID infection. On the night of 12/31/2020 I began to feel more SOB than usual and was unable to correct my SOB with rescue inhaler. Became more SOB with exacerbated tachycardia and tachypnea, My family had to call 911 because I became aphasic and showing signs of possible stroke. I was taken to the ER and admitted for respiratory recovery and to role out stroke. The stroke was ruled out and I recovered with IV prednisone therapy, twice daily and supplemental oxygen. Released after HR, BP, & respiratory effort returned to normal: 01/03/2021

I was 28 weeks and 5 days pregnant when I received the first dose of the COVID19 vaccine. Two days later (12/25/2020 in the afternoon), I noticed decreased motion of the baby. The baby was found to not have a heartbeat in the early am on 12/26/2020 and I delivered a 2lb 7oz nonviable female fetus at 29 weeks gestation. I was 35 years old at the time of the fetal demise and the only pregnancy history for this pregnancy included a velamentous cord insertion that was being closely monitored by a high risk OB. My estimated due was March 12, 2021.

At around 40 hours post vaccination, developed severe abdominal pain and went to an emergency room for evaluation on 1/1/21. Abdominal pain was eventually diagnosed as appendicitis requiring appendectomy on 1/2/21. Emergency room visit and hospital discharged patient early on 1/2/21. It was then determined that the on-call team covering mis-read the CT scan and acute appendicitis was found. Patient then went to Medical Center on 1/2/21 for appendectomy and was discharged later that night following operation.

Headache, muscle pain on the site of injection, chills, nausea, fever. Started time 01.03.2021 8:15pm.

15 min after the vaccine I was flushed and felt hot , ears felt hot as well. I had a macular rash on chest and arms. My throat felt itchy and they immediately gave me benedryl. I was tahycardic as well. When I got home from the ER that night I had to take more benedryl and then the next morning I was still itchy and my voice was hoarse so I took more xyzal and famotidine. The rash subsided and I continued taking xyzal twice a day , benedryl and famotidine for a week. After my vaccine the itching did not subside for about 48 hours and it was very difficult to control. I had to take max doses of antihistamines to control the hoarseness In my voice and itching

High fever (104.2 degrees) at present, fatigue, chills

Blood pressure and pulse rate increased to 164/64, 85

1/1/2020: Residents was found unresponsive. Pronounced deceased at 6:02pm

Approximately 11:00pm on 12/29/20: Hives/itching on bilateral hands/wrists/forearms/lower legs/ankes, red face/swelling on face, rapid pulse, headache, nausea, extreme fatigue.

At about almost 4 hrs after receiving the injection I started to experience a tingly feeling to my lips, some lip swelling and tightness in my throat. I had my epi pen on hand incase I needed it but I ended up taking 25mg of Benadryl, then 50 mg of Benadryl 5 hrs later. The following morning my lips where feeling tingly again so I took 25mg of Benadryl again and continued for the next 48 hrs at the advice of my doctor.

About 5 minutes after injection: fast growing wave of internal burning sensation throughout body, feeling that I would pass out, lightheafdedness, increased heart rate and blood pressure, mild difficulty with speech/thought/concentration, freezing hands, wabbly/shaky., chest tightness, very slight throat soft tissue sensation

Fatigue, sore muscle

extreme body aches, fever of 101 degrees F, pain at injection site, severe headache

Swollen painful lymph node left clavicle

Redness and swelling an inch away from the injection site, hives on face

Migraine with nausea and dizziness preceded by visual aura, severe left arm pain (could not raise arm without significant pain), left wrist pain

about 1 hour and 15 minutes post injection (I waited in area as recommended for thirty minutes because of hx), I had the sudden onset of itchy runny nose and chest tightness and wheezing of significant intensity that I needed to use inhaler then and again later in the day. Noteworthy, I had as a precaution taken prednisone 20mg p.o about 2 hours before the injection. I had to take more later that afternoon because of symptoms. I then seem better but several times since the vaccine I have needed to uses the inhaler and take prednisone more than I have except after an infection about 6 years ago that precipitated similar symptoms to now. Today I had a flare significant enough that except for covid I might have gone to the ER or urgent care.

Resident noted with right sided facial swelling and lip droop. diagnosed as bells Palsy

Slight headache a few ours later after vaccination. The next morning I had headache, some joint/muscle pain, right arm pain and a Fever. That evening/night Fever and chills. The following morning still had a fever and chills. All symptoms were gone later that evening (within 48 hours of initial vaccination time)

4 hours after vaccine, sore arm, fatigue, headache, blurred vision 12 hours after vaccine, full body tremors, fever of 102, extreme muscle weakness, fatigue, deep chest cough, shortness of breath. fatigue, weakness and cough continued for three days after vaccine before subsiding

on the following day after the vaccination, I developed chills, awful headache, body aches, extreme fatigue, malaise, no fever

Fatigue, headache, body aches, chills, localized rash

I received the shot around 0730 on 12/30/2020. Went home and got ready for work. Around 12am 12/31/2020 my arm started to radiate at the injection site and was very tense. I placed a heat pack on the right harm but the pain did not dissipate. My arm continued to be in pain for the rest of the night. Around 0240 I ate dinner, had water and still had some arm pain. Around 0345 my arm started to flare up and sent pain sensations throughout my body. My right arm was increasingly discomforting, I could barely move it. The sensations spread to my legs, numbing them and my throat had felt as if it were closing up. I got up to get the attention of the nurse and was able to flag her down. She said I was pale as a ghost. My vision was very blurry, I could not hear anything because my ears had filled up and everything was muffled. My head had begun to ring and I was on the brink of fainting when a chair was given to me. My eyes had become extremely sensitive to the light, I was given water and spoken to about what had happened leading up to the event. I was greeted by the paramedics who drew my blood, placed an IV and transferred me to the Acute Care portion of the Emergency Department. My vitals were 76/49, 80/50, 90/56, 100/60 before being brought to the ER. On 1/1/2021 My thighs have been sore/tense, my knees and ankles have been stiff and just feeling sickly. On 1/2/2021 much of the same symptoms are present. The soreness in the muscles isn't as prevalent, however joints still are stiff On 1/3/2021, congestion and runny nose are still present, stiffness in ankles and now shins are prevalent.

On 12-22-2020, approx. 2 days after vaccine, I noticed several non-tender lumps under my chin/adjacent to left jaw line ~ small gum drop size lumps seemed to congeal together over next 9 days into a single half-dollar dollar sized lump - not completely round.

Headache Chills Temp (101.6) Body aches Skin hurts to touch Soreness in arm (injection site)

Hospitalized with COVID-related pneumonia on 03 Jan 2021. Close contact exposure on 25 Dec, with positive COVID PCR test on 29 Dec... managed as outpatient until respiratory sxms prompted hospitalization on 03 Jan. Care team anticipates at least 4 inpatient days... but patient remains hospitalized at date of this report.

Patient developed SVT 15 minutes after receiving vaccine. Admitted to ICU. ER presentation: BP: 160/109 heart rate 132. No e/o anaphylaxis or allergic reaction.

Sore throat, cold symptoms 3 days after, bone pain

The vaccine was given in the deltoid tendon/shoulder bursa area NOT in the deltoid muscle.

Jan 3, 2021 mild pain at injection site, diarrhea all day, chills in morning , no fever, temp 97.6 Jan 4, 2021 significant arm pain at injection site (awakened by it at 3 am) with chills, temp 99.6. Took One tablet ALEVE followed by temp 98.6

Rash on sides started Thursday. Woke up Friday and rash is all over body itching red and hurts. Taken Benadryl, pepsid and hydrocortisone cream. Called tele doc they gave prednisone nothing is working getting worse

Patient is a 49 y.o. female with a PMHx of AAT deficiency, HPV infection, DVT, Vitamin D Deficiency, Hypercholesterolemia and Anxiety with complaints of acute left arm numbness that radiates into her left digits and chest tightness that began 12-13 min after receipt of the COVID-19 vaccine. She noted numbness radiation into the left side of the neck and the bilateral ears. She voices she has also developed chest tightness and wheezing. Evaluated in the emergency department treated with diphenhydramine 25mg, epinephrine 0.3mg and dexamethasone 10mg

sore arm at injection site for about 1 day

"Pain and swelling in arm where injection was received. Lymph nodes in axilla and in neck were also swollen and painful. Eyes were described as ""glassy"", Two medications prescribed Lidocaine Patch and Naproxen"

Patient had swollen lymph nodes under his left arm 3 days after injection was administered. He stayed he had surgery to remove lymph nodes in June 2020.

Arm pain at injection site, fatigue, mild headache, swollen lymph nodes

riggors, fever,, severe body aches, flank pain, headache, eyes hurt

"Patient was anxious when arrived. After receiving the vaccine, felt light headed and revealed he has ""spells"" of anxiety similar to current experience. Became diaphoretic and needed to lie down."

itching, redness and swelling at injection sight. Took Benadryl on 12/31. Reappeared on 1/1, visited Er, got dexamethasone, Pepcid po and bendaryl

Itchy around the vaccine site, stiff muscle, sore arm

Muscle aches, palm size red ring for 3 days, day 4 rash, Diarrhea, vomiting, arm sore 3 days.

shortness of breath, hypotension, presumed anaphylaxis

Pain at site of injection

Painful/sore joints (shoulders and elbows) for two days. Almost went for treatment after about 48 hrs, but got through a rough night and the next morning it was gone.

Moderate local reaction. Swelling, redness, pain, hot to touch, itchy for 5+ days.

Mild swelling, pain, and itching at the injection site 8 days after injection

MODERNA COVID 19 VACCINE EUA PAIN TENDERNESS SWELLING/ FATIGUE, HEADACHE, MUSCLE PAIN, JOINT PAIN, CHILLS/ THEN CAME THE ALL OVER BODY RASH AND I STILL HAVE THIS

Pfizer-BioNtech COVID-19 Vaccin EUA-. Severe Dizziness, light- headed.

Redness to the area after a week. resolved

Thursday 12/29/20 : Started wheezing, I am using my nebulizer but the wheezing seems to be getting worse My throat also is swollen and red. Fatigue/sleeping a lot Headache

Very swollen lymph node in front of my left ear.

Flue like symptoms but no fever.

I am currently breastfeeding my 11 month old son. On Thursday, December 31st, 2020 (2 days after receiving my vaccine), my son developed a fever x24-36hours and diarrhea that is still on going as of today (1/4/2021). There are no known exposures for my son and his illness. I am reporting this as a possible reaction to the Moderna COVID 19 vaccine I received that could have some how passed through the breastmilk to him.

About 1 week after receiving the vaccine (on 12/31/2020) I developed an itchy, raised, and red hive-like rash at the injection site. It got worse over the next day, and I put some steroid cream on it. It went away gradually and was completely resolved by 1/03/2021

redness and swollen to inj site, rash to hands Benadryl given for sysmptoms

Arm soreness at injection site, worse than a flu shot and starting an hour after the shot and lasting approx 2 days. Increased phelgm production for approx 24 hours following injection.

Moderna COVID-19 Vaccine On day 9 after injection, began to get itching at the injection site. Now on day 10 with red area ~ 5 cm x 3 cm. Mild fatigue on day 9 as well.

Pfizer-BioNTech COVID-19 Vaccine EUA - Patient witnessed another patient with syncope prior to her injection. She was already anxious about receiving vaccination and this increased her anxiety, though she proceeded with immunization. Patient was in 15 min observation window in a chair and began to feel light-headed like she may pass out. A SWAT was called. With RN assistance, patient was lowered to the floor, with no loss of consciousness. Patient was pale and reported anxiety, racing /pounding heart, and felt hot with facial flushing. Patient was transferred to ED and was noted to be tachycardic (120s), but dropped to 80s. She noted that this episode felt different than her prior syncopal episodes associated with anemia. Patient was observed for 5 hours and discharged to home. Patient returned to ED roughly 2.5 hours later complaining of continued dizziness and unsteady gate. Patient was pale and anxious. Patient reported had not eaten/drank enough during her shift and received vaccine immediately post a stressful shift. Additionally, patient witnessed another patient have syncopal episode prior to her receiving her vaccine which made her anxious. Patient was given IV fluids and had electrolytes replacement. Patient additionally received diazepam. Patient was discharged at 2358 on 12/23. Patient returned to ED on 12/24 at 0239 complaining of near syncope and lightheadedness. Patient had tachycardia and self-reported palpitations. Received IV fluids and observation on telemetry with no rhythm disturbance. Patient discharged 1428 on 12/24. On 12/29, patient returned to ED at 0326 for continued dizziness, fatigue and near syncope. Was admitted for cardiac evaluation. Noted to have unprovoked tachycardia and was discharged with a Halter Monitor to evaluate cardiac symptoms. patient was discharged 12/31 at 1619

Received the injection on Wednesday afternoon. I woke up around 3am with an excruciating headache, started vomiting around 6am and continued until 7:30pm. The headache continued and as of this morning 1/4 the headache is still there and my stomach is not settled completely.

Patient received the vaccine and had slight chest tightness, had a slight headache and has mild nausea. He worked the day and still has the symptoms at 1:30 pm

Pt developed urticaria on both arms 4 hours after COVID vaccine administration. Pt received dexamethasone 10mg IM for treatment and diphenhydramine PO 25 mg. Symptoms subsequently resolved.

I received the Moderna COVID-19 vaccine on Tuesday, December 29th at work and on Wednesday, December 30th when I woke up my entire neck had broken out in hives. I did not have hives anywhere else or any other reaction. After taking 25 mg of Benadryl po and applying hydrocortisone cream, the hives had cleared up about 75%. I continued to use the hydrocortisone cream throughout the day, but the hives/redness had fully cleared up by Saturday, January 2nd.

Swollen L armpit, medial, at same side of vaccine. Resolved in 2 days with ibuprofen

Circular redness at injection site about 2 inch in diameter.

Flu like symptoms (fever, chills, aches, fatigue, headache); redness, swelling, warmth and firmness at injection site

Stuffy nose tingling lips tingling face i took 50 mg of over the counter benedryl..symptoms resolved

Arm soreness Arm swelling Headache Right side neck pain Bumps on both cheeks (face)

Patient experienced feeling flushed and nauseated after receiving covid vaccine injection. Declines ED evaluation. No further symptoms reported on 12/19 follow-up

"Pfizer-BioNTech COVID-19 Vaccine EUA - Patient with history of anaphylaxis requiring intubation to benzonatate. Patient answered ""no"" to questionnaire about allergic reactions prior to vaccination. 11 minutes after vaccination, patient reported tingling of lips and swelling of face. Developed hoarseness. SWAT was called and patient given benadryl and taken to ED (1055). Patient received steroids and H1/H2 blockers in addition to epinephrine. Patient brought to ICU for monitoring. Patient continued on therapy and was discharged 1/2 at 1113. Patient returned to ED on 1/3 at 1558 with macular papular rash on leg, chest and back with itching on eyelids and face. No respiratory involvement. Patient given benadryl and predinisone and discharged from ED at 2016."

Generalized body aches that evening, same day as injection. Woke up the next morning, 12/31/2020 with a headache, fever of 100.2, and fatigue

Patient had chills and a fever that started on 12/30/2020 @ 12:00am. The highest fever recorded was 100.6. He took Tylenol on 12/30/2020 @ 6:00am. His symptoms resolved on 12/30/2020 at 8:30pm.

Anterior cervical lymphadenopathy on the ipsilateral side of the vaccination. It seemed to begin on the third day but was most pronounced and painful on the fourth day.

Increasing redness and itchiness, swelling, and discomfort at injection site on R arm, delayed response not present at time of injection, symptoms began 12/27/20 and gradually worsened since then, no improving. Tried Benadryl and cold compresses, as well as Tyelnol.

Body aches, stomach cramping, rash on abdomen, arms. Start of period early (last period 12/22). Itchy all over

Patient developed muscle twitching, fatigue, dizziness and headache minutes after vaccine was given. Day after vaccine given, patient developed small red area around injection site that also had swelling and was warm to touch. No fever or other complication.

Hives and facial swelling. Swelling within the ears. Migrain. Nausea.

Severe joint pain, especially in hips, knees and hands lasting approximately 72 hours after first onset of symptoms. Treatment Tylenol/NSAIDs. Resolved on its own.

Upon injection, vaccine leaked out of syringe at hub site. Stopped injection after noticing after ~0.1mL expelled. Syringe removed, needle noticeably noted to have a curve and retracted into the syringe partially engaged safety.

I received the COVID vaccine on Monday Dec. 21, 2020 at 14:30. By 17:00 I was not feeling well. I was tired, had a headache, muscle aches, nausea and a fever of 101 F. The headache, low grade fever and significant malaise continued through Tues Dec 22 and Wed Dec 23. On Thursday morning Dec 24 at 2:30 AM, I woke from sleep with the urge to use the bathroom. I suddenly felt light-headed and dizzy and had a diaphoresis that soaked my hair and PJs. Fortunately my husband who is a nurse anesthetist helped me through the episode safely and was able to get me back to bed. I am not sure if that event was related to the vaccine or if I happened to be a little dehydrated and had a vaso-vagal event. I did not take any medications because I was allowing my body to have a natural response to the vaccine.

Woke up with a case a vertigo that lasted 30-45 minutes, Headache that lasted around 6 hours that same day

2 Red Area-, itching, burning-the size of a golf ball, the other the size of a quarter- Located at the front of my neck I had vaccine on 12/30/20 at 1:30 pm, and woke up on 01/01/21 at 7am with the red areas.

Patient developed a headache one to two hours post vaccination that lasted approximately 24 hours.

I felt like I was having palpitations, and my blood pressure shot up to 169/119.

About 6 hours after receiving dose, experienced aching in both arms that extended down into both hands - hands was resolved by next morning. Achiness in both arms remained x 48 hours

* TESTED POSTIVE FOR COVID ANTIBODIES 06/2020 - 'STILL HAVE RESIDUAL COUGH' 12/21/2020 - VACCINATION 12/22/2020 9:30 WERE AT WORK; FELT SUPER FLUSHED, SOB, COULDN'T FOCUS, FELT FEVERISH, FELT NAUSEOUS. OCCUPATIONAL HEALTH REFERRED TO URGENT CARE; DR STATED 'NOT TYPICAL RESPONSE'; COVID TEST; NEGATIVE

12/26/20 started to experience covid -19 symptoms.

patient developed fatigue approximately 24 hours after immunization that lasted for about 24 hours. Patient also had soreness at injection site 24 hours after that lasted 24 hours.

first 24 hours: nausea, left arm pain and heaviness 1/2/2021 until present: body aches, very strong headache, sore throat, very tired, coughing with pain, flushed, feel as if my eyes are on fire.

6 days after injection, left supraclavicular lymph node swelling and tenderness and axillary tenderness and swelling

52 year old female received the Pfizer vaccine on 30 Dec 2020. Noticed a slight left sided facial droop as left lower lip numbess on 31 Dec 2020, which has become more pronounced over the past 2 days. She states she spoke to the nurse hotline right before speaking to me who told her to go to the ED (she was on her way). Denies any extremity weakness, numbness, HA or dizziness. No pain to face or ear. Speech

clear on the phone. No recent illness or history of Bell's palsy. NKDA or any prior adverse reactions to immunizations.

Client called clinic on 12/30/2020 in the am requesting us to call in prescription pain medication due to having severe arm pain at the injection site. He stated he had not slept any for the last two nights. Encouraged client to see his PMD if he was in the kind of pain that required a Rx pain medication. Encouraged client to ice down his arm for pain.

"Patinet is a 37 y.o. female ER nurse who received her Covid vaccine just prior to arrival. While being observed at the vaccine site, she developed itching and a rash. She was brought down to the ER for evaluation. Mainly she is itchy all over. She notes a rash across her chest. But she has no cough shortness of breath wheezing. There is no problem swallowing there is no facial swelling. She does not have a history of anaphylaxis, or medication allergies. Review of Systems Constitutional: Negative for chills, diaphoresis and fever. HENT: Negative for congestion, trouble swallowing and voice change. Eyes: Negative for redness and itching. Respiratory: Negative for cough, shortness of breath, wheezing and stridor. Musculoskeletal: Negative for myalgias. Skin: Positive for rash. Pruritus Allergic/Immunologic: Negative for environmental allergies, food allergies and immunocompromised state. Neurological: Negative for headaches. 01/04/2021- Speaking with the patient she states noticed ""hives"" accross chest, right lower extremity, and left upper extremity."

I am breastfeeding-Milk supply significantly decreased (<50% of typical) day of vaccine. Milk supply still decreased 5 days later,

Patient developed fatigue approximately 24 hours after immunization that lasted a couple days.

Approx 25 min after injection I became dizzy and my HR went to the 130?s, at around 30 min post injection my tongue started to swell

Left arm warm, red, sore, swelling noted

dizziness, itching/small hives on forearm (not at injection site) , 30 minutes after vaccine given. Vitals monitored, were normal, sent home and advised to take Benadryl. More hives on upper lip/chin appeared 36 hours after vaccine given. Patient was at home, self-treated with benadryl, zyrtec, famotidine and ice pack applied to area.

Significant neck and upper back pain as soon as 1 hour post vaccine lasting until at least 24 hours - tylenol and heat/ice (no change) chills without fever overnight the night of - no treatment soreness in arm 1 hr post to up to its worst at 24 hours later when I could not abduct >90 degrees for 24 more hours

I got moderna COVID19 vaccine on 12/26/2020. Day 1-3 local pain and swelling, no redness. All resolved after day 3-4. Very tired all week post vaccine,. Day 5-6 noticed ipsilateral axillary lymph node swelling. On day 7 post vaccine I got a localized area of itching swelling and redness as if I had been bitten by a few mosquitoes at injection site that was new. Milder on day 8, less itchy and swollen, but still red and a little raised. Mild shortness of breath.

Really bad headache first 3 days Horrible Chills still ongoing Disoriented and almost like hallucinations Most interesting randomly talking to himself. I mean like a full conversation with someone that isn?t there. He also sometimes feels like when holding something he doesn?t see it or feel it and drops it or vice versa ?.. thinks holding something and isn?t Balance is off Shortness of breath No fever thank goodness and taste and smell are normal

After got vaccinated, I walked out of the clinic to monitoring area approximately 15 walking steps, I felt a little off balance but I was able to make to the chair and sat down. Few seconds later, my heart beat increased faster and faster, my neck turned red. I called for help, they gave me some apple juice to drink and talked to me. About 5 minutes later, my heart beat went back to normal rate and my redness turned back to normal skin color. I only had a little vertigo symptom but I was able to manage myself. About 2 hours later, symptoms disappeared and I was back to my normal health

12/31/20 - cough, sneezing, weakness. Felt ill all weekend. 1/3/21 - called Employee Health with low-grade fever, chills, nausea, weakness and elevated blood pressure 165/104, which had come down by the afternoon to 155/95

Developed Tachycardia approximately 40 minutes post vaccine

patient developed fatigue day after vaccination that lasted about 1 day.

After receiving the vaccine, my arm was in a lot of pain. Then that night and the next day, it was extreme pain, I couldnt lay on it. Then about 3-4 days later, the color is blue and black. Then I started having cold symptoms. Like a head cold. On my left side, my arm and my leg is sore. In addition, my face broke out too. I did not go to the ER. I let Employee health examine my arm . No ER visit

Warm to touch, redness, hard area, sore to touch

patient developed headache and arm pain day after vaccination. Patient stayed and worked from home on this day as a result.

1/2/21 @ 1030: EE called to report she received the vaccine on 12/31/20 between 1030 and 1100. And then around 2330 on 12/31/20 she experienced facial swelling, arm swelling, headache, chills, and dizziness. EE stated she felt it was an allergic reaction to the vaccine and took Benadryl for the next 24 hours to help with the symptoms. EE reported she hasn't had anything since the initial 24 hours, but is concerned about taking the next vaccine. Encouraged EE to contact PCP regarding concern for taking next vaccine. After speaking with Administration, EE encouraged to report vaccine side effects to CDC via V-Safe (https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html).

about two inches around the site was red and outlined. Felt slightly raised and was itching. Is still red today 1/4/21

"C/O of ""smokey vision"", outside in parking lot. Sat in car for about 10 minutes before coming into the building. A&O, ambulatory, denies dizziness, HA or lightheadedness. States feels SOB with exertion, ""heaviness in trachea"" increasing with inspiration. Hand off to EMTs. EKG performed, Sinus Tach 108

initially then NSR 80s-90s with occ MF PVCs, couplets. BP 162/94, O2SAT 100% RA, BS POC 208. Patient brought to ER by EMTs"

Within 10 mins. Tongue was tingling lips were swelling and tingling left arm fingers were tingling , headache

Itching, redness and swelling on the injection site. Dr. Prescribed antiniotic Bactrim DS 800-160 Tab

Chills and shaking consistent with flu-like symptoms began about 12 hours following vaccination. The next morning, I had a headache and vomited about 5 times. Over the next several hours, I began to feel better and by that evening, was feeling pretty much normal, except for some lingering fatigue.

This patient is a 56 y.o. female presenting to the emergency department with a chief complaint of a possible reaction to the COVID vaccine onset 2 days ago. The patient states that she has had a fever, chills, adenopathy, and body aches since her vaccination. Her highest recorded temperature was 101F, and she has been taking Tylenol. She states that her biggest concern is the adenopathy under her right armpit which is painful to touch. She denies any masses. She saw her PCP on 12/24 and had blood work done, which showed an elevated white count of 17.

patient developed arm pain day after vaccination that lasted about 1 day.

Left arm soreness, Headache 30 mins after, Fever 100.9 T 5am and 9am, monitoring until now

After initially receiving vaccine 12/28/2020 my arm was sore and slightly red for approx 2 days and resolved on 12/30/20. When I awoke this morning my right shoulder ached and I thought massage might make it feel better - at that time I noted it was swollen and warm tender to touch at site and again appeared red. I did report this to the clinic who administered vaccine

Patient developed arm soreness at injection site day after vaccination

Migraine for 2 days controlled with medication, Severe swollen eyes with discharge from eyes, itchy, red watery eyes began the evening of the vaccine and ongoing. using BENEDRYL and ALLEGRA to decrease symptoms.

Weakness, almost paralysis both lower extremities worse than baseline paresis from ms.

Arm itchy at injection site, warm feeling at injection site

Patient c/o feeling tachycardia, flush and dizziness, flushness upper torso neck region and bilateral upper arms. Rash/hives not present. Placed on stretcher , monitored immediately with BP 156/100, HR 88, O2 99%, alert and oriented x3, verbalizing clearly. Placed on EKG monitor, noted in NSR 80. POC 102. Shortly after at 1001, redness subside ,briefly noted with tingling of bilateral feet and hands for only seconds. Patient was monitored for 40 minutes, returned to baseline 142/81 HR 58 O2 100%. Nutrition given . Discharged to home, ambulatory feeling well.

Asthma-like fatigue, cough due to fatigue, mild.

Noticed itching and slight rash on distal portion of extremities the evening of Dec. 30, rash became worse over next few days and became more inflamed/raised even with Benadryl taken as directed on box. I went to urgent care on Jan 1, 2021 and was started on Steroid taper of 60-40-20 each dose for 3 days. Improvement noted after 2nd steroid dose. No respiratory involvement with vaccine or rash episode

Modern a covid 19

Moderna vaccine received on 12/21 from my workplace. Rash (reddened skin not raised) appeared after vaccine was given (within 24hrs) the size of a quarter and was gone 3 days later. Now on 1/3 the rash (red bullseye not raised) came back the size of a baseball and is warm to the touch. Went to urgent care and physician called it a delayed adverse reaction to the moderna vaccine 1st dose

I got the shot, didn?t feel it at all so it went good. I went to the bathroom and went pee and got my arm back in my long sleeve shirt under my scrub top. I wasn?t anxious about getting the vaccine. Then I went to sit down and be monitored. After about another minute I felt very weird like a warm feeling going all over my body. I started pulling my mask away from my face to get a deep breath. Then I broke out in a sweat from head to toe. I think I became pale (I apparently didn?t look good). I started feeling more ?weird? as I had never felt this way before and I stood up to walk because the nurse there wanted me upstairs near the ED but I was weak so I sat down and had tunnel vision. After that it?s a bit of a blur. After I stopped sweating I got very cold and shaky but vitals were ok. It scared me because I have never had a reaction before to a vaccine.

fever 100.6- 100.5, chills, headache, general weakness, sweating, and loss of appetite.

felt hot, prickly, right arm red. Later felt chest tightness

Starting on Thursday, Dec. 31, patient began having shoulder and neck tightness. That night patient began having chills, and noticed redness at the vaccine sight and then the redness started streaking. Also complaints of itching at the vaccine sight. Started taking Tylenol for the two days following the vaccine, states feels like it is improving. Referred to PCP for evaluation. Has appt. Monday, January 4th

Triage for COVID 19 SEVERE post Vaccine Reaction VAERS reportable Your concerns: Vaccine at noon without immediate effect. Driving home at 1400 developed itching and redness at scalp, face, neck, chest, back, arms and sides. Reports that she did not feel warm but looked like she had a sunburn. It appeared to fade over the next two hours but re-occurred at 1700 with all previous symptoms. She took 50mg of Benadryl and went to sleep. She woke at 0200 the re-occurrence of all symptoms, she did not take any Benadryl as that would make her too sleepy to come to work. The symptoms subsided and when we spoke at 1050 she had only small bumps/hive like spots on her fore arms and cleavage. They do not itch or burn at this time. Discussed with PA and Dr. after which I spoke with patient again regarding pending plan. She will call the clinic if she has any further symptomatic episodes in the near future. We will investigate moving her second dose ahead 2 days from 1/12/2021 (day off) to 1/14/2021 this way she will be here at work should it happen again, she works 0630-1900. Med provider will consult with allergy to determine if further steps are needed for dose #2. Dept: Respiratory Therapy

Have you missed work? #shifts: none Did you seek emergency care? none Date and Time of Vaccine: 12/22/2020 at 1200 Age at time of vaccination, 46 years 6 months Sex: female Was the vaccine received at facility? yes Site of vaccine (LD or RD): RD Type of Vaccine Pfizer (X) Moderna ( ) Other _____ 1st or 2nd dose: first When did your symptoms start? 12/22/2020 at 1400 Please note reported symptoms yes or no, these symptoms are considered mild to moderate and are NOT VAERS reportable Injection site pain no Tiredness no Headache no Muscle Pain no Chills no Joint Pain no Fever (note temp if known) no Injection Site Swelling no Injection Site Redness no Nausea no Feeling Unwell no Swollen Lymph Nodes (lymphadenopathy) no Other: no Employee reports THE FOLLOWING SEVERE post vaccine ADVERSE reactions (reportable): Difficulty breathing no Swelling of your face and throat no A fast heartbeat no A bad rash all over your body yes, see above Dizziness and weakness no If COVID-19 symptoms persist and/or worsen beyond 48 hours consider COVID-19 testing Treatment/Advise: see above Plan: see above If employee was vaccinated at another facility, they need to contact that facility , it is an expectation that the facility that gave the vaccine complete the VAERS report. N/A Employee verbalizes understanding and agreement with plan. yes VAERS report is completed electronically vaccine given at facility. Pending further review. 12/24/2020 01:51pm Follow up to VAER 12/23/2020 Patient called this morning to update regarding vaccine reaction. Yesterday she went home and did some shoveling. Later, around 1900, she developed a itchy, red rash that started on her chest and the right side of her neck which later covered her entire body. The skin on her face was bright red and very hot to the touch, there were small raised hives on her face which were likened to 'petechia if they were raised'. She took pictures of the raised/red areas. She took 50mg of Benadryl and went to sleep, when she woke at 0230 she was asymptomatic. Regarding the bumps on her forearms and cleavage, she has residual mottling on her arms. Updated providers.

Moderna vaccine given 12/28/2020, 6 days after injection have left supraclavicular lymph node swelling and axillary swelling and tenderness

Extreme fatigue, weakness, lightheaded, malaise

Began noticing itching and redness on left had on 1/3 PM. When I woke up on 1/4 the itching in the had was persistent and the redness was about the same. I also noticed a raised, red patch of skin on my right anterior ribs. The rash on the ribs is less itchy than the hand.

receive vaccine on 12/24/2020 arm was red and sore few days. then on 1/1/2021 at injection site a rash developed and had HA, tired , weakness, chills. I continue to feel this way on 1/4/2021

About 1 hour after receiving my first dose of the Moderna vaccine for COVID-19, I started feeling extreme pain in my left shoulder and arm, where the shot was administered. The pain continued to intensify throughout the day and night and was 10/10 on a pain scale. In addition, I began to lose my ability to lift my left arm or use it. It became so weak that I had to use my right hand/arm to pick up my left arm to move it. My left arm was 'hanging and drooping' and my left shoulder was very noticeably lower then my right shoulder. I called my primary care and employee health. My primary care doctor advised me to take advil and go to urgent care if the pain persisted and worsened. I could not sleep at all that evening of 12/29/20 because the pain was so intense and I had to keep picking my left arm up with

my right arm to keep re-adjusting to try and get comfortable. The next morning I went to an orthopedic urgent care where I was diagnosed with nerve damage from the shot and prescribed Methylprednisolone 4mg dosepack. The doctor who saw me explained that he could not assess the extent of the damage at this time because my nerves were so agitated and inflamed. He scheduled a follow up visit with me for Thursday, January 7th and stated he will then proceed with an MRI and further investigation to assess the extent of the nerve damage. During the days that followed my immunization, I was unable to do anything with my left arm and was dependent on my husband to help me get dressed, showered, household chores, etc. It is unknown at this time whether this will be temporary or permanent damage and disability.

swelling, redness that started 1 wk after injection

Moderna COVID-19 Vaccine Vaccine on day 0 GI symptoms on days 1, 2, 3, and 4 including abdominal cramps, constipation, gas Uterine cramps (not related to menstruation) and light spotting on day 2 Soreness at injection site days 0, 1, 2, and 3

arm pain

Injection received at 0815. At 0900 I started getting diaphoretic, clammy, nauseas and my face was flushed. At 0930, I developed hives on my neck, chest and arms. I immediately went back to the vaccination site (I was still in the hospital at work) and was administered 25mg oral Benadryl and monitored for 30 minutes. The hives resolved, but I still felt unwell. At 1600 I noticed a swelling in my right upper thigh about the size of my hand. It was about 2 inches inferior to my inguinal crease and was the width of my thigh. It was mildly painful to the touch. My injection site was red, inflamed and itchy. I continued taking 25-50mg Benadryl Q4 and took 100 mg at night due to itchiness on my eyes, face, neck, chest and arms. This is still present, although less each day, as of Monday 1/4/21 morning. I have felt feverish but have not had a recorded fever. I took some Ibuprofen for the pain in my arm at the injection site. The redness, swelling and itchiness has decreased each day at the injection site, but is also still present as of Monday 1/4/21 morning. I still feel unwell and have continued diarrhea throughout the weekend.

The day of the vaccine I had a initial diarrhea and headache, minimum pain on the site of the injection but at 2AM on the 22nd I woke up from my sleep with chills, and shaking even my teeth were clacking. Took Tylenol and it got better around 30 min later. Felt very fatigued and still nauseated almost threw up. By the end pf the day it resolved itself.

patient developed headache, nausea and abdominal pain day of vaccination that continued for two days post vaccination.

Flu-like symptoms - nausea, sweat. Arm sore immediately after injection - sore for 2 days.

12/17/2020 VACCINE 12/18/2020 SWOLLEN LYMPHNODES IN GROIN, FATIGUE 12/21/2020 EXPERIENCED A STEMI; RUSHED TO ER; FELT LIKE COULDN'T BREATHE, INCREASED HR CARDIAC CATH

Employee states reaction to every vaccine she receives. Employee states ticks, perseveration, uncontrolled laughing and crying which resolve on own. This happened today immediately after vaccine administered. Employee given water, cold pack. Symptoms resolving on own as stated. Will keep longer for observation.

patient developed headache, nausea and abdominal pain day of vaccination that lasted two days following administration.

EE received Covid-19 Moderna vaccine on 12/29/20 at 5:10 p.m. at Covid vaccination site. 12/30/20 at 3:00 a.m.EE had pain in left side, hip and leg waking EE up from sleep . Lesions times two, one on hip and one on posterior upper leg. MD insructed EE to double Vitamin C orally and to place Bacitracin on the two lesions, which at first appeared to contain bloody drainage. Lesions are now dry. VAERS document completed.

fever 100.6, chills, headache

patient developed flu like symptoms such as body aches, chills, fever, as well as arm pain day after vaccination.

Resident found unresponsive without pulse, respirations at 04:30 CPR performed, expired at 04:52 by Rescue

Patient complained of increased shortness of breath, generalized weakness and fatigue with mild cough worsening today and was admitted on 12/25/20. Patient is an employee of the hospital in the ICU and received the covid-19 vaccine on 12/25/20. Patient believes symptoms started after the vaccination. On admission, patient was in sinus tachycardia with O2 saturation 91% on room air. Tested SARs CoV 2 RNA, RT PCR positive on 12/24/20. Transferred to ICU for closer monitoring after transitioning to high flow nasal cannula on 12/26. Patient recovered and discharged on 12/31/20.

Resident became SOB, congested and hypoxic requiring oxygen, respiratory treatments and suctioning. Stabilized after treatment and for the next 72 hours with oxygen saturations in the 90s. On 1/3/2021 was found without pulse and respirations. Resident was a DNR on Hospice.

Two days post vaccine patient went into cardiac arrest and passed away.

syncopal episode - arrested - CPR - death

Severe diarrhea, cold chills, 101 fever, and nausea

""""Pfizer-BioNTech COVID-19 Vaccine"" 12/29 patient developed SOB, fever tmax 103 degrees F, diaphoretic, dry heaves all started approximately 16 hours after vaccination given. patient then transferred to Hospital for further treatment and observation. 12/30 seen at injection site- erythema, swelling, warmth and tenderness Discharged back to home on 1/1 with RX for cephalexin to treat cellulitis of injection site"

"Tingling in lower legs- neuropathy like; Fever 102.9; Tingling in lower legs- neuropathy like; Severe cramping in hands and feet; Severe bone pain; This is a spontaneous report from a contactable other healthcare professional (patient). A 39-year-old female patient received the first dose of bnt162b2 (COVID-19 vaccine) lot no: EL0140, via an unspecified route of administration in left arm on 18Dec2020 15:15 at a single dose for COVID-19 immunization. Medical history included acid reflux and known allergies to PCN, both from an unknown date and unknown if ongoing. The patient was not pregnant at the time of report. Concomitant medication included omeprazole (PROTONIX), ibuprofen (MOTRIN). No other vaccines were administered in four weeks. On 19Dec2020 at 14:30, the patient experienced fever 102.9 ""normal for vaccines i know"", tingling in lower legs neuropathy like, severe cramping in hands and feet, and severe bone pain. The patient recovered from the events in Dec2020. The patient did not receive treatment for the events. The events were reported as non-serious. The patient didn't have COVID prior to vaccination and was not tested post vaccination.; Sender's Comments: A possible causal association between administration of bnt162b2 and the onset of neuropathy like cannot be excluded, considering the plausible temporal relationship. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate."

Scratchy throat; itching lips; This is a spontaneous report from a non-contactable nurse. A 36-year-old patient of an unspecified gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), lot number EK5730, via an unspecified route of administration on Right arm from 22Dec2020 to 22Dec2020 as single dose for COVID-19 immunization. Medical history included food allergy (Shrimp). The patient's concomitant medications were not reported. The patient experienced scratchy throat and itching lips for approximately 1.5 hours starting 20 mins post vaccine on 22Dec2020. The event caused prolonged hospitalization. The outcome of the events was recovered on 22Dec2020. No follow-up attempts are possible. No further information is expected.; Sender's Comments: Based on temporal association, a possible contributory role of suspect BNT162B2 vaccine cannot be excluded for reported events throat irritation and lip itching. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

delirious; hypoxic; fever; ataxic; incontinent; confused; Chills; HA; anorexia/had no appetite; myalgias; extreme fatigue; slept all and had no appetite; This is a spontaneous report from a contactable physician. A 74-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 15Dec2020 16:00 at single dose for COVID-19 immunization. Medical history included diabetes mellitus (DM). The patient has no known allergies. The patient's concomitant medications were not reported. He was an ER doctor and the medical director of his hospital. The patient was asymptomatic when he got the vaccine on 15Dec2020. 3 hours after the vaccine he began to get chills, HA, anorexia, myalgias, and extreme fatigue. This worsened and he slept

all and had no appetite. On 19Dec2020 he woke up delirious with a fever and was ataxic, hypoxic, incontinent, and confused. The patient was hospitalized due to the events on 15Dec2020. The events also caused prolonged hospitalization due to the events. The patient was not diagnosed with COVID prior to vaccination. The patient was tested for COVID via nasal swab post vaccination with unknown results. The patient did not receive any other vaccines within 4 weeks prior to COVID vaccine. The outcome of the events was not recovered. Therapeutic measures were taken as a result of the events as the patient required oxygen, plasma, and remdisivir. The batch/lot numbers for the vaccine, BNT162B2, were not provided and will be requested during follow up.; Sender's Comments: A possible causal association between administration of BNT162B2 and the onset of reported serious events might not be excluded, considering the plausible temporal relationship. Fever, chills, headache, fatigue and muscle pain are the known adverse event profile of the suspect product. More information such as detailed underlying medical conditions and concomitant medications are needed for fully medical assessment. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Allergic reaction; Diarrhea; Chills; Palpitation; Tongue and throat swelling; Tongue and throat swelling; This is a spontaneous report from a contactable other healthcare professional (patient). A 38-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number: ELO141), via an unspecified route of administration on 21Dec2020 at a single dose for covid-19 immunization. The patient's medical history included asthma and allergy. Concomitant medication included levosalbutamol hydrochloride (XOPENEX) for asthma and cetirizine hydrochloride (ZYRTEC) for allergy. About hour and a half to two hours after the vaccine, on 21Dec2020, the patient experienced had an allergic reaction with symptoms set of diarrhea, chills, palpitations, and tongue and throat swelling. The patient took diphenhydramine (BENADRYL) 25 mg as treatment. It helped some. She woke up this morning (22Dec2020) and still had the symptoms. So, she went to the emergency room. They gave her diphenhydramine 25 mg IV, methylprednisolone (SOLUMEDROL), and famotidine (PEPCID). The patient underwent lab tests and procedures which included blood count and chemistry and lab work which showed normal on 22Dec2020. Outcome of the events was unknown. The patient thinks that the product had causality to the events. Information on the lot/batch number has been requested.; Sender's Comments: The patient's medical history included asthma and allergy. Based on information available, the reported allergic reaction with symptoms set of diarrhea, chills, palpitations, and tongue and throat swelling was likely related to the use of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), due to temporal relationship and clinical course. The case will be reassessed should additional information become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

shaking uncontrollably/she was full of shakes to the point the bed was shaking; chills; Woke up in the middle of the night; body aches; as painful as a strep infection; sore throat that was as painful as a strep infection/throat feels sore to the point of Strep/Throat soreness: Felt like sharp razor blades; Feels like she is having an extreme immune response; Feels congestion; severe serum sickness/weird serum sickness; high fever/Had a fever over 101; This is a spontaneous report from a contactable nurse(patient). A 32-year-old female patient received BNT162B2(lot number EH9899) via an unspecified route of administration at Arm Left on 21Dec2020 (from 16:30 to 17:00) at the age of 32 years old at single dose for doesn't want to bring COVID home to her family. The medical history included Migraine headaches. The concomitant medications were not reported. The patient had so many immunizations for international travel, had Yellow Fever vaccine, all of the Guardasil vaccines, had MMR vaccine four times because she never developed immunity to it until the fourth round, got a flu shot yearly,got TDap vaccine every five years because she was an HCP, did Emgality shots(not done it this month. Emgality had a protein inhibitor, was supposed to get Emgality shot on 21Dec2020). On 22Dec2020 the patient experienced severe serum sickness, high fever, body aches to the point that she was shaking uncontrollably, sore throat that was as painful as a strep infection; Caller mentioned she was taking tylenl and benadryl for her symptoms. The patient was a Nurse Midwife. She got the vaccine on Monday evening at 4:30PM. Feeling like she was having a weird serum sickness. Woke up in the middle of the night and she was full of shakes to the point the bed was shaking. She had a fever over 101. Felt like she was having an extreme immune response. She was taking Tylenol and Benadryl around the clock. Woke up this morning and her throat feels sore to the point of Strep. Wondering if she need to distance and get some kind of test. Has been wearing a mask all of the time and doesn't know of anyone people who have COVID that she has been in contact with. Feels congestion and sore throat. Shakes and chills: Began at 02:30. Hard core chills and shakes. High fever over 101: same time as chills and shakes. Woke up from a dead sleep. Didn't have a working thermometer but knows her temperature must have been over 101 by the way she felt. She didn't feel that crappy unless her fever is over 101. She can gauge her own temperature. She experienced throat soreness: Felt like sharp razor blades. The patient was taking numbing throat lozenges. Seriousness: Would say serious. Didn't require hospitalization. She self-treated. Had she not had to work, she would probably have stayed in bed. Has been taking round the clock medicine. The outcome of the events was unknown. The information on the batch number has been requested.; Sender's Comments: The Company cannot completely exclude the possible causality between the reported serious events including severe serum sickness, high fever, body aches, shaking uncontrollably, sore throat that was as painful as a strep infection, feels like having an extreme immune response, congestion, chills, woke up from a dead sleep and the administration of the COVID 19 immunization with BNT162B2, based on the reasonable temporal association. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to those, as appropriate.

Have a fever with a high of 99.6 Fahrenheit; felt winded like she has exerted herself more than expected/shortness of air; Coughing/cough got worse; She is covid positive/Tested positive for COVID 19; She is covid positive/Tested positive for COVID 19; Shortness of breath/Shortness of breath was

reported as worsened/feels winded; Tachycardia; Has been sick ever since; Felt like she was in a fog, on a cloud, heavy and out of it; She felt hot and weird but had no fever; Headache; Burning sensations in her legs; Extreme fatigue, want to go to bed; headache went away and she felt like the congestion was clearing up some; Arm was sore; This is a spontaneous report from a contactable ICU nurse (patient [Registered nurse ADN]) via Pfizer-sponsored program. A 38-year-old female patient received single dose of BNT162B2 (lot number: EK5730) , via an unspecified route of administration (right arm) on 16Dec2020 20:30 for immunization (for front line health care worker). Medical history included allergies; acid reflux; patent foramen ovale (PFO); supraventricular tachycardia (SVT) without treatment, vitamin D low and ongoing smoker. The patient had no other history/family history. Concomitant medication included loratadine (CLARITIN) taken for at least 5 years for allergy, famotidine from Dec2020 for acid reflex, and vitamin D taken for 5 or more years for vitamin D low; all given orally and were ongoing. The patient had no other prior vaccines within 4 weeks of Covid vaccination. Patient had been taking Covid tests on and off due to her immunocompromised daughter. On 15Dec2020 she took the PTR that took three to four days for results; she tested negative for Covid and was completely asymptomatic. She then received the COVID 19 vaccine 16Dec2020. Her test was positive for COVID 19 on 18Dec2020 and she had been sick ever since. She received the vaccine at the hospital where she works. The vaccine was not administered at facility. She further reported she was fine after getting the COVID 19 vaccine. Her right arm was sore/ started to hurt about four or five hours later on 16Dec2020 but then was fully after 24 to 48 hours. She started to feel sick on 18Dec2020 (Friday evening). States she went to bed Friday morning after the night shift. She felt fine, better than normal. That same day (18Dec2020) she woke up at 1700 and felt like she was in a fog, on a cloud, heavy and out of it. She walked around for a while and that sensation didn't go away. She felt hot and weird but had no fever. Then at 1830 she got the alert on her phone that told her she was positive for COVID 19. She started to feel other symptoms on 18Dec2020 including headache, shortness of breath, tachycardia, burning sensations in her legs; extreme fatigue, wanting to go to bed that persisted from Friday to Sunday. Then on 20Dec2020, Sunday afternoon, her headache went away and she felt like the congestion was clearing up some. Mentions she did have a fever (onset date unspecified) with a high of 99.6 Fahrenheit; but it went back down to 99.0 Fahrenheit (date/s unspecified). On 20Dec2020 the patient experienced coughing. On 21Dec2020 (Monday) she started coughing more but states her O2 was fine and her breathing was okay. However, when walking around she felt winded like she has exerted herself more than expected. She then clarified that on 21Dec2020, she experienced shortness of air and the cough got worse but it has now plateaued. She did call her HCP and they were holding off on treatment at the time. No investigation assessment was performed. The patient was not admitted to an Intensive Care Unit. The patient did not display clinical signs at rest indicative of severe systemic illness nor did she require supplemental oxygen or receive mechanical ventilation. No preexisting diseases worsened during the SARS-CoV2 infection. The patient considered shortness of breath, and tachycardia as serious: medically significant while the events headache, burning sensations in her legs, fatigue, Coughing, and feels winded were considered as not serious. The events headache, shortness of breath, tachycardia, burning sensations in her legs, fatigue, Coughing, and feels winded were ongoing at the time of reporting. Shortness of breath worsened. The patient recovered from arm was sore on an unspecified date in Dec2020; and was recovering from tachycardia, sick, headache and congestion. The outcome of felt like she was in a fog, on a cloud, heavy and out of it; felt hot, and fever was unknown while not

recovered for the other events.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the reported events due to temporal relationship. However, the reported events may possibly represent intercurrent medical conditions in this patient. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics including chest x-ray, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

General weakness requiring assistance to stand.; General weakness requiring assistance to stand; Rash on chest/neck; This is a spontaneous report from a contactable Pharmacist. A 33-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (lot number EK5730), intramuscularly on 22Dec2020 13:15 at single dose for covid-19 immunization. Vaccine location was right arm and it was the first dose. The facility type vaccine was hospital. None medical history. No known allergies. Patient was not diagnosed with COVID-19 prior to vaccination nor tested for COVID-19 since the vaccination. There were no concomitant medications. The patient didn't receive any other vaccines within 4 weeks prior to the COVID vaccine nor received any other medications within 2 weeks of vaccination. The patient experienced rash on chest/neck. General weakness requiring assistance to stand on 22Dec2020 17:00 with outcome of recovered in Dec2020. The date report was first received from source was 23Dec2020. Patient received Fluid bolus, IV benadryl, IV steroid as treatment for the adverse events. The action taken in response to the events for BNT162B2 was not applicable. The events were reported as non-serious.; Sender's Comments: The reported events rash on chest/neck and general weakness requiring assistance to stand were likely related to the use of first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), due to temporal relationship and clinical course. The case will be reassessed should additional information become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Flushing; she noticed that there was a ringing in her left ear; Experienced a weird heaviness on her upper chest and arms/ heavy legs and arms/really heavy arms and legs; experienced a weird heaviness on her upper chest and arms; really cold hands; felt really hot at the injection site/really hot sensation at injection site; lightheadedness/Light-headed; Palpitations; Feeling faint; shortness of breath; Her blood pressure went up to 134/100; paleness; went up to her face; felt tired/She was really tired and slept it off; This is a spontaneous report from a contactable nurse, who is also the patient. This 34-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Lot number EK5730) intramuscular in the left deltoid on 20Dec2020 at single dose for COVID-19 immunisation. Relevant medical history included ongoing asthma (diagnosed as a teenager with sports asthma and uses an

inhaler). There were no concomitant medications. The patient experienced lightheadedness/light-headed (medically significant) on 20Dec2020 with outcome of recovering, palpitations (medically significant) on 20Dec2020 with outcome of recovered on 20Dec2020, feeling faint (medically significant) on 20Dec2020 with outcome of recovered on 22Dec2020, flushing (medically significant) on 21Dec2020 with outcome of recovered on 22Dec2020, she noticed that there was a ringing in her left ear (medically significant) on 21Dec2020 with outcome of recovering, shortness of breath (medically significant) on 20Dec2020 with outcome of recovering, her blood pressure went up to 134/100 (non-serious) on 20Dec2020 with outcome of recovered on 20Dec2020, she experienced a weird heaviness on her upper chest and arms (non-serious) on 21Dec2020 with outcome of recovering, really cold hands (non-serious) on 21Dec2020 with outcome of not recovered, paleness (non-serious) in Dec2020 with outcome of unknown, felt really hot at the injection site/really hot sensation at injection site (non-serious) on 21Dec2020 with outcome of recovered on 23Dec2020, went up to her face (feeling hot) (non-serious) in Dec2020 with outcome of unknown, heavy legs and arms/really heavy arms and legs (non-serious) on 21Dec2020 with outcome of not recovered and felt tired/she was really tired and slept it off (non-serious) in Dec2020 with outcome of unknown. The patient specified that she experienced a moderate reaction after having the COVID-19 vaccine. She had the vaccine last Sunday morning 20Dec2020. She was told to wait 20 minutes before leaving. In the waiting area, she felt lightheaded, had palpitations and was feeling faint. After 20 minutes she started feeling better. Then she started to have more intense light headedness. She went to the ER and was given oxygen. Her blood pressure was 134/100 on 20Dec2020. She had an EKG on 20Dec2020 that was normal. They gave her steroids and Benadryl. She had another episode while being injected with the steroids. On Monday 21Dec2020, she experienced a weird heaviness of her upper chest and arm. She had really cold hands and flushing. On Monday night 21Dec2020 she went to work. She experienced a really hot sensation to the injection site that went to her neck and face. Her left ear was ringing. This lasted until Tuesday 22Dec2020. She took Benadryl again on Tuesday 22Dec2020. She had shortness of breath which started on 20Dec2020 and on 22Dec2020 she had shortness of breath that lasted until 11am. She had really heavy legs and arms and went back to the ER. She had a chest X-ray and D-dimer on 22Dec2020 that were normal per the ER. The night before the report, she had some of the same symptoms. She was really tired and slept it off. She didn't take anything. The morning of the report, she was feeling good and better. She still has heavy feeling on upper chest and arms. Caller clarifies that she did not have a heavy feeling in her legs. Her arms feel heavy if she holds her phone too long. She continues to have ringing in her ear. The flushing went up to her face. The patient specified that she developed sports asthma as a child and uses an inhaler. She gets short of breath if she overexerts herself. Additional laboratory investigations on 20Dec2020 included blood work with unknown results and Troponin which was normal. She was provided with a general steroid. She did not know the name of it. She was also given Benadryl and monitored on telemetry. She was given IV fluids again on 22Dec2020.; Sender's Comments: Based on the compatible temporal association and the known pattern of response, the Company considers the reported events are possibly related to vaccination with BNT162B2. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

just kind of having blackout; Severe fatigue/fatigue; Severe myalgia; Some congestion; Severe headache; Haziness; This is a spontaneous report from a contactable other healthcare professional (HCP), who is also the patient. This patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration in Dec2020 at single dose for COVID-19 immunisation. Relevant medical history and concomitant medications were not reported. In Dec2020, the patient experienced just kind of having blackout, severe fatigue, severe myalgia, some congestion, severe headache and haziness. On day six, symptoms improved and suddenly he/she was having symptoms again, severe myalgia, some congestion severe headaches and fatigue. The outcome of the events was unknown. The information about batch/lot number has been requested.; Sender's Comments: This report fails to include the basic information that is required for an independent medical evaluation. Assessment is postponed after receipt of a more complete case report. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

Flu like symptoms like myalgia, achy head, mental cloudiness; Flu like symptoms like myalgia, achy head, mental cloudiness; Flu like symptoms like myalgia, achy head, mental cloudiness; Flu like symptoms like myalgia, achy head, mental cloudiness; Deep cough; This is a spontaneous report from a non-contactable physician. A female patient of unspecified age received the first single dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on an unspecified date in Dec2020, in left upper arm like deltoid, for COVID-19 immunization. Medical history and concomitant medications were not reported. On an unspecified date in Dec2020, immediately after receiving the vaccine, the patient experienced a deep cough which came on all of a sudden, followed 31 hours post vaccine by flu like symptoms like myalgias, achy head and mental cloudiness. She was feeling a bit better on 22Dec2020 morning and she was back at work. So, it was like a short couple of hours, maybe 24 hours turnaround. The events were resolving at the time of report. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Sender's Comments: The Company cannot completely exclude the possible causality between the reported flu like symptoms like myalgias, achy head and mental cloudiness and the administration of the COVID 19 vaccine BNT162B2 based on the plausible temporal association. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified, as appropriate.

Urination bleeding; This is a spontaneous report from a contactable consumer (patient). A patient of unspecified age and gender received BNT162b2 (Solution for injection, lot number and expiration date not provided), via an unspecified route of administration at single dose on 22Dec2020 for COVID-19 immunization. The patient medical history and concomitant medications were not reported. The patient experienced urination bleeding in Dec2020 and wanted to know if it was going to be a side effect. The outcome of the event was unknown. Information on the lot/batch number has been requested.

"severe fever; chills; severe night sweats; hives throughout my body; a rash on my face; This is a spontaneous report from a contactable nurse. This nurse reported for helf that the 37-year-old female patient received first dose of bnt162b2 (BNT162B2, product: COVID 19, brand: Pfizer), via an unspecified route of administration on Left Arm on 19Dec2020 10:30AM at single dose for covid-19 immunisation. No Pregnant at the time of vaccination. Medical history included Known Allergies to medications, food, or other products:Cocoa butter. Concomitant medications were unknown. Facility where the most recent COVID-19 vaccine was administered was Hospital. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient reported that ""Starting seven hours after the vaccine, I experienced severe fever and chills. The next morning, despite multiple anti-pyretics, the fevers/chills were worse. Also I experienced severe night sweats, likely related to the fevers. Three days after the vaccine, I began to have hives throughout my body and a rash on my face. Responds to Benadryl, but eventually reappears."" The event started from 19Dec2020 05:30 PM. Treatment was received for the adverse event included Anti-pyretics, anti-inflammatories, anti-histamine. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. Facility type vaccine was hospital. No other vaccine in four weeks. The patient recovered with lasting effects. No Covid prior vaccination. No Covid tested post: vaccination. The outcome of the event was recovered/resolved with sequel in Dec2020. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Sender's Comments: The reported events severe fever and chills, severe night sweats, and hives and a rash on face were likely related to the use of first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), due to temporal relationship and clinical course. The case will be reassessed should additional information become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate."

Left sides shock like pains in head. Lasts 3-5 seconds and go away. It's a stabbing shock like pain. Started on Thursday 17Dec2020 at 7:45 pm; Left sides shock like pains in head. Lasts 3-5 seconds and go away. It's a stabbing shock like pain. Started on Thursday 17Dec2020 at 7:45 pm; This is a spontaneous report from a contactable nurse reported for herself. A 28-year-old female patient (no pregnant) received her first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), intramuscularly in left arm on 16Dec2020 14:00 at single dose for COVID-19 immunization. Medical history was none. The patient's concomitant medications were not reported. The patient experienced left sides shock like pains in head, lasted 3-5 seconds and went away. It's a stabbing shock like pain. The events started on Thursday 17Dec2020 at 19:45. It was unknown whether treatment was received for the events. The events resulted in doctor or other healthcare professional office/clinic visit. The events were reported as non-serious. The most recent COVID-19 vaccine was administered in hospital. The patient had not received any other vaccines within 4 weeks prior to the COVID-19 vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. The outcome of the events was not recovered. Information on the lot/batch number has been requested.; Sender's Comments: Based on the compatible time association, the event left sides shock like pains in head is possibly related to suspect BNT162B2 administration. The impact of this report on the

benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

patient began to experience dizziness/shakiness.; patient began to experience dizziness/shakiness.; This is a spontaneous report from a non-contactable other hcp reporting for a patient. A 58-year-old female patient received first dose of BNT162B2 (Pfizer product, lot number: EH9899), intramuscular on 21Dec2020 16:00 at single dose on left arm for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. It was reported that during her 15 minute waiting period after the injection (21Dec2020 16:15), the patient began to experience dizziness/shakiness. This provider was notified of patient reaction and she was then transferred to the emergency bay via wheelchair where she was assessed. Monitored patient for severe reaction symptoms, including rapid progression of symptoms, respiratory distress with dyspnea, increased work of breathing, persistent cough and cyanosis, vomiting, hypotension, dysrhythmia, chest pain and collapse. Treatment included no therapy, but did continue with vital checks at approximately 5 minute intervals. Patient discharge: stable to go home and follow up with PCP. The outcome of the events was unknown. No follow-up attempts are possible. No further information is expected; Sender's Comments: Based on the compatible time association, the dizziness and shakiness are possibly related to suspect BNT162B2 administration. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Small bowel obstruction with diffuse bowel and pelvic lymphadenopathy 36 hours after injection; Small bowel obstruction with diffuse bowel and pelvic lymphadenopathy 36 hours after injection; This is a spontaneous report from a contactable physician (patient). A 61-years-old female patient (not pregnant) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number: EH9899), intramuscularly on 21Dec2020 12:30 to at single dose on left arm for COVID-19 immunization in hospital. Medical history included crohn's disease. No known allergies. Concomitant medications within 2 weeks of vaccination included estradiol, progesterone, colestipol hydrochloride (COLESTID), ustekinumab (STELARA), cyanocobalamin (B12). The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient experienced small bowel obstruction with diffuse bowel and pelvic lymphadenopathy 36 hours after injection on 22Dec2020 22:00 with outcome of recovered in Dec2020. The adverse events resulted in emergency room/department or urgent care, hospitalization for 3 days. Therapeutic measures were taken as a result of event included inpatient observation, nothing by mouth (reported as NPO), intravenous fluids. No COVID prior vaccination, COVID test nasal swab was negative on 23Dec2020 post vaccination. It was not reported as serious.; Sender's Comments: There is not a reasonable possibility that reported events small bowel obstruction and lymphadenopathy are related to BNT162B2 vaccine. The patient had underlying Crohn's disease, which put patient at risk of developing the event. The impact of this report on the benefit/risk profile of the Pfizer product is

evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

"burst blood vessel in left eye/blood in her eye; This is a spontaneous report from a contactable physician (patient). A 35-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (lot number EH9899, expiry date 01Mar2021), via an unspecified route of administration on 23Dec2020 at single dose for covid-19 immunization. Vaccine location was left deltoid. The facility type vaccine was hospital. Medical history included ongoing rheumatoid arthritis for about 8 years. No known allergies. Patient didn't do relevant test. Concomitant medication included duloxetine hydrochloride (CYMBALTA) for rheumatoid arthritis for 2 years, sulfasalazine for rheumatoid arthritis for 4 months, it's unknown if they were ongoing. The patient didn't receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient received the vaccine yesterday (23Dec2020), which she was very excited about, but today (24Dec2020) she woke up with a burst blood vessel in her left eye, she appears to have blood in her eye. This has never happened to her before. She knows this can occur with patients that have COVID but didn't know if it was a side effect to receiving the vaccine. Patient didn't receive treatment for the adverse event. The action taken in response to the event for BNT162B2 was not applicable. The outcome of event was not recovered. The relatedness between COVID vaccine and event ""burst blood vessel in left eye"" was related by reporter. Pfizer is a marketing authorization holder of [BNT162B2] in the country of incidence or the country where the product was purchased (if different). This may be a duplicate report if another marketing authorization holder of [BNT162B2] has submitted the same report to the regulatory authorities.; Sender's Comments: ""Burst blood vessel in eye"" is not uncommon in general population, and there are many causes of the event. Considering temporal relationship, a contribution role of the injection of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) to the reported Eye haemorrhage cannot be excluded. The case will be reassessed should additional information become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate."

Tachycardia; Intermittent palpitations; Low grade fever/fever; muscle aches; This is a spontaneous report from a contactable physician. A 27-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), intramuscularly in unknown arm on 17Dec2020 at single dose for routine mass immunizations (covid-19 immunization). The COVID-19 vaccine was administered at Hospital. Not a military facility. The patient's medical history was reported as none and concomitant medications was none (he was on no other medications). The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient experienced tachycardia, intermittent palpitations, low grade fever/fever all started somewhere in the morning of 18Dec2020 and muscle aches on 17Dec2020. Physician assessed tachycardia and intermittent palpitations as serious due to medically significant. Physician stated that one of his workers had the vaccine and proceeded to have tachycardia and low

grade fever. He would like to know if patient should get the second dose. The patient had mostly tachycardia with some intermittent palpitations. Patient was seen in his office on 18Dec2020, and got the COVID vaccine on 17Dec2020. He also reported fever and muscle aches, although the fever was subjective and was not documented. Tachycardia improved and sent him to cardiology on 21Dec2020. It was not life threatening and they did an Electrocardiogram (EKG). His initial heart rate was 130. When he was seen again in their office on 21Dec2020, it was 93, which was baseline. It improved. He never got his temperature. The highest in office was 99.5 degrees Fahrenheit. He had some muscle aches. The physician just sent patient to cardiology because he was having intermittent tachycardia and intermittent palpitations. Two visits to physician office. He was seen on 18Dec2020 and again on 21Dec2020. Relevant tests: they did testing for tachycardia but not related specifically. They did thyroid and EKG in office and he did not know if test were back. EKG was ok. The Thyroid, Complete blood count (CBC) and lipid (all were on an unknown date in Dec2020) were not back and were just done to make sure there were no cardiac issues. The outcome of the events was recovering. The lot/batch number has been requested.; Sender's Comments: Based on temporal association, the causal relationship between BNT162B2 and the events tachycardia and palpitations cannot be excluded. This case will be reassessed once additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate.

Cellulitis: below left elbow; Soft tissue swelling; This is a spontaneous report from a contactable nurse (patient). A 63-year-old female patient (62 years old at time of vaccination) received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Lot number: EH9899), intramuscular in left upper arm on 21Dec2020 13:00 at a single dose for COVID-19 immunization administered in the hospital. Medical history included ongoing hypertension and cervical cancer from 2015 and ongoing. The patient has been taking unspecified concomitant medication/s. The patient previously took amoxicillin and had allergies and nausea. On 24Dec2020 16:00, patient had cellulitis below left elbow and soft tissue swelling. On 25Dec2020, patient went to ER and X-ray was taken and patient was prescribed Keflex 500mg 3x day. Prior to vaccination, the patient was not diagnosed with COVID-19: Since the vaccination, the patient has not been tested for COVID-19. The outcome of the events was recovering.; Sender's Comments: Based on the information currently provided, the vaccination with BNT162B2 might play a contributory role in triggering the onset of cellulitis. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

congestion in the throat and upper lungs; congestion in the throat and upper lungs; This is a spontaneous report from a contactable other healthcare professional (patient). A 61-year-old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number: EK5730), intramuscular on the left arm on 21Dec2020 09:30 at a single dose for COVID-19

immunization. The patient's medical history included herpes 2. The patient was not pregnant. The patient had no known allergies to medications, food, or other products. There were no concomitant medications. The patient was not diagnosed with COVID-19 prior to vaccination and had not been tested for COVID-19 since the vaccination. On 26Dec2020 09:00, the patient experienced congestion in the throat and upper lungs. Oxygen level was 98 and temperature was 97.7. She had a good diet, no dairy, and no Christmas junk food, so for the patient, it was inexplicable. She was also consistent at mask wearing and all the precautions. No treatment was received for the adverse events. Outcome of the events was not recovered. The events were reported as non-serious.; Sender's Comments: Considering the temporal gap between the vaccination and the event onset, the Company considers the event pulmonary congestion is unlikely related to vaccination with BNT162B2. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

She was hospitalized for a month Occurred after a flu two months prior and a stomach flu 2-3 weeks prior; She was hospitalized for a month Occurred after a flu two months prior and a stomach flu 2-3 weeks prior; This is a spontaneous report from a contactable consumer. A 75-year-old female patient received bnt162b2 (BNT162B2, lot number and expiry date were not reported), via an unspecified route of administration on an unspecified date at a single dose for covid-19 vaccination. Medical history included guillain-barre syndrome from 2011 at the age of 65 and Levaquin allergy. The patient's concomitant medications were not reported. On an unspecified date, the patient was hospitalized for a month that occurred after a flu two months prior and a stomach flu 2-3 weeks prior. The outcome of the events was unknown. Information about lot/batch number has been requested.

I got my left arm pit, lump on it, I have bigger than 1 cm 2 lumps, hidradenitis/Pain under my arm; Patient received Pfizer Covid-19 Vaccine who is a nursing mom; Patient received Pfizer Covid-19 Vaccine who is a nursing mom; Mastitis; I got Myalgia all over the body, especially on my shoulders and back; I had chills but my temperature was normal; This is a spontaneous report from a contactable physician (patient herself). This physician reported information for herself (mother) and baby. This is the mother case. A 40-year-old female patient received her first dose of bnt162b2 (BNT162B2, also reported as Pfizer Covid-19 Vaccine, lot/batch number and expiry date were not reported), via an unspecified route of administration on 20Dec2020 18:30 at single dose for Covid-19 immunisation. The patient medical history and concomitant medications were not reported. The patient informed that she got in her left shoulder and left arm pit, lump on it. It was bigger than 1 cm 2 lumps, hidradenitis under her pits arm same size on 21Dec2020. She also reported that she was nursing mom to her self-kid which is 16 months old. She had Mastitis right now (20Dec2020) and informed that she hadn't it her life before. She got her vaccine on Sunday (20Dec2020) in night. She started to have pain under her arm on monday afternoon (21Dec2020) and then since yesterday (20Dec2020) she had mastitis. The mastitis in the right side, lump and the in the left side, which was the site of the vaccine. She never got a fever but got myalgia all over the body, especially on her shoulders and back and also she had chills but her temperature was normal. The outcome of events was unknown. Information on the Lot/Batch Number has been requested.;

Sender's Comments: Based on the close temporal relationship, the association between the event mastitis with BNT162b2 can not be completely excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.,Linked Report(s) : US-PFIZER INC-2020520371 Fetal case

26Dec2020 continued decreased perfusion added bilateral knee joint pain; 26Dec2020 continued decreased perfusion added bilateral knee joint pain; 25Dec2020 added facial edema; 24Dec2020 ++6 pitting edema on ankles and feet +3 pitting legs and abdomen; 24Dec2020 ++6 pitting edema on ankles and feet +3 pitting legs and abdomen; throat scratchy and tight; throat scratchy and tight; 23Dec2020 slight swelling on feet and ankles; 23Dec2020 slight swelling on feet and ankles; Tingling and best flutter 5 minutes after administration; Tingling and best flutter 5 minutes after administration; This is a spontaneous report from a contactable nurse (patient). A 48-year-old female patient (not pregnant) received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot/batch number: EJ1685, expiration date: Mar2021), intramuscularly on 22Dec2020 at 09:45 at single dose for COVID-19 immunization in hospital. The patient medical history included known allergies: Sulfa, Penicillin; fibromyalgia; hypertension; high cholesterol. Prior to vaccination, patient was not diagnosed with COVID-19. The patient's concomitant medications included other medications was received within 2 weeks of vaccination. Patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient experienced on 22Dec2020 09:45 tingling and best flutter 5 minutes after administration; 23Dec2020 slight swelling on feet and ankles; 24Dec2020 ++6 pitting edema on ankles and feet +3 pitting legs and abdomen, throat scratchy and tight; 25Dec2020 added facial edema; 26Dec2020 continued decreased perfusion added bilateral knee joint pain. Since the vaccination, patient had not been tested for COVID-19. Therapeutic measures were taken as result of the events included diphenhydramine hydrochloride (BENADRYL) 50 mg every 6 hours. The outcome of the events was not recovered. The report was reported as non-serious, with seriousness criteria-Results in death: No; Life threatening: No; Caused/prolonged hospitalization: No; Disabling/Incapacitating: No; Congenital anomaly/birth defect: No.; Sender's Comments: Flutter occurred 5 minutes after vaccination; a possible causal association between administration of the suspect vaccine bnt162b2 and the serious event onset cannot be fully excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

dizzy/feel faint; perspiring; like blood not getting to my head; had to get on hands and knees, crawl; felt like my heart may be racing 10 min after vaccine/heart felt off beat and like blood not getting to my head/heart rate was 142; felt like my heart may be racing 10 min after vaccine/heart felt off beat and like blood not getting to my head/heart rate was 142; arm sore day #1 and #2- not unexpected; This is a spontaneous report from a contactable Physician(patient). A 48-year-old female patient received first

dose (BNT162B2, lot number EK5730) , intramuscular at Arm Right on 18Dec2020 14:15 at the 48-year-old at single dose for COVID-19 immunization. The medical history included elevated blood pressure , allergic to sulfa, hypertension and Covid. The concomitant products included alprazolam, diphenhydramine hydrochloride (BENADRYL), spironolactone, metoprolol for hypertension, colecalciferol (VITAMIN D 3). The patient previously took nubaine and experienced drug allergy. The patient also happened to be a physician in private practice and received the vaccine at her local hospital. The patient had hypertension which was under excellent control on metoprolol 25 mg. She took it as prescribed every day surrounding the vaccine. On day #1 at the vaccine she felt like her heart may be racing 10 min after vaccine was about 80 on 18Dec2020 14:25. nothing serious. The patient experienced arm sore day #1 and #2 and not unexpected. On about 7 pm the day after the vaccine 19Dec2020 she was tachy at rate of about 105. She took her metoprolol heart rate never came down. At about 9:30 pm on 19Dec2020 when her rate should have been about70- she got up from couch after falling asleep. Upon standing felt like she was very dizzy. Walked upstairs, started to feel faint, perspiring, heart felt off beat and like blood not getting to my head. She had to get on hands and knees, crawl and heart rate was 142 and sustained for almost a minute. It took over an hour for it to come back to 86 and stayed there all night. There was not treatment to all of the adverse events. The outcome of the events was Recovering.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the palpitations, tachycardia and other reported events due to temporal relationship. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics including EKG, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Severe rash; This is a spontaneous report from a contactable healthcare professional (patient). A 42-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number: EK5730 (pending clarification)), intramuscularly at the left arm on 21Dec2020 at 16:00 (04:00 PM) at single dose for COVID-19 immunization. The patient was vaccinated at a hospital. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient was not pregnant at the time of vaccination. The patient's medical history included Diabetic, type 1, allergies to penicillin, and the patient diagnosed with COVID-19 prior to vaccination. The patient was not tested for COVID-19 since the vaccination. The patient previously took codeine and experienced allergies. The patient received other unspecified medications within 2 weeks of vaccination. The patient experienced severe rash on 23Dec2020 at 21:30 (09:30 PM). The adverse event resulted in emergency room/department or urgent care: the patient was treated at local ER with prednisone and benadryl. The event was reported as non-serious. The patient recovered from the severe rash on an unspecified date in Dec2020.; Sender's Comments: Based on the information currently provided, the vaccination with BNT162B2 might play a contributory role in triggering the onset of severe rash. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety

evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Diarrhea persisted 24 hours with mucous and bloody mucous after all fecal material was exhausted.; Did have one episode of chills; This is a spontaneous report from a contactable physician. A 51-year-old female patient received the first dose of bnt162b2 (BNT162B2) lot no: EK9231, intramuscular on 23Dec2020 09:45 at a single dose for COVID-19 immunization in workplace clinic. Medical history included hypothyroid, allergies from bee sting, and covid-19 from Apr2020, all unknown if ongoing. Concomitant medication included levothyroxine sodium (SYNTHROID). The patient did not receive other vaccine in four weeks. On 25Dec2020, in the late evening at 11:45 PM-almost midnight, the patient experienced diarrhea, severe, without nausea or vomiting. Did have one episode of chills that resolved. Diarrhea persisted 24 hours with mucous and bloody mucous after all fecal material was exhausted. The patient had COVID-19 in Apr2020 and had positive antibodies in Jun2020 with high titers. She confirmed with their ID chief that she should proceed to receive the vaccine. Diarrhea resolved in 24 hours. Some lingering increased GI activity. No fever (temp 99.0F) (Dec2020). The patient recovered from events without treatment in Dec2020. The events were reported as non-serious. The patient was not tested for COVID-19 post vaccination.; Sender's Comments: A possible causal association between administration of BNT162B2 and the onset of diarrhea, severe cannot be excluded, considering the plausible temporal relationship and the known adverse profile of the suspect product. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate

Difficulty breathing; This is a spontaneous report from a contactable pharmacist. A 54-year-old female patient received her first dose of intramuscular BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 22Dec2020 at 04:15 PM at single dose in left arm for COVID-19 immunisation at the age of 54-year-old. Lot number was ELO140. Medical history was unknown, concomitant medications were unspecified. Patient was not pregnant at the time of vaccination. On 22Dec2020 at 04:30 PM, the patient experienced difficulty in breathing, and she was hospitalized for one day. The patient was treated with EPI for the event. The patient was recovering from the event.; Sender's Comments: Based on the compatible temporal association, the Company considers the event difficulty in breathing is possibly related to vaccination with BNT162B2. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

short of breath; Intense headache; tiredness; body aches; This is a spontaneous report from a contactable other healthcare professional (patient). A 47-year-old female patient (not pregnant) received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number: ELO124), via an unspecified route of administration on 23Dec2020 at 14:30 on Left arm at

single dose for COVID-19 immunization in hospital. The patient medical history included Rheumatoid arthritis, lupus. No known allergy, no allergies to medications, food, or other products. Prior to vaccination, patient was not diagnosed with COVID-19. Concomitant medications included baricitinib (OLUMIANT), hydroxychloroquine, prednisone. Patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient experienced Intense headache, tiredness, body aches, short of breath on 24Dec2020; events were resulted in: Doctor or other healthcare professional office/clinic visit. Since the vaccination, patient had been tested for COVID-19 on 27Dec2020: Nasal Swab, result was unknown. No treatment was received for the events. The outcome of the events was not recovered.

"have COVID; have COVID; bone-crushing-pain; fever; This is a spontaneous report from a contactable consumer reporting for a patient (nurse). A 47-year-old female patient received first single dose of BNT162B2 (Solution for injection, batch/lot number and exp date not reported), via an unspecified route of administration on 20Dec2020 for immunization. The patient's medical history concomitant medications were not reported (unknown). Patient was an ER Nurse and took first dose of vaccine and then described mild/moderate symptoms on day one only. On 23Dec2020, patient posted they have COVID (positive COVID test). Contracted from spouse who got it from work. She further described it as ""hit by a truck."" On Day 4 she describes her COVID symptoms: bone-crushing-pain when fever rises. Symptoms were COVID symptoms, not directly related to vaccine. The events/symptoms started on 20Dec2020. Patient had no Covid prior vaccination. The patient was COVID tested post vaccination. The patient considered the events as non-serious. The outcome of events was not recovered. Information on Lot/Batch number has been requested."

abdominal pain; nausea; high blood pressure; This is a spontaneous report from a contactable consumer. A 93-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL0140), via an unspecified route of administration on 22Dec2020 at a single dose for COVID-19 immunization. Medical history included diabetic and irritable bowel. The patient's concomitant medications were not reported. The patient received the COVID vaccine and had abdominal pain, nausea and high blood pressure within 12 to 18 hours of vaccine received. The events lead to nursing home to emergency room and admitted to hospital. The patient was hospitalized due to events since 23Dec2020. Outcome of the events was recovering.

Golf ball size lump in armpit of injection arm; This is a spontaneous report from a contactable nurse. A 49-year-old female patient received bnt162b2 (BNT162B2), via an unspecified route of administration on left arm on 19Dec2020 18:15 at SINGLE DOSE for COVID-19 immunization. There was no medical history reported. Concomitant medication included estradiol (ESTROGEN), and meloxicam. On 26Dec2020 08:00, the patient experienced golf ball size lump in armpit of injection arm. The patient did not receive treatment for the adverse event. The outcome of the event was not recovered. Information on the lot/batch number has been requested.

I had seizure like 3 times; Vasovagal reaction; Fever; Headache; Weakness; It's just little bit shaky and breathless; It's just little bit shaky and breathless; allergic reaction; This is a spontaneous report from a contactable consumer. A 40-year-old female patient received bnt162b2 (BNT162B2, lot number:

EK5730), via an unspecified route of administration on 24Dec2020 at a single dose for covid-19 vaccination. There were no relevant medical history and concomitant medications. The patient reported that on an unspecified date, she had an allergic reaction. She had vasovagal reaction and seizures. Vasovagal was an allergic reaction that happened, and added that basically it's an allergic reaction. The patient experienced fever, headache, and weakness like right now. It was just little bit shaky, ever since yesterday and she had been way off like she take it as instruction yesterday, weakness, headache and breathless did not stopped from yesterday. The patient had been taking Tylenol for fever and headache. The patient reported that the events persisted. On 24Dec2020, lab work was done at the hospital, and she was told that the lab work was okay and they did CT scan of head because she developed seizure. She had seizure like 3 times so they scanned her brain. The outcome of the events was not recovered.

developed a migraine; nausea; sensitivity to light and sound; sensitivity to light and sound; she developed significant loss of mental clarity (brain fog); On 18Dec in the AM, developed progressive severe soreness at injection site, worse than any other vaccine, hurt even just the the touch. This lasted about a total of 36 hours and progressively improve; brain fog; retroorbital headache/intermittent mild tension type frontal headache; This is a spontaneous report from a contactable physician (patient). A 29-year-old female patient received first dose BNT162B2 (lot number EH9899), via an unspecified route of administration on 17Dec2020 12:00 at 29 years old at single dose at Left arm for COVID-19 immunization. Medical history included Mirena IUD, personal and family history of retinal migraines (without headache). The concomitant medications were magnesium citrate, melatonin, ademetionine (SAME) and fish oil. On 18Dec2020 in the AM, developed progressive severe soreness at injection site, worse than any other vaccine, hurt even just the touch. This lasted about a total of 36 hours and progressively improved. There was no swelling, redness, or other local symptoms. In the afternoon on 18Dec2020, she developed significant loss of mental clarity (brain fog) while at work. In the evening on 18Dec2020, developed mild retroorbital headache (this was actually the first headache of my life). All day 19Dec2020 and about half the day of 20Dec2020 developed a migraine (also the first of my life), experienced as retroorbital pounding headache, sensitivity to light and sound in 19Dec2020, nausea without vomiting in 19Dec2020, and loss of mental clarity. She had intermittent mild tension type frontal headache on 20Dec2020 PM with all other symptoms resolved, all symptoms resolved by 21Dec2020 AM. The patient used naproxen 440 mg and Tylenol 1000 mg on 19Dec2020. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. The patient was not Allergic to medications, food, or other products. The outcome of the events was recovered on 21Dec2020. The information on the batch number has been requested.; Sender's Comments: Based on information available, the reported loss of mental clarity together with other events was likely related to the first dose BNT162B2 due to temporal relationship and clinical course. The case will be reassessed should additional information become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

"husband and daughter tested positive/after taking the shot, she was feeling sick and had a fever/wondering if the vaccine can give the reaction, or maybe she has the virus; husband and daughter tested positive/after taking the shot, she was feeling sick and had a fever/wondering if the vaccine can give the reaction, or maybe she has the virus; having a lot IO symptoms; fever; has been feeling ""sick""; This is a spontaneous report from a contactable consumer. A 56-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899), via an unspecified route of administration on the left arm on 22Dec2020 at single dose for COVID-19 immunisation. The patient's husband and daughter tested positive (COVID-19). There were no concomitant medications. The patient stated, ""had the first vaccine shot, later clarified as Pfizer COVID vaccine, on 22Dec2020, and didn't have any symptoms before that, her husband and daughter tested positive, but she was staying away from that, had no symptoms, but after taking the shot, on 24Dec2020, she was feeling sick and had a fever, and has had a fever ever since, and she is taking Tylenol and Motrin every six hours, and even then she still gets the fever, it hasn't stopped, she is having a lot IO symptoms, and is wondering if the vaccine can give the reaction, or maybe she has the virus. On 24Dec2020 is when the fever started and she was feeling sick. States she filled out a report online, on (Website)"". The outcome of the events was not recovered."

his gums became discolored and turned purple/gums (both sides up and down) remain purple/discoloration to the gums in his mouth; his mouth started hurting; feeling hot; Body aches; Fever; Pain to the gums in his mouth; muscle aches; sore throat; neck pain; This is a spontaneous report from a contactable nurse (patient). A 26-year-old male patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number and expiration date were not reported), via an unspecified route of administration to right shoulder on 24Dec2020 11:30 at a single dose for COVID-19 immunization. There were no medical history and concomitant medications. The patient received vaccine on 24Dec2020. He experienced body aches, fever, and feeling hot with onset of about 3-4 hours after he was administered (24Dec2020). Next day (25Dec2020), his mouth started hurting, his gums became discolored and turned purple. Gums (both sides up and down) remained purple. He will be seeing a dentist. He also reported pain and discoloration to the gums in his mouth on 25Dec2020. He had been experiencing some of the regular side effects such as muscle aches, sore throat, neck pain on an unspecified date in Dec2020. Outcome of the event gum discoloration was not recovered, of the events feeling hot, generelized aching, and fever was recovered on 26Dec2020, of the event gum pain was recovering, and of the remaining events was unknown. He reported seriousness criteria as what he thinks to be medically significant at this point; that they could be medically significant. He is scheduled to receive the second dose of the product which at this point he does not plan to change. Dose change is unknown until he determines cause of these events and on what the doctor and dentist he is going to see recommend. He believes events could be caused by the vaccine. Information on the lot/batch number has been requested.; Sender's Comments: A causal association between BNT162 and the reported events cannot be excluded based on a compatible temporal relation. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

extreme muscle ache that she couldn't move; I couldn't take the pain/severe body ache severe like I couldn't walk; I couldn't take the pain/severe body ache severe like I couldn't walk; extreme muscle ache that she couldn't move; High fever; Lot of chills; Itchiness; Hives; she was crying; This is a spontaneous report from a contactable Nurse (patient). A 44-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiry date unknown), intramuscular on an unspecified date at single dose for covid-19 immunization. Patient history was no and investigation assessment was no. There were no concomitant medications. The patient had hives and itchiness and then that was the first day that was after 8 minutes and then the next day the patient had severe body ache severe like I couldn't walk, she cried. The patient took Tylenol and Ibuprofen as she couldn't take the pain (further clarification was unknown). The patient had high fever 102.4 and was having a lot of chills. Start date of event was 24th, the 23rd she had the hives and the 24th she had the extreme muscle ache that she couldn't move and she was crying and she had the chills and the fever on the 24th. So it on started 23rd with the hives so then it started with the body aches and the fever on the 24th. Outcome of the events was recovered. The causality between the events and drug was considered as related by the reporter via Global Introspection. Information on the batch/lot number has been requested.; Sender's Comments: The Company cannot completely exclude the possible causality between the reported body ache severe like I couldn't walk, extreme muscle ache that she couldn't move, and the administration of BNT162B2, based on the reasonable temporal association. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RA, IEC, as appropriate.

"left sided weakness; it has weakened his heart; stutter; severe stroke like symptoms; Ventricular tachycardia/help keep his heart rate at bay; Loss of balance; extreme numbness and tingling in left hand and foot; tingling in left hand and foot; oral motor impairment; mouth weakness and not coordinated/mouth is fatigued easily; Issues finding words and trouble speaking; Issues finding words and trouble speaking; Ejection fraction down to 25%; The initial case was missing the following minimum criteria: adverse event. Upon receipt of follow-up information on 28Dec2020, this case now contains all required information to be considered valid. This is a spontaneous report from a contactable other healthcare professional (HCP). A 29-years-old male patient received bnt162b2 (lot number: EJ1685), intramuscular (deltoid left) on 21Dec2020 at 05:30 at 0.3 mL single (first dose) for Covid. Medical history was reported as ""none"". Concomitant medications were not reported. The patient previously received Flu vaccine in Oct2020 for immunization. The patient is an Occupational Therapist, and he called to report an adverse event that he experienced with the first dose of the COVID Vaccine. He received the vaccine last Monday, 21Dec2020 at 5:30AM before his shift at work, then 20 minutes later, he was having severe stroke like symptoms. He experienced severe left sided weakness, loss of balance, extreme numbness and tingling in his left hand and foot, he had issues finding his words and he couldn't speak, and he had an oral motor impairment where his mouth was weak and not coordinated. The staff at the hospital did a neurological exam on him, and he failed, so he had to go to the emergency room (ER). The patient added that he was already in the hospital when this happened, and the ER doctors suspected that he had a CVA, and they gave him TPA to prevent any permanent brain damage and it

worked. The patient then added that due to the shock of this whole event, from everything that happened, it has weakened his heart. Reportedly, he is a healthy 29 year old man, with no preexisting conditions, and he works out, and he has no heart conditions, but he had to get a cardiology follow up a few days after he got the vaccine, because he started going in to Ventricular Tachycardia, which he had never had in his life. So, the doctors at the hospital went ahead and did an Echocardiogram and an EKG, and he was told that his Ejection Fraction is down to 25%. He stated his heart is so weak, that he cannot work right now, but the structure of his heart is fine and has not had any damage. The hospital staff thought that maybe the patient had a chronic heart issue that he just did not know about, and that the stress of this event maybe made it kick into overdrive, but he states that the cardiologist said that was not the case, because the structure of his heart is fine, and the only thing they can see is that the heart is pumping weak. One physician even suggested that due to the shock of the event, he might have Takotsubo Cardiomyopathy, which is a broken heart, but because the structure of his heart is okay, it should be reversible. He stated that he is hoping he will heal up good, because he is young and has no pre-existing conditions. He added that his heart is in such a state right now; he has to wear an external defibrillator. The patient stated that all these happened about 20 minutes after he received the vaccine, and he was admitted to the hospital from 21Dec2020 to 25Dec2020. His neurological symptoms have resolved except that he has a stutter that he did not have before and his mouth is fatigued easily, so he has to slow down when he is eating, but now he can eat regular for the most part. The patient confirmed that he was not specifically prescribed the product; it was administered to him at his place of work, but it was optional. He stated he considered how he is working with COVID patients every day, and given the circumstance, he thought that it would be a best practice for him to get the vaccine. He had not gone to his primary care doctor in a while because he had been fine and healthy, but he called them and found out that his primary care had retired, so he has to find a new one now. Regarding the issues finding words and trouble speaking, he stated that he has improved, but it is still ongoing, he is just stuck in a plateau zone. With the Ventricular Tachycardia, he stated that this is an ongoing issue, as he has to wear the life vest even though he has no need to activate it yet. He did have one minor bought of the VTach, but because he is a therapist, he knows how to take care of it with relaxation techniques, he knows how to manage it. He had one bought of VTach the evening prior, but he was able to get it under control. The doctors have him on medication to help keep his heart rate at bay. He has never had to use medication before and is on the following medications to help keep his heart rate at bay: Metoprolol 25mg one tablet once daily by mouth and Lisinopril 5mg one tablet once daily by mouth. The VTach has improved, it was good enough he was able to discharge home, but it is still a concern. His cardiologist said that, basically his hope, is that once his body recover from the whole shock of everything, then his ejection fraction will heal, and his heart will heal. He again stated that the doctor told him that the structure of his heart is perfectly fine; he has thick walls in his heart, no leaking valves, and the heart was not conducting any abnormal signals. The doctor just said that right now, his heart is super weak and that it is an acute problem. With the Takotsubo Cardiomyopathy, he states that two doctors mentioned this diagnosis, but he confirmed that he was not actually diagnosed with this issue, he was just diagnosed with Ventricular Tachycardia. The outcome of the ejection fraction down to 25% was unknown to the patient at this time as he has not had another EKG or echocardiogram, but the cardiologist told him that the cardiologist expects that this will not be resolved quickly anyway. The patient confirmed that he did not receive any other vaccines on the same day he received the COVID

vaccine. The only other vaccine he had this year was the flu vaccine which he got back in Oct2020. He has gone on to his online portal and there are the bloodwork results and all the imaging results on there from his CTs and MRIs, but he did not see the EKG or Echocardiogram results yet. He does not have this pulled up at this time, but he does have access to this stuff and can provide it later, if requested. He is curious about the next steps from here to how his case is processed. He is also curious if this information would help Pfizer make modifications to the vaccine if it is found that a lot of people are having the same reaction as he did. He is also wondering, given his situation, that probably he is not going to get the second dose, for his safety, but he is wondering what percentage of effectiveness the first dose does having just covered. The events left sided weakness, loss of balance, extreme numbness and tingling in left hand and foot resolved on 25Dec2020; severe stroke like symptoms and oral motor impairment; mouth weakness and not coordinated/mouth is fatigued easily resolved in 2020. The events ventricular tachycardia/help keep his heart rate at bay and issues finding words and trouble speaking were resolving, stutter had not resolved while the outcome of the events it has weakened his heart, and ejection fraction down to 25% was unknown.; Sender's Comments: The reported information is unclear and does not allowa meaningful assessment of the case. It will be reassessed upon receipt of follow up information. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate."

Left sided hearing loss; This is a spontaneous report from a contactable physician who was also the patient. A 42-year-old non-pregnant female patient received bnt162b2, lot number and expiration date were unknown, via an unspecified route of administration on 16Dec2020 , 8:30 at a single dose for covid-19 immunization. The patient's medical history included antiphospholipid antibody from an unknown date and unknown if ongoing. The patient's concomitant medications were not reported. On 22Dec2020, the patient experienced left sided hearing loss. It was unknown if patient received treatment for the event. The outcome of the event was not recovered. The patient was not diagnosed with COVID prior to vaccination and has not been tested for COVID-19 since vaccination. Patient has no allergies. Patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Information on the lot/batch number has been requested.; Sender's Comments: As an individual case report there is not enough evidence to establish a causal relationship with the suspect vaccine. Currently there is no clear biological plausibility between the vaccine use and the even onset. More information such as complete medical history and concomitant medications are needed for fully medical assessment. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

severe hearing loss; This is a spontaneous report from a contactable physician (patient). A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an

unspecified route of administration on 16Dec2020 at single dose for covid-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient experienced severe hearing loss on Dec2020 and was inquiring if it was a reported side effect of the vaccine. Outcome of event was unknown. Information about lot/batch number has been requested.; Sender's Comments: A causal association between BNT162 and the reported event cannot be excluded based on a compatible temporal relation. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

tightness in throat and lump in throat/had a tightness and lump in her throat; tightness in throat and lump in throat/had a tightness and lump in her throat; allergic reaction like rash, tightness in throat, and lump in throat; allergic reaction like rash/red rash on her chest and rash was on her arms too; cheeks were flushed; This is a spontaneous report from a contactable nurse (patient). This nurse reported similar events for 3 patients. This is the first of 3 reports. A 23-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) lot number: EK9231, intramuscular in the right deltoid, first dose on 27Dec2020 14:15 at a single dose for covid-19 prevention. Medical history included ongoing asthma and reactive airway which she was diagnosed when she was like 5 years old (2002). Concomitant medication included albuterol [salbutamol] for asthma which started when she was 8 years old or so. The patient wanted to know if she can receive the second dose of covid vaccine after experiencing symptoms of allergic reaction like rash, tightness in throat, and lump in throat. She wanted to know the ingredients and specific proteins in the covid vaccine. The patient received the COVID Vaccine and she developed a reaction. On 27Dec2020, she had a red rash on her chest, and her cheeks were flushed, and the rash was on her arms too, and she had a tightness and lump in her throat, it was not painful to swallow but she could feel the pressure with swallowing. She stated that she did not experience shortness of breath, but regardless, she was seen in the ER and she was given IV SOLUMEDROL, and BENADRYL, and she was watched for 5 or 6 hours and then she was sent home with an Epi Pen, around the clock Benadryl, and prednisone. She asked the ER doctors if they thought it was okay for her to receive the second dose of the product, and they told her to contact employee health for that question. She mentioned that she contacted that employee health and was told to contact her primary care provide which she did. Her primary care doctor instructed the caller to call Pfizer and gather some more information regarding ingredients, as the she may have had the reaction to a particular protein filler. She was also wondering if this is a known reaction to the product. She received the vaccine on 27Dec2020 at 2:15 PM. She reported that the red rash on her chest and arms, and her cheeks being flushed, resolved yesterday after receiving IV BENADRYL. Had a tightness and lump in her throat which was still ongoing, and it was kind of off and on and when the she takes Benadryl it goes away. She reported that this one is medically significant because even though she did not have shortness of breath, it could have affected her airway. She confirmed that she received no other vaccines on the same day as the COVID vaccine. The outcome of the events 'had a tightness and lump in her throat', allergic reaction was not recovered (a s reported); while recovered on 27Dec2020 for allergic reaction like rash/red rash on her chest and rash was on her arms too and cheeks were flushed.;

Sender's Comments: Based on temporal association, the causal relationship between bnt162b2 and the events throat tightness, sensation of foreign body, allergy to vaccine, rash erythematous and flushing cannot be excluded. This case will be reassessed once additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate.,Linked Report(s) : US-PFIZER INC-2020517134 different patient, same drug and same event;US-PFIZER INC-2020517133 different patient, same drug and same event.

Fever up to 120F; Bodyaches; Headache; dulled taste and smell; dulled taste and smell; Pain at the injection site; This is a spontaneous report from a contactable other HCP. A 25-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (reported as COVID 19 vaccine), intramuscular on 27Dec2020 12:00PM at single dose for covid-19 immunization. Vaccine location was left arm and it was the first dose. The patient medical history was not reported. Concomitant medication included influenza vaccine (FLU) on 16Dec2020 at right arm. Patient was not diagnosed with COVID-19 prior to vaccination nor tested for COVID-19 since the vaccination. The patient didn't receive any other medications within 2 weeks of vaccination. The patient experienced fever up to 120F, bodyaches, headache, dulled taste and smell, pain at the injection site on 27Dec2020. Patient didn't receive treatment for the adverse events. The action taken in response to the events for BNT162B2 was not applicable. The outcome of events was not recovered. The events were reported as non-serious. Pfizer is a marketing authorization holder of [BNT162B2] in the country of incidence or the country where the product was purchased (if different). This may be a duplicate report if another marketing authorization holder of [BNT162B2] has submitted the same report to the regulatory authorities. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Sender's Comments: A causal association between BNT162B2 and the event hyperpyrexia cannot be excluded based on compatible temporal relation. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

High blood pressure 187/95; Heart rate at one time 210 bpm; chest pain; Shortness of breath; This is a spontaneous report from a contactable pharmacist (patient) reported for herself that a 45-years-old female patient received first dose of BNT162B2 (lot number: EH9899), via intramuscular in left arm on 22Dec2020 07:00 AM at single dose for COVID-19 immunization. The patient was not pregnant. No known allergies. No allergies to medications, food, or other products. No other vaccine was received within 4 weeks prior to the COVID vaccine. No other medications were received within 2 weeks of vaccination. The patient was not diagnosed with COVID-19 prior vaccination and patient was not tested for COVID-19 since the vaccination. There were no medical history or concomitant medications. The patient experienced high blood pressure 187/95, heart rate at one time 210 bpm, shortness of breath and chest pain on 23Dec2020 10:00 AM. The events resulted in doctor or other healthcare professional

office/clinic visit, emergency room/department or urgent care. Treatment was received for heart rate at one time 210 bpm which included lab works and medication given propranolol to decrease heart rate. The outcome of the event was recovering.; Sender's Comments: Based on temporal association, the causal relationship between BNT162B2 and the events hypertension, heart rate increased, chest pain and dyspnoea cannot be excluded. The information available in this report is limited and this case will be reassessed once additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate.

She had an immediate reaction of accelerated heart rate and elevated blood pressure; She has very slightly elevated heart enzymes.; She had an immediate reaction of accelerated heart rate and elevated blood pressure; She's very anxious and very anxious tonight being alone at the hospital.; This is a spontaneous report from a contactable consumer (patient's father). A 30-years-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 18Dec2020 at single dose for COVID-19 immunisation. The patient medical history and concomitant medications were not reported. The patient had an immediate reaction of accelerated heart rate and elevated blood pressure. She was monitored for an hour and it subsided. On unspecified date in Dec2020 at 1:00am in the morning she had racing heart rate and went to ER. She was still in hospital. Things were not entirely stabilized. She had very slightly elevated heart enzymes in Dec2020 with outcome of unknown. They keep her overnight for an echocardiogram in morning. The patient was very anxious being alone at the hospital. Caller questioned if this has been reported with the vaccine. Lot/Batch and Expiry date has been requested.

mental cloudiness; bruising of injection site; arm pain; fatigue; This is a spontaneous report from non-contactable Pharmacist (patient). A 33-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection) intramuscular at right arm on 19Dec2020 08:15 at single dose for Covid-19 immunization. The Covid-19 vaccine was administered in a hospital facility. Medical history included seasonal allergies, heartburn, and allergies to ethanol. The patient has no Covid prior vaccination. Concomitant medication included cetirizine, esomeprazole, melatonin; all from unspecified date for unspecified indication. The patient did not receive other vaccines in four weeks prior to the Covid vaccine. On 19Dec2020 at 15:00, the patient experienced bruising of injection site (x 1 week), arm pain, fatigue, mental cloudiness (approximately x 1 day). The patient was not tested post vaccination. The patient did not received treatment due to the events. The outcome of the events mental cloudiness, bruising of injection site, arm pain and fatigue was recovered in Dec2020. No follow-up attempts are possible. Information about lot/batch number cannot be obtained.; Sender's Comments: Based on temporal association, the causal relationship between BNT162B2 and the event mental impairment cannot be excluded. The information available in this report is limited and this case will be reassessed once additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as

part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate.

30 minutes after receiving vaccine, patient reported heart racing, dizziness, flushing, burning pain in her chest, dizziness. tachycardia, nausea and throat tightness; 30 minutes after receiving vaccine, patient reported heart racing, dizziness, flushing, burning pain in her chest, dizziness. tachycardia, nausea and throat tightness; 30 minutes after receiving vaccine, patient reported heart racing, dizziness, flushing, burning pain in her chest, dizziness. tachycardia, nausea and throat tightness; 30 minutes after receiving vaccine, patient reported heart racing, dizziness, flushing, burning pain in her chest, dizziness. tachycardia, nausea and throat tightness; 30 minutes after receiving vaccine, patient reported heart racing, dizziness, flushing, burning pain in her chest, dizziness. tachycardia, nausea and throat tightness; 30 minutes after receiving vaccine, patient reported heart racing, dizziness, flushing, burning pain in her chest, dizziness. tachycardia, nausea and throat tightness; 30 minutes after receiving vaccine, patient reported heart racing, dizziness, flushing, burning pain in her chest, dizziness. tachycardia, nausea and throat tightness; This is a spontaneous report from a contactable pharmacist. A 58-year-old non-pregnant female patient received first dose of BNT162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number= EH9899), intramuscular on 19Dec2020 07:00 at SINGLE DOSE at Left arm for covid-19 immunization. Medical history included breast cancer female and allergies to shell fish and Latex. The patient's concomitant medications were not reported. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. 30 minutes after receiving vaccine on 19Dec2020 07:30 am, patient reported 'heart racing, dizziness, flushing, burning pain in her chest, dizziness. tachycardia, nausea and throat tightness. Patient was taken to the ED where she received IV Benadryl and was observed for 4 hours. Patient was discharged home and symptoms subsided. The events resulted in emergency room/department or urgent care. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, the patient was not been tested for COVID-19. Outcome of the events was recovered in Dec2020.; Sender's Comments: There is a plausible temporal relationship between immunization and onset of allergic reaction in a subject with a positive medical history for allergy to food (shellfish); causality cannot be completely excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

exacerbation of cryptogenic organizing pneumonia; fever; malaise; wheezing; This is a spontaneous report from a contactable physician reported for himself. A 60-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection) via an unspecified route of administration from an unspecified date at single dose for Covid-19 immunization. Medical history included rheumatoid arthritis. The patient's concomitant medications were not reported. The patient experienced having fever and malaise after vaccination and then a few days later he has been wheezing. The patient believed it was an exacerbation of cryptogenic organizing pneumonia. The outcome of the events exacerbation of cryptogenic organizing pneumonia, fever, malaise and wheezing was unknown. Follow-up activities are possible, information on the batch number has been requested.; Sender's Comments:

The association between the event cryptogenic organizing pneumonia with BNT162b2 can not be fully excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

Sudden onset Acoustic Neuritis without Labyrinthitis, hyperacusis, loss of hearing, fullness in ears, dizziness and tinnitus.; Sudden onset Acoustic Neuritis without Labyrinthitis, hyperacusis, loss of hearing, fullness in ears, dizziness and tinnitus.; Sudden onset Acoustic Neuritis without Labyrinthitis, hyperacusis, loss of hearing, fullness in ears, dizziness and tinnitus.; Sudden onset Acoustic Neuritis without Labyrinthitis, hyperacusis, loss of hearing, fullness in ears, dizziness and tinnitus.; Sudden onset Acoustic Neuritis without Labyrinthitis, hyperacusis, loss of hearing, fullness in ears, dizziness and tinnitus.; sore arm; nerve related hearing loss; This is a spontaneous report from a contactable physician reporting for himself. A 69-years-old male patient received bnt162b2 (BNT162B2; Lot : EKS730) vaccine , intramuscular in the left deltoid on 21Dec2020 15:30 at single dose for covid-19 immunisation . Medical history included atrial fibrillation from 2009. There were no concomitant medications. The patient stated he experienced sore arm on the same day 21Dec2020 and this was not a big deal. On 26Dec2020 the patient experienced sudden onset of acoustic neuritis without labyrinthitis, hyperacusis, fullness in ears, dizziness and tinnitus . The patient also experienced nerve related hearing loss from Dec2020. Sore arm was considered non serious events, while the remaining were considered Important Medical Events. The outcome of nerve related hearing loss was recovered, the outcome of sore arm was unknown, while the outcome of the remaining events was recovering.; Sender's Comments: Based on the temporal association, it cannot be fully excluded that the vaccination with BNT162B2 might play a contributory role in the events onset. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

I have lost hearing in my right ear; the right side of my face was numb; This is a spontaneous report from a contactable consumer (patient). A 58-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) Batch/lot number number EJ1685, expiration date Mar2021, on 25Dec2020 09:30 at single dose on left arm for Covid-19 vaccination. Medical history and concomitant medications were none. The patient had not received other vaccine in four weeks. The patient had no covid prior vaccination. The patient had no covid tested post vaccination. The patient received her first Covid-19 vaccination on Christmas morning. She worked at a medical center. Within an hour of when she got home, she lost hearing in one ear and also had some numbness on the same side of her face, She was wondering if that was something she should be concerned and she still didn't have hearing in her right ear. Treatment received for the events included Tylenol. The outcome of the events was not resolved.

She suspected that she had an undiagnosed autoimmune disease.; Spinal pain that elicits nausea; spinal pain that elicits nausea; Headache that is worse at night/Headache worse at night time, sometimes gets better during the day/bad head ache; Body aches; Feeling crappy; Low grade fever; Pressure in the head; Terrible pain; Neck pain; This is a spontaneous report from a contactable other health professional (patient). A 43-yearsold female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 19Dec2020 at single dose for covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient received Covid19 vaccine on 19Dec2020 and reported that at 36 hours she had body aches, feeling crappy, and low grade fever in Dec2020, she had since developed at headache that is worse at night, and spinal pain that elicits nausea. She suspected that she had an undiagnosed autoimmune disease. She was inquiring about duration of the reported AE's from clinical trials, and tried to decide how long she will feel this way. And going on 10 days and she's just struggling, bad headache and neck pain headache worse at night time, sometimes gets better during the day. Terrible pain and nausea. Any info on length of side effects: 36 hours- body aches feeling crappy. Low grade fever. Nausea with the spinal pain, pressure in the head. Difference in people with autoimmune issues- infertility - suspected autoimmune. The outcome of the events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Based on the information currently available, there is no biological plausibility to implicate the suspect vaccine to the occurrence of the serious event autoimmune disease. More information such as medical history and concomitant medications and confirmative diagnostic workups are needed for full medial assessment. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Heart rate high; Blood pressure high; bruise at the site of the vaccination; This is a spontaneous report from a contactable other health professional reporting for herself. A female patient of an unspecified age received the 1st dose of bnt162b2 (BNT162B2, Manufacturer Pfizer-BioNTech), via an unspecified route of administration, on 22Dec2020, at single dose, for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. On 22Dec2020, 1-1.5 hours after vaccination, the patient experienced heart rate high with outcome of unknown , blood pressure high with outcome of unknown and bruise at the site of the vaccination with outcome of unknown. The patient underwent lab tests and procedures which included: blood pressure, high (22Dec2020); heart rate, high (22Dec2020). She returned to the emergency room (ER) of the hospital where she received the vaccine due to all the events. Therapeutic measures were taken as a result of heart rate high and blood pressure high and included treatment with a beta blocker. The patient was also prescribed with a blood pressure medicine from the ER physician. The events heart rate high and blood pressure high were considered medically significant. The information on the lot/batch number has been requested.; Sender's Comments: Based on the compatible temporal association, the Company considers the events heart rate high and blood pressure high are possibly related to vaccination with BNT162B2. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety

concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

tingling of the lips/Lips tingled; Throat got tight; This is a spontaneous report from a contactable other hcp(patient). The 49-year-old female patient received first dose BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EK5730, Expiry Date: 31Mar2021), via an unspecified route of administration at left arm on 21Dec2020 at single dose for COVID-19 immunization. There were no concomitant medications nor medical history. Patient got first dose of the COVID vaccine and experienced her lips tingled/ tingling of the lips and her throat got tight, both on 21Dec2020, led to medically significant, lasted about 20 minutes. They observed her and she did not need any further treatment. Outcome of events was recovered in 21Dec2020.; Sender's Comments: A possible causal association between administration of BNT162B2 and the onset of her lips tingled/ tingling of the lips and her throat got tight cannot be excluded, considering the plausible temporal relationship and the known adverse event (anaphylactic adverse reaction) profile of the suspect product. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate

"disoriented; hit her head and cut herself; hit her head and cut herself; Passed out at night; This is a spontaneous report from a contactable consumer (patient). A 67-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK5730), via an unspecified route of administration on 23Dec2020 at single dose at left arm for COVID-19 immunization. Medical history included Atrial fibrillation/heart problems diagnosed prior to the vaccine, got the COVID virus on 18Nov2020, disoriented in Nov2020. Concomitant medications included her heart medication every day and vitamins, nothing out of the normal. Caller stated she had heart problems. The heart problems were diagnosed prior to the vaccine. Caller also stated that she got the COVID virus this year before the vaccine as well and she was off, of work for like a month. On 23Dec2020 she got the vaccine. Then on Thursday 24Dec2020 and Friday 25Dec2020 she had a reaction. She had passed out in the night, hit her head and cut herself, she was then disoriented for 1 full day. Caller stated that the last time she was disoriented like this was when she had the COVID Virus, because she had heart problems. Caller stated that she was fine now. Caller stated that she had been off, of work so much. The heart problem she had was Atrial Fibrillation. Caller clarified that she had the COVID virus this year in Nov2020, it was before thanksgiving, on 18Nov2020 she had the virus, then on 19Nov2020 she got tested and it was positive. She got the vaccine on the 23Dec2020 Wednesday then on 24Dec2020 at night she passed out and on 25Dec2020 she was disoriented all day. Investigation Assessment: No. On 24Dec2020 she was going to bathroom, and found herself on the floor, then the following day 25Dec2020 was when she was disoriented. She knew this because when she had the actual COVID virus previous in Nov2020 this happened previously. When queried outcome of being disoriented she stated that she still felt a little weird but if getting better very, very slow. The Second dose was schedule for 13Jan2021. Caller confirmed that she did have a Positive Test for Covid Previously. Her treatment at the time was in the Emergency Room, they gave her an Antibody infusion, she had to schedule it because it was actually a

clinical trial. Caller was asked if she knew the name of covid test, she stated that she does not know, she only recalled that she opened her mouth and they test her that way. The outcome of the event ""disoriented"" was recovering, of the other events was unknown."

Bells Palsy; This is a spontaneous report from a contactable consumer. This consumer reported similar events for three patients. This is 1st of three reports. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (also reported as Comirnaty), via an unspecified route of administration on an unspecified in Dec2020 at single dose for COVID-19 immunization. The patient medical history and concomitant medications were not reported. The patient experienced bells palsy on Dec2020. The action taken in response to the event for bnt162b2 was not applicable. The outcome of event was unknown. No follow-up attempts are possible; information about batch/lot number cannot be obtained.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2020519118 same reporter/drug/event, different patient;US-PFIZER INC-2020519119 same reporter/drug/event, different patient

Bell's Palsy; This is a spontaneous report from a contactable consumer or other non HCP. This consumer reported same events for three patients (nurses). This is 2nd of 3 reports. A patient of an unknown age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, also reported as COMIRNATY), via an unspecified route of administration on unknown date in Dec2020 at single dose for covid-19 immunization. The patient's medical history and concomitant medications were unknown. Healthcare worker reported that 3 nurses who work in her facility received Pfizer's COVID vaccine last week (Dec2020) came in with Bell's Palsy in Dec2020. Event took place after use of product. The outcome of event was unknown. No follow-up attempts are possible. Information about batch/Lot number cannot be obtained.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2020519105 same reporter, same drug, same event, different patients;US-PFIZER INC-2020519119 same reporter, same drug, same event, different patients

Bells Palsy; This is a spontaneous report from a contactable consumer or other non HCP. This consumer reported same events for three patients. This is a 3rd of 3 reports. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, also reported as Comirnaty), via an unspecified route of administration on an unspecified in Dec2020 at single dose for COVID-19 immunization. The patient medical history and concomitant medications were not reported. Healthcare worker reported that 3 nurses who work in her facility received Pfizer's COVID vaccine last week (Dec2020) came in with Bells Palsy. Event took place after use of product. The outcome of event was unknown. No follow-up attempts are possible; information about batch/lot number cannot be obtained.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2020519118 same reporter, same drug, same event, different patients;US-PFIZER INC-2020519105 same reporter, same drug, same event, different patients

Gallbladder removed, septic, 11mm axillary lymph node.

she got the COVID 19 vaccine on the 16Dec2020 and got tested positive on the following day; she got the COVID 19 vaccine on the 16Dec2020 and got tested positive on the following day; This is a

spontaneous report from a Pfizer-sponsored program IBCC (Inbound Call Center for HCPs). A contactable nurse (patient) reported that a female patient of an unspecified age received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 16Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient reported that she got the COVID 19 vaccine on the 16Dec2020 and got tested positive on the following day (17Dec2020). She is scheduled to take her second dose on 20Jan2021. The patient wanted to know what Pfizer recommendations are. Outcome of the event was unknown. That information on the lot/batch number has been requested.; Sender's Comments: A causal role of BNT162B2 would seem unlikely based on the temporal gap between the vaccination and the event onset.

being tested positive; being tested positive; felt very sick; congestion; This is a spontaneous report from a contactable other healthcare professional (patient herself). A female patient of an unspecified age received her first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date not reported), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient felt very sick and that's not her normal. The patient felt great after getting the vaccine she hadn't felt that in a while. Today (23Dec2020) the patient had this congestion and 4 -5 people came back positive post covid-19 vaccination on unknown date. All of them sent home after being tested positive. The patient just someone to keep track, she just wanted Pfizer to know. She didn't have any problems, she was working COVID patients. They had a lot new cases. She just didn't feel 100%. The patient wanted to know if it's safe for her to get the second dose after being tested COVID positive post vaccination. The outcome of events was unknown.; Sender's Comments: The information available in this report is limited and does not allow a medically meaningful assessment of the case. The company cannot completely exclude a causal relationship between the reported events and vaccination with BNT162B2. Additional information regarding therapy vaccination date, lot number and investigation results will aid in comprehensive assessment of the case.

she reported on 18Dec2020 got vaccine later that day tested positive; she reported on 18Dec2020 got vaccine later that day tested positive; This is a spontaneous report from a contactable nurse. A female patient of an unspecified age received the 1st dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration at single dose on 18Dec2020 for Covid-19 immunisation. The patient medical history and concomitant medications were not reported. She reported on 18Dec2020 got vaccine later that day tested positive with outcome of unknown. She asked can she still receive the 2nd dose of the vaccine or should she repeat the vaccination series. The patient underwent lab tests and procedures which included Sars-Cov-2 test: positive on 18Dec2020. Information on the lot/batch number has been requested.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the reported events due to temporal relationship. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile

of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

received the (1st dose of) COVID-19 vaccine 5 days ago and tested positive; received the (1st dose of) COVID-19 vaccine 5 days ago and tested positive; This is a spontaneous report from a contactable pharmacist. A patient of unspecified age and gender received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Device Type: Vial), intramuscularly on 18Dec2020 at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient received the (1st dose of) COVID-19 vaccine 5 days ago and tested positive on 23Dec2020. PharmD asked if it's possible to administer Bamlanivimab to a patient who received the (1st dose of) COVID-19 vaccine 5 days ago and tested positive. Pharmacist mentioned that as Bamlanivimab was an EUA drug, they cannot go outside of the recommendations, and given that no information was available about its use after a dose of the COVID-19 vaccine, it is possible that Bamlanivimab may not be administered. Explained Pfizer MI is unable to provide a direct recommendation, was referred to the patient's Docton for guidance: Before receiving the next dose of the COVID-19 vaccine, and to clarify if Bamlanivimab should be administered. The outcome of events was unknown. Information on the Lot/Batch number has been requested.; Sender's Comments: The reported tested positive 5 days after COVID-19 vaccine is considered related to the administration of BNT162B2.

PCR test positive for COVID-19 but no signs of COVID-19; PCR test positive for COVID-19 but no signs of COVID-19; This is a spontaneous report from a contactable physician reporting for himself. A 70-year-old male patient received the 1st dose of bnt162b2 (BNT162B2), via an unspecified route of administration in arm left, on 17Dec2020 at 09:00 AM, at single dose, for Covid-19 immunisation. Medical history included hypertension, high cholesterol, benign prostatic hyperplasia, drug allergy and food allergy all from unknown date and unknown if ongoing. The patient had not been diagnosed with COVID-19 prior to vaccination. The patient received unknown medications within 2 weeks of vaccination. Historical vaccine included typhoid vaccine (unknown trade name) on unknown date and the patient experienced drug allergy. The day after vaccination with bnt162b2, on 18Dec2020 at 04:00 PM, the patient experienced PCR test positive for COVID-19 but no signs of COVID-19. The patient did not receive any treatment as a result of the event. The event resulted in doctor or other healthcare professional office/clinic visit. The patient underwent lab tests and procedures which included: COVID-19 PCR test positive (18Dec2020), nasal swab positive (18Dec2020). Outcome of the event was unknown. The information on the lot/batch number has been requested.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the reported events of COVID-19 PCR test positive and suspected lack of efficacy due to temporal relationship. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for

adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

guillain barre syndrome; stroke; left thigh burning; Left b/l gluteal burning/bilateral gluteal burning; paresthesia; mid back burning; right side burning / right thigh burning; b/l hand numbness/bilateral hand numbness; left facial numbness; b/l foot numbness/bilateral foot numbness; This is a spontaneous report from a contactable physician (patient). A 39-year-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EK5730), via an unspecified route of administration on 19Dec2020 at single dose for prevention. Medical history included none. There were no concomitant medications. Caller states, he received the covid vaccine 19Dec2020 and on 25Dec2020 he was experiencing left facial numbness, b/l foot numbness, b/l hand numbness on 26Dec2020, right side burning on 28Dec2020, Today (29Dec2020) he has had left thigh burning, and Left b/l gluteal burning and paresthesia. No motor issues and no tendon issues, all intact. Also had mid back burning on 28Dec2020 that comes and goes. He has heard that there is a described neuropathy with the virus and/or with the vaccine and wants more information on that. Curious if anyone has anything similar? and makes mention of possible Gillian Barre Syndrome. States that he has had a potential reaction. He had his dose on 19Dec2020. On 25Dec2020 he developed left facial numbness, then later that day he developed bilateral foot numbness. On 26Dec2020, he developed bilateral hand numbness, on 28Dec2020 he developed right thigh burning, and today (29Dec2020) he has developed left thigh burning, and bilateral gluteal burning and paresthesia. States that he has been kind of freaking out about it. He doesn't have any motor issues. States that he heard that there is a described neuropathy with the virus, but not with the vaccine, is that true? The left facial numbness resolved on either 26Dec2020 or 27Dec2020. States that the symptoms were concerning because it could have been a stroke. States his symptoms were moderate. States that due to the bilateral foot and hand numbness, he had a LP, brain and spine MRI, and blood work done on 26Dec2020. All came back completely normal. When asked about causality, caller states that it makes the most sense for his symptoms to be caused by the vaccine due to his age and the fact that all his testing was completely normal. Reporter seriousness for left facial numbness, bilateral foot numbness, bilateral hand numbness, right thigh burning, left thigh burning and bilateral gluteal burning and paresthesia: Medically significant. The outcome of the event left facial numbness was recovered in Dec2020. The outcome of the events guillain barre syndrome, stroke and mid back burning was unknown. The outcome of the other events was not recovered.; Sender's Comments: Based on the temporal relationship the association between the reported serious adverse events with BNT162b2 can not be fully excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

Approximately 4 days after vaccine I started experiencing sharp lower back and left hip pain. Also my left foot feels like pins and needles.

Complete loss of vision in the left eye 12 hours after receiving second dose (Moderna mRNA-1273) while having a fever of 102 F for 6 hours. Loss of vision lasted for 1 minute. Loss of vision occurred while standing. Referral to primary care and ophthalmology specialist found normal eye exam and MRI of orbits but presence of tachycardia especially while standing (fluctuations between 60 beats at rest/laying down to 130 beats per minute standing). Postural tachycardia syndrome (POTS) is suspected. Currently pursuing cardiac workup with cardiologist and Covid POTS specialist. POTS specialist believes autoantibody development after vaccination could be suspected as recovering covid patients similarly present to clinic with POTS like symptoms.

Patient with extreme nausea and vomiting that started soon after receiving the Moderna vaccine. Patient with loss of consciousness, diaphoresis and garbled speech during a foley catheter exchange thought to be from dehydration. Patient was admitted to Hospital for observation for 2 days

12/18 VACCINATION 12/19 WOKE UP, RINGING IN BOTH EARS. CALLED PCP, CONSULTED ENT ABNORMALITY - L INNER EAR; HIGH DOSE STEROIDS, 10 DAYS, 60 MG/DAY. WEEK 2; TINNITUS GOT WORSE. DR. PRIMARY CARE PHYSICIAN MEDICAL EXAM ON 1/6/2021 INJECTION OF STEROIDS.

Acute Pericarditis. Patient was admitted from 12/27-12/28/2020 at hospital by cardiology team who strongly felt the acute pericarditis was due to the Pfizer Vaccine (Dr. was senior cardiologist).

Fever, Malaise

After the 15 min monitoring, I went back to work 15 min later. the left side of my face started tingling which went to a numbing feeling down the left side of my body affecting my neck, shoulder, arm, elbow and up the upper left torso. My face and neck was numb for about 48 hrs and the rest came back to sensation within 24 hrs. D/T the numbness I was admitted into the hospital for a 24hr observation.

""""Pfizer-BioNTech COVID-19 Vaccine EUA."" Patient received first dose of vaccine on 12/21/2020. Patient called on 1/3/2021 to notify that she developed symptoms on 12/27/2020 and had an appendectomy on 12/28/2020 at another facility. Patient also reports that CDC V-Safe Application was used to report event as well. Patient reports that she is recovering well."

Patients adverse reactions started day of vaccination with right arm pain up to right ear as well as complete tongue numbness. On 1-1-21 patient had increased Bell's Palsy symptoms including; inability to raise left eyebrow, inability to close left eye in its entirety, teeth being numb on left side, and numbness and tingling in left foot and left hand (from palm to fingers). ER physician prescribed on 1-1 Prednisone, Keflex and Valtrex. Patient went to ER again on 1-2-21 with lower extremity numbness on left side that is moving proximally toward her hip. Patient went home on 1-3-21 with an RX for Prednisone as well as Valtrex. Symptoms have improved but have not fully resolved at this time.

She was hospitalized on 01/04 but exact situation unknown. COVID +. Hospitalized at Medical Center.

Employee received COVID 19 vaccination at 9:45am on 12/30/20. ~15 min. later she developed a rash down her left arm, then down her Rt. arm. about 4 hours later she decided to go to the emergency room

for Hearty Palpitations, Fever, Chest discomfort and feeling of generalized sunburn. Later developed severe headache..

Right arm swelling very bad right after shot, next day woke up to get ready to work I started to get light headed, dizzy, sweating, felt like I was going to pass out. My husband then called 911. They took me to Hospital ,I stayed there for a couple hours then released. They told me to stay home and the next day I felt fine. I did a televisit with my Nephrologist (Kidney doctor) the following week.

noticed twitching in L arm shortly after receiving vaccine, numbness , weakness and pain in arm and shoulder girdle, diagnosed with parsonage turner syndrome by neurologist, currently taking neurontin for pain as steroids not tolerated

Felt slight warmth throughout body about 5 minutes after vaccine. Disappeared 2 minutes later. Arm started to feel sore as the day went on and was very sore by nighttime. Next day, arm started to feel better and over the next 3 days was no longer sore. On the morning of the 30th, woke up feeling fine, took a 3.5 mile walk and felt fine. Around 12:30 pm, experienced sudden pain and a burning sensation in the chest and both upper arms. Thought it was possibly heartburn ; took a Prilosec. The discomfort (mild but steady) continued so checked blood pressure which was 141/91. Called cardiologist and went to emergency room per instruction, around 1:30. Admitted overnight with the diagnosis of a mild heart attack and performed a heart catheterization where they found no major blockage. One artery noted 30% blocked but that overall heart function looked good. Discharged on 12/31/2020. -reported by patient via email, on 1/3/2021 @ 4:49pm

Bell?s palsy, right side of face is numb, with difficulty closing eyes, smiling, raising eyebrows, eating, drinking, swallowing.

12/21 had covid vaccine (dose 1). On evening of 12/29 had sudden onset of mild neck pain and significant weakness and numbness of left arm, weak hand grip, clumsiness in hand . Did not improve after trying to shake arm/move around , and took prednisone 40mg oral. Went to ER and had CT Cspine which did not show evidence of cervical pathology. Continued with corticosteroids, sought consultation with PMR and neurology specialists, and steroid dose increased to 60mg/day. Some improvement in strength , but still have diminished sensation and strength in left hand/arm. Unable to perform full job tasks as I am left hand dominant. Likely brachial neuritis / parsonage turner syndrome per both specialists seen. Continuing with corticosteroids at this time, pending bloodwork and OT evaluation

Resident exhibited no adverse events during 30 minute monitoring following vaccine administration. Resident found without pulse at 1900.

thrombotic stroke -necessitating hospitalization; and craniotomy; required mechanical ventilator for 2 days. Patient now extubated, breathing on her own. Patient remains hospitalized with marked deficits (aphasic)

Pt experienced nausea, shortness of breath, chest tightness and anxiety and then lost consciousness. Vitals were obtained several times during the medical intervention. Respirations were within normal

limits throughout, BP was 135/89 initially, then rose to 210/110, then declined to 180s/? prior to EMS assuming care. Heart rate was 47 initially, then rose to normal limits. Treated with epinephrine, Benadryl and ammonia smelling salts and transported by ambulance to hospital.

Lightheadedness, throat tightness. Increasing chest tightness. History of atrial fibrillation and bilateral breast implants. Received two doses of epinephrine and one dose of diphenhydramine.

Patient developed a septic knee (history of arthroplasty) need for immediate surgery, hospitalization and months to years of antibiotics in his future now.

Presented to the ED after developing chest tightness, cough, lightheadedness, and throat closing sensation. She received the Moderna COVID-19 vaccine on the morning of presentation. Within 15 minutes of receiving the vaccine she developed pain and numbness, starting at the injection site traveling down the ulnar aspect of her arm, and nausea. Over the next several hours she continued to develop worsening nausea, chest tightness, cough, lightheadedness, and the sensation that her throat closing. She took PO Benadryl 25mg; however, her symptoms were not alleviated. She was subsequently evaluated in the ED. á Received PO Benadryl 25mg, IV Benadryl 25mg, Epinephrine 0.3mg x 2, IV Famotidine 20mg, IV Solumedrol 125mg & 60mg, DuoNebs x 3, Racepinephrine x 1.

Decompensation and temp 103.6.

Around 10 or 11 pm, arm pain, chills, fatigue, headache, nausea, swollen lymph nodes, lightheadedness, fainted in tub. Next day, fatigue all day, couldn't talk, or eat. Went back to bed again. The following day hot flashes, weakness. went to ER. Felt like blood pressure was dropping, tingling in legs, difficulty lifting her head.

20 minutes after receiving the vaccination the resident started to not feel well. She said she felt very far away and just kept repeating I don't feel well. She was diaphoretic and her chest was very red and she kept scratching and rubbing it at it. I asked if she wanted IM Benadryl or epipen and she at first denied. She also said she felt like she needed to focus on her breathing. At this time we decided it was best to administer Epipen x 1 dose. Immediately after she felt better. She was observed for another 30 minutes and then went home. at 7:17pm I called and spoke with her. She said her arm was sore and that her oxygen levels were about 88-89% which is low for her but she said she felt fine and is currently working right now.

Presented to the ED with cc of left sided facial and LUE numbness and weakness x 1 days. Patient received her COVID-19 vaccination on 12/30/2020 around 1PM. Immediately after the injection in her left shoulder, she began to feel warmth and numbness in her left shoulder, arm, neck, face, and chest. She reports later experiencing nausea, palpitations, and left arm weakness. Her symptoms persisted, and her family noted a left sided facial droop which prompted her ED visit. á In the ED, patient was noted to have some left sided facial droop and left arm and leg weakness. CT head and CTA showed no acute abnormalities. Tele-neurology was consulted who recommended admission to rule out acute stroke. Ultimately, work up was negative and symptoms resolved. Symptoms appear to be related to the vaccine.

Severe joint aches, fever-type symptoms, nausea

Cough began approx 5 min post vaccine, then pt experienced flushing of neck, chest tightness and SOB. Placed on O2 mask at 8L/min, given 1 dose of Epi and transferred to ED

On 12/24 at around 10 PM, circulation to my 4th left digit significantly decreased after being outside of my car for around 15 minutes during a temperature of about 50 degrees. I realized when sharp pain was felt at the digit. After about 5 minutes the digit felt numb. I got in my car, turned on the heater, and massaged my finger. Sharp pain was felt again as circulation returned to the digit. The event last approximately 10 minutes from the moment I realized the finger was pale until color returned. This occurred again on 12/27 at around 2 PM as I walked from my car into a store at a temperature of about 40 degrees. This time, discoloration occurred bilaterally on my left 3rd, 4th, and 5th digits and my right 2nd, 3rd, 4th, and 5th digits. The event lasted more than 15 minutes with constant massaging. This has occurred two more times since then, both times occurring bilaterally with minimal exposure to cold.

Fever to 103.4F for approximately 4 hours. Myalgias.

within 20 of the injection I strted to salivate and feeling nauseated. returned to clinic and was monitor there. my blood pressure was noted to be low at 115/41. HR 74. reepat BP was 121/48 which is much lower than my usal BP. i was observed for about 1 hrs. the sx's did not go away but the BP improved a little to 130/64 standing. I went home develop injection site pain, fatigue, headache and the pesistent salivation did not go away. after 1 wk it decreased in frequency but still present today. I can not do my normal activity as this worsen the symptom. and my blood pressure has not normalized. still run in 110's/60's. the headaches and fatigue are becoming a burden.

7 days post injection developed significant hives and edema at injection site

Left antecubital rash and pruritic lasting last 5 days, self treated with hydrocortisone 2.5% cream two times partially relieving the pruritic and redness, but still present at time of report.

At 17:00, the injection site started to itch and was warm to the touch. At 4:00 on 01/04/2021, I experienced extreme vertigo while washing my hands at a sink. I returned to bed to get the vertigo to pass, but then vomited at 4:30. I was extremely tired the remainder of the day, sleeping often and have been flushed all day as well.

after the injection I became lightheaded and my blood rose to 155/94. after a hour both my pressure and lightheadness went away. on 1/1 I felt fatigue at work and the injection site began to hurt. On 1/2 I stood home and was still fatigue and had some tension in my neck area. On 1/3 began to feel better no pain at the injection site, no longer fatique, and no tension on my neck.

"15 minutes after patient received her #1 Pfizer vaccine, she started to feel flushed with some throat irritation. She states she feels "" a bit shaky inside "". Given juice and crackers. BP 143/84. heart rate 89. O2 sat 99%. She was moved into another quieter observation area. She claims she felt better. Given H20 to drink. States she had a bit of chest discomfort but this was nothing new to her. She has been having chest discomfort for the past 1-2 weeks periodically. Upon observing patient for 40 minutes, patient

states, she felt better. BP 115/78, heart rate 80. Patient was then released. She states this is the first time this has happened while taking an IM injection."

One hour post shot, heart beat went up to 120 at rest. Slight dizziness. This passed. Later in the evening compared injection sites with others in the household. Mine is redder, more swollen and seems more tender than others.

Fever, nausea, body aches

Received covid vaccine 1/2 at 2pm. Around 7pm that night, left arm pain and slight itching of whole body. did not think much of it. woke up once in middle of night at 4am with racing heart but went back to sleep. Around 9 am next morning started getting chills, initially mild then severe and developed severe myalgias; could not get out of bed or lift arms or limbs. having chest tightness and shortness of breath. pressing on chest wall hurts, hard to take deep breath. Temps of 99.5 most of morning. started taking tylenol total of 1 gram. 1 hour after tylenol shaking and rigors with sweating. had temp of 101 after tylenol. HR 110 at this time (my baseline is around 60s). O2 sat remained normal. Went to ER for testing for covid in case this was covid--test negative. Felt a little better morning of 1/4--no fever. tried to work 1/2 day; called out sick. lots of brain fog, fatigue mental slowing. still having intermittent chest tightness and sob; feel like i cannot expand my lungs. deep breath makes me cough. had few small red bumps on left antecubital fossa that resolved. i'm a physician, i'm concerned this was a severe reaction and was advised to report this.

About 3 minutes after getting the injection, my heart rate elevated, I was dizzy and felt faint with some chest tightness. I told RN, the nurse who gave me the injection and I was told to lay down on my back and she lifted both of my legs perpendicular to the floor. My hands and feet were tingling. My blood pressure was taken and the first reading was elevated and hear rate was 102. I was given a can of apple juice and I felt better after drinking it. Since the blood pressure cuff was too large for me, I was able to go downstairs to urgent care and get a reading with a smaller cuff. The last BP reading was had lowered and I was able to leave. I did not feel well for a good 45 min. My left arm was very sore for the first 48 hours. It did not go away for at least 5 days.

Injection sight pain and swelling, headache, fatigue, omalaise.

I developed severe hives all over my body hours about 19 hours after the shot. Intense itching woke me up at 4:40am the day after receiving the vaccine. The reaction worsened for the next 3 days and began to settle/decrease at the end of the 3rd day. I also felt somewhat disoriented through the allergic reaction period, and on the day after the vaccine I felt slight pain on my chest. I did not experience shortness of breath or have trouble breathing at any point.

High grade fever with chills almost like rigors 103.8 F Happened after 9 pm Initially started with malaise Fever being monitored throughout the night

Numbness in right cheek of face almost immediately after injection.

tiredness, headache muscle pain, chills, nausea, feeling unwell

paleness, weakness, then a few hours later chills, fever, extreme pain at the injection site, body aches, malaise

Soreness of deltoid resolved 2 days after vaccine. Normal shoulder for 7 days. Day 8 post vaccination onset of itching, swelling and redness of left should, continuing now x2 days. No other systemic symptoms. No pain.

Began experiencing nausea and general stomach pains the morning after receiving the vaccine. After one day of pain and discomfort I woke the following morning (~44hrs after receiving the vaccine) to extreme acute abdominal pain in the lower right abdomen. Went to Urgent Care facility and was diagnosed by CT scan as having acute appendicitis. An emergency appendectomy was scheduled and performed for later that evening. I stayed at the Hospital overnight on 12/24/2020 post operatively on IV antibiotics to recover from the appendectomy. Was discharged from the hospital on 12/25/2020 and have been recovering for about 10 days now with limitted activity.

Fever 101.0

At time of injection and for about 30 minutes after, had light tingling to left arm to fingertips, face flushed and warm. Resolved without intervention. No other side effects except muscle soreness to this arm. (Wouldn't report but a coworker had a similar but more severe reaction and is still having effects 3 wks out)

Patient reported swelling on the injection site, itchiness, warmth and soreness.

12/31, 08:30pm: Immediate pain & welt developed at sight 12/31, 08:45pm: Slight numbness & tingling in left hand, persisted approximately 12 hours 12/31, 09:30pm (the following s/s persisted in varying degrees until 01/02): exhaustion/fatigue, headache, dizziness, nausea, chills 01/02, 08:30am: chills/cold sweat/fever (temp not confirmed, as my home thermometer had died, but I woke up later that night drenched in sweat as though a fever had broken, and since then my body temp has been normal (no cold chills or hot flashes) and other s/s have also decreased significantly) 01/03: minimal s/s - lingering fatigue, mild 01/04: 03:00a: woke up with cough - uncertain if related (seasonal allergies?)

Symptoms were chills, fatigue, body aches, headache, fever, tachycardia that started about 12 hours after receiving the vaccine and lasted for about 3 days.

Age at the time of vaccination was 16. Not identified until after the vaccine was administered.

light headed and nausea for 3 days

"10 minutes after receiving vaccination, patient reported rapid heart rate, fatigue, felt weak, hot, and palpitations. Patient reported tachycardia with heart rate 160-170's. Transient numbness to hands and perioral region. Presented to ED, was monitored with resolution of symptoms. On 1/4/21 patient presented to ED with tachycardia with HR up to 160s, Episode was severe, causing lightheadedness, ""throat squeezing"", with bilat UE paresthesias. Episode lasted 20 minutes. Patient evaluated in ED and discharged with outpatient follow up with cardiology and endocrinologist."

Tight throat.Drank 1 pill benadryl.After few hours the symptoms were gone

less than 24 hours after getting shot #1 i felt as if i was coming down with a cold, very congested, stuffy nose, slight sore throat probably from drainage. injection site pain which is normal, but i just felt under the weather. it cleared up within 48 hours of time of injection.

Cold legs, Fever, bodyache including fingers ache, chills, nausea, body weakness, headache. From Saturday to Tuesday. Tylenol

tested positive for COVID19 via antigen test; tested positive for COVID19 via antigen test; having no sense of taste and smell; having no sense of taste and smell; fever; scratchy throat; This is a spontaneous report from a contactable nurse. A 26-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EJ168J), via an unspecified route of administration on 21Dec2020 at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. After getting vaccinated, patient developed a fever on 22Dec2020. On 23Dec2020, the patient has no taste and smell and tested (used the Sofia test) positive for COVID. The patient was told to quarantine and take off work for 10 days. The patient has felt like she has had a scratchy throat. Patient has not taken her allegra. The outcome of events was unknown.; Sender's Comments: A causal role of BNT162B2 would seem unlikely based on the temporal gap between the vaccination and the event onset.

"patient received the PFIZER-BIONTECH COVID-19 MRNA VACCINE and then tested positive for COVID; patient received the PFIZER-BIONTECH COVID-19 MRNA VACCINE and then tested positive for COVID; This is a spontaneous report from a contactable pharmacist. A 40-year-old female patient received the bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot Number and Expiration Date: Unknown), via an unspecified route of administration on 18Dec2020 at a single dose for COVID-19 immunization. The patient's medical history included high body mass index (BMI) from an unknown date and unknown if ongoing. Concomitant medications were not reported. On 22Dec2020, the patient received the PFIZER-BIONTECH COVID-19 MRNA VACCINE and then tested positive for COVID; and showed symptoms. The events were assessed as medically significant. The clinical course was reported as follows: The 40-year-old female patient, with comorbidities ""like high BMI"", received the Pfizer BioNTech COVID vaccine on 18Dec2020 and she had tested positive for COVID on 22Dec2020 and she was showing symptoms; however, they were not severe. The pharmacist did not describe the symptoms. In response to further probing, the pharmacist stated, ""can I do this tomorrow because I need to call patient and ask her about if they have an opinion regarding the monoclonal antibodies treatment."" The pharmacist wanted to know if there was information on consumers receiving antibodies after receiving the vaccine. The pharmacist stated the patient was eligible for antibody treatment. The patient underwent lab tests and procedures which included SARS-CoV-2 test: positive on 22Dec2020. The clinical outcome of the events was unknown. The batch/lot numbers for the vaccine, BNT162B2, were not provided and will be requested during follow up.; Sender's Comments: The reported tested positive for COVID after immunization with BNT162B2 is considered related to the administration of the suspect, BNT162B2."

tested positive for covid; tested positive for covid; coughing; congestion; could not sleep that night; her temperature is still low/temperature was lower around 96 or 97; fever; This is a spontaneous report from a contactable consumer (patient). A female patient of an unspecified age received first dose of BNT162B2 (Pfizer-BIONTECH Covid-19 Vaccine, lot number: EH9899), via an unspecified route of administration on 15Dec2020 at a single dose, for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient received the Covid-19 shot 8 days ago on 15Dec2020. She tested positive for COVID on 23Dec2020. She worked in the emergency room, clarified she was a certified Nurse Assistant (CNA). She was hesitant about taking the COVID-19 vaccine. She was curious since she has been around the virus 24/7 since the pandemic started since she works in the emergency room. When she took the COVID-19 shot, stated she felt great the next day and could not sleep at night in Dec2020 which is not normal for her. It's nothing like the flu shot. It was strange since she has been around the virus all this time, she felt like she had COVID in Feb2020, but she was not tested then. She does not ever get sick and she was down for two days with a fever in Dec2020. After those two days, she always had a low-grade fever of 98 or 99 which was constant. After she took the COVID vaccine her temperature was normal, her temperature was lower around 96 or 97 in Dec2020. She woke up on 23Dec2020 and she had congestion and her temperature was still low. She went to work, and she was told she looked like she had no sleep. She was coughing 23Dec2020 morning, but she did not have any symptoms as far as temperature. She realized that the COVID 19 shot is only 50% effective. She is asking if she should get the second dose. The outcome of events was unknown.

30 mins after vaccination caller was notified patient tested positive for covid; 30 mins after vaccination caller was notified patient tested positive for covid; This is a spontaneous report from a contactable pharmacist. A patient of unspecified age and gender received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for immunization. The patient's medical history and concomitant medications were not reported. 30 mins after vaccination caller was notified patient tested positive for covid on an unspecified date with outcome of unknown. Information on the lot/batch number has been requested.; Sender's Comments: Based on the information currently available (30 mins after vaccination Covid test found positive), no effect of the suspect vaccine could be reasonably achieved to protect from the targeted infection/disease due to the very short time lag. Instead, the positive COVID represents the pre-existing infection prior to vaccine use. Further information like confirmative COVID 19 Nucleic acid/ PCR test together with any associated symptoms are needed for full medical assessment.

tested positive COVID; tested positive COVID; nasal congestion; loss of smell; This is a spontaneous report from a contactable physician (patient). A 46-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number EK5730, Expiration Date Mar2021), via an unspecified route of administration in her right deltoid on 19Dec2020 at single dose for COVID-19 immunization. Medical history included ongoing Crohn's disease from 2007/ diagnosed at 33 years old. There were no other concomitant drugs. The doctor who received the COVID vaccine stated that she must had been exposed to the virus prior to receiving the vaccine because she became symptomatic 48 hours after getting the vaccine. She noted that on Pfizer website recommended that a person not get the vaccine until 6 weeks after active infection but she of course did not know she had been exposed and when her second dose

was due, she would not be 6 weeks after active infections. The vaccine was received on 19Dec2020 and she tested positive on 22Dec2020. The only symptoms she had experienced after testing positive are nasal congestion and loss of smell and they started on 21Dec2020 in the morning. She had had no worsening of her Crohn's disease. The only testing she had had done was the PCR testing for COVID. No treatments for the symptoms at this point. The outcome of the events tested positive COVID was not recovered, while for other events was unknown.; Sender's Comments: A causal role of BNT162B2 would seem unlikely based on the temporal gap between the vaccination therapy and the event onset.

Tested positive for covid; Tested positive for covid; This is a spontaneous report from a contactable nurse (patient). A 33-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899) intramuscularly at right arm on 18Dec2020 14:30 at single dose for COVID-19 immunization. Medical history included asthma. No allergies to medications, food, or other products. The patient's concomitant medications were not reported. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient developed severe nasal burning sensation the first two days of injection along with severe headache that lasted for 4 days. He lost his sense of taste and smell (23Dec2020) 5 days after vaccine was administered, tested positive for Covid (23Dec2020 16:30) with use of ABBOTT rapid test which was performed at his employment. Pending Covid nasal swab fulgent which was obtained on 23Dec2020 and sent out to reference lab. Patient was just wondering if any of these symptoms and/or testing positive after administration was a rare side effect. The adverse event resulted in doctor or other healthcare professional office/clinic visit. No treatment received for the adverse events. Prior to vaccination, the patient was not diagnosed with COVID-19. The outcome of the events was not recovered.; Sender's Comments: Vaccine BNT162B2 provides protection to COVID-19 after at least 7 days have elapsed from the second dose (21 days post first injection). These conditions are not met in the present report. The reported symptoms are compatible with COVID-19 illness.

positive for Covid with symptoms; positive for Covid with symptoms; positive for streph; positive for influenza; This is a spontaneous report from a contactable physician and nurse. A 68-year-old female patient received bnt162b2, via an unspecified route of administration on 17Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced positive for COVID with symptoms, positive for streph and positive for influenza in Dec2020. Additional Context: caller stated that she had a patient that got Covid vaccine on 17Dec2020 who was complaining of muscle aches, no fever, sudden loss of taste and smell in the last 24 hours, sore throat and a cough. Stated that she cannot attribute the cough to the vaccine. Stated that she was screened for COVID, streph and influenza. Stated that she was positive for covid and streph. Stated that she does not think that and wanted to know if the vaccine would cause a positive from a rapid test. Outcome of the events was unknown. The Lot/Batch and expiry date has been requested.; Sender's Comments: The reported positive for COVID with symptoms after immunization with BNT162B2 is considered related to the suspect, BNT162B2.

Chills, fever and a headache; Chills, fever and a headache; Chills, fever and a headache; tested positive; tested positive; This is a spontaneous report from a contactable nurse. This nurse reported similar events for two patients. This is 1st of two reports. An adult female patient of unspecified age (30-40 yrs

of age) received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 17Dec2020 at single dose for COVID-19 immunization. The relevant medical history and concomitant medications were not reported. The nurse stated that they gave the vaccines to the patient the past week and the patient was COVID-19 positive at the time of the report. The nurse needed some guidance and needed to know if the patient could receive the second dose or what they were supposed to do. The patient tested positive for COVID-19 on 24Dec2020 after having chills, fever and a headache. The outcome of the events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Based on the information currently available, a lack of efficacy with BNT162B2 in this patient might not be completely excluded. The case will be reassessed should additional information become available.,Linked Report(s) : US-PFIZER INC-2020513401 different patient, same drug and event

had another COVID test with positive results on 23Dec; had another COVID test with positive results on 23Dec; This is a spontaneous report from a contactable consumer. A 43-year-old female patient received bnt162b2 (BNT162B2, lot number and expiry date were not reported), via an unspecified route of administration on 18Dec2020 at a single dose for covid-19 vaccination. The vaccination was done in the hospital. The patient's medical history and concomitant medications were not reported. The patient was initially tested negative for covid-19 on 13Dec2020. The patient was not pregnant. The patient believed she may have been infected with COVID as early as 13Dec2020 based on symptoms but test results at that time came back negative. She had vaccine on 18Dec2020 and when symptoms hadn't resolved had another COVID test with positive results on 23Dec2020. The event resulted to a doctor or other healthcare professional office/clinic visit. There was not treatment for the event. The reporter considered the events as non-serious. The outcome of the event was recovering. Information about batch/lot number has been requested.

Received the vaccine and tested positive for Covid today; Received the vaccine and tested positive for Covid today; This is a spontaneous report from a contactable nurse. This nurse is reporting similar events for two patients. This is the first of two reports. A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date were not reported), via an unspecified route of administration on 17Dec2020 at single dose for Covid Vaccine/ COVID-19 immunisation. The patient medical history and concomitant medications were not reported. It was reported that the patient received the vaccine and tested positive for COVID today (24Dec2020). She was having symptoms on Saturday (unspecified date in Dec2020), she received her vaccine on Thursday 17Dec2020. The reporter asked several questions, if do they get the second vaccination in 3 weeks and what will be the process, does it do anything to it, or if does it make it worse or better. The outcome of the event was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Based on the information currently available, a lack of efficacy with BNT162B2 in this patient might not be completely excluded.,Linked Report(s) : US-PFIZER INC-2020513377 same reporter, same drug, similar event, different patient.

Received the vaccine and tested positive for Covid today; Received the vaccine and tested positive for Covid today; This is a spontaneous report from a contactable nurse. This Nurse reported similar events for two different patients. This is second of two reports. A female patient of an unspecified age received

bnt162b2, via an unspecified route of administration on 21Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient received the vaccine and tested positive for covid today (24Dec2020).It was further reported that the patient showed up positive today (24Dec2020) and her symptoms have been on and off, she just got her vaccine 21Dec2020. The outcome of the event was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Preventive effect of BNT162b2 is documented after 7 days from the second dosing. This case does not match this requirement.,Linked Report(s) : US-PFIZER INC-2020513367 same reporter/drug. different patient and event.

Drug ineffective; tested positive; chills; fever; headache; This is a spontaneous report from a contactable nurse. This nurse reported similar events for two patients. This is 2nd of two reports. A female patient of an unspecified age (30-40 year-old)started to receive bnt162b2 (BNT162B2) , via an unspecified route of administration on 02Dec2020 at single dose for covid-19 immunisation . The patient medical history and concomitant medications were not reported. The patient was tested positive to COVID-19 on 24Dec2020 after having chills, fever and a headache. The outcome of the events was unknown. The reporter stated that these were worse than just side effects. The reporter is wondering if the patient can receive the second dose. Information on the lot/batch number has been requested.; Sender's Comments: Preventive effect of BNT162b2 is documented 7 days after the 2 dose. This case does not match this requirement,Linked Report(s) : US-PFIZER INC-2020512742 different patient, same drug and event

tested positive for covid; tested positive for covid; This is a spontaneous report from a Pfizer-sponsored program, Pfizer First Connect. A contactable consumer (patient) reported that a female patient of an unspecified age received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number and expiration date were not reported), via an unspecified route of administration on 23Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient received the COVID vaccine on Wednesday this week (23Dec2020) and she tested positive for COVID yesterday (25Dec2020). She wanted to know if she should take the second dose of the vaccine. Outcome of the events was unknown. Information on the lot/batch number has been requested.

"I received the covid-19 vaccine and then afterwards contracted covid-19; I received the covid-19 vaccine and then afterwards contracted covid-19; This is a spontaneous report from a contactable nurse. A female patient of an unspecified age received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for covid-19 vaccine. The patient medical history and concomitant medications were not reported. The patient stated on an unspecified date, ""I received the covid-19 vaccine and then afterwards contracted covid-19. I was told by my hospital that because of this I needed to defer the second dose for 90 days. Is this best practice? Or should I take the second dose in 3 weeks as scheduled?"". The outcome of the events was unknown. Information on the batch/lot number has been requested.; Sender's Comments: BNT162b2 provides protection against COVID-19 seven days after the second dose is administered. This case does not match this condition"

"tested positive for Covid; tested positive for Covid; No symptoms at present time; This is a spontaneous report from a contactable nurse (patient). A 50-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EV1685) via an unspecified route of administration on 22Dec2020 at single dose for COVID-19 immunization. The patient's medical history included Covid-19 12 weeks before 25Dec2020. The concomitant drug was reported as levothyroxine sodium (SYNTHROID), hydrochlorothiazide and vitamins. The patient got the vaccine (Covid 19 Vaccine) on 22Dec2020 (Tuesday) and then on 25Dec2020 (today) had to be tested at work and was tested positive for Covid. So, she was wondering if that might have something to do with the vaccine or it was not for sure. Patient had already had Covid once and this is the first time she got tested since for 12 weeks. It just happened to be three days after the vaccine. So, the lady she work with told her a study was done and people were shown to test positive like two days after they got the vaccine. So, that's what she wanted to find out. If that could be."" She states the test on 25Dec2020 was a routine follow up Covid-19 test. No symptoms at present time. The outcome of the events was unknown.; Sender's Comments: BNT162b2 provides protection against COVID-19 after 7 days from the second dose. This case does not match this condition."

received the vaccine on Friday and tested positive; received the vaccine on Friday and tested positive; This is a spontaneous report from a Pfizer-sponsored program Pfizer First Connect from a contactable other healthcare professional. A 27-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date not reported), via an unspecified route of administration in Dec2020 (reported as on Friday) at single dose for COVID-19 immunization. The patient medical history was not reported. The patient's concomitant medications were not reported. The patient received the vaccine on Friday and tested positive today 26Dec2020. The outcome of event was unknown. Information about batch/lot number has been requested.; Sender's Comments: Based on the information available, a possible contributory role of the suspect BNT162B2 cannot be excluded for the reported event COVID-19 virus test positive based on the known safety profile.

Moderna COVID-19 Vaccine EUA Injection site redness, swelling, itching, discomfort the size of a fist 7 days after injection.

tested positive for COVID with symptoms such as nasal congestion, sore throat, weakness, and flu-like symptoms; tested positive for COVID with symptoms such as nasal congestion, sore throat, weakness, and flu-like symptoms; This is a spontaneous report from a contactable physician (patient). A 46-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (lot number EJ1685), via an unspecified route of administration on 20Dec2020 at single dose for covid-19 immunization. Vaccine location was left deltoid. The facility type vaccine was hospital. Medical history included polycystic ovarian diseases from an unknown date. Concomitant medication included metformin, omeprazole, apremilast (OTEZLA). Patient stated she got the vaccine on the 18th. She took the vaccine on 20Dec2020. Yesterday (25Dec2020) she started to feeling sick and today (26Dec2020) patient got tested and she have Covid. She reported to have tested positive for COVID today (26Dec2020) with symptoms such as nasal congestion, sore throat, weakness, and flu-like symptoms yesterday at around 4:00pm. This was the first time she has taken the Covid test. The physician stated she didn't know the causality between the event and vaccine. The action taken in response to the events for BNT162B2 was not

applicable. The outcome of events was unknown.; Sender's Comments: Based on the information available, a possible contributory role of the suspect BNT162B2 cannot be excluded for the reported event positive test for COVID based on the known safety profile. However the short duration of 5 days since the vaccine first dose is given it is unlikely patient would have fully developed immunity.

Got vaccinated and contracted COVID the following week; Got vaccinated and contracted COVID the following week; This is a spontaneous report from a contactable consumer (patient). A patient of unspecified age and gender received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number unknown as the reporter did not have any of that information at the moment of reporting), via an unspecified route of administration on 15Dec2020 at single dose for COVID-19 vaccination. The patient's medical history and concomitant medications were not reported. It was reported that the patient got vaccinated on December 15th and contracted COVID the following week (Dec2020). Treatment included regeneron infusion last night (24Dec2020). Patient was wondering if zinc supplements should be taken or how to handle own's immune system because the patient had the first immunization. The outcome of the event was unknown. Information on lot/batch number has been requested.

had a testing, came up positive; had a testing, came up positive/sporadic coughing and a little short of breath. Maybe a little sore throat; This is a spontaneous report from a contactable consumer. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EJ1685), via an unspecified route of administration on 20Dec2020 at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient received Pfizer COVID Vaccine (further clarified) on 20Dec2020. And maybe two days after that, the patient kind of developed a little like very sporadic coughing, it was very mild and a little short of breath. Maybe a little sore throat so that's why the patient was concerned. The patient had a testing in Dec2020, they did swab the patient's throat, it came up positive. The outcome of events was unknown.

Very tired; Cold/head cold; upset stomach; she was not feeling well; it got her all congested and she got the head cold in Dec2020; little whooping cough; I had severe headaches and it was just too uncomfortable; my head was so congested; worst headache; it was just too uncomfortable; This is a spontaneous report from a contactable consumer(patient). A 59-year-old female patient received BNT162B2 via an unspecified route of administration on 22Dec2020 at the 59-year-old at single dose for Covid virus. The medical history included Congested, head cold and Covid virus. There was no concomitant medication. The patient work at a hospital and she went for a Covid shot (clarified as Covid 19 vaccine) on 22Dec2020 and she got a very bad reaction from it which bothered her, she had severe headaches in Dec2020 and it was just too uncomfortable and on 24th she was very tired, she didn't had too much of upset stomach in Dec2020 but it was not all that bad by 9 in the clock by morning she was at work and everything and she was told by if she was not feeling well she can walk by a day, but her question and her concern was back on November okay she had called in sick around, she had a funeral that she gone too and people that were at the funeral, unfortunately were smoking outside and smoke bothers me very much, she get congested and she get head cold from it you know and I was thinking it's nothing it's just a cold and somebody told her no (name) you better go get yourself to the employee health office and get checked out and she didn't bother doing that, she said no it's just the cold she will

be fine but then it just got worse down the road and she said to herself may be she better just to say she did it, so she called in sick on 24th because she had the cold still and she called and she went to employee health office on 25th she still had the headache and she still had the cold, however when she went to the health office they said to her well stay out of work and we will get back in touch with her and she said okay and she will do that so when they got back in touch with her they said they do have the Covid and she said ohhh she said okay so she stayed out of work and she went to work on the 07Dec so she was wondering whole time, so her confusion was this she was told if you already had the virus in her which at that time, she did not know what it was she just thought it was from cigarette smoke because it got her all congested and she got the head cold in Dec2020 and the whole thing that went along with it and the health employee officer know you had the virus and it's just the virus and she go oh great and that's when they told her to stay out of work and she said okay fine then she just have to that, so in the meantime everybody in the work said hi calling me checking up on her and she said it's so nice of you people, she appreciate it but then she went back to work she was still feeling you know much better than she was but she had little whooping cough in Dec2020 but that was not really that bad, so they said you going to get the shot or not, and she said she don't know she kind of debatable, she don't know if she should get it, because she work in the hospital or she should not get, she said she don't know she was kind of up and some people like she get it sometime your health was not that good but on the other hand everybody that is working here in the hospital working with patients because was work right in the ICU, all over the floor you know spreading right there so she said oh alright so she kicked myself and said go get the shot, get it just over with and get it out of here so that is when she took her shot that was on 22nd and on 24th she was very tired all day no she was tired all day but she was kind of dragging most of the day but she had on the 20th no that was fine on the 20th okay for some reason she guess it was after work that week on 19th, she came home and her head was so congested and she had the worst headache and she felt like a wand had hit her over the head, it was horrible and all she could smell was cigarette smoke, like is her neighbor smoking here so she went down the hall because in live in building that used to be hotel but now they turned that into Condominium and she walk up and down the hall and she was like was somebody smoking or why this or why smell this so strong and the all the lights off in a hallway and she don't want to offend anybody but they had to go to work and somebody elsewhere and she am like she can't stand this smell and they gave this shot and she went for this shot, and they told us to come back she think it was a week or something like that to get the second shot, and she am saying if this going to cost her going to feel this way again, she don't want to get the second shot, she told them that and they told her to call this number and talk to them.The only reason she got it because they encouraged to get it. Even though she had the Covid virus, people said if you already have the virus you don't need to get a shot but people were encouraging because that's she thought well she guess she will get it. But she was mad that she got because it made her sick in Dec2020. And because we already got it they want us to go back and get the second shot and what she was m trying to say to you is, without take and hour 3 hour of conversation here she just want to say she don't want to get back and get the second shot and if it is okay by you guys somehow send her a letter or whatever it is, whoever she have to talk to because she don't want to go back and get the second shot just because of getting sick. She took Excedrin because that works for my headache. She didn't understand why you need all this information history with all this when all she want to say was she didn't want to get a second shot. The outcome of events Head

cold and Headache was not recovered, the other events was unknown. Information on the lot/batch number has been requested.

Coworker who received the shot is positive too; Coworker who received the shot is positive too; This is a spontaneous report from a contactable consumer. This consumer reporter similar events for two patients. This is the second of two reports. A patient of unspecified age and gender received bnt162b2 (BNT162B2, lot number and expiry date were not reported), via an unspecified route of administration on an unspecified date at a single dose for covid-19 vaccination. The patient's medical history concomitant medications were not reported. The reporter's coworker who received the shot was positive too. The outcome of the event was unknown. Information about lot/batch number has been requested.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2020513735 same reporter/product, different patient, similar event

Caller stated that she received covid vaccine on Tuesday and was tested positive on Friday.; Caller stated that she received covid vaccine on Tuesday and was tested positive on Friday.; This is a spontaneous report from a contactable nurse reporting for herself. A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE lot number and expiration date not reported), via an unspecified route of administration on Dec2020 at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient stated that she received the vaccine on Tuesday (Dec2020) and was tested positive on Friday (Dec2020). The patient stated she was told that vaccine was contraindicated in people who have COVID-19. The outcome of the events was unknown. Information on the Lot/Batch number has been requested.; Sender's Comments: Based on the information currently available, a lack of efficacy with BNT162B2 in this patient might not be completely excluded.

hypersensitivity reaction to COVID-19 Vaccine; throat pain that progressed to a little bit of tightness; ear pain; wheals develop on her back bilaterally; This is a spontaneous report from a contactable pharmacist. A female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EJ1685 and Expiry date: 31Mar2021, strength: 0.3ml) (NDC number: 59267-1000-2) via Intramuscular on 21Dec2020 12:21PM at 0.3ml single dose for COVID-19 immunization. The patient's medical history and concomitant drug was reported as none. The patient experienced a hypersensitivity reaction to COVID-19 Vaccine late last night on 21Dec2020. Hypersensitivity reaction: Further described as patient developed throat pain that progressed to a little bit of tightness; some ear pain; and had wheals develop on her back bilaterally. She was transported to the emergency room on 21Dec2020 where she received treatment and was under observation. The outcome of events was unknown. Since whether outcome recovered completely, recovered with lasting effects or just improved is unknown. She was not admitted to the hospital; she was sent home from the emergency room after 2.5 hours. Caller reported seriousness criteria as medically significant because event required medical intervention. Causality was very likely. Patient at time of this report is scheduled to receive the second dose of vaccine; they have not determined if she will receive the second scheduled dose or change/stop dose in response to this event. First dose; scheduled to receive a second dose; have not determined if will be continuing with it.; Sender's Comments: Based on the compatible time association, the hypersensitivity reactions are reasonably related to suspect BNT162B2 administration.

positive COVID-19 test with symptoms; positive COVID-19 test with symptoms; This is a spontaneous report from a contactable nurse, who is also the patient. This 31-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration in Dec2020 at single dose for COVID-19 immunisation. Relevant medical history and concomitant medications were not reported. The reporting nurse stated that she received her first dose of the COVID-19 vaccine on Saturday (e.g. Dec2020). She had taken a PCR test on Thursday and received a negative result on Saturday, the same day she received her vaccination. She reported developing a fever on Monday night and testing positive for COVID-19 on Tuesday. At the time of the report, the outcome of the events was unknown. The information about lot/batch number has been requested.; Sender's Comments: Based on the information currently available, a lack of efficacy with the suspect vaccine BNT162B2 in this patient cannot be completely excluded. More information such as laboratory findings on viral nucleic acid /PCR test needed for meaningful medical assessment.

All of a sudden I did not have any taste or smell; All of a sudden I did not have any taste or smell; Tested positive; Tested positive; This is a spontaneous report from a contactable nurse reported for herself. A 29-year-old female patient received bnt162b2 ((PFIZER-BIONTECH COVID-19 VACCINE, batch/lot EH9899), via an unspecified route of administration on 22Dec2020 at single dose for covid-19 immunisation. Medical history included seasonal allergy. Concomitant medication included cetirizine hydrochloride (ZYRTEC [CETIRIZINE HYDROCHLORIDE]). The patient was taking a multivitamin a day. The patient experienced typical symptoms no taste, smell on 22Dec2020, Slight tingling, body aches, chills, all the other symptoms for Covid and now positive for Covid in Dec2020. Outcome of events was unknown.; Sender's Comments: Based on the information available, a possible contributory role of the suspect BNT162B2 cannot be excluded for the reported event positive for Covid based on the known safety profile.

"I am not feeling well; had a Covid PCR done swapped on yesterday and I am Covid positive; had a Covid PCR done swapped on yesterday and I am Covid positive; This is a spontaneous report from a contactable nurse. This nurse reported for herself that the 35-year-old female patient who received bnt162b2 (BNT162B2), via unknown route of administration on 23Dec2020 at single dose for covid-19 immunisation. Medical history was none. Concomitant medications were none. Nurse stated, ""I received the Pfizer Vaccine this Wednesday and right before getting the vaccine, I had a Covid test (captured as per verbatim) on before the vaccine on Tuesday (22Dec2020) was negative. I had a Covid PCR done swapped on yesterday (25Dec2020) and I am Covid positive. So I have the vaccine and I am Covid positive"" Nurse stated ""It's ""140"" ""130"" pounds (further bot clarified)."" The patient was not feeling well. The outcome of the events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Based on the limited available information, the company considers that a causal relationship between the SARS-CoV-2 test positive and vaccination with BNT162B2 cannot be excluded."

positive with Covid; having Covid symptoms; positive with Covid; having Covid symptoms; This is a spontaneous report from a contactable nurse. A 54-year-old female patient (mother) received BNT162B2 (Batch/lot number: EK5730), via an unspecified route of administration on 18Dec2020 at single dose for COVID-19 immunisation. Medical history included asthma. Concomitant medications

were not reported. Patient got the vaccine administered on 18Dec2020 and after that she was diagnosed positive with Covid on 24Dec2020, so now she was having Covid symptoms obviously after the vaccine but like not due to the vaccine. Reporter was just concerned what her next dose supposed to be scheduled for 08Jan2021, was she still supposed to get the second dose or what. No treatment received. Patient was just taking vitamins. Reporter also reported that typically it was not supposed to be but was trying to get the information on enhanced immune response. Outcome of the event was unknown.; Sender's Comments: The reported positive with Covid after COVID-19 immunization is considered ineffective of BNT162B2, and the Company cannot completely exclude the possible causality between the reported event and BNT162B2 administration.

sinus issues; positive COVID-19 test with symptoms; positive COVID-19 test with symptoms; right arm sore; This is a spontaneous report from a Pfizer Sponsored Program. A contactable consumer (patient) reported that a 58-year-old male patient received the first dose of BNT162B2 (lot number: EH9899; Expire Date: 31Mar2021), via an unspecified route of administration, in arm, right upper, on 16Dec2020 11:10 AM at single dose for COVID-19 immunization. The vaccination facility type was hospital. The vaccine was not administered at military facility. Patient's medical history (including any illness at time of vaccination) was none. The patient got ill from all pain medications- from prescription strength pain killers to OTC products such as tylenol, ibuprofen and aspirin. All of them make him sick- experienced hot flashes and nausea. No additional vaccines administered on same date of the Pfizer suspect vaccine. Prior vaccinations (within 4 weeks) was none. The concomitant medication included 2 different blood pressure pills, mentioning Lisinopril, but stated he did not think his blood pressure pills were relevant to what he was experiencing with the COVID-19 Vaccine. A MRI tech (clarified by caller as MRI technologist) at a hospital who received the COVID-19 Vaccine on 16Dec2020 (caller clarified he received the vaccine at 11:10 AM on 16Dec2020). Caller stated on 17Dec2020 he had signs of aches and pains allover, a sore arm (clarified as his right arm), no fever. He also experienced sinus issues and a loss of sense of smell. Clarified his right arm was sore for only a day, his sinus issues started on 20Dec2020, and his loss of the sense of smell gradually started on 22Dec2020. He stated on 23Dec2020 he had a COVID-19 test performed and the test result was positive for the COVID-19 virus. Caller asked since he had the first COVID-19 Vaccine dose, and has now tested positive for the COVID-19 virus, should he get the second COVID-19 Vaccine dose scheduled for 06Jan2021. Patient's Height: 5' 8'' as provided by caller, who stated he has shrunk 1''. No further details provided. Patient's Weight: 169 lbs. as provided by caller, who stated his weight was as of today. Reported he worked an overnight shift, clarifying he was injected with the COVID-19 Vaccine after his overnight shift was finished on the morning of 16Dec2020. He stated he came back to work later in the day on 16Dec2020 to work another overnight shift from 9:00 PM to 7:30AM. He said after he finished is overnight shift on the morning of 17Dec2020, he went home to bed, and woke up around 12:00 PM on 17Dec2020. He said when he woke up, he started to feel aches and pains allover, and after that noticed he was getting chills periodically. Clarified he experienced the aches and pains allover for a couple of days, and then the aches and pains went away. He said he then started to get the feeling a sinus infection was coming on, but he never got a sinus infection. He said the aches, pains, and chills came back. Reported his co-worker received the COVID-19 Vaccine on Saturday, 19Dec2020, clarifying his co-worker did well with the COVID-19 Vaccine. He clarified his employer was concerned that he may have exposed his co-worker to COVID-19 when the

two worked together on the overnight shift of 22Dec2020. He said both he and his coworker kept their PPE on the whole time they worked except when the two ate dinner. He said the two of them sat at a round table about 6 feet apart, and took off their masks to eat. He said his partner agreed that the two of them were right at 6 feet apart when the sat at the table to eat dinner, so their employer deemed his coworker as low risk. Reported on 22Dec2020 he had to go back to work, so he was asked for his temperature at the time, which was 98.8 degrees. He did have a flu shot previously. He was instructed as long as he doesn't have a fever over 100 degrees, he can work. The caller said he went to work on 22Dec2020, and read an email from his employer's wellness office. He said the wellness office email spoke about the COVID-19 Vaccine side effects, and instructed employees to contact the wellness office with any COVID-19 Vaccine side effects experienced. He said he left a voicemail with his employer's wellness office explaining exactly what his COVID-19 Vaccine side effects were. He said he instructed his employer's wellness office call him in the afternoon because he was going to go home, go to bed, and wake up at noon on 23Dec2020. He stated he spoke with his employer's wellness office at around 11:30 AM on 23Dec2020, and the wellness office asked for him to go to the hospital, and have a COVID19 test. Caller stated his employer performed a COVID-19 nasal swab test, and on 24Dec2020, he was told he was COVID-19 positive. He said his employer backed up his quarantine start date to 17Dec2020 (the first day he experienced symptoms), and had him follow a 10-day quarantine until 27Dec2020. He stated today, 28Dec2020, was the first day he has been off quarantine. Reported he was not saying he got COVID-19 from receiving the COVID-19 Vaccine, but should he have the second COVID-19 Vaccine injection. Clarified his symptoms were intermittent, and started coming back around 20Dec2020. Reported he was not experiencing any scratchiness in his throat, and his eyes were not watering. He said he has had no cough, no sneezing, and no trouble breathing. He said in general, it felt like something was coming on, saying it was building up, but not getting out. Clarified he had gone back to work on 23Dec2020 to have his COVID-19 nasal swab test performed, and was told by his employer on 24Dec2020 that the COVID-19 nasal swab test was positive. No AE required a visit to emergency room or physician office. The outcome of the event right arm sore was recovered on 18Dec2020 and the other events was unknown.

patient had COVID two days after vaccination; This is a spontaneous report from a non-contactable consumer. A male patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number/expiration date unknown) via an unspecified route of administration on 26Dec2020 at a single dose for COVID-19 immunization. Medical history and concomitant medications were not reported. The patient had COVID two days after vaccination (28Dec2020). The outcome of the event was unknown. No follow-up attempts are possible, information about lot/batch number cannot be obtained.

four days after getting her first COVID vaccine injection, she had a COVID positive test result (antigen rapid response test); four days after getting her first COVID vaccine injection, she had a COVID positive test result (antigen rapid response test); This is a spontaneous report from a contactable consumer. A 29-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number EK5730/expiration date unknown), dose number 1 via an unspecified route of administration on 23Dec2020 09:00 at a single dose on the left arm for COVID-19 immunization. Medical

history included vaccination of unspecified flu vaccine in Oct2020. No vaccines or new medications were received on the day of the vaccination. The patient stated that on 27Dec2020, four days after getting her first COVID vaccine injection, she had a COVID positive test result (antigen rapid response test). The patient stated that she had been mostly asymptomatic for COVID. The outcome of the events was unknown.

angioedema; swelling of the lips; This is a spontaneous report from a non-contactable nurse (patient). A 45-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on an unspecified date at a single dose as COVID-19 vaccine. Medical history included angioedema 23 years ago. Concomitant medications were not reported. The caller wanted to report AE for the COVID-19 vaccine. AE reported that she took the COVID-19 vaccine and after 23 hours, she developed angioedemia on unspecified date. Additionally, she said that she woke up with swelling of the lips on an unspecified date. Given the AE from the first request, it was inquired if it was recommended to get a second dose. The outcome of the events was unknown. No follow-up attempts are possible. Information about lot/batch number cannot be obtained.; Sender's Comments: A possible causal association between administration of BNT162B2 and the onset of angioedemia with lip swelling cannot be excluded, considering the plausible temporal relationship and the known adverse event profile of the suspect product. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate

she had a rapid test performed which indicated a positive test result; she had a rapid test performed which indicated a positive test result; This is a spontaneous report from a contactable nurse (patient). A female patient of unspecified age received the first dose of BNT162B2, via an unspecified route of administration on 18Dec2020 at a single dose for immunization. The patient's medical history and concomitant medications were not reported. The patient indicated she received the first dose of the vaccine on the 18th and due to a family member testing positive, she had a SARS-CoV-2 rapid test performed in Dec2020 which indicated a positive test result. Her employment was questioning as to whether this is due to her receipt of vaccine. The outcome of the events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: The reported information is limited. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

resident (patient) tested positive for COVID, 10 days after the first dose of COVID vaccine; resident (patient) tested positive for COVID, 10 days after the first dose of COVID vaccine; This is a spontaneous report from a contactable physician via a Pfizer sponsored program Pfizer First Connect. A 29-year-old female patient received their first dose of BNT162B2 (lot number and expiry date not reported), via an unspecified route of administration on 17Dec2020 at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The reporter wanted to know

how long they have to wait for the second dose of the COVID vaccine as her resident (patient) tested positive for COVID on 27Dec2020, 10 days after the first dose of COVID vaccine given to her on the 17Dec2020. The patient underwent lab tests and procedures which included SARS-CoV-2 test: positive on 27Dec2020. The outcome of the events was unknown. Information on the lot/ batch number has been requested.; Sender's Comments: Based on available information, a possible contributory role of subject vaccine cannot be excluded for the reported events of LOE and SARS-CoV-2 test positive, based on temporal relationship. There is very limited information provided in this report. This case will be reassessed upon receipt of follow-up information.

tested positive for COVID-19; was given the first COVID-19 dose. After some time, the employee got symptomatic and was tested positive for COVID-19; This is a spontaneous report from a contactable pharmacist. A patient of unspecified age and gender received the first dose of bnt162b2, via an unspecified route of administration on an unspecified date at a single dose for Covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient who is employed in a hospital tested negative for COVID-19 then was given the first COVID-19 dose. After some time, the patient got symptomatic and was tested positive for COVID-19. The outcome of the events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: The reported information is limited. The case will be reassessed upon receipt of follow up information. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

Angioedema of lips, throat, eyes, hands. Flushing of hands; Angioedema of lips, throat, eyes, hands. Flushing of hands; Dizziness; Fatigue; Legs became heavy; Joint stiffness of hands; This is a spontaneous report from a contactable healthcare professional (patient). A 36-year-old female patient received the first dose of BNT162B2 (Pfizer-BIONTECH Covid-19 Vaccine; Lot number: EJ 1685), intramuscular on the left arm on 23Dec2020 at 06:30 AM in a hospital at a single dose for COVID-19 immunization. Medical history included known allergies of seasonal allergies, cats, and metals; migraines, chronic idiopathic urticaria, and angioedema. The patient was not pregnant and did not have any other vaccine in four weeks. The patient did not have COVID prior to the vaccination and did not test positive to COVID post vaccination (also reported as not been tested for COVID-19 after the vaccination). Concomitant medication included propranolol, cetirizine hydrochloride (ZYRTEC), and sertraline (reported as other medications in two weeks). On 23Dec2020 at 06:45 AM, the patient experienced immediate symptoms of angioedema of lips, throat, eyes, hands; flushing of hands, dizziness, fatigue, legs became heavy, and joint stiffness of hands. She was monitored by colleagues for an hour, prescription for Epi pen refilled, and available angioedema and fatigue persisted for three days. It was reported that the patient was not treated for the adverse events but it was also reported that the AE treatment also included X-ray and antibiotic. Outcome of the events was recovered in Dec2020.; Sender's Comments: A possible causal association between administration of BNT162B2 and the onset of immediate symptoms of angioedema of lips, throat, eyes, hands, flushing of hands, dizziness, fatigue, legs became heavy, and joint stiffness of hands cannot be excluded, considering the plausible temporal relationship and the known adverse event

profile of the suspect product. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate

Angioedema; This is a spontaneous report from a contactable Other Health Professional (patient). A 40-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) lot number: EL1284, intramuscular in the right arm (also reported as right shoulder), first dose on 22Dec2020 00:30 at a single dose for Covid-19 immunization. The patient's relevant medical history included severe reaction to some animal dander and pollen, severe reactions to poison oak, possible drug induced reactions (unspecified) post C-section, mild rash with influenza vaccine this year (2020) (with no other hx of adverse reaction to a vaccine); had allergies to pollen, mold, some animals. The patient previously took influenza vaccine (split virion, inactivated) and experienced rash. The patient had no covid prior vaccination nor was she tested post vaccination. Adverse event reported was angioedema on 24Dec2020 with outcome of recovering. Systems started appearing on 23Dec2020 evening with slight rash and fluid collection under right eye. Developed more rash on 24Dec2020. In the evening to early morning of 25Dec2020, symptoms worsened significantly. Rapid swelling to face occurred. Swelling was concentrated around eyes and cheeks the most. Both right and left side of the face and neck were affected. However, the right side face had a more pronounced reaction. MD ordered oral prednisone and Benadryl as treatment plan. Also, ordered episode-pen for a worst case scenario. Symptoms have been improving under treatment but still persist some. The events were reported as non-serious. The adverse event start date was 24Dec2020 (as reported). The event resulted in doctor or other healthcare professional office/clinic visit.; Sender's Comments: There is a reasonable possibility that the event angioedema was related to BNT162b2 based on known drug safety profile and temporal relationship. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

tested positive for the COVID virus/she was having a symptom, she lost her sense of smell; tested positive for the COVID virus/she was having a symptom, she lost her sense of smell; sinus infection; tested positive for the COVID virus/she was having a symptom, she lost her sense of smell; Her nose being stuffed; tension headache on the back of head; her deltoid was hurting for 24 hours; active infection after getting the first dose; This is a spontaneous report from a contactable pharmacist (patient). A 37-year-old female patient received her first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on the right deltoid on 18Dec2020 at single dose for COVID-19 immunization. Medical history reported as none. There were no concomitant medications. The patient had active infection after getting the first dose, consult if it was still recommended to get the second dose next week or she should be delaying getting the second dose. The patient got the COVID vaccine on the 18Dec2020. Then on the 24Dec2020 she tested positive for the COVID virus. She was due to get the second vaccine on 08Jan2021. She was asking should she still get the 2nd dose of the

vaccine since came up positive. The patient was having a symptom, she lost her sense of smell of 22Dec2020. She lost her sense of smell on the evening on 22Dec2020, it still had not come back at all. She did have sense of taste on the tongue. She thought it was sinus infection, because her head didn't hurt and she was not stuffed anymore. She stated that after the vaccine, she had a tension headache on the back of head, and her deltoid was hurting for 24 hours. Her headache started the same day in the evening, went on till lunch time next day. Her nose being stuffed which she thought was a sinus infection started on Tuesday 22Dec2020, it was more located in the front middle of her forehead. Her nose being stuffed which she thought was a sinus infection started on Tuesday 22Dec2020, it was more located in the front middle of her forehead. She did not have her Card to provide Lot and Expiry, it was at work at the hospital. She was administered the vaccine on the right deltoid, since she didn't want to sleep on it. Prior to vaccine she has had no positive test for Covid. Caller stated that this was super unfortunately coincidental. She had had no antibody test. She had no reactions to vaccines in the past. Test: Respiratory Panel. Result: Negative on unknown date. The outcome of events drug ineffective, COVID-19 and sinus infection was not recovered. The outcome of event tension headache and muscle pain was recovered in Dec2020. The outcome of rest events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Based on available information, a possible contributory role of subject vaccine cannot be excluded for the reported events of LOE, COVID 19 and other events, based on temporal relationship. There is very limited information provided in this report. This case will be reassessed upon receipt of follow-up information.

tested positive; tested positive; Symptoms experiencing include having no taste, smell and slight bodyache; Symptoms experiencing include having no taste, smell and slight bodyache; Symptoms experiencing include having no taste, smell and slight bodyache; This is a spontaneous report from a Pfizer-sponsored program IBCC (Inbound Call Center for HCPs). A contactable other-healthcare professional (patient) reported that a female patient of an unspecified age received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 17Dec2020 at single dose for covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient was tested positive on 24Dec2020, and symptoms experiencing include having no taste, smell and slight body ache in Dec2020. The patient asked if she could get the second dose. The outcome of the events was unknown. Information about the Lot/batch number has been requested.; Sender's Comments: Based on the limited available information, the company considers that a causal relationship between the COVID-19, with symptoms of having no taste, smell and slight body ache, and vaccination with BNT162B2 cannot be excluded.

Positive rapid test and PCR test after 1st vaccination; Positive rapid test and PCR test after 1st vaccination; This is a spontaneous report from a contactable nurse reporting for her/himself. A patient of unspecified age and gender received the 1st dose of bnt162b2 (BNT162B2), via an unspecified route of administration, on 15Dec2020, at single dose, for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient tested positive on 27Dec2020 on a rapid test and on 28Dec2020 on a respiratory panel by PCR. Next dose was scheduled on 05Jan2021. The information on the lot/batch number has been requested.; Sender's Comments: Based on the information available, a possible contributory role of the suspect BNT162B2 cannot be excluded for the

reported event Positive rapid test and PCR test based on the known safety profile. However the short duration of 12 days since the vaccine first dose is given it is unlikely patient would have fully developed immunity.

tested positive for coronavirus; tested positive for coronavirus; This is a spontaneous report from a contactable physician (patient). A female patient of an unspecified age received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 22Dec2020 at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced tested positive for coronavirus on 24Dec2020. The patient worked in a hospital. She got the first dose of Pfizer coronavirus vaccine on Tuesday, 22Dec2020. She tested positive for coronavirus on Thursday 24Dec2020 after exposure to patients and staff. She had mild symptoms. Her 2nd dose was scheduled for 12Jan2021. The patient was inquiry whether she should receive it, or should she take an antibody test first, but it would be less than 3 weeks from the onset of illness. The outcome of event was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Based on the information available, a possible contributory role of the suspect BNT162B2 cannot be excluded for the reported event tested positive for coronavirus based on the known safety profile. However the short duration of 2 days since the vaccine first dose is given it is unlikely patient would have fully developed immunity.

"tested positive for covid; tested positive for covid; This is a spontaneous report from a Pfizer-sponsored program Pfizer First Connect. A contactable Pharmacist reported similar events for 2 patients. This is the first of two reports. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 14Dec2020 at single dose for covid-19 immunization. The patient medical history and concomitant medications were not reported. Caller is a pharmacist asked if there is a contraindication for administering antibody therapy to a person after they have received the first dose of the covid vaccine. He reported that there are 2 patients that received the covid vaccine the week of 14Dec and subsequently tested positive for covid on the 23rd and 24th of December. He was trying to determine the safety of administering antibody therapy for those patients even though they already got the first vaccine dose. He reported this question has some urgency and needed the information within 48 hours. Attempted to warm transfer but caller reported that he does not have any patient specific information or identifiers at this time. Escalating Urgently for additional research. Outcome of event was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Based on the limited available information, the company considers that a causal relationship between the event ""tested positive for COVID"" and vaccination with BNT162B2 cannot be excluded.,Linked Report(s) : US-PFIZER INC-2020516661 same reporter/ drug/ AE, different patient"

meningitis; headache; fever; weakness; rash; This is a spontaneous report from a contactable consumer (patient). A male patient of an unspecified age received bnt162b2 (lot/batch number and expiration date not provided), via an unspecified route of administration, on 16Dec2020, at single dose, for COVID-19 immunization. The patient medical history and concomitant medications were not reported. The patient received the Pfizer-BioNTech COVID-19 Vaccine on 16Dec2020, he experienced headache, fever, weakness and rash; went to the ER and after testing blood work and suspecting of meningitis. They did a spinal tap. Test came out negative for Flu and COVID; was told the rash could be due to a drug reaction

and they attributed side effects to a generic bactrim, so he stopped taking all medications. If he continues to have issues the primary concern is whether he should get the second dose of the COVID-19 vaccine or not. The outcome of the events were unknown. Information on the lot/batch number has been requested.

High fevers (103/104 degree F) with chills for five days followed by low fevers (upto 101) for another six days and still ongoing; High fevers (103/104 degree F) with chills for five days followed by low fevers (upto 101) for another six days and still ongoing; headaches; fatigue; This is a spontaneous report from a contactable physician, the patient. A 49-year-old non-pregnant female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot Number: UNKNOWN), via an unspecified route of administration in the left arm on 18Dec2020 at 15:15 (at 49-years-old) as a single dose for COVID-19 immunization. Medical history included severe iron deficiency, hypothyroidism, osteoporosis, and low baseline IgM antibodies levels (unknown cause). The patient did not have any allergies to medications, food, or other products. Concomitant medications included gabapentin (MANUFACTURER UNKNOWN), iron (MANUFACTURER UNKNOWN), calcium (MANUFACTURER UNKNOWN), and biotin (MANUFACTURER UNKNOWN). The patient did not receive any other vaccines within four weeks prior to the vaccination. On 19Dec2020 at 18:00, the patient experienced high fevers (103/104 degrees Fahrenheit) with chills for five days followed by low fevers (up to 101 degrees Fahrenheit) for another six days, headaches, and fatigue; all reported as non-serious. On 24Dec2020, the patient had a post vaccination nasal swab rapid antigen test and SARS-CoV-2 PCR test with negative results. The patient took paracetamol (TYLENOL) and ibuprofen (ADVIL) for treatment for the events. The clinical outcomes of the fever, chills, headaches, and fatigue were recovering. The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up.; Sender's Comments: Based on the compatible temporal association and the drug's known safety profile, the vaccination with BNT162B2 might play a contributory role in triggering the onset of high fevers with chills. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

"tested positive for Covid; tested positive for Covid; This is a spontaneous report from a contactable other healthcare provider. A 44-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration at single dose on 21Dec2020 for Covid-19 immunisation. The patient medical history and concomitant medications were not reported. The patient said that she received the Pfizer-BioNTech Covid-19 Vaccine last Tuesday, 21Dec2020, then tested positive for Covid on 26Dec2020. She said the symptoms started on 24Dec2020. Now, she wants to know if it is still okay to get the 2nd dose of the vaccine on the scheduled date. The outcome of events was unknown. Information about Lot/Batch number has been requested.; Sender's Comments: Based on the limited available information, the company considers that a causal relationship between the event ""tested positive for COVID"" and vaccination with BNT162B2 cannot be excluded."

difficulty thinking; brain fog; Injection site pain and swelling; Injection site pain and swelling; axillary lymph node swelling; wrist pain and swelling/joint pain; wrist pain and swelling; muscle and joint pain;

skin pain; kidney and liver pain; kidney and liver pain; dizziness; nausea; weakness; fatigue; chilling; This is a spontaneous report from a contactable nurse (patient). A 49-year-old female patient (not pregnant) received first dose bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot/batch number and expiry date were not provided), intramuscular in right arm on 22Dec2020 14:30 at single dose for COVID-19 immunisation. Facility where the most recent COVID-19 vaccine was administered was hospital. Medical history included asthma. Prior to vaccination, the patient was not diagnosed with COVID-19. No allergies to medications, food, or other products. Concomitant medication included fluticasone propionate, salmeterol xinafoate (ADVAIR). The patient experienced Injection site pain and swelling, axillary lymph node swelling, wrist pain and swelling, muscle and joint pain, skin pain, kidney and liver pain, dizziness, nausea, weakness, fatigue, chilling, difficulty thinking, brain fog on 23Dec2020 01:15. Symptoms lasting x 6 days. The patient not received any other vaccines within 4 weeks prior to the COVID vaccine. No treatment received for the adverse event. Since the vaccination, the patient has not been tested for COVID-19. The outcome of events was reported as recovering. Information about lot/batch number are requested.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the difficulty thinking, brain fog and other reported events due to temporal relationship. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics including head CT/MRI and chemistry panel, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Got first vaccine dose on the 18th and came out Covid test positive; Got first vaccine dose on the 18th and came out Covid test positive; This is a spontaneous report from a non-contactable consumer (patient). A female patient of an unspecified age received first dose of BNT162B2 (Pfizer-BioNTech COVID-19 mRNA vaccine; lot/batch number and expiry date were unknown) via an unspecified route of administration on 18Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient got the first dose on the 18th, and she came out Covid test positive yesterday (unspecified date in Dec2020). She wanted to know if she should get the second vaccine or what is the protocol into that. The outcome of the event was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.

Diagnosed with COVID after receiving first dose of COVID-19 Vaccine; Diagnosed with COVID after receiving first dose of COVID-19 Vaccine; This is a spontaneous report from a contactable nurse (patient). A 61-years-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, lot number PAA156051, expiration date unknown), via an unspecified route of administration on 15Dec2020 16:00 at a single dose at the right arm for COVID-19 immunization. The patient has no medical history, no family medical history and no concomitant medications. The patient is a nurse in the Emergency Room. She had a first dose of COVID-19 vaccine on 15Dec2020. She was diagnosed with

COVID after receiving first dose of COVID-19 vaccine on 23Dec2020. Due for second dose of COVID-19 vaccine on 04Jan2021. She wanted to know if she should go through with second dose if her symptoms subside. The COVID swab was done in the Emergency Room and was not admitted to hospital. The outcome of the event was unknown.; Sender's Comments: Based on the information currently available, a lack of efficacy with BNT162B2 in this patient cannot be completely excluded.

tested positive for covid; tested positive for covid; This is a spontaneous report from a Pfizer-sponsored program Pfizer First Connect. A contactable Pharmacist reported similar events for 2 patients. This is a 2nd of two reports. A patient of unspecified age and gender received BNT162B2, via an unspecified route of administration on 14Dec2020 at single dose for covid-19 immunization. The patient medical history was not reported. The patient's concomitant medications were not reported. The reporter was a pharmacist asking if there was a contraindication for administering antibody therapy to a person after they had received the first dose of the covid vaccine. He reported that there was a patient that received the covid vaccine the week of 14Dec and subsequently tested positive for covid on the 23rd and 24th of December. The reporter was trying to determine the safety of administering antibody therapy for the patient even though the patient already got the first vaccine dose. The reporter reported this question had some urgency and needed the information within 48 hours. The patient underwent lab tests and procedures which included covid test: positive on 23Dec2020, positive on 24Dec2020. The outcome of the events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Based on the limited available information, the company considers that a causal relationship between the COVID test positive and vaccination with BNT162B2 cannot be excluded.,Linked Report(s) : US-PFIZER INC-2020516319 same reporter/ drug/ AE, different patient

tested positive; tested positive; This is a spontaneous report from a contactable nurse reported for herself. A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection) via an unspecified route of administration on 22Dec2020 at single dose for Covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient got the COVID vaccine on 22Dec2020 and tested positive (COVID) on 27Dec2020, she didn't expect to be immune. The outcome of the event tested positive was unknown. Follow-up activities are possible, information on the batch number has been requested.; Sender's Comments: Based on the information currently available, a lack of efficacy with BNT162B2 in this patient cannot be completely excluded. Further information like specific SARS-CoV-2 test and any symptom associated with SARS-CoV-2 test positive needed for full medical assessment

Received the first dose of the vaccine; Have now tested positive; Received the first dose of the vaccine; Have now tested positive; This is a spontaneous report from a pharmacist. It was reported that a patient of unspecified age and gender received bnt162b2 (BNT162B2) vaccine , via an unspecified route of administration on an unspecified date at single dose for covid-19 immunisation . The patient medical history and concomitant medications were not reported. The patient received the first dose of the vaccine; and have now tested positive. The patient underwent lab tests and procedures which included sars-cov-2 test: positive No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Sender's Comments: Based on the limited available information, the company

considers that a causal relationship between the reported events and vaccination with BNT162B2 cannot be excluded.

had a positive COVID test; had a positive COVID test; O2 Saturation of 80% / Hypoxia; shortness of breath; He has a CT scan which showed extensive infiltration in the lungs; muscle pain; chills; body aches; low grade fever; cough; This is a spontaneous report from a contactable physician (pulmonary medicine). This physician reported similar events for 2 patients. This is 1st of 2 reports. A 35-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 18Dec2020 at single dose for covid-19 immunization. There were no medical history and concomitant medications. Caller stated that his close friend who was ER physician (front line worker) and within 24 hours after receiving the COVID vaccine, developed COVID or symptoms of COVID. Patient received the COVID vaccine on 18Dec2020 and the same night patient started with a low grade fever, body aches, chills, muscle pain, shortness of breath, cough, O2 saturation of 80% (hypoxia) and was in the intensive care unit now. Patient swore this was related to the vaccine. This patient tested positive for COVID. He had a CT (computerised tomogram) scan which showed extensive infiltration in the lungs in Dec2020. Patient was admitted to the hospital on 24Dec2020 and then was moved to the ICU 2 days later, on 26Dec2020. Caller thought patient had a positive COVID test at another hospital. Caller did know that tested positive at the current hospital on 26Dec2020 which was done to confirm the previous positive test. Caller thought patient had his first positive COVID test either the same day or the next day after receiving the vaccine. Event of O2 Saturation of 80% / hypoxia was reported as hospitalization from 24Dec2020 and life threatening; infiltration in the lungs and shortness of breath caused hospitalization from 24Dec2020, muscle pain, chills and positive COVID test was reported as medically significant; and other events were reported as non-serious. Outcome of O2 saturation of 80% / hypoxia and shortness of breath was not recovered, outcome of cough was recovering; and outcome of other events were unknown. Information about lot/batch number has been requested. ; Sender's Comments: Based on the information currently available, a lack of efficacy with suspected vaccine BNT162B2 in this patient cannot be completely excluded.,Linked Report(s) : US-PFIZER INC-2020519020 same reporter/drug , different patient/AE.

Anaphylactic reaction requiring two doses of Epinephren to control. Still having issues; other vaccine same date product received; This is a spontaneous report from a contactable nurse (patient). A 54-year-old female patient received her first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), intramuscularly on right arm at 12:30 PM on 18Dec2020 at single dose for COVID-19 immunization, and first dose of other Pfizer vaccine same date product (other vaccine same date lot number: elt9899) on right deltoid on 18Dec2020 for unknown indication. Medical history reported as none. Concomitant medication included vitamin C and colecalciferol (VITAMIN D). The patient experienced anaphylactic reaction at 12:30 PM on 18Dec2020 requiring two doses of epinephren to control. still having issues, resulted in: Doctor or other healthcare professional office/clinic visit, Hospitalization in Dec2020. days hospitalization: 1. The patient received treatment: 2 doses of epinephrine, solumedrol, benadryl, IV and O2 for event anaphylactic reaction to vaccine. The outcome of anaphylactic reaction was not recovered. Lot/Batch and Expiration date has been requested.; Sender's Comments: The information available in this report is limited and anecdotal and does not allow a medically meaningful assessment of the case.

There is a plausible temporal association between vaccines administration and onset of the reported event. It is unclear what is the nature of the vaccine co-administered with BNT162b2. Currently no information is available on the co-administration of the Pfizer-BioNTech COVID-19 Vaccine with other vaccines.

patient received the first dose of COVID 19 vaccine on 16Dec2020. She got tested positive on 20Dec2020; patient received the first dose of COVID 19 vaccine on 16Dec2020. She got tested positive on 20Dec2020; This is a spontaneous report from a contactable nurse (patient). A female patient of an unspecified age received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 16Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient received the first dose of COVID 19 vaccine on 16Dec2020. She got tested positive on 20Dec2020. The patient wanted to know if it's safe for her to get the second dose of covid-19 vaccine scheduled for 07Jan2021. Outcome of the event was unknown. Information on the Batch/Lot number has been requested.; Sender's Comments: Based on the information currently available, a lack of efficacy with BNT162B2 in this patient might not be completely excluded.

anaphylactic shock/numb throat; high heart rate; light headed; anaphylactic shock/numb throat; This is a spontaneous report from a contactable consumer (patient himself). A male patient of an unspecified age (reported as 39: unknown unit) received bnt162b2 (BNT162B2 also reported as PFIZER-BIONTECH COVID-19 VACCINE, lot/batch number and expiry date were not reported), via an unspecified route of administration on 22Dec2020 at single dose, for covid-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient experienced anaphylactic shock, numb throat, high heart rate and light headed on an on 22Dec2020. The outcome of events was unknown. Information on the lot/batch number has been requested.

tested positive for COVID-19; tested positive for COVID-19; feeling sick; This is a spontaneous report from a consumer or other non hcp. A male patient of an unspecified age received bnt162b2 (BNT162B2) vaccine, via an unspecified route of administration on 22Dec2020 at single dose for covid-19 immunisation . The patient medical history and concomitant medications were not reported. On 24Dec2020 the patient was sick and was tested positive for covid-19, the outcome of the event was unknown. Information about Lot/Batch number has been requested.

Rhonchi, frothy sputum, low grade temp, elevated HR, 12/30 MD assessed 1:00PM and increased prednisone and added Cefdinir. Sent to hospital 12/30 at approximately 6:30PM with worsening symptoms

Redness and warmth with edema to right side of neck and under chin. Resident was on Hospice services and expired on 1.1.21

12/30/2020 07:02 AM Resident noted to have some redness in face and respiration were fast. Resident vital signs were abnormal except blood pressure. Temp at the time was 102.0 F taken temporal. Resident respirations were 22 labored at times. Pulse is 105 and pulse ox 94% on room air. Resident is made comfortable in bed. Notified triage of change in condition also made triage aware of resident

receiving Covid vaccination yesterday morning. Resident appetite and fluid consumption has been poor for few days. 12/30/2020 07:32 AM Received order from agency to administer Acetaminophen 650mg suppos rectally due to resident not wanting to swallow anything including fluids, medications and food. This writer administered medication as NP ordered. Will monitor for effectiveness and adverse effects if any. 12/30/2020 08:41 AM Received new orders to obtain Flu swab, obtain CBC and BMP, and Chest Xray all to be obtained today. Notified family of resident having temperature and vital signs excluding b/p that was abnormal. Family was thankful for call and inierated to nurse that family does not want resident sent to hospital. Did educate family on benefits of Hospice services, but family persistant on continued daily care provided by nursing staff. Requests visits if decline continues. Family assured if resident continues to decline, facility will accomandate resident family to be able to be at bedside when time comes to do so. NP ordered IVF and IV Levaquin on 12/31/20. Family chose at that time to sign for Hospice services and not have resident provided with IVF or IV Antibiotics

Numbness from Neck to face to head on the left side. Lasted a few days. 12-30-2020 to January 3rd, 2021.

Patient received her Vaccine on 12/16/2020. Afterwards she developed symptoms of fever, chills, diarrhea, nausea, vomiting and headache that became worse over time and on day os presentation to our hospital on 1/2/2021 she was having photophobia. Current headache at time of admission had been persistent for over a week. Patient has no immunocompromising risk factors and was diagnosed with confirmed CMV meningitis. She was also admitted with transaminitis.

"The resident received is vaccine around 11:00 am and tolerated it without any difficulty or immediate adverse effects. He was at therapy from 12:36 pm until 1:22 pm when he stated he was too tired and could not do anymore. The therapist took him back to his room at that time and he got into bed himself but stated his legs felt heavy. At 1:50 pm the CNA answered his call light and found he had taken himself to the bathroom. She stated that when he went to get back into the bed it was ""abnormal"" how he was getting into it so she assisted him. At that time he quit breathing and she called a RN into the room immediately. He was found without a pulse, respirations, or blood pressure at 1:54 pm. He was a DNR."

6-7 hours after the vaccine she developed arm pain, fever and chills. About an hour later she started to have abdominal pain which worsened over the course of the day to excruciating. She went to the Emergency Room where a CT scan revealed a perforation of her sigmoid colon and had a resection of the area of the colon and a diverting colostomy surgery done the evening of 1/3/2021.

starting to feel lethargic and weak. Had menses with increased blessed. Called physician to have blood work done to see if I was experiencing anemia. Blood work complete on 12/31/2020. On 1/3/2021, I woke up with blood blisters all over the inside of my mouth and petechia on my trunk and bilateral upper and lower extremities. I called my primary physician to report the symptoms. He suggested to go to the ER if my symptoms worsened. Later that evening I started with a nose bleed and did go to the ER. Upon arrival to the ER, my platelet count was 9. I was admitted to the hospital and diagnosed with ITP.

12/31/20 around 11am Numbness in right hand and right cheek, 5 minutes later, slurred speech. Episode lasted approximately 10 minutes. Treated in ER. Labs, MRI, all normal 1/3/21 Swollen lymph node to left axilla 1/4/21 Rash to injection site

Tachycardia, resident was sent out to the hospital for evaluation on 12/30/2020 and came back to the facility on 12/31/2020.

Anaphylactic Reaction, facial swelling, facial Redness, Face felt like it was burning, face flushing, throat swelling, heart palpitations, trouble swallowing , feet swelling, light headed, anxiety. Hospitalized from the 12/23/20 to 12/26/2020 . Medications now on Epinephrine, diphenhydramine, cetirizine, famotidine, prednisone, lorazepam, cephalexin. on 1/1/2021 was taken to E.R. by ambulance around 11:00 am left hand was tingle started to go numb traveled up my arm into left side of my face ,ear, tongue, and then down to the left side of my leg and into left foot, could not move left side of body for a good 7 to 8 mins then went away transferred to ambulance enroute to ER blood pressure was high and and started having right ear pain and right side frontal severe headache, arrived to ER and was given diphenhydramine ,ketorolac, metoclopramide HCl, lorazepam. MRI was ordered and Neurologist found two small lesions on right side of frontal brain, following up now with neurologist. added more meds naproxen

2 minutes after vaccine was administered, noticed swelling back of tongue, progressed to posterior 2/3 of tongue, tachycardia, elevated BP. Progressive angioedema involving larynx, cough, shortness of breath. No wheezing. Physical exam did do show any obvious swelling. O2 sat decreased to 80, 1st epinephrine IM administered, 50mg benadryl IV and Famotidine administered. some improvement in symptoms. In 30mins, reoccurrence of angioedema and second epinephrine vaccine administered. Monitored for 2 hours without reoccurrence of symptoms and discharged from ER.

palpitations, chest tightness/heaviness, scratchy throat/frequent throat clearing, head heaviness, blurred vision, elevated blood pressure. Evaluated in ED received solumedrol, benadryl. Discharged home and returned to hospital as direct admit due to continued symptoms. Pertinent labs reveled AKI, elevated LFTs. AKI and LFTs improved with IVFs.

Found deceased in her home, unknown cause, 6 days after vaccine.

Vaccine 12/30/2020 Screening PCR done 12/31/2020 Symptoms 1/1/2021 COVID test result came back positive 1/2/2021 Deceased 1/4/2021

Abdominal pain that proceeded to get worse into the next day. Connected with PCP, had labs drawn and ultrasound ordered. Ended up going to ER. Determined to have Appendicitis, needed and had appendectomy on 12/29/2020.

felt like she had a stroke; fell down; Pain in leg; itchiness in her head; left leg not functioning normally; This is a spontaneous report from a contactable nurse (reporting for herself). A 51-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot number: EH9899), via an unspecified route of administration in the left deltoid on 21Dec2020 at 10:00 (at the age

of 51-years-old) as a single dose for COVID-19 immunization. Medical history was none. There were no concomitant medications. There were no prior vaccinations within 4 weeks prior to the first administration of the suspect vaccine. On 21Dec2020, the patient experienced left leg not functioning normally, which was reported with the seriousness criteria of disability. On 21Dec2020, the patient had itchiness in her head. The patient felt like she had a stroke, fell down and pain in leg on 22Dec2020, which were all reported with the seriousness criteria of disability. The patient called the doctor office and spoke with the doctor on call and was told to use diphenhydramine hydrochloride (BENADRYL). No further details provided. The patient was sent home for 10 days and she was sent back to work. The patient underwent lab tests and procedures which included COVID: negative in Dec2020. The outcome of the events was not recovered. The reported assessed the events related to the suspect product, BNT162B2.; Sender's Comments: The reported events leg dragging, leg pain and fall and suspected stroke were possibly related to the use of first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), due to temporal relationship. However, stroke was not diagnosed. The case will be reassessed should additional information become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Had a rapid test for COVID, and it was positive; Had a rapid test for COVID, and it was positive; This is a spontaneous report from a contactable pharmacist. A male patient of an unspecified age started to receive BNT162B2 (lot number unknown), via an unspecified route of administration from an unspecified date to an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The pharmacist stated that they have vaccinated all their caregivers, and a physician (patient) who got the vaccine, called and reported to her that he had a rapid test for COVID, and it was positive. She is wondering if there was any data from the clinical trials where people tested positive after having the vaccine. The patient is now freaking out because he does not know if he needs to go to the hospital and get treatment for COVID. He works night shift and may have been exposed to COVID, but now she does not know how to guide him. The outcome of the events was unknown. The following information on the batch number has been requested.; Sender's Comments: The reported positive rapid test for COVID after COVID-19 immunization is considered related to the administration of BNT162B2.

"Systemic pruritis (itching) all over body; COVID test type: Nasal Swab and Rapid Antigen and were both positive; COVID test type: Nasal Swab and Rapid Antigen and were both positive; This is a spontaneous report from a contactable nurse (patient). A 26-year-old female patient started to receive BNT162B2 (lot number: EJ1685), intramuscular on 17Dec2020 16:30 at single dose in the left arm for COVID-19 immunization. Medical history included hypothyroidism from an unknown date. The patient was not pregnant at the time of vaccination. Concomitant medication included levothyroxine sodium (SYNTHROID) and spironolactone. The patient previously took cefprozil (CEFZIL) and tapazole and both experienced allergies. The patient experienced systemic pruritis (itching) all over body on 22Dec2020 10:00. The patient was not diagnosed with COVID-19 prior to vaccination and since the vaccination, the

patient has been tested for COVID-19. On 22Dec2020, the patient took COVID test type: Nasal Swab and Rapid Antigen and were both positive. No treatment received for the event ""Systemic pruritis (itching) all over body"". The outcome of the event ""Systemic pruritis (itching) all over body"" was not recovered. The outcome of the other events was unknown.; Sender's Comments: BNT162b2 provides protection against COVID-19 after 7 days from the second dose. This case does not match this codition"

result back w positive covid; positive COVID-19 test with symptoms; This is a spontaneous report from a contactable nurse reporting for herself. A 39-years-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration on 19Dec2020 11:00 (at age 39 years old) as a single dose (Dose 1) in the left arm for COVID-19 vaccination. The patient was not pregnant at the time of vaccination. The patient was not administered any other vaccine in the 4 weeks prior to COVID-19 vaccination. Medical history was none. There were no allergies to medication, food, or other products. The patient's concomitant medications were not reported; however the patient had not received any other medications in the last 2 weeks. The patient experienced a sore throat, voice loss on day 4, loss of smell on day 5, went to test, and the result came back with positive COVID. The events resulted in a Doctor's office visit. The patient was tested post vaccination on 22Dec2020 via NAAT-PCR (nasal swab), with a positive result. The patient had not been diagnosed with COVID-19 prior to vaccination. There was no treatment received for the event(s). The clinical outcome of the event positive COVID was unknown The event was reported as non-serious. The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up.; Sender's Comments: The association between the event drug ineffective (COVID-19 infection) with BNT162b2 can not be fully excluded.

tested positive for covid19/diagnosed with Covid; tested positive for covid19/diagnosed with Covid; she had SOB the day of her first vaccination; I am very sick; I feel bad; This is a spontaneous report from a contactable consumer (patient). A female patient of an unspecified age received 1st dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899), via an unspecified route of administration on 21Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient got the first dose of COVID-19 vaccine on Monday, 21Dec2020 and then was diagnosed with COVID-19 on 23Dec2020. Added that she was very sick and wondering if he'll get her second dose or not. The patient feel bad and is due for her second dose on 11Jan2021. The patient also reported that she had shortness of breath (SOB) the day of her first vaccination on 21Dec2020 and then tested positive for COVID-19 later. She posits she may have received the vaccine when she had an active COVID-19 infection. She is wondering if she can still get her second vaccination. Outcome of the events was unknown.

"tested positive for COVID-19; headache; cough; voice being hoarse; Drug ineffective; This is a spontaneous report from a Pfizer Sponsored Program Pfizer First Connect from a Contactable nurse reporting for herself. A 58-years-old female patient received bnt162b2 (BNT162B2; Lot # EK5730) vaccine , via an unspecified route of administration on 18Dec2020 10:30 at single dose for covid-19 immunisation . Medical history included hypertension from an unknown date and blood cholesterol increased. Concomitant medication included losartan (LOSARTAN), hctz (HCTZ), ezetimibe (ZETIA), famotidine (PEPCID). The patient started having a headache and cough on 25Dec2020 and these

symptoms worsened on 26Dec2020 in addition to her voice being hoarse. On 26Dec2020 she went to get tested at an urgent center and tested positive for Covid-19. The outcome of the event was not recovered.; Sender's Comments: The association between the event ""tested positive for COVID-19, headache, cough, and dysphonia"" with BNT162b2 can not be fully excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate."

It looks like one of the ingredients may have an animal cell lipid; Syncope; Dizziness; feeling faint; like going to pass out now and then; overall achiness, severe headaches, fever; overall achiness, severe headaches, fever; overall achiness, severe headaches, fever; This is a spontaneous report from a contactable nurse reporting for herself. This A 30-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (Lot # EH9899), intramuscular at single dose in the left arm on 22Dec2020 09:00 for covid-19 immunisation. Medical history included reaction to pork, porsine and/or if she ever was exposed to exposed to heparin. There were no concomitant medications. On 23Dec2020, the patient experienced syncope (medically significant), dizziness (medically significant), feeling faint; like going to pass out now and then (medically significant), overall achiness, severe headaches, fever. The outcome of the events syncope, dizziness, feeling faint; like going to pass out now was recovering and outcome of overall achiness, severe headaches, fever was recovered on 24Dec2020. The patient ask: are there any animal products, pork gelatin or a lipid form of that contain in the vaccine? The events were described as follows: She experienced a significant amount of syncope and dizziness, for greater than 4 or 5 days post-receiving the vaccination. Also feeling faint like she is going to pass out every now and then. Has a more important question, wondering along with the doctors if one of the ingredients may have an animal product, like pork gelatin or a lipid form of that. It looks like one of the ingredients may have an animal cell lipid and was wondering if she was having a reaction to that. Declines to provide primary care provider details. States she received this first dose at occupational health in her workplace. Received the vaccine on the 22Dec2020 at 9am. 24 hours post vaccination, 1 day after, the syncope, dizziness, feeling faint started. Also the other symptoms, overall achiness, severe headaches, and fever were also experienced, but they stopped after that 24 hours. Those were expected since it was listed as side effects that popped up, so she expected those and they stopped after 24 hours. The syncope, dizziness, and faint feeling are not any worse and are very slowly improving, but she still has it and had to call out of work today because of it. That's consistent. Mentions it takes her a while to get down the stairs when getting product details for the COVID-19 vaccine. Unable to provide the vaccine NDC or expiry, or dose. Did not have any other vaccines at time of this one and none 4 weeks prior. Had to call a (company withheld) doctor and has to go to occupational health tomorrow to be seen. Declines having COVID virus. No further details provided.; Sender's Comments: Based on the compatible time association, the events syncope and dizziness are possibly related to suspect BNT162B2 administration. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in

response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

positive COVID-19 antigen test with symptoms (ache, cough, fever); positive COVID-19 antigen test with symptoms (ache, cough, fever); This is a spontaneous report from a contactable physician (patient). A 51-year-old male patient received the first dose bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number EH9899), via an unspecified route of administration on 17Dec2020 at 10:30 at single dose in left arm for covid-19 immunization. Medical history included borderline diabetes, ongoing hypertension, ongoing hyperlipidemia, ongoing rhinitis allergic, and currently ill. Concomitant medication included ongoing fexofenadine hydrochloride (ALLEGRA, strength: 180 mg) at 180mg once daily by mouth for Rhinitis allergic taking for years, ongoing lisinopril (strength: 40 mg) at 40 mg once daily by mouth for hypertension taking for two or three years, ongoing atorvastatin (strength: 40 mg) at 40 mg once daily by mouth for hyperlipidemia taking for a year. The patient experienced positive covid-19 antigen test with symptoms (ache, cough, fever) from 19Dec2020. Event details: The patient received the COVID 19 Vaccine on 17Dec2020 10:30AM in the left arm. Tested for COVID 19 with the antigen test, on 20Dec2020 and his result was positive, he experienced ache and cough on 19Dec2020. Clarified he started having symptoms in the evening (19Dec2020) and then tested in the morning (20Dec2020). He experienced the low grade fever on 20Dec2020. His maximum temperature was 100.4 fahrenheit. He had only been treated with over the counter products. No further information provided for the over the counter products. He was not hospitalized. He will take the second dose of the COVID 19 vaccine on 07Jan2021. The patient didn't have SARS-CoV2 antibodies at diagnosis. The patient was not admitted to an Intensive Care Unit. The patient didn't display clinical signs at rest indicative of severe systemic illness. The patient didn't require supplemental oxygen (including high flow or ECMO) or receive mechanical ventilation. The patient didn't have any pre-existing diseases worsened during the SARS-CoV2 infection. The patient was not treated with immunomodulating or immunosuppressing medications or received any other vaccines around the time of COVID-19 vaccination. The outcome of all his symptoms was resolving.; Sender's Comments: The reported events drug ineffective and COVID-19 are likely intercurrent and are unrelated to suspect drug BNT162B2 based on short temporal relation between vaccination and onset of events.

positive COVID-19 rapid test with symptoms; positive COVID-19 rapid test with symptoms; headache; nasal congestion; This is a spontaneous report from a contactable physician. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, on an unspecified date at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced positive COVID-19 rapid test with symptoms, headache and nasal congestion on an unspecified date. The patient developed headache and nasal congestion by the third day after the vaccination. The patient underwent lab tests and procedures which included COVID-19 rapid test: positive on an unspecified date. The clinical outcome of positive COVID-19 rapid test with symptoms, headache and nasal congestion was unknown. The batch/lot number for the vaccine, BNT162B2, was not provided and has been requested during follow up.; Sender's Comments: The reported positive COVID-19 rapid test with symptoms after

COVID-19 immunization is considered ineffective of BNT162B2, and the Company cannot completely exclude the possible causality between the reported event and BNT162B2 administration.

positive COVID-19 test with symptoms; positive COVID-19 test with symptoms; This is a spontaneous report from a contactable nurse (patient). A 37-year-old female patient received their first dose of BNT162B2 (lot number: EL0140; expiry date unknown), intramuscular on 21Dec2020 at single dose for COVID-19 immunization. Medical history included congestion and dry cough (before vaccination), and not tasting anything from an unknown date. Concomitant medication included vitamins. The patient reported that they just have the concern about the vaccination last Monday that was 21Dec2020, on 25Dec2020, Christmas day they were diagnosed with Covid. They were thinking because the day before their vaccination they already had like some kind of congestion and also some kind of dry cough but they didn't really think that it was Covid but they were still able to get the vaccination on Monday. When they started to feel like they were not tasting anything, that's when they decided to get tested and it turns out to be positive. They were confirmed positive on the 25th but in their mind they were probably having Covid since the day before they got they vaccination. So their worry is, is there any effect where they got the vaccine where they already have the Covid in their body. So that is really their worry right now. The patient underwent lab tests and procedures which included SARS-CoV-2 test: positive on 25Dec2020. The outcome of the events was unknown.; Sender's Comments: The association between the event drug ineffective (COVID-19) with BNT162b2 can not be completely excluded.

developed rashes on the chest area, not spreading; This is a spontaneous report from a contactable nurse (patient). A 43-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot number EK5730), via an unspecified route of administration into the left deltoid on 18Dec2020 as the first single dose for covid-19 immunization. Medical history was reported as none. Concomitant medication included rosuvastatin calcium (CRESTOR). The patient developed rashes on the chest area, not spreading on 22Dec2020. The event as reported between not serious and medically significant by the reporter. Details were as follows: and patient was a nurse that had her vaccine through her workplace on 18Dec2020, so she was 10 days out, and noticed a rash on her chest on day 4, which was still present. It did not seem to be spreading, and she could not think of any reason for the reaction. She was scheduled to receive the second dose in three weeks. The outcome of developed rashes on the chest area, not spreading was not recovered. The relatedness of the event to the suspect drug was reported as unknown from the reporter.; Sender's Comments: Based on the information currently provided, the vaccination with BNT162B2 might play a contributory role in triggering the onset of rash. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

blurred vision; little spots on the inside of her eyelids; This is a spontaneous report from a contactable nurse (patient). A 53-year-old female patient received first dose of BNT162B2 (Pfizer-BioNTech COVID-19 mRNA vaccine; batch/lot number and expiry date were unknown), via an unspecified route of administration on 18Dec2020 at a single dose for COVID-19 immunization. Medical history included

eyeglasses wearer (reported as with her glasses). The patient's concomitant medications were not reported. The patient is experiencing symptoms from the COVID-19 vaccine received on 18Dec2020. She began to have blurred vision that night, and it worsened over the following weekend. She saw the eye doctor on 22Dec2020, and they stated her vision had changed even with her glasses. Now she has little spots on the inside of her eyelids that were also noticed on the eye examination in Dec2020. She has already reported these symptoms to the V-safe program. She mentioned that she is not the only nurse in the workplace that has experienced blurry vision. She asked if she should receive the second dose on 08Jan2021. It was still blurry, but it was better than it was a week ago. It still affected her reading and seeing at a distance. It scared her to get the second one because she doesn't want to go blind. She went to the eye doctor for visit on Tuesday. The outcome of the event blurred vision was recovering, while for the other event was unknown. The reporter considered blurred vision as serious due to being medically significant. Information about lot/batch number has been requested.; Sender's Comments: There is not a reasonable possibility that the reported event vision blurred and eyelid disorder related to the suspect product event most likely due to patient underlying contributory factors

positive COVID-19 test; positive COVID-19 test; This is a spontaneous report from a contactable pharmacist. A patient of unspecified age and gender received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, on an unspecified date at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced positive COVID-19 test on an unspecified date. The patient underwent lab tests and procedures which included COVID-19 test: positive on an unspecified date. The clinical outcome of positive COVID-19 test was unknown. The batch/lot number for the vaccine, BNT162B2, was not provided and has been requested during follow up.; Sender's Comments: The reported positive COVID-19 test after COVID-19 immunization is considered ineffective of BNT162B2, and the Company cannot completely exclude the possible causality between the reported event and BNT162B2 administration.

having symptoms/She tested positive to COVID-19; having symptoms/She tested positive to COVID-19; This is a spontaneous report from a contactable nurse (patient). A 30-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 16Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient started having symptoms on Thursday. On Friday, her supervisor had her get tested for COVID. She tested positive to COVID-19 in Dec2020. Outcome of the events was unknown. The patient wanted to know if she is symptom free, should/can she still get the 2nd dose as planned. Information on the lot/batch number has been requested.; Sender's Comments: Based on the information available, a possible contributory role of the suspect products cannot be excluded for the reported event of positive for corona virus infection for the lack of efficacy of the vaccine. However, based on the mechanism of action of the vaccine, it is unlikely the patient would have fully developed immunity for the vaccine to be effective, due to the single dose and short duration

single hive on abdomen (itchy)/full body hives and itching; single hive on abdomen (itchy)/full body hives and itching; This is a spontaneous report from a contactable Physician. A 36-year-old female

patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number EL0140, expiry date unknown) intramuscular at left arm on 24Dec2020 at single dose for Covid-19 immunization in a hospital facility. Medical history included Anxiety, Hypertension, and GERD (gastrooesophageal reflux disease). The patient was not diagnosed with Covid-19 prior to vaccination. Concomitant medications included diphtheria vaccine toxoid, pertussis vaccine acellular, tetanus vaccine toxoid (TDAP) on 08Dec2020 for immunization; bupropion hydrochloride (WELLBUTRIN), amlodipine, omeprazole; from unspecified date for unspecified indication. On 25Dec2020, the patient developed a single hive on abdomen (itchy), and on 26Dec2020 the patient developed full body hives and itching but spared the face and mucosal surfaces. The patient has no swelling, no respiratory symptoms. The patient has not been tested for Covid-19 since the vaccination. The patient received treatment of antihistamines (steroids if no improvement) on unspecified date. The hives responded to antihistamines temporarily. The outcome of the event single hive on abdomen (itchy)/full body hives and itching was not recovered. The reporter considered the events non-serious; did not results in death, was not life threatening, did not caused/prolonged hospitalization, was not disabling/incapacitating, not a congenital anomaly/birth defect.; Sender's Comments: Based on the information available, a possible contributory role of the suspect products cannot be excluded for the reported event hives and itching due to temporal association.

ended up testing positive for COVID virus after receiving the first dose of Pfizer-BioNTech COVID-19 Vaccine/ She had symptoms; ended up testing positive for COVID virus after receiving the first dose of Pfizer-BioNTech COVID-19 Vaccine/ She had symptoms; This is a spontaneous report from a contactable nurse. This nurse reported similar events for two patients. This is 1st of two reports. A female patient of an unspecified age received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899; expiry date unknown), via an unspecified route of administration, on an unspecified date, at 0.3 mL, single for COVID-19 vaccination. The patient's medical history and concomitant medications were not reported. The nurse reported on an unspecified date that the patient tested positive after the first dose. The reporter works in employee health at their hospital. The employee ended up testing positive for COVID virus after receiving the first dose of Pfizer-BioNTech COVID-19 Vaccine. She had symptoms the first 2-3 days after getting the vaccine and assumed it was a normal immune response, but after that she continued to have the symptoms. They went to see the provider and tested positive for COVID virus. They were asking how to handle their second doses. Outcome of the events was unknown.; Sender's Comments: Based on the information available, a possible contributory role of the suspect products cannot be excluded for the reported event of corona virus infection for the lack of efficacy of the vaccine. However, based on the mechanism of action of the vaccine, it is unlikely the patient would have fully developed immunity for the vaccine to be effective, due to the short duration of less than 5 days since the vaccine first dose is given.,Linked Report(s) : US-PFIZER INC-2020516628 same reporter, same drug, same event, different patient.

a patient received Pfizer COVID-19 vaccine, couple of days later the patient tested positive for COVID-19; a patient received Pfizer COVID-19 vaccine, couple of days later the patient tested positive for COVID-19; This is a spontaneous report from a contactable pharmacist. A patient of unspecified age and gender received the first dose of BNT162B2 (Pfizer-Biontech Covid-19 Vaccine) via an unspecified route of

administration on an unspecified date at a single dose as Pfizer COVID-19 vaccine. Medical history and concomitant medications were not reported. It was reported that on an unspecified date, a patient received Pfizer COVID-19 vaccine, couple of days later the patient tested positive for COVID-19, patient subsequently received monoclonal antibody treatment: a combination of Casirivimab and Imdevimab. It was inquired if the patient could receive the second dose of COVID-19 vaccine. The outcome of the events was unknown. Information about Lot/batch number has been requested.; Sender's Comments: Based on available information, a possible contributory role of BNT162B2 vaccine cannot be excluded for the reported events of LOE and COVID 19. There is very limited information provided in this report. This case will be reassessed upon receipt of follow-up information. Based on the information provided in the case, this individual report would not seem to modify the risk-benefit profile of the subject product.

I took the vaccine and two days after I tested positive/had lost my sense of smell and taste; I took the vaccine and two days after I tested positive/had lost my sense of smell and taste; Lost my sense of smell and taste; Lost my sense of smell and taste; This is a spontaneous report from a non-contactable consumer (patient). A patient of unspecified age and gender received BNT162B2 (Pfizer-BioNTech COVID-19 mRNA vaccine; lot/batch number and expiry date were unknown), via an unspecified route of administration on 23Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The consumer stated that he/she just got the vaccine on Wednesday (23Dec2020), and he/she started experiencing some symptoms on 24Dec2020 where he/she had lost his/her sense of smell and taste. On 25Dec2020, he/she went 'health' to get tested, and he/she tested positive. The consumer is asking whether this has been reported that one of the side effects of getting the vaccine. The consumer said he/she hasn't read anything about loss of taste and smell after taking the vaccine. He/she was wondering if this has been reported or this is one of those small side effects that the vaccine has. The consumer further stated that he/she took the vaccine and two days after, he/she tested positive. Now, his/her whole family is also positive but only his/herself had the vaccine, because he/she is the only one that works in healthcare (further clarification was unknown, hence reporter was captured as consumer). The outcome of the events was unknown. No follow-up attempts are possible; Information about lot/batch number could not be obtained. No further information is expected.; Sender's Comments: The association between the event lack of effect (COVID19, lost of taste and smell) with BNT162b2 can not completely excluded.

ended up testing positive for COVID virus after receiving the first dose of Pfizer-BioNTech COVID-19 Vaccine/had symptoms; ended up testing positive for COVID virus after receiving the first dose of Pfizer-BioNTech COVID-19 Vaccine/had symptoms; This is a spontaneous report from a contactable nurse. This nurse reported similar events for two patients. This is the 2nd of two reports. A patient of an unspecified age and gender received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, strength: 0.3 mL, lot number: EH9899; expiry date was unknown), via an unspecified route of administration on an unspecified date at 0.3 mL, single for COVID-19 vaccination. The patient's medical history and concomitant medications were not reported. The patient ended up testing positive for COVID virus after receiving the first dose of Pfizer-BioNTech COVID-19 Vaccine. The patient had symptoms the first 2-3 days after getting the vaccine and assumed it was a normal immune response, but after that the patient continued to have the symptoms. The patient went to see the provider and tested positive for COVID

virus. The patient was asking how to handle his/her second dose. The outcome of the event was unknown.; Sender's Comments: Based on the information currently provided, the company considers that a causal relationship between the COVID-19 and vaccination with BNT162B2 cannot be excluded.,Linked Report(s) : US-PFIZER INC-2020516297 same reporter, same event, different patient.

tested positive after receiving Covid-19 vaccine; tested positive after receiving Covid-19 vaccine; This is a spontaneous report from a contactable nurse. A 38-years-old female patient started received her first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date not reported), via an unspecified route of administration on 18Dec2020 at a single dose for prevention of Covid 19. The patient medical history and concomitant medications were not reported. The nurse reported that a staff member received the first dose of Covid-19 vaccine on 18Dec2020. Approximately 9 days later, on 27Dec2020, the patient developed/experienced tested positive after receiving Covid-19 vaccine. The seriousness criteria for this event was none. The nurse asked if the patient will be able to receive the second dose and what is the advice for the patient. The outcome of the event was unknown. The reporter considered the relationship of the event to treatment with BNT162B2 as not applicable. Information about lot/batch number was requested.; Sender's Comments: Based on the information available, a possible contributory role of the suspect BNT162B2 cannot be excluded for the reported event tested positive Covid-19 based on the known safety profile. However the short duration of 9 days since the vaccine first dose is given it is unlikely patient would have fully developed immunity.

had loss of sense of smell and tested positive for the virus; had loss of sense of smell and tested positive for the virus; This is a spontaneous report from a contactable healthcare professional (patient). A 42-years-old female patient received her first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date not reported), intramuscular on 17Dec2020 at a single dose on the left arm, for Covid-19 immunization. The patient has no medical history and no concomitant medications (no other vaccines in four weeks and no other medications in two weeks prior to vaccination). The patient has no known allergies to medications, food, or other products. The patient had loss of sense of smell, no other symptoms on 25Dec2020 and tested positive for the virus yesterday, on 27Dec2020. The patient has no Covid-19 prior to vaccination. The patient underwent Covid test (Nasal Swab) and result was positive on 27Dec2020. The patient did not receive any treatment for the event. Outcome of the event was unknown. The events were assessed as non-serious by the reporter. No follow-up attempts are possible, information about lot/batch number cannot be obtained.; Sender's Comments: A possible contributory role of BNT162B2 vaccine cannot be excluded for event based on available information.

PATIENT VACCINATED AROUND 9AM. SHE REPORTS SHE FELT WARM/FLUSHING, FAINT AND STOMACH SPASMS WITHIN ABOUT 4-5 MINS. SHE FELT BETTER AND GOT UP TO WALK ABOUT 30 MINS LATER. SYMPTOMS WORSENED AFTER WALKING ~9:45AM: FAINT AGAIN, SEVERE RETCHING, BP196/140 TO 199/164, TROUBLE SWALLOWING, SOB, WHEEZING. AT 9:58AM, EPI PEN 0.3MG ADMINISTERED AND EMS ACTIVATED. SYMPTOMS REPORTED IMPROVED FOLLOWING EPI. EMS ARRIVED 10:05AM. PATIENT REPORTED RECEIVING 2 BAGS OF PEPCID, STEROIDS, AND ZOFRAN AT HOSPITAL. WAS RELEASED BETWEEN 11:30AM-12PM ON 1/4/21, BP 140/90 AND ACUTE SYMPTOMS RESOLVED. FOLLOW UP WITH PATIENT 1/5/21: NO PRIOR HX OF HTN, BP 120/60, NO SOB/ BREATHING DIFFICULTY. C/O SEVERE HEADACHE, LOW TEMP, FATIGUE, MUSCLE ACHES, SORE THROAT.

Droopy left cheek.; This is a spontaneous report from a contactable nurse. A 52-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Lot number: EJ1685), intramuscularly in the left arm, on 17Dec2020 at 14:30 (at the age of 52-years-old) at a single dose for COVID-19 immunization. The patient had no medical history or concomitant medications. The patient had no other medications within two weeks of vaccination. The patient was not pregnant at the time of vaccination. Prior to the vaccination, the patient was not diagnosed with COVID-19. The patient previously took sulfamethoxazole, trimethoprim (SEPTRA) and experienced allergy. The patient did not receive any other vaccines within four weeks prior to the vaccination. The patient experienced droopy left cheek on 21Dec2020. No therapeutic measures were taken as a result of the event. The clinical outcome of droopy left cheek was recovered in Dec2020. It was also reported that since the vaccination, the patient had not been tested for COVID-19.; Sender's Comments: A possible causal association between administration of BNT162B2 and the onset of droopy left cheek might not be excluded considering the plausible temporal relationship. The patient had previous allergy reaction to antibiotic (sulfamethoxazole, trimethoprim) use. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

patient tested positive for COVID; patient tested positive for COVID; This is a spontaneous report from a contactable physician from a Pfizer-sponsored program Pfizer First Connect. A 29-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot Number: UNKNOWN), via an unspecified route of administration on 17Dec2020 as a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. On 27Dec2020, the patient tested positive for COVID. The clinical outcome of patient tested positive for COVID was unknown. The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up.; Sender's Comments: The efficacy of a drug varies from one patient to another and can be affected by different factors; however, a contributory role of the suspect drug BNT162B2 to the reported events Drug ineffective and COVID 19 cannot be ruled out.

"she was administered the first dose of Pfizer COVID-19 Vaccine and later got COVID-19; she was administered the first dose of Pfizer COVID-19 Vaccine and later got COVID-19; This is a spontaneous report from a Pfizer-sponsored program Pfizer First Connect. A contactable female physician (patient) of an unspecified age received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date not reported), via an unspecified route of administration from an unspecified date in 2020 at a single dose for Covid-19 immunization. The patient medical history and concomitant medications were not reported. On an unspecified date in 2020, the patient got the first shot of COVID vaccine and got COVID, she was wondering if she should still get the dose scheduled for 04Jan2021. The patient clarified that she is both a medical doctor/physician as well as the patient. She clarified that she was administered the first dose of Pfizer COVID-19 Vaccine and later got COVID-19. She called to ask if she should still get the second dose of COVID-19 Vaccine which is scheduled for 04Jan2021. She clarified that she does not think anything went wrong with the COVID-19 Vaccine. She does not think her

receiving the COVID-19 Vaccine and developing COVID-19 are related; there was no way she would have had time to develop any protection from the COVID-19 Vaccine at the time she was exposed to COVID-19 2 days later. She does not think she can provide any relevant medical information that would be helpful for this report and declined to continue report. The outcome of the event was unknown. Information on the lot/batch number has been requested.; Sender's Comments: The reported ""developing COVID-19"" after COVID-19 immunization is considered ineffective of BNT162B2, and the Company cannot completely exclude the possible causality between the reported event and BNT162B2 administration."

"She tested positive for COVID-19; She tested positive for COVID-19; This is a spontaneous report from a contactable healthcare professional (patient) via Pfizer sales representative. A 55-years-old female patient received her first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date not reported), via an unspecified route of administration on 22Dec2020 at a single dose for Covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient, who is a frontline medical worker, informed that she tested positive for COVID-19 today (28Dec2020). The patient stated that she was informed by her employee health division at (place) that she was exposed to a patient with COVID-19 prior to her vaccination. She asked to be contacted regarding the timing of her second dose in light of her current status. The outcome of the event was unknown. Information on the lot/batch number has been requested.; Sender's Comments: There is not a reasonable possibility that reported ""tested positive for COVID-19"" is related to BNT162B2 vaccine. The patient exposed to a patient with COVID-19 before vaccination."

Not feeling well; chills; muscle aches; headache; ears bothering; stuffy/runny nose; stuffy/runny nose; This is a spontaneous report from a non-contactable nurse (patient). A 43-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Lot number: EL0140), intramuscularly in the right arm, on 18Dec2020 at 06:00 (at the age of 43-years-old) at a single dose for COVID-19 immunization. Medical history included hypothyroid, breast cancer, and penicillin allergy. The patient was not pregnant at the time of vaccination. Prior to the vaccination, the patient was not diagnosed with COVID-19. Concomitant medications, taken within two weeks of vaccination, included levothyroxine (MANUFACTURER UNKNOWN) and tamoxifen (MANUFACTURER UNKNOWN). Other concomitant medications included unspecified multivitamin. The patient did not receive any other vaccines within four weeks prior to the vaccination. The patient experienced not feeling well, chills, muscle aches, headache, ears bothering, and stuffy/runny nose on 25Dec2020 at 20:00. The events were reported as non-serious. No therapeutic measures were taken as a result of the events. The clinical outcome of not feeling well, chills, muscle aches, headache, ears bothering, and stuffy/runny nose was unknown. It was also reported that since the vaccination, the patient had not been tested for COVID-19. No follow-up attempts are possible. No further information is expected.

tested positive for COVID-19; tested positive for COVID-19; This is a spontaneous report from a contactable nurse (patient). A 39-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 17Dec2020 at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient is a nurse anesthetist that got Covid vaccine on 17Dec2020 and tested positive for

COVID-19 after the vaccine on 26Dec2020. The patient was wondering if have seen this. Stated that she was signed up for the booster scheduled for 05Jan2021 and wanted to know if they had any information about taking this. The outcome of the events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: The efficacy of a drug varies from one patient to another and can be affected by different factors; however, a contributory role of the suspect drug bnt162b2 to the reported events drug ineffective and COVID-19 cannot be ruled out.

nauseous; weak; no appetite; numbness on the skin of my arms and legs; I was post Ictal for 2+ hours; seizures/having 2 non epileptic seizures; dizzy and lightheaded; This is a spontaneous report from a contactable nurse (patient). A 21-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE. Batch/lot number: EK5730), intramuscularly on 28Dec2020 07:45 AM at right arm, at single dose for covid-19 immunization. Medical history was none. There were no concomitant medications. The patient was not pregnant at the time of vaccination. The patient received vaccine around 7:45 AM. Within 2 minutes she felt extremely dizzy and lightheaded on 28Dec2020. She sat down and drank some Gatorade and took deep breaths. The feelings persisted 5 minutes later. She then woke up after having 2 non epileptic seizures while still in 15m waiting period, (This included posturing and color change) a rapid response was called and she was taken to the ER. She was post Ictal for 2+ hours. Dizzy and nauseous, weak and no appetite for the rest of the day. She had no history of epilepsy. She also have numbness on the skin of my arms and legs within 24 hours of the vaccine. Onset date of all events (except dizzy and lightheaded) was reported as 28Dec2020 08:00AM. Treatment fluids, Zofran was received for all events. All event resulted in emergency room. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The outcome of the events was recovered with sequel.; Sender's Comments: A possible contributory effect of suspect BNT162BW on reported seizures cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

"Patient had SVT; flushing; hives; heart rate increased to 160's (had been 180's earlier in the day); This is a spontaneous report from a contactable pharmacist. A 46-year-old female patient received the first dose of BNT162B2 (lot number: EK5730), via intramuscular, on 28Dec2020 at single dose for COVID-19 immunization. Facility where the most recent COVID-19 vaccine was administered was hospital. The patient was not pregnant at the time of vaccination. The patient was not diagnosed with COVID-19 prior to vaccination. Since the vaccination, it's unknown if the patient was tested for COVID-19. No other vaccines were received within 4 weeks prior to the COVID vaccine. The patient's medical history and concomitant medications were not reported. The patient had SVT, flushing, hives 20 min after receiving vaccine on 28Dec2020. Patient was taken to ED and evaluated. SVT resolved. Patient sent home on heart monitor. Later that night while in bed, heart rate increased to 160's (had been 180's earlier in the day) and patient was admitted to hospital. Patient is a NP. Treatment received for the adverse event included cold water to face, vagal massage. The outcome of the event""Patient had SVT"" was

recovered on 28Dec2020 and of other events was recovering.; Sender's Comments: A causal association between BNT162B2 and the reported events supraventricular tachycardia, flushing, hives, heart rate increased cannot be excluded based on the compatible temporal relation. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate."

"Hypertensive crisis; Numbness to my left ear; progressively it went down to my mandible, my face and my left shoulder numbness; Radial blood pressure cough; This is a spontaneous report from a contactable nurse reporting for himself. A 48-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899), via an unspecified route of administration on 28Dec2020 at single dose for covid-19 immunization. Medical history reported as none. There were no concomitant medications. During the administration the patient did experience some types of reaction where it wanted medical supervision. So, basically when he did got the injection he was waiting for his 15 minute prolapse. But within probably he would say 7 to 8 minutes he started to experiencing some numbness to his left ear and usually he thought it was secondary to the that he had (not clarified) but progressively it went down to his mandible, his face and his left shoulder numbness and he was experiencing some numbness that radiate towards his fingertips only to the left side. At that time he waived to the Nurse to supervise and at that time he wait again and a Physician came over. He checked his pulse and noted that he had normal rhythm during the pulse check and at that time and he had Emergency medical technician (EMT) come over. The EMT checked his blood pressure he thought multiple times through the left and to the right brachial. He was having what they would consider a hypertensive crisis where systolic were in 170's, 180's, diastolic numbers were between like 120's and 130's and his heart rate was in 70's. So, initially it was not anxiety induced. But he do not have no blood pressure. They wanted he to go to the hospital to treat the hypertensive crisis that was in. The patient opted not to. So he went home in a quieter environment he did have a radial blood pressure cough that he had been checking his blood pressure rigorously, tried different techniques and now he was back to normal state to 120-130 systolic and his diastolic was 70-80. This instance was weird that he did not see as a part of one of the side effects listed with Pfizer BioNTech Vaccine. No treatment received for the events, because he had no history of hypertension it was just more of decreasing the ambient around he. At that time he wanted to go to a quiet environment, took a shower and check his blood pressure. He did orthostatic while laying down sitting up, standing up and he was not hypertensive. For the causality, the nurse stated, ""I think it did. This is a fact I mean I was doing fine prior to administration and then this event is slowly subsiding."" The outcome of the events was recovering.; Sender's Comments: A possible contributory effect of suspect BNT162B2 on reported hypertensive crisis cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate."

huge welt on her arm; This is a spontaneous report from a contactable nurse (patient). A female patient of an unspecified age received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on an unspecified date at a single dose for covid-19 immunization. Medical history included covid-19 from end of Oct2020 to an unknown date. The patient's concomitant medications were not reported. The patient reported that she is an nurse in the ICU. She had received the 1st dose of the vaccine after she had covid the end of Oct2020. Her reaction to the vaccine was, she felt exactly how she did when she had covid. It lasted 3 days. She had a huge welt on her arm. Her pulmonologist suggested that she contact Pfizer for advice on if or when she should receive the 2nd dose, which is currently due 08Jan2021. Outcome of the event huge welt was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the reported event of giant urticaria due to temporal relationship. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Appendicitis / colic pain to her right midsection; This is a spontaneous report from a contactable Other-HCP (Nurse Practitioner). A female patient of an unspecified age received bnt162b2 (BNT162B2) at single dose on 20Dec2020 for covid-19 immunisation. The patient medical history and concomitant medications were not reported. In Dec2020 3 days after vaccination she experienced colic pain to her right midsection. She was diagnosed with appendicitis. The outcome of events was unknown. Information about lot/batch number has been requested.; Sender's Comments: The event appendicitis is most likely an intercurrent medical condition and is assessed as unrelated to BNT162B2.

Fever; feels weak; tired; lightheaded; pain at the injection site; back and hip pain; back and hip pain; This is a spontaneous report from a contactable other healthcare professional (patient). A 47-year-old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number: EK5730), via an unspecified route of administration on 29Dec2020 at a single dose for COVID-19 immunization. The patient's medical history included sick with coronavirus infection from 11Aug2020. There were no concomitant medications. The patient was experiencing the expected side effects fever, feels weak, tired, lightheaded, pain at the injection site in the right deltoid, hip and back joint pain on Dec2020. She does not know exactly when these events started but that she noticed them when she was trying to sleep last night. Outcome of the events was not recovered. The events were considered serious due to being medically significant.; Sender's Comments: Based on temporal association, the causal relationship between BNT162b2 and the events pyrexia, asthenia, fatigue, dizziness, vaccination site pain, back pain and arthralgia cannot be excluded.

a high fever; extreme fatigue; have allergies; This is spontaneous report from a non-contactable consumer. This consumer reported similar events for eight patients. This is the first of eight reports.

Only this report is serious. A patient of unspecified age and gender received bnt162b2 (BNT162B2 also reported as Pfizer version of the vaccine, lot/batch number and expiry date were not reported), via an unspecified route of administration on unknown date in Dec2020 at single dose, for Covid-19 immunisaton. The patient medical history and concomitant medications were not reported. The patient got the vaccine at a facility then had a high fever and extreme fatigue after getting the vaccine on Dec2020. The patient was admitted to the ICU. The patient had allergies, but it was unknown what the allergies are to. The outcome of events was unknown. No follow-up attempts are possible. Information on batch/Lot number can not be obtained. No further information is expected.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2020520700 same reporter/drug/AE, different patients;US-PFIZER INC-2020520703 same reporter/drug/AE, different patients;US-PFIZER INC-2020520699 same reporter/drug/AE, different patients;US-PFIZER INC-2020520704 same reporter/drug/AE, different patients;US-PFIZER INC-2020520705 same reporter/drug/AE, different patients;US-PFIZER INC-2020520701 same reporter/drug/AE, different patients;US-PFIZER INC-2020520702 same reporter/drug/AE, different patients;US-PFIZER INC-2020520700 same reporter, drug, events, and different patients;US-PFIZER INC-2020520701 same reporter, drug, events, and different patients

extremely lightheaded; This is a spontaneous report from a contactable physician (patient's husband). The physician reported same events for 2 patients. This is 2nd of 2 reports. A 74-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL0140), via an unspecified route of administration on 30Dec2020 at a single dose in deltoid left for Vaccination/COVID-19 vaccine. Medical history included COVID-19 in Jul2020, ongoing overweight. There were no concomitant medications. The patient experienced extremely lightheaded on 30Dec2020. Reporter seriousness for extremely lightheaded is medically significant. The reporter stated his wife (patient) was feeling about the same thing and believed his wife was feeling better. She got up and was walking around and is no longer beside him. No Emergency Room or Physician Office visited. The outcome of event was recovering.; Sender's Comments: Based on temporal association, the causal relationship between BNT162B2 and the event dizziness cannot be excluded. ,Linked Report(s) : US-PFIZER INC-2020520760 same reporter/drug/event, different patient

Pt received COVID Vaccine at 1055, 1120 pt began coughing severely and could not stop, unable to speak. 1120 25mg Benadryl liquid given, Pepcid 20 mg given PO, cough worsening. 1122 second dose of Benadryl given, called for MD. Brought pt to Private room via wheelchair. Upon arrival, audible stridor noted. Epinephrine 0.3 mg IM given at 1126. IV started, placed patient on monitor and O2 via 1L NC. MD at bedside along with RT and pharmacy. 1134 Solumedrol 125 mg IV given, 1 puff of Ventolin given. Lungs clear. 1140 Coughing stopped, pt able to speak now. Vital signs: 1130 SPO2 99% Pulse 142 1135 99% pulse 106 BP 168/102 1140 sats 100% HR 93 BP 157/105 1145 sats 100% HR 97 BP 159/93 1200 sats 99% HR 103 155/97 114

Pt vaccinated on 12/23. PCP notified that SOB and fatigue getting worse on 1/4. Unable to keep pre-op Dental work planned prior to mitral valve surgery on 1/14/2021. PCP referred her to our ED where she was diagnosed with COVID-19 and transferred to facility, which is where her surgery was planned.

Pt received vaccination and left after 15 min. observation symptom free. He drove a short distance away from the clinical site when he felt profuse sweating and had syncope (seconds) crashing into curb. He was aroused from impact and was able to stop car. He then developed profuse nausea and sudden urge to defecate. He went to restroom. Given these events he returned to the clinical site in another vehicle. Upon arrival he denied chest pain, shortness of breath or ongoing nausea or abdominal pain. He reported his AM blood sugar was 72 and does not take insulin. No history of coronary disease or syncope. EMS was activated and assumed care.

The resident who was known to have seizures, and under control for many yeas with Keppra 1000 mg twice a day, on the second day after vaccination developed recurrent seizures requiring hospitalization to an intensive care unit, with intubation and mechanical ventilation until 1/5/21 (to be extubated today). She is still at the hospital.

RECEIVED VACCINE ON 12/22; ON 12/24, STARTED FEELING WEAK AND HAVING GI ISSUES WITH DIARRHEA. ON 12/27, STARTED HAVING SHORTNESS OF BREATH AND WHEEZING MORETHAN HER NORMAL WITH HER ASTHMA ILLNESS AND CAME TO ER. WAS TESTED AND FOUND TO BE COVID POSITIVE.

Resident received Covid Vaccine, noted after 30 mins with labored breathing BP 161/77, HR 116, R 38, T 101.4,

22 year old patient with no known allergies or medical history admitted 12/21 with TTP and currently being worked up. Currently unclear if related or unrelated to COVID vaccination, but received Pfizer vaccine Thursday 12/17.

Contracted Covid after receiving the first vaccine; Contracted Covid after receiving the first vaccine; This is a spontaneous report from a contactable consumer (patient). A 51-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 21Dec2020 at single dose for covid-19 immunisation. Medical history included asthma, dry cough due to inhalation from fires over the years. The patient's concomitant medications were not reported. Contracted Covid after receiving the first vaccine was reported. The patient received the first dose of the Covid vaccine, then contracted Covid. He now had the option to receive antibodies through plasma. Since he had the vaccine, was that still an option? Or was that a no-no? He received the vaccine at work on 21Dec2020. He got sick on 22Dec2020 and he was at home. He didn't feel like eating, and can't lay down because it made it worse to cough. He didn't know what vitamins they were giving him. The patient probably should be in a hospital, but was not. The outcome of events was not recovered. Information on Lot/Batch number has been requested.

patient receive the first dose of the vaccine and has now tested positive for Covid; patient receive the first dose of the vaccine and has now tested positive for Covid; This is a spontaneous report from a Pfizer-sponsored program. A contactable pharmacist reported a patient of unspecified age and gender received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on an unspecified date at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The pharmacist reported that they had a

patient receive the first dose of the vaccine and has now tested positive for Covid. He stated the patient is a week out from receiving the second dose and asks what information Pfizer can provide on receiving the second dose for someone with Covid infection. Outcome of the event was unknown. Information on the Batch/Lot number has been requested.; Sender's Comments: Based on the information currently available, a lack of efficacy with BNT162B2 in this patient might not be completely excluded.

"lost my sense of smell and tested positive for Covid; lost my sense of smell and tested positive for Covid; This is a spontaneous report from a non-contactable consumer (patient) received via a Pfizer-sponsored program. A patient of unspecified age and gender received BNT162B2 via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. Medical history and concomitant medications were not reported. The content of a post was noted that on Dec2020, ""Got mine! And in a stroke of weird ironic awfulness, lost my sense of smell and tested positive for Covid later that day....If only a month sooner! Thank you for creating this vaccine. I know it had nothing to do with my diagnosis!"". The outcome of the events was unknown. No follow-up attempts are possible. Information about lot/batch number cannot be obtained. Sender's Comments: The events drug ineffective and COVID 19 are likely intercurrent and are unrelated to suspect drug BNT162B2 based on the short temporal relation between vaccination and onset of events."

"she is positive that she is positive"" and is having symptoms, although not yet been tested; she is positive that she is positive"" and is having symptoms, although not yet been tested; This is a spontaneous report from a contactable pharmacist (patient). A female patient of an unspecified age received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date not reported), via an unspecified route of administration on Dec2020 at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient reportedly asking if she should keep her appointment for the second dose of the vaccine as scheduled if she thinks she was positive for COVID and having symptoms. The patient had vaccine on Tuesday (Dec2020), and husband tested positive yesterday, ""she was positive that she was positive"" and was having symptoms, although not yet been tested. The 2nd dose was in 2 weeks. The outcome of the events was unknown. Information on the Lot/Batch number has been requested.; Sender's Comments: Based on the information currently provided, the company considers that a causal relationship between the suspected COVID-19 and vaccination with BNT162B2 cannot be excluded."

Tested positive for COVID-19; Tested positive for COVID-19; Sick; He got the chills and later came down with muscle aches and fatigue; He got the chills and later came down with muscle aches and fatigue; He got the chills and later came down with muscle aches and fatigue; His arm was sore for a day; This is a spontaneous report from a Pfizer-sponsored program Corporate (Pfizer) Social Media Platforms. A non-contactable consumer reported for a 45-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 18Dec2020 at single dose for covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced his arm was sore for a day on 18Dec2020 but he suffered no other side effects. Six days later on Christmas Eve (24Dec2020), after working a shift in the COVID-19 unit, the patient became sick. He got the chills and later came down with muscle aches and fatigue. The day after Christmas (26Dec2020), he went to a drive-up hospital testing site and tested positive for COVID-19. The patient

was feeling better since his symptoms peaked on Christmas Day but still felt fatigued. The outcome of event fatigue was not recovered, the outcome of the events sick, chills, muscle aches was recovering, the outcome of other events was unknown. No follow-up attempts are possible. Information about lot/batch number cannot be obtained.; Sender's Comments: The efficacy of a drug varies from one patient to another and can be affected by different factors; however, a contributory role of the suspect drug BNT162B2 to the reported events drug ineffective and COVID-19 cannot be ruled out.

"Severe allergic reaction; BP of 170/104; felt like his whole body was on fire; chest tightness; HR elevated at 110bpm; Severe allergic reaction with symptoms that include/ rash all over his body including his throat, chest, and inner legs.; Right side of neck was swollen and sore; Right side of neck was swollen and sore; his neck was stiff to turn; he feels ""really weak and tired""; he feels ""really weak and tired""; This is a spontaneous report from a contactable other healthcare professional. A 46-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number and expiry date unknown) via an unspecified route of administration, on 29Dec2020, at a single dose, for COVID-19. The patient's medical history and concomitant medications were not reported. Patient is a 46y/o male certified nursing assistant (CNA). He received his first dose of Pfizer-Biontech Covid19 vaccine, yesterday 29Dec2020. On an unspecified date in Dec2020, patient experienced severe allergic reaction with symptoms that include: felt like his whole body was on fire, chest tightness, BP of 170/104, HR elevated at 110 bpm, rash all over his body including his throat, chest, and inner legs. Right side of neck was swollen and sore. Both sides are swollen, today, and his neck was stiff to turn, he feels ""really weak and tired"". Patient was taken by ambulance to the emergency room. Patient then asked if he should get the second dose of the vaccine. Outcome of the events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: A possible causal association between administration of BNT162B2 and the onset of severe allergic reaction with multiple symptoms cannot be excluded, considering the plausible temporal relationship and the known adverse event profile of the suspect product. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate."

potential person infected with Sars-Cov-2 following the administration of the first dose of vaccine and was isolated during the timing of the second dose; potential person infected with Sars-Cov-2 following the administration of the first dose of vaccine and was isolated during the timing of the second dose; This is a spontaneous report from a contactable Pharmacist. A female patient of unspecified age received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The relevant medical history and concomitant medications were not reported. The pharmacist was questioning as to guidelines to the potential person infected with Sars-Cov-2 following the administration of the first dose of vaccine and was isolated during the timing of the second dose. The outcome of the event was unknown. Information on the Batch/Lot number has been requested.; Sender's Comments: The reported potential person infected with Sars-Cov-2 following the administration of the first dose of

vaccine is considered ineffective of BNT162B2, and the Company cannot completely exclude the possible causality between the reported event and BNT162B2 administration.

Migraines for several days, nausea on day three; nausea; This is a spontaneous report from a contactable other healthcare professional, the patient. A 51-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, Lot number: EL0140), via intramuscular route of administration in the left arm on 18Dec2020 at 09:00 (at the age of 51-years-old) as a single dose for COVID-19 vaccination. Medical history included fibromyalgia and history of migraines. The patient did not have any known allergies to medications, food, or other products. The patient was not pregnant at the time of vaccination. Prior to the vaccination, the patient was not diagnosed with COVID-19. The patient's concomitant medications were not reported; however, there were other medications the patient received within 2 weeks of the vaccination. The patient had not received any other vaccine within 4 weeks prior to the vaccine. On 21Dec2020 at 13:00 the patient experienced migraines for several days, nausea on day three. The patient did not receive any treatment for the events. The clinical outcome of the migraines for several days, nausea on day three was recovering. It was also reported that since the vaccination, the patient had not been tested for COVID-19.

Felt sore throat and tachycardia; Felt sore throat and tachycardia; COVID test came back positive; COVID test came back positive; This is a spontaneous report from a contactable physician, the patient. A male patient of an unspecified age received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), via an unspecified route of administration on 18Dec2020, as a single dose for COVID-19 immunization. The patient medical history and concomitant medications were not reported. It was unknown whether the patient received any other vaccine within 4 weeks prior to the vaccine. On 28Dec2020, the patient felt sore throat and tachycardia. The patient also reported that on an unspecified date, in Dec2020, the COVID test came back positive (the Sepheid test, not the rapid test). The events were reported as non-serious. The patient underwent lab tests, which included COVID-19 test: positive on an unspecified date in Dec2020. It was unknown if the patient received treatment for the COVID test came back positive, felt sore throat and tachycardia. The clinical outcome of the events the COVID test came back positive, felt sore throat and tachycardia was unknown. The batch/lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up.; Sender's Comments: Based on available information, a possible contributory role of subject vaccine cannot be excluded for the reported events of LOE, COVID 19, Oropharyngeal pain and tachycardia, based on temporal relationship. There is very limited information provided in this report. This case will be reassessed upon receipt of follow-up information.

positive for covid; positive for covid; positive for covid; This is a spontaneous report from a contactable nurse (patient). A 43-year-old female patient received 1st dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 18Dec2020 at a single dose for COVID-19 immunization. completely excluded. More information such as laboratory findings on nucleic acid /PCR test needed for meaningful medical assessment.The patient's medical history and concomitant medications were not reported. The patient tested positive for COVID on 20Dec2020. Outcome of the events was unknown. Information on the lot/batch number has been requested.; Sender's Comments:

Based on the information currently available, a lack of efficacy with the suspected vaccine BNT162B2 in this patient cannot be completely excluded. More information such as virus genome /nucleic acid detection needed for meaningful medical assessment

Swelling arm/ swelling down to their biceps after receiving the COVID-19 Vaccine; arm soreness/ soreness in their arms after receiving the COVID-19 Vaccine; light redness around the vaccine injection site; body felt cold; felt real tired right after; fell asleep quickly; This is a spontaneous report from a contactable consumer. A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 28Dec2020 13:00 at SINGLE DOSE for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. It was reported the patient got the COVID-19 Vaccine at the same time as her husband did, and she had some symptoms afterwards, but her symptoms went right away. It was reported both she and her husband had soreness in their arms after receiving the COVID-19 Vaccine. She said a micro needle was used when the COVID-19 Vaccine was administered to both her and her husband's left upper arms. It was also reported both her and her husband had swelling down to their biceps after receiving the COVID-19 Vaccine. She said the swelling went away on both of their left arms after 12-14 hours. It was also reported the husband and his wife continuously monitored each others vaccine injection sites. She said the husband used a LED light to look at her left upper arm, and saw a light redness around her vaccine injection site. The husband said the light redness around the vaccine injection site went away in 2 hours after receiving the COVID-19 Vaccine. It was reported her body felt cold after receiving the COVID-19 Vaccine on 28Dec2020, and that she felt real tired right after she noticed her body felt cold. The husband said his wife fell asleep quickly on 28Dec2020, which is not normal for her, and slept for awhile. The husband said after she woke up she was fine. It was reported their arm swelling and soreness didn't really effect either one of them right away. He said the vaccine injection site redness for his wife started about 45minutes to an hour after she received the COVID-19 Vaccine. He said they both started to feel the soreness in their left arms later. He said he could feel the soreness at the vaccine injection site when he moved his left arm. He said it was the same for his wife when she moved her left arm, clarifying it was a very subtle feeling of soreness. The outcome of the events was recovered. Lot/Batch has been requested.

51-year-old female with history of intermittent asthma presented to the ED with 1 week of intermittent fevers, myalgias, arthralgias and headache. Patient reports receiving first dose of moderna vaccine last week. She initially developed arm soreness followed by chills and body aches. Subsequently developed frontal headache, photophobia, back pain, nausea and vomiting. She was seen in the ER on 1/1/21, when her work-up including labs, CT spine, chest x-ray were negative therefore she was discharged home. She continued to have symptoms and also developed bilateral intermittent ear pain. She also developed rash in her extremities and torso. Rash is pruritic but not painful. reports ongoing history of neck pain for which she sees PT. Denies sore throat, cough, chest pain or shortness of breath.

Vaccine given on 12/29/20 by Pharmacy. On 1/1/21, resident became lethargic and sluggish and developed a rash on forearms. He was a Hospice recipient and doctor and Hospice ordered no treatment, just to continue to monitor. When no improvement of codition reported, doctor and Hospice ordered comfort meds (Morphine, Ativan, Levsin). Resident expired on 1/4/2021

DEATH ON 1/4/2021, RESIDENT RECIEVED VACCINE ON 1/2/20

Began experiencing increased temp of 101.4 on 1/4/2021 at 0701. Temp did not resolve with the use of Tylenol. HR increased to >100 and BP was decreasing below baseline. Increased weakness also noted. Temp increased to 102.9 on 1/4/2021 at 2220. Transferred from SNF to ER for evaluation.

Resident had body aches, a low O2 sat and had chills starting on 12/30/20. He had stated that they had slightly improved. On 1/1/21 he sustained a fall with a diagnosis of a displaced hip fracture. On 1/2/21 during the NOC shift his O2 sat dropped again. He later went unresponsive and passed away.

Administered first dose of COVID19 vaccine at 1:29pm on 1/4/21. At approximately 11:00pm resident exhibited acute respiratory decompensation with very limited air entry and hypoxemia. Patient received Benadryl, steroids, epinephrine, and Duoneb without improvement. Resident was referred to the emergency room and found to be COVID positive. No fever or rash were reported.

LTCF Pfizer Vaccine clinic conducted 12/29/2020 Vaccine lead received a call indicating that a staff member deceased somewhere between 1/3/2021 and 1/4/2021. Cause of death is unknown, and an autopsy is being performed.

Vaccine received at about 0900 on 01/04/2021 at her place of work, Medical Center, where she was employed as a housekeeper. About one hour after receiving the vaccine she experienced a hot flash, nausea, and feeling like she was going to pass out after she had bent down. Later at about 1500 hours she appeared tired and lethargic, then a short time later, at about 1600 hours, upon arrival to a friends home she complained of feeling hot and having difficulty breathing. She then collapsed, then when medics arrived, she was still breathing slowly then went into cardiac arrest and was unable to be revived.

tremors resident sent hospital facility.

Started out vague. Started with headache at the base of her head and then it felt like a web that covered her entire head. By 10:00 she did not feel good. Went to sleep instantly. Slept for about an hour. Began to have nausea. Sunday headache got worse. Started ringing , buzzing sound in her head. Took Zofran because of nausea. Sunday night chest discomfort. Monday had horrible chest pain, headache was horrible, then vomiting. went to ER, doctor felt it was a reaction to the vaccine. was give medicine for nausea and Decadron for the reaction. Gave fluids for dehydration. Got medicine for headache. Keep taking Zofran for nausea. Still has headache. Has appointment with pcp in the morning.

"Received COVID-19 Moderna vaccine on 12/28. Developed nausea, vomiting, diarrhea, fever, and hypoxia at facility the day follow vaccine administration (12/29). He was sent to the hospital on 12/29 and admitted for post vaccine fever where he had a chest x-ray that showed infiltrates but WBC count was normal and fever resolved upon admission to hospital. Provider documented ""expected reaction to vaccination in a patient with previous COVID exposure"". He returned to the facility on 12/30."

The resident was found deceased a little less than 12 hours following COVID vaccination, and he had had some changes over the last 2 days. He was 96 and had been on hospice care for a little while. Noone noticed any side effects from vaccine after it was given

Within 10 minutes of receiving the vaccine patient began to look sleepy and started to gasp for breath. She called for help and slouched over in a chair and was moved to lay on the floor. Her feet were elevated and 911 was called. Epinephrine was given, patient responded by being able to gasp for breath and her face returned to a more natural state. Within 5 min she began to struggle to breath and epi was given again. Some improvement did occur. EMS arrived and she was taken to the hospital.

Bell?s palsy

Anaphylactic reaction (swelling and redness of face and torso, shortness of breath, constriction of airway and dizziness)

Pt describes falling with onset of weakness below the hip level about 6 inches above the patella with missing clonus reflex. The pt cannot squat down with associated observable loss of strength, pt is not able to stand up. The pt has fallen 7 times since symptom onset around lunchtime between 1200 and 1300. Pt denies LOC.

After three days, couldn't sleep the whole night. The next day, went to work, came home felt jittery. Close to midnight bp 200/90. Took Clonidine 0.1 and went to ER, bp 180/90. waited for almost two hours bp came down to 141/80. Today, bp is back to normal. Took sleeping medication Zzzquil to go to sleep.

Aseptic meningitis, prolonged fever for more than a week, headache, elevated transaminase (ALT is 124). Lumbar tap showed elevated WBC of 23, 76% polys and 24% mononuclear, 25 RBC. Glucose and protein are normal. CSF PCR viral panel is negative. Patient was initially given Acyclovir and was stopped when HSV and VZV PCR were negative. He was given vancomycin IV for Gram positive bacteremia which was later stopped because it was deemed a contaminant.

Arm weakness increased each day by post vaccine day 4 arm weak and unable to raise arm, conduct ADLs, painful interrupting sleep. Unable to initiate movement in arm. Use other arm to help move arm. Went to ED on post vaccine day 4. Wbc 12. Crp 4. CT no abscess. Mri on 1/4 shows bursitis. DX SIRVA. Bursa aspirated. Pending cultures. PO MEDROL DOSEPAK.

3 Days after the covid vaccine. I Started to have these symptoms around 1am: fever, chills, body aches, cold sweats. I took ibuprofen fell asleep. Around 330am. Woke up with dizziness, headache, chills. Took tylenol. Fell asleep body was extremely cold esp hands and feet. Woke up around 7am. Still had severe body aches and was extremely dizzy, headache worsening. Took ibuprofen. Woke up around noon. Extremely dizzy with chills and body aches headache still severe. Took tylenol. I was not getting better. went to hospital . It was found I had extremely high wbc and had extremely low blood pressure. Diagnosed as septic shock.

Immediate warm rush to my head and body. Heart was beating out of my chest and difficultly breathing. Heart rate spiked to 150 (normal around 55). Hand, legs, and mouth started to go numb. Eventually settled down after about 1 hr. Have not felt normal since which has been 3 days.

Patient presented to receive COVID-19 vaccine, received vaccine at approximately 10 am. Patient waited 15 minutes for observation and left observation area without complaining of any sx. Patient returned a few minutes after reporting tongue tingling which eventually got to her lips. . No difficulty breathing or any other sx. No history of allergies. NP/RN administered PO Benadryl 25 mg. As of report of this iReport no additional symptoms or intervention needed. Last vitals: 131/83 75spo2. BP higher than usual per patient, sp02 normal.

red dotted rash only on my chest. the rash starts at my jaw line and goes behind my ears, around the front on my neck, then my entire chest in between each best down to bra strap line and stops.

Itching, pain, swelling, and redness at injection site; fevers, myalgia, fatigue, malaise.

Painful, swollen lymph node in arm of injection

Left side, neck near collar bone. Swollen bulge in neck (lymph nodes?) severely painful and swollen. No treatment.

Arm pain, extreme fatigue, body/muscle aches, fever, shortness of breath, sensitivity to light, unable to go to work or preform daily activities Onset 5 hours after vaccination

Itchy, red, swollen lump at injection site, 2-3 inches in diameter. Painful, swollen axillary lymph nodes on the same side (right).

I suffered a miscarriage on 12/31/2020. I was at 5 weeks gestation. This was my first pregnancy. I had uterine bleeding and abdominal cramps on 12/31/2020 and underwent evaluation by my Obstetrician and was diagnosed with a miscarriage after ultrasound.

Fever of 101 for the first 48 hrs, ibuprofen, fever went down Pain in the arm for first 24 hrs, ice, ibuprofen, pain went away

Ipsilateral axillary swelling and tenderness beginning 2 days after vaccine with notably increasing swelling and tenderness at 5 days post vaccine. Continuing to monitor at home.

Patient went to get in her car after completing time of wait after vaccination, felt cloudy, compared it to how she feels after having a glass of wine, denied vision changes but states perception of environment felt foggy. EMT assessed patient, HR normal at 71, O2 100%, Bp elevated at 182/100, patient did report anxiety, monitored for another 15-20min until patient felt better, cloudiness improved, Bp improved. Advised to consult with PCP re: Bp.

Significantly sore left shoulder (injection arm) with pain now radiating up into neck & downward around shoulder blade, severe headaches, nausea (no vomiting), sore throat, FATIGUE, chills/cold sweat, general body aches.

Pt states that she developed a rash on her chest along with chest and back pain around 1012pm on 4Jan2021

"19th received Covid Vaccine at noon 21st negative Covid surveillance test completed due to ED Cluster 22nd Bedtime approx. 2100 A very strange feeling of overwhelming fatigue ""spacey feeling""""" 23rd nausea dizzy general malaise 24th nausea dizzy general malaise 25th nausea dizzy general malaise Contacted Health Service 26th still nauseous dizzy general malaise and then chills Health Service Ordered Covid Test 26th negative Covid. 26th video appointment with PCP states no need for labs feels it's Vaccine related 27th minimal nausea no chills episodes of feeling ?spacey? and tired 28th Minimal nausea 29th Morning nausea and fatigue 30th Morning nausea and fatigue 31st increased nausea and fatigue all day easing as day progresses ""spacey"" with fatigue"

Approximately 10 minutes after injection tingling in right hand, red splotchy skin on palm of hands and forearms. Approximately 15-20 minutes after injection. Tingling in feet and lower extremities. Thirty minutes after injection slight itching at injection site. Approximately 1 1/2 hours after injection splotchy red skin inside both thighs and mild generalized itching. At 2:00 pm that day of injection tingling began in face with slight swelling in cheeks. Itching lasted 3 days. Currently intermittent itching since Monday 01/03/2021.

Shortness of breath Dizziness Nausea Soreness in arm of injection

Nausea vomiting chills headache fever

I was instructed to stay for 30min as i have been anaphylatic to cipro in past. at 30min was told i could leave. while driving home on rt 91 my cheekbones became numb. then slowly a few min later my cheeks became numb. a few min later my lips became numb. as i was driving off exit to rt 5 in longmeadow i developed a lump in my throat. i turned around at top of exit and went back to highway to go to ER. this was approx 1645-1650. i went to ER arrived approx 1655. i was shaking. my bp and pulse were elevated. no tingling or swelling in my face. nurse checked my pupils and my smile and were wnl. no history of bells palsy. i received iv fluids, solucortef 125mg ivp, pepcid 20mg ivp, and benedryl 25mg ivp approx 1840pm. approx 45 min after solucortef numbness better but not gone. it started to come back a little more before discharge, which i let md know. she discharged me with scripts for epi-pen, prednisone, and OTC pepcid and benedryl. follow up with my pcp's office in am 12/24 at 10am with his NP. total time with facial numbness/lip numbness 29 hours.

EE starting with migraine about 5 minutes after receiving vaccine. That night had rash to trunk and back with the chills. Took benadryl that night. Next am, had swollen eyes and hands. Within 24 hours,those sx resolved- but then had 48 hours of sx similar to past covid infection.

Severe chills and weakness. Ran 6 miles day of getting vaccinated (21st) unable to even reach the end of the street on the 22nd.

the top of her stomach felt swollen and gassy; Diarrhea/had diarrhea that was like liquid-y water; top of her stomach had a bad burning sensation; Vomiting; she got choked on some saline and sweat ran down

her face, and she had to concentrate on breathing; sore throat with a mild cough, like she needed to be clearing her throat; sore throat with a mild cough, like she needed to be clearing her throat; got a chill; food was not tasting right; arm was sore; could not raise her arm; her weight on 21Dec2020 when she got the vaccine, was 200.6, but her weight today, was 196.0 pounds; This is a spontaneous report from a contactable consumer (patient). A 52-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: unknown) via an unspecified route of administration on 21Dec2020 on left upper arm at a single dose for COVID-19 prevention. Current medical history included a lung disease called asthma and allergies, diagnosed in her late 20's; Diabetes Type 2, diagnosed about 10 years ago and High Blood pressure, diagnosed when she was in her 30's. Caller also wanted to include that she did have COVID before, she had COVID in Jul2020. Current concomitant medications included salbutamol (ALBUTEROL) at 2 Puffs via inhalation, twice daily for asthma; Unspecified Blood Pressure Medication One pill, once daily by mouth in the morning; Unspecified Nasal Spray 1 spray in each nare, once daily via nasal inhalation; montelukast sodium (SINGULAIR) at 1 pill via oral, once a day for allergies; metformin at 1 pill, daily, by mouth for Diabetes Type 2. The patient stated that her place of employment did not give her the card that has the lot number on it, they said they would give it to her with her second injection. The patient did not know the dose received, just that it was the first in the series. The patient had no other vaccines on the same day as the COVID vaccine. The patient reported that her weight on 21Dec2020 when she got the vaccine, was 200.6, but her weight today, was 196.0 pounds. The patient received the vaccine on 21Dec2020, and as soon as she got the shot, her arm was sore like a flu shot. When she got the shot, she could not raise her arm past her shoulder without pain, but now she can raise her arm again. On Thursday, 24Dec2020, patient got a chill, and later that same night, food was not tasting right. On 25Dec2020, the chill continued, and she had a little bit of a sore throat with a mild cough, like she needed to be clearing her throat. On 26Dec2020 morning, the patient experienced vomiting when she woke up, and the top of her stomach had a bad burning sensation, and she had diarrhea. The patient stated that while she was vomiting, she got choked on some saline and sweat ran down her face, and she had to concentrate on breathing. But the patient stated that she vomited, had diarrhea, and the burning sensation, the whole day on Saturday. The patient stated that on 27Dec2020, it calmed down, and she did not vomit at all. The patient stated that she felt like she needed to vomit, but she did not. The patient states that on Sunday, she still had the chills a little, and the top part of her stomach was still burning. The patient took some Pepto-Bismol and that helped calm down the caller's stomach. The patient stated that she could feel the Pepto-Bismol cooling her stomach off, like it had been hot, and patient stated that the top of her stomach felt swollen and gassy. The patient stated that later Sunday night, things calmed down, but she still has the burning sensation and she did not feel like she needed to vomit anymore. This morning, patient reported that she still has some burning sensation, but now, it is coming and going like labor pains. The patient stated that she did go to the bathroom once this morning and had diarrhea that was like liquid-y water. The patient stated that during all this over the last few days, each and every time that she tried to eat, she couldn't eat much because her stomach would burn more with eating. But yesterday, the patient had some fried fish and stated that the fried fish did not burn as much as the rest of the food she tried eating. The outcome of the events vomiting and the top of her stomach felt swollen and gassy was recovered on 27Dec2020, arm was sore and could not raise her arm was recovered on 26Dec2020, chills, top of her stomach had a bad burning sensation was recovering,

Diarrhea/had diarrhea that was like liquid-y water was not recovered and other events was unknown. Information about batch/lot number has been requested.; Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of events Vomiting and Foreign body aspiration cannot be totally excluded. The case will be reassessed if additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

I woke up with tingling in my right hand and arm, my right side, and down my right leg. I went to the ER at Hospital, and was confirmed to have had a stroke in my left thalmus.

Patient woke on 1/3/2021 weak having uncontroled bowels and off and on confusion.

12/22 Vaccination 12/24 sore throat, sniffles, diarrhea, malaise. Contacted PCP; Covid test; negative. Had symptoms to following Tues. Following week, felt better; 1/1/2021

Fever, RespDepression & COVID positive REMDESIVIR (EUA) 200 mg x1 then 100 mg daily

The patient received the vaccine indicated above. Immediately following vaccination the patient states that they began feeling lightheaded and dizzy.

Severe right lower quadrant pain, anorexia over 12 hours. Went to the emergency department. Lab results showed elevated WBC and CT scan showed acute appendicitis. Admitted for urgent surgery: laparoscopic appendectomy. Was hospitalized from 12/26/20-12/28/20.

Rapid heart rate, shakiness, headache, rash, scratchy throat, raspy voice, dizziness, extreme weakness

tested positive for the Covid 19; tested positive for the Covid 19; This is a spontaneous report from a Pfizer-sponsored program Pfizer First Connect from a contactable consumer. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), via an unspecified route of administration on 18Dec2020 as the first single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient tested positive for the COVID 19 on 27Dec2020. The patient underwent lab tests and procedures which included a test for Covid 19 virus, which was positive on 27Dec2020. The outcome of tested positive for the COVID 19 was unknown. The batch/lot number for the vaccine, BNT162B2, was not provided and will be requested during follow-up.; Sender's Comments: The information currently provided is too limited to make a meaningful medical assessment hence, the events are conservatively assessed as related to the suspect drug BNT162B2 until further information becomes available.

"drooping on one side of the face/ eye hurts to open and hurts to close it; Her eyes are droopy; ""my eye is hurting so bad"", it hurts to open and hurts to close it/pain in the eyes; Face is tender to the touch and hurts on that one side; Swelling of her left side of her face that hasn't gone down/swelling and drooping on one side of the face; This is a spontaneous report from a contactable nurse (patient). A 20-

year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot/batch number and expiry date were not provided), via an unspecified route of administration on 23Dec2020 at single dose for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. Caller asking if pain in the eyes and swelling and drooping on one side of the face a side effect of the vaccine. Patient received the Covid vaccine on 23Dec2020 and noticed the next day (24Dec2020) swelling of her left side of her face that hasn't gone down. Her face is tender to the touch and hurts on that one side. Her eyes are droopy, ""my eye is hurting so bad"", it hurts to open and hurts to close it. The outcome of the events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: A possible causal association between administration of BNT162B2 and the onset eye hurts to open and hurts to close/ eyes droopy cannot be excluded, considering the plausible temporal relationship. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate."

received the COVID-19 vaccine on 19Dec2020 and then contracted COVID-19/positive COVID-19 test after receiving COVID-19 vaccine; received the COVID-19 vaccine on 19Dec2020 and then contracted COVID-19/positive COVID-19 test after receiving COVID-19 vaccine; This is a spontaneous report from a Pfizer sponsored program Pfizer First Connect via a contactable consumer. A 22-year-old female patient receive bnt162b2 (BNT162B2, also reported as PFIZER-BIONTECH COVID-19 VACCINE, lot/batch number and expiry date were not reported), via an unspecified route of administration in left arm/deltoid on 19Dec2020 at 0.3 mL, single for Covid-19 immunisation (as protection). Medical history included ulcerative colitis. The patient's concomitant medications were not reported. On 28Dec2020, the patient was positive for COVID-19 test after receiving COVID-19 vaccine. She informed she contracted COVID-19 due to an exposure from a co-worker. The outcome of events was not recovered. Information about lot/batch number has been requested.

"received his first dose of the vaccine and tested positive for Covid yesterday; received his first dose of the vaccine and tested positive for Covid yesterday; This is a spontaneous report from a contactable healthcare professional. A male patient of an unspecified age received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date were not reported), via an unspecified route of administration on 17Dec2020 at single dose for COVID-19 immunisation. The patient medical history and concomitant medications were not reported. It was reported that the patient received his first dose of the vaccine on 17Dec2020 and tested positive for Covid yesterday (28Dec2020). He is scheduled to have his second dose in January. The outcome of the events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Based on available information, a possible contributory role BNT162B2 vaccine cannot be completely excluded for event ""tested positive for COVID""."

tested positive for COVID after the first dose; tested positive for COVID after the first dose; This is a spontaneous report from a contactable Pharmacist reported for herself. A female patient of an unspecified age received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for

injection, lot number and expiry date unknown) via an unspecified route of administration on 22Dec2020 at single dose for Covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient informed that she had the COVID-19 vaccine exactly a week ago (22Dec2020). However, she was tested positive for COVID (Dec2020) after the first dose. The outcome of the events tested positive for COVID after the first dose was unknown. The patient asked if she can take the second dose. Follow-up activities are possible, information on the batch number has been requested.; Sender's Comments: Based on the information currently available, a lack of efficacy with the suspected vaccine BNT162B2 in this patient cannot be completely excluded. Further information like confirmative virus genome /nucleic acid detection needed for meaningful medical assessment.

We have a patient that received the 1st vaccine, then 7days later they tested positive for COVID-19.; We have a patient that received the 1st vaccine, then 7days later they tested positive for COVID-19.; This is a spontaneous report from a contactable pharmacist (Pharmacy Intern) via Pizer-sponsored program: A patient of unspecified age and gender received first single dose of BNT162B2 (lot number, and exp date not reported), via an unspecified route of administration on an unspecified date for immunization. The patient's medical history and concomitant medications were not reported. The patient received the 1st vaccine, then 7days later tested positive for COVID-19 (date unspecified). It was asked if patient needed to wait 90 days to receive the 2nd Vaccine dose. The outcome of the event was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

tested positive for Covid; tested positive for Covid; This is a spontaneous report from a contactable consumer (patient). A female patient of an unspecified age received first single dose of BNT162B2 (Pfizer-Biontech Covid-19 Vaccine, lot number and exp date not reported), via an unspecified route of administration on 17Dec2020 for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. Patient received first Covid vaccine and on 26Dec2020, tested positive for Covid. Patient asked when if it was safe for her to get second dose. Asked if she get it on 21 days or if she had to wait. The outcome of the event was unknown. Information about Lot/Batch number has been requested.; Sender's Comments: Based on the information currently available, a lack of efficacy with the suspected vaccine BNT162B2 in this patient cannot be completely excluded. Further information like confirmative virus genome /nucleic acid detection is needed for meaningful medical assessment.

had covid and also received the Pfizer covid 19 vaccine.; had covid and also received the Pfizer covid 19 vaccine.; This is a spontaneous report from a contactable nurse. A patient of unspecified age and gender started received single dose of BNT162B2 (Solution for injection, batch/lot number and exp date not reported), via an unspecified route of administration on an unspecified date for immunization. The patient's medical history and concomitant medications were not reported. They have a patient that meets the criteria to receive product bamlanivimab. The patient had Covid and received the Pfizer covid 19 vaccine. The nurse asked if patient can still get the bamlanivimab after receiving vaccine. The outcome of the events was unknown. No follow-up attempts are possible; information about batch number cannot be obtained.; Sender's Comments: Based on the information currently available, it is unclear if Covid developed after BNT162B2 Pfizer covid 19 vaccine, pending further clarification, at this

moment, the Company would handle the reported COVID related to the suspect, BNT162B2, for reporting purpose.

flare of existing autoimmune disease (undifferentiated connective tissue disease (UCTD) with predominant features of systemic sclerosis); flare of existing autoimmune disease (undifferentiated connective tissue disease (UCTD) with predominant features of systemic sclerosis); flare of existing autoimmune disease (undifferentiated connective tissue disease (UCTD) with predominant features of systemic sclerosis); This is a spontaneous report from a contactable physician. A 35-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot EH9899) intramuscular on 22Dec2020 16:15 (04:15 PM) at a single dose on the left arm as COVID-19 vaccine. Medical history included autoimmune disease (undifferentiated connective tissue disease (UCTD) with predominant features of systemic sclerosis); secondary Raynaud's phenomenon with calcinosis; known allergies to sulfa drugs, pine nuts. Concomitant medications included mycophenolate mofetil (MMF) 1000mg bid (twice a day), hydroxychloroquine sulfate (PLAQUENIL) 300mg qd (once a day), and prednisone 15mg daily (received within 2 weeks of vaccination). The patient had an adverse event (AE) of flare of existing autoimmune disease (undifferentiated connective tissue disease (UCTD) with predominant features of systemic sclerosis) on 23Dec2020 09:00 PM (also reported as flare began about 36-48 hours after vaccine) which required increased daily dose of prednisone (higher dose) up to 80mg total daily dose (80mg daily x3d, then tapered down) (treatment received for AE) and lasted about 4-5 days. The patient was not pregnant at the time of vaccination. She had no other vaccine in four weeks (did not receive other vaccine within four weeks prior to the COVID vaccine). She was not diagnosed with COVID-19 prior to vaccination and did not have Covid tested post vaccination (had not been tested for COVID-19 since the vaccination). The patient was vaccinated in a hospital (facility where the most recent COVID-19 vaccine was administered). The outcome of the events was recovered on Dec2020.; Sender's Comments: The Company cannot completely exclude the possible causality between the reported flare of existing autoimmune disease (undifferentiated connective tissue disease (UCTD) with predominant features of systemic sclerosis) and the administration of BNT162B2, based on the plausible temporal association. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to agencys, as appropriate.

developed symptoms/mild/thought the symptoms were from the vaccine but turned out she did test positive for Covid; developed symptoms/mild/thought the symptoms were from the vaccine but turned out she did test positive for Covid; This is a spontaneous report from a contactable other healthcare professional (HCP) (patient). A 33-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 19Dec2020 at a single dose as vaccine. Medical history and concomitant medications were not reported. The patient received the vaccine on 19Dec2020 and 2 days later on 21Dec2020, she developed symptoms. Her symptoms had been mild. She thought the symptoms were from the vaccine but turned out she did test positive for Covid on Dec2020. She inquired what would happen if you get the vaccine and you test positive. She also inquired if her symptoms would be worse. The outcome of the events was unknown. Information on the

lot/batch number has been requested.; Sender's Comments: Based on the information currently available, a lack of efficacy with the suspected vaccine BNT162B2 in this patient cannot be completely excluded. Further information like confirmative virus genome /nucleic acid detection is needed for meaningful medical assessment.

positive for Covid/ symptoms of Covid; positive for Covid/ symptoms of Covid; This is a spontaneous report from a contactable nurse (reported for himself). A 33-year-old male patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot/batch number and expiration date not provided), via an unspecified route of administration on 17Dec2020 at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. Patient got the first dose of the vaccine on 17Dec2020 and then around Christmas he developed symptoms of Covid (Dec2020). On 27Dec2020, he came back positive for Covid and wanted to know if he skip the second dose. Patient questioned what percentage of persons obtained immunity after the first product dose. The outcome of the events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Based on the information currently available, a lack of efficacy with the suspected vaccine BNT162B2 in this patient cannot be completely excluded. Further information like confirmative virus genome /nucleic acid detection is needed for meaningful medical assessment.

tested positive for COVID-19 by PCR the following day and developed covid symptoms; tested positive for COVID-19 by PCR the following day and developed covid symptoms; This is a spontaneous report from a contactable physician (patient). A female patient of an unspecified age received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient received the first dose of the Pfizer-biontech covid-19 vaccine and tested positive for COVID-19 by PCR the following day and developed COVID symptoms. The outcome of the events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: The reported tested positive for COVID-19 by PCR after COVID-19 immunization is considered ineffective of BNT162B2, and the Company cannot completely exclude the possible causality between the reported event and BNT162B2 administration.

they suspect that I have rheumatoid arthritis; this is like abnormal I mean anybody with arthritis should not be a part of these trials; Never felt this kind of joint pain in my life/these are hitting my every joint in my hand, I can barely move; I have never been in as much pain in my life; I am really bad nauseous; soreness in your arm; This is a spontaneous report from a contactable consumer (patient) (Food service worker in the hospital). A 48-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: Unknown), via an unspecified route of administration on 28Dec2020 at single dose for COVID-19 immunisation. Medical history included Meniere's disease (reported 'Meniere's disease in my left ear'). The patient's concomitant medications were not reported. Consumer stated, ''I just took the COVID 19 vaccine I work at (institute name), (city name), I took it yesterday around 1 and all through the night; they suspect that I have rheumatoid arthritis I got an injection in one of my hips, my right hip and both my shoulders I can inject in cortisone injection and I have never felt this kind of joint pain in my life, I can barely move, I had been calling and I let my director know and anybody that has any kind of arthritis on these trials, I have never been in as much pain in my life and I

am really bad nauseous.'' When offered for the website consumer stated, ''I just wanted to report the side effects, I am really nauseous and I can barely move; this is like abnormal I mean anybody with arthritis should not be a part of these trials.'' When probed if vaccine was prescribed by Physician, Consumer stated, ''No it was voluntary, it was not mandatory it was given my hospital administration.'' Product details for vaccine (LOT#, Expiration date, NDC#, UPC#): Consumer stated, ''EH9894, I think for the last number.'' Treatment for adverse events: Consumer stated, ''I don't have anything for nausea, I did take, they told to me take Ibuprofen my doctor said that it would help with the soreness in your arm, I take my Ibuprofen every six hours because it is prescribed to me, but I could barely move my, I can barely move; these are hitting my every joint in my hand.'' Expiry Date of Ibuprofen: 16Jul2021. The outcome of the events was unknown. Information on the Batch/Lot number has been requested.

"Tested positive for COVID after receiving the vaccine/runny nose and felt achy/coughing/ dizzy and weak. It was affecting her legs and she had no taste; Tested positive for COVID after receiving the vaccine/runny nose and felt achy/coughing/ dizzy and weak. It was affecting her legs and she had no taste; This is a spontaneous report from a Pfizer-sponsored program IBCC (Inbound Call Center for HCPs). A contactable consumer (patient) reported a 53-year-old female received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: Unknown, did not see this information on the vaccination card), via an unspecified route of administration in the left arm on 20Dec2020 at single dose for covid-19 immunization (certified nurse assistant in healthcare). Other products, patient history and investigation assessment was No. There were no concomitant medications. The patient was vaccinated with the COVID Vaccine on 20Dec2020 but tested positive afterwards on 27Dec2020. The patent thought she had COVID in the vaccine and COVID in her body. She was scheduled for next dose on 10Jan2021 and would like to know if she should get the scheduled dose or if she needs to wait longer and re-schedule it. She was now a COVID patient and sick. She was waiting to get better. Before the vaccine she tested negative and felt great. Then she got the vaccine. She had a runny nose and felt achy. She asked her coworker, and her coworker felt the same. She thought if it continued that maybe it was a side effect. Caller confirmed her symptoms were runny nose, feeling achy, and coughing. She took Tylenol and the aches went away. They then came back, and she had more aching and she was wondering why. Caller clarified that these symptoms did not start the next day after receiving the vaccine. Achiness/body aches was started on 23Dec2020 when she was at work. It would wake her up at night. She did have aches right now, but her fever had lowered down. She was also dizzy and weak. It was affecting her legs and she had no taste. She was not eating but needs to eat. If she did, she eat something sweet. Runny nose was started on 24Dec2020. She went back to work on 26Dec2020 but told them she could not work because she had symptoms of COVID. She went to her second job where they do COVID testing and asked her boss for a test. She tested positive on 27Dec2020. Dose was unknown. She said she thought she got 1 vial. The whole thing. The outcome of events ""tested positive for COVID after receiving the vaccine"" was not recovered. Information on lot/batch number has been requested."

testing positive for COVID after getting the vaccine; testing positive for COVID after getting the vaccine; This is a spontaneous report from a contactable Other Health Professional reported for herself. A female patient of an unspecified age (reported as 42) received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for COVID-19

immunization. The patient's medical history and concomitant medications were not reported. The patient experienced testing positive for COVID after getting the vaccine in Dec2020 with outcome of unknown. The patient underwent lab tests and procedures which included COVID test in Dec2020: negative; positive. The reporter would like an explanation as to the rapidness of her testing positive for COVID after getting the vaccine. Can the vaccine cause false positive test results? Information on interpretation of SARS-CoV-2 test results. The patient tested negative on Monday, got the vaccine on Monday. However tested positive today, asymptomatic. Information about batch/lot number has been requested.; Sender's Comments: A possible contributory effect of suspect BNT162B2 on reported events cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

Had the vaccine eventually then I ended up getting the virus; I ended up going through a rapid test that turned positive; This is a spontaneous report from a contactable consumer reporting for himself. A 53-years-old male patient started to receive bnt162b2 (BNT162B2; Lot # EK5730) vaccine , intramuscular in the left arm on an unspecified date at single dose for Covid-19 immunisation . Medical history included hypothyroidism from an unknown date. Concomitant medication included levothyroxine sodium (SYNTHROID). The patient stated that he does get test for the virus twice weekly. He did end up getting the Pfizer, the first round of Pfizer vaccine a week ago. The patient had a test, a virus test before, a swab test afterwards, both were negative but by Christmas eve the patient started getting, what he thought was side effect of the vaccine and he ended up going through a rapid test and it turned out he was positive for the virus.

Tested positive for COVID /she received the first dose of the vaccine last 16Dec2020 but tested positive via Nasal Swab test on 24Dec2020; Tested positive for COVID/positive via Nasal Swab test/fever/body aches/headaches/She was very very weak, almost lethargic/felt really bad/fatigued; gas; bloated; the weight last week she was 167 and this week she was 180; This is a spontaneous report from a contactable nurse reporting for herself. A 48-year-old female patient received her first dose of BNT162B2 (Pfizer-Biontech Covid-19 Vaccine) Lot #EH9899, via an unspecified route of administration on 16Dec2020 at single dose by injection in the right deltoid for COVID-19 immunisation. Medical history included borderline hypertension from 2018 and ongoing. Concomitant medication included olmesartan medoxomil (BENICAR) from 2018 and ongoing for borderline hypertension. The nurse reported that she received the first dose of the vaccine last 16Dec2020 but tested positive via Nasal Swab test on 24Dec2020. She said this kinda weird. She received the COVID vaccine on 16Dec2020. She tested positive for COVID on 24Dec2020. Obviously she was exposed to COVID prior to the vaccine. She was scheduled to have the 2nd dose on 05Jan2021 but her hospital deferred it to 23Mar2021. She was asking if this was what's recommended.She said this was another weird thing, regarding the weight last week she was 167 and this week she was 180 (in Dec2020). She was very bloated in Dec2020, it was bizarre. He husband did not receive the vaccine and had symptoms on 24Dec2020. She had normal seasonal allergy symptoms. She did not think much of it. She took her Xyzal and her normal things.She

took her husband to get tested and he tested positive, so she got tested, and was positive. She worked at (address withheld), and all of her patients were immunocompromised. She was shocked. She did not think this had anything to do with the vaccine. If anything, it has helped her fight the virus.By Christmas day 25Dec2020 her fever was 102, she had body aches, she went into overdrive. She had headaches and lots of gas in Dec2020.She went into overdrive from partial recognition from the vaccine.She was very very weak, almost lethargic. Her O2 saturation have stayed good around 98% in Dec2020. She has done really well. Yesterday or the day before she felt really bad again. She did a virtual visit with (name withheld), and the doctor started her on steroids and gave her an inhaler just in case she needed it. She felt better on 30De2020. On 29De2020 she was so bad and bloated, she only had one dose of the steroids, but had unusual weight gain. Then 2 pounds were gone this morning on 30De2020.She had no pitting edema or edema period. She was very fatigued, but had more energy this morning, probably because of the steroids. She had the vaccine, even though day 7 post-injection, instead of day 10, which was about 50%, her body reacted more so than her husbands because her body recognized it. The outcome of the events was unknown. She was unsure of the outcome. It was up and down. She has felt worse and she has felt better. The reporter considered the event Tested positive for COVID was Not serious and unrelated to the BNT162B2.; Sender's Comments: While reporter causality is noted, a possible contributory effect of suspect BNT162B2 on reported events cannot be excluded.

Bell's palsy on the left side of his face; Headaches; Overall was not feeling well; This is a spontaneous report from contactable consumers (including the patient). A 64-year-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number EH9899), via an unspecified route of administration in right arm on 18Dec2020 04:00 at a single dose for covid-19 vaccination. There were no relevant medical history and concomitant medications. On, 19Dec2020, the patient had headaches and overall was not feeling well. On 28Dec2020, the patient experienced bell's palsy on the left side of his face. He said it was a little hard to talk as his mouth was not working at the moment. The provider he saw gave him steroids- Prednisone, and Valaciclovir. He was also told to get some eyedrops as one eye does not close very well. He laughed and said it was a little hard to drink his coffee. The outcome of the events headache and not feeling well was recovered on 21Dec2020 while the outcome of bell's palsy was not recovered. The information on the batch/lot number and expiration date has been requested.

positive COVID-19 test with symptoms; positive COVID-19 test with symptoms; This is a spontaneous report from a contactable physician reporting for a nurse (patient) from a Pfizer-sponsored program Pfizer First Connect. A 43-year-old female patient received first dose of BNT162B2 (Pfizer Covid-19 vaccine), via an unspecified route of administration on 22Dec2020 at single dose for covid-19 immunisation. There were no medical history and concomitant medications. The physician was reporting that a nurse received the vaccine and had a headache after receiving it. She also tested positive for Covid 6 days after getting the vaccine (on 28Dec2020). He was asking if there was any connection with getting the first shot and testing positive. She was very keen with social distancing and wearing a mask. The physician is a medical oncologist. He was reporting on one of the nurses that worked at the hospital. She also developed nasopharyngeal congestion 4-5 days later. The nurse was at work today. She was disappointed because she had to go home. The patient underwent lab tests and procedures which included SARS-CoV-2 test: positive on 28Dec2020. The outcome of the events was

unknown. Information on Lot/Batch number has been requested.; Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of events Drug ineffective and COVID-19 cannot be totally excluded. The case will be reassessed if additional information becomes available.

has tested positive shortly after; has tested positive shortly after; This is a spontaneous report from a contactable pharmacist. A patient of unknown age and gender received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on unknown date at single dose for COVID-19 immunization. Medical history and concomitant medications were not reported. The pharmacist asked for recommendation for the 2nd dose of the patient who had received the 1st dose but had tested positive shortly after. The outcome of the events was unknown. information on the LOT/Batch number has been requested.; Sender's Comments: A possible contributory effect of suspect BNT162B2 on reported event cannot be excluded.

"fatigue; arm soreness; chills; muscle pain/muscle aches; fever; vomiting; he was positive for COVID-19; he was positive for COVID-19; This is a spontaneous report from a contactable consumer and a nurse. A 45-year-old male patient started to receive BNT162B2, via an unspecified route of administration on 18Dec2020 at single dose for COVID-19 immunization. Medical history included bronchiolitis obliterans, and ulcerative colitis. Concomitant medications were not reported. Patient experienced arm soreness. Six days later, after working a shift in the COVID-19 unit, patient had chills, muscle pain and fatigue. A drive-up hospital test confirmed he was positive for COVID-19. Patient was tested positive after receiving vaccination on 18Dec2020. Patient experienced muscle aches, fever, chills, and vomiting. On 30Dec2020, patient was tested positive for Covid-19 after receiving Pfizer vaccination. Outcome of the events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: A possible contributory effect of suspect BNT162B2 on reported event ""he was positive for Covid-19"" cannot be excluded."

palpitations; Shortness of breath; Heart rate was 160s; This is a spontaneous report from a contactable Physician. This 29-Year-old female physician reported that she received 1st dose of BNT162B2 on 30Dec2020 08:30 AM at right arm for COVID-19 immunisation. Medical history included allergies: Citrus and cinnamon- perioral contact dermatitis. Concomitant therapy included birth control- Mylan. The patient reported within 5 mins of vaccine administration, she experienced palpitations and shortness of breath. Heart rate was 160s on 30Dec2020. No rash or fever. Event onset time was reported as 30Dec2020 8:30. She needed to be taken to the emergency room. Treatment was received as Steroids epinephrine Benadryl. The outcome of the event was recovering. The events were reported as non-serious. Lot/Batch and Expiration date has been requested.; Sender's Comments: A possible contributory effect of suspect BNT162B2 on reported events cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

tested positive; tested positive; This is a spontaneous report from a contactable Nurse. A female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 27Dec2020 (reported as about 3 days ago, as of 30Dec2020) at single dose for covid-19 immunisation. Medical history, concomitant medications or past drug history were not provided. She received the vaccine about 3 days ago and later tested positive in Dec2020 and asked if the patient needs to restart the 2 doses series. Outcome of the events were unknown. Lot/Batch and Expiration date has been requested.; Sender's Comments: The reported events drug ineffective and COVID-19 are likely intercurrent conditions and are unrelated to BNT162B2 based on the short temporal relation between vaccination and onset of event.

Caller stated that a patient tested positive for covid 19 after the first dose of the vaccine; Caller stated that a patient tested positive for covid 19 after the first dose of the vaccine; This is a spontaneous report from a contactable Pharmacist. A female patient of an unspecified age (age: 74; unit- unknown) received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient medical history was not reported. The patient's concomitant medications were not reported. The patient tested positive for COVID 19 after the first dose of the vaccine. Reporter wants to know if the patient can be treated with monoclonal antibodies after having received the vaccine. Reporter also wanted to know if the storage in the thermal shipper can be extended past the 30 days. Event outcome was unknown. Information on the lot/batch number has been requested.; Sender's Comments: The information currently provided is too limited to make a meaningful medical assessment hence, the events drug ineffective and COVID-19 are conservatively assessed as related to the suspect drug BNT162B2 until further information becomes available.

Patient who got the vaccine a week ago tested positive now for COVID; Patient who got the vaccine a week ago tested positive now for COVID; This is a spontaneous report from a contactable pharmacist. A patient of unspecified age and gender received first dose bnt162b2 (BNT162B2), via an unspecified route of administration on Dec2020 at single dose for covid-19 immunisation. The patient medical history was not reported. The patient's concomitant medications were not reported. The pharmacist reported the patient who got the vaccine a week ago tested positive now for covid on Dec2020 with outcome of unknown. The patient underwent lab tests and procedures which included covid: positive on Dec2020. the doctor is thinking of giving antibody. The event was reported at non-serious. Information on lot/batch number has been requested.; Sender's Comments: The information currently provided is too limited to make a meaningful medical assessment hence, the events are conservatively assessed as related to the suspect drug BNT162B2 until further information becomes available.

Moderate to severe Chills; body and head aches; head aches; Fever (99.6 F); This is a spontaneous report from a non-contactable other hcp. A 32-year-old male patient received BNT162b2 (COVID 19, Lot number: EK9231, dose number was 1), intramuscular at right arm on 28Dec2020 08:00 AM at single dose for COVID-19 immunization in hospital. Medical history was none. There was no known allergies to medications, food, or other products. The patient's concomitant medications were not reported. There was no other vaccine in four weeks. The patient experienced Moderate to severe Chills, body and head aches, and Fever (99.6 F) on 28Dec2020 20:30(08:30 P.M). There was no treatment. There was no COVID prior vaccination nor COVID tested post vaccination. Outcome was recovering. Events were assessed as

non-serious by the reporter. No follow-up attempts are possible. No further information is expected.; Sender's Comments: A causal association between BNT162B2 and the reported event chills cannot be excluded based on known safety profile of suspect drug and compatible temporal relation.

bell's palsy; This is a spontaneous report from a contactable physician. A female patient of an unspecified age (age: 37 unit: unknown), received BNT162B2(PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date were not reported), via an unspecified route of administration on 29Dec2020 at single dose for COVID-19 immunisation. The patient medical history and concomitant medications were not reported. The patient experienced bell's palsy on 30Dec2020. The outcome of the event was unknown. Information on the lot/batch number has been requested.; Sender's Comments: A possible causal association between administration of BNT162B2 and the onset of bell's palsy might not be excluded, considering the plausible temporal relationship. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

"heart rate (HR) was 180; tongue and lips tingled; walking for a short distance and felt ""off; This is a spontaneous report from a contactable Nurse reported for herself. This 34-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Lot number: EK9231), via an unspecified route of administration on 29Dec2020 15:15 at single dose on left arm for Covid-19 immunisation. Medical history included allergies to hepatitis B vaccine rhbsag (HEY B VACCINE) booster and poison ivy. Concomitant medication included biotin / calcium pantothenate / cyanocobalamin / folic acid / nicotinamide / pyridoxine hydrochloride / riboflavin / thiamine mononitrate (B COMPLEX), fexofenadine, ascorbic acid (VIT C) and Multivitamin. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. Immediately after shot (29Dec2020 15:15), her tongue and lips tingled but it went away quickly. She was walking for a short distance and felt ""off."" The patient checked her pulse and pulse ox and her heart rate (HR) was 180. Her HR had bounced around from 150-180 with minimal exertion and was in the 90s at rest. No treatment received for the events. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The outcome of not recovered. The events were non-serious.; Sender's Comments: A causal association between BNT162B2 and the event heart rate increased cannot be excluded based on a compatible temporal relation. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate."

dizzy; fever; elevated blood pressure; flushed feeling day of vaccine. The next day she continued to feel flushed; This is a spontaneous report from a contactable pharmacist. This pharmacist reported for a 60-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via intramuscular route on 29Dec2020 15:00 at single dose for COVID-19 immunization. Medical history included COVID-19, hypertension and depression. Concomitant medications included vitamins received

within 2 weeks of vaccination. The patient previously took duloxetine and experienced allergies. Facility that the most recent COVID-19 vaccine was administered in Workplace clinic. Prior to vaccination, the patient was diagnosed with COVID-19. Since the vaccination, the patient hasn't been tested for COVID-19. On 29Dec2020, the patient was dizzy, had fever, elevated blood pressure, and flushed feeling day of vaccine. The next day she continued to feel flushed that moved through her face and down her neck. It felt like she was on fire. The adverse events resulted in the following: Emergency room/department or urgent care. Outcome of the event feel flushed was recovered on 30Dec2020, outcome of other events was recovered in Dec2020. Treatment received for the adverse events included IV fluids, prednisone, diphenhydramine hydrochloride (BENADRYL). Events were reported as non-serious. Information on the lot/batch number has been requested.; Sender's Comments: A causal association between BNT162B2 and the events dizzy, fever, elevated blood pressure and flushed feeing cannot be excluded based on a compatible temporal relation. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

"swelling/cellulitis in her left arm/redness, inflammation, swelling that looked like cellulitis to the arm/deltoid area; redness; to the arm/deltoid area; inflammation; to the arm/deltoid area; swelling/cellulitis in her left arm/swelling; to the arm/deltoid area; This is a spontaneous report from a contactable nurse reported for herself. A 28-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number EK5730, expiry date unknown) intramuscular at left deltoid on 16Dec2020 16:45 at single dose for Covid-19 immunization at a hospital facility and not in a military facility. Medical history included ongoing acne. Concomitant medications included ongoing spironolactone for acne. The patient did not receive any other vaccines the day or 4 weeks prior Covid-19 vaccine. The patient informed that after 8 days of getting Covid vaccine she has swelling/cellulitis in her left arm. The patient got the COVID-19 vaccine and had kind of a delayed reaction. She got the vaccine on 16Dec2020 16:45 pm at her workplace. The patient informed that she had no reaction right after the vaccine. On 24Dec2020, the patient experienced redness, inflammation, swelling that looked like cellulitis to the arm/deltoid area. The patient got antibiotics and it has improved. The reporter informed that the events required visit to physician office. The outcome of the events swelling/cellulitis in her left arm/redness, inflammation, swelling that looked like cellulitis to the arm/deltoid area was recovering. The patient was queried regarding seriousness of the events and the patient stated ""it could have potentially dangerous."" The patient wanted to know if she should get second dose of the vaccine.; Sender's Comments: Based on temporal association, the causal relationship between BNT162B2 and the events vaccination site cellulitis, vaccination site erythema, vaccination site inflammation and vaccination site swelling cannot be excluded."

she had developed symptoms and tested positive to COVID-19; she had developed symptoms and tested positive to COVID-19; This is a spontaneous report from a contactable physician (patient). A female patient of unspecified age received BNT162B2 first dose on 20Dec2020 at single dose for COVID-19 immunization. Medical history and concomitant medications were not reported. She tested negative on

18Dec2020. She received the first dose of the COVID 19 vaccine on 20Dec2020. On the following Friday (25Dec2020), she had developed symptoms and tested positive to COVID-19. The outcome of the events was unknown. Information on the batch/lot number has been requested.; Sender's Comments: The causal relationship between BNT162B2 and the events drug ineffective and SARS-CoV-2 test positive cannot be excluded as the information available in this report is limited and does not allow a medically meaningful assessment. This case will be reassessed once additional information becomes available.

received the 1st dose of the COVID-19 vaccine on 21Dec2020, however, on 28Dec2020 she tested positive to COVID-19; received the 1st dose of the COVID-19 vaccine on 21Dec2020, however, on 28Dec2020 she tested positive to COVID-19; This is a spontaneous report from a contactable other healthcare professional (HCP) (patient) from a Pfizer-sponsored Program Pfizer First Connect. A 26-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EJ1685), intramuscularly on left deltoid on 21Dec2020 (between 2:15PM and 2:30PM) at single dose (reported as 225mcg/.45ml intramuscular suspension) for COVID-19 immunization. The relevant medical history included birth control. Concomitant medications included ongoing ethinylestradiol, ferrous fumarate, norethisterone acetate (TAYTULLA) for birth control. The patient received the 1st dose of the COVID-19 vaccine on 21Dec2020, however, on 28Dec2020 she tested positive to COVID-19. She wanted to know if the vaccine could have caused a positive test result, if the test assesses IgM or IgG (to the viral spike proteins), could a false positive result be caused by the vaccine. She hadn't been able to get up with her primary care on the phone. This was her first dose. The window to get the second vaccine is 07Jan2021 through 11Jan2021. The patient did not require a visit to emergency room or physician office. The outcome of the events was unknown.; Sender's Comments: The causal relationship between BNT162B2 and the events drug ineffective and SARS-CoV-2 test positive cannot be excluded as the information available in this report is limited and does not allow a medically meaningful assessment. This case will be reassessed once additional information becomes available.

acute pericarditis; This is a spontaneous report from a contactable physician. A male patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot/batch number not reported), via an unspecified route of administration on 23Dec2020 at a single dose for covid-19 immunization. The patient medical history and concomitant medications were not reported. It was unknown if other vaccines were given in four weeks and unknown if patient had Covid prior vaccination. The patient experienced acute pericarditis on 24Dec2020. Clinical course as follows: Doctor colleagues at the institution admitted (at Emergency room/department or urgent care) and treated a patient with acute pericarditis who received his first dose of Pfizer SARS-CoV-2 EUA vaccine on 23Dec2020. The physician (reporter) considered the event as non-serious. The outcome of the event was recovering. Information about batch/lot number has been requested.; Sender's Comments: The causal relationship between BNT162B2 and the event acute pericarditis cannot be excluded as the information available in this report is limited and does not allow a medically meaningful assessment. This case will be reassessed once additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as

well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate.

received the vaccine last week and tested positive for covid this week; received the vaccine last week and tested positive for covid this week; This is a spontaneous report from a contactable other Healthcare Professional (patient). A 30-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: Unknown), via an unspecified route of administration on 23Dec2020 at single dose by injection in the right arm for COVID-19 immunization (to be protected and to protect her family with other conditions like diabetes). The patient's medical history and concomitant medications were none. The patient got the first dose of the COVID vaccine last week on 23Dec2020 and then she tested positive for COVID on Monday on 28Dec2020. She was asking if it was safe to get the second dose. Patient was a pharmacy technician. The outcome of the events was not recovered. Information on the Lot/Batch number has been requested.; Sender's Comments: The causal relationship between BNT162B2 and the events drug ineffective and SARS-CoV-2 test positive cannot be excluded as the information available in this report is limited and does not allow a medically meaningful assessment. This case will be reassessed once additional information becomes available.

Headache; blurred vision; unable to read at time; Difficulty focusing; right hand numbness; This is a spontaneous report from a contactable Nurse (patient). A 35-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 28Dec2020 04:15 PM, Intramuscularly at single dose (Vaccine location: Left arm) for COVID-19 immunization. Medical history was reported none. Concomitant medications were not reported. Patient did not have any allergies. Patient did not receive other vaccine in four weeks. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. Patient experienced Headache, blurred vision and unable to read at time, Difficulty focusing and right hand numbness on 30Dec2020 12:00 AM. Patient did not receive any treatment. The outcome of the events was not recovered. This case was assessed non-serious by reporter. The events did not result in death, Life threatening, Caused/prolonged hospitalization, Disabling/Incapacitating, Congenital anomaly/birth defect. Information on the lot/ batch number has been requested.; Sender's Comments: The causal relationship between BNT162B2 and the events headache, vision blurred, cognitive disorder, disturbance in attention and hypoaesthesia cannot be excluded as the information available in this report is limited and does not allow a medically meaningful assessment. This case will be reassessed once additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate.

"mild supraglottic swelling of my aryepiglottic folds; feel difficulty swallowing (globus); allergic response; This is a spontaneous report from a contactable physician. A 41-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK5730), intramuscular on 23Dec2020 12:30 at single dose for COVID-19 immunisation. Medical history included allergies to medications, food, or other products: Penicillin. There were no concomitant medications. The patient previously took benzoyl peroxide and experienced allergies. The patient experienced stated that on

23Dec2020 12:31, ""I am an ENT surgeon. I received the first dose of the vaccine at 12:30pm. Within 1-2 minutes I started to feel difficulty swallowing (globus). I reported this to the nurse and she offered me ginger ale. My symptoms worsened and then stabilized after 10 minutes. I went upstairs and got the residents to perform a fiberoptic nasoendoscopy and this demonstrated mild supraglottic swelling of my aryepiglottic folds. I choose not to receive treatment as I did not want to dampen my allergic response and as an ENT surgeon manage airways on a daily basis. I stayed at the hospital for a further 6 hours and continued to work. My symptoms resolved after 9 hours"". The outcome of the events was recovered on 23Dec2020.; Sender's Comments: Based on temporal association, the causal relationship between BNT162B2 and the event laryngeal oedema cannot be excluded. This case will be reassessed once additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate."

chronic auto immune response; angioedema/tongue is swollen; urticaria/hives; This is a spontaneous report from a contactable other healthcare professional. A 35-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number and expiration date were not reported), intramuscular in the right arm on 28Dec2020 10:15 at a single dose for COVID-19 immunization. The patient's medical history was not reported. The patient was not pregnant. Concomitant medications included cetirizine hydrochloride (ZYRTEC), omeprazole (PROTONIX), naproxen sodium (ALEVE), and birth control. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient was not diagnosed with COVID-19 prior to vaccination and had not been tested for COVID-19 since the vaccination. On 30Dec2020 16:00, the patient have a chronic auto immune response in the form of urticaria and angioedema. The symptoms of hives as well as swollen tongue was maintained with antihistamines. Outcome of the events was not recovered. The events were considered non-serious. The following information on the batch number has been requested.; Sender's Comments: Based on the temporal relationship, the association between the events chronic autoimmune response in the form of urticaria and angioedema with BNT162b2 can not be completely excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

Tachycardia/her heart rate at 11:00PM last night was at around 100/ she checked her pulse it was 115; she was not feeling right, so she took the day off from work today; Lightheadedness; wobbly; she felt weak; This is a spontaneous report from a contactable nurse (patient). A 50-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Lot Number: EL1284, expiration date: Apr2021), via an unspecified route of administration at right deltoid on 29Dec2020 17:45 at a single dose for Covid-19 immunization. Medical history included asthma from 2003 and ongoing, tachycardia and major surgery. Concomitant medication included maintenance inhaler (unspecified) for asthma.

Patient was officially diagnosed with asthma in 2003. She said her asthma was controlled, and she takes a maintenance inhaler every day. She said she has been taking the same maintenance inhaler since she was first diagnosed with the asthma. She said she rarely uses a rescue inhaler. Reported she was prescribed the Metoprolol Tartrate 25mg for her tachycardia that she had after her major surgery, but she did not take the full 25mg dose during that time. She said she hasn't had taken the Metoprolol Tartrate 25mg in almost a year, clarifying it was last Jan2020 that she used the Metoprolol Tartrate. The patient previously received a flu shot in Oct2020, and felt rundown for a day afterwards, but that she always does after she receives a flu shot. She said she had no heart issues after receiving the flu shot in Oct2020. The patient who is a registered nurse reported she received the COVID-19 vaccine last night at work, on 29Dec2020, at 5:45PM, and had experienced some tachycardia after receiving the vaccine. Reported the COVID-19 Vaccine was offered through her employer. She said the COVID-19 vaccine was optional and offered to all employees if they work at the hospital. She experienced the tachycardia at 11:00 PM last night, 29Dec2020. She said her normal resting heart rate is between the high 60s to low 70s. She said her heart rate at 11:00PM last night was at around 100, clarifying she was not running a fever at that time. She stated after she received the COVID-19 vaccine, she was not feeling right, so she took the day off from work today, and slept in. She said when she woke up this morning (in Dec2020), she still didn't feel right, saying she felt weak and wobbly, and when she checked her pulse it was 115. She said she does have a past history of tachycardia. She said a year ago she had major surgery, and she had tachycardia after the major surgery. She said the tachycardia eventually went away, but she did have to see a cardiologist and take a beta blocker. She said she took a tiny dose of the beta blocker this morning, and called the cardiologist to let him know what was going on. She said she has not heard back from the cardiologist yet. She said the tachycardia went away once she took the beta blocker this morning. She said she took the beta blocker because her heart rate was going higher, and higher. She said she didn't want to end up like last year after her major surgery with a heart rate in the 170s. She said the tachycardia she was experiencing after receiving the COVID-19 Vaccine was not normal for her. She said once she got over the major surgery last year, her heart rate was fine. Reported her employer was making employees wait around for 15 minutes after the employees received the COVID-19 Vaccine to make sure no one had a major reaction to the COVID-19 Vaccine. She said after she received the COVID-19 Vaccine, she waited around longer than the 15 minutes. She said she felt weird after she received the COVID-19 Vaccine and thought maybe she was experiencing anxiety. She said she was lightheaded on 29Dec2020 after she received the COVID-19 Vaccine and completed a report right then on the website. She said the website is for reporting adverse events, and she was sent a website link to complete the adverse event reporting. She said she signed into the website link while she was still at the hospital. She said one of the website's first questions asked was how she was feeling. She said the question made her wonder if her lightheadedness was due to her heart rate being up because she becomes lightheaded when that happens. She clarified she reported only the lightheadedness on the website, and not the tachycardia. She said her lightheadedness got better and she was fine, and then at 11:00PM the tachycardia hit her like a switch. Reported this morning she felt fine, and then all of sudden she wasn't fine. Tachycardia Treatment: Reported she took a 8.5mg dose, or one quarter of a 25mg tablet (as provided by the reporter) of the beta blocker Metoprolol Tartrate 25mg tablet this morning and called her cardiologist to let him know. She said she split the Metoprolol Tartrate 25mg tablet this morning, and only took a quarter of the 25mg tablet (reported as a 8.5mg dose by the reporter).

Reported she believes 100% that her tachycardia was caused by the COVID-19 Vaccine, saying she has been fine up until receiving the COVID-19 Vaccine. She said she got the COVID-19 Vaccine because she was afraid of getting the COVID-19 Virus with her asthma. She said she has no other preexisting conditions besides the asthma. Reported she is not going to get the second COVID-19 Vaccine dose. She said it was scary when her heart rate shot up out of nowhere. She said the COVID-19 Vaccine is the only thing different she has done. She said before the COVID-19 Vaccine, she was completely fine. Patient asked if the Pfizer DSU agent had heard of anyone else who has experienced tachycardia after receiving the COVID-19 Vaccine. The outcome of the event tachycardia was recovered in Dec2020, event lightheadedness was recovering and unknown for the other events. The reporter assessed the event 'tachycardia' as Serious (Medically Significant).; Sender's Comments: Based on the close temporal relationship, the association between the event tachycardia with BNT162b2 can not be fully excluded. The medical history of tachycardia and asthma medication may be contributory as well. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

swelling and joint pain in the little finger on left arm; swelling and joint pain in the little finger on left arm; She got a bruise at the injection site; It bled a little bit when she put it in; This is a spontaneous report from a contactable nurse (patient). A 62-years-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number EK9231), via an unspecified route of administration on the left arm, on 28Dec2020 at 14:15 at a single dose for Covid-19 immunization. Medical history included environmental allergies, she has allergies and can have an asthmatic attack from cat dander and perfume, blood pressure (abnormal) and sleep (disorder). Concomitant medications included ongoing lisinopril for blood pressure, colecalciferol (VITAMIN D), acetylsalicylic acid (BABY ASPIRIN), paracetamol (TYLENOL). The patient previously took novocaine but was allergic. She got all this information when she got the vaccine on Monday at (place name) in (state name). It tells all the side effects from the first injection. She wanted to report that it is the same arm that she got the vaccine in. She has swelling and joint pain in the little finger on left arm. It says you can have joint pain, but nothing about swelling. She thought she better report it. This was her first shot. She is supposed to get the second one on 18Jan2021. She wanted to make sure she can take it. She received the vaccine on 28Dec2020. She laid around that day. Today is the first day she doesn't have arm pain and swelling at the injection site. It was the first time she has had arm pain. She has never had that with flu shot. The arm pain started within the 15 minutes she was observed. It hurt like hell until that day. She got a bruise at the injection site. It bled a little bit when she put it in. Swelling and joint pain in the little finger on left arm: she doesn't know if it was later that day. She can't remember. She really noticed it yesterday. She has never had joint pain or swelling. She doesn't have any problems with arthritis. Now her little finger is bigger than the rest of her fingers. It hurts because of the swelling. She doesn't want to take anything. It might be fluid. She has a high pain tolerance. She keeps bending it thinking it will get better. It isn't as bad, but its still swelled up. At first she thought it was better, but it is still pretty swollen. To her this is a reaction. She was thinking if she took paracetamol before, it wouldn't hurt as bad, but she can't remember if she took it that morning. She takes 500mg before bed for the heck of it at night. It helps

her sleep better. She has allergies and can have an asthmatic attack from cat dander and perfume. They think she was allergic to the preservative in the flu shot, but she has never had any trouble with the flu shot since. She has environmental allergies. They thought she was allergic to Novocaine once at the dentist office. Who knows, it only happened once. She's been to the dentist many times and who knows what they injected and why she reacted that way. She felt like she was going to pass out. They don't give it to her anymore. She doesn't know what was in it. She is worried since this vaccine is emergency authorization. She doesn't want to get the next one and have a worse reaction. She is not sure if she should be worried. The events of swelling and joint pain in the little finger on left arm were assessed as medically significant. Outcome of the event of 'swelling of fingers' was not recovered, the other events were unknown.; Sender's Comments: There is a reasonable possibility that the event joint pain was related to BNT162b2 based on known drug safety profile. Based on the temporal relationship, the association between the event swelling with BNT162b2 can not be fully excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

Covid 19 test: Nasal Swab Result: Positive; Covid 19 test: Nasal Swab Result: Positive; Severe joint swelling oral viral sores left lung fluid exhaustion; Severe joint swelling oral viral sores left lung fluid exhaustion; Severe joint swelling oral viral sores left lung fluid exhaustion; This is a spontaneous report from a contactable Other HCP (patient). A 56-year-old non-pregnant female patient received 1st dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), intramuscular in the left arm on 24Dec2020 12:00 at a single dose for COVID-19 immunization at the hospital. Medical history included juvenile idiopathic arthritis (JRA). The patient was not diagnosed with COVID-19 prior vaccination. Concomitant medications included imipramine, nebivolol hydrochloride (BYSTOLIC), and topiramate (TOPAMAX). The patient received other vaccine within 4 weeks prior to the COVID vaccine which is J&J cv trial. The patient experienced severe joint swelling, oral viral sores, and left lung fluid exhaustion on 25Dec2020 06:00; it was reported that no treatment was given for these. The patient tested for COVID-19 post vaccination. The COVID-19 test post vaccination was a Nasal Swab (Abbott Binax) on 27Dec2020. The COVID-19 test result was positive. Outcome of the events severe joint swelling, oral viral sores, and left lung fluid exhaustion was recovering; for the other events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: The association between the event lack of effect (COVID-19 test positive) with BNT162b2 can not be fully excluded. Based on the close temporal relationship, the association between the event left lung fluid exhaustion with BNT162b2 can not be fully excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

"blood pressure went up to 150/101; feeling like fainting; feeling really tired; Weakness; irregular heart beat; sob; feeling like flushing in the body; chills; This is a spontaneous report from a contactable

healthcare professional. A 39-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL1284), intramuscular on the left arm on 30Dec2020 07:15 at single dose for COVID-19 immunisation. Medical history included hypothyroidism, depression, cardiac murmur and pvc. The patient hadno known drug allergies and had not tested for COVID-19 prior and after vaccination. Concomitant medication included levothyroxine sodium (SYNTHROID), ergocalciferol (VITAMIN D), tocopherol (VITAMIN E) and sertraline hydrochloride (ZOLOFT). The patient experienced weakness, irregular heart beat, feeling like fainting, sob, blood pressure went up to 150/101, feeling like flushing in the body, chills, feeling really tired, all on 30Dec2020 07:15. The patient received treatment. The outcome of the events was recovering.; Sender's Comments: Based on the close temporal relationship, the association between the event ""blood pressure went up to 150/101"" with BNT162b2 can not fully excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate."

Got the first Pfizer COVID Vaccine and today I tested positive for COVID; Got the first Pfizer COVID Vaccine and today I tested positive for COVID; Congestion; Sore throat; This is a spontaneous report from a contactable consumer reporting for herself. A 26-years-old female patient received bnt162b2 (BNT162B2; Lot # EL0140) vaccine , via an unspecified route of administration on an unknown date in Dec2020 at single dose for Covid-19 immunisation . The patient medical history was not reported. There were no concomitant medications. The patient stated she got the first Pfizer Covid vaccine and on an unknown date in Dec2020 she tested positive for Covid 19, she also experienced nasal congestion and sore throat. The outcome of the events is unknown.

anaphylaxis; throat swelling; This is a spontaneous report from a contactable physician. A 50-year-old female patient (non-pregnant) received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 29Dec2020 at single dose for COVID-19 immunization. Medical history included hypertension, lipids (as reported) and asthma. The patient was known allergies: codeine, iodine, shellfish, latex, and cefatrizine propyleneglycolate (CEFTIN). Prior to vaccination, the patient was diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The most recent COVID-19 vaccine was administered in hospital. The patient experienced anaphylaxis and throat swelling on 22Dec2020 with outcome of recovered in Dec2020. The events were reported as non-serious. The events resulted in Emergency room/department or urgent care. Treatment of epinephrine, steroids, antihistamines, observation was received for the events. Information on lot/batch number has been requested.; Sender's Comments: A possible causal association between administration of BNT162B2 and the onset of anaphylaxis and throat swelling cannot be excluded, considering the plausible temporal relationship and the known adverse event profile of the suspect product. The underlying predisposing condition of allergies to multiple materials may put the patient at high risk of anaphylactic reactions. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of

aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

she got tunnel vision; almost passed out; Blood pressure dropped to 70/50; heart rate went up to 140; whole body got cold and tingly; whole body got cold and tingly; This is a spontaneous report from a contactable pharmacist (patient) reported for herself. A 25-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; brand: Pfizer Biotech; lot number: EL0142) via an unspecified route of administration at left arm on 30Dec2020 at 12:45 PM at a single dose (dose number: 1) for COVID-19 immunization. Facility where the most recent COVID-19 vaccine was administered was workplace clinic. Medical history included premature ventricular contractions (PVCs). No known allergies (no allergies to medications, food, or other products). The patient was not pregnant. No other vaccine in four weeks and no other medications in two weeks. The patient experienced adverse events included blood pressure dropped to 70/50, heart rate went up to 140, whole body got cold and tingly and she got tunnel vision and almost passed out. The events all started on 30Dec2020 at 12:45 PM. The events were reported as non-serious. No treatment received for events. The outcome of events was resolving. Prior to vaccination, the patient was not diagnosed with COVID-19, and since the vaccination, the patient had not been tested for COVID-19. No follow-up attempts are possible. No further information is expected.; Sender's Comments: Based on the close temporal relationship, the association between the event tunnel vision with BNT162b2 can not be fully excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

"The body aches started in his shoulder and now are all over his neck, back and whole body aches; The body aches started in his shoulder and now are all over his neck, back and whole body aches/ feeling like he has 1,000 pounds on his back; The body aches started in his shoulder and now are all over his neck, back and whole body aches; Body aches/The body aches started in his shoulder and now are all over his neck, back and whole body aches; Headache; Chills; Feel like crap; Low grade temperature; This is a spontaneous report from a contactable Nurse (patient). A 49-year-old male patient received BNT162B2 (Pfizer-BioNTech Covid-19 vaccine, lot number EL0142) intramuscularly at right shoulder approximately at 17:30 on 29Dec2020 for Covid-19 immunization. The patient's medical history included diagnosed allergies, compromised immune status, respiratory illness, genetic / chromosomal abnormalities, endocrine abnormalities (including diabetes) and obesity (a little over weight but he is fit). The patient had COVID in the end of Apr2020. The patient had no family medical history and had no prior vaccinations within four weeks. The patient had no concomitant medication. The second day of the vaccination, the patient called to report body aches, headache, chills, low grade temperature. As he reported, he just woke up and was walking around feeling like he had 1000 pounds on his back and felt like crap. The body aches started in his shoulder and currently all over his neck, back and whole body aches. Chills started last night (vaccination night). He was just trying to get to sleep and had to put an extra sweatshirt on last night. He did not check his temperature until he got up and it was 99.2 degrees

Fahrenheit. He was not able to provide a start date for the temperature. ""Body aches, headache between, chills between, low grade temperature (unspecified start date), feels like crap"" were considered developing between 24:00-01:00. He stated that they were all medically significant and he needs a day to recover hopefully. He just felt like he was hit by a truck. The patient had not visited physician or went to ER yet. The outcome of low grade temperature was unknown, chills was resolving and all other events did not resolve at the time of reporting.; Sender's Comments: There is a reasonable possibility that the events vaccination site pain, headache, chills, and pyrexia were related to BNT162b2 based on known drug safety profile. The association between the other reported events with BNT162b2 can not be completely excluded based on temporal relationship. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate."

"A nurse got Bell's Palsy after the vaccine; heart attack; This is a spontaneous report from a contactable consumer. A female patient (nurse) of an unspecified age received single dose of BNT162B2 (batch/lot number and exp date not reported), via an unspecified route of administration on an unspecified date for immunization. The patient's medical history and concomitant medications were not reported. The consumer asked if Pfizer have more information if so then what's the ingredients. States that ""injury lawyers know how many deaths because of the vaccine. Bell's palsy, a nurse got Bell Palsy after the vaccine, she is all distorted, and 30 days later, that's the 2nd one to have a heart attack."" The outcome of the events was unknown. Information on the Lot/Batch number has been requested."

2nd one to have a heart attack; This is a spontaneous report from a contactable consumer. A female patient of an unspecified age received BNT162B2 via an unspecified route of administration on an unspecified date at a single dose as Covid vaccine. Medical history and concomitant medications were not reported. After stating Pfizer has submitted a request for Emergency Use Authorization for potential COVID-19 vaccine and it was now in the FDA's hands, the reporter inquired if Pfizer had more information if so then what's the ingredients. It was then reported that the patient's the 2nd one to have a heart attack on an unspecified date. The outcome of the event was unknown. Information on the Batch/Lot number has been requested.; Sender's Comments: The association between the event heart attack with BNT162b2 can not be completely excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

"right mouth drop; right face numbness from eyebrow to below chin with right mouth drop; pins and needles feeling at injection site; then ears itching; This is a spontaneous report from a contactable nurse, the patient. A 63-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE Lot number: EK9231), via an unspecified route of administration, on 30Dec2020 at 03:45 AM (at the age of 63-years-old) as a single dose for COVID-19 vaccination. The facility where COVID-19 vaccine was administered was at a workplace clinic and anatomically located on

the right arm. Medical history included: History of Guillain Barre in 1970's with Swine Flu Vaccine. Concomitant medications included: clonidine (MANUFACTURER UNKNOWN), hydralazine ((MANUFACTURER UNKNOWN), spironolactone (MANUFACTURER UNKNOWN), pantoprazole (MANUFACTURER UNKNOWN); all for unknown indications from unknown dates and unknown if ongoing. The patient was not pregnant at the time of vaccination. Prior to the vaccination, the patient was not diagnosed with COVID-19. The patient did not receive any other vaccines within four weeks prior to the vaccination. The patient previously took unspecified medications (MANUFACTURER UNKNOWN), from unknown dates to unknown dates for unknown indications and experienced sensitivity to some medications, and unknown if ongoing. On 31Dec2020 04:15 PM, the patient reported ""'Within 30 minutes of vaccine, I had pins & needle feeling at injection site. Then ears itching followed by right face numbness from eyebrow to below chin with right mouth drop.'"" The patient did not receive any treatment for the events. The clinical outcome of the events pins & needle feeling at injection site, ears itching followed by right face numbness from eyebrow to below chin with right mouth drop, was not recovered. It was also reported that since the vaccination, the patient had not been tested for COVID-19.; Sender's Comments: A possible contributory role of the suspect products cannot be excluded for the reported events based on the temporal association."

Bell's Palsy; This is a spontaneous report from a contactable physician. A 37-year-old female patient (nurse) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot EK9231) via an unspecified route of administration on 29Dec2020 17:50 (5:50 pm) at a single dose as Covid vaccine. Medical history included hypertension and depression. Concomitant medications included venlafaxine hydrochloride (EFFEXOR); olmesartan medoxomil (BENICAR); and unspecified medications for depression and blood pressure medication (hypertension). It was reported that the reporter's nurse got her vaccine last night, about 6'o clock at night, and woke up with Bell's Palsy on Dec2020. She woke up in midnight to go to the bathroom and when she looked in the mirror, she noticed that there was discrepancy. The physician examined her this morning, so it was in several hours getting the vaccine that she noticed it. She got the vaccination last night at 5:50 pm. When she went to bed it wasn't a problem. She woke up at midnight and noticed it. The patient was started on Medrol dose pack but she hasn't taken it yet because she's at work so she would start it today (unknown if the treatment was already received); it's steroid, Methylprednisolone, at 24 mg on day one and then decreases 4 mg a day over the next five days until it's done. The doctor inquired what should the patient do about her second dose and also asked if she should not get her second dose. The outcome of the event was unknown.; Sender's Comments: Based on temporal association, the causal relationship between BNT162B2 and the event facial paralysis cannot be excluded. This case will be reassessed once additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate.

edema started in her feet and ankles and then moved 3 quarter way to her shin; 4+ pitting edema; This is a spontaneous report from a contactable nurse (patient). A 47-year-old female patient received the

first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 17Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient reported she received the Covid vaccine on 17Dec2020 and on 25Dec2020 she noticed her shoes were snug and on 26Dec2020 she noticed 4+ pitting edema lasting 3 days. She went and brought some compression stockings and this has helped the edema improve but was still mild. The edema started in her feet and ankles and then moved 3 quarter way to her shin. She would like to know if she should receive second dose of Pfizer vaccine. Outcome of the event was unknown. Information on the lot/batch number has been requested.; Sender's Comments: The reported information is limited. Based on the close temporal relationship and the description of the events, there is a reasonable possibility that the events are related to BNT162 vaccine. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

Having trouble clearing my throat, felt like it was closing up; Having trouble clearing my throat, felt like it was closing up; Uncontrollable rigors; High heart rate; Numb lips and hands; Numb lips and hands; Nausea; Shortness of breath, difficulty catching my breath; This is a spontaneous report from a contactable healthcare professional (reporting for herself). A 38-year-old female received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number EJ1685, expiry date 30Dec2020) intramuscular (Arm Left), on 30Dec2020 09:15, single dose, for COVID-19 immunization. Relevant medical history included bariatric surgery, had anterior vaginal repair and bladder sling, had gall bladder removed, and had tonsils removed. It was reported that the patient cannot take NSAIDS, patient was not allergic to them. No allergies to food or other products. Concomitant medications included rizatriptan and paracetamol (TYLENOL). On 30Dec2020, within about 10 minutes of the injection of the vaccine, the patient had trouble clearing her throat, felt like it was closing up, had uncontrollable rigors, high heart rate, numb lips and hands, and nausea. The patient was discharged from the ED, went home and took a nap. Later that evening, the patient began to have a rapid heart rate again, began to had shortness of breath, difficulty catching her breath, and was admitted to the ED again and given more IV medications. Therapeutic measures given in response to the event included administration of IV medications, epinephrine injection and breathing treatment. Prior to the COVID vaccine, the patient did not receive any other vaccines within 4 weeks, was not tested or diagnosed with COVID-19. Facility where the most recent COVID-19 vaccine was administered was in the workplace clinic. Outcome of the events was recovering at the time of the report.; Sender's Comments: Based on temporal association, the causal relationship between BNT162B2 and the events oropharyngeal discomfort, throat tightness, chills, heart rate increased, hypoaesthesia oral, hypoaesthesia, nausea and dyspnoea cannot be excluded. This case will be reassessed once additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate.

patient was noted to be flushed by residential home staff on 12/30/2020, approximately 2.5hrs after vaccination, fever present at that time. Prior to COVID19 vaccine administration, this patient did have exposure and was close contact with a known case of COVID19 in a residential care employee. Patient was taken to hospital for evaluation of febrile status, had positive COVID19 test at that time, and reported hypotension per residential care staff.

PATIENT SPOUSE REPORTS THAT PATIENT RECEIVED VACCINE ON 1/4/2021 AND ON 1/5/2021 PATIENT'S ARM BEGAN TO TURN RED AND SWELL AT THE INJECTION SITE. THE SWELLING AND REDNESS BEGAN TO GO DOWN HIS ARM AND HE BROKE OUT INTO A RASH. PATIENT THEN BECAME SHORT OF BREATH. EMS WAS CALLED AND PATIENT WAS TRANSPORTED TO HOSPITAL, WHERE HE WAS TREATED FOR ANAPHYLACTIC SHOCK TO THE COVID MODERNA VACCINE.

Anaphylaxis Narrative: 12/22 received COVID-19 vaccine at 1209 and developed SOB at 12:15. Took her own albuterol inhaler without relief. Transported to ED. PE: red hands with swelling, throat and lip swelling with difficulty swallowing. Later developed headache and dizziness then tachypnea and stridor. Meds given - See section 5 PLUS epinephrine IM and infusion @ 0.05 mcg/kg/min, Alb and ipratropium negs, racemic epi nebs. Admitted to the hospital on 12/22 and still hospitalized at the time of this report on 12/23. She remains on an epinephrine drip and was given methylprednisolone 125 mg IV x 2. No previous history of anaphylaxis. History of Reye's syndrome as a child when given aspirin.

Agitation, Sedation, Anaphylaxis, Rash & HYPOtension

"covid; covid; This is a spontaneous report from a contactable physician. A male patient of an unspecified age received single dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, batch/lot number and exp date not reported), via an unspecified route of administration on an unspecified date for immunization. The patient's medical history and concomitant medications were not reported. The physician inquired whether a person with previous history of COVID would experience more significant reaction to the COVID vaccine than a person without a previous diagnosis due to having already produced antibodies. Reporter's colleague (physician) had the vaccine 2 weeks ago, had a severe reaction (unspecified) wherein he got a shot of epi. Patient recovered and was okay. At the time of reporting, patient now had Covid or maybe he had Covid before, reporter was not sure. The outcome of the events was unknown. Information on the Batch/Lot number has been requested.; Sender's Comments: Based on available information, a possible contributory role of suspect BNT162B2 vaccine cannot be completely excluded for event ""Covid""."

positive COVID-19 test with symptoms; positive COVID-19 test with symptoms, tested for COVID (PCR); night sweats; Soreness at injection site; slight temp 99.5 degrees/her temperature was 101 degrees Fahrenheit/it was 102.5 degrees Fahrenheit/99 degrees Fahrenheit and then 98 degrees Fahrenheit; Tiredness she related to giving blood; This is a spontaneous report from a contactable nurse (patient). A 54-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL0140) via intramuscular on 19Dec2020 15:45 on left deltoid at a single dose for prevention as frontline health worker at hospital (COVID-19 immunisation). The patient donated blood on 18th and no antibodies were present then. The patient was a former smoker and quit 2 or 3 years

ago. Patient diagnosed Osteoporosis in 2015, benign heart arrhythmia in 2005. The patient took 70 mg alendronate sodium (FOSAMAX) once weekly and just a regular OTC daily multivitamin. Caller reported she was having the covid vaccine on 19Dec2020 and began having fever, night sweats, loss of taste and smell and then tested positive for covid. The patient received the Pfizer COVID 19 vaccine through work on 19Dec2020. She received it at 3:45 pm and should have taken temperature before, but she was afebrile the day before because she donated blood. At 7pm, she had slight temp 99.5 degrees Fahrenheit and by 10:30, her temperature was 101 degrees Fahrenheit and she still felt fine. She was surprised that it was that. She woke up at 2:30 am on 20Dec2020 and took her temperature and it was 102.5 degrees Fahrenheit. She took 2 Tylenol and went back to bed and felt fine. By morning it was 99 degrees Fahrenheit and then 98 degrees Fahrenheit a little later. She has been afebrile since then. She was a little tired because she gave blood and though it was related. She does not know if it was a side effect or not. It was not significant tiredness and was just not having energy in the evening of 19Dec2020. She also had soreness at injection site that night after 22:00 and the next day. It did not bother her until she woke up in the middle of night, and she noticed her left arm was sore. She received the vaccine at 3:45pm and started with low grade fever at 6:30 pm, earlier stated at 7:00 pm. There was no prescriber. She tested for COVID (PCR) on Saturday, 26Dec2020 at 14:50and it came back positive 28Dec2020 18:45. At 10pm on 19Dec2020, her temperature was 101 degrees Fahrenheit. If she had not been monitoring her temperature, she would not have known. She has been Afebrile since morning of 20Dec2020. Tiredness she related to giving blood and the holidays. She was a little stressed about the holidays and running around. It was very mild. Soreness at injection site was during the night after 10pm when she went to bed. On Wednesday, 23Dec2020, she woke up congested, sniffly, sneezy, with a runny nose. This persisted through Wednesday night. Her sense of taste was off. She had no problem with that on Tuesday. She had some horrible smell at work she recalled, so she knew her sense of smell was fine. On Thursday, 24Dec2020, she had no sense of taste or smell. She could not smell a pine candle. She was congested on Thursday and called employee health on 24Dec2020. This both improved and persisted. She is still congested but it has improved. She has never had a complete loss of sense of taste or smell before. Mild cough started yesterday morning. On the night of 20Dec2020, and 21Dec2020, she developed night sweats. She had not had any night sweats before this since menopause and she woke up really wet. The patient was not hospitalized and not admitted to an Intensive Care Unit. NO ER or physician's office required. She did not know if she was exposed on the day of the vaccine or if a couple of days later if the fever is from the vaccine. She stated what are the chances she goes 10 months and is super careful and then gets the vaccine and test positive. The patient did not display clinical signs at rest indicative of sever systemic illness. The patient did not require supplemental oxygen nor receive mechanical ventilation. No Multiorgan failure. The patient did not receive any additional therapies for COVID- 19. No initiation of new medication or other treatment or procedure. Not any preexisting diseases worsen during the SARS-CoV2 infection. She would like to know if there is a chance of false positive for this. It would just be her luck to be 10 months and not getting it. She has not gone anywhere without her N95 and then gets the vaccine and gets COVD. She wears mask and face shield at work always. She also wanted to know if she should get the second dose. The outcome of the event slight temperature was recovered on 20Dec2020 and the other event was recovering.; Sender's Comments: Based on the information currently available, a lack of efficacy with the suspected vaccine BNT162B2 in this patient cannot be completely excluded.

tested positive for Covid two days after getting vaccine; tested positive for Covid two days after getting vaccine/nasal swab/ NP PCR and result was positive; This is a spontaneous report from a contactable physician. A 39-years-old male patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number and expiration date not reported), intramuscular on the left arm on 24Dec2020 at 08:30 at a single dose for Covid-19 immunization. There were no medical history and no concomitant medications. The patient has no known allergies to medications, food, or other products. On 25Dec2020 at 09:00 am, also reported as 26Dec2020, the patient was tested positive for Covid two days after getting vaccine. He was wondering if he should get the booster dose in 3 weeks or not since he will have natural immunity. The patient did not receive any treatment for the events. The patient had a nasal swab/ NP PCR and result was positive on 26Dec2020. The outcome of the events was not recovering. The events were assessed as non-serious. Information on the lot/batch number has been requested.; Sender's Comments: No effect of the suspect vaccine could be reasonably achieved to protect from the targeted infection/disease due to the very short time lag. Instead, the COVID-19 PCR test positive represents the pre-existing infection prior to vaccine use. Further information like confirmative COVID 19 nucleic acid/ PCR test together with any associated symptoms are needed for full medical assessment.

positive COVID-19 test with symptoms; positive COVID-19 test with symptoms; This is a spontaneous report from a contactable unspecified HCP reporting for herself. This 61-year-old female patient received on 22Dec2020 BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) at single dose for COVID-19 vaccination. Medical history and concomitant medications were not reported. On 24Dec2020, the patient had a bad reaction, coughing, headache, no taste, tiredness and body aches. The patient thought originally, she was having a reaction to the vaccine, and took some ibuprofen (ADVIL). The patient was still congested and was sent for testing. She was tested positive on 28Dec2020. The test was a nasal swab. Outcome was unknown. The patient was wondering if this was part of the side of effect of the vaccine. Information on the batch number has been requested.; Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of events Drug ineffective and COVID-19 cannot be totally excluded. The case will be reassessed if additional information becomes available.

got the COVID-19 vaccine last week and six days later tested positive for COVID-19; got the COVID-19 vaccine last week and six days later tested positive for COVID-19; This is a spontaneous report from a contactable pharmacist. A patient of unspecified age and gender received bnt162b2 (BNT162B2 also reported as PFIZER-BIONTECH COVID-19 VACCINE, lot/batch number and expiry date were not reported), via an unspecified route of administration on unspecified date in Dec2020 at single dose, for covid-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient got the covid-19 vaccine last week and six days later (Dec2020) tested positive for Covid-19. The outcome of event was unknown. Information about Lot/Batch number has been requested.; Sender's Comments: The information currently provided is too limited to make a meaningful medical assessment hence, the events are conservatively assessed as related to the suspect drug BNT162B2 until further information becomes available.

anaphylaxis; ALOC/decreased level of consciousness; This is a spontaneous report from a contactable Pharmacist (patient). a 40-year-old female patient (no pregnant) received first dose BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number EL0140) via intramuscular at Left arm on 23Dec2020 at single dose for COVID-19 immunization. The patient's medical history included known allergies to egg, seafood, azithromycin, orange and seasonal allergies. The concomitant was reported as cetirizine hydrochloride (ALLERTEC) and PRN 1371. The patient with no known past medical history brought in by CODE Team to RUH ED with concern for ALOC after getting the COVID vaccination 30-40 minutes PTA. Patient was a nurse and experienced decreased level of consciousness following her COVID vaccination. Patient reports h/o anaphylaxis. She was given epinephrine PTA. Denies SOB, oral swelling, CP. Blood glucose (BGL) within normal limits. Patient denies any other complaints or symptoms at this time. Adverse event start date: 23Dec2020. Treatment was unknown for decreased level of consciousness. The outcome of the events was recovered in Dec2020.; Sender's Comments: A possible causal association between administration of BNT162B2 and the onset of anaphylaxis /decreased level of consciousness cannot be excluded, considering the plausible temporal relationship and the known adverse event profile of the suspect product. The underlying predisposing condition of allergies to multiple materials may put the patient at high risk of anaphylactic reactions. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

"caller couldn't hear properly; got the Covid vaccine last 18Dec2020/her second dose of COVID-19 Vaccine was scheduled on 06Jan2021; Caller got the Covid vaccine last 18Dec2020 and was tested positive, 29Dec2020; Caller got the Covid vaccine last 18Dec2020 and was tested positive, 29Dec2020; Nausea; Headache; Body aches; fatigue; Cold sweat; This is a spontaneous report from a contactable other health professional. A 51-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number reported as either EK5730, ER5730, or EX5730), via an unspecified route of administration on 18Dec2020 16:00 at single dose at left deltoid for COVID-19 immunisation. Medical history and concomitant medications were none. The patient previously had shingles shot in Sep2020, previous shingles shot either three months or six months prior to the one in Sep2020 (2020), both for immunization, and severe myalgia and fever that lasted for two days after the second shingles shot (adverse events followed prior vaccinations). It was reported that did a callback as caller couldn't hear properly. Caller got the Covid vaccine last 18Dec2020 and was tested positive, 29Dec2020. Want to know if it's safe for her to get the second dose. The patient received Pfizer COVID-19 Vaccine on 18Dec2020 at 16:00. Patient had a couple days worth of symptoms. Now patient had COVID. Patient believed most likely got COVID from her son who was home from college. She was in between dosages of COVID-19 Vaccine. Looked like from research her quarantine would be done on 05Jan2021 and her second dose of COVID-19 Vaccine was scheduled on 06Jan2021. Everything she had read stated if her symptoms were gone to go ahead and get the second COVID-19 Vaccine. Patient wanted to know if Pfizer was doing any studies regarding people who test positive for COVID after receiving the COVID-19 Vaccine. Not sure if Pfizer would be interested in doing antibody studies. Declined obtained COVID-19 Vaccine through work Clarified caller's days worth of symptoms as: Headache the same evening as

vaccination. Body Aches: began overnight on 18Dec2020. Fatigue that lasted all week, began overnight on 18Dec2020. Cold sweats: Lasted two days and began overnight on 18Dec2020. Nausea: began on 21Dec2020, not sure if it was related to COVID-19 Vaccine or not. The reporter considered the events weren't serious, but felt like she was having an immunological response. Diagnosed with COVID Seriousness: As of now, not serious. Is having a recurrence of all of those same symptoms as the COVID-19 Vaccine and then some. Lot number provided from patient card. Stated she was unable read it accurately. would take picture in case Pfizer wanted it. Stated lot number was either EK5730, ER5730, or EX5730. A sample of the product was not available to be returned. Vaccination facility type was Hospital, not administered at military site. No additional vaccines administered on same date of Pfizer suspect. No adverse events required a visit to. No prior vaccinations received within 4 weeks. The outcome of the event ""Cold sweat"" was recovered on 20Dec2020. The outcome of the other events was unknown. The reported considered the events Headache, Body aches, fatigue, Cold sweat, Nausea were related to the suspect drugs. Information on the lot/batch number has been requested.; Sender's Comments: The reported COVID test positive after COVID-19 immunization is considered ineffective of BNT162B2, and the Company cannot completely exclude the possible causality between the reported event and BNT162B2 administration."

had her shot of Covid vaccine last (22Dec2020) 7 days and was tested positive on Dec2020; had her shot of Covid vaccine last (22Dec2020) 7 days and was tested positive on Dec2020; This is a spontaneous report from a contactable consumer (patient). A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 22Dec2020 at a single dose as Covid vaccine. Medical history and concomitant medications were not reported. It was reported that the patient had her shot of Covid vaccine last (22Dec2020) 7 days and was tested positive on Dec2020. She wanted to know if this was normal to get false positive results after getting the vaccine. The outcome of the events was unknown. Information on the lot/batch number has been requested.

Positive for Covid after receiving the vaccine; Positive for Covid after receiving the vaccine; This is a spontaneous report from a Pfizer Sponsored Program. This consumer reported similar event for two patients. This is the 2nd of 2 reports. A female patient of an unspecified age received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number and expiration date not reported), via an unspecified route of administration on 22Dec2020 at a single dose for Covid-19 immunization. The patient medical history and concomitant medications were not reported. On an unspecified date, the patient was positive for Covid after receiving the vaccine. It was reported that patient was positive and they were all in the breakroom without a mask. The patient (person that is positive) got the vaccine and got worse, so co-workers are thinking that she (patient) had the virus before getting the vaccine and just didn't have any symptoms. Outcome of the events was unknown. Information on the batch/lot number has been requested.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2020518090 same reporter/drug, similar event, different patient

Asymptotic positive rapid COVID test 12 days post vaccination. Close contact testing/Nasal Swab positive; Asymptotic positive rapid COVID test 12 days post vaccination. Close contact testing/Nasal Swab positive; This is a spontaneous report from a contactable Other HCP (patient). A 52-year-old

female (not pregnant) patient received first dose bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EK5730), intramuscular in arm left on 17Dec2020 13:15 at single dose for COVID-19 immunisation. Medical history included seasonal allergies, depression and Allergies: Sulfa. Prior to vaccination, the patient was not diagnosed with COVID-19. Concomitant medications included sertraline hydrochloride (ZOLOFT), cefixime (FLEXERIL), fluticasone propionate, salmeterol xinafoate (ADVAIR), montelukast sodium (SINGULAIR), omeprazole (PRILOSEC). The patient previously took pethidine hydrochloride (DEMEROL) and experienced 'allergies: Demerol', codeine and experienced 'allergies: codeine'. The patient experienced asymptotic positive rapid COVID test 12 days post vaccination. Close contact testing on 29Dec2020. The patient underwent lab tests and procedures which included [{covid test type post vaccination= Nasal Swab, covid test date=29Dec2020, covid test result= Positive}]. Facility type vaccine was workplace clinic. No treatment received for the adverse event. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The outcome of the events was unknown.; Sender's Comments: Based on the information currently available, a lack of efficacy with the suspected vaccine BNT162B2 in this patient cannot be completely excluded.

"I got the Pfizer vaccine, the first shot; I tested positive for Covid; I got the Pfizer vaccine, the first shot; I tested positive for Covid; This is a spontaneous report from a contactable consumer (patient). A patient of unspecified age and gender received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EH9899), via an unspecified route of administration on 18Dec2020 at single dose for covid-19 immunization. The patient medical history and concomitant medications were not reported. Consumer stated, ""I had a question, I got the Pfizer vaccine, the first shot on the 18Dec but I tested positive for Covid on the 27Dec, so, my question is this and I asked my healthcare institution and they still haven't got back to me, so I just wanted to call you guys, what do I do about the second dose because I am scheduled to get the second dose net week?"" The outcome of event was unknown."

she received the COVID Vaccine on the evening of Christmas, and then she tested positive for COVID on Sunday; she received the COVID Vaccine on the evening of Christmas, and then she tested positive for COVID on Sunday; This is a spontaneous report from a contactable consumer, the patient. A 48-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE); in the left arm on 25Dec2020 as a single dose, for COVID-19 immunization. The patient had no known medical history. There were no concomitant medications. Caller confirmed the product was not specifically prescribed to her, but she received it via an options at her company and had received no other vaccines on the same day as the COVID vaccine. The patient received the COVID Vaccine on the evening of Christmas 25Dec2020, and then she tested positive for COVID on Sunday, 27Dec2020. The patient had a positive SARS-CoV-2 test on 27Dec2020. The clinical outcome of the event Drug ineffective and COVID-19 was unknown. Information regarding lot number has been requested.

tested positive for COVID; tested positive for COVID; This is a spontaneous report from a contactable consumer (patient). The consumer reported for self and husband. This is the first of two reports, and concerns the reporter (patient). A patient of an unspecified age and gender received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE) (lot number EJ1685/expiration date: 31Mar2021), via an unspecified route of administration, on 19Dec2020, as a single dose for COVID-19 immunization. Relevant medical history and concomitant medication were not provided. On an

unspecified date in Dec2020, the patient tested positive for COVID. The outcome of the event tested positive for COVID was unknown.

tested positive for COVID; tested positive for COVID; Flu; This is a spontaneous report from a contactable consumer. The consumer reported for self and husband. This is the second of two reports and concerns the reporter's husband. A male patient of an unspecified age received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE) (lot number EH9899/expiration date: not provided), via an unspecified route of administration, on 18Dec2020, as a single dose for COVID-19 immunization. Relevant medical history and concomitant medication were not provided. On an unspecified date in Dec2020, the patient experienced the flu after receiving the vaccine. On an unspecified date in Dec2020, the flu symptoms went away and the patient tested positive for COVID. The outcome of the event flu was recovered in Dec2020 and the outcome of tested positive for COVID was unknown.

Caller received COVID vaccine on the 18th then tested positive on the 24th; Caller received COVID vaccine on the 18th then tested positive on the 24th; This is a spontaneous report from a contactable healthcare professional. A female patient of an unspecified age received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiry date not reported), via an unspecified route of administration on 18Dec2020 at single dose for COVID-19 immunisation. Medical history and concomitant medications were not reported. It was reported that the patient received COVID 'vaccine on the 18th then tested positive on the 24th'. The reporter mentioned that a friend who works for Pfizer told her to call and report. Clinical outcome of the events was unknown. Information on batch/lot number was requested.; Sender's Comments: Based on the information available, a possible contributory role of the suspect products cannot be excluded for the reported event of positive for corona virus infection for the lack of efficacy of the vaccine. However, based on the mechanism of action of the vaccine, it is unlikely the patient would have fully developed immunity for the vaccine to be effective, due to the short duration of 6 days since the vaccine first dose is given.

Was diagnosed with the COVID-19 virus after receiving the COVID-19 Vaccine on 18Dec2020; Was diagnosed with the COVID-19 virus after receiving the COVID-19 Vaccine on 18Dec2020; This is a spontaneous report from a contactable Other Health Professional (patient) from a Pfizer-sponsored program IBCC (Inbound Call Center for HCPs). A 38 years old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 18Dec2020 at single dose in Deltoid Right for COVID-19 immunization. Medical history and concomitant medications were none. After receiving the COVID-19 Vaccine, the patient was diagnosed with the COVID-19 virus on 28Dec2020. she saw Dr. at the clinic where she works to seek treatment. She stated she is supposed to receive the 2nd dose of the COVID-19 Vaccine on 08Jan2021. She asked now that she is COVID-19 positive, should she get the 2nd COVID-19 Vaccine dose. Reported she had a rapid nasal swab COVID-19 test performed. Reported she is taking Hydroxychloroquine and a bunch of vitamins for treating COVID-19. Caller stated she did not have the COVID-19 Vaccine card with her to provide the Lot Number. The patient underwent lab tests and procedures, which included COVID-19 rapid POC test with positive result. Outcome of event was unknown. Information on the Batch/Lot number has been requested.; Sender's Comments: Based on the information available, a possible contributory role of the suspect

BNT162B2 cannot be excluded for the reported COVID-19 based on the known safety profile. However the short duration of 10 days since the vaccine first dose is given it is unlikely patient would have fully developed immunity.

"Lost sense of taste; Lost sense of smell; Whole body is sore; Rapid test came back positive for COVID; Rapid test came back positive for COVID; This is a spontaneous report from a Pfizer-sponsored program IBCC (Inbound Call Center for HCPs) via a contactable consumer (patient). A 21-year-old male patient received his first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number: EK5730, expiration date: 31Mar2021), via intramuscular on 29Dec2020 07:40 at 0.3 mL, single dose on his left deltoid for covid-19 immunization. Medical history included allergic to wasp stings. There were no concomitant medications. The patient had no additional vaccines administrated on the same date and no prior vaccinations were received within 4 weeks. Caller on the line calling about the COVID Vaccine he received on 29Dec2020. The day after receiving it he woke up and had a loss of sense of smell on 30Dec2020 12:00. That afternoon he went to get tested and the rapid test came back positive for COIVD on 30Dec2020. He was now waiting on the other one, clarified to be the PCR test, the lab test. The next day he also lost his sense of taste on 31Dec2020 11:00 and his whole body feels sore on 30Dec2020 around noon. Transfer agent stated the caller needs to be transferred to Medical Information as he was scheduled to get the next shot on 19Jan2021 and he was calling to ask if he should proceed with that. It was reported that the patient works in a hospital (not an HCP). No emergency room was visited and no physician office was visited. The outcome of the event ""rapid test came back positive for covid"" was unknown, the outcome of the other events ""lost sense of smell"", ""lost sense of taste"", ""whole body is sore"" were not recovered."

Went to the ER on the 31st, my face swelled and chest was covered in hives. Lips swelled. I would get nauseated and I felt like there was acid in my stomach. I also had a headache. I have been taking Zyrtec, Benadryl as needed.

The day after the vaccine I had fatigue and body aches. Then on 12-23 fevers of 101.4, chills, body aches, diarrhea, vomiting, productive cough, and profuse sweating. Jan 1st I was in the shower and was dizzy with a headache. Loss of consciousness almost happened and that is when i got out of the shower and laid down. Went to the ED and was diagnosed with bilateral pneumonia

I did let the nurse know right after I got the vaccine It did feel like a huge water balloon was sitting on my arm and very heavy at the site. I went to the waiting area and the last 5 minutes and I started feeling weird, kind of getting dizzy and my heart started racing really fast. Am I can tell I was getting really hot and my face was flushed and my heart was racing and my hands started shaking, trembling almost like I couldn't control it. I've never experienced something like this. The part that really scared me was my heart racing like it was going to come out of my chest. They called a code, put me in a wheel chair and took me to the ER (where I work). They took my blood pressure which was really high, they did EKG, blood work and urine test. They kept me there for about five hours, while watching me. And the last weird thing that happened at one point I felt like liquid was running thru my body and my feet were really cold for several hours, It felt like someone was pouring liquid over me. I kept asking the nurse if this is normal and no one knew what to tell me. After everything started slowing back down and it had

been a couple hours and the next day i felt like I had a slight head ache and felt out of it, kind of like I had a hangover and of course my arm was really sore. The Doctor in the ER did advise me not to get the second dose as it will be worse than the first one.

LEFT SIDED CHEST PAIN, SHORTNESS OF BREATH, FELT WARM AND FLUSHED

I got my shot on the 19th and that evening it was like a light switch and I was so tired I went to sleep at 730pm I had severe chills and fever and had to go to bed. The next day I still wasn't feeling well and I was called in to get covid tested and I went to the ER on the 21st and took a rapid covid test that was positive. I was stable and had good oxygenation and was discharged. I have fever nausea vomiting I also had problems with O2 stat i was in the 80s and realized I was having respiratory failure so I was admitted on the 27th and I've been here ever since. I had kinetic storm and infusions my O2 stats were bad and I was sent to the covid unit and put on high flow oxygen and negative for a PE, I'm still on the covid unit but I feel much better today

Patient was vaccinated Dec 30, 2020. Prime dose of Moderna vaccine. Observed for full 15 minutes post-injection. No complaints when asked during observation. Released. Subsequently, vaccine clinic staff learned from the patient's supervisor that on Jan 4, 2021 that the patient had expired on Jan 2, 2021. By report from the supervisor, the patient was found dead at his home. The patient's primary care provider was unaware of his death when contacted by this reporter today (Jan 6, 2021). Electronic Medical Record without any information since the vaccination.

5 MIN POST ADMINISTRATION: SOB, DIZZINESS, CHANGE IN VISION - GAVE BENADRYL 25 MG AND 1 VIAL ALBUTEROL VIA NEB 1 HOUR POST ADMINISTRATION: SWOLLEN LIPS, RASH ON CHEST AND ARMS - GAVE 1 DOSE OF EPI PEN AND IM SOLU-MEDROL, CALLED EMS, LEFT TO GO TO ER BP, HR, OXYGEN STABLE THROUGHOUT

after 20-30 minutes my throat started to get tight, I could not swallow properly, I felt dizzy & my heart was beating fast.

anaphylaxis, dyspnea

"Client received vaccine at approximately 3:50pm, waited in observational area x30min. Left with husband, stated that she got a few miles down the road and starting experiencing tightness in her chest and flushing. She took 50 mg of Benadryl, 30mg of prednisone and two puffs on her inhaler. She returned to the clinic, upon assessment from nursing she looked extremely flushed and anxious, she stated that she still felt tightness and that she had a history of anaphylaxis once before and had used an epi pen in the past. She had an epi pen with her and questioned whether or not she should give it to herself. BP was 190/68, pulse was normal, respirations normal, she continued to experience tightness and ""not able to catch my breath"", encouraged to use epi pen. She administered epi pen to right thigh at approximately 4:45PM, 911 called. Within a few minutes, she stated she was feeling better, less tightness in the chest, flushing was subsiding. BP at 190/70 at 4:52. EMS on scene at 5:03pm. Vitals normal , EKG normal. Client decided not to transport with EMS."

resident expired 1/1/2021

I started having intermittent chest pain moderate in intensity and palpitations.

Resident expired 1/3/21

Migraines, right side of face swollen, nausea, tingling

Patient tolerated the vaccine well with no apparent side effects. Ten days later awoke 12:30 AM with severe chest and upper back pain, presented to Med Center where he was found to have an Acute Coronary Syndrome. Transferred to Medical Center where he underwent successful PCI with two drug eluting stents for a 99% mid-LAD stenosis

Shortness of breath, fever, fatigue

At around 11:40am resident was observed to be unresponsive. resident noted with pulse and respiration. Not in any distress. lung sounds clear. Vital Signs BP162/82 P86 R18 T97.1 O2 Sat 96%, fingerstick is 133mg/dl .Resident received COVID 19 vaccine at 11:25am. O2 via 2l NC initiated. Nurse Stat call, 911 initiated, MD at Bedside. Resident awake and responsive. EMT responded and resident left with EMT to be transferred to hospital, remains awake and not in any respiratory distress.

Adult failure to thrive; Chronic hypoxemic respiratory failure; Generalized weakness

Patient did not display any obvious signs or symptoms; the vaccination was administered at approximately 10:00 AM and the patient continued throughout her day without any complaints or signs of adverse reaction. Patient was helped to bed by the nursing assistant estimated at around 9:00 PM. The facility received notification from the lab around 11:00 PM that the patient's COVID-19 specimen collection from Sunday, 1/3/21, detected COVID-19. When the nursing staff went to the room to check on the resident and prepare her to move to a COVID-19 care area the patient was found unresponsive, no movement, no chest rises, noted regurgitated small amount of food to mouth left side, lying on left side. Pupils non reactive.

coughing up blood, significant hemoptysis -- > cardiac arrest. started day after vaccine but likely related to ongoing progression of lung cancer

PATIENT REPORTING ITCHING AT 30 MINUTES POST INJECTION. AT 1.5 HOURS POST INJECTION PATIENT REPORTED ITCHY THROAT AND NUMBESS OF LEFT SIDE OF FACE. AT THAT TIME ADVISED TO GO TO EMERGENCY ROOM. NEXT DAY WHEN I FOLLOWED UP WITH PATIENT, SHE REPORTED HER AIRWAY STARTED TO CLOSE AND SHE RECEIVED EPINEPHRINE, AFTER 5 HOURS HER STARTED TO CLOSE AGAIN AND RECEIVED ANOTHER DOSE OF EPINEPHERINE, WAS RELEASED FROM HOSPITAL ROUGHLY 15-16 HOURS AFTER GOING TO ER.

At 10:12 am, Client c/o of sore throat, tightness in throat that relieve quickly, nausea, dry heaves, flushed, light headed and dizziness. Called for EMT. They arrive at 10:25 am and transported her to the

local hospital for observation. 01/06/21-Treatment in hospital blood draw, medications given Zofran, Decadron, Benadryl, and Pepcid, and IV fluids. Discharged home at 1244.

5 minutes after injection, my feet and palms itched and I was lightheaded but I tried to shake it off and it faded over the next 10 minutes. I did report it and stayed longer and was ok. Then i went straight home and layed down because i did not sleep well night before (was on call) i awoke 1 hour post injection dry heaving, very nauseated, mild headache, achy, itchy over different parts of my body and weak. Sat up and my face was getting itchier, lips started to swell, tongue started to swell and itch, throat felt like someone was strangling me, had trouble swallowing and trouble breathing. took 2 benadryls immediately and went out into cold air, thought about calling 911 but got better in 10-15 minutes. never have had a reaction like this in my life. have had hives though in the past. If I would have had an epi pen I would have used it (never have had an epi pen) I was frightened but the benadryl worked and I slept due to the benadryl for 5 hours, when I woke up the benadryl wore off and it started again. took more benadryl, and it improved. before bedtime, the benadryl wore off and I had a hard time swallowing my night time meds like my throat was swollen. Took 2 more benadryls, today I am weak and nauseated and ate very little and feel like my face is still red and itchy. I told my sister and she said she is allergic to PEG which i later noted was in the vaccine. i am very disappointed that I had this reaction- I have desparately wanted this vaccine as a medical worker with a lot of covid patients- I onlu hopr this one shot will protect me enough because it is clear to me that i cannot take this vaccine again.

Severe Hypotension, Redness, Warmth and sensitivity all over skin surfaces, lack of responsiveness, low oxygen saturation.

At approximately, 1855, I was alerted by caregiver, resident was not responding. Per caregiver, she was doing her rounds and found resident in bed, unresponsive, mouth open, observed gurgling noises and tongue hanging out of mouth. This primary caregiver observed resident at baseline and ambulating after dinner at approximately, 1800 less than an hour prior to incident. This PCG called 911 for EMS and gave report of incident. Resident was taken to Medical Center Emergency Department. At ER, CT scan and X-ray was performed. Per report from ER RN, CT scan and x-ray revealed an intracranial aneurysm and fluid in the lungs. Per RN, resident was still unresponsive and was admitted to Medical Center for observation and comfort measures. This primary caregiver reported to RN, resident recently received the first dose of COVID-19 vaccine on 1/2/21. Primary caregiver received a call from Castle RN at 0700, resident expired at 0615.

Three to four hours after vaccine had bruising, major loss of range of motion, severe sharp pain, elevated temp and chills due to reaction of injection site Treatment given 24 hrs later- strong antibiotics, anti inflammatory, exercise, and three days out of work Due to loss of function of left arm due to inflammation

Severe shortness of breath, administered inhaler, hydralazine with no improvement. Dr. notified. Sent to ER

COUGH, RIGORS, NAUSEA, VOMITING, URINARY URGENCY/FREQUENCY, DYSURIA - FOUND TO HAVE LLL PNEUMONIA, CONCERNING FOR POSSIBLE CYRPTOGENIC ORGANIZING PNEUMONIA

PATIENT DEVELOPED PROGRESSIVE NEW DYSPNEA, DIFFERENT FROM HER BASELINE. SHE HAS BEEN HOSPITALIZED TWICE FOR PERSISTENT DYSPNEA AND CENTRALIZED CHEST PAIN, WHICH HAS OTHERWISE HAD NEGATIVE WORK UP.

103.5 Fever that wouldn?t come down with Tylenol, chills, sharp headache, tachycardia, site pain, dizziness, body aches, nausea All symptoms started 11 hours after first dose of vaccine (3AM), went to hospital 15 hours after symptoms started and was treated for 9 hours until all symptoms abruptly stopped

positive COVID test; positive COVID test; fever; chills; sore throat; cough; nasal congestion; runny nose; little diarrhea; tiny bit of shortness of breath; Caller received the COVID-19 vaccine on 17Dec2020 and is scheduled to take the second dose on 5Jan2021.; Caller received the COVID-19 vaccine on 17Dec2020 and is scheduled to take the second dose on 5Jan2021.; sore arm; This is a spontaneous report from a Pfizer-sponsored program Pfizer First Connect via a contactable physician (patient himself). A 56-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Lot number: EH9899), via intramuscular route on 17Dec2020 at single dose (dose 1, left deltoid) for COVID-19 immunization. The patient medical history included non-smoker. Concomitant medications were reported as none. The patient was scheduled to take the second dose on 05Jan2021, also reported as 08Jan2021. The patient experienced sore arm for 24 hours afterwards on Dec2020. Patient experienced mild COVID symptoms such as fever, chills, sore throat, cough, nasal congestion, runny nose, little diarrhea, and tiny bit of shortness of breath on 24Dec2020, but stated he was better now. The patient was positive in the COVID test on 28Dec2020. He wanted to know if it was normal to get COVID after getting the vaccine and if he should get the booster shot if he gets better. He commented that testing positive for COVID was medically concerning. The patient did not require supplemental oxygen (including high flow ECMO) or receive a mechanical ventilation. Treatment included over the counter medication. No additional testing was done. The patient was not hospitalized. Outcome of the event sore arm was unknown; cough was not recovered; fever, chills, sore throat, nasal congestion, runny nose, little diarrhea, tiny bit of shortness of breath was recovering. No follow-up attempts are needed. Information about lot/batch number was already obtained. No further information is expected.; Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of events Drug ineffective and COVID-19 virus test positive cannot be totally excluded. The case will be reassessed if additional information becomes available.

2days after my 1st Covid vaccine I broke out into a rash with hives requiring me to go to the ER; 2days after my 1st Covid vaccine I broke out into a rash with hives requiring me to go to the ER; This is a spontaneous report from a contactable nurse (patient). A 58-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot/batch number: EH9899, expiry date was not provided) solution for injection, via an unspecified route of administration on left arm on 17Dec2020 08:00 at a single dose for Covid-19 immunization. Medical history included eczema, chronic kidney disease, thyroid disease. Patient had known allergies. The patient was not pregnant. Concomitant medications included apixaban (ELIQUIS), allopurinol (ALLOPURINOL), levothyroxine (LEVOTHYROXINE), iron (IRON), magnesium (MAGNESIUM). The patient reported that 2 days after her 1st Covid vaccine,

she broke out into a rash with hives requiring her to go to the ER on 19Dec2020 12:00. She also visited a physician. She was treated with steroids, Atarax, and Epi shot. The events were reported as non-serious. Outcome of the events was not recovered. No follow-up activities are needed. No further information is expected.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the reported events of urticaria and rash due to temporal relationship. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

tested positive within 2-4 days of the vaccine; tested positive within 2-4 days of the vaccine; This is a spontaneous report from a contactable nurse. This nurse reported similar events for two patients. This is the first of 2 reports. A patient of unspecified age and gender received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date not reported), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The nurse had questions about patients that received the first dose of the COVID 19 vaccine. One patient tested positive within 2-4 days of the vaccine and this patient had a known exposure to a COVID positive person. The nurse wanted to know if this patient should receive the second dose. The outcome of the events was unknown. Information about batch/lot number has been requested.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the reported events of SARS-CoV-2 test positive and LOE due to temporal relationship. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.,Linked Report(s) : US-PFIZER INC-2020520414 Same reporter, drug, and events; different patients

Tested positive for COVID; Tested positive for COVID; This is a spontaneous report from a contactable healthcare professional (patient). A 40-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899), via an unspecified route of administration on 18Dec2020 at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient received the first dose of the vaccine on 18Dec2020, and was tested positive for COVID yesterday, 29Dec2020. States that she knows she only has had the first dose and states her exposure level was high, states that she cannot believe she made it this far before testing positive. Second dose scheduled for 08Jan2021, wanting to know if she should get the second

dose since she was now positive. The outcome of the events was unknown.; Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of events Drug ineffective and COVID-19 virus test positive cannot be totally excluded. The case will be reassessed if additional information becomes available.

positive Covid results with symptoms; positive Covid results with symptoms; This is a spontaneous report from a contactable nurse (patient). A 56-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date not reported), via an unspecified route of administration on 20Dec2020 at single dose for COVID-19 immunization. Medical history included hypertension (diagnosed 3-4 years ago), hyperlipemia (diagnosed 3-4 years ago), supraventricular tachycardia since 2017, and asthma; all ongoing. Family history included hypertension. She has no history of adverse reactions or allergies to any vaccines received previously. The patient's concomitant medications were not reported. The patient explains that she got the COVID-19 vaccine on 20Dec2020. Afterward she had some coughing, so she went for a rapid test and found she tested positive after the vaccine. The patient was wondering if this has been reported previously, where someone tested positive after getting the vaccine. She has never tested positive before. She got the results on 28Dec2020 that she was positive. She was now in a hotel quarantining. She was looking trying to find information on this occurring. Since she was in the hotel, she would prefer to use email as communication for follow-up. The patient noticed the cough on 25Dec2020. She works nights so she stayed home on the 26Dec2020. Then on 27Dec2020 she had the test done and on 28Dec2020 the results were given to her and she was positive. Her second dose was due on 10Jan2020 and it was before the 14 days of quarantine will be up. She was checking to see is there anywhere else she can get the second dose. The patient explains that she has been researching and she wanted to get it because she was with elderly family members. She wanted to know how she was tested positive, what test was used as she had the rapid test. There were no treatments for the events. The caller patient was also experiencing a cough, sore throat, and nasal congestion. There was no shortness or anything else going on at this point. The outcome of the events was not recovered. Information on the lot/batch number has been requested.; Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of events Drug ineffective and COVID-19 virus test positive cannot be totally excluded. The case will be reassessed if additional information becomes available.

positive person for Covid after receiving the Covid vaccine; positive person for Covid after receiving the Covid vaccine; This is a spontaneous report from a contactable nurse. A patient of unspecified age and gender received bnt162b2 (BNT162B2 also reported as Pfizer-BioNTech COVID-19 Vaccine, lot/batch number and expiry date were unknown), via an unspecified route of administration on unknown date at single dose, for Covid-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient was a positive person for Covid after receiving the Covid vaccine on an unspecified date. The outcome of the event was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the

development of events Drug ineffective and COVID-19 cannot be totally excluded. The case will be reassessed if additional information becomes available.

"Her measured blood pressure at 7:35 am was 180/80 but came down to 146/62 at 9:37 am; arms had some pain; chills; headache; a stiff neck pain at the back of her neck; a stiff neck pain at the back of her neck; a trembling pain; This is a spontaneous report from a contactable consumer. This is the 1st of two reports. A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 29Dec2020 at single dose for COVID-19 immunisation. The patient medical history and concomitant medications were not reported. The patient stated on Dec2020, ""she reported that she herself felt fine but her arms had some pain. She was having chills, a headache, a stiff neck pain at the back of her neck, and a trembling pain. Her measured blood pressure at 7:35 am was 180/80 but came down to 146/62 at 9:37 am. Her pulse was at 62 bpm, Caller is asking for recommendations"". The outcome of ""her measured blood pressure at 7:35 am was 180/80 but came down to 146/62 at 9:37 am"" was recovering and other events was unknown. Information about Lot/batch no has been requested.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2020520380 same reporter/drug, different patient/event"

"extremely lightheaded; like he was about to fall down; This is a spontaneous report from a contactable physician. This physician reported similar events for 2 patients. This is the 1st of 2 reports. An 89-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number; EL0140), intramuscular on the right arm on 30Dec2020 10:10 at single dose for vaccination. Medical history included covid-19 on Jul2020 and had it fairly severe and almost died and he mentions he was overweight. There were no concomitant medications. The patient previously took flu shot (INFLUENZA VACCINE), a couple of months ago. He mentions he was in the military so he had a lots of shots in his life but he has never had a reaction like this. The patient stated that on 30Dec2020 10:30, ""he became extremely lightheaded, like he was about to fall down. He sat down and is currently sitting down. This lightheadedness started about 20 minutes after the injection. When probed for the outcome, the caller explains it might be improving a little. The lightheadedness is not still not gone, but it has not worsened. When probed for seriousness criteria, the caller explains he is just resting and sitting. He would say its not serious but it could be medically significant. He states he isn't sure if this is something that happens to just people who have had COVID before. He states none of his friends or relatives have this type of reaction. He lives in a retirement home and everybody is getting the injection. This is the second day of injections. He doesn't know if anybody had a reaction to the COVID-19 vaccine here"". The outcome of the events were recovering.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the reported events of lightheadedness and pre-syncope due to temporal relationship. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics

Committees and Investigators, as appropriate.,Linked Report(s) : US-PFIZER INC-2020520862 same reporter/drug, similar event, different patient."

Vomiting/threw up; Headache; muscles got rigid and tight in her neck; muscles got rigid and tight in her neck; sick; She doesn't know if she had the flu bug or not; She also had very high blood pressure. It was through the roof/Blood pressure was high and she was concerned she would have a stroke; Muscle soreness; Arm soreness; This is a spontaneous report from a contactable healthcare professional (physical therapist). A 57-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiry date not reported), intramuscular on the left arm on 21Dec2020 08:15 at a single dose for COVID-19 immunisation; and sumatriptan from 25Dec2020 to an unspecified date at unknown dose and frequency (standard unknown dose/ She only gets 9 pills a month) for migraine. Medical history included ongoing migraine, obesity (She would say she was kind of obese), coeliac disease (She had Celiac disease and cannot eat gluten which was diagnosed since she was 4), chronic back pain (this was diagnosed a couple of years before she took the COVID vaccine), spinal stenosis (this was diagnosed a couple of years before she took the COVID vaccine), and pain (she took hydrocodone for pain but did not take any that day). Concomitant medication included hydrocodone for pain. Prior Vaccinations (within 4 weeks) and events following prior vaccinations were none. The patient had the vaccine on 21Dec2020, and she got sick on Christmas day. She was vomiting at 14:00 and did not know if it was a side effect or not. She did have arm soreness muscle soreness at 15:00, that evening and the next day too. She normally gets a migraine once a month. She does not normally throw up with a headache though. The vomiting started when she threw up twice on 25Dec2020, then once on morning of 26Dec2020. She also had very high blood pressure. It was through the roof. She did not know if that was related to drug for migraine or vaccine. She also had the headache at 14:00 the whole time. She believed she threw up before she took Sumatriptan. The muscles got rigid and tight in her neck and she doesn't think she took it. She threw up and then she took it. She did not have a lot or expiration. There was no ER nor physician's office required. She would have it if her car was not buried in snow. Her blood pressure was high and she was concerned she would have a stroke. It was usually around 110/70 and was always very low usually. She did not know if it was accurate, but it was 165/124 at one point and she did know her pulse was accurate. She did not provide her pulse rate. She did not know if she was throwing up because her blood pressure was high and did not know if blood pressure was high because of Sumatriptan. She only gets 9 pills a month. She did not know if high blood pressure was one of the side effects. It was not a real safe medication to take once a day. She only took it once a month and only once that day. She had never thrown up with migraines before and was just concerned. She doesn't usually take her blood pressure and doesn't know if the Sumatriptan always makes it go up or not. She doesn't know if she had the flu bug or not. The action taken in response to the events for bnt162b2 was not applicable, while for sumatriptan was unknown. Clinical outcome of sickness and influenza was unknown, for headache was recovered on 27Dec2020, while for the other events was recovering. Information on the lot/batch number has been requested.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the elevated BP and other reported events due to temporal relationship. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics, counteractive treatment measures and concomitant medications. This case

will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

allergic reaction; This is a spontaneous report from a contactable other healthcare professional reported for herself. A 45-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number EK 5730, expiry date unknown) via unspecified route of administration at left arm on 30Dec2020 08:30 at single dose for Covid-19 immunization in a hospital facility. The patient was not diagnosed with Covid-19 prior vaccination. Medical history was none. Concomitant medications was not reported. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. On 30Dec2020 at 08:45, the patient experienced allergic reaction which resulted to patient visiting doctor or other healthcare professional office/clinic and emergency room/department or urgent care visit. The patient received treatment of epinephrine, decadron and Benadryl due to the event. The patient was not Covid tested post vaccination. The outcome of the event allergic reaction was recovering at this time of the report. The reporter considered the event non-serious; did not results in death, was not life threatening, did not cause/prolong hospitalization, was not disabling/incapacitating, and no congenital anomaly/birth defect.; Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of event Allergic reaction cannot be totally excluded. The case will be reassessed if additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

peripheral neuropathy type symptoms; tingling of the feet, legs, hands, arms; This is a spontaneous report from a contactable Other Health Professional (patient). A 34-year-old non-pregnant female patient received first dose of BNT162b2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration at Left arm on 22Dec2020 10:00 at single dose for covid-19 immunization. The COVID-19 vaccine was administered at Hospital. Medical history included hypothyroidism. The patient had no known allergies. Concomitant medication included levothyroxine and multivitamin. No other vaccine in four weeks. The patient was not sure if this was related to the vaccine or not. The patient didn't know if anyone else was having peripheral neuropathy type symptoms such as tingling of the feet, legs, hands, arms. The symptoms started a few days ago. The patient did not even sure if it related to the vaccine. Adverse event start date was 27Dec2020. Covid was not tested post vaccination. The outcome of the events was not recovered. No treatment received for the events. Information on the lot/batch number has been requested.; Sender's Comments: The temporal relationship between the onset of the event and administration of the vaccine does not support a causal relationship. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern

identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

tested positive for covid; tested positive for covid; fever; headache; runny nose; nasal congestion; This is a spontaneous report from a contactable consumer (patient). A 34-year-old female patient received the first single dose of BNT162B2 (Solution for injection, lot number: EK5730, exp date: Mar2021), intramuscular (injected in left upper arm) on 20Dec2020 12:30 to 20Dec2020 12:30 at 0.3 mL for immunisation. The vaccine was administered in a hospital and not in a military facility. Medical history included birth control. The patient had no other history. NO ER or physician's office required Prior Vaccinations (within 4 weeks). Patient had no relevant family history. Concomitant medication include unspecified birth control.There was no previous immunization. Patient, who was a Respiratory therapist, got the covid vaccine on 20Dec2020 (Sunday). She first stated she doesn't have any side effects and just had a question. Patient had COVID Symptoms on 26Dec2020 21:00 which was minimal like a runny nose. She further reports that on 26Dec2020 she started to have nasal congestion. On 27Dec2020 the nasal congestion worsened, and she started having a headache. She then experienced a 102.6 fever on 28Dec2020 (Monday). She has since tested positive for Covid on 28Dec2020 11:30. Patient asked if it was ok that she received the 2nd dose after testing positive for covid. Investigation assessment was not performed. There was no prescriber. She received at work because she was a front line healthcare worker. The patient does not have SARS-CoV2 antibodies at diagnosis but never tested for antibodies. The patient was not in the hospital, nor was admitted in ICU. The patient did not display clinical signs at rest indicative of severe systemic illness. The patient did not require supplemental oxygen (including high flow or ECMO) or receive mechanical ventilation. No Multiorgan failure. The patient did not receive any additional therapies for COVID-19. The patient did not require the initiation of new medication or other treatment or procedure. PCR on 28Dec2020 (Saturday) Results: just detected. No units available. No reference ranges provided. Standard range was not detected. It was just detected or not detected ranges. No other test or diagnostic imaging performed. The patient had not been treated with immune modulating or immunosuppressing medications or received any other vaccines around the time of COVID-19 vaccination. No pre-existing diseases worsened during the SARS-CoV2 infection. The patient was recovering from event positive for covid and runny nose; nasal congestion was not recovered and outcome of the other events was unknown.; Sender's Comments: Based on the information available, a possible contributory role of the suspect products cannot be excluded for the reported event of positive for corona virus infection for the lack of efficacy of the vaccine. However, based on the mechanism of action of the vaccine, it is unlikely the patient would have fully developed immunity for the vaccine to be effective, due to the number of days passed since the vaccine is given.

"had side effects of ""tongue feels swollen and globus sensation in my throat.""; had side effects of ""tongue feels swollen and globus sensation in my throat.""; she did not have a lot of injection site pain, it very minimal.; bruise or ecchymosis at the injection site; bruise or ecchymosis at the injection site; This is a spontaneous report from a contactable physician (patient) via a Pfizer sponsored program Pfizer First Connect. A 37-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot EH9899) via intramuscular on 19Dec2020 09:00 on left deltoid at a single dose for COVID-19 prophylaxis. The patient medical history, family history and relevant tests were reported

as none. Current concomitant medications included multivitamin took 2 chewable gummies sporadically for years as supplementation therapy. The patient previously took Flu shots she got a sore arm. It was not bad. Tetanus gives her a sore arm, but that was all. Caller wanted to know what she should do for preparation to safely get second dose of Covid vaccine and how to fix what she was feeling right now, making sure it doesn't get worse, considering she is still having symptoms. Caller stated that she had side effects of tongue felt swollen and globus sensation in her throat. The transferring agent stated that he has a caller on the line that was calling about the Covid-19 Vaccine and reported that the patient got the shot on the 19Dec2020 and was inquiring about to proceed with her weird side effects. Caller had not told her physician about her symptoms yet. Caller clarified that she said a half an hour after the dose on 19Dec2020 09:30 she said that she had a Globus sensation or like a lump in her throat. Caller also reported that the back of her tongue felt swollen. Caller said that the Globus sensation was intermittent and it was not as prominent now as it was. Caller said that it was medically significant, but she has not sought medical treatment yet. Caller said that she still had a bruise or ecchymosis at the injection site. She said that the injection was high but reported that she did not have a lot of injection site pain, it very minimal. No emergency room or physician office required. The outcome of the event tongue felt swollen and globus sensation in her throat was recovering and the outcome of the event a bruise or ecchymosis at the injection site was not recovered and the outcome of the event minimal injection site pain was unknown.; Sender's Comments: There is a plausible chronological association between vaccine administration and onset of the events. Causality cannot be completely excluded."

"had a reaction of bells palsy with mild symptoms 5 minutes of receiving covid vaccine; facial numbness right sided ear discomfort, difficulty closing right eye, only right side numbness and weakness of her face. It has gotten a lot better; facial numbness right sided ear discomfort, difficulty closing right eye, only right side numbness and weakness of her face. It has gotten a lot better; facial numbness right sided ear discomfort, difficulty closing right eye, only right side numbness and weakness of her face. It has gotten a lot better; This is a spontaneous report from a contactable Other Health Professional reported that a 35-year-old female patient receives first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot/Batch Number and Expiration Date unknown) via an unspecified route of administration on 21Dec2020 at single dose for covid-19 immunization. The patient's medical history and concomitant medications was not reported. The patient experienced a reaction of bells palsy with mild symptoms 5 minutes of receiving Covid vaccine. ""facial numbness right sided ear discomfort, difficulty closing right eye, only right side numbness and weakness of her face. It has gotten a lot better, patient was vaccinated 10 days ago on 21Dec2020. Patient was treated with 60mg of Prednisone for 5 days which was started today."" Question is regarding the 2nd dose of Covid vaccine, whether or not she should have it. The outcome of events was recovering. No follow-up attempts are possible; information about lot/batch number cannot be obtained. .; Sender's Comments: There is a positive chronological association between vaccine administration and onset of the events. Causality cannot be completely excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate."

now have a positive cov-19 test results; now have a positive cov-19 test results; This is a spontaneous report from a contactable nurse reporting for herself. A female patient of an unspecified age received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number and expiry date not reported) via an unspecified route of administration, on an unspecified date, single dose for COVID-19 immunization. Relevant medical history and concomitant medications were not reported. The patient took first round of cov-19 shot and due to take 2nd one Saturday but now have a positive cov-19 test result. Information on the lot/batch number has been requested.; Sender's Comments: Based on the information available, a possible contributory role of the suspect products cannot be excluded for the reported event of positive for corona virus infection for the lack of efficacy of the vaccine. However, based on the mechanism of action of the vaccine, it is unlikely the patient would have fully developed immunity for the vaccine to be effective, due to the number of days passed since the vaccine is given.

Contracted covid 19 virus after receiving first dose of vaccine; Contracted covid 19 virus after receiving first dose of vaccine; This is a spontaneous report from a contactable nurse. A 46-year-old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number Eh9899), intramuscular in left arm on 17Dec2020 18:00 at a single dose for covid-19 vaccination. Vaccine was administered in the hospital. There were no relevant medical history. The patient had no known allergies. Concomitant medication included levothyroxine sodium (SYNTHROID). On 27Dec2020 20:00, the patient contracted covid 19 virus after receiving first dose of vaccine. The outcome of the event was recovering. The patient did not received any treatment. The event resulted in a doctor or other healthcare professional office/clinic visit. The patient did not have COVID prior to vaccination. The patient was tested for COVID post vaccination. The patient had nasal swab on 31Dec2020 and had a positive result.; Sender's Comments: Based on the information available, a possible contributory role of the suspect products cannot be excluded for the reported event of positive for corona virus infection for the lack of efficacy of the vaccine. However, based on the mechanism of action of the vaccine, it is unlikely the patient would have fully developed immunity for the vaccine to be effective, due to the number of days passed since the vaccine is given.

tested positive following the first dose of vaccine; tested positive following the first dose of vaccine; This is a spontaneous report from a contactable healthcare professional. A female patient of an unspecified age received BNT162B2 (Pfizer-BioNTech COVID-19 mRNA vaccine; lot/batch number and expiry date were unknown), via an unspecified route of administration on unspecified date at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The reporter stated that she has a patient who tested positive following the first dose of vaccine and inquiring as to second dose recommendations. The outcome of the event was unknown. Information about lot/batch number has been requested.; Sender's Comments: There is scant information at this point. Case will be reevaluated based on additional information during the follow-up

"sore arm; aches and pains for a couple of days; a little headache; I received results yesterday and I am positive; I received results yesterday and I am positive; This is a spontaneous report from a non-contactable physician (patient). A male patient of an unspecified age started to receive bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), lot number and expiry date was unknown, via an unspecified route of administration on 19Dec2020 at single dose for COVID-19 immunization. The patient's medical

history and concomitant medications were not reported. The patient received his first covid vaccine dose on 19Dec2020, and due to get his second dose on 09Jan2021. The problem is he tested for the covid virus on Wednesday 26Dec2020 (was negative). He was tested again on the 30Dec2020, because his wife and son had tested positive on the 26Dec2020, he received the results yesterday and he is positive. He asked if he should proceed with the 2nd dose, another test on the 30th and tested positive. He reports that, other than initial side effects from the vaccine administration, sore arm, aches and pains for a couple of days, never had fever, a little headache for a day or two, he feels fine. The outcome of the events ""a little headache"" was recovered on an unspecified date while outcome of the other events was unknown. No follow-up attempts are possible. Information about lot/batch number cannot be obtained. No further information is expected.; Sender's Comments: Based on the information available, a possible contributory role of the suspect products cannot be excluded for the reported event of positive for corona virus infection for the lack of efficacy of the vaccine. However, based on the mechanism of action of the vaccine, it is unlikely the patient would have fully developed immunity for the vaccine to be effective, due to the number of days passed since the vaccine is given."

tested positive with COVID; tested positive with COVID; This is a spontaneous report from a contactable nurse. A male patient (Age:22 Units: unspecified) received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiry date were not reported), via an unspecified route of administration on 15Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient had the 1st dose last 15Dec2020 and tested positive with COVID on 25Dec2020. The outcome of the event was unknown. He will have the COVID result 04Jan2021 to check if he was still positive. Information on the Lot/Batch number has been requested.; Sender's Comments: Based on the information available, a possible contributory role of the suspect products cannot be excluded for the reported event of positive for corona virus infection for the lack of efficacy of the vaccine. However, based on the mechanism of action of the vaccine, it is unlikely the patient would have fully developed immunity for the vaccine to be effective, due to the number of days passed since the vaccine is given. Case will be reevaluated based on follow-up information

developing a left facial droop; Bell's palsy; This is a spontaneous report from a Pfizer-sponsored program IBCC (Inbound Call Center for HCPs). A contactable physician reported that a female patient of an unspecified age received the first dose of bnt162b2 (COVID-19 Vaccine) via an unspecified route of administration on an unspecified date in Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The physician reported that the patient received the COVID-19 vaccine roughly two weeks ago (Dec2020) and is developing a left facial droop, they are concerned if that is a sign of facial Bell's palsy. It's left side and it's a facial droop. The physician was concerned if patient is developing Bell's palsy and they are wondering if she should get the second dose or not. The physician further stated that her patient got the vaccine like about 2 weeks ago and developed Bell's palsy three days after the administration of the vaccine (Dec2020) and of course she won't be able to get to see because we are all booked up until yesterday and that is like about a week ago, after the onset of Bell's palsy. Outcome of the event was unknown. Information about lot and batch has been requested.; Sender's Comments: The event is considered possibly related to the suspect product based on the assumed positive temporal association. The information available in

this report is limited and does not allow a medically meaningful assessment of the case. In particular the following relevant information is not available: patient's medical history and concomitant medications, exact vaccination date, event outcome. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

nurse got Covid after getting the vaccine; nurse got Covid after getting the vaccine; This is a spontaneous report from a contactable nurse. A patient of unspecified age and gender received BNT162B2 (Pfizer-BioNTech COVID-19 mRNA vaccine; lot/batch number and expiry date were unknown), via an unspecified route of administration on unspecified date at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. It was reported that a nurse got Covid after getting the vaccine. The reporter wanted to know if the chills were common. She wanted to know if it is okay to feel chills every now and then. She wanted to know how people would know if they are positive when getting the vaccine. The outcome of the event was unknown. Information about the lot/batch number has been requested.; Sender's Comments: Based on the limited information available, a possible contributory role of the suspect products cannot be excluded for the reported event of positive for corona virus infection for the lack of efficacy of the vaccine. However, based on the mechanism of action of the vaccine, it is unlikely the patient would have fully developed immunity for the vaccine to be effective, due to the number of days passed since the vaccine is given. Case will be reevaluated based on follow-up information

a strong, whole body heat, and flushing; a strong, whole body heat; tachycardic; Palpitations; This is a spontaneous report from a contactable Nurse(patient). This Nurse reported for similar events for 6 patients. This is 1st of 6 reports. A 49-year-old female patient received BNT162B2(PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 28Dec2020 at the 49 years old at single dose for COVID-19 immunization. The medical history and concomitant medications were not reported. The registered nurse and 5 other registered nurses she worked with, had a serious reaction right after receiving the COVID-19 Vaccine. The patient had a weird reaction right after she was injected with the COVID-19 Vaccine. She had a strong, whole body heat, and flushing. She said she became tachycardic and had palpitations that lasted a few minutes. She said the tachycardia and palpitations then slowly resolved in less than 5 minutes. The patient said she had no other symptoms after receiving the COVID-19 Vaccine. The reporter said there were 5 other registered nurses that received the COVID-19 Vaccine at the same time and had the same exact symptoms she experienced. The reporter said stated the registered nurse who was monitoring the people who received the COVID-19 Vaccine indicated that the same feeling had occurred in many other workers who had received the COVID-19 vaccine. The reporter stated she did not know if the patient had received any other vaccines at the same time as the COVID-19 Vaccine, and if the patient had received any other vaccines within the last 4 weeks. The patient works at a hospital but didn't received any medical treatment. The patient just waited her symptoms out, and within 5 minutes her symptoms had gone away. The outcome of the events was recovered on 28Dec2020. Information on the lot/batch number has been requested.;

Sender's Comments: A possible contributory role of the suspect products cannot be excluded for the reported events based on the known safety profile and temporal association. Case will be reevaluated based on follow-up information ,Linked Report(s) : US-PFIZER INC-2021001363 same reporter/drug/event, different patient.;US-PFIZER INC-2021001364 same reporter/drug/event, different patient.;US-PFIZER INC-2021001195 same reporter/drug/event, different patient.;US-PFIZER INC-2021001204 same reporter/drug/event, different patient.;US-PFIZER INC-2021001329 same reporter/drug/event, different patient.

anaphylaxis; This is a spontaneous report from a contactable other healthcare professional (patient). A patient of unspecified age and gender received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for immunization. The patient's medical history and concomitant medications were not reported. Pfizer covid vaccine caused anaphylaxis on 30Dec2020 and landed patient in hospital. Patient was an anesthesiologist and had high IgG to thyroid with hashimotos. Patient thought he/she had IgG/neutrophil mediated anaphylaxis (not the typical IgE) as absolute neutrophil count elevated but everything else normal in labs. Had tachycardia into 140-150s and mild facial and throat edema. Still having sudden bouts of elevated heart rate in the morning of 31Dec2020. Heart tests all normal. Outcome of event elevated heart rate was not recovered, and outcome of other events was unknown. Information on the Lot/Batch number has been requested.; Sender's Comments: A possible contributory role of the suspect products cannot be excluded for the reported events based on the known safety profile and temporal association. Case will be reevaluated based on follow-up information

12/29/2020 2 hr after vaccination patient became hypotensive, decreased oxygen levels was transferred to Hospital currently inpatient at hospital - admitted for cardiac arrest

Deceased

Woke up Thursday am with hives on right lower abdomen and leg getting progressively worse throughout the day. By that afternoon had back pain in right back and continuing hives. Woke up Friday with numbness to right leg, hives, and back pain all on right side of body. Had numbness to foot, face but especially thigh, back and across upper buttocks. Saturday hives subsiding, numbness receding to face, upper thigh and foot only on right side of body. Sunday, back pain some improved, no hives or hives minimal, numbness persists upper thigh face and foot on right side of body. Monday, Tuesday and Wednesday the same. Woke up Thursday with shingles rash to upper thigh back, numbness to foot face and upper thigh persist only on right side of body. Darn!!!

I woke the next morning with flu like symptoms my arm was hurting, I was feelin tired and really couldn't get out of bed. As the day progressed I got chills, started running a fever, It went up to 104 and my heart rate went up and down from 120-165 so I went to the ER. They gave me fluids and ran a whole bunch of test, tested me for Covid and Sepsis and everything came back normal and negative for Covid. They monitored my heart rate and once it started getting back to normal, they ended up letting me go home, I was there from 8pm to about 3am. After that I felt tired and felt like when I had Covid back in

November. I started feeling better about Sunday, still a little tired but felt more back to normal. My heart rate is still getting back to normal so my Dr is following me on that.

PT was found deceased in his home on 1/5/2021

Expired 1/05/2021

"worry; frustration; regrets/wishing she would have never taken it; phlegm; can't talk; taking her voice, she felt like she was losing her voice; scary/""scaring"" her; coughing/cough; difficult for her to catch her breath/lost her breath, couldn't catch her breath/couldn't breath; allergic reaction to the vaccine; This is a spontaneous report from a contactable consumer (patient). A 61-year-old female patient received first dose BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number EL1284, expiry date 30Apr2021) intramuscular on 29Dec2020 09:16 at 0.3 mL, single for Covid-19 immunization in a hospital. Medical history included diabetic, allergy reactions, blood pressure (abnormal), cholesterol (abnormal); all ongoing, and reaction to dust. Concomitant medications included ongoing amlodipine;hydrochlorothiazide;valsartan for blood pressure, ongoing potassium for unspecified indication, BP pills (unspecified) and has cholesterol medications. The patient informed that yesterday (29Dec2020), she got the COVID vaccine shot at work, received it at 9:16 am and was monitored for 30 minutes post administration. The patient went to work and was holding the babies. The patient worked in transport in the NICU at a hospital. Few hours after the injection, while working in the NICU, she experienced coughing to the point where it was difficult for her to catch her breath. The patient started coughing so bad, she had no control. She mentioned trying to drink water and continued coughing more. The patient lost her breath, couldn't catch her breath, she had to call for the charge nurse (manager), as she couldn't breath and they took her to the ER and consulted at the ER of her facility. The patient informed that she kept coughing and couldn't catch her breath. They made her drink water. The patient has allergies, so she always has an epi pen with her. The patient felt like she had an allergic reaction to the vaccine. The doctor there explained that her symptoms were not related the Covid-19 vaccine she received earlier. The patient specified that the last time she had a similar reaction was at work and was due to dust. The patient explained that she was perfectly fine before receiving the vaccine, laughing, and so what can her symptoms be related to, if it was not the vaccine. The patient was coughing all night, can't get rid of the cough. She has called her doctor. The nurse said just to watch herself for now. The patient informed that she was supposed to go back to work tomorrow and she was afraid to go around the babies. The patient informed that today (30Dec2020), she gargled apple cider vinegar and salt water, and phlegm came out. The patient continued saying that she has still been coughing, can't talk and that it was scary. The patient informed that she was taking her voice, she felt like she was losing her voice. It was ""scaring"" her. She was unsure if it was the Pfizer vaccine. The patient attempted to reach her HCP and that she cannot be seeing at her clinic due to her cough. The patient mentioned that she won't have access to a respiratory clinic until Tuesday. The patient expressed her concerned about returning to work with babies and asked if she should return to work tomorrow. The patient pursued verbalizing her worry and frustration. The patient asked if she can decide not to get the second dose. The patient voiced her regrets on receiving the first dose of the COVID-19 vaccine. She stated wishing she would have never taken it and that all who have an EpiPen should not receive it. The outcome of the event cough was not recovered, Dyspnoea, Allergy to vaccine,

Productive cough, Speech disorder, Aphonia, Nervousness, Anxiety, Frustration tolerance, Depressed mood was unknown."

her face started to go numb/felt like a dental block you would get with Lidocaine; She got on her left side, a cold spike feeling up her shoulder and neck and up to her face; upper esophageal sphincter got tight and felt funny like she was going to throw up; her whole body was shaking- her head, hands, and legs; feeling giddy; blood pressure was up; being stressed; was going to throw up/transient nausea; felt a little funny; This is a spontaneous report from a contactable Nurse(patient). A 54-year-old female patient received BNT162B2 (lot number EL0140), via an unspecified route of administration at left deltoid on 30Dec2020 14:28 at the 54 years old at 0.3 mL single for where she works she was exposed to patients who need rehab that were exposed and getting COVID. The patient medical history included Primary Essential Tremors and ongoing (had these for about 10-11 years. Her mother and grandmother also had them. Normally they were very fine, small tremors that people didn't notice. She can hold and turn her head and hide it) and Sulfa drug allergy (would get shortness of breath). The concomitant product was none. The patient previously took flu vaccine and experienced preservative made neck twitch and joint sores. Yesterday the patient got the COVID Vaccine and had a pretty significant adverse event. She was calling to report it and to see if she should get the second dose of the vaccine. The patient was also a licensed speech pathologist. She received the vaccine yesterday at 2:28 PM. She was allergic to Sulfa drugs and would get shortness of breath, so they wanted her to wait 30 minutes for monitoring. She was feeling giddy on 30Dec2020, but she ran into a friend that she had not seen before quarantine, so they were talking. It was exciting. After her 30 minutes she went to her car and felt a little funny. She thought she was hungry so she ate half a banana and had some water. She had an appointment to get to so she started to drive off, and by the time she got to the interstate she was feeling funny. She got on her left side, a cold spike feeling up her shoulder and neck and up to her face on 30Dec2020. This was like the precursor. Then on 30Dec2020 her face started to go numb. It felt like a dental block you would get with Lidocaine. It went from her temple area, below her eye all the way to her lips. It was midline on the left side. She was breathing fine. She was trying to figure out if she should pull over or call(Number), but her airway did not close up. Her upper esophageal sphincter got tight and felt funny like she was going to throw up. She drove to the hospital close to her house which is affiliated with where she got the vaccine. She normally had primary tremors, small to where people do not notice. But her whole body was shaking- her head, hands, and legs on 30Dec2020. She looked like a bobble head. But she could still breath. They took her right in and they did an EKG to make sure it was not her heart. Her blood pressure was up on 30Dec2020, she assumes for being stressed. They monitored her. They gave her Pepcid and Benadryl. She did not want any nausea medications. She stayed for about 2 hours and slept some from the Benadryl. Her face slowly became less numb. The numbness went away started from her lips and outward to her check and temple area. Then it just felt funny. When she touched it, which she never lost sensation, it was like, whose face is this? It was strange. She is not numb anymore. It took a while for it to go away, and it still felt weird. When she woke up this morning it was completely gone. She had recovered completely from all of these things. The only thing she has now was some transient nausea. It was very mild. It comes and goes. It had improved. She had not taken anything for it. The events Feeling funny, her face started to go numb, upper esophageal sphincter got tight, a cold spike feeling up her shoulder and neck and up to her face, Her whole body was shaking- her

head, hands, and legs, were all assessed as Medically significant. The outcome of the event Nausea was recovering, the events Felt giddy, blood pressure was up, Stress was recovered on 31Dec2020, the other events were recovered on 30Dec2020. The reporter considered there was a reasonable possibility that the events Feeling funny, a cold spike feeling up her shoulder and neck and up to her face, Face started to go numb from her temple area, below her eye all the way to her lips, upper esophageal sphincter got tight , whole body was shaking- her head, hands, and legs, Nausea, were related to the product BNT162B2.; Sender's Comments: Based on the compatible temporal association, the vaccination with BNT162B2 might play a contributory role in triggering the onset of the events. The impacts of this report on the benefit/risk profile of the product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

"DVT; This is a spontaneous report from a contactable nurse. A patient of unspecified age and gender received BNT162B2, via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient medical history and concomitant medications were not reported. The nurse asked if there is any DVT cases reported following the administration of Pfizer-BioNTech COVID-19 Vaccine. E-transmitting duplicate AE caller already reported a DVT case post vaccination. Caller also asked ""Why is there's a statement indicating that individuals with a history of bleeding disorder or taking anti-coagulant should contact their vaccination provider? How did they prove 95 % efficacy? Why aren't antibodies produced after the 1st dose of Covid-19 vaccine?"" The outcome of the event DVT was unknown. Information on Lot/batch number has been requested.; Sender's Comments: Very limited information was provided for this individual patient, such as pre-existing medical history, suspect administration details, clinical course and relevant supportive lab data for the reported Deep vein thrombosis (DVT). Pending further details, the Company would handle this reported DVT related to the administration of BNT162B2, COVID-19 immunization, for reporting purpose. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RA, IEC, as appropriate."

throat swelling; Initially had headache; dizziness; irritability; Throat tingling; difficulty swallowing; This is a spontaneous report from a contactable other healthcare professional (HCP) (patient). A 49-year-old female patient received a single dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (Lot#: EJ1685) as the first dose via an unspecified route of administration in the left arm on 29Dec2020 06:00 for COVID-19 immunization. Medical history included fibromyalgia, asthma, prediabetes, and carpal tunnel syndrome. There were no concomitant medications. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. There were not any other medications the patient received within 2 weeks of vaccination. The patient was not diagnosed with COVID-19 prior to vaccination. The patient had not been tested for COVID-19 since the vaccination. The patient had no previous allergies to vaccines. The patient allergies to medications which included: doxycycline, medroxyprogesterone acetate (DEPO-PROVERA), metoclopramide (REGLAN), gluten. The patient initially

had headache, dizziness and irritability, throat tingling, throat swelling, and difficulty swallowing started around 12 hours after injection, event onset date reported as 29Dec2020 18:00. The events resulted in emergency room/ department or urgent care. The events were reported as non-serious by HCP. Treatment received for the events included diphenhydramine and hydroxyzine embonate (HYDROXYZINE PAMOATE). The outcome of the events was recovering.; Sender's Comments: The reported pharyngeal swelling together with other symptoms was likely related to the single dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) due to temporal relationship. The case will be reassessed should additional information become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics committees and Investigators, as appropriate.

Moderate to severe headache 24-48 hours post injection. Complete sensorineural hearing loss in left ear 1 week after injection; Moderate to severe headache 24-48 hours post injection. Complete sensorineural hearing loss in left ear 1 week after injection; This is a spontaneous report from a contactable physician (patient). A 37-year-old female non-pregnant patient received her first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 22Dec2020 17:15 at single dose on her left arm for covid-19 immunization. Medical history included known allergies to penicillin. The patient had no other medical history. There were no concomitant medications. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine and the patient was not received list of any other medications within 2 weeks of vaccination. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. The patient experienced moderate to severe headache 24-48 hours post injection. Complete sensorineural hearing loss in left ear 1 week after injection on 23Dec2020. These events resulted in doctor or other healthcare professional office/clinic visit, disability or permanent damage. The patient had received prednisone to treat the events. The outcome of the events was not recovered.; Sender's Comments: A possible contribution role of first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) to the onset of sensorineural hearing loss in left ear and headache cannot be excluded due to temporal relationship. The case will be reassessed should additional information become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics committees and Investigators, as appropriate.

jaw tightening; muscle spasms; entire face and around her mouth went numb; entire face and around her mouth went numb; heart palpitations; I had hives on my chest; a wave of heat rush up her back; This is a spontaneous report from a contactable nurse (patient). A 46-years-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899), via an unspecified route of administration in left arm on 22Dec2020 10:30 at first single dose for COVID-19 immunization. Medical history included ectopic pregnancy, hay fever. Concomitant medication received within 2 weeks

included: loratadine, colecalciferol (vitamin D), olly womens multivitamin. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. No known allergies. About 15 minutes after the vaccine the patient experienced jaw tightening and muscle spasms. The patient was given oral Benadryl 50 mg. About 5 minutes after taking the Benadryl, her entire face and around her mouth went numb. The patient began having heart palpitations and felt a wave of heat rush up her back. She had hives on her chest. The patient received 1 dose of epinephrine from an Epi-Pen and transported to the emergency room for further treatment. Adverse event start date: 22Dec2020 11:00 AM. Events were considered as non-serious. Events resulted in: Doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care. Treatment received for the adverse event included: Benadryl, Epinephrine, Solumedrol, Pepcid. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had been tested for COVID-19. Test Name: SARS-CoV-2 by PCR (Nasal Swab) on 30Dec2020: Negative. Outcome of the events was not recovered.; Sender's Comments: The temporal relationship is suggestive of an acute anaphylactic reaction. Based on the temporal relationship and the known pattern of response, the vaccination with BNT162B2 might play a contributory role in triggering the onset of the reported events. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

"Joint pain; loss of balance; increased drowsiness; Headaches induced by allergies; Limited neck mobility/lessened neck pain but still limited mobility; Scalp tenderness and sensitivity; Significant migraines/debilitating migraines (light & noise sensitivity, covers whole head, pulsating, sharp pain, loss of balance, increased drowsiness); Sharp pains in neck/Neck pain; Sharp pains in neck, ear, head pain (similar to an ear infection pain); head pain/sharp pains in lower head/covers whole head, pulsating, sharp pain/Increase in headaches but no longer centralized to back of head/ headaches induced by allergies; Nausea; Neck stiffness; This is a spontaneous report from a contactable Other Health Professional (patient). A 29-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) Solution for injection, lot number was unknown, via an unspecified route of administration in the right arm on 22Dec2020 07:30 at a single dose for COVID-19 immunization. Medical history was none. There were no concomitant medications. The patient was not pregnant. The patient had not receive any other vaccines within 4 weeks prior to the COVID vaccine. It was reported that the patient received vaccine in Tuesday (22Dec2020). The following Sunday (27Dec2020) at 12:00, she had nausea and neck stiffness. On Monday (28Dec2020), she had sharp pains in neck, ear, head pain (similar to an ear infection pain), and nausea. She used teledmed appt and got antibiotics (unspecified). On Tuesday (29Dec2020), she had significant migraines, limited neck mobility, sharp pains in neck and lower head, scalp tenderness and sensitivity which felt like whiplash when she moved her head w/ her head feeling ""swimmy"". She tried to see urgent care but was to go to ER. On Wednesday (30Dec2020), there was lessened neck pain but still limited mobility, increased in headaches but no longer centralized to back of head. She went to ER and they said that she had headaches induced by allergies. She mentioned that she never had migraines or allergies in her life. They also reported no ear infection. She did complete CT Scan with no concerning results on 30Dec2020. On Thursday (31Dec2020) & Friday, she

no longer has neck pain but with continued nausea, joint pain, debilitating migraines (light & noise sensitivity, covers whole head, pulsating, sharp pain, loss of balance, increased drowsiness). The events were reported as non-serious. The treatment received for the adverse events included fluids, pain & nausea meds. The patient was not diagnosed with Covid prior to vaccination. She was tested for covid post vaccination on 30Dec2020 through a nasal swab with negative result. The outcome of the events neck stiffness, ear pain, scalp tenderness and sensitivity, and 'Headaches induced by allergies' was unknown; while neck pain was recovered on 31Dec2020. The outcome of the events 'significant migraines/debilitating migraines', nausea, limited neck mobility, head pain/Headache, joint pain, loss of balance, and increased drowsiness was not recovered. Information on the lot/batch number has been requested.; Sender's Comments: A causal association between BNT162B2 and the event migraine cannot be excluded based on a compatible temporal relation between vaccination and onset of event. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate."

Miscarriage; patient was pregnant while taking BNT162B2; patient was pregnant while taking BNT162B2; This is a spontaneous report from a contactable Other Health Professional. A 34-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EL0140), intramuscularly on 22Dec2020 06:00 AM at single dose at Arm Right at Hospital for COVID. Medical history included ongoing sleep apnoea. There were no concomitant medications. There were no allergies to medications, food, or other products. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient did not receive any other medications the patient received within 2 weeks of vaccination. Prior to vaccination, the patient was not diagnosed with COVID-19. The patient experienced miscarriage on 29Dec2020 13:00. The patient was pregnant while taking BNT162B2. The patient was 4 Weeks pregnant at the onset of the event. Patient last menstrual period date was 24Nov2020. The Pregnancy due to deliver was on 07Sep2021. The pregnancy resulted in spontaneous abortion. Since the vaccination, the patient has been tested for COVID-19 on an unknown date with unknown results. Nasal Swab on 28Dec2020 was Negative. There was no treatment received for the adverse event. The outcome of event was recovering.; Sender's Comments: The information currently provided is too limited to make a meaningful medical assessment hence, the events are conservatively assessed as related to the suspect drug BNT162B2 until further information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to agency, Ethics Committees, and Investigators, as appropriate.

DVT left calf; This is a spontaneous report from a contactable Physician (patient). A 60-year-old male patient started to receive the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) Intramuscular on 20Dec2020 08:00 at single dose on right arm for COVID-19 immunization. Medical history included Gastric reflux. The patient had no known allergies. The patient had no covid prior vaccination. The patient had no covid tested post vaccination. Concomitant medications included

omeprazole (PRILOSEC) and ergocalciferol (VIT D). The patient had not received other vaccine in four weeks. The patient experienced deep vein thrombosis (DVT) left calf on 27Dec2020 09:00 which resulted emergency room visit. Treatment received for the event included Xarelto. The outcome of the event was not resolved. Information on the lot/batch number has been requested.; Sender's Comments: The information currently provided is too limited to make a meaningful medical assessment hence, the events are conservatively assessed as related to the suspect drug BNT162B2 until further information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

"reaction to excipient; kidneys tried to shut down; This is a spontaneous report from a contactable consumer from a Pfizer Sponsored Program. A female patient of an unspecified age received the bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), and potassium (MANUFACTURER UNKNOWN); both via an unspecified route of administration on an unspecified date at a single dose for COVID-19 immunisation. The patient's medical history included ongoing kidney issues from an unknown date, allergic to antibiotics and pain pills from an unknown date and unknown if ongoing. Concomitant medications were not reported. On an unspecified date, the patient experienced: kidneys tried to shut down and reaction to excipient; which were assessed as medically significant. The consumer stated, ""I looked at the ingredient list: potassium is listed. I have kidney issues and potassium is really bad, my kidneys tried to shut down on me. I'm allergic to ""antibiotics and pain pills."" The clinical outcome of the events, renal failure and reaction to excipient, was unknown. The batch/lot numbers for the vaccine, PFIZER-BIONTECH COVID-19 MRNA VACCINE, were not provided and will be requested during follow up."

Mild difficulty with thought/speech/concentration; strong wave of burning sensation growing inside the body; Lightheadedness; Blood pressure went up; Heart rate went up; Hands freezing; Mild difficulty with thought/speech/concentration; Mild difficulty with thought/speech/concentration; Weakness; Mildly shaky; Anxiety; Feeling that may pass out; This is a spontaneous report from a contactable other healthcare professional (HCP) (patient). A 61-year-old female patient received 1 dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EJ1686) via unspecified route on left arm single dose for COVID-19 immunization on 02Jan2021, 02:30 PM, at 61-year-old. Medical history: allergies to sulfa, paclitaxel (TAXOL); breast cancer in 2003 and 2007. Prior to vaccination, the patient did not be diagnosed with COVID-19. Concomitant medication in two weeks included: escitalopram oxalate (LEXAPRO, strength: 10m); omeprazole; multivitamin; ibuprofen. About 5 minutes after the vaccine (02Jan2021, 02:35 PM), the patient had a strong wave of burning sensation growing inside the body, lightheadedness, blood pressure went up, heart rate went up, hands freezing, mild difficulty with thought/speech/concentration, weakness, mildly shaky, anxiety, feeling that may pass out. Emergency room/department or urgent care visited. Treatment received for the adverse event included: heart rate H20 and BP monitor, water, observation. Since the vaccination, the patient did not have been tested for COVID-19. Action taken for BNT162B2 was not applicable. Outcome of the events was resolving. It was reported as non-serious per the reporter.; Sender's Comments: Based on the current available

information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of event Mental impairment cannot be totally excluded. The case will be reassessed if additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

"reported increased hand stiffness after vaccination; This is a spontaneous report from a contactable pharmacist via Pfizer sales representative. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for Covid-19 immunisation. Medical history included psoriasis and psoriatic arthritis. The patient's concomitant medications were not reported. The patient previously took adalimumab (HUMIRA) and non compliant with Humira. The patient had psoriasis and psoriatic arthritis, reported increased hand stiffness after vaccination on an unspecified date with outcome of unknown. Information on the lot/batch number has been requested.; Sender's Comments: The Company cannot completely exclude the possible causality between the reported ""psoriasis and psoriatic arthritis with increased hand stiffness after vaccination"" and the administration of BNT162B2, based on the reasonable temporal association. The patient's pre-existing medical condition of psoriasis and psoriatic arthritis might have provided alternative explanations. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RA, IEC, as appropriate."

"Confirmed DVT in the left leg; COVID test (PCR swab): positive on 26Dec2020; COVID test (PCR swab): positive on 26Dec2020; This is a spontaneous report from a contactable other healthcare professional. An 85-year-old female patient received 1st dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot# ELO140, expiration date: Mar2021), via an unspecified route of administration in arm (deltoid; unknown side) on 23Dec2020 at single dose for Covid-19 immunisation. Medical history included type 2 diabetes mellitus from 2017 and ongoing, high blood pressure from 2017 and ongoing, atrial fibrillation (A-Fib) from 2019 and ongoing. The patient's concomitant medications were not reported. The patient was administered first dose of the COVID vaccine on 23Dec2020 and then was swabbed for COVID on 26Dec2020, and then on 28Dec2020 her PCR swab was positive for COVID. She was asymptomatic until she started complaining of leg pain. She ordered an ultrasound for the patient on 30Dec2020, and it confirmed a deep vein thrombosis (DVT) in left leg. The patient was being treated with anticoagulant apixaban (ELIQUIS) currently. Caller stated that this could be that it (DVT) is from COVID, but her real question was, could it be from the vaccine? In Pfizer's information packet for patients, there is section on what to tell your provider prior to getting vaccinated. One of the things on there is if you have a bleeding disorder or are on an anticoagulant. There is no explanation as to why it was in the packet of information. Caller has looked everywhere and can not figure out why that is on the FAQ/packet information. The patient was due for the second dose on 13Jan2020, but she was worried and hesitant

to approve it. The patient underwent lab tests and procedures which included COVID test (PCR swab): positive on 26Dec2020, ultrasound of the left leg: confirmed DVT on 30Dec2020. The outcome of events was not recovered.; Sender's Comments: There is not a reasonable possibility that event ""COVID test (PCR swab): positive"" is related to BNT162B2 vaccine. The event occurred 3 days after vaccination, when vaccine was not expected to achieve the effect. The event DVT of legs is not considered related to BNT162B2 vaccine. The patient had underlying diabetes and cardiovascular disorders, which are considered as risk factors for DVT. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate."

Patient was poorly responsive to her inhalers that she used for asthma; Persistent shortness of breath and chest tightness starting within a few days after vaccine; Persistent shortness of breath and chest tightness starting within a few days after vaccine; This is a spontaneous report from a contactable physician (patient). A 40-year-old male patient received the first single dose of BNT162B2 (Solution for injection, lot number: EK5730, exp date not reported), via an unspecified route of administration (vaccine location: left arm) on 18Dec2020 04:15 for COVID-19 immunization. Medical history included allergy induced asthma, allergies to cats and dust, and occasional seasonal allergies. Concomitant medication included other vaccine/s received within 4 weeks prior to the COVID vaccine: first dose of diphtheria vaccine toxoid, pertussis vaccine acellular 3-component, tetanus vaccine toxoid (BOOSTRIX, GlaxoSmithKline) administered as single dose via unspecified route of administration (vaccine location: left arm) on 08Dec2020. There were no other medications the patient received within 2 weeks of vaccination. The patient experienced persistent shortness of breath and chest tightness starting within a few days after vaccine (24Dec2020). Patient was poorly responsive to her inhalers that she used for asthma (onset date not reported). She rarely needed the, used about once or twice a year). It was constant, but with periods of improvement followed regression. Will likely seek medical evaluation as it's been over a week now and rather concerning. The patient did not consider the events shortness of breath and chest tightness as serious. Treatment for the adverse events shortness of breath and chest tightness included fluticasone propionate, almeterol (ADVAIR), albuterol, and unspecified anti-allergy medications. Patient did not have covid prior vaccination. Patient was tested for COVID post vaccination wherein patient tested negative for COVID via Covid test rapid on 30Dec2020. The adverse event resulted in doctor or other healthcare professional office/clinic visit and emergency room/department or urgent care. The outcome of shortness of breath and chest tightness was not recovered and unknown for the other event.; Sender's Comments: Based on the time association, the possible contribution of BNT162B2 to the events shortness of breath , chest tightness and asthma aggravated cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

"diabetes was high; seeing double vision; Headache on the right side; This is a spontaneous report from a contactable nurse. A patient of an unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number/expiration date unknown) dose number 1, via an unspecified route of administration on 18Dec2020 at a single dose for COVID-19 immunization. Medical history and concomitant medications were not reported. The patient had the vaccine in a hospital on a Friday (18Dec2020). No side effect was noted over the weekend. On 21Dec2020, when the patient woke up, s/he was seeing double vision, so s/he went to the doctor; they ran some test (unknown result). Because the patient was having headache on the right side in Dec2020, s/he went back to the doctor on 23Dec2020; the patient was sent to the eye doctor and they ran all kind of test. On 24Dec2020, the only thing they could find was that the patient's diabetes was high, so they kind of felt that what that could have been was kind of coincidental. The outcome of the events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: The mentioned ""diabetes was high"" is likely an intercurrent disease, unlikely related to the administration of BNT162B2, the COVID-19 immunization. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RA, IEC, as appropriate."

joint pain; it doesn't seem to be feeling well; sweating; Fever; chills; night sweats, that he will randomly start sweating; headache; muscle pain/mild muscle aches; gastric upset; Fatigue; he had mild arm soreness right after he got the vaccine; This is a spontaneous report from a contactable Other-HCP (patient). This 45-year-old male Other-HCP received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EJ1685, NDC number: 59267-1000-1) on 22Dec2020 at single dose in his right arm for COVID-19 immunization. Medical history and concomitant drug were not reported. It was reported that patient experienced Fever on 27Dec2020 with outcome was recovered on 29Dec2020, chills and night sweats on 27Dec2020 with outcome was not recovered, Headache on 27Dec2020 with outcome was not recovered, muscle pain 27Dec2020 with outcome was not recovered, gastric upset on 27Dec2020 with outcome was Recovering, Fatigue on 27Dec2020 with outcome was unknown, arm soreness on 22Dec2020 with outcome was not recovered, joint pain with outcome was unknown, it doesn't seem to be feeling well with outcome was unknown, sweating with outcome was unknown. All events were serious (medical significant). Caller stated that he thought having a reaction to the vaccination, spoken with Occupational Health at his job and with a doctor, stated everyone is a bit stumped. Caller stated he has had for over a week now, fever, chills, night sweats, that he will randomly start sweating, headache, joint pain, gastric upset, and it doesn't seem to be feeling well. Stated the joint pain is actually more muscle pain. Stated he got the vaccination on Tuesday 22Dec2020, stated he has been having these symptoms for over 5 days now. Stated he does not think this is something infectious, that no one in his family is getting sick, his wife or child are not catching it from him. Stated he tried to do research online for data about delayed side effects, would like to know if we have any information on delayed side effects. Stated he considers these events medically significant because he cannot be cleared to go back to work. Stated he had mild arm soreness right after he got the vaccine, states he had mild muscle aches Wednesday and Thursday, then they went away and came back all on Saturday night and Sunday. Stated he is worried about getting a second vaccine. Stated he tested

negative for the COVID on 29Dec2020. Stated he has a CBC and other blood work scheduled for today, results unknown at this time. No follow-up attempts are possible. No further information is expected.; Sender's Comments: Based on the compatible temporal association and the drug's known safety profile, the vaccination with BNT162B2 might play a contributory role in triggering the onset of the events. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Tachycardia; Palpitations; had a strong, whole body heat, and flushing; had a strong, whole body heat, and flushing; This is a spontaneous report from a contactable nurse. This nurse reported similar events for 6 patients. This is the 4th of 6 reports. A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot/batch unknown) via an unspecified route of administration on 28Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The reporter said her friend is a registered nurse, and received the COVID-19 Vaccine on Monday, 28Dec2020. She said her friend stated she, and 5 other registered nurses she works with, had a serious reaction right after receiving the COVID-19 Vaccine. The patient had a strong, whole body heat, and flushing. The patient said she became tachycardic and had palpitations that lasted a few minutes. She said the tachycardia and palpitations then slowly resolved in less than 5 minutes. She had no other symptoms after receiving the COVID-19 Vaccine. There is unknown whether the patient received the treatment or not. The outcome of the events was recovered on 28Dec2020. Information on lot/batch number has been requested.; Sender's Comments: Based on the compatible temporal association, the vaccination with BNT162B2 might play a contributory role in triggering the onset of the events flushing, feeling hot, tachycardia and palpitations. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.,Linked Report(s) : US-PFIZER INC-2021001345 same reporter/drug/event, different patient.

It sounds like to be an allergic reaction; She passed out; Tachycardia; Nausea; Lightheadedness; This is a spontaneous report from a non-contactable physician. A 32-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) in Dec2020 at single dose to be vaccinated for her protection. Medical history was none. The patient's concomitant medications were not reported. Patient took the Pfizer COVID-19 vaccine and next day she had a very serious reaction. She did not know that if it was due to the vaccine. But she had tachycardia requiring her to go to the emergency room and she passed out and she had nausea and lightheadedness as well. It sounds like to be an allergic reaction. Given the seriousness of tachycardia and passing out as well as the lightheadedness and nausea it sounds too severe just to be a mild immune response. So, it was sort of rare immune response or it was unrelated it was unknown at this time. Outcome of event was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Sender's Comments: Based on the compatible time association, the contribution of suspect BNT162B2 to the events cannot be excluded. The impact of

this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

strong, whole body heat, and flushing; strong, whole body heat, and flushing; Tachycardia; Palpitations; This is a spontaneous report from a contactable Nurse. This Nurse reported for similar events for 6 patients. This is 2nd of 6 reports. A 49-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot/batch unknown), via an unspecified route of administration on 28Dec2020 at single dose for covid-19 immunization. The patient's medical history and concomitant medications were not reported. The reporter said her friend was a registered nurse, and received the COVID-19 Vaccine on Monday, 28Dec2020. She said her friend stated she, and 5 other registered nurses she works with, had a serious reaction right after receiving the COVID-19 Vaccine. The patient had a strong, whole body heat, and flushing. The patient said she became tachycardia and had palpitations that lasted a few minutes. She said the tachycardia and palpitations then slowly resolved in less than 5 minutes. She had no other symptoms after receiving the COVID-19 Vaccine. It was unknown whether the patient received the treatment or not. The outcome of the events was recovered on 28Dec2020. Information on lot/batch number has been requested.; Sender's Comments: The reported transient events of whole body heat, flushing, tachycardia and palpitations were likely related to BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) due to temporal relationship and clinic course. The case will be reassessed should additional information become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics committees and Investigators, as appropriate.,Linked Report(s) : US-PFIZER INC-2021001345 same reporter/drug/event, different patients.

Serious, weird reaction/had a strong, whole body heat, and flushing; Serious, weird reaction/had a strong, whole body heat, and flushing; Serious, weird reaction/tachycardic; Serious, weird reaction/had palpitations; This is a spontaneous report from a contactable nurse. This nurse reported similar events for 6 patients. This is 5th of 6 reports. A patient of unspecified gender and age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 28Dec2020 at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The reporter did not know if the patient had received any other vaccines at the same time as the COVID-19 Vaccine, and if the patient had received any other vaccines within the last 4 weeks. It was reporter that the reporter's friend texted her last night, on 30Dec2020, at around midnight. The reporter, and 5 other registered nurses she works with in a hospital, received the COVID-19 vaccine at the same time and had the same exact symptoms she experienced. They had a serious reaction right after receiving the COVID-19 Vaccine. The patient had a weird reaction right after being injected with the COVID-19 Vaccine. The patient had a strong, whole body heat, and flushing. The patient became tachycardic and had palpitations that lasted a few minutes. The tachycardia and palpitations then slowly resolved in less than 5 minutes. The patient had no other symptoms after

receiving the COVID-19 Vaccine. The registered nurse who was monitoring the people who received the COVID-19 Vaccine indicated that the same feeling had occurred in many other workers who had received the COVID-19 vaccine. For treatment information, the reporter didn't believe the patient received any medical attention. Reporter believed that the patient just waited symptoms out, and within 5 minutes the symptoms had gone away. The outcome of the events was recovered on 28Dec2020. Information on the lot/batch number has been requested.; Sender's Comments: Based on the compatible temporal association, the vaccination with BNT162B2 might play a contributory role in triggering the onset of the events flushing, feeling hot, tachycardia and palpitations. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.,Linked Report(s) : US-PFIZER INC-2021001345 same reporter/drug/event, different patient.

"Back of my right leg has a quarter size oblong shape lump it's little bit red but not warm to the touch; Back of my right leg has a quarter size oblong shape lump it's little bit red but not warm to the touch; Back of my right leg has a quarter size oblong shape lump it's little bit red but not warm to the touch, it may be a blood clot; This is a spontaneous report from a contactable consumer (patient). A patient of unspecified age and gender received single dose of BNT162B2 (Solution for injection, batch/lot number and exp date not reported), via an unspecified route of administration on 30Dec2020 18:30 SE for immunization. The patient's medical history and concomitant medications were not reported. Patient received the Pfizer Vaccine the day of reporting: 30Dec2020 at about 06:30 (tonight). Patient felt fine and still felt fine but when was going to rub some lotion on the back of right leg, has a quarter size oblong shaped lump (onset date not reported) which was little bit red but not warm to the touch. Patient didn't do anything to make it happen. Patient doesn't know if it may be a blood clot which was patient's question. ""The blood clot something may be concerned about."" Patient asked ""Is this a blood clot, it could go to my heart and I could die tomorrow? So I am going to call my family doctor but thank you."" The outcome of the events was unknown. Information about lot/batch number has been requested."

Fatigue and overall lethargic feeling/Sore throat; Dark colored urine despite pushing fluids; Frequent urination; Migraine; Swollen joints and could not move arm that received vaccine in; Swollen joints and could not move arm that received vaccine in; Stomach pains, nausea, diarrhea, swollen lymph nodes; Stomach pains, nausea, diarrhea, swollen lymph nodes; Stomach pains, nausea, diarrhea, swollen lymph nodes; Stomach pains, nausea, diarrhea, swollen lymph nodes; Chills, body aches, spiked fever of 102.; Chills, body aches, spiked fever of 102.; Chills, body aches, spiked fever of 102.; Fatigue and overall lethargic feeling; Fatigue and overall lethargic feeling; Sore throat; The initial case was missing the following minimum criteria: Invalid for no adverse effect. Upon receipt of follow-up information on (31Dec2020), this case now contains all required information to be considered valid. This is a spontaneous report from a contactable Nurse. A female patient of an unspecified age received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, batch/lot number EH9899, Expiry Date: Mar2021), intramuscular at Deltoid Left on 29Dec2020 07:20 at single dose for COVID-19 immunization. Medical

history included covid-19 from Nov2020 to an unknown date (had covid in the middle of November), surgeries from an unknown date and unknown if ongoing (She also had previous surgeries and has foreign objects in her body. Those areas were super hot. Those antibodies were like rejecting those foreign bodies because they were super hot.) There were no concomitant medications. Received call from RN calling about the Pfizer COVID vaccine. She got the vaccine on Tuesday and had a terrible reaction to it and she called a couple of different hotlines and spoke with the people who administered it. She confirmed that she did not report to Pfizer though. The people at her work that she spoke with told her to go to an Urgent care. They told her she should not get it within 90 days of having COVID. She had COVID in the middle of Nov2020. She went ahead and got it on Tuesday and had this terrible reaction. She would like to know if she should get the second dose or wait until 90 days after she had COVID and start again. There was no prescriber. She received it as part of the (hospital name withheld) front line health worker precaution. She thought that this was a normal reaction, but was told it was not. Fatigue and overall lethargic feeling happened exactly 12 hours after receiving. She works night shift and that is her base line. Pretty much everything hit after that within an hour. She was told low grade fever was normal, but not 102. She never spikes fevers, so it is medically significant. It persisted for 24 hours and is better today. She is on the 48 hour mark now. Stomach pains, nausea, diarrhea, lymph node swelling all over, including swelled armpits and groin area, Migraine, Frequent urination, were also listed as side effects. She was trying to push more fluids but her urine was dark color more than normal, despite pushing fluids. Swollen lymph nodes in her groin and armpits were concerning. Her head is lumpy. Meaning, she can feel swollen lymph nodes in back of neck area. Migraine was consistent through 24 hours and now has improved. Urine color remains dark and she will keep an eye on color. She had swollen joints, but really terrible swollen joints, and she could not move the arm that she got the vaccine in. She could not lift to above shoulder height. AE Details and time of onset: Sore Throat 12:00 on 29 Fatigue and overall lethargic feeling 20:00 Chills, body aches, spiked fever of 102: 21:00 Stomach pains, nausea, diarrhea, swollen lymph nodes- 21:00 Migraine- 21:00 Frequent Urination 23:00 Dark colored urine despite pushing fluids 23:00 Swollen joints and could not move arm that received vaccine in: 21:00. ER or physician's office required: Went to urgent care 36 hours after administration. No treatment given. She just wanted to make sure no additional infection was causing anything weird. All test were negative. Prior Vaccinations (within 4 weeks): none. Events Swollen joints and could not move arm that received vaccine in, Stomach pains, nausea, diarrhea, swollen lymph nodes, Chills, body aches, spiked fever of 102 were serious with criteria of medically significant, while the other events were non-serious. The outcome of the event Fatigue and overall lethargic feeling/Sore throat (Condition worsened) was unknown, the outcome of the events Swollen joints and could not move arm that received vaccine in, Chills, body aches, spiked fever of 102., Migraine, Dark colored urine despite pushing fluids, Frequent urination was recovering, while the outcome of the other events was not resolved.; Sender's Comments: Based on the information available, a possible contributory role of the suspect products cannot be excluded for the reported events due to temporal association. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators as appropriate.

anaphylactic reaction; neuropathy in fingers, toes, roof of mouth/lips; This is a spontaneous report from a contactable nurse (patient). This 48-year-old female patient (not pregnant at the time of vaccination) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot#: EL0140) at single dose on left arm on 30Dec2020 at 09:00 for COVID-19 immunization. Medical history included asthma (controlled); hypertension diagnosis 1 year ago; allergies to medications, food and environmental. Concomitant medications in two weeks included antihypertensives - amlodipine and losartan. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. On 30Dec2020 at 9:15 AM, the patient experienced anaphylactic reaction within 10 minutes of administration, neuropathy in fingers, toes, roof of mouth/lips. Neuropathy continued to date. The adverse events resulted in emergency room/department or urgent care. The patient received treatment Epinephrine IM (intramuscular) and IV (intravenous) steroids. The outcome of events was recovering.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the reported events of anaphylactic reaction and neuropathy peripheral due to temporal relationship. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics including serum tryptase and nerve conduction studies, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

"brain felt swollen; glands were also swollen; bad headache; minimal arm pain; fatigue; This is a spontaneous report from a contactable nurse (patient). A female patient of an unspecified age received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date not reported), via an unspecified route of administration on 30Dec2020 at single dose for COVID-19 immunization. Medical history included lupus-like history and chronic Lyme disease. The patient's concomitant medications were not reported. The patient stated she received the first vaccine dose on 30Dec2020 and had minimal arm pain, fatigue that went to a very bad headache on Thursday (31Dec2020). By Friday headache and fatigue were terrible until this morning. Her brain felt swollen and her glands were also swollen on 03Jan2021. The patient stated that she called healthcare professional (HCP) and was told that her body was ""having an auto immune response"", ""due to a lupus like history and a history of chronic Lyme disease and to hydrate well"". It was so hard to talk, she was so fatigued. Her doctor compared it to like an encephalopathy. The patient was feeling better today but was concerned about taking the second dose. She works in a facility with a lot of Covid-19 patients. The outcome of the events was recovering. Information on the lot/batch number has been requested.; Sender's Comments: Based on the current available information, a possible contributory role of the suspect product to the development of event brain felt swollen cannot be totally excluded. Medical history of lupus-like history and chronic Lyme disease may provide plausible alternative explanations for the event. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part

of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate."

numbness and weakness in left arm; numbness and weakness in left arm; had a brachial plexus pathology; her grip and fine motor are affected in her left arm/she could not do her job; This is a spontaneous report from a contactable physician (patient). A 35-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot# EH9899), via an unspecified route of administration in right arm on 21Dec2020 at single dose for Covid-19 immunisation. Medical history included ongoing birth control. No other medical history. Concomitant drug included other medication she took for birth control. On 29Dec2020, the patient experienced numbness and weakness in left arm, had a brachial plexus pathology, went to the emergency department on 30Dec2020 and was seen by one of the facility doctors and stated this doctor had her on steroids for treatment. She got the vaccine in her right arm, stated her grip and fine motor are affected in her left arm. States this was disabling since she could not do her job. She was following up with neurology on Monday (unspecified), that she had a CT scan of her neck and it was normal. Only other medication she was taking was for birth control, but she did not feel like it was relevant. The outcome of events numbness and weakness in left arm was recovering, while outcome of other events was unknown. This case was reported as serious, seriousness criteria was disabling.; Sender's Comments: Based on the information currently provided, the vaccination with BNT162B2 might play a contributory role in triggering the onset of the reported events. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

it hits a nerve; perceived it along the face still and the arm; Bell's Palsy; numbness in a small area of her tongue; right eye was irritated a little dry; right eye was irritated a little dry; right sided ear pain; fluid in the ear but no infection; This is a spontaneous report from a contactable health care professional (nurse practitioner). A 35-year-old female patient received her 1st dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) at single dose via an unknown route on the right side on 21Dec2020 for Covid-19 immunization. Medical history included intermittent hives. Concomitant drug included ongoing cetirizine hydrochloride (ZYRTEC) 5 mg for intermittent hives. The reporting nurse practitioner saw a patient on 31Dec2020 who was vaccinated on 21Dec2020 and had a Bell's Palsy reaction (reported as not serious). She did some research and saw no more incidents in the general population but she wanted to report this. She also wanted to get more information on if the patient should proceed with dose number 2 of the vaccine. The patient developed the Bell's Palsy within 5 minutes after getting the vaccine. She thought it was because she was anxious to get the vaccine, so she brushed it off. The Bell's Palsy was still occurring but per the patient it had improved. On exam she did not have any weakness, facial droop or dumbness with sharp or dull testing. The patient perceived it along the face still and the arm. The reporting nurse practitioner said that the arm was probably not Bell's Palsy, but more related to getting the vaccine in the arm and it hits a nerve. Patient stated that her smile was also unequal and it

was difficult for her to close her right eye, although now (as of 31Dec2020) she can. Her right eye was irritated a little dry. Regarding treatment, the patient was started on steroids on 31Dec2020. She did not start her on an anti-viral as she did not want it to impact her immunity to the vaccine. The patient also complained of right sided ear pain. She was unsure if that was related to the Bell's Palsy, but it was also on the right side. There was fluid in the ear but no infection. The pain was still ongoing. The patient also mentioned numbness in a small area of her tongue when she first got the vaccine. This was still ongoing. Outcome of Bell's Palsy was resolving. Outcome of the event numbness in a small area of her tongue, right sided ear pain was not resolved. Outcome of the other events was unknown. The reporting nurse practitioner stated that this was not serious as this was a mild case and was thankfully resolving. The reporting nurse practitioner comment that nothing of history was relevant besides for the last several months (as of 31Dec2020) the patient had been taking 5mg of cetirizine hydrochloride for intermittent hives. She wondered if she had not been taking it how she would have reacted or if the reaction would have been more severe. Information on the lot/Batch number has been requested.; Sender's Comments: A possible causal association between administration of BNT162B2 and the onset of Bell's Palsy cannot be excluded, considering the plausible temporal relationship. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Pitting edema/Edema: It was her feet, ankles, and 3/4 way up her shins.; This is a spontaneous report from a contactable nurse (patient). A 47-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number: EK5730, expiry date: Mar2021), intramuscular in the left deltoid on 17Dec2020 at 07:15 at single dose for COVID-19 immunization. Medical history included ongoing neuralgia since 2003 (has nerve pain in her face and neck. It has never caused swelling and that she has had it for a long time. Symptoms started 17 years ago, became apparent in 2009), ongoing hypothyroidism since 2003 (Diagnosed about 17 years ago. Nothing has changed medication wise). The patient's concomitant medications were not reported. The patient reported that she got the vaccine on 17Dec2020. On 25Dec2020, her shoes felt snug and by the next day she had 4 plus pitting edema. She could not fit in the shoes. She had the pitting edema for several days. She said that she went and bought compression stockings to help with the edema. It was her feet, ankles, and 3/4 way up her shins. It was more of the pedal area that was pitting. The patient further reported that she never had pitting edema before and the only thing new she had was the vaccine. Therapeutic measures were taken as a result of the event which included compression stockings. The patient was recovering from the event.; Sender's Comments: Based on temporal association, a possible contributory role of BNT162B2 cannot be excluded for reported event pitting edema. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

a strong, whole body heat, and flushing; a strong, whole body heat, and flushing; Tachycardia; Palpitations; This is a spontaneous report from a contactable Nurse. This Nurse reported similar event for 6 patients. This is 3rd of 6 reports. A 24-Year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 28Dec2020 at single dose for COVID-19 immunisation. Medical history and concomitant medications were not reported. Pfizer employee reporting on behalf of a friend, reported her friend texted her last night, 30Dec2020, at around midnight. The nurse and 5 other registered nurses she works with, had a serious reaction right after receiving the COVID-19 Vaccine. Caller said she had a strong, whole body heat, and flushing. She said she became tachycardic and had palpitations that lasted a few minutes. Caller said there were 5 other registered nurses that received the COVID-19 Vaccine at the same time and had the same exact symptoms she experienced. Outcome of events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Based on temporal association, a possible contributory role of BNT162B2 vaccine cannot be excluded for events flushing, feeling hot, tachycardia and palpitations. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate. ,Linked Report(s) : US-PFIZER INC-2021001345 same reporter/drug/event, different patient.

she had a strong, whole body heat, and flushing; she had a strong, whole body heat, and flushing; Tachycardia; Palpitations; This is a spontaneous report from a contactable nurse. This nurse reported similar events for 6 patients. This is the 6th of 6 reports. A 49-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot/batch unknown) via an unspecified route of administration on 28Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The reporter said her friend is a registered nurse, and received the COVID-19 Vaccine on Monday, 28Dec2020. She said her friend stated she, and 5 other registered nurses she works with, had a serious reaction right after receiving the COVID-19 Vaccine. The patient had a strong, whole body heat, and flushing. The patient said she became tachycardic and had palpitations that lasted a few minutes. She said the tachycardia and palpitations then slowly resolved in less than 5 minutes. She had no other symptoms after receiving the COVID-19 Vaccine. The registered nurse who was monitoring the people who received the COVID-19 Vaccine indicated that the same feeling had occurred in many other workers who had received the COVID-19 vaccine. The reporter did not know if the patient received any other vaccines at the same time as the COVID-19 Vaccine, and if had received any other vaccines within the last 4 weeks. The patient works at a hospital but doesn't believe that she received any medical attention. she believed just waited her symptoms out, and within 5 minutes her symptoms had gone away. The outcome of the events was recovered on 28Dec2020. Information on lot/batch number has been requested.; Sender's Comments: The Company cannot completely exclude the possible causality between the reported whole body heat, flushing, tachycardia and palpitations, and the administration of BNT162B2, based on the reasonable temporal association and lacking alternative explanations. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any

appropriate action in response, will be promptly notified to RA, IEC, as appropriate.,Linked Report(s) : US-PFIZER INC-2021001345 same reporter/drug/event, different patient.

Rash; Welts; she had a very sore arm; This is a spontaneous report from a contactable nurse (patient herself). A 65-year-old female patient received her first dose of bnt162b2 (BNT162B2 also reported as Pfizer Covid Vaccine, lot EH9099 or EH9899), via an unspecified route of administration in her left deltoid on 22Dec2020 09:32 at single dose for Covid-19 immunisation. Medical history included broken toe for 3 weeks. This was from her taekwondo and doesn't complain. No history of all previous immunization with the Pfizer vaccine considered as suspect drug. There were no additional vaccines administered on same date with Covid-19 vaccine. There were no concomitant medications. On 24Dec2020, she broke out in a rash on different parts of her body. She said the rash would come and go. She said she then had welts appear on different parts of her body and the welts would come and go. She said on the 3rd day, she had rash and welts together only on her trunk. She said on days 4, 5, and 6, she would have either a rash or welts come and go on different parts of her body. She clarified she had the rash and welts on her hands, wrists, ankles, and body. She reported that the rash and welts were serious-medically significant. On 22Dec2020, she had arm soreness and was just inconvenient and uncomfortable. She said she was not saying that what she was experiencing was related to receiving the COVID-19 Vaccine, but she doesn't know what else can be causing the rash and welts. She said she hasn't changed anything she has been eating or doing. She said she was worried about taking the 2nd COVID-19 Vaccine dose. She used Hydrocortisone 1% cream, Equate brand (reported to be expired) and took an oatmeal bath. She also took Benadryl and brand of Zyrtec called Wal-Zyr. Her height was 175cm, weight was 63kg. The rash and welts recovered on 30Dec2020; arm soreness recovered on 23Dec2020. Information about lot/batch number has been requested.; Sender's Comments: Based on temporal association, the causal relationship between BNT162B2 and the events rash and urticaria cannot be excluded. This case will be reassessed once additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate.

Saturation down to 84%; Temperature of 101.3; Rapid pulse having some difficulty; This is a spontaneous report from a contactable consumer. A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number and expiry date not reported) via an unspecified route of administration, on 30Dec2020, single dose for COVID-19 immunization. Relevant medical history and concomitant medications were not reported. The reporter is working in long term in Nursing care facility. It was reported that they have a resident who recovered from COVID. They are having some questions following the guidelines stuff, just kind of asking some more questions. Just one of their resident had temperature of 101.3, saturation down to 84%, 'frustration' at 24% and rapid pulse having some difficulty. The patient was put in her bed. The reporter contacted the doctor in house. 'The reporter wanted to see if any of the recommendation were for (incomplete sentence). The long term care facilities recovered COVID, the reporter wanted to know any of the lasting short term and any guideline for treating. They were all recovered COVID, all of two of the resident two weeks or more out

and we (Further clarification was unknown) just had the vaccine yesterday' (as reported, pending clarification). Outcome of the events was unknown. Information on the batch number has been requested.

Fainting; Red Palms; blotching; sweating profusely; heart palpitations; Chest pain; Elevated BP; This is a spontaneous report from a contactable consumer (patient). A 46-years-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 28Dec2020 09:15 at single dose on left arm (Lot number: ek9231) for COVID-19 immunisation. Medical history included asthma, bronchitis, mitral valve regurgitation, herpes, depression, ADHD. COVID prior vaccination: Yes. Known allergies: tramadol, milk products. No other vaccine in four weeks. Concomitant medication included amfetamine aspartate, amfetamine sulfate, dexamfetamine saccharate, dexamfetamine sulfate (ADDERALL), bupropion, and, losartan/hydrochlorothiazide. The patient experienced red palms/blotching, sweating profusely, heart palpitations, chest pain and fainting, elevated BP, all on 28Dec2020 09:15. All these events required Emergency room visit. Therapeutic measures were taken as a result of the events included 50 mg of Benadryl, 60 mg of Prednisone, omepresol. No COVID tested post vaccination. Outcome of events was recovered with sequelae.

I have a sleep problem almost eight hours; I was so tired; Headache; My arm was sore for 24 hours; so stiff; This is a spontaneous report from a contactable physician. A 69-year-old patient of an unspecified gender received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiry date were not reported), via an unspecified route of administration on an unspecified date at a single dose for COVD-19 immunization. The patient's medical history and concomitant medications were not reported. The patient had the first dose of the vaccine and had a pretty significant reaction, one say serious to moderate reaction. The patient's question was do they know yet if you take a second shot was your reaction get even worse because the patient had a sleep problem almost eight hours. The patient was so tired, had headache and so stiff, arm was sore for 24 hours. The patient was a little afraid to take a second shot. The outcome of the events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: A causal association between BNT162B2 and the reported events cannot be excluded based on a compatible temporal relation between vaccination and onset of events. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to agencys, Ethics Committees, and Investigators, as appropriate.

feeling close to loss of consciousness; intense chest pressure/tightness; shortness of breath; chills while driving home; This is a spontaneous report from a contactable healthcare professional (patient). A 50-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Lot number: EL0142), via an unspecified route of administration in the left arm, on 02Jan2021 at 11:30 (at the age of 50-years-old) as a single dose for COVID-19 immunization. The patient's medical history was not reported. The patient was not pregnant at the time of vaccination. Prior to the vaccination, the patient was not diagnosed with COVID-19. Concomitant medications, taken within two weeks of vaccination, included ibuprofen (MANUFACTURER UNKNOWN). The patient previously took amoxicillin (MANUFACTURER UNKNOWN) and experienced allergy. The patient did not receive any other vaccines

within four weeks prior to the vaccination. The patient experienced feeling close to loss of consciousness, intense chest pressure/tightness, shortness of breath, and chills while driving home on 02Jan2021 at 12:00. The patient did not receive any treatment for the events. The clinical outcome of feeling close to loss of consciousness, intense chest pressure/tightness, shortness of breath, and chills while driving home was recovering. It was also reported that since the vaccination, the patient had not been tested for COVID-19.; Sender's Comments: A possible causal association between administration of BNT162B2 and the onset of feeling close to loss of consciousness, intense chest pressure/tightness, shortness of breath cannot be excluded, considering the plausible temporal relationship. The underlying predisposing condition of penicillin allergy may put the patient at high risk of anaphylactic reactions. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Right sided facial & top lip Numbness & recurring pain; Right sided facial & top lip Numbness & recurring pain; Right sided facial & top lip Numbness & recurring pain; This is a spontaneous report from a contactable consumer reporting for herself. A 66-year-old female patient (not pregnant at the time of vaccination) received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number EK9231), via unspecified route of administration on 29Dec2020 13:30 on left arm at single dose for COVID-19 immunization. Facility where the most recent COVID-19 vaccine was administered in Hospital. Medical history included Hypertension, Reflux and low back pain. Concomitant medications included ibuprofen, dicycloverine hydrochloride (BENTYL), Valsartan and omeprazole. The patient previously took codeine, Bactrim, Zyrtec and experienced allergies. The patient experienced Right sided facial and top lip Numbness, recurring pain on 31Dec2020 16:00. All events resulted in emergency room visit and Hospitalization on 31Dec2020 for 1 day. The patient underwent lab tests and procedures, which included Cat scan, MRI, ultrasound of heart and labs on unspecified dates, Nasal Swab/Covid 19 test on 01Jan2021 with negative result. The outcome of the events were not resolved.

hives on her legs; a slight rash on abdomen (started morning on the next day when she woke up) and it spread to her legs (leg rash started 2 days later in the morning); This is a spontaneous report from a contactable nurse (patient). A 58-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) intramuscularly at left arm on 29Dec2020 10:30 at single dose for COVID-19 Immunization. No medical history. No family medical history. There were no concomitant medications. Patient received first dose last Tuesday, 29Dec2020, at the hospital. The next day, she had a slight rash on abdomen (started morning on the next day when she woke up) and it spread to her legs (leg rash started 2 days later in the morning). It was a pretty severe case of hives on her legs now (31Dec2020). Spread to legs and now has hives on legs was reported as worsened. Physician's office visit involved. She had a question. Her doctor prescribed a dosing pack of prednisone to get rid of the hives and her question was, will it affect the effectiveness of the vaccine if she takes it, also, is it ok to get 2nd dose in 2 weeks. She confirmed she had not taken the prednisone yet. There was no prescriber. She received it because she is a healthcare worker. Patient asked if there is any recommendation on getting pre medicated with ex: Benadryl before getting the vaccine. No previous history of all previous

immunization with the Pfizer vaccine considered as suspect. No additional vaccines administered on same date of the Pfizer suspect product. No medications prior vaccinations (within 4 weeks). No test done. This is a serious report. The slight rash on abdomen, spread to legs and now has hives on legs was considered medically significant per reporter. The outcome of the events was not recovered. Information about lot/batch number has been requested.; Sender's Comments: Based on temporal association, the causal relationship between BNT162B2 and the events rash and urticaria cannot be excluded. This case will be reassessed once additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate.

experienced eye puffiness; light headed ness; scratchy throat; This is a spontaneous report from a non-contactable consumer via Pfizer Sales Representative. A male patient (Health care worker) of an unspecified age and gender received BNT162B2(Pfizer BioNTech COVID-19 vaccine) via an unspecified route of administration in Dec2020 at single dose for COVID-19 immunization. The medical history and concomitant medications were not reported. The patient experienced eye puffiness, light headed ness and scratchy throat 10 minutes after vaccination in Dec2020. Reaction was not considered anaphylaxis. Patient received epinephrine, Pepcid and Benadryl in the ED, felt completely back to normal within an hour and was released. Event took place after use of product. The outcome of events was recovered in Dec2020. No follow-up attempts are possible; information about batch number cannot be obtained.

Felt sharp pain under jaw, then facial numbness. Then quickly developed facial swelling, left eye swelling and tongue swelling. Then felt like throat closing up within 7 minutes of receiving vaccine. Received vaccine in the clinic, was transported to Emergency Room. In ER received Epinephrine, steroids, Benadryl and Pepcid.

1 day after the vaccine he had a low grade fever... 1 week later he had a seizure and then multiple ones in the ER...

Developed shortness of breath, swelling of tongue, persistent cough within 5 minutes of vaccination. Was treated with EpiPen and kept in ER for observation overnight. Symptoms resolved.

Patient contacted provider 12/26 with following symptoms: Dry cough, diarrhea, fatigue for 7 days. Covid test ordered and positive. presented to ED on 12/31 and admitted into hospital. Still inpatient as of 1/7/2021.

Patient experienced an episode of SVT and then sinus tachycardia for approximately 6 hours after injection

"Pt last seen at 1200 by nurse for ID band check. No visible signs of distress noted. Pt states ""I just want to be left alone"". 1230 nurse was called to pt room. Pt was noted unresponsive, no pulse and respiration noted. CPR started immediately, at 1239 first shock given. 1245 EMT took over, at 1319 EMT called time of death"

Hemmoragic Stroke. Began with vision difficulty in the morning. Then I noticed she had left sided neglect. Went to ER. Treated with Andresxa (to counteract Elaquis). In SICU for 2 nights then telemetry unit for 3 nights. CUrrently in Rehab.

"Following vaccination the patient had progressively worsening abdominal pain over the next 24 hours. Presented to the ER and was initially thought to have appendicitis. However, it was then discovered during surgery that the appendix was surgically absent. The surgeon did not that the patient did have a ""Round, infarcted ligamentous tissue was wrapped around ascending colon. """

Patient developed hypoxia on 1/4/2021 and did not respond to maximal treatment and passed way on 1/5/2021

When vaccine was administered, seemed high on my arm. I had immediate soreness and shoulder discomfort, I was told this was normal. It continued to progress and I eventually had decreased ROM, weakness and sharp shooting pain in my shoulder. Working at OI, I consulted provider, xrays were obtained and I was evaluated. He strongly suggested an MRI be obtained as well. That was completed the same day as my evaluation on 12/31/2020 (1 week and 2 days after the vaccine was administered). The provider informed me that they have had patients with similar situations that were evaluated for frozen shoulder after having a vaccine d/t administration site and vaccine going into subacromial space. He does report that this was my case/situation, upon my exam, I had severe inflammation with this as well-he is now having me follow up for a surgical consultation for my shoulder to be repaired. Today's date is 1/7/2021, I have these same ongoing symptoms that have continued since day of administration, without diminishing in severity. He is unable to provide an injection d/t my upcoming second dose of the COVID vaccine this next week, 1/12/2021. He strongly suggests that my 2nd vaccine be administered elsewhere-advised NOT be administered in the same shoulder OR in opposite to cause these symptoms to flare. He advised in gluteus if possible to avoid any further issues if at all possible.

patient declined 12/30/2020 and was transferred to hospital where he did not respond to treatment and passed away 1/4/2020

Patient did not report any signs or symptoms of adverse reaction to vaccine. Patient suffered from several comorbidities (diabetes and renal insufficiency). Patient reported not feeling well 01/06/2021 and passed away that day.

Guillain Barre syndrome/AIDP event. Paresthesia and nerve pain developed in bilateral legs 4 hours after shot and progressed slowly for 4 days in intensity and area involved. Symptoms progressed distally to superior. On the 5th day symptoms progressed rapidly and involved bilateral legs up to the groin, left arm up to lateral shoulder, and right hand. I went to the hospital and was admitted to start IVIG treatment for Guillain Barre Syndrome/AIDP.

Vaccine Candidate received vaccine approxat 2:30pm, was monitored for 15 min no complications at the time, went home. Around 5:30pm while walking into her home she became unresponsive, was assisted in a siting position, became incoherent, mumbling and started to convulse to the right side of her r upper extremity. Foaming at the mouth and stopped breathing, CPR was initiated for 1-2 min, EMS

arrived was transported to Medical Center. She was admitted and is currently hospitalized. MD reports this event is highly unlikely related to the vaccine given her medical history but suggested to report being its a new vaccine. Current status: stable.

Person had a fever of 102.4, pulse rate of 118, he was non-responsive with edema of the right calf & ankle this morning when he was assessed.

Resident had the COVID vaccine 12/30/2020. 12/31/20, resident has been in bed all shift. Staff became concerned when resident was not easily aroused. Resident displayed signs of tremors, twitching, confusion, in and out of consciousness, low O2 sats, elevated pulse and fever, fatigue and weakness. Writer called NP. NP stated this is most likely a reaction d/t the COVID vaccine. She gave orders for Benadryl 25mg IM x1 now and Tylenol 1000 mg now. NP also stated resident will not be getting the second dose of vaccine. Will continue to monitor and update NP if worsening symptoms. After receiving Benadryl and Tylenol at 145pm, resident began to appear as though she was feeling better and was talking to talk, fever had gone down. Tonight resident is not easily aroused, lethargic, continues to have tremors and twitches, almost appearing as convulsions. When asked if she knows where she is or what day it is, resident can properly answer. Resident denies SOB but staff has noted loud squeals while breathing. NP was updated and gave new orders to give Benadryl 25 mg IM x1 if needed and Ok to send resident to ED. Resident currently refuses to go to the hospital. Will continue to monitor. BP 152/112, P 116, T 99.1, O2 87-91. Resident's O2 at 1205am was 80% on 3LPM. Resident unable to be aroused from sleep by writer. NAR called to assist. NAR could not arouse resident. Writer and NAR attempted to reposition resident and resident's breathing became more labored. Resident turned back to previous position and writer called on call MD at approx. 1220am. MD returned call approx. 1235am with orders to send resident to ED. 911 called and ambulance arrived about 1245am. History of present condition given to EMTs and they stated resident would be going to Hospital. Writer has attempted to contact Hospital ED x3 but have been unable to get through. An EMT did just call to clarify when vaccine was given, what symptoms have been present and when they started. She said she has everything she should need and she will let Hospital ED staff know to call if they need anything else. Writer will again attempt to contact them though. Resident's temp was 97.5 and BG 128. When EMTs arrived they got an O2 reading of 60%. Resident did open her eyes a couple times during transfer from bed to stretcher and while stretcher was going outside but no responses from resident were made.

had a vaccination on 12/31/2020 late morning passed away early morning 01/01/2020. This is a 93 year old with significant heart issues. EF of 20% among other comorbidities. He died suddenly approximately 0430, it is unlikely it was related to receiving the vaccine.

Immediate pain and loss of range of movement of left shoulder. Physical examination today demonstrates a healing injection site which is fairly superior on the left shoulder, and abduction of the left shoulder which is limited secondary to pain. Patient's physician's impression is that he has a subdeltoid bursitis which was temporally associated to the COVID-19 vaccination. (SIRVA)

RED CIRCULAR RASH AND LUMP UNDER SKIN. SKIN IS VERY ITCHY

Diffuse polyarthropathy starting the day after vaccination and continuing for 7+ days. Currently treating with abx for concern of possible cellulitis, and prednisone 60mg for polyarthropathy. Currently admitted.

woke up with fever and sore throat on 22nd; went to job and got tested and tested positive; on the 23rd developed right upper lobe pneumonia; on 27th was hospitalized with three lobe pneumonia; On 22nd received got zpack - azithromycin and sudafed; received at hospital doxicycleln IV ; ivermectin and went home with them, as well. Hospital

Day 2 (12/29/20): Fever (<100 degrees), Mild muscle aches, Fatigue Day 3 (12/30/20): Fatigue, Muscle aches Day 4 (12/31/20): Alternating chills and profuse sweating starting at 8am, Full body flushing, Grand Mal Seizure at 4:30pm

Patient was vaccinated at 11am and was found at the facility in his room deceased at approximately 3:00pm. Nurse did not have cause of death

Nausea, hives, anaphylactic shock, throat swelling, hypotension, headache, dizziness, weakness . The symptoms returned at 1:25pm the best day as well. I?ve now had two anaphylactic reactions

No adverse effects noted after vaccination. Patient with cardiac history was found unresponsive at 16:45 on 1/6/21. Abnormal breathing patterns, eyes partially closed SPO2 was 41%, pulseless with no cardiac sounds upon auscultation. CPR and pulse was regained and patient was breathing. Patient sent to Hospital ER were she remained in an unstable condition had multiple cardiac arrest and severe bradycardia and in the end the hospital was unable to bring her back.

Hives-like appearance on both arms within 10 minutes of administering vaccine. Resolved by itself in 30-40 minutes.

45 min later after receiving the vaccine I felt a lump in my throat. No other symptoms of an allergic reaction. Took benadryl with improvement of symptoms. Had intermittent difficulties swallowing seven hours afterwards. Went to the ED and was prescribed prednisone/ pepcid/benadryl. Symptoms improved but next day felt intermittent difficulty swallowing again. Returned to the ED and was given IV solumedrol and, IV pepdcid, IV benadryl.

Patient alerted pharmacist to feeling light headed at 12:10pm. Patient was instructed to sit down on the floor. She stated she felt hot and hadn't eaten all day. She was given a few bites of apple sauce and some Dr. Pepper to drink in case of low blood sugar. She was also given 25mg of diphenhydramine in case of an allergic reaction after the vaccine adminstration at 12:15pm. A few minutes later, she began shaking and stated she thought she was having an anxiety attack. At this time, the patient requested we call 911 because that would make her feel better and so we did.

Symptoms started during bedtime and woke me up. Began with severe full body chills and full body muscle shaking and weakness during the night of 1/5 and early morning of 1/6, around 1000 to 0200. Slight headache began during that time as well. Upon waking at 0900 on 1/6, chills and shaking decreased to mild severity, muscles still felt moderately weak and shaky, headache had increased in

severity to a severe throbbing pain that worsened upon standing and walking, and moderate visual photosensitivity began. The headache persisted until I took 2 tablets of ibuprofen 200 mg, which is when the severity decreased to moderate after a few hours and then mild by bedtime. The photosensitivity persisted through the day and did not decrease much by bedtime. Upon waking 1/7, there was only a mild headache and mild photosensitivity that faded completely within a few hours, no medication required. No more symptoms in the afternoon.

Moderna covid 19 vaccine EAU

2 hrs after vaccine felt sweating, clammy. Gas pains and cramps began. Loose stool once. 7 pm arm was sore and throbbing 6 of 10, injection site flushed and warm to the touch 9pm pain worsened to 8of 10. Unable to grab toothbrush with left arm sharp pain 10 of 10. Unable to sleep on left side due to pain and pressure . 6:00 am Thursday pain worse and unable to lift arm above the shoulder. Was unable to drive with left hand. All day today bad gas and abdominal cramps.by the end of the work day I was unable to hold anything in my left hand, body aches started, legs tight and achy. Frontal headache. Took Tylenol extra strength q 6 hrs, nsaid 800mg bid. And aleve, no relief

Had chills fever and body ache starting 01/07/21 Temperature went as high as 102.0 took ibuprofen and came down 97.9

On day 7, a red rash appeared just below the injection site and is indurated, hot, and tender. It spread in size within the next day.

Morning 8 days after injection, emergence of rash above injection site and redness and swelling at injection site. Morning 9 days after injection rash became a larger hive and doubled regular Zyrtec dosage. Morning 10 days after injection symptoms gone.

"Tire on day one-slept for 18 hours. Day 2: Woke up and was mildly achy, not wanting to do anything and red large swelling in my right deltoid. Very tender. Also, edema starting in my right axilla extending down my lateral chest about 7"". Day 3 to 7: Achiness is gone. Edema and swelling continue. Eventually the red swollen area became itchy. The edema under my arm (not a lymph node) was tender when my arm was close to my body. Woke me up during the night frequently. Very hard to sleep."

4 days later after the vaccine my left eye turned really red with crust and mucus coming out. I went to walk in clinic and was being treated for pink eye. I was started on an antibiotic eye drop. A day later my right eye started to have the same problem. I scheduled an appt with a eye specialist where he examined both eyes and said I had a major infection. I was started on steroid eye drops which I am still taking but seems my eyes are not getting better. I have a follow up with another specialist next week for further testing. I have been out of work due to this matter.

"Severe allergic reaction; anaphylactic reaction; A spontaneous report was received from a physician, who was also a male patient who received Moderna's COVID-19 Vaccine and developed a severe/anaphylactic allergic reaction. The patient's medical history, as provided by the reporter, included a shellfish allergy and elevated Immunoglobulin E. He reported no history of adverse events

following other immunizations, that all his immunizations were up to date, and that he gets the flu shot annually. Products known to have been used by the patient, within two weeks prior to the event, included pantoprazole, vitamin D, and vitamin B12. On 24 Dec 2020, minutes prior to the onset of the event, the patient received the first of two planned doses of mRNA-1273 intramuscularly for COVID-19 infection prophylaxis. Within minutes, the patient felt dizzy and his heart was racing. His throat felt swollen and he experienced shortness of breath (""heavy breathing"") with no wheezing or stridor, but with chest tightness that he felt was possibly related to anxiety about receiving the vaccine and the potential for allergic reaction. No supplemental oxygen was required. Vital signs showed a heart rate of 145, with normal blood pressure (BP) and oxygen saturation. After a few more minutes, he started to feel numbness and tingling in his mouth and tongue. He experienced diaphoresis (""drenched in a cold sweat""), skin pallor (""skin was severely pale""), felt faint, and reported that his blood pressure was undetectable by a monitor. He did not lose consciousness and denied any skin rash. The patient felt he was developing an allergic reaction and self-administered his personal epinephrine auto-injector. He felt better within five to six minutes after self-administration of epinephrine and was taken by stretcher to the Emergency Department for further evaluation and treatment of shortness of breath, dizziness, palpitations, and numbness. The patient was evaluated, treated, observed, and discharged four hours later. Treatment provided for the events while in the Emergency Department included diphenhydramine hydrochloride, intravenous (IV) fluids, IV steroids, and famotidine. On 25 Dec 2020, the patient felt fully recovered. On 26 Dec 2020, the patient felt dizzy and reported experiencing a ""rapid heart rate"" of 70-120 with a systolic BP that was abnormal for him at 150 mmHg. He also reported that he felt premature atrial contractions, for which he took his wife's propranolol. His heart rate came down, but he still felt flushing and dizziness for a few more hours. Action taken with mRNA-1273 in response to the event was not reported. The outcome of the event, severe/anaphylactic allergic reaction, was considered resolved on 26 Dec 2020. The reporter assessed the event of severe/anaphylactic allergic reaction as related to Moderna's COVID-19 Vaccine due to the temporal association and the similarity of symptoms previously experienced with severe/anaphylactic allergic reactions to shellfish.; Reporter's Comments: Company Comment: This case concerns a male patient with medical history of shellfish allergy , who experienced an unexpected events of severe allergic reaction; anaphylactic reaction, dizzy, faint, heart racing, tongue prickled and went numb, cold sweat, blood pressure plummeted, shortness of breath, numbness and skin was pale..The onset of event occurred 15 hrs the first dose of vaccine administration . The events are assessed as possibly related to vaccine."

throwing up; fever; body aches; her whole intestines hurt; it was horrible; thought she had contracted COVID-19; thought she had contracted COVID-19; tired; This is a spontaneous report from a contactable consumer. A 54-years-old female patient received her first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number EL0140), via an unspecified route of administration on left arm on 17Dec2020 at 19:15, at a single dose for vaccination. Medical history included ongoing ulcerative colitis, onset date was unknown, but when she was about 25 years of age. Concomitant medication included ongoing azathioprine for ulcerative colitis, started probably 5-10 years ago and taken daily since. In the past, she took different products for ulcerative colitis off and on when she had an episode. This patient reported she was administered her first Pfizer COVID-19 Vaccine injection on 17Dec2020 and was just kind of tired on 17Dec2020; but she had onset of serious reactions to the

COVID-19 Vaccine starting 18Dec2020 for 2 days straight and then as suddenly as the events started they suddenly stopped after 2 days with no lasting effects. She called to ask if there is any data about if the second dose of the COVID-19 Vaccine will be just like the first shot or if the events are just hit or miss; she is really hoping not to be that sick again with the second dose. Serious reactions to the COVID-19 Vaccine further described as sick for like 2 days straight. Afternoon of 18Dec2020 she was throwing up; had fever; body aches; thought she had contracted COVID-19 in between injection and onset of symptoms; she had no lung issues; her whole body hurt; she could not stop throwing up; her whole intestines hurt; it was horrible; she could not hold anything down for like 2 straight days and then just left on 20Dec2020. Scheduled date for second dose was on 06Jan2021, she has no plan to change dose schedule. The outcome of the event of tired recovered in Dec2020, while other events recovered on 20Dec2020.

positive COVID-19 test with symptoms; positive COVID-19 test; gastritis; diarrhea; This is a spontaneous report from a contactable other hcp (patient). A 50-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number: EJ1685; expiry date was not reported), via an unspecified route of administration on the upper right arm on 21Dec2020 at single dose for COVID-19 immunization. Medical history included blood pressure high, attention deficit hyperactivity disorder (ADHD), hypertension all from an unknown date and unknown if ongoing, and was a former smoker. Concomitant medication included lisinopril and methylphenidate. The patient reported that after he received the vaccine, he tested positive for Covid on 30Dec2020. The patient further reported that he ended up getting significant gastritis on Christmas Eve, which he didn't think about acquiring COVID, he had had the vaccine, he ate a bunch of holiday fare, so he thought he had got a stomach bug or something like that. He says he had considerable diarrhea on Christmas morning, but no fever or chills, then those symptoms resolved by Saturday, and he didn't think about it, he didn't have any issues. He says that he went to get tested, which they do frequently, and his temperature was checked frequently at the places he goes and he had no fever, and is still not febrile now. He says that he gets a weekly COVID test which allows for him to enter different facilities, and this was the first time in 9 months that he tested positive since this all came out. He says he has worked in some heavy duty places, but he wears his PPE, his respirator, his shield, and still did this stuff after he got the vaccine, he didn't let his guard down since it might take a while for immunity to kick in, but he still didn't think that it could be possible to have COVID on Christmas Eve, he was rather surprised he was positive. The patient confirms that he hasn't had the second dose of the vaccine yet. He says that his diarrhea improved on day or two starting after he had been having bloating on Christmas Eve and Christmas morning. He says his diarrhea resolved, he took no medication for it, and had no change in his heart rate or breathing, no problems anywhere else, he didn't feel that bad, except for the going to the bathroom. The patient underwent lab tests and procedures which included sars-cov-2 test: positive on 30Dec2020. The outcome of the events was unknown.; Sender's Comments: Based on the information currently available, a lack of efficacy with the suspected vaccine BNT162B2 in this subject cannot be completely excluded. Further information like confirmative virus genome /nucleic acid detection needed for meaningful medical assessment.

Reported to get the vaccine, and within a couple of hours or days, test positive for COVID; Reported to get the vaccine, and within a couple of hours or days, test positive for COVID; This is a spontaneous

report from a contactable other HCP received from a Pfizer-sponsored program IBCC (Inbound Call Center for HCPs). A patient of unspecified age and gender received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiry date were not reported), via an unspecified route of administration on an unspecified date at a single dose for covid-19 vaccination. The patient's medical history and concomitant medications were not reported. The patient reported to get the vaccine, and within a couple of hours or days, test positive for covid. The outcome of the event was unknown Information on the lot/batch number has been requested.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the reported events of SARS-CoV-2 test positive and LOE due to temporal relationship. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.,Linked Report(s) : US-PFIZER INC-2020520145 different patients, same drug and event

Cough; Fever; body aches; Tested positive for COVID after the first dose of the vaccine/tested positive for COVID-19; Tested positive for COVID after the first dose of the vaccine/tested positive for COVID-19; This is a spontaneous report from a contactable physician reporting for himself from a Pfizer sponsored program, IBCC (Inbound Call Center for HCPs). A 31-year-old male received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number EK5730) intramuscular Deltoid Left, on 17Dec2020 9:00, single dose for COVID-19 immunisation. Relevant medical history included seasonal allergies and asthma. Concomitant medications were reported as none. The patient took the first dose of the COVID-19 Vaccine and he is schedule on 07Jan2021 for his second dose. After the first dose he tested positive for COVID on 30Dec2020. The patient got tested for COVID-19 around 10:30 a.m. The patient hasn't seen a physician and he doesn't don't plan on it. The patient had a cough on an unspecified. Early on he had a fever and body aches but that passed after the first day. Caller clarifies the fever and body aches started Sunday and were gone by Tuesday morning. The cough started on Monday and is still ongoing and persisting. The patient was not hospitalized in response to the events. Outcome of the event cough was not recovered, the events fever and body aches recovered on an unspecified date, while it was unknown for tested positive for COVID after the first dose of the vaccine.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the SARS-CoV-2 test positive, LOE and other reported events due to temporal relationship. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Test positive for COVID after the first vaccine dose; Test positive for COVID after the first vaccine dose; This is a spontaneous report from a contactable Physician. This Physician reported similar events for 2 patients. This is the 2nd of 2 reports. A female patient of unspecified age received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiry date were not reported), via an unspecified route of administration on an unspecified date at a single dose for COVID-19 vaccination. The patient's relevant medical history and concomitant medications was not reported. The patient was tested positive after the first dose of the vaccine. The outcome of the event was unknown. Information on the lot/batch number has been requested; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the reported events of COVID-19 virus test positive and LOE due to temporal relationship. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.,Linked Report(s) : US-PFIZER INC-2020520651 same reporter/product/event, different patient

Test positive for COVID after the first vaccine dose; Test positive for COVID after the first vaccine dose; This is a spontaneous report from a contactable Physician. This Physician reported similar events for 2 patients. This is the 1st of 2 reports. A 42-year-old female patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number EH9899), via an unspecified route of administration in left deltoid on 16Dec2020 at a single dose for COVID-19 vaccination. There were no relevant medical history and concomitant medications. The patient was test positive for covid after the first vaccine dose on 27Dec2020 with outcome of not recovered.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the reported events of COVID 19 test positive and LOE due to temporal relationship. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.,Linked Report(s) : US-PFIZER INC-2020520645 same reporter/product/event, different patient

positive for COVID-19 after 1st dose; positive for COVID-19 after 1st dose; This is a spontaneous report from a contactable nurse. A female patient of an unspecified age received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on an unspecified date at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The nurse was inquiring about receiving the second dose of vaccine

after testing positive for COVID-19 after 1st dose. Outcome of the event was unknown. Information on Lot/batch number has been requested.; Sender's Comments: Based on the information currently available, a lack of efficacy with the suspected vaccine BNT162B2 in this patient cannot be completely excluded. Further information like confirmative virus genome /nucleic acid detection needed for meaningful medical assessment.

came out positive for Covid-19; came out positive for Covid-19; This is a spontaneous report from a contactable pharmacist. A male patient of an unspecified age received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration in 29Dec2020 at a single dose for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient came out positive for covid-19 on 30Dec2020 and inquired if he should still get the 2nd dose. Information on the lot/batch number has been requested.

"testing positive for covid/ they have had a patient have a positive COVID test after vaccine was given; testing positive for covid/ they have had a patient have a positive COVID test after vaccine was given; This is a spontaneous report from a contactable pharmacist via medical information team and a Pfizer-sponsored program IBCC (Inbound Call Center for HCPs). A 43-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (lot number EK5730, expiration date 31Mar2021), via an unspecified route of administration on 18Dec2020 at single dose for COVID-19 immunization. The patient's medical history included ongoing asthma. The reporter was not aware of any allergies, adverse reactions to previous vaccines, significant medical history or any relevant family medical history of the patients. Concomitant medications were reported as none. It was reported that that they had a patient who had a positive COVID test after vaccine was given. The patient who received the vaccine on 18Dec2020 now testing positive for COVID. The patient received the first vaccine dose on 18Dec2020. She tested positive 30Dec2020. They wanted to give her monoclonal antibodies (Bamlanivimab) but they don't know how that would interact with the vaccine. Also, they didn't know how the product and the positive test would play into her already having the first dose and getting the second dose. The second shot would be due on 08Jan2020. The patient was not at the facility at the point of reporting, they had been talking to her by phone. The type of test done was unknown. No treatments known. The outcome of the event ""positive COVID test after vaccine was given"" was not recovered. The event was assessed as medically significant, and unrelated to vaccine by reporter. The seriousness assessment option was made due to her history of asthma.; Sender's Comments: Based on available information, a possible contributory role of suspect BNT162B2 cannot be completely excluded for reported ""positive COVID test after vaccine was given""."

Contracted Covid; Contracted Covid; This is a spontaneous report from a contactable Other Health Professional (patient). A 59-year-old female patient received the first dose of BNT162b2 (Lot/batch number and Expiration date were not provided), via an unspecified route of administration at left arm on 21Dec2020 18:00 at single dose for COVID-19 immunization. Medical history included chronic obstructive pulmonary disease (COPD). The patient received the unspecified concomitant medications within 2 weeks of vaccination; patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient was contracted COVID on 29Dec2020 20:00. The event resulted in Doctor or other healthcare professional office/clinic visit. Patient received the treatment Monochrome antibiotic

for event. The patient received the COVID test post vaccination on 29Dec2020. The COVID test type post vaccination was Nasal Swab, COVID test name post vaccination was RNA, COVID test result was Positive. The patient was not COVID prior vaccination. The patient was not pregnant at the time of vaccination. The outcome of the events was not recovered. Information on the Lot/batch number has been requested.; Sender's Comments: Based on the information currently available, a lack of efficacy with the vaccination with BNT162B2 in this patient cannot be completely excluded.

He lost the sense of smell on 28Dec2020 and later tested positive; He lost the sense of smell on 28Dec2020 and later tested positive; He lost the sense of smell on 28Dec2020 and later tested positive; This is a spontaneous report from a contactable other healthcare professional (HCP). A male patient (respiratory therapist) of an unspecified age received a single dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) as the first dose via an unspecified route of administration on 16Dec2020 for COVID-19 immunization. The patient medical history and concomitant medications were not reported. He lost the sense of smell on 28Dec2020 and later tested positive in Dec2020. The outcome of the events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Based on the information currently available, a lack of efficacy with the suspected vaccine BNT162B2 in this patient cannot be completely excluded. Further information like confirmative virus genome /nucleic acid detection is needed for meaningful medical assessment.

"I came down with a COVID infection; I came down with a COVID infection; This is a spontaneous report from a contactable healthcare professional (HCP) reporting for herself. A female patient of an unspecified age received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (lot number not reported) via an unspecified route of administration on 18Dec2020 at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient came down with a COVID infection on 23Dec2020 with outcome of unknown. Information on the lot/batch number has been requested.; Sender's Comments: Based on the information available, a possible contributory role of the suspect BNT162B2 cannot be excluded for the reported event ""came down with a COVID infection"" based on the known safety profile. However the short duration of 5 days since the vaccine first dose is given it is unlikely patient would have fully developed immunity."

Anaphylactic reaction; hives in the first 10 minutes of the vaccine; This is a spontaneous report from a contactable Other Health Professional (Physician Assistant). A 29-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 29Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The reporter stated that she is treating a patient in ICU that got the COVID-19 vaccine on 29Dec2020. The patient developed hives in the first 10 minutes of the vaccine and had an anaphylactic reaction 1 hour later. Seriousness of events was reported to be hospitalization. Outcome of the events was unknown. The reporter also mentioned that it was not a mild reaction and patient was still in the ICU, 48 hours later. Information about lot/batch number has been requested.; Sender's Comments: A possible causal association between administration of BNT162B2 and the onset of anaphylactic reaction and hives cannot be excluded, considering the plausible temporal relationship and the known adverse event profile of the suspect product. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation,

including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

"She tested positive PCR; She tested positive PCR; This is a spontaneous report from a contactable Nurse. A female patient of unspecified age received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 17Dec2020 at single dose for COVID-19 immunization. The relevant medical history and concomitant medications were not reported. Resident inoculated on 17Dec. She tested positive PCR on 29Dec2020. Currently in quarantine and asymptomatic. She was scheduled for dose 2 on 06Jan2021. This still fell in quarantine period. The nurse wanted to know if the patient could get the second dose on 06Jan, if not when should she get second dose. The outcome of the events was unknown. Information about lot/batch number has been requested.; Sender's Comments: Based on available information, a possible contributory role of suspect BNT162B2 vaccine cannot be completely excluded for reported event ""test positive PCR""."

I tested positive for COVID 9 days after receiving the vaccine; I tested positive for COVID 9 days after receiving the vaccine; Rhinorrhea; aches; fatigue; cough; This is a spontaneous report from a contactable physician. This physician reported similar events for two patients. This is the first of the two reports. A 68-years-old female patient (not pregnant) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number and expiry date not reported), via an unspecified route of administration on the left arm on 21Dec2020 at 09:30 at a single dose for COVID-19 immunization. Medical history included hypertension. The patient had no known allergies. Concomitant medications included losartan (LOSARTAN), amlodipine (AMLODIPINE), and atorvastatin (ATORVASTATIN). On 28Dec2020, the patient had rhinorrhea, aches, fatigue, and cough. The patient had no COVID prior vaccination, and when tested post vaccination showed a positive result. It was reported that the patient was tested via nasal swab (PCR SARS) and showed positive for COVID on 30Dec2020, 9 days after receiving the vaccine. The patient had no other vaccines in four weeks. No treatment was administered for the events. The events had not resolved. Information on the lot/ batch number has been requested.; Sender's Comments: A causal association between BNT162B2 and the events drug ineffective and SARS-COV-2 test positive cannot be excluded based on a compatible temporal relation. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.,Linked Report(s) : US-PFIZER INC-2021001246 Same reporter, same drug, similar events, different patients.

She also complained of all the COVID signs and symptoms; She also complained of all the COVID signs and symptoms; left cervical, axillary, clavicular and periscapular lymphadenopathy; left arm and shoulder pain; left arm and shoulder pain; This is a spontaneous report from a contactable physician. An adult female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) Solution for injection, lot number was unknown, intramuscular in the left arm on 28Dec2020 at a single dose for COVID-19 immunization. Medical history included covid-19 from an unknown date and unknown if ongoing. The patient's concomitant medications were not reported. The patient is not pregnant. It was

unknown if the patient received any other vaccines within 4 weeks prior to the COVID vaccine. It was reported that after receiving the Pfizer COVID-19 vaccine in the left deltoid, the patient experienced left cervical, axillary, clavicular and periscapular lymphadenopathy in Dec2020 with outcome of not recovered. She also complained of left arm and shoulder pain and all the COVID signs and symptoms in Dec2020 with outcome of not recovered. The onset was within a day of immunization. She has a history of COVID-19, she had Covid prior vaccination. It was unknown if the patient tested for Covid post vaccination. The onset date of the events was reported as Dec2020. The events was reported as non-serious and it was unknown if the patient received treatment for the events. Information on the lot/batch number has been requested.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the suspected LOE, COVID 19 and other reported events due to temporal relationship. Of note, it is reported that the patient had a history of COVID-19, and she was diagnosed with COVID 19 infection prior to the vaccination. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics , counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

tested positive for Covid test; tested positive for Covid test; difficulty breathing; chills; fluctuating fever; nausea; weakness; weakness/extreme fatigue; loss of taste and smell; loss of taste and smell; muscle pain; cough; sore throat; nasal drip; dizziness; fast heartbeat; injection site pain; anxiety; crying; This is a spontaneous report from a contactable healthcare professional. This 21-year-old female patient reported for herself that she received BNT162B2 1st dose on 31Dec2020 10:00 AM intramuscular at left arm for COVID-19 immunisation. Medical history included known allergies: Penicillin and Covid-19. Concomitant therapy included BC as reported. The patient experienced difficulty breathing, chills, fluctuating fever, nausea, dizziness, weakness, fast heartbeat, tiredness, loss of taste and smell, muscle pain, injection site pain, anxiety, cough, sore throat, nasal drip, crying, extreme fatigue, Etc on 31Dec2020 at 06:00 PM. The events resulted in doctor or other healthcare professional office/clinic visit, emergency. The patient was hospitalized for 1 day and received treatment included blood thinner rivaroxaban (XARELTO) and had 2 weeks quarantine. The patient had Covid prior to vaccination and tested positive for Covid test post vaccination on 01Jan2021. The outcome of the events was not resolved. Information on Lot/batch number has been requested.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the suspected LOE, SARS-CoV-2 test positive and the other reported events due to temporal relationship. Of note, it is reported that the patient had history of COVID 19 infection prior to the vaccination. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part

of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

polyneuropathy; facet joint diagnosis/new left forefoot paresthesia; This is a spontaneous report from a contactable physician (patient). A 45-years-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (lot EJ1685) at the first dose in left arm on 17Dec2020 12:45 at single dose for COVID-19 immunisation. Facility where the most recent COVID-19 vaccine was administered at Doctor's office/urgent care. Medical history included ongoing back pain (thinking it was due to running/physical therapy overuse injury). No allergies to medications, food, or other products. There were no concomitant medications. Patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. No any other medications the patient received within 2 weeks of vaccination. It was reported that 20Dec2020 morning: new left forefoot paresthesia. no weakness. Patient thought this might be due to the back pain he had been watching for 3 months, thinking it was due to running/physical therapy overuse injury. On 21Dec2020 sports medicine physician evaluation. numbness was gone, facet joint diagnosis, MRI lumbar ordered (still pending). On 24Dec2020 9 pm, paresthesia both hands and feet, no weakness nor other symptoms those continued and were slightly worse on 27Dec2020 morning, including face/teeth. no other symptoms; 27Dec2020 afternoon: internal medicine physician evaluation, working diagnosis polyneuropathy. Neurologist appointment will be 07Jan2021, 2 hours before 2nd shot was scheduled. The patient had been tested for COVID-19 test type post vaccination: negative on 22Dec2020. No treatment for event. Prior to vaccination, the patient was not diagnosed with COVID-19. Outcome of events was not resolved.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the reported events of polyneuropathy and facet joint diagnosis/new left forefoot paresthesia due to temporal relationship. However, the reported events may possibly represent intercurrent medical conditions in this patient. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics including nerve conduction tests, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

got COVID-19 from his son and tested positive; got COVID-19 from his son and tested positive; This is a spontaneous report from a contactable physician. A 51-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 18Dec2020 at single dose for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient got COVID-19 from his son and he tested positive 31Dec2020. The patient's son got the COVID-19 virus on 20Dec202020. The patient is due to have 2nd vaccine on 07Jan2021. Outcome of the events was unknown. Information on batch number has been requested.;

Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of events Drug ineffective and COVID-19 virus test positive cannot be totally excluded. The case will be reassessed if additional information becomes available.

was diagnosis with COVID-19 through nasopharyngeal swab today, 02Jan2021; was diagnosis with COVID-19 through nasopharyngeal swab today, 02Jan2021; This is a spontaneous report from a contactable pharmacist (patient himself). A 34-year-old male patient received his first dose of bnt162b2 (BNT162B2 also reported as COVID 19 brand Pfizer, lot EJ1685, expiry date not reported), via an unspecified route of administration in his right arm on 23Dec2020 15:30 at single dose, for Covid-19 vaccination. The patient's medical history was not reported. Prior to vaccination the patient was not diagnosed with COVID-19. He did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Concomitant medication included bupropion. The patient informed that he was diagnosed with Covid-19 through nasopharyngeal swab (COVID-19 Nucleic Acid Amplification test) on 02Jan2021 01:00 and Influenza virus test was unknown results (02Jan2021). It was unknown if there was a treatment used. The outcome of event was not recovered.; Sender's Comments: Based on the information available, a possible contributory role of the suspect products cannot be excluded for the reported event of positive for corona virus infection for the lack of efficacy of the vaccine. However, based on the mechanism of action of the vaccine, it is unlikely the patient would have fully developed immunity for the vaccine to be effective, due to the number of days passed since the vaccine is given. Case will be reevaluated based on follow-up information

she received the Pfizer vaccine on 29Dec2020. She tested positive for coronavirus on 01Jan2021. Is the efficacy of the vaccine after the second dose?; tested positive for coronavirus; This is a spontaneous report from a contactable nurse reported for herself. A female patient of an unspecified age received first dose of BNT162B2 (Pfizer-BioNTech COVID-19 mRNA vaccine; lot/batch number and expiry date were unknown), via an unspecified route of administration on 29Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. VA nurse calling stating that she received the Pfizer vaccine on 29Dec2020. She tested positive for coronavirus on 01Jan2021. She wanted to know how to proceed with getting her second vaccine, and if the efficacy of the vaccine is after the second dose. The outcome of the event was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of events Drug ineffective and Coronavirus test positive cannot be totally excluded. The case will be reassessed if additional information becomes available.

received vaccine on 17Dec2020, then tested positive for coronavirus on 25Dec2020; received vaccine on 17Dec2020, then tested positive for coronavirus on 25Dec2020; This is a spontaneous report from a contactable nurse (patient). A female patient of an unspecified age received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 17Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient received vaccine on 17Dec2020, then tested positive for coronavirus on 25Dec2020. The patient was calling to inquire if she can get second vaccine. Outcome of the event was

unknown. Information on the lot/batch number has been requested.; Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of events Drug ineffective and COVID-19 cannot be totally excluded. The case will be reassessed if additional information becomes available.

became positive for covid 19; became positive for covid 19; This is a spontaneous report from a contactable other healthcare professional (patient). A female patient of an unspecified age received the first dose of bnt162b2 (Pfizer-Biontech Covid-19 Vaccine) via an unspecified route of administration on 22Dec2020 at a single dose for covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient she received covid vaccine on 22Dec2020 and on 30Dec2020 became positive for covid 19. The patient wanted to know when she can schedule her 2nd dose. Outcome of the event was unknown. Information about Batch/Lot number has been requested.; Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of events Drug ineffective and COVID-19 cannot be totally excluded. The case will be reassessed if additional information becomes available.

slight cough; diarrhea; shortness of breath; no sense of smell; positive for covid 19 virus; positive for covid 19 virus; feel tired; sore arm; This is a spontaneous report from a non-contactable consumer (patient). A 44-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) first dose on 20Dec2020 at single dose for COVID-19 immunization. Medical history and concomitant medications were not reported. Patient was Diagnosed with covid 19 virus on the 31Dec2020, she was set to have the second vaccine on the 10Jan2021. She wanted to know if she can get the second dose and if so, when. Also asked if she should get tested before taking the 2nd dose of the covid 19 vaccine. Her Adverse effects are sore arm on vaccination day (20Dec2020), and she began to feel tired on 27Dec2020 and thought that was normal. She went to a Christmas eve party 24Dec2020 and no one was masked, friend had several people from work tested positive. was tested and was positive for covid 19 virus on 31Dec2020. She also was experiencing slight cough, diarrhea (which is normal for her), shortness of breath is improving and she had no sense of smell but she was able to taste. The outcome of event shortness of breath is recovering. The outcome of other events was unknown. No follow-up attempts are possible. information about lot/batch number cannot be obtained.

Tested Positive for COVID-19/nausea, occasional dry cough, neck and lower back soreness, and sore throat; Tested Positive for COVID-19/nausea, occasional dry cough, neck and lower back soreness, and sore throat; Weakness/generalized weakness; This is a spontaneous report from a contactable nurse (patient). A 62-year-old female patient received first dose of BNT162b2 (Pfizer, Lot number: 5730), via an unspecified route of administration at right arm at 22Dec2020 21:00 at single dose for covid-19 immunization. Medical history included Mayonaise allergies. The patient's concomitant medications were not reported. The patient previously took codeine and experienced allergies. At 31Dec2020 06:00, the patient experienced Weakness, nausea, occasional dry cough, generalized weakness, neck and lower back soreness, and sore throat which has now dissipated. Tested Positive for COVID-19 on 02Jan2021 (also reported as 01Jan2021, pending clarification). The covid test type post vaccination was Nasal Swab, Covid test name post vaccination was COVID-19 PCR ROCHE c6800(NTX), RNA SARS CoV2 TGT1, PAN

SARS RNA TGT2. No treatment received for events. The events result in Emergency room/department or urgent care. The patient was not pregnant. The outcome of the events were nor recovered.; Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of events Drug ineffective and COVID-19 cannot be totally excluded. The case will be reassessed if additional information becomes available.

Took the COVID vaccine; Rapid Antigen Test turned out positive, PCR test came out negative; Took the COVID vaccine; Rapid Antigen Test turned out positive, PCR test came out negative; This is a spontaneous report from a non-contactable consumer. A patient of unspecified age and gender received BNT162b2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on an unspecified date at single dose for covid-19 immunization. The patient medical history and concomitant medications were not reported. The patient took the COVID vaccine, and a few days later they took the Rapid Antigen Test, the COVID test. And it turned out positive. The person took other tests as well, PCR test which came out negative. The reporter didn't know if there was any research or data if that was done maybe during clinical trials of whether it is possible to come out positive on an antigen test which tests for bio-protein. The reporter believe that was what in the vaccine. The reporter guess the vaccine causes the reaction in the body to make that protein in the body. The reporter wonder if it was possible it could be false positive on one of those tests because of the vaccine, because of the way that rapid test works. The outcome of the events was unknown. No follow-up attempts are possible. Information about lot/batch number cannot be obtained. No further information is expected.

"Got tested positive; Got tested positive; This is a spontaneous report from a contactable nurse from a Pfizer-sponsored program Pfizer First Connect. A male patient of an unspecified age received first dose bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EJ1685, Expiry Date: 31Mar2021), via an unspecified route of administration on 17Dec2020 at single dose for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. Transferring agent stated, ""I have a nurse (reporter) on the other line. She is currently on hold. She is reporting an adverse event about COVID Vaccine because she is saying that their doctor (Incomplete sentence). I mean, the nurse on the other line is working at the vaccine clinic. One of their doctors in the clinic had COVID Vaccine on 17Dec2020. I mean, the Doctor got positive or tested positive on 23Dec2020. Should that mean that the COVID Vaccine or the first dose of COVID Vaccine did not take effect for the Doctor itself because the Doctor got positive? They would like to know if they should still need to take second dose of COVID Vaccine."" When paraphrased the concern, reporter stated, ""Correct. And the question is would he need to get his second dose. It is said that it's two doses."" The outcome of the events was unknown.; Sender's Comments: Based on the information available, a possible contributory role of the suspect BNT162B2 cannot be excluded for the reported event test positive based on the known safety profile. However the short duration of 6 days since the vaccine first dose is given it is unlikely patient would have fully developed immunity."

Anaphylactic reaction; This is a spontaneous report from a contactable nurse. A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899), via an unspecified route of administration on deltoid (unknown which) on 31Dec2020 at 0.3 mL, single for

COVID-19 immunization. There were no medical history and concomitant medications. The patient experienced anaphylactic reaction on 31Dec2020. The event required emergency room visit for observation and treatment.; Sender's Comments: A possible causal association between administration of BNT162B2 and the onset of anaphylactic reaction cannot be excluded, considering the plausible temporal relationship and the known adverse event profile of the suspect product. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

"Tested positive for COVID after having received the vaccine; Tested positive for COVID after having received the vaccine; This is a spontaneous report from a contactable nurse. This nurse reported similar events for 2 patients. This is second of 2 reports. A 7-decade-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (lot number EJ1685, expiration date Mar2021), via an unspecified route of administration on 19Dec2020 at 0.3 mL, single in the left deltoid for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. It was reported that on 30Dec2020, the patient tested positive for COVID after having received the vaccine. The reporter said that they had been vaccinating people at their work. The reporter had vaccinated two people now who within about a week after, they tested positive for COVID. The patient was exposed to COVID outside of work. This patient was a healthcare worker (Doctor) in his 60's, weight within normal limits. He seemed healthy. He was fit. He showed up for work everyday. He was vaccinated on 19Dec2020, then tested positive for COVID yesterday, on 30Dec2020. The reporter was wondering if the patient should still get the second dose in 3 weeks, or wait 90 days after tested positive. The reporter needed to know whether to stick with the 21 day time period for the second dose, or wait 90 days. They had been telling people who were already positive, or who had COVID in the past, to wait 90 days to get the vaccine. The reporter had read all of the literature and looked online and could not find any information on this. The outcome of the event ""tested positive for COVID after having received the vaccine"" was not recovered. The event was assessed as non-serious, and unrelated to vaccine by reporter. She did not think, with either of these patients that them getting COVID had anything to do with the vaccine. She thought it was a coincidence and they were obviously exposed prior to receiving the vaccine.; Sender's Comments: Based on the information currently available, the reported event ""tested positive for COVID"" which was further reported as getting COVID by the nurse, was likely related to patient's exposure to SARS-CoV-2 virus prior to vaccination, and unlikely causally related to BNT162B2 vaccine. Further information like confirmative virus genome /nucleic acid detection needed for more meaningful medical assessment.,Linked Report(s) : US-PFIZER INC-2021001215 Same drug and events, different patient"

"Got the vaccine and developed COVID; Got the vaccine and developed COVID; This is a spontaneous report from a Pfizer-sponsored program IBCC (Inbound Call Center for HCPs) from a contactable physician. This pharmacist reported similar events for two patients. This is the second of two reports for Infection Control Nurse's daughter. A female patient of an unspecified age received her first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date not reported), via an

unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient got the vaccine and 10 days later, got COVID, so, she got swabbed on unknown date. The patient was wondering if she needed to start over or if she was okay to get the second dose. The outcome of events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Based on the information available, a possible contributory role of the suspect BNT162B2 cannot be excluded for the reported ""got COVID"", based on the known safety profile. However the short duration of 10 days since the vaccine first dose is given it is unlikely patient would have fully developed immunity.,Linked Report(s) : US-PFIZER INC-2021001217 same reporter/product, similar events, different patients."

"Tested positive for COVID after having received the vaccine; Tested positive for COVID after having received the vaccine; This is a spontaneous report from a contactable nurse. This nurse reported similar events for 2 patients. This is 1st of 2 reports. A 7-decade-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, batch/lot number: EJ1685, expiration date: Mar2021), via an unspecified route of administration on 18Dec2020 at left deltoid, at 0.3 mL, single for covid-19 immunization. Medical history included ongoing diabetic. Concomitant medication included insulin for diabetic; pioglitazone hydrochloride (ACTOS) for diabetic and all ongoing. The patient received the vaccine on 18Dec2020 and then less than a week later, on 23Dec2020 was positive for COVID. The reporter said that they had been vaccinating people at their work. The reporter had vaccinated two people now who within about a week after, they tested positive for COVID. The patient was exposed to COVID outside of work. This patient was a healthcare worker (Doctor) in his 60's, weight within normal limits. The reported stated that obviously this person was exposed prior to getting the vaccine and was not symptomatic. But she needed to know, should she stick with the 21 day time period for the second dose or wait 90 days. The patient described COVID as the flu with an attitude. He was staying home and resting. The reporter did not think, with either of these patients that them getting COVID had anything to do with the vaccine. She thought it was a coincidence and they were obviously exposed prior to receiving the vaccine. The event was assessed as non-serious, and unrelated to vaccine by reporter. The outcome of the events was not recovered.; Sender's Comments: There is not a reasonable possibility that event ""tested positive for COVID"" is related to BNT162B2 vaccine. Patient most likely was exposed to SARS-CoV-2 virus prior vaccination.,Linked Report(s) : US-PFIZER INC-2021001199 Same drug and events, different patient"

Patient got the vaccine and 10 days later got Covid; Patient got the vaccine and 10 days later got Covid; Sinus drainage; This is a spontaneous report from a Pfizer-sponsored program IBCC (Inbound Call Center for HCPs) from a contactable physician. This pharmacist reported similar events for two patients. This is the first of two reports for Infection Control Nurse. A female patient of an unspecified age received her first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date not reported), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient got the vaccine and 10 days later, got COVID. So, the patient got swabbed because of the sinus draining but she was not ill. The patient was not sick she got some sinus drainage. The outcome of event was unknown. The patients were wondering if they need to start over or if they were okay to get the

second dose. Information on the lot/batch number has been requested.; Sender's Comments: Based on the information currently available, a lack of efficacy with the suspected vaccine BNT162B2 in this patient cannot be completely excluded. However, the duration of 10 days since the vaccine first dose is short, and it is unlikely patient would have fully developed immunity. Further information like confirmative virus genome /nucleic acid detection needed for meaningful medical assessment.,Linked Report(s) : US-PFIZER INC-2021001212 same reporter/product, similar events, different patients.

patient tested positive for COVID 1 week after vaccination; patient tested positive for COVID 1 week after vaccination; This is a spontaneous report from a contactable physician (patient's wife). This physician reported similar events for two patients. This is the second of two reports. A male patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number and expiry date not reported) via an unspecified route of administration, on 21Dec2020, single dose, for COVID-19 immunization. Relevant medical history and concomitant medications were not reported. The patient tested positive for COVID on 28Dec2020 (1 week after vaccination). Outcome of the events was unknown. Information about lot/batch number has been requested.; Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of events Drug ineffective and COVID-19 virus test positive cannot be totally excluded. The case will be reassessed if additional information becomes available.

chills and not feeling very good; chills and not feeling very good; rapid COVID test positive; rapid COVID test positive; This is a spontaneous report from a contactable consumer. This consumer reported similar events for two patients. This is the first of two reports. This case is serious, the other one is non-serious. A 22-year-old female patient received first dose of BNT162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/Lot Number: EH9899) intramuscular at left deltoid on 22Dec2020 19:00 at single dose for covid-19 immunization. The patient medical history and concomitant medications were not reported. No other vaccines given at the same time. The patient received a flu shot back between 27th or 28th Nov2020 in her left deltoid. Caller reported getting the COVID vaccine on the 22Dec2020 and feeling fine before that. On the 28Dec2020 she started feeling chills and not feeling very good and that hasn't gone away. The patient went and got a rapid COVID test and it came back positive, not sure if it was because of the vaccine having antigens in it or she came into contact with it or if she just weakened immune system from the shot. The patient wanted to know if that was true. Then stated she and her mom got the COVID vaccine and her mom received it on the 23Dec. On the 29Dec her whole family started to get sick and experiencing the same things she experienced. The patient was not feeling well at the time of the call. The outcome of the events was not recovered.; Sender's Comments: Linked Report(s) : 2021001266 same reporter/ drug, different patient/event

PCR was positive last night; PCR was positive last night; This is a spontaneous report from a contactable Other Health Professional (Patient) reported that a 39-year-old female patient receives first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot/Batch Number: EH9899 and Expiration Date unknown) via an unspecified route of administration on 18Dec2020 at single dose for covid-19 immunization. The patient's medical history was unknown. The concomitant medications were reported as none. The patient experienced received the Pfizer's COVID Vaccine on 18Dec2020 (later clarified) at

work, at (Institution name) and she just wanted to report that on 23Dec2020, her husband developed symptoms, he was positive on the 26Dec2020 and then she was just converted and her PCR was positive last night on 30Dec2020 (later clarified). Patient think her husband exposed then she was exposed. Treatment included Advair is twice a day and albuterol is three times a day. The outcome of events was unknown.; Sender's Comments: Based on the information available, a possible contributory role of the suspect BNT162B2 cannot be excluded for the reported COVID-19 PCR test positive based on the known safety profile. However the short duration of 12 days since the vaccine first dose is given it is unlikely patient would have fully developed immunity. Of note, the patient was exposure to COVID-19 (her husband developed COVID-19).

tested positive for the Covid antigen with no signs or symptoms; tested positive for the Covid antigen with no signs or symptoms; This is a spontaneous report from a contactable consumer(an administrator of skilled nursing facility). A patient of unspecified age and gender received BNT162B2 (Covid vaccine) , via an unspecified route of administration on an unspecified date at single dose for covid-19 immunisation. The patient medical history and concomitant medications were not reported. The reporter stated the pharmacy did a Pfizer vaccine clinic at his facility, stated that after looking at the FAQs he would like to know if they should not expect a positive antigen test after the vaccine, states the reason he was asking was because the patient they tested today(31Dec2020) that got the vaccine tested positive for the Covid antigen with no signs or symptoms. Outcome of event was unknown. Information on the lot/batch number has been requested.

given the Covid 19 vaccine and subsequently tested positive for SARS CoV2 a day or so later; given the Covid 19 vaccine and subsequently tested positive for SARS CoV2 a day or so later; This is a spontaneous report from a non-contactable healthcare professional via Pfizer sales representative. A patient of an unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number and expiry date not reported) via an unspecified route of administration, from an unspecified date, single dose for COVID-19 immunization. Relevant medical history and concomitant medications were not reported. The patient was given the COVID 19 vaccine and subsequently tested + for SARS CoV2 a day or so later on an unspecified date. Outcome of the events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Sender's Comments: Based on the information available, a possible contributory role of the suspect products cannot be excluded for the reported event of positive for corona virus infection for the lack of efficacy of the vaccine. However, based on the mechanism of action of the vaccine, it is unlikely the patient would have fully developed immunity for the vaccine to be effective, due to the number of days passed since the vaccine is given. Case will be reevaluated based on follow-up information

Allergic reaction; Hives on back; Flushed; Chills; Swollen tongue; Burning tongue; This is a spontaneous report from a contactable consumer (patient). This 47-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 29Dec2020 07:00 at single dose on left arm for COVID-19 vaccination. There were no medical history and concomitant medications. The patient previously took flu shot. Vaccination Facility Type was hospital. Patient did not receive any other vaccines at time COVID-19 vaccine given and no vaccines given 4 weeks prior. Patient got the Pfizer COVID-19 vaccine on 29Dec2020 and had an allergic reaction

to it. Had hives on her back, was flushed, had chills, and swollen tongue on 29Dec2020. There was swelling on either side of tongue not in the center. Swelling seemed to bounce around sides of tongue. Patient mentioned she also had burning sensation of tongue first on 29Dec2020 and then the swelling was after that. Adverse events hives, flushed, chills, burning sensation of tongue and swelling of tongue required a visit to emergency room. Patient was seen in the emergency room and given diphenhydramine hydrochloride (BENADRYL) and an Epi-pen to take home. This all happened after receiving the vaccine on 29Dec2020. Patient wasn't getting any better/feeling better and went back to the emergency room on 30Dec2020. Patient was treated with dexamethasone and told her to take diphenhydramine hydrochloride every 4 hours, her last dose was at 2pm 31Dec2020. Patient said all events still persisting, but there maybe a little more swelling of the tongue, but not much. Patient had had a flu shot before, but never had anything to happen like this. Outcome of allergic reaction, hives, flushed, chills and burning tongue was not recovered, outcome of swollen tongue was unknown. Information on the lot/batch number has been requested.

tested positive for Covid; tested positive for Covid; This is a spontaneous report from a contactable Nurse reported for self. This 42-year-old patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on an 22Dec2020 08:00 on Left arm at single dose (Lot # EH9899) for covid-19 immunisation. Medical history, concomitant medications were none. The patient tested positive for Covid in 25Dec2020. The patient was scheduled to receive the second dose in 08Jan2021 so should the patient get it. (Further clarified the dates and years). Outcome of the events were unknown.; Sender's Comments: A possible contributory effect of suspect BNT162B2 on reported event cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

"Left axillary, supraclavicual, and cervical chain lymphadenopathy > 1-week post-injection.; since the vaccination, has the patient been tested for COVID-19?: Yes; since the vaccination, has the patient been tested for COVID-19?: Yes; This is a spontaneous report from a contactable healthcare professional. A 26-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899), intramuscular on the left arm on 21Dec2020 20:00 at single dose for COVID-19 immunisation. The patient medical history was not reported. The patient's concomitant medications were not reported. The patient experienced left axillary, supraclavicual, and cervical chain lymphadenopathy > 1-week post-injection on 22Dec2020 16:00. in which the patient received no treatment. It was also reported on Dec2020, ""since the vaccination, has the patient been tested for COVID-19?: Yes"". The patient has other pending test. The outcome of left axillary, supraclavicual, and cervical chain lymphadenopathy > 1-week post-injection was not recovered and other events was unknown.; Sender's Comments: Based on the information provided, the COVID-19 test positive are possibly related to drug ineffective of BNT162B2 vaccine."

One of my partners was the same way, tested positive after getting the vaccine; One of my partners was the same way, tested positive after getting the vaccine; This is a spontaneous report from a contactable nurse. This nurse reported similar events for 2 patient. This is the second of 2 reports. A patient of

unspecified age and gender received bnt162b2 (BNT162B2, Pfizer biontech Covid-19 Vaccine, solution for injection, lot number and expiation date unknown), via an unspecified route of administration on an unspecified date at a single dose for covid-19 immunization. The patient's medical history and concomitant medications were not reported. On an unknown date, the patient was tested positive after getting the vaccine. The outcome of the event was unknown. Information on Lot/batch number has been requested.; Sender's Comments: The association between the event lack of effect (SARS CoV2 test positive) with BNT162b2 can not be fully excluded.,Linked Report(s) : US-PFIZER INC-2020510419 same reporter/ drug/similar events, different patient

positive COVID-19 test with symptoms; her arm ached; positive COVID-19 test with symptoms; This is a spontaneous report from a non-contactable nurse (patient) and two consumers. A 45-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number and expiry date not reported), via an unspecified route of administration on Dec2020 at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient who is a nurse got the disease after getting coronavirus vaccine. This nurse reported that her arm ached after the vaccination and that she did not experience any other side effects. This nurse who worked in the coronavirus unit after the vaccine, fell ill 6 days after the vaccine. Stating that she was cold, the nurse later reported that she was experiencing muscle pain and feeling weak. The nurse, who applied to the hospital after becoming increasingly sluggish, performed a coronavirus test. The nurse's corona test was positive on an unspecified date in Dec2020. The patient underwent lab tests and procedures which included sars-cov-2 test: positive on Dec2020. The outcome of the events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.; Sender's Comments: The association between lack of effect (SARS CoV test positive) with BNT162b2 can not be fully excluded based on the temporal relationship. Occupational exposure may have played a contributory role as well.

she woke up sick and was having the same symptoms as her husband so she was positive; she woke up sick and was having the same symptoms as her husband so she was positive; This is a spontaneous report from a contactable pharmacist reported for herself. A 31-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration in Dec2020 at single dose for COVID-19 immunization. The patient medical history was not reported. The patient's concomitant medications were not reported. Caller stated that she was a pharmacist and on Tuesday last week that she received the Pfizer BioNTech Vaccine. Stated that her husband tested positive yesterday (on 29Dec2020). Stated that she was positive that she was positive because that was her husband. Stated that she woke up sick and was having the same symptoms as her husband so she was positive. Stated that she was due for second dose in 2 weeks. Stated that she received the vaccine last week and was negative. The patient underwent lab tests and procedures which included covid test: negative in Dec2020. The outcome of the events was unknown. Information about Batch/Lot number has been requested.; Sender's Comments: The information currently provided is too limited to make a meaningful medical assessment hence, the events are conservatively assessed as related to the suspect drug BNT162B2 until further information becomes available.

symptomatic of Covid; symptomatic of Covid; inoculated on 15Dec2020; patient was scheduled on 04Jan2021 for 2nd dose; inoculated on 15Dec2020; patient was scheduled on 04Jan2021 for 2nd dose; This is a spontaneous report from a contactable nurse. A patient of unspecified age and gender received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number and expiry date unknown) via an unspecified route of administration on 15Dec2020 at single dose for Covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient was inoculated on 15Dec2020 and currently on 28Dec2020 the patient was symptomatic of Covid. The patient was scheduled on 04Jan2021 for 2nd dose. The outcome of the events symptomatic of Covid was unknown. Follow-up activities are possible, information on the batch number has been requested.; Sender's Comments: The information currently provided is too limited to make a meaningful medical assessment hence, the events are conservatively assessed as related to the suspect drug BNT162B2 until further information becomes available.

got the vaccine within the past 24 hours and resulted positive for the test; got the vaccine within the past 24 hours and resulted positive for the test; This is a spontaneous report from a contactable consumer (patient). A 24-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL1284), via an unspecified route of administration on an unspecified date in 2020 at a single dose for COVID-19 immunization. There were no medical history or concomitant medications. The patient got the vaccine within the past 24 hours and resulted positive for the test, the patient took 48 hours ago like was that going to some adverse reaction like patient had the positive results before knowing the result patient got the vaccine so at present patient was just kind of anxious about what going to happen. Next shot will be due on 20Jan2021. The outcome of events was unknown.

tested positive for Covid a week after receiving the vaccine; tested positive for Covid a week after receiving the vaccine; patient stated that she was pregnant; patient stated that she was pregnant; patient stated that she was pregnant; This is a spontaneous report from a contactable nurse (patient) from a Pfizer sponsored program. A 37-year-old female patient received 1st dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot# EH9899), via an unspecified route of administration on 18Dec2020 at left deltoid for Covid-19 immunisation. The patient medical history was not reported. There were no concomitant medications. The patient experienced tested positive for Covid a week after receiving the vaccine on 28Dec2020 (as reported), the patient stated that she was pregnant. The patient underwent lab tests and procedures which included Covid test: positive on 28Dec2020. The outcome of events was unknown.; Sender's Comments: Based on the information currently available, a lack of efficacy with the suspected vaccine BNT162B2 in this patient cannot be completely excluded. Further information like confirmative virus genome /nucleic acid detection is needed for meaningful medical assessment.

had the vaccine and later tested positive for COVID-19; had the vaccine and later tested positive for COVID-19; This is a spontaneous report from a non-contactable consumer. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on Dec2020 at single dose for COVID-19 immunisation. Medical history included that the patient previously was positive from the virus COVID-19. The patient's concomitant medications were not reported. The patient that had the vaccine and later tested positive for COVID-19. The outcome of

the events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

Severe anaphylaxis; This is a spontaneous report from a non-contactable consumer. This consumer reported similar events for six patients. This is the second of six reports. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date not reported), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced severe anaphylaxis on an unspecified date. The outcome of the event was unknown. No follow up attempts are possible; information about lot/batch number cannot be obtained.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021003207 same drug/event; different patient

severe anaphylaxis; This is a spontaneous report from a non-contactable consumer. This consumer reported similar events for 6 patients. This is 5th of 6th reports. A patient of unspecified age and gender received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number and expiration date were not reported), via an unspecified route of administration on an unspecified date at a single dose for vaccination. The patient's medical history and concomitant medications were not reported. The patient experienced severe anaphylaxis on an unspecified date. Outcome of the event was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021003207 same drug/event and different patients

severe anaphylaxis; This is a spontaneous report from a non-contactable Consumer. This Consumer reported similar event for six patient. This is 6th of sixth reports. A patient of unspecified age and gender received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date not reported), via an unspecified route of administration on an unspecified date a single dose for covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced severe anaphylaxis on an unspecified date with outcome of unknown. No follow-up attempts are possible. Information about batch number cannot be obtained.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021003207 same drug/event and different patients

tested positive for COVID after receiving the COVID Vaccine; tested positive for COVID after receiving the COVID Vaccine; This is a spontaneous report from a contactable other HCP from a Pfizer-sponsored Program Pfizer First Connect. A female patient (sister) of an unspecified age received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot/batch number and expiry date were not provided), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. Caller stated that her sister tested positive for COVID after receiving the COVID Vaccine. Caller stated that her sister is a respiratory therapist and she has it (COVID) at the same time as the caller. Caller's sister tested positive at the same time as the caller on 01Jan2021. Caller's sister received the COVID Vaccine from a different facility from the caller. The outcome of the events was unknown. Information on the Batch/Lot number has been requested.; Sender's Comments: Based on the information currently available, a lack of efficacy with the

suspected vaccine BNT162B2 in this patient cannot be completely excluded. Further information like confirmative virus genome /nucleic acid detection is needed for meaningful medical assessment.

He received his first dose on 22Dec2020, then on 29Dec2020, he tested positive COVID.; He received his first dose on 22Dec2020, then on 29Dec2020, he tested positive COVID.; This is a spontaneous report from a Pfizer-sponsored program IBCC (Inbound Call Center for HCPs). A contactable healthcare professional (patient) reported for himself that a 30-year-old male patient received his first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EH9899), via an unspecified route of administration on 22Dec2020, at single dose for COVID-19 immunization. Medical history and concomitant medications were not reported. The healthcare professional is physician assistant. He received his first dose on 22Dec2020, then on 29Dec2020, his COVID 19 test revealed positive. He is supposed to get a second dose on 14Jan2021. He wondered if he is going to be able to take second dose or not. He doesn't have a prescribing doctor. He got it (vaccine) at work/at the hospital he works at. Outcome of the events was not recovered.; Sender's Comments: Based on the information currently available, a lack of efficacy with the suspected vaccine BNT162B2 in this patient cannot be completely excluded. Further information like confirmative virus genome /nucleic acid detection is needed for meaningful medical assessment.

Abdominal pain, chills, n/v, dark urine, elevated LFT's, Bilirubin in urine. Patient currently admitted to hospital

Received Moderna vaccine on 12/29/2020. 12/30/2020 fever of 100.4 Tylenol given and monitored and fever went down. 12/31/2020 Chest x-ray completed and sent to the hospital and admitted with pneumonia. 1/3/2021 reported by the hospital that Covid-19 results were positive. He had had Covid-19 positive results back on 11/4/2020 prior to vaccine.

"Pt experiencing and c/o left nasal burning, left upper lip tingling progressing to numbness with slight swelling noted, scattered patchy hives to upper front chest, sharp HA above right eye, denies SOB, no acute respiratory distress noted or reported, slurring of words shortly after onset of other symptoms. Pt repeating ""something ain't right"". Pt received Moderna COVID vaccine at 4:35pm with no reactions or side effect noted within the post 15 and 30 minutes. EMS notified at 5:49pm. MD notifed and ordered Benadryl 50mg IM (given at 5:53pm), EpiPen and DepoMedrol 40mg IM if needed. No respiratory distess noted, pt denies SOB. EMS arrived and transported pt to ER."

Developed SOB and fatigue 1 day after vaccine, went to urgent care and tested positive for COVID at urgent care. Returned to our ED after going to urgent care again on 1/7/21, had o2 sat of 84% on room air, impoved to 98 on 3 liters. Was transferred to another facility for admission.

vomiting later on 01/05/21. Lethargy and hypoxia in pm of 01/06/21. Hypotension am of 01/07/21. Hospitalized, intubated, cardiac arrest, died 01/07/21.

Swollen lips/tongue, shortness of breath, cough, hives, nausea, headache Epi shot, Benadryl, Pepcid, prednisone

Less than 5 minutes after vaccine, nose drained, weird taste in mouth, tingle in nose and on tongue. Throat and tongue swelled, couldn?t speak. Dizzy and slurring speech. Was taken to ambulance outside, BP was 191/101. Given beta blockade. Confused and dizzy for next 2 hours in ER. Evaluated for stroke and given a 12-lead ECG. Given benedryl and prednisone. Felt better after 3 1/2 hours. Continued steroids for 5 days and had to take benedryl every 4 hours for 3 days or swelling/itching/bad taste in mouth would return. Sore arm on day 3.

symptoms:chest and stomach pain Has markedly elevated liver function tests that were normal 2 weeks prior to immunization Is being admitted the hospital to monitor liver function test.

headache, sore throat, runny nose, arm pain that migrated to the axilla and down the side of the body, joint pain (hands, wrist, feet, hips, knees, spine, neck), insomnia, general malaise, fatigue, and lower grade fever. Most symptoms lasted about 7 -10 days. However, it is now day 20 after the initial vaccine and I still have joint pain that has not gone away. esp in hands, wrists, and feet. When I sleep I still wake up with all my joints hurting it gets better as I start moving but the wrist, hands, and feet pain has not gone away. This pain will wake me in the night when I change positions. I called my doctor today to inquire if it is a good idea if I should take the second dose because the first dose made me so dibiliated. Awaiting for a response. I am due to take the second vaccine on 2/9/21.

Fever, coughing, drowsiness, generalized weakness. Was found to be hypercalcemic (corrected calcium 14) and admitted 1/2-4. No prior history of hypercalcemia.

Congestion Shortness of breath Tachycardia Transferred out 911. Per hospital, patient had a myocardial infarction, is unresponsive, and on hospice services.

Anaphylactic reaction, Severe edema and raised red rash entire body, Severe itching ,Soft tissue edema of throat. Swelling of, eyes, lips, face. Multiple trips to ER, treated with steroids, Benadryl, prevacid. , CURRENTLY IN ICU ON EPINEPHRINE DRIP, STEROIDS, MULTIPLE MEDS

Resident passed away in her sleep

Patient c/o fatigue and cough on 1.4.2021 and was encouraged to be tested for COVID. We were notified that the patient was hospitalized on 1.7.2021 with COVID symptoms and positive test results. She is currently on a ventilator and dialysis.

On December 25th I had mild chest pain and then on January 1st, 2021 I had severe chest pain that persisted and on January 3rd I was admitted into the hospital. My Ddimer was elevated and my Troponin levels were elevated. An angiogram was performed and Dr. injected nitro into my arteries because they were constricted from Coronary Spasms.

Sxs started 3-5 minutes post vax. Dizziness, hypotension, throat fullness, CODE called, given IM Epi at vax site. Taken to ED from vax site. Started on epi drip. Admitted to SHC.

Nausea/ dizzy, Syncope 12 hours later.

Patient felt warm with palpitations 5 minutes after vaccine administered. was monitored for 30 mins & then returned to work. on 12/30/2020 patient was at work in Presurgical testing dept & experienced near syncope, dizziness & elevated BP. reported to ED & was admitted to telemetry unit.

Dr. called this morning and reported that an employee that works in billing had her vaccine on Wednesday and developed and anaphylactic reaction to Moderna. This was 24 hours later with rash, SVT heart rate above 140, low grade fever, redness at site. Admitted and treated with steroids and Benadryl.

Came to ER on 12/20/20 with chills, heart palpitations, body aches and increased SOB. Had ST elevation on EKG in ER, taken to Cath Lab- no intervention done. D/C home 12/22/20. Previous Hx of COVID per patient

Initial event was soreness at site which resolved on its own within a few days. 2 days after receiving vaccine, I began having an allergy reaction to the same brand N95 that I had been utilizing since the beginning of the pandemic. Symptoms are swollen cheeks and welts , sudden itchiness at the site of my mask placement. The reason for this report is a sudden onset of excruciating and debilitating pain throughout my body specifically pain of my right shoulder radiating down my sprightly arm. I have been receiving testing and treatment for ongoing neuropathy due to Longhauler syndrome, however This recent pain is so debilitating, I spend most of my time in bed. I have been experiencing chills then profuse sweating. I also so fatigued, I sleep much of the day. I have been having episodes of tachycardia with chest tightness which has increased since after having the vaccine. I also become short winded on exertion. I?ve been waking up in a panic and sweating.

Patient received first dose of Pfizer COVID-19 vaccine on December 26. On the next day, December 27, patient started having pressure in her head and sinuses, weakness. Then she developed nonproductive cough and progressive shortness of breath. She was seen at urgent care and tested positive for COVID-19 on December 29. She had low oxygen saturation on home oximeter and severe shortness of breath. Patient's husband is also ill with COVID-19 at home. Patient was sent to the ED and admitted to the hospital.

Patient had been diagnosed with COVID-19 on Dec. 11th, 2020. Symptoms were thought to have started on 12/5/2020. Received Moderna vaccine on 12/23. Unexpected death on 1/8/2021. Resuscitation attempts unsuccessful

infection of SARS-COV-2; infection of SARS-COV-2; This is a spontaneous report from a contactable healthcare professional. A 31-year-old male patient started to receive received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot number EL0140), intramuscular into the left arm on 18Dec2020, at 10:30 as single dose for covid-19 immunization. There was no medical history and no concomitant medications. The patient experienced infection of SARS-COV-2 on 25Dec2020. Details were as follows: The patient received the first dose of the two dose series. On 20Dec2020, he was exposed to COVID-19. Official positive diagnosis of COVID-19 was made on 25Dec2020. Patient had symptoms of fatigue, joint pain and a small fever on an unspecified date, and had been exposed to SARS-COV-2 on 20Dec2020, and the infection on 25Dec2020. The patient underwent lab tests and procedures which

included sars-cov-2 test which was positive on 25Dec2020. The patient was scheduled to receive second dose of the vaccine; he will be out of quarantine around five to six days before that dose. The outcome of infection of SARS-COV-2 was recovering.; Sender's Comments: The efficacy of a drug varies from one patient to another and can be affected by different factors; however, a contributory role of the suspect drug BNT162B2 to the reported events drug ineffective and COVID-19 cannot be ruled out.

recipient of the covid 19 vaccine received a positive antigen test within 10 days of getting the vaccine; recipient of the covid 19 vaccine received a positive antigen test within 10 days of getting the vaccine; This is a spontaneous report from a contactable nurse. This nurse reported similar events for two patients. This is the second of 2 reports. A female patient of an unspecified age (Age: 30, Unit: Unknown) received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number and expiration date were not reported), via an unspecified route of administration on an unspecified date at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient received a positive antigen test within 10 days of the vaccine and wanted to know if the vaccine could cause a positive antigen test. There was no mention of exposure to a positive person. Outcome of the events was unknown. Information on lot/batch number has been requested.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the reported events of COVID-19 antigen test positive and LOE due to temporal relationship. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.,Linked Report(s) : US-PFIZER INC-2020519946 same reporter, drug, and events; different patients

"neuropathy/ started acutely in feet bilaterally / persist intermittently in left extremities; One-time episode of upper extremity (UE) numbness; This is a spontaneous report from a contactable health care professional (patient). A 40-year-old female patient (not pregnant) received her 1st dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, batch/lot unknown) at single dose via an unknown route at left arm on 26Dec2020 for Covid-19 immunization. COVID-19 vaccine was administered in Pharmacy or Drug Store. Medical history was reported as ""none"". Patient had no COVID prior vaccination, further reported as patient was not diagnosed with COVID-19 prior to vaccination. No known medications, food, or other products allergies. Concomitant drugs (Other-medications-in-two weeks) included levocabastine hydrochloride (ZYRTEC), diphenhydramine hydrochloride (BENADRYL) as needed, ibuprofen (MOTRIN), and multivitamin. No other-vaccine-in-four weeks received. Patient experienced adverse-event of neuropathy, which started acutely in feet bilaterally and now (as of 02Jan2021) persist intermittently in left extremities (LEs). One-time episode of upper extremity (UE) numbness. No weakness. Patient inquired if 2nd dose should be held. Adverse-event-start-date was 26Dec2020. The adverse event result in doctor or other healthcare professional office/clinic visit. No treatment received.

The event was reported as non-serious. Since the vaccination, patient had not been tested for COVID-19. Outcome of the event was not resolved. Information about lot/batch number has been requested.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the reported events of peripheral neuropathy and upper extremity (UE) numbness due to temporal relationship. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics including head CT/MRI and nerve conduction tests, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate."

Became extremely flushed; tingling in hands and feet; disorientation; This is a spontaneous report from a non-contactable nurse (patient). A 34-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE) (lot number: EL0140/expiration date unknown), via intramuscular route of administration, on 28Dec2020 (at the age of 34 years old) as a single dose in the left arm for COVID-19 immunization at hospital facility. Relevant medical history included Gastrooesophageal reflux disease (GERD), Attention deficit hyperactivity disorder (ADD), Generalised anxiety disorder (GAD). The patient did not have any known allergies to medications, food, or other products. Prior to the vaccination, the patient was not diagnosed with COVID-19. Concomitant medications included esomeprazole sodium (NEXIUM), venlafaxine hydrochloride (EFFEXOR), amfetamine aspartate, amfetamine sulfate, dexamfetamine saccharate, dexamfetamine sulfate (ADDERALL). The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. On 28Dec2020, at 09:00 PM, the patient became extremely flushed, tingling in hands and feet, disorientation. Treatment was received for the events became extremely flushed, tingling in hands and feet, disorientation included Diphenhydramine 50mg @2200 and again at 0200. The outcome of the events became extremely flushed, tingling in hands and feet, disorientation was recovered on unknown date. Since the vaccination, the patient had not been tested for COVID-19.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the reported events of extremely flushed, tingling in hands and feet and disorientation due to temporal relationship. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics including chemistry panel and Head CT/MRI, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Around 10:30pm I felt like my throat was closing and I was choking; Around 10:30pm I felt like my throat was closing and I was choking; I had chest pain, chest tightness; I had chest pain, chest tightness; Very

SOB at rest; Throughout the day I was cough and my face started flushing so I tool Benadryl/severe facial flushing; On 23Dec I got nerve blocks for my migraines.; Throughout the day I was cough and my face started flushing so I tool Benadryl.; This is a spontaneous report from a contactable nurse who reported for herself. A 36-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot: EK5730) dose number 1, via an unspecified route of administration on 19Dec2020 11:30 at single dose for COVID-19 immunization. Medical history included von willebrand's disease, narcolepsy with cataplexy, IIH (Idiopathic intracranial hypertension), HTN (hypertension), GERD (gastrooesophageal reflux disease), migraines. Patient also had known allergies: PCN (penicillin), shellfish, IV contrast, cefdinir and bees. On 23Dec2020, patient got nerve blocks for her migraines. Throughout the day patient was cough and her face started flushing so she tooled diphenhydramine hydrochloride (BENADRYL). Around 22:30, patient felt like her throat was closing and she was choking. She had chest pain, chest tightness. EMS (emergency medical services) was called and patient was brought to the hospital. On 25Dec2020, patient felt like her throat was closing, like someone was sitting on her chest and chest tightness still with chest pain. Very SOB (shortness of breath) at rest. Patient went to the ER (emergency room) and received IV dexamethasone (DECADRON) and diphenhydramine hydrochloride. On 26Dec2020, patient had the same symptoms but with severe facial flushing and patient went back to the ER and was given IV dexamethasone. Patient was sent home on a maximum amount of medications. I had seen her primary care, ENT (ear nose throat centre), Allergy, ID (infectious disease), and pulmonology. Her CT (computerised tomogram) of chest on 25Dec2020 was negative along with her COVID test. Patient SOB on rest and exertion still. Onset date of the adverse events was reported as 23Dec2020, 22:30. Patient received treatment for the events included multiple medications and high dose prednisone. Lab data on 25Dec2020 included CT of chest: negative, influenza type A/B combo: negative, Covid 19: negative and nasal swab: negative. Action taken in response to the events for bnt162b2 was not applicable. Outcome of the events was not resolved.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the reported events due to temporal relationship. The clinical presentation of the events is suggestive of possible allergic reactions. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

I tested positive for COVID today; I tested positive for COVID today; This is a spontaneous report from a contactable other Health Care Professional (HCP). A female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, lot number and expiration date unknown) via an unspecified route of administration on 24Dec2020 (at an unknown age) at an unknown dose for COVID-19 vaccination. The patient's medical history was not reported. The patient's concomitant medications were not reported. The patient tested positive for COVID on 01Jan2021. The patient was inquiring as to if she can still get the second dose since she has tested positive in between. The patient underwent lab

tests and procedures which included SARS-COV-2 test: positive on 01Jan2021. The clinical outcome of COVID-19 virus test positive was unknown. The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up.; Sender's Comments: The information currently provided is too limited to make a meaningful medical assessment hence, the events are conservatively assessed as related to the suspect drug BNT162B2 until further information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

experienced loss of smell, taste and a headache/she came down with signs and symptoms/she got tested and got the results on Thursday that she was positive for covid 19 virus; experienced loss of smell, taste and a headache/she came down with signs and symptoms/she got tested and got the results on Thursday that she was positive for covid 19 virus; This is a spontaneous report from a contactable Other Health Professional (patient). A 45-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) Solution for injection, lot number, via an unspecified route of administration from 14Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient had the first dose of COVID vaccine on 14Dec2020. Eleven days following first dose, she experienced loss of smell, taste and a headache. She stated that she came down with signs and symptoms on 25Dec2020 and she got tested and got the results on Thursday that she was positive for Covid 19 virus. She was due for the 2nd dose of the COVID vaccine on the 6th of January. She asked what she should do about the second dose. She mentioned that her symptoms and positive test results were reported where she works in (State name). She wanted to know information as to whether she should get the second dose. Her second dose's scheduled was 6Jan2021. The event outcome was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the reported events of suspected LOE and COVID 19 infection due to temporal relationship. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

had a positive covid test results; had a positive covid test results; This is a spontaneous report from a contactable physician. A male patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 17Dec2020 at a single dose for COVID-19 immunization.On 22Dec2020 he started to experience COVID like symptoms. On 26Dec2020, he had a positive COVID test results. On 28Dec2020, he received the Regeneron antibody infusion. Patient wants to know more about receiving the 2nd dose based on his positive diagnosis/antibody

treatment. Outcome of the event was unknown. Information on batch number has been requested.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the reported events of SARS-CoV-2 test positive and suspected LOE due to temporal relationship. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

diarrhea; headache; lower back pain; Fatigue; arrhythmia; Tachycardia; High Blood pressure; Redness on chest; Chest tightness; Lightheaded; possible tongue swelling; possible tongue swelling (felt heavy after vaccine); dry mouth; sore throat; This is a spontaneous report from a contactable nurse (patient) who reported for herself that a 31-year-old female patient received her first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899) via an unspecified route of administration, on 20Dec2020 14:15 at left arm/arm right (pending clarification), single dose for COVID-19 immunization. Medical history included factor II, history of melanoma. She has no known allergies. She was not pregnant at the time of the vaccination. Concomitant medications included bupropion hydrochloride (WELLBUTRIN), ibuprofen (MOTRIN), multivitamin. Nurse reported administering COVID-19 vaccine at hospital, experiencing tachycardia, high blood pressure, redness on chest, chest tightness, lightheaded, possible tongue swelling (felt heavy after vaccine), arrhythmia, dry mouth, sore throat (after leaving emergency department) at 14:30 on 20Dec2020; After one day, she experienced diarrhea, headache, lower back pain and fatigue since 21Dec2020. Fatigue lasting for several days. Adverse events resulted in emergency room/department or urgent care (pending clarification). Nurse received intravenous diphenhydramine hydrochloride (BENADRYL) and fluids as treatments. Nurse assessed the events as non-serious. Nurse also reported that, prior to vaccination, she was not diagnosed with COVID-19; since the vaccination, she has not been tested for COVID-19. She did not receive other vaccine in four weeks. Outcome of fatigue was not recovered, outcome of the rest of the events was recovered.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the tachycardia, high blood pressure, arrhythmia and the other reported events due to temporal relationship. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics including EKG at baseline and during subject drug therapy, echocardiogram, cardiac enzymes, electrolytes, chemistry panel and serum toxicology screen, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

"Chills; Soreness at the injection site; generalized body aches/Body aches; Shortness of breath; Asthma attack; Difficulty sleeping; Light headed and dizzy; Nausea; high BP 140's; HR 110's to 120s; Nasal congestion; Swelling of the face; Sore throat; This is a spontaneous report from a contactable nurse. A 42-years-old female patient received her first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number EK5730, expiration date not reported), intramuscular on the right arm on 31Dec2020 at 10:15 AM, at a single dose for Covid-19 immunization. Medical history included asthma, allergy, hypothyroidism, and some fish allergy. There were no concomitant medications (no other vaccine in four weeks and no other medications in two weeks). Patient previously took ibuprofen and experienced allergy. The patient is not pregnant. On 31Dec2020, after ten-15 minutes (10:30 AM) of receiving the vaccine, she was light headed and dizzy with some nausea. Monitored in the emergency room (ER) with high BP 140's and heart rate (HR) 110s to 120s. After an hour of saline bolus, she was better but she got nasal congestion and swelling of the face with sore throat. On 01Jan2021, after 24 hours, she got some soreness at the injection site with generalized body aches. Also she got some shortness of breath which lead to her asthma attack and difficulty sleeping. On 02Jan2021, after 48hours, she was feeling still light headed with some sore throat, chills, body aches and severe headache which lead her to go to the ER and got herself tested for flu, covid and strep, which came back all negative but her signs and symptoms (s/sx)still after discharge was getting worst especially the headache and generalized body aches. As well as congestion and sore throat. The patient had given ""Ivf"" for the events. The patient was not diagnosed with Covid prior to vaccination and was not Covid tested post vaccination. The outcome of the events was not recovered. The reporter assessed the events as non-serious.; Sender's Comments: A causal association between BNT162B2 and the reported events cannot be excluded based on a compatible temporal relation between vaccination and onset of events. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate."

becoming incoherent and talking nonsense; This is a spontaneous report from a contactable physician (patient). A female patient of an unspecified age received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiry date not reported), via an unspecified route of administration on 23Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. Physician calling about whether or not she should receive the second dose of vaccine. She received dose on 23Dec2020. On 26Dec2020 she started experiencing several side effects including becoming incoherent and talking nonsense. Her daughter who is an EMT suggested that she go to the ER. While in the ER she received TPA but it was later decided she did not have a stroke. Her EKG, bloodwork and other testing came back negative. She otherwise healthy and has no comorbidities. She already spoke with agency. She has also already spoken with an infectious disease doctor and her neurologist. The outcome of the event was unknown. Information on the lot/batch number has been requested.; Sender's Comments: The information currently provided is too limited to make a meaningful medical assessment hence, the event incoherent is conservatively assessed as related to the suspect drug BNT162B2 until further information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety

evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to agencys, Ethics Committees, and Investigators, as appropriate.

tingly feeling to my lips; some lip swelling; tightness in my throat.; This is a spontaneous report from a contactable Other HCP. A 35-years-old female patient started to receive BNT162B2, via an unspecified route of administration from 30Dec2020 12:00 to 30Dec2020 12:00 at SINGLE DOSE for covid-19 immunisation. Medical history included hypersensitivity from an unknown date and unknown if ongoing, gastritis from an unknown date and unknown if ongoing, anxiety from an unknown date and unknown if ongoing, depression from an unknown date and unknown if ongoing. Concomitant medication included lorazepam (ATIVAN), ivermectin (IVERMECTIN), escitalopram oxalate (LEXAPRO), esomeprazole magnesium (NEXIUM [ESOMEPRAZOLE MAGNESIUM]), levocetirizine dihydrochloride (XYZAL). The patient previously took tamiflu and experienced drug hypersensitivity. The patient experienced tingly feeling to my lips (paraesthesia oral) (non-serious) on 30Dec2020 15:30 with outcome of recovered, some lip swelling (lip swelling) (non-serious) on 30Dec2020 15:30 with outcome of recovered, tightness in my throat. (throat tightness) (non-serious) on 30Dec2020 15:30 with outcome of recovered. The action taken in response to the event(s) for BNT162B2 was not applicable. Therapeutic measures were taken as a result of tingly feeling to my lips (paraesthesia oral), some lip swelling (lip swelling), tightness in my throat. (throat tightness). This is a spontaneous report from a contactable other HCP. This 35-year-old female other HCP reported that: Report about covid vaccine: Yes Reporter type: Patient Age group: Adult (18-64 Years) Is pregnant: No Race: (race provided) Ethnicity: (ethnicity provided) Patient occupation: Other Health Professional Covid vaccine details: product-COVID 19, Lot number-EL1284, Lot unknown-False, Administration date-30Dec2020, Administration time-12:00 PM, Vaccine location-Left arm, Dose number-1 Facility type vaccine: Hospital If other vaccine in four weeks: Yes Other vaccine 4weeks details: other vaccine 4weeks product -Allergy Immunotherapy injections , Other vaccine 4weeks vaccine date -07Dec2020, Other vaccine 4weeks dose number -2 , Other vaccine 4weeks vaccine location-Left and right arm. Other medications in two weeks: Nexium, xyzal, Ativan, Lexapro, Ivermectin Adverse event: At about almost 4 hrs after receiving the injection I started to experience a tingly feeling to my lips, some lip swelling and tightness in my throat. I had my epi pen on hand incase I needed it but I ended up taking 25mg of Benadryl, then 50 mg of Benadryl 5 hrs later. The following morning my lips where feeling tingly again so I took 25mg of Benadryl again and continued for the next 48 hrs at the advice of my doctor. Adverse event start date: 30Dec2020 Adverse event start time: 3:30PM AE resulted in: None of the above If patient recovered: Recovered If treatment AE: Yes AE treatment: Benadryl for 48 hrs If covid prior vaccination: No If covid tested post vaccination: No Known allergies: Tamiflu Other medical history: Chronic allergies, gastritis, anxiety, Depression Identification of the case safety report Serious: No Seriousness criteria-Results in death: No Seriousness criteria-Life threatening: No Seriousness criteria-Caused/prolonged hospitalization: No Seriousness criteria-Disabling/Incapacitating: No Seriousness criteria-Congenital anomaly/birth defect: No VAERS Primary Reporter Addl Qualification: Patient Relevant medical history and concurrent conditions: Structured information (Patient episode name): Chronic allergies, gastritis, anxiety, depression Reaction(s)/Event(s): Reaction/event as reported by primary source: At about almost 4 hrs after receiving the injection I started to experience a tingly feeling to my lips, some lip swelling and tightness in my throat. I had my epi pen on hand incase I

needed it but I Reaction/event in terminology (LLT) : At about almost 4 hrs after receiving the injection I started to experience a tingly feeling to my lips, some lip swelling and tightness in my throat. I had my epi pen on hand incase I needed it but I ended up taking 25mg of Benadryl, then 50 mg of B Date of start of reaction/event: 30Dec2020 Outcome of reaction/event at the time of last observation: RECOVERED/RESOLVED Drug(s) Information: Characterization of drug role: Suspect Batch/lot number: EL1284 Date of start of drug:30Dec2020 Anatomical location: Arm left Dose number:1 Active drug substance information: Active drug substances name: COVID 19 Drug(s) Information: Characterization of drug role: CONCOMITANT Proprietary medicinal product name: Allergy Immunotherapy injections Date of start of drug:07Dec2020 Dose number:2 Narrative case summary and further information: Case narrative Age at vaccination: 35 Pregnant at the time of vaccination?: No Start Date/Time:30Dec2020 12:00 PM Facility where the most recent COVID-19 vaccine was administered: Hospital Did the patient receive any other vaccines within 4 weeks prior to the COVID vaccine: Yes List of any other medications the patient received within 2 weeks of vaccination: Nexium, xyzal, Ativan, Lexapro, Ivermectin Reported Event: At about almost 4 hrs after receiving the injection I started to experience a tingly feeling to my lips, some lip swelling and tightness in my throat. I had my epi pen on hand incase I needed it but I ended up taking 25mg of Benadryl, then 50 mg of Benadryl 5 hrs later. The following morning my lips where feeling tingly again so I took 25mg of Benadryl again and continued for the next 48 hrs at the advice of my doctor. Was treatment received for the adverse event?: Yes: Benadryl for 48 hrs Prior to vaccination, was the patient diagnosed with COVID-19?:No Since the vaccination, has the patient been tested for COVID-19?:No Allergies to medications, food, or other products: Tamiflu Vaccine Facility information available. Ethnicity information is available. Race information is available. Location of injection information is available for other vaccines within 4 weeks PRIOR.; Sender's Comments: A causal association between BNT162B2 and the reported events cannot be excluded based on a compatible temporal relation between vaccination and onset of events. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

About 15 minutes after receiving the vaccine she felt palpitations. She was monitored for another 15 minutes and while she was walking to her car se started noticing sore throat associated with inability to talk, unable to swallow secretions, and swelling the lips. Patient presented to the emergency room where she received EpiPen dose. Received diphenhydramine, famotidine, and prednisone. Lip swelling and sore throat began improving in ED.

I was given a vaccine on Dec17th, on Dec21st I tested positive for Covid; I was given a vaccine on Dec17th, on Dec21st I tested positive for Covid; This is a spontaneous report from a contactable nurse. A 46-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number EK5730), via an unspecified route of administration on 17Dec2020 at a single dose for COVID-19 immunization. There was no relevant medical history. The patient's concomitant medications were not reported. The patient was given a vaccine on 17Dec2020, the on 21Dec2020, the patient tested positive for COVID. The outcome of the event was unknown.; Sender's Comments: Based on the information

available, a possible contributory role of the suspect products cannot be excluded for the reported event of positive for corona virus infection for the lack of efficacy of the vaccine. However, based on the mechanism of action of the vaccine, it is unlikely the patient would have fully developed immunity for the vaccine to be effective, due to the number of days passed since the vaccine is given. Case will be reevaluated based on follow-up information

TSH level has been borderline hypothyroidism; Almost feel like somebody is gently holding my throat, so I could still breathe, talk, eat but I had the feeling that my throat was being kind of squished; This is a spontaneous report from a contactable nurse. A 64-year-old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number EK5730), via an unspecified route of administration in right deltoid on an unspecified date at a single dose for covid-19 immunization. Medical history included hypertension and high cholesterol. Concomitant medication included evolocumab (REPATHA) for high cholesterol and two unspecified medications for hypertension. The got the first dose of Pfizer Vaccine for COVID, and for about 3 or 4 almost 5 days afterwards, she felt like somebody, it almost feel like somebody was gently holding her throat, so she could still breathe, talk, eat but had the feeling that throat was being kind of squished. The patient had her lipid panel liver and TSH level done because of the Repatha and TSH level has been borderline hypothyroidism, so she haven't really been on medicine for it but it might be. The patient added that the events had certainly correlated with the vaccine. She didn't have the events until she got the vaccine, so she feel like it was and then her concern was it wouldn't be safe to take the second one. The patient did not visit emergency room and physician office because of the issue 'feel like somebody was gently holding her throat' and all she did was take Benadryl at night. The outcome of the events was unknown.; Sender's Comments: The causal relationship between bnt162b2 and the event hypothyroidism cannot be excluded as the information available in this report is limited and does not allow a medically meaningful assessment. This case will be reassessed once additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate.

test positive for COVID-19/fever, chills, body aches, joint pain; test positive for COVID-19/fever, chills, body aches, joint pain; This is a spontaneous report from a contactable other HCP. A 35-year-old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK5703), via an unspecified route of administration in left arm on 15Dec2020 17:30 at a single dose for covid-19 immunization. Administration was done in the hospital. Medical history included seronegative rheumatoid arthritis and allergies to latex and actemra. Concomitant medication included tofacitinib citrate (XELJANZ), and ibuprofen. Eight days after vaccination, on 23Dec2020 at 13:30, the patient came down with fever, chills, body aches, joint pain. The patient was initially tested negative for COVID (nasal swab) and influenza on 27Dec2020 but did test positive for COVID-19 on 29Dec2020 (nasal swab). The patient stated that she knew that the vaccine did not cause COVID however as she was on immunosuppressants (Xeljanz), she wanted to record this information. There was no treatment included for the events. The outcome of the events was recovering. Prior to vaccination, the patient was not

diagnosed with COVID-19.; Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of events Drug ineffective and COVID-19 cannot be totally excluded. The case will be reassessed if additional information becomes available.

COVID-19 rapid POC test positive; COVID-19 rapid POC test positive; the amount of vaccine given as 1 cc; This is a spontaneous report from a Pfizer-sponsored program, IBCC (Inbound Call Center for HCPs). A contactable nurse (patient) reported that a 52-year-old female patient received first dose of BNT162B2 (Pfizer-BioNTech COVID-19 mRNA vaccine; lot number: EH9899), via an unspecified route of administration on 17Dec2020 at 1 mL, single dose for COVID-19 immunization. Medical history included ongoing hypertension diagnosed when she was 33 years old. There were no concomitant medications. The patient got the vaccine on 17Dec2020. The patient stated that the amount of vaccine given was 1 cc. She took a COVID-19 rapid POC test on the 28Dec2020 and tested positive. She wanted to know if she should have the second dose of the vaccine. The outcome of the events was unknown.; Sender's Comments: The information currently provided is too limited to make a meaningful medical assessment hence, the events are conservatively assessed as related to the suspect drug BNT162B2 until further information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

"When she went back to work on 25Dec2020 it was positive/On the weekend she had to come back to do a PCR test on28Dec2020 and it was positive.; When she went back to work on 25Dec2020 it was positive/On the weekend she had to come back to do a PCR test on28Dec2020 and it was positive.; This is a spontaneous report from a contactable nurse. A 43-year-old female patient receive bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EH9899), via an unspecified route of administration given in the left arm on 22Dec2020 at a single dose for covid-19 immunization. The patient medical history included ""patient's a blood donor"" reported as, she donated blood on 12Sep2020 and it was negative for covid. The patient's concomitant medications were not reported. The patient experienced ""when she went back to work on 25Dec2020 it was positive/on the weekend she had to come back to do a pcr test on28dec2020 and it was positive"" on 25Dec2020 with an unknown outcome. It was further reported that the patient was a registered nurse that works night shift. She clarified that the rapid test was taken each time she goes to work. When she went to work on the night of 21Dec2020 the rapid test was negative.Then she got the Covid vaccine in the morning of 22Dec2020. When she went back to work the night of 22Dec2020 the rapid test was negative. When she went back to work on 25Dec2020 it was positive. On the weekend she had to come back to do a PCR test on28Dec2020 and it was positive. Caller clarifies that the rapid tests were Nasal Swabs. The patient's latest test was on 28Dec2020, she was told that when she comes back, they do not have to do the rapid test daily anymore, it will now be every 90 days. The patient did not have a test before the vaccine. She has had no issues with Vaccines in the past.; Sender's Comments: Based on the information available, a possible contributory role of the suspect BNT162B2 cannot be excluded for the reported event positive

for corona virus infection based on the known safety profile. However given the short duration of 3 days since the vaccine first dose, it is unlikely patient would have fully developed immunity."

positive COVID-19 test with symptoms/had like a head cold and cold like symptoms/he tested positive for COVID.; positive COVID-19 test with symptoms/had like a head cold and cold like symptoms/he tested positive for COVID.; This is a spontaneous report from a contactable nurse. A 67-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EJ1685), intramuscular on left deltoid on 18Dec2020 at single dose for COVID prevention. The patient had no medical history. There were no concomitant medications. The patient got his first dose of the COVID Vaccine on 18Dec2020, and he states that he did fine and had no problems. But on 28Dec2020, when he was going to work, he noticed that he had like a head cold and cold like symptoms. He was swabbed and tested for COVID PCR on that day, and he tested positive for COVID. After his positive COVID test, he was tested for monoclonal antibodies, and at first, he was told that test came back positive, but then about 12 hours later, he was told that the staff had misread it, and he was actually negative for monoclonal antibodies, so the caller was given monoclonal antibody therapy and he did fine with that, and he is recovered now. He is scheduled to go back to work this Thursday, and he is supposed to receive the second dose of the vaccine, on Friday. He checked the schedule for getting the second dose, and he was not on the list, so he called the infection control nurse, and she told the caller that because he received the monoclonal antibody therapy, he now has to wait 90 days to receive the second dose of the vaccine. Caller states that he looked for that information, and he did not see that anywhere, so he is wondering if that is correct, because it almost seems to him that if he waits 90 days, he would have to start the series again. The outcome of the event was recovered on an unspecified date.; Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of events Drug ineffective and COVID-19 cannot be totally excluded. The case will be reassessed if additional information becomes available.

low grade fever/low grade fever of 103; chills; dry cough; lethargy; This is a spontaneous report from a contactable nurse. A 62-year-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number EJ1685 with expiry date Mar2021), via an unspecified route of administration in left deltoid on 30Dec2020 14:30 at a single dose for COVID-19 immunization. The administration was one in a local pharmacy. There were no relevant medical history and concomitant medications. On Saturday night, 02Jan2021, the patient started getting a low grade fever of 103, had chills, lethargy and an intermittent dry cough. The outcome of the events was not recovered. The events were considered medically significant events.; Sender's Comments: A possible contributory effect of suspect BNT162B2 on reported events cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

a left sided nystagmus; urgent MRI showing multiple brain lesions consistent with Acute disseminated encephalomyelitis; Patient developed paresthesias on entire right side of body / The paresthesias continued, not progressing; a brief headache; episode of dizziness / developed severe dizziness; This is a

spontaneous report from a contactable physician (patient). A 34-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK5730) intramuscularly at right arm on 21Dec2020 07:00 at single dose for COVID-19 immunization. Medical history included known allergies to sulfa meds. The patient's concomitant medications included multivitamins [vitamins nos] within 2 weeks of vaccination. Patient developed paresthesias on entire right side of body after a brief headache and episode of dizziness, all since 29Dec2020 15: 00. The paresthesias continued, not progressing, but patient was advised to obtain an MRI Brain and C spine as an outpatient. On 02Jan2021, the patient developed severe dizziness and a left sided nystagmus. She went to the ER and underwent urgent MRI showing multiple brain lesions consistent with acute disseminated encephalomyelitis. Lumbar puncture (LP) was performed, awaiting final results. Patient was admitted and was receiving IV steroids (solumedrol). Duration of hospitalization was 5 days since Dec2020. Patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. The patient underwent lab tests and procedures, which included Nasal Swab and Rapid covid swab, both on 02Jan2020 with result of negative. The outcome of the events was recovering.; Sender's Comments: Based on temporal association and lack of other provided etiology, a possible contributory role of suspect BNT162B2 vaccine cannot be excluded for reported acute disseminated encephalomyelitis, paraesthesia, headache, dizziness and nystagmus. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

hives; face swelling; itching; rash; This is a spontaneous report from a contactable nurse (patient). A 71-year-old female patient received 1st dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot# EH9899), intramuscular in left arm on 22Dec2020 11:08 at single dose for COVID-19 vaccination. Medical history included ongoing blood pressure high, ongoing cholesterol, ongoing depression. Concomitant medication included atenolol (tablet, strength 50 mg) from an unknown date and ongoing for blood pressure high, simvastatin (tablet, strength 20 mg) from an unknown date and ongoing for cholesterol, paroxetine hydrochloride (PAXIL, tablet, strength 40 mg) from an unknown date and ongoing for depression. The patient experienced hives, face swelling, itching and rash on 27Dec2020. No additional vaccines administered on same date of the Pfizer suspect. Prior vaccination within 4 weeks was none. She got the first Covid 19 dose on 22Dec2020 and was fine, then on 27Dec2020 she had hives, itching, and face swelling for several days. Caller stated her lungs were clear and she was okay other than the extreme itching. The face swelling was what worried her. The hives and itching went away within about 36 hours. The face swelling kind of got worse for a couple of days before it went away. Caller verifies she recovered from the hives/rash/itching within 36 hours. She got a steroid shot and things like that and it went away pretty quickly. The face swelling was completely gone but did last for a good 5 days. She didn't know if this reaction was related to the vaccine. She wanted to call and let Pfizer know and see if there was any reports of anything else like that or similar to that type of reaction. She was not sure if that really matters or not except she was not sure about taking the booster. She was kind of leaning towards taking the second vaccine. She didn't have any breathing issues. She asked as far as the second

dose after those side affects, was it recommended? Her doctor said she could get the second one and prescribed her an Epi pen and would give a dose of Benadryl at the time of the second vaccine. She may take some Benadryl before getting the second vaccine and have her EpiPen with her just in case. She hadn't seen her doctor about this experience with the COVID-19 vaccine. She only went to an urgent care. The caller stated she went to urgent care twice. She received a steroid shot but doesn't have any name, NDC/UPC, Lot number or expiration date for any of the medication she received. She probably threw that paperwork out. She knew she wasn't given anything the second time she went to the urgent care. The second time she went back was because the face swelling was getting worse. She was prescribed an EpiPen and was told to take Zyrtec which did help. Everything had gone away. She would consider these events to be medically significant because of the face swelling, it kind of scared her. She made the comment she was taking high blood pressure medicine and cholesterol medicine, but other than that she was very healthy. She was not really an allergic person. She had not had any testing done since she received the vaccine. She did have bloodwork done prior but not since the vaccine. The patient underwent lab tests and procedures which included blood work prior vaccine with unknown result. The outcome of hives, rash and itching was recovered on an unspecified date of Dec2020 (within about 36 hours); face swelling was recovered on 01Jan2021.; Sender's Comments: Based on the time gap between the vaccine and the events there is not a reasonable possibility that the reported events were related to the suspect product, events are most likely due to patient underlying contributory factors The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators as appropriate.

drop in blood pressure resulting in fainting; drop in blood pressure resulting in fainting; Severe headache; fever; This is a spontaneous report from a contactable other healthcare professional (patient). A 26-year-old female patient (non-pregnant) received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number EK9231), via an unspecified route of administration on 03Jan2021 at single dose at left arm for immunization. Medical history included allergies to Penicillins. The patient's concomitant medications within 2 weeks of vaccination included birth control pill, prenatal vitamin. Patient didn't receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, patient was diagnosed with COVID-19. Since the vaccination, patient has not been tested for COVID-19. The patient experienced severe headache, fever, and drop in blood pressure resulting in fainting the morning following receiving the vaccine on 04Jan2021 with outcome of recovering. Patient didn't receive treatment for events. Adverse events resulted in doctor or other healthcare professional office/clinic visit. This report is considered non-serious. No follow-up attempts are possible. Information about Batch number cannot be obtained. No further information is expected.; Sender's Comments: Based on the close temporal relationship, the association between the event fainting with BNT162b2 can not be completely excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

Test positive for COVID-19/have symptoms on 26, 27 and 28Dec2020; Test positive for COVID-19/have symptoms on 26, 27 and 28Dec2020; This is a spontaneous report from a contactable physician (patient). A 59-year-old male patient started to receive first dose of BNT162B2 (Batch/lot number: EH9899) intramuscular into left deltoid on 15Dec2020 at single dose for covid-19 immunisation. Medical history included hypertension and the patient was on blood pressure (BP) medications. The patient received no other vaccines on the same day as the COVID Vaccine. The patient received first dose on 15Dec2020 and was exposed to someone with COVID on 24Dec2020 and tested positive for COVID 28Dec2020. The patient stated that he was wondering what the recommendations are for receiving the second dose of the product, if someone contracted COVID-19 after receiving the first dose. He tested Positive for COVID-19 on 28Dec2020 and he does not know if it is ongoing or not, as he does not re-test for COVID-19 until Wednesday (30Dec2020), but he currently has no symptoms. The patient stated that he did have symptoms on 26, 27 and 28Dec2020. The lab tests and included COVID-19 PCR test: positive on 28Dec2020. The outcome of events was unknown.; Sender's Comments: The association between the event lack of effect (COVID-19) with BNT162b2 can not be completely excluded.

Patient fainted in the ICU setting.; dizziness; hypotension; This is a spontaneous report from a contactable Other HCP. A 25-year-old male patient received BNT162B2 (Lot number: eh9899) via an unspecified route of administration on 24Dec2020 13:00 at single dose for covid-19 immunisation. The patient did not have any known allergies or medical history. Prior to vaccination, the patient was not diagnosed with COVID-19. There were no concomitant medications. On 24Dec2020, patient experienced dizziness and hypotension. Patient's blood pressure (BP) was 50/30 and heart rate (HR) 45. Patient fainted in the intensive care unit (ICU) setting. This happened during work hours while treating a patient. Patient was treated in the emergency department (ED). The adverse events resulted in emergency room/department or urgent care. It was unknown if treatment was received for the adverse event. Since the vaccination, the patient has not been tested for COVID-19. The outcome of events was recovered.; Sender's Comments: A possible contributory effect of suspect BNT162B2 on reported events cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

temperature of 101 ¦F; body aches; headache; nausea; chills; This is a spontaneous report from a contactable Other HCP (patient). A 26-year-old female patient started to receive BNT162B2 (Batch/lot number: EK9231) at right deltoid via an unspecified route of administration on 03Jan2021 12:20 at single dose for covid-19 immunisation. Medical history was none. The patient's concomitant medications were not reported. The patient experienced temperature of 101 ¦F, chills, body aches, headache and nausea on 04Jan2021 02:00. Patient stated for the second one, she was hoping for the best, but she got the vaccine yesterday (03Jan2021), at 12:20, and today (04Jan2021), at 2 AM, she had a temperature of 101, and chills, body aches, headaches, and nausea. She was out of it today, she was not feeling good, and was told to do this. Caller got the vaccine at Employee Health. After 4 hours of Tylenol (expiry is May2021, lot is P115252), her temperature went right back up. It was about 99 when she had Tylenol.

Chills started late this morning (04Jan2021) and were ongoing when she was not on Tylenol, but her body aches were ongoing. 9AM was when her headache started, and she was intermittently on Tylenol, but if past the 4 hour mark, they were as bad as they were this morning, but with Tylenol they were better. Nausea was mostly this morning, and had gotten better. Patient stated that due to her current symptoms her employer had required her to be tested for COVID-19. She had not yet received the results of that test. Seriousness for events temperature of 101 ¦F, chills, body aches, headache and nausea was Medically significant. Lab data included COVID test on 23Dec2020 was negative. The outcome of temperature of 101 ¦F, headache and nausea was recovering; of body aches was not recovered; of chills was unknown. Primary Source Reporter (Method of assessment was Global Introspection) considered the events were related to BNT162B2.; Sender's Comments: There is a reasonable possibility that the events reported were related to BNT162b2 based on known drug safety profile and close temporal relationship. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

"Itching and redness over whole body/I turned all red and was itching all over my body by about 10:30-10:45 am/I still have mild itching; Itching and redness over whole body/I turned all red and was itching all over my body by about 10:30- 10:45 am/I still have mild itching; Elevated heart rate and blood pressure; Elevated heart rate and blood pressure; Had an allergic reaction; This is a spontaneous report from a contactable nurse (patient). A 43-year-old female patient received the first dose of bnt162b2 (BNT162B2) lot no: EK9231, via an unspecified route of administration in left arm on 30Dec2020 09:00 at a single dose for COVID-19 immunization. Medical history HTN and exercise-induced asthma, both from an unspecified date and unknown if ongoing. The patient was not pregnant at the time of vaccination. The patient had no covid prior to vaccination and was not covid tested post vaccination. Concomitant medication included colecalciferol (VITAMIN D), montelukast sodium (SINGULAIR), and biotin. No other vaccines were administered in four weeks. Known allergies include tapendalol (NUCYNTA) and trimethoprim/sulfamethoxazole (BACTRIM). On 30Dec2020 09:30, the patient experienced itching and redness over whole body, elevated heart rate, and blood pressure. The patient was given IV diphenhydramine (BENADRYL) 50 mg, IV famotidine (PEPCID), IV methylprednisolone (SOLU MEDROL), ""flui"" as treatment for AEs. The patient further clarified that she received the COVID 19 vaccine on 30Dec2020 at 9:00 and she had an allergic reaction. She turned all red and was itching all over her body by about 10:30- 10:45 am and was at the ER by about 11am. She started on prednisone 40mg for 3 days and diphenhydramine every 6 hours, as needed on 30Dec2020. On Sunday (03Jan2021), she was still severely itching and turning red so prednisone was continued for an additional 3 days and was switched to cetirizine (ZYRTEC) because she can't function on diphenhydramine. Cetirizine was not helping so she had to take diphenhydramine yesterday morning (04Jan2021). Last night (04Jan2021), she was ok without any diphenhydramine but this morning (05Jan2021), she still have mild itching, and no redness. The redness comes and goes; it is on the face, chest, arms, legs. When it first started, it was whole body redness. Then it moved to different areas on different days; she don't have a rash or hives, just redness. She had a 4 inch band of redness on both arms one day. The events were reported as non-serious. The

patient had not recovered from the events.; Sender's Comments: A possible causal association between administration of BNT162B2 and the onset of allergic reactions cannot be excluded, considering the plausible temporal relationship and the known adverse event profile of the suspect product. The underlying predisposing condition of drug allergies to multiple materials may put the patient at high risk of allergic reactions. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate"

contracted Sars-Cov-2 in between her two doses; contracted Sars-Cov-2 in between her two doses; This is a spontaneous report from a Contactable Other HCP. A female patient of an unspecified age started to receive the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on unknown date at single dose for covid-19 immunisation. The patient medical history was not reported. The patient's concomitant medications were not reported. Patient was due for her 2nd dose of Pfizer-Biontech Covid19 vaccine on 06Jan2020. She contracted Sars-Cov-2 in between her two doses, want to know if she should receive her second dose as scheduled. Patient had COVID-19 test with unknown result. Outcome of events was unknown. Information about lot/batch number has been requested.; Sender's Comments: The association between the event lack of effect (contracted SARS CoV 2) with BNT162b2 cannot be completely excluded.

tested positive for COVID-19 more than a week after receiving our COVID-19 vaccine; tested positive for COVID-19 more than a week after receiving our COVID-19 vaccine; This is a spontaneous report from a non-contactable consumer. A 45-years-old patient of an unspecified gender started received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number and expiration date not reported), via an unspecified route of administration from an unspecified date at a single dose for Covid-19 immunization. The patient medical history and concomitant medications were not reported. The patient tested positive for COVID-19 more than a week after receiving COVID-19 vaccine. Outcome of the event was unknown. No follow up attempts are possible. Information on lot/batch number cannot be obtained.; Sender's Comments: Based on the information available, a possible contributory role of the suspect products cannot be excluded for the reported event of positive for corona virus infection for the lack of efficacy of the vaccine. However, based on the mechanism of action of the vaccine, it is unlikely the patient would have fully developed immunity for the vaccine to be effective, due to the number of days passed since the vaccine is given. Case will be reevaluated based on follow-up information

"I was pretty sick, I felt palsy; I was pretty sick, I felt palsy; I developed the fever for all about 30 hours after the vaccination; Headache; This is a spontaneous report from a contactable physician. This physician reported for himself that a 67-years-old male patient received BNT162B2 (BioNTech Covid 19 vaccine; Batch/lot number: EL1284), via an unspecified route of administration on 30Dec2020 at SINGLE DOSE for ""Because I am a physician, a healthcare provider"" (covid-19 immunization). Medical history included had Covid back on the 4th of December. There were no concomitant medications. Physician stated he was wondering he just took your Pfizer Covid vaccination, the first one. He took it couple of

days ago. He took it on the 30th of this month, two days ago. Physician further stated he developed the fever for all about 30 hours after the vaccination. Just because he developed the fever with the first one, it was like a 101.7 that was about 36 hours. So the question was just because he developed the fever with the first one, he was pretty sick, he meant he felt palsy, you know headache and all that it was like probably developed the same with the second one? Patient weight was maybe 125 pounds. When probed if vaccine was prescribed by any Physician, Physician stated he went himself. Causality by physician stated as ""he think so"". Lab work reported as He did not have the results yet. He just look a Covid screening test because he had Covid back on the 04Dec. So, he just took a Covid screening test. Treatment received included aspirin. The outcome of all events was unknown.; Sender's Comments: The causal relationship between BNT162B2 and the event palsy cannot be excluded as the information available in this report is limited and does not allow a medically meaningful assessment. This case will be reassessed once additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate."

had the COVID-19 vaccine on 28Dec2020 and was tested positive today (04Jan2021) for COVID-19; had the COVID-19 vaccine on 28Dec2020 and was tested positive today (04Jan2021) for COVID-19; This is a spontaneous report from a contactable other hcp via the Pfizer-sponsored program. A male patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 28Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient had the COVID-19 vaccine on 28Dec2020 and was tested positive today (04Jan2021) for COVID-19. Outcome of the events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: The reported positive with Covid 19 test after COVID-19 immunization is considered ineffective of BNT162B2, and the Company cannot completely exclude the possible causality between the reported event and BNT162B2 administration.

blurriness on the right eye with consistent optic neuritis; read up on transverse myelitis that may be related to her condition; blurriness on the right eye with consistent optic neuritis; This is a spontaneous report from a contactable physician. This physician (patient) reported for self that the 31-year-old female patient received bnt162b2 (BNT162B2, PFIZER-BIONTECH COVID-19 VACCINE, lot: EK5730), via an unspecified route of administration on Deltoid, Left on 20Dec2020 13:00 at single dose for covid-19 immunisation. Medical history and concomitant medications were none. Reported she has a flu vaccine in Sep2020, and had no reaction to the flu vaccine. She clarified she has never had a reaction to a vaccination before. The patient received the vaccine last 20Dec2020 and has reported to have blurriness on the right eye with consistent optic neuritis since 24Dec2020. She has already consulted with an ophthalmologist who said her case was interesting and referred her to Pfizer. She is scheduled to have her second dose on 10Jan2021 and is asking if she should still take it. She also mentioned that she read up on transverse myelitis that may be related to her condition and is asking for any information we may have on this. Doctor reporting she is having a possible adverse event to the COVID-19 Vaccine. The

patient clarified she received the COVID-19 Vaccine on Sunday, 20Dec2020 at approximately 1:00PM. Reported the COVID-19 Vaccine was administered at her employer. Doctor reported she is experiencing blurry vision in her right eye only, consistent with optic neuritis in Dec2020 (Medically significant). She said her right eye blurry vision gets worse after working out or showering. She said she has read some medical information that states some kind of autoimmune reaction, like transfer myelitis, may occur after receiving the COVID-19 Vaccine. The patient asked if she should get the second COVID-19 Vaccine, clarifying she is scheduled to receive her second dose on 10Jan2021. Clarified she started experiencing the right eye blurry vision on either 24Dec2020 or 25Dec2020. Treatment: Reported she saw an ophthalmologist, and the ophthalmologist said he didn't see anything concerning or not normal. She said the ophthalmologist referred her to see a neurologist, and to get a MRI of her head. She clarified her MRI appointment is on 19Jan2021. She clarified her ophthalmologist called her back 2 hours after she left her appointment. She said the ophthalmologist told her he found what she was experiencing to be interesting, as to when she received the COVID-19 Vaccine, and the start of her right eye blurry vision, and that he wanted her to get further evaluation. She said the ophthalmologist performed visual field testing, and took a fancy picture of her retina. No further details provided. Vaccination Facility Type was hospital. No Vaccine Administered at Military Facility. History of all previous immunization with the Pfizer vaccine considered as suspect (or patient age at first and subsequent immunizations if dates of birth or immunizations are not available) was none. Additional Vaccines Administered on Same Date of the Pfizer Suspect was none. No AE(s) required a visit to Emergency Room but AE(s) required a visit to Physician Office. Prior Vaccinations (within 4 weeks) was none. Patient's Medical History(including any illness at time of vaccination) was none. Family Medical History Relevant to AE(s) was not provided. Relevant Tests included Visual field test, and picture of her retina. The outcome of the events was not recovered.; Sender's Comments: Based on temporal association, the causal relationship between bnt162b2 and the events optic neuritis, vision blurred and myelitis transverse cannot be excluded. The information available in this report is limited and does not allow a medically meaningful assessment. This case will be reassessed once additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate.

tested positive for Covid-19; tested positive for Covid-19; This is a spontaneous report from a contactable healthcare professional (reporting for herself). A female patient of an unspecified age received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number and expiry date not reported) via an unspecified route of administration, on 24Dec2020, single dose for COVID-19 immunization. Relevant medical history and concomitant medications were not reported. The patient tested negative for Covid-19 on 22Dec2020, received her first vaccine dose on 24Dec2020 and then tested positive for Covid-19 on 26Dec2020. Outcome of the events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: The efficacy of a drug varies from patient to patient and can be affected by different factors; however, a contributory role of the suspect product bnt162b2 to the reported drug ineffective and SARS-CoV-2 test positive cannot be ruled out.

Cp initially that resolved in seconds. Then severe muscle aches, fatigue, temp 1 week,excruciating joint pain continues now. Malaise.

full body rash; heart palpitations; reaction to drug excipient; This is a spontaneous report from a contactable nurse, the patient. A female patient of an unspecified age received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot Number: UNKNOWN), via an unspecified route of administration on 26Dec2020 as a single dose for COVID-19 immunization. Medical history included several outdoor allergies, but no known food allergies. The patient's concomitant medications were not reported. On 28Dec2020, the patient experienced full body rash and heart palpitations. The clinical course was as follows: the patient developed a full body rash and heart palpitations on 28Dec2020 and went to the emergency room. The patient had a full work-up which included electrocardiogram, troponin levels, and electrolytes, and all were normal. She was instructed to take diphenhydramine hydrochloride (BENADRYL). She thought it may have been due to the polyethylene glycol; however, she did mention that she previously took macrogol 3350 (MIRALAX) on unknown dates for an unknown indication and was fine. The clinical outcomes of the full body rash, heart palpitations, and reaction to polyethylene glycol, were unknown. The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up.; Sender's Comments: The Company cannot completely exclude the possible causality between the reported full body rash and the administration of the suspect, BNT162B2, based on the reasonable temporal association. While the possibility of allergic to polyethylene glycol (drug excipient) might have provided alternative explanations. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RA, IEC, as appropriate.

neuropathy; This is a spontaneous report from a contactable Nurse. A male patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient medical history was not reported. The patient's concomitant medications were not reported. Reporter called about Covid vaccine and has a question connected to the AE he has reported. Wants to know if neuropathy is a side effect of the vaccine. Event outcome was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Very limited information was provided in this case, pending further details such as medical history, clinical course, specified event description, at this moment, the mentioned neuropathy is considered related to BNT162B2 for reporting purpose. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RA, IEC, as appropriate.

Development of microemboli on distal, fourth right phalange on the ventral surface. Just past the DIP. Small blue hue below skin surface with mild tenderness on deep palpation.; This is a spontaneous report from a non-contactable Physician (patient). This adult female patient (not pregnant at the time of vaccination) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number:

EH9899), intramuscular on 23Dec2020 09:30 at single dose on right arm for COVID-19 immunisation. Medical history included migraine with aura. Concomitant medication included propranolol, loratadine (CLARITINE) and multivitamin. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient previously took cefprozil (CEFZIL) and experienced allergies. The patient experienced development of microemboli on distal, fourth right phalange on the ventral surface. Just past the DIP. Small blue hue below skin surface with mild tenderness on deep palpation on 24Dec2020 12:00. The event was considered as non-serious. Treatment for the events was unknown. The outcome of the event was unknown. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, the patient had not been tested for COVID-19. No follow up attempts are possible. No further information is expected.; Sender's Comments: Based on the close temporal relationship, the association between the event microemboli on distal phalange with BNT162b2 can not be fully excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

Went to ER left side of face sagging. They did MRI it showed he had stroke. happened before 4pm that same day as vaccine. Happened between 2-4 pm; Went to ER left side of face sagging. They did MRI it showed he had stroke. happened before 4pm that same day as vaccine. Happened between 2-4 pm; This is a spontaneous report from a contactable consumer (patient). A 78-year-old male patient receive BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (lot number: EK5730), on 31Dec2020 11:00 AM via unknown route of administration at single dose for COVID-19 immunization. Medical history included high blood pressure, but went up and down and had to readjust. His BP was high and not sure how long it was that way. Concomitant medications included unspecified blood pressure medications. There were no known allergies. Patient went to ER left side of face sagging. They did MRI it showed he had stroke. It Happened before 4pm that same day as vaccine on 31Dec2020 02:00 PM. And it Happened between 2-4 pm. Patient received treatment. Patient had ER test blood, cat scan, MRI. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient did not have been tested for COVID-19. The outcome of the events was recovering. This case was assessed non-serious by reporter. And the events did not result in death, Life threatening, Caused/prolonged hospitalization, Disabling/Incapacitating, Congenital anomaly/birth defect.

occipital neuralgia; left-side Bells Palsy; bilateral headache; This is a spontaneous report from a contactable physician (patient). A 65-year-old male patient received BNT162b2 (Lot/batch number and Expiration date were not provided), via an unspecified route of administration at right deltoid on 21Dec2020 19:00 at single dose for covid-19 immunization. The patient's medical history included low high density lipoprotein (HDL). There were no concomitant medications. The patient previously took influenza vaccine (longer than 4 weeks ago, and he did not have any reaction), pravastatin for low HDL. Reported 2 days ago (02Jan2021) he developed a bilateral headache. He stated he was asymptomatic until then. He said he now has Bells Palsy on 02Jan2021, clarified he has left-side Bells Palsy. He said it is

unknown to him if the bilateral headache and Bells Palsy are related to taking the COVID-19 Vaccine. He stated he started wearing a N95 mask for the past 2 weeks. He said the N95 mask is very tight on the back of his head. He said he believes he is experiencing occipital neuralgia caused by wearing the N95 mask. He said studies show that the N95 mask can cause Bells Palsy, and the N95 mask maybe a confounding factor. He stated he doesn't have any further information on the N95 mask he was using. Initially he had a severe headache and administered to himself a sphenopalatine block of Lidocaine 1% in his nose. He stated being an ER doctor, he knows how to administer the sphenopalatine block to a patient. He went to the ER on 03Jan2021 to make sure he did not have a tumor or a stroke. He said the hospital performed a CT of his head, a MRA, labs, and a COVID-19 test (clarified as a PCR COVID-19 test) with a full viral count. He said all the tests were negative. His wife noticed his Bells Palsy yesterday, 03Jan2021. He said he thinks the Bells Palsy started the night before on 02Jan2021. He said he noticed on the night of 02Jan2021 when he was brushing his teeth, he hit a tooth on that side (clarified as left side) of his mouth with his tooth brush. He hasn't started taking steroids yet, but will be starting steroids real soon. He clarified his doctor prescribed a Medrol dose pack and Valtrex for the Bells Palsy. He stated he has not started the Medrol dose pack and Valtrex. He is ordering Lidocaine 1% viscous for himself, so he can do an internasal sphenopalatine block on himself. He does not know if the bilateral headache and Bells Palsy were caused by taking the COVID-19 Vaccine. The events required Emergency Room visit. The outcome of the event Bell's palsy was not recovered, Headache was recovering, Occipital neuralgia was unknown. Information on the Lot/Batch number has been requested.; Sender's Comments: A possible causal association between administration of BNT162b2 and the onset of Bell's palsy/Headache might not be excluded, considering the plausible temporal relationship. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Headache; Fever: She said that she started with kind of chills and shakes; Fever: She said that she started with kind of chills and shakes; she was not feeling too good; real high heart rate that were in the 110's that last for lasted for hours; Fever; This is a spontaneous report from a contactable nurse reported for herself. A 59-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, batch/lot number: EK9231 and expiration date unknown), via intramuscular on left deltoid on 03Jan2021 09:13 at single dose for COVID-19 prophylaxis. The patient medical history and concomitant medications reported as none. The reporter is a registered nurse that reported that she had the first Covid-19 vaccine yesterday morning on 03Jan2021 and she had side effects. She reported that she had a fever, headache, and a real high heart rate that was in the 110's that last for lasted for hours. She said that she started with kind of chills and shakes 11 hours and 40 minutes after receiving the vaccine. One minute she was fine and the next minute she was feeling chilled. By the time she got home from her mother's house, which is a hours drive, she was not feeling too good. Her fever broke today 04Jan2021 at around 04:00 and when she checked her temperature it was 98.7 degrees. She said that 100.2 degrees was the highest temperature she recorded. The patient said that it was a mild fever. Her headache started about 22:00 03Jan2021. The patient said that she still has the headache a little bit and she has been treating it with Tylenol and it has gotten better. She said that she wears a fit bit that tracks

her heart rate and she can hear her heartbeat in her ears and she could hear it going fast. Caller said that her heart rate was down to 98 beats per minute at 06:30 this morning. She said that her current heart rate was Body temperature. Caller said that her high heart rate had her very concerned. She said that it is not normal. She is supposed to go back on 30Jan2021 to get her 2nd injection. Should she still plan on getting the second part of the vaccine? The reporter assessed event real high heart rate that were in the 110's that last for lasted for hours as serious with medically significant. Other events were assessed as non serious. The outcome of the events fever and real high heart rate that were in the 110's that last for lasted for hours was recovered on 04Jan2020, outcome of the event headache was recovering, outcome of the other events was unknown.; Sender's Comments: Based on the close temporal relationship, the association between the event high heart rate with BNT162b2 can not be completely excluded.

I was having trouble clearing my throat, felt like it was closing up; high heart rate/rapid heart rate agai; uncontrollable rigors; numb lips and hands; numb lips and hands; nausea; shortness of breath, difficulty catching my breath; This is a spontaneous report from a contactable Other Health Professional (patient). A 38-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) lot number: EJ1685, intramuscular in the left arm, on 30Dec2020 09:15 at a single dose for COVID-19 immunization. Medical history included bariatric surgery, had anterior vaginal repair and bladder sling, had her gall bladder and tonsils removed. Concomitant medication included rizatriptan and paracetamol (TYLENOL). The patient had no known allergies but mentioned that she cannot take the NSAIDs eventhough she was not allergic to them. She had no allergies to food or to other products. It was reported that within about 10 minutes of the injection of the vaccine, she had trouble clearing her throat, felt like it was closing up, had uncontrollable rigors, high heart rate, numb lips and hands, and nausea on 30Dec2020 at 09:30 AM. She was discharged from the ED (emergency department), went home and took a nap. Later that evening, she began to have a rapid heart rate again, began to had shortness of breath, difficulty catching her breath and she was admitted to the emergency department again and given more IV medications. The onset of the events was reported to be 30Dec2020 at 09:30 AM with outcome of recovering. As a result of the events, the patient visited that Emergency room/department or urgent care. Treatment received with IV medications (unspecified), breathing treatment, and epinephrine injection. The patient had no covid prior vaccination. She had not had Covid test post vaccination.; Sender's Comments: Based on temporal association, the causal relationship between BNT162B2 and the events throat tightness, heart rate increased, chills, hypoaesthesia oral, hypoaesthesia, nausea and dyspnoea cannot be excluded. The information available in this report is limited and does not allow a medically meaningful assessment. This case will be reassessed once additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate.

fibromyalgia and neuropathy on the lower cervical/pain has exacerbated; fibromyalgia and neuropathy on the lower cervical/pain has exacerbated; headache; channeled body pain; fever at 100.7F; This is a

spontaneous report from a contactable consumer (patient). A male patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, on an unspecified date (reported as 31Jan2020) as a single dose for COVID-19 immunization. Medical history included fibromyalgia and neuropathy on the lower cervical. The patient's concomitant medications were not reported. The patient experienced fibromyalgia and neuropathy on the lower cervical/pain has exacerbated, headache, channeled body pain, and fever at 100.7 F on an unspecified date. It was reported that headache, channeled body pain, and fever at 100.7 F occurred 1 hour after vaccination. The patient underwent lab tests and procedure, which included: body temperature: 100.7 Fahrenheit on an unspecified date. The patient has been taking unspecified medications for the condition, in addition to acetaminophen (TYLENOL FOR ARTHRITIS). Therapeutic measures were taken as a result of all of the events as aforementioned. The clinical outcome of fibromyalgia and neuropathy on the lower cervical/pain has exacerbated, headache, channeled body pain, and fever at 100.7 F was unknown.

Fainting; This is a spontaneous report from a non-contactable consumer (patient). This consumer reported similar events for 02 patient. This is the 1st of 2 reports. A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 23Dec2020 at single dose for COVID-19 immunization. The patient medical history was not reported. The patient's concomitant medications were not reported. The patient experienced fainting on 31Dec2020. The patient went to the emergency department in regards to fainting and was told the fainting couldn't be related to the COVID-19 Vaccine. Then she heard about someone else fainting. Outcome of the event was unknown. No follow-up attempts are possible, information about lot/batch cannot be obtained. No further information is expected; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021006463 same reporter/drug/event, different patient

difficulty breathing/swallowing; difficulty breathing/swallowing; Hives/hives all over including in her mouth; This is a spontaneous report from a contactable consumer (spouse). A 46-year-old female patient (wife) received BNT162B2 (Pfizer-Biontech Covid-19 Vaccine, lot number: EH9899) via unspecified route of administration at arm right on 29Dec2020 at single dose for Covid-19 vaccine. Medical history included ongoing anxiety diagnosed 22 years ago. Concomitant medications were not none. Patient received the vaccine and was one big hive (01Jan2021). She went to the ER on sat and will have to go back. Caller is asking where she should go. patient went through the VAERS report 3 times. She did not have any sides effects. patient is a frontline worker. On 29Dec2020 she got the Covid vaccine. On Sat 02Jan2021 she went the ER with hives all over including in her mouth, stated she had difficulty breathing/swallowing, was given medication to take home and discharged. She was readmitted yesterday 05Jan2020 with worsening symptoms and needed to be given a prednisone nebulizer. they had two ER visits. No Investigation Assessment. patient was not recovered from the event hives/hives all over including in her mouth, the final outcome of other events was unknown.

"What I believe may have triggered this reaction is that in October I had a carpal and ulnar tunnel release in the same extremity/affected the nerves; my entire upper arm began aching-pain from my trapezius down to my elbow; my index and middle finger began tingling; I am noting pain in each of the major joints of my arm-shoulder, elbow and wrist; I am noting pain in each of the major joints of my

arm-shoulder, elbow and wrist.; I am noting pain in each of the major joints of my arm-shoulder, elbow and wrist.; This is a spontaneous report from a contactable nurse (patient). A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), via an unspecified route of administration on the arm on 19Dec2020 as single dose for covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced the following: "" my entire upper arm began aching-pain from my trapezius down to my elbow "" in Dec2020 with outcome of unknown; ""my index and middle finger began tingling "" in Dec2020 with outcome of unknown; "" I am noting pain in each of the major joints of my arm-shoulder, elbow and wrist "" in Dec2020 with outcome of unknown; "" what I believe may have triggered this reaction is that in October I had a carpal and ulnar tunnel release in the same extremity "" in Dec2020 with outcome of unknown. Therapeutic measures were taken as a result of the events. Details were as follows: The injection itself was without any issues. However, 6-7 hours later, the patient described the following: patients entire upper arm began aching-pain from trapezius down to the elbow. This continued throughout the weekend and then Monday, patients index and middle finger began tingling (as if asleep). This symptom never subsided. The patient noted pain in each of the major joints of the arm shoulder, elbow and wrist. The patient tried trigger injections in the trapezius, ibuprofen, muscle relaxers, heat, exercises, and a steroid burst-all without relief of symptoms. Patient was able to move arm and had strength in the extremity. Patient saw a specialist in physical medicine and rehabilitation. The patient believed that what triggered this reaction is that in October the patient had a carpal and ulnar tunnel release in the same extremity. The patient wondered whether the medication affected the nerves that had been manipulated during surgery. The events outcome was unknown. The batch/lot number for the vaccine, BNT162B2, was not provided and will be requested during follow-up .; Sender's Comments: Based on the time association, the possible contribution of suspect BNT 162B2 injection to the event Neuropathy peripheral cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate."

"Rash; Itching at different spot at different time; Hives; This is a spontaneous report from a contactable consumer. A 58-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL3246), via an unspecified route of administration on 02Jan2021 at single dose as reported for ""Indication: Consumer stated, ""Because I work in Covid testing, in healthcare."" Medical history included hypertension and allergy. Concomitant medication included amlodipine, lisinopril, metoprolol, hydrochlorothiazide (HYDROCHLORZIDE), desloratadine and montelukast. The patient stated, ""had the first dose of the Pfizer vaccine yesterday for the Covid 19, 2 hours after I started itching and it has been different places all over my body. I do not know has it anything to do with the way that it goes through the body, I do not know. I have had to take a lots of Benadryl. I have had to take some steroids that I had here at the house I never had started and I thought it was okay. Last night my husband put hydrocortisone cream (later clarified as treatment) on areas I was itching and had hives. I slept all night I did not have any problem since I got up this morning I started itching in other place. So, I have done the whole thing again. I am going to has to go. I did not want to go ER because I am not

having trouble on breathing or anything like that but I have got various places it is like different places every time it starts. So, I need to I am going to go and have a probably a strong steroid shot and have strong steroid given to me, not for oral but I just want to let you know if that is a side effect and I do not know whether I am going to take the second one or not?"" I have taken Benadryl and I have taken Methylprednisolone and I have used on the Cortisone Cream, the topical cream"". The outcome of the events was unknown.; Sender's Comments: A causal association between BNT162B2 and the events rash, pruritus and urticaria cannot be excluded based on a compatible temporal relation between vaccination and onset of events. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate."

"Coughing so hard; coughed during COVID but not like this; Hard to stand up; Pain/body wrecking pains; Fever; Started heaving; Dizzy; Nauseous; Throwing up; Chills; Draining; This is a spontaneous report from a contactable consumer. An adult female patient (consumer's daughter) received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for covid-19 immunization. Medical history included covid-19 from Nov2020. The patient had COVID in the middle of Nov2020 and her father and reporter had it two weeks before and then about two weeks later, she got it. She took her 14 days quarantine, she coughed and had some tummy issues. She had fever, the aches and pains with Covid, a little bit of dry cough. She did not feel good for probably about 5 days, after that she started working again. She had COVID and did not have to be hospitalized, any IV drip or anything before vaccination. 6 weeks later, she got the vaccine shot. The patient's concomitant medications were not reported. The vaccine came out on Wednesday (30Dec2020), the patient signed up at work to take it. Within about 12 hours (unknown onset date), she did start to feel 'oily', and had started having aches, pains and very shortly after that she started running a fever, all of a sudden the cough came out of the blue, she started heaving, dizzy, nauseous and it's three days later, she was coughing so hard. She coughed during COVID but not like this, this was like COVID ten times over, same symptoms though, throwing up, throwing up, hard to stand up, aches, pains, fever, chills, body wrecking pains. The patient can hardly talk because she kept coughing and draining. The reporter asked that ""Should her daughter be given vaccine? Does her antibodies, daughter was asked - Did you have any severe case, and she told - No, I was able to stay home and just stay in bed, they said - Okay we'll give it to you. Should she have gotten so close to the signs that she had COVID? Why her daughter be asked that question? What is going on regarding the symptoms. What should we do about it?"" Consumer tried to get daughter to go to a COVID Clinic today (02Jan2021), and know she didn't have COVID, that's not how it worked, but normal doctors didn't want to see her daughter. Consumer called the COVID Clinic and they said ""Yes, we could probably see her"". The outcome of events was unknown. Information about lot/batch number has been requested; Sender's Comments: A causal association between BNT162B2 and the reported events cough and difficulty standing cannot be excluded based on temporal relation of vaccination and onset of events. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety

concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate."

3:07 pm lung sounds diminished oxygen sats 68%, oxygen applied Oxygen sats remained low for next 36 hours (patient on Hospice care) expired 6:22 am 1-8-21

1/6/21 Pt received vaccine and complained of difficulty swallowing and rapid heart rate. Pt received methylprednisolone 125mg IVP, diphenhydramine 25mg IVP, & famotidine 20mg IVP. Pt reported improvement and was discharged. Sent home on diphenhydramine and oral prednisone. 1/7/21 Pt unable to swallow her own secretions and experienced eyelid swelling. Pt vomitted. Pt received epinephrine and Benadryl X 1 dose each. Pt then transported to hospital via ambulance. Reason for admission - acute respiratory failure secondary to anaphylactic reaction. Decision was made to emergently intubate the patient for airway protection despite aggressive intervention. Pt successfully extubated 1/8/21. Plan to discharge home and start Medrol Dose Pack 1/9/21.

Sudden onset of tinnitus followed by complete hearing loss in Right ear upon awaking from sleep (7 hours)

Swelling of lips & tongue, tightening of throat. Quivering of arms & legs. Tightening of chest. Dizzyness lightheaded.

tested positive for COVID-19; tested positive for COVID-19; Headache; feeling unwell; muscle pain; This is a spontaneous report from a contactable nurse reporting on himself. A 61-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE) (lot number/expiration date: not provided), via an unspecified route of administration, on 28Dec2020 at 08:15 AM (at the age of 61 years old) as a single dose in the left arm for COVID-19 vaccination. Relevant medical history and concomitant medication were not provided. The patient did not have any known allergies to medications, food, or other products. Prior to the vaccination, the patient was not diagnosed with COVID-19. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. On 01Jan2021, the patient experienced mild side effects consisting of headache with feeling unwell and muscle pain. The patient reported this happened on 01Jan2021, and 02Jan2021 and on 03Jan2021 and later, the patient did not experience any side effect. Since the vaccination, the patient was tested for COVID-19 on 02Jan2021 with a Nasal Swab Rapid Test and tested positive for COVID-19. The adverse events resulted in Emergency room/department or urgent care visit. The patient did not receive any treatment for these events. The outcome of the events headache with feeling unwell and muscle pain and tested positive for COVID-19 was recovering. The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow-up.; Sender's Comments: The information currently provided is too limited to make a meaningful medical assessment hence, the events are conservatively assessed as related to the suspect drug BNT162B2 until further information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

felt the need to have a COVID test, which turned out positive; felt the need to have a COVID test, which turned out positive; felt the need to have a COVID test, which turned out positive; Chills; Fever; This is a spontaneous report from a contactable Other HCP. A 55-year-old female patient received frist dose of BNT162B2 (Batch/lot number: EK5730) via an unspecified route of administration on 21Dec2020 at single dose for covid-19 immunisation. The patient medical history was not reported. There were no concomitant medications. The patient explained receiving the COVID-19 vaccine on the 21Dec2020 and experienced fever and some chills. She pursed explaining that she was fine afterwards but felt the need to have a COVID test, which turned out positive of the 31Dec2020. The patient stated that she only had chills and fever the evening of 29Dec2020 and had been fine every since. Her fever that night did not hit 100 degrees. She thought that it would be better if she did not go to work on that Wednesday since she had had a fever the night before. She called her doctor who told her to come into the office on 31Dec2020 to have a rapid COVID test done and it came back positive. She only had fever and chills that one night and has not had any other symptoms. She received no treatment and did not take anything for the fever. This all happened during the night. She felt fine when she got up the next morning. Because she had received the first dose of the COVID vaccine, she thinks that this helped her. She thinks if she had not had the vaccine, then the virus would have been a lot worse. She stated that her second dose of the vaccine is scheduled on the 11Jan2021, and asked if it is safe to get the second dose of the COVID-19 vaccine. The outcome of events chills and fever was recovered; of other events was unknown.; Sender's Comments: The association between lack of effect (suspected COVID-19, SARS CoV2 test positive) with BNT162b2 can not be completely excluded.

Caller tested positive for COVID after the first dose; Caller tested positive for COVID after the first dose; This is a spontaneous report from an other Health Care Professional (HCP). A male patient of an unspecified age received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE lot number and expiration date unknown) via an unspecified route of administration on an unspecified date (at an unknown age) at an unspecified dose for COVID-19 vaccination. The patient's medical history was not reported. The patient's concomitant medications were not reported. The patient tested positive for COVID after the first dose. The patient underwent lab tests and procedures which included sars-cov-2 test: positive on an unspecified date. The clinical outcome was unknown. The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up.; Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of events Drug ineffective and COVID-19 cannot be totally excluded. The case will be reassessed if additional information becomes available.

got the 1st dose of the vaccine then tested positive after; got the 1st dose of the vaccine then tested positive after; This is a spontaneous report from a contactable nurse (patient). A female patient of an unspecified age received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on an unspecified date at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient got the 1st dose of the vaccine then tested positive after. She was asking if she can get the 2nd dose even if she is tested positive. She asked if it can cause to have a false positive result if she received the vaccine.

Outcome of the event was unknown. Information about lot/batch number has been requested.; Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of events Drug ineffective and COVID-19 cannot be totally excluded. The case will be reassessed if additional information becomes available.

his regular COVID test came back positive; his regular COVID test came back positive; This is a spontaneous report from a contactable nurse (reporting for himself) from a Pfizer-sponsored program. A 48-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number and expiry date not reported) via an unspecified route of administration, on 23Dec2020, single dose for COVID-19 immunization. Relevant medical history and concomitant medications were not reported. On 23Dec2020, the patient received the COVID vaccine. On 28Dec2020, he had a negative rapid COVID test, and then on 01Jan2021 his regular COVID test came back positive. The patient would like to see if he should still get the second dose of the vaccine. Outcome of the events was unknown. Information on the Batch/Lot number has been requested.; Sender's Comments: Based on the information available, a possible contributory role of the suspect BNT162B2 cannot be excluded for the reported event SARS-CoV-2 test positive based on the known safety profile. However given the short duration of 9 days since the vaccine first dose, it is unlikely patient would have fully developed immunity.

"tested positive for covid ""yesterday""/asymptomatic; tested positive for covid ""yesterday""/asymptomatic; This is a spontaneous report from a contactable nurse (patient). A female patient of an unspecified age received 1st dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 21Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient received the first dose of the vaccine on 21Dec2020 and was scheduled for the second on 11Jan2021. The patient tested positive for COVID yesterday, 03Jan2021 and wanted to know what to do about her second dose. The patient added that she was asymptomatic at this point and not taking any medications. Outcome of the events was unknown. The events was assessed as non-serious. Information on the lot/batch number has been requested.; Sender's Comments: The reported positive test with Covid-19 after COVID-19 immunization is considered ineffective of BNT162B2, and the Company cannot completely exclude the possible causality between the reported event and BNT162B2 administration."

severe anaphylaxis; This is a spontaneous report from a non-contactable consumer. This consumer reported similar events for 6 patients. This is the first of 6 reports. A patient of unspecified age and gender received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date not reported), via an unspecified route of administration from an unspecified date at a single dose for vaccination. The patient's medical history and concomitant medications were not reported. The patient experienced severe anaphylaxis, on an unspecified date. Outcome of the event was unknown. No follow up attempts are possible; information about lot/batch number cannot be obtained.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021003208 different patient/same drug/event;US-PFIZER INC-2021003209 different patient/same drug/event;US-PFIZER INC-2021003210 different patient/same

drug/event;US-PFIZER INC-2021003211 different patient/same drug/event;US-PFIZER INC-2021003212 different patient/same drug/event

This is a spontaneous report from a non-contactable consumer. This consumer reported similar events for six patients. This is third of six reports. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date not reported) via an unspecified route of administration on an unspecified date at a single dose as vaccination. Medical history and concomitant medications were not reported. The patient experienced severe anaphylaxis with vaccination on an unspecified date. The outcome of the event was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021003207 same drug/event and different patients

severe anaphylaxis; This is a spontaneous report from a non-contactable consumer. This consumer reported similar events for 6 patients. This is 4th of six reports. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date not reported), via an unspecified route of administration on an unspecified date at a single dose for vaccination. The patient's medical history and concomitant medications were not reported. The patient experienced severe anaphylaxis with vaccination on an unspecified date. Outcome of the event was unknown. No follow up attempts are possible; information about lot/batch number cannot be obtained.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021003207 same drug/event and different patients

"diagnosed with COVID-19; diagnosed with COVID-19; This is a spontaneous report from a contactable nurse. A female patient of an unspecified age received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date were not reported), via an unspecified route of administration on 19Dec2020 at single dose for COVID-19 immunisation. The patient medical history and concomitant medications were not reported. The patient stated, ""I received the first dose of the COVID-19 vaccine last 19Dec2020 and unfortunately was exposed to COVID-19 in the evening. I was diagnosed with COVID-19 on 22Dec2020 or 23Dec2020. Should I have my second dose as scheduled tomorrow considering that I have the COVID-19?"". The outcome of the event was unknown. Information on lot number has been requested.; Sender's Comments: The efficacy of a drug varies from patient to patient and can be affected by different factors; however, a contributory role of the suspect product bnt162b2 to the reported drug ineffective and COVID-19 cannot be ruled out."

"Received the first COVID vaccine and then tested positive for COVID; Received the first COVID vaccine and then tested positive for COVID; This is a spontaneous report from Pfizer sponsored program Pfizer First Connect. A contactable nurse (patient) reported that a 22-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date not reported), via an unspecified route of administration on 15Dec2020 at single dose for COVID-19 immunization. There were no medical history and concomitant medications. The patient received the first COVID vaccine on 15Dec2020 and then tested positive for COVID on the 25Dec2020. He was not sure on the time frame, but he wanted to call in for an adverse event, just in case (incomplete sentence) and then he was scheduled to get the second dose within the next week or so. He forgot what date it was but, he wants

to see if it was safe for him to get the second dose. The patient stated that he has a lot of lab work like blood cultures, basic metabolic panel, lactic acid, CBC; results were unknown. The outcome of the event was unknown. Information on the lot number/batch number has been requested.; Reporter's Comments: :; Sender's Comments: Based on available information, a possible contributory role of BNT162B2 vaccine cannot be completely excluded for reported ""tested positive for COVID""."

Tested positive for covid a week later after his first shot; Tested positive for covid a week later after his first shot; This is a spontaneous report from a contactable consumer. A 68-year-old male patient received the first dose of BNT162B2 (Pfizer-BIONTECH Covid-19 Vaccine), via an unspecified route of administration in the left arm on 28Dec2020 at 12:00 PM in a hospital at a single dose as a COVID vaccine. The patient's medical history and concomitant medications were not reported. The patient had no known allergies but had other medical history (unspecified). The patient did not receive any other vaccine within four weeks prior to the COVID vaccine, had other medications in two weeks (unspecified), and was not diagnosed with COVID-19 prior to the vaccination. The patient tested positive for COVID a week later after his first shot. The test used was via nasal swab on 04Jan2021. The patient did not receive any treatment for the events. Outcome of the events was reported as recovering. The case was reported as non-serious (did not result in death, was not life-threatening, did not cause/prolong hospitalization, was not disabling/incapacitating, and did not result to any congenital anomaly/birth defect). Information on the lot/batch number has been requested.

Patient received Positive Covid 19 test result on 02Jan2021; Patient received Positive Covid 19 test result on 02Jan2021; This is a spontaneous report from contactable consumers. An adult male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: IL0140), via an unspecified route of administration on 28Dec2020 at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient received positive COVID 19 test result on 02Jan2021. The patient had unknown test with positive result on 31Dec2020. The case was identified as non-serious by reporter. Facility where the most recent COVID-19 vaccine was administered was in hospital. It was unknown that the patient received any other vaccines within 4 weeks prior to the COVID vaccine. It was unknown that the treatment received for the adverse event. Prior to vaccination, patient was not diagnosed with COVID-19. Since the vaccination, the patient had been tested for COVID-19. The outcome of event was recovering.

"developed active Covid within 24 hours of receiving vaccine; developed active Covid within 24 hours of receiving vaccine; This is a spontaneous report from a contactable physician received via a Pfizer sales Representative. A female patient (physician) of an unspecified age received first dose of BNT162B2 via an unspecified route of administration on an unspecified date at a single dose as vaccine. Medical history included exposed to COVID-19 a few days prior to receiving the COVID-19 vaccine (works within a hospital and had been exposed to COVID-19 active infected patients). Concomitant medications were not reported. A physician reported that a female physician developed active Covid within 24 hours of receiving vaccine (also reported as received the vaccine and within 24 hours developed active symptoms of Covid) on an unspecified date. Requested information on whether to receive the second vaccine at this point. Unsure of the need or complications that could potentially rise from receiving a second vaccine in the series. The events took place after use of product. The outcome of the events was

unknown. Information about Lot/Batch number has been requested.; Sender's Comments: There is not a reasonable possibility that reported ""active Covid"" is related to BNT162B2 vaccine. Event occurred within 24 hours of receiving vaccination, when the vaccine is not expected to achieve the effect. The event is most likely intercurrent medical condition."

"developed Covid infection after being vaccinated with COVID-19 vaccine; developed Covid infection after being vaccinated with COVID-19 vaccine; This is a spontaneous report from a contactable physician (patient) received via a Pfizer sales representative. A female patient of an unspecified age received BNT162B2 via an unspecified route of administration on an unspecified date at a single dose as COVID-19 vaccine. Medical history included exposed several days prior to patients with Covid (exposed prior to receiving the vaccine to individuals who had an active Covid infection). Concomitant medications were not reported. It was reported that on an unspecified date, the female physician developed Covid infection after being vaccinated with COVID-19 vaccine (also reported as she received the COVID-19 vaccine and developed active Covid a few days later). The events took place after use of product. The outcome of the events was unknown. Information on the Lot/Batch number has been requested.; Sender's Comments: There is not a reasonable possibility that reported ""Covid infection"" is related to BNT162B2 per current available information. The patient exposed to individuals who had an active Covid infection prior to receive the vaccine."

received a covid positive diagnosis; received a covid positive diagnosis; This is a spontaneous report from a contactable nurse (patient). A 35-year-old non-pregnant female patient received 1st dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), intramuscular in the left arm on 21Dec2020 09:45 at a single dose for COVID-19 immunization at the hospital. The patient has no medical history. The patient has no known allergies. The patient's concomitant medications were not reported. The patient did not received any other vaccines within 4 weeks prior to the COVID vaccine and did not received other medications within 2 weeks of vaccination. The patient received a COVID positive diagnosis on 29Dec2020, 8 days later. The events led to a doctor or other healthcare professional office/clinic visit. The patient underwent COVID tests post vaccination on 29Dec2020 - Nasal Swab (NAA nasal swab) and Rapid COVID test, both showed positive test results. The patient was not diagnosed with COVID-19 prior to vaccination. Outcome of the events was recovering. No treatment was given for the events. The events were assessed as non-serious. Information on the lot/batch number has been requested.; Sender's Comments: The efficacy of a drug varies from patient to patient and can be affected by different factors; however, a contributory role of the suspect product BNT162B2 to the reported drug ineffective and COVID-19 cannot be ruled out.

tested positive after taking the first dose of the vaccine; exposed to a family member with the virus/tested positive after taking the first dose of the vaccine; tested positive after taking the first dose of the vaccine; This is a spontaneous report from a Pfizer-sponsored program Pfizer First Connect. A contactable nurse reported for a 60-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 28Dec2020 at single dose for covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient who tested and was positive for the virus after being exposed to a family member with the virus after taking the first dose of the vaccine. Patient was asymptomatic. The Nurse asking if

we have any recommendations for the 2nd dose. The outcome of the events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: The association between the events lack of effect (suspected COVID-19, tested and was positive) with BNT162b2 can not be completely excluded.

contracted covid after getting the vaccine; contracted covid after getting the vaccine; This is a spontaneous report from a Pfizer-sponsored program. A contactable physician reported similar events for 4 patients. This is 1st of 4 reports. A 46-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: Unknown, does not have lot number to provide) via an unspecified route of administration on 24Dec2020 at single dose for covid-19 immunization. The patient medical history and concomitant medications were not reported. The patient contracted COVID after getting the vaccine on 01Jan2021. The outcome of the events was unknown. Information on the Lot/Batch number has been requested; Sender's Comments: The association between the event lack of effect (contracted COVID) with BNT162b2 can not be completely excluded.,Linked Report(s) : US-PFIZER INC-2021003894 same reporter/drug/event, different patient;US-PFIZER INC-2021003893 same reporter/drug/event, different patient;US-PFIZER INC-2021003895 same reporter/drug/event, different patient

Contracted covid after getting the vaccine; Contracted covid after getting the vaccine; This is a spontaneous report from a Pfizer Sponsored Program. A contactable physician reported similar events for 4 patients. This is 2nd of 4 reports. A patient of unspecified age and gender received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot/batch number and expiration date not provided), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced contracted covid after getting the vaccine on an unspecified date. The report was non-serious per the reporter. The outcome of the events was unknown. Information on Lot/Batch number has been requested.; Sender's Comments: The association between the event lack of effect (contracted COVID) with BNT162b2 can not be completely excluded.,Linked Report(s) : US-PFIZER INC-2021003873 same reporter/drug/event, different patient

contracted covid after getting the vaccine; contracted covid after getting the vaccine; This is a spontaneous report from a Pfizer-sponsored program. A contactable Physician reported similar events for 4 patients. This is 3rd of 4 reports. A patient of an unknown age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: Unknown) via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient medical history and concomitant medications were not reported. The patient contracted COVID after getting the vaccine. The outcome of the events was unknown. Information on the Lot/Batch number has been requested.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021003873 same reporter/drug/event, different patient

contracted covid after getting the vaccine; contracted covid after getting the vaccine; This is a spontaneous report from a Pfizer-sponsored program IBCC (Inbound Call Center for HCPs). A contactable physician reported similar events for 4 patients. This is 4th of 4 reports. A patient of unspecified age and

gender received bnt162b2 (lot/batch number and expiration date not provided), via an unspecified route of administration, on an unspecified date, at single dose, for Covid-19 immunization. The patient medical history and concomitant medications were not reported. The patient contracted COVID after getting the vaccine. The outcome of the events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: The association between the event lack of effect (contracted COVID) with BNT162b2 can not be fully excluded.,Linked Report(s) : US-PFIZER INC-2021003873 same reporter/drug/event, different patient

"Headache; Body aches; This is a spontaneous report from a contactable nurse (patient). A 55-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (lot number EH9899), intramuscular (hope it was IM, but did not know for sure because she was not watching) at right arm deltoid on 29Dec2020 08:40 at single dose for COVID-19 immunization, at the hospital where she works. The vaccine was not administered at military facility. The patient's second dose was scheduled to be 19Jan2021. The patient's medical history included potassium low, hypertension, pericarditis, asthma, herniated disc in back, pain, gastrointestinal infection (GI), Vitamin D low, wheezing, exposed to someone who was positive with COVID at a wedding on 28Dec2020, ""diuretic"", ""cardiac/heart"" and ""Cholesterol"". Concomitant medication included ranolazine (RANEXA) for heart, isosorbide for cardiac, potassium chloride for potassium Low, furosemide for diuretic, atorvastatin (LIPITOR) for cholesterol, acetylsalicylic acid (ASPIRIN) for cardiac, montelukast sodium (SINGULAIR) for asthma, pregabalin (LYRICA) for herniated disc in back take for pain, nebivolol hydrochloride (BYSTOLIC) for blood pressure, pantoprazole sodium sesquihydrate (PROTONIX) for GI, celecoxib (CELEBREX) for pain, spironolactone for diuretic, vitamin D for Vitamin D low, nitroglycerin for angina, salbutamol (ALBUTEROL) for wheezing, and oxycodone for pain; all ongoing. History of all previous immunizations with the Pfizer vaccine considered as suspect was reported as none. No additional vaccines administered on same date of the Pfizer Suspect. No prior vaccinations within 4 weeks. The patient reported events on the Pfizer COVID Vaccine. She reported after getting the vaccine she had body ache and headaches. On 30Dec2020 16:00, the patient experienced headache and body aches. The event headache was reported as serious medically significant. She received the COVID vaccine on 29Dec2020 and had significant body aches, but she still had a headache that had not gone away since she got the vaccine. The patient explained the body aches were mild to non-existent/resolved, later confirmed as still ongoing, but better. Her main issue was the headaches that had not gone away. The events headache and body aches started around 16:00. She worked nightshift and she woke up with it. The events did not require a visit to the emergency room or physician office. The day after she received the COVID Vaccine she was tested for COVID. She found out she was exposed the day before she received the COVID vaccine, 28Dec2020 to someone who was positive with COVID at a wedding. She later found out her COVID test on 30Dec2020 was negative. The reporter assessed both events headache and body aches as related to the suspect vaccine. She believed the body ache and headache were related to the COVID Vaccine itself. She added, she felt it's related because these events are not part of her typical health problems. She added they're not going away even with medications (oxycodone, Celebrex, and ibuprofen). Oxycodone was located in an orange pharmacy filled bottle and she was unable to provide a lot/exp/NDC. Celebrex was located in an orange pharmacy filled bottle and unable to provide a lot/exp/NDC. She saw a use by date of 10Mar2021. Ibuprofen (Lot number: OCE2824A and expiration

date: Dec2021). The outcome of the event headache was not recovered, for the event body aches was recovering.; Sender's Comments: There is a reasonable possibility that the event headache was related to BNT162b2 based on known drug safety profile and close temporal relationship. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate."

covid 19 test result came up positive; covid 19 test result came up positive; severe left arm pain; This is a spontaneous report from a contactable unspecified Healthcare professional reporting for himself. This 52-year-old male patient received on 20Dec2020 02:30 PM first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot EK5730) at single dose intramuscular in the left arm for COVID-19 immunization. No allergies to medications, food, or other products. Medical history was not reported. Prior to vaccination, the patient was not diagnosed with COVID 19. Concomitant medications (all started on an unknown date and received within 2 weeks of vaccination) included buspirone hydrochloride (BUSPIRON), atorvastatin (manufacturer unknown) and acetylsalicylic acid (BABY ASPIRIN). On 21Dec2020, 10 hours after getting vaccine the patient had body aches, cold and severe left arm pain. 4 days after getting vaccine again the patient had cold, body aches and sore throat for couple of days. On 28Dec2020, covid 19 test (nasal swab) result came up positive. The patient went to Emergency room. Outcome was recovered on an unknown date. It was unknown if a treatment was performed.; Sender's Comments: The association between the event lack of effect (COVID 19 nasal swab test result came up positive) with BNT162b2 can not be fully excluded.

Anaphylactic reaction 6 days post vaccine 24Dec2020; I had severe chest tightness; SOB; throat soreness; hoarse voice; mouth swelling; This is a spontaneous report from a contactable physician, the patient. A 34-year-old non-pregnant female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot Number: EL0140), via an unspecified route of administration in the left arm on 18Dec2020 at 15:30 (at the age of 34-years-old) as a single dose for COVID-19 immunization. Medical history included severe dust mite allergy (based on skin test). Prior to the vaccination, the patient was not diagnosed with COVID-19. Concomitant medications included cetirizine hydrochloride (MANUFACTURER UNKNOWN), hydrocodone bitartrate/paracetamol (NORCO), ibuprofen (MANUFACTURER UNKNOWN), and ondansetron (ZOFRAN); all for unspecified indications from unknown dates and unknown if ongoing. The patient did not receive any other vaccines within four weeks prior to the vaccination. On 24Dec2020 at 10:00, 6 days post vaccination, the patient experienced anaphylactic reaction, severe chest tightness, shortness of breath, throat soreness, hoarse voice, and mouth swelling; all reported as life threatening. The events led to an emergency room visit and she was given epinephrine (EPI-PEN), methylprednisolone (SOLUMEDROL), and diphenhydramine hydrochloride (BENADRYL) as treatment. The patient stated that she developed the reactions 45 minutes after she took premedications for a dilatation and curettage procedure. The premedications included ibuprofen, hydrocodone bitartrate/paracetamol, ondansetron. She stated she had taken these medications several times before and this was the first time she had this reaction. Since the vaccination, the patient had not been tested for COVID-19. The clinical outcomes of the anaphylactic reaction, severe chest tightness,

shortness of breath, throat soreness, hoarse voice, and mouth swelling were recovered on unknown dates.; Sender's Comments: Anaphylactic reactions presented as chest tightness, shortness of breath, throat soreness, hoarse voice, and mouth swelling, developed 45 minutes after premedications including included ibuprofen, hydrocodone bitartrate/paracetamol, ondansetron for a dilatation and curettage procedure and 6 days post vaccination with BNT162B2, the event therefore is most likely attributed to these premedications unrelated to the vaccine use. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

"Tested positive for covid; Received first Pfizer covid vaccine on 23Dec, tested positive for covid; This is a spontaneous report from a contactable pharmacist. A 75-year-old patient of an unspecified gender started to receive bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 23Dec2020 at SINGLE DOSE for COVID-19 immunization. The patient medical history and concomitant medications were not reported. The reporter stated ""75 year old patient with some comorbidities who received first Pfizer covid vaccine on 23Dec, tested positive for covid on 28Dec. Patient has been treated at home and is doing well. What is the protocol for their second dose of Pfizer covid vaccine due on 13Jan?"" The outcome of the events was unknown. Information about lot/batch number has been requested."

Covid positive/ testing positive for the virus/ asymptomatic; Covid positive/ testing positive for the virus/ asymptomatic; This is a spontaneous report from a contactable consumer who reported for herself. A 30-year-old female consumer received her first single dose of BNT162B2 (Pfizer/ BioNTech Covid-19 vaccine, Lot number: EH9899) on 17Dec2020 per works recommendation (COVID-19 immunization). The patient had a history of back pain and had no concomitant medications. The patient got the vaccine and tested for Covid as a preventative to make sure she was safe to travel for a wedding. Her Covid test was pending and she found out that she was Covid positive the day after receiving her first dose of the Pfizer Covid vaccine. Her primary care informed her to get the booster despite testing positive for the virus. She was told since she was asymptomatic that she could get the vaccine. She received the second dose on 04Jan2021. The outcome of the event Covid positive was not reported.

COVID; COVID; This is a spontaneous report from a Pfizer-sponsored program Pfizer First Connect from a non-contactable consumer (patient). A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on Tuesday 29Dec2020 at single dose for COVID-19 immunization. The patient medical history and concomitant medications were not reported. The patient was diagnosed with COVID on Saturday 02Jan2021. The outcome of the event was unknown. No follow up attempts are possible; information about lot/batch number cannot be obtained.

Tested positive for COVID; Tested positive for COVID; This is a spontaneous report from a contactable other HCP via a Pfizer-sponsored program IBCC (Inbound Call Center for HCPs). A patient of unspecified age and gender started to receive BNT162B2, via an unspecified route of administration from

23Dec2020 to 23Dec2020 at first single dose for COIVD-19 immunization. The patient medical history was not reported. The patient's concomitant medications were not reported. Pharmacy student on the line who had patient who received the first dose of the COVID vaccine shot on 23Dec2020. Then the patient went home on Christmas break and later tested positive for COVID on 29Dec2020. She was calling to see how to proceed with the second dosage. Outcome of the event was unknown. information on the lot/batch number has been requested.; Sender's Comments: Based on the information available, a possible contributory role of the suspect BNT162B2 cannot be excluded for the reported event positive for corona virus infection based on the known safety profile. However given the short duration of 6 days since the vaccine first dose, it is unlikely patient would have fully developed immunity.

I tested positive for COVID-19; I tested positive for COVID-19; This is a spontaneous report from a contactable nurse. A 29-year-old female patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899), intramuscular in left arm on 17Dec2020 19:45 at single dose for covid-19 immunisation. Medical history was not reported. There were no concomitant medications. The patient tested positive for COVID-19 on 03Jan2021. Outcome of event was recovering. Patient has not been diagnosed with COVID-19 prior to vaccination.

Patient tested positive for COVID-19 about 2 weeks after receiving the 1st dose of COVID vaccine; Patient tested positive for COVID-19 about 2 weeks after receiving the 1st dose of COVID vaccine; This is a spontaneous report from a contactable consumer reported that a male patient of unspecified age received his first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on an unspecified date, at single dose for COVID-19 immunization. Medical history and concomitant medications were not reported. Patient is a health care worker who works with COVID patients as part of his daily work duties. He tested positive for COVID-19 about 2 weeks after receiving the 1st dose of BNT162B2. Outcome of the events was unknown. No follow up attempts are possible; information about lot/batch number cannot be obtained.

Tested positive; Tested positive; This is a spontaneous report from a contactable nurse via Pfizer sales representative. A 35-year-old female patient received BNT162B2 (lot: EKS730), via an unspecified route of administration on 17Dec2020 at single dose for COVID-19 immunization. Medical history and concomitant medications were not reported. Patient received 1st COVID vaccine dose on 17Dec2020 and tested positive on 23Dec2020. Patient was exposed to COVID. She was curious if and when she should get a second dose having tested positive after her first dose. Outcome of the events was unknown.; Sender's Comments: Based on the information available, a possible contributory role of the suspect BNT162B2 cannot be excluded for the reported event SARS-CoV-2 test positive based on the known safety profile. However given the short duration of 6 days since the vaccine first dose, it is unlikely patient would have fully developed immunity.

C/o shortness of breath routine oxygen increased cannula changed to mask oxygen sats at 88%

started to feel a little sick; had COVID-19 test and results came back positive; had COVID-19 test and results came back positive; This is a spontaneous report from a contactable healthcare professional. A 27-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for

injection, lot number EH9899/expiration date unknown) via an unspecified route of administration on 27Dec2020 at a single dose for COVID-19 immunization. The patient had no relevant medical history. Concomitant medications were not reported. The patient stated that he got the vaccination on the 27th and then that same night he started to feel a little sick. He was assuming that it has just to be the side effect of the vaccine (unspecified vaccine). On 28Dec2020, he was feeling pretty sick; he did not go to the work. He had COVID-19 test (Dec2020) and results came back positive. He added that he didn't know if it was the COVID because he was reading up on the vaccines and it said that one could not get COVID from the vaccine. The outcome of the events was unknown.; Sender's Comments: The reported positive with COVID-19 test after COVID-19 immunization is considered ineffective of BNT162B2, and the Company cannot completely exclude the possible causality between the reported event and BNT162B2 administration.

Labored breathing with oxygen running at 4l/min, muscle weakness

Fever to 103.7F, respiratory rate 36. Was transferred from facility to hospital. Since then has been found to have gram-negative rod bacteremia, although urinalysis was negative, urine culture pending. Patient has since defervesced after receiving 1 dose of cefepime. Overall the most likely cause of fever seems to be urosepsis w/ bacteremia, pending confirmation with urine & blood cultures.

The patient was found deceased at home about 24 hours after immunization. Date of Death:: 12/29/2020; estimated time of death 6:00pm

Patient received vaccine on 1/4/2021. He was in Hospice for CHF and renal failure, but was able to get up in his wheelchair and eat and take medications and talk. On 1/5/2021 am, he was noted to be very lethargic an could only mumble, could not swallow. No localizing neurologic findings. He was too lethargic to get up in chair.

initial; swelling of tongue, tingling and numbness in legs, syncope. later; HA

Resident displayed with confusion/shaking at 1400, condition worsens at time went. Resident unable to state where he is, knows his name. can tell you he does not feel right. Temp 97.3, p 88, O2 91%, Bp 214/116 Transferred to ED with fever, temp of 103, and shortness of breath, admitted to ICU Positive COVID-19 test at hospital. Diagnoses include acute COVID-19 pneumonia and hypoxia. PO had confusion, fatigue, weakness, hypoxia, increased BP

Swelling of throat and tongue, anaphylaxis, hives, redness, swelling

shoulder joint pain, injection was given in joint.... I am now on prednisone, physical therapy, if this doesnt help will need a MRI .

She began with an earache and dizziness. Pain got so severe that she could no longer take it. Went to the doctor which she was put on pain medications. Went to ER on 1/6 and on 1/7 went to her PCP. Still in severe pain.

Patient experiencing Chest pain and elevated troponin. Patient taken to the cath lab and treated for suspected stress induced cardiomyopathy.

ITP Plt 2

Notified today that he passed away. No other details known at this time.

Hospital on 1/2 - then again on 1/5, transferred and admitted to hospital, discharged 1/6 Abnormal reflex/weakness back pain paresthesia and weakness of legs abdominal pain evaluation for possible GBS post covid 19 vaccine

29-year-old previously healthy female presenting today with difficulty sleeping, sore throat, and nausea after receiving the second Pfizer COVID-19 vaccine around 10 AM. Patient says that after her first dose of the vaccine she had mild sore throat and hoarse voice that resolved spontaneously. She had her vaccine around 10, several hours later before coming to the emergency department between 2--230 she had the sudden onset of difficulty speaking with associated sore throat and nausea. She has had dry heaving but no large amounts of vomiting. She has not had stridor, wheezing, shortness of breath, syncope, or the development of a rash or hives. She has not had a reaction to her prior vaccines she does not have any other allergies in general. She has otherwise been well recently without infectious symptoms including fevers, chills, cough, and has not been exposed to Covid to her knowledge. Medications administered in ED included diphenhydramine 50 mg IV once, dexamethasone 10 mg IV once, famotidine 40 mg IV once, ondansetron 4 mg IV once. Had brief episode of shaking and R arm rigidity in the ED. Patient denies LOC during the episode, did not have a post ictal state, no tongue biting or episodes of incontinence. Given single event without LOC, less concern about episode being a seizure. Patient has had no further episodes of shaking since admission. CT brain was wnl, no FNDs noted on exam.

I am breastfeeding. My daughter had seizure like episodes starting on Saturday 1/2, Sunday 1/3, Monday, 1/4 and 2 times on Tuesday 1/5.

Patient received first dose of vaccine on 12/28, developed COVID-19 infection shortly thereafter and expired on 1/6/2021.

Patient received first dose of vaccine on 12/28, developed COVID-19 infection shortly thereafter and expired on 1/4/2021

Cardiac event, 2 days after vaccination, patient expired.

Fever, shortness of breath and chest pain that resulted in a heart attack a few hours after vaccination

Acute allergic reaction Tongue swelling Facial swelling Throat swelling Rash on throat and chest Redness in throat Diaphoresis Momentary loss of consciousness

Altered Mental Status began the middle of the night of 01/06/21 and 01/07/21 with worsening overall status- definitive symptoms unknown to this reporter, this person was admitted to the local hospital at

approximately 1800 01/07/2021. This reporter was not told the admitting diagnosis or any defining symptoms, only that the person was admitted.

Medical docter state patient has a acute cardiac attack

Initial itching at injection site, observed and returned to work. Came back ~30-40 minutes later with itchiness in throat and hives to arm. Given Benadryl PO and observed for extended period of time. Symptoms not resolving. Patient transferred to Emergency Department for further care. At that point observed to have full body rash, SOB. Given Epi while in ED. Developed tachycardia, hypotension. Treatment continued.

After about 15 min: hr went to over 170bpm , flushed sensation, brain fog, was driving at the time and my brain wouldn?t figure out how to call 911 , eventually I figured it out but it took extreme mental effort. Paramedics came and my pulse was From 100 - 170 changing rapidly, bp 150-175/x changing rapidly, symptoms would come and go about 8 times on way to hospital. In ER same thing then about 2 hrs go by and then all started again. Pulse remained at 90- 100bpm at least until 2am. (My resting hr is between 40 and 50, my normal bp is usually sub 120/80) I later realized my hands were swollen, mostly on my left side. Lingering symptoms include brain fog, tiredness, and headache. Maybe an exasperating issue was I had low potassium levels likely making symptoms worse - I worked out heavily early in the morning, probably had low intake of potassium that day and day before, and maybe slightly dehydrated from my workout - I do Functional lifting, run, and other types of exercise regularly.

Developed hypercapnic respiratory failure, CHF exacerbation - readmitted to Hospital. In ICU with BIPAP

patient begin to feel bad that night was admitted into hospital sometime in the next couple of days for dehydration, patient discharged home and then readmitted to hospital for positive covid testing after feeling very ill.

At 1431, pt received the first dose of the Moderna COVID-19 vaccine. Hx of anaphylactic reactions to penicillin as a child. At 1445, pt started complaining of tongue swelling, which proceeded to increase in severity. At 1449, Epi-Pen administered (0.3 mg) in R deltoid. At 1450, 50 mg diphenhydramine IM administered in L deltoid, followed by an additional dose at 1452 in R deltoid. 911 was called between 1445 - 1450. Pt was moved to another exam room where she could lay down because she was hypotensive, lightheaded, and pale. O2 sats remained between 95-98%, BP 81/53-190/100, P 94-136, RR 16-24 throughout. Tongue swelling improved slightly after receiving Epi-Pen. EMS arrived and were able to start an IV before transporting her to the local hospital at 1502.

Patient presented to the emergency department with sensory loss and loss of reflexes, evaluated by neurology and diagnosed with Guillain- Barre Syndrome thought to be secondary to the Pfizer Covid Vaccine

Death

I had a myocardial infarction on December 27, 2020. I had received my first vaccination for COVID-19 on December 22, 2020. Not sure if these are related but I felt I should report it.

Low grade Fever, headache needing admission Intracranial hemorrhage with hypertension Medical management for hypertensive emergency Received surgical evacuation admitted in Intensive care,

1/4/21: Headache, Dizziness & Fatigue 1/7/21: Left Sided Facial Droop

Shortness of breath, cough, rash on face and neck, arthralgia

Patient received COVID vaccination around 12:15pm. Patient was monitored for the appropriate amount of time by nursing staff. Patient passed away at 2:15pm.

Diarrhea followed by death 24 hrs after vaccination

Patient is a 32 yo G2P1001 with EDD 5/2/2021 by 7w US. She had the first dose of the Pfizer Covid 19 vaccination on 12/17/2020 at the Health Clinic and the second dose on 1/7/2021 at 1115 am. She began having abdominal pain and vaginal bleeding at 315 sm on 1/8/2021 progressing to a previable (22w2d) preterm birth at 739pm on 1/8/2021.

Pt experienced extreme fatigue and sleepiness the day following her second vaccination for Covid 19 and was found by her family after collapsing on 1/6/21 at 05:30. Upon arousal, she experienced headache, vomiting, weakness, difficulty speaking and difficulty walking with lower extremity weakness. She was taken to urgent care and subsequently admitted for evaluation at hospital and found to have a normal chemistry, blood count, normal lumbar puncture and normal imaging of her neck and brain. Discharge summary notes 3/5 strength and hyporeflexia throughout. Pt had televisit consult with psychiatry and neurology. She is subsequently to be discharged to a Facility without explanation for her sudden onset of progressive lower extremity and vocal weakness. She is noted to have a history of shellfish allergy. She experienced mild symptoms after the first vaccination, but no neurologic or vascular symptoms at that time.

I am a physician and I got dose 2 at 1:30pm on Jan 4. Next afternoon, Jan 5, I got severe myalgias, fever up to 100, severe fatigue, went home after work and slept til the next morning, went to work, took ibuprofen, and the myalgias improved and felt better. But around 3 pm, Jan 6, I got mild vertigo. By about 7pm Jan 6, I noticed my L ear didn't hear well. I changed the battery in my hearing aide and cleaned it but It made no difference. I woke up on Jan 7 with severe vertigo and hearing loss. I did Epley's maneuvers with no effect. I have had similar episodes. I went to work, but gave up when I could not hear patients talking to me. I went to the Emergency Dept and got admitted. I was too unsteady on my feet. Audiogram showed profound hearing loss both ears and almost complete loss of discrmination in R ear. I was put on high dose steroids. Also having tinnitus (mostly whooshing sound of my own pulse). MRI negative. Blood work negative. Some mild improvement now, after 1 dose steroids.

Fever up to 102.9, chills, headache, hypertension, tachycardia, dyspnea.

"Myocardial Infarction: patient began to complain of severe chest pain 3 hours after the vaccine was given .. Vaccine NDC # 59267-1000-1. 0.3 ml given by RN. Patient called his PCP: ""... I had very bad chest and shoulder pains, neck pains and slight fever from 9 pm until early this morning (Jan 8). My blood pressure was 155/95 mmHg. Should I see you today? Still feel sore all upper body. Above message

received at 0720 am (Jan 8) and the patient was called back at 0757 am (Jan 8): patient was told that many of the side effects above were related to the vaccine but the chest pain was worrisome and the provider requested the patient go to the emergency room. Patient understood the importance to seek medical attention..... Emergency Room notes: seen by MD on Jan 9. Note at 0749: patient complained of chest pain on/off since received COVID vaccine on Jan 7. Pain was substernal and radiated to the left shoulder, assoc with some SOB. EKG obtained and revealed ST segment elevation and a ""cardiac alert"" was called."

At around 11:45pm tingling started in my left eyebrow. I thought there was something in my eyebrow and after time of wiping it a few times I went to look into the mirror and realized that nothing was there. about and hour later I got a drink and a snack to eat and I realized I had a numb sensation in the left corner of my lip. As a nurse I went though the signs of a stroke with 2 other nurses I called. Everything was normal other than that sensation. Thinking I was just overly tired I went to bed. When I woke up the next day I felt okay until I went to drink some coffee and the numb sensation in my corner lip was still there. Now I was concerned and called employee health and was instructed to go to the ER to role out a stoke. I followed employee health's instructions and went to the ER. I was diagnosed with facial paresthesia and discharged with instructions to come back if symptoms got worse. Symptoms persisted all day and around 7 I called my mom on video chat to show a visual facial twitch on the left side of my face. right after I got off the phone with her the left side of my face drooped and my fiance immediately drove me to the closest ER. I was seen immediately and they decided to admit me. The did labs and head CT. They admitted me to labor and delivery because there were no other rooms. The next day I was seen by a neurologist and many doctors.

Patient was unresponsive in her room during the night, had gotten the vaccine this morning, 911 called. Had right arm pain and loss of consciousness. EMS got 180/104 BP and blood glucose was 122. Was transported to hospital. Returned to the facility the next day with no complications, was just fatigued.

8 hours after vaccine I experienced stomach pain and nausea. I then became very ill and extremely weak. I was laying on floor. Very difficult to talk and very dizzy. Unable to walk. Called 911 and went to ER. Had chest pressure and cardia work up was done. Dx wi ST elevation.

7 day after site itching, hot swelling. Unsure if related 9 day after suffered CVA and have hyper coagulation

sudden sensorineural hearing loss in the right ear, audiology and ENT assessment, currently being treated with steroid medication

after receiving vaccine patient immediately felt warm, dizzy and started dry heaving. we dosed Zofran 4mg, gave one dose epi-pen, and 50mg Benadryl. patient still complained of chest pain and was dry heaving. she was then transported by ems to the hospital at 4pm.

Received vaccine 12/19/2020 at hospital around lunch time. Severe abd pain started 10 hours after vaccine administration with vomiting. I went to emergency room next morning Emergency appendectomy 12/20/2020. Had bleeding after surgery. Second surgery 12/21/2020

Anaphylaxis

After the vaccine was administered I walked away maybe 50' and I started to feel dizzy I felt light headed and as if I was drunk my legs feel real week they took me outside so I could catch some fridge fresh air and they set me down on a chair I was very dizzy my legs and my knees felt like I couldn't stand up and they were very weak I kept seeing a the rails double vision and I started to have a tightness in the back of my neck I felt they warrant come over my head and my forehead got very very cold And then I felt as I was gonna blackout and pass out and I was gasping for air and suddenly my tongue went into a spasm and it went to the top of my the roof of my Roof of my mouth and I couldn't breathe and I was able to send a message for someone to come and help me as I was sitting there by myself they rushed over by now looking at my text message it was for 02 which was within 15 minutes of the vaccine when I had my 1st episode and then minutes after that 3 more came with the same oh unable to swallow I lost the ability to swallow and my tongue fell like I had no control it was just automatically stuck to the roof of my mouth.. Upon the arrival of Ems I was told there was no treatment and there was nothing they could do told me to wait 24 to 48 hours in the symptoms should subside it's been over 72 hours in the symptoms are still occurring. I continue to feel dizzy light headed and now have high blood pressure which was not present before visit ER prescriptions for steroids with issued, I Told to go home and rest. Followed up with family doctor in the morning and was told it was not an allergic anaphylactic reaction probably more so neurologically ransom blood tests waiting for results continue to have loss of control over tounge spasms unable to eat Accompanied by fatigue dizziness and high blood pressure

On 01/07/2021 I woke up at 0300am with chills, headache, body aches, joint pain, fever of 101.2 and swollen left axillary lymph nodes. I took Tylenol and Benadryl and it relieved the fever/headache/body aches/joint pain, however the lymph nodes in my left axillary remained swollen. I continue to take Tylenol for the fever/body aches/pains without relief for the swollen and painful axillary lymph nodes. Warm compresses do help to relieve the pain temporarily but they remain painfully swollen. On 01/08/21 I called my doctors office to ask if it was normal to experience such painfully swollen axillary lymph nodes to which they stated ?we don?t know, it is too soon for us to tell what?s normal and what isn?t normal right now.? They did not offer any suggestions to relieve the pain or swelling. The morning of 01/09/2021 , I called Employee Health at my hospital (my place of work and also where I received the vaccine) and they also stated they didn?t know if this was a normal reaction due to the newness of the vaccine. A couple hours later, employee health emailed me a link to the VAERS reporting website and asked me to file a report.

I am currently breastfeeding my 5-month-old son. I received my first vaccine on 12/28/2020 and directly breastfed within 4 hours of receiving the vaccine. Two days after my vaccine my son was at daycare and had two large diarrhea blowouts and two large emeses followed by a 1-minute episode where he was limp with entire body cyanosis and in-and-out of consciousness. He also had a maculopapular rash on his torso. EMS was called. He was observed in the emergency department for a few hours then recovered well without intervention and did not require hospitalization. EKG was normal. He has continued to be well and back to baseline since the event.

"Dizziness started within 30 minutes after injection on 01/08/21 and felt ""off"". On 01/09/21 approx. 0800 Patient began feeling body aches, fevers, injection site pain, increased dizziness, and nausea. At approximately 1pm patient began vomiting and having diarrhea. Symptoms worsened over the next couple hours to where patient was unable to walk without stumbling. Wife witnessed patient becoming very pale and almost pass out at approx. 5:30pm. Patient states he feels like he's in slow motion. Patient is unable to maintain balance when walking and reports increasing fatigue and weakness."

Started severe belly pain and went to Emergency room and diagnosed with mesenteric vein thrombosis after the CT scan of the abdomen, treated with heparin drip, antibiotic and discharged with anticoagulant pills(Eliquis). I am not sure that it is because of the vaccine my doctors are also not sure about it, but I am sure that I am a healthy person without any health issues . I am working as registered nurse, our unit is for covid-19 patient's since march 2020 and I had covid -19 on August month and recovered after 3 weeks.

Pfizer-BioNTech COVID-19 Vaccine EUA Miscarriage - (date of vaccination 1/6/21, miscarriage symptoms (cramping) started 1/8/21, confirmed 1/10/21; estimated date of delivery 8/30/21)

Patient came into the emergency department on 1/8/21 with an acute ischemic stroke with complete occlusion of her left MCA. She had acute and complete flaccid paresis of her right face, arm, and leg, complete aphasia, and neglect of the right side of her body. NIHSS of 27. Onset of deficit was between 6:30pm-7:10pm. She recieved her 1st COVID-19 vaccine dose that morning at 10:31am.

I was injected high on my shoulder, significantly higher than I?ve ever been injected in my life. I believe I have SIRVA. The pain has become so severe that I cannot use my left arm. The pain is intolerable. I take four Advil every six hours, ice my arm regularly, and keep my arm in a sling. The pain has gotten significantly worse with time (not better). I?ve never experienced pain like this from a vaccine in my life. No history of bursitis or shoulder injury. Again, the pain gets worse with time. I?m almost 48 hours post injection

1/7-21 - Received second dose of pfizer covid-19 vaccine 1/8/21 - Fever, dizziness, headache 1/10/21 0250 was found not breathing. EMS performed CPR and patient deceased

The patient presented with left eye peripheral visual loss, left upper and lower extremity and facial numbness sensation and weakness. This started 1 hour after receiving COVID-19 vaccine at her place of employment. Pt was brought to CRMC via EMS.

Facial (cheek) numbness and swelling with slight face droop Swelling continued on 1/7/2021 On 1/8/2021, lip swelling and numbness and tongue numbness By 1/9/2021 4pm, swelling and numbness resolved but chills and muscle aches began

Patient received the Moderna Vaccine 1/2/21 at his VA Clinic. He received the vaccine that morning and by the evening he was not feeling well. He developed cough, weakness and fever and now is unable to ambulate. He has since been hospitalized and has tested positive for COVID-19.

Headache, Myalgia, Arthralgia, Fever, CoughWheeze & Syncope

NauseaVomiting History of vasovagal episodes; c/o warm feeling and nausea without vomiting. Recovered Narrative: 10 minutes after vaccine admin. c/o/ warmth and nausea. Triaged by the ER nurse and observed for 45 minutes. Discharged in stable condition 133/84, 104, 18

I am not sure if related on not. This event was 13 days after my COVID-19 1/2 immunization. Otherwise, I am a very healthy physician, normal BMI, I have also been tested 5-6 times negative for COVID. I do get exposed in my job, but wear proper PPE. Viral infection in FEB that was like COVID-19 sx, I did AB test as soon as it was available, and negative. ---The Event: Monday morning (1/4/21), after getting out of shower, I was talking to my husband (who is MD)and started having BROCA's aphasia sx (could not get words out coherently), then fell into bed and started right wrist and right foot posturing. This lasted 10 min. I have non-memory of it, but my MD husband witnessed it. After 10 minutes, I was back to normal, except shaky and some word finding difficulties. After 30 min, totally back to normal.

pt received Moderna vaccine. next day he had high fevers up to 103, confusion. admitted to hospital. infectious work up negative. improved off antibiotics.

Resident appeared to be jaundice with yellow skin and eyes. Resident also complained of not feeling well. Urine was dark yellow. Resident short of breath. Resident was admitted to hospital and diagnosed with post-covid pneumonia.

Throat closing Pruritic throat and tongue Tingling lips and tongue Throat clearing Hoarse voice

Acute ischemic stroke, basilar occlusion

SOB

Nausea/vomiting and diarrhea loss of appetite tachicardia sent to er for hydration.

I immediately felt dizzy, and there was ringing in my ears, I felt faint. I also felt shakey. I have had these symptoms for 12 days, unchanged. I cannot work because of these symptoms. I have been to urgent care and have had lab work and an EKG

RECIEVED VACCINE 1/8/21 EXPIRED UNEXPECTED 1/10/21, NO ADVERSE REACTIONS NOTED

Two days following the first COVID vaccination he developed epigastric pain and was evaluated in the ER and was admitted for gallbladder surgery. He has a 6 year history of gallbladder disease but was not experiencing symptoms until after the COVID vaccination.

The patient had an apparent cardiac arrest on 12/23/20 and was admitted to the ICU. He was taken off of life support on 12/30/20. He had known cardiac disease.

Severe thrombocytopenia (plts 3k/uL), oral mucosal bleeding, bruising

Sudden, severe worst headache of her life, coupled with onset of oral herpetic lesions and inflammation to unrelated body part (belly button piercing) occurred one week after vaccination received. She presented to ED 12/28 noted to have hypokalemia and head CT showed mild occipital encephalitis,

admitted overnight for obs subsequent brain MRI was normal. She was seen in my clinic 2 days later (1/4/21) and was started on 3 day course of Decadron, topical acyclovir for herpetic lesion. As she is a nurse, I kept her off work until resolution of symptoms. Seen again on 1/8/21, headache resolved. She did discuss CT and MRI results with neurologist. He was not convinced this was vaccine related. She is having 2nd dose of vaccine on 1/11/21.

Patient died, I have a copy of his vaccination card

Moderna vaccine dose #1 received in right shoulder on 12/31/20 at 2:15PM. Injection was uneventful other than sensation of pressure. I did notice at the time, but could not fully see, that the injection appeared to be much higher on the shoulder than normal. I immediately came home afterwards and relaxed. Approximately 2hrs later, I began experiencing extreme pain in my right shoulder. As the night progressed, the pain worsened to 10/10 with inability to move my arm. Later that night after requiring assistance to take off my shirt, I noticed that the bandaid overlying the injection site was very high, immediately below and bordering the acromion process. This was concerning but I was hopeful the pain would go away over the next few days. I took tylenol that night. I woke up multiple times during the night because the pain was so severe. When I woke up, the pain and inability to move my arm were still present. I began taking 800mg ibuprofen and 1000mg tylenol alternating Q4 throughout the next few days. The pain and disability remained so severe that I required assistance performing ADLs for the next 4 days. On day four, with the pain not resolved and still severe despite consistent advil and tylenol use, I began having concern for shoulder injury related to vaccine administration. The next day I decided to seek an evaluation by an orthopedist. I am a physician and was unable to perform basic tasks and ADLs. I happened to have a few days off after the injection but would not have been able to work had I not. After an evaluation by the an orthopedic PA, I obtained an MRI of my right shoulder with results shown below - as I expected evidence of rotator cuff tendinopathy and subdeltoid bursitis consistent with SIRVA. As of now, I still have limited range of motion and shoulder pain on the right which has improved slightly but is far from resolved. I still have difficulty with certain ADLs including putting clothes on and off, lifting items, and tasks that require raising my right arm above my head. I am concerned with the possibility of long term and/or permanent damage after reviewing the literature. I am also concerned about how many other healthcare workers the person who gave me my vaccine may be injuring and/or causing permanent harm to.

Pain at site of injection, eyes, throat, face swelling. Unclear thinking, hoarse speech, headache, hives, swelling. Intervention taken immediately. Ongoing 11 days: SOB, headaches, nose bleeds, coughing, blood sugars triple, hair falling out, major swelling, dizziness.

feeling flushed elevated HR dizzy nausea evaluated by EMS, VSS and wnl except HR 100 bpm lungs cta at 5:36 patient reported to be feeling better - drank water - declined transport to ER - felt able/safe to drive home

Headache, Muscle aches and chills

"Chills; Fever; Loss of consciousness x 2; GI upset; Diarrhea; Difficulty sleeping; Pallor; Stomach flu; A spontaneous report was received from a nurse concerning a 31-year-old, male patient, who received

Moderna's COVID-19 vaccine (mRNA-1273) and experienced loss of consciousness (LOC) x 2, gastrointestinal (GI) upset, diarrhea, difficulty sleeping, pallor, stomach flu, chills and fever. The patient's medical history, as provided by the reporter, included allergy to cefaclor and hereditary hemorrhagic telangiectasia. Concomitant medications reported included desvenlafaxine succinate, gabapentin and dexlansoprazole. On 23 Dec 2020 at 11:30 am, approximately six hours prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (Lot number: 025J20A) intramuscularly in the left arm for prophylaxis of COVID-19 infection. On the morning of 23 Dec 2020, prior to receiving mRNA-1273, the patient felt ""achy"". At 5:30 pm, the patient experienced chills, fever to 102, GI upset and diarrhea. At 11:00 pm, the patient reported difficulty sleeping, GI upset, LOC x 2 and pallor. The patient was transported to the emergency room via ambulance. A COVID-19 polymerase chain reaction test and routine labs were collected; however, results were not provided. Treatment for the events included paracetamol, unspecified intravenous (IV) medications, ondansetron and ketorolac tromethamine. The emergency room discharge diagnosis was stomach flu. Action taken with mRNA-1273 in response to the events was not reported. The events, loss of consciousness (LOC) x 2, GI upset, diarrhea, difficulty sleeping, pallor, stomach flu, chills and fever, were considered resolved on 24 Dec 2020.; Reporter's Comments: This case concerns a 31-year-old, male subject with a medical history of hereditary hemorrhagic telangiectasia, who experienced the unexpected events of loss of consciousness (LOC) x 2, gastrointestinal (GI) upset, diarrhea, difficulty sleeping, pallor, and stomach flu, and the expected events of chills and fever. The events of chills, fever occurred approximately 6 hrs. and the events of GI upset, loss of consciousness, difficulty sleeping occurred after 12 hrs. after the first dose of Moderna COVID-19 Vaccine. The time to onset for the events of GI upset and diarrhea were unknown. The reporter did not provide the causality assessment for the events. Due to the temporal association between the LOC and the administration of the vaccine, a causal relationship cannot be excluded, however, the subject's medical history of hereditary hemorrhagic telangiectasia and other concurrent conditions of GI upset, diarrhea, and stomach flu remain as confounders."

Sharp shooting pain up my arm, upper chest, the shoulder, above my brest; Trouble swallowing, slurred speech, red across the chest and hoarse/raspy voice; A report was received from a consumer concerning a patient who was participating in the mRNA-1273 Emergency Use Program and who experienced sharp shooting pain up my arm, upper chest, the shoulder, above my brest, trouble swallowing - could not swallow my saliva, slurry speech, red across my chest, and hoarse/raspy voice. The patient's medical history included diphenhydramine hydrochloride allergy, shellfish allergy, and latex allergy. Concomitant medications included salbutamol sulfate. The patient received their first dose of mRNA-1273 intramuscularly for prophylaxis of COVID-19 infection in their right arm on 26 Dec 2020. Five minutes following administration of the vaccine, the patient felt sharp shooting pains up her arm, upper chest, the shoulder, above the breast. Five to 10 minutes after, the patient had trouble swallowing and began to have slurred speech. The patient was administered epinephrine in her right thigh. Following this, she began to experience redness across the chest and was administered another dose of epinephrine. She also experienced hoarse/raspy voice. The patient was then transported to the emergency room in an ambulance, where she received intravenous fluids and solumedrol after which she began feeling better. The patient was observed in the hospital for several hours and discharged on the same day. Action taken with mRNA-1273 in response to the event was not reported. The outcome of the event, sharp shooting

pain up my arm, upper chest, the shoulder, above my brest, was unknown. The event, trouble swallowing - could not swallow my saliva, was considered resolved on 26 Dec 2020. The outcome of the event, slurry speech, was unknown. The outcome of the event, red across my chest, was unknown. The outcome of the event, hoarse/raspy voice, was unknown. The reporter did not provide an assessment for the events, sharp shooting pain up my arm, upper chest, the shoulder, above my brest, trouble swallowing - could not swallow my saliva, slurry speech, red across my chest, or hoarse/raspy voice.; Reporter's Comments: This case concerns a female patient with a medical history of diphenhydramine hydrochloride allergy, shellfish allergy, and latex allergy who experienced the events of pains up her arm, upper chest, the shoulder, hypersensitivity reaction with symptoms of trouble swallowing, slurred speech, erythema of the chest and hoarse/raspy voice, occurring between five and ten minutes following administration of the first dose of mRNA-1273 vaccine. The patient was treated with 2 shots of epinephrine, was transported to the hospital and received and IV solumedrol, after which symptoms improved. Based on the information provided and temporal association, the event is assessed as possibly related to mRNA-1273. The patient's medical history of multiple allergies could have contributed to the event. Further information has been requested.

generalized itchiness; woke up with headache; feeling fatigued; anaphylactic reaction; right arm started going numb; right arm was tingling; A spontaneous report was received from a 26-year-old, female consumer who received Moderna's COVID-19 vaccine and experienced anaphylactic reaction, right arm numbness and tingling, headache, fatigue, and generalized itchiness. The patient's medical history was not provided. No relevant concomitant medications were reported. On 23 Dec 2020 prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (Lot number: OU520A/011520A) intramuscularly in the left arm for prophylaxis of COVID-19 infection. On 23 Dec 2020, within minutes of receiving the vaccine, the patient experienced an anaphylactic reaction and was rushed to the emergency room (ER). When transported to the ER she began to experience throat swelling, redness of arms and chest, trouble breathing with lower chest pain shooting into lungs, and numbness with tingling in her right arm. Treatment for the event included epinephrine, steroids, and diphenhydramine. She was released from the ER on 23 Dec 2020. On 24 Dec 2020 patient awoke with a headache, fatigue, and generalized itchiness. Treatment for the event included ibuprofen and diphenhydramine. Action taken with the second dose of mRNA-1273 in response to the event was not reported. The outcome for the events, anaphylactic reaction, right arm numbness and tingling, were reported as resolved on 23 December 2020. The events of headache, fatigue, and generalized itchiness were considered resolving.; Reporter's Comments: This case concerns a 26-year-old female patient who received their first of two planned doses of mRNA-1273 (Lot OU520A/011520A), and who experienced the unlisted events of anaphylactic reaction, right arm numbness and tingling, and generalized itchiness, and the listed events of headache and fatigue. The events were considered to be possibly related to the vaccine due to the temporal relationship with onset on the day of vaccination.

Anaphylactic reaction; Chest pressure; Rash (on neck,belly and arm); Metallic taste in mouth; Hot flashes; Headaches; A spontaneous report was received from a 49-year-old female nurse, who was also a patient, who received Moderna's COVID-19 vaccine and experienced anaphylactic reaction, chest pressure, rash (on neck, belly and arm), metallic taste in mouth, hot flashes and headaches. The

patient's medical history was not provided. No relevant concomitant medications were reported. On 22 Dec 2020, at 7:00 pm, approximately 15 minutes prior to the onset of the events, the patient received her first of two planned doses of mRNA-1273 intramuscularly, for prophylaxis of COVID-19 infection. On 22 Dec 2020, approximately 15 minutes after the mRNA-1273 vaccination, the patient experienced anaphylactic reaction, chest pressure, rash (on neck, belly and arm), metallic taste in mouth, hot flashes and headaches. She was taken immediately to the emergency room. Laboratory values included a negative troponin level and low potassium at 3.3. All other laboratory results were normal. Treatment included prednisone for five days, diphenhydramine hydrochloride, famotidine and paracetamol. Action taken with mRNA-1273 in response to the events was not reported. The outcome for the events, anaphylactic reaction, chest pressure, rash (on neck, belly and arm), metallic taste in mouth, hot flashes and headaches was not reported The causality assessment for the events, anaphylactic reaction, chest pressure, rash (on neck, belly and arm), metallic taste in mouth, hot flashes and headache was not reported.; Reporter's Comments: This case concerns a 49-year-old, female patient who received their first of two planned doses of mRNA-1273 (Lot-# and expiration date -unknown), reporting an unexpected event of anaphylactic reaction, chest pressure, rash, metallic taste in mouth, hot flush and an expected event of headache. The events occurred the same day, 15 minutes after vaccine administration. The reporter did not provide the causality assessment for the events. Due to the temporal association between the events and administration of the vaccine, a causal relationship cannot be excluded, and the events are assessed as possibly related to vaccine.

Anaphylactic type of reaction; A spontaneous report was received from a female consumer who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced an anaphylactic type of reaction. The patient's medical history was not provided. Concomitant product use was not provided by the reporter. On an unknown date, the patient received their first of two planned doses of mRNA-1273 intramuscularly for prophylaxis of COVID-19 infection. On an unknown date, after receiving the Moderna vaccine, patient reported that she had some adverse side effects and believed she needed an Epi-pen before getting a second dose due to the anaphylactic type of reaction she had. Treatment information was not provided. Action taken with mRNA-1273 in response to the event was not provided. The outcome of the event, anaphylactic type of reaction, was not reported.; Reporter's Comments: This case concerns a female patient of unreported age. The patient's medical history is not provided. The patient experienced an unexpected event of anaphylactic type of reaction. The event occurred on an unknown date and unknown duration after receiving the first dose of mRNA-1273. Very limited information regarding this event has been provided at this time. Based on temporal association between the use of the product and the event, a causal relationship cannot be excluded. Additional information about the event details are required for further assessment.

"I developed symptoms on 29Dec2020 and test obtained on 30Dec2020. My results are back today and I'm positive.; I developed symptoms on 29Dec2020 and test obtained on 30Dec2020. My results are back today and I'm positive.; This is a spontaneous report from a contactable other HCP (healthcare professional) who reported for himself. A male patient of unspecified age received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE) via an unspecified route of administration on 16Dec2020 (at an unspecified age) as a single dose for COVID-19 immunization. Medical history and

concomitant medications were not reported. The patient tested positive for coronavirus on 30Dec2020. It was reported that the patient obtained his first Pfizer vaccine dose on 16Dec2020. The patient reported that he was a physician assistant and worked in a dedicated COVID patient care area. The patient developed symptoms on 29Dec2020, and a test was obtained on 30Dec2020. The patient's results were back ""today"" and he was positive. The patient was scheduled for his second dose of the vaccine on 06Jan2021. He reported that he would cancel that because he would still be in his 10-day isolation period. Given those circumstances, the patient inquired as to ""when would be the most ideal time to obtain my second dose of the vaccine? When should I take my second dose of the vaccine if I contracted COVID after receiving the first dose?"" The clinical outcome of the event ""I developed symptoms on 29Dec2020, and test obtained on 30Dec2020. My results are back today and I'm positive"" was unknown. The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up.; Sender's Comments: Based on a compatible temporal asociation, a causal relationship between event ""patient developed symptoms on 29Dec2020 and test obtained on 30Dec2020. was positive"" (coded to Drug ineffective / COVID-19) and BNT162B2 vaccine cannot be completely excluded."

person then became symptomatic and tested positive within 7 days of receiving the vaccine; person then became symptomatic and tested positive within 7 days of receiving the vaccine; This is a spontaneous report from a contactable pharmacist. A patient of unspecified age and gender received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE lot number and expiration date unknown) via an unspecified route of administration on an unspecified date (at an unknown age) at an unknown dose for COVID-19 vaccination. The patient's medical history was not reported. The patient's concomitant medications were not reported. The patient became symptomatic and tested positive within seven (7) days of receiving the COVID-19 vaccine. The patient underwent lab tests and procedures which included sars-cov-2 test: positive on an unspecified date. The clinical outcome was unknown. The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up.; Sender's Comments: Based on the information available, a possible contributory role of the suspect products cannot be excluded for the reported event of positive for corona virus infection for the lack of efficacy of the vaccine. However, based on the mechanism of action of the vaccine, it is unlikely the patient would have fully developed immunity for the vaccine to be effective, due to the number of days passed since the vaccine is given. Case will be reevaluated based on follow-up information

Complete loss of smell and taste; Complete loss of smell and taste; This is a spontaneous report from a contactable physician reported for herself. A 37-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; brand: PfizerbioNtech, lot number: EH9888) intramuscularly at left arm on 17Dec2020 at 03:00 PM at a single dose (dose number: 1) for COVID-19 immunization. Medical history was reported as none. No known allergies (no allergies to medications, food, or other products). The patient was not pregnant. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. No other medications the patient received within 2 weeks of vaccination. Facility where the most recent COVID-19 vaccine was administered was at hospital. The patient experienced adverse event complete loss of smell and taste on 19Dec2020 at 07:00 AM. The event was considered as serious due to resulted in disability or permanent damage. No treatment received for the event. The outcome of

event was not resolved. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19.; Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of events complete loss of smell and taste cannot be totally excluded. The case will be reassessed if additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

ball palsy, facial dropping; painful shingles; This is spontaneous report from a contactable consumer reported for herself. A 47-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; batch/lot number: EK5730; dosage form: injection) via an unspecified route of administration as injection to left arm on 24Dec2020 at 7:30 am at a single dose for COVID-19 immunization. Relevant medical history and concurrent conditions included slight hypertension from Jul2020 and ongoing. Concomitant medications included lisinopril from Jul2020 and ongoing for slight hypertension. The patient developed ball palsy, facial dropping which did not lasted long but she still had the painful shingles on 27Dec2020, after the first dose. She wanted to know the recommendations for taking the second dose which is due in 10 days. The patient wanted to know if she should receive the shingles vaccine. This caller was a lab tech who works in the healthcare industry and manages a medical office; but clarified she did not call on behalf of a healthcare professional. She was the patient who received her first dose of Pfizer SARS-CoV-2 Vaccine on 24Dec2020. She reported onset of what the Urgent Care Physician believed was Shingles on 27Dec2020. She called to ask if she should or should not receive the second dose of Pfizer SARS-CoV-2 Vaccine on 14Jan2021 as scheduled due to the Shingles. The Urgent Care Physician advised her to still get the second dose, as there was about a 1:10,000 chance of developing shingles with the vaccine. She reported shingles as a reaction subsequent to the Pfizer SARS-CoV-2 Vaccine. Initially on 27Dec2020 she developed sites of what she thought were canker sores or fever blisters in her mouth which had gotten pretty large and stopped her from being able to eat on 29Dec2020. Then on 30Dec2020 she developed sites on her face which have gotten scarily large; and was causing some deep nerve pain going to her eye and down her chin; the sites felt like lesions on her face with roots. The sites in her mouth were now completely gone; but the sites on her face are ongoing. Now it has kind of taken over her face. She saw the Urgent Care Physician regarding this who believed the sites to be shingles. She had never had fever blisters or shingles before this event. She was still kind of reeling. The report was reported as non-serious. The outcome of event ball palsy/facial dropping was resolved and of shingles was unknown.

received the Covid 19 vaccine/then tested positive for the virus/symptomatic; received the Covid 19 vaccine/then tested positive for the virus/symptomatic; This is a spontaneous report from a contactable nurse (patient). A female patient of an unspecified age received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 17Dec2020 at a single dose as Covid 19 vaccine. Medical history and concomitant medications were not reported. It was reported that the patient received the Covid 19 vaccine on 17Dec2020 and then tested positive for the virus on an

unspecified date. She was scheduled to have the second vaccine on 07Jan2021, but she was not able to go to work because she's still symptomatic. She would like to know if there's an extension to the 21 days since she has the virus now. The outcome of the events was unknown. Information about Lot/Batch number is requested.; Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of events Drug ineffective and COVID-19 cannot be totally excluded. The case will be reassessed if additional information becomes available.

developed UTI very quickly; Puffy face and eyes; Puffy face and eyes; Burning inside digestive tract; Diarrhea; Dehydrated; arm pain; Headache; At bedtime neck stiffness began and worsened; This is a spontaneous report from a contactable healthcare professional. A 39-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number EL3246/expiration date unknown), dose number 1, via an unspecified route of administration on 02Jan2021 10:30 at a single dose on the left arm for COVID-19 immunization. The patient had no relevant medical history. Concomitant medications included alprazolam (XANAX). The patient experienced arm pain and headache 4 hours post injection requiring Excedrin. At bedtime, neck stiffness began and worsened. She was treated with lidocaine patches and Aleve. She developed diarrhea 33 hours post injection. She went ER because she was dehydrated. She developed UTI very quickly by hour 35 post injection. She had puffy face and eyes, and burning inside her digestive tract. She was treated with Benedryl at home for allergic reaction, Toradol for pain, IV fluids for dehydration and Keflex for infection. The patient was not diagnosed with COVID-19 prior vaccination and was not tested for COVID-19 since vaccination. The outcome of the events was recovering.; Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of event Dehydration cannot be totally excluded. The case will be reassessed if additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

"vomited; diarrhea; a severe headache; severe muscle pain; severe fatigue like being ""beat up in a bar""; This is a spontaneous report from a contactable nurse (patient). A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot and expiry not reported), via an unspecified route of administration on 28Dec2020 at single dose for covid-19 immunisation. The patient's medical history and concomitant medications were not reported. On 29Dec2020, patient experienced a severe headache, severe muscle pain and severe fatigue; further reported as like being ""beat up in a bar"" for over 1 week. It was also reported that the patient vomited and experienced diarrhea on an unspecified date. The patient was also inquiring if there is difference between the symptoms in dose 1 and 2. Outcome of events was unknown. Information of lot and batch number has been requested.; Sender's Comments: Based on the available information and known BNT162B2 vaccine safety profile, a causal relationship between events severe headache, severe muscle pain and severe fatigue and BNT162B2 vaccine cannot be excluded. The impact of this report on the benefit/risk profile

of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate."

Bell's Palsy; This is a spontaneous report from a contactable physician (patient). A 62-years-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), intramuscular on left arm on 19Dec2020 19:00 at single dose for COVID-19 immunisation. Known allergies: No. Other medical history: None. No other vaccine in four weeks. No other medications in two weeks. The patient experienced bell's palsy on 03Jan2021 21:00 and required visit to physician office. Covid test type post vaccination: Nasal Swab (PCR) on 29Dec202: Negative. Therapeutic measures were taken as a result of bell's palsy included Prednisone, Valtrex. Outcome of event was not recovered. Information on the lot/batch number has been requested.; Sender's Comments: Based on a compatible association, causality between event Bell's palsy and BNT162B2 vaccine cannot be completely excluded. The case will be reevaluated should additional information become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

"Tested positive with covid 19 with symptoms; Tested positive with covid 19 with symptoms; This is a spontaneous report from a contactable healthcare professional. A male patient of an unspecified age received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date were not reported), via an unspecified route of administration on 22Dec2020 at single dose for COVID-19 immunisation. The patient medical history and concomitant medications were not reported. The patient stated, ""I received the covid 19 vaccine on 22Dec; was supposed to have 2nd dose on 12Jan2021. Tested positive with covid 19 on 01Jan2021 with symptoms. I want to know how long I need to wait to get the second dose"".The outcome of the events was unknown. Information on the lot number has been requested.; Sender's Comments: Although, BNT162B2 vaccine immunogenicity is not in full effect after short time (10 days in this case) of first dose administration, a causal relationship between event ""Tested positive with covid 19 with symptoms"" (coded to Drug ineffective / COVID-19) and BNT162B2 vaccine cannot be completely excluded."

"received covid vaccine then contracted covid-19, 9 days after getting the vaccine; received covid vaccine then contracted covid-19, 9 days after getting the vaccine; This is a spontaneous report from a contactable physician. A male patient of an unspecified age received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date were not reported), via an unspecified route of administration on Dec2021 at single dose for COVID-19 immunisation. The patient medical history and concomitant medications were not reported. It was stated, ""received covid vaccine then contracted covid-19, 9 days after getting the vaccine, should he get his 2nd dose which is on Friday? Tested positive on the 30th, received monoclonal antibody infusion on the 31st. Any information regarding this?"". The outcome of the event was unknown. Information on the lot number has been requested.; Sender's Comments: Although, BNT162B2 vaccine immunogenicity is not in full effect after

short time (9 days in this case) after first dose administration, a causal relationship between event ""received covid vaccine then contracted covid-19"" (coded to Drug ineffective / SARS-CoV-2 test positive) and BNT162B2 vaccine cannot be completely excluded."

"Bell's palsy/Face was turning side ways; This is a spontaneous report from a contactable nurse. A female patient of unspecified age received BNT162B2 (reported as ""Covid-19 Vaccine, manufacturer: Unspecified"", Batch/lot number: not provided) via unspecified route of administration on unspecified date at single dose for COVID-19 immunization. Medical history and concomitant medication were not reported. A woman received a Covid vaccine. She did not know which one. The woman experienced Bell's Palsy. The woman was crying and her face was turning sideways. Outcome of the event was unknown. Pfizer is a marketing authorization holder of Covid-19 Vaccine in the country of incident or the country where the product was purchased (if different). This may be a duplicate report if another marketing authorization holder of Covid-19 Vaccine has submitted the same report to the regulatory authorities. Information on the Batch/Lot number has been requested.; Sender's Comments: Based on a compatible temporal relationship, causality between reported event Bell's Palsy and BNT162B2 vaccine cannot be completely excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate."

memory care patients received Pfizer-BioNTech covid vaccine, and then were diagnosed with COVID, all three had COVID symptoms; memory care patients received Pfizer-BioNTech covid vaccine, and then were diagnosed; This is a spontaneous report from a contactable other health professional. This reporter reported same events for three patients. This is first of three reports. A patient of unspecified age and gender received BNT162B2 (Pfizer BioNTech COVID vaccine), via an unspecified route of administration on an unspecified date at single dose for Covid-19 immunization. The patient's medical history and concomitant medications were not reported. The memory care patient received Pfizer-Biontech Covid vaccine, and then was diagnosed with Covid and had Covid symptoms on an unspecified date, the patient was scheduled to receive monoclonal antibody. Event took place after use of product. The outcome of events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Sender's Comments: Based on the information available, a possible contributory role of the suspect products cannot be excluded for the reported event of positive for corona virus infection for the lack of efficacy of the vaccine. However, based on the mechanism of action of the vaccine, it is unlikely the patient would have fully developed immunity for the vaccine to be effective, due to possibly short number of days passed since the vaccine is given. Case will be reevaluated based on follow-up information,Linked Report(s) : US-PFIZER INC-2021004747 same reporter/product/event, different patient;US-PFIZER INC-2021004748 same reporter/product/event, different patient

Diagnosed with COVID; Diagnosed with COVID; This is a spontaneous report from a contactable other health professional. This reporter reported same events for three patients. This is second of three reports. A patient of unspecified age and gender received BNT162B2 (Pfizer BioNTech COVID vaccine),

via an unspecified route of administration on an unspecified date at single dose for Covid-19 immunization. The patient's medical history and concomitant medications were not reported. The memory care patient received Pfizer-Biontech Covid vaccine, and then was diagnosed with Covid and had Covid symptoms on an unspecified date, the patient was scheduled to receive monoclonal antibody. Event took place after use of product. The outcome of events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Sender's Comments: Based on the information available, a possible contributory role of the suspect products cannot be excluded for the reported event of positive for corona virus infection for the lack of efficacy of the vaccine. However, based on the mechanism of action of the vaccine, it is unlikely the patient would have fully developed immunity for the vaccine to be effective, due to possibly short number of days passed since the vaccine is given. Case will be reevaluated based on follow-up information,Linked Report(s) : US-PFIZER INC-2021004746 same reporter/product/event, different patient;US-PFIZER INC-2021004748 same reporter/product/event, different patient

Diagnosed with COVID; Diagnosed with COVID; This is a spontaneous report from a contactable other health professional. This reporter reported same events for three patients. This is 3rd of three reports. A patient of unspecified age and gender received BNT162B2 (Pfizer BioNTech COVID vaccine), via an unspecified route of administration on an unspecified date at single dose for Covid-19 immunization. The patient's medical history and concomitant medications were not reported. The memory care patient received Pfizer-Biontech Covid vaccine, and then was diagnosed with Covid and had Covid symptoms on an unspecified date, the patient was scheduled to receive monoclonal antibody. Event took place after use of product. The outcome of events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Sender's Comments: There is limited information reported, it is possible patient would have taken only single dose, a possible contributory role of the suspect products cannot be excluded for the reported event of positive for corona virus infection for the lack of efficacy of the vaccine. However, based on the mechanism of action of the vaccine, it is unlikely the patient would have fully developed immunity for the vaccine to be effective, due to the number of days passed since the vaccine is given. Case will be reevaluated based on follow-up information,Linked Report(s) : US-PFIZER INC-2021004746 same reporter/product/event, different patient;US-PFIZER INC-2021004747 same reporter/product/event, different patient

had a positive test for COVID; had a positive test for COVID; This is a spontaneous report from a Pfizer-sponsored program Pfizer First Connect from a contactable physician who reported for himself. A male patient of an unspecified age received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 19Dec2020 at single dose for COVID-19 immunisation. The patient medical history and concomitant medications were not reported. Patient had a PCR COVID-19 swab performed on 23Dec2020 which returned positive on 26Dec2020. The action taken in response to the event for bnt162b2 was not applicable. Outcome of the event was unknown. Information for lot number has been requested in follow up activity.; Sender's Comments: Based on the information available, a possible contributory role of the suspect products cannot be excluded for the reported event of positive for corona virus infection for the lack of efficacy of the vaccine. However, based on the mechanism of action of the vaccine, it is unlikely the patient would have fully developed immunity for

the vaccine to be effective, due to the number of days passed since the vaccine is given. Case will be reevaluated based on follow-up information

positive COVID-19 test with symptoms; positive COVID-19 test with symptoms; This is a spontaneous report from a non-contactable pharmacist via Pfizer Sales Representative. A 25-year-old male patient (nurse) received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot/batch number and expiration date unknown as did not have this information), via an unspecified route of administration in Dec2020 (reported as received either 17Dec2020 or 18Dec2020) at single dose for COVID-19 immunization in hospital. The patient's medical history and concomitant medications were not reported. One of the reporter's employees (patient) got the COVID-19 Vaccine. Ended up testing positive for COVID probably due to patient care. Patient was taking care of two to three people who were not positive for COVID while in the hospital, but tests came up as positive. Patient developed symptoms in Dec2020 and tested positive for COVID on 24Dec2020. Patient received COVID-19 Vaccine either 17Dec2020 or 18Dec2020. Began coughing three to four days after vaccination in Dec2020. Rapid test was negative in Dec2020. On 24Dec2020, the M20 test came back as positive for COVID. Only other symptom patient experienced was loss of taste and smell in Dec2020. Had been a stressful situation for the patient. The outcome of the events was unknown. Information on the Lot/ Batch number has been requested.; Sender's Comments: Based on the information available, a possible contributory role of the suspect products cannot be excluded for the reported event of positive for corona virus infection for the lack of efficacy of the vaccine. However, based on the mechanism of action of the vaccine, it is unlikely the patient would have fully developed immunity for the vaccine to be effective, due to the number of days passed since the vaccine is given. Case will be reevaluated based on follow-up information

encephalitis; This is a spontaneous report from a contactable consumer. A patient of unspecified age and gender received BNT162B2(PFIZER-BIONTECH COVID-19 VACCINE) , via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient was allergic to UTI(urinary tract infection) infection medication (i.e. sulfamethoxazole, trimethoprim etc.). Concomitant medications were not reported. The patient got encephalitis and was put in the ICU(intensive care unit) after getting vaccinated, led to hospitalization. Outcome of event was unknown. Information about lot/batch number has been requested.

Anaphylactic reaction

Pronounced dead 1/9/2021 at 12:42. Received first dose of vaccine 1/8/2021

"Staff member checked on her at 3am and patient stated that she felt like she couldn't breathe. 911 was called and taken to the hospital. While in the ambulance, patient coded. Patient was given CPR and ""brought back"". Once at the hospital, patient was placed on a ventilator and efforts were made to contact the guardian for end of life decisions. Two EEGs were given to determine that patient had no brain activity. Guardian, made the decision to end all life saving measures. Patient was taken off the ventilator on 1/9/2021 and passed away at 1:30am on 1/10/2021. The initial indication from the ICU doctor was the patient had a mucus plug that she couldn't clear."

Aprox 5 minutes after vaccine was given, patient stated he was not feeling well, asked for water and stated he was having trouble breathing. Was then assisted to clinic treatment room, vitals were taken: 08:45 B/P 171/110, HR 84, R 28 O2 97. EMS was activated. At 0900 158/94 HR 84 R 24 O2 97. Patient then voice he was having tightness in his throat. Epi Pen 0.3mg administered at 0900. At 0904 EMS arrived and patient taken to the nearest hospital.

Numbness and tingling bil upper extremities, seizure, temporary paralysis R arm. Started day after vaccine given, was observed overnight in hospital.

"Manager was notified that the employee had suffered a stoke-like ""serious medical event"" hours after the end of her shift, while at home."

Patient had vaccine in Left arm. That same night patient had temp of 100.1 and the right neck at base of head to shoulder began to hurt patient was unable to swallow without pain in the next few days. Patient went to ER and was hospitalized for 2 days treated with IV steroids and 2 antibiotics (clindamycin and acyclovir). Patients symptoms resolved and patient was discharged without additional issues. The admitting physician was unable to identify the cause of these symptoms, but the vaccine could not be ruled out.

"1-2-2021 10:30 PM Complained Right arm/back hurt - took Tylenol 1-3-2021 Complained Right arm hurt, dizzy 1-4-2021 Felt better - did laundry, daughter found her deceased at 3:30 pm. Dr. at hospital said it was ""cardiac event"" according to death certificate."

Upon assessment resident noted to have increased respirations, lungs CTA. Resident c/o increased fatigue and muscle aches. VS 202/180, 118, 22, 97.1, 96%.

Sever thrombocytopenia (platelet count 2,000) 8 days following Moderna COVID vaccine. Clinically suspicious for ITP.

Received vaccine on 1/5, began having swelling in bilateral hands and lower extremities on 1/7, along with fatigue. On 1/8 she reports new swelling started in her face (eyes and cheeks). Swelling has not improved today and fatigue has worsened.

Found on floor by CNA at 6 am. On assessment by charge nurse, VS: 99.6-94-16 212/105 manual. Noted increased confusion. Temp. 99.6 FBS 114. Resident had been provided tylenol just prior in shift for general discomfort (sore muscles) and low grade temp. On call for Dr notified of all and received order to send to ER.

Staff reported that patient was found Friday morning (Jan 8) sitting at a table with his head tilted forward and unresponsive to verbal or physical stimuli. Staff lowered patient to floor and started CPR. EMS was called and continued CPR at scene, however they were not able to revive patient. Patient was pronounced dead at the scene. Staff written statements following the death of patient show that he had a fall about 1 hr. prior. It is unknown if this fall contributed to patient's death. An autopsy has been requested.

Acute anterior MI with death

Approximately 15 minutes after receiving the vaccine, client started c/o itching to face and lips. Transported to triage area. Where she started c/o burning lips also. vital signs monitored, Benadryl 50mg po given. In a few minutes she reported chest tightness, labored breathing. 1:44pm Epinephrine was given IM. client was on 02 increased to 15 Liters. She admits to decreased chest tightness and itching of face improving. She was taken by ambulance to hospital, where she was admitted overnight for observation. She was given Benadryl and epi X2 more time, once in ambulance and once at the hospital. She denies any problems since then. She did say that approx 3 weeks ago she was a contact to a case of covi

Patient is a 41 y.o. female who presented to the ED with complaints of a reaction after she took the COVID vaccine. Patient is an RN here and had earlier received COVID-19 vaccination (Moderna) around 0130 this afternoon. Soon after she experienced rash which was burning and itchy on her arms thighs and back. She reported to Occ health and was directed to the ED. While in the ED she experienced throat tightness and nausea. She had one episode of diarrhea. No tongue, lip swelling, SOB or difficulty swallowing. Denies any chest pain, palpitations, pre-syncope/syncope. No vomiting abdominal pain. H/o of allergy to fish mix and dust mite.

01/06/21 at 6 pm, body aches, and chills 01/07/21 at 12am T102.2, SPO2 62% on room air. Was sent to ER and returned. 01/08/21 at SPO@ less then 60% on room air, non responsive to verbal tactile stimuli. Responsive to sternal rub only. Was sent to ER and admitted to ICU.

The resident resides in an independent living facility/apartment. The reporter at the center was informed by his daughter he was not feeling well on 1/1/2021 (specific symptoms could not be ascertained). He reportedly went to be COVID tested on 1/1/2020 and observed to be deceased in his apartment on 1/2/2020. I do not have confirmation of his COVID results, although the reporter indicates his daughter reports his test was positive.

Patient went to bed around 11pm on Saturday PM and sometime between then and 1:30am on Sunday morning got up and went into the living room without waking up her husband (which is normal). At 1:30am, the husband got up to use the restroom and she was out of bed then, but the husband did not know if she was having any problems at this time. When he got up at 7:45am, she was in the recliner and did not move or anything, which is normal for her. At 8:45am, the husband went back into the living room and tried to wake his wife and that is when he noticed there was no pulse and he called 9-1-1 at this time. EMS got on scene and did CPR for 30 mins and she was pronounced dead at 9:21am.

Approximately 10 minutes after receiving the vaccine she started experiencing numbness and inability to move all 4 extremities. No difficulty breathing or swallowing. Benedryl 25 mg was administered with no relief. EMS was called, she was transported to the ED and admitted to the hospital for evaluation. She was given Ativan 0.5 mg IV with some mild improvement in symptoms. She has had gradual improvement in her symptoms, now able to move her arms normally. She has persistent weakness and discomfort in both lower extremities and is unable to ambulate without assistance.

1/8/2021 tachycardia Pulse 140, Fever T99.4 then 100.2 Lethargy, Somewhat Altered Mental status

"Her voice became raspy, she could hardly talk, she could barely talk; her hand and whole arm swelled up; her hand and whole arm swelled up; Trouble breathing; This is a spontaneous report from a contactable healthcare professional (patient). A 57-year-old female patient received the 1st dose of bnt162b2 (BNT162B2, Manufacturer Pfizer-BioNTech) (lot# EK9231, exp date Apr2021), via an unspecified route of administration in the right arm, on 29Dec2020, at single dose, for COVID-19 immunization and diphenhydramine hydrochloride (BENADRYL), via an unspecified route of administration, at unknown posology, on 29Dec2020 (20 minutes prior to taking bnt162b2), for anaphylactic reaction. Medical history included ongoing thyroid disorder. Concomitant medications included apixaban (ELIQUIS), diltiazem (unknown trade name), losartan (unknown manufacturer), rosuvastatin calcium (CRESTOR), levothyroxine (unknown trade name), ongoing levothyroxine sodium (SYNTHROID) for thyroid disorder and metformin (unknown trade name). Previously the patient received unspecified influenza vaccine (reported as flu shot) for immunisation, on unspecified date, and experienced anaphylactic reaction treated with Benadryl. On 29Dec2020, an hour after getting the vaccine, the patient experienced her voice became raspy, she could hardly talk, she could barely talk with outcome of unknown, her hand and whole arm swelled up with outcome of unknown, trouble breathing with outcome of unknown. The reporter stated that her voice and everything reacted and made her go to the emergency room on 29Dec2020. She reported that had adverse effect more than normal. The event ""Her voice became raspy, she could hardly talk, she could barely talk"" caused patient's hospitalization on unknown date. The action taken as a result of the events with diphenhydramine hydrochloride was post-therapy. Therapeutic measures were taken at the emergency room as a result of the events and included treatment with Topcid and Benadryl every 6 hours, 2x 40 mg of steroid. The information on the lot/batch number has been requested. Follow-up (02Jan2021): New information received from the same contactable healthcare professional reporting for herself includes: patient's details, medical history, events updated, vaccine lot# and exp date, concomitant, seriousness of event ""Her voice became raspy, she could hardly talk, she could barely talk"" added as hospitalization, historical vaccine, suspect Benadryl details, therapeutic measures updated.; Sender's Comments: A causal association between BNT162B2 and the reported events cannot be excluded based on a compatible temporal relation between vaccination and onset of events. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate."

Resident died suddenly and expectantly on 01/05/2021

Patient received COVID-19 (Moderna) vaccine from the Health Department on afternoon of January 8, 2021 and went to sleep approximately 2300 that night. Was found unresponsive in bed the following morning and pronounced dead at 1336 on January 9, 2021

Chills Hip pain

Resident had seizure like activity followed by a vagel response with large bowel movement. Resident then began to show signs of blood clot to left lower extremity. No pedal pulse, area on leg warm to touch. Left lower leg now cold to touch, stiff, purple and white in color. No other signs of modeling, body warm to touch, no fever noted. Respirations and pulse increased with low oxygen levels. Resident not responding to stimuli.

38-year-old female who is healthcare worker and received first dose of COVID vaccine (Pfizer). Immediately after receiving the vaccine, patient developed lightheadedness, flushing, hives, wheezing and throat swelling. Patient was treated in an emergency department with epinephrine, gradually improved and was able to be sent home with an EpiPen, prednisone, hydroxyzine, and famotidine. The next day, patient again developed shortness of breath and her husband administered the EpiPen. EMS arrived and gave another dose of IM epinephrine and IV diphenhydramine. On arrival to the emergency department, the patient was altered, diaphoretic, tachypneic, tachycardic, and stridulous. Patient was given multiple doses of IM epinephrine and started on epinephrine drip. Stridor continued and was unresponsive to nebulized albuterol. Patient was then intubated and placed on mechanical ventilation. Other treatments included solumedrol, pepcid, magnesium sulfate, nebulized epinephrine, and IV fluids. admitted to the intensive care unit, weaned off epinephrine drip, and extubated the next day. Patient was monitored on hospital floor for one additional day and was then discharged with no residual symptoms.

Patient had a rash prior to COVID vaccine. Prednisone 10mg started on 1/5/21 (only one dose administered) 1/6/21, 1am - Rash worsened with increase redness, warmth and extending of body surface, Temp 100.4, 1/6/21, 1:20am Benadryl 25mg administered, (Keflex was ordered at this time, however never administered). 1/6/21, 3am rash improved, temp 99.1 1/6/21, 6:50am Right facial droop and right sided weakness, sent to ER 1/6/21 transferred to hospital, continues to be hospitalized 1/11/2021

Patient expressed: Pain in the left side of the face and migraine on 25Dec2020, and came to emergency room where apparently they diagnosed facial paralysis; Patient expressed: Pain in the left side of the face and migraine on 25Dec2020, and came to emergency room where apparently they diagnosed facial paralysis; This is a spontaneous report from a contactable nurse. A 42-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number EK5730) intramuscular, on 17Dec2020 04:15, single dose arm left for COVID-19 immunization. Relevant medical history included hypothyroidism, hypertension, hyperlipidemia, obesity, and penicillin allergy. Concomitant medications included levothyroxine sodium (SYNTHROID), butalbital, caffeine, paracetamol (FIORICET 50-40- 325mg), dexamethasone 4mg Inj., diclofenac (VOLTAREN 1% Gel), Magnesium, valsartan (VASOFLEX) (pending confirmation), cyanocobalamin (VITAMIN B12), losartan potassium. The patient was not pregnant and did not received any vaccine in four weeks. The patient previously took cephalosporin and experienced allergy. On 24Dec2020, the patient experienced pain left side of the face and migraine, and came to emergency room where apparently they diagnosed facial paralysis. The events resulted in emergency room visit/ urgent care where the patient was administered dexamethasone 4mg Inj, Medrol dose pack, Vit B12 500mcg, and Fioricet 50-325-40. Facility where the most recent COVID-19 vaccine was administered was in the doctor's office/urgent care. It was unknown if the patient was diagnosed with

COVID-19 prior or since the vaccination. The events were assessed by the nurse as non-serious. Outcome of the events was recovering at the time of the report.; Sender's Comments: A causal association between BNT162B2 and the reported events cannot be excluded based on a compatible temporal relation between vaccination and onset of events. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

HPI narrative: Patient was fine until 2 days ago. Patient does have chronic dementia but got Covid vaccine 11:00 2 days ago and that night seem to be confused and not able to walk since then. Patient poor appetite since yesterday. Patient had diarrhea 3 x 2 days ago. No vomiting no fever no cough does not appear to be short of breath. Patient also with left hip pain for few days with no injury.All history obtained from caretaker at bedside.

Started as a red raised rash under my arms and my waistline; rash turned to hot to touch; raised red large hives all over my body including my face/head; numbness to my hands/feet/chest area; the SOB started; This is a spontaneous report from a contactable nurse, the patient. A 53-year-old non-pregnant female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot Number: EU9231), via an unspecified route of administration in the left arm on 30Dec2020 at 08:30 as a single dose for COVID-19 immunization. Medical history included hypothyroidism and chronic low back pain. Prior to the vaccination, the patient was not diagnosed with COVID-19. Concomitant medications included levothyroxine (MANUFACTURER UNKNOWN), baclofen (MANUFACTURER UNKNOWN), and etodolac (MANUFACTURER UNKNOWN). The patient did not receive any other vaccines within four weeks prior to the vaccination. The patient previously took miconazole nitrate (MONISTAT) on unknown dates for an unknown indication and experienced drug allergy. On 31Dec2020 at 10:00, the patient started with a red raised rash under her arms and waistline and as the day progressed the rash turned hot to touch with raised red large hives all over her body including her face/head. By 23:00 on 31Dec2020, the patient had already taken 3 doses of diphenhydramine (BENADRYL) which was not effective. Then, later on 31Dec2020, shortness of breath started with numbness in the hands/feet/chest area. Her daughter took her to the emergency room. She was started on intravenous diphenhydramine, dexamethasone, and famotidine (PEPCID). The medications took time to work but they did resolve her shortness of breath and the hives subsided to mild redness. She was sent home and given the following medications to take: diphenhydramine 50 mg every 4 hours, methylprednisolone (MEDROL DOSE PAK), cetirizine (ZYRTEC) daily, and famotidine (PEPCID) daily. Since the vaccination, the patient had not been tested for COVID-19. The clinical outcomes of the red rash, rash was hot to touch, shortness of breath, and numbness, were reported as recovered with lasting effects; while that of the hives was recovering as they still flared up if she did not take the medications every 4 hours. The reporter assessed all the events as non-serious.; Sender's Comments: The reported shortness of breath together with red rash was probably related to the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE together with rash was probably related to the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), due to temporal relationship and clinical course. The impact of this report on the

benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory authorities, Ethics committees and Investigators, as appropriate.

Rectal bleeding; Stomach ache; Diarrhea; sick; This is a spontaneous report from a contactable consumer (patient) from a Pfizer sponsored program Pfizer First Connect. A 41-year-old female patient received the first dose of the bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot Number: EK5730 and Expiration Date: 31Mar2021), via an unspecified route of administration in the right arm on 20Dec2020 at a single dose for COVID-19 immunization. The patient's medical history was reported as none. There were no concomitant medications. On 01Jan2021, the patient experienced: rectal bleeding, stomachache, diarrhea, sick; all assessed as medically significant. The clinical course was reported as follows: The patient received the first dose of the COVID-19 vaccine on 20Dec2020; as she was at high risk due to working with COVID patients in the hospital. The patient became sick on 01Jan2021. The patient experienced a stomach-ache, diarrhea, and rectal bleeding. When these events occurred, the patient went to the emergency room (ER). A doctor there prescribed the patient the antibiotics metronidazole 500 mg and cefdinir 300 mg. The patient was also scheduled to follow up with a gastrointestinal (GI) doctor. The patient called asking if she should get the second dose since she was taking antibiotics. The patient was scheduled for the second dose on 08Jan2020.The patient reported she had improved. The symptoms, at the time of the report, were not that bad. Therapeutic measures were taken as a result of rectal bleeding, stomachache, diarrhea, and sick. The clinical outcome of the events was recovering.

Numbness lips,mouth; Was feeling bad; leg numbness/numbness in head, face; pain in head; increased BP; blood pressure was up and down; This is a spontaneous report from a contactable consumer (patient). A 55-year-old female patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EL0140) via an unspecified route of administration in left arm on 29Dec2020 6 am at single dose for covid-19 immunisation. Co-suspected drug amoxicillin;clavulanic acid (AUGMENTIN, Batch/lot number: KN4291, Expiry Date: Mar2022) by mouth from Dec2020 to 28Dec2020 at 875mg, 1 tablet twice daily for pain or infection; MOXIFLOXACIN HYDROCHLORIDE (AVELOX, strength:400mg) by mouth from 29Dec2020 and ongoing at 400mg, 1 tablet once daily for infection; fluconazole (DIFLUCAN, strength:200mg) orally (by mouth) from unknown date and ongoing at 200mg, 1 tablet once daily for Infection.The patient's medical history was reported as ongoing high blood pressure, ongoing pains in her fingers and toes and they thought she had an infection from 02Dec2020, white count went down on 09Dec2020, ongoing pain was up and down. No other vaccines given at that time and none given 4 weeks prior. Had a Flu shot back in Oct2020, but no problems. None diagnosed allergies and family medical history relevant to adverse event. The concomitant medications included unspecified blood pressure medication by mouth daily for high blood pressure. She had also started 2 antibiotics around the same time that she received the vaccine. No further details provided Was on antibiotics at the time she was given the Pfizer COVID-19 vaccine. Patient experienced increased BP/ high blood pressure, pain in head, and leg numbness; all started 2 days (on 31Dec2020) after receiving the vaccine and persisted for 48 hours. First her blood pressure was up and they had to get it

stable and had numbness in her head, face, and mouth for 48 hours. Her blood pressure was up and down and she has history of blood pressure and takes medicine. Was taken off work for a few hours and went to the emergency department on Fri night about 2am. Her blood pressure was 170/92 on 01Jan2021. Not sure if this was related to the vaccine, but the numbness in her head started from her upper neck to face to the right side of her check and she also had leg numbness. Wanting to know if this was related because she was worried about getting the second dose. Had a hard time for 48 hours. Weight was between 150-155 pounds. Stated everything improved after 48 hours. Her lip was also just a little bit numb, but it is feeling better. Patient was feeling bad from 01Jan2021, all Fri and Sat and much better by Sun. Events of increased BP/ blood pressure up and down, leg numbness, numbness in lips, head, face, mouth with emergency room visiting. Wanted to know if she should have the second dose. The action taken in response to Augmentin was permanently discontinued on 28Dec2020, for Avelox and Diflucan was dose not changed. The outcome of events was recovering.

eventually inability to move arm; pain; joint pain; tenderness at injection site; loss of strength; This is a spontaneous report from a contactable nurse. A 36-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, Batch/lot number: EJ1685) intramuscular at arm left, on 19Dec2020 06:45 at single dose for covid-19 immunisation. Medical history included ongoing acne. Patient had no known allergies. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Concomitant medication included isotretinoin (ACCUTANE). On 19Dec2020 11:30, approximate 5 hours after vaccine, the patient experienced pain, joint pain and tenderness at injection site, progressively loss of strength and eventually inability to move arm. Since the vaccination, the patient hasn't been tested for COVID-19. The outcome of events was recovered.; Sender's Comments: Based on the compatible temporal association, the vaccination with BNT162B2 might play a contributory role in triggering the onset of the reported events. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

she is positive for blood in her stool; left hip/back/kidney pain; left hip/back/kidney pain; left hip/back/kidney pain; This is a spontaneous report from a contactable consumer reporting for herself. A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (lot number and expiration date unknown) via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient received the vaccine on 28Dec2020 (reported on 05Jan2021 as 'a week ago Monday'). After getting the vaccine (2-3 days after getting the vaccine) she started to have some events happen that she was not sure were side effects from the vaccine. She mentioned she started to experience blood in her stool - following a test at her doctor's she was positive for blood in her stool. Also, the left side of her lower back and hip started hurting. She was experiencing left hip/back/kidney pain, as reported. She took hydrochlorothiazide. The outcome of the events was unknown. She wanted to know if this had anything to do with the vaccine and if this could be a side effect. These events did

not start happening until after she got the vaccine. Information on the lot/Batch number has been requested.

difficulty of breathing; chest pain; nearly passing out/fainting; This is a spontaneous report from a contactable consumer. A 50-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number and expiry date unknown) via unspecified route of administration on unspecified date at single dose for Covid-19 immunization. The patient's medical history and concomitant medications were not reported. The reporter called in behalf of her friend that has been experiencing serious adverse event. The patient experienced difficulty of breathing, chest pain, nearly passing out/fainting on unspecified date. They felt that the vaccination provider did not provide enough support about the adverse event that happened. Follow-up activities are possible, information on the batch number has been requested.

believed it was injected incorrectly because she didn't have pain in her deltoid but she did have all the pain inside her shoulder, like in the bursa; received the first dose 17DEC2020 / received the second dose 4JAN2021; anterior medial shoulder joint/shoulder pain/pain in shoulder after second dose of COVID 19 vaccine; can't actively use shoulder / can't move her arm; weakness in her hand; bone pain; This is a spontaneous report from a contactable healthcare professional (HCP) reporting for herself. A 40-year-old female patient received the first single dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (lot number EJ1685, expiry date not provided) via an unspecified route of administration in the left arm on 17Dec2020 13:30, and the second dose (lot number EK9231, expiry date not provided)via an unspecified route of administration in the left arm on 04Jan2021 13:30, for COVID-19 immunization. There was no relevant medical history. The patient's concomitant medications were not reported. The patient experienced anterior medial shoulder joint/shoulder pain/pain in shoulder after second dose of the vaccine on 04Jan2021, and couldn't actively use shoulder. She believed it was injected incorrectly because she didn't have pain in her deltoid but she did have all the pain inside her shoulder, like in the bursa, and she couldn't move her arm and felt weakness in her hand. She noticed the pain and all other symptoms immediately when they were injecting it. She told the nurse who said she was tensing up. The events were considered medically significant by the patient. She also reported experiencing bone pain, unable to put in sutures at work. She was taking 600mg Ibuprofen and 1000mg paracetamol (TYLENOL) every 6-8 hours. The events were not resolved. The pain had gotten worse. The other symptoms were persisting.; Sender's Comments: Based on the compatible temporal association, the vaccination with BNT162B2 might play a contributory role in triggering the onset of the events. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

SEVERE ABDOMINAL PAIN

"tongue not swollen but felt sluggish/tongue felt strange, it was sluggish to swallow; tongue felt strange like hard to swallow/tongue felt strange, it was sluggish to swallow/Her tongue felt strange; tongue felt strange like hard to swallow/tongue felt strange, it was sluggish to swallow/felt hard to swallow; hot

flash; flush feeling all over her face/flush all over her face/she felt flush; arm was sore; arm was sore and heavy; drowsiness; pain and redness at injection site; pain and redness at injection site; This is a spontaneous report from a contactable nurse reporting for herself. A 36-year-old female patient received the first single dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (lot number EL1284, expiry date not provided) on 23Dec2020 09:15 intramuscularly in the left arm for COVID-19 immunisation (reported as preventive). There was no relevant medical history and no concomitant medications. The nurse (patient) received her first dose of the vaccine on 23Dec2020 at the hospital that she worked at. She was kept there for 15 min for monitoring and she felt fine. About 30 minutes post vaccination she got a hot flash, a flush over her face, she does not know if she was red but she felt flush. Her tongue felt strange, nothing swelled that she could tell, it felt hard to swallow, to make the motion to swallow it felt kind of sluggish. She felt weird swallowing which lasted for only a few minutes. She never struggled to breathe. She went back to park in the hospital parking lot since she was not sure if she was experiencing a anaphylactic reaction and then after a few minutes it went away. Her arm was sore and heavy feeling for that day. She had drowsiness for a couple of hours and pain and redness at the injection site for a couple of days that was not bothersome, it was mild. No relevant test. She wanted to know if she should get the second dose of the vaccine due to the symptoms she had after the first dose. The pain and redness at injection site was resolved on an unspecified date in Dec2020, while the other events were resolved on 23Dec2020. The reporting nurse considered the events hot flash, flush all over her face, arm was sore and heavy, drowsiness, pain and redness at injection site were non-serious, while the events ""tongue felt strange, it was sluggish to swallow"" were serious that she drove back to the hospital (no emergency room/phycian office visit). She considered the events were related to the vaccine.; Sender's Comments: A possible contributory effect of suspect BNT162Bw on the reported events cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate."

Sudden and rapid onset of generalized Urticaria accompanied by dyspnea; sudden and rapid onset of generalized uritcaria accompanied by dyspnea; This is a spontaneous report from a contactable nurse (patient). A 34-year-old female patient (non-pregnant) received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EH9899), intramuscular on 30Dec2020 11:00 at single dose at right arm for covid-19 immunization. Medical history included Grave's dse, psoriasis, bronchial asthma. Concomitant medication in two weeks included propranolol, methimazole, fluticasone furoate, vilanterol trifenatate (BREO ELLIPTA), colecalciferol (VITAMIN D). Patient didn't receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient previously took adalimumab and experienced drug allergies. The patient was not diagnosed with COVID-19 prior to vaccination. Since the vaccination, patient has not been tested for COVID-19. 9hrs post-vaccine, patient developed sudden and rapid onset of generalized uritcaria accompanied by dyspnea on 30Dec2020 20:00 with outcome of recovered with sequelae. Adverse events resulted in emergency room/department or urgent care. Patient received intramuscular epinephrine, intravenous solumedrol & benadryl, and oral prednisone x5 for events. This report is considered as non-serious.; Sender's Comments: Based on temporal

association, the causal relationship between bnt162b2 and the events urticaria and dyspnoea cannot be excluded. The information available in this report is limited and does not allow a medically meaningful assessment. This case will be reassessed once additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate.

Facial paralysis; stress; This is a spontaneous report from a contactable Nurse. A 42-year-old female patient received first dose of BNT162B2(PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The reporter felt worried about the patient(partner) that had facial paralysis and asked if they could administer the second dose of the vaccine of covid-19 from Pfizer. The paralysis it was previous from the fist dose of the vaccine, a consequences of the stress, the partner had 42 years. The reporter considered that the event was non-serious. The outcome of the event was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Based on temporal association, the causal relationship between BNT162B2and the event facial paralysis cannot be excluded. The information available in this report is limited and does not allow a medically meaningful assessment. This case will be reassessed once additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate.

"experienced symptoms of TIA; Severe aphasia; blurred vision; confusion; short term memory loss; elevated blood pressure; This is a spontaneous report from a contactable Other-HCP(Patient). A 57-year-old female patient received first dose of BNT162B2(PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration at right arm, on 22Dec2020 08:15 at single dose for COVID-19 immunization. The patient was not pregnant. Medical history included herpes simplex on lips, post menopause, elevated cholesterol w/lifestyle changes. Known allergies reported as no. Concomitant medication included varicella zoster vaccine rge (cho) (SHINGRIX) for immunization. On 04Jan2021 08:30, the patient experienced symptoms of transient ischaemic attack(TIA), severe aphasia, blurred vision, confusion, short term memory loss, elevated blood pressure. The patient admitted to (Hospital name) (still here, hospitalization days reported as 2). Symptoms resolved except very mild aphasia. The patient had very few risk factors for TIA but did have family history of cardiovascular(CV) disease at young age, low density lipoprotein(LDL) was 192. The patient did not have diabetes, HTN, or known heart disease. She did not have severe anxiety. She did not smoke or use any substances. She walked about five miles 4x a week. Weigh reported as 157. Events reported as serious due to hospitalization. The patient had no Covid prior vaccination. Covid(nasal swab) was tested post vaccination on 04Jan2021, Covid test result was Negative. The event resulted in emergency room/department or urgent care. Treatment received for the adverse event included clopidogrel bisulfate(PLAVIX),

acetylsalicylic acid (ASPIRIN), statin; potassium, CT, MRI, ""telemet"". The outcome of the events was recovering. Information on the lot/batch number has been requested.; Sender's Comments: The Company cannot completely exclude the possible causality between the reported symptoms of transient ischaemic attack(TIA), severe aphasia, blurred vision, confusion, short term memory loss, elevated blood pressure and the administration of BNT162B2, based on the reasonable temporal association. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RA, Agency, as appropriate."

"two skin procedures performed in his surgeons office the day before- one on his nose and one on his arm; nose was still slightly bleeding; This is a spontaneous report from a contactable consumer(patient). áA 72-year-old male patient received first dose of BNT162B2(PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 30Dec2020 at single dose for COVID-19 immunization. Medical history included phlebotomy in Sep2020 because his blood was ""too thick"" and he had no history of a clotting problem until the time of the report. The patient's concomitant medications were not reported. He reported having two skin procedures performed in his surgeons office the day before- one on his nose and one on his arm. The surgeon nicked a vein on his arm and it began bleeding again last night. The arm was addressed in the emergency deportment(ED) and was fine at time of the report. His nose was still slightly bleeding. This morning his blood was drawn for a CT scan and it took a little while to get the bleeding to stop. He had a ""phlebotomy"" in Sep2020 because his blood was ""too thick"" and he had no history of a clotting problem until the time of the report. The patient asked if the Covid vaccine act as an anticoagulant. He had not spoken to this HCP yet. He was not on a blood thinner. The reporter considered that the event was non-serious. The outcome of the event arm bleeding/bleeding was recovered, of event ""nose was still slightly bleeding"" was not recovered. á Information about lot/batch number has been requested."

soreness around the injection site; Had severe arm pain; Had a fever on the night of the 31Dec2020 of 101.3; I have painful lymph nodes/the swollen lymph nodes under her right arm, the armpit area had swollen and painful lymph nodes; I have painful lymph nodes/the swollen lymph nodes under her right arm, the armpit area had swollen and painful lymph nodes; had joint pains/knees and hip joint pain; severe fatigue; muscle pain; This is spontaneous report from a contactable nurse (patient). A 59-years-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK9231), via an unspecified route of administration in right arm on 30Dec2020 14:15 at first single dose (0.3 cc, but really uncertain of dose) for covid-19 immunization. Medical history included COVID virus from Nov2020 to 2020 (The patient was not hospitalized. It was a mild case and lasted about 10 days. she had any positive antibodies at that time. Was off work for about 12 days and was very lucky to have had a very light case with fever, cough, cold, and super fatigue). The patient's concomitant medications were not reported. The patient did not receive any other vaccines at the same time or 4 weeks prior. No problems with vaccinations in past or events. Caller reported she had the first injection of the Pfizer BioNTech COVID-19 vaccine on the 30Dec2020 and having some side effect symptoms and her supervisor recommended for her to report these things, they are not life threatening, obviously, but things were

still lingering. Side effect of severe fatigue started on the 31Dec2020 and lasted for 72 hours. It was so severe, now it is mild. The patient reported soreness around the injection site. Had a fever on the night of the 31Dec2020 of 101.3 and had that for 6 hours then it dissipated and was gone. Had never had a fever after injections before. Had severe arm pain that usually goes along with an injection. It started also that night of 31Dec2020. She had rolled over in the middle of the night and it hurt. That lasted for about 48 hours, but it has improved. Had some muscle aches since 31Dec2020 but that had improved and had joint pains since 31Dec2020. What was worrisome was the swollen lymph nodes under her right arm, the armpit area had swollen and painful lymph nodes, since 31Dec2020. The patient was still having that and that is why she was so concerned because shouldn't that have gone away after a week. Had knee and hip joint pain, but that had improved. Again, mentioned she had never had that before with an injection. The patient received vaccine at her workplace. Some of her coworkers got it the same day and no one else has this. Mentioned she did have COVID virus back in Nov2020 and wonders if this correlates with her getting the vaccine. Was not hospitalized or notified she had any positive antibodies at that time. Was off work for about 12 days and was very lucky to have had a very light case with fever, cough, cold, and super fatigue. This is the same way she felt back when she had the virus back in November. The patient was concerned about having these side effects would it be okay for her to get the next injection in 3 weeks. AEs did not require a visit to emergency room and physician office. No further details provided. Outcome of the events Fever was recovered, of event swollen and painful lymph nodes was not recovered, of events knees and hip joint pain, fatigue, muscle pain, severe arm pain was recovering, of event soreness around the injection site was unknown. The reporter considered the events severe fatigue, fever, swollen lymph nodes and pain under right arm, knees and hip joint pain as serious (medically significant). The reporter considered the events severe fatigue, fever, severe arm pain, muscle ache, swollen lymph nodes and pain under right arm, knees and hip joint pain as related to BNT162B2.; Sender's Comments: Based on the compatible temporal association, the vaccination with BNT162B2 might play a contributory role in triggering the onset of the reported events. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

chest pressure; tightness /pressure in throat; Face red; BP 186/90; within 2 min. of injection had near syncope that would come in waves every 2-3 minutes; Headache; rapid HR; Chills; mild cough; Dizziness; fatigue; This is a spontaneous report from a non-contactable health care professional nurse, the patient. A 53-years-old non-pregnant female patient (nurse) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot Number: EJ1685), in the right arm on 28DEC2020 08:15 as a single dose, for COVID-19 vaccination. Facility where the most recent COVID-19 vaccine was administered was a Hospital. Medical history included asthma and gastroesophageal reflux disease from an unknown date and unknown if ongoing. Known allergies include Tape, Walnuts, and Cat hair. Concomitant medication received within 2 weeks of vaccination included acyclovir [aciclovir] (ACYCLOVIR [ACICLOVIR]), ferrous gluconate, herbal nos, vitamins nos (FLORADIX), lansoprazole (PREVACID), cholecalciferol (VITAMIN D [COLECALCIFEROL]). No other vaccines were given within 4 weeks. Prior to vaccination, the patient was not diagnosed with COVID-19. On 28DEC2020 08:15 within

2 min. of injection had near syncope that would come in waves every 2-3 minutes, face red, chest pressure, tightness /pressure in throat, headache, BP 186/90, rapid HR. The patient Spent 1 hour in ER. Later in day 28Dec2020, continued to have dizziness, chest pressure, chills, headache, fatigue. This continued for 4 days and had mild cough. The adverse events resulted in an emergency room (ER) visit. and Physician Office Visit. Treatment included Xyzal which relieved majority of symptoms. Laboratory test and procedures on 28Dec2020 include Electrocardiogram (EKG) with normal results, Blood Pressure Measurement 186/90 and Heart Rate Rapid. Treatment was given for chest tightness, throat tightness and red face and No treatment was given for chills, cough, dizziness, fatigue, headache, heart rate increase, blood pressure high and near syncope. The clinical outcome of near syncope that would come in waves every 2-3 minutes, face red, chest pressure, tightness /pressure in throat, headache, BP 186/90, rapid HR, dizziness, chest pressure, chills, headache, fatigue, mild cough was recovered. No follow-up attempts are possible. No further information is expected.; Sender's Comments: The Company cannot completely exclude the possible causality between the reported face red, chest pressure, tightness /pressure in throat, blood pressure increased (BP 186/90), near syncope and the administration of BNT162B2, based on the reasonable temporal association. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RA, IEC, as appropriate.

DVT; have pain in same site where DVT is; This is a spontaneous report from a contactable consumer. A 28-years-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number EK9291), via an unspecified route of administration in left deltoid on 24Dec2020 10:00 at first single dose for COVID-19 immunization. Medical history was none. There were no concomitant medications. Caller was calling to report a possible adverse reaction to the Pfizer Covid-19 vaccine. The patient was currently at hospital, she was admitted for deep vein thrombosis (DVT) of left iliac vein, the patient had no past history as to why this would happen, that she is only 28 years old. Received the vaccine on 24Dec2020, the following day she did have pain in same site where DVT was. Took ibuprofen for the pain. The patient was admitted yesterday 04Jan2020 for the DVT, they were currently treating her with Lovenox injections and prescribing dose for discharge is Eliquis. CT scans and three shots of Lovenox for it, doing a doppler of bilateral legs and echocardiogram (echo) of her heart to make sure there is nothing else. The AEs require a visit to emergency room. The patient was asking if she can still get the 2nd dose based off the adverse event she experienced. Outcome of DVT was not recovered, of pain was unknown.

Chills; Headache; Coughing; Tiredness; Nasal congested; Feels like her sinus were blocked; Body ache; feeling sick; Sneezing; This is a spontaneous report from a contactable nurse (patient, front line health care worker). A 51-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (Lot#: EH9899) via an unspecified route of administration in the left arm on 28Dec2020 (at 10:30 or 11:00 AM) at single dose for COVID-19 immunization. Medical history included hypertension, diabetes, and stroke, all reported as family history (her parent). There were no concomitant medications. There was no history of all previous immunization with the Pfizer vaccine considered as suspect. There was no additional vaccines administered on same date of the Pfizer

suspect. The patient did not have prior vaccinations within 4 weeks. The patient had body ache (reported as medically significant) on 01Jan2021 with outcome of recovering, had been sick for a week/ very ill on 28Dec2020 with outcome of unknown, sneezing on 28Dec2020 with outcome of not recovered, chills on 01Jan2021 with outcome of unknown, headache on 01Jan2021 with outcome of recovering, coughing on 01Jan2021 with outcome of not recovered, tiredness on 01Jan2021 with outcome of unknown, nasal congested on 01Jan2021 with outcome of not recovered, feels like her sinus were blocked on 01Jan2021 with outcome of unknown. Treatment was received for the events. Reported she had a lot of sickness, by evening that day (28Dec2020) she got sneezing and feeling sick. Then the next day was the same, then the third day. She became very ill with chills, body ache, headache, coughing, and tiredness on 01Jan2021 (also reported as 3 days later vaccination). And she had no fever, but stated she had been sick for a week. Added the headache and body ache were a little better but still she felt so congested. Clarified she had nasal congested that feels like her sinus were blocked. She treated herself with acetaminophen, once daily 500 mg by mouth starting 01Jan2021. Added the body ache pain was still on the back of her chest but her legs and arms were better. She used steam inhalation for the congestion. She was not scheduled for the next dose yet, she was just waiting. The patient was wondering if she should do a test for COVID 19. Mentioned she had been healthy all through this year and digging in the COVID 19 all the time but then after the vaccine she got so sick. This was the first day she could get up and did anything. Advised caller to consult her HCP.; Sender's Comments: Based on the information currently provided, the vaccination with BNT162B2 might play a contributory role in triggering the onset of the body ache. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

TB test; This is a spontaneous report from a contactable consumer. This female consumer (patient) reported that received received bnt162b2 (BNT162B2, PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 30Dec2020 at single dose for covid-19 immunisation. Medical history and concomitant medications were unknown. Certified Nursing Assistant got the first dose of the covid vaccine on January 2nd and also she needs to get her TB test. She was told to wait 2weeks between the application and the TB test but the 2 weeks period ends on January 15th and she needs to have the test before that day, so she was wondering if she could get the test done a couple of days early. The outcome of the event was unknown. Information about lot/batch number has been requested.

"miscarriage at 5 weeks of gestation; pregnant patient received the vaccine; pregnant patient received the vaccine; This is a spontaneous report from a contactable physician (patient herself) from a Pfizer Sponsored program. This physician only reported information for the mother (herself). This is the maternal case. A pregnant female patient of an unspecified age received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Lot number: EK5730), via an unspecified route of administration, on 17Dec2020 as a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The pregnant patient received the vaccine on 17Dec2020

and experienced miscarriage at 5 weeks of gestation on 31Dec2020. The clinical outcome of pregnant patient received the vaccine and miscarriage at 5 weeks of gestation was unknown.; Sender's Comments: The association between the event ""miscarriage"" with BNT162b2 can not be fully excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate."

2 week migraine; headache; flushed/Got flushed; persistent extreme dizziness; This is a spontaneous report from a contactable nurse (patient). A 37-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) Batch/lot number: EK5730, Intramuscular at single dose on 17Dec2020 19:00 on right arm for precaution as front line health care worker. Medical history included Hemiplegic migraine. Her mother also had migraines. Concomitant medication included ranitidine hydrochloride (ZANTAC) and H1 and H2 blocker. The patient called to report AE of flushed, persistent extreme dizziness, and a headache that has evolved into a 2 week migraine. She has a history of hemiplegic migraines and was taking and h1 and h2 blocker when she received the vaccine. She was calling on guidance whether or not to receive the second vaccine. She was scheduled for second dose on Thursday, but wanted to speak with someone before she got it to see if it was OK. About 15 minutes after receiving the first dose, she got flushed and extremely dizzy. She had a mild headache when she woke up on 18Dec2020 06:00, which then developed into a severe migraine on 22Dec2020 08:00 that she has had for 2 weeks and dizziness continues. She received it at work and there was no prescriber. She called and left a message with Pfizer but has not heard back from anyone yet about this. She would say the flushed and dizziness would be medically serious because she had allergies and had medication on board. She takes daily allergy medication and Zantac and not sure she would not have had a worse reaction if she hadn't had that on board. She took it every night. She had an H1 and H2 blocker on board. Flushed has improved but the dizziness has stayed constant. She had been treated twice for headache and now they have put her on a Prednisone taper. She got it on her right arm so she could work her arm out. On 22Dec2020, she saw a Neurologist for the Migraine. They gave her Toradol 30 mg and Zofran 4mg injection in office. They were given IM. Then, she had another office visit for urgent care on 02Jan2021, and that was for the exacerbation of the migraine. They prescribed 1 liter of fluids and then another Toradol injection, Zofran injection and Decadron injection. The dose of the Toradol was 30 mg, Decadron was 6 mg, and Zofran was 4mg. These were given IV in urgent care. The patient had no prior vaccinations within 4 weeks. The outcome of flushed/Got flushed was resolving. The outcome of other events was not resolved.; Sender's Comments: Based on the compatible temporal association, the vaccination with BNT162B2 might play a contributory role in triggering the onset of the events flushing, dizziness, headache and migraine. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

syncope; diaphoresis; varying HR; blurred vision; This is a spontaneous report from a contactable physician (patient). A male patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), via an unspecified route of administration on 05Jan2021 as single dose for COVID - 19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced syncope, diaphoresis, varying HR (heart rate) and blurred vision in Jan2021. The patient underwent lab tests and procedures which included heart rate: varying in Jan2021. Details were as follows: Patient received the vaccine in the morning. He reported diaphoresis, syncope, varying HR, and blurred vision within 10 minutes of receiving the vaccine. He was taken to the emergency room and therapeutic measures were taken as a result of the events; he was given fluids. The patient generally tolerated vaccines and has recovered from the episode. The events, syncope, diaphoresis, varying HR (heart rate) and blurred vision recovered in Jan2021. The batch/lot number for the vaccine, BNT162B2, was not provided and will be requested during follow-up .; Sender's Comments: Based on the information available, a possible contributory role of the suspect products cannot be excluded for the reported event due to temporal association. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators as appropriate.

one of those biopsies was bleeding pretty heavy/looked at the incision/The one on his nose is still dripping blood and its coming up on 24 hours now; This is a spontaneous report from a contactable consumer (patient). A 72-year-old male patient received his first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (Batch/lot number: E70124), Intramuscular in arm on 30Dec2020 at single dose for COVID-19 vaccination. Medical history included ongoing blood pressure high and he had been treated for that for a number of years, diabetes from 2009 and ongoing, COPD (chronic obstructive pulmonary disease) issues from 2020 and ongoing and his issues began within the last year, ongoing kidney failure and this started occurring within the last 2 or 3 years, had a urostomy done, had bladder cancer and he had had phlebotomy performed around 3-4 months ago in 2020 and he knew his blood was thick at the time. There were no concomitant medications. The patient received the first vaccine on Wednesday, 30Dec2020. He had noticed something. He had a couple of things happen that basically involved a couple of skin biopsies. He had some lab work drawn for a CT scan, and he didn't clot right away on 05Jan2021. Last night 04Jan2021, he went to the emergency room because one of those biopsies was bleeding pretty heavy. He wanted to know if there is any known connection with the COVID vaccine and anti-clogging. He was going to follow up with the surgeon that did the biopsies. He stated its weird. He had had phlebotomy performed around 3-4 months ago in 2020 and he knew his blood was thick at the time. There had been 2 or 3 incidents where he was not clogging up. He clarified they were skin cancer biopsies, which was something diagnosed prior to receiving the vaccine. It was a follow-up because they didn't get it all the first time and they had to go back in. His skin biopsies were done yesterday, 04Jan2021. He verified when he went to the emergency room last night 04Jan2021 he was not admitted into the hospital. It was outpatient and they looked at the incision and put a little clotting tape (or whatever it is) on him and wrapped it up. He hadn't been bleeding. He knew the doctor nicked a vein. There were 2 biopsies done- one was on his nose. The one on his nose was still dripping blood and its

coming up on 24 hours now. The blood drawn for the CT scan was drawn early this morning 05Jan2021 around 7:30 AM. The outcome of the event was not resolved.

Followed by neurological symptoms staring day 4; parasthesias of both upper extremity; progression to muscle weakness of all four extremities/Currently with significant muscle weakness, Left hand weakness leading to dropping of objects and left foot drop; progression to muscle weakness of all four extremities/Currently with significant muscle weakness, Left hand weakness leading to dropping of objects and left foot drop; Flu like symptoms first 3 days; This is a spontaneous report from a contactable physician (patient). A 39-year-old male patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number: ek5730) at left arm, via an unspecified route of administration on 16Dec2020 at single dose for covid-19 immunisation. Medical history included hypertension, diabetes, migraines, Eosinophilic granulomatosis with polyangiitis (EGPA) remission. Prior to vaccination, the patient was not diagnosed with COVID-19. The patient did not have any allergies to medications, food, or other products. The patient's concomitant medications were not reported. On 21Dec2020, the patient experienced flu like symptoms first 3 days. Followed by neurological symptoms staring day 4, parasthesias of both upper extremity with progression to muscle weakness of all four extremities. Leading to 2 ER visits and hospital admission. Evaluation by internal medicine, neurology and rheumatology. Currently with significant muscle weakness, Left hand weakness leading to dropping of objects and left foot drop. The events resulted in Doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care, Hospitalization, Disability or permanent damage. The treatment for events included High dose steroid. Covid test included Nasal Swab: negative on 19Dec2020. The outcome of events was not recovered.; Sender's Comments: Based on temporal association, the causal relationship between bnt162b2 and the events influenza like illness, neurological symptom, paraesthesia, muscular weakness and peroneal nerve palsy cannot be excluded. The information available in this report is limited. This case will be reassessed once additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate.

tired; no energy; low back pain; her fingers are hurting; passed out on toilet; Nauseated; hit head on wall, head just hurts; hit head on wall, head just hurts; Chills; she was very cold; could not sleep good; site of vaccine was sore; Muscle pain; Joint pain; This is a spontaneous report from a contactable consumer. A 58-year-old female patient started to receive first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, Batch/lot number: EK9231) by injection once to left arm, via an unspecified route of administration on 04Jan2021 12:30 at single dose for covid-19 immunisation. Medical history included thyroid disorder. Concomitant medication included levothyroxine sodium (SYNTHROID) for thyroid disorder; patient started it after she had her son, and her son is 18 years old. The patient had her vaccine yesterday (04Jan2021) at 12:30, and at nighttime, around 22:00, she started having chills, she was very cold, so she went to bed, she could not sleep good, she kept waking up, and the site of vaccine was sore, she had muscle pain, joint pain, she didn't have fever, but she got up late

today (05Jan2021), around 11:00, and had breakfast and felt nauseated, so she stopped eating, and she went to the bathroom and passed out on the toilet, when she woke up, she had her nightgown inside the toilet, it was all wet, she felt better, so she stood up and then she woke up again, and was inside the tub, her legs were inside the basin, she was lying down with her back inside the tub, she thinks she hit her head on the wall, and it just hurts, it didn't bleed or nothing. The patient stated she had the paper she was given. Again stated she can not even function. Patient still feels Chills a little bit, not as bad as last night. She is awake now, but she feels very very tired, like she has no energy, she is laying down on couch right now. She kept waking up and noticed this morning, she had low back pain, in the muscles, even her fingers are hurting. Regarding hitting her head on the wall, states she has a terrible headache, not a little pain, she thinks it is because she hurt her head. The patient is supposed to get second vaccination on 25Jan2021. The outcome of events Chills, Joint pain and nauseated was recovering; of events site of vaccine was sore and muscle pain was not recovered; of other events was unknown.

Fainting; This is a spontaneous report from a non-contactable consumer. This consumer reported similar events for 2 patients. This is 2nd of 2 reports. A patient of unspecified age and gender received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for covid-19 immunisation. The patient medical history and concomitant medications were not reported. The patient experienced fainting on an unspecified date with outcome of unknown. The action taken in response to the event for bnt162b2 was not applicable. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021006219 same reporter/drug/event, different patient

Auditory & visual hallucinations; Auditory & visual hallucinations; tachycardia; extreme panic; confusion; felt like skin was on fire/pulsating; felt like skin was on fire/pulsating; severe pain especially at knees/hips/base of head and neck; severe pain especially at knees/hips/base of head and neck; severe pain especially at knees/hips/base of head and neck; uncontrollable vomiting; bad chills and fever; bad chills and fever; insomnia; felt as if she had been given drugs; This is Spontaneous report from a contactable Other Healthcare Professional reported for herself. This 40-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, lot number: EK9231), via an unspecified route of administration on 04Jan2021 14:30 at single dose on right arm for COVID-19 immunization. Medical history included COVID prior vaccination and latex allergy. There were no concomitant medications. No other vaccine in four weeks. The patient previously had allergic to diazepam (VALIUM), clonazepam (KLONOPIN), ondansetron (ZOFRAN) and lorazepam (ATIVAN). The patient experienced auditory & visual hallucinations, tachycardia, extreme panic, confusion, felt like skin was on fire/pulsating, severe pain especially at knees/hips/base of head and neck, uncontrollable vomiting, bad chills and fever, insomnia. She felt as if she had been given drugs. All of the events happened on 05Jan2021 01:30 and resulted in Doctor or other healthcare Recovering professional office/clinic visit. No treatment received for the events. No COVID tested post vaccination. The outcome of the events was recovering.; Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of events Auditory hallucinations and Visual hallucinations cannot be totally excluded. The case will be reassessed if additional information becomes available. The impact of

this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

rash; All over rash with some itching; This is a spontaneous report from a contactable Nurse reported for self. This 34-year-old female patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 05Jan 2021 12:50 on right arm at single dose (Lot # EK4176, Expiration Date: Mar2021) for covid-19 immunisation. Medical history was not provided. Concomitant medications were none. Past drug history included the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 15Dec2020 16:00 at age of 34 year old at single dose (Lot # EH9899) for covid-19 immunisation. About 30 minutes after being administered (05Jan2021 13:20) that second dose she developed all over rash with some itching. She took Benadryl and Pepcid in response. Today the all over rash with some itching came back at the same persistent level. She wants to know what kind of timeframe she can expect with the continued allergic reaction of all over rash with some itching. She was made to check into the emergency room for observation, but did not have any testing/lab work/investigations done and was not admitted to the hospital. Outcome of the events was not recovered. Reporter seriousness for All over rash with some itching was Medically significant. Drug result was related.; Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of events Rash and Itching cannot be totally excluded. The case will be reassessed if additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Chills with no fever; Cramping in legs; super tired with no energy; Body aches; tiredness/Feeling super tired with no energy; This is a spontaneous report from a contactable consumer. This consumer (patient) reported for self that the 45-year-old female patient who receive first dose of bnt162b2 (BNT162B2, PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EH9899), via an unspecified route of administration on Saturday (02Jan2021) at single dose (once by injection in the right arm) for covid-19 immunisation. Medical history included ongoing Hypothyroidism from 2008. Concomitant medications included levothyroxine at 75 ug ongoing from 2008 for Hypothyroidism. Medical Professional and told by her work that she could get it because contact with COVID patients. The consumer calls for information about if the side effects she is experiencing after the administration of the COVID-19 vaccine will last for more days. The consumer reported tiredness and other side effects to DSU. A Consumer calls for information about if it would be appropriate the second dose of the COVID-19 vaccine is not administered considering that she had adverse reactions. Consumer calls for information about if the second dose of the COVID-19 vaccine would cause her more side effects than the first one. Received the vaccine on Saturday, 02Jan2021. The day she got it she did not feel anything at all. She was completely fine. She did not even have pain at the injection site. The next day, on Sunday she started

feeling super tired with no energy, had body aches, and cramping in legs from 03Jan2021. She has had these for the past 3 days now. She also had chills with no fever from 03Jan2021 to 05Jan2021. She took Tylenol for the first 2 days, but it did not help her at all. She is feeling a little better today, but not much. Her question is, how long will these side effects last? Tylenol: She says it did help a little bit. She think she would just sleep because she was uncomfortable. The Tylenol just did not make her symptoms go away completely. LOT/Batch: AA46487, EXP: Apr2022 UPC: The consumer says the number under the barcode is: 5187536. Feeling super tired and body aches: Has improved about 20%. She says these are all medically significant as she is not able to do what she was able to do before getting the vaccine. She is super tired with no energy and she is confined to her bed most of the time. The consumer confirms this is her first dose of the COVID Vaccine. She thinks she got the standard dose. Vaccine card does not have the expiration date or NDC written on it. Unknown causality. She said that she could be positive for COVID. She is unsure. The outcome of the event Chills with no fever was recovered. The outcome of the event Cramping in legs was not recovered. The outcome of the other events was recovering.; Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of reported events cannot be totally excluded. The case will be reassessed if additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

I was in a low disease state of SLE, 2 days after injection i had a severe flare of lupus requiring steroids; This is a spontaneous report from a contactable other Hcp (patient). This 36-years-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (lot number: EH9899), intramuscularly on 16Dec2020 13:30 at single dose in Arm left for COVID-19 immunisation. Facility where the most recent COVID-19 vaccine was administered was Hospital. Medical history included systemic lupus erythematosus (SLE) and in remission. No Pregnant at the time of vaccination. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient did not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19.Concomitant medication received within 2 weeks of vaccination included hydroxychloroquine, topiramate (TROKENDI), prucalopride succinate (MOTEGRITY). The patient was in a low disease state of SLE, 2 days after injection and had a severe flare of lupus requiring steroids on 18Dec2020. The adverse event result in Doctor or other healthcare professional office/clinic visit. Steroids received as treatment. The outcome was recovering. The events were assessed as non-serious; Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of event Systemic lupus erythematosus syndrome aggravated cannot be totally excluded. The case will be reassessed if additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this

review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

experiencing an allergic reaction; Hives all over her face and neck/hives on face and neck; This is a spontaneous report from a contactable Physician (patient). A 30-years-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (lot number: EL0140, Expiry Date: 31Mar2021) via an unspecified route of administration in left upper arm on 31Dec2020 13:25 at single dose for COVID-19 immunisation. Medical history included crohn's disease from Jul2005 and ongoing, ongoing psoriasis, gastrooesophageal reflux disease (GERD), hand tremor. Concomitant medication included ongoing infliximab (REMICADE) for Crohn's, ongoing esomeprazole sodium (NEXIUM) for GERD, ongoing propranolol for hand tremor, copatsol topical steroid for Psoriasis, ongoing Multivitamin, ongoing vitamin B complex (B COMPLEX), ongoing biotin, ongoing iron, ongoing Calcium/Vitamin D, ongoing curcuma longa (TURMERIC). The patient had an allergic reaction after getting the COVID vaccine. She had an allergic reaction after getting the vaccine. She had hives all over her face and neck. She already had a Medrol Dose Pack at home and some Benadryl. She contacted her doctor who prescribed an Epi Pen for her, but she did not have to use the Epi Pen. She stated she used the Benadryl for three days. She started to get hives all over her face and neck the same date she got the vaccine. It started 2 hours after she got the vaccine (31Dec2020 15:25). She confirmed this was the first dose of the COVID Vaccine. She asked that if it is safe to take the second dose after experiencing an allergic reaction to the first dose. Symptoms include hives on face and neck. Patient had no trouble breathing. Took steroids and Benadryl for 3 days or until symptoms have been managed. No any of the events require a visit to emergency room. Reporter seriousness for hives all over her face and neck was reported as medically significant. Events outcome was recovered on 03Jan2021.; Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of events Allergic reaction and Hives cannot be totally excluded. The case will be reassessed if additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

blasting headaches; chills all night; dry heaving all night; Nausea; no fever but her skin felt hot; sore left arm; This is a spontaneous report from a contactable nurse for herself. This 64-year-old female patient started to receive BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), intramuscular on 18Dec2020 at single dose on left upper arm (lot: EKS730), via an unspecified route of administration on 05Jan2021 14:30 at single dose (lot: EL1284 or EKI284) for COVID-19 immunisation. Medical history and concomitant medications were none. The patient did not have anything with the first shot except a sore left arm on 18Dec2020. She stated that if she lays on left side it is sore. The patient had the sore left arm both times that she got the vaccine. She got second dose of vaccine on 05Jan2021 at 2:30pm and had a blasting headache and just had chills that went away about hour ago on 05Jan2021. She did not have a fever but her skin felt hot on 05Jan2021. She stated that she had dry heaves on 05Jan2021. The patient started that she had a blasting headache within a few hours of the vaccine and it gradually got worst by

the time she went to bed. Stated that the chills and dry heaves started then and throughout the night. The chills stopped an hour before she got up. Stated that she went to check her temperature and did not have a fever despite having chills and her skin feeling hot. Stated that nausea started about 10 at night on 05Jan2021. Seriousness for blasting headache, chills and dry heaves was disabling, for nausea was medically significant, for other events was non-serious. The patient took Ibuprofen for the headache. Stated that she was going to try to drink something. The outcome of sore left arm was not recovered; of chills was recovered on 06Jan2021. The outcome of other events was recovering. The causality for blasting headache, chills, dry heaves, nausea and skin felt hot was related (Source of assessment: Primary Source Reporter, Method of assessment: Agency Information on the batch number has been requested.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the headache, chills, dry heaves and other reported events due to temporal relationship. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

severe muscle pain, diagnosis of polymyalgia rheumatica; This is a spontaneous report from a contactable other HCP (patient). A 53-year-old female patient received the first dose of BNT162b2 (Lot/batch number and Expiration date were not provided), at the age of 53-year-old, via an unspecified route of administration at right arm on 18Dec2020 08:30 at single dose for covid-19 immunization. Medical history included hypertension (htn), allergies: penicillin. Concomitant medication included cefatrizine propyleneglycolate (CEFTIN), lisinopril, levothyroxine sodium (SYNTHROID). The patient experienced severe muscle pain, diagnosis of polymyalgia rheumatica on an unspecified date. The patient was not pregnant at the time of vaccination. The patient underwent lab tests and procedures which included COVID test rapid (Nasal Swab): negative on 06Jan2021. The outcome of the event was unknown. Information on the lot/batch number has been requested.; Sender's Comments: A possible contributory effect of suspect drug BNT162B2 on reported event cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

shaking; weak; cough; shortness of breath; very ill/ sick; horrible chills; I had a 103 degree fever for 4 days, horrible chills that were just debilitating; ached everywhere/ severe aches; site soreness; This is a spontaneous report from a contactable nurse (patient). A 62-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EH9899) via an unspecified route of administration at left upper arm on 18Dec2020 at single dose for COVID-19 immunization. Medical history included auto immune problems, diabetes, thyroid condition, all ongoing since age 28;

pemphigusvulgarism since Sep2020 and ongoing. No concomitant medications. Patient is a frontline worker. She received the vaccine on 18Dec2020 at (Name) where she works. 9 days later she got very ill. she didn't know if it's unrelated. She wanted to know if there is anything she need to be watching out for in order to get her second vaccine on Friday. She was so sick and she did have some autoimmune problems. She was really healthy. On 26Dec2020, she had a 103 degree fever for 4 days, horrible chills that were just debilitating. She was just shaking. She ached everywhere, she had severe aches since 26Dec2020. She got tested for Covid and it was negative on 28Dec2020, she had no cough and no vomit. She stayed in bed and drank lots of fluids and toughed it out. By New Year's Day (reported as 30Dec2020) her fever broke but she was so weak and didn't work. She was back at work now. Also, she experienced site soreness from the injection since 19Dec2020. She did have a cough or any shortness of breath. She felt awful. She had recovered. She was just a little nervous because everything she read said the reaction was more severe with second injection. She planned on getting the second shot. She would have a repeat Covid test on 07Jan2020. Reporter seriousness for fever 103: Medically significant. Reporter seriousness for severe aches: Medically significant. Reporter considered the causality of the event site soreness was related with bnt162b2, of the events fever 103 and severe aches was unknown. The outcome of the event fever was recovered on 30Dec2020, of event ache was recovered on 31Dec2020, of event chills was recovering, of event vaccination site pain was recovered on an unspecified date in Dec2020, of events cough and shortness of breath was recovered on an unspecified date.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the fever, pain and other reported events due to temporal relationship. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

(doctor) was not sure whether or not he might get a staph infection, a viral infection; (doctor) was not sure whether or not he might get a staph infection, a viral infection; thought he had a mosquito bite; area on the opposite side of his body, on the left hand side, he noticed that there were several small pustules; the area was raised, it was red, it was warm; Pain; extremely uncomfortable; It was very, very itchy and the area felt like it got itself swollen; It was very, very itchy and the area felt like it got itself swollen; irritation; Initially an area under his left arm which was very swollen it appeared to be filled with fluid of some type/thought it was edema/now had it under his right arm, it's probably impacting lymph system; This is a spontaneous report from a contactable consumer (patient wife). A male patient of an unspecified age started to receive bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number: EH9899, expiration date not reported), via an unspecified route of administration on 03Jan2020 16:00, at a single dose for Covid-19 immunization. Medical history included heart bypass 15 years ago and some orthopedic problems. The patient's concomitant medications were not reported. The patient previously took codeine and epinephrine experienced sensitivity. On 03Jan2020, the patient

had an injection the Pfizer vaccine in county (not clarified further) (place name withheld) which is the (place name withheld) area on Sunday at approximately 4:00 PM EST. He has no significant medical problems other than the prior history of, he had heart bypass 15 years ago and some orthopedic problems, but nothing else other than that. She had never had any adverse reactions to any medications although he has, he shouldn't say, he does have a sensitivity to Codeine which he reported and Epinephrine which he had a sensitivity to also. He got the vaccine after waiting three and half hours in line and they went off, last night that would be Sunday night, several hours later he noticed an odd sensation and did not really take a look at it, he thought he had a mosquito bite perhaps as they live in (place name withheld) and they live in the land that has lots of mosquito, so he didn't pay too much attention to it. Approximately four hours after the injection, he was going to go to bed and removed his shirt and found that the area on the opposite side of his body, on the left hand side he noticed that there were several small pustules, the area was raised it was red it was warm, it was on the opposite side under his arm on his chest he was extremely uncomfortable. It was very, very itchy and the area felt like it got itself swollen and he shared with his wife, the wife suggested that he contact the physician of course he didn't contact, his primary physician said he can see a dermatologist and sent images and yesterday he went to see a dermatologist, so prophylactically he took the 25 mg of diphenhydramine hydrochloride (BENADRYL) and also 2 acetaminophen (EXTRA STRENGTH TYLENOL) and he treated the pain and itching with ice. He slept with an ice bag and woke up just in morning and in New Year they were able to see a dermatologist, he thought it was dermatological. He was concerned but not overly concerned with the area pretty swollen. He saw a dermatologist yesterday, and gave him a topical treatment, the dermatologist gave him three different, naproxene (NAPROSYN), the other one is Triamcinolone Acetonide cream now the irritation he got the MUPIROCIN ointment now as the dermatoligist told him to do, continue what he was doing as he was comfortable, The dermatologist took some specimens from the pustules and send them to lab and she (doctor) is not sure whether or not he might get a staph infection, a viral infection he was not sure. Initially there was an area under his left arm which is very swollen it appeared to be filled with fluid of some type, he was not sure what was it. He thought it was edema but when he popped it, it felt very much like fluid not like blood but it is some type of fluid filled area most likely his wife said the size are greater and less that it was yesterday and that seems to go down over the last night but not all the way it's decreased by what 20%, 30%, 40% he can't tell, alright 50% but now he has it under under right arm, it's probably impacting his lymph system and he put a call into his cardiologist. So he was asking now what does he do. The outcome of the events were unknown.

Her arm is a little sore; the tissue paper is red after wiping her anal area/ reddish looking poop/ there are pieces of blood or something is different; This is a spontaneous report from a contactable other Health Professional (patient). A 75-year-old female patient receive BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EL0142), via an unspecified route of administration on 05Jan2021 at single dose for covid-19 immunization, also reported as for work. Medical history included ulcer (15 to 20 years before 06Jan2021). Concomitant medication included prasugrel from Apr2020 and ongoing as blood thinner, acetylsalicylic acid, ascorbic acid (ASPIRIN) from Apr2020 and ongoing as blood thinner. The patient went to the bathroom in the morning 06Jan2021, she had to poop. When she wiped, it was reddish looking. The patient stated her stool color was normal, but the tissue paper is red after wiping

her anal area. At first she thought hm oh well. Then she had been to the bathroom a couple of times 06Jan2021, and that the same thing happened. She had never experienced that before. It seems to her that there were pieces of blood or something was different. She wasn't hurting or anything. She was not weak or anything at this time. Her arm was a little sore, but she expected that. She was concerned about the color. She worked in the mammography department. She didn't have a prescribing doctor. She got it at work. She had noticed a difference of color in her poop. It had been the same all day. The outcome of the reddish poop was not recovered, of sore arm was unknown. The patient asked would the vaccine cause rectal blood upon wiping after defecation?; Sender's Comments: Reported blood in stool is considered intercurrent and unrelated to BNT162B2. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

The subject experienced acute pericarditis on 27Dec2020; Other vaccine same date vaccine date= 23Dec2020; This is a spontaneous report from a contactable consumer. A 50-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 23Dec2020 at single dose for covid-19 immunization. The facility type vaccine was hospital. None medical history. The patient's concomitant medications were not reported. Other vaccine same date vaccine date on 23Dec2020. The patient experienced acute pericarditis on 27dec2020 with outcome of recovered. The adverse event resulted in Doctor or other healthcare professional office/clinic visit. It's unknown if treatment was received for the adverse event. The event was reported as non-serious. Pfizer is a marketing authorization holder of [BNT162B2] in the country of incidence or the country where the product was purchased (if different). This may be a duplicate report if another marketing authorization holder of [BNT162B2] has submitted the same report to the regulatory authorities. Information on the lot/batch number has been requested.

Joint pain /felt like it was worsening joint pain; just severe pain to where she couldn't walk; This is a spontaneous report from a contactable Other HCP. A 70-year-old female patient received BNT162B2(Lot Number: ET1685), via an unspecified route of administration at Deltoid Left on 23Dec2020 08:00 at the 70 years old at single dose for COVID-19 immunization. The medical history included rheumatoid arthritis. The concomitant medications were none. The patient received the shot on 23Dec2020 and experienced Joint pain afterward on 02Jan2021. The patient did have rheumatoid arthritis so there was that. The patient felt like it was worsening joint pain on 02Jan2021. She has had no fever, just severe pain to where she couldn't walk on 02Jan2021. The joint pain has gotten worse and it has gotten to where she is going to advise her not to take the second shot. The Reporter assessed the seriousness for the events was Disabling. The events did not require a visit to Emergency Room but required a Physician Office visit on 06Jan2021. The patient received a steroid injection on 06Jan2021. There was none History of all previous immunization with the Pfizer vaccine considered as suspect. There was none Additional Vaccines Administered on Same Date of the Pfizer Suspect. There was no Prior Vaccinations within 4 weeks. The patient underwent lab tests and procedures, which included x-rays on 06Jan2021: unknown results (they were awaiting the X-rays). The outcome of the events was not recovered. The information

on the batch number has been requested.; Sender's Comments: Based on the available information the events worsening joint pain and walking difficulty are attributed to underlying Rheumatoid arthritis; however, based on a compatible temporal association, contributory role of BNT162B2 vaccine to events occurrence cannot be completely excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

it was debilitating for her at work; It even hurts to move the right eye in one direction and hurts to speak, the pain was so bad.; pain in right leg and bottom sole of right foot; hurts to speak; numbness right upper side of lip; pins and needle feeling right upper quadrant of face; pain and dull aching right upper side of face; right hand numbness, wasn't able to feel anything; generalized headache; generalized muscle weakness and pain; generalized muscle weakness and pain; This is a spontaneous report from a contactable other hcp (patient). A 31-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 03Jan2021 at single dose in deltoid right for covid-19 immunization. There were no medical history or concomitant medications. The patient received the vaccine on 03Jan2021 and within 15 minutes had a generalized headache. Later that night she had generalized muscle weakness and pain, but really didn't think too much about it. The next day at work (04Jan2021), she had numbness on the right upper side of her lip and a pins and needle feeling in the right upper quadrant of the face. Had a lot of pain in the area as well on the right upper side of the face as well as a dull aching pain that lasted for hours. Later that day when using the computer and she was trying to reach for her mouse she noticed her right hand wasn't able to feel anything and that lasted about 20-25 minutes. Kept slapping the mouse with her hand, but could not feel anything, her hand went numb. Yesterday (05Jan2021), she had the same pins and needle feeling in the same area of the face and that dull achy feeling and it occurred for hours and it was very kind of debilitating for her at work. Later that night she had pain in her right leg and felt the same way, that very severe achiness, which was the pins and needles feeling up and down the leg and underneath the right foot. All these symptoms tend to be on her right side and it definitely lasted for hours. It started about 1 and didn't end until 6-7pm. It even hurts to move the right eye in one direction and hurts to speak, the pain was so bad. This morning (06Jan2021) she had to call out of work because at 3am the generalized headache, pain was unbearable. She was still experiencing the pain in right leg and bottom sole of right foot. She did not receive any vaccines the same day or 4 weeks prior. No problems with vaccines in past. She had made an appointment with a neurologist and will have a MRI done on Friday, 08Jan2021. No further details provided. All events required a visit to physician office. All events were reported as serious per medically significant. The outcome of all events was not resolved. The reporter considered all events were related to the vaccine. Information about Lot/Batch number has been requested.; Sender's Comments: Based on a compatible temporal relationship, causality between reported events and BNT162B2 vaccine cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as

well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

soreness/The pain radiates down to her left elbow and also goes up the neck; The pain radiates down to her left elbow and also goes up the neck; The pain radiates down to her left elbow and also goes up the neck; This is a spontaneous report from contactable other HCP (patient' husband). A 43-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number EK9231), via an unspecified route of administration on 31Dec2020 at single dose for COVID-19 immunization. Medical history reported as none. No concomitant medications. The patient had a whole lot of soreness on 01Jan2021 and it was not getting any better. His wife had called her health care provider. She had an appointment in several days. The pain radiates down to her left elbow and also goes up the neck in Jan2021. The reporter seriousness for soreness: Medically significant. The outcome of event pain was not recovered. The outcome of rest events was unknown.; Sender's Comments: Based on a compatible temporal relationship, causality between event pain and BNT162B2 vaccine cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

She is having an allergic reaction; Itching was reported as worsened/Swelling was reported as worsened/loss of appetite was reported as worsened; From the time she got the vaccine to now, she has lost 20 lbs; shake/shaking; swelling in the lips, throat, and eye lids; swelling in the lips, throat, and eye lids; swelling in the lips, throat, and eye lids; She has been sick since Wednesday; itching all over from head to toe; loss of appetite; This is a spontaneous report from a contactable consumer (patient). A 59-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration at left arm on 30Dec2020 at single dose for COVID-19 immunization. Medical history included hypertension and allergic to ace inhibitors. There were no concomitant medications. Patient was calling about the Covid Vaccine. She was having an allergic reaction. She did not know what to do to stop it. She went to the ER yesterday (04Jan2021). She had been sick since Wednesday (30Dec2020), she was itching all over from head to toe since 30Dec2020, she got a prescription for Prednisone, she took 2 doses yesterday, 1 dose today, and would take another this evening. She took Benadryl, an hour ago and had an episode, and so she had to jump in the shower and let the cold water run to stop itching, the itching did not stop but it has minimized. She put Benadryl gel and she was still itching, she had taken enough Benadryl. Patient asked what is the best way and if she needed an IV of something, she went to ER on Sunday, she was not seen by doctor, it was a nurse practitioner, she didn't do anything but just listen to her and she only looked at ankles to check for swelling. Patient stated that she had been drinking water and urinating, she had no appetite and lost 20 lbs. Patient confirmed that she got her first dose of the Covid vaccine on 30Dec2020 at 1 o clock, the itching started the same day at 5 o clock, the itching was from head to toe. She experienced swelling in the lips, throat, and eye lids, which started 02Jan2021. She began losing her appetite on 30Dec2020. From the time she got the vaccine to now (05Jan2021), she has lost 20 lbs. An hour ago (05Jan2020) she had an episode, which made her shake, and she did not have the shakes before, this was the first date

she started shaking. Itching was reported as worsened/Swelling was reported as worsened/loss of appetite was reported as worsened. Her 2nd dose was scheduled in 21 Days. However, she may not get the second dose, patient stated that she could not get through this no more. She had no positive test for Covid prior to vaccine. She had no antibody test prior to the vaccine. She had not any issues with vaccines in the past. Patient stated that if she was still feeling this way, she would go to a different hospital. When she went to the ER, she was not hospitalized, they sent her back home the same day. Patient would like to know if there was anything that can remove the vaccine from the body. The outcome of the events itching all over from head to toe, loss of appetite, swelling in the lips, throat, and eye lids was not recovered, of the other events was unknown. Information about lot/batch number has been requested.

Acute demyelinating encephalomyelitis; Slurring his speech; Stroke; This is a spontaneous report from a contactable physician. A 35-year-old male patient received first dose bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), intramuscular in deltoid (unknown if right or left) on 17Dec2020 at 30 ug, single for 'Preventative'. Medical history included hypertension. There were no concomitant medications.(Physician) He is calling about the Pfizer Covid 19 vaccine. States what is going on with the patient may be associated as a side effect. The patient got the vaccine two to three weeks ago, he clarifies the patient received the vaccine on 17Dec2020 and the patient ended up acutely developing (states it is a presumptive diagnosis) Acute demyelinating encephalomyelitis, states it looks like a radiologic diagnosis. The patient is an employee at hospital. When querying seriousness states it is medically significant but could be disabling but he thinks the patient will recover. Reporter seriousness for acute demyelinating encephalomyelitis: Medically significant, Hospitalization. Patient was hospitalized on Sunday and he is still admitted at this time. Dates when patient was in hospital for acute demyelinating encephalomyelitis was from 03Jan2021 to ongoing. Caller thinks the patient was flown to (Place) yesterday. The patient's mother asked the caller if the caller thought the acute demyelinating encephalomyelitis was from the vaccine and the caller responded that he did not think it was from the vaccine. He confirms the patient is still admitted in the hospital and the patient's attending neurologist is doctor. The caller heard about the patient from doctor. When querying covid vaccine dose, the caller states the standard dose is 30 mcg. This was clarified and documented as provided. The patient has not received his second dose yet. He asks if the patient should receive the second dose. He asks a general question if a pregnant patient can be given the Pfizer covid vaccine. He heard the patient had a stroke then the CFO tried to talk to him and the patient was slurring his speech. Caller spoke to the patient's mother this morning and caller told the mother that he would try to find out what is going on with the patient. He asked that the patient get an HIV test even though he does not think the patient is at risk. Vaccination facility type was Hospital. Vaccine administered at military facility was No. None additional vaccines administered on same date of the PFIZER suspect. AE acute demyelinating encephalomyelitis require a visit to Emergency Room, not visit to physician office. Prior Vaccinations (within 4 weeks) was none. He has heard of acute demyelinating encephalomyelitis being associated with vaccines in the past and states that it is rare and usually in kids. States he saw patients that may have had acute demyelinating encephalomyelitis back in the 80s and 90s. Therapeutic measures were taken as a result of acute demyelinating encephalomyelitis (Patient will get steroids tonight pending the review of the x-ray). The outcome of the events was unknown. Information on the lot/batch number has been

requested.; Sender's Comments: The reported stroke with speech slurred, and the presumptive diagnosis of acute demyelinating encephalomyelitis (looks like a radiologic diagnosis by the reporting physician), was most likely an intercurrent disease, and unlikely causally related to the first dose bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE). The case will be reassessed should additional information become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

"her nerve was bad; Getting all sick, cold, sick and experiencing terrible side effects; Getting all sick, cold, sick and experiencing terrible side effects; Fatigue; Muscle ache; Nauseous; Felt awful; Can't eat all the day, no appetite; phobic something to drinking water; This is a spontaneous report from a contactable consumer (patient). A 49-year-old female patient received bnt162b2 (lot/batch number and expiration date not provided), via an unspecified route of administration, on an unspecified date, at single dose, for COVID-19 immunization. No relevant medical history. The patient's concomitant medications were not reported. The patient experienced getting all sick, cold, sick and experiencing terrible side effects, fatigue, muscle ache, nauseous, cannot do anything, felt awful, cannot eat all the day, no appetite, phobic something to drinking water. The patient has been sick for three days now. The patient was a ""senior"" (not clarified) care giver at the nursing home. Everybody at nursing home at the nursing home got the shot and now everybody has cold and sick. She has only one day of work and she has to come into her job to take care of elderly people. As since current everybody is experiencing the terrible adverse, terrible side effects, everything. Fatigue, muscle ache everything. The bosses at her nursing home cannot give them three days or even seven days off of work after receiving a contract to give them shot. It was confirmed that the patient received the COVID vaccine. The patient also stated that they are off of that side effects. They are not interrupted not just the ""arm"" (not clarified) been there. The patient said she getting everything. She was getting all the side effects. So when they had this Pfizer drug shot ""they didn't get seven days off of"" (not clarified) work. If a person gets a shot, they are feeling fatigue, nauseous (incomprehensible voice). They can't do anything. They should be allowed to stay home from work. Right now everybody in the nursing home is feeling the adverse effect. The entire building. So, she was telling Pfizer to report the report is that all of sudden that the nursing home ""seniors"" (not clarified) and nurses they got the shot, they can't even get to work. The effects are so bad that they can't do anything. The patient also stated that fatigue, she had fatigue all day. The first day she got the shot her nerve was bad but the second day was everything fatigue. She felt awful, she could not eat, she had no appetite. She was phobic something to drinking water, she cannot eat all the day. ""Fruit or something 5 I can eat"" (incomprehensible voice)."" When probed for the LOT#, the reporter stated, ""No they did not give me anything. All they did is I think 037 I think it looks like a 'K' 20A. (further not clarified) like it says (further not clarified) 037K20A that's (further not clarified)."" The outcome of the events was unknown. Information on lot number/batch number was requested."

aware of 6 cases of Bell's Palsy by the companies making these vaccines; This is a spontaneous report from contactable Other HCP. This Other HCP reported same events for 6 patients. This report is for 2nd

of 6 patients. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for covid-19 immunization. The patient medical history and concomitant medications were not reported. The other HCP was aware of 6 cases of Bell's Palsy by the companies making these vaccines since an unknown date. The event was reported as non-serious. The event outcome was unknown. Information about lot/batch number has been requested.; Sender's Comments: Based on a compatible temporal relationship, causality between event Bell's Palsy and BNT162B2 vaccine cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.,Linked Report(s) : US-PFIZER INC-2021007605 same reporter, same drug, same event, different patients.

aware of 6 cases of Bell's Palsy by the companies making these vaccines; This is a spontaneous report from a contactable other HCP. This Other HCP reported similar events for 6 patients. This report is for 3rd of 6 patient. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at SINGLE DOSE for covid-19 immunization. The patient medical history and concomitant medications were not reported. The reporter reported since the use of modified RNA in covid vaccines, he/she had aware of 6 cases of Bell's Palsy by the companies making these vaccines since an unknown date. The outcome of the event was unknown. Information about batch/lot number has been requested.; Sender's Comments: Based on a compatible temporal relationship, causality between event Bell's Palsy and BNT162B2 vaccine cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.,Linked Report(s) : US-PFIZER INC-2021007605 Different patient, same drug/event.

aware of 6 cases of Bell's Palsy by the companies making these vaccines; This is Spontaneous report from a contactable Other HCP. This Other HCP reported similar events for 6 patients. This is 4th of six reports. A patient of unspecified age and gender received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot/batch number and expiration date not provided), via an unspecified route of administration on an unspecified date at single dose for covid-19 immunization. The patient medical history and concomitant medications were not reported. The reporter reported since the use of modified RNA in covid vaccines, he/she had aware of 6 cases of Bell's Palsy by the companies making these vaccines since an unknown date. The outcome of the event was unknown. Information on the Lot/batch number has been requested.; Sender's Comments: Based on a compatible temporal relationship, causality between event Bell's Palsy and BNT162B2 vaccine cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly

notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.,Linked Report(s) : US-PFIZER INC-2021007605 same reporter, same drug, same event, different patient

aware of 6 cases of Bell's Palsy by the companies making these vaccines; This is a spontaneous report from a contactable other health professional (HCP). This other HCP reported similar events for 6 patients. This is the 5th of 6 patient. A patient of unspecified age and gender received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot/batch number and expiration date not provided), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The reporter reported since the use of modified RNA in covid vaccines, he/she had aware of 6 cases of Bell's Palsy by the companies making these vaccines since an unknown date. The outcome of the event was unknown. Information about batch/lot number has been requested.; Sender's Comments: Based on temporal association, the causal relationship between bnt162b2 and the event facial paralysis cannot be excluded. The information available in this report is limited and does not allow a medically meaningful assessment. This case will be reassessed once additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate.,Linked Report(s) : US-PFIZER INC-2021007605 Different patient, same drug/event.

"Looked like an encephalopathy; Face was all swollen; Head swelled; Glands swelled; Fatigue; Headache/ So much pain in my head; Couldn't talk; Complete brain fog; nausea; This is a spontaneous report from a contactable nurse. This 60-year-old female nurse (Patient) reported that received bnt162b2 (BNT162B2, Pfizer COVID-19 vaccine), via an unspecified route of administration on 30Dec2020 at single dose for covid-19 immunisation. Medical history included Atrial fibrillation, Chronic Lyme, Lupus and Autoimmune. Concomitant medications included Metoprolol at 12.5 mg for Atrial fibrillation and acetylsalicylic acid (BABY ASPIRIN). No diabetes, no hypertension. None of the usual common diseases. Registered Nurse stated, ""I received vaccine this past Wednesday. I was just talking to a couple of my colleagues and honestly I received the vac. at work. I did not really read through the paperwork and was 'weird' sharing reactions to the vaccine which for me was pretty bad reaction and thought like I need to go through your paperwork and report it. So I thought I should call and just give some information. The usual fatigue which I go to after being normal, my arm was not sore. However, as the week progressed into Friday I had a constant headache but it was manageable and then by Friday night my glands swelled, my nerves behind my ears, my neck and I was extremely fatigued, bad headache and went to bed and I had not gone out and finally I got out today I spoke with my Physician yesterday. What happened it looked like an encephalopathy but my head swelled, my face was all swollen, complete brain fog, fatigue and I couldn't talk. I was in so much pain in my head resulting in (incomplete sentence)."" Lab work included the only thing is the PCR swabbing. No blood test. Registered Nurse further stated, ""I don't know if that is important. But I will tell you and if it is you can send me the questions. I do have a history of Autoimmune. So my Physician thought that this was just like an enhancement of like my bodies reaction I have Chronic Lyme and I have lupus like my ANA has

always been stressful. But we think that it is a family thing. No treatment for the Lyme. I did a lot of antibiotic and a lot of naturopathic stuff but that is in the past. But anyhow for anything else what I did was when I got the injection they said try and just take Tylenol not Ibuprofen but there was no way I was going to make it through with just that . So I took Ibuprofen. I called my Physician yesterday morning because I was not sure about what was is happening and I thought it might be secondary sinus infection or something else going on and it reassured me that it is definitely due to the vaccine. He said it is just your body's reaction, take the Ibuprofen, hydrate. Had me take what I had in my house Tigan for nausea. So I was extremely nauseous from the severity of the headache."" Registered Nurse stated, ""I just wanted to let you know what happened and the intensity of what it was because normally I would expect a headache. But this was a 'go dated'. Registered Nurse stated, ""I guess the only question that I have is so do my work has this question and I was going to call my doctor tomorrow may be might know it better. I know that I have to take the second dose. But I understand the second round can be worse than the first. Is there anything that they are recommending that I can do may be prior to ease the reaction?"" The outcome of the events was unknown. Information on the Lot/Batch number has been requested.; Sender's Comments: The reported clinical manifestations including swelling face and head swelled, which was suspected as encephalopathy by the reporting nurse, was probably related to the bnt162b2 (BNT162B2, Pfizer COVID-19 vaccine), due to temporal relationship. The subject's underlying Chronic Lyme, Lupus and Autoimmune were likely the risk factors to the onset of the events. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory authorities, Ethics committees and Investigators, as appropriate."

"Swollen lymph nodes; blood pressure was 90/50; Chills; body aches; Fatigue; Joint pain; Bone pain; Headache; Swelling, pain, redness and soreness at the injection site; Swelling, pain, redness and soreness at the injection site; Swelling, pain, redness and soreness at the injection site; Tachycardia / heart rate was 144-152; painful to breath and she was grunting; also said that the injection site itched a little bit.; Fever; First dose on 17Dec2020, second does on 04Jan2021; This is a spontaneous report from a contactable nurse reporting for herself. A 35-year-old female patient received the first single dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) ((lot number was unknown) intramuscularly on 17Dec2020 at 0.3ml, and the second single dose (lot number EJ1685) intramuscularly on 04Jan2021 07:45 at 0.3ml, for COVID-19 prophylaxis. Medical history included ongoing diabetes. Her diabetes was diagnosed about 6 months ago (reported on 06Jan2021) and was well controlled. Her glucose was at 140 at the ER (emergency room) even after drinking a drink that had sugar in it. The patient's concomitant medications were not reported. The patient received the second dose on 04Jan2021 at 07:45 and experienced a severe reaction hours after she received it, and she ended up having to go the ER and that they were baffled about what happened. She reported her symptoms were: fatigue, joint pain mainly in her knees, bone pain that did not feel like muscle pain, headache, swollen lymph nodes in the left axilla, and swelling, redness, pain, and soreness in the left arm at the injection site and also said that the injection site itched a little bit. Her symptoms started about 9-10 at night on 04Jan2021. She said that she felt like with the second dose she noticed the soreness and pain and redness at injection site after about 2 hours after receiving the second dose, which was sooner than with the first injection.

The fever started with the chills and body aches. The chills and body aches started at 22:00 on 04Jan2021. She took acetaminophen and melatonin to try and sleep it off. Fever was after that at around midnight 04Jan2021 and she was burning in fever and her temperature was 104. She stated she started taking layers off and got out from under her covers. She had a sweater on when she took her temperature and her axillary temperature was 105. She said that she got into a hot shower because that was the only thing that provided comfort to her chills. She had not had any chills in about the last 12 hours though (as reported on 06Jan2021). She said that the body aches were so severe that she just sat in her bed and cried. She had tachycardia and she was grunting in pain. She was rotating ibuprofen and acetaminophen and then her fever was not as high. She stated that if her fever came back it was lower each time, and if she did not take the medications though, the bone pain was excruciating. She said that with the bone pain it was like no-one can hold her hand or hug her. Fatigue started at around midnight 04Jan2021. Her headache was at midnight. She felt like she had a headband on and was radiating down the back of her neck. She noticed the lymph nodes were swollen after she went to the ER at around 07:00-08:00 05Jan2021. She was walking with pillow under her arm, and if she moved or lifted her arm it hurt. She went to the ER at 01:00 05Jan2021. Her blood pressure was 90/50, her heart rate was 144-152 at rest, temperature was 102.8, O2 saturation was 95-96. She said that it was painful to breath and she was grunting, but did not have any breathing issues. The nurse thought she was septic and notified the doctor. The nurse and the doctor did not think it was the vaccine and thought that she was COVID-19 positive. But after they tested her, she was negative for flu and COVID and they were baffled. They were unclear on what happened and did not think it was from the vaccine. They bolused her 1 liter of Normal Saline and gave her a dose of Fentanyl that minimally helped with the bone pain. She was also given 30mg of ketorolac (TORADOL) IV (intravenous) and that significantly improved her pain. She was there a total of 3 hours. She was admitted to the back area of the ER. She said that they drew labs and everything was within normal limits. Her CRP (C-reactive protein) was 30 and her lactate was at 1.5. She said that they told her that she was most likely having an immune response to the vaccine. Her heart rate and blood pressure came to a more normal range and everything returned to baseline. Her heart rate was 109. She was told to rotate paracetamol (TYLENOL) and ibuprofen for at least the next 24 hours and hydrate. The events fever, chills, fatigue, joint pain, bone pain, headache, swollen lymph nodes, and swelling, pain, redness and soreness at the injection site were serious due to hospitalization from 05Jan2021 to 05Jan2021. The patient was recovering from fever, chills, joint pain, headache, heart rate and blood pressure, not recovered from fatigue, bone pain, swollen lymph nodes and swelling, pain, redness and soreness at the injection site. The event swollen lymph nodes worsened. The outcome of ""injection site itched a little bit"" was unknown. The reporter considered the events fever, chills, fatigue, joint pain, bone pain, headache, swollen lymph nodes, and swelling, pain, redness and soreness at the injection site were all related to the vaccine; Sender's Comments: Based on temporal association, the causal relationship between BNT162B2 and the events pyrexia, chills, fatigue, pain, arthralgia, bone pain, headache, lymphadenopathy, vaccination site erythema, vaccination site swelling, vaccination site pain, blood pressure decreased, tachycardia, grunting and vaccination site pruritus cannot be excluded. The information available in this report is limited and does not allow a medically meaningful assessment. This case will be reassessed once additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern

identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate."

Death; This is a spontaneous report from a contactable Physician. An elderly male patient received BNT162B2 (COVID vaccine), via an unspecified route of administration on an unspecified date in Dec2020 at single dose for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient experienced death in Jan2021. It was unknown if an autopsy was performed. It was unknown if any treatment was received for the event. It was unknown if the patient was diagnosed with COVID prior vaccination or if the patient had been tested for COVID post vaccination. Seriousness criteria for the event was reported as death and hospitalization. Pfizer is a marketing authorization holder of [COVID vaccine] in the country of incidence or the country where the product was purchased (if different). This may be a duplicate report if another marketing authorization holder of [COVID vaccine] has submitted the same report to the regulatory authorities. Information about lot/batch number has been requested.; Sender's Comments: Current information is very limited for full assessment. Further information such medical history, concomitant medications, concurrent illness and event term details especially death cause and autopsy results are needed for meaningful evaluation. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.; Reported Cause(s) of Death: Death

"The lip starting ripping and the face started itching; The lip starting ripping and the face started itching; It started spreading from the ear to the neck, it started itching bad and getting hive in that area; having trouble in breathing because it was swelling up; having trouble in breathing because it was swelling up; The lip was swelled to red and then it started to going up the jaw; The lip was swelled to red and then it started to going up the jaw; This is a spontaneous report from a contactable consumer (patient). A 64-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (Lot#: EJ1686, expiration date: Mar2021) via an unspecified route of administration on the arm right in Dec2020 at single dose for COVID-19 immunisation. Medical history included ongoing blood pressure high. Concomitant medication included lisinopril taken for blood pressure high. The patient had the BNT162B2 on Thursday morning (Dec2020) and Thursday evening the patient had a reaction to that, the lip was swelled to red and then it started to going up the jaw. So the next day it was in the jaw and in the lip and then the lip starting ripping and the face started itching and that's didn't go away and then yesterday it started spreading from the ear to the neck, it started itching bad and getting hive in that area. The patient went to the emergency room, consumer stated that she had nurse practitioner that called her on a steroid (treatment). The consumer stated, ""the thing she called her also in an Epi Pen in case she has started having trouble in breathing because it was swelling up. The patient didn't have to end up using that but she just has to use in case she has"". Treatment was received for the events. The outcome of the events was unknown."

COVID-19; COVID-19; Pneumonia; respiratory failure; This is a spontaneous report from a contactable consumer. An 80-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19

VACCINE) via an unspecified route of administration on 02Jan2021 for COVID-19 immunization. Medical history included Alzheimer's and others. No known allergies. Concomitant medications included unspecified medications. The reporter's mother in law was tested for COVID-19 at a nursing facility on 25Dec2020 and she was negative. On 02Jan2021, she received the first dose of Pfizer vaccine. On 04Jan2020, she developed a high fever, needed oxygen and was positive for COVID-19. Date of death was 04Jan2021. The cause of her death was listed as pneumonia, respiratory failure and COVID-19. No autopsy performed. No treatment received. No one knew if the vaccination contributed to her death. It was hard to know if her death was due to the administration of the vaccine or it exacerbated the COVID19 symptoms which led to her death. Since this was unknown, it could have been a possibility. The reporter wanted to give us this information because we might want to consider having high risk population, patients with underlying conditions, older population tested for COVID-19 prior to the vaccination, as this is not currently a recommendation or a requirement. All is very new and they are all learning so the reporter wanted to share this information with us. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. There are medications the patient received within 2 weeks of vaccination. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has been tested for COVID-19. The outcome of the events was fatal. Information about Lot/Batch has been requested.; Sender's Comments: The association between the fatal event lack of effect (pneumonia, respiratory failure and COVID-19) with BNT162b2 can not be fully excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.; Reported Cause(s) of Death: Pneumonia, respiratory failure and COVID-19; Pneumonia, respiratory failure and COVID-19; Pneumonia, respiratory failure and COVID-19; Pneumonia, respiratory failure and COVID-19

he passed away; not responsive; mind just seemed like it was racing; body was hyper dried; Restless; not feeling well; ate a bit but not much; kind of pale; Agitated; Vomiting; trouble in breathing; This is a spontaneous report from a contactable consumer (brother of the patient). A 54-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, on 04Jan2021 (at the age of 54-years-old) as a single dose for COVID-19 immunization. Medical history included diabetes and high blood pressure. Concomitant medications included metformin (MANUFACTURER UNKNOWN) taken for diabetes, glimepiride (MANUFACTURER UNKNOWN) taken for diabetes, lisinopril (MANUFACTURER UNKNOWN), and amlodipine (MANUFACTURER UNKNOWN). The patient experienced not feeling well, ate a bit but not much, kind of pale, vomiting, trouble in breathing, and agitated on 04Jan2021; body was hyper dried and restless on 05Jan2021; mind just seemed like it was racing on 06Jan2021; and not responsive and he passed away on 06Jan2021 at 10:15 (reported as: around 10:15 AM). The clinical course was reported as follows: The patient received the vaccine on 04Jan2021, after which he started not feeling well. He went right home and went to bed. He woke up and ate a bit but not much and then was kind of pale. The patient then started to vomit, which continued throughout the night. He was having trouble in breathing. Emergency services were called, and they took his vitals and said that everything was okay, but he was very agitated; reported as not like

this prior to the vaccine. The patient was taken to urgent care where they gave him an unspecified steroid shot and unspecified medication for vomiting. The patient was told he was probably having a reaction to the vaccine, but he was just dried up. The patient continued to vomit throughout the day and then he was very agitated again and would fall asleep for may be 15-20 minutes. When the patient woke up, he was very restless (reported as: his body was just amped up and could not calm down). The patient calmed down just a little bit in the evening. When the patient was awoken at 6:00 AM in the morning, he was still agitated. The patient stated that he couldn't breathe, and his mind was racing. The patient's other brother went to him and he was not responsive, and he passed away on 06Jan2021 around 10:15 AM. It was reported that none of the symptoms occurred until the patient received the vaccine. Therapeutic measures were taken as a result of vomiting as aforementioned. The clinical outcome of all of the events was unknown; not responsive was not recovered, the patient died on 06Jan2021. The cause of death was unknown (reported as: not known by reporter). An autopsy was not performed. The batch/lot number for the vaccine, BNT162B2, was not provided and has been requested during follow up.; Reported Cause(s) of Death: not responsive and he passed away

Acute appendicitis; Severe acute abdominal pain; Chills; Fever; This is a spontaneous report from a contactable Nurse (patient). A 42-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (expiration date Mar2021, incomplete lot number L0140, not sure the first letter it is C or E), via an unspecified route of administration on 23Dec2020 at single dose for covid-19 immunization. None medical history. Concomitant medication included escitalopram oxalate (LEXAPRO). The patient experienced a little bit chills and fever she felt coming exactly on the 26th but she expected that and that was all fine but patient ended up in (Incomplete sentence). She went to work on 30th December and had some onset of severe acute abdominal pain and she ended up in an emergency appendectomy by 6 O'clock that evening. So she had an acute appendicitis and she did some research and it says that she can be listed in to the severe complications that the number in the vaccinated group was double back to the procedural group. The 26th it resided and patient felt better until the 30th when she have acute severe abdominal pain onset. She left work went for emergency room and she was in surgery within four hours. The outcome of events chills and fever was recovering, the other events was unknown. Because of the research that is on the website patient cannot help and think that it is related. Patient believed the relatedness of drug to events was related. Information about lot/batch number has been requested.; Sender's Comments: A possible contributory effect of suspect BNT162B2 on reported events cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate

26-year-old lady came in after she noticed she had bruises on her left hand after a CPR procedure at hospital. Patient was apparently in well health, she had received COVID-19 mRNA vaccine on January 7 at 3 PM, she has taken 2 pills with ibuprofen and tylenol for pain in right deltoid following vaccination. She was doing the CPR at 1:00 this afternoon, and she noticed that her left dorsum had some bruises. She took day off and went home and noticed that she also had bruises in both medial thighs, above the

knee and some bruises in scalp. Patient presented to the Emergency Room 1/9/2021 ~6PM and platelet count was found to be 2x10^3/uL. Patient required transfusion of 7 units of platelets, steroids, and IVIG.

SOB, Sleeplessness,

Scratchy throat, dizziness and eventually feeling like her throat is closing in

Patient was reported to be deceased at home by law enforcement on 1/7/21

"Patient presents with abdominal pain that started in the middle of the night. Had first COVID vaccine the previous day. Patient states the pain is intermittent ""comes and goes"" ""cramping"" ""pressure and bloating"" feeling. Patient states her normal bowel movements are 12 times per day. The last time she went was this morning. She is concerned about an ""obstruction"" Patient states she has ""some nausea"" She states she has ate and drank normally today. Patient has a history of ulcerative colitis and a complete colectomy with a ileal rectal pouch. She has had abdominal pain since this morning which is crampy, associated with nausea and recurrent vomiting. She normally has 6-12 bowel movements a day, but none since this morning. She does feel her abdomen is distended as well. The last time she had anything like this was when she developed pouch itis last spring, but that was much less painful than this. Her appendix is gone, but she believes she still has her gallbladder."

Went into the ED for bilateral hand and feet tingling. Worked up for possible Guillain Barre.

"Patient reported stroke-like symptoms as he was driving to work: started ""feeling funny"" with dizziness; progressed to feeling weakness in left side of face with facial drooping; tingling in left hand progressed to numbness and weakness in left arm and leg; difficultly coordinating motor movement in right arm; difficulty/ diminished speech ""tongue felt fat."" Symptoms resolved within appx 1+ hour from onset. Per patient, he was given an injection at the hospital (unsure for what?) and was discharged with a prescription for chlorthalidone 25mg daily, blood pressure was elevated."

There were no adverse reactions. Resident Died, she had a history of issues with her health prior to the vaccine.

Patient was found unresponsive at home with SpO2 20% 1/2/2021

1/6/21 8pm started with Nasuea, vomiting, diarrhea and fever. 1/7/21 started having intermittent chest pain in the morning. Then in the evening it became constant. Went to ER that evening due to chest pain. EKG showed t wave abnormality. 1st Trop was negative went from 0.08 to 2.3 Had 2 Echo's done and they were normal. Platelets were 85. Was discharged without chest pain. Troponin on discharge was 0.67 and platelets 61. Was admitted due to Chest pain and troponin. Attending provider diagnosed as myocarditis and thrombocytopenia R/T vaccine.

right after vaccine was given i got a head to toe hot flush. i thought it was just anxiety. within 2 minutes i had expolsive diarrhea, felt dizzy. looked in the mirror and saw my neck and chest covered in red rash and hives. felt hot flush again. dr came in noticed hives all over both my arms as well. felt sob and if someone was holding my neck with their hand. given benadryl and epi taken to local er.

Patient received the 1st dose of Moderna and was found deceased in her home the next day.

In the first 2 days (probably a couple of hours after the shot) I felt achiness, and it got worse body pains, joint pains and fatigue. Almost a week after I started getting sick, aches, shore throat, headache and fever (101.5F) that is when I went to the ED and it lasted about 2 days and then it went away. At the ED they did COVID and strep tests both negative. This was with my first dose and my second one the same thing happened.

Pfizer COVID-19 Vaccine A couple hours after the vaccination the patient experienced pain in the vaccine arm, headache, and feeling ache. Day 1 post vaccination patient experienced sore arm, headache, low grade fever, feeling ache, and GI symptoms with diarrhea. Day 2 post vaccination patient experienced sore arm, Migraine, and diarrhea. Day 3 post vaccine patient woke up with chest pain that radiated into her left arm and some weakness. Patient's blood sugar was >500 and was admitted to hospital for DKA.

My mother was given Pfizer vaccine on Thursday and she died 3 days later yesterday on Sunday!!!

Extremely tired went to bed at 8:30. At 11:00, tossed and turned until 12:16 a.m. Did not think she could stand up. Walked in the bathroom had pain in stomach, was very hot and freezing at the same time, was shaking. Head hurt was hurting so bad. Tried standing up from toilet, was passed out. Eye, half of face is bruised and swollen , eye shut for two days. More than forty minutes passed before she could call her husband. Does not remember anything because she was passed out. Husband came in and grabbed her, to get her back into bed. she could not stand. Went to ER at Hospital. Had CT scan, blood work , EKG, chest xray. Was still kind of out of it but was able to communicate with nurses. Face is still black and blue. Last night got up at 4:00 a.m. something was wrong with her throat. Felt like a walnut was in her throat. Went to doctor this morning. They said it was a reaction from the shot. Got an EpiPen, prednisone. Call them in 2 days to let them know how she's doing and also wear a heart monitor because they do not know how to take care of her, Has had vision blurriness in both eyes. Has not felt well at all.

Difficulty breathing, death.

Noted left lymph nodes left neck. On January 7, 10 days post injection had acute appendicitis requiring emergency appendectomy.

Metallic taste in the back of throat between 15-20 minutes post vaccination, noticeable swallowing and throat irritation at 20-25 minutes post vaccination, tongue and lip numbness and throat tightness at 25-30 minutes, dry hacking cough at 30 minutes. Treated in the ED approximately 1 hour post vaccination, at time of arrival in respiratory distress with subcostal retractions, coughing, speaking 1-2 word sentences, with tachycardia and tachypnea. Treated with IM epinephrine, IV solumedrol and IV Benadryl and IV Benadryl with marked improvement in symptoms.

Woke up 1/4/21 with right sided facial weakness consistent with Bell's Palsy. Started high dose Prednisone and Valtex. Received IVIG infusion on 1/6/21 and 1/7/21. Mild improvement 1/11/21.

About 15 minutes after vaccine, hr 155, fever 102, covered in hives, sick to her stomach and a pounding headache. Has had headache since then and been extremely fatigue.

Anaphylaxis within 5 minutes of dose given. Tachycardia 130-140s, hot body temperature, trouble swallowing, lightheaded/dizzy, ekg changes, feeling like I was going to pass out even when in bed. IV fluids, benedryl, soul-medrol, famotadine and IM epi given.

Trouble swallowing, tingling around the mouth within 5 minutes of vaccine administration. IV started with 25mg Benadryl within 5 minutes of symptom onset. Transfer to ER at 1430. Symptoms unresolved, hr - 120, bp 140/100, O2 sats 100, resp: 21 Additional 25mg Benadryl, 125mg solumedrol, 1ml Ativan given IV at 1435. Symptoms began to resolve, patient discharged at 1600 to home with instructions to return if needed. Patient returned to ER Sunday January 10 at 1300 complaining of throat tightness. Patient was seen by doctor, no acute distress and airway issues seen. Patient elected to stay for 50mg benadryl and 40mg prednisone PO. Patient was discharged to home with script for 40mg prednisone q day for 3 days. Patient feels any remaining allergic symptoms have resolved.

RESIDENT 1ST DOSE OF MODERNA VACCINE ADMINISTERED ON 01/04/2021 AT 8:30PM, RESIDENT FOUND UNRESPONSIVE ON 01/05/2021.

Herpatic infection left eye causing a herpatic dendrite

One week after administration, I had sudden onset inability to move left arm. I was transported to ER immediately. Treated, scanned with CT of brain, MRI of brain, c-spine and brachioplexus. In hospital for 2 days and no answers. Still no answers to left arm paresthesia and proprioreceptor deficits. Spreading into left leg and mild systemic symptoms. I have been to the ER, seen by primary physician, Physiatrist and Neurology and Occupational Therapy. I am scheduled for many more appointments and trying to find and answer.

COVID-19/Caller received the first dose of the vaccine and she tested positive with Covid; COVID-19/Caller received the first dose of the vaccine and she tested positive with Covid; arm pain; she felt like crap the night; chills; This is a spontaneous report from a contactable pharmacist (patient). A 51-year-old female patient received her first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number: EH9899, expiration date Mar2021), intramuscular on left arm, on 18Dec2020 at 0.3 mL, a single dose for vaccination. The patient medical history and concomitant medications were not reported. The patient received the first dose of the vaccine and she tested positive with Covid. She received the Pfizer Covid vaccine on 18Dec2020. She was exposed to the virus through close personal contact right around this same time-frame and did develop the virus herself. She wanted to know if there were any recommendations regarding her needing to get the second dose in series. She stated that her husband, who was not vaccinated, had the virus and developed more serious symptoms than she did. She is concerned about worsening side effects with the second dose and stated that she felt like crap the night after her first dose with chills and arm pain. The patient tested positive for COVID-19 on 26Dec2020. Specific test name was unknown, but she knows it was not a rapid test. She is scheduled to get the second dose of the Pfizer COVID-19 Vaccine on 08Jan2021. She called to ask if she should or should not get the second dose relative to the COVID-19 diagnosis. She has not been able to find the

information she is asking about. The outcome of the event of Covid-19 was recovering while other events was unknown. The Covid-19 was assessed as unrelated to the suspect drug.; Sender's Comments: No effect of the suspect vaccine could be reasonably achieved to protect from the targeted infection/disease due to the very short time lag. Instead, the positive COVID represents the pre-existing infection prior to vaccine use. Further information like confirmative COVID 19 Nucleic acid/ PCR test together with any associated symptoms are needed for full medical assessment. COVID-19 antigen test positive.

tested positive for Covid-19 after receiving 1st dose; COVID-19 PCR test: positive on 31Dec2020, Covid-19 rapid test: positive on 31Dec2020; smell was gone/no sense of smell; no sense of taste; This is a spontaneous report from a contactable nurse (patient). A 59-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number EH9899, expiry date unknown) via unspecified route of administration in the left arm on 26Dec2020 at single dose for Covid-19 immunization. Medical history included cholesterol, blood pressure (controlled blood pressure), hypothyroidism. Concomitant medications included TELMISARTAN (MICARDIS) for blood pressure and ATORVASTATIN (LIPITOR) for cholesterol; both on unspecified date. The patient was asking if she was able to get the 2nd dose of vaccine, since she was tested positive for Covid-19 (31Dec2020) after receiving 1st dose. The patient was asking information about missing 2nd dose and when can she get it and wanted to know if it was still okay to get the second dose. The patient asked if she needed to have a test negative for covid-19 prior to receiving 2nd dose. The patient experienced no sense of taste and actually realized it on 29Dec2020 that her food was not tasting good. The patient didn't notice her smell was gone until she was cooking the chicken curry, she even tested it out by spraying some perfume, she has no sense of smell on 30Dec2020. The patient informed that both her taste and smell returned 02Jan2021 but was not recovered completely. The patient underwent lab tests and procedures which included A1C: 6.4 on 12Dec2020, COVID-19 PCR test: positive on 31Dec2020, Covid-19 rapid test: positive on 31Dec2020. The patient informed that she had no positive test before the Covid-19 vaccine, she took Covid-19 antibody test in Apr2020 and it was negative. The outcome of the events tested positive for Covid-19 after receiving 1st dose was unknown, no sense of taste and smell was gone/no sense of smell was recovered with sequel on 02Jan2021.; Sender's Comments: No effect of the suspect vaccine could be reasonably achieved to protect from the targeted infection/disease due to the very short time lag. Instead, the positive COVID represents the pre-existing infection prior to vaccine use.

congestion; positive for Covid-19; positive for Covid-19; This is a spontaneous report from a contactable healthcare professional (patient). A 61-years-old female patient received her first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number EH9899, expiration date not reported), via an unspecified route of administration on left arm on 31Dec2020 at 08:15 at a single dose for Covid-19 immunization/precaution because she works with hospice patients. Medical history included blood pressure (abnormal), diabetes, cholesterol (abnormal), and acid reflux, all are ongoing. The patient has no family medical history. Concomitant medications included amlodipine besilate, benazepril hydrochloride for blood pressure taking about 4-5 years, metformin for diabetes taking about 5 years, rosuvastatin for cholesterol Taking about 5 years, pantoprazole for acid reflux taking 5 years, and vitamin D as supplement taking for 3 years. No previous immunization nor vaccines administered on

same date of the suspect drug. The patient was calling about the COVID vaccination, which she received on Thursday, 31Dec2020. Her husband tested positive on Thursday, so she took the test on Thursday after she took the vaccination and they just told her today, 04Jan2021, that she is positive for Covid-19. She wanted to know if that was going to mess up her vaccination in any way and if there are recommendations for second dose. She is a CNA. There was no prescriber. She received it because she works with hospice patients. Test was administered on 31Dec2020. COVID Test resulted on 10:00 04Jan2020 as positive. ER or physician's office required: She just went to get a COVID test when her husband tested and they gave her a azithromycin (Z-PACK) 250 mg because she had congestion. Take two tabs first day and then one daily for 4 more days. She is taking last one today (04Jan2021). Outcome of the events was unknown.; Sender's Comments: A causal association between reported events and BNT162B2 cannot be excluded.

slight sore arm; slight chest congestion; positive COVID-19 test after first dose of vaccine; positive COVID-19 test after first dose of vaccine; Fever; cold like symptoms; stuffy head; horrible headache; Cough; This is a spontaneous report from a contactable healthcare professional (patient) from a Pfizer-sponsored program, Pfizer First Connect. A 44-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, on 16Dec2020 as a single dose (reported as 0.3 mL) (at the age of 44-years-old) for COVID-19 immunization. Medical history included ongoing hypothyroidism, one thyroid gland removed due to a nodule on an unspecified date (years ago), ongoing acid reflux, ongoing hypercholesteremia, ongoing fluid retention, and ongoing history of headaches. Concomitant medications included levothyroxine sodium (SYNTHROID) taken for hypothyroidism and for one thyroid gland removed due to a nodule from an unspecified date and ongoing, dexlansoprazole (DEXILANT) taken for acid reflux from an unspecified date and ongoing, atorvastatin (LIPITOR) taken for hypercholesterolemia from an unspecified date to an unspecified date, and hydrochlorothiazide (MANUFACTURER UNKNOWN) taken for fluid retention from an unspecified date and ongoing. Additional concomitant medications included unspecified vitamins. The patient had a positive COVID-19 test after first dose of vaccine on 01Jan2021; cold like symptoms, stuffy head, horrible headache, cough, and fever on 31Dec2020; slight chest congestion on 02Jan2021; and slight sore arm on an unspecified date. The events, stuffy head and horrible headache, were reported as medically significant. The events, cough, fever, and slight chest congestion, were reported as non-serious. The clinical course was reported as follows: It was reported that the patient was vaccinated on 16Dec2020, became symptomatic on 31Dec2020, and tested positive for COVID-19 on 01Jan2021. The patient stated that she became symptomatic one day prior to testing positive for COVID-19, on 31Dec2020. She initially had cold-like symptoms with a stuffy head, cough and a horrible headache; the worst headache she had ever had. These symptoms occurred earlier in the day on the 31Dec2020. Then later that night about 10:00 PM, she had a fever with a body temperature of 102 degrees Fahrenheit. Her body temperature had been normal at 98 degrees all day that day until that night. She also had slight chest congestion and then was fever free for over 48 hours. The patient stated that she had a history of headaches and can tolerate a headache. The headache started 31Dec2020 and was significant. It was reported that after the vaccine, she had no other symptoms other than a slight sore arm, which lasted a day; maybe 24 hours after she received the vaccine. The patient stated that she does not think any of the other symptoms, other than the sore arm, have anything to do with the

vaccine. The clinical outcome of positive COVID-19 test after first dose of vaccine and slight sore arm was unknown; cold like symptoms, horrible headache, and cough was recovering; fever was recovered on 02Jan2021; and stuffy head and slight chest congestion was not recovered. The reporter assessed the causality assessment between the events, positive COVID-19 test after first dose of vaccine, cold symptoms, stuffy head, cough, horrible headache, fever, and slight chest congestion, as unrelated. The batch/lot number for the vaccine, BNT162B2, was not provided and has been requested during follow up.; Sender's Comments: The efficacy of a drug varies from one patient to another and can be affected by different factors; however, a contributory role of the suspect drug BNT162B2 to the reported events cannot be ruled out. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

suspected COVID-19; suspected COVID-19; Fatigue; Body aches; Headache; chills; The initial case was missing the following minimum criteria: no adverse event. Upon receipt of follow-up information on 04Jan2021, this case now contains all required information to be considered valid. This is a spontaneous report from a contactable healthcare professional, the patient, from a Pfizer sponsored program IBCC (Inbound Call Center for HCPs). A 32-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot Number: EK5730), intramuscular in the left deltoid on 15Dec2020 at 21:00 (at the age of 32-years-old) as a single dose for COVID-19 immunization. Medical history included ongoing hypertension from 2009 and COVID-19 from 10Jun2020 to an unknown date in 2020. Ongoing concomitant medications included fosinopril (MANUFACTURER UNKNOWN) taken for hypertension from 2017. The patient did not receive any other vaccines on the same day as the BNT162B2 vaccine. On 19Dec2020, shy of about 96 hours of getting the vaccine, the patient experienced fatigue, body aches, headache and chills. He did not have any fever. The patient stated that he recovered from the fatigue, body aches, headache and chills by 19Dec2020. The patient was fine from 19Dec2020 until 01Jan2021. On 28Dec2020, the patient had a COVID-19 PCR test that came back negative. On 01Jan2021, the patient suspected that he had COVID-19. He had a fever of 103.1 degrees Fahrenheit, body aches, chills like he was freezing to death, fatigue, diarrhea; however, he did not have nausea or loss of taste or smell. He had swollen lymph nodes, but no sore throat and his oxygen saturation was okay in Jan2021. He was also having chest pain but it was more like intercoastal pain. He stated that these current symptoms were significantly worse than the ones he had just after getting the vaccine and felt more like the symptoms he had when he had COVID-19 before on 10Jun2020 (positive IgG for COVID-19-tested in 2020). The patient had a COVID nasal swab (PCR) done at an urgent care (physician's office) on 02Jan2020 or 03Jan2020 and was awaiting the results. The clinical outcome of the suspected COVID-19 was not recovered.; Sender's Comments: A causal association between reported suspected COVID-19 cannot be excluded.

Patient complained of itching starting on her legs, which went upwards; Redness on her arms, neck, face; Redness on her arms, neck, face; Redness on her arms, neck, face; Itching up to her scalp; Dry cough; Rash; This is a spontaneous report from a contactable nurse (patient). A 44-year-old non-

pregnant female patient received the first dose of BNT162B2 (Pfizer-Biontech Covid-19 Vaccine) at single dose, in the left arm, on 26Dec2020, at 09:00 AM, for COVID-19 immunisation. COVID-19 vaccine was administered at hospital. The patient had not received any other vaccines within 4 weeks prior to the BNT162B2 vaccine. Relevant medical history included asthma, hypertension, hypothyroidism, penicillin allergy, food allergy (melon and pineapple) and latex allergy. Concomitant medications, received within 2 weeks of vaccination, included omalizumab (XOLAIR), levothyroxine sodium (LEVOXYL), levocetirizine dihydrochloride (XYZAL), losartan and formoterol fumarate, mometasone furoate (DULERA). After covid vaccination, the patient was advised to stay 30 minutes for observation. On 26Dec2020 at 09:15, less than 15 minutes later, the patient complained of itching starting on her legs, which went upwards. The patient took 25 mg oral diphenhydramine hydrochloride (BENADRYL). She noted to have redness on her arms, neck, face, itching up to her scalp. By then she started to have a dry cough, removed her mask, nurse who was with her called for a rapid response team. Patient's epi pen was used, they then started IV and pushed emergency meds and transported to ED. Emergency room/department or urgent care was required. Another dose of epinephrine IM and additional meds were given. Placed on oxygen via non-rebreather with albuterol. Epinephrine drip started. Stabilized after 3 hours, stayed in observation for 12 hours then discharged to home. Around the clock 50 mg diphenhydramine hydrochloride (BENADRYL) at home x 2 days, then levocetirizine (ZYXAL) thrice daily x 7 days to control itching and redness/rash. Other treatment included steroids, pepcid. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, the patient has been tested for COVID-19 (PCR, Nasal Swab) on 26Dec2020 and the result was negative. Clinical outcome of the adverse events was recovering at time of this report. Information on the lot/batch number has been requested.; Sender's Comments: Based on a close temporal association, a causal relationship between reported events and BNT162B2 vaccine cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

anaphylaxis; This is a spontaneous report from a contactable consumer. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), on an unspecified date as single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced anaphylaxis on an unspecified date. The outcome of anaphylaxis was unknown.

tested positive for COVID-19; tested positive for COVID-19; loss of taste and smell; loss of taste and smell; excruciating headache; runny nose; congestion; shortness of breath when she started talking; having aches and pains; lightheaded, experienced dizziness; tied; This is a spontaneous report from a contactable consumer(patient). The 58-year-old female patient received first dose BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EJ1685, intramuscular injection), intramuscularly in left arm on 23Dec2020 at single dose for COVID-19 vaccination in nursing home. Medical history included she had a right knee injury so she had some inflammation, She had stomach issues in the past-Barrett's syndrome, H. pylori(Helicobacter infection), GERD(Gastrooesophageal reflux disease), so,

Pantoprazole is just a maintenance medicine, she was stable right now. She had a Vitamin D deficiency at one point. Ongoing concomitant medication included meloxicam for inflammation, thyroid for thyroid(Thyroid disorder), pantoprazole for stomach issues, colecalciferol (VITAMIN D 3) for supplementation therapy. There was no vaccination within 4 weeks. She received her first vaccine on 23Dec2020. There no other vaccine received in the same day. By 26Dec2020, she started with symptoms and then she tested positive for COVID-19 on 29Dec2020. She felt horrible with an excruciating headache and was wondering if she was going to die now. She can really feel for the residents she works with who get it. Right now, she was hopefully going back to work next week, but she was wondering about the second vaccine. People are saying she got COVID-19 because of receiving the first vaccine and she was hoping it was not the case. Is it going to be an issue getting the second vaccine after testing positive? The caller declines to include her healthcare professional for this report, stating she has been talking with her doctors over the week. Her symptoms included runny nose, congestion, and what seemed like shortness of breath when she started talking. She started having aches and pains over the weekend. By Monday, 28Dec2020, there was loss of taste and smell, it was totally gone. She also was lightheaded, experienced dizziness, was tied. She went through a lot of symptoms which was shocking to her. She clarified these symptoms first began the morning of the 26Dec2020. Christmas she was fine, and then she to go out to get snow off of her car and do some running around on 26Dec2020 and she noticed she started having symptoms. When probed for outcome, the caller state she was most definitely feeling better. She was having some excruciating headaches and she has worked with her doctor on what they needed to do. She is still working with the doctor on her lightheadedness. She has set up a follow-up appointment, but she was feeling better. There was no emergency room nor physician office. Relevant test was none. It was also reported lot number was either EJ1685 or EJ1085, she can't tell. Outcome of loss of taste and smell was recovered, of dizziness was not recovered, of other events was recovering.

tested positive for COVID virus; tested positive for COVID virus; cold all day; tiny cough; chills; sweating/ woke up sweating wet; arm pain/Very sore arms; body aches; fever; some muscle aches; This is a spontaneous report from a contactable consumer(Patient's Wife). A 67-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration in left arm on 02Jan2021 13:30 at single dose for COVID-19 vaccination. There were no concomitant medications nor medical history. He did not receive any other vaccines that day or 4 weeks prior. No history of any other vaccines or events. He got his vaccine on Saturday(02Jan2021) at 1:30pm(13:30) and by 5:30pm(17:30) had very sore arms/arm pain, at 7:30pm(19:30) he had chills off and on and was sweating. He woke up soaking wet and did that on Sunday, but was feeling a little better today. He also experienced body aches and fever in Jan2021. Today is testing day at his work and he tested positive for COVID virus on 05Jan2021. Not sure if it's a coincidence. Again, he got the shot and then started having all these symptoms at 5:30 and 7:30. Now they are both on quarantine for the 10-14 days. He wanted to see if it's possible to test positive for the virus after getting the shot or is it just a coincidence. He also had some muscle aches in Jan2021. Last night (04Jan2021), he woke up again sweating, but not like on Saturday, but he got really warm and started to sweat a little, and on Sunday(03Jan2021) he was cold all day and had a tiny cough, but it wasn't significant. Ever so often she would hear him cough. All of a sudden patient would wake up sweating. Again, Saturday he soaked everything. There was no

Emergency Room nor Physician Office. Outcome of Very sore arms, sweating was recovering, of pain and fever was unknown, of other events was not recovered. Information on Lot/Batch has been requested.

a little bit of a cough.; headache; runny nose; Aside from her taste and smell still being gone; Aside from her taste and smell still being gone/loss of taste; fogginess; Patient had since tested positive; Patient had since tested positive; patient likely had exposure on 22Dec2020; This is a spontaneous report from a contactable physician. A female patient of an unspecified age received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 21Dec2020 at single dose for covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient likely had exposure on 22Dec2020. She showed the first covid symptoms on 31Dec2020. Patient experienced loss of taste, headache, fogginess, runny nose, and a little bit of a cough on unspecified date. Patient received her first covid dose on 21Dec2020. The first dose likely helped her, she has rapidly gotten better and was feeling much better today. Aside from her taste and smell still being gone. The patient was scheduled to receive her second dose on 11Jan2021. Patient had since tested positive. Caller clarified that the patient didn't get a test until 03Jan2021. Outcome of events taste and smell still being gone was not recovered, and outcome of other events was unknown. Information on batch/lot number was requested.; Sender's Comments: No effect of the suspect vaccine could be reasonably achieved to protect from the targeted infection/disease due to the very short time lag. Instead, the positive COVID likely represents the pre-existing infection prior to vaccine use. Further information like confirmative COVID 19 Nucleic acid/ PCR test together with any associated symptoms are needed for full medical assessment.

tested positive; tested positive; runny nose; headache; This is a spontaneous report from a Pfizer-sponsored program Pfizer First Connect. A contactable consumer reported that a 51-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced tested positive, runny nose, headache after getting the vaccine on an unspecified date with outcome of unknown. This report is considered as non-serious.

"tested positive for COVID-19; tested positive for COVID-19; This is a spontaneous report from a contactable nurse (patient) from a Pfizer-sponsored program Pfizer First Connect. A 55-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EK5730), via an unspecified route of administration in the right arm on 18Dec2020 at single dose for covid 19 immunisation as healthcare professional and husband was high risk. Medical history included hypertension from 2019 and ongoing. Concomitant medication included amlodipine besilate (NORVASC, 5 mg) from 2019 and ongoing for high blood pressure. The patient experienced tested positive for covid-19 on 03Jan2021 with outcome of not recovered, congestion and headache in Jan2021 with outcome of unknown. The patient underwent lab tests and procedures which included COVID test on 03Jan2021 and the results came back positive on 04Jan2021. The patient was scheduled to receive her second injection on 08Jan2021. Since her first injection she had tested positive for COVID-19. The second dose had to be given a certain amount of days after the first. She would be outside that window. She would like to

know if there is any guidance regarding the if/when she should get the second dose. The reporter would like to know if she waits longer than the recommended 21 days to receive her second dose of the COVID-19 vaccine would she need to restart the vaccination series. The reporter said this was not serious as she only had congestion and headache with treatment: using over the counter stuff. Event relatedness with COVID vaccine was unknown.; Sender's Comments: Based on available information, a possible contributory role of suspect BNT162B2 vaccine cannot be completely excluded for reported ""tested positive for COVID-19""."

it was like having Covid again; it was like having Covid again; body aches; dry mouth; generalized weakness; temp was 38.1 Celsius; head feels weird; can't sleep; decreased appetite; pain at the injection site; This is a spontaneous report from a contactable Nurse (patient). A 36-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 04Jan2021 at single dose for COVID-19 immunization. Medical history included COVID-19 from Mar2020 to an unknown date. The patient's concomitant medications were not reported. The patient experienced body aches, dry mouth, can't sleep, generalized weakness, decreased appetite, and pain at the injection site, temp was 38.1 Celsius, head feels weird in Jan2021. The patient got her first dose and was looking online to see the symptoms. She said that she saw that during the trials, people were experiencing the symptoms she was experiencing after the second dose and she was concerned. She said that she wanted to make sure her symptoms are ok and to make sure that the symptoms are not just caused from the booster, but also from the first dose. The caller said that her mom told her that someone died from the Pfizer vaccine. No further details provided. The patient was having body aches, could not sleep, her mouth is really dry, her temp was 38.1 Celsius, her head feels weird, she has generalized weakness, pain at the injection site, and decreased appetite. She said that it was like having Covid again. She said that she had Covid back in Mar2020. The patient underwent lab tests and procedures which included body temperature: 38.1 centigrade. The outcome of all the events was unknown. The events were reported as non-serious. Information on the lot/batch number has been requested.; Sender's Comments: No effect of the suspect vaccine could be reasonably achieved to protect from the targeted infection/disease due to the very short time lag. Instead, the suspected COVID likely represents a pre-existing infection prior to vaccine use. Further information like confirmative COVID 19 Nucleic acid/ PCR test is needed for full medical assessment.

she is pregnant as well; she reported to be diagnosed positive for COVID last 01Jan2021 after showing symptoms on 31Dec2020; she reported to be diagnosed positive for COVID last 01Jan2021 after showing symptoms on 31Dec2020/tested positive for COVID-19; This is spontaneous report from a contactable Other Health Professional (patient) via a Pfizer Sponsored Program. A 29-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot# EJ1685), intramuscularly in right deltoid on 23Dec2020 14:30 at single dose for COVID-19 vaccination while pregnant. Medical history was none. Concomitant medication included ongoing ascorbic acid, betacarotene, calcium carbonate, colecalciferol, docosahexaenoic acid, ferrous fumarate, folic acid, nicotinamide, pyridoxine hydrochloride, riboflavin, thiamine mononitrate, tocopheryl acetate, vitamin b12 nos, zinc oxide (PRENATAL MULTIVITAMIN + DHA, Prenatal Multi + DHA), one soft gel, every morning as prenatal medication. The reporter was asking for recommendations for her in taking the second dose as she

reported to be diagnosed positive for COVID last 01Jan2021 after showing symptoms on 31Dec2020. She received the first dose of the vaccine last 23Dec2020. She is asking if she should wait 90 days before taking the 2nd dose. Agent has a physical therapist on the phone. She had her first dose of the COVID vaccine on 23Dec2020. She started to show symptoms of COVID on 31Dec2020. She tested positive on 01Jan2020. Caller wants to know does she need to wait 90 days for the second dose. Caller wanted to add she is pregnant as well. She declined to include a healthcare professional for the report. The caller states she started to feel symptoms towards the end of the day on 31Dec2020. She clarifies she felt like she was having a cold coming on. She had some congestion. When probed for outcome, caller stated it had improved quite a bit. She had been improved but today, its kind of like she had a cold again, but that had improved. Vaccination Facility Type: Hospital. Vaccine Administered at Military Facility: No. Prior Vaccinations (within 4 weeks): None within 4 weeks. Additional Vaccines Administered on Same Date of the Pfizer Suspect: None. Relevant Tests: None. Investigation Assessment: Yes. Is a sample of the product available to be returned, if requested (Y/N): Vaccine was administered in hospital. No AE required a visit to emergency room and physician office. The reporter stated her symptoms have been pretty mild. The patient underwent lab tests and procedures which included COVID Fast-acting (rapid) test: positive on 01Jan2021. Outcome of events was recovering.; Sender's Comments: Based on available information, a possible contributory role of suspect BNT162B2 cannot be completely excluded

She did a rapid antigen test and was positive; She did a rapid antigen test and was positive; her arm hurt after vaccination; she lost taste; This is a spontaneous report from a contactable Consumer. An adult female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 04Jan2021 at single dose for COVID-19 immunization. The patient medical history was not reported. The patient's concomitant medications were not reported. Friend shared that the patient's arm hurt after vaccination and the following day she lost taste. She did a rapid antigen test and was positive. Adverse event start date was 04Jan2021. No treatment was received for the adverse event. AE resulted in doctor or other healthcare professional office/clinic visit. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had been tested for COVID-19. Test name: antigen (positive). Outcome of the events was not recovered. Information on the lot/batch number has been requested.

"Received the Pfizer COVID-19 on 21Dec2020. I got Covid from a family member, sore throat, felt like a flu or bad cold,headache, body aches and sinus issue. She now has congestion and cough; Received the Pfizer COVID-19 on 21Dec2020. I got Covid from a family member, sore throat, felt like a flu or bad cold,headache, body aches and sinus issue. She now has congestion and cough; This is a spontaneous report from a contactable health care professional nurse, the patient. A female patient (nurse) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE) on 21Dec2020 as a single dose for COVID-19 vaccination. The patient had no known medical history. The patients concomitant medications were not reported. On an unspecified date the patient experienced I got Covid from a family member. She reported being symptomatic on 1Jan2021 started with a sore throat, felt like a flu or bad cold. She reported sore throat, headache, body aches and sinus issue. She now has congestion and cough. She had no issue when she got the vaccine. The patient will be getting the second dose 11Jan2021 and she would like to know if she is eligible to receive the second dose Pfizer Covid-19

Vaccine. The clinical outcome of the event was unknown . Information on the Lot number has been requested.; Sender's Comments: The reported ""got COVID from a family member"" after COVID-19 immunization is considered ineffective of BNT162B2, and the Company cannot completely exclude the possible causality between the reported event and BNT162B2 administration."

received the vaccine on December 17th and tested positive for Covid on December 27th/COVID PCR (polymerase chain reaction) test: positive on 28Dec2020; received the vaccine on December 17th and tested positive for Covid on December 27th/COVID PCR (polymerase chain reaction) test: positive on 28Dec2020; This is a spontaneous report from a Pfizer sponsored program Pfizer First Connect. A contactable nurse (patient) reported that a 65-year-old female patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EK5730), via an unspecified route of administration on 17Dec2020 11:00 in left deltoid at single dose for covid-19 immunization. Medical history included thyroid cancer from an unknown date and unknown if ongoing, bilateral thyroidectomy in 2014. Family Medical History: Father died of lung cancer. Mother died of cardiac arrest in 1972. Concomitant medication included levothyroxine sodium (SYNTHROID) for bilateral thyroidectomy. The patient received the vaccine on 17Dec2020 and tested positive for covid on 27Dec2020. The adverse events resulted in emergency room visit. The patient underwent lab tests and procedures which included tested positive for COVID on 27Dec2020, COVID PCR (polymerase chain reaction) test: positive on 28Dec2020. Vaccination facility type was hospital. No additional vaccines administered on same date of Pfizer suspect. Received COVID Vaccine on 17Dec2020. Tested positive for COVID in emergency room on 27Dec2020. Tested positive on a COVID PCR test on 28Dec2020. Prior vaccinations within 4 weeks was none. Caller received the first dose of the COVID Vaccine. Tested positive for COVID on 27Dec2020. Is about to get the second dose of COVID Vaccine and would like to know if she should proceed or wait. Since quarantine, she has had no fever. Is slightly short of breath and has a headache. Works in COVID units in a hospital. Wants to make sure she can receive the second dose. Stated she had no adverse reaction to the COVID Vaccine unless an adverse reaction can occur two weeks after. Is attributing the shortness of breath and headache to testing positive for COVID. Shortness of breath and headache only occurred after testing positive for COVID. Reason she went to the hospital is because she lost her sense of smell. She got tested and was positive for COVID. Lost sense of smell, went to Emergency Room, and notified doctor of positive test the following day, 28Dec2020. Clarified she just went to the emergency department to get tested for COVID and then went home. Was called with positive results in an hour. Caller wanted to know when she should proceed with getting her second dose of Covid vaccine. She is supposed to receive her second dose tomorrow. She thought she was going to take second dose when I completely recovered. Caller asked if she waited until the 13th to receive second dose of Covid vaccine, would it be effective. She would feel more comfortable doing that. The outcome of events was unknown.; Sender's Comments: Based on the information available, a possible contributory role of the suspect BNT162B2 cannot be excluded for the reported COVID-19 based on the known safety profile. However the short duration of 9 days since the vaccine first dose is given it is unlikely patient would have fully developed immunity.

"Felt like he couldn't breath; He still has his sense of taste, but it is dulled; Recently got the vaccine and also came down with covid; Recently got the vaccine and also came down with covid; Exhaustion/feeling

tired; Loss of smell; Mild congestion/The congestion went into full nasal drainage; This is a spontaneous report from a contactable pharmacist (patient). A 30-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EL0140, Expiry Date: 31Mar2021), via an unspecified route of administration on 31Dec2020 13:00 at single dose for Covid-19 immunization. The patient had no relevant medical history and concomitant drug. The patient experienced recently got the vaccine and also came down with covid on 04Jan2021 00:30, mild congestion/the congestion went into full nasal drainage on 31Dec2020, loss of smell on 02Jan2021, exhaustion/feeling tired on 03Jan2021, felt like he couldn't breathe, he still has his sense of taste, but it is dulled on an unspecified date. He was a pharmacist. He received his first dose of the COVID vaccine on Thursday 31Dec2020 1pm. Shortly thereafter, he got the typical side effects of the vaccine that are posted. Then 2.5 days letter he no longer had a sense of smell. Everything he read said that he probably came in contact with COVID prior to administration. His questions was since he test positive for COVID, should he still get the second shot. He got it at a clinic. He did experience mild congestion which started by 6 o'clock. He started to notice slight congestion that kind of went away. Then, on Friday, about 24 hours later, he really noticed he had congestion. He took pseudoephedrine hydrochloride (SUDAFED) and paracetamol (TYLENOL). Then his sense of smell diminished with the congestion and felt like he couldn't breathe. On Saturday, he decided to not take medication. That was when he noticed he could not smell anything. He had full blown congestion. It probably took two days when he started to lose his sense of smell. He received the shot on Thursday. On Saturday, he lost his sense of smell. He still has his sense of taste, but it was dulled. Sunday, he was just exhausted and feeling tired. These were all listed as typical side effects except for the loss of smell. Saturday was the worst. The congestion went into full nasal drainage. On Sunday he had no sinus issues. He still hasn't gained his sense of smell back. The exhaustion set in Sunday 03Jan2020. He doesn't feel like any of the side effects are serious. The exhaustion has started to let up some so it is improving. He was pretty much back to normal. He just couldn't figure out why he had a loss of smell. He had a COVID rapid test on 04Jan2021 at 8:30 am (as reported). He received an alert and hour later that it was positive. He was wondering whether the loss of smell could be from the vaccine. The patient underwent lab tests and procedures which included COVID-19 rapid POC test: positive on 04Jan2021. The outcome of events for mild congestion/the congestion went into full nasal drainage was resolved on 03Jan2021, for loss of smell was not resolved, for exhaustion/feeling tired was resolving, for other events was unknown. The events were reported as non-serious.; Sender's Comments: Reported event ""recently got the vaccine and also came down with covid"" is considered possibly related to suspect BNT162B2 based on temporal association and known drug safety profile."

"Doctor had the 1st dose last 16Dec2020 then tested positive for COVID 17Dec2020; Doctor had the 1st dose last 16Dec2020 then tested positive for COVID 17Dec2020; This is a spontaneous report from a Pfizer-sponsored program Pfizer First Connect, received from a contactable physician (patient). A male patient of an unspecified age started to the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), unspecified route of administration on 16Dec2020 as a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The physician inquired ""is it recommended to receive the 2nd dose despite having antibodies and recovered from COVID?"" The doctor had the 1st dose on 16Dec2020 then tested positive for COVID

17Dec2020. He will receive the 2nd dose tomorrow 06Jan2021 and he was recovering. The patient underwent lab tests and procedures which included COVID test: result positive on 17Dec2020. Outcome of the event doctor had the 1st dose last 16Dec2020 then tested positive for COVID 17Dec2020 was recovering. Information on the lot/batch number has been requested.; Sender's Comments: The reported tested positive for COVID after COVID-19 immunization is considered ineffective of BNT162B2, and the Company cannot completely exclude the possible causality between the reported event and BNT162B2 administration."

"he received his first dose of the vaccine on 22Dec2020 and tested positive for Covid yesterday (04Jan2021).; he received his first dose of the vaccine on 22Dec2020 and tested positive for Covid yesterday (04Jan2021).; This is a spontaneous report from a contactable other healthcare professional (patient). A male patient of an unspecified age started to the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), unspecified route of administration on 22Dec2020 as a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. He received his first dose of the vaccine on 22Dec2020 and tested positive for COVID yesterday (04Jan2021). He stated his ""symptoms were general at first, then weakness after 10 days, chilly and muscle strain"". The other HCP reported ""do I need to take the second dose on 11Jan2021?"" The patient underwent lab tests and procedures which included COVID test: result positive on 04Jan2021. Outcome of the event he received his first dose of the vaccine on 22Dec2020 and tested positive for COVID yesterday (04Jan2021) was unknown. Information on the lot/batch number has been requested.; Sender's Comments: The reported positive test for Covid after COVID-19 immunization is considered ineffective of BNT162B2, and the Company cannot completely exclude the possible causality between the reported event and BNT162B2 administration."

she had COVID symptoms; she had COVID symptoms; chills; low grade fever; muscle joint pain; muscle joint pain; exhausted with a headache/ She doesn't want to get up she is tired; exhausted with a headache/slight headache; muscle joint pain which is a stabbing pain all over her body; feeling unwell; This is a spontaneous report from a contactable nurse (patient). A 47-year-old female patient receive first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EH9899, manufacturer: Pfizer), via an unspecified route of administration on 04Jan2021 14:00 at single dose for Covid-19 immunization. Medical history included ongoing childhood asthma, COVID 19 positive from 07Dec2020 to an unknown date. There were no concomitant medications. The patient felt like she had covid symptoms, chills, low grade fever, muscle joint pain, exhausted with a headache/ she doesn't want to get up she was tired, muscle joint pain, which was a stabbing pain all over her body, feeling unwell, all on 05Jan2021 05:00. The events were reported as non-serious. Caller had Sars-COV-2 infection diagnosed 07Dec2020. Received first dose of vaccine 04Jan2021 at 14:00. She was experiencing chills, low grade fever, muscle joint pain, exhausted with a headache. Asking for information on efficacy of second dose. She didn't have any side effects or anything initially. Then, 12 hours later at 5- 6 am she felt like she had COVID symptoms. She already had COVID so she known what it feels like. She was wondering how long would last. It was almost like having real COVID. She didn't have a prescribing doctor. She had COVID 07Dec2020. She was currently experiencing Chills, fever low grade, muscle joint pain which was a stabbing pain all over her body, and she was feeling unwell. She didn't want to get up

she was tired. She has a slight headache. This all started at 5 am on 05Jan2021. Even with medication. She has been taking paracetamol (TYLENOL) and excedrin. She cannot work if she wanted to, but these effects are not serious. Her fever has went down. The chills have stayed the same. She was diagnosed with childhood asthma. Caller asked about interval information between the SARS-COV-2 infection diagnosed 07Dec2020 and her first dose of vaccine 04Jan2021 at 14:00. The outcome of events for felt like she had covid symptoms was unknown, for low grade fever was resolving, for other events was not resolved.; Sender's Comments: There is not a reasonable possibility that event suspected COVID-19 is related to BNT162B2. There is no test done to confirm whether patient got COVID-19 or not. And symptoms that were suspected by reporter as due to COVID-19 occurred one after the vaccination, when vaccine was not expected to achieve the effect.

he tested positive for COVID; he tested positive for COVID; This is a spontaneous report from a Pfizer-sponsored program IBCC (Inbound Call Center for HCPs) from a contactable physician (patient). A 73-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on the right deltoid on 28Dec2020 09:30 at single dose for COVID-19 immunization. Medical history included diabetic (he is a diabetic, but he is not on medication for it) from Nov2018 and ongoing, hepatitis (not ongoing) (He had hepatitis virus for 15 to 20 years. It resolved 5 or 6 years ago. It corrected on it's own), supplement, hypertension and carcinoma of the lung. Everyone in his family has hypertension. His sister had carcinoma of the lung. There was no history of all previous immunization with the Pfizer vaccine considered as suspect. The patient did not have additional vaccines administered on same date of the Pfizer suspect. There were no prior vaccinations within 4 weeks. There were no adverse events following prior vaccinations. Concomitant medication included doxazosin mesilate (CARDURA), bisoprolol fumarate, hydrochlorothiazide (ZIAC), nystatin (STATIN) taken for lipids, colecalciferol (VITAMIN D) taken for supplement, fish oil, acetylsalicylic acid (BABY ASPIRIN), vitamin C [ascorbic acid]. The patient also received multivitamin. He has been on all concomitant medications for at least three to four years. The patient was scheduled for the next dose on 18Jan2021. On 05Jan2021 he tested positive for COVID. The event was reported as serious as medically significant. The patient was given the antibody infusion and steroid injection. It was outpatient. He was not admitted. Treatment was received for the events. The outcome of the events was unknown. Information on lot number/batch number has been requested.; Sender's Comments: Based on the information currently available, a lack of efficacy with the suspected vaccine BNT162B2 in this patient cannot be completely excluded. However individuals may not be protected until at least 7 days after their second dose of the vaccine.

she previously had a SARS-Cov-2 infection; she previously had a SARS-Cov-2 infection; This is a spontaneous report from a Pfizer-sponsored program Pfizer First Connect. A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunisation. Caller just had wisdom teeth extracted and was currently on antibiotics. She stated she previously had a SARS-Cov-2 infection on an unspecified date. Outcome of SARS-Cov-2 infection were unknown. Information on the lot/batch number has been requested.

following the receipt of the first dose of the COVID-19 vaccine; testing positive to COVID; This is a spontaneous report from a non-contactable other Healthcare Professional reported for herself. A female

patient of an unspecified age (Age: 47, Unit: Unknown) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 20Dec2020 at single dose for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient explained testing positive to COVID on the 29Dec2020, following the receipt of the first dose of the COVID-19 vaccine on the 20Dec2020. She stated that minor symptoms remain, and asked if she could receive the second dose of the vaccine due on the 10Jan2021. The outcome of the events was not reported. No follow-up attempts are possible; information about lot/ batch number cannot be obtained.; Sender's Comments: The reported testing positive to COVID after COVID-19 immunization is considered ineffective of BNT162B2, and the Company cannot completely exclude the possible causality between the reported event and BNT162B2 administration.

"Flu-like symptoms; Cold symptoms; tested positive for SARS-COV-2 infection; tested positive for SARS-COV-2 infection; muscle and body aches; muscle and body aches; loss sense of taste; Congestion nasal; Sore throat; Loss of smell; Sinus pressure; Headache; general fatigue; This is a spontaneous report from a contactable consumer (patient). A 28-year-old female patient received BNT162B2(PFIZER-BIONTECH COVID-19 VACCINE) Batch/lot number: EJ1685, via an unspecified route of administration on 17Dec2020 16:00 at single dose for COVID-19 immunisation. Medical history was none. There were no concomitant medications. The patient got the COVID Vaccine and the day after, was exposed to the virus, got sick right away and tested positive for the virus. The patient stated that she got vaccinated around 4pm, 17Dec2020. She was exposed to the virus by the same coworker twice on 18Dec2020 and then the next week, she believed, on 22Dec2020, the coworker tested positive for COVID. Patient stated that her symptoms started 24Dec2020. She did not think she had a fever as she did not feel feverish. She had flu like symptoms from an unspecified date with muscle and body aches from 25Dec2020. She lost her sense of taste and smell from 25Dec2020. She had cold-like symptoms from an unspecified date with congestion nasal and sore throat from 25Dec2020, sinus pressure and headaches from 24Dec2020. She had general fatigue from 24Dec2020 for a while. Patient had not had another COVID test since the one she had 28Dec2020, when she tested positive for COVID. She became symptoms-free on 03Jan2021. Patient was asking should she still get the 2nd dose of the COVID Vaccine. She was also concerned about the reaction her body was going to have to the vaccine after being sick. The patient had recovered from Flu-like symptoms and Cold symptoms on an unspecified date, recovered from muscle and body aches on 29Dec2020, recovered from loss sense of taste and loss of smell on 31Dec2020, recovered from congestion nasal, sinus pressure and headache on 03Jan2021, recovered from Sore throat on 01Jan2021, recovered from general fatigue on 02Jan2021. And outcome of ""tested positive for COVID after receiving the COVID Vaccine"" was unknown."

He received the 1st dose of the vaccine on Friday 18DEC2020. He developed COVID the following Thursday.; He received the 1st dose of the vaccine on Friday 18DEC2020. He developed COVID the following Thursday.; This is a spontaneous report from a contactable Physician (patient's wife). A 55-year-old male patient received the 1st dose of bnt162b2 (BNT162B2) on 18Dec2020 at single dose for Covid-19 immunisation. The patient medical history and concomitant medications were not reported. The patient experienced developed Covid on 24Dec2020 (reported as the following Thursday). The patient underwent lab tests and procedures which included Sars-Cov-2 test: developed Covid. He was

fairly symptomatic for 7 days but he was doing well now. The outcome of events was recovering. The reporter quereide whether he should receive the 2nd dose, which is due on 08Jan2021 or should it be deferred. Information on Lot/Batch number requested.; Sender's Comments: The Company cannot completely exclude the possible causality between the reported positive Sars-Cov-2 test, which is considered ineffective of BNT162B2, and the administration of BNT162B2.

began having Covid symptoms on 24Dec and tested positive for Covid on Christmas; began having Covid symptoms on 24Dec and tested positive for Covid on Christmas; Arm was sore; This is a spontaneous report from a contactable physician reported for herself. A 55-year-old female patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK5730), via an unspecified route of administration on 17Dec2020 at single dose for COVID-19 vaccination. Medical history was not reported. There were no concomitant medications. Patient had arm sore on 18Dec2020. She started having COVID symptoms on 24Dec2020. She tested positive on Christmas, 25Dec2020. She was asking if she should get the second vaccine. When she got the vaccine she didn't pay attention to the paperwork. She was busy. Her arm was a little sore for a day that was the only reaction she had. She was hoping when she developed COVID symptoms that she was not sick. She was not hospitalized, and she is wondering if maybe the vaccine helped her not get as sick, and not end up in the hospital. It was the first dose she received. She has no other medical conditions. All the previous agent did was read off information to her. It sounds to her like she should go ahead and get the second dose. Outcome of event Arm was sore was recovered in 19Dec2020, of others was unknown.; Sender's Comments: Based on available information, a possible contributory role of BNT162B2 vaccine cannot be completely excluded for reported events.

developed covid like symptoms a few days later/ tested positive on the 26th; developed covid like symptoms a few days later/tested positive on the 26th; This is a spontaneous report from a contactable physician. A patient of unspecified age and gender received the first dose bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 18Dec2020 at single dose for covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient received the vaccine on 18Dec2020 and developed covid like symptoms a few days later in Dec2020 and believed the patient was likely exposed. The patient was tested positive on 26Dec2020. The outcome of the events was unknown. Information about Lot/Batch number has been requested.; Sender's Comments: The reported covid like symptoms a few days with tested positive after COVID-19 immunization is considered ineffective of BNT162B2, and the Company cannot completely exclude the possible causality between the reported event and BNT162B2 administration.

tested positive for the COVID-19 virus; tested positive for the COVID-19 virus; This is a spontaneous report from a contactable nurse. A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient medical history and concomitant medications were not reported. The patient was tested positive for the COVID-19 virus on an unspecified date after being administered with the vaccine. The outcome of the event was unknown. Information on Lot/Batch number has been requested.; Sender's Comments: Based on the information currently available, a lack of efficacy with the suspected vaccine BNT162B2 in this patient cannot be completely excluded. Further

information like confirmative virus genome /nucleic acid detection is needed for meaningful medical assessment. ,Linked Report(s) : US-PFIZER INC-2021005630 same reporter and drug, different patient and event

"was tested and diagnosed positive for the SARS-CoV-2 infection; was tested and diagnosed positive for the SARS-CoV-2 infection; developed symptoms after being exposed at work on 27Dec2020; This is a spontaneous report from a contactable nurse. A male patient (reporter's husband) of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) as the first dose via an unspecified route of administration on 22Dec2020 at single dose for COVID-19 immunization. The patient medical history and concomitant medications were not reported. The patient got exposed as a first line nurse working in the emergency room. The nurse reports that her husband developed symptoms after being exposed at work on 27Dec2020 five days after being administered with the first dose of BNT162B2 and he was tested and diagnosed positive for the SARS-CoV-2 infection on 27Dec2020. The outcome of the events was unknown. Information about Lot/batch number has been requested.; Sender's Comments: There is not a reasonable possibility that reported ""tested and diagnosed positive for the SARS-CoV-2 infection"" is related to BNT162B2. Event occurred only 5 days after receiving first vaccine and patient was exposed to virus at work."

positive COVID test result; positive COVID test result; cough; This is a spontaneous report from a contactable consumer reporting for herself. A 49-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE) (lot number/expiration date: not provided), via an unspecified route of administration, on 16Dec2020 (at the age of 49 years old) as a single dose for COVID-19 vaccination. Relevant medical history and concomitant medication were not provided. On 21Dec2020, the patient experienced a strange cough. The patient reported that she received the first dose of COVID vaccine on 16Dec2020 and that she was then exposed to her husband who tested positive on 17Dec2020. Due to a strange cough, she was tested on 21Dec2020, which resulted in a positive COVID test result. The outcome of the events strange cough and positive COVID test was unknown. The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow-up.

Developed covid symptoms 21Dec, tested positive 26Dec; Developed covid symptoms 21Dec, tested positive 26Dec; This is a spontaneous report from a contactable physician reporting for a patient. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration on 18Dec2020 as a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient developed COVID symptoms 21Dec2020, tested positive 26Dec2020. The outcome of the event was unknown. The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up.; Sender's Comments: Based on the information currently available, a lack of efficacy with the suspected vaccine BNT162B2 in this patient cannot be completely excluded. However individuals may not be protected until at least 7 days after their second dose of the vaccine.

received the first dose of the Pfizer COVID vaccine on 28Dec2020 and tested positive for COVID 03Jan2021 (nasal swab) & symptomatic; received the first dose of the Pfizer COVID vaccine on

28Dec2020 and tested positive for COVID 03Jan2021 (nasal swab) & symptomatic; This is a spontaneous report from a contactable Nurse (patient). A female patient of unspecified age received BNT162B2 (Pfizer, lot number: EL0140) first dose on 28Dec2020 at single dose for COVID-19 immunization. Medical history and concomitant medications were not reported. Patient was tested positive for COVID 03Jan2021 (nasal swab) & symptomatic, her second dose of the vaccine is scheduled 18Jan2021. She was wondering if she still get the second dose. The outcome of the events was unknown.; Sender's Comments: The reported tested positive for COVID (nasal swab) & symptomatic after COVID-19 immunization is considered ineffective of BNT162B2, and the Company cannot completely exclude the possible causality between the reported event and BNT162B2 administration.

within 6 hours experienced severe chills and covid-like symptoms, she also tested positive for COVID-19; within 6 hours experienced severe chills and covid-like symptoms, she also tested positive for COVID-19; This is a spontaneous report from a contactable nurse. A 30-year-old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiry date were not reported), via an unspecified route of administration in left arm on 04Jan2021 11:30 at a single dose for COVID-19 vaccination. Medical history included allergies to Sulfa diagnosed in 2008, Allergies to Strawberries diagnosed when she was very young, Diamox allergy diagnosed in 2008, dyslexic, and Obesity but never been treated. Concomitant medication included levothyroxine (LEVOTHYROXINE), ascorbic acid, betacarotene, calcium sulfate, colecalciferol, cyanocobalamin, ferrous fumarate, folic acid, nicotinamide, pyridoxine hydrochloride, retinol acetate, riboflavin, thiamine mononitrate, tocopheryl acetate, zinc oxide (PRENATAL VITAMINS), zinc (ZINC), nd cetirizine hydrochloride (ZYRTEC). The patient previously took diamox [acetazolamide] and experienced drug hypersensitivity. Patient received first dose Monday, 04Jan2021, then she experienced severe chills and Covid like symptoms. Apparently, she tested positive for COVID 19. She ws not sure if it was a false positive or if she actually has COVID, but was concerned because her husband has cancer and was immunocompromised. Literally, she got the vaccine because her OB/GYN told her she needs to get it as soon as possible. She did blood work and she tested negative for pregnancy. There was no prescriber as it was given as part of her work. Fifteen minutes after receiving the vaccine, she had the worst headache she has ever had in her life. Six hours after that, she had such bad chills. That night, it worsened and it got better every hour when she took something. She said her congestion was still present. She stated she took Tylenol and hour later and it subsided. The outcome of the events was not recovered. The patient underwent laboratory date including negative antibodies on an unknown date, blood work on Mar2020 with unknown result, then on 05Jan2020 tested positive to COVID 19 by saliva test at 09:15 and nasal test at 11:30 Information about Lot/batch number has been requested.; Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of events Drug ineffective and COVID-19 cannot be totally excluded. The case will be reassessed if additional information becomes available

patient got the first dose of the COVID vaccine on 18Dec2020/was positive via COVID PCR test on 26Dec2020; patient got the first dose of the COVID vaccine on 18Dec2020/was positive via COVID PCR test on 26Dec2020; had a COVID exposure on 23Dec2020; This is a spontaneous report from a contactable physician. A patient of unspecified age and gender received the first dose of bnt162b2

(PFIZER-BIONTECH COVID-19 VACCINE; lot number and expiration date not provided), via an unspecified route of administration on 18Dec2020 at single dose for COVID-19 immunization. Patient's medical history was not reported. Concomitant medication included chemotherapy. It was reported that patient got the first dose of the COVID vaccine on 18Dec2020 and then had a COVID exposure on 23Dec2020 and was positive via COVID PCR test on 26Dec2020. It was mentioned that patient is a chemotherapy patient. The patient was given the antibodies for COVID on 28Dec2020 and the patient is currently doing well. Reporter's question was that the patient was scheduled to get the second dose of the vaccine on 08Jan2021 and the reporter is wondering if given this patient's situation, is it safe for the patient to receive the second dose or if there are any recommendations on when the patient should receive the second dose. Outcome of the events was recovering. Information on the lot/batch number has been requested.; Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of events Drug ineffective and SARS-CoV-2 test positive cannot be totally excluded. The case will be reassessed if additional information becomes available.

tested positive for covid; tested positive for covid; This is a spontaneous report from a contactable consumer. A 35-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration at the left upper arm on 18Dec2020 15:30 at a single dose for COVID-19 immunisation. Medical history included high blood pressure and had electrocardiogram (EKG) unknown result a week before vaccination in Dec2020. Concomitant medication included acetylsalicylic acid (ASPIRIN), lisinopril, and guaifenesin (MUCINEX). It was reported that patient tested positive for COVID on 31Dec2020. She has not gotten her second dose but it was scheduled for 08Jan2021 for which will still be in quarantine then and requested guidance on when/if she should get the second dose. Patient explained her parents have COVID and that the rapid test for the COVID test was how she found out she had COVID. The patient has not recovered from the events.

Developing symptoms of covid/ symptoms of Covid after having the vaccine; Developing symptoms of covid/ symptoms of Covid after having the vaccine; This is a spontaneous report from a contactable consumer (patient) via a Pfizer-sponsored program. A 31-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection) lot number: EJ1688, via an unspecified route of administration in the left arm, on 21Dec2020 at a single dose for covid-19 immunisation as she works with disabled people and for general community health. Patient's medical history was none. Family history included her kids/children had covid (unknown if ongoing). There were no concomitant medications. It was reported that the patient had symptoms of covid after having the vaccine with outcome of recovering. The patient received the first dose of covid vaccine on 21Dec2020 and on the 02Jan2021 she started developing symptoms of covid. She mentioned that her children have virus and she had the covid test done. She wanted to know if she can get the second dose of the vaccine. She queried for her co-worker who has the Covid and was told to not take the vaccine yet and how long they need to wait. She was tested this morning. She has not gotten the results. Her kids had Covid and she felt certain she had it because she has symptoms. It comes and goes. It was better during the day and worse at night. She received the vaccine because she works with disabled people where

there are extremely high numbers of the virus. She also got it for general community health. The Covid test was done on 06Jan2021 with unknown result.

had a positive Covid test after receiving the vaccine; had a positive Covid test after receiving the vaccine; This is a spontaneous report from a contactable nurse (patient) via a Pfizer Sponsored program, Pfizer First Connect. A 30-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection) lot number: EH9899, intramuscular in the left arm, on 18Dec2020 at 0.3 mL, single dose for COVID-19 immunization. Medical history included was none. There were no concomitant medications. The patient had a positive Covid test after receiving the vaccine with outcome of unknown. It was reported that the patient got the first dose of the vaccine on 18Dec2020, and tested positive on 28Dec2020 due to some exposure. She asked for any recommendations on the second dose whether or not she could get it. She is scheduled to get it this weekend. The reporter considered the event as non-serious and unrelated to the use of the vaccine.; Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of events Drug ineffective and COVID-19 virus test positive cannot be totally excluded. The case will be reassessed if additional information becomes available.

He tested positive last Tuesday for SARS-Cov-2; He tested positive last Tuesday for SARS-Cov-2; This is a spontaneous report from a Pfizer Sponsored Program, Pfizer First Connect via a contactable other health professional (HCP) (patient). A male patient of an unspecified age received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 18Dec2020 at single dose for covid-19 immunization. The patient medical history and concomitant medications were not reported. The patient tested positive last Tuesday (05Jan2021) for SARS-Cov-2 and the patient wanted to know if he could receive his second dose of vaccine. The outcome of the event was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Based on the information currently available, a lack of efficacy with the suspected vaccine BNT162B2 in this patient cannot be completely excluded. Further information like confirmative virus genome /nucleic acid detection is needed for meaningful medical assessment.

she received the COVID-19 vaccine and the next day she tested positive for the viral infection; she received the COVID-19 vaccine and the next day she tested positive for the viral infection; This is a spontaneous report from a contactable consumer (patient) from a Pfizer sponsored program Pfizer First Connect. A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 05Jan2021 at single dose for COVID-19 immunisation. The patient medical history and the concomitant medications were not reported. The patient was tested on 02Jan2021, and did not get the results till 06Jan2021 and tested positive. The patient wanted to know if she could have any side effects if she received the COVID-19 vaccine and the next day she tested positive for the viral infection. She is unsure of when she contracted the infection. The outcome was unknown. Information on the lot/batch number has been requested.

chest tightness; palpitations; elevated heart rate; fatigue; This is a spontaneous report from a contactable Other HCP. A 37-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19

VACCINE), via an unspecified route of administration on 31Dec2020 at single dose for covid-19 immunisation. Medical history included Dermatographia. The patient is allergic to Penicillin, lactose, Cephalosporins and Beepen-VK. There were no concomitant medications. Seventy two hours after the vaccine was given the patient had an elevated heart rate, chest tightness and fatigue. Are this consistent with the vaccine. She does not have a history of elevated heart rate or palpitations. She checked her heart rate with her Apple watch and sent in a strip to the doctor. The doctor is concerned and is asking if this is related. She went to the ER to make sure she was ok but was not admitted. Outcome of event heart rate increased as recovered on 05Jan2021, of fatigue was not recovered, of others was recovering. Information about Lot/batch number has been requested.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the reported events of elevated heart rate, chest tightness, palpitations and fatigue due to temporal relationship. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics including 12-lead EKG , counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

if a patient experienced an allergic reaction to the first dose is there anything prophylactically needing to be done when administering the second dose of the Covid vaccine; delayed hyper sensitive reaction; Angioedema; Urticarial rash; This is a spontaneous report from a contactable other hcp. A 47-years-old male patient received first dose of bnt162b2 (BNT162B2), unknown on 18Dec2020 (lot number: EK5730) at SINGLE DOSE for COVID-19 immunisation. The patient medical history and concomitant medications were not reported. Caller is a Physician Assistant. Caller states that she is calling about the Covid Vaccine. She had a patient received his first dose of the vaccine on Friday 18Dec2020, 3 days later on 21Dec2020 he had an urticarial rash that persisted, The urticarial rash was treated with prednisone and resolved by 27Dec2020, it has not reoccurred. The allergist said it was a delayed hyper sensitive reaction that was Prompted by the immune simulation from the vaccine. The Patient was treated for the urticaria. Caller would like to know if a patient experienced an allergic reaction to the first dose is there anything prophylactically needing to be done when administering the second dose of the Covid vaccine? Caller is very upset and frustrated and stating she wants to speak to someone that is a clinician with the clinical trial team who can give her recommendations for a specific patient. Caller asks if they should do Prophylaxis with antihistamines for the second dose. He did not have anaphylaxis but he had angioedema. Caller states that she did a Vaers report on 22Dec2020, but no one contacted her. He started taking Zyrtec and Vistaril. The Allergist said it was fine and he will still need the 2nd Booster Dose. The Angioedema started on 22Dec2020, it was also treated with prednisone, in addition to being administered Benadryl IM, and Vistaril. The outcome of the event urticarial rash was recovered on 27Dec2020 and Angioedema was recovered on 22Dec2020. No follow-up attempts are needed; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the angioedema and the other reported events due to

temporal relationship. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics including serum tryptase level and complement panel, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Angioedema; Tongue numb observer notified about 10 minutes after vaccine, then tongue and Lower lips numb; tachycardia with throat tightness; tachycardia with throat tightness.; This is a spontaneous report from a contactable nurse (patient). The 37-years-old female patient received first dose of bnt162b2 (BNT162B2, Lot number: EK9231), unknown on 05Jan2021 07:45 at SINGLE DOSE on left arm for COVID-19 immunisation. The patient is not pregnant. No covid tested post vaccination. Medical history included Idiopathic angioedema, HTN, PCOS, Allergies to medications, food, or other products: Latex, penicillin, coconut. Prior to vaccination, the patient was diagnosed with COVID-19. Concomitant medication included spironolactone (ALDACTONE), fexofenadine hydrochloride (ALLEGRA), hydrochlorothiazide, amlodipine besilate (NORVASC). The patient did not take other vaccine in four weeks. The patient experienced Angioedema event occurred approximately 18 hrs later with repeat of treatment in ER on 06Jan2021, tongue numb observer notified about 10 minutes after vaccine, then tongue and lower lips numb on 05Jan2021 08:00, taken to ER became tachycardia with throat tightness on 05Jan2021 08:00. EPIPEN administered, benadryl and prednisone (steroids), and famotidine administered along with a saline bolus. The outcome of the events was recovered. No follow-up attempts are needed.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the angioedema and other reported events due to temporal relationship. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics including complement levels, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

"extremely bad dry mouth; lips were going numb; facial numbness; rash from his neck to his nipple line; BP was 180/110 / BP stayed around 160/100; felt an ""amped"" feeling; felt flush; uncomfortable; This is a spontaneous report from a contactable healthcare professional. A 44-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number/expiration date unknown), dose number 1, intramuscularly on 21Dec2020 14:00 at a single dose on the right arm for COVID-19 immunization. Medical history included gluten allergy with causes dermatitis herpetiformis, osteoporosis, and fibromyalgia. The patient previously took Benadryl and experienced allergies. Concomitant medications were not reported. The patient reported that immediately after receiving

vaccine on 21Dec2020, he felt an ""amped"" feeling and felt flush. It was uncomfortable but not alarming at first. About ten minutes after shot, he started to have extremely bad dry mouth. He went back to work, but he went back downstairs after feeling like he was getting seriously ill and his lips were going numb. His BP was 180/110. The facial numbness went away but his BP stayed around 160/100. He was asked to go to ER, but he refused because he would have to pay for it and he was feeling better. He also noticed after going back upstairs that he had a rash from his neck to his nipple line. The doctor asked for Benadryl, but he was not given due to possible Benadryl allergy. He went home and his BP returned to normal 2 hours later. The patient was not diagnosed with COVID-19 prior to vaccination, and was not tested for COVID-19 since the vaccination. The outcome of the events was recovered in 21Dec2020 for blood pressure increased and facial numbness, and recovered on an unspecified date for the other events. Information on the lot/batch number has been requested.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the BP increased and other reported events due to temporal relationship. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics including EKG and chemistry panel, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate."

crystals in her urine; muscle pain; joint pain; flu like symptoms/feeling like she has the flu; having no energy; feeling tired/Tiredness; kidney stone; pain in her back; did not feel good; This is a spontaneous report from a contactable consumer (patient). A 54-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot EL0140) intramuscular on 31Dec2020 16:00 at a single dose on left arm for Covid-19 prophylaxis. Medical history included rheumatoid arthritis. There were no concomitant medications. The patient wanted to know if she could receive the second dose of the COVID-19 vaccine if she presented the following side effects with the first shot: feeling tired/tiredness on 02Jan2021; having no energy on 03Jan2021; muscle pain, joint pain, and flu like symptoms/feeling like she has the flu, on 04Jan2021. She went to work on Monday and has taken the last couple of days off because she did not feel good on Jan2021. She did have rheumatoid arthritis, but it was different and has not been like this. She went to the doctor on Monday after she got off of work and thought at first maybe she had a UTI; treated herself with AZO, but had a urinalysis that was negative on an unspecified date. She was told some of the pain in her back might have been a kidney stone on Jan2021 because they found crystals in her urine on 04Jan2021, but she did not know about that. She noticed having no energy on Sunday. She wanted to know if it was recommended that she get the second vaccine since she was having side effects. The events required a visit to physician office and did not require a visit to Emergency Room. Prior vaccinations within 4 weeks was noted as none. Family medical history relevant to the events (AE) was noted as none.The outcome of the events of feeling tired/tiredness was not recovered; of having no energy, muscle pain, joint pain, flu like symptoms/feeling like she has the flu was recovering; of the rest of events was unknown.

Left Bell's palsy/left side of face, inability to raise left eyebrow; numbness and paresthesia of tongue; numbness and paresthesia of tongue; pain in left upper arm between elbow and shoulder; tachycardia; elevated blood pressure; This is a spontaneous report from a contactable physician. A 35-year-old female patient (not pregnant at the time of vaccination) received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EH9899), intramuscular at arm left on 31Dec2020 at single dose for covid-19 immunization. The vaccine was administered at other (as reported). Medical history included asthma (Allergy induced asthma). Concomitant medication within 2 weeks of vaccination included cetirizine hydrochloride (ZYRTEC) from Dec2020 at 10mg daily. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. On 31Dec2020, the patient experienced Left Bell's palsy, numbness and paresthesia of tongue, left side of face, inability to raise left eyebrow, pain in left upper arm between elbow and shoulder, tachycardia, elevated blood pressure. The adverse events result in emergency room/department or urgent care. The patient received treatment for the adverse events which included Prednisone 20mg daily, Valacyclovir 1000mg twice a day. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, the patient was not been tested for COVID-19. The outcome of events was not recovered.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the Bell's palsy and other reported events due to temporal relationship. However, the Bell's palsy may possibly represent a concurrent medical condition. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics including viral serologies, and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Shortness of breath, stridor, migraine for 5 days and 10 days later cellulitis at injection site.; Shortness of breath, stridor, migraine for 5 days and 10 days later cellulitis at injection site.; Shortness of breath, stridor, migraine for 5 days and 10 days later cellulitis at injection site.; Shortness of breath, stridor, migraine for 5 days and 10 days later cellulitis at injection site.; This is a spontaneous report from a contactable Nurse (patient). A 51-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (lot number EH9899), intramuscularly on 28Dec2020 14:30 at single dose for covid-19 immunization. Vaccine location was left arm and it was the first dose. The facility type vaccine was hospital. Medical history included migraine from an unknown date. Concomitant medication included erenumab aooe (AIMOVIG), estradiol, diphenhydramine hydrochloride (BENADRYL), trazodone hydrochloride (TRAZODON). No known allergies. Patient was not diagnosed with COVID-19 prior to vaccination nor tested for COVID-19 since the vaccination. The patient didn't receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient experienced shortness of breath, stridor, migraine for 5 days and 10 days later cellulitis at injection site on 28Dec2020 15:00. Patient received Antibiotics, steroids epi as treatment for the adverse events. The adverse events resulted in Doctor or other healthcare professional office/clinic visit. The outcome of event migraine was recovered in Jan2021, other events was recovered on an unknown date. The events were reported as non-serious.;

Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the reported events of Vaccination site cellulitis, shortness of breath, stridor and migraine, due to temporal relationship. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics, and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

to get Botox injection for her Dystonia; got her 1st dose of Covid vaccine last 04Jan and was scheduled to have her 2nd dose on 22Jan; This is a spontaneous report from a Pfizer-sponsored program. A contactable consumer(patient) reported that a 62-year-old female received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 04Jan2021 at single dose for covid-19 immunization. The patient medical history and concomitant medications were not reported. The patient got her 1st dose of Covid vaccine last 04Jan2021 and was scheduled to have her 2nd dose on 22Jan2021, but she had an appointment 2 days prior this to get botulinum toxin type a (BOTOX) injection for her Dystonia. The patient wanted to know if it's ok for her to get 2nd dose of Covid vaccine after getting botulinum toxin type A. Outcome of the events was unknown.

she tested positive 5 days after taking the first COVID19 Vaccine dose; she tested positive 5 days after taking the first COVID19 Vaccine dose; This is a spontaneous report from a contactable nurse (patient). A female patient of an unspecified age received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number and expiration date were not reported), via an unspecified route of administration on an unspecified date at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. On an unspecified date, the patient tested positive 5 days after taking the first COVID-19 vaccine dose. Outcome of the events was unknown. Information about lot/batch number has been requested.

received first dose of covid vaccine on 19Dec2020 tested positive on 31Dec2020; received first dose of covid vaccine on 19Dec2020 tested positive on 31Dec2020; This is a spontaneous report from a contactable other HCP (patient). A male patient of an unspecified age received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) , via an unspecified route of administration on 19Dec2020 at the first single dose for covid-19 immunisation. The patient medical history was not reported. The patient's concomitant medications were not reported. The patient received first dose of covid vaccine on 19Dec2020 tested positive on 31Dec2020. The outcome of events was unknown. Information about Lot/Batch has been requested.; Sender's Comments: A causal association between reported event and BNT162B2 cannot be excluded.

tested positive for covid19; tested positive for covid19; This is a spontaneous report from a contactable nurse (patient). A 22-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 21Dec2020 at single dose for COVID-19

immunization. The patient medical history and concomitant medications were not reported. The patient received vaccine 1st dose on 21Dec2020 and on 29Dec2020 she tested positive for covid19. She is coming up on 2nd dose on Friday (will be out of quarantine on the same day), she asked if she should get the vaccine. Her primary care physician advised her not to receive, within 30 days because there had been reports of people having reactions (ie: high fevers) to the vaccine. If she has a high fever she can't go to school. She asked if waiting 90 days make the vaccine not as effective and if she need to restart the series. The outcome of the events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Test positive for covid19 found 7 day following the vaccination, no adequate effect of the suspect vaccine thus could be reasonably achieved to protect from the targeted infection/disease due to the very short time lag

collapse/rapid progression of symptoms; hypotension/rapid progression of symptoms; respiratory distress with stridor; respiratory distress with stridor; dizziness/rapid progression of symptoms; not limited to abdominal pain/rapid progression of symptoms; blood pressure abnormality/rapid progression of symptoms; chest pain/rapid progression of symptoms; drooling/rapid progression of symptoms; increased swelling/rapid progression of symptoms; wheezing; dyspnea and increased work of breathing; skin changes; tongue swelling and vomiting; tongue swelling and vomiting; This is a spontaneous report from a non-contactable other health professional. A 35-year-old female patient (Age at vaccination: 35) received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK9231), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. During her 15 minute waiting period after the injection, the patient began to experience dizziness. Monitored patient for severe reaction symptoms, including but not limited to abdominal pain, blood pressure abnormality, chest pain, collapse, drooling, hypotension, increased swelling, rapid progression of symptoms, respiratory distress with stridor, wheezing, dyspnea and increased work of breathing, skin changes, tongue swelling and vomiting. Treatment included: no therapy. The outcome of the events was unknown. No follow up attempts are possible. No further information is expected.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the collapse, hypotension, respiratory distress and other reported events due to temporal relationship. There is very limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics including BP measurements, chest x-ray, EKG and chemistry panel, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Escherichia Coli infection; This is a spontaneous report from a non-contactable consumer (daughter) from a Pfizer sponsored program Pfizer First Connect. A female patient of unspecified age received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. Medical history and

concomitant medications were not reported. The reporter's mother has Escherichia Coli infection and is taking Nitrofurantoin antibiotic (Macrodantin). Asked if it is safe to take the second dose of the vaccine while on antibiotic. Caller asking if we could update info regarding antibiotic as even her doctor does not have info on this. Saying that even her doctor is unsure as Pfizer should know information regarding this more than her doctor. Treatment for event was Nitrofurantoin antibiotic (Macrodantin). Outcome of event was unknown. No follow up attempts are possible; Information about lot/batch number cannot be obtained.

"tested positive for Covid; tested positive for Covid; This is a spontaneous report from a contactable physician (patient). A female patient of an unspecified age received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 20Dec2020 at single dose for COVID-19 immunization. The patient medical history and concomitant medications were not reported. The patient tested positive for Covid on 22Dec2020. She wanted to know if there is any more information on receiving the second dose after testing positive. The outcome of the event was unknown. Information on the Lot/batch number has been requested.; Sender's Comments: Based on the mechanism of action of BNT162B2 vaccine, it is unlikely the patient would have fully developed immunity for the vaccine to be effective, due to the number of days passed since the vaccine was given (in this case 2 days). However, a causal relationship between event ""tested positive with Covid "" (coded to Drug ineffective / SARS-CoV-2 test positive) and BNT162B2 vaccine cannot be completely excluded."

she received the Pfizer-BioNTech Covid-19 Vaccine .She said she tested positive for Covid-19 after being exposed to someone infected with the virus last Christmas; she received the Pfizer-BioNTech Covid-19 Vaccine .She said she tested positive for Covid-19 after being exposed to someone infected with the virus last Christmas; after being exposed to someone infected with the virus; This is a spontaneous report from a contactable Physician (patient). A female patient of an unspecified age receive the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) , via an unspecified route of administration on 18Dec2020 at single dose for covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient she received the Pfizer-BioNTech Covid-19 Vaccine on 18Dec2020. She said she tested positive for Covid-19 after being exposed to someone infected with the virus last Christmas (25Dec2020). Now, she wanted to know if she can still take the 2nd dose. The outcome of the events was unknown. Information on the Lot/Batch number has been requested.; Sender's Comments: A causal association between reported event and BNT162B2 cannot be excluded.

tested positive for covid; tested positive for covid; This is a spontaneous report from a contactable consumer received from a Pfizer-sponsored program Pfizer First Connect. A 64-years-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number EH9899, expiry date Mar2021, NDC 59267-1000-1), intramuscular in right arm on 18Dec2020 11:45 at a single dose as prevention. The vaccine was administered in the hospital. Medical history included ongoing cardiomyopathy diagnosed about 32 years ago and had pacemaker defibrillator Placed about 12 years ago. There were no concomitant medications. She was supposed to get the second dose of the Covid vaccine but she was positive for Covid. She found out she was positive for covid on Monday 04Jan2021 after she had a nasal swab test on 02Jan2020. The outcome of the event was unknown.

Bell's Palsy; developed flu like symptoms; This is a spontaneous report from a contactable pharmacist. A female patient of an unspecified age (reported as 32-40) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date in 2020 at single dose for COVID-19 immunization. The patient medical history and concomitant medications were not reported. The patient developed side effects side effects from first vaccine, Bell's palsy 4 days after vaccination (Dec2020) which lasted for 2 weeks and flu like symptoms (Dec2020) which also lasted 2 weeks. The events outcome was unknown. The patient was receiving 2nd dose on 06Jan2021, the reporter asked any information regarding this? Information on the lot/batch number has been requested.; Sender's Comments: Based on a compatible temporal relationship, causality between event Bell's palsy and BNT162B2 vaccine cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Fatigue; tested positive after receiving Covid-19 vaccine; tested positive after receiving Covid-19 vaccine; severely congested; This is a spontaneous report from a Pfizer-sponsored program IBCC (Inbound Call Center for HCPs). A contactable consumer (patient) reported that a 47-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EJ1685, Expiry Date: Mar2021) via an unspecified route of administration at right deltoid on 20Dec2020 at single dose for COVID-19 immunization. Medical history included ongoing severe asthmatic diagnosed as a child. There were no concomitant medications. Patient (a front line worker) is Grief Counselor. She tested positive after receiving BNT162B2 on 29Dec2020. She was supposed to get the second dose on 10Jan2021. She was having fatigue since 01Jan2021 and was severely congested since 26Dec2020. She was asking if she should get the second dose. The outcome of the events severely congested and fatigue was recovering, of the other events was unknown.

recently got vaccinated unwillingly knowing she had Covid; recently got vaccinated unwillingly knowing she had Covid; This is a spontaneous report from a contactable Other healthcare professional (HCP) reporting for herself. A female patient of an unspecified age received her first dose BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient recently got vaccinated unwillingly knowing she had covid on an unspecified date. The patient wanted to known if she should get her second dose still and in the same timely manner. The outcome of the events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Based on available information, a possible contributory role of suspect BNT162B2 cannot be completely excluded for reported event.

she received the first dose of the vaccine on the 22nd of December and tested positive on the 28th; she received the first dose of the vaccine on the 22nd of December and tested positive on the 28th; This is a spontaneous report from a Pfizer-sponsored program Pfizer First Connect. A contactable consumer(patient) reported that a female patient of an unspecified age received first dose BNT162B2, via an unspecified route of administration on 22Dec2020 at single dose for COVID-19 immunization. The

medical history and concomitant medications were not reported. The patient received the first dose of the vaccine on the 22nd of December and tested positive on the 28Dec2020, she was scheduled to get the 2nd dose on Jan 12th. The reporter wanted to know if it was safe for her to take the 2nd dose. The outcome of the events was unknown. Information about lot/batch number has been requested.

testing positive for COVID on nasal swab after first dose of COVID vaccine; testing positive for COVID on nasal swab after first dose of COVID vaccine; This is a spontaneous report from a non-contactable pharmacist. A patient of unspecified age and gender received 1st dose of BNT162B2 (reported as COVID vaccine), via an unspecified route of administration on an unspecified date at single dose for Covid-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient experienced testing positive for Covid on nasal swab after first dose of Covid vaccine on an unspecified date with outcome of unknown. No follow-up attempts are possible. Information about lot/batch number cannot be obtained. Pfizer is a marketing authorization holder of COVID vaccine in the country of incidence or the country where the product was purchased (if different). This may be a duplicate report if another marketing authorization holder of COVID vaccine has submitted the same report to the regulatory authorities.; Sender's Comments: The reported testing positive for Covid on nasal swab after COVID-19 immunization is considered ineffective of BNT162B2, and the Company cannot completely exclude the possible causality between the reported event and BNT162B2 administration.

She thinks there has been more anaphylactic reactions than usual and said that a physician female friend had experienced one; This is a spontaneous report from a non-contactable Other Health Professional via Pfizer sales representative. A female patient of unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunisation. Medical history and concomitant medications were not reported. During a conference call, (Name) mentioned that she thinks there has been more anaphylactic reactions than usual and said that a physician female friend had experienced one. It was unclear whether it was after a Pfizer or Moderna vaccine. She did mention that her friend recovered without any issues. Outcome of event was recovered on an unspecified date. No follow-up attempts are possible. Information about lot/batch number cannot be obtained.; Sender's Comments: A possible causal association between administration of BNT162B2 and the onset of anaphylaxis cannot be excluded, considering the plausible temporal relationship and the known adverse event profile of the suspect product. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Tested positive for COVID; Tested positive for COVID; This is a spontaneous report from a Pfizer-sponsored program from a contactable consumer (patient). A 68-year-old female patient received first dose of bnt162b2 (Pfizer BioNTech COVID vaccine), via an unspecified route of administration on an unspecified date at a single dose in left arm for COVID-19 immunization. Medical history included ongoing rheumatoid arthritis, open heart surgery had this done a year ago, knee replacement, and hip

replacement. Concomitant medications included patient took a lot of different medications, but no additional details provided. The test done on Saturday 02Jan2021 and on Sunday 03Jan2021, she got the results that she was positive for COVID. Clinical details: She received the first dose of her COVID vaccine, and she will be due for her second dose on Saturday. However, she tested positive for COVID after getting her first dose. The doctor informed her she should have a COVID infusion. She took the COVID infusion and now after getting the infusion she is told she is not able to get her second dose of the COVID vaccine for 60-90 days. She is not sure what to do. She cannot remember the date she got the COVID vaccine, she knew she is due for her second one on Saturday. She received the COVID infusion this morning, originally she was told she would be able to have a second shot even after getting the COVID infusion. Now they are saying she cannot have the next dose on Saturday. She was told later she would have to wait two weeks. Then she was told she would have to possibly wait 90 days. She was thankful for the vaccine because even though she tested positive it probably kept her from dropping dead. Information on the lot/batch number has been requested.

"got Covid/She tested positive for SARS-Cov-2 04JAN2021; got Covid; This is a spontaneous report from a contactable other healthcare professional (patient). A female patient of an unspecified age received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 21Dec2020 at single dose for covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient indicated she received her first dose of vaccine 21Dec2020. She tested positive for SARS-Cov-2 04Jan2021. She was asking how she ""got Covid"" and if she should receive the second dose. The outcome of the event was unknown. Information on Lot/Batch number has been requested.; Sender's Comments: The reported tested positive for SARS-Cov-2 after COVID-19 immunization is considered ineffective of BNT162B2, and the Company cannot completely exclude the possible causality between the reported event and BNT162B2 administration."

The day after vaccine administration, pt was still experiencing vertigo, spinning and headache.; The day after vaccine administration, pt was still experiencing vertigo, spinning and headache.; This is a spontaneous report from a non-contactable other healthcare professional (hcp). A 27-year-old female patient receive first dose of bnt162b2 (Pfizer BioNTech COVID vaccine, lot number: EL0140), intramuscularly on 30Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. There is unknown if any other vaccine received in four weeks. The patient experienced the day after vaccine administration, patient was still experiencing vertigo, spinning and headache, all on 31Dec2020 the day after vaccine administration. The outcome of events was unknown. This is a non-serious report. It's unknown if patient was diagnosed with COVID-19 or tested for COVID-19 since the vaccination. The adverse did not result in 'doctor or other HCP visit or emergency room or urgent care, hospitalization or prolongation, life threatening illness, disability or death or congential anomaly'. No follow-up attempts are possible. Information about Lot/Batch cannot be obtained.

anaphylaxis; throat tightening; throat tightening/tingling; throat tightening/tingling/soreness; dry wheezy cough a little dizziness; dizziness; tachycardia; Itching; chills; numb R foot; Low grade temp; h/a today; This is a spontaneous report from a contactable Nurse (patient). A 51-years-old female patient (no pregnant) started to receive bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number el3248),

via an unspecified route of administration on 06Jan2021 11:00 at the first single dose at left arm for covid-19 immunisation. Medical history included supraventricular tachycardia, adrenal insufficiency, hypothyroidism, attention deficit hyperactivity disorder, hypermobility syndrome, developmental hip. Concomitant medication included hydrocortisone, trazodone, levothyroxine sodium (LEVOTHROID), bupropion hydrochloride (WELLBUTRIN). The patient previously took erythromycin, morphine and experienced drug hypersensitivity. The patient experienced anaphylaxis, throat tightening/tingling/soreness, dry wheezy cough a little dizziness and tachycardia. Itching, numb R foot, Low grade temp and chills and headache on 06Jan2021 11:15. Seriousness criteria reported as life threatening. Taken to ER had IV benadryl, solumedrol, pepcid for anaphylaxis. Placed on O2 and given albuterol nebulizer. Had IV fluid bolus. Now on benadryl and 5 days of prednisone. The patient felt completely fine prior to vaccine. The patient underwent lab tests and procedures which included sars-cov-2 test: negative on 06Jan2021. The outcome of events was recovering. No other vaccine in four weeks; No covid prior vaccination.; Sender's Comments: A possible causal association between administration of BNT162B2 and the onset of anaphylaxis presented as throat tightening/tingling/soreness, dry wheezy cough a little dizziness and tachycardia. Itching, numb R foot, Low grade temp and chills and headache cannot be excluded, considering the plausible temporal relationship and the known adverse event profile of the suspect product. The underlying predisposing condition of drug allergies may put the patient at high risk of anaphylactic reactions. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Soreness at injection site started at 1600 Body aches, headache, and low grade fever woke me up around 0100

Patient with Covid between their first and second doses of the Covid vaccine; Patient with Covid between their first and second doses of the Covid vaccine; This is a spontaneous report from a Pfizer-sponsored program from a contactable Pharmacist reported similar events for 2 patients. This is the 2nd of 2 reports. A patient of an unspecified age and gender received the first dose of BNT162B2 (Pfizer/BioNTech Covid-19 vaccine) on an unspecified date for Covid-19 immunization. The patient's medical history and concomitant medications were not reported. On an unspecified date, the patient got Covid between first and second doses of the Covid vaccine. The outcome of the event was unknown. Information on the lot/batch number has been requested.; Sender's Comments: The association between the event lack of effect (got COVID between first and second doses) with BNT162b2 can not be fully excluded.,Linked Report(s) : US-PFIZER INC-2021011515 same reporter/drug/AE, different patient

patient with covid between their first and second doses of the covid vaccine; patient with covid between their first and second doses of the covid vaccine; This is a spontaneous report from a Pfizer sponsored program IBCC (Inbound Call Center for HCPs). A contactable pharmacist reported similar events for two patients. This is the first case out of 2 cases. A patient of unspecified age and gender received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK9231, expiration date: Apr2021, NDC#59267-1000-1), via an unspecified route of administration on an unspecified date at

single dose for covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient with Covid between the first and second doses of the Covid vaccine on an unspecified date. The reporting pharmacist wanted to know if the patients with covid between their first and second doses of the covid vaccine what their risk would be, Reportedly 2 different patient. The outcome of the events was unknown.; Sender's Comments: The association between the event lack of effect (COVID between first and second dose) with BNT162b2 can not be fully excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.,Linked Report(s) : US-PFIZER INC-2021011471 same reporter/drug/event, different patient..

tested positive and also received the vaccine from COVID-19; tested positive and also received the vaccine from COVID-19; This is a spontaneous report from a Pfizer sponsored program. This contactable physician reported similar events for the physician herself and a patient. This is the second report, the patient report of 2 reports. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for covid-19 immunization. The patient medical history and concomitant medications were not reported. The physician reported there was another person in her clinic that tested positive and also received the COVID vaccine on an unspecified date with outcome of unknown. The information on the batch number has been requested.; Sender's Comments: Based on the information currently available, a lack of efficacy with the suspected vaccine BNT162B2 in this patient cannot be completely excluded. Further information like confirmative virus genome /nucleic acid detection needed for meaningful medical assessment.,Linked Report(s) : US-PFIZER INC-2021000799 Same reporter, same drug, different patients

"did develop COVID that week probably symptoms in general by 25Dec/probably infected whenever got the vaccine; did develop COVID that week probably symptoms in general by 25Dec/probably infected whenever got the vaccine/I don't feel very well right now; This is a spontaneous report from a contactable consumer (patient). A patient of unspecified age and gender received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EJ1685), via an unspecified route of administration on 21Dec2020 at single dose for covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient received 1st vaccine on 21Dec2020. The patient did develop COVID that week probably symptoms in general by 25Dec2020. She was probably infected whenever she got the vaccine and the patient was scheduled to have second vaccine on 11Jan2021 which was next Monday and the patient was still sick, should the patient delayed that. The patient also did not feel very well on an unknown date (""right now""). The outcome of the events was not recovered."

"had covid after his first dose; had covid after his first dose; headaches; This is a spontaneous report from a Pfizer-sponsored program Pfizer First Connect from a contactable Physician. A male patient of an unspecified age received his first single dose of BNT162B2 (Pfizer/ BioNTech Covid-19 vaccine) on an unspecified date in Dec2020 for Covid-19 immunization. The patient previously had Covid in Apr2020.

Concomitant medications were not reported. After his first dose of vaccine, in Dec2020, the patient had Covid and headaches. The outcome of the events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: The reported ""had Covid"" after COVID-19 immunization is considered ineffective of BNT162B2, and the Company cannot completely exclude the possible causality between the reported event and BNT162B2 administration."

Got the first dose of the vaccine on 23Dec2020, this week the patient was tested positive for COVID; Got the first dose of the vaccine on 23Dec2020, this week the patient was tested positive for COVID; This is a spontaneous report from a Pfizer-sponsored program Pfizer First Connect from a contactable other healthcare professional (HCP) (patient). A female patient of an unspecified age received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 23Dec2020 at single dose for COVID-19 immunisation. The patient medical history and concomitant medications were not reported. The patient got the first dose of the vaccine on 23Dec2020, this week the patient was tested positive for COVID in Jan2021. The outcome of the events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: The reported tested positive for COVID after COVID-19 immunization is considered ineffective of BNT162B2, and the Company cannot completely exclude the possible causality between the reported event and BNT162B2 administration.

she tested positive in the middle; she tested positive in the middle; This is a spontaneous report from a contactable female consumer (patient) via a Pfizer-sponsored program . A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 16Dec2020 at first single dose for COVID-19 immunization. The patient medical history was not reported. The patient's concomitant medications were not reported. Caller was asking if it was safe for her to get the second dose, she had the 1st dose on the 16Dec2020 and scheduled for the second dose today (reported on 06Jan2021), however she tested positive in the middle. Outcome of the event was unknown. information on the lot/batch number has been requested.

tested positive for Covid-19; tested positive for Covid-19; This is a spontaneous report from a contactable healthcare professional (HCP) reporting for himself via a Pfizer-sponsored program Pfizer First Connect. A male patient of an unspecified age received the first single dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (lot number and expiry date not reported) via an unspecified route of administration on 21Dec2020 for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient was tested positive for COVID-19 on 28Dec2020 and he was wondering if he was still able to receive the second dose of the vaccine. The outcome of the event was unknown. Information on the lot/ batch number has been requested.; Sender's Comments: The reported tested positive for COVID-19 after COVID-19 immunization is considered ineffective of BNT162B2, and the Company cannot completely exclude the possible causality between the reported event and BNT162B2 administration.

Anaphylactic reaction; Flushed; Diaphoretic; redness and rash; hives on chest; Tachycardia; shortness of breath; Chest tightness; Dizziness; Headache; This is a spontaneous report from a contactable nurse, the patient. A 47-year-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-

19 mRNA VACCINE; Lot Number: EL1283), via an unspecified route of administration on 08Jan2021 at 08:49 (at the age of 47-years-old) as a single dose for COVID-19 immunization. There were no known medical history or concomitant medications. The patient previously received the first dose of BNT162B2 on 18Dec2020 (Lot Number: EK5730) for COVID-19 immunization and experienced nausea, headache, and fatigue. On 08Jan2021, about 5-10 minutes after the second dose, the patient experienced anaphylactic reaction, flushed, diaphoretic, redness and rash, hives on chest, tachycardia, shortness of breath, and chest tightness, reported as life-threatening. She reported that these events occurred within less than 10 minutes of receiving the vaccine. She went to the emergency room and was treated with methylprednisolone (SOLUMEDROL), diphenhydramine hydrochloride (BENADRYL), famotidine (PEPCID), and epinephrine (MANUFACTURER UNKNOWN). She was sent home and prescribed methylprednisolone and epinephrine (EPI-PEN). Later on 08Jan2021, she experienced dizziness and headache, which were consistent. She stated she would most likely take ibuprofen (MOTRIN) as treatment (not specified if taken). The clinical outcomes of the flushed, diaphoretic, redness and rash, hives on chest, tachycardia, shortness of breath, and chest tightness were recovered on 08Jan2021; while the outcomes of the dizziness and headache were not recovered and that of the anaphylaxis was reported as recovering.; Sender's Comments: The reported information is limited. Based on the close temporal relationship and the description of the events, there is a reasonable possibility that the events are related to BNT162 vaccine. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

Approx 10-15 post vaccine, employee said she felt lightheaded and like her heart was racing. Within 10 minutes she said she felt difficulty breathing, She then vomited. The observation nurse at the clinic administered Epi Pen and called a Code. The employee was transported to the Emergency Dep't and then to intensive care. She was placed on an Epi drip.

loss of consciousness Narrative: Patient received COVID-19 vaccine dose #1 on 1/6/21 w/o complications. Per 1/6/21- 1/9/21 nursing notes, patient did not experience any injection site reactions, denied pain or tenderness at injection site, no dizziness, no n/v, remained afebrile. Around 1/9/21 @1810, patient became acutely nonresponsive after being helped to the edge of bed. Per nurses, he was previously awake/alert, talking and asymptomatic. Patient is DNR/DNI but facility rapid response emergency team called d/t patient's sudden change of condition. Emergency team helped patient into lying position. Per 1/9/21 ICU emergency team note, patient appeared comfortable w/ no palpable radial pulse and had minimal shallow agonal breathing. Pulse ox 94%, HR in 60s per machine. BP unmeasurably low by BP cuffx3. Resident passed at 18:20 pm.

Approximately 1 - 2 hours after receiving I had numbess and soreness to my neck. A few days later started experiencing tingling, buzzing, weakness and heaviness to my right arm and leg. I reported this to my MS doctor who ordered an MRI of the brain and told me to report to you

Patient received the vaccine on 12/22/20 without complication. It was reported today that the patient was found unresponsive and subsequently expired at home on 1/11/21.

Increased weakness leading to a fall and fever of 101.3

Patient began experiencing fevers, body aches, back pain, fatigue, chills the night she received the vaccine. Symptoms progressed for the following four days when she was ultimately seen in PCP office. Laboratory evaluation demonstrated atypical pneumonia and elevated WBC count. Patient was diagnosed with Acute Myeloid Leukemia via bone marrow biopsy and is receiving treatment at the hospital.

LEFT FACIAL AND TONGUE NUMBNESS - WORK UP CVA NEG Narrative: Developed left facial and tongue numbness 4 hours after vaccine - went to ER and admitted for 2 days, negative workup for CVA or other acute etiology. Symptoms resolved prior to discharge from hospital

Reported feeling faint and nauseated during observation period. Placed on cart in trendelenberg

Within 24 hrs, developed headaches, burning sensation down spine and neck. fullness in head intensified next day. balance was off, numbness and tingling throughout body. Went to ER. Diagnosed Paresthesia

The facility had positive cases of COVID when we were able to begin vaccinating residents. Within about a week of vaccination, patient was tested positive for COVID. He was 91 years old and his immune system did not have the time to allow the vaccine to begin working before exposure. His age was a major contributing factor to his death.

The facility had positive cases for COVID 19 when the vaccine was received and administered to patient. With her advanced age and chronic conditions, she did not have time to build immunity between the time of vaccination and her testing positive.

The facility had a number of positive COVID 19 cases prior to patients vaccination. Due to her advanced age, chronic condition, and exposure, patient did not have the time to build immunity after exposure before becoming positive.

Within approximately 30 minutes after vaccine (Thursday), patient presented with red rash to upper chest, severe headache, dizziness and nausea. Was treated with Benadryl and Tylenol per anesthesia onsite. Symptoms remained throughout the day with minimal improvement. The following morning (Friday) only headache remained. patient began having abdominal pain, and was admitted to hospital the next day (Saturday). It is now Tuesday and patient is still hospitalized. Unclear if this entire event is vaccine related.

Pt expired due to possible cardiac arrest. Unsure if this was vaccine related.

Resident was found deceased at approximately 6pm in her apartment

Pt experienced the following morning: fever (100 F) chills, malaise, nausea, and numbness in hands at 0624 and 0836. Pt went to hospital at 1000, tx with IV fluids.

"In the early morning of Monday, January 11th the patient developed a significant headache with neck pain. She also reported parathesia and tingling in bilateral upper extremities with weakness of the right upper extremity. She reported feeling very anxious and ""wound up"". Patient presented to the Emergency Department 3 hours later. CT of the head/brain, EKG, CBC,CMP, Magnesium and Cardiac profile were performed with no significant findings. Ativan 0.5mg was administered orally. Patient was admitted to the facility for observation. Symptoms gradually resolved with no additional treatment."

Large red area surrounding injection site.

unsure if related to vaccine, but was notified by her next of kin that she died on 1/4/2021. No reports of side effects or hospitalization were reported to the facility prior to the notification of death.

patient reported expired 1/7/2021

On 12/31/2020, at approximately 00:15, pt developed a fever of 102.9 F and tachycardia with rate of 120. He was treated with acetaminophen. Later in the morning, he complained of nausea, generalized muscle aches, intermittent increase in confusion. At approximately 14:00, he had a fall out of bed and at that time noted to be short of breath, tachypneic. He was taken via ambulance to Emergency Department. From there he was transferred to Hospital for admission with acute respiratory distress, suspected sepsis with lactic acid 7.4 and Bilateral Pulmonary Emboli. He was started on heparin and broad spectrum antibiotics and transitioned to ELIQUIS on 1/3/2021. Infectious etiology of sepsis was unclear. He continued broad spectrum antibiotics with clinical improvement. Abdominal CT scan was obtained due to intermittent nausea, vomiting, abdominal pain, loose stools. His heart rhythm flipped to Atrial Fibrillation with RVR on 1/2 and his rate improved with titration of metoprolol. He was also treated with prednisone for suspected underlying undiagnosed COPD. It is noted in his hospital summary that PEs presumed provoked in the setting of his recent COVID 19 infection. He was discharged from the hospital on 1/8/2021 and readmitted to the Veterans Home. He has been stable.

Received Moderna vaccine on 1/5. Had a single episode of vomiting approximately 1 hour after vaccine. Hx of Asthma, started to develop SOB approximately 2 days later. She reached out to PCP and used inhaler with little relief. SOB worsened and she was admitted to the hospital on 1/8/21. Eval was negative for COVID (3 tests completed), flu and pneumonia. She has elevated WBCs and was given steroids and supplemental oxygen. She is improving but remains inpatient.

Patient was sent to the ED due to significant hematuria. He was afebrile.

Patient presented with myalgias, fevers, and chest pain on 1/10/21 and was found to have diffuse ST elevation and elevation troponin. He was evaluated by cardiology and diagnosed with acute myopericarditis. He was treated with NSAIDs and colchicine. He improved with this treatment and was discharged on 1/12/21 with ibuprofen and colchicine and outpatient cardiology follow up.

Rash on neck; gall bladder attack; This is a spontaneous report from a contactable nurse (patient). A 34-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK5730), via an unspecified route of administration at the left arm on 18Dec2020 10:30 at a single dose for COVID-19 immunization in the hospital, and morphine sulfate (manufacturer unknown), via an unspecified route of administration from an unspecified date at unspecified dose and frequency for an unspecified indication. Medical history included S/P rouxen-y gastric bypass, sleep apnea, cholelithiasis, HSV-2, obesity, and Hashimoto hypothyroid disease. The patient was not pregnant at the time of vaccination. Concomitant medications included ursodiol, valacyclovir, levothyroxine sodium (LEVOTH) and vitamins. The patient previously took morphine and experienced allergies. The patient did not receive any other vaccine within 4 weeks prior to the vaccine. Prior to the vaccination, the patient was not diagnosed with COVID-19. The patient experienced Rash on neck, morphine reaction and May or may not be related - gall bladder attack on 18Dec2020 14:30. The events resulted in Doctor or other healthcare professional office/clinic visit and Emergency room/department or urgent care. The patient was administered with NS bolus, diphenhydramine (BENADRYL) and also morphine in response to the events. Since the vaccination, the patient had been tested for COVID-19 via Nasal Swab/COVID-19 rapid ABBT which was negative on 18Dec2020. The action taken in response to the events for morphine sulfate was unknown. The outcome of the events was recovered with sequel. The patient assessed the events as non-serious. Pfizer is a marketing authorization holder of morphine sulfate in the country of incidence or the country where the product was purchased (if different). This may be a duplicate report if another marketing authorization holder of morphine sulfate has submitted the same report to the regulatory authorities.; Sender's Comments: The information currently provided is too limited to make a meaningful medical assessment hence, the events are conservatively assessed as related to the suspect drug BNT162B2 until further information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

mild elevation of his sed rate and leukocytosis; mild elevation of his sed rate and leukocytosis; myalgia (was reported as worsened); Arthralgia; Ten days later and still having pain/started in neck and migrated to his back, the buttocks and gluteal and quadriceps area; Ten days later and still having pain/started in neck and migrated to his back, the buttocks and gluteal and quadriceps area; Ten days later and still having pain/started in neck and migrated to his back, the buttocks and gluteal and quadriceps area; Ten days later and still having pain/started in neck and migrated to his back, the buttocks and gluteal and quadriceps area; This is a spontaneous report from a contactable physician (patient). A 76-years-old male patient received bnt162b2 (Pfizer-Biontech Covid-19 Vaccine), via an unspecified route of administration on 23Dec2020 at single dose on deltoid Right for covid-19 immunisation. Medical history included ongoing type 2 diabetes mellitus (diagnosed about 8 years ago). There were no concomitant medications. Patient developed myalgia on 27Dec2020 and arthralgia on 28Dec2020. Patient also experience ten days later and still having pain/ started in neck and migrated to his back, the buttocks and gluteal and quadriceps area in Dec2020. He had labs a few days ago. He had a mild elevation of his sed rate and leukocytosis. Events myalgia and arthralgia considered serious due to medically significant.

Outcome of events myalgia (was reported as worsened) and arthralgia was not recovered. Information about batch/lot number has been requested.; Sender's Comments: Based on the time association, the events myalgia and arthralgia are possibly related to suspect bnt162b2 administration. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

blood pressure increased and her pulse; blood pressure increased and her pulse; Chest pain; Numb fingers and later numb face; Mind fog; This is a spontaneous report from a contactable other HCP. This 37-year-old female other HCP (patient) reported that she received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: 1685), via intramuscular at left arm on 02Jan2021 08:15 AM at single dose for COVID-19 immunization. Facility type of vaccine was pharmacy or drug store. Medical history included panic disorder (last attack 2 years prior) and known allergies: latex, Iodine dye. Concomitant medications were not reported. No other vaccine in four weeks. No covid prior vaccination. No covid tested post vaccination. On 02Jan2021 08:15 AM, within a few minutes while still under observation at pharmacy, her blood pressure increased and her pulse. Numb fingers and later numb face. Chest pain presented. She went to ER (emergency room) 3hours later with ongoing symptoms that never resolved until 6 or 7 that evening while still in ER waiting room. Mind fog (02Jan2021 08:15 AM) was currently ongoing. The treatment for events included lorazepam (ADIVAN), diphenhydramine (BENADRYL), ibuprofen. Outcome of event mind fog was not recovered, and the rest of events was recovered/resolved with sequel.; Sender's Comments: Based on the compatible temporal association, the vaccination with BNT162B2 might play a contributory role in triggering the onset of the reported events. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

lost the sense of smell and taste; lost the sense of smell and taste; nasal congestion/stuffy nose; runny nose; tiredness/felt tired; eye pain; pain in the muscles; chills; sore pain in the arm; This is a spontaneous report from a contactable Other HCP (Dentist) reporting for herself. A 43-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) at single dose on 31Dec2020 at 10:00AM in the left arm for COVID-19 immunization. Lot number was EJ1685. Medical history and concomitant medications were none. On 01Jan2021 in the morning, she had a sore pain in her arm, and by nighttime she had chills. On 02Jan2021 and on 03Jan2021, Saturday and Sunday she had pain in her muscles, felt tired, and had some pain around her eye every time she moved her eyes. On 04Jan2021, Monday everything went away but she had stuffy nose and runny nose. Her stuffy and runny nose was better but she still had some congestion, but she could not blow anything out of her nose. On 05Jan2021, Tuesday she noticed she could not smell and she still could not smell. On 06Jan2021, she had no smell and no taste either. Stated everything was good at the time of report but she still could not smell or taste anything. She treated herself with Tylenol for the muscle aches. She

took one 500mg Tylenol by mouth on 02Jan2021 at bedtime and then one Tylenol 500mg by mouth again on 03Jan2021. She was scheduled for the next dose 19Jan2021. Mention she was planning to get a COVID 19 test to see if she had the disease. The patient recovered from fatigue, eye pain, pain in muscles on 03Jan2021, the patient recovered from chills on 02Jan2021, the patient recovered from sore pain in the arm on 01Jan2021, the patient was recovering from nasal congestion/stuffy nose, the patient did not recover from runny nose and loss the sense of smell and taste. Information on the lot/batch number has been requested.; Sender's Comments: The Company cannot completely exclude the possible causality between the reported pain in her muscles, felt tired,had some pain around her eye every time she moved her eyes, had no smell and no taste, and the administration of the COVID-19 vaccine, BNT162B2, based on the reasonable temporal association. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RA, IEC, as appropriate.

aware of 6 cases of Bell's Palsy by the companies making these vaccines; This is a spontaneous report from a contactable Other HCP. This Other HCP reported similar events for 6 patients. This is 1st of 6 reports. A patient of unspecified age and gender received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for covid-19 immunisation. The patient medical history was not reported. The patient's concomitant medications were not reported. The reporter reported since the use of modified RNA in covid vaccines,he/she had aware of 6 cases of Bell's Palsy by the companies making these vaccines since an unknown date. The event outcome was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Bell's Palsy is not uncommon in general population. The information provided in this case is limited and does not allow a full medically meaningful assessment. The case will be reassessed should additional information become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics committees and Investigators, as appropriate.,Linked Report(s) : US-PFIZER INC-2021009409 Different patient, same drug/event.;US-PFIZER INC-2021009412 Different patient, same drug/event.;US-PFIZER INC-2021009410 Different patient, same drug/event.;US-PFIZER INC-2021009411 Different patient, same drug/event.;US-PFIZER INC-2021009408 Different patient, same drug/event.

joint pain and muscle; joint pain and muscle; Vertigo; an itchy rash bilaterally on her arms; developing swollen, tender, and hard lymph nodes under the Left subclavian area/ swollen left subclavian lymph nodes; developing swollen, tender, and hard lymph nodes under the Left subclavian area; extreme fatigue; Runny nose; Headache; This is a spontaneous report from a contactable nurse (RN) reporting for herself. A 42-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) first dose on 23Dec2020 h 09:00 intramuscularly in left deltoid (left arm) lot number: EK5730 at single dose for COVID-19 immunization. Concomitant medications were not provided. Patient stated that she has had double mastectomy, and missing a lot of lymph nodes, states she got the first dose of Pfizer Covid

vaccine on 23Dec2020, states it made her left subclavian lymph nodes swollen and hard. States that when she gets the flu vaccine at her hospital every year, she gets swollen lymph nodes ever since she had a double mastectomy and chemotherapy. She originally was wondering if she could get the vaccine in another large muscle group. States she even went as far as to cross reference flu shot ingredients with the Pfizer Covid ingredients to see if something in the vaccines were causing the swollen lymph nodes but was unable to come to any conclusion, the only think in common is the Sodium Chloride and she does not feel like that would cause any issue. States the swollen lymph nodes occurred after the Sanofi brand flu vaccine (no other information known or provided). Patient is on day 15 post vaccination and they are still swollen and hard, she is wondering if there is any data on how long this side effect can last. She made an appointment with her oncologist, she knows that the swollen lymph had the first dose, lymph nodes are still swollen and hard, knows it can cause swollen lymph nodes but wants to know what is the typically length of the event. Patient also experienced other side effects, on 30Dec2020 (last week), she developed vertigo that lasted through the weekend intermittently, states she at first thought she was having a stroke. States it seems to have subsided as of 05Jan2021 (yesterday). Patient also reported she had an itchy rash twice as part of her side effects reported from the COVID 19 vaccine. She noticed an itchy rash and it went away but she is unsure exactly the day or time. Stated she definitely remembered the rash on 28Dec2020 as she took pictures. It was gone in about three hours on the same day. She did not treat the rash because it was gone and not itching. The rash came and went and had not come back. It was mostly on the bends of the arms, bilateral arms. Patient reported developing swollen, tender, and hard lymph nodes under the Left subclavian area the day after the injection, on 24Dec2020. They were not as tender at the time of the report but were continuing and this was 15 days from her vaccination. Patient also experienced an itchy rash bilaterally on her arms that occurred twice and only lasted a few hours each time, onset date reported as 25Dec2020. She was advised to take diphenhydramine hydrochloride (BENADRYL) for it however she did not take it. On 23Dec2020 patient experienced headache. On 24Dec2020 patient experienced extreme fatigue, swollen left subclavian lymph nodes and runny nose. On 30Dec2020 patient experienced joint pain and muscle and vertigo. The events headache, experienced extreme fatigue, swollen left subclavian lymph nodes, runny nose, joint pain and muscle and an itchy rash bilaterally on her arms were considered serious as medically significant events. Patient had not recovered from swollen left subclavian lymph nodes, joint pain and muscle, extreme fatigue and swollen, tender, and hard lymph nodes under the Left subclavian area, she was recovering from headache, runny nose and vertigo and recovered completely from an itchy rash bilaterally on her arms on 28Dec2020.; Sender's Comments: The Causality between the events, headache, experienced extreme fatigue, swollen left subclavian lymph nodes, runny nose, joint pain and muscle and an itchy rash bilaterally on her arms, and the administration of the COVID 19 vaccine cannot be denied based on the reasonable temporal association. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RA, IEC, as appropriate.

Seizure; This is a spontaneous report from a contactable physician (patient). A female patient of an unspecified age received BNT162B2 (Pfizer-Biontech Covid-19 Vaccine) on an unspecified date, at single

dose, for COVID-19 immunisation. Relevant medical history and concomitant medications were unknown. On an unspecified date, after the vaccination, the patient had a seizure. Clinical outcome of the adverse event was unknown at time of this report. The information on the lot number has been requested.; Sender's Comments: A possible causal relationship between seizure and BNT162B2 cannot be completely ruled out considering the temporal relationship. However, more information would allow for a full medically meaningful assessment, especially medical history, concomitant medications, concurrent illness and event details description including time lag between the onset of the event and vaccination date of BNT162B2. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

"Her INR was 5.8 (normal range 1 to 2)/increasing INR; Scratched arm; Scratched arm and bled through 3 shirts, it kept bleeding; This is a spontaneous report from a contactable nurse (patient). A 64-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (lot number EC1284), via an unspecified route of administration administered to left arm/deltoid on 29Dec2020 13:15 at single dose for COVID-19 immunization at a research medical facility; and received warfarin sodium (COUMADIN, strength 2 mg), oral (by mouth) from an unspecified date in 2017 and ongoing at ""3 1/2 tablets once daily in the evening at 5:30pm (total 7mg)"" for metal heart valve. The patient's medical history included had the surgery (for her metal heart valve), about 01Mar in 2017 (about 4 years ago) and so she thought she had been on Coumadin for about 4 years, had been on the 7mg dose for over a year; and has a history of metal heart valve and takes Coumadin for the metal heart valve. Denied illness. Denied family medical history relevant to event. There were no concomitant medications. The patient previously received Shingrix vaccine in past and remenbered she had the usual side effects from it, had mild symptoms. History of all previous immunization with the Pfizer vaccine considered as suspect was none. The patient did not receive any other vaccines the same date of the Pfizer Suspect or 4 weeks prior. On Jan2021, the patient experienced scratched arm and bled through 3 shirts, it kept bleeding. On 04Jan2021, her international normalised ratio (INR) was 5.8 (normal range 1 to 2). The events did not lead to emergency room visit, however led to physician office visit. The events were reported as serious medically significant. The nurse got the first Pfizer COVID-19 shot on 29Dec2020 because she is a healthcare provider. She wanted information on increasing INR. The nurse has a history of metal heart valve and takes Coumadin. Her INR was typically 1.7 to 2.3. She reported her last INR, before the covid-19 vaccine was given, was ""some time ago"" but it had not varied much over the years. Normally she got her INR run and it was about 2. She had to be scheduled for her INR on the 04Jan2021 and it was 5.8 (normal range 1 to 2) and they asked about anything that may have changed and the only thing was that she got her first shot. The nurse reported not having any changes in her medications, food, or life style to account for the change, other than receiving the COVID-19 vaccine. The patient stated that it could be a serious problem if she had an accident or fell and started bleeding. A normal person's lab result is between 1 and 2, but they like to keep people with the metal heart valves between 2 and 3. She had been bleeding. She had barely scratched her arm the other day and went through 3 shirts because she kept bleeding. This is more than unusual for her, it's kind of unusual.

Getting the vaccine is the only variant she has had since getting her last INR. The patient underwent lab tests and procedures which included INR (normal range 1 to 2): typically 1.7 to 2.3 on an unspecified date; it's about 2 on an unspecified date: and 5.8 on 04Jan2021. The action taken in response to the events for warfarin sodium was dose not changed. The outcome of the event INR was 5.8 was not recovered, for the other events was unknown. The nurse (patient) assessed the event ""INR was 5.8; it's normally about 2"" as related to the COVID-19 vaccine.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the reported events of International normalised ratio increased and wound hemorrhage due to temporal relationship. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics coagulation panel, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate."

Dizziness; palpitations; resting tachycardia that persisted for 3 days; muscles aches; Chills; Restlessness; feeling unwell; arm pain; This is a spontaneous report from a contactable physician reported for herself. This 37-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: Ek5730) via intramuscular on 23Dec2020 09:30 AM on left arm at single dose for COVID-19 immunisation. Medical history included chronic kidney disease, HTN (hypertension), persistent proteinuria. No known allergies. Concomitant medication included losartan. The patient did not have other vaccine in four weeks and did not diagnosed with COVID-19 prior to vaccination. The patient was not pregnant at the time of vaccination. On 24Dec2020, the patient experienced dizziness, palpitations, resting tachycardia that persisted for 3 days, muscles aches, chills, restlessness, feeling unwell and arm pain, and resulted in Emergency room/department or urgent care. Treatment included paracetamol (TYLENOL). The patient had COVID tested on 28Dec2020 post vaccination, covid test type post vaccination=Nasal Swab, covid test name post vaccination=PCR, covid test result=Negative. Outcome of events was recovered.; Sender's Comments: The reported events dizziness, palpitations, resting tachycardia that persisted for 3 days, muscles aches, chills, restlessness, feeling unwell and arm pain, were likely related to the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) due to temporal relationship and clinical course. The case will be reassessed should additional information become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics committees and Investigators, as appropriate.

Hellucinogenic visions of monsters and violent events; This is a spontaneous report from a contactable consumer (patient). A 68-year-old female patient (not pregnant) received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EK5730), via an unspecified route of

administration on 05Jan2021 at 14:30 on Right arm at single dose for COVID-19 immunization in hospital. The patient medical history included Hypertension, Hypothyroid. Prior to vaccination, patient was not diagnosed with COVID-19. Concomitant medications included levothyroxine sodium (LEVOXYL); Olmesartan; aluminium hydroxide gel, dried, magnesium carbonate (PEPCID); bifidobacterium bifidum, bifidobacterium lactis, bifidobacterium longum, lactobacillus acidophilus, lactobacillus rhamnosus (PROBIOTIC); ascorbic acid, biotin, folic acid, iodine, pantothenic acid, pyridoxine hydrochloride, retinol, vitamin b12 nos, vitamin d nos, vitamin e nos, zinc (CENTRUM MULTIGUMMIES). Patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient previously took and had known allergies with bacitracin zinc;neomycin sulfate;polymyxin b sulfate (NEOSPORIN) and bacitracin zinc;neomycin sulfate;polymyxin b sulfate (POLYSPORIN). The patient experienced hellucinogenic visions of monsters and violent events on 06Jan2021 at 02:00 AM. Since the vaccination, patient had not been tested for COVID-19. No treatment was received for the event. The outcome of the event was recovering. The report was reported as non-serious, with seriousness criteria-Results in death: No; Life threatening: No; Caused/prolonged hospitalization: No; Disabling/Incapacitating: No; Congenital anomaly/birth defect: No.

severe ITP; This is a spontaneous report from a contactable physician. A 22-years-old male patient received his first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 17Dec2020 at single dose for COVID-19 immunization. The patient medical history and concomitant medications were not reported. The patient developed severe ITP (Idiopathic thrombocytopenic purpura) on 20Dec2020, 3 days after first dose of the vaccine on 17Dec2020. He was hospitalized for 3 days and now the patient was healthy with a normal platelet count on an unspecified date. The physician wanted to know if this patient can get the second dose. The outcome of the event was recovered on an unspecified date. Information on the lot/batch number has been requested.; Sender's Comments: A possible contributory effect of suspect BNT162B2 on reported ITP cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

"immune deficiencies; She said the joint pain felt like ""flu"" joint pain; She said she was really sweaty, so much so, that she had sweat under her eyes; thyroid problems; feels shaky inside; Numbness facial; Exhaustion; Foggy feeling in head/feeling rundown; felt exasperated; sweating like crazy and then gets chills; felt yucky/she didn't feel good at all; Joint pain; Nausea; Chills; after receiving the COVID-19 Vaccine on (Dated), she had left upper shoulder pain.; She clarified she had some injection site pain; and the injection site was a little itchy; This is a spontaneous report from a contactable consumer (patient). A 58-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot EL3246), via an unspecified route of administration on 02Jan2021 14:30 at single dose in the left upper arm for COVID-19 immunization. Medical history included Pernicious anaemia from 2006 and ongoing, Hashimoto's disease ongoing, stated she was diagnosed with Hashimoto's disease in either 1994 or 1995. Psoriatic arthritis from Nov2020 and ongoing. Potassium low ongoing, reported she has

had low potassium off and on for years. She said she can't remember when she didn't have low potassium. She said she normally finds out her potassium is low when she has blood work done. She stated she has had low potassium most of her adult life. IgA deficiency from Feb2019 and ongoing, Psoriasis ongoing, paralysis in her left trapezius muscle. Concomitant medication included B-12 for pernicious anemia. She said she had the typical reactions that one might get with a vaccine. She clarified she had some injection site pain and the injection site was a little itchy on 02Jan2021. She stated on the second day (03Jan2021) she had joint pain, felt yucky, had nausea, and chills. She said the next day (04Jan2021) she felt a little better, but still had chills. She said yesterday (05Jan2021) she thought she was feeling better, but by yesterday, clarified as late afternoon and evening, she crashed. She said she has a lot of autoimmune issues and immune deficiencies, saying she has pernicious anemia and Hashimoto's disease. She said yesterday evening she experienced extreme body temperature issues. She said she was really sweaty, so much so, that she had sweat under her eyes. She said she would get really hot and had chills. She said she was feeling really bad and was feeling shaky inside. She said she thought it was important that she report what she was experiencing to Pfizer. She stated she has psoriatic arthritis, too. Reported after receiving the COVID-19 Vaccine on 02Jan2021, she had left upper shoulder pain. She clarified that she had a previous history of paralysis in her left trapezius muscle and had surgery in 1998 on her left shoulder. She said she had a weird feeling that went around where her scar was from the surgery on the back of her left shoulder. She said maybe the left shoulder pain had to do with how she held her left shoulder. She said on Monday, 04Jan2021, she had a little bit of pain in her left shoulder and by yesterday night, 05Jan2021, there was not much pain at all. Clarified her joint pain was in her ankles, wrists, hips, neck, back, and knees. She said the joint pain felt like ""flu"" joint pain. She stated she normally has joint pain with the other issues she has, but this joint pain felt different. She said the joint pain she experienced after taking the COVID-19 Vaccine was all over her body. She said yesterday (05Jan2021) her joint pain felt so much better, but later in the afternoon she didn't feel right. She said she has pernicious anemia, and thought maybe she needs her B-12 shot. She said yesterday (05Jan2021) she experienced a lot more symptoms. She said she had numbness in her face, felt extremely exhausted, had a foggy feeling, and felt exasperated. She said the symptoms didn't start until late in the afternoon into the evening of 05Jan2021. She said she did not feel well and went to bed at 8:45PM, which is early for her. She said she did give herself a B-12 1mcg/ml shot intramuscularly yesterday. She provided the B-12 1mcg/ml NDC Number: 7006900510, Lot Number: C0495, and Expiration Date: Aug2022. She said the name (company name) was listed on the B-12 1mcg/ml packaging. She said she gives herself a B-12 shot every 10 days. She said she still has some joint pain, but the joint pain is not like it was on 03Jan2021. She said she still has a tiny bit of heaviness in her joints with a constant throbbing pain, which is a different joint pain from her normal. Reported last night (05Jan2021) she didn't feel good at all. She said she felt horrible, and had to go to bed. She said she felt shaky inside all night, and still feels that way now. She said she was sweating like crazy, and then would get chills. She clarified she is used to being hot and cold in her normal life because of her thyroid problems, but stated what she experienced last night was beyond that. She said her hot and cold issue was bumped up several levels last night. She said she was chilled or sweating all the time last night, but did not have a temperature. She clarified her normal body temperature is 96.7, and when she checked her temperature at one point, her temperature was 98 degrees. Reported the hot and cold with sweating and chills, and nausea come and go. She said if she has nausea, it is a mild feeling of nausea.

Clarified if Sunday, 03Jan2021. was a work day, she would have called out sick. She said Monday (04Jan2021) and Tuesday (05Jan2021) she did go to work. Reported she has low potassium and made herself an electrolyte cocktail. Reported if her system feels off, she said her electrolytes maybe off. She said her heart felt like it may be shaky, so she ate a banana to get potassium in her system. She said she does her little routine before she would call her doctor to get blood work done. She said she had her blood work done not too long ago. She said she wasn't feeling this way before she had the COVID-19 Vaccine, and is feeling rundown now. She said she was feeling good before she had the COVID-19 Vaccine. She said she feels like something is going on with her body now. Reported her last blood work was done on 04Dec2020 and everything was kind of normal. She clarified her thyroid was a little off, and her doctor adjusted her medication. She said her potassium was a little down. Reported she was told when she got the COVID-19 Vaccine shot she has to be a little more careful, and she might not be as protected as some people. She said she was told there have not been enough studies on the COVID-19 Vaccine. She clarified she was told that information by a person at the site where she received the COVID-19 Vaccination, saying the person was helping her with the COVID-19 Vaccination authorization form. Reported she thought she was doing OK after she received the COVID-19 Vaccine, until after last night and yesterday afternoon. She said if she continues feeling the way she is, she will see her doctor. She said her system seems off. She said she normally tries everything she knows first, like drinking a lot of water, and drinking electrolytes, and will take potassium to see if that is the issue. She said those are her own things that she does before she calls her doctor. Clarified sometimes she has numbness in her face due to not having her B-12. She said she still has a little numbness in face. She said on 05Jan2021, the numbness went across her face from the bridge of her nose down through to her mouth. She said the numbness was nothing like paralysis in her face, but her face was really hot at the same time she had the numbness. Reported she took Tylenol (clarified as (company) brand Tylenol, stating she doesn't have the UPC, Lot and Expiration Date). She said the Tylenol wasn't kicking in, so she took Ibuprofen (clarified as (company)brand Ibuprofen, and she doesn't have the Ibuprofen NDC, Lot and Expiration date). She said she took her normal medications. Outcome of events ""She clarified she had some injection site pain"" ""and the injection site was a little itchy"" and Shoulder pain were recovered on an unspecified date, ""Chills"" and ""feels shaky inside"" were not recovered, ""Joint pain"" ""Nausea"" ""Numbness facial"" were recovering, while outcome of other events was unknown."

Bell's Palsy; This is spontaneous report from a contactable Other Health Professional. This reporter reported similar events for 6 patients. This is a 6th of 6 reports. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced bell's palsy on an unspecified date with outcome of unknown. Since the use of modified RNA in COVID vaccines, the reporter aware of 6 cases of Bell's Palsy by the companies making these vaccines. Information about lot/batch number has been requested.; Sender's Comments: Based on temporal association, the causal relationship between BNT162B2 and the event facial paralysis cannot be excluded. The information available in this report is limited and does not allow a medically meaningful assessment. This case will be reassessed once additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and

analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate.,Linked Report(s) : US-PFIZER INC-2021007605 Different patient, same drug/event.

The numbness began to intensify and I could not feel myself blinking or smiling on the left side of my face; pain and numbness to my left ear and left jaw that began to spread down my left jaw and upward across my left cheek, left eye, and left temple, and above my left eyebrow; pain and numbness to my left ear and left jaw that began to spread down my left jaw and upward across my left cheek, left eye, and left temple, and above my left eyebrow; pain and numbness to my left ear and left jaw that began to spread down my left jaw and upward across my left cheek, left eye, and left temple, and above my left eyebrow; pain and numbness to my left ear and left jaw that began to spread down my left jaw and upward across my left cheek, left eye, and left temple, and above my left eyebrow; pain and numbness to my left ear and left jaw that began to spread down my left jaw and upward across my left cheek, left eye, and left temple, and above my left eyebrow; This is a spontaneous report from a contactable nurse reported for herself. A 39-years-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (lot number EL0142) via an unspecified route of administration on 07Jan2021 07:00 at single dose for covid-19 immunization. Vaccine location was left deltoid. The facility type vaccine was Workplace Clinic. Medical history included food allergy at shrimp. Concomitant medications were not reported. The patient did not received any other vaccines within 4 weeks prior to the COVID vaccine. On 07Jan2021 at 07:15 AM the patient notice pain and numbness to her left ear and left jaw that began to spread down left jaw and upward across left cheek, left eye, and left temple, and above left eyebrow. The numbness began to intensify and patient could not feel herself blinking or smiling on the left side of my face. The numbness slowly began improving over the next hour in the same order that it began, but she still have mild left ear and jaw pain and mild numbness. Events outcome are recovering. No treatment was received. The action taken was not applicable.; Sender's Comments: Based on the compatible time association, the facial palsy is possibly related to suspect BNT162B2 administration. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Burst blood vessel in left eye 24 hours after vaccine was given.; This is a spontaneous report from a contactable other-HCP. A 45-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) lot number not available, via an unspecified route of administration on 21Dec2020 07:45 AM at single dose for covid-19 immunization. Vaccine location was left deltoid. The patient did not received any other vaccines within 4 weeks prior to the COVID vaccine. Medical history included morbid obesity and blood pressure high. No known allergies. Patient didn't do relevant test. Concomitant medication included amlodipine (AMLODIPINE) at 5mg daily. The patient experienced burst blood vessel in left eye 24 hours after vaccine was given (eye haemorrhage) on 22Dec2020 08:30 with outcome of recovered. No treatment received. The action taken in response to the event for BNT162B2 was not applicable. Information on the lot/batch number has been requested.; Sender's Comments: Based on the available

information, the company considers that a causal relationship between the eye haemorrhage and vaccination with BNT162B2 cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer drug is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Had ruptured blood vessels x 2 spontaneously in eyes; This is a spontaneous report from a contactable nurse reported for herself. A 54-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (lot number EK5730), via an unspecified route of administration on 17Dec2020 03:00 P.M at single dose for covid-19 immunization. The facility type vaccine was: workplace clinic. Medical history included manifesting carrier BMD (Becker's muscular dystrophy). Allergies to medication: allergies rash on Sulfa. The patient did not received any other vaccines within 4 weeks prior to the COVID vaccine. Concomitant medication included pregabalin (LYRICA), duloxetine hydrochloride (DULOXETINE [DULOXETINE HYDROCHLORIDE]). The patient experienced ruptured blood vessels x 2 spontaneously in eyes (eye haemorrhage) on 18Dec2020 with outcome of recovered. No treatment received. The action taken in response to the event for BNT162B2 was not applicable.; Sender's Comments: Based on the available information, the company considers that a causal relationship between the eye haemorrhage and vaccination with BNT162B2 cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer drug is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

some congestion that just came on; her arm was really aching after the injection; she started coughing; voice was hoarse; light wheeze; soles of her feet were hurting; pressure in bilateral groin; aching all over; very tired; balance issues; This is a spontaneous report from a contactable nurse (patient). A 62-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EK9231) intramuscularly in left upper arm on 05Jan2021 at single dose for covid-19 immunisation. The patient got her Covid vaccine yesterday (05Jan2021) around 11 or 11:30 am in her left upper arm. She had bilateral breast cancer and had lymph nodes removed in each arm but more removed from her Right, so she got the vaccine in the left arm. She also had some skin cancers removed, one would not heal properly on her left arm and formed a blister, and her dermatologist popped it and put a band aid on it. The vaccine was given 3 inches above it. The patient's concomitant medications were not reported. The patient experienced pressure in bilateral groin, aching all over, very tired and balance issues on 05Jan2021; light wheeze on 06Jan2021. Seriousness for these events was medically significant. The patient stated she had some congestion that just came on. She felt fine yesterday (05Jan2021) right after getting the vaccine, that at work she did notice that there was something different feeling in the left side of her groin. She was not in direct patient care. She noticed on her left side in the groin, something felt different, then yesterday evening (05Jan2021) after work she was really tired in the evening, aching all over last night, even the soles of her feet were hurting, woke up like her balance was off, she would walk one way and go another, states it is not like an orthostatic issue, that

she knows what that feels like. She stated that in her inguinal area she could feel pressure, bilaterally. Her arm was really aching after the injection. Her breathing, heard a light wheezing, was clearing her voice, and then she started coughing, voice was hoarse. The outcome of events pressure in bilateral groin, very tired and light wheeze was not recovered; of events aching all over and balance issues was recovering; of other events was unknown.; Sender's Comments: The reported events bilateral groin, aching all over, very tired, balance issues and light wheeze were possibly related to the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), due to temporal relationship. The case will be reassessed should additional information become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics committees and Investigators, as appropriate.

Severe respiratory distress; This is a spontaneous report from a contactable pharmacist. A 51-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection),Lot# lot number: EL1284, intramuscular at right arm on 07Jan2021 12:00 PM, at SINGLE DOSE for COVID-19 immunization. No known allergy , no other medical history.No COVID prior vaccination. Facility where the most recent COVID-19 vaccine was administered was Nursing Home/Senior Living Facility .No any other vaccines within 4 weeks prior to the COVID vaccine. No Concomitant medications (received within 2 weeks of vaccination) . On 07Jan2021 the patient experienced Severe respiratory distress that resulted in Emergency room/department or urgent care.It was unknown if treatment was received for the event. The patient had not been tested for COVID post vaccination. The outcome of the event was unknown.; Sender's Comments: A possible causal relationship between Severe respiratory distress and BNT162B2 cannot be completely ruled out considering the temporal relationship. However, more information would allow for a full medically meaningful assessment, especially medical history, concomitant medications, concurrent illness and event details. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

she was transferred to the hospital with tachycardia, congestion, shortness of breath, and is now unresponsive; she was transferred to the hospital with tachycardia, congestion, shortness of breath, and is now unresponsive; she was transferred to the hospital with tachycardia, congestion, shortness of breath, and is now unresponsive; she was transferred to the hospital with tachycardia, congestion, shortness of breath, and is now unresponsive; This is a spontaneous report from a contactable nurse. A 95-year-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), Lot# EH9899 Exipration on 06Jan2021 at 15:00 at SINGLE DOSE at deltoid for COVID-19 immunization. The patient received first dose of the same vaccine BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), Lot# EH9899 Exipration date : 31Mar20221, on 16Dec2020. Medical history included : cardiac failure congestive, hypertension, cardiac murmur .There were no concomitant medications. The patient previously took cymbalta , vasotec and

zocor and experienced drug hypersensitivity. The patient didn't receive any other vaccines within 4 weeks prior to the COVID vaccine.This nurse,worker at a skilled nursing facility, reported that this patient with a history of heart failure, received her second dose of the Pfizer-BioNTech Covid-19 vaccine yesterday, 06Jan2021, at 3pm. At 7am on 07Jan2021 she was transferred to the hospital with tachycardia, congestion, shortness of breath, and is now unresponsive. Patient was stable prior to vaccination, but will now be transferred to hospice care. The nurse added the patient had the second COVID vaccine on 06Jan2021 yesterday and has now been transport to hospital due to a drastic decline after the shot. It was explained that this morning around 7 am she was transferred to the hospital. She was experiencing tachycardia, shortness of breath, and congestion. The events started this morning around 6-6:30am. The patient was admitted to the hospital. The shot was given at the facility. She received it at 3pm on 06Jan2021, First dose was on 16Dec2020.The caller relays she didn't know how aggressive the hospital will be for the patient. She was a full code when left and now a DNR and is unresponsive. The patient will be going on hospice care. The causality was reported as related. The outcome of the events was not recovered.; Sender's Comments: The Company cannot completely exclude the possible causality between the reported tachycardia, shortness of breath, congestion, unresponsive, and the administration of the COVID 19 vaccine, BNT162B2, based on the reasonable temporal association. The patient's pre-existing medical condition of cardiac failure congestive, hypertension, cardiac murmur are confounding factors. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RA, IEC, as appropriate.

patient developed acute onset of right-sided facial palsy and pain; patient developed acute onset of right-sided facial palsy and pain; Brain MRI done showing T2 hyperintensity in the brainstem and basal ganglia, suspicious for inflammation; This is a spontaneous report from a contactable physician. A 46-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), on 18Dec2020 at SINGLE DOSE for COVID-19 immunization. Medical history included psoriasis. No COVID prior vaccination. It was unknown if the patient received any other vaccines within 4 weeks prior to the COVID vaccine.No known allergies. Concomitant medications (received within 2 weeks of vaccination) included fluoxetine. days following vaccination,on 23Dec2020,the patient developed acute onset of right-sided facial palsy and pain. Brain MRI done showing T2 hyperintensity in the brainstem and basal ganglia, suspicious for inflammation. Work-up is ongoing. AE Resulted in: Doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care, Disability or permanent damage].It was unknown if the event was treated. The event was assessed as serious for Disabling/Incapacitating. The patient had been tested for COVID post vaccination (covid test result-Negative). The outcome of the events werenot recovered Information about lot/batch number has been requested.; Sender's Comments: A possible causal relationship between acute onset of right-sided facial palsy and pain with MRI findings suspicious for brain inflammation and BNT162B2 cannot be completely ruled out considering the temporal relationship. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as

well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

myositis; This is a spontaneous report from a contactable physician. A 43-year-old male patient received first dose BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number/expiration date unknown) on an unspecified date in Dec2020 reported as around the end of December, at single dose for COVID-19 immunization. Relevant medical history and concomitant medications were not reported. On an unspecified date after he received the vaccine he had right arm pain and swelling (states it was in his bicep brachial radialis in the muscle) which is the opposite arm of the injection site. He had an MRI done on an unknown date that showed myositis. He thinks could be due to the vaccine since it started two days after he received the vaccine. His pain peaked at about a week and a half and now the pain was improving and the swelling was down. He still had function in the right arm but when he strained it would hurt. His concern was that the reaction may be an autoimmune reaction and the first response was muted. He was worried the second dose may elicit a larger response. At the time of the reporting the patient was recovering from the events. Information on Lot/Batch number has been requested.; Sender's Comments: Based on the available information, the company considers that a causal relationship between the myositis and vaccination with BNT162B2 cannot be excluded. Additional information regarding onset latency, relevant medical history, concomitant medications and detailed clinical course around the event onset will aid in comprehensive assessment of the case. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics committees and Investigators, as appropriate.

Atrial fibrillation; Was not feeling well; Warm sensation in chest; This is a spontaneous report from a contactable nurse (patient). This 62-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot EJ 1685), intramuscular, on 21Dec2020 at 09:30 PM at single dose for COVID-19 immunisation. Vaccine location was left arm. The patient was vaccinated at hospital, age at vaccination was 62-years-old. The patient received also varicella zoster vaccine RGE (CHO) (SHINGRIX) on 19Nov2020. Medical history included gastrooesophageal reflux disease (GERD) and high cholesterol. Concomitant medications included omeprazole, colestyramine (QUESTRAN), and vitamins. On 22Dec2020, the patient was not feeling well intermittently starting the day after the injection with warm sensation in chest that would go away until 31Dec2020 when the warm sensation of chest would not go away. The patient was sent for EKG that showed atrial fibrillation that she is now being treated for. The events resulted in doctor or other healthcare professional office/clinic visit. The events were reported as non-serious. Outcome of the events was unknown.; Sender's Comments: The Company cannot completely exclude the possible causality between the reported atrial fibrillation and the administration of COVID 19 vaccine, BNT162B2. More information regarding the clinical course, the patient's underlying concurrent medical condition are required for the Company to make a more meaningful causality assessment. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for

adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RA, Agency, as appropriate.

blood in the stool; fevers; night sweats; chills; aches; This is a spontaneous report from a contactable Physician reporting for herself. A 30-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 30Dec2020 at single dose for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. She experienced chills and aches after 24 hours (on 31Dec2020) and experienced significant fevers that wouldn't break and cycles of chills and fevers that would last for 2 hours each cycle over the next 24 hours. She also experienced night sweats and blood in the stool and mentioned it was the first time that happened to a healthy 30 year old like her. She is asking for reports of these side effects, especially blood in the stool and for recommendations regarding taking the 2nd dose as she is still not sure on whether to take it due to hearing that the 2nd dose side effects were worse. The outcome of the events was unknown. Information on the Lot/Batch number has been requested.; Sender's Comments: Based on the information currently provided, the vaccination with BNT162B2 might play a contributory role in triggering the onset of blood in the stool. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Tested positive for COVID-19; CT showed increased infiltrates 10-15%; Dehydration/Dehydrated; Chills; Tested positive for COVID-19; Hypotensive; Achy; Severe achy cramps/Severe cramps all over body; This is a spontaneous report from a contactable nephrologist (patient himself). This 78-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number EK5730), via an unknown route, on 17Dec2020 at single dose for COVID-19 immunisation. Age at vaccination was 78-year-old. The patient was diabetic and hypertensive. Additional medical history included hyperlipidaemia. No relevant concomitant medications were provided. On 18Dec2020, the patient developed severe achy cramps/severe cramps all over body. On 19Dec2020, the patient developed achy. On 20Dec2020, the patient was dehydrated and hypotensive, he had also chills. On unknown date, blood pressure was down to 76/50. His symptoms for COVID were severe achy cramps, hypotension, and dehydration. On 20Dec2020, COVID-19 test was positive. On 21Dec2020, the patient was given monoclonal antibodies. A computerized tomogram (CT) of the lungs was performed on 21Dec2020 and it was ok. A week later (Dec2020), he had a repeat CT which showed increased infiltrates of 10 to 15%. He then started on dexamethasone, apixaban (ELIQUIS) and the rest of the things. He had a repeat CT on 05Jan2021 which showed resolution of the infiltrates; most of the lesions went gone. CT results had improved significantly. The patient underwent a second COVID test a week ago which was still positive. He had a third COVID on 06Jan2021, but results were not available yet. The patient queried if he can proceed with second dose planned on 07Jan2021 or if he should wait. The clinical outcome was recovered for the event 'severe achy cramps/severe cramps all over body' on 19Dec2020, for 'dehydration/dehydrated' on 20Dec2020, for 'chills' on unknown date in Dec2020, for 'achy' on 30Dec2020, for 'hypotensive' on 20Dec2020; the outcome of the event 'CT showed increased infiltrates

10-15%' was recovering; the outcome for 'Tested positive for COVID-19' was unknown. The reporter considered the events 'achy' and 'severe achy cramps/severe cramps all over body' serious because causing disability; the events 'tested positive for COVID-19', 'dehydration/dehydrated', 'chills' and 'hypotensive' were considered medically significant. The reporter considered the events 'Tested positive for COVID-19', 'CT showed increased infiltrates 10-15%' and 'dehydrated/dehydration' unrelated to BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE).; Sender's Comments: A possible contributory effect of suspect BNT162B2 on reported events cannot be excluded. Case will be reassessed when new information is received. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

Possible cellulitis; slight redness in left upper within 24 hours; severe redness and swelling and warmth of entire upper left arm and half of lower arm; severe redness and swelling and warmth of entire upper left arm and half of lower arm; Some pain; This is a spontaneous report from a contactable Physician. A 94-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number: EL0140) on 30Dec2020 at 12.00 pm at single dose Intramuscular on left arm for COVID-19 immunization. Relevant medical history included COVID 19 infection, on 19Jul2020, post COVID left femoral DVT oral anticoagulation, Alzheimer dementia, Osteoarthritis, Spinal Stenosis, Gait Dysfunction and Constipation. Known allergies included acetazolamide, penicillin and sulfa. Concomitant medications included apixban (ELIQUIS) 5 mg twice a day, colecalciferol (VIT D3) 1000u once a day. On 31Dec2020 at 12:00 pm patient experienced slight redness in left upper within 24 hours. The patient also experienced possible cellulitis, severe redness and swelling and warmth of entire upper left arm and half of lower arm. Some pain. No fever. It was also informed that patient underwent nasal Swab test for Coronavirus (Abbott BinaxNOW) on 05Jan2021 and on 07Jan2021 and resulted negative, for both. Treatment received for cellulitis included Cefuroxime. Outcome for the event possible cellulitis was unknown. Outcome of other reported events was recovering.; Sender's Comments: Based on the information available, a possible contributory role of the suspect products cannot be excluded for the reported events due to temporal association. However patient old age and other underlying conditions cannot be excluded for a contributory role The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators as appropriate.

Facial paralysis; This is a spontaneous report from a contactable Pharmacist. A 70-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number EH9899, Expiration Date 30Mar2021), via intramuscular, on 17Dec2020 (at 15:35), at single dose of 0.3 mL for COVID-19 immunisation. The patient was vaccinated at hospital, age at vaccination was 70-year-old. Vaccine location was deltoid but unsure which deltoid. The patient did not have a relevant medical history and concomitant medications. Pharmacist said that after vaccination, she waited to be

monitored the standard 15 minutes at hospital and then when she got in the car and was on the way home like 20 minutes later she had brief episode of what the patient described as facial paralysis. It was like the side of her face in one area felt funny, it felt numb and it was not anywhere else on her face. It lasted the 20 minutes and then went away. The patient had recovered from the events on 17Dec2020. The pharmacist queried if the patient can proceed with the 2nd dose of the vaccine. The reporting pharmacist considered the event 'facial paralysis' as non-serious.; Sender's Comments: A possible causal relationship between acute onset of facial paralysis and BNT162B2 cannot be completely ruled out considering the temporal relationship and the known adverse event profile of the suspect vaccine. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

got home from the shot at 1145a. Fell asleep until 930pm. During sleep was told by family that i was angry, cursing and yelling in my sleep. I don't remember any of it , i felt delirious and out of co; got home from the shot at 1145a. Fell asleep until 930pm. During sleep was told by family that i was angry, cursing and yelling in my sleep. I don't remember any of it , i felt delirious and out of co; got home from the shot at 1145a. Fell asleep until 930pm. During sleep was told by family that i was angry, cursing and yelling in my sleep. I don't remember any of it , i felt delirious and out of co; got home from the shot at 1145a. Fell asleep until 930pm. During sleep was told by family that i was angry, cursing and yelling in my sleep. I don't remember any of it , i felt delirious and out of co; Left arm was extremely painful; This is a spontaneous report from a contactable Other-HCP. A 51-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number # EL1284) on 02Jan2021 at 10:00 AM at single dose via intramuscular on left arm for COVID-19 immunization. Medical history included allergy to codeine hypertension and asymptomatic HIV infection. Concomitant medications were not reported. Patient got home from the shot on 02Jan2021 at 11: 45 am. Fell asleep until 930p:m. During sleep was told by family that He was angry, cursing and yelling in his sleep. He didn't remember any of it, He felt delirious and out of control. Left arm was extremely painful. At the time of the reporting had recovered from the events without any treatment.; Sender's Comments: A possible contributory effect of suspect BNT162B2 on reported event delirious cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

"lymph node swelling and lymphedema in the right forearm side and the right upper arm; lymph node swelling and lymphedema in the right forearm side and the right upper arm; cold blister on lip; significant swelling on the right side of the base of her neck near her clavicles; slightly itchy scalp; redness, swelling, tenderness at injection site; redness, swelling, tenderness at injection site; redness, swelling, tenderness at injection site; This is a spontaneous report from a contactable Registered nurse reporting for herself. A 58-years-old female patient received the first dose of BNT162B2 Pfizer-BioNTech COVID-19 Vaccine (Batch/lot number: EL0140), in Hospital, by intramuscular route in right upper arm on

23Dec2020 at 08:30, at 58-year-old of age, at single dose for COVID-19 immunization. The patient had no relevant medical history. She didn't receive any prior vaccinations within 4 weeks. There were no concomitant medications. The patient reported that it has been 2 weeks since she received the COVID-19 Vaccine now and she still has a considerable amount of lymph node swelling and lymphedema in the right forearm side and the right upper arm. The nodes on the right side of her neck around the clavicle have been quite swollen for about 2 weeks. She has the list of side effects so she was not concerned, as this was listed but now she's not sure. When she got the vaccine she had the expected redness, swelling and tenderness at injection site (onset reported as 23Dec2020). On the evening of the 24Dec2020 she had an itchy scalp but she didn't see any rash and that only lasted a short time. On 29Dec2020 the patient had a significant swelling on the right side of the base of her neck near her clavicles that wrapped around to the posterior of her neck and was assessed as medically significant. She treated it by putting ice on it in the evening. On 30Dec2020 the swelling seemed to be slightly decreased but it is still a visible lump, the nodes are firm and there is swelling around those and it has not improved since the 30Dec2020. On 30Dec2020 she noticed a little cold blister or hive on the center of her lower lip and that was resolved by 03Jan2021, she did not have fever and did not feel sick, but her main problem is the swollen lymph nodes around base of neck around clavicle and it is considerably swollen there. The patient reported that last night (06Jan2021) it looked like her right arm was swollen, she thinks she is having lymphedema on the right arm, her right forearm is half an inch circumference larger than her left arm and was measured at her work. The patient reported she is seeing her new primary care doctor on 26Jan2021 and will follow up with the doctor. The patient wanted to know if she should get the second dose scheduled for the next week or should wait until the swelling resolves. Moreover the patient asked how long do the side effects usually last (specifically systemic side effects). The events ""redness, swelling and tenderness at injection site"" and ""slightly itchy scalp"" resolved on 25Dec2020, the event ""Cold blister on lip"" resolved on 03Jan2021. The event ""Swelling on the right side of the base of her neck near her clavicles"" had not resolved yet at the time of the report. All the reported events were assessed as related to the COVID-19 Vaccine by the Primary Source Reporter (Method of assessment:Agency).; Sender's Comments: Based on temporal association, the causal relationship between BNT162B2 and the events swelling and lymphadenopathy cannot be excluded. The information available in this report is limited and does not allow a medically meaningful assessment. This case will be reassessed once additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate."

kidney infection; urine turning a different color/urine was an orange color/urine was a tea color; This is a spontaneous report from a contactable Nurse reporting for herself. A 24-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 06Jan2021 at single dose for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient stated earlier this afternoon (07Jan2021) urine turning a different color, her urine was an orange color, and this afternoon her urine was a tea color. She had no other symptoms as if she had a kidney infection. The outcome of the events was

unknown. Information on the lot/ batch number has been requested.; Sender's Comments: The causal relationship between BNT162B2 and the event kidney infection cannot be excluded as the information available in this report is limited and does not allow a medically meaningful assessment. This case will be reassessed once additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate.

Nausea; Diarrhea; Jitteriness; foggy head or brain; she can't concentrate /she didn't pay it any attention; sleeping a lot; sick; Headache; body aches; This is a spontaneous report from a contactable nurse. A 62-years-old female patient started to receive BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot# EK5730), via an unspecified route of administration on 05Jan2021 08:15 at single dose for COVID-19 immunisation. Anatomical location of administration of vaccine was right deltoid. Medical history was not reported. The patient previously took omeprazole (PRILOSEC) and experienced drug hypersensitivity and lip swelling. Concomitant medication included atorvastatin (LIPITOR). The patient experienced headache on Jan2021, body aches on Jan2021, nausea on 06Jan2021, diarrhea on Jan2021, jitteriness on Jan2021, foggy head or brain on Jan2021, sleeping a lot on Jan2021, sick on Jan2021, she can't concentrate /she didn't pay it any attention on Jan2021. The outcome of headache and she can't concentrate /she didn't pay it any attention was recovering, of pain, jitteriness, foggy head or brain was not recovered, of sleeping a lot and sick was unknown. Nausea, and diarrhea recovered on 07Jan2021.; Sender's Comments: Based on temporal association, the causal relationship between BNT162B2 and the events headache, pain, nausea, diarrhea, feeling jittery, feeling abnormal, disturbance in attention and hypersomnia cannot be excluded. The information available in this report is limited and does not allow a medically meaningful assessment. This case will be reassessed once additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate.

High fever; Vomiting; Severe fatigue; Weakness; This is a spontaneous report from a contactable physician (patient himself). This 61-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number EL1442), via intramuscular, on 05Jan2021 at single dose for COVID-19 immunisation. Age at vaccination was 61-year-old. Vaccine location was deltoid left. The subject did not have a relevant medical history and concomitant medications. On 06Jan2021, the patient developed high fever, vomiting, severe fatigue and weakness. He did not experience anaphylaxis. The events were considered serious as medically significant. The patient stated that side effects mentioned lasted 3 hours and he felt much better now. However, the final clinical outcome was unknown. The patient is not sure if he should get the shot again in 3 weeks since he was really sick. The reporting physician considered the events 'high fever', 'vomiting', 'severe fatigue' and 'weakness' related to BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE).; Sender's Comments: Based on temporal association, the causal

relationship between BNT162B2 and the events pyrexia, vomiting, fatigue and asthenia cannot be excluded. The information available in this report is limited and does not allow a medically meaningful assessment. This case will be reassessed once additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate.

feeling of fullness in her ear; it felt like fluid in her right ear; Hearing loss in right ear; Soreness in the left arm; This is a spontaneous report from a contactable Other-HCP. A 34-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number # EH9899) 16Dec2020 at 07:40AM in the left arm at single dose via intramuscular for COVID-19 immunization. Medical history included seasonal allergy. Concomitant medications included fluticasone propionate for seasonal allergy. The day after vaccination she noticed soreness of the left arm. Then two days later she noticed hearing loss secondary to a feeling of fullness in her ear; it felt like fluid in her right ear which has improved and she states it was not serious after the first dose. Patient received the second dose of vaccine on 04Jan2021 at 08:00AM in the left arm. That night she experienced myalgia, fever, chills, back pain, and started with a constant ringing in her right ear and the hearing loss that worsened from before (reported under AER 2021012152. All of these effects have resolved except the hearing loss and ringing in her ear. Additionally she went to see an ENT doctor and get a hearing test. The Hearing test showed moderate hearing loss and speech clarity of 96% in her left ear compared to 52% in the right ear. They don't know if it is permanent. She was currently being treated with 80mg of Prednisone daily by mouth and getting Dexamethasone injections to her middle eardrum. Patient informed that on 17Dec2020 she was tested for COVID 19 with the PCR test due to an exposure at work. The result was negative. The patient recovered from soreness in the left arm on 19Dec2020. The patient had not yet recovered from deafness.; Sender's Comments: Based on temporal association, the causal relationship between BNT162B2 and the events ear congestion and hearing loss unilateral cannot be excluded. The information available in this report is limited and does not allow a medically meaningful assessment. This case will be reassessed once additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate.

constant ringing in right ear; Myalgia; Fever; Chills; back pain; Inappropriate schedule of vaccine administered; hearing loss that worsened from before; hearing loss that worsened from before; This is a spontaneous report from a contactable physician (patient). This 34-year-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot EH9899), via an unspecified route of administration, on 04Jan2021 at 08:00AM at single dose for COVID-19 immunisation. The first dose was received on 16Dec2020 at 7:40 AM at single dose. Vaccine location was in the left arm. The patient was vaccinated at hospital, age at vaccination was 34-years-old. No other vaccine was received in four weeks. Medical history was none. Concomitant medications included ongoing fluticasone proprionate

(FLONASE) for seasonal allergy taking for two years. On 17Dec2020, COVID-19 PCR test was negative. On 04Jan2021 at night, she experienced myalgia, fever, chills, back pain and started with a constant ringing in her right ear and the hearing loss that worsened from before (started on 18Dec2020 after first dose, see AER # 2021012126). Start date of constant ringing in right ear was 05Jan2021. The events resulted in Physician Office visit. Hearing loss in right ear worsened and constant ringing in right ear were reported serious as medically significant while the other events were reported as non-serious. She went to see an ENT doctor and get a hearing test. The hearing test showed moderate hearing loss and speech clarity of 96% in her left ear compared to 52% in the right ear. They don't know if it is permanent. She is currently being treated with 80mg of Prednisone daily by mouth and getting dexamethasone injections to her middle eardrum. All of these effects have resolved except the hearing loss and ringing in her ear. All the events were considered related to the vaccine per reporter.; Sender's Comments: A causal association between BNT162B2 and the reported events cannot be excluded based on a compatible temporal relation between vaccination and onset of events. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

fever of 103.7; Cough; body aches; Joint pain; chills; This is a spontaneous report from a contactable Nurse reporting for herself. A 54-year-old female patient received first dose of intramuscular BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 06Jan2021 at single dose in left deltoid for COVID-19 immunisation at the age of 54-year-old. Lot number was EL1284. Medical history included Asthma since 1991 and ongoing, high blood pressure since 2020 (6 months before the report) and ongoing. Concomitant medications were unknown. On 07Jan2021, the patient experienced fever of 103.7 at 1:30PM, chills at 9:00AM, body aches at 11:00AM, Joint pain at 09:00AM, cough at 1:00PM; the events were considered medically significant. The patient was not treated for the events. On 13Nov2020, test showed she had COVID-19. On 07Jan2021, body temperature was 103.7 Fahrenheit. The patient did not recover from the events. The nurse considered the events were related to suspect vaccine.; Sender's Comments: A causal association between BNT162B2 and the reported events cannot be excluded based on a compatible temporal relation between vaccination and onset of events. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

"Hypokalemia; Hypomagnesemia; Hypocalcemia; Hemoglobin dropped little bit; Tetany; Muscle cramps; This is a spontaneous report from a contactable healthcare professional, a physician assistant. A 50-year-old female patient received the first dose of the BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot Number: UNKNOWN), via an unspecified route of administration on 18Dec2020 (at the age of 50-years-old) as a single dose for COVID-19 immunization. Medical history included tachycardia, tension headache, and glucose tolerance impaired. Concomitant medications included rosuvastatin calcium (CRESTOR), gabapentin (MANUFACTURER UNKNOWN), and metoprolol (MANUFACTURER

UNKNOWN). On 18Dec2020, the patient experienced hypokalemia, hypomagnesemia, hypocalcemia, tetany, muscle cramps, and hemoglobin dropped little bit. The clinical course was as follows: The patient received the vaccine and about 30 minutes later she started to ""feel bad"". She went to the urgent care and about an hour after they took her to the emergency room (also reported as hospital). She had a complete blood count, complete metabolic panel, and magnesium level done on the 18th, 21th, 23rd, 26th, 28th, 30th of Dec2020 and then again on 04Jan2021. On 18Dec2020, her initial lab test showed potassium: 2.6, hemoglobin: 10.2, magnesium: 1.2, and calcium: 5.7. The physician assistant reported that a potassium of 2.6 was critically low and a hemoglobin was 10.2 was about normal for the patient. She received oral medications of potassium 20 mEq twice a day and calcium and magnesium supplements once a day. On 04Jan2021, lab data showed: potassium: 4.2, magnesium: 2.1, calcium: 9.5 and hemoglobin: 14.5. Per the reporting physician assistant, the above levels went back to normal but stated she had to be supplemented to get back to that point. The clinical outcomes of the hypokalemia, hypomagnesemia, hypocalcemia, and hemoglobin dropped little bit were recovered on 04Jan2021; while that of the tetany and muscle cramps, were unknown. The physician assistant assessed the events as related to the suspect vaccine. The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up.; Sender's Comments: A possible contributory effect of suspect BNT162B2 on reported events cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate."

patient felt tingling in their neck, arms and hand and then few days later it went to their feet; This is a spontaneous report from a contactable consumer (patient). A patient of unspecified age and gender received the bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot Number and Expiration Date: unknown), via an unspecified route of administration on an unspecified date at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. On an unspecified date, the patient felt tingling in their neck, arms and hand and then few days later it went to their feet (medically significant). The clinical outcome of the event was unknown. The batch/lot numbers for the vaccine, PFIZER-BIONTECH COVID-19 MRNA VACCINE, were not provided and will be requested during follow up.; Sender's Comments: A causal association between BNT162B2 and the reported events cannot be excluded based on a compatible temporal relation between vaccination and onset of events. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

Bell's palsy; Flu like symptoms; This is a spontaneous report from a non-contactable consumer reported that a female patient of an unspecified age received bnt162b2, via an unspecified route of administration on an unspecified date at a single dose for COVID-19 vaccination. The patient's medical history and concomitant medications were not reported. It was reported that the patient got Bell's palsy four days after the vaccine and had flu-like symptoms for two weeks. Added that patient is completely

symptom free at the time of report. The outcome of the events was recovered. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

"Got very hot and clammy but at the same time had the goosebumps; Got very hot and clammy but at the same time had the goosebumps; Got very hot and clammy but at the same time had the goosebumps; My whole body was as if I was sun burnt; My heart started to race; This is a spontaneous report from a contactable consumer (patient). A 45-year-old female patient received BNT162B2, (Pfizer COVID Vaccine, lot number: EK9231, expiry date: Apr2021) intramuscular on an unspecified date at single dose on right arm for COVID-19 immunisation. Medical history included migraine from an unknown date and unknown if ongoing. Concomitant medication included nortriptyline for migraine, botulinum toxin type a (BOTOX) for migraine and birth control medication. The patient stated that, ""I was wondering if this was a reaction to the vaccination I had today. So I ended up 3 hours after I received the vaccine, I got very hot and clammy but at the same time had the goosebumps and then my whole body was as if I was sun burnt and my heart started to race. And then my whole body was red as if I had a sunburn. Actually I went to the ER today and they just did lab work because of the way I was feeling. All they gave me in the emergency room is IV fluids."" Therapeutic measures taken as a result of the events included IV fluids. The outcome of the events was unknown."

died; This is a spontaneous report from a non-contactable consumer via a Pfizer-sponsored program. A patient of unspecified age and gender received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, via an unspecified route of administration on an unspecified date at single dose for covid-19 immunisation. The patient medical history and concomitant medications were not reported. It was reported the patient was a doctor, died after the vaccine with no apparent disease. It was not reported if an autopsy was performed. No follow-up attempts are possible. Information about lot/batch number cannot be obtained.; Reported Cause(s) of Death: Unknown cause of death

COVID-19 positive and admitted to hospital 6 days post-vaccination

Received first dose Moderna COVID vaccine on 12/28/2020; on that same day 12/28 he noticed a dry cough; on 1/1/2021 he reported fever, chills, body aches, Headache, sinus congestion. On 1/1/2021 he tested positive for COVID-19, he reported being with a family member on Christmas who had COVID symptoms. On 1/11/2021 he required hospitalization for COVID-19 pneumonia

on 1/8/2021 17:30 patient taken to ER, cerebellar hemorrhage, stroke, aneurysm

Following the first COVID vaccine dose on Dec/18/2020, I had headaches that started on the third day and ended on the tenth day. The headaches were usually light, unilateral, and alternating from one side to the other. I was usually functional except on the fourth and seventh days where the headaches were moderate to severe, and I took naps to help with the headaches for those two days. I have never had an issue with headaches before, and these symptoms were a new experience for me. I did not take any medications as treatment for the headaches. Following the second COVID vaccine dose on January/7/2021, I felt fatigue and generalized muscle aches within six to twelve hours, and these symptoms lasted for two days. On January/10/2021, when I woke up that morning I again felt light, unilateral, and alternating headaches. In addition, I noticed that I was unable to move the left side of my

face. I felt moderate tingling sensations associated with the distribution of the paralysis. When I looked in the mirror, I could quite noticeably see asymmetry in my face. I immediately went to the emergency department at the hospital where my primary care doctor is located. I was kept in the hospital into the next day for observation. After evaluation by a neurology team and an MRI, I was provided with the diagnosis of Bells Palsy. I have never previously been diagnosed with Bells Palsy, and I have never previously had a hospital stay before. The doctors prescribed medications which I am currently taking. As of today January/12/2021, the symptoms have had some improvement, but the symptoms still continue.

Beginning at 6:30 am on 1/8, two days following vaccination, the individual was driving to work and began to experience nausea while at a traffic light. He pulled over and threw up. Once he got to work he vomited again. He drove to another facility for work and then threw up 3 or 4 more times. He began experiencing hot flashes at this time. He went to the hospital and was seen in the emergency room. He threw up several more times in the ER and stated that his heart was racing and that he had diarrhea. The emergency room gave him medications for the nausea and he stayed there for 2 or 3 hours. He began to feel better and was discharged to home.

Immediately developed intense burning that progressed over the next 30 minutes and continued to burn for 3 days. The next day progressive extreme fatigue last 4 days. felt like it was going to pass out. full on body pain, dizzy and lightheaded. need assistance to get to the walk, intense headache.

Very large, reddened, tender area at injection site (like the size of an angry red egg), and fever of 103.2.

GIVEN ON 12/23. SORENESS FELT ON LEFT ARM SITE THE NEXT DAY, WITH DECREASED MOBILITY AND STRENGTH DUE TO SEVERE SORENESS AND PAIN. PAIN PROGRESSIVELY LESSENED BUT THE SORENESS STILL VERY APPARENT. ON 1/5, SPOKE TO PRIMARY MD, XRAY ON LEFT SHOULDER DONE ON 1/6. ON 1/7, STIFFNESS WITH SEVERE PAIN UPON MOVEMENT NOTED ESP IN THE MORNING. ULTRASOUND WAS DONE ON 1/8, NOTED BICEPS TENOSYNOVITIS. ORTHOPEDIC SURGEON SEEN ON 1/11, W DX OF ADHESIVE CAPSULITIS, SUGGESTED FOR PT FOR NOW, AND OFF WORK, AND TO BE FOLLOWED UP ON 2/1 BY SAME ORTHO SURGEON. WILL NOT OFFER CORTISONE SHOT FOR NOW AS IT MAY COMPROMISED OR WEAKEN IMMUNE RESPONSE, IN WHICH MY SECOND COVID SHOT DUE ON THE 15TH OF JANUARY. FIRST APPT FOR PT ON 1/15

Sudden hearing loss right ear accompanied by tinnitus

Sudden hearing loss right arm accompanied by tinnitus

Patient presented on the morning of 1/10/2021 with swollen lips and hives. Vaccination took place on Wednesday January 6th, 2021.

Patient had mild bilateral knee and hip pain 1 month ago, then she received her 1st dose of COVID vaccine on 12/14/20. Her joint pain worsened then on 1/4/21 she received her 2nd dose of COIVD vaccine on 1/4/21 and then her pain increased in spread up to her shoulders. She was seen at immediate care on 1/11/21 because her joint pain had worsened throughout and her shoulder pain was

making it difficult to raise her arms above the level of her shoulders. Her pain was made worse w/ movement.

Woke up on 1/6/2021 with hot flashes, palpitations, dizziness and heart racing. Went to urgent care and they did an EKG which showed A-Fib, so I was sent to the ER and from there, I was transferred to an ICU at a different facility . I stayed until 1/8/2021. No cause was found and no history of A-Fib or family history.

immediate tingling of lips, followed by fullness of posterior oropharynx, hoarseness and pruritus

"Fever (103-104 oF) and 4""x1"" red, swelling area around site of injection. Pt states she received an IV."

Acute approximate respiratory failure secondary to acute COPD

first day after shot, nausea, body aches, 2nd day Sunday headache, Monday 5 am woke up itching, then 9 am hives everywhere, trouble breathing, anaphylaxis, went to ER, got epi X 2, solumedrol, benadryl, pepcid, then still with hives, tachycardia, dyspnea, iv fluids were influsing and epi drip started, went to ICU

Back pain, bilateral PE and DVT

"Patient states that she received her second vaccination and in the hours after she had flu-like symptoms. Then over the next few days, she started to notice tingling and a ""prickly"" sensation in various areas. This progressed to symmetric BLE weakness which started in her feet and had reached to just above her knees bilaterally time and she arrived. The weakness had progressed to her hips. She also noticed weakness in her arms and they are easily fatigued. She is able to walk but it takes much effort."

coughing, flushing, cyanosis, diaphoresis

Within 3 minutes of receiving vaccine felt flush and throat swelling, responded to Epi Pen and Benadryl p.o. EMS took him to ED where he remained several hours receiving 1 liter NS 125 mg solumedrol IV, discharge with 4 days of prednisone 40 mg daily and a prescription for an Epi Pen. As of 1.12 he is totally okay with no after effects.

First Day after the injection I had a headache and nausea the entire day into the next day. The second day I still had the headache and the nausea. I work overnights. When I awoke in the afternoon, my throat was closing up. It was hard to swallow and I struggled to breath. I immediately drank liquid Benadryl and called my doctor in the morning.

Patient presents to the Emergency Department who was doing well up until she received COVID-19 vaccine at 1150. 15 minutes later patient started to experience throat tightening and tongue swelling. She was administered Epipen at 1217 by staff at vaccination clinic. EMS was called and prior to arrival at ER tongue swelling had subsided.

-0715 vaccine administered. -0735 started to feel dizzy/off and right side of tongue felt like it was mildly swelling and itchy. -0735 asked to have blood pressure taken as know when I am having anaphylaxis my

blood pressure escalates. -0740 took blood pressure and it was 141/86 in right arm. Normal is 110s/60s-70s. No anxiety feelings. -0740 throat started to have increased mucous production. Had the tickle and tightness in throat. Asked and received 25mg Benadryl with cup of water. -0742 started clearing throat frequently and slight cough. Knew it was anaphylaxis and told the team I need to go to the ER. Asked for additional 25mg Benadryl. Also took 20mg Famotidine and 2 puffs Albuterol inhaler--this is my prescribed anaphylaxis routine. Had Epipens on standby. -0743 put on O2 saturation monitor and watched O2 drop into 90-92 range. Asked for epipen on standby as I know when I need to start it. Didn't want to take that when I knew I was about to get it in the ER and knowing self hadn't progressed that far. Felt chest tightness and shortness of breath. Voice started becoming hoarse. -0800 EMS arrived (delay as team didn't know if they were supposed to call 911 or a Code--they chose EMS even though in hospital). Then staff at COVID vaccine clinic kept emphasizing need to go in ambulance while EMS and self fought to go through hospital (much quicker route). Finally cleared to go through hospital to ER. To get some air via breathing in had to sit up leaning forward. Voice completely hoarse by this time. -About 0817 arrived to ER bay. At this time, frequently coughing and cough started to sound stridorous. Difficulty getting breaths in. Had chest pain near heart. Greeted by MD, 2 RNS, and technician. -0819 received IM epinephrine. Attached to 5 lead EKG monitoring and O2 monitoring. Blood pressure done again. Higher than previous. -About 0821 had working IV (previous two attempts failed as veins were constricting). Given IV Solumderol. Started bolus of 1L Normal Saline. -Not sure how long after by cough subsided, increased mucous production subsided, as well as hoarseness decreased. -Held for observation for 2hours (would be longer if not resolved). - Discharged around 1015. At this time, hoarseness almost all gone. Minimal throat clearing. Cough resolved. -Prescribed epipen inhalers (mine expired) and Prednisone. Prednisone is PRN for mild breathing difficulties if it starts again tomorrow 1/13/21. -At 1400 took 50mg Benadryl and 20mg Famotidine as previously prescribed for anaphylaxis maintenance. Will continue this as previously prescribed every 6hours until symptoms stay resolved. - Made follow up appointment with Primary Care Physician per protocol

Immediately after she felt faint, heart rate 121, felt faint again bp 62/33. Was taken to the ER, within a half hour, she fully recovered. Vitals went back to normal.

Hospice Resident received first Covid 19 vaccine dose on 1/6/21. 1/7/21 resident had decreased appetite noted in am but ate 100% of meal at dinner. 1/9/21 resident had decreased appetite with emesis x 2, loose BM x 2. Call placed to hospice. 1/10/21 5:44 am resident able to take HS meds, ingest 2 cups of shake. No emesis or loose stool noted. 12PM nurse noted resident not eating meals but ingesting milkshake and medications without any problems. Hospice contacted for change in condition. 1:00 pm hospice ordered Phenergan 12.5 mg Q 6 hrs PRN. Labs to be drawn 1/11/21. Hospice notified POA. 1/11/21 12:24am Resident had blood in stool. Resident denies any pain, on 2L of O2 for comfort.

Severely dizzy, left hand totally numb but painful, cold to touch. Felt better before she got to ER.

Patient vaccinated on 12/28. Approximately one day later, develops cough and on azithromycin x 1 week. On 1/3, patient develops left-sided weakness and aphasia. Taken to the hospital, tested COVID+, required intubation -- acute hypoxic respiratory failure secondary to COVID - on H&P. Patient died on 1/4/21 at 7:20am.

Attempting to confirm which COVID 19 vaccine was given (Moderna or Pfizer). They did not send the record when they sent the patient to General ER the next am. Did not answer the phone.

Started to feel lightheaded, weak, faint like I was going to pass out, heart rate increased, confusion, trouble speaking, brought to the ED, throat started to swell and started having thick spit and clearing my throat excessively. Diagnosed as anaphylaxis.

within 1 hr post-vaccine on 1/7 I had a mild headache that resolved with Tylenol. At about 12 hours post-vaccine I developed nausea, fever (100.4) and chills and secondary to this had poor sleep. The next day I took scheduled alternating Tylenol & ibuprofen during the day and then overnight 1 episode of chills that woke me up. no events Saturday or Sunday. Then Monday 1/11 in the early morning I started to develop a rash on my b/l elbow and right foot 3rd toe. I applied mometasone topical cream to these locations. while at work the rash extended down both forearms then by 5pm it was on both hips and extending along both legs. I applied Benadryl cream to the most irritated sites and took PO Benadryl 50mg at bedtime and again at 1am when the itching woke me up. I repeated Benadryl 25mg at 8am. The rash seems to be getting better on the arms but then by noon I had a new breakout on my neck and face. I took Benadryl 50mg at 1pm. The rash continued to have a rapid progression over the next hour and resulted in angioedema with my throat swelling, lips puffed and numb and eye swelling. I was injected with an epi pen and sent to the ED where I received PO prednisone, famotidine, and Benadryl. The face/neck rash then greatly improved and I was sent home on prednisone 40mg daily for 3 days.

Blurred vision, difficulty breathing (pale skin/blue lips), profuse sweating, muscle fatigue, headache. This lasted about 15 minutes. Until severity went down. Followed by 20 minutes of profuse sweating and headache. I thought I was going to die

Sudden cardiac death

"COVID-19 PCR test/he was positive per the PCR test; COVID-19 PCR test/he was positive per the PCR test; Sweating; Fever; running to bathroom with urination every 15 minutes with a large amount of urine; running to bathroom with urination every 15 minutes with a large amount of urine; Heart pounding; tired and fatigue; Weight loss; Chills; pain all over the body; Sluggishness; This is a spontaneous report from a contactable consumer. A 63-years-old male patient received his first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number EH9899, expiry date was unknown), via an unspecified route of administration on the left arm on 21Dec2020 14:40, at a single dose for Covid 19. The patient's medical history and concomitant medications were not reported. The patient has no prior vaccinations -within 4 weeks. The patient is an EEG technician. On 22Dec2020, the patient reported the next day he started to feel sluggish, chills, tired/fatigue, pain all over his body, patient mentioned he has lost weight everyday since he got the shot from 153 pounds to 142 pounds; then on Wednesday evening 23Dec2020, it was a nightmare, he got sweating; fever with a high of 101.4 Fahrenheit; he was running to bathroom with urination every 15 minutes with a large amount of urine; and he was so tired and fatigued. Added when he was getting up all that night he was having night sweats up to five times a night and chills; and his heart was pounding. The urination, heart pounding resolved the next day. All of these events have improved at the time of report (now) or gone away but

he is still sweating once at night for the last two days and he is tired and fatigued. He stated that he is scheduled for the second dose on 11Jan2021 and he is concerned if he should take the vaccine. He mentioned that he was tested for COVID 19 on 18Dec2020 and the result was inconclusive. He went again 23Dec2020 they called him on 25Dec2020 and informed he was positive per the PCR test. He treated himself with 500mg acetaminophen (UPC 0904672059; lot OBE2896 and expiration Oct2021) and azithromycin Z-Pack (NDC 65862-641-69; Lot ZYSA20012-A; and expiration date Mar2022). The sample of the product is not available to be returned. Predisposing factor was that the patient's wife was at home and was sick too at the same time. She was tested Sunday with no results yet. The outcome of the events of fever recovered on 28Dec2020, sluggishness recovered on 29Dec2020, pain all over the body was recovered on 02Jan2021; running to the bathroom with urination every 15 minutes with a large amount of urine and heart pounding were recovered on 24Dec2020, weight loss was not recovered, and for other events was recovering.; Sender's Comments: Based on the mechanism of action of BNT162B2 vaccine, it is unlikely the patient would have fully developed immunity for the vaccine to be effective, due to the number of days passed since the vaccine was given (4 days in this case). However, a causal relationship between event ""COVID-19 PCR test/he was positive per the PCR test"" (coded to Drug ineffective / SARS-CoV-2 test positive) and BNT162B2 vaccine cannot be completely excluded"

Tested positive to COVID; Tested positive to COVID; This is a spontaneous report from a contactable nurse, the patient. A 41-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration on 23Dec2020 as a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. On 02Jan2021, the patient tested positive to Covid. The outcome of the event, tested positive to Covid, was unknown. The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up.

neuropathy; pain; nausea; fatigue; bone, muscle, stomach pain; bone, muscle, stomach pain; bone, muscle, stomach pain; flare; increase in joint pain from his baseline; This is a spontaneous report from a Pfizer sponsored program Accredo Xeljanz Program. A contactable nurse and contactable consumer (patient) reported that a 56-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration on 18Dec2020 at a single dose for COVID-19 immunization and tofacitinib citrate (XELJANZ XR), orally from 02Oct2020 at 11 mg, daily for rheumatoid arthritis. The patient's medical history and concomitant medications were not reported. On 19Dec2020, the patient experienced neuropathy, pain, nausea, fatigue, bone, muscle, stomach pain and flare. In Dec2020, the patient experienced increase in joint pain from his baseline. The physician was aware. The patient was placed on unspecified steroids for the events, neuropathy, pain, nausea, fatigue, bone, muscle, stomach pain and flare which minimized symptoms. While weaning off steroids, the severity of symptoms returned. The patient was instructed by the doctor to stop taking tofacitinib citrate which was stopped on 29Dec2020. The action taken in response to the events for BNT162B2 was not applicable and for tofacitinib citrate was permanently withdrawn on 29Dec2020. The patient reported slight improvement after stopping tofacitinib citrate. The outcome of neuropathy, pain, nausea, fatigue, bone, muscle, stomach pain and flare was recovering and of increase in joint pain from his baseline was

unknown. The batch/lot number for the vaccine, BNT162B2, was not provided and will be requested during follow-up.; Sender's Comments: Based on the information available, the reported events are most likely due to patient underlying contributory factors and unlikely that it is related to the suspect product. However due to temporal association with the vaccine, a possible contributory role of vaccine cannot be ruled out. Case will be reevaluated based on additional information during the follow-up. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators as appropriate.

I developed Covid -19 (positive PCR) on 02Jan2021 after respecting quarantine, mask wearing, and was not onsite at work; I developed Covid -19 (positive PCR) on 02Jan2021 after respecting quarantine, mask wearing, and was not onsite at work; This is a spontaneous report from a contactable pharmacist. A 25-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE) lot number: EK5130, via an unspecified route of administration at left arm from 23Dec2020 16:30 to 23Dec2020 16:30 at a single dose for COVID-19 immunization. Medical history and concomitant medications were not reported. The patient developed Covid-19 (positive polymerase chain reaction (PRC)) on 02Jan2021, after respecting quarantine, mask wearing, and was not onsite at work. The patient did not received treatment for the adverse events. The outcome of the events was recovering.; Sender's Comments: A causal association between reported event and suspect BNT162B2 cannot be excluded.

she received her first dose of COVID vaccine on 18Dec and a week later contracted COVID; she received her first dose of COVID vaccine on 18Dec and a week later contracted COVID; This is a spontaneous report from a Pfizer-sponsored program IBCC (Inbound Call Center for HCPs) from a contactable registered nurse (patient). This 67-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) at single dose on 18Dec2020 for COVID-19 immunization. Medical history and concomitant medication were not reported. Patient stated she received her first dose of COVID vaccine on 18Dec and a week later contracted COVID (in Dec2020) after receiving COVID vaccine. She just wanted to find out the answer to some medical questions. She had questions about antibodies and whether or not she should take the second dose. She stated her second dose was scheduled in two days, on Friday. She said after being positive on 28Dec2020 for COVID-19 virus test, she received the medication Bamlanivumab 700 mg intravenous passive antibodies therapy to lessen the COVID symptoms and to keep her out of the hospital, which it did. The outcome of events was unknown. Information about lot and batch number was requested.; Sender's Comments: Based on the information currently available, a lack of efficacy with the suspected vaccine BNT162B2 cannot be completely excluded. However, it is unlikely that the patient would have fully developed immunity due to the very short time lag between the first vaccine dose and the event onset.

COVID Rapid Test and COVID-19 PCR test positive/ symptomatic/ fever/ not feeling well; COVID Rapid Test and COVID-19 PCR test positive/ symptomatic/ fever/ not feeling well; This is a spontaneous report from a Pfizer-sponsored Program Pfizer First Connect. A contactable nurse reported for a male patient (husband) with unspecified age received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK5730) via IM injection left deltoid on 19Dec2020 at single dose for COVID Prevention.

Medical history and concomitant medications were none. The patient did not receive any other vaccines on the same day as the COVID vaccine. The patient was a healthcare professional. The vaccine was not specifically prescribed to the patient, but rather was given to him via his workplace policy, although it was not mandatory. The patient received 1st dose on 19Dec2020, and he had exposure to the virus at work, and on 01Jan2021 he woke up with a fever and was not feeling well and tested positive for COVID-19. Currently he is still symptomatic. The reporter is inquiring about how to follow up with the second dose for the patient, as the patient is due for his second dose on 09Jan2021. It was reported that it had mostly been a low grade fever. The patient had both COVID Rapid Test and COVID-19 PCR test performed on 01Jan2021, and both were positive. The outcome of event was unknown. The reporter was unsure of seriousness for the patient's positive COVID tests, so far it had not been terrible, but he was still symptomatic, so it was hard to say seriousness at this time. Relatedness of vaccine to event fever and positive COVID test both rapid and PCR from the reporter was unrelated.; Sender's Comments: Based on the information currently available, a lack of efficacy with the suspected vaccine BNT162B2 cannot be completely excluded. However, it is unlikely that the patient would have fully developed immunity due to the very short time lag between the first vaccine dose and the event onset.

"got the covid 19 vaccine on 29Dec2020 and tested positive for covid on 05Jan2021; got the covid 19 vaccine on 29Dec2020 and tested positive for covid on 05Jan2021; This is a spontaneous report from a contactable nurse (patient). A female patient of an unspecified age (reported as ""Age-48, Unit-Unknown"") received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 29Dec2020 at single dose for COVID-19 immunization. The patient medical history and concomitant medications were not reported. The patient stated she got the covid 19 vaccine on 29Dec2020 and tested positive for covid on 05Jan2021. She wanted to know what to do about the second dose of the vaccine. Information about Lot/batch number has been requested."

"I ended up testing positive on Monday 04Jan2021; I ended up testing positive on Monday 04Jan2021; This is a spontaneous report from a contactable Other Health Professional (patient). A male patient of an unspecified age received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection) lot number was not reported, via an unspecified route of administration on 30Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. Family history included patient was ""99.9% sure that his daughter at day care had direct contact (COVID-19)"". It was reported that the patient received first dose on 30Dec2020, and that same Wednesday morning 99.9% sure that his daughter at day care had direct contact (COVID-19). He ended up testing positive on Monday 04Jan2021 with outcome of unknown, and was scheduled for second dose on 04Jan2021. He asked for specific recommendation for his weird situation. Information on Lot/Batch has been requested.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the reported events of suspected LOE and SARS-CoV-2 test positive due to temporal relationship. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available."

anaphylactic reaction; arm was really sore; tiredness; dizzy; This is a spontaneous report from a contactable other health professional (patient). A 53-year-old female patient received bnt162b2 (Pfizer-biontech covid-19 vaccine), via an unspecified route of administration on 31Dec2020 at single dose for covid-19 immunization. Medical history included shellfish allergy. The patient's concomitant medications were not reported. The patient experienced anaphylactic reaction on an unspecified date, dizzy on 31Dec2020, arm was really sore on an unspecified date, tiredness on an unspecified date. Event details: She was dizzy that day especially with changing positions, she didn't need to go to the doctor or anything. It wasn't severe. She was just a little dizzy. It's probably just the vaccine and it did go away. Her arm was really sore and went away after a few days. the tiredness, it wasn't a big deal. She did feel better about. it wasn't a serious anaphylactic reaction. It didn't happen right away. She had arm soreness. it wasn't immediate. She usually didn't have. It was really weird. She thought she was well hydrated. The outcome of event was really sore was resolved, outcome of other events was unknown. Information on the Lot/Batch number has been requested.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the anaphylactic reaction and other reported events due to temporal relationship. There is very limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

she tested positive for COVID-19 after receiving the first dose of the Pfizer-Biontech COVID-19 vaccine.; she tested positive for COVID-19 after receiving the first dose of the Pfizer-Biontech COVID-19 vaccine.; This is a spontaneous report from a contactable physician. A 41-year-old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number EH9899) intramuscular in left arm on 26Dec2020 14:30 at a single dose for COVID-19 immunization.The patient's medical history and concomitant medications were not reported. The physician received her first dose of the COVID vaccine on 26Dec2020 and on 02Jan2021, tested positive for COVID. She actually tested negative 2 days before testing positive (26Dec2020). The outcome of the event was recovered on an unknown date. According to the physician, the event was unrelated to the vaccine as her nanny and her son was also tested positive.; Sender's Comments: The Company cannot completely exclude the possible causality between the reported tested positive for COVID, which is considered ineffective of BNT162B2, and the administration of BNT162B2.

Tested positive for COVID; Tested positive for COVID; This is a spontaneous report received from a contactable Registered Nurse (patient) via a Pfizer sponsored program IBCC (Inbound Call Center for HCPs). A female patient of an unspecified age received BNT162B2, via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient experienced tested positive for COVID on an unspecified date with outcome of unknown. The patient just received the COVID vaccine,

and also tested positive for COVID. The patient underwent lab tests and procedures which included COVID test: positive. Information on the lot/batch number has been requested.

has COVID now and was pretty ill and in their ICU, positive COVID-19 test; has COVID now and was pretty ill and in their ICU, positive COVID-19 test; This is a spontaneous report from a contactable pharmacist. A 55-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), on unspecified date in Dec2020 at SINGLE DOSE for COVID-19 immunization. The patient developed positive COVID-19 test with symptoms on unknown date. The clinical course was as follows: the patient received the first dose of the vaccine 2 weeks ago and has COVID now and was pretty ill and in their ICU. Laboratory data included: SARS-CoV-2 test (unknown date): positive. The pharmacist was wondering if the participants in the trials received their second dose if they tested positive before the second dose and if there is any data on when to give the second dose of the vaccine for patients that test positive before the second dose. The outcome of the events was unknown. Information on lot/batch number has been requested.; Sender's Comments: No effect of the suspect vaccine could be reasonably achieved to protect from the targeted infection/disease due to the very short time lag. Instead, the positive COVID likely represents a pre-existing infection prior to vaccine use. Further information is needed for full medical assessment.

"Anaphylactic reaction; Tongue was swelling; Difficulty breathing; This is a spontaneous report from a contactable Pharmacist. A 55-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), at SINGLE DOSE for COVID-19 immunization. The patient experienced ""Tongue was swelling, Difficulty breathing, and an Anaphylactic reaction"".No other details provided. The outcome of the events was unknown Information on lot/batch number has been requested.; Sender's Comments: A possible causal relationship between acute onset of Anaphylactic reactions presented as Tongue swelling/Difficulty breathing and BNT162B2 cannot be completely ruled out considering the temporal relationship and the known adverse event profile of the suspect vaccine. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate."

Positive COVID-19 rapid test; Positive COVID-19 rapid test; Positive COVID-19 rapid test; Patient got sick; 2 weeks of on and off fever and unproductive cough; Patient got sick; 2 weeks of on and off fever and unproductive cough; Patient got sick; 2 weeks of on and off fever and unproductive cough; Lost sense of taste and smell; Lost sense of taste and smell; sore throat; This is a spontaneous report from a contactable nurse (patient). A 50-year-old male patient received the 1st dose of bnt162b2 (BNT162B2), via an unspecified route of administration, on 16Dec2020, at single dose, for COVID-19 immunisation. Medical history and concomitant medications were none. On 17Dec2020 patient got sick; 2 weeks of on and off fever and unproductive cough. In Dec2020 the patient also experienced lost sense of taste and smell. On 20Dec2020 the patient underwent COVID-19 rapid POC test and was found positive. The events required emergency room visit. Therapeutic measures were taken as a result of the events and included treatment with Tylenol 650 every 4 hours. The events recovered on unspecified date except unproductive cough and sore throat that were recovering. The information on the lot/batch number has

been requested.; Sender's Comments: The association between the event lack of effect (COVID-19 rapid POC test) with BNT162b2 can not be completely excluded.

Covid; Covid; This is a spontaneous report from a contactable Other Healthcare Professional (HCP). A female patient of unknown age received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, on an unknown date at single dose for COVID-19 immunisation. Medical history and concomitant medications were unknown. The patient was scheduled for her second dose of vaccine tomorrow (08Jan2021) but she was diagnosed with Covid on 07Jan2021. Outcome was unknown. Information on the lot/ batch number has been requested.; Sender's Comments: Based on the information available, a possible contributory role of the suspect products cannot be excluded for the reported event of positive for corona virus infection for the lack of efficacy of the vaccine. However, based on the mechanism of action of the vaccine, it is unlikely the patient would have fully developed immunity for the vaccine to be effective, due to the number of days passed since the vaccine is given. Case will be reevaluated based on follow-up information

Drug ineffective; tested positive for COVID-19; This is a spontaneous report from a contactable pharmacist reporting for his/her mother-in-law. A 99-years-old female patient in good health received the first dose of BNT162B2 Pfizer-BioNTech COVID-19 Vaccine, via an unspecified route of administration on an unspecified date (presumably on 02Jan2021 - to be confirmed) at single dose for COVID-19 immunization. The patient's medical history was not reported. Concomitant medication included monoclonal antibody bamlanivimab on an unknown date. On 06Jan2021 the patient experienced tested positive for COVID-19. It was reported that the patient is scheduled to have her 2nd dose on 23Jan2021. The reporter asked if the patient should wait 90 days before taking the second dose. Information on the lot/batch number has been requested.; Sender's Comments: A causal association between event and suspect BNT162B2 cannot be excluded

"positive with covid; positive with covid; sinus strainagned at the back of the throat.; sinus strainagned at the back of the throat.; This is a spontaneous report from a contactable nurse. A female patient of an unspecified age started to receive BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot# unknown), via an unspecified route of administration on an unspecified date single dose for COVID-19 immunisation. The patient medical history was not reported. The patient's concomitant medications were not reported. The patient experienced positive with COVID on an unspecified date, sinus strainagned at the back of the throat on an unspecified date. The outcome of the events was unknown. Information on the Batch/Lot number has been requested.; Sender's Comments: A causal association between reported ""positive with covid"" and suspect BNT162B2 cannot be excluded."

received her 1st COVID vaccine shot 22Dec2020, however she got diagnosed with COVID; received her 1st COVID vaccine shot 22Dec2020, however she got diagnosed with COVID / pneumonia; rash; This is a spontaneous report from a contactable consumer (patient). This 77-years-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, on 22Dec2020 at single dose for COVID-19 immunisation. Medical history and concomitant medications were unknown. After the first dose, the patient got diagnosed with COVID. She does not want to waste a second dose if it will not be useful. Everyone on her department has had

COVID, and have been told to wait 3 months before getting their second dose. Caller had a 'rash' after her 1st dose of the COVID vaccine. The patient is now recuperating from the pneumonia. Outcome of pneumonia was recovering while outcome of the other events was unknown. Information on the Lot/Batch Number has been requested.

headaches on both sides of his head; This is a spontaneous report from a contactable Physician reporting for himself. A 53-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) at 0.3ml single dose on 30Dec2020 in the left deltoid for COVID-19 immunisation at the age of 53-year-old. Lot number was EK9231, expiration date 30Apr2021. Medical history and concomitant medications were unknown. On 31Dec2020, headaches on both sides of his head; the event was considered medically significant. The patient received TYLENOL for the event. The patient did not recover from the event. The physician considered the event was related to suspect vaccine. Information on the lot/batch number has been requested.; Sender's Comments: A causal association between BNT162B2 and the reported events cannot be excluded based on a compatible temporal relation between vaccination and onset of events. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

Received the first dose of Pfizer COVID Vaccine and then tested positive after receiving it; Received the first dose of Pfizer COVID Vaccine and then tested positive after receiving it; This is a spontaneous report from a Pfizer-sponsored program. A contactable consumer (patient) reported that a male patient of an unspecified age received the first dose of bnt162b2 (lot no. and expiry date were unknown), via an unspecified route of administration on an unspecified date at single dose for Covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient received the first dose of Pfizer COVID Vaccine and then tested positive after receiving it. He says it has been 14 days after he tested positive and he is wondering about getting his second dose. The outcome of the event was unknown. Information on the Lot/batch number has been requested.

increased respiratory infection; Allergic reaction; Yeast infection; Non-diagnosed allergic conjunctivitis; seasonal allergies; This is a spontaneous report from a Pfizer-sponsored program, IBCC (Inbound Call Center for HCPs), from a contactable nurse (patient) reported for herself. A female patient of an unspecified age received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 22Dec2020 at a single dose for COVID-19 immunization. Medical history and concomitant medications were not reported. The patient was having an allergic reaction and had a yeast infection. She was supposed to get the next dose soon (on 12Jan2021) but she was worried about getting the second dose. The patient stated so she had some increased (incomplete sentence).The patient stated she had a non-diagnosed allergic conjunctivitis followed by a yeast infection, followed by increased respiratory infection and she did make a report of the seasonal allergies that I did not used to get at this time of year. So, she did not report the conjunctivitis because it was not diagnosed and did not report the yeast infection because she handled it herself. The outcome of events was unknown. Information about Lot/Batch number is requested.; Sender's Comments: Based solely on a compatible

temporal association causality between reported events and BNT162B2 vaccine cannot be excluded. The case will be reevaluated should additional information become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

On 1/5/2020, I, the patient woke up at 3:30 with sharp boring epigastric pain. Progressed to include nausea. On evaluation in the ED was diagnosed with acute pancreatitis. Prior hx includes 2 episodes with hospitalization for gallstone pancreatitis in 2016. Subsequently had laparoscopic cholecystectomy in 2016. Last alcoholic beverage prior to 2020 ED presentation was 3 weeks prior. No tobacco or drug use.

The patient presented to hospital on 1/6/2021 with a primary complaint of Fatigue (pt had covid vaccine yesterday. Now displaying increased weakness, blood in urine, increased confusion and urinated on herself today. Fever of 101.9) 79-year-old female presents to the emergency room with fatigue. The patient states yesterday she had the Moderna COVID-19 The patient states today she had a temperature 101.8¦ prior to arrival. Her son noted that she was having episodes of urinary frequency and also that she was profoundly weak and fatigued. They denied falling or hitting her head. The patient also states she been having nausea vomiting with diarrhea.

Vaccine was given on 12/23/20 on 01/07.21 went to get a routine physical and received an emergency call that my pallet blood count was around 10K instead of 150k. Was instructed to go to the ER asap. However didn't received the message until the next morning at 6:30am. Was checked into the E.R. , given sterioids, pallets, hemogolibin. Stayed overnight in the hospital was able to leaved the next day around 1pm with pallets at 47k.

swelling at the injection site, pain, headache, feeling like numb, change in the taste, fever the 1st day x2, body ache, lower back pain.

Three hours after receiving COVID 19 vaccination, Patient oxygen level decreased to a critical level and went into cardiac arrest. Staff performed full code but was unable to bring back patient from cardiac arrest.

2230 feeling of unease, body aches, site arm tingling, general mild aches 0220 awoke from sleep choking, having difficulty breathing, felt very SOB, worse with exertion or trying to speak, great difficulty swallowing and speaking even in brief words. Took 50mg of Benadryl PO and went to the ED, about a 15 minute car ride. Had tingling and numbness of the tongue and back of throat by arrival but still able to breath with focus. Exertion of just walking into the ED greatly increased the SOB. Was triaged, Benadryl starting to help, was able to speak a little better, 3-4 words without too much SOB caused. Was walked to a room, SOB milder with that exertion. Seen by Dr. Given IV Sol-u-Medrol and 50mg Benadryl. Was observed on cardiac monitor/Q15VS for a few hours and discharged home around 5:30. Given Rx of Prednisone 20mg -3tabs x2 days, 2tabs x5 days all once a days and told to take 50mg of Benadryl Q4H for the next 24 hours at least and to return prn. I did need to stay on Benadryl, as the Sol-u-Medrol wore off some of the swelling in thr throat did return but not severe, Benadryl did help, along with taking my

Asthmnex I already had. I also continued my normal HS antihistamines. I had SOB on exertion, progressively better from the 6th-10th with it mostly resolved to yesterday. Body aches have continued but also progressively better. Yeasterday1/12/21 the Rx of prednisone was completed and I did have some mild swelling /tingling in the throat/face/mouth return in the evening, took Benadryl 50mg again and inhaler used. I have an appointment today to seek further care at my primary doctor's office. Asthmnax used again this morning as well, only mild tightness in the throat currently with mild body aches this whole time.

Systemic: Fever-Severe, Systemic: hypotension, dyspnea-Severe; symptoms lasted 1 day

Patient day after vaccination had fever, chills, headache and malaise but recovered the next day. starting four days after vaccination started to have left neck swelling . Of note day prior vaccination had left wisdom teeth removal and maxillary root canal. 1 week after vaccination and 8 days after oral procedures worsening left neck swelling, trouble swallowing's and change voice found resulting left neck 3x2cm necrotic neck abscess and significant neck inflammation. Patient was seen by ENT and started on IV Unysan and admitted for airway monitoring due to swelling with improvement over next 48 hours.

12/23/2020-RECEIVED VACCINE AT 9:52 AM. REPORTS NOT FEELING WELL IN THE AFTERNOON, LIGHTHEADED AND DIZZY, THROBBING HEADACHE. CRAMPING/ACHING IN BACK OF CALVES. 12/24/2020 CONTINUED WITH DIZZINESS, THROBBING HEADACHE, BLOOD PRESSURE ELEVATED, CHEST PRESSURE 8:00 PM REPORTED FEELING THAT SHE WAS GOING TO DIE, WENT TO LAKE CITY MEDICAL CENTER- BLOOD PRESSURE ON ARRIVAL 184/101 HR. 117. GIVEN NITRO AND MEDICATIONS. ADMITTED, DISCHARGED 48 HOURS LATER ON 12/26/2020. DISCHARGED ON BLOOD PRESSURE MEDICATION 12/27/2020-LESS THAN 24 HOURS AFTER BEING DISCHARGED SHE WAS READMITTED TO MEDICAL CENTER WITH SAME SYMPTOMS. 36 HOURS AFTER ADMISSION, TRANSFERRED TO MEDICAL CENTER. FOR CARDIC WORKUP AND HIGHER LEVEL OF CARE.

Became dizzy, headache, felt like she was going to faint, rigors and a temperature of 101.5. Next morning she had upset stomach, feeling dizzy, thought she was going to faint and a headache.

Had Covid Vaccine AM of 1.8.2021. Woke up with Nausea, Vomiting X 4, Chills the following AM. Presented to ED. Found to be hypotensive during ER. Nausea Vomiting resolved. Tx with fluid replacement and dismissed home instructed to monitor BP. B/P dropped again at home returned and admitted to hospital.

Site: Pain at Injection Site-Medium, Systemic: Generalized Body Aches -Severe, Systemic: Headache-Severe, Systemic: Severe drop in blood pressure, pulse, and o-sat-Severe

Patient reported symptoms started ~15 mins s/p dose. Symptoms reported LUE and LLE numbness/tingling, and notable tachycardia

NauseaVomiting, HYPERtension, Tachycardia, throat swelling Narrative: Went home after vaccine and starting vomiting, throat swelling. HR and BP elevated Went to ER was given beta blockers, in hospital for observation.

"Patient received vaccine on 1/8/2021. On 1/9/2021 I checked on patient via phone for symptoms or problems and he reported none but mild soreness at injection site. On 1/10/2021 family friend called me to tell me that patient had expired at about 8:00 pm. Patient reportedly complained of ""pain"" unspecific and collapsed at home. Hospital reportedly told family that it appeared to be a ""heart attack""."

I was being monitored for 15 mins since I was allergic to tree nuts stayed 20 mins. I started feeling dizzy and exp nausea lasted 20 sec. After about 12 hrs later I woke up had difficult swallowing felt like something in my throat. I went to ER received a dose pack, Benadryl and steroid injection.

Jan 1st, patient had a seizure after breakfast. Temperature was 98.5 Pulse 95. B.P. 160/70 Two hours later another seizure at the home, with emesis, Sent to hospital at 2pm. Focal Status elepticus. Seizure activity along with continuous persistent activity with emesis throughout the 12 hour time in the ED. Seizure during the CT scan.

severe stabbing-shooting lower back pain; severe stabbing-shooting lower back pain that radiated to both legs; Pricking, pins and needles sensations in the hands and feet; numbness; weakness to both legs but mostly the right leg; Coordination problems, unsteadiness; Coordination problems, unsteadiness; This is a spontaneous report from a contactable nurse (patient). A 39-year-old male patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EL0140), intramuscular on 20Dec2020 08:00 at single dose at left arm for covid-19 immunization. Medical history included hypertension from an unknown date and unknown if ongoing. The patient's concomitant medications in two weeks included multivitamins. Patient didn't receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient was not diagnosed with COVID-19 prior to vaccination. No known allergies to medications, food, or other products. On 22Dec2020 at approximately 19:15, the patient experienced sudden onset of severe stabbing-shooting lower back pain that radiated to both legs. Pricking, pins and needles sensations in the hands and feet. Coordination problems, unsteadiness, numbness, and weakness to both legs but mostly the right leg. The patient underwent lab tests and procedures post-vaccination which included nasal swab for covid test: negative on 30Dec2020 (Antigen Test). Adverse events resulted in doctor or other healthcare professional office/clinic visit, emergency room/department or urgent care, disability or permanent damage. Patient received pain medication, steroid dose pack, MRI (pending), and physical therapy (pending) as treatment. Outcome of all events was not recovered.; Sender's Comments: Based on the compatible temporal association, a contributory role of vaccination with BNT162B2 in the onset of the events cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

high blood pressure within 15 min post vaccination. BP 180/94/BP rose to 202/110; This is a spontaneous report from a contactable nurse. An adult female (age:18-64 Years) patient (pregnant: No) received first dose of BNT162B2 (Pfizer), intramuscularly in left arm on 05Jan2021 10:30 at single dose for COVID-19 immunization. The patient's medical history was not reported. The patient was received

other concomitant drugs. The patient experienced high blood pressure within 15 min post vaccination. BP (blood pressure) 180/94 rose to 202/110 on 05Jan2021 10:45. The event resulted in doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care. The events were reported as non-serious. Recipient experienced high blood pressure within 15 min post vaccination. Went to hospital where her pressure was 202/110, vaccine given on 05Jan2021 at 10:30 am, by 10:45 am BP was 180/94, recipient refused hospitalization. Sister took her home but made her go to the hospital where her BP rose to 202/110. IV (intravenous) steroids given. The outcome of event was resolved in Jan2021. The patient didn't receive any other vaccines within 4 weeks prior to the COVID vaccine. The medications the patient received within 2 weeks of vaccination: Protein drink. Unknown whether was the patient diagnosed with COVID-19 prior to vaccination. Unknown whether the patient been tested for COVID-19 Since the vaccination. Unknown allergies to medications, food, or other products. Information on the lot/batch number has been requested.; Sender's Comments: Based on temporal association, a possible contributory role of BNT162B2 cannot be excluded for reported event hypertension. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

First dose on 16Dec2020, second dose on 05Jan2021; Tinnitus; constant ringing in ears; louder this time; This is a spontaneous report from a contactable nurse (patient). A 51-year-old female patient (no pregnancy) received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), with first dose (lot number: EH9899) on 16Dec2020 via intramuscular route, with second dose (lot number: EK4176) on 05Jan2021 via an unspecified route of administration, both at single dose for covid-19 immunization. Medical history included allergies: penicillin. Concomitant medication included famotidine, ibuprofen (DUEXIS), iron (IRON) and multivitamins, all received within two weeks of vaccination. On 17Dec2020, the patient experienced tinnitus, constant ringing in ears that started 24 hours after first vaccine, lasted about 2-3 days and went away. Ringing in ears started again and is louder this time on 06Jan2021. Facility where the most recent COVID-19 vaccine was administered was in hospital. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. No treatment received for the adverse event. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. The event was identified as serious and resulted in disability or permanent damage. The outcome of event tinnitus was not recovered. The outcome of the other event was unknown.; Sender's Comments: Based on the compatible temporal association with positive rechallenge result, the Company considers the event tinnitus is possibly related to vaccination with BNT162B2. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Injection site was red and a little swollen the next day and has become increasingly larger. Today (3 days later) the injection site is red, warm, swollen, and about the size of a grapefruit.; Injection site was red and a little swollen the next day and has become increasingly larger. Today (3 days later) the injection site is red, warm, swollen, and about the size of a grapefruit.; Injection site was red and a little swollen the next day and has become increasingly larger. Today (3 days later) the injection site is red, warm, swollen, and about the size of a grapefruit.; This is a spontaneous report from a contactable other HCP. A 39-yearsold female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number EL1284), intramuscular in left arm on 04Jan2021 14:00 at a single dose for COVID-19 immunization. Medical history included COVID-19 prior to vaccination. Concomitant medication included desvenlafaxine succinate (PRISTIQ), fluoxetine (FLUOXETINE), bupropion hydrochloride, naltrexone hydrochloride (CONTRAVE), hydrochlorothiazide (HYDROCHLOROTHIAZIDE), etonogestrel (NEXPLANON) , ergocalciferol (VITAMIN D [ERGOCALCIFEROL]), cyanocobalamin (VIT B12), and iron. On 05Jan2021, the patient experienced injection site was red and a little swollen and has become increasingly larger. 3 days later, on 08Jan2021, the injection site was red, warm, swollen, and about the size of a grapefruit. The outcome of the event was not recovered. Treatment included over the counter medications and ice. The patient was not tested for COVID-19 post vaccination.; Sender's Comments: Based on the information currently provided, the vaccination with BNT162B2 might play a contributory role in triggering the onset of the reported injection site reactions. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

"dizzy; felt like I was going to pass out; shaky; ringing in ears; This is a spontaneous report from a contactable nurse (patient herself). A 63-year-old non-pregnant female patient received her first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: unknown), via intramuscular route of administration on the left arm on 30Dec2020 17:00 at a single dose for COVID-19 immunization at hospital facility. The patient had no relevant medical history and no known allergies. The patient's concomitant medications were not reported. The patient did not receive any other vaccines within 4 weeks, or any other medications within 2 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. The patient reported ""almost immediately, dizzy, felt like I was going to pass out, shaky, and ringing in ears"" on 30Dec2020 17:00. Events were reported as non-serious but resulted in visit to the Emergency room/department or urgent care. Ondansetron (ZOFRAN) was given as treatment for nausea and meclizine. The outcome of the events was not recovered. Since the vaccination, the patient had not been tested for COVID-19. Information on the lot/batch number has been requested.; Sender's Comments: The Company cannot completely exclude the possible causality between the reported ""dizzy, felt like I was going to pass out, shaky, and ringing in ears"" and the administration of COVID 19 vaccine, BNT162B2, based on the plausible temporal association. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RA, IEC, as appropriate."

felt flushed; BP elevated 226/97; dull occipital headache/dull headache; This is a spontaneous report from a contactable other HCP (patient). A 64-year-old female patient received second dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number: EL1284; expiration date not provided) via an unspecified route of administration (vaccination location: left arm) on 06Jan2021 09:30 at SINGLE DOSE for COVID-19 immunisation. Medical history was reported as 'none'. It was also reported that patient didn't receive any other vaccines within 4 weeks prior to the COVID vaccine, and prior to vaccination, the patient was not diagnosed with COVID. The patient has no allergies to medications, food, or other products (no known allergies). The patient's concomitant medications were not reported. The patient previously took bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number: EH9899; expiration date not provided), via an unspecified route of administration (vaccination location: left arm) on 18Dec2020 18:00 at SINGLE DOSE for COVID-19 immunisation. It was reported that patient received second dose of Pfizer Covid vaccine on 06Jan2021 at 09:30 am. One hour after the 2nd dose (10:30 am), patient experienced dull occipital headache. Patient took paracetamol (TYLENOL). At 10:45 am, patient felt flushed. The nurse took patient's vital signs and noted no fever, normal heart rate and respiratory rate. BP elevated 226/97 (reported at 10:30, no unit provided; normal BP: 130's/80's). At 12:45, patient was taken to ED. CT scan and lab work were reported as all normal. BP continues to be elevated. Amlodipine (NORVASC) 10 mg was given at 17:00. BP slowly came down. Twenty-four hours later, BP was normal at 137/72 (no unit provided). No additional medication taken. It was reported that patient continues to have dull headache. No arm soreness or other symptoms. It was also reported that since the vaccination, the patient has not been tested for COVID-19. Outcome of the events 'BP elevated 226/97' and 'felt flushed' was recovering, outcome of the event 'dull occipital headache/dull headache' was not recovered.; Sender's Comments: Based on the compatible temporal association and in absence of strong confounding factors, the Company considers the reported event blood pressure increased is possibly related to vaccination with BNT162B2. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

"rash/getting this rash on my face and everywhere/rash and it is breaking out her face and now it is all over; a lot of muscle pain; could not sleep; This is a spontaneous report from a contactable consumer (patient). A 27-year-old female patient received first dose bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), intramuscular in left deltoid on 24Dec2020 09:30 at single dose for preventative. Medical history included none. There were no concomitant medications. The patient previously took influenza vaccine (FLU) for immunization and experienced sick (Flu shot if it contains egg she gets really sick). Patient reported experiencing a rash 2 weeks on 06Jan2021 after getting her first dose of the vaccine. Caller stated ''I'm concerned because I'm getting this rash on my face and everywhere and I'm due for my booster on 13Jan2021.'" Caller questioned if others had reported this. She had a lot of muscle pain on 24Dec2020 and could not sleep from the pain in Dec2020. Reports the pain is gone now and lasted till 28Dec2020. She has a rash and it is breaking out her face and now it is all over. States nothing has changed and the vaccine was the only new thing. States the rash started two weeks since she got the vaccine. Vaccination facility type was Hospital. Vaccine administered at military facility was No.

Additional Vaccines Administered on Same Date of the Pfizer Suspect was none. AE not require a visit to emergency room. Therapeutic measures were taken as a result of rash/getting this rash on my face and everywhere/rash and it is breaking out her face and now it is all over (Doctor ordered steroids for her today she is a CNA). The outcome of the event a lot of muscle pain was recovered on 28Dec2020. The outcome of the event rash/getting this rash on my face and everywhere/rash and it is breaking out her face and now it is all over was not recovered. The outcome of the event could not sleep was unknown. Information about lot/batch has been requested."

"passed out; blood pressure was lowered; blood sugar high; weakened; feeling tired and her legs are heavy; feeling tired and her legs are heavy; This is a spontaneous report from a contactable consumer (Patient's Mother). A 23-years-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 04Jan2021 Monday at single dose for COVID-19 immunisation. The patient medical history and concomitant medications were not reported. The patient experienced passed out 12 hours post injection (Jan2021). She specified that her daughter was therefore brought to hospital by ambulance. She continued explaining that her blood pressure was lowered, her blood sugar high and that she was weakened (Jan2021). On 08Jan2021, ""day 4"", she said that her daughter had been feeling tired and her legs are heavy (Jan2021). The event outcome was unknown. She then asked if those side effects were experienced after the vaccine. It was not reported as serious. Information on the batch number has been requested."

left side will blur; Left side of face was sagging/ water leaking out of mouth/Progressive weakness on left side of face/ Swelling on lower left mandible/ diagnosed with Bell's Palsy.; Eye tearing; This is a spontaneous report from a contactable nurse who reported for himself. A 61-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Batch/lot number: EK5780) in left arm on 26Dec2020 at 08:30 at single dose for covid-19 immunisation (worked in surgical ICU and was over 61 years old). Medical history included Pre-diabetic. Family history included: mother died; mother's side had colon cancer and grandparents and uncles had cardiovascular diseases.Concomitant medication included exenatide (BYDUREON), amlodipine besilate (NORVASC), omeprazole (PROTONIX), hydrochlorothiazide, lisinopril and pneumococcal vaccine on 08Dec2020 and tetanus vaccine on 08Dec2020. It was reported that on 31Dec2020 at 07:30, the patient had eye tearing and water leaking out of mouth, left side of face was sagging, swelling on lower left mandible (eye tearing was first, as reported); on 31Dec2020 he also experienced progressive weakness on left side of face; on 02Jan2021 the patient was diagnosed with Bell's Palsy. Then on an unknown date, left side will blur occurred. All events required emergency room visit and physician office visit. Diagnosis of Bell's Palsy and event eye tearing were serious per disability; left side will blur was non serious. Patient described the events as follows: on 31Dec2020 he was brushing teeth and noticed the water was going everywhere. Left side of face was sagging, noticed some swelling and thought it was from a bug bite. He wasn't sure if it was a stroke or not. In the morning of 01Jan2021 noticed it was progressively causing a problem. Days before noticed tearing of left eye (as reported). On 31Dec2020 before midnight, something felt wrong. He saw four cases on clinical trial with similar side effects (he clarified he had no patient information for the four patients mentioned with similar side effects from Pfizer Clinical trial. He saw this information from a article; stated four from Pfizer and Moderna). In the morning of 02Jan202, he went to Emergency Room

(ER) and was diagnosed with Bells Palsy. He was given prednisone 20mg to take 3 times by mouth every day for 5 days, tetracycline 100mg, at 1 capsule by mouth twice a day for 10 days and methylprednisolone (SOLU MEDROL; Lot: 9945776;Exp: Nov2021) 4mg dose pack, started with 6 tablets first day. It was told by doctor it might cause tick problems. He was waiting for results. On 04Jan2021 went to family doctor and more blood work was taken. Because he was taking prednisone, noticed his sugar was up a little bit (date unspecified). It was prescribed Glitizide extended release, 2.5mg one tablet twice a day with breakfast. Patient was checking sugar every 6 hours. It was also prescribed Acyclovir 400mg one tablet orally five times per day for 10 days. 08Jan2021 is last day of prednisone 5 day dose and will follow up with methylprednisolone tablets. Patient had an appointment with a neurologist on 13Jan2021. Patient was still having symptoms. It was really hard for him. Not hard to swallow. Face was still drooping. Eyes were still tearing. Could not work with eyes tearing all of the time. Needed to be alert. When driving, had to focus on the right side because his left side will blur. He had to chew only on the right side because food will be left behind in between his cheeks and gums. If he drank through a straw, he had to cover the left side of his lips so he was able to suck out fluids. He thought symptoms were progressively getting worse, he didn't see much improvement. He clarified swelling was on lower part of mandible on left side. It was slightly bigger than right. When looking at face, the lines on his forehead on the left side were down. If he smiled he cannot raise his left eye brow, when before the COVID-19 vaccine he could. Noticed left side of nose was lower than the right. Cannot raise left side of lips. Outcome of the event Eyes tearing and Bell's Palsy was not recovered; outcome of the other event was unknown. Information on the batch number has been requested.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the reported events of Bell's palsy, Lacrimation increased and vision blurred due to temporal relationship. However, the Bell's palsy may likely possibly represent concurrent medical condition in this patient. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics including head CT/MRI and viral serologies, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Bell's Palsy; This is a spontaneous report from a contactable nurse. A 33-year-old male patient received his first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for covid-19 immunization. The patient medical history and concomitant medications were not reported. The reporter reported a patient developed Bell's Palsy after receiving the first dose of the vaccine. This patient was a physician, the reporter stated that the patient was scheduled to receive the second dose on Monday (unspecified date) and questioned if he should or should not get the second dose. The outcome of the event was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Based on temporal association, the causal relationship between bnt162b2 and the event facial paralysis cannot be excluded. The information available in this report is limited and does not allow a medically meaningful

assessment. This case will be reassessed once additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate.

hearing loss; ringing and pulsating in her ears; Chills; Headache; This is a spontaneous report from a contactable consumer (patient). A 36-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EK9231), via an unspecified route of administration in in the left arm on 04Jan2021 at single dose for covid-19 immunization. Medical history included ongoing acid reflux. The patient had no concomitant medications. The patient previous received the flu shot. The patient experienced hearing loss, ringing and pulsating in her ears on 05Jan2021, headache on 04Jan2021, chills on 05Jan2021. Treatment was none. She had the vaccine on Monday at work and some of the symptoms that she has had have not resolved. She was having ringing in her ears and hearing loss. Went to see them and had her ears looked at. Everything was normal. Got the vaccine on 04Jan2021. Ringing in ears and hearing loss: Had been very consistent with no improvement. If anything, it had worsened. She was going to re-contact her doctor. She was also going to ask, should she go on Prednisone or something. She was worried she was going to lose her hearing. Her doctor said that a hearing test may need to be done. History: Takes one medication that she has been taking for years. She has never had an adverse event to any vaccine before. She got the flu shot every year. She was expecting the chills and headache, but they resolved fast. The next vaccine was 25Jan2021, the patient was asked whether she should get the second dose. The outcome of events for hearing loss, ringing and pulsating in her ears was not resolved, for headache and chills was resolved on 06Jan2021.

she was dying as her blood pressure dropped to 70/40 and to come for a last visit; This is a spontaneous report from a contactable consumer. A 100-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 02Jan2021 at single dose for COVID-19 immunization. Medical history included COVID in Dec2020, urinary tract infection (UTI), dehydration and Covid sickness (vomiting) (was treated earlier in month for UTI and dehydration from the Covid sickness (vomiting)). Known allergies: no. The patient's concomitant medications were not reported. After testing positive in mid December to COVID and being declared Covid free on 30Dec by the nursing staff and in good health, with normal vitals and oxygen levels, the patient was given a vaccination on 02Jan2021. In the early evening the patient's blood pressure dropped to 70/40 and the reporter was told to come for a last visit. The patient was sleeping comfortably. She did not wake up when spoke with her. No one expected her to make it through the night. The next morning she work up, ate breakfast, watched TV, got IVs and oxygen and her vitals improved significantly. Lab tests and procedures included blood pressure: 70/40 on 02Jan2021, oxygen levels: normal, COVID test: positive in Dec2020 (testing positive in mid December to COVID and being declare Covid free on 30Dec), vitals: normal; improved significantly. Facility where the most recent COVID-19 vaccine was administered: Nursing Home/Senior Living Facility. If the patient received any other vaccines within 4 weeks prior to the COVID vaccine: No. Prior to vaccination, was the patient diagnosed with COVID-19: Yes. Since the vaccination, has the patient been tested for COVID-19: No. AE resulted in: Life threatening illness

(immediate risk of death from the event). Serious: Yes. Seriousness criteria-Results in death: No. Seriousness criteria-Life threatening: Yes. Seriousness criteria-Caused/prolonged hospitalization: No. Seriousness criteria-Disabling/Incapacitating: No. Seriousness criteria-Congenital anomaly/birth defect: No. Information about lot/batch number has been requested.

dizzy; itchy throat; coughing; swollen throat; This is a spontaneous report from a contactable pharmacist. A 21-year-old female patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EL0142, NDC number: 59267-1000-1; Expiry Date: Mar2021), via an unspecified route of administration on 07Jan2021 11:20 at 0.3 mL, single at left arm for vaccination. Medical history included Cushing's disease (recovering), bipolar disorder from an unknown date and unknown if ongoing. Concomitant medication included lamotrigine (LAMICTAL) for bipolar disorder. On 07Jan2021, looked like after receiving the vaccine about 30 minutes later patient was standing and felt like dizzy. About 15 or 20 more minutes, or 45-50 minutes after received injection, she felt like itchy throat, then itchy throat triggered coughing, then she felt like swollen throat. For the treatment on scene patient was administered 50mg of diphenhydramine hydrochloride (BENADRYL) and when she complained of swollen throat was administered epinephrine (EPI-PEN) 0.3mg injection to right thigh. Then they called EMS who transported her to the hospital where she was admitted to the hospital. Outcome of events was unknown. This report was considered as serious per caused/prolonged hospitalization. Causality: Cannot jump to that conclusion.; Sender's Comments: Based on temporal association, the causal relationship between bnt162b2 and the events dizziness, throat irritation, cough and pharyngeal swelling cannot be excluded. The information available in this report is limited and does not allow a medically meaningful assessment. This case will be reassessed once additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate.

horrible body aches; Nausea; head fogginess; felt like a lump and couldn't move; not wanting to eat; This is a spontaneous report from a contactable nurse (patient). A 63-year-old female patient received BNT162B2 (Batch/lot number: E10140) first dose on 28Dec2020 11:15AM in the right arm at single dose since she is front line health care worker. Medical history included pain. Medical history included tramadol for pain. No Prior Vaccinations (within 4 weeks). Family Medical History Relevant to AE was none. She received the vaccine 28Dec2020 and it flattened her for two days. Her primary care provided has advised her not to take the next dose. Within 45 minutes she noticed nausea. She was eating lunch and she felt like everything was coming up and she forced herself not to vomit. The she noticed horrible body aches; head was foggy; she felt like a lump and couldn't move;. The body aches hurt in her arms, legs, hips, and back. Adds she was out of work for two days. She could feel it working as the symptoms would peak and then drop. She did go back to work but shouldn't have as she continued to feel nauseous and not wanting to eat. All of these symptoms have now resolved. Vaccination Facility Type was nursing home. No Vaccine Administered at Military Facility. Facility Name: Nursing Home. History of all previous immunization with the Pfizer vaccine considered as suspect was none. Additional Vaccines

Administered on Same Date of the Pfizer Suspect was none. Event not resulted in Physician office or ER. The outcome of the event nausea was recovered on 02Jan2021. The outcome of event not wanting to eat recovered on 03Jan2021. The outcome of other events was recovered on 01Jan2021. The seriousness criteria for event horrible body aches was reported as medical significant.; Sender's Comments: The patient had medical history included pain. A possible contribution role of the first dose of BNT162B2 to the horrible body aches cannot be excluded. The case will be reassessed should additional information become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

patient passed away after receiving the Covid vaccine; This is a spontaneous report from a contactable nurse. An 81-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), intramuscular into the right arm on 07Jan2021 at 0.3 mL, single for covid-19 immunization. There was no medical history and no concomitant medications. On 08Jan2021, the patient passed away after receiving the COVID vaccine. The patient died on 08Jan2021. An autopsy was not performed. Investigations indicate that unspecified labs were done, but nothing two weeks prior; no further details were provided. The patient received the first dose the day prior. The reporting nurse discussed it with the medical director, and he thought that he potentially passed away from the COVID vaccine. The relatedness of the event to the suspect vaccine was reported as related by the reporting nurse per The Agency. The batch/lot number for the vaccine, BNT162B2, was not provided and will be requested during follow-up .; Sender's Comments: Based on the limited information available, it is medically not possible to make meaningful causality assessment, it is unlikely the vaccine could have contributed to the death of the patient based on the known safety profile. However case will be reevaluated when additional information is received during the follow-up The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.; Reported Cause(s) of Death: Stated that the patient passed away after receiving the Covid vaccine

Patient received her vaccination on 1/12/21 administered by pharmacy*+. She expired on 1/12/21 an approximately 7:30pm. Resident did not have any adverse reactions and was a hospice patient.

"Patient was found ""acting abnormal"" on 1/9/2021 at 1215. VS HR 20-30's. EMS activated. EMS arrived and patient was found pulseless in PEA/ asystole, CPR and ACLS initiated and then transported to the MC. Unsuccessful resuscitation and expired on 1/09/2021 at 1348. Clinical impression Cardiopulmonary arrest."

"5 days after administration- heavy uterine bleeding; constipation; severe knee/shoulder joint pain; light sensitivity; dizziness/ light headedness; thigh numbness; pain when prodded on either sides of thighs; harsh headache; This is a spontaneous report from a contactable Other healthcare professional

(patient). A 21-year-old female patient received BNT162B2 first dose on 31Dec2020 03:15 PM intramuscularly on left arm at single dose for COVID-19 immunization. Medical history included Depression, Anxiety, Factor V Leiden, Known allergies to Penicillin and Onion sensitivity. Patient is not pregnant. No other vaccine in four weeks. Concomitant medications in two weeks included unspecified medications. ""5 days after administration"" (also reported as 01Jan2021)- heavy uterine bleeding (resulting with trip to ER), constipation, severe knee/ shoulder joint pain, light sensitivity, dizziness/ light headedness, thigh numbness, pain when prodded on either sides of thighs, harsh headache. No treatment received for the events. Events resulted in ER and physician office visit. No covid prior vaccination. No covid tested post vaccination. The outcome of the events was not recovered. The seriousness was reported as no. Information on the lot/batch number has been requested.; Sender's Comments: A possible contributory effect of suspect BNT162B2 on reported uterine bleeding cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate."

thrombopenia; pulmonary embolism; neutropenia fever; This is a spontaneous report from a Pfizer-sponsored program . A contactable consumer reported for a patient that received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration on an unspecified date at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced thrombopenia, pulmonary embolism and neutropenia fever on an unspecified date. The clinical outcome of thrombopenia, pulmonary embolism and neutropenia fever was fatal. The patient died on an unspecified date. It was unknown if an autopsy was performed. The batch/lot number for the vaccine, BNT162B2, was not provided and will be requested during follow-up.; Reported Cause(s) of Death: thrombopenia; pulmonary embolism; neutropenia fever

"Began to start having bulbar reaction with clearing of throat and tightness of chest; Began to start having bulbar reaction with clearing of throat and tightness of chest; Numb bottom lip progressed to both lips with swelling, then tip of tongue and progressed to tongue with numbing /swelling sensation; Numb bottom lip progressed to both lips with swelling, then tip of tongue and progressed to tongue with numbing /swelling sensation; Numb bottom lip progressed to both lips with swelling, then tip of tongue and progressed to tongue with numbing /swelling sensation; This is a spontaneous report from a contactable Other-HCP (patient herself). This 48-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number EL0142), via an unknown route, on 07Jan2021 at 14:15 at single dose for COVID-19 immunisation. Vaccine location was left arm. The patient was vaccinated at hospital, age at vaccination was 48-year-old. The patient was not pregnant. No other vaccine was received in four weeks.Relevant medical history included COVID 19 complications (prior to vaccination). The patient has allergy to contrast dye, sulfa and molds. Relevant concomitant medications included nebivolol hydrochloride (BYSTOLIC), topiramate (TOPAMAX), atorvastatin (LIPITOR), ascorbic acid, betacarotene, biotin, calcium, chromium, copper, folic acid, iodine, iron, lycopene, magnesium, manganese, nicotinamide, pantothenic acid, phytomenadione, pyridoxine hydrochloride, retinol,

riboflavin, selenium, vitamin b1 nos, vitamin b12 nos, vitamin d nos, vitamin e nos, xantofyl, zinc (CENTRUM WOMEN), and acetylsalicylic acid (ASA). After vaccination, within 5 min she started with numb bottom lip progressed to both lips with swelling, then tip of tongue and progressed to tongue with numbing /swelling sensation. Began to start having bulbar reaction with clearing of throat and tightness of chest. She was given diphenhydramine hydrochloride (BENADRYL) total 50 mg, famotidine (PEPCID) 20 mg, dexamethasone (DECADRON) 4 mg and racemic epinephrine. The events required visit at emergency room/department and urgent care. However, the events were reported as non-serious by the reporter. Post-vaccination COVID test was not performed. The patient had not recovered from the events.; Sender's Comments: The reported ""numb bottom lip progressed to both lips with swelling, then tip of tongue and progressed to tongue with numbing /swelling sensation"", ""bulbar reaction with clearing of throat and tightness of chest"" developed within 5 min administration of BNT162B2, is likely an allergic reaction to BNT162B2, and considered related. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RA, IEC, as appropriate."

My b/p shot up as well 180/107; My heart started racing....noted at 133/I had strong heart palpitations; Feeling of lightheadedness; This is a spontaneous report from a contactable nurse reporting for herself. A 50-years-old female patient received the first dose of BNT162B2 Pfizer-BioNTech COVID-19 Vaccine, via an unspecified route of administration in the right arm on 29Dec2020 at 12:15 pm, at 50-years of age, at single dose for COVID-19 immunization. The patient received the vaccine in Hospital and didn't receive any other vaccine in the previous four weeks. Medical history included hypertension from an unknown date (controlled) and no known allergy. Concomitant medication included amlodipine besilate 10 mg (NORVASC). The patient reported that, on 29Dec2020, within 6 minutes after receiving the vaccine dose, her heart started racing, it was noted at 133, her blood pressure shot up as well to 180/107, she had strong heart palpitations with feeling of lightheadedness. Prior to the vaccine the patient was at work, feeling well and taking care of her patients. Emergency Room visit and Physician Office visit were required, moreover fluids and potassium were administered to the patient as a result of the events. She reported she spent 8 hours in the ER. The events were reported as non-serious but they were assessed as important medical events by the Company. At the time of the report the reported events were resolving. Information about Lot/Batch number has been requested.; Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of events Hypertensive crisis, Palpitations, and Lightheadedness cannot be excluded. The case will be reassessed if additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

"Heart attack; This is a spontaneous report from a contactable consumer. An 82-year-old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot Number: and Expiration Date: Unknown), via an unspecified route of administration in the left arm on 05Jan2021 at 13:00 at a single dose for COVID-19 immunization; administered in doctor's office/urgent care. The patient's medical history and concomitant medications were not reported. It was unknown if the patient received any other vaccines within four weeks prior to the COVID vaccine. Prior to the vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. On 05Jan2021, the patient experienced heart attack; which resulted in death and was assessed as medically significant. The patient also experienced the associated symptoms of cold sweats, chest pain, shortness of breath. Therapeutic measures were taken as a result of heart attack, which included ""life saving measures"" by the paramedics performed upon arrival with no success. The clinical outcome of the event, heart attack, was fatal. The patient died on 05Jan2021 due to heart attack; as ruled by the paramedics. It was unknown if an autopsy was performed. The batch/lot numbers for the vaccine, PFIZER-BIONTECH COVID-19 MRNA VACCINE, were not provided and will be requested during follow up.; Reported Cause(s) of Death: Heart attack"

"Cardiac Arrest; Patient was found pulseless and breathless 20 minutes following the vaccine administration.; Patient was found pulseless and breathless 20 minutes following the vaccine administration.; This is a spontaneous report from a contactable other healthcare professional (HCP). A 66-year-old female patient (pregnant at the time of vaccination: no) received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL1284) via intramuscular at left arm on 11Jan2021 12:15 PM at single dose for COVID-19 immunization. Medical history included diastolic CHF, spinal stenosis, morbid obesity, epilepsy, pulmonary hypertension and COVID-19 (Prior to vaccination, the patient was diagnosed with COVID-19). The patient received medication within 2 weeks of vaccination included amiodarone, melatonin, venlafaxine hydrochloride (EFFEXOR), ibuprofen, aripiprazole (ABILIFY), lisinopril, cranberry capsules, diltiazem, paracetamol (TYLENOL), famotidine, furosemide (LASIX [FUROSEMIDE]), ipratropium bromide, salbutamol sulfate (IPRATROPIUM/ALBUTEROL), buspirone, senna alexandrina leaf (SENNA [SENNA ALEXANDRINA LEAF]), polyethylene glycol 3350 and morphine. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Patient used took Penicillin, propranolol, quetiapine, topiramate, Lamictal and had allergy to them. Patient used took the first dose of BNT162B2 (lot number: EJ1685) via intramuscular at right arm on 21Dec2020 12:00 PM at single dose for COVID-19 immunization. Since the vaccination, the patient been tested for COVID-19 (Sars-cov-2 PCR) via nasal swab on 06Jan2021, covid test result was negative. Patient was found pulseless and breathless 20 minutes following the vaccine administration (11Jan2021 12:30 AM). MD found no signs of anaphylaxis. Patient died on 11Jan2021 12:30 AM because of cardiac arrest. No treatment received for the events. Outcome of pulseless and breathless was unknown. the autopsy was performed, and autopsy remarks was unknown. Autopsy-determined cause of death was unknown. It was reported as non-serious, not results in death, Life threatening, caused/prolonged hospitalization, disabling/Incapacitating nor congenital anomaly/birth defect.; Sender's Comments: Based on the available information this patient had multiple underlying medical conditions including morbid obesity, diastolic CHF, epilepsy, pulmonary hypertension and COVID-19 diagnosed prior to vaccination. All these conditions more likely contributed to patients cardiac

arrest resulting in death. However, based on a close temporal association (""Patient was found pulseless and breathless 20 minutes following the second dose of BNT162B2 vaccine administration, contributory role of BNT162B2 vaccine to the onset of reported events cannot be completely excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.; Reported Cause(s) of Death: Cardiac arrest; Autopsy-determined Cause(s) of Death: autopsy remarks was unknown. Autopsy-determined cause of death was unknown"

Patient admitted for a fib; This is a spontaneous report from a contactable consumer. A female patient in her 70s received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection) lot number was unknown, via an unspecified route of administration on 05Jan2021 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. It was reported that the patient received vaccine on Tuesday, 05Jan2021. On Thursday, 07Jan2021, patient did not feel good-pulse and blood pressure. It was mentioned that the patient admitted for a fib. Two days after receiving Pfizer-BioNTech Covid 19 vaccine, the woman patient in her 70s was admitted for a fib. Information about lot/batch number has been requested.

Vaccine administered at 08:16--08:25 patient c/o feeling unwell and dizzy 87, 143/84, 18, 100%; 08:28: Pt c/o dizzy & chest tightness, appeared pale, monitoring; 08:34: Pt c/o increased chest tightness 130, 144/81, 22, 100% monitoring 08:36: Epinephrine .3mg given IM to R thigh, pt. reported flushing, pounding heart, 911 called; 08:40: Pt flushed.

5 days after Moderna vaccine, developed severe abd pain, mid epigastrium. No Nausea or vomiting. No fever. Mild diarrhea. after 48 hrs with no improvement went to ED

At first I has some injection site pain and soreness nothing too bad. But around 01:30 I awoke with a really high fever. My fever was 102.8 when I first woke up. I was very nauseous and my fever felt worse. My thermometer would not read any more until my temp came down. I can only guess how high it got but at least 103 degrees. I took Advil Liquid Gells and then my fever broke. I was actually scare for my life. In March I actually caught coronavirus and developed anti bodies for Covid. I can only guess my body was fighting for it's life.

positive COVID-19 test with symptoms; positive COVID-19 test with symptoms; After the shot i have headache, sorethroat, cough and cold till this date; After the shot i have headache, sorethroat, cough and cold till this date; After the shot i have headache, sorethroat, cough and cold till this date; After the shot i have headache, sorethroat, cough and cold till this date; A 48-years-old non-pregnant female patient, receivedBNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), via an unspecified route of administration, in left arm, on 18Dec2020 (at the age of 41 years-old) as a single dose for COVID-19 immunization. The vaccination was administered at a pharmacy/drug store. Medical history was not reported. Concomitant medication included sertraline hydrochloride (SERTRALINE HYDROCHLORIDE). The patient had not received any other vaccines within four weeks prior to the vaccination nor received

any other medications withing 2 weeks prior. It was reported that the patient had been tested for COVID-19 prior to vaccination and was negative. On 18Dec2020, the patient experienced itchy sore eyes one hour after vaccination, sore and itchy arm for 5 days, headache, swollen sore throat, tiredness all 5 days after. The patient was not hospitalized nor received treatment for the events. The clinical outcome of the events of Itchy, sore eyes 1 hour after, sore and itchy arm for 5 days, headache, swollen sore throat, tiredness all 5 days after, was not recovered., the outcome of the COVID-19 positive was unknown. It was reported that the patient tested positive for COVID-19 via nasal swab, post vaccination on 31Dec2020. No follow-up attempts possible. No further information expected. Lot/batch number was not provided and unable to obtain

tested positive for Covid; tested positive for Covid; This is a spontaneous report from a contactable consumer. A 7-decade-old female patient (in her 60s) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 23Dec2020 at a single dose for COVID-19 immunisation. Medical history and concomitant medications were not reported. A pharmacy student received this drug information question in which a female patient in her 60s received the first Covid vaccine on 23Dec2020 and tested positive for Covid on 04Jan2021. Could the patient receive antibody treatment? Could she get the second vaccine and when? The outcome of the events was unknown. Information about Lot/Batch number has been requested.

Caller is a respiratory therapist who reports that he tested positive for covid after receiving the first dose of the vaccine on 17Dec; Caller is a respiratory therapist who reports that he tested positive for covid after receiving the first dose of the vaccine on 17Dec; This is a spontaneous report from a contactable consumer (patient) reported that a 32-year-old male patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EH9899), via an unspecified route of administration from on 17Dec2020 at single dose (once by injection in the right arm/bicep) for COVID-19 immunization (Healthcare worker). There were no medical history and concomitant medications reported. The patient/caller is a respiratory therapist who reported that he tested positive for covid after receiving the first dose of the vaccine on 17Dec2020. He called to ask if he can get the second dose. He also wanted to ask if people experienced side effects or what side effects people experience after the second dose. He tested positive for Covid-19 on 21Dec2020, after receiving the first dose of the vaccine. He said it had been 14 days since he tested positive for COVID and he is if he can get the second dose. He says he is actually on his way to get the second dose right now, and thought he should call. The outcome of the event was unknown.

hypertension like 190/90; I had tachycardia to 165; Flushing; This is a spontaneous report from a contactable consumer (patient). A 22-year-old female patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) lot number: EK9231, intramuscular on 06Jan2021 at single dose for COVID-19 immunization. Medical history included migraine. Concomitant medication included cyproheptadine for migraine, unspecified multivitamins; and diphenhydramine (BENADRYL) and famotidine as pre-medications. The patient previously received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 17Dec2020 for COVID-19 immunization, and experienced dizziness, palpitations, tingling in face and legs, myalgia, nausea, headache, fatigue. It was reported that patient got the second dose and had tachycardia to 165 and hypertension like 190/90 and had some flushing

(event onset: 06Jan2021). Patient was no longer tachycardiac or hypertensive; lasted for about 30-40 minutes. Outcome of the events tachycardia and hypertension was recovered on 06Jan2021. Outcome of the event flushing was unknown.

Actual event and cause of death were unknown; This is a spontaneous report from a non-contactable consumer. A 90-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 06Jan2021 at single dose for COVID Prevention. The relevant medical history included aortic valve replacement from Nov2019. Concomitant medications were not reported. The consumer stated that she was taking the reporting responsibilities to report that a friend of hers, informed that the patient passed away on Friday, and had received the COVID vaccine on Wednesday. The consumer stated that it was unknown to her at this time, if the friend had called to complete a report herself, regarding the incident. Their conversation was very brief. The patient was 90 years old, and it was her friend's mother that was the patient. Actual event and cause of death were unknown. The patient had her vaccine on Wednesday 06Jan2021, and then the patient collapsed in front of the reporter at Friday night on 08Jan2021 and passed away that same day. The autopsy was unknown. The outcome of the event was fatal. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Reported Cause(s) of Death: Actual event and cause of death were unknown

episodes of severe dyspnea and lightheadedness over the past couple of weeks; episodes of severe dyspnea and lightheadedness over the past couple of weeks; ventricular tachycardia with a rate of 270; severe right ventricular dilatation and dysfunction with inflammation and fibrosis throughout the RV and septum, but minimal LV involvement.; severe right ventricular dilatation and dysfunction with inflammation and fibrosis throughout the RV and septum, but minimal LV involvement.; severe right ventricular dilatation and dysfunction with inflammation and fibrosis throughout the RV and septum, but minimal LV involvement.; This is a spontaneous report from a contactable physician (patient). A 4-decade-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via unspecified route of administration on 18Dec2020 at single dose for COVID-19 immunization. Patient medical history and concomitant medications were not reported. Patient reported that on 18Dec2020, she received the first dose of Pfizer / BioNTech vaccine. On 30Dec2020 (Wednesday), she was diagnosed of ventricular tachycardia with a rate of 270, severe right ventricular dilatation and dysfunction with inflammation and fibrosis throughout the RV and septum, but minimal LV involvement. On 30Dec2020, EKG showing RBBB with PR 234 (in presence of normal EKG and ECHO from Dec2016), and positive troponin 0.07 that has remained stable in the following week. On unspecified date in Jan2021, the patient had been having episodes of severe dyspnea and lightheadedness over the past couple of weeks, but it had been sporadic - it became significantly worse in the last 2 weeks, which is why patient sought out an electrophysiologist (and purchased at-home EKG monitor on which she saw the VT). Patient do not know the cause at all. She was tested for SARS-CoV-2 antibody yesterday (unspecified date in Jan2021), which was negative. Patient was also trying to determine if she should get the second dose or not. She will have cardiac PET scan next week, which hopefully further elucidate causes. Outcome of the events dyspnea and lightheadedness was not recovered; while outcome of other events was unknown. Information on the Lot/Batch number has been requested.; Sender's Comments: Based on the available

information, a causal relationship between reported events and BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) cannot be completely excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

My right leg from the knee down was purple and they thought I have a blood clot; My right leg from the knee down was purple and they thought I have a blood clot; This is a spontaneous report from a non-contactable consumer (patient). A patient of unspecified age and gender received bnt162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient medical history and concomitant medications were not reported. Three days after vaccination the patient felt very sick and he/she was so bad that he/she thought he/she might die with outcome of recovered after one week. The patient reported also that on unknown date his/her right leg from the knee down was purple and they thought he/she have a blood clot, due to which the patient was hospitalized for 14 days. The patient ended in the hospital because his/her right leg from the knee down was purple and they thought he/she have a blood clot but they did an ultrasound that was not the case but they put he/she on antibiotic. The patient was still taking them but his/her leg has got better. No follow-up attempts are possible. Information about lot/batch number cannot be obtained. No further information is expected.

Covid symptoms began 2-3 days after shot. Presented to ER day 11 day after positive with extreme dyspnea O2 Sat at 88% Chest xray opacities throughout the bilateral hemithoracies would suggest multifocal infiltrate Admitted on high flow oxygen reduced to 6 liters currently D-dimer is >35.20

Patient is a 99yr old female who got a covid vaccine in the afternoon of 1/10/21 and woke up in the morning of 1/11/21 with altered mental status, weakness, and dysarthria. She was taken from her assisted living facility to the hospital and MRI showed a small stroke in the right medial thalamus. She was also found to have new onset atrial fibrillation. She was treated appropriately for both conditions and discharged to a skilled nursing facility on 1/13/21.

Pt was accompanied by daughter, who drove pt to clinic. Pt was correctly identified, screened, given vaccine, monitored for appropriate time. Pt left clinic as passenger of vehicle and was being driven by daughter. Pt started complainingg of Shortness of breath and not feeling right.. Daughter brought pt to local emergency room, Pt was later transferred to higher care hospital. Information regarding symptoms and further medical care was relayed to clinic by family member.

Patient received vaccine in afternoon of 12/28. She works in ER as housekeeper 7pm-7am. The day she received the vaccine she became ill with fever chills and nausea and left work at 2am. On 12/31 she developed hemianopia. She went to ER and they did CT scan. She was told it was complex migraine. She left and came Home. On 1/1/21 her vision was back to normal. On 1/3 she suffered bilateral cerebellum ischemic stroke. She is currently in medical center. In Trauma.

Patient experienced a syncopal episode post vaccination, accompanied by feeling hot and tachycardic. Prior to the syncope, she reported hyperventilating. She remained unresponsive for about 10 minutes and was brought to the ED. There she became responsive, and reported chest pain and had sinus tachycardia episodes. She also had lower extremity weakness. This has improved per the latest neurology notes. She also had a negative EEG. Unsure if this is an allergic reaction or if the syncope was due to hyperventilation. Patient is currently on day 3 of hospitalization.

Systemic: Headache, Systemic: Eyes dilated and difficulty remembering information; symptoms lasted 2 days

I was short of breath and went to emergency room on 1/5/2021. I was diagnosed with bilateral pulmonary embolisms. I was Covid negative and had no other symptoms.

2 Hours after the injection, my arm hurt so bad I could not raise it laterally. This continued for 3 days. After that I felt tired and achy until Jan 4th, I had chills and whole body aches. I came home from work, took the next day off. Feeling better, I worked 3 more days and developed the worst headache of my life. I consulted my PCP and went to the emergency room. I was diagnosed with viral meningitis and admitted to the hospital for 3 days. .

Staff walked into resident's room around 10:00am and noted resident's left side of his face was flaccid. Nurse was called and upon assessment resident noted to have an unequal hand grasp with left worse. He was able to talk but was mumbled and hard to understand. Physician, hospice, and family were notified. Resident had a stroke at 10:06 am on 1/8/2020. He lost all ability to use his left side. Resident passed away on 1/11/2020.

Patient received COVID-19 Vaccine at 0956 and reported symptoms of itchy face and chest pressure at approximately 1008 during observation period. Pt vital signs were 133/86, HR 130 and oxygen saturation 100% on room air. Pt reported worsening symptoms of chest pressure and itchiness to face. Provider instructed Epi Pen be given and pt to be transported to ED for further evaluation. EKG obtained and showed sinus tachycardia. Nonrebreather oxygen mask applied with 2L/min and oxygen saturation remained at 100%. Pt was transported via ambulance to at 1038 and pt reported feeling improved symptoms prior to leaving the clinic at approximately 1034. Pt stable at time of transfer.

Employee was awaken at 5:30 am on 1/13/2021 by chills and a feverish feeling. She then became nauseous and faint. She passed out and was noted by her mother who is a RN to have a seizure. She remained out for several minutes and then aroused. She has remained groggy the rest of today but has improved. She has a history of non-epileptic seizures since she was 14 and has been on medications for this. Employee stated she has not has any seizure activity in over a year. She did not see medical attention due to recovering quickly from this.

The patient passed away today, 1/13/2021. She was a hospice patient. She showed no adverse effects after receiving the vaccine on 1/12/2021. This morning she woke up as normal and during her morning shower she had a bowel movement, went limp and was non-responsive. The patient passed away at 7:45 am.

The morning following COVID-19 vaccination, patient's right shoulder had swelling, generalized weakness and myalgia. Hospitalized for 2 days, received intravenous fluids and bedrest, and acetaminophen. He was prostrate for 2 days.

numbness to forearm then to lower leg that then took on a dermatomal pattern, brain fog w word finding issues that progressively worsened, LLE weakness. ct brain neg. MRI/MRA head and neck neg. labs neg. MRI of c spine t spine l spine s spine neg. emg and eeg neg. discharged from hospital. symptoms fluctuating. slowly improving.

Presented to MD'S office on 01/05/2021 with cough, HA, fever 101.9, chills, and fatigue. Returned on 01/07/2021 with no improvement. Returned on 01/11/2021 with fatigue, elevated temp 101.2, SOB, 02 Sat at 90%, Rocephin 1G IM administered, CXR revealed pneumonia. MD received call from patients husband stating worsening 02 Sat levels at 81-82%. Was transferred to hospital and admitted with pneumonia..

This person was found to be deceased on routine rounds during the night, 3am. No symptoms of reaction noted post vaccine. No injection site reaction. No reports of any allergic reaction.

Resident began having fever on 1/11/21 @0600. VS= T-102 B/P- 100/57 P- 112 RR- 24 O2 Sat 92% on RA. MD called. Rapid COVID Test was negative. CBC,CMP, U/A were ordered as well as CXR. Resident's condition declined. At 3:00pm resident started having respiratory distress and hypoxia O2 Sat 89%. Supplemental O2/mask @ 5LPM. Neb TX, EKG, and Rocephin 1 GM ordered. Condition worsened. Resident sent to nearest ER for evaluation. Later in the evening the staff AT Medical Center called to inform staff that resident had expired @ 2230 as a result of Respiratory Failure and Sepsis.

about 14 hours after vaccination I experienced what appeared to be a severe case of Cytokine storm. I had a moderate case of COVID in May 2020 and had positive IgG AB in August. The symptoms started with heavy shaking chills, lasting 1 1/2 hours , fever and most concerning sustained tachycardia with heart rate of 180' to 200' over hours, which then destabilized into runs of Vtach and complex ventricular dysrythmia, low BP, profound weaklness, head aches and joint and muscle pains (similar to the experienced COVID symptoms)

"Patient received vaccine at 0939. 30 minute wait period related to history of previous anaphylactic reaction. 10:05 patient walked from observation area to vaccinator and reported that her ""chest was burning"" and ""feels like it is getting tighter to breathe. Pt had change in voice. Patient moved to chair and started on oxygen 1.5 L/m per nasal cannula. MD came to room to assess patient. ED arrived and checked patient B/P. Patient transferred by cart to ED."

Patient began having cramping of her upper extremities and subsequent swelling of her face and neck and also shortness of breath, chest pressure and flushed appearance. She denies any tongue or throat swelling. She is also complaining of bilateral arm pain. The initial reaction treatment was started in the conference room and then the patient was transferred to the emergency room. She continued to has arm and chest pain in the emergency room. She had muscle tension/rigidity in the upper extremity which caused significant pain. She also developed a nonspecific rash on the chest and abdomen that

persisted for through out he hospital stay. Treatment was started with epinephrine 0.5 mg IM x2 and diphenhydramine 50 mg IM x1, prior to transfer to emergency room. In the emergency room treatment was dexamethasone 10mg IV x 1, famotidine 20mg IV x1, Ketorolac 30mg IV x 1, lorazepam, 1mg IV x 2, morphine 4mg IV x 2, 1000ml Saline Solution. As an inpatient the treatment included scheduled acetaminophen 500mg TID, as need morphine for pain after treatment with fentanyl, scheduled diphenhydramine 25mg IV q8 and compazine 5mg IV for nausea, cyclobenzapine 10mg as need for muscle spasms, dexamethasone as a scheduled dose started at 4 mg BID and tapered to 2 mg BID, Naproxen 500mg BID and Norco 7.5/325 as need for pain. with famotidine 20mg BID .

Note: I am currently breastfeeding. Had body aches; chills; fever of 102.6; headache; nausea; cough; shortness of breath - I went to ER and that is where I received COVID positive test and positive tests for COVID Pneumonia and Microplasm Pneumonia as well. Stayed overnight in ER observation - 2 am to 8 am . Went home next morning and was quarantined approximately 8 days. Body aches and a cough had started two days prior to injection. IV antibiotics at the hospital and oral antibiotics at home. Received nebulizer breathing treatments. Pain meds and anti-inflammatory medication.

Onset of tachycardia was 8:30pm on 1/12/21 with a noted HR of 164 and SR. Went to ER and had HR of 171 upon arriving to triage window. EKG said Sinus Tachycardia. Admitted to observation station with telemetry to monitor HR. HR normalized around 100 when up and walking at 10:45am on 1/13/21.

I received my covid vaccine on 12/29/2020 at 4:42pm. In 10 minutes after the shot, I went into anaphylactic shock, I broke out in hives, and my throat was closing

Pt reported chest tightness and throat tightness following vaccination. Time course following vaccination unknown.

little bit of a reaction light headed after 5 minutes. vitals were low, so observed for 30 minutes after being light headed. Patient was found unresponsive and pronounced dead later that day.

Death occurred 3 days after vaccine receipt; attributed to complications of her chronic advanced dementia with aspiration at age 87. No evidence of acute vaccine reaction.

No adverse effects from vaccination seen on 1/2/21. On 1/6/21 resident was seen by Dr and her baclofen pump was refilled with 20 ml Baclofen 4,000mcg/ml. ITB Rate increased by 6% to 455.5 mcg/day simple continuous rate over 3 days. On 1/8/21 at 0615 resident was shaking, lower extremities mottled, Sa02 70%, pulse 45. Oxygen started at 2 L/m per NC. At 0715 her primary physician was notified as well as her daughter. Oxygen increased to 4 L/min, sats at 83%. SOA noted, reported all over pain. At 0850 when they attempted to reposition the resident, she was not responsive. Licensed nurse assessed her and no heartbeat heard or pulse found.

I had a mild headache the evening of the shot, I had a headache the next two days that was relieved by Advil. I had a very sore arm at the injection site Friday and Saturday after the shot was given. The arm pain was gone Sunday morning. I was very tired on Saturday especially and slept through the morning and early afternoon on and off until about 3:00 pm. On Friday during the day, I noticed my right ear

starting to feel unusual and uncomfortable. On Saturday, the ear issue continued, I felt like I had some hearing loss and a constant buzzing and ear fullness feeling. On Sunday, the ear issued continued with the hearing loss, buzzing and fullness and has through today and hasn't stopped. I tried some nasal decongestant on Sunday afternoon, but it didn't have any effect. I made an appointment with the ENT doctor on Monday morning for Tuesday. I had a hearing test on Tuesday and saw the ENT doctor on Wednesday. He prescribed prednisone and ordered an MRI. I will be starting the prednisone later today (Wednesday) when the pharmacy has the prescription ready.

54 y/o M with PMH of HTN, HLD, Alcoholic Cirrhosis, Aortic Valve Stenosis, and angina BIBA as a Medical Alert for cardiac arrest noted PTA. Per EMS, the patient called because he was having constant, diffuse abdominal pain x 1 day that radiated to his chest. On scene, the patient had a witnessed arrest with EMS starting CPR. He was given 3 rounds of epi without ROSC. Pt had no associated shockable rhythm. Of note, pt's wife, had noted pt had received covid vaccine the prior day.

A few minutes after the vaccine, she had mild tongue swelling. It only lasted a few minutes, and then she felt fine. However, her BP went up. I'm not sure how high. she then has a short run of asymptomatic V tach. Taken to hospital observed overnight. No further events or problems.

She got the vaccine on Dec 23, and then on Jan 4 she had a mild stroke with left sided arm and face weakness. She did recover fully. She already has known CAD and risk factors for CVD. It is possible, but by no means certain, that the vaccine was an indirect cause of the event. Since the vaccine provoked an immune response, as it was supposed to, it is possible that this inflammation may have set up a metabolic predisposition that may have contributed to the event, which was 12 days later.

New onset altered mental status after fall. Per son, she was found in bed, unresponsive at around 12:15 AM on 1/10 by her husband. Brought to the emergency room and admitted, Began treatment for UTI w/ CTX. Discharged 1/11/21 with f/u appointments

Resident received 1st dose on 1/4/2021. On 1/6/2021 resident having SOB, increased weakness with O2 sats at 91% RA. On 8th resident sustained a fall, O2 sats 88-92, dizzy, weakness. Rapid COVID test performed with negative results. Evening of 8th resident was lethargic and diaphoretic with fever of 99.9. Resident transferred to ER, on 5lt of oxygen. Resident returned from the ER on 1/9/2021 with new diagnosis of Leukemia and orders for hospice. Continued with fever, crackles and N/V and loss of appetite from the 9th and 10th of January. Resident expired at 820am on 1/11/2021.

I had a headache at the top of my head, and a tingling sensation down my left leg from my buttocks to my calf. The tingling lasted until the next morning then went away. On 1/3/2021 I experienced a strong headache followed by facial numbness and tingling. This lasted for an hour or so and slowly subsided. The headache lingered for 3 days.

Headache; migraine; tenderness at injection site; Ten hours after injection he had shaking, sweats, hot and cold flashes, and augmentation of myalgias; Ten hours after injection he had shaking, sweats, hot and cold flashes, and augmentation of myalgias; Ten hours after injection he had shaking, sweats, hot and cold flashes, and augmentation of myalgias; Ten hours after injection he had shaking, sweats, hot

and cold flashes, and augmentation of myalgias; Ten hours after injection he had shaking, sweats, hot and cold flashes, and augmentation of myalgias; Fatigue; This is a spontaneous report from a contactable physician (patient). A 53-year-old male patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK9231), via an unspecified route of administration on right deltoid on 05Jan2021 07:45 at single dose for covid-19 immunization. Family history included migraine (other family members). Medical history included mild blood pressure and kidney stones, reactive airway disease. Concomitant medication included colecalciferol (VITAMIN D), potassium, allopurinol and hydrochlorothiazide/valsartan for mild blood pressure and kidney stones, fluticasone propionate, salmeterol xinafoate (ADVAIR) for reactive airway disease, atorvastatin, and multivitamins. The patient previously took fluticasone propionate, salmeterol xinafoate (ADVAIR) and experienced dry mouth and lost sense of taste. The patient also previously took Tdap booster on Aug2020, Shingrix on 10Aug2020, and influenza on 12Oct2020; all for immunization; and tetanus injections for immunization and experienced localized tenderness. The patient had the first dose of BNT162B2 (lot number: EH9899) for COVID-19 immunization on 15Dec2020 and experienced localized tenderness at injection point. The received his second dose of COVID vaccine on 05Jan2021. With the first dose he had increased localized tenderness at injection site on 15Dec2020, and he rated it mild to moderate. He would say it was 80% resolved in 24 hours. It had completely resolved in 36 hours. He would say that he has recovered completely form the localized tenderness with the first dose. Then he noted his second dose was yesterday, in the context of not having much sleep the night before. The actual injection was uncommonly eerily painless. The other folks in his department had similar experience. Maybe it was the nurse who gave the injection. Maybe it was because it was the same area and sensitivity was decreased. They had to check the Band-Aid to make sure blood was there. The administration was painless. He was relieved when the arm started getting sore to know he actually received it. He had increased arm tenderness at injection site which he rated as moderate which has now resolved. It got to moderate where lifting the arm up was sore. He definitely knew that he had been vaccinated. He got the vaccine at 7:45AM and now it is 16 to 17 hours later and he would say the pain is mild now. It did persist. The first vaccine hurt a little more. He expects this to go away. Ten hours after injection he had shaking, sweats, hot and cold flashes, and augmentation of myalgias. He had unrelenting headache over night that was moderate to severe. He said it kept him awake. It was exacerbated by lying down. Sitting up helped him. It became a migraine which is something he doesn't often experience. Migraines are pretty rare for him. He took 800mg of Advil at 6AM that helped for headache and migraine. The weight of the patient was 250 to 255 pounds. Shaking, sweats, hot and cold flashes, and augmentation of myalgias have resolved. Everything has resolved except for a little headache. In the background he literally had one or two hours of sleep. He thinks that likely precipitated a migraine was increased. Last night he slept literally an hour. He took 800mg of Advil and fell asleep. He is operating on 2 hours of sleep in 48 hours. Most of the stuff is gone except a little headache and expected fatigue. Headache Seriousness Criteria: he would say that it was relatively disabling. He would not have been able to carry on. He wouldn't have been able to operate last night. It would have interfered. It was dissimilar to others. He gets rare migraines. Everything was amplified with a migraine. He certainly felt that. It was fair to say the vaccine precipitated the migraine that was mild or severe. He doesn't want to falsely attribute these things to the vaccine. Causality Headache: precipitated by the vaccine. In the context that he had not slept the night before. He had a nasopharyngeal COVID test and it was negative. He has been in a COVID study

where they are looking at combination. They developed a saliva test at (Name). There is a combination of saliva oropharyngeal and immunoglobins. He has been negative multiple times. The outcome of the events headache and fatigue was not recovered and recovered for the rest of the events.; Sender's Comments: A causal association between BNT162B2 and the reported event headache cannot be excluded based on a compatible temporal relation between vaccination and onset of events. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

A PCR test was done and received results Monday (4th) as positive; A PCR test was done and received results Monday (4th) as positive; Had some scratchy throat late friday night; Saturday called out sick to work as the cough started; Saturday called out sick to work as the cough started.; Lost taste and smell monday; Lost taste and smell monday; Running fever; fatigue; This is a spontaneous report from a contactable Pharmacist (the patient). A 52-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, lot number EJ1686, expiration date unknown) via an unspecified route of administration on 28Dec2020 at 12:00 PM (at the age of 52-years-old) via an unspecified route of administration at an unspecified dose in the right arm for COVID-19 vaccination. Medical history included hypertension, high blood cholesterol from unknown dates. Allergy information was not provided. Prior to the vaccination, the patient was not diagnosed with COVID-19. The patient was administered the vaccine at a Nursing Home/Senior Living Facility. Concomitant medication included hydrochlorothiazide, valsartan (VALSARTAN/HYDROCHLOROTHIAZIDE), atorvastatin (LIPITOR), fenofibric acid (FENOFIBRIC ACID), amlodipine besilate (NORVASC). The patient did not receive any other vaccines within four weeks prior to the vaccination. The patient received the vaccine on Monday 28Dec2020. A PCR test for COVID was done on Tuesday and a rapid test on Wednesday both of which were negative. The patient experienced some scratchy throat late Friday night on Saturday, 02Jan2021 the patient called out sick to work as a cough had started. A PCR test was done on 02Jan2021 and he received results Monday (4th) as positive. The patient continued to say that the cough had subsided, as he took Delsym. He lost taste and smell on Monday. He reports running a fever that varies from 99-101.5. He took Tylenol and Motrin to control the fever. In addition he has experienced fatigue. It was also reported, in contradiction of the above reported chronology of events, that the onset date of events was 25Dec2020 (CONFIRMATION PENDING for onset date of events relative to vaccine administration). The patient experiences of COVID 19 positive test, scratchy throat, sickness, cough, loss of test and smell, fever and fatigue resulted in a physician office visit (date not specified). The patient underwent lab tests that includes a PCR test on 29Dec2020 which was negative, a rapid test on 30Dec2020 which was negative and a PCR test on 02Jan2021 which was positive. Treatment for the events was reported as Motrin and Tylenol for fever and Delsym. for cough. The clinical outcome of COVID 19 positive test, scratchy throat, sickness, cough, loss of test and smell, fever and fatigue was reported as not recovered.; Sender's Comments: The patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE) on 28Dec2020, and COVID-19 PCR test positive on 02Jan2021. No effect of the suspect vaccine could be reasonably achieved to protect from the targeted

infection/disease due to the very short time lag. Instead, the positive COVID likely represents the pre-existing infection prior to vaccine use. Further information is needed for full medical assessment.

"he tested positive for COVID-19 / (probably infected by a family member); runny nose; dry cough; flu-like symptoms; he tested positive for COVID-19 / (probably infected by a family member); he tested positive for COVID-19 / (probably infected by a family member); This is a spontaneous report from a contactable consumer (patient). A 40-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 17Dec2020 at single dose for COVID-19 immunisation. The relevant medical history and concomitant medications were not reported. The patient stated that the next dose is scheduled for the time of the report, however he tested positive for COVID-19 on 05Jan2021 (probably infected by a family member). Representatives at the administration site are not sure if he should get the second dose. The patient reported minor symptoms ""flu-like symptoms, runny nose, dry cough, no major symptoms"". The outcome of the events was unknown. Information on the lot/batch number has been requested."

diagnosed with covid 30Dec2020; diagnosed with covid 30dec2020; This is a spontaneous report from a contactable nurse (patient). A 27-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number EK5730), via an unspecified route of administration in right deltoid on 21Dec2020 13:45 at single dose for Vaccination. There were no medical history and concomitant medications. The patient was diagnosed with covid on 30Dec2020 with outcome of recovering. The patient underwent lab tests and procedures which included COVID test: positive on 30Dec2020. The patient received the first dose of the covid vaccine on 21Dec2020, and was diagnosed with covid on 30Dec2020. The patient had COVID test on 30Dec2020 and received positive result of COVID test on 31Dec2020. He was scheduled for the second dose between 08Jan2021 and 11Jan2021. He asked if he should continue to get the second dose as scheduled in relation to the diagnosis of COVID. COVID: the patient still had chest congestion, but no fever without medication, no cough anymore. He was having cough, fever, loss of taste and smell, fatigue and malaise. Reporter seriousness for COVID: Not serious. Relatedness of drug to reaction/event: Reaction assessed: COVID, Source of assessment: Primary Source Reporter, Method of assessment: Global Introspection, Drug result: Unrelated. Verbatim event relatedness: Pfizer COVID-19 Vaccine: COVID-Unrelated.; Sender's Comments: The patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE) on 21Dec2020, and was diagnosed with COVID-19 on 30Dec2020. No effect of the suspect vaccine could be reasonably achieved to protect from the targeted infection/disease due to the very short time lag. Instead, the diagnosed COVID-19 likely represents the pre-existing infection prior to vaccine use, and unrelated to BNT162B2.

she got Covid; she got Covid; This is a spontaneous report from a contactable physician. A female patient (Patient Age: 18; Unit: Unspecified) received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiry date were not reported), via an unspecified route of administration on an unspecified date t a single dose for covid-19 immunization. The patient's medical history and concomitant medications were not reported. The nurse that her first Pfizer Covid 19 vaccine and a couple of days later developed symptoms of Covid and tested positive. Stated that she recovered and had no symptoms. Information on Lot/Batch number has been requested.; Sender's Comments: The

reported symptoms of Covid with tested positive after COVID-19 immunization is considered ineffective of BNT162B2, and the Company cannot completely exclude the possible causality between the reported event and BNT162B2 administration.

covid test result=Positive; covid test result=Positive; This is a spontaneous report from a contactable other healthcare professional (other HCP reporting for himself). A 39-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE Solution for injection, batch/lot no. and expiry date unknown), via an unspecified route of administration on 16Dec2020 12:45 (1st dose) at a single dose on his left arm for COVID-19 immunization. The patient medical history was not reported. Concomitant medication included hydrochlorothiazide, losartan potassium (HYZAAR), omeprazole, and ibuprofen; all on unspecified dates for unspecified indications. The patient previously took amoxicillin and experienced allergies. Patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine, he was also not diagnosed with COVID-19 prior to vaccination. However, since the medication, the patient has been tested positive for COVID-19. Patient had his nasal swab on 22Dec2020, and it turned out positive (COVID test result=positive). Outcome of the event drug ineffective and COVID-19 virus test positive was unknown. Facility where the most recent COVID-19 vaccine was administered at the hospital. Information on the lot/batch number has been requested.; Sender's Comments: Based on the information currently available, a lack of efficacy with the suspected vaccine BNT162B2 cannot be completely excluded. However, it is unlikely that the patient would have fully developed immunity due to the very short time lag between the first vaccine dose and the event onset.

covid test result=Positive; covid test result=Positive; nasal congestion; sneezing runny nose; sneezing runny nose; sinus pressure; dry cough; This is a spontaneous report from a contactable Nurse (patient herself). This 37-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number EL0140), via an unknown route, on 19Dec2020 at 16:15 at single dose for COVID-19 immunisation. Vaccine location was arm left. The patient was not pregnant. The patient was vaccinated at hospital, age at vaccination was 37-year-old. No other vaccine was received in four weeks. No relevant medical history was provided. Relevant concomitant medications included amoxicillin sodium, clavulanate potassium (AUGMENTIN, formulation: tablet) at dose of 875 mg twice daily from an unknown. Pre-vaccination COVID test was not performed. On 25Dec2020 at 20:00, the patient complained of nasal congestion, sneezing runny nose, sinus pressure, and cough. On 28Dec2020, COVID test Nasal Swab (SOFIA SARS ANTIGEN FIA/QUIDEL) was performed and resulted positive. She was given oral azithromycin 500 mg 1 tab Daily and oral benzonatate (TESSALON PERLES) 1 Capsule three times a day (TID). The symptoms of nasal congestion, sneezing runny nose, sinus pressure, and cough were improving. The outcome of 'COVID test result=Positive' was unknown.; Sender's Comments: The efficacy of a drug varies from patient to patient and can be affected by different factors; however, a contributory role of the suspect product BNT162B2 to the reported drug ineffective and SARS-CoV-2 test positive cannot be ruled out.

two staff members who tested positive for covid after receiving the first dose.; two staff members who tested positive for covid after receiving the first dose.; This is a spontaneous report from a Pfizer-sponsored program from a contactable pharmacist reported similar events for 2 patients. This is a first of two reports. A staff member of unknown age and gender received the first dose of BNT162B2 Pfizer-

BioNTech COVID-19 Vaccine, via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medication were unknown. The reporter stated that have a staff member took the first shot and afterward got a positive COVID test. He is asking about the recommendation regarding taking the second shot. The reporter explained he is the immunizer and 2.5 weeks ago he gave the employ at the facility the first does of the vaccine. He has very little information to provide on this event. He called to go over the procedure for administering the second dose and that is when in was inform. Information on the lot/batch number has been requested.; Sender's Comments: The efficacy of a drug varies from patient to patient and can be affected by different factors; however, a contributory role of the suspect product BNT162B2 to the reported drug ineffective and SARS-CoV-2 test positive cannot be ruled out.,Linked Report(s) : US-PFIZER INC-2021011912 Same reporter/ drug/ event for different patients.

received first dose of the vaccine on 19Dec and tested positive on 30Dec; received first dose of the vaccine on 19Dec and tested positive on 30Dec; This is a spontaneous report from a contactable nurse reported for herself. A female patient on unknown age received the first dose of BNT162B2 Pfizer-BioNTech COVID-19 Vaccine, via an unspecified route of administration on 19Dec2020 at single dose for COVID-19 immunization. The patient's medical history and concomitant medication were not provided. On 30Dec2020 the patient experienced tested positive for COVID-19. It was reported that the patient is scheduled to have her 2nd dose on 09Jan2021however she's been getting roundabout information on what to do in her case. Information on the lot/batch number has been requested.; Sender's Comments: The efficacy of a drug varies from patient to patient and can be affected by different factors; however, a contributory role of the suspect product BNT162B2 to the reported drug ineffective and SARS-CoV-2 test positive cannot be ruled out.

She tested positive to COVID on 29DEC2020; She tested positive to COVID on 29DEC2020; This is a spontaneous report from a contactable nurse (patient). A female patient of an unspecified age received first dose of bnt162b2 (BNT162B2, lot no. and expiry date were unknown), via an unspecified route of administration on 21Dec2020 at single dose for Covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient was tested positive to COVID on 29Dec2020. She received the 1st dose of the vaccine on 21Dec2020. She is due for the 2nd dose on 11Jan2020. They asked if she should still receive the 2nd dose. The outcome of the event was unknown. Information on the lot/batch number has been requested.; Sender's Comments: No effect of the suspect vaccine could be reasonably achieved to protect from the targeted infection/disease due to the very short time lag. Instead, the positive COVID likely represents the pre-existing infection prior to vaccine use. Further information like confirmative COVID 19 Nucleic acid/ PCR test together with any associated symptoms are needed for full medical assessment.

"got the covid 19 vaccine on 21Dec2020 and tested positive for covid on 24Dec2020; got the covid 19 vaccine on 21Dec2020 and tested positive for covid on 24Dec2020; This is a spontaneous report from a contactable Nurse (patient) from a Pfizer-sponsored program Pfizer First Connect. A 36-year-old female patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, batch/lot number: EK5730), via intramuscular in left deltoid on 21Dec2020 10:00 at 0.3 ml, single for precaution as front line healthcare worker in hospital which is not a military facility. Medical history included nonsmoker.

She did not provide causality but stated that she probably already had COVID when she got the vaccine. It was unknown if the patient had SARS-CoV2 antibodies at diagnosis as she had never been tested. Other history was none. The patient did not have a history of hypertension, diabetes, heart disease, lung disease, liver disease, kidney disease, cancer, immunosuppressive disorder, obesity. There was not any pre-existing diseases worsened during the SARS-CoV2 infection. The patient hadn't been treated with immunomodulating or immunosuppressing medications or received any other vaccines around the time of COVID-19 vaccination. Concomitant medication included bupropion hydrochloride (WELLBUTRIN SR), sertraline hydrochloride (ZOLOFT), amfetamine aspartate, amfetamine sulfate, dexamfetamine saccharate, dexamfetamine sulfate (ADDERALL). Prior Vaccinations (within 4 weeks) were none. AE following prior vaccinations were none. There was no additional vaccines administered on Same Date (21Dec2020) of the Pfizer bnt162b2. The patient got the covid 19 vaccine on 21Dec2020 and tested positive for covid on 24Dec2020. The patient wanted guidance on receiving the 2nd dose of the vaccine. The reporter considered event was non-serious. The patient received the first dose of the vaccine on 21Dec2020, and after that on 24Dec2020, she tested positive for COVID . She was supposed to be revaccinated on 07Jan2021. She would like to know if she should she get this or does she need to be revaccinated. There is no prescriber. She received it through her work. She received the first dose on 21Dec2020, and assumed she was positive when she got it. She just had cough and muscle aches and a headache. Her dad was hospitalized. Hers was not that serious. She had not completely recovered yet. Her smell had not come back yet and she was just tired still. She said the headache was prior to getting vaccine. She did not provide causality but stated that she probably already had COVID when she got the vaccine. The cough occurred on 25Dec2020, muscle aches on 22Dec2020 at 08:00. There was no emergency room of or physician's office required for the events. The patient was not hospitalized or admitted to an ICU. Nasal swab test done. Imaging for COVID-Pneumonia, other radiological investigations, hematology, clinical chemistry, inflammatory markers, urinalysis, evidence of hypoxemia, other relevant test were none. The patient did not display clinical signs at rest indicative of severe systemic illness. The patient did not require supplemental oxygen (including high flow or ECMO) or receive mechanical ventilation. The patient did not receive any additional therapies for COVID-19. The event did not require the initiation of new medication or other treatment or procedure. She did start taking extra vitamins on her own. The patient was recovered with some lasting effects such as not being able to smell and is tired still.; Sender's Comments: The Company cannot completely exclude the possible causality between the reported COVID with symptoms and the administration of COVID 19 vaccine, bnt162b2. However, as the reporter claimed ""she probably already had COVID when she got the vaccine"", this may provide an alternative explanation."

had the first dose of the COVID-19 vaccine last 24Dec2020 and the second dose is scheduled on 14Jan2021/tested positive for COVID-19; had the first dose of the COVID-19 vaccine last 24Dec2020 and the second dose is scheduled on 14Jan2021/tested positive for COVID-19; This is a spontaneous report from a contactable Nurse (patient). A male patient of an unspecified age received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number and expiry date: unknown), via an unspecified route of administration on 24Dec2020 at single dose for COVID-19 immunization. The patient medical history and concomitant medications were not reported. The patient had the first dose of the COVID-19 vaccine last 24Dec2020 and the second dose is scheduled on 14Jan2021. However, last 04Jan2021, the patient

tested positive for COVID-19. The patient was looking for recommendations on when he/she can take the COVID-19 vaccine. The patient underwent lab tests and procedures which included COVID-19 test: positive on 04Jan2021. The outcome of the event was unknown. Information on the Batch/Lot number has been requested.

Received the vaccine on 23Dec2020. She tested positive for COVID on 31Dec2020.; Received the vaccine on 23Dec2020. She tested positive for COVID on 31Dec2020.; This is a spontaneous report from a Pfizer-sponsored program Pfizer First Connect. A contactable other healthcare professional (patient herself) reported that a 37-year-old female patient received bnt162b2 (BNT162B2 also reported as PFIZER-BIONTECH COVID-19 VACCINE, lot EH9899), via an unspecified route of administration in the left arm 23Dec2020 at single dose, for Covid-19 immunization. Medical history included migraine (takes a migraine medication). Her height was 168cm, weight of 72.5kg. There were no concomitant medications. Received the vaccine on 23Dec2020. She tested positive for COVID on 31Dec2020. Then she had another test and was negative for COVID on 03Jan2021 and was also negative for another test on 05Jan2021. She was wondering if this was like a super vaccine and knocked it out or if there was an error with the test. She acknowledged that there was a lag time for the second dose of 21 days. She was wondering if there was a grace period for that since she cannot be cleared for work. She was also wondering what to do before her second dose of the vaccine. The outcome of event was unknown.; Sender's Comments: The Company cannot completely exclude the possible causality between the reported positive Sars-Cov-2 test, which is considered ineffective of BNT162B2, and the administration of BNT162B2.

she tested positive for the Covid-19; she tested positive for the Covid-19; This is a spontaneous report from a contactable nurse (patient). A female patient of an unspecified age received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot no. and expiry date were unknown), via an unspecified route of administration on 17Dec2020 at single dose for Covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient received the Covid-19 vaccine on 17Dec2020. She said that she tested positive for the Covid-19 after that (unspecified date) and she is due to get her second dose of the vaccine today 07Jan2021. She said that she is wondering if she needs to get the second dose. The outcome of the event was unknown. Information about Batch/Lot number has been requested.; Sender's Comments: Based on available information, a possible contributory role of BNT162B2 cannot be completely excluded for reported event.

tested positive for COVID; tested positive for COVID; This is a spontaneous report from a non-contactable nurse (patient) and a contactable consumer. A 43-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 23Dec2020 at single dose for COVID Prevention because of occupation. The patient's medical history and concomitant medications were not reported. The patient experienced tested positive for COVID on 02Jan2021 with outcome of unknown. The patient underwent lab tests and procedures which included COVID test: positive on 02Jan2021. The patient got the first dose of the COVID vaccine, and then tested positive for COVID afterward. The patient was inquiring about if there are any recommendations for getting the second dose, if the person tested positive for COVID after getting the first dose. The patient

did not provide prescriber information. The patient should come off of quarantine on 15Jan2021. It was unknow if the patient received any other vaccines on the same day as the COVID vaccine and if there were any concomitant medications, history or investigations other than the COVID test. The type of COVID test the patient received was unknown, just that she got the positive result on 02Jan2021. Information on the lot/batch number has been requested.; Sender's Comments: The information currently provided is too limited to make a meaningful medical assessment hence, the events are conservatively assessed as related to the suspect drug BNT162B2 until further information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

He is losing some taste/but reduced by 30-40%; received first dose of vaccine 21DEC2020 and SARS-Cov-2 positive/Nasal swab COVID positive; received first dose of vaccine 21DEC2020 and SARS-Cov-2 positive/Nasal swab COVID positive; Sniffles; This is a spontaneous report received from Pfizer sponsored program Pfizer First Connect via a contactable other HCP (parent) reported for the patient (son). A 22-years-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (lot: EK5730) intramuscularly in left arm on 21Dec2020 (15:00-16:00) at single dose for COVID-19 immunisation. There was no medical history. There were no concomitant medications. The patient received first dose of vaccine 21Dec2020 and SARS-Cov-2 positive 06Jan2021 13:00. The patient got COVID vaccine 21Dec2020, and was scheduled to get second dose on 11Jan2021. He had a sniffle the other day on 05Jan2021 night time and tested positive for COVID on 06Jan2021, so reporter wanted to know if he should still get second dose. His symptoms are stable. He is quarantining. He is on his way to do a PCR now. Reporter read somewhere people could have false positive in nasal. He is losing some taste from 07Jan2021 (01:00 - 02:00). Most things he can taste. Some he cannot. It is not completely gone but reduced by 30-40%. He did a mouthwash with a sting and is not feeling that sting anymore. He said last night, same thing. He did a mouth wash and did not really taste much. It is not as prevalent as it was before. The patient underwent lab tests and procedures which included SARS-CoV-2 test: positive on 06Jan2021, positive COVID test 06Jan2021, 13:00, Nasal swab COVID. Event outcome of sniffles was recovering, while for other events was unknown.; Sender's Comments: The efficacy of a drug varies from one patient to another and can be affected by different factors; however, a contributory role of the suspect drug BNT162B2 to the reported event ___ cannot be ruled out. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

woke up in the middle of the night; lower legs felt kind of numb and tingly; weak; nausea; anaphylactic reaction; hot flash started on my head, went over my body; dizzy/lightheaded; blurred vision; chest became very tight/chest tightness; throat felt like there was a lump in it; coughing; irritated throat; heart rate was in the 140s; sinus tachycardia; lower legs felt kind of numb and tingly; chills; fever; body aches; diarrhea; This is a spontaneous report from a contactable nurse. A 26-year-old female patient

started to receive BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot# EH9899) via an unspecified route of administration on 29Dec2020 07:30 at single dose for COVID-19 immunisation. The patient medical history was not reported. The patient's concomitant medications were not reported. The patient experienced anaphylactic reaction, hot flash started on my head, went over my body, dizzy, lightheaded, blurred vision, chest became very tight/chest tightness, throat felt like there was a lump in it, coughing, irritated throat, heart rate was in the 140s, sinus tachycardia, fever, chills, body aches, diarrhea, lower legs felt kind of numb and tingly, weak, all on 29Dec2020 and , woke up in the middle of the night on an unspecified date. She reported severe reaction to Pfizer COVID-19 Vaccine onset 8 minutes after being administered that first dose. She asked for information regarding her severe reaction related to the product. This event started with a hot flash that started in her head and went all the way through her body; became really lightheaded; dizzy; her chest became really tight; felt like there was a lump in her throat closing her throat up. They took her to the emergency room where she was treated and kept for a couple of hours, but was not admitted to the hospital in response to this event. While in the hospital she received IV fluids; steroids clarified as Prednisone; Benadryl; Pepcid; and was sent home. On 30Dec2020 afternoon she ended up with the same type of severe reaction: her chest felt tight, she felt her throat closing and itching; she started coughing. She went back to the emergency room in response to the severe reaction. The emergency room thinks it was the same thing again as on 29Dec2020; she again was not admitted to the hospital in response to this event, but was treated and kept for a couple of hours; while in emergency room they again gave her IV fluids; steroids clarified as Prednisone; Benadryl, and because her heart rate was like in the 140s also gave her Ativan to help bring her heart rate down. The anaphylactic aspect of the severe reaction is not ongoing any longer. She then developed fever; body aches; nausea; diarrhea; all the kind of what you would call normal side effects. She reported that on 03Jan2021 morning she woke super dizzy, lightheaded and her vision was blurred. In response to those events she went to her Primary Care Physician on 04Jan2021. The Primary Care Physician told patient to just ride it out for a little bit to see what happens; so that is what the patient has been doing. The dizziness and blurred vision have improved over the last couple of days; but last night she was up all night because she felt a numbness in her lower legs; she can still walk, it is not painful; it's just a weird numbness, tingling kind of feeling. Severe reaction events reported as improved, but ongoing. The patient underwent lab tests and procedures which included electrocardiogram: sinus tachycardia on 30Dec2020, heart rate: was in the 140s on 29Dec2020. The outcome of anaphylactic reaction was recovering, of hot flash started on my head, went over my body, dizzy/lightheaded, blurred vision, chest became very tight/chest tightness, throat felt like there was a lump in it, coughing, irritated throat, heart rate was in the 140s, sinus tachycardia, fever, chills, body aches, diarrhea, woke up in the middle of the night, lower legs felt kind of numb and tingly, weak was unknown. Caller explained she will not receive the second dose.; Sender's Comments: A possible causal association between administration of BNT162B2 and the onset anaphylactic reactions cannot be excluded, considering the plausible temporal relationship and the known adverse event profile of the suspect product. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

an employee who received the first dose of the Covid 19 vaccine, has tested positive for Covid 19 today; an employee who received the first dose of the Covid 19 vaccine, has tested positive for Covid 19 today; This is a spontaneous report from a contactable other HCP and a nurse. A female patient of an unspecified age received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiry date were not reported), via an unspecified route of administration on an unspecified date at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient employee who received the first dose of the COVID 19 vaccine, has tested positive for COVID 19 today, 07Jan2021. The outcome of the event was unknown. The reporter would like to know if the patient can get the second COVID-19 vaccine. Information on the lot/batch number has been requested.; Sender's Comments: Based on available information, a possible contributory role of BNT162B2 cannot be completely excluded for reported event.

Tested positive for COVID after receiving the first dose of the vaccine; Tested positive for COVID after receiving the first dose of the vaccine; This is a spontaneous report from a contactable other healthcare professional (patient). A 26-year-old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number: EJ-685, expiration date: Mar2021), via an unspecified route of administration in the right arm on 21Dec2020 at a single dose for COVID-19 immunization. There were no medical history and concomitant medications. The patient tested positive for COVID on 26Dec2020. Now, she is wanting to know if she should still get the second dose. Outcome of the events was unknown.; Sender's Comments: The patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE) on 21Dec2020, and COVID-19 test positive on 26Dec2020. No effect of the suspect vaccine could be reasonably achieved to protect from the targeted infection/disease due to the very short time lag. Instead, the positive COVID likely represents the pre-existing infection prior to vaccine use. Further information is needed for full medical assessment.

tested positive/had the COVID infection/cough; tested positive/had the COVID infection/cough; PFIZER-BIONTECH COVID-19 VACCINE at 1.3 mL; This is a spontaneous report from a contactable nurse (patient). A 39-year-old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number and expiration date were not reported), via an unspecified route of administration on 19Dec2020 at 1.3 mL, single for COVID-19 immunization. There were no medical history and concomitant medications. She received the first COVID-19 vaccine dose on 19Dec2020 then she tested positive on 22Dec2020. She got the first dose of the COVID vaccine and now she had the COVID infection. She was wondering if she should continue to get the second dose. She was also wondering if it will affect whether or not she gets the second dose. She couldn't find information online about what to do. Before she got the vaccine, she did take a test on an unspecified date to make sure she was negative, and she was. She had a cough at the end of the call. Outcome of the events was unknown. Information on lot/batch number has been requested.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the reported events of COVID-19 and suspected LOE due to temporal relationship. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this

report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Idiopathic trigeminal neuralgia; This is a spontaneous report from a contactable nurse (patient). A 34-year-old female patient started to receive BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number EL0140), intramuscular (right deltoid) first dose on 21Dec2020 at single dose for Covid-19 immunization. The patient's medical history included multiple sclerosis from 2015 (Diagnosed 5 year) and ear infection from 03Dec2020 prior to vaccination, she was seen in urgent care with an ear infection, states it was super painful and lasted about 7-10 days treated it with drops.. There were no concomitant medications. The patient requested guidance on whether or not she should get the second dose of the covid vaccine after being diagnosed with Trigeminal Neuralgia following the first dose. The patient stated that she received the first done on 21Dec2020 and on 27Dec2020 was diagnosed with Idiopathic trigeminal neuralgia. The patient was unclear if the vaccine played a part in the diagnosis and wonders if there is any data available about this as an adverse event as she read that Bells Palsy was reported and this was similar. The patient need guidance on whether to get second dose of the Covid vaccine scheduled for on Monday. Wondering if getting the second dose would be risking it flaring up, states she was now on anticonvulsant medication and gabapentin and they have increased the anticonvulsant medication. The patient experienced idiopathic trigeminal neuralgia (trigeminal neuralgia) (non-serious) on 27Dec2020 with outcome of not recovered. The action taken in response to the event(s) for bnt162b2 was not applicable. The outcome of the event was not recovered.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the reported event of Trigeminal Neuralgia due to temporal relationship. However, the event may possibly represent concurrent medical condition in this patient with medical history of multiple sclerosis. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics including head CT/MRI and viral serologies, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

rash developed on 50% of her body; vomiting; nausea; headache; severe muscle aches; This is a spontaneous report from a contactable nurse reported for herself. This 39-year-old female patient received the 1st dose of BNT162B2 (Pfizer-BioNTech COVID-19 vaccine) via Intramuscular at left arm on 16Dec2020 at 01:00 PM at single dose (lot number: EK5730) for COVID-19 immunisation. Medical history was unknown. Concomitant medications included bupropion hydrochloride (WELLBUTRIN), zolpidem tartrate (AMBIEN) and vitamins. The patient previously took dicycloverine hydrochloride (BENTYL), amlodipine and azithromycin (ZITHROMAX), all experiencing allergies. The patient experienced rash developed on 50% of her body, vomiting, nausea, headache, severe muscle aches 24

hours post vaccination on 17Dec2020 10:45 AM. The patient was treated with Benadryl, Tylenol, IM Solumedrol. The patient had Covid test post vaccination by Nasal Swab on 28Dec2020 and on 04Jan2021, both with negative results. The patient was not pregnant at the time of vaccination. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Outcome of all events was recovered.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the rash and other reported events due to temporal relationship. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

COVID-19 virus test positive; COVID-19 virus test positive; Headache; Sinus congestion; This is a spontaneous report from a contactable consumer reported for himself. A 61-year-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EN9899 and expiration date unknown), via intramuscular on left arm on 22Dec2020 at single dose for COVID-19 prophylaxis. The patient medical history reported as none. Concomitant medications reported as none. The patient is a radiology technician that reported that he got the Pfizer vaccine on the 22Dec2020. He said that he got a positive Covid test on 04Jan2021. The patient had the Covid symptoms as of last Monday night on 04Jan2021. He stated that he developed a headaches and sinus congestion on the 04Jan2021. Stated that he has not had a fever. He said that there was no adverse reaction from the vaccine itself. He said that he was due for the second dose on the 11Jan2021 and he is currently quarantined so he will not be getting the second dose. The outcome of the events was unknown.

two staff members who tested positive for covid after receiving the first dose.; two staff members who tested positive for covid after receiving the first dose.; This is a spontaneous report from the Pfizer Sponsored Program called 'Pfizer First Connect' received by a contactable pharmacist. This pharmacist reported similar events for 2 staff members. This is 2nd of 2 reports. A patient (demographics unknown) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unknown route, in Dec2020 at single dose for COVID-19 immunisation. No relevant medical history and concomitant medications were provided. On unknown date, after first shot of vaccine, COVID test resulted positive. The reporting pharmacist is asking about the recommendation regarding taking the second shot. The outcome of the event was unknown. Information about Batch/Lot number has been requested.; Sender's Comments: A causal association between reported event and suspect BNT162B2 cannot be excluded. ,Linked Report(s) : US-PFIZER INC-2021010495 Same reporter/ drug/ event for different patients.

positive COVID-19 test with symptoms; positive COVID-19 test with symptoms; The patient had MS and was immune compromised; The patient had MS and was immune compromised; This is a spontaneous

report from a contactable consumer (patient). This female consumer of unspecified age received the first single dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 04Jan2021, for COVID-19 immunization. She had MS and was immune compromised. Concomitant medications were not reported. On 07Jan2021 the patient woke up with headache, runny nose, groggy and muscle aches. She went to pharmacy and got a rapid COVID test that resulted positive. She was asking if the 1st dose could have caused her to be positive on the test. Events outcome was unknown. Information on the batch/lot number has been requested.; Sender's Comments: Based on the information available, a possible contributory role of the suspect products cannot be excluded for the reported event of positive for corona virus infection for the lack of efficacy of the vaccine. However, based on the mechanism of action of the vaccine, it is unlikely the patient would have fully developed immunity for the vaccine to be effective, due to the number of days passed since the vaccine is given. Case will be reevaluated based on follow-up information

tested COVID Positive; tested COVID Positive; This is a spontaneous report from a contactable nurse. A female patient of an unspecified age received 1st dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 22Dec2020 at single dose for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient experienced tested COVID positive on 01Jan2021. She still has a few symptoms and is scheduled for the 2nd dose on 12Jan2020 or 13Jan2020. She was asking if there were any recommendations on the scheduling of the vaccine for her. The outcome of event was unknown. information on the lot/batch number has been requested.; Sender's Comments: Based on the information currently available, a lack of efficacy with BNT162B2 in this patient cannot be completely excluded.

severe angioedema, hives, tachycardia, hypertension, pruritus, chest tightness and shortness of breath.; severe angioedema, hives, tachycardia, hypertension, pruritus, chest tightness and shortness of breath.; severe angioedema, hives, tachycardia, hypertension, pruritus, chest tightness and shortness of breath.; severe angioedema, hives, tachycardia, hypertension, pruritus, chest tightness and shortness of breath.; severe angioedema, hives, tachycardia, hypertension, pruritus, chest tightness and shortness of breath.; severe angioedema, hives, tachycardia, hypertension, pruritus, chest tightness and shortness of breath; severe angioedema, hives, tachycardia, hypertension, pruritus, chest tightness and shortness of breath; This is a spontaneous report from a contactable nurse (reporting for herself). A 41-year-old non-pregnant female patient received two doses of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), both via an unspecified route of administration in the left arm, the first dose on 16Dec2020 09:00 (lot number: EH9899) and the second dose on 08Jan2021 07:15 (lot number: EL0140), both at a single dose for COVID-19 immunization. Medical history included ongoing anxiety, from an unspecified date. The patient had no known allergies. Concomitant medication included escitalopram oxalate (LEXAPRO), acetaminophen (MANUFACTURER UNKNOWN), naproxen sodium (MANUFACTURER UNKNOWN), ibuprofen (MANUFACTURER UNKNOWN). The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, has not been tested for COVID-19. On 09Jan2021 at 01:30 AM, the patient experienced severe angioedema, hives, tachycardia, hypertension, pruritus, chest tightness and shortness of breath, all of which were reported as being life-threatening. The patient went to the

Emergency room due to the events. Therapeutic measures were taken as a result of the events and included: methylprednisolone sodium succinate (SOLUMEDROL) 125 mg, famotidine (MANUFACTURER UNKNOWN) 20 mg and diphenhydramine hydrochloride (BENADRYL) 50 mg. The clinical outcome of severe angioedema, hives, tachycardia, hypertension, pruritus, chest tightness and shortness of breath was recovering.; Sender's Comments: A possible causal association between administration of BNT162B2 and the onset severe angioedema, hives, tachycardia, hypertension, pruritus, chest tightness and shortness of breath cannot be excluded, considering the plausible temporal relationship and the known adverse event profile of the suspect product. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

the person who took the 1st dose of the vaccine and still tested positive; the person who took the 1st dose of the vaccine and still tested positive; This is a spontaneous report from a Pfizer sponsored program Pfizer First Connect. A non-contactable consumer reported that a patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via unspecified route of administration on unspecified date at single dose for COVID-19 immunization. Patient medical history and concomitant medications were not reported. ~The patient took the 1st dose of the vaccine and still tested positive on unspecified date. They would like to know if the patient still needs to take the 2nd dose of the vaccine or not. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

Received 2nd vaccination in series on 11 JAN 21. By next morning started to experience some muscle and joint symptoms. By afternoon of 12 JAN 21 experienced sudden onset loss of bladder control for first time in his life, followed a few hours later by blurry vision, vertigo, motion sickness, emesis and cold sweats that drenched his clothes. Taken to ER by paramedics, and admitted for further observation and evaluation for underlying neurologic vs. cardiogenic problems. Given positional treatments by PT for possible otoliths. Feels much improved on afternoon of 13 JAN 21, but symptoms not fully resolved. Will likely be discharged from hospital on 14 JAN 21 if problems continue to resolve.

Admission Note: ? Weakness - Generalized á á Patient reports feeling weak prior to dialysis, but demanded clinic to perform dialysis. Had full tx done and brought to ER. Reports still feels weak after dialysis. á 84 year old male comes in today after completing dialysis for evaluation of generalized weakness x 5 days. He has also lost his voice. He tells me he received his COVID vaccine yesterday, but he is concerned he may have COVID. He denies any fevers, cough, sore throat, NVD, abd pain. Transfer Note: HOSPITAL COURSE: Patient is a 84 y.o. male who presented with shaking chills and was found to have Gram-negative rods in the blood. The source of infection was unclear. Initially it was thought that it could possibly be cholecystitis but imaging was negative for that. There was concern that it could be UTI but the patient is on dialysis and is an uric and therefore no urinalysis could be got. Early this morning when I saw the patient the patient did have significant pain and tenderness in the right knee and is not able to put weight on that. I.e. Consulted Dr. Today with per lumbar from Orthopedics who said that it would be in the best interest of the patient for him to be transferred to hospital where he could decide on aspiration and or washout of the right knee. á Transfer center has been called and we are trying to

finalize a transfer of the patient hospital at this point of time á Please see problem list listed below. á REASON FOR ADMISSION/ ADMISSION DIAGNOSES á Sepsis cause unclear

History of Present Illness: á Patient is a 80 y.o. male who presents with chest pain. Patient reported that he 1st had the chest pain approximately 2 weeks ago when he woke from sleep. At that time patient pain lasted about 5 minutes or so and resolved when he got out of bed. He did well for the rest of the day up until yesterday. Patient reported that yesterday morning he woke up with the pain at the lasted about 30 minutes or so. Patient also had associated burping felt that it is likely GI in nature. The pain was located mainly in the left side of the chest without any radiation. No diaphoresis. No shortness of breath or palpitation. No radiation for the pain. Since yesterday morning he had another 3 episodes of pain the last after dinner tonight. Patient reported that this pain was located more on the left side of the chest, likely lasted about 10 minutes or so. There was no exertional component to the pain. No known history of heart disease. Due to rather recurrent nature of the pain patient was brought to the hospital by his son who is a cardiologist to be evaluated. No fever or chills. No cough . Patient reported that he got vaccination for COVID 2 days ago-of a concern that this may be a side effect of the vaccine. No dizziness lightheadedness. Patient with history of GI bleed in the past at that time patient was on NSAIDs. Patient with burping associated with the pain

Chief Complaint Patient presents with ? Generalized Body Aches á á Pt presents via EMS c/o DOE, dry non-productive cough, subjective fevers Tmax 101.9, decreased appetite, aches since testing + for COVID on 1/5. á Patient is a 50 year old male with PMH of Crohns/MS on fingolimod presenting to the Hospital for fevers, shortness of breath and weakness. Patient received COVID vaccine on 12/29. Patient had initial left arm discomfort though has had worsening weakness, cough, shortness of breath and fevers since that time. Patient tested positive for COVID19 on Patient has shortness of breath with exertion that is relieved by rest. Patient denies N/V/D. Patient has taken tylenol at home to attempt to alleviate symptoms.

Chief Complaint Patient presents with ? Vomiting á á pt reports dry heaving and nausea that started an hour ago á Patient is an 68 y.o. year old male with PMHx significant for HTN, BPH, who presents to the ED today with nausea and dry heaving for one hour PTA. States that he was at work as a courier when he had onset of sensation of room spinning, nausea, and dry heaving. Also having tinnitus which he thinks is b/l. This happened once about two weeks ago and resolved spontaneously overnight when he was asleep. No preceding illnesses, medication changes, or other associated symptoms. Vertigo has no clear exacerbating or relieving factors. Has not yet taken anything for symptoms. á The patient denies fevers, chills, headaches, syncope, chest pain, shortness of breath, rhinorrhea, sore throat, cough, abdominal pain, changes in usual bowel movements, changes with urination, back pain, pain anywhere else in body. The patient has no sick contacts, recent travel history.

HOSPITAL COURSE: Patient is a 50 y.o. female with a history of anxiety and migraine headaches who presented to hospital with cough and diarrhea. The patient had felt the symptoms on 12/31/2020 and eventually went to have a COVID test on 1/1/2021. She was subsequently positive but due to dehydration and diarrhea she came to the emergency department where she was admitted for

remdesivir and dexamethasone. She was able to be weaned off any supplemental oxygen. Her diarrhea resolved. She is feeling well and will be discharged home in good condition.

None stated.

Peripheral neuropathy

Pt experienced 103.7 fever and muscle spasms. Hospitalized.

Numbness tingling in feet, toes progressed to waist. ER Sunday hosp, pt was admitted inpatient, diagnosis transverse myelitis.

Systemic: Dizzy, hyperventolation-Medium

Began with tingling/itching to tongue and roof of mouth approx 15 minutes after administration, progressed to tingling of lips, was sent to the ED for observation. Within 20-30 minutes developed cough, throat tightness, difficulty swallowing, breathing, vomiting, shortness of breath. Noted to have uvular swelling and wheezing on examination. Given Benadryl, Pepcid, Solumedrol, Zofran, Albuterol MDI, Epi IM. within a few minutes symptoms returned and were worse where I felt like I could not breathe, throat was closing, could not talk. Noted to be pale, HR in 140?s. Given second dose of epi IM and symptoms improved. Was transferred to Obs Unit., within 2 hours (approx 6 hours after administration), developed SOB, throat tightness, cough, vomiting, difficulty breathing. Again noted to have swelling of uvula, wheezing on exam. Given Solumedrol, Benadryl, SQ epi, Albuterol, Racemic Epi nebulizer. Was transferred to ICU, all meds held except Pepcid. Day #2 ~10 am (25 hours from administration) developed throat tightness, diffuse red rash to arms, difficulty breathing, vomiting. Again noted to have uvular swelling and wheezing. Given Solumedrol, Benadryl, Pepcid, Albuterol MDI, Racemic Epi neb. Solumedrol started q12hour dosing. Strange feeling/fullness in throat continued all day, got additional racemic Epi neb that night with improvement of symptoms. Following morning (day#2 after vaccine) noted to have diffuse red rash to chest and face, spread to arms, then began coughing. Given Solumedrol, Pepcid, Benadryl, Advair, Racemic Epi nebulizer. Solumedrol changed to q8 dosing. Approx 4 hrs later nurse noted rash worse on face, associated with itching, throat tightness. Given additional Benadryl, Racemic Epi neb with improvement. Rash continued that night with throat tightness, got additional Benadryl and Racemic Neb that night (total of 3 Racemic nebulizer on Day#2 post vaccine). Transferred to telemetry floor. Day#3 post vaccine rash improved, but still present to chest and face. Throat fullness present, especially after drinking. Am still hospitalized while writing this report

Initial pain in back of head and extreme headache. Some vomiting. At emergency, went into coma and was intubated. Hole drilled in skull to relieve pressure. MRI taken. Lot of bleeding in brain - anuerism lead to death approximately 14 hours after initial symptoms.

Systemic: Anaphylaxis-Medium; symptoms lasted 1 day

Unprovoked seizure (clonic tonic) 13 days later, requiring hospitalization and testing

Pt collapsed at home approx 5:30 pm and died

On day due for 2nd dose, Patient was found unresponsive at work in the hospital. Patient pupils were fixed and dilated. Full ACLS was initiated for 55 minutes with multiple rounds of bicarb, calcium chloride, magnesium, and epinephrine. Patient was intubated. Patient continued into V. Fib arrest and was shocked multiple times.

Systemic: reported by staff patient expired under suspicious circumstnces after receiving vaccine. Patient was on hospice, reported not expected to pass this soon; symptoms lasted 0 days

Extreme lockjaw unable to barely talk or chew

Day 7 post vaccine, woke with vertigo, nausea and double vision prior to my alarm going off at 5:30am, told my husband that I did not feel right and it felt like something was wrong with me. I asked him to send a message to work that I was not feeling well and would not be in. I was not able to see my phone clearly as I had double vision. I went back to sleep to try to get relief, woke up and called out to husband for help and he said I was just making groaning noises but I know in my head I was saying please help me as I could not move my right side and I was not sleeping or having a dream. At approximately 9:30am my husband kept telling me someone was trying to text me and needed a response. I tried to get up and still could not move my right side. He helped me sit up and I could not use my right arm and hand. He helped me get some clothes on and took me to the ED. When we arrived I still could not use my right hand and my arm still felt weak. The weakness resolved within a couple of hours and I got the strength back in my hand. I did have some concern that my TIA type symptoms could possibly be related to vaccine but it was just a thought until I received my second dose. 3 hours post vaccine my face became numb and tingly. It remained that way until I went to sleep. This is why I am reporting this incident.

Per patient report on follow-up: admitted to hospital following initial vaccine on 12/29 with N/V and severe HA. Patient placed on Morphine for pain, now resolved. Admission occurred outside of hospital system providing initial vaccine.

Patient reports no symptoms until 1/8/21 at which time a rash developed along with fatigue and fevers. Patient was seen in ED 1/8 and 1/11/21. Was admitted 1/11/21 with Concern for STevens Johnson and sepsis. Patient subsequently developed full body macular rash and mucosal lesions. Fevers to 102-104.

Reported redness, swelling and pain at injection site, diarrhea and light headedness1/5/21. Evaluated in ED and hospitalized for neurological symptoms that started 1/8/21.

vaccinated at Hospital on 1/12/2021. According to patients father she developed stomach pains, constant vomiting, sweating which started at approx. 4am. She arrived at Medical center at approx. 7:20 stating she had been vomiting since 4am. Attempted PO fluids while in ED. Uncontrolled nausea persisted despite medication. Admitted to Hospital for observation for uncontrolled nausea. IV fluids given

Developed pulmonary embolism in right lung one week after vaccination. Sharp pain on right side when breathing. Treated with IV Apixaban while inpatient for 2 days, oral Apixaban 5 mg, 2 tabs twice daily 1/5/21-1/11/21, then one 5 mg tab twice a day. Pain has subsided as of 1/14/21.

No adverse reactions observed after administration of medication. Patient starting complaining of shortness of breath around 0500 the following morning. SP02 checked in the 80s. Patient expired 01/09/2021;

altered mental status, hypoxic, fever 39.3, agitated

a positive Covid test after receiving their first dose; a positive Covid test after receiving their first dose; The initial case was missing the following minimum criteria: No adverse effect. Upon receipt of follow-up information on 06Jan2021, this case now contains all required information to be considered valid. This is a spontaneous report from a Pfizer-sponsored program IBCC (Inbound Call Center for HCPs). A contactable other healthcare professional (student pharmacist) and a contactable pharmacist reported that a patient of unspecified age and gender received BNT162B2 (PFIZER BIONTECH COVID-19 VACCINE, lot number unknown), via an unspecified route of administration, on an unspecified date, at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. Reporter that works at a hospital pharmacy called about a patient that received their first dosage of COVID-19 vaccine who had a positive COVID test on an unspecified date after receiving their first dose of the vaccine. They wanted to know hoe to proceed and if they needed the second dose. The outcome of the event was unknown. Information on the lot/batch number has been requested.

covid a week after the1st dose of the vaccine. When to get the 2nd dose?/tested positive for COVID; covid a week after the1st dose of the vaccine. When to get the 2nd dose?/tested positive for COVID; body aches; fever; Headache; This is a spontaneous report from a contactable physician. A 31-year-old female patient (healthcare worker) received the 1st dose of bnt162b2 (BNT162B2) at single dose in Dec2020 (9 days before 07Jan2021) for Covid-19 immunisation. The patient medical history and concomitant medications were not reported. The patient received the 1st dose of the COVID vaccine 9 days before 07Jan2021 and got a headache afterward in Dec2020. After 6 days, in Jan2021 the patient had a worse headache, body aches, and fever. She was swabbed for COVID on 06Jan2021 and tested positive. The reporter wanted to know what to do about the 2nd dose. The outcome of events was unknown. A product complaint was filed. information about lot and batch number was requested.

tested positive for covid/headache, ever, cough, diarrhea; tested positive for covid/headache, ever, cough, diarrhea; This is a spontaneous report from a contactable consumer (patient) via a Pfizer Sponsored Program IBCC (Inbound Call Center for HCPs). A 47-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EK5730, expiration date: 20Mar2021), via an unspecified route of administration on 19Dec2020 16:15 at left arm, at single dose for covid-19 immunization. Medical history included hysterectomy in 2010, pulmonary Embolism in 2010, gallbladder removed on an unknown date. There were no concomitant medications. The patient received 1st dose 19Dec2020, she was supposed to get her second dose, but tested positive for covid. She thought she had side effects after vaccine, she began with a headache, fever a week later and

thought they were from the vaccine, but then her sister-in-law was positive for COVID, her sister-in-law passed away from covid virus. Then the patient, her mom, and husband tested positive for COVID. She tested positive for COVID on 27Dec2020. She developed symptoms of COVID on 27Dec2020. It was exactly one week after receiving the first dose. It was also reported that she got tested on the 30th (as reported) and received results on 31Dec2020 that she was positive. After she got sick she has taken Mucinex. Day eleven, she is doing ok, but has a little cough. No more fever. Sometimes she has diarrhea but today no diarrhea. The patient asked if she can get her second dose of the covid vaccine on day 24. The outcome of the events was recovering.

arm is red, warm, and itchy; arm is red, warm, and itchy; arm is red, warm, and itchy; Chest tightness; bitter taste in her mouth; funny feeling; arm was hurting; swelling; patient thinks the vaccine was given to her subcutaneously instead of intramuscularly; This is a spontaneous report from a contactable nurse (reporting for herself). A 43-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot number: EK9231), subcutaneously in the left arm on 05Jan2021 15:00 at 0.3 mL, single for COVID-19 immunization. The patient's medical history was not reported. Concomitant medication included an unspecified multivitamin, taken at one tablet daily by mouth for supplementation therapy. The patient previously took the flu vaccine (MANUFACTURER UNKNOWN) in 2016 for immunization and experienced chest tightness, which she took diphenhydramine hydrochloride (BENADRYL). The patient experienced arm is red, warm, and itchy on 05Jan2021, which was reported as being medically significant. On 05Jan2021, the patient experienced chest tightness, bitter taste in her mouth, funny feeling, arm was hurting, swelling and patient thinks the vaccine was given to her subcutaneously instead of intramuscularly. On 06Jan2021, the patient experienced arm is red, warm, and itchy was reported as worsened. The outcome of arm is red, warm, and itchy, chest tightness and arm is red, warm, and itchy was reported as worsened was not recovered and of bitter taste in her mouth, funny feeling, arm was hurting, swelling and patient thinks the vaccine was given to her subcutaneously instead of intramuscularly was unknown. The reporter assessed the relatedness to the event, arm is red, warm, and itchy to the Covid-19 Vaccine as related; Sender's Comments: Based on the time association, the possible contribution of suspect BNT162B2 to the events pruritus, erythema and feeling hot cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

The patient had an ongoing medical history of Crohn's disease/Concomitant medication included vedolizumab (ENTYVIO) for Crohn's disease; shortness of breath; difficulty swallowing; fever; headache; nausea; she was feeling as if her throat was closing; Chest tightness; This is a spontaneous report from a contactable physician reporting for a patient. A 34-year-old female patient received the first dose of BNT162B2 (COIVD-19 Vaccine) , via an unspecified route of administration on 03Jan2021 at single dose for covid-19 immunisation. Medical history included Crohn's disease from an unknown date and unknown if ongoing, COVID-19 in 2020 to an unknown date and unknown if ongoing. Concomitant medication included vedolizumab (ENTYVIO) for Crohn's disease. The reporter is a physician who is

reporting and AE for a patient who received the vaccine and subsequently developed symptoms including short of breath, fever, headache, nausea, difficulty swallowing with seriousness criteria of Medically significant on 03Jan2021. The patient self-medicated with benadryl and symptoms resolved briefly but then went to urgent care with re-occurring symptoms and was prescribed prednisone. Caller states the patient's symptoms have resolved. She is calling to get more information to determine if the patient should receive the second dose. The reporter further stated that she has a patient who received her first shot, clarified as the COVID-19 Vaccine. About an hour and 45 minutes later, the patient had shortness of breath and then later had a fever, headache and nausea. It was later that night when the patient had a fever. The patient had difficulty swallowing which worsen; she was feeling as if her throat was closing. The patient is a nurse, so she self medicated with Benadryl. After taking the Benadryl, the patient was better in the early morning. When the doctor's office opened, the patient called and was having similar symptoms, clarified as all the symptoms mentioned above. The patient went to the urgent care where she received more Benadryl and was started on prednisone. Caller did not know the dose of prednisone the patient had received. After that, the patient started feeling better. The patient's second dose of the COVID19 Vaccine is due around 24 to 26Jan2021. The patient has not called the doctor/caller back. The caller assumes that the patient has recovered but could not be certain. Caller added that the patient also experienced chest tightness when she was having shortness of breath. The patient's fever was 101 on 03Jan2021. The patient was not drooling with her difficulty swallowing. Caller stated that the patient had a positive COVID test earlier, she thinks it was maybe 3 to 4 months ago (in 2020). The patient has not received another COVID test since she received the first dose of the COVID-19 vaccine to the caller's knowledge. Reporting physician is an internal medicine physician. Therapeutic measures were taken as a result of the events. The outcome of the events was unknown. Information on the Batch/Lot number has been requested.; Sender's Comments: The Company cannot completely exclude the possible causality between the reported short of breath, fever, headache, nausea, difficulty swallowing, throat closing, chest tightness, and the administration of COVID 19 vaccine, BNT162B2, based on the plausible temporal association. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RA, IEC, as appropriate.

headache; injection site is itchy and swelled up; injection site is itchy and swelled up; But this one turned red; can't lift her arm it's heavy and painful; can't lift her arm it's heavy and painful; shortness of breath; palpitation; Dizziness, lightheaded/ feeling dizzy; Uneasiness; hands are so cold; nauseous; This is spontaneous report from a contactable nurse reported for herself. This 42-year-old female patient (No pregnant) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via Intramuscular on Left arm on 29Dec2020 17:00 PM on left arm at single dose (Lot # EL1284) for COVID-19 immunisation. Medical history included None. No Allergies to medications, food, or other products. Concomitant medications included ascorbic acid, bioflavonoids nos, hesperidin, malpighia glabra, rosa canina, rutoside (VITAMIN C), collagen, colecalciferol (VITAMIN D), cynara cardunculus, malus spp. vinegar extract, taraxacum officinale (APPLE CIDER). No other vaccine in four weeks. The patient experienced Dizziness, lightheaded, palpitation, uneasyness, shortness of breath on 29Dec2020 17:15 pm. Then when the patient drove home, she felt so uneasy and hands are so cold, nauseous and feeling

dizzy on 29Dec2020 17:15 pm. Felt the same way in the house for a good 2 hours after the vaccination. Drank water and didn't sleep right away. Tried to monitor herself. After that day the patient felt better but with bouts of headache and dizziness every now and then. The injection site was itchy and swelled up. But it went down if didn't scratch it. The patient didn't have allergies to any medications. But this one turned red. And the next day after the vaccination (30Dec2020) the patient can't lift her arm it's heavy and painful. Then pain went away. But now it was the itchiness in the site that bothered her. But the patient didn't scratch it. So it didn't swell up as much. Prior to vaccination, was the patient did not diagnose with COVID-19. Lab data on 07Jan2021 Nasal Swab post vaccination for Covid 19: result was pending. No treatments received for the events. Outcome of the events Dizziness, lightheaded/ feeling dizzy, palpitation, Uneasiness, shortness of breath, hands are so cold, nauseous was recovering. Outcome of the event pain in arm was recovered. Outcome of other events was unknown.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the dizziness, lightheaded, palpitation, shortness of breath and other reported events due to temporal relationship. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics including chest x-ray, EKG and chemistry panel, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

trouble breathing; She had bad pain in her chest; Her oxygen saturation dropped to 92 and it is usually 98 or 100; not been feeling well; A fast heartbeat 5-10 minutes after initial dose; This is a spontaneous report from a contactable healthcare professional (dental assistant) reporting for self. This female patient with unspecified age received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 22Dec2020 at single dose for COVID-19 immunisation. Medical history and concomitant medications were not reported. The patient previously had reactions with the flu shot in the past for immunisation and she only was able to take the vegan version of the flu shot due to the egg content in the regular version of the flu shot. She also stated not being able to take the flu shot in the arm, leg, hip etc. Patient stated she was scheduled to take her second dose of vaccine tomorrow. She received the first dose on 22Dec2020. She stated she was in the ER on Monday for 5 hours because she was unable to see her primary care physician because his office was filled with patients with Covid and they could not provide her with guidance. She stated after receiving the first dose of vaccine she had not been feeling well ever since. Stated she had had trouble breathing and this took her by surprise. She had bad pain in her chest and a fast heartbeat 5-10 minutes after initial dose (on 22Dec2020). Her oxygen saturation dropped to 92 and it was usually 98 or 100. She stated something inhibited her ability to breathe and this scared her because she was healthy prior to the vaccine and never been in hospital and wasn't born in the hospital. She stated the condition she was diagnosed with will take 6-12 months for her to recover from and go back to normal. She stated during her ER room visit there were a lot of tests done. She would like to know if she should receive the second dose of the vaccine. The outcome of events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Based on available

information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the dyspnea, chest pain, oxygen saturation decreased and other reported events due to temporal relationship. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics including chest x-ray, arterial blood gas and pulmonary function tests, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

On 1/12/20 resident woke up and was not able to stand in the E-Z stand. E-Z lift was needed. In addition he needed assistance with eating. At that time VS were stable, equal hand grasp noted, and no further concerns. Around 3pm resident became flaccid on the left side of his face and speech became mumbled. Hand grasp was equal at that time and VS were stable, but B/P was elevated compared to previous recordings earlier in the day. Family did not want him sent to the hospital and asked for comfort cares. Hospice referral obtained and he will be admitted to hospice in the near future. Resident's left side of face has improved within the last 48 hours. He remains total assist with all cares.

develops symptomatic covid; develops symptomatic covid; This is a spontaneous report from a contactable physician received via a Pfizer sales representative. This physician reported similar events for two patients. This is the first of two reports. A patient of unspecified age and gender received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot/batch number and expiry date were not provided) solution for injection, via an unspecified route of administration on an unspecified date at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient developed symptomatic Covid on an unspecified date. The patient received dose #1 of a Covid-19 vaccine and contracted Covid-19 prior to dose #2. The patient underwent lab test which included Covid-19 test in which he/she developed a symptomatic Covid-19 on an unknown date. Outcome of the event was unknown. Information about batch/lot number has been requested.; Sender's Comments: A causal association between BNT162B2 and the reported events cannot be excluded based on a compatible temporal relation between vaccination and onset of events. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate. ,Linked Report(s) : US-PFIZER INC-2021014755 Same reporter/drug/event, different patient

"flushed; hives; tongue felt ""thick""; the lump in my throat feels bigger; This is a spontaneous report received from a contactable pharmacist. A 23-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, lot number EL0142), via an unspecified route of administration in the left arm on 22Dec2020 (at the age of 23-years-old) as a single dose for COVID-19 immunization. The patient's medical history included: allergies to medications, food, or other products (unspecified). It was unknown if the patient was pregnant at the time of vaccination. The patient's

concomitant medications were not reported. It was unknown if the patient received any other vaccine within 4 weeks prior to the vaccine. On 22Dec2020, approximately 8 minutes after vaccine administration, the patient began feeling flushed. She reported to the observation area, and the registered nurse noted hives on her left neck (22Dec2020). The patient was brought back for closer monitoring. The doctor evaluated the patient. Vital signs were monitored every 5 minutes (22Dec2020). The patient was given 50 mg diphenhydramine (BENADRYL) orally. Some improvement was noted in hives; however, the patient began to state her tongue felt ""thick"" and ""the lump in my throat feels bigger"" (both on 22Dec2020). Per doctor, 0.3 mg epinephrine (MANUFACTURER UNKNOWN) given intramuscularly with rapid improvement in hives. The patient reported feeling some improvement as well. The patient was taken to the emergency department for ongoing observation. The patient was released from emergency department after observation. The clinical outcome of flushed, hives, tongue felt ""thick"", and ""the lump in my throat feels bigger"" was recovered on an unspecified date.; Sender's Comments: Based on the compatible time association, the events flushing, urticaria, tong disorder, sensation of foreign body are possibly related to suspect BNT162B2 administration. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate."

Egg sized lymphadenopathy under right arm 36 hours after 2D injection; flu symptoms; joint aches; muscle and joint aches; arm pain; arm pain and swelling; 1st dose of BNT162B2 on 17Dec2020 15:45/ 2nd dose on 06Jan2021 14:30; 1st dose of BNT162B2 on 17Dec2020 15:45/ 2nd dose on 06Jan2021 14:30; This is a spontaneous report from a contactable nurse (patient). A 55-year-old female patient received 2nd dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration in right arm on 06Jan2021 14:30 at single dose for COVID-19 immunisation. Medical history included mild hypertension and arthritis. The patient was not pregnant. No Covid prior vaccination, no Covid tested post vaccination. No known allergies. Concomitant medication included estradiol, norethisterone acetate (COMBIPATCH), meloxicam, propanol. The patient previously received 1st dose of BNT162B2 in left arm on 17Dec2020 15:45 for COVID-19 immunisation. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient experienced egg sized lymphadenopathy under right arm 36 hours after 2D injection (08Jan2021 03:00), after flu symptoms of muscle and joint aches, arm pain and swelling at 20 hours (07Jan2021 12:00). No treatment received for the events. The outcome of events was not recovered. This case was reported as non-serious. Information on the lot/batch number has been requested.; Sender's Comments: Based on the compatible temporal association and the drug's known safety profile, the vaccination with BNT162B2 might play a contributory role in triggering the onset of lymphadenopathy. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

She was wiped out the next day with aches and pains still.; tired; brain fog; started to get cold; shake/her hands were shaking so hard; they took her temperature and it was 100/her fever went to 101/temperature had gone to 102.6; heart rate was elevated at 100/heart rate was 110/heart rate went to the high 120s; headache; backache; nauseated; chest was hurting; The initial case was missing the following minimum criteria: Invalid for unspecified adverse event. Upon receipt of follow-up information on 08Jan2021, this case now contains all required information to be considered valid. This is a spontaneous report from a contactable nurse (patient). A 54-year-old female patient received 1st dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot# EK5730), via an unspecified route of administration in deltoid left on 29Dec2020 07:30 at single dose for COVID-19 immunisation. Medical history included ongoing sleep apnoea (diagnosed about 3-4 years ago, wear her CPAP religiously), Hashimoto's hypothyroid, and chronic low vitamin d (lack of sunlight). Concomitant medication included levothyroxine sodium (SYNTHROID) from 2016 and ongoing for Hashimoto's hypothyroid, ergocalciferol (VIT D) from 2018 for chronic low vitamin d; lack of sunlight (She did not take it religiously, but was supposed to take it everyday). At 10:30 AM (29Dec2020), she started to get cold and shake. She thought that this was insane and it was in her head. It became so severe she could not use her computer her hands were shaking so hard. She went back up to where they were giving vaccines, they took her temperature and it was 100. It had been normal the morning before she got the vaccine. Her heart rate was elevated at 100. They put a blanket on her and said they wanted to watch her for 15 minutes. In that time her fever went to 101 and her heart rate was 110. They took her to the ER. She was there for 5 hours. Her heart rate went to the high 120s. They did a 12 lead EKG. Her temperature had gone to 102.6, which was the highest. They gave her a liter of Normal Saline. She also had a headache, backache, and felt nauseated. The liter of fluid helped, no doubt. She was not admitted. She was wiped out the next day (30Dec2020) with aches and pains still. Their concern was they said they did not give her epinephrine because her heart was too high. She had no breathing issues. Just extreme cold. At one point she had woke up in the ER (29 or 30Dec2020) and her chest was hurting, she knows from her heart rate being too fast. She was so cold. She had on 6 blankets. The next day (30Dec2020) she still had the aches and pains, she was tired, and had brain fog. It all went away on 30Dec2020. She had nothing after that. What scared her was the heart rhythm. The ER doctor says its not great, but felt that getting the second dose was better than her having COVID. The Electrophysiologist she saw, said she was unsure if she should get the second dose. The hospital said that for this next dose, they would give her the injection, wait 15 minutes, then send her home, expecting that she would have the same thing happen. When after the first dose, she was in the ER on a 12 lead EKG with an intravenous (IV). She had no arm pain the whole time. The reporter assessed all events related. She felt fine prior, walking in to get the vaccine. But she was much better the next day and recovered completely. She was just worried about the second dose. The outcome of events was recovered on 30Dec2020.; Sender's Comments: Based on the compatible temporal association and the drug's known safety profile, the vaccination with BNT162B2 might play a contributory role in triggering the onset of the reported events. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Myocardial Infarction; This is a spontaneous report from a contactable Other healthcare professional (patient). A 64-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, Batch/lot number: 20201216-1), via an unspecified route of administration on 16Dec2020 08:15 at single dose for COVID-19 immunization, vaccine location provided as Left arm. Medical history included arthritis and sulfa allergy. Prior to vaccination, the patient was not diagnosed with COVID-19. The patient's concomitant medications were not reported. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient experienced myocardial infarction on 19Dec2020 23:00. The patient was hospitalized for myocardial infarction for 3 days. The patient underwent lab test which included Covid test via Nasal Swab post vaccination on 20Dec2020 with test result Negative. Therapeutic measure Cardiac cath procedure was taken as a result of myocardial infarction. The outcome of the event was recovering. This case was reported as Serious with seriousness criteria hospitalization.; Sender's Comments: The Company cannot completely exclude the possible causality between the reported myocardial infarction and the administration of COVID-19 vaccine, BNT162B2, based on the reasonable temporal association. However, more information is required, such as the complete medical history, clinical course, for the Company to make a more meaningful causality assessment. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RA, IEC, as appropriate.

Rash over all over body, started at neck.; itching; This is a spontaneous report from a contactable Nurse. A 25-year-old female patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number: EL3246, expiry date: unknown), intramuscular on 06Jan2021 15:15 at single dose (Left arm) for COVID-19 immunization. The patient medical history and concomitant medications were not reported. Facility type vaccine was Clinic/Facility. The patient experienced rash over all over body, started at neck and also complained of itching on 06Jan2021 15:30. Patient denied breathing difficulties. EMTs arrived and gave client oxygen and Benadryl. AE resulted in Emergency room/department or urgent care. It was unknown if patient had COVID prior vaccination. The patient was not tested for COVID post vaccination. Therapeutic measures were taken as a result of rash over all over body, started at neck and itching. The outcome of the events was recovering.; Sender's Comments: Based on the close temporal association, the Company considers the events rash and pruritus are possibly related to vaccination with BNT162B2. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

took a rapid test and it came up positive; took a rapid test and it came up positive; fever 100.8; coughing; This is a spontaneous report from a contactable consumer (patient herself). A 41-year-old female patient (non-pregnant) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, reported as Pfizer covid19 el1284), via an unspecified route of administration on 30Dec2020 14:30 in left arm at single dose for covid-19 immunisation. Medical history included asthma and

arthritis. Concomitant medication included ibuprofen and paracetamol (TYLENOL). The most recent COVID-19 vaccine was administered in public health clinic/ veterans administration facility. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had been tested for COVID-19. Patient got the vaccine on Wednesday 30Dec2020, and by Saturday (02Jan2021 22:30) she started with a little coughing that increase on Monday (04Jan2021), Monday afternoon she had fever 100.8. She thought she was experiencing side effects and reported to her supervisor and didn't work the 2 next days. She when back to work on Thursday (07Jan2021), she was sent to a covid clinic and took a rapid test and it came up positive. The patient underwent lab tests and procedures which included nasal swab (rapid antigen testing - SARS-CoV-2): positive on 07Jan2021. The events were reported as non-serious. No treatment was received for the events. Outcome of events were recovering. Information on the lot/batch number has been requested.

diebities; overweight; This is a spontaneous report from a contactable consumer. A 53-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiry date were not reported), via an unspecified route of administration on an unspecified date t a single dose for COVID-19 immunization. Medical history included 'dibeities'. The patient's concomitant medications were not reported. The patient experienced 'diebities' and was overweight on an unspecified date with outcome of unknown. The patient was not tested for COVID-19 post vaccination. Information on the Lot/batch number has been requested.

Received the first dose of the COVID Vaccine on 29Dec2020 and tested positive for COVID on 08Jan2021; Received the first dose of the COVID Vaccine on 29Dec2020 and tested positive for COVID on 08Jan2021; This is a spontaneous report from a non-contactable consumer. A 45-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK5730), via an unspecified route of administration on 29Dec2020 at single dose for COVID-19 immunisation. The patient medical history and concomitant medications were not reported. The patient received the first dose of the COVID Vaccine on 29Dec2020 and tested positive for COVID (Nasal Swab) on 08Jan2021. The outcome of the event was not recovered. No follow-up attempts are possible. No further information is expected.

12/31-mild facial weakness left forehead, left cheek/smile asymmetry.; 12/30-headache, left ear pain, left face pain/continued numbness tingling; 12/30-headache, left ear pain, left face pain/continued numbness tingling; 12/30-headache, left ear pain, left face pain/continued numbness tingling; 12/30-headache, left ear pain, left face pain/continued numbness tingling; 12/29-+fatigue, SOB, left sided lowback pain - severe; 12/29-+fatigue, SOB, left sided lowback pain - severe; 12/29-+fatigue, SOB, left sided lowback pain - severe; 19:00- chills, myalgias, cold sensation of b/l feet; 19:00- chills; 19:00- chills, myalgias; At 16:00- palpitations; At 16:00- palpitations, chest tightness; At 12:00 (within 4 hrs) began experiencing L sided facial and Left foot numbness/tingling and left hand.; Reported to health care provider, began steroids for early onset bell's palsy; This is a spontaneous report from a contactable other health professional (patient). An adult female patient (not pregnant) received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) lot number EL1284 via intramuscular in left arm on 28Dec2020 08:30 at single dose for COVID-19 immunization. Medical history included Crohns, asthma,

migraine, GERD (gastrooesophageal reflux disease), Known Allergies: pyridium. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient did not have COVID tested post vaccination and did not have COVID prior vaccination. Concomitant medication included mesalazine (PENTASA), famotidine (PEPCID), paracetamol (TYLENOL), calcium phosphate, colecalciferol (VITAFUSION CALCIUM), ascorbic acid, biotin, calcium, choline bitartrate, chromium, copper, folic acid, inositol, iodine, iron, magnesium, manganese, molybdenum, nicotinamide, pantothenic acid, phosphorus, potassium, pyridoxine, retinol, riboflavin, selenium, thiamine, tocopherol, vitamin b12 nos, vitamin d nos, zinc (MULTIVITAMIN) , biotin, colecalciferol (VITAMIN D). Reported Event: on 28Dec2020 at 12:00 (within 4 hrs) began experiencing L sided facial and Left foot numbness/tingling and left hand. At 16:00- palpitations, chest tightness. 19:00- chills, myalgias, cold sensation of b/l feet. 12/29-+fatigue, SOB, left sided low back pain - severe. 12/30-headache, left ear pain, left face pain/continued numbness tingling. 12/31-mild facial weakness left forehead, left cheek/smile asymmetry. Reported to health care provider, began steroids for early onset bell's palsy. On 08Jan2021 continue to have paresthesia of my left face, left hand, left foot, headache, mild left facial weakness/altered sensation. The events resulted in Doctor or other healthcare professional office/clinic visit. The patient received treatment received for the adverse events on 01Jan2021. The outcome of the events was recovering.; Sender's Comments: A possible causal association between administration of BNT162B2 and the onset of bell's palsy /facial paresis cannot be fully excluded, considering the plausible temporal relationship and the known adverse event profile of the suspect product. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate

Bell's palsy; Loss of taste; Can not close one eye, no muscle movement on one side of the face.; This is a spontaneous report from a contactable nurse. An adult female (not pregnant) patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), intramuscular in left arm on 05Jan2021 15:30 at single dose for COVID-19 immunization. There were no medical history or concomitant medications. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient did not have COVID tested post vaccination and did not have COVID prior vaccination. The patient had no known allergies. The patient experienced Half face paralysis, Bell's palsy. Loss of taste. Can not close one eye, no muscle movement on one side of the face. All on 08Jan2021 14:30 with outcome of unknown. No treatment was received.; Sender's Comments: A possible causal association between administration of BNT162B2 and the onset of Half face paralysis/Bell's palsy cannot be fully excluded, considering the plausible temporal relationship and the known adverse event profile of the suspect product. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate

He collapsed with left sided hemiparesis; Stroke; Rt basal ganglia hemorrhage w/ edema and mass effect.; Rt basal ganglia hemorrhage w/ edema and mass effect.; Low platelets, 114; His bp as high as

200s/100; Hand weakness; Myalgia; Fever; Severe fatigue; This is a spontaneous report from a contactable physician. A 58-year-old male patient received first dose of bnt162b2 (Pfizer BioNTech COVID vaccine), intramuscularly on 16Dec2020 at a single dose for COVID-19 immunization. Medical history included hypertension with reported med noncompliance in the last few months due to stress. Concomitant medication included hypertension medications in two weeks. The patient was presumed neg covid status prior to vaccine. He worked as a Pulm/critical care physician. He reported fever, myalgia, fatigue on 16Dec2020. Next day (17Dec2020), he took off from work due to his symptoms. The following day (18Dec2020), he came to work. He c/o ongoing severe fatigue & hand weakness in am. Staff noted him to be evaluating his hands during clinic. At 12:15, he collapsed with left sided hemiparesis. The reporter had suspicion for stroke. He was transported to the Emergency Room (ER), head CT showed Rt basal ganglia hemorrhage w/ edema and mass effect. Labs notable for Low platelets, 114 (unknown baseline) on 18Dec2020, normal coags on an unspecified date. BP recorded as 179/101, but it was noted in trauma room his bp as high as 200s/100. He had a history of hypertension with reported med noncompliance in the last few months due to stress. Patient was transferred for further care. Full course was unknown but had rebleed there with low plts. Adverse event (he collapsed with left sided hemiparesis) resulted in hospitalization (22 days), life threatening illness (immediate risk of death from the event), disability/incapacitating or permanent damage. Treatment was received for adverse events. Results of tests and procedures for investigation of the patient: on 18Dec2020, Nasal Swab test: negative. The outcome of events was not recovered. Unknown if any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient was not tested for COVID-19. Information on the lot/batch number has been requested.; Sender's Comments: Collapsed with left sided hemiparesis/suspicion for stroke are as consequences of basal ganglia hemorrhage with edema, which is caused by worsening of hypertension. Low platelet also contributes to brain hemorrhage. All these serious events are unrelated to the vaccine use. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

"Sore throat, severe chest tightness and pressure, very hard to breathe in, more than 30 minutes after covid vaccine, dizziness, headache, lightheadedness; severe chest tightness and pressure; very hard to breathe in, more than 30 minutes after covid vaccine; Dizziness /lightheadedness; headache; This is a spontaneous report from a contactable consumer (patient). A 35-year-old female (not pregnant at the time of vaccination) patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (lot number EL0142), via an unspecified route of administration at left arm on 09Jan2021 10:30 at single dose for COVID-19 immunization at a hospital. The patient's medical history included migraines, asthma, diabetes, sleep apnea, low immune system, post-traumatic stress disorder (PTSD), depression, panic attacks, insomnia, borderline personality disorder, and known allergies to medications, food, or other product (10 total). Concomitant medications included adult tetanus vaccine on 04Jan2021 received at right arm, for immunization (within 4 weeks prior to the COVID vaccine); first dose of botulinum toxin type a (BOTOX) on 06Jan2021 at single (31 shots in 7 muscle groups) for migraines (within 4 weeks prior

to the COVID vaccine); and clindamycin antibiotic for infection in finger (took within in two weeks). The patient was not diagnosed with COVID-19 prior to vaccination, and had not been tested for COVID-19 since the vaccination. On 09Jan2021 11:00, the patient experienced sore throat, severe chest tightness and pressure, very hard to breathe in, more than 30 minutes after COVID vaccine, ""dizziness/lightheadedness"", and headache. The above mentioned events resulted in emergency room/department or urgent care visit, and patient received breathing treatment, oxygen for over an hour for these events. The outcome of the events was unknown. The reporter considered the events as non-serious."

complete hearing loss at the right ear, 5 hours post injection, continued till now 3 days past injection, not resolved yet prior to report; This is a spontaneous report from a contactable physician. A 72-years-old male patient started to receive bnt162b2 (BNT162B2) Lot number# ek9231 intramuscularly on 06Jan2021 12:00 at single dose for covid-19 immunisation. Anatomical Location: Arm Right. Facility where the most recent COVID-19 vaccine was administered: Hospital. Medical history included diabetes mellitus, hypertension. The patient did not received any other vaccines within 4 weeks prior to the COVID vaccine. Concomitant medication included alprazolam (AZOR [ALPRAZOLAM]), metformin hydrochloride, sitagliptin phosphate monohydrate (JANUMET [METFORMIN HYDROCHLORIDE;SITAGLIPTIN PHOSPHATE MONOHYDRATE]), atorvastatin calcium (LIPITOR [ATORVASTATIN CALCIUM]). The patient on 06Jan2021 18:00 reported complete hearing loss at the right ear, 5 hours post injection, continued till now 3 days past injection, not resolved yet prior to report. The action taken was not applicable.; Sender's Comments: A possible contributory effect of suspect BNT162B2 on reported hearing loss cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

Allergic reaction to vaccine; tingling to upper lip and face; tingling to upper lip and face; red rash on bilateral forearms; Patient developed Bell's Palsy 2-3 days later; This is a spontaneous report from a contactable consumer. A 45-year-old non-pregnant female patient received the first dose bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EL1284), via an unspecified route of administration on 23Dec2020 at 14:30 at single dose in left arm for covid-19 immunization. Medical history included mitral valve prolapse from an unknown date, and allergies: Cephalosporins and nut (peanut derived). Concomitant medication included epinephrine (EPIPEN) 0.3MG/0.3ML, fluticasone propionate 50MCG/ACT nasal spray. On 23Dec2020 at 14:45, the patient experienced allergic reaction to vaccine, tingling to upper lip and face, red rash on bilateral forearms. Reactions resolved with no treatment. The patient developed Bell's Palsy 2-3 days later in Dec2020. Currently being treated with high dose steroids and acyclovir. All events required emergency room visit and physician office visit. All events were reported as non-serious by reporter. The outcome of event Bell's Palsy was not resolved, outcome of other events was resolved on an unspecified date. The patient was not diagnosed with COVID-19 prior to vaccination, and it was unknown if the patient has been tested for COVID-19 since the vaccination.

fever and chills; fever and chills; blood pressure was low, about 90/50; did not feel well; syncope episode; unconscious; This is a spontaneous report from a contactable other health professional. A 27-year-old non-pregnant female patient received the first dose of the bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot Number: EH9899), via an unspecified route of administration in the left arm on 08Jan2021 at 12:00 at a single dose for COVID-19 immunization; received at a nursing home/senior living facility. The patient did not receive any other vaccines within four weeks prior to the COVID vaccine. Medical history included COVID-19 from an unknown date and unknown if ongoing. No known allergies. Concomitant medications included unspecified birth control taken for an unspecified indication from an unknown date to an unknown date; within two weeks of vaccination. The patient experienced the following events and outcomes: syncope episode in Jan2021 with outcome of unknown, unconscious in Jan2021 with outcome of unknown, fever and chills on 09Jan2021 with outcome of unknown, blood pressure was low, about 90/50 on 09Jan2021 with outcome of unknown, did not feel well in Jan2021 with outcome of unknown; all of which were assessed as medically significant. The clinical course was reported as follows: the fever and chills began about one hour after vaccination (as reported). About 18 hours after the vaccination, the patient was getting up to take more paracetamol (TYLENOL) and did not feel well. The patient had a syncope episode in the bathroom (no issues as she sat on the floor before hand). The patient was unconscious for about 1-2 minutes. The patient's blood pressure several minutes later was low, about 90/50; however, the patient took the blood pressure measurement herself, so it may not have been exactly accurate. The patient underwent lab tests and procedures which included blood pressure measurement: low, about 90/50 on 09Jan2021. Therapeutic measures were taken as a result of fever. Prior to vaccination, the patient was diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19.; Sender's Comments: A possible causal association between administration of BNT162B2 and the onset of all reported serious events cannot be excluded, considering the plausible temporal relationship and the known adverse event profile of the suspect product. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

"Heart rate shot up to 170 with numbness of feet.; Heart rate shot up to 170 with numbness of feet.; Chest pain; feeling like I was going to vomit and faint; feeling like I was going to vomit and faint; This is a spontaneous report from a contactable other hcp (patient). A 25-year-old non-pregnant female patient received the first dose bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 06Jan2021 at 11:45 at single dose in left arm for covid-19 immunization. There was no medical history. Concomitant medication included valaciclovir hydrochloride (VALTREX), topiramate (TOPAMAX), lamotrigine (LAMICTAL), duloxetine hydrochloride (CYMBALTA), ziprasidone hydrochloride (GEODON). On 06Jan2021 at 12:30, The patient experienced heart rate shot up to 170 with numbness of feet, started to feel chest pain, and feeling like she was going to vomit and faint. The events required emergency room visit and were reported as serious per hospitalization. Heart rate at the hospital was 135-140 where two EKG were done and fluids were given. An x-ray of the heart was done and blood work was completed. The patient didn't receive treatment for the events. The patient didn't receive any

other vaccines within 4 weeks prior to the COVID vaccine. The patient was not diagnosed with COVID-19 prior to vaccination, and has not been tested for COVID-19 since the vaccination. The outcome of the events was resolved in Jan2021. Information on batch/lot number has been requested.; Sender's Comments: There is a reasonable possibility that the event ""feeling like she was going to vomit"" was related to BNT162b2 based on known drug safety profile. Based on the temporal relationship, the association between the other reported serious events with BNT 162b2 can not be completely excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate."

resident coded on 09Jan at 8am and expired; This is a spontaneous report from a contactable Other Health Professional. A 70-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EL0140), intramuscularly in left arm on 05Jan2021 15:15 at single dose for COVID-19 immunization. Medical history included DM2(Type two diabetes mellitus), CHF(congestive heart failure), open wound, wound infection, heart failure. Allergies to medications, food, or other products: none. Concomitant medications included unspecified products (List of any other medications the patient received within 2 weeks of vaccination: yes). If the patient received any other vaccines within 4 weeks prior to the COVID vaccine: Unknown. Facility where the most recent COVID-19 vaccine was administered: Nursing Home/Senior Living Facility. The resident coded on 09Jan2021 at 8 AM and expired. The patient died on 09Jan2021. An autopsy was not performed. AE resulted in: patient died. Death cause: unknown at this time. Was treatment received for the adverse event: Unknown. Prior to vaccination, was the patient diagnosed with COVID-19: No. Since the vaccination, has the patient been tested for COVID-19: No. Serious: Yes. Seriousness criteria-Results in death: Yes. Seriousness criteria-Life threatening: No. Seriousness criteria-Caused/prolonged hospitalization: No. Seriousness criteria-Disabling/Incapacitating: No. Seriousness criteria-Congenital anomaly/birth defect: No.; Sender's Comments: The old patient had diabetes mellitus, congestive heart failure, open wound complicated by infection, all these pre-existing medical conditions contribute to the patient death. More information including complete medical history, concomitant medications and event term details especially death cause and autopsy results are needed for a full assessment of the case. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate; Reported Cause(s) of Death: resident coded on 09Jan at 8am and expired

Saturday had. Sweating. Chills. Headache. Nausea.; Saturday had. Sweating. Chills. Headache. Nausea.; Saturday had. Sweating. Chills. Headache. Nausea.; Saturday had. Sweating. Chills. Headache. Nausea.; Sunday had emergency appendectomy for actuate appendicitis.; Friday at 3pm, the patient had numbness and tingling to left hand, lips and throat; Friday at 3pm, the patient had numbness and tingling to left hand, lips and throat; Friday at 3pm, the patient had numbness and tingling to left hand, lips and throat; Friday at 3pm, the patient had numbness and tingling to left hand, lips and throat; Friday

at 3pm, the patient had numbness and tingling to left hand, lips and throat; Friday at 3pm, the patient had numbness and tingling to left hand, lips and throat; Post surgery had allergic reaction unknown reason with head to toe rash; Post surgery had allergic reaction unknown reason with head to toe rash; This is a spontaneous report from a contactable nurse (patient). A 34-year-old female patient (pregnant: No) received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via intramuscular (lot number: EL1283) on left arm on 08Jan2021 at 6:30 AM at single dose for covid-19 immunisation. The relevant medical history included celiac, anemia, known allergies: Sulfa and Gluten. Concomitant medications were not reported. The patient received first dose of BNT162B2 via intramuscular (lot number: Ek5730) on left leg on 18Dec2020 at 11:00 AM at single dose for covid-19 immunisation. The patient previously took Codeine, fish oil and experienced allergies. Friday at 3pm, the patient had numbness and tingling to left hand, lips and throat. On Saturday the patient had sweating, chills, headache, nausea. On Sunday had emergency appendectomy for actuate appendicitis. Post surgery had allergic reaction unknown reason with head to toe rash. It was also reported that the adverse event started on 08Jan2021 at 03: 15 PM (as reported). The patient had 1-day hospitalization. The patient received treatment for the events. The adverse events resulted in Emergency room/department or urgent care. The events were reported as serious due to life threatening and hospitalization. The most recent COVID-19 vaccine was administered at hospital. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The outcome of the events was recovering.; Sender's Comments: A causal association between BNT162B2 and the reported events cannot be excluded based on a compatible temporal relation between vaccination and onset of events. Medications administered during appendectomy may confound reactions experienced post-surgery. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

passing out sensation; heart palpitations; sweating; diarrhea; This is a spontaneous report from a contactable consumer (patient's boyfriend). A female patient of an unspecified age received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for covid-19 immunization. The patient's medical history and concomitant medications were not reported. The reporter reported that symptoms were related to the use of Covid 19 vaccine. The patient received the first dose on 15Jan (as reported) and the day after developed sweating, passing out sensation, heart palpitations and this morning on 11Jan2021 when she woke up she had the same symptoms plus diarrhea. The outcome of the events was unknown. Information on the lot number/batch number was requested.

severe hypertension (190/100); flushing tachycardia; flushing tachycardia; blurred vision in the left eye; This is a spontaneous report from a contactable healthcare professional reporting for self. This 65-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via unspecified route of administration on unspecified date at single dose for COVID-19 immunisation. Medical history included ongoing underlying HTN (hypertension). Concomitant medications were not reported. The patient experienced AE following administration of first dose of vaccine of including:

severe hypertension (190/100), flushing tachycardia, and blurred vision in the left eye. These symptoms started 20minutes after administration. The patient stated her PCP thought that she had underlying hypertension and had since started her on medications. She was looking for guidance with regard to receiving the second dose. The outcome of events was unknown. Information about Batch/Lot number has been requested.; Sender's Comments: The administration of BNT162B2 might have played a contributory role in triggering the onset of serious event hypertension worsened, considering the plausible temporal relationship. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate

"he was in AFIB for about 3 hours after receiving his first dose of the COVID19 Vaccine; he noticed the rest of the day, right up to going to bed that he felt cold; This is a spontaneous report from a contactable consumer. A 66-year-old male patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot Number: EL1284) at arm, left upper, via an unspecified route of administration on 29Dec2020 06:15 at single dose for covid-19 immunisation. Medical history included atrial fibrillation (Afib) formally diagnosed around Jan2020. There were no concomitant medications. The patient reported he got the COVID-19 Vaccine at 06:15 on 29Dec2020 and had to sit for 15 minutes afterwards before he could leave. He said everything was fine, and he walked out to the hospital lobby, and was speaking with a work associate for 10 minutes before he headed to his car. When he got ready to leave, he got in his car, and started his car. He started driving home, and realized he was in AFIB. He did have an AFIB issue. His AFIB has been pretty well controlled for a year now, as long as, he didn't do something stupid. He had a moderately aggressive run of AFIB. He said his ""smart"" watch told him his heart rate was 117. His normal heart rate is around 60-70. He was in AFIB for about 3 hours. His typical runs of AFIB are considerably shorter. He only had a total of 2 episodes of AFIB in the last year. His prior AFIB episodes would have been about 4-5 minutes. The last time he had AFIB that lasted any length of time was when he was hospitalized for AFIB around Jan2020. He said at that time, he was hospitalized overnight for observation. He received medication during the hospitalization and his AFIB broke. He didn't remember what medications were given to him during the hospitalization. He said he had flutters before that hospitalization, but the flutters were always gone after a few minutes, so he never sought treatment because there would be nothing to treat. The patient reported he noticed the rest of the day on 29Dec2020, right up to going to bed that he felt cold. His house wasn't cold, and he didn't have a fever. He said the cold feeling went away during the night while he was sleeping. He said the cold feeling easily lasted for a 12 hours. He said the cold feeling could have been something else. The outcome of ""he was in afib for about 3 hours after receiving his first dose of the covid19 vaccine"" was recovered on 29Dec2020; of ""he noticed the rest of the day, right up to going to bed that he felt cold"" was recovered on 30Dec2020."

she was diagnosed with bilateral deep vein thrombosis (DVT) and pulmonary embolism (PE); she was diagnosed with bilateral deep vein thrombosis (DVT) and pulmonary embolism (PE); This is a spontaneous report from a contactable nurse (patient). A 22-year-old female patient received 2nd dose

of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot# EK9231), via an unspecified route of administration in left arm on 06Jan2021 13:45 at single dose for COVID-19 immunisation. Medical history included allergy to all fish, and clots. The patient was not pregnant. There were no concomitant medications. The patient previously received 1st dose of BNT162B2 (lot numer: EH9899) in left arm on 16Dec2020 13:45 for COVID-19 immunisation and experienced left sided lower back pain on 20Dec2020. No other vaccine received in four weeks. It was reported that the patient had the first covid vaccine on 16Dec2020 and on 20Dec2020 started with left sided lower back pain and then received the second on 06Jan2021 and then on 09Jan2021 11:00 her legs became blue and swollen and she was diagnosed with bilateral deep vein thrombosis (DVT) and pulmonary embolism (PE). The patient otherwise healthy and had never had covid. Other than the clots, she had no other health issues. The patient underwent lab tests and procedures which included nasal swab: negative on 09Jan2021. Events resulted in doctor or other healthcare professional office/clinic visit, emergency room/department or urgent care, hospitalization, and life threatening illness (immediate risk of death from the event), hospitalized for 2 days (in Jan2021). Adverse event treatment: heparin drip and xarelto at home. Recovered with lasting effects on an unspecified date of Jan2020. This case was reported as serious, serious criteria was life threatening, caused/prolonged hospitalization.; Sender's Comments: The underlying risk factors/predisposing condition of thrombotic diathesis have been assessed to have played a contributory role toward the events.

Resident expired on 12/30/20, dx cardiac arrest.

Resident expired on 1/2/21.

Per pt, sx onset began at 1520 with pruritus/hives of the scalp. She was in the post vaccine observation area at this time. At 1530, EE returned to vaccination room to alert staff of her reaction. Upon hearing her new onset cough, an assessment was performed immediately. Reported tingling and swelling of her lips, cough, minor difficulty breathing with mask on, facial flushing and feeling hot, and severe pruritus, especially on the scalp. 50 mg IM Benadryl administered and was taken to ED via wheelchair which is 7 minutes away. Epi Pen administered in ED and admitted overnight for observation d/t irregular HR and ST depression on monitor.

felt kind of tired; Tested positive for COVID after receiving the first dose of the COVID Vaccine; Tested positive for COVID after receiving the first dose of the COVID Vaccine; slight fever; body aches; headache; This is a spontaneous report from a Pfizer-sponsored program. A contactable nurse (the patient) reported that a 39-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EK5730) via unspecified route of administration on the left arm/shoulder on 22Dec2020 at single dose for COVID-19 immunisation. Medical history included gained weight since the pandemic started. The patient's concomitant medications were not reported. Patient received first dose of the vaccine. She had symptoms right after she got the vaccine the next day, on 23Dec2020. She had a slight fever, body aches, and a headache, which she never gets. She had these for about 2-3 days, they lingered around, and kicked back up around 26Dec2020/27Dec2020. She also felt kind of tired. She got covid 19 infection tested on 02Jan2021 and the results came back positive on 03Jan2021. Patient was calling to report this and see what to do about the second dose. She was

supposed to get her second dose next Tuesday. The outcome of events was unknown.; Sender's Comments: Based on the information currently available, a lack of efficacy with the suspected vaccine BNT162B2 cannot be completely excluded. However, individuals may not be protected until at least 7 days after their second dose of the vaccine. It is unlikely that the patient would have fully developed immunity due to the very short time lag between the first vaccine dose and the event onset.

received the first dose of the vaccine on 21Dec2020 and tested positive for Covid-19; received the first dose of the vaccine on 21Dec2020 and tested positive for Covid-19; This is a spontaneous report from a contactable consumer. A patient of unspecified age and gender received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number and expiration date was not provided) via an unspecified route of administration on 21Dec2020 at single dose for covid-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient received the first dose of the vaccine on 21Dec2020 and tested positive for covid-19 on 07Jan2021. The patient was isolated for 10 days. Outcome of event was unknown. Information on the lot/batch number has been requested.

COVID virus/on 29Dec2020 tested positive/symptoms of cough, chills, lost of taste and smell; COVID virus/on 29Dec2020 tested positive/symptoms of cough, chills, lost of taste and smell; This is a spontaneous report from a contactable other health professional (patient). A 57-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number EJ1685, expiration date: 31Mar2021), intramuscularly on 20Dec2020 17:43 at left deltoid, at single dose for vaccination. Medical history included asthma and diabetes. There were no concomitant medications. The patient received the first dose of vaccine on 20Dec2020. On 22Dec2020 she was exposed to Covid, on 28Dec2020 developed symptoms of cough, chills, lost of taste and smell, she had onset of COVID virus symptoms on 28Dec2020 with positive COVID result from COVID nasal swab test performed on 29Dec2020. She has already completed her Bamlanivimab infusion therapy to treat COVID virus on 31Dec2020. Her 2nd dose is due on 10Jan2020 and she wanted information on the use of antibody therapy with the Covid-19 vaccine. She asked if she should still get the second dose of Pfizer-BioNTech COVID-19 Vaccine as scheduled on 10Jan2021 relative to these events. She reported she still has COVID symptoms which have improved, but the symptoms she can't taste or smell are ongoing and persistent. Seriousness criteria: she thought it was serious but she was not injured or anything with it; she thought event was offset it by taking some medication and the Bamlanivimab infusion. In addition to Bamlanivimab infusion for treatment of the COVID virus she was also prescribed Azithromycin for 5 days started on 29Dec2020 which she completed; and Prednisone for 7 days started on 29Dec2020 which she stopped after 5 days of therapy because she did not like how it made her feel. The outcome of the event was recovering. Event relatedness between Pfizer-BioNTech COVID-19 Vaccine and COVID virus was unrelated.; Sender's Comments: Based on the information currently available, lack of efficacy of the suspected vaccine BNT162B2 cannot be completely excluded. However, individuals may not be protected until at least 7 days after their second dose of the vaccine. It is unlikely that the patient would have fully developed immunity due to the very short time lag between the first vaccine dose and the event onset.

positive COVID-19 test; positive COVID-19 test; positive COVID-19 test; This is a spontaneous report from a contactable pharmacist. A around 50-year-old male patient received bnt162b2 (PFIZER-

BIONTECH COVID-19 VACCINE, lot/batch number and expiration date not provided), via an unspecified route of administration on 22Dec2020 at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The physician reported that he knew the patient got the vaccine on 22Dec2020. On 02Jan2021, he tested positive to COVID-19. The outcome of the events was unknown. Information on the Lot/batch number has been requested.; Sender's Comments: The association between the event lack of effect (tested positive for COVID-19) with BNT162b2 can not be completely excluded.

Tufts of my hair came out by the handful - first time in my life I have experienced ANY hair loss! It is still ongoing and I am worried it will result in permanent baldness.

Cardiac arrest within 1 hour Patient had the second vaccine approximately 2 pm on Tuesday Jan 12th He works at the extended care community and was in good health that morning with no complaints. He waited 10-15 minutes at the vaccine admin site and then told them he felt fine and was ready to get back to work. He then was found unresponsive at 3 pm within an hour of the 2nd vaccine. EMS called immediately worked on him 30 minutes in field then 30 minutes at ER was able to put him on life support yet deemed Brain dead 1-14-21 and pronounced dead an hour or so later

He died nine hours later.

Patient died on 1/21-2021

1/7/2021 @ 5:00 a.m. patient woke up and couldn't move her right side (neck, arm and leg). Sister helped dress her and drove her to the hospital. During the ride the hospital the patient had 2 seizures and a 3rd seizure in the ER at the hospital. Patient states she has never had multiple, back to back seizures before. States she hasn't had a seizure for 2 years. EEG was done. Was released from the hospital on 1/9/2021 and to have outpatient MRI of head, shoulder, c-spine. Does not have full range of motion of right neck, and arm, hand and fingers and is painful. 1/14/2021 - full release back to work on 1/14/2021.

Resident had been monitored and had shown no signs or symptoms of any kind until 2 pm on 1/14/2021. Resident was found in the floor of her room. She had fallen and was having a seizure, temperature was 99.7F and Oxygen saturation was 82%.

Resident found unresponsive and without pulse at 05:45am.

on 1/14/21 patients HR 155 at 0800 per patient's home pulse ox device. arrived at ER, HR 148 at 1130. Continued to stay up even after 2 doses of 10mg iv push Cardizem and one dose of 30mg Cardizem. Cardizem drip started, heparin drip started, patient admitted to hospital

"12/23/2020: 2 hr after injection, patient noted swollen lymph nodes, nausea, room spinning (motion sickness-like) sx. Stayed home from work that day and slept. 12/24/2020: ""typical injection site pain"" 12/30/2020: injection site hot, itchy, welts 12/31/2020: area of welts doubled in size to entire upper left arm; throat starting to close up"

Patient presented herself to LPN slurring words and 'not herself'. Upon evaluation, patient denied drinking alcohol, knew she was not able to speak correctly and visibly frustrated . With great difficulty she was able to communicate that she had a headache and was slightly dizzy. Failed FAST and does have a history of CVAs. EMS called and patient was taken to ER where they admitted her for observation post Stroke. Per the hosp nurse, patient received tPA treatment and will be moved to step-down unit when a bed is available.

On 1/11/21 noted with headache, nausea/vomiting, severe melaise. On 1/12/21 resident expired.

Vaccination given 1314 and sent to waiting room for monitoring. Began to have itching at 1325. PO benadryl administered. Then with throat swelling. Epinephrine administered by EMS/Fire at 1:32pm: 0.5mg IM right arm. 1342 improving 1350 itching/throat swelling returning while EMS/Fire on phone with medical director. 1352 second dose of epinephrine administered by De Pere EMS/Fire: 0.5mg IM left arm Medical Director on site for evaluation. Client given option to transport to hospital or stay for monitoring with EMS/Dr. Condition improving, chose to stay for monitoring. Client improved and up walking halls 1513 Client cleared to be released home via private transport

EXTREME LETHERGY, NAUSEA, REFUSING TO EAT OR DRINK, ELEVATED HEARTRATE, FATIGUE, ELEVATED TEMP

Day after vaccine : mild shortness of breath, sensation of swelling in my throat/neck area. Took Benadryl 50mg before bedtime. 2 days after vaccine: woke up with voice changes, coughing/choking with speaking. Used epipen once, felt full relief for about 1-2 hours. Trouble speaking again. Then went to ER, had epipen again twice, over two hours, Benadryl 50IV and Pepcid and steroids. Sitting in the ER now debating admission. Likely being admitted., home epipen are too expensive to treat q2h by myself.

Generalized myalagias, weakness, vertigo, nausea with emesis, one episode of urinary incontinence. Admitted for observation. Patient improved without intervention with some residual dizziness on day two of symptoms.

Dec 24 felt light headed and loss of appetite, Dec 25, fever 103 and chills, Dec 26 Team member Covid hub had me do a Covid test, negative result, continue high fever, no appetite, chills and body ache, Health Hub contacted me daily with app to review symptoms, Dec 27-29 continued symptoms, unable to eat and little bit of water intake, Dec 29 appointment made with Health Urgent Care, received text from Urgent Care cancelling appointment and instructed to take sips of water and Tylenol that I was having an immune reaction to vaccine. Dec 29 virtual appointment with PCP continued symptoms, Dec 31 repeat of COVID swab along with Flu swab both negative, Jan 2-3 hospital admission for abnormal labs, jaundice, dehydration, Sodium/Potassium and Magnesium boluses given, and work up for infectious process was negative. Discharged to home Jan 3 with low grade fever, dry mouth, dry eyes, nausea, body ache and continued loss of appetite. Jan 4-7 continued worsening jaundice and appetite with low grade fever, GI Clinic consulted at Health Clinic, PCP in daily contact, repeat liver function labs on Jan 8 showed worsening labs. Jan 9-12 afebrile, started Ursodiol, low appetite better energy, continue dry mouth, GI appointment Jan 12 with plan to repeat liver functions on Jan 15, jaundice improved and able to eat liquids. No Tylenol or antipyretic taken since Jan 3 due to liver function tests.

Developed chest pressure 8.5 hours after vaccine, unrelieved after 3 hours, went to ED, elevated troponin, EKG changes. Admitted to hospital low grade fever next day

I developed severe abdominal pain 3 days after injection that turned out to be pancreatitis

71yo female resident who died after receiving Pfizer BioNTech vaccine. On 1/14/2021, VS taken at 10am, B/P 99/60, O2 sats, 95% (trach w/O2). At 11:30am, Patient showed no s/sx of distress, A&Ox3. At 11:50am, a nurse went to perform a COVID test and assessment (the facility is experiencing an outbreak), and found the patient unresponsive on the bathroom floor. CPR was immediately started; no shock advised per AED; 12:15pm EMS arrived and took over. At 12:38pm, EMT called time of death.

Has underlying dementia and often with difficulty eating. 1 week after immunization she developed a stroke with left sided weakness and difficulty swallowing. Comfort measures instituted. Not sure if this is related to the vaccine, but thought I should report

"83yo female resident who died after receiving Pfizer BioNTech vaccine. On 1/14/2021, the patient reportedly got up in the middle of the night with c/o feeling ""blah"", restlessness, and nausea. VS normal, no other s/sx. At 4:15am, the patient was asked to go back to bed, assisted by a nurse and GNA. At 6am, GNA was going to do morning VS and found the patient unresponsive, no pulse, no respirations. GNA notified the nurse. At 6:03am, CPR started and EMS called. At 6:15am, EMS arrived and took over. At or around 6:30am, EMT called time of death"

I had fatigue, headache, pain, weakness and I was so miserable decided to go to ER on (12/24/20) and then was transferred to hospital admitted (12/25/20) one day - discharged on 12/26/20 at night

Staff reported that he wasn't being himself. He was leaning more towards the right. Had symptoms similar to Bell's Palsy, some right sided facial droop, right eyelid drooping. On CT right maxillary sinusitis, ventriculomegaly.

Shortness of breath Chest pain Ongoing since

Fever to 100.4 on day 1 after vaccine, to 101.9 on day 3 after vaccine. Acute kidney injury (creatinine rose from 1.73 to 2.43) requiring hospitalization.

After first vaccine i experienced fatigue, body aches, headache and nausea for 2 days and injection site pain for two weeks. After second Vaccine given at 9:55am. tingling of feet for about 20 mins, 30 mins after the vaccine. Two hours later fatigue, body aches, headache and nausea began. At 0030 1/12/2021 I woke up with severe chills and left chest pain, temp was 101.6 and heart rate was 160. I began to see black and chest pain was severe feeling like i was having a heart atack and was going to pass out so i called 911. I then began to get short of breath and got numbess on my legs, left arm and left side of neck. Chest pressure/pain radiated to left arm and neck. I was taken by the ambulance to hospital. Arrived around 0130. My heart rate sustained at 140s in the ER so I was admitted at 0530 am. My D Dimer was a bit elevated as well as my lactic so I was given a bolus of fluids plus maintenance. I had a CXR done, CTA chest(negative for PE), UA, Labs, entire cardiac workup including an ECHO during my admission. I also began to have loose stools and wrist joint pain. MY heart rate sustained at 125-147 for

about 30 hours. Fevers on and off. After everthing was negative we determined this was secondary to the covid 19 vaccine. I was discharged 1/13/2021 at around 1:30 pm. My heart rate is still not at baseline which is 87-90. I'm 100-130 and still get very fatigued with a simple slow walking. Still having tachycardia, fevers, body aches, joint wrist pain, chest discomfort and headaches. My potassium was 3.0 at discharge so will be needing labs in a week. Also bruised a little different than I usually do with lab draws so keeping an eye on them and will be checking my platelets again in a week. Ive been taking tylenol for my fever and pain and ativan for any anxiety when my heart rate goes up. (treatment during hospital stay was normal saline bolus, nomal saline maintenance fluids at 150 cc/hr, tylenol, ativan, ice packs, rest)

Fever, joint pain, weakness. Pain at the injection site.

No reactions immediately after vaccine was given. Resident has dementia, has had multiple hospitalizations related to a renal stone recently. Had a tooth that was bothering her, went to see her dentist and it was extracted on 1/6/21. On 1/10 they noted feet and ankles are dark purple with white splotches appears to be mottling. Minimally responsive to voice and touch. Not eating. Compassionate visit with family. Family did not want hospice, did not feel it was needed, said, what more could they do for her than you're already doing? On 1/11 at 1950 was determined to be deceased.

Anaphylaxis- throat tightness , nausea , rash , pruritis , chest tightness, wheezing . 9-11 called epinephrine x 2 , decade on , IV Benadryl , duo-nebs, famotidine, admission to icu high dose prednisone , nebulizers , zofran , duo-neb nebulizers

Had no immediate issues with the vaccine. He had returned from the hospital on 12/21 and had some concerns about his weight which were shared with his physician on 1/4/21. On 1/5/21 had a visit with his cardiologist for a pacemaker check. On 1/8/21 staff were called to his room, he was on the floor, bluish skin color. No vital signs found, no heart rhythm heard at 2200.

Had COVID infection 10 days after the getting the vaccine; Had COVID infection 10 days after the getting the vaccine; This is a spontaneous report from a contactable physician. A 48-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number: EK5730), intramuscular in right arm on 24Dec2020 09:00 at a single dose for Covid-19 immunization. Medical history was reported as none. The patient's concomitant medications were not reported. The patient was not pregnant at the time of vaccination. Patient did not receive any other vaccines within 4 weeks prior to Covid vaccine. The patient was not diagnosed with Covid-19 prior to vaccination. Patient has no allergies to medications, food, or other products. Physician would like to know if her patient can receive second dose of vaccine. Patient received vaccine 10 days ago. On 05Jan2021, the patient had Covid infection 10 days after the getting the vaccine. No treatment was received for the event. Patient tested positive for Covid after receiving vaccine. The patient underwent lab test which included nasal swab: positive on 04Jan2021. The outcome of the event was recovering.; Sender's Comments: Based on the information available, a possible contributory role of the suspect BNT162B2 cannot be excluded for the reported COVID 19 infection based on the known safety profile. However the short duration of 10 days since the vaccine first dose is given it is unlikely patient would have fully developed immunity.

Caller received the first dose of covid 19 vaccine and tested positive for covid.; Caller received the first dose of covid 19 vaccine and tested positive for covid.; Caller received the first dose of covid 19 vaccine and tested positive for covid.; This is a spontaneous report from a Pfizer-sponsored program Pfizer First Connect. A contactable other health professional (patient) reported that a female (age: 22; unit: not reported) patient of an unspecified age received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient received the first dose of COVID 19 vaccine and tested positive for COVID on an unspecified date. She was under quarantine and wanted to know when and if she should get the second dose. Due date for second dose is 11Jan2021. The patient underwent lab tests and procedures which included Covid-19: positive on an unspecified date. The outcome of event was unknown. Information on the lot/ batch number has been requested.; Sender's Comments: The association between the event lack of effect (Covid-19 test positive) with BNT162b2 can not be completely excluded.

had her 1st dose of Covid vaccine yesterday and started experiencing all expected side effects today including lost of smell and taste/ Rapid PCR Test which came back positive; had her 1st dose of Covid vaccine yesterday and started experiencing all expected side effects today including lost of smell and taste/ Rapid PCR Test which came back positive; This is a spontaneous report from a contactable nurse (patient). A female patient of an unspecified age received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date not provided), via an unspecified route of administration on 07Jan2021 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient had her 1st dose of COVID vaccine yesterday, 07Jan2021 and started experiencing all expected side effects today (08Jan2021) including loss of smell and taste. She also had a Rapid PCR test done today which came back positive. She wanted to know if this could be a false positive result from the vaccine. The outcome of the events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of events Drug ineffective and COVID-19 cannot be totally excluded. The case will be reassessed if additional information becomes available.

It felt like a viral meningitis; arm soreness; feel some tension; migraine headache; body started shaking; chills/Rigors; temperature 104; I had sensitivity that I never had; headache; photophobia; Sinophobia; paresthesia/tingling sensation along my upper extremity; I felt like I was freezing; I didn't feel comfortable; vertigo; nausea; hard time to focus; This is a spontaneous report from a contactable other health professional (patient himself). A male patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration in Jan2021 at single dose for covid-19 immunization. The patient's medical history and concomitant medications were not reported. He didn't have any allergies. He was in good health, no underlying issue. He never had a surgery. In Jan2021, patient got the vaccine last night around. It started with arm soreness. Around 10:00 am he started to feel some tension, migraine headache. Around 11:00 he felt his body started shaking. He had chills, rigors and temperature 104. For 5-6 hours he had sensitivity that he never had. Patient had a headache, photophobia, sinophobia, paresthesia and tingling sensation along his upper extremity. he

felt like he was freezing. He didn't feel comfortable. It resolved afterwards, he felt no weakness, no facial paralysis. It felt like a viral meningitis. He also had vertigo, nausea and hard time to focus. Outcome of events were unknown. Information about lot/batch number has been requested.; Sender's Comments: Based on the temporal relationship, the association between the event viral meningitis with BNT162b2 can not be fully excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

"I have latent TB and am diagnosed with herpes 1 and 2; I have latent TB and am diagnosed with herpes 1 and 2; This is a spontaneous report from a contactable other health professional. A female patient of an unspecified age received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 11Jan2021 at single dose for covid-19 immunization. Patient had the first dose of the vaccine on 11Jan2021 and she/he had pre-existing conditions. A long time ago, she/he had 2 tachycardia episodes and was sensitive to epinephrine. Patient had latent TB and was diagnosed with herpes 1 and 2 in Jan2021. Outcome of events were unknown. Information about lot/batch number has been requested.; Sender's Comments: The association between the events ""latent PTB and Herpes 1 and 2"" with BNT162b2 can not be completely excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate."

difficulty breathing and stridor; difficulty breathing and stridor; noises on inspiration; dizziness; headache; sore throat; Anaphylaxis developed within 2 hours of injection; This is a spontaneous report from a contactable other health professional (patient). A 57-year-old female patient (not pregnant) received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (lot number EL0142), via an unspecified route of administration in arm left on 08Jan2021 09:00 at single dose for covid-19 immunisation. Medical history included Idiopathic Angioedema, Hypothyroidism. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient did not have COVID tested post vaccination and did not have COVID prior vaccination. The patient's concomitant medications were not reported. Reported Event: Anaphylaxis developed within 2 hours of injection. 9:00 am injection; 9:05 am Developed sore throat, 9:20 am Developed dizziness and headache, 10:00 am developed noises on inspiration, 10:20 am Presented to Emergency Services, 10:40 am IV (intravenous) diphenhydramine (BENADRYL) and dexamethasone (DECADRON), 10:45 am difficulty breathing and stridor, 11:00 am intramuscular Epinephrine, 11:10 am Racemic Epi Nebulizer, 11:20 am Breathing improved, 14:00 Discharged home. The adverse events result in Emergency room/department or urgent care. The outcome of all the events was recovering.; Sender's Comments: A possible causal association between administration of BNT162B2 and the onset of anaphylaxis reactions considering the plausible temporal relationship and the known adverse event profile of the suspect product. The underlying predisposing condition included Idiopathic Angioedema. The impact of this report on the benefit/risk profile of the

Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Receives dose #1 of the covid vaccine and contracts covid prior to dose #2; Receives dose #1 of the covid vaccine and contracts covid prior to dose #2; This is a spontaneous report from a contactable physician via Pfizer sales representative. This physician reported similar events for two patients. This is 2nd of two reports. A patient of unspecified age and gender received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot/batch number and expiry date were not provided) solution for injection, via an unspecified route of administration on an unspecified date at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. It was reported that patient received dose #1 of the COVID vaccine and contracts COVID prior to dose #2 on an unspecified date. The patient underwent lab test which included Covid-19 test in which he/she tested positive on an unknown date. Outcome of the events was unknown. Information about batch/lot number has been requested.; Sender's Comments: A causal association between BNT162B2 and the reported events cannot be excluded based on a compatible temporal relation between vaccination and onset of events. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate. ,Linked Report(s) : US-PFIZER INC-2021012928 Same reporter/drug/event, different patient

"My heart rate, I was like in AFib; very high fever of 103; dizzy, light headed; arms sore; exhausted like an extreme fatigue; palpitations; This is a spontaneous report from a contactable consumer (patient). A 38-year-old female patient received the bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot Number: EH9899), via an unspecified route of administration on 30Dec2020 at 38-years-old at a single dose for COVID-19 immunization. Medical history included blood clotting disorder from an unknown date and unknown if ongoing. The patient experienced the following events and outcomes: my heart rate, I was like in AFib (medically significant) on 31Dec2020 with outcome of recovering, very high fever of 103 (non-serious) on 31Dec2020 with outcome of unknown, dizzy, light headed (non-serious) on 31Dec2020 with outcome of unknown, arms sore (non-serious) on 31Dec2020 with outcome of unknown, exhausted like an extreme fatigue (non-serious) on 31Dec2020 with outcome of not recovered, palpitations (non-serious) on 31Dec2020 with outcome of not recovered. The clinical course was reported as follows: The patient stated, ""the day after the shot I got a very high fever of 103. I was dizzy, lightheaded. My heart rate I was like in AFib, it was going from 60s to 50s all over the place. And this was the next day after the vaccination. That evening nothing my arms was just sore. But the next day all of these side effects just started in and even still today I just feel so exhausted like an extreme fatigue and I am still getting like palpitations."" The patient stated, ""So I went to urgent care and they check my vitals and stuff and when they wanted me to send me to the hospital. But I told them I will get a ride and I go by myself just because I didn't want, capable of an ambulance ride and I ended up just going home because I couldn't get a hold up anybody. So, I came home and took my blood thinner

medication because I do have blood clotting disorder."" In regard to the outcomes of the events, the patient stated, ""I am not experiencing all of them still definitely my heart is much better. I am still getting palpitations but nothing near how it was that first day. I am experiencing extreme fatigue."""

received the vaccine on 17Dec2020 the next dose is today but during this time she was positive for covid; received the vaccine on 17Dec2020 the next dose is today but during this time she was positive for covid; This is a spontaneous report from a Pfizer-sponsored program, Pfizer First Connect. A contactable nurse reported for herself, a female patient of an unspecified age who received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date unknown), via an unspecified route of administration on 17Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. It was reported that patient received the vaccine on 17Dec2020, the next dose is today (07Jan2021) but during this time she was positive for covid since an unspecified date. She was asking if she would take the second vaccine or if she needed to be revaccinated with the first dose. She was also asking what should she do. The outcome of the events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: The association between the event lack of effect (positive for COVID) with BNT162b2 can not be fully excluded.

"received first dose of bnt162b2/ symptoms started on the 26th (26Dec2020) but did not test positive until the 29th (29Dec2020); received first dose of bnt162b2/ symptoms started on the 26th (26Dec2020) but did not test positive until the 29th (29Dec2020); This is a spontaneous report from a Pfizer-sponsored program via a contactable nurse (patient). A 61-year-old female patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE; lot/batch number: VAC0002881; expiration date not provided), via an unspecified route of administration on 17Dec2020 at SINGLE DOSE for COVID-19 immunisation. Patient's medical history included hypothyroidism and osteoporosis from unknown dates, both ongoing. Concomitant medications included levothyroxine for hypothyroidism and alendronate sodium (FOSAMAX) for osteoporosis. Patient reported that her symptoms started on the 26th (26Dec2020) but did not test positive until the 29th (29Dec2020). Patient further stated ""She received the first dose of Pfizer vaccine last 17Dec (17Dec2020) and 26Dec she was positive with COVID (later clarified of tested positive on 29Dec2020) because of someone else, it seems that it has been transferred, the virus has been transferred to her and then after a few days she got fully recovered, no symptoms, just fully recovered. She is just asking if she really need the second dose of vaccine if she is fully recovered right now."" It was reported that patient did not receive treatment for the event. Laboratory test included COVID-19 virus test on 29Dec2020 with positive result. Outcome of the event was recovered.; Sender's Comments: Based on the information currently available, lack of efficacy of the suspected vaccine BNT162B2 cannot be completely excluded. However, individuals may not be protected until at least 7 days after their second dose of the vaccine. It is unlikely that the patient would have fully developed immunity due to the very short time lag between the first vaccine dose and the event onset."

Tested positive for Covid, 10 days after receiving the vaccine; Tested positive for Covid, 10 days after receiving the vaccine; This is a spontaneous report from a contactable consumer. A patient of unspecified age and gender started to receive bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE; Solution

for injection, lot number and expiry date were not reported), via an unspecified route of administration on an unspecified date at a single dose for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient tested positive for COVID on an unspecified date 10 days after receiving the vaccine. The patient underwent lab tests and procedures which included Covid test: positive on an unspecified date. The outcome of the events was unknown. The information on the batch/lot number has been requested.

coughs once in a while, may be a nervous cough every 40 min; voice hoarse; tested positive for Covid-19; tested positive for Covid-19; didn't feel well at all; bad headache; dry cough; This is a spontaneous report from a contactable consumer who reported for himself, a 70-year-old male patient who received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, lot number and expiration date unknown), via an unspecified route of administration on 06Jan2021 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient stated that he received the first dose of the Pfizer-BioNtech Covid-19 vaccine on Wednesday, 06Jan2021, and on that day he had no problem. On Thursday, 07Jan2021, he started experiencing dry cough. On Friday, 08Jan2021, he didn't feel well at all and had a bad headache. On Saturday, 09Jan2021, he felt better but he tested positive for Covid-19. Today, 11Jan2021, he stated he feels good, he coughs once in a while, may be a nervous cough every 40 min. He had not experienced fever or chills, he breathes well, he can hold his breath for 5-10 seconds, no chest pain or congestion, but his voice was hoarse. Patient wanted to know if this has been reported before, and wanted to know how long should he test himself again for Covid-19. The events were reported as non-serious. The outcome of the events was unknown. Information about lot/batch number is requested.

I was exposed to Covid-19 4 days after and tested + 9 days after dose #1; I was exposed to Covid-19 4 days after and tested + 9 days after dose #1; I was exposed to Covid-19 4 days after and tested + 9 days after dose #1; This is a spontaneous report from a contactable female nurse (patient) via Pfizer sponsored program. A female patient of an unspecified age received bnt162b2 (BNT162B2) on 26Dec2020 at single dose for Covid-19 immunisation. The patient medical history and concomitant medications were not reported. The patient was exposed to Covid-19 4 days after on 30Dec2020 and tested + 9 days after dose #1 on 04Jan2021. The outcome of events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Based on the information available, a possible contributory role of the suspect products cannot be excluded for the reported event of positive for corona virus infection for the lack of efficacy of the vaccine. However, based on the mechanism of action of the vaccine, it is unlikely the patient would have fully developed immunity for the vaccine to be effective, due to the number of days passed since the vaccine is given. Case will be reevaluated based on follow-up information

positive for covid19; positive for covid19; got or felt sick; This is a spontaneous report from a contactable physician reported for self and consumer. This 51-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on Dec2020 at single dose for covid-19 immunisation. As soon as patient got vaccine she got or felt sick in Dec2020 and had the test and finds out she was positive, so she stays home two weeks and doesn't have no symptom at all and wants to know when has to take a test. The day after the patient developed symptoms thought it was the

vaccine, but the symptoms continued for 2-3 days, the 3rd day the patient got herself tested. The patient was positive for covid19 at the time had the shot/ as soon as she got vaccinated she became positive. The patient hasn't had any symptoms for the past 2 weeks. The patient was scheduled to get retested. The patient was scheduled for 2nd dose of vaccine. The patient asked if there are any risks since developed covid the day after getting the vaccine. What if miss today. The patient wanted to know time after having no symptoms past two weeks, when she has to take a test. Outcome of the events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Test positive for covid19 found as soon as following the vaccination, no adequate effect of the suspect vaccine thus could be reasonably achieved to protect from the targeted infection/disease due to the very short time lag.

I've got the 1st dose of vaccine and then unfortunately, in the interim, I started feeling sick and tested positive for Covid.; I've got the 1st dose of vaccine and then unfortunately, in the interim, I started feeling sick and tested positive for Covid.; This is a spontaneous report from a Pfizer-sponsored program, received from a contactable consumer (patient). A male patient of an unspecified age received his first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot/batch number and expiry date were not provided) solution for injection, via an unspecified route of administration on an unspecified date at a single dose for Covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient reported he got the 1st dose of the vaccine and then unfortunately, in the interim, he started feeling sick and tested positive for Covid. The patient underwent Covid test and resulted positive on an unknown date. Outcome of the event was unknown. No follow-up activities are needed. No further information is expected.

13 people, who were applied the vaccine previously, were corona positive after a week; 13 people, who were applied the vaccine previously, were corona positive after a week; This is a spontaneous report from a non-contactable consumer. This consumer reported similar events for 13 patients. This is 12th of 13 reports. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Solution for injection; lot number and expiration date: not known), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. It was reported that 13 people, who were applied the vaccine previously, were corona positive after a week on an unspecified date. The outcome of the events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021018407 same reporter, similar suspect drug and event; different patient

Positive COVID-19 test with symptoms; Positive COVID-19 test with symptoms; This is a spontaneous report from a Pfizer-sponsored program, from a contactable nurse (patient). A 35-year-old female patient (weight 55.79 kg, height 160 cm) received the first dose of BNT162B2 (Pfizer-Biontech Covid-19 Vaccine, Lot. EK5730) intramuscularly, in the left deltoid, at single dose, on 23Dec2020 at 12:30, for COVID-19 immunisation. The patient had not received any other vaccines within 4 weeks prior to the BNT162B2 vaccine. Relevant medical history and concomitant medications were none. On 25Dec2020, the patient felt extremely tired (fatigue). On 28Dec2020, the patient had headache and minor cough noticed. On 29Dec2020, the patient experienced back pain and she said that it felt like sunburn soreness

more than anything else. She said that she literally slept 3 days in a row (29Dec2020, 30Dec2020, and 31Dec2020). On 31Dec2020, the patient lost her sense of smell and developed dizziness. On 01Jan2021, the patient experienced nausea and lost her sense of taste. COVID-19 virus test was found positive on 01Jan2021.The patient recovered from back pain, sunburn and sleepy on 31Dec2020, recovered from tiredness on 01Jan2021, recovered from nausea and dizziness on 06Jan2021. Clinical outcome of the events, smell loss, cough, headache, and loss of taste was recovering. Final clinical outcome of positive COVID-19 test with symptoms was unknown at time of this report. The case was assessed as serious (medically significant). She is scheduled to get 2nd dose of BNT162B2 (Pfizer-Biontech Covid-19 Vaccine) on 13Jan2021 and is wanting to know if she is supposed to get it.; Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of events Drug ineffective and COVID-19 cannot be totally excluded. The case will be reassessed if additional information becomes available.

Received Covid vaccine and tested positive for Covid 10 days after; Received Covid vaccine and tested positive for Covid 10 days after; This is a spontaneous report from a contactable consumer. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number and expiry date were not reported), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient received COVID vaccine and tested positive for COVID, 10 days after on an unspecified date. The patient underwent lab tests and procedures which included sars-cov-2 test: positive on an unspecified date. The outcome of the events was unknown. Information on the lot/batch number has been requested.

started with left sided lower back pain; This is a spontaneous report from a contactable Nurse (patient). A 22-year-old female patient received the first dose of BNT162B2 (lot number: EH9899), via an unspecified route of administration at left arm on 16Dec2020 13:45 at single dose for covid-19 immunization. Medical history included allergies for All fish. The patient's concomitant medications were not reported. The patient had the first covid vaccine on 16Dec2020 and on 20Dec2020 started with left sided lower back pain. The event resulted in Doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care, Hospitalization (2 days), Life threatening illness (immediate risk of death from the event). The patient received the Heparin drip and xarelto at home for the event. The patient was not pregnant. The patient received the covid test post vaccination on 09Jan2021. Test type was Nasal Swab. The result was negative. The outcome of the event was recovered with sequel on unspecified date.; Sender's Comments: From the information provided it is unclear what is the nature of the reported event and what are the reasons that have put the subject at immediate risk of death. The event is considered possibly related to the suspect product based on the positive temporal association.

throat closing up; struggled the breath; This is a spontaneous report from a contactable consumer (patient). A 44-year-old female patient (non-pregnant) received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: Pfizer EL 3302), via an unspecified route of administration on 09Jan2021 07:30 am at single dose at left arm for covid-19 immunization. Medical history included diabetes, high blood pressure, allergies. The patient's concomitant medications were

not reported. Patient didn't receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient was not diagnosed with COVID-19 prior to vaccination. Since the vaccination, patient has not been tested for COVID-19. On 10Jan2021 14:30, patient woke up with throat closing up and struggled the breath. Patient immediately drank a dose of diphenhydramine hydrochloride (BENADRYL). Patient did that two more time in the evening of 10Jan2021. Patient called the doctor in the morning. Events were considered serious per life-threatening. The adverse events resulted in doctor or other healthcare professional office/clinic visit, life threatening illness (immediate risk of death from the event). Patient received treatment liquid diphenhydramine hydrochloride, epinephrine (EPI-PEN) for events. Outcome of events was recovered in Jan2021.

chills; body aches; fever; flu like symptoms; headache; was drenched in sweat; This is a spontaneous report from a contactable nurse (patient). A 46-year-old female patient received the second dose of BNT162b2 (lot: EL1283), via an unspecified route of administration in left deltoid on 09Jan2021 15:30 at single dose for covid-19 immunization. Medical history included asthma from Dec2019 and ongoing, insomnia, hypertension. Concomitant medication included ongoing hydrochlorothiazide, metoprolol tartrate (LOPRESSOR HCT) for Hypertension. The patient previously took lopressor and experienced edema. The patient previously received the first dose of BNT162b2 (Lot number: EK5730), intramuscularly in right deltoid at single dose on 19Dec2020 for covid-19 immunization. The patient experienced fever, chills, flu like symptoms, headache all day long on 10Jan2021. The above events were reported as serious as medical significant. No nausea or diarrhea. She had chills and was drenched in sweat on 10Jan2021. She woke up at 10:30 am with chills, body aches on 10Jan2021. Last night at 10 pm she finally fell asleep. She woke up this morning (11Jan2021) and felt fine. The outcome of the event sweating was unknown, other events was recovered on 11Jan2021.; Sender's Comments: Based on a close temporal relationship there is a reasonable possibility of an association between the events and the product. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

Moderna COVID-19 Vaccine At 2 PM I went blind in my left eye. Went to emergency room at Hospital Was told I have Blood clot in my eye causing the blindness and Ophthamologist says it will probably be permanent

At approximately 10:30pm on 1/14/2021, resident was noted to have a rash on her face, hands, arms, and chest. VS:100.2, 113, 20,108/59, 84% room air. applied nasal cannula at 4-L, telephoned Physician orders 6mg Decadron one time order, a second set of Vitals , reads 99.3, 110, 20, 106/60, 90% on 4-L N/C. On coming shift advised. At approximately 2:00am on 1/15/2021, resident congested and coughing. BP 151/70, pulse 124, temp 98.1 forehead, resp 20 and pulse oc 79% on 3L. At approximately 2:30am PRN cough syrup and breathing tx. Resident's condition began to worsen with breathing tx. This LPN updated at 0248 doctor on resident's condition. Doctor gave permission for resident to go to hospital. At 4:19am the Er called to say resident passed away.

THAT EVENING BETWEEN 10-11 PM HAD A GRAND MAL SEIZURE AND WAS UNRESPONSIVE. TAKEN TO ER WHERE BLOOD WORK WAS DONE AND CT SCAN. SENT HOME AROUND 6:30 AM ON JAN 1ST. (I DO NOT REMEMBER MUCH JUST WHAT MY FAMILY HAD TOLD ME) . I DO REMEMBER BEING SEVERLY SICK WITH VOMITING IN THE ER. CURRENTLY FOLLOWING UP WITH MY FAMILY MD AND HAVE MRI AND EEG TESTS SCHECULED WITHIN THE NEXT COUPLE OF WEEKS.

51 year old M with h/o O2 dependent COPD, Severe pulmonary fibrosis became increasingly hypoxic around 1800hours 1/7/2021. He was transported to hospital for acute on chronic hypoxia respiratory failure. On 1/12/2021 he decompensated further, and after discussing with family and palliative care, He was changed to comfort care. He expired on 1/12/2021@2325 at medical center.

Maybe 1 minute after receiving the vaccine I began to have a syncopal episode, the nurse practitioner thought that since I was heavy I began to have a vasovagal reaction. From there they asked me to sit with the others waiting 15 minutes to make sure they were ok to leave. As I sat the symptoms would come and go, as if in a pattern, and then return. The longer I sat there the more the symptoms began to grow, after sitting for an hour they decided to send me to the ER. At this time I was experiencing nausea, vomiting, sweating, I was itchy, I could not stop coughing, it was difficult to breath, and I had the worse headache. When I got to the ER they gave me drugs to reverse the allergic reaction and told me they would watch me for a while. In the next 4 hours all of the symptoms started again and I had to get another round of the reaction drugs, I ended up going through this process 4 times before I was safe enough to go home the next day. The provider that saw me and admitted me did not do any blood work or labs, they simply provided me with the reaction drugs when needed and my home medications.

Increased lethargy on 1/14/21 at 9pm, Vital signs-106/66, Heart rate-112, temp 98.2; Sent to ER for eval admitted with fever.

On 1/8 she took her 2nd dose of Pfizer vaccine around 3 PM. She went home in the evening and started sweating. She passed out. Her daughter was at home and she took her to the nearest hospital. Her BP was 60/34 and she had a temp of 100.3F on 1/8 during hospital admission. Her K was low. She received lot of fluids. She called our office on 1/10 and during the f/u she was still in the hospital. On 1/10 she has a temp of 98.4F and BP of 109/61. But she still has dizziness, nausea, anorexia and mild cough (Former smoker). COVID-19 test was done on 1/9, its negative. Dx was dehydration. Discharged from the hospital on 1/11, feels better but is tired. Will follow up with PCP on 1/16/21.

anaphylaxis by lethargy, nausea, vomiting, palpitations, funny feeling in chest, swollen lips

"Patient received Pfizer COVID-19 vaccine without any immediate complication on 1/14/21approx 1455, was then escorted to observation area for a 30 minute observation time. Pt had previously had a known reaction to contrast media. Approximately 5 -8 minutes into observation, pt had one audible cough. Nurse asked patient if this was a new onset cough. The patient stated she would try to ""manage"" cough. Pt escorted to bay for monitoring. Pt developed shortness of breath and wheezing rapidly. Rapid response team called and local 9-11 also called. Pt received albuterol nebulizer treatment, placed on O2 at 8L. O2 sat 99%, HR 115-120. Respiratory therapy assisted and Rapid Response Team monitored pt while waiting for EMS. Physician order to give Epinephrine 0.3 mg IM in right deltoid, given as directed

at approx 1515. Second epinephrine 0.3 mg IM given approx 1530-1535. HR 144, O2 sat 99%. Patient transported to local ER, pt intubated approx 1927."

Received the 2nd vaccine at 10am on 1/11/21 intramuscular in the right arm. At 3pm on the same day, I had a painful swolle lymph node on left side of neck. That same evening I developed pain, swelling, in my right armpit radiating to the right upper breast and down my right arm with a swollen lymph node under the right arm pit. The pain was about a number 7 on a scale of 1 to 10. The pain and swelling still persist today on 1/15/2021 Still painful, especially to touch. Still radiating down the arm. Lymph node still swollen The pain is about a 2 on a scale of 1 to 10

Rash, swollen tongue and 2 seizures. Admitted to hospital with diagnosis of seizure and allergic reaction.,

7:00PM fatigued, burning up fever 100., ibuprofen/tylenol dose; Sunday afternoon nausea, loss control of body, anxious, feeling of fainting, unable to move-paralyzed, pressed button for medical help, ambulance arrived, pt transported to ER -- 102. temp ambulance, RN at hosp temp 98., pt was shaky, 8:30PM erratic heartbeat per admitting doctor - pt admitted. Pt PCP/Cardiologist contacted, kept on heart monitor, pt discharged Monday afternoon. 1/14/21 chest pain, nausea, 102. fever. symptoms

#Right parietal/temporal subarachnoid hemorrhage and right intra-axial hemorrhage CT brain (1/12/21): Right parietal intra-axial hemorrhage toward the convexity measuring 2.3 x 1.1 x 1.7 cm with decompression into the subarachnoid space, mild right predominantly temporal and parietal subarachnoid hemorrhage is seen with minimal associated hemorrhage along the tentorium. Mild diffuse right cerebral sulcal effacement with minimal leftward midline shift measuring 2.5 mm. #Dural sinus thrombosis CTA head (1/11/21): Increased density within the superior sagittal sinus, inferior sagittal sinus, and transverse sinuses on noncontrasted images with no flow seen on postcontrast sequences consistent with venous sinus thrombosis #Left sided weakness 2/2 above #Recent jaw alignment procedure

Patient developed headache and nausea on 1-11-2021. She was hospitalized on 1-14-2021 at Hospital. Found to have dural sinus thrombosis of the superior sagittal and right transverse/sigmoid sinus on MRV brain. Currently admitted to ICU at Hospital, getting injectable blood thinners. Neurology and hematology have been consulted.

Hospital Course: á Patient is a 43 y.o. female patient who originally presented to the hospital on 1/3/2021 due to Left lower extremity pain and swelling. Patient found to have extensive DVT of left lower extremity and started on heparin drip. Vascular was consulted and recommended thrombolysis. Patient was also seen by IR who took patient for thrombectomy and left iliac stent placement on 01/05/2021. Patient tolerated procedure well. Patient was transitioned from heparin drip to Eliquis upon discharge. Patient given vascular follow-up as well as Hematology follow-up.

Sudden death 18 hours post vaccine .

Onset of shortness of breath and cough on 1/3 that progressively got worse. Clinical diagnosis of pneumonia without fever was made, patient started azithromycin on 1/5 and albuterol treatments every 4-6 hrs. Initially he improved, but then worsened. chest xray on 1/6 was negative for pneumonia, PCR covid test was negative, albuterol treatment did not bring much relief. He started respiratory distress on 1/10 and was taken by car to the local ER where another covid test was negative and chest CT revealed multiple bilateral pulmonary emboli. The leg US revealed blood clots in both of his legs. He had an emergency catheter-delivered thrombolysis and was discharged home from the ICU on 1/12 on oral anticoagulants. He is gradually improving, but very weak. He tires easily and gets a drop in oxygen to 90- 93%, as well as an increase in the heart rate to 120 when walking less than half a mile. He runs out of breath with exertion.

Patient developed a hoarsenss of voice and tightness of throat and flushed feeling immediately following vaccination. Epi Pen was administered and 50 mg Benadryl given p.o., EMS transport to ED after administration of solumedrol 125 mg - received Pepcid and Zofran and NS IV in the ED. Discharged from ED with prednisone 40 mg daily x 4 day with Epi Pen prescription.

Resident received Moderna vaccine on 12/23/2020 around 5 pm. At approximately 3:35 am on 12/25/2020, resident had a CVA and died on 1/1/2021 at 3:00 am.

"it hard to inject; some came out and squirted down her arm; some came out and squirted down her arm; he did not get the full 0.3mL dose; This is a spontaneous report from a contactable nurse (patient). A 74-year-old-female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot EK9231) via Intramuscular on 05Jan2021 13:00 at single dose in the left arm for COVID-19 immunisation. Medical history included COPD and high cholesterol. Concomitant medications included Symbicort for COPD. Patient took COVID vaccine (Verbatim) since precaution as frontline healthcare worker. On Tuesday, she received the first dose of the Pfizer COVID Vaccine. The nurse who was injecting found it hard to inject, and at the end of the injection, it came back and squirted down her arm. It was a decent amount. She is unable to say if she got 0.1ml, 0.2ml, but she certainly did not get full 0.3ml. The hospital said they are just going to go ahead and give her the second dose, but she wanted to call and find out what would be the safest thing. Would it be best to receive another dose or go ahead with the second dose or get a third dose. She is due in 2 1/2 weeks to get second dose. She also has COPD and is a little more concerned than if she were 25 years old. There was no prescriber provided. When asked about other medications, she stated she has a list of medications, but did not think they were relevant. She was diagnosed with COPD last year and had a series of test. Reporter seriousness for ""it came back and squirted down her arm"" is medically significant. Outcome of events was unknown.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the reported events due to temporal relationship. There is limited information provided in this report. This case will be reassessed once additional information is available."

positive COVID-19 test with symptoms; positive COVID-19 test with symptoms; This is a spontaneous report from a contactable nurse (patient). A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number and expiry date were not reported), via an

unspecified route of administration on 23Dec2020 at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient received her first dose on 23Dec2020 and was subsequently exposed at work to the virus and became symptomatic and tested positive on 31Dec2020. Her next scheduled dose is on Sunday, they may have to reschedule. The patient queried on how long should they delay the next dose. The patient underwent lab tests and procedures which included sars-cov-2 test: positive on 31Dec2020. The outcome of the events was unknown. Information about Lot/Batch number is requested.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the reported events of suspected Covid-19 infection and suspected LOE due to temporal relationship. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

fainting spell; almost passed out; dizzy spells; weak; This is a spontaneous report from a contactable consumer (patient herself). A 22-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot: EL3246), via an unspecified route of administration on 07Jan2021 in right upper arm shoulder area at single dose for prevent covid. Medical history included ongoing acne. Concomitant medication included doxycycline from 2020 (taking it 6 months ago) and ongoing for acne. Patient stated that she got the Covid vaccine yesterday 07Jan2021 and almost passed out in her kitchen after a couple hours. Patient stated got in shower had dizzy spells and was weak 07Jan2021, she felt better now. Patient stated that she was a small girl of 105 pounds and the dose could have made her sick. She wanted to make sure she did not need to go and be seen. Patent had another spell in shower this morning and stated that the fainting spell and feeling weak started at 9:00 yesterday evening on 07Jan2021. Outcome of dizzy spells was recovering, and outcome of other events were unknown.

Body chills; fever that went up to 100.4 degrees F.; fatigue; excess mucus; bone pain 10/10; muscle pain 8/10; other vaccine same date vaccine date 05Jan2021; This is a spontaneous report from a contactable other health professional (patient). A 66-year-old female patient (not pregnant at the time of vaccination) received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot/batch number and expiration date not provided), via an unspecified route of administration on 05Jan2021 at single dose for COVID-19 immunization. Medical history included DM type 2, hypertension (HTN), fibromyalgia, chronic asthma, Covid prior vaccination, No Allergies to medications, food, or other products. Concomitant medications received within 2 weeks of vaccination. Facility where the most recent COVID-19 vaccine was administered at Nursing Home/Senior Living Facility. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Other vaccine same date included other vaccine same date product was Pfizer, other vaccine same date vaccine date 05Jan2021. On 06Jan2021, the patient experienced Body chills, fever that went up to 100.4 degrees F., bone pain 10/10, muscle pain 8/10,

fatigue and excess mucus. No treatment received for the adverse events Body chills, fever that went up to 100.4 degrees F., bone pain 10/10, muscle pain 8/10, fatigue and excess mucus. The events were non-serious per the reporter. Prior to vaccination, the patient was diagnosed with COVID-19. Since the vaccination, the patient hadn't been tested for COVID-19. The outcome of the events Body chills, fever that went up to 100.4 degrees F., bone pain 10/10, muscle pain 8/10, fatigue and excess mucus was recovering. No follow-up attempts are possible. Information about Lot/Batch cannot be obtained.; Sender's Comments: A possible causal association between administration of BNT162B2 and the onset of bone and muscle pain cannot be excluded, considering the plausible temporal relationship and the known adverse event profile of the suspect product. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

burning of the tongue; Difficulty in breathing; headaches; Pressure in the chest area; nausea; dizziness; fast heartbeat; tiredness; Had a hard time swallowing at night from the dryness; bitter taste; her mouth went completely dry; patient received 0.45 mL, single dose (225mcg) of PFIZER-BIONTECH COVID-19 VACCINE; This is a spontaneous report from a contactable nurse (patient). A 64-year-old female patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EJ1685), via an unspecified route of administration on 23Dec2020 15:00 at 0.45 mL, single dose (225mcg) at left arm to prevent COVID. Medical history included a bout of dry mouth about 7 years ago, no other relevant medical history (including any illness at time of vaccination). The patient's concomitant medications were not reported. There's no adverse events following prior vaccinations. Patient didn't receive any other vaccines within 4 weeks prior to the COVID vaccine. From the time she got the vaccine her mouth went completely dry on 23Dec2020 and she kept thinking it would go away and she still had it. Event was reported as serious per medically significant. Had a hard time swallowing at night from the dryness. Patient had the bitter taste was also on 23Dec2020, but it went away. It lasted about 5-6 hours. Then after that the dry mouth started right after. It is tolerable but she still had it. Mentioned she had a bout of dry mouth about 7 years ago and it did go away, but she never got a diagnosis for it. Patient thought that something underlying may have triggered it again. Patient also experienced burning of the tongue, tiredness, headaches, pressure in the chest area similar to difficulty in breathing, nausea, dizziness, and a fast heartbeat on unspecified date. Outcome of event dry mouth was not recovered, outcome of event bitter taste was recovered on unspecified date in Dec2020, outcome of other events was unknown. No family medical history relevant to adverse events. No relevant tests. No history of all previous immunization with the Pfizer vaccine considered as suspect. No additional vaccines administered on same date of the Pfizer suspect. The adverse events resulted in neither doctor or other healthcare professional office/clinic visit, nor emergency room/department or urgent care. Relatedness of Pfizer BioNTech Covid-19 vaccine with dry mouth and bitter taste per primary source reporter with method of assessment of global Introspection was related. Reporter seriousness for event bitter taste was not serious.; Sender's Comments: A possible causal association between administration of BNT162B2 and the onset of dry mouth cannot be excluded, considering the plausible temporal relationship. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures

for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

throat tightness; This is a spontaneous report from a non-contactable other healthcare professional (HCP). An 18-year-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot EK9231) via an unspecified route of administration on Jan2021 at a single dose in the left deltoid muscle for COVID 19 vaccination. Medical history and concomitant medications were not reported. The patient denied any history of previous adverse reactions to vaccines and denied reaction to her first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) for COVID 19 vaccination on an unspecified date. The patient was seen at a COVID vaccine clinic today for her second dose of the COVID 19 vaccination. She was given the Pfizer vaccination in the left deltoid muscle. During her 15-minute waiting period after the injection, the patient began to experience throat tightness on Jan2021. Treatment included: Benadryl 25mg po (orally) and Solumedrol 125mg IM. The event did not result in death, not life threatening, did not caused/prolonged hospitalization, not disabling/incapacitating, did not cause congenital anomaly/birth defect. The outcome of the event was unknown. No follow-up attempts are possible. Information about lot/batch has been obtained. No further information is expected.; Sender's Comments: A possible causal association between administration of BNT162B2 and the onset of throat tightness cannot be excluded, considering the plausible temporal relationship. Sever allergic reaction is the known risk for the product. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

blood pressure skyrocketed, it was 175/110/Very high blood pressure; almost falling down; Severe fatigue; Dizzy/dizziness; Bad headache/severe headache; Neck pain; This is a spontaneous report from a contactable nurse (reporting for herself). An adult female patient (over the age for 60) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration in an unspecified deltoid on 28Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced dizzy/dizziness, bad headache/severe headache, neck pain on 28Dec2020 and almost falling down, blood pressure skyrocketed (175/110)/very high blood pressure and severe fatigue on 29Dec2020 10:00. Clinical details were reported as follows: After the vaccine the patient was there waiting for 20 minutes and when she got in her car, after about an hour after the patient was really dizzy and was driving and was going to get in the next lane and thank God did not get in an accident. The patient parked and called her family to come pick her up. She had a bad headache, neck pain and dizziness that lasted for an hour. Finally, they came in and took me home. The patient slept for 7 hours. 9 hours after, the headache, neck pain, and dizziness were gone. The next day at 10:00 at work the patient almost fell down and one of the coworkers held her. The patients blood pressure skyrocketed, it was 175/110 and the patient was very dizzy again had severe fatigue. Her blood pressure was high for about 2 hours and slowly came down, but the fatigue lasted for almost a week and it slowly got better. The patient underwent lab tests

and procedures which included blood pressure measurement: 175/110 on 29Dec2020 skyrocketed/very high. The outcome of the events was recovered on an unspecified date. The batch/lot number for the vaccine, BNT162B2, was not provided and will be requested during follow-up.; Sender's Comments: Based on the time association, the possible contribution of suspect BNT162B2 to the event blood pressure increased cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

exposed to my sister/she did not know she had Covid/I tested positive with Covid test; exposed to my sister/she did not know she had Covid/I tested positive with Covid test; This is a spontaneous report from a contactable other HCP (patient). This female patient of unspecified age reported for herself that she received dose one of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number and Expiration date were not reported) on 21Dec2020 00:00 (at unspecified age) as single dose, unspecified route, for COVID-19 immunisation. Medical history and concomitant medications were not reported. The Patient received the vaccine on 21Dec2020 and was exposed to her sister on 22Dec2020 she did not know she had Covid. Patient tested positive with Covid test on 26Dec2020. Patient is scheduled to get second dose 11Jan2021. Lab data included a positive Covid test on 26Dec2020. The outcome of exposed to my sister/she did not know she had Covid/I tested positive with Covid test was unknown. The lot number for the vaccine BNT162B2 was not provided and will be requested during follow up.; Sender's Comments: The information currently provided is too limited to make a meaningful medical assessment hence, the events are conservatively assessed as related to the suspect drug BNT162B2 until further information becomes available. Efficacy of suspect drug however, is documented 7 days after second dose. Patient has received only the 1st dose.

"old scar that I forgot that I have there, it just swelled up really bad; The injection site looked like ""a small pox vaccine,"" in which appear red and scabby with a blue dot in the middle; The injection site looked like ""a small pox vaccine,"" in which appear red and scabby with a blue dot in the middle; The injection site looked like ""a small pox vaccine,"" in which appear red and scabby with a blue dot in the middle; The injection site looked like ""a small pox vaccine,"" in which appear red and scabby with a blue dot in the middle; Injection site began to itch; Injection site soreness; This is a spontaneous report from a contactable nurse (patient). A 50-year-old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL0142 (also reported as EL0140, pending clarification), expiry date: 03Mar2021 (also reported as 31Mar2021, pending clarification), intramuscular on the right arm on 08Jan2021 06:30 at a single dose for covid-19 immunisation. Medical history included heartburn, hot flashes, Grave's disease (father also has Grave's disease), had a thyroidectomy in Dec2015, menopause, weight loss, and appetite control, allergies, compromised immune status (brother and father side with autoimmune), respiratory illness, genetic/chromosomal abnormalities, endocrine abnormalities (including diabetes) and obesity, and diabetes type 2 diagnosed in 2019 (both parents and brother also with diabetes). Concomitant medications included levothyroxine sodium (SYNTHROID) in Dec2015 for Grave's disease and had a thyroidectomy, esomeprazole sodium (NEXIUM

[ESOMEPRAZOLE SODIUM]) on 02Jan2021 for heartburn, phentermine for weight loss and appetite control, estradiol on 02Jan2021 for hot flashes and menopause, medroxyprogesterone acetate (PROVERA) on 02Jan2021 for hot flashes and menopause, prednisone for unexplained whelps (pending clarification), and cimicifuga racemosa (also reported as black cohosh) for hot flashes. The patient previously took metformin and experienced GI upset (she quit taking metformin/it was causing GI upset because they increased dose/current dose is 1,000mg twice daily increased from 500 mg twice daily) and generic levothyroxine sodium and experienced feels like crap. The patient had no previous history of immunization with the Pfizer vaccine. No additional vaccines administered on same date of the bnt162b2. No prior vaccinations within four weeks. The patient wanted to know if she can receive the second dose of the Covid vaccine after experiencing adverse events. On 08Jan2021, the patient experienced some injection site soreness, in which she took TYLENOL for. Around 14:30, she noticed that the injection site began to itch. Around 16:00, the injection site looked like ""a small pox vaccine,"" in which appear red and scabby with a blue dot in the middle. The patient also reported, ""scar that I have on my arm, it is not a reaction, it is an old scar that I forgot that I have there, it just swelled up really bad."" Event injection site looked like a smallpox vaccine was assessed as serious-other medically important condition. No emergency room or physician's office required. Therapeutic measure was taken as a result of injection site soreness. Outcome of the event injection site looked like a smallpox vaccine was not recovered. Outcome of the events injection site soreness, injection site began to itch, vaccination site erythema, vaccination site scab, vaccination site discoloration, and old scar that I forgot that I have there, it just swelled up really bad was unknown.; Sender's Comments: Based on the time association, the possible contribution of suspect BNT162B2 to the event vaccination site discomfort cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate."

Dizzy; headaches; flu feeling; side effects she had were like the COVID symptoms she had, like the chills and everything; lethargic feeling; weak; Nausea; the whole left side of her body went numb including even her vagina; left side of her body was so numb and weird and tingly feeling/left leg went numb; whole left side of face swelled up; left eye turned red; pressure in head; felt like someone squeezing her eyeball out; eye went black/left eye looked bruised/blackness around the eyes; whole face went numb/left side of face slightly numb; bells palsy; allergic reaction; This is a spontaneous report from a contactable consumer (patient). A 44-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration in arm left on 05Jan2021 at single dose for COVID-19 immunization. Medical history included cutaneous t-cell lymphoma from 2017 and ongoing, ongoing cholesterol, ongoing thyroid, covid-19 from Nov2020 to an unknown date not ongoing (lasted about 1-1.5 months; she did not have any breathing problems) and blood cancer. Concomitant medication included bexarotene ongoing for cutaneous T-cell lymphoma, rosuvastatin ongoing for cholesterol, levothyroxine ongoing for thyriod. The patient underwent lab tests and procedures which included COVID 19: positive in Nov2020, found out tested positive around holiday. Clinical course: onset about 26 hours after administered the first dose; onset as soon as she got back to

work next day: 06Jan2021. The side effects were at their worst for at least 24-48 hours. Further described as all side effects occurred only on left side of her body: whole left side of face swelled up on 06Jan2021; left eye turned red on 06Jan2021; whole face went numb/left side of face slightly numb on 05Jan2021; eye went black/left eye looked bruised on 05Jan2021; pressure in head on 06Jan2021; felt like someone squeezing her eyeball out on 06Jan2021, within the first 24-48 hours, her 'left leg went numb'. She called to talk to physician and nurse who advised her to take Benadryl; which she did take and the Benadryl stopped the side effects; but she could not take a lot of Benadryl or anything because she was at work. She stayed at work because at least there were healthcare professionals, adults in case she passed out; at home she has 7 young children and is also raising her grandchild. The side effects did not completely go away. The arm thing was normal; The next day she was at work and had the swelling on left side of face; blackness around the eyes; arriving home she had headaches on 07Jan2021 and then her leg went numb for like 20 mins; the whole left side of her body went numb including even her vagina; left side of her body was so numb and weird and tingly feeling that she started panicking because she was driving on 06Jan2021. She calmed herself down thinking it's only the left side; you can drive with your right side to get home and be fine. It was more like left side of her body was asleep, tingling, she has never had that happen before. Everything else like the headache, flu feeling was about 48 hours later (on 07Jan2021). She had COVID already back in Nov2020 for about 1-1.5 months; the next side effects she had were like the COVID symptoms she had, like the chills and everything on 06Jan2021. She had the lethargic feeling again, her head was hurting, she felt extremely weak on 06Jan2021. Patient also felt nausea on 06Jan2021, Dizzy on 08Jan2021. Another doctor said it sounded like the side effects she experienced with the vaccine sounded like allergic reaction or Bell's palsy. Patient was asking the doctor if she could get like an Epi-pen or prescription Benadryl or something because she is afraid to get the second dose of Pfizer COVID-19 Vaccine and not have something to respond to side effects with. The outcome of event whole face went numb/left side of face slightly numb was recovered on 07Jan2021, for headaches was recovering, chills and nausea was recovered on 08Jan2021. Outcome of other events was unknown. Information about lot/batch number has been requested.

"felt like she had Covid; felt like she had Covid; stomach cramps; chills; aches; not feeling good; temp was around 101- 101.6/fever 102; Icy hot sensation; lethargy; arm was red and swollen; arm was red and swollen; This is a spontaneous report from a non-contactable nurse (patient). A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for covid-19 immunization. Medical history included covid-19 from Jul2020. The patient's concomitant medications were not reported. The patient got her injection on Tuesday (specified date unknown) at 3pm. Felt good but then woke up with stomach cramps. She went to work and at around 1pm she started having chills, aches and not feeling good at 4:30 pm her temp was around 101- 101.6 so she took Tylenol went to bed. She woke up with fever 102 and felt like she had Covid all over again reporting that she had covid in Jul. Having what she has heard described as ""Icy hot sensation"" and lethargy and not feeling good with chills aches. Then on Thursday her arm was red and swollen with the redness expanding swelling and her fever was going back up. The outcome of the events was unknown. No follow-up attempts are possible. Information about lot/batch number cannot be obtained. No further information is expected.; Sender's Comments: Based on the information currently available, the local reactions and flu like symptoms following

vaccination with BNT162B2 are more likely attributed to the vaccine use. Further information like diagnostic detection of virus genetic material or virus protein antigen needed for meaningful medical assessment on protective effects with the vaccine."

"convulsive chills, fever- (high); convulsive chills; fever- (high); all of my muscles and joints were flaring in extreme pain; all of my muscles and joints were flaring in extreme pain; I could NOT move my vaccine arm more than 3 inches and my whole body hurt; my vision was extremely blurry; When I tried to walk, it was slow; achy/whole body hurt; tired, and took a nap; This is a spontaneous report from a contactable consumer (patient). A 54-year-old female patient (no pregnant) received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EL0142) via an unspecified route of administration on the left arm on 05Jan2021 11:00 AM at single dose for COVID-19 immunisation. Medical history included having Covid the 3rd week in Mar2020, Positive for Antibodies in early May2020. Fairly sick but not emergency situation ""Long haulers"" covid symptoms that continued through Nov2020. Patient still had skin pain. Other medical history included hashimoto's. Past drug event included known allergy to codeine. The patient's concomitant medications included 25 mg of Levothyroxine in two weeks. No other vaccine in four weeks. On 05Jan2021 at 12:30, patient felt achy, tired, and took a nap. By 2:00ish. The patient's vision was extremely blurry and continued for 2 days. At 05Jan2021 8 pm- 6 hours later of convulsive chills, fever- (high) and all of her muscles and joints were flaring in extreme pain. Patient could not move vaccine arm more than 3 inches and whole body hurt as if she had been hit by a train. When patient tried to walk, it was slow. Patient groped walls for support. Patient had a televisit with a doctor friend who said this was not a normal side effect and go to emergency room (ER). Doctor or other healthcare professional office/clinic visit. Covid test post vaccination included nasal swab, Covid -19 diagnostic on 08Jan2021 with pending result. No treatment received for events. The outcome of convulsive chills fever was unknown. The outcome of other events was recovered in Jan2021."

tunnel vision; experienced a sudden onset of vertigo; presyncope; My hands became cold and numb; My hands became cold and numb; fatigue; sore arm, leg/thigh aching; sniffles; sore throat; brief dry cough; slight headache; neck ache; This is a spontaneous report from a contactable Nurse (patient). A 34-year-old non-pregnant female patient received the first dose bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), intramuscular on 05Jan2021 at 12:30 at single dose in left arm for covid-19 immunization. Medical history included Mild ADHD/ADD. The patient's concomitant medications were not reported. Approximately 5 minutes after receiving vaccination, she was standing in the observation room (where they had all of them stay for at least 15 minutes to ensure no severe reactions) and experienced a sudden onset of vertigo, tunnel vision and pre-syncope. Her hands became cold and numb and she was trying to talk to another staff member who was arranging/scheduling her second vaccination dose at the same time when this event occurred, but it subsided quickly and she started to feel normal again. All these events occurred at 12:45 on 05Jan2021. She reported this event right away and they had her stay in the room longer. She was stable at that point but experienced these symptoms again but very mildly twice more while she walked back to her car to go home. Other side effects on 05Jan2021 that started in the evening and for the following 2-3 days included fatigue, sore arm, leg/thigh aching, sniffles/sore throat, brief dry cough and slight headache/neck ache. Very mild and tolerable symptoms. All events

were reported as non-serious by reporter. The patient did not receive treatment for the events. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient was not diagnosed with COVID-19 prior to vaccination, and the patient has not been tested for COVID-19 since the vaccination. The outcome of all events was resolved in Jan2021. Information on the lot/batch number has been requested.; Sender's Comments: Based on temporal association, a possible contributory role of BNT162B2 cannot be excluded for reported events. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Experienced vasovagal syncope after standing, resulting in fall; Experienced vasovagal syncope after standing, resulting in fall; Awoke with severe chills; nausea; body/muscle aches; body/muscle aches; left arm pain; extreme thirst; fatigue; This is a spontaneous report from a contactable consumer. A 44-year-old female patient (non-pregnant) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot: EK9231), via an unspecified route of administration on 08Jan2021 14:30 in left arm at single dose for covid-19 immunization. There was no medical history and concomitant medications. Allergies to medications, food, or other products was no. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The most recent COVID-19 vaccine was administered was in hospital. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. On 09Jan2021 01:30 am, patient woke with severe chills, nausea, body/muscle aches, left arm pain, nausea, extreme thirst. Patient experienced vasovagal syncope after standing, resulting in fall. Worst symptoms were lasted about 30 minutes, muscle aches and fatigue continue about 16 hours later. All events were reported as non-serious. No treatment was received for these events. Outcome of all events were recovering.

foggy minded; on first vaccine it made him feel a little sluggish; tired; This is a spontaneous report from a contactable pharmacist. A 36-year-old male patient started to receive BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK5730), intramuscular from 18Dec2020 to 18Dec2020 at SINGLE DOSE for COVID-19 immunisation. Medical history included ADHD. Concomitant medication included amfetamine aspartate, amfetamine sulfate, dexamfetamine saccharate, dexamfetamine sulfate (ADDERALL) and escitalopram oxalate (LEXAPRO). On an unspecified date, the patient stated that on first vaccine, it made him feel a little sluggish, tired and foggy minded. Outcome of the events was unknown.; Sender's Comments: Based on temporal association, a possible contributory role of suspect BNT162B2 cannot be excluded for event mental dullness. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

partial complex seizure; I lost muscle tone and collapsed; severe LUE weakness; severe pain; aura; I lost muscle tone and collapsed; This is a spontaneous report from a contactable other health care professional (HCP) reporting for herself. A 40-year-old female not pregnant patient received first dose of

BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration in the Left arm on 30Dec2020 h 05:00 PM at single dose for COVID-19 immunisation, lot number: EH9899. Patient did not receive any other vaccines within four weeks prior to the vaccination. Prior to the vaccination, the patient was not diagnosed with COVID-19. Medical history included epilepsy (well controlled with medications) and she was allergic to phenytoin (DILANTIN). Concomitant medications in two weeks prior to the vaccination included carbamazepine, lamotrigine (LAMICTAL) and fluoxetine. It was reported that on 31Dec2020 h 14:00 (also reported as approximately 22 hours after vaccine) patient experienced severe left upper extremity (LUE) weakness and severe pain. She then experienced an aura and had a partial complex seizure. Patient lost muscle tone and collapsed. The episode lasted approximately 1.5 minutes, no treatment was given. Patient was tested for Covid post vaccination, she underwent Covid-19 PCR Test (Nasal Swab) on 04Jan2021 and on 07Jan2021, both with negative results. She also underwent a Covid-19 PCR Test on unknown unknown date in Jan2021 with unknown results. Patient recovered on 31Dec2020 from the events.; Sender's Comments: There is not a reasonable possibility that the reported events were related to the suspect product event most likely due to patient underlying contributory factors. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators as appropriate.

spontaneous rupture of membranes at 36-0 weeks; Pregnant at the time of vaccination?: Yes; This is a spontaneous report from a contactable physician. This physician reported information for both mother and fetus/baby. This is the maternal report. A 29-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), intramuscular (left arm) on 18Dec2020 and 08Jan2021 at a single dose for COVID-19 immunization. Medical history included cold sores, no active cold sore at time of labor. On an unspecified date, it was reported that a healthy 29-year-old G1P0 with good prenatal care and no pregnancy complications who had spontaneous rupture of membranes at 36-0 weeks, one day after her second Pfizer CoVid vaccine (09Jan2021). She felt well after her vaccine and had no symptoms today. The mother reported she became pregnant while taking BNT162B2. The patient takes prenatal vitamins. The mother was 33 Weeks pregnant at the onset of the event. The mother was due to deliver on 06Feb2021. Therapeutic measures were taken as a result of premature rupture of membranes. The outcome of the event was recovering. Information about Batch/Lot number has been requested.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the reported event of spontaneous rupture of membranes due to temporal relationship. However, the reported event may possibly represent intercurrent medical condition in this patient. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any

appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Within 15 minutes, I began feeling dry throat; Within 15 minutes, I began feeling dry throat, then itching, then it felt like I had a lump inside my throat.; it felt like I had a lump inside my throat.; Then I began to have difficulty swallowing my saliva.; difficulty breathing; very groggy; This is a spontaneous report from a contactable pharmacist. A 47-year-old female patient received the first dose bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number EL0140), intramuscular in left arm on 20Dec2020 at a single dose for COVID-19 immunization. Vaccination was administered in a hospital. Prior to vaccination, the patient was not diagnosed with COVID-19. Medical history included hypertension, overweight, and known allergies to bee stings and hair dye. The patient's concomitant medication included multivitamins. On 20Dec2020, within 15 minutes, the patient began feeling dry throat, then itching, then it felt like she had a lump inside her throat. Then she began to have difficulty swallowing her saliva. And then the lump inside her throat started to feel larger and larger. By this time, the doctor had already injected the patient with Epipen and the pharmacist injected her with Solumedrol and she still felt as if she was having difficulty breathing and then she was taken to ER and she really can't remember too much after that. The patient was very groggy and then was discharged from ED about 9:30 pm. The outcome of the events was recovered on an unknown date. Treatment for the events included epinephrine, methylprednisolone, diphenhydramine. Since the vaccination, the patient has not been tested for COVID-19.; Sender's Comments: A possible causal association between administration of BNT162B2 and the onset of feeling dry throat, itching, felt like having lump inside her throat, having difficulty swallowing saliva, difficulty breathing and very groggy cannot be excluded, considering the plausible temporal relationship and the known adverse event profile of the suspect product. Severe allergic reaction is the known risk for the product. The underlying predisposing condition of allergies to multiple materials may put the patient at high risk of anaphylactic reactions. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

significant swelling to lymph nodes under armpit of injection side (L arm); This is a spontaneous report from a contactable consumer. A 26-year-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK9231), via an unspecified route of administration at the left arm on 09Jan2021 08:00 at SINGLE DOSE for COVID-19 immunization at a hospital. Medical history included asthma, food allergy with peanuts and pine nuts. No known medication allergy. The concomitant medications included albuterol and unspecified multivitamin. The patient previously took the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899) at the left arm on 19Dec2020 08:00. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient was not diagnosed with COVID-19 prior to vaccination and was not tested for it since the vaccination. The patient was not pregnant. On 10Jan2021 16:00, the patient noted significant swelling to lymph nodes under armpit of injection side, swelling in the left armpit lymph nodes began approximately 32 hours after injection. Swelling measuring approximately size of a ping pong ball. At

time of this reporting (approximately 40 hours post-injection) lymph node swelling still persists, with no change in size. The patient did not receive any treatment for the events. The patient has not recovered from the events. No follow-up attempts are needed. No further information expected.

Patient was tested for Covid post vaccination/ Covid test on 28Dec2020 and resulted positive; Patient was tested for Covid post vaccination/ Covid test on 28Dec2020 and resulted positive; This is a spontaneous report from a contactable healthcare professional (patient). A 40-year-old female patient received her first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK7530) solution for injection, intramuscular on left arm on 16Dec2020 12:00 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient was not pregnant. It was reported that patient was tested for Covid post vaccination. Nasal swab for Covid test was done on 28Dec2020 and resulted positive. Outcome of the event was unknown. No follow up attempts are possible. No further information is expected.; Sender's Comments: Based on the information currently available, a lack of efficacy with BNT162B2 in this patient cannot be completely excluded.

had a metallic taste; turned to swollen tongue; hives around chest and neck; difficult to breathe; tachycardia; This is a spontaneous report from a contactable other HCP (Patient). A 33-year-old non-pregnant female received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number=EL 3248), via an unspecified route of administration at right arm on 07Jan2021 16:15 at single dose for covid-19 immunization. Vaccine was administered at hospital. Known allergies included cyclobenzaprine and dairy latex. Concomitant medication included amfetamine aspartate, amfetamine sulfate, dexamfetamine saccharate, dexamfetamine sulfate (ADDERALL) 10 mg, gabapentin 300 mg, venlafaxine 150 mg. No other vaccine in four weeks. Three minutes after vaccination the patient had a metallic taste, turned to swollen tongue, hives around chest and neck, difficult to breathe, and tachycardia on 07Jan2021 16:18. The events resulted in Emergency room/department or urgent care. Treatment received included Epinephrine, methylprednisolone sodium succinate (SOLU-ME dork) and famotidine (PEPCID) also diphenhydramine HCl (BENADRYL). The outcome of the events was unknown.; Sender's Comments: Based on temporal association, a possible contributory role of suspect BNT162B2 cannot be excluded for events metallic taste, swollen tongue, hives, difficulty breathing and tachycardia. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

tested (COVID-19 virus test) positive after receiving first dose of vaccine; tested (COVID-19 virus test) positive after receiving first dose of vaccine; This is a spontaneous report from a contactable pharmacist. A patient of unspecified age and gender received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number and expiration date not provided) via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunisation. Patient's medical history and concomitant medications were not reported. It was reported that patient tested (COVID-19 virus test) positive after receiving first dose of vaccine. It was also reported that they are looking for administration recommendations following receipt of monoclonal antibodies and interval information. Outcome of the

events was unknown. Information of the lot number/batch number was requested.; Sender's Comments: A causal association between reported event and suspect BNT162B2 cannot be excluded.

really extreme high blood pressure (202/104); feeling very sick; This is a spontaneous report from a contactable consumer (patient). A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration, on 04Jan2021 at a single dose for COVID-19 immunization. Medical history included strokes and bleeding disorder (gene that makes blood clot). The patient's concomitant medications were not reported. The patient experienced really extreme high blood pressure (202/104) and feeling very sick on an unspecified date. The clinical course was reported as: The patient received the vaccine on 04Jan2021 and experienced a lot of side effects, the most concerning of which was really extreme high blood pressure. The patient went to the emergency room (ER) on an unspecified date and her blood pressure was 202/104 on an unspecified date. The patient stated that she had been very sick and in bed for days. The patient had a follow-up appointment with her doctor on the day of the report. The clinical outcome of really extreme high blood pressure (202/104) and feeling very sick was unknown. The batch/lot number for the vaccine, BNT162B2, was not provided and has been requested during follow up.

tested positive for COVID; tested positive for COVID; This is a spontaneous report from a contactable nurse (patient). A 64-year-old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK5730, expiration date: 31Mar2021), via intramuscular on 21Dec2020 at 0.3 mL single in left deltoid for preventative. Medical history included she only had one kidney from 25Feb2020. There were no concomitant medications. It was reported that the patient was supposed (was scheduled) to get her second dose today (11Jan2021) but this past weekend she tested positive for COVID on 09Jan2021. The patient wanted to know if it would affect getting the second dose of the vaccine. The patient supposed to be quarantining right now and she was not symptomatic. On 09Jan2021 she found out she was positive for covid. The outcome of the event was unknown.; Sender's Comments: A causal association between reported event and suspect BNT162B2 cannot be excluded.

he is infected with COVID-19; he is infected with COVID-19; This is a spontaneous report from a contactable nurse (patient). A male patient of an unspecified age received 1st dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient called to find out if there should be a delay in the second dose because he was infected with COVID-19 on an unspecified date. His second dose was scheduled on 13Jan2021 and he was wondering if he should continue in 2 days. Outcome of the events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Based on the information currently available, a lack of efficacy with BNT162B2 in this patient cannot be completely excluded.

she had a little bleed in the blood vessel of her left eye; This is a spontaneous report from a contactable other healthcare professional (patient). A female patient of unspecified age received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot/batch number and expiration date not provided), via an unspecified route of administration on 21Dec2020 at single dose for COVID-19 immunization. The

patient's medical history and concomitant medications were not reported. The patient asking if bleeding of the eye was an adverse reaction to bnt162b2. Patient received the Covid vaccine on 21Dec2020 and on the 27Dec2020, she had a little bleed in the blood vessel of her left eye. She was supposed to get the second vaccine today (11Jan2021) at 12:30. The outcome of the event was unknown. Information on the lot/batch number has been requested.; Sender's Comments: A possible contributory effect of suspect BNT162B2 on reported event cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

"got the first dose of the vaccine and on 25Dec2020, he started getting symptoms of possible covid; got the first dose of the vaccine and on 25Dec2020, he started getting symptoms of possible covid; This is a spontaneous report from a contactable pharmacist. A 7-decade-old (65 years or 66 years) male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 25Dec2020 at single dose for COVID-19 immunisation. The patient medical history and concomitant medications were not reported. The stated, ""my uncle got the first dose of the vaccine and on 25Dec2020, he started getting symptoms of possible Covid. He got tested for covid today (11Jan2021). He's supposed to get the second dose on 15Jan2021. If he is positive for covid, what does that mean for his second dose? If he is positive, and waits for quarantine, then he wouldn't be able to get the second dose until day 36."" The outcome of the events was unknown. Information on the Lot/Batch Number has been requested.; Sender's Comments: A causal association between reported event and suspect BNT162B2 cannot be excluded."

On (Dated) tested positive for Covid; On (Dated) tested positive for Covid; On (Dated) tested positive for Covid; Felt run down; This is a spontaneous report from a contactable other health professional (HCP). A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 28Dec2020 at a single dose (first dose) for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient got her first dose on 28Dec2020 and on 07Jan2021, she felt run down so she decided to get tested for COVID. On 09Jan2021, she tested positive for COVID. Her second dose is due 18Jan2021 and she needed to know if it is ok for her to get her second dose. The patient underwent lab tests and procedures which included sars-cov-2 test: positive on 09Jan2021. The outcome of the events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: The association between the event lack of effect (tested positive for COVID) with BNT162b2 can not be completely excluded.

Caller tested positive on 05Jan2021.; Caller tested positive on 05Jan2021.; Caller tested positive on 05Jan2021.; This is a spontaneous report from a contactable physician (patient). A male patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 29Dec2020 at a single dose for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. Patient received the first dose of the COVID 19 vaccine on 29Dec2020, second dose is due on 20Jan2021. Patient tested positive on 05Jan2021. Patient wanted

to know if he should get the second shot and if he chooses to wait the 90 days, would he need to start over. The patient underwent lab tests and procedures which included sars-cov-2 test: positive on 05Jan2021. The outcome of the events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: The association between the event lack of effect (tested positive) with BNT162b2 can not be completely excluded.

13 people, who were applied the vaccine previously, were corona positive after a week; 13 people, who were applied the vaccine previously, were corona positive after a week; This is a spontaneous report from a non-contactable consumer. This consumer reported similar events for 13 patients. This is second of 13 reports. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Solution for injection; lot number and expiration date: not known), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. It was reported that 13 people, who were applied the vaccine previously, were corona positive after a week on an unspecified date. The outcome of the events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021018407 same reporter, similar suspect drug and event; different patient

13 people, who were applied the vaccine previously, were corona positive after a week; 13 people, who were applied the vaccine previously, were corona positive after a week; This is a spontaneous report from a non-contactable consumer. This consumer reported similar events for 13 patients. This is third of 13 reports. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Solution for injection; lot number and expiration date: not known), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. It was reported that 13 people, who were applied the vaccine previously, were corona positive after a week on an unspecified date. The outcome of the events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021018407 same reporter, similar suspect drug and event; different patient

13 people, who were applied the vaccine previously, were corona positive after a week; 13 people, who were applied the vaccine previously, were corona positive after a week; This is a spontaneous report from a non-contactable consumer. This consumer reported similar events for 13 patients. This is fourth of 13 reports. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Solution for injection; lot number and expiration date: not known), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. It was reported that 13 people, who were applied the vaccine previously, were corona positive after a week on an unspecified date. The outcome of the events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021018407 same reporter, similar suspect drug and event; different patient.

13 people, who were applied the vaccine previously, were corona positive after a week; 13 people, who were applied the vaccine previously, were corona positive after a week; This is a spontaneous report from a non-contactable consumer. This consumer reported similar events for 13 patients. This is fifth of 13 reports. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Solution for injection; lot number and expiration date: not known), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. It was reported that 13 people, who were applied the vaccine previously, were corona positive after a week on an unspecified date. The outcome of the events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021018407 same reporter, similar suspect drug and event; different patient.

13 People, who were applied the vaccine previously, were corona positive after a week; 13 People, who were applied the vaccine previously, were corona positive after a week; This is a spontaneous report from a non-contactable consumer. This consumer reported similar events for 13 patients. This is 6th of 13 reports. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Solution for injection; lot number and expiration date: not known), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. It was reported that 13 people, who were applied the vaccine previously, were corona positive after a week on an unspecified date. The outcome of the events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021018407 same reporter, similar suspect drug and event; different patient.

13 people, who were applied the vaccine previously, were corona positive after a week; 13 people, who were applied the vaccine previously, were corona positive after a week; This is a spontaneous report from a non-contactable consumer. This consumer reported similar events for 13 patients. This is 7th of 13 reports. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Solution for injection; lot number and expiration date: not known), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. It was reported that 13 people, who were applied the vaccine previously, were corona positive after a week on an unspecified date. The outcome of the events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021018407

13 people, who were applied the vaccine previously, were corona positive after a week; 13 people, who were applied the vaccine previously, were corona positive after a week; This is a spontaneous report from a non-contactable consumer. This consumer reported similar events for 13 patients. This is 8th of 13 reports. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Solution for injection; lot number and expiration date: not known), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. It was reported that 13 people, who were applied the vaccine previously, were corona positive after a week on an unspecified date. The outcome

of the events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021018407

13 people, who were applied the vaccine previously, were corona positive after a week; 13 people, who were applied the vaccine previously, were corona positive after a week; This is a spontaneous report from a non-contactable consumer. This consumer reported similar events for 13 patients. This is 9th of 13 reports. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Solution for injection; lot number and expiration date: not known), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. It was reported that 13 people, who were applied the vaccine previously, were corona positive after a week on an unspecified date. The outcome of the events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021018407 : same reporter, similar suspect drug and event; different patient.

13 people, who were applied the vaccine previously, were corona positive after a week; 13 people, who were applied the vaccine previously, were corona positive after a week; This is a spontaneous report from a non-contactable consumer. This consumer reported similar events for 13 patients. This is tenth of 13 reports. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Solution for injection; lot number and expiration date: not known), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. It was reported that 13 people, who were applied the vaccine previously, were corona positive after a week on an unspecified date. The outcome of the events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021018407 same reporter, similar suspect drug and event; different patient

13 people, who were applied the vaccine previously, were corona positive after a week; 13 people, who were applied the vaccine previously, were corona positive after a week; This is a spontaneous report from a non-contactable consumer. This consumer reported similar events for 13 patients. This is 11th of 13 reports. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Solution for injection; lot number and expiration date: not known), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. It was reported that 13 people, who were applied the vaccine previously, were corona positive after a week on an unspecified date. The outcome of the events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021018407 same reporter, similar suspect drug and event; different patient

13 people, who were applied the vaccine previously, were corona positive after a week; 13 people, who were applied the vaccine previously, were corona positive after a week; This is a spontaneous report from a non-contactable consumer. This consumer reported similar events for 13 patient. This is the 13th of 13 report. A patient of unspecified age and gender received bnt162b2 (PFIZER-BIONTECH COVID-19

VACCINE; Solution for injection, batch/lot number unknown), via an unspecified route of administration on an unspecified date at a single dose for covid-19 immunisation. The patient's medical history and concomitant medications were not reported. It was reported that 13 people, who were applied the vaccine previously, were corona positive after a week. on an unspecified date. The outcome of the events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021018407 same reporter, similar suspect drug and event; different patient

She tested positive for Covid-19 a week later after receiving the first dose of the vaccine; She tested positive for Covid-19 a week later after receiving the first dose of the vaccine; This is a spontaneous report from a Pfizer-sponsored program IBCC (Inbound Call Center for HCPs) received from a contactable consumer (patient). A female patient of an unspecified age received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot/batch number unknown), via an unspecified route of administration on 29Dec2020 at a single dose for covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient took the first dose of Covid-19 vaccine on 29Dec2020. She tested positive for Covid-19 a week later after receiving the first dose of the vaccine. She is scheduled to get the second dose on 19Jan2021 and she was asking what to do. The outcome of the event was unknown. Information about lot/batch number has been requested.

tested positive for COVID; tested positive for COVID/fatigue, headache, body aches again; allergies were flaring up; Coughing; congestion; body aches; This is a spontaneous report from a Pfizer-sponsored program IBCC (Inbound Call Center for HCPs). A contactable nurse (female) reported that a female patient of an unspecified age received first dose of bnt162b2, via an unspecified route of administration on 21Dec2020 at single dose for covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced tested positive for covid on 31Dec2020, coughing, congestion, body aches on 24Dec2020, fatigue, headache, allergies were flaring up on 28Dec2020. The caller got her first COVID-19 injection on 21Dec2020. She didn't have symptoms until 2 days after the vaccine. She then experienced coughing, congestion, body aches, but no fever. Then the next day, she felt fine. On 28Dec2020, she thought her allergies were flaring up. She started to feel fatigue, headache, body aches again. She went and got tested for the virus. She tested positive on 31Dec2020. Caller was due for a second vaccine on 11Jan2021. She was to remain in quarantine until 10Jan2021. Caller wanted to know should she get her second shot on 11Jan2021 or should she wait. The patient underwent lab tests and procedures which included Covid-19: positive on 31Dec2020. The outcome of events for tested positive for covid, fatigue, headache and allergies were flaring up was unknown, for other events was resolving. No further information was obtained. Information on lot/batch number has been requested.; Sender's Comments: A causal association between BNT162B2 and the events drug ineffective and COVID-19 cannot be excluded based on a compatible temporal relation between vaccination and onset of events.

short of breath; aching so bad again; was still short of breath, getting worse, aching so bad again; choking; got as cold as ice; throat was real swollen; started itching terribly; This is a spontaneous report from a contactable consumer (patient). A 73-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number EK4176), via an unspecified route of administration

on 06Jan2021 single for COVID-19 immunization. Medical history included hypertension and had 4 heart attacks. The patient's concomitant medications were not reported. The patient just had the Covid 19 Vaccine first shot. After the shot he went to the dining room to get some lunch. He was reading since 'calculative'. He started itching terribly. Onset date for started itching terribly was reported as 06Jan2021. He got as cold as ice. He started getting real short of breath, he was choking but he managed to get them out of his throat. His throat was real swollen and choked. He went back to the clinic and the Nurse took him straight to the emergency room. He was there in his wheelchair freeze in and crawling himself, struggling to breathe for almost 25 minutes before the Nurse finally came in and helped him get him on the stretcher. She took his time, she got the IV started and gave him a steroid a shot and Benadryl. He did not know the dosage and some capsules. He did not know why the capsules and he was still struggling for a while but he found day tough for about an hour. When he came too he was still short of breath, getting worse, aching so bad again. He was struggling to breathe, he was still having some breathing problem, some choking and aching. The events was still short of breath, getting worse, aching so bad again were serious as hospitalization. Laboratory work: Work was normal. The COVID Test was negative. The outcome of events short of breath and started itching terribly was not recovered while for other events were unknown.

dehydration; This is a spontaneous report from a contactable Nurse. A patient of unknown age and gender received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, on an unknown date at single dose for COVID-19 immunisation. Medical history and concomitant medications were unknown. After vaccination on an unknown date, the patient went to ER and was diagnosed with dehydration. Patient was hydrated and recovered. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Sender's Comments: The information currently provided is too limited to make a meaningful medical assessment hence, the events are conservatively assessed as related to the suspect drug BNT162B2 until further information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

died two days after receiving the vaccine; Fever; This is a spontaneous report from a contactable consumer (patient's stepchild). A 66-year-old male patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration, on 07Jan2021 (at the age of 66-years-old) as a single dose for COVID-19 immunization. The patient's medical history was not reported. Concomitant medications included an unspecified statin. The patient experienced fever on 08Jan2021. The patient died two days after receiving the vaccine on 09Jan2021, which was reported as fatal. The clinical course was reported as follows: The patient had a fever the day after getting the vaccine and then he just died in the middle of night. It was reported that it was not clear what exactly happened, but they are looking into this. The clinical outcome of fever was unknown and of died two days after receiving the vaccine was fatal. The patient died on 09Jan2021. The cause of death was not reported. An autopsy was not performed (was reported to be taking place soon). The batch/lot

number for the vaccine, BNT162B2, was not provided and has been requested during follow up.; Reported Cause(s) of Death: died two days after receiving the vaccine

Pt. with dizziness, then Afib with RVR, then massive cerebral hemorrhage Pt. non oriented & unable to give history - History provided by S.O and daughter

Accelerated decline in condition with decreased input, decreased responsiveness, somnolence, and death

Received vaccine in left deltoid within minute felt throat tighten self administered personal epi pen.

I had no side effects after my vaccine on 12/24/20 until 1/8/21. On Friday, 1/8/21 at 830pm I began with severe abdominal pain, low grade fever, nausea and loss of appetite. My abdominal pain persisted and worsened over the next 24-36hours. I presented to the ER on Sunday, January 10, 2021 at 8am with severe right lower quadrant pain, pelvic pain, nausea and low grade fever. I was promptly diagnosed with appendicitis and taken to the OR at approximately 2pm on the same day. In the OR my appendix was gangrenous, there was pus in the pelvic area nd fluid in my peritoneum. My appendix was not ruptured. My appendix was removed as well as part of the omentum. I remained in the hospital on IV Metronidazole and Ciprofloxacin for 2 days and was discharged on 1/13/21 at 9pm. I am continuing to recvoer at home on the same 2 antibiotics in oral form. I have a JP drain that is still in place. Of note I had two negative COVID 19 tests on 1/9/21 and 1/10/21. Both were PCR tests.

Tingling and throat swelling to Moderna COVID-19 Vaccine EUA

Patient had no immediate effects from the vaccine, but died approximately 8 hours after receiving first dose of vaccine.

positive for Covid; positive for Covid; This is a spontaneous report from a contactable healthcare professional (patient). A 48-years-old female patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number EH9899, expiration date unknown), via an unspecified route of administration in right deltoid, on 18Dec2020 07:15 at a single dose for Covid-19 immunization. Medical history included ongoing hypothyroidism and hysterectomy. Concomitant medications included estradiol (taking after hysterectomy) and levothyroxine for hypothyroidism, both ongoing. The patient has no any other vaccinations within four weeks prior to the first administration date of the suspect vaccine. The patient stated that she received the Covid vaccine mid- Dec2020. She stated she was supposed to receive the 2nd dose 2 days ago, 06Jan2021. On 03Jan2021, she started feeling bad the day before testing positive, went to urgent care to be tested, thought she had the flu. She tested positive for Covid on Monday 04Jan2021, so she has been in quarantine. She was unable to receive her 2nd dose because she was in quarantine. She wanted to know if it's ok to delay the second dose or if she needs to re-start the series. The reporter assessed the event relatedness was unknown, patient stated that she doesn't know the causality, she has not been in contact with anyone that was known to be positive, but she is a healthcare worker who sees multiple patients a day, so one of them could have been asymptomatic. Outcome of the events was not recovered.; Sender's Comments: The information currently provided is too limited to make a meaningful medical assessment hence, the

events are conservatively assessed as related to the suspect drug BNT162B2 until further information becomes available.

received first dose of bnt162b2/by the 3rd (03Jan2021), he was diagnosed as covid positive; received first dose of bnt162b2/by the 3rd (03Jan2021), he was diagnosed as covid positive; patient lost his sense of smell and taste; patient lost his sense of smell and taste; This is a spontaneous report from a contactable nurse (patient). A male patient of an unspecified age received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number and expiration date not provided), via an unspecified route of administration on 17Dec2020 at SINGLE DOSE for COVID-19 immunisation. Patient's medical history and concomitant medications were not reported. The patient reported he needs advice on the second dose of the vaccine. Patient stated he is an ER nurse and received the first dose of the vaccine on 17Dec2020. On 31Dec2020, patient lost his sense of smell and taste and by the 3rd (03Jan2021), he was diagnosed as covid positive. The patient underwent lab tests and procedures which included Covid test: positive on 03Jan2021. The patient is asking how safe it is to get the second dose now and if there's a time period that he should wait so that he can get the second dose. Outcome of the events was unknown. Information about lot/batch number has been requested.; Sender's Comments: Based on the information currently available, a lack of efficacy with BNT162B2 in this patient cannot be completely excluded. Further information like diagnostic detection of virus genetic material or virus protein antigen needed for meaningful medical assessment.

"she tested positive for COVID-19 on Monday 27Dec2020; she tested positive for COVID-19 on Monday 27Dec2020; This is a spontaneous report from a contactable nurse (patient herself). A female patient of an unspecified age received her first dose of bnt162b2 (BNT162B2 also reported as Pfizer-Biontech Covid-19 Vaccine, lot/batch number and expiry date not reported), via an unspecified route of administration on 19Dec2020 at single dose, for Covid-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient was scheduled for her second dose today 09Jan2021. However, she tested positive for COVID-19 on Monday, 27Dec2020. She stated that she has still some of the symptoms of COVID-19 even though she has been declared fit to work. She was asking if she could take the second dose today. Information about batch/lot number has been requested.; Sender's Comments: Based on available information, a possible contributory role of BNT162B2 cannot be excluded for reported event ""she tested positive for COVID-19""."

Resident was found without a pulse and not breathing 20 minutes after vaccine administration. Upon MD review, no signs of anaphylaxis were noted.

About 10 minutes after getting my vaccine I noticed the roof of my mouth itching as well as my tongue and back of my throat. I waited to see if it would go away and then a couple minutes later noticed my lips started itching and swelling and from there it just got worse. I told the nurse practitioner that I think I was having a reaction, she had me take a seat told her my entire mouth throat & lips felt swollen and itching and she looked and said it was full blown anaphylaxis reaction. Administered EpiPen, benadryl and called ambulance where they took me to medial emergency department.

Patient had just recovered from COVID and ended quarantine on 1/1/21. On 1/4/21, she received the first COVID vaccination. While driving home on 1/6/21, she experienced an MI diagnosed in the emergency room 30 minutes later. She was admitted to the hospital and underwent a heart catheterization and received a STENT. She had previous cardiogenic shock in 2003.

Pfizer-BioNTech COVID- 19 Vaccine EUA Received communication that patient experienced a stroke and received alteplase at a non-facility (Medical Center) 5 days after receiving COVID-19 vaccination.

increase weakness and fatigue, weakness in extremities, incontinent, jerky arm movements, within first 24 hours, continue to decline sent to hospital returned weaker, within 24 hrs hours BP dropped, low pulse oximeter reading, diaphoretic, lung sounds diminished, loss consciousness and passed away. 01-12-2021

01/11/2021- Found lying on bed in apartment, incontinent, lethargic, unable to respond to questions, unable to do hand grasps. sent to hospital. 01/14/2021- remains in hospital- confusion and disorientation continues, poor verbal skills, limited ability to feed self, out of bed to sit in chair. uncertain of return to facility status.

Abdominal pain, Headaches, chest pain, loss of appetite, confusion, elevated liver enzymes 1/8-1/15/21

01-09-2021 Very confused, nauseous, sweating profusely. sent to hospital- admitted with encephalitis, severe cognition decline. 01-13-2021 still in hospital, cognition Improved.

Death Chest pain; irreg heart rhythm; evening of vaccine; death on toilet on 1/13/21

Initially headache and body aches. Within 24 hours developed chest pain, dyspnea on exertion and shortness of breath. Patient still currently hospitalized.

Patient reportedly expired the day following receipt of the vaccine.

Observed in her room having seizure activity and unresponsive to stimuli. BP of 200/120, oxygen level dropped to 86%, HR was 116. She was transferred from Hospital A and later transferred to Hospital B and placed on a ventilator. This remains her current status

We (myself and 2 other pharmacists) were conducting a COVID-19 vaccine clinic. The patient is on staff at the clinic and came in for her 1st dose of the Pfizer/BioNTech COVID vaccine. 10 minutes post-vaccination, patient started experiencing SOB, tingling fingers and face, and swelling of her lips and tongue. She moved herself outside to cooler air and then sent someone back inside to ask us for help. I ran outside with an EpiPen and immediately noted her pulse of 158 on her watch and she appeared to be experiencing an anaphylactic reaction. Patient stated she did not want to use the EpiPen but wanted to try chewing Benadryl instead first. I asked the staff for a blood pressure monitor and pulse oximeter. The 1st readings, approximately 12 minutes after vaccination, were HR 158, BP 155/105, and pulse ox 97%. Patient stated the Benadryl was working and her swelling was decreasing. The patient was not having trouble breathing at the time. I continued monitoring vitals and talking with the patient and approximately 20 minutes post-vaccination, she was improving (BP down to 134/80 and HR 120) but

agreed we should call 911. She decided she wanted to move inside and lie down. I escorted her with support to a bed. Her vitals then increased again to BP 152/95 and HR 133 and her lips and tongue started swelling again. The patient appeared to be more labored in breathing then but still refused the EpiPen. Roughly 5 minutes after lying down, the medics showed up and took over and I went back to the vaccination area. I learned later that the patient refused to go to the hospital and after more observation was eventually allowed to leave with a friend/coworker driving her home.

Patient was at work on 1/15/21 after having received the vaccine on 1/12/21. She complained of being diaphoretic and her heart rate was 156. She was taken to Hospital. She is being admitted to hospital and has reported that her heart rate is 122 and she has a temperature of 99.4 and elevated lactic acid levels.

1/5/2021 0718 Pt received 2nd COVID vaccine 1/4/21. Oral temp 100.6, near syncope, muscle aches and head aches. Per EMS NSR, denies SOB, and chest pain. 500 ml bolus received in route. In ED, Pt c/o nausea. Pt anxious, sweating and uncomfortable. 0855 Pt resting comfortably, reports decease in pain/body aches 4/10. 1043 Discharge disposition: home. Accompanied By: self. Mode: walk. --Hospital

Expired on 1/12/2021; unknown cause of death

We got a call from a home health nurse Brandu Talamo, stating that the patient passed away.

5-6 HOURS AFTER VACCINATION. CONVULSIONS/SEIZURE, HIGH BLOOD PRESSURE, INCREASED HEART RATE,

Severe pain at injection site with some swelling, lethargy, and fever to 101.6 degrees F the day after the injection. He was given acetaminophen, which reduced fever to normal. Low grade fever (99-100 degrees F) two days after vaccine. On the third day after vaccine, on 12/31, he became confused and anxious. Temperature was 104.8 degrees F. He was given acetaminophen and oral hydration overnight. He continued to have a fever to 102 on the following day and was taken to the ED. He was COVID-positive and admitted to the hospital for treatment of COVID-19.

Initially started as shortness of breath followed by fevers, aches, muscle cramps. Ultimately ended up in the hospital with hypoxemia, pleural effusions. Laboratory values showed evidence of acute renal insufficiency, eosinophilia. Physical exam consistent with pulmonary edema and lower extremity macular rash. Entire presentation concerning for DRESS syndrome

Resident had lunch on 01/14/21 and after lunch around 2:00pm, he vomited and stopped breathing. We coded the resident and 911 paramedics came. They pronounced him dead at 2:18pm.

Around 00:50am on 01/15/21, C.N.A. reported that the resident looked different and not responding. Initiated Code Blue and started CPR. 911 arrived and pronounced resident dead at 1:01 am.

"The patient stated "" I just feel Blah"". vital signs obtained. 156/75 p-84 spo2 94% via NC 2L. T-96.7, c/o feeling restless, c/o nausea with no vomiting. Patient observed at 0600 nonresponsive, CPR initiated, and EMS notified Patient expired"

Received Pfizer vaccine, first dose on Wed. 01/13/21 between 12 and 1 P.M. Thurs. 01/14/21 in the afternoon he began to note that he had difficultly walking. Went to bed when he woke up at 5:48 A.M. he reported he had ataxia. Patient reported having to walk in tiny steps to stay upright. He went to the emergency room. Had CT scan of head and found blood clots. MRI performed. Stroke found in right PCA territory, but no loss in strength in left lower extremity. Sensation and vision intact. Strength in all four extremities is 5 out of 5.

At 6 days after my second COVID-19 Pfizer vaccine (first dose given 12/17/20), I had acute onset of chest pain and shortness of breath prompting a trip to the Emergency Department. A chest CT Angio to rule out pulmonary embolus was done and negative for pulmonary embolus. My EKG showed some mild ST changes and a troponin I level was elevated at 0.08 (normal 0.04). Subsequent troponin levels 90 minutes apart showed a rising troponin at 0.18 and 0.38. An echocardiogram was performed which showed regional wall motion abnormalities consistent with Takotsubo cardiomyopathy and an ejection fraction of 45%. I was then taken to cardiac catheterization lab for coronary angiograms which were normal. My LV angiogram was consistent with Takotsubo cardiomyopathy and my LVEDP was elevated. I was started on a beta blocker and sent home the following day.

This patient has been under hospice care for over 2 years at the nursing home. She has had a steady decline with gradual weight loss. She was totally dependent in her care needs. She received the vaccine on 1/2/2021 as part of the facility vaccination campaign. No adverse events noted initially. On 1/3/2021 at 6:06 pm, she was noted on vital sign checks (done every 4 hours for first 72 hours after vaccination) with BP 64/52 but otherwise asymptomatic. Subsequent BP improved. On 1/4/2021 at 4:45 am, pt found with respiratory rate of 30 with otherwise normal vital signs. Tachypnea persisted, so she received liquid morphine 2.5 mg without improvement. Supplemental oxygen was applied. Tachypnea persisted. She had poor oral intake after that point had persistent tachypnea and worsening hypoxemia despite clear lungs on exam. She remained under hospice care and comfort measures were continued. No blood testing or imaging tests were done. She required increasing amounts of oxygen, became hypotensive, and died peacefully on 1/8/2021 at 7:45 pm.

Veteran was found by family slumped over and unresponsive at the breakfast table on 1/13/21, had expired

Anaphylaxis

Pt had 3 vessel CABG on 1/14/21 after presenting to ED with chest pain on 1/9/21. Pt is critically ill following OR after cardiogenic shock, bleeding. Requiring inotropes and Impella.

vertigo nausea / vomiting diarrhea low-grade fever pain at injection site

Bells Palsy 1st injection on 12/20/21 symptoms started 1/7/21, 2nd dose on 1/10/21 immediate numbness in mouth and tightness in throat which triggered bells palsy symptoms immediately

Patient information was reviewed. Patient was asked if they ever had any form of severe reaction to anything they had had in the past. Patient did not state yes to anything other than having a reaction that

was managed at home to shellfish as a child. They stated their throat had swollen as a child during the event. Patient was told that it was an anaphylactic reaction and shouldn't have been managed at home as a child by nurse and should have been taken to the hospital. Patient was told they would be monitored for 30 minutes after receiving the vaccine. Within 2-3 minutes after receiving the vaccine the patient reported tingling or burning around the site of injections. Within 5 minutes they stated to be feeling tired and that their arm had felt numb. After this the patient began starring into the distance and was unresponsive. Called for help and advice by turning around as patient had syncoped. Got nurses and other team members attention and had an epi-pen ready just in case it was needed. Patient began having notable distress with respiration and administed an epi-pen. Advised for a nurse to call EMS for patient and crash cart/oxygen was also obtaine dby the facility. Oxygen was required. Patient was not responsive after the first dose and was given a second as they remained un-alert with notable distress. The patient became alert a while after receiving the second shot and not long after that the EMS arrived to the event.

Resident reported loose stool, not feeling well, resident complaint of lost taste. Hospitalization on 01/14/2020.

Vomiting

"Per husband, was in usual state of health on the AM of 1/10/20, AOx3 able to perform all I/ADLs. At around 2:30pm that day was complaining of chills and generalized malaise. Then at ~9:30pm when husband returned home from work found patient diaphoretic, confused (stating things like ""not now, I want to go to lake""), and complaining of chills and weakness. Unable to provide any additional hx regarding other sx. Initially presented to ED, where mental status had deteriorated to AOx0, unable to respond to verbal commands. Initial vitals notable for T102.6F (unclear other vitals). Patient is now AOx0 most concerning for encephalopathy."

Patient 101 years old, nursing home resident, received vaccine 1/11, on 1/13 found on floor without obvious trauma, unresponsive. Brought to ED and was bradycardic, hypotensive, hypothermic and refractory to aggressive medical management. No obvious cause of death found on exam or labs, cxr. Unknown if event could be related to vaccine or not. Medical Examiner accepted case although initially unknown that patient had recently received vaccine. ME updated with that information today as soon as discovered.

Throbbing head ache, difficulty breathing, lips numbness, chest discomfort, upper back, lower legs, fingers tingling/numbness, high blood pressure 148/83, underarm sweating, feels weak

Nausea with emesis, headache, upper abdominal pain.

Patient suffered a cardiac arrest and was unable to give details about her symptoms. Per husband, patient did not complain of any symptoms after vaccine administration. She began seizing without warning which was complicated by cardiac arrest of uncertain etiology

Right arm weakness 2 hrs after vaccine and then right leg weakness later that evening

"On 1/15/2021 at 1800, resident noted to be lethargic and shaking, stating ""I don't care."" repeatedly. C/O head and neck pain. T100.6. Given Tylenol with no relief of pain. Order received for Aleve and administered.. Assisted to bed as usual in evening. Monitored during night shift and noted to be resting comfortably/sleeping.. Noted agonal breathing at 4:10 AM 1/16/2021 , T 99.4, Absence of vital signs at 4:15AM 1/16/21 and death pronounced at 4:40AM 1/16/21."

"""Moderna COVID-19 Vaccine EUA"" It has been reported to me that pt. had gone into hospital for a heart catheterization on 1/12/2021. It was found during this procedure that pt. had suffered a MI. She was release to home the following day and passed away at her residence on 1/15/2021."

anaphalactic shock reaction, epi injection by hospital emergency staff at vaccine site, emergency room admission . We were very lucky vaccine site was Hospital was concerned that this might happen as patient had a previous anaphalactic shock by antibiotic injection few years ago

Right thumb joint pain. I can't hold unto things in my right hand that requires me using pressure from my thumb. Pain is a 9/10 when holding, grabbing, or using the thumb in any way. When not using the thumb there is no pain at all. I work out everyday and I am no longer to lift weights using my right hand because of the excruciating pain when I try to.

Patient had COVID-19 infection April 2020, ataxia and myoclonus developed, treated with IVIG and steroids at that time. June 2020 had full recovery after PT. Pt received Pfizer COVID-19 dose 1 on 12/22/20 and developed similar symptoms to above on 1/7/2021. Ataxia and tremor on examination, no myoclonus at this time.

Appendectomy Narrative: Developed abdominal pain with nausea on 12/24/2020, went to ER and noted to have appendicitis, resulting in an appendectomy

Swollen tongue and sob with decreased swallow

Vaccinated at 8:55am, Per Nurse Practitioner note patient started experiencing itching upper chest, medicated with Benadryl P.O., started with throat itching, medicated with Benadryl IM, EPI IM, EMS called, placed on O2, diminished breath sounds bases, slight stridor, EPI IM, Solumedrol IM, EMS transported to local ED. Patient called NP later in day and said she was admitted to the hospital.

Pt had witnessed arrest by wife. Pt wife started CPR and called EMS. CPR started at 15:12. Continued by EMS. Pt arrived to medical center asystole with CRP in progress and ventilated via igel device. He was in refractory ventricular fibrillation and continued CPR for a total of 1 hour. At that point, we checked a bedside ultrasound which showed his heart at a standstill. He was unresponsive to verbal and tactile stimulus and had fixed unreactive pupils. He was pronounced at 16:13.

Tachypnea, Angina, Tachycardia, Sore Muscles Narrative: Started feeling ill on the 28th. Drove himself to get checked out at the hospital. Hospital sent him home. Called EMS at 12/30/2020 @ 0200 and was hospitalized for 1 day. He is more stable now but still has these symptoms at a moderate level.

ADVERSE REACTION REPORTED AS TEMPERATURE OF 100.0, CONFUSION, AND VERTIGO. PATIENT WAS TAKEN TO HOSPITAL, UNAWARE OF CURRENT STATUS, TREATMENTS, OR OUTCOME.

After vaccination on 1.8.21 felt fatigue, metallic taste, and intermittent tingling. on 1.15.21 at approximately 8 am developed occipital headache (4/10 pain) inability to move right upper or lower extremities and slurred speech. No evidence of intracranial hemorrhage on CT. Patient administered Alteplase and transferred to higher level of care

Day 1-3 after the dose flu like symptoms Day 3-7 swelling in lymph nodes on left side of body (baseball sized) took ibuprofen and Tylenol Day 8 angioedema, anaphylaxis. Received epi subq, IVP 50mg Benadryl, Pepcid 20mg IVP, liter of NS Day 9 raised red rash all over body and face still going on Day 16-present: severe joint pain and fever, unable to obtain any relief

Muscle Spas; Weakness in both limbs. Pressured speech

Pounding headache, heart racing to over 145 bps, chest burning and tightness and hard to breath. I was taken to the Emergency Room at Hospital immediately. Reaction occurred within 30 minutes of the injection. An EKG was administered. I was prescribed prednisone and Benadryl. I was diagnosed with Anaphylaxis.

Patient had slow progression of kidney disease but since vaccine had unexpected acute kidney failure. He had to have dialysis and may need biopsy of kidney to confirm if he needs lifelong dialysis. He is still being hospitalized.

Numbness and tingling sensations in both hands and sometimes radiating up my forearms, more severe in right hand and right thumb; these symptoms still didn?t go away since 1/11

Death

After 2nd dose in the afternoon at 2:30pm pt collapse in the unit V/S was high blood sugar was high. Pt was held over at work for 16 hours. Shot was given at 6:45am. Paramedics was called. Sent to ER.

Remarkable Myalgia of extremities and back, interfering with rolling or sitting. Spasmodic twitching of upper extremities, These resulted in Hospitalization.

Resident expired

On 1/9/2021 started to have Postural Orthostatic Tachycardia Syndrome and PVCs associated with SOB and chest tightness and not recovered yet.

Headache after dose was given at 10:00 a.m Died at after 7:30 pm the same night the dose was given.

On January 14, 2021, I noticed generalized petechiae all over my body. I went to seek medical care and was found to have platelet count of 2. I was hospitalized for idiopathic thrombocytopenic purapura. I was given platelets which increased my platelets to 4. Next day, given IVIG dose. Also receiving 4 doses of decadron. Day after IVIG, platelets to 20. I am still in the hospital getting treatment today.

Moderna COVID-19 Vaccine EUA. Patient has tested positive for Covid 19 as of 1/10/2021, when he was hospitalized. Patient's wife had been rushed to the ER previously, and they discovered she was Covid positive when she was admitted. Patient immediately notified public health and was being restricted and followed up with. During his quarantine, he started developing symptoms (08Jan2021). On 10 Jan, he was rushed to the ER and diagnosed with pneumonia due to Covid. He was also experiencing painful stomach cramps, low oxygen saturations and fluctuations in blood pressure. He spent 3 days inpatient in the Covid wing then was discharged to resume resting at home. Our provider immediately reached out to the member and checked in with them. At this time, the patient's only real complaint is lack of energy or getting winded when doing projects around the house. Patient will isolate at home and monitor his symptoms. Public health and the provider will follow up with the member and her family periodically to ensure recovery.

PATIENT GOT HER FIRST COVID PFIZER VACCINE AT 12/31 IN THE AM. HAD GOTTEN FLU LIKE SYMPTOMS AND HAD BEEN SICK FOR A COUPLE OF DAYS. HAD NAUSEA AND VOMITTING DURING THIS TIME AS WELL. ON 1/3 THE CARE GIVER WENT TO CHECK ON HER PT AT HER LTC FACILITY WHERE SHE LIVES AND SHE WASN'T ACTING RIGHT. SHE WAS UNABLE TO DO A STROKE EXAM. PT HAD NO MOVEMNET IN ARMS OR LEGS AND WAS UNABLE TO SPEAK. PT WAS VITALLY STABLE AT THE TIME. EMS RECORDED THAT THEY THOUGHT DIAGNOSIS WOULD BE STROKE, PNEUMONIA OR SEPSIS. AFTER ARRIVAL AT THE HOSPITIAL DETERMED THAT SHE HAD A STORKE, ACUTE KIDNEY INJURY, ABNORMAL LFTS.

allergic reaction- skin rash , throat itching. patient visited the ER and was given episode and steroids but returned because symptoms were not improving. She was hospitalized on 1/11 for this reason

12/29/2020 Vaccination 12-13 minutes later started left arm was tight and sore. Wasn't feeling right; hot, hives, rash at injection site up neck and face; tightness in throat; tachychardic, BP increase. I took benadryl and Pepcid . Sat for another 30-45 min. Palpitations, heaviness. Transported to ER. IV and medications. Stayed till 1:30, went home, and then came that evening. 5:00 that same night, hives, chest pressure, burning sensation, 'didn't feel right', anxious. Benadryl. Tachychardic; admitted to hospital that evening. Stayed in house admission till the 12/31/2020. Went back to admission in house, 1/3/2021 - 1/4/2021. Two hospital admissions.

Approximately 28 hours after vaccine, I began to feel tingling in my right eye Approximately 12 hours after that, my face started drooping and was numb so I went to ER. Today is Sunday, and the numbness and drooping was called Bells Palsy at the hospital.

Injection given without unusual pain, but appeared to be at higher site than usual for other vaccinations patient has received. No immediate reactions. No redness or swelling at injection site. Approximately 3 hours later with restriction of abduction of left arm, which became worse over 24 hours. No numbnness, pain 4-5/10 diffusely over deltoid and in acromium, posterior suprascapular area.. Able to passively move arm, treated with topical Voltaren gel, Naproxyn 500 x 1 dose. D2 with increased ROM, but still restricted.

New onset leukopenia/neutropenia with fever, unclear if related to vaccination, but temporally occurred the day after receiving 1st dose. No labs immediately prior to vaccination, so leukopenia may have

preceded vaccine. No other new medications to explain neutropenia. Off chemotherapy since 8/2020. Possible relapsed disease though no other evidence in support of this as remainder of CBC stable.

Shortness of breath, Congestive heart failure, Afib

RespDepression found to have low potassium Narrative: Patient reports experiencing shortness of breath 24 hours after the vaccine was administered, went to ER and admitted for one night. Informed her supervisor she had low potassium.

Patient presented with diffuse petechiae, easy bruising and oral bruises. She has a history of stable ITP with her last required infusion of IVIG 12 years prior during pregnancy and monitors her CBC every 6 months. Her baseline platelet count is ~50-60k. She received treatment with dexamethasone 40 mg IVPB x 3 doses and IVIG 95 grams (1 gram/kg) IVPB x 2 doses.

3 days after receiving the first dose of the vaccine on 12/21/2020, experienced flu-like symptoms that lasted 24 hours. About 17 hours after receiving the second does on 1/11/2021, flu-like symptoms reoccurred. The following day (1/13/2021) severe chills, and difficulty breathing occurred. Patient was admitted to Medical Center, where blood work, EKG, and oxygen were given and ordered. After overnight observation, the patient was discharged and informed that he had a severe reaction due to the Pfizer vaccine for Covid-19. As of 1/17/2021, patient still recovering and feeling generally weak and tired without much appetite.

Vaccine was administered on 1/12/21 at Memory Care. On 1/15/21 at 12:30 he developed slurred speech at his facility and slumped to his left side. Out of concern for stroke he was sent by ambulance to Hospital. There he was found to have no evidence of stroke on MRI or CT angiogram. He was admitted to the hospital due to fever and elevated inflammatory markers (ferritin, CRP) and transaminases. He was found to have a positive SARS-CoV-2 PCR and IgG. His symptoms resolved the following morning and may have represented a TIA. He had many markers consistent with COVID-19 and his CT pulmonary angiogram did show ground glass opacities but no pulmonary embolism. It was difficult to assess if this was a reinfection with COVID-19, persistent PCR positivity from November, or an adverse event to the vaccine.

I received the dose at 1:45 pm on 1/13/2021 at Medical Center. Almost 1 hour post vaccine I started to feel a lump in my throat, as the minutes passed my throat started to feel tighter and fight and flight mode kicked in. It was hard to swallow, my tongue was swelling and I called EMS at 2:40 pm 1/13/2021. EMS noticed hives on my chest and left arm where I got the first dose of Moderna. I received epinephrine IM and IV benadryl in the ambulance. I was sinus tachycardic with heart rate in the 140s oxygen was 99% room air, lungs clear.. I was taken to ER where I was on observation for 2 hours. I was discharged around 5:10 pm on 1/13/2021. On my car ride home around 5:40pm I again started to feel my throat tighten, tongue swell, and heart race. I called EMS again, and was treated with IV benadryl, and epinephrine IM. I was taken to Medical Center where I was given IV solu-medrol and got blood taken and a pregnancy test done. My potassium was 3.1 and I took 2 potassium tablets to supplement. My EKG was normal sinus tach, oxygen 100% room air, blood pressure 140s/90s and got down to

120/80s. I was transported to another Medical Center for overnight observation because first Medical Center was full.

"Narrative: Patient with severe aphasia and only able to say ""hey, hey, hey"" or ""uh huh"" or shake his head no as a way to communicate. Patient previously able to ambulate with significant limp and hyperextension of right knee, but mostly wheelchair bound over last several years as he had had a slow and steady decline in overall health and mobility. Patient developed aggressive behavior of shouting ""hey"" and grabbing of groin in 2016. This was worked up with CT scans, labs, referral to urology, neurology, and referrals to psychiatry. The exact etiology of this action was never able to be affirmed, but thought to be more psychiatrically related. It improved significantly with addition of antipsychotics, worsened when antipsychotics were reduced, and improved again with addition of injectable antipsychotic on 12-10-2020.Patient suffered from falls on occasion given his significantly impaired physical mobility. His last documented fall was 8-31-2019. Patient began utilizing wheelchair most of time following that fall. No significant injuries noted in documentation of the falls. In the last 3 months, patient would often refuse medications. He would sometimes indicate that they would cause dizziness, and other times he would simply refuse. We attempted to hide medications in his food/fluid (with wife's blessing) and when he detected this he would occasionally refuse to eat. Patient previously on DOAC. After pharmacy review in 12/2020 it was recommended to discontinue this as no clear indication to continue use. He was high fall risk and would often refuse this medication as well since 10/2020. Noted to be in NSR on EKGs and decision made to discontinue the DOAC. Patient had no evidence of adverse effects noted after vaccination on December 28th. Patient seen by provider on the morning of his death (1/4/2021) with no noticeable significant change in health condition. Temperature 36.8Con January 4th at 19:45. During routine bedtime cares, patient suddenly collapsed and death was pronounced January 4, 2021 at 20:05. Autopsy was requested from next of kin and no autopsy was granted. Symptoms: & DEATH Treatment:"

Narrative: Symptoms: Palpitations & Syncope Treatment: EPINEPHRINE 1 MG ONCE ,EPINEPHRINE 1 MG ONCE ,SODIUM BICARBONATE 50 ML ONCE

Ventricular fibrillation- Code blue

Severe Right sided chest pain, right sided muscle spasms and difficulty breathing two weeks after vaccine was administered Diagnosis of bilateral pulmonary embolism was made on presentation to ER. No personal or family history of clots in arteries or deep veins or any risk factors in patient. Received heparin drip, pain medications, muscle relaxants inpatient. Pain progressively improved over days. Was discharged after 6 days on admission. Was discharged on oral anticoagulant (Rivaroxaban aka xarelto)

Developed dizziness and nausea within 90minutes of vaccine; then developed tingling, and flushing of my skin. Then rapid heart rate and chest tightness by 2.5hrs post vaccine. I went to urgent Care and they thought it was an allergic reaction (BP 182/90, HR 82) and gave me 125mg solumedrol and Benadryl intramuscularly which caused worsened dizziness and a racing heart which caused me to collapse and they gave me a epi pen and called 911. I was transferred to ER and they completed EKG which was

normal and monitored vitals for a few hours and I was released. I continue to remain extremely dizzy and nauseated 2days after the vaccine.

"2.5 hours after receiving vaccine, I started getting dizzy and vomiting. I vomited 6 or 7 times. I was so dizzy I couldn't open my eyes without getting sick. We called ER and explained that we thought I was having a reaction to the vaccine, and their response was they had never heard of that type of reaction. I was sick all night, called my primary Dr in the am and they told me to go to ER. We had to call ambulance to take me there because I was so sick and couldn't open my eyes without having to vomit. Room spun in circles. My arrival at ER, they did MRI, EKG, blood work. My blood pressure was very high, so they connected me to a heart monitor. I had low Magnesium due to vomiting so much. I was treated with Valium and anti-vert medication and fluids. I stayed overnight in hospital- had PT Jan 13th for DX of Vertigo. Then referred to Outpatient PT for Vertigo. Dr's felt it was a ""coincident"" that I got Vertigo shortly after vaccine, and strongly felt it was not related. . Today is Jan 17th, and I am still dizzy, but feeling better. I have an appointment with my primary Jan 18th and not sure if I should take the 2nd dose. That is the question."

Acute Appendicitis

Heart attack death medical test

Resident expired 1/17/21

29yo female patient reports feeling her throat tingling and closing sensation in her throat with a metallic taste and diaphoretic approximately 3 minutes after receiving vaccine. She did not report these sensations until about 15min after injection. EMS assist was immediately called and pt was brought into one of the patient rooms. She was given Epipen injection approx. 20min after injection and EMS arrived to transport patient down to ER within 1-2 minutes after Epipen administered. Patient was monitored in ER and recovered well

rash on the arm and side of my body where the injection was given. i took some Benadryl on 01/14/2021 the rash came back and the injection spot became really warm and harden. i took Benadryl again it went away. the rash came back 01/16/2021 and i took more Benadryl and the itcing stop. isaw a few red spots on my arm today bot no itching.

lymphadenopathy on left side (starting in axillary and progressing to supraclavicular and eventually neck as well. swollen and extremely tender) in addition to normal side effects of chills, fatigue. also was having irregular heart rhythm (reason for hospitalization) do not know if the heart rhythms are related to the vaccine or not, onset was a few days after vaccination (ER 12/30/2020, then another hospital 1/1-1/2). but the hospitalization below is referring to the heart rhythm not the lymphadenopathy.

The patient received her first Moderna COVID-19 vaccination on 12/29/2020. However the patient was diagnosed with a positive COVID-19 test on January 4, 2021. Patient complained of nausea, vomiting, back pain, and sharp chest pain. On January 13, the patient presented to the emergency department again with shortness of breath and sharp, stabbing left-sided chest pain radiating to her back and right

side. Initial work up ruled out cardiac etiologies. CTA chest demonstrated COVID-19 pneumonia. The patient complained of bilateral lower extremity weakness which had been progressing since her COVID-19 vaccination, per patient report. However, during her hospitalization the patient's bilateral lower extremity weakness began to accelerate. On the 13th, the patient was able to ambulate to and from the bathroom herself. Then on January 14 the patient required maximum assistance. Neurology was consulted and work up initiated for suspected possible Guillain-BarrT syndrome (GBS) secondary to recent COVID-19 infection. On January 15, 2021, the patient became obtunded and unable to protect airway. She was emergently intubated for acute hypercapnic respiratory failure secondary to GBS. Neurology started GBS treatment with IVIG. Patient also developed NSTEMI and Takotsubo cardiomyopathy. Patient remains critically ill requiring mechanical ventilation.

The day after receiving the second vaccination, I began to have mild intermittent abdominal pain2-3/10. The pain gradually increased, became more intense, and more constant. Mild fever and chills started happening, and I took Ibuprofen. By about 4 days after the vaccine, the abdominal pain was severe enough that I had some difficulty walking and I couldn?t sleep at night. Pain was 6-8/10. I went to the ER, and CT scan with IV contrast showed 18 mm appendicitis. I underwent laparoscopic surgery and it was found to be perforated. It was removed. I am currently recovering in the hospital. I received the vaccine as a health care provider at my hospital, specifically I am a practicing pediatrician physician for over 10 years.

I felt quite sick, like I had the flu; became very lightheaded and dizzy; passed out; felt quite sick; This is a spontaneous report from a contactable consumer (patient). A 69-year-old non-pregnant female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 08Jan2021 at 12:30 at single dose in left arm for covid-19 immunization. Medical history included R.A.D., osteopenia, migraine with aura, the patient had previously suffered episodes of vasal vagal syncopy when she got the flu or other severe illnesses, and the patient was diagnosed with COVID-19 prior to vaccination. Concomitant medication included atenolol, atorvastatin, azelastine, and fluticasone. The patient previously took gramicidin, neomycin sulfate, polymyxin b sulfate (NEOSPORIN) and experienced allergies. The morning after receiving the vaccine, she felt quite sick, like she had the flu. When she got up from bed and went to the bathroom to urinate, she became very lightheaded and dizzy. She attempted to return to bed, but passed out on the bedroom floor before she could get to the bed, and seized while she was unconscious. Once she came to, she was helped to bed and, after about 90 minutes, felt much better, and got up, and ate food and had coffee. All events occurred at 07:30 AM on 09Jan2021. All events were reported as non-serious by reporter. The patient did not receive treatment for the events. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient has not been tested for COVID-19 since the vaccination. The outcome of the events was resolved in Jan2021. Information on the lot/batch number has been requested.

Blacked out; Fainted; Felt very unwell; Nauseous; Chills; Fell; Knocked out, hit her nose, started to bleed; Humongous scar on her nose; In her hand there's a rash with different dots/red; She has petechiae/rash on the forearm; hit her face; knocked out, hit her nose; This is a spontaneous report from a contactable physician. This physician reported that a 30-year-old female patient (daughter) received second dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on

08Jan2021 at single dose for covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced blacked out, fainted, felt very unwell, nauseous, chills, fell, knocked out, hit her nose, started to bleed, humongous scar on her nose, in her hand there's a rash with different dots/red, she has petechiae/rash on the forearm, all on an unspecified date in Jan2021. The Caller wanted information on side effects specifically looking at platelet or clotting or bleeding issues. Her daughter, (female, age 29 date of birth) received the 2nd dose of Pfizer vaccine, received it at the (State name), last night. She felt very unwell, nauseous, chills, and then blacked out, fell, knocked out, hit her nose, started to bleed; fainted and hit her face, didn't stop bleeding for 2 hours. There's a humongous scar on her nose. It took 2 hours to stop bleeding. She's going to urgent care today. Her daughter was healthy, yesterday was 2nd dose. In her hand, there's a rash with different dots/red. She has petechiae/rash on the forearm. Thankfully it (bleeding) did stop. The outcome of events for 'knocked out, hit her nose, started to bleed' was resolved on an unspecified date, for other events was unknown. The case was reported as non-serious. Information on the Batch/Lot number has been requested.; Sender's Comments: Based solely on a chronological association a causal relationship between events blacked out and fainted and BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), cannot be completely excluded. The case will be reevaluated should additional information become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

fist dose on 21Dec2020, second dose on 07Jan2021; pain and stiffness radiating from injection site all the way down arm,into breast, and middle of back; pain and stiffness radiating from injection site all the way down arm,into breast, and middle of back; pain and stiffness radiating from injection site all the way down arm,into breast, and middle of back; Started having chills; Severe headache; collapsed on the way back to bathroom and was unable to get up for about 20 minutes; tachycardia; extremely fatigued entire day; This is a spontaneous report from a contactable Pharmacist who reported for herself. A 30-year-old female patient received her second dose of BNT162B2 (Pfizer/ BioNTech Covid-19 vaccine, lot number Ej1685) at a single dose at 09:45 AM 07Jan2021 at left arm for Covid-19 immunization in a hospital. The patient had her first dose of Pifzer Covid-19 vaccine on 21Dec2020 at 12:00 PM at left arm, and experienced very mild reactions which included mild pain at injection site and runny nose/sneezing day after vaccine. The paitent had a medical hisotry of rash to penicillin as a child. Concomitant medications were not reported. The patient did not receive any other vaccines within 4 weeks prior to her first dose of Pfizer COVID vaccine. In the evening of second vaccine (around 17:00), pain and stiffness radiated from injection site all the way down arm, into breast, and middle of back. She started having chills. Around 10 hours after dose chills became somewhat violent despite being under 4 blankets. Severe headache also started. In the middle of the night to go to bathroom, she collapsed on the way back and was unable to get up for about 20 minutes. She also suffered from tachycardia overnight. her baseline heart rate runs in 60s- 70s, but was in 110s-120s (based on Apple Watch monitoring). Day after vaccine, she was extremely fatigue entire day and spent all but a few hours in bed. Arm pain mostly gone. Headache was very strong and persistent through the day. On second night chills not as bad but still occurred overnight. HR still elevated in 80s overnight. Morning of day 2 still had

headache and fatigue. The patient did not receive any treatment for the events. The outcome of collapse and unable to get up for 20minutes, pain and stiffness radiating from injection site all the way down arm,into breast, and middle of back was resolved, chills and tachycardia was resolving, headache, fatigue was not resolved. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. The reporter considered that the events was non-serious.; Sender's Comments: Based on a chronological temporal association and known BNT162B2 vaccine safety profile, causality between events fainting, violent chills and severe headache and BNT162B2 ((Pfizer/ BioNTech Covid-19 vaccine) cannot be completely excluded. The case will be reevaluated should additional information become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

anaphylactic reaction/anaphylaxis; This is a spontaneous report from a Pfizer Sponsored Program from a contactable pharmacist. A female patient of an unspecified age received first dose of bnt162b2 (Pfizer BioNTech COVID vaccine, lot number: EK4176), via an unspecified route of administration on 09Jan2021 at 0.3 mL, single (standard like 0.3ml by injection once to deltoid, side unknown) to prevent from getting COVID. The patient's medical history and concomitant medications were not reported. The patient experienced anaphylactic reaction/anaphylaxis on 09Jan2021. Clinical course: The patient got the vaccine while waiting to go into the watch room, to be watched for a few minutes, and she experienced anaphylactic reaction/anaphylaxis, she went down, they gave her an Epinephrine, she didn't respond to the first dose, a second dose was given in the arm where the vaccine was given, then she was picked up by an ambulance. Agent stated the caller has been on hold for almost an hour. Caller clarifies dose was given in the arm, it occurred on Saturday with the same lot. Saturday and it went away on Saturday, the patient was worried about it coming back, thus why she asked about Epinephrine pen, the patient was taken to the hospital, and given Epinephrine a couple more times, and it resolved eventually, the patient was not admitted, she went to the Emergency Department. It could have required hospitalization but would most likely say life threatening had she not been treated. Reporter seriousness for anaphylaxis is life threatening. The outcome of event was recovered on 09Jan2021. Relatedness of bnt162b2 to reaction anaphylaxis is related for primary source.; Sender's Comments: A possible causal association between administration of BNT162B2 and the onset anaphylactic reaction/anaphylaxis cannot be excluded, considering the plausible temporal relationship and the known adverse event profile of the suspect product. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

developed symptoms for Covid/tested positive after receiving the vaccine; developed symptoms for Covid/tested positive after receiving the vaccine; developed symptoms for Covid/tested positive after receiving the vaccine; This is a spontaneous report from a contactable physician (patient) and a

consumer (patient's spouse). A 67-year-old male patient received first dose BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Solution for injection; lot number: EH9899; expiration date: not known), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The physician had a question. As a patient, he received the first dose of Pfizer BioNTech vaccine and on an unspecified date, two days later, he developed symptoms for Covid and tested positive after receiving the vaccine. He stated this had nothing to do with vaccine but had to do with the timing. He wanted to know if should take or delay vaccine. He is doing fine now. His second dose is coming up next week. The outcome of the events was recovered on an unspecified date.; Sender's Comments: The association between the event lack of effect (he developed symptoms for COVID and tested positive) with BNT162b2 can not be completely excluded.

got the first vaccine and then tested positive for the virus; got the first vaccine and then tested positive for the virus/fairly sick; This is a spontaneous report from Pfizer-sponsored Program IBCC (Inbound Call Center for HCPs). A contactable physician reported similar events for two patients. This is the first of two reports. A patient of unspecified age and gender received first dose BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Solution for injection; lot number and expiration date: not known), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The reporter is a cardiologist. He is inquiring about the COVID-19 vaccine. He had several patients (pending clarification) who got the first vaccine and then tested positive for the virus. He is asking when can they get the second dose after testing positive. He had two patients that are fairly sick now. He has had patients who have monochromal antibodies (pending clarification). He is asking when they can get the vaccine after that treatment. The outcome of the events was unknown. Information about lot/batch number has been requested.; Sender's Comments: A causal association between BNT162B2 and the reported events cannot be excluded based on a compatible temporal relation between vaccination and onset of events.,Linked Report(s) : US-PFIZER INC-2021022171 same reporter, similar suspect drug and event; different patient

got the first vaccine and then tested positive for the virus; got the first vaccine and then tested positive for the virus/fairly sick now; This is a spontaneous report from Pfizer-sponsored Program. A contactable physician reported similar events for two patients. This is the second of two reports. A patient of unspecified age and gender received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Solution for injection; lot number and expiration date: not known), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The reporter is a cardiologist. He is inquiring about the COVID-19 vaccine. He had several patients (pending clarification) who got the first vaccine and then tested positive for the virus. He is asking when can they get the second dose after testing positive. He had two patients that are fairly sick now. He has had patients who have monochromal antibodies (pending clarification). He is asking when they can get the vaccine after that treatment. The outcome of the events was unknown. Information about lot/batch number has been requested.; Sender's Comments: A causal association between BNT162B2 and the reported events cannot be excluded based

on a compatible temporal relation between vaccination and onset of events.,Linked Report(s) : US-PFIZER INC-2021022153 same reporter, similar suspect drug and event; different patient

The day following vaccination, the patient experienced nausea/vomiting, shortness of breath, followed by extremity paresthesia, and increased heart rate. The patient went to the emergency room and was assigned an overnight admission for a potential post-vaccination adverse event. Patient was discharged the following day.

The day of vaccination, the patient presented to the emergency room with a complaint of dizziness and syncope. Reported that she became dizzy, presyncopal feelings, and had a witnessed syncopal event. The patient stated she does have vasovagal syncopal events after blood draws in the past. The patient was assigned an overnight admission for a potential post-vaccination adverse event, new onset atrial fibrillation, dehydration, and syncope. Patient was discharged the following day.

Myalgia Narrative:

Patient became sick 3 hours after the vaccine and was found deceased 1 day after his vaccination. He passed away in his sleep.

nausea and vomiting possible cause of diabetic ketoacidosis and svt

0900 IM Covid 19 vaccine 0905 Sore throat 0920 Dizzy episode followed by headache 0945 Stridor upon deep breath 1000 Facial tingling, top lip and eye swelling 1015 Present to Emergency Services 1040 IV benadryl - Tingling throughout body, stridor worsening, , visible facial swelling 1045 IV Decadron - Throat swelling worsening, chest heaviness, wheezing 1050 IM Epinephrine 1055 Racemic Epi nebulizer treatment 1100 Facial and throat Swelling reducing, breathing easier, 1105 Breathing back to normal 1430 Discharged from Emergency Services with prescription for Dexamethasone 4Mg for 3 days, 2 allegra 2x daily, famotidine 2 x daily

Jan 11-vaccination day. On Jan 14, in afternoon had tinnitus and muffled hearing that went away. The next morning Jan15, complete sudden hearing loss on left ear. Tinnitus and muffled hearing that has not went away.

Patient experienced abdominal pain on January 12th. She reported having a headache and joint pain as well. Her temperature was 103.5. On January 14th the patient was admitted for acute appendicitis with perforation, localized peritonitis, and gangrene. Patient was discharged on January 16th post appendectomy.

Patient received Moderna Covid vaccine on Friday evening 1/8/21. She awoke Saturday am around 2AM with a severe headache. She also developed a fever during the day. She did not seek treatment until Sunday and went to Hospital ED. She was treated and released same day. She went back to hospital on Monday as she felt worse and she was admitted at that time and treated for a bloodstream infection and meningitis. We are not sure it was caused by the vaccine. She consulted her PCP and her PCP feels it may be more coincidental given her medical HX.

A few days after the vaccine I began to have a cough about mid morning which changed to SOB. Covid test on 12/27 which was neg. I went to work on 12/28 but woke up 12/29 with a low grade fever and felt like my throat was on fire. so on the 29th I went and got a Strep and flu test which were negative. I was feeling so bad so on the 6th of Jan do I went to the stand alone ER and got a chest xray and CT scan which revealed I did have pnemonia. I went back home but was feeling worse and was taken to and admitted in hospital for 2 days. Initially I was admitted into the COVID unit but never was diagnosed COVID positive so I was moved off the COVID unit. I was given albuterol pills to try to help with the symptoms but didnt work causing me to have to be admitted and was given several doses of steorid and other antibioics and had to use O2 at night because my stats kept falling.

Patient reported to the emergency room from fever and shortness of breath the day after receiving the COVID-19 vaccine. Patient was found to have a UTI and possible sepsis. Unknown if truly related to COVID vaccine.

Severe fatigue, Headache frontal and temporal, dizziness/vertigo, tinnitus,

"Pt is 33 yo female with h/o multiple drug allergies , including allergy to benadryl. She has received first dose of COVID vaccine made by Phfizer at 3:45. She reports about 10 minutes after the vaccination she started feeling tingling in her lips, throat and prickly sensation on her chest and feeling ""off"". Felt dizzy, developed small hives on her chest. She was attended to immediately at the vaccine site and our team was called to white code. Pt was sitting on the floor, alert , breathing comfortably. Her BP was 151/84, HR 90, O2 Sats 100%. Her lungs were clear the whole time, no wheezing, no difficulty swallowing or talking. Patient received 125 mg of IV solumedrol and 20 mg of pepcid in vaccination room, she felt the same, still breathing comfotably, speaking full sentences, hives faiding away. She was transported to Urgent Care clinic on wheelchair. Pt kept her EpiPen by her site the whole time but refused to used it, states she is afraid to use it and wants to hold off or get it in ER if necessary. About 16:30 patient reported her tingling, prickly sensation In her chest is getting worse, developed sensation of lump in her throat, able to swallow and breath without problems, lungs exam clear. Again recommended to give Epipen but patient again refused as she feels very anxious about getting new medicine. She was able to speak full sentences and breathing well, O2 Sats 100% the whole time, she repetitively refused EpiPen. EMS called and patient transported to ER, ER notified. Pt left in stable condition."

On 01/13/2021 at about 11pm I began having pain in both arms and across my chest. Also nausea and vomiting. At midnight I went to the Emergency room and was diagnosed with a heart attack, underwent emergency catheterization and stent placement. I had complete occlusion of the right coronary artery

Patient is 39-year-old male with no significant past medical history who works at long-term care facility. He received COVID-19 vaccine on 1/13/2021 and immediately developed numbness and tingling in the area of injection which was the left shoulder. Over the next 15 to 30 minutes numbness and tingling expanded to the left side of his body including face arm and leg and the left side of his trunk. He began to feel foggy and had some slurred speech. He presented to the Emergency Room and tests were performed to rule out a stroke. The patient denies any other symptoms such as fever chills myalgias. He

did not have any weakness of the extremities. He did not have any speech disturbances or visual disturbances. This morning on examination he states his symptoms are much better. He still has some residual numbness in his leg and arm. Facial numbness is almost all gone. As of 1/18/2021, residual numbness and tingling is only in his left ring and pinky finger.

"Patient with PMH of depression and GERD who presented 1/8 with constipation, abdominal discomfort and worsening dyspnea. Symptoms began around 12/29. COVID vaccine 12/19. Previously quite active, marathon runner, gained some weight over last couple years but was still in good enough shape to complete 10K in New Orleans in early February. In late February, had a flu-like illness, as did one of his friends from church. 2020 was hard on him - weight gain, decreased activity, stress, overall deconditioning. No issues apart from sore arm after COVID vaccine 12/19 but then starting getting abdominal fullness/discomfort around 12/29, which steadily worsened, also develop worsening dyspnea on slight exertion. No known sick contacts.. Work-up notable for pericardial effusion, pleural effusions. Echo with severe diffuse LV hypokinesis, concern raised for myocarditis. COVID PCR negative, serology negative. RVP negative. . Concern raised that COVID vaccine may have played a role in myocarditis. He was found to have the following conditions Acute heart failure with reduced EF NYHA FC II, non-ischemic cardiomyopathy. Myocarditis appears subacute per MRI hypertension obesity small pericardial effusion-asysmptomatic no pericarditis suspected obstructive sleep apnea. .Started on the following medications. Continue Carvedilol 12.5mg BID, Farxiga 5mg daily, Digoxin 0.125mg daily, Entresto 97-103mg BID, and Spironolactone 25mg daily. Per MD note. While it remains uncertain, team is doubtful COVID vaccine played a role in his cardiac issues. Given the MRI findings are not acute, more likely that the cardiac insult occurred weeks to months ago - potentially in the setting of the February 2020 illness. Perhaps his ""deconditioning"" in 2020 was related to worsening cardiac function. Nevertheless, will hold on 2nd COVID vaccine dose given absence of a clear explanation for his myocarditis. conversation with team will continue to determine if candidate for second covid vaccine. If consensus is that myocarditis pre-dated vaccine, might be able to proceed with dose 2 of vaccine."

"PATIENT RECEIVED VACCINE 1/7/21 AT 1000. THE NEXT DAY, PATIENT PRESENTS TO ER ON 1/13/21 WITH COMPLAINTS OF PALPITATIONS AND DIZZINESS OCCURING SINCE HER FIRST DOSE OF VACCINE. ""The patient states she has had these episodes for the last 6 days and they started when she got her COVID vaccine. The patient states she has had numerous episodes over the last 6 days of this that lasts between 2 and 4 hours. The patient can feel her heart fluttering and she gets a little dizzy with it. The patient has not had any nausea, shortness of breath or chest pain with these episodes however. The patient has not had any prior episodes of this. The patient takes no regular medications apart from vitamins."" PATIENT WAS DIAGNOSED WITH NEW FOUND A. FIB WITH RVR. ADMITTED TO HOSPITAL FOR OBSERVATION. PATIENT RETURNED TO NORMAL SINUS RHYTHM THE NEXT DAY AFTER INITIATING DILTIAZEM AND ELIQUIS."

EDD July 4, 2021 January 15th baby no longer had a heartbeat after two previous visits confirming heartbeat and EDD.

DVT in right leg 4 days after injection, severe pain in thigh/calf, difficulty walking Placed on Xarelto 15mg 2X daily for 21 days and then 20mg daily for 9 days. Next Doctor visit is 1/26/2021 at 9:00am Next scheduled Covid 19 vaccine is scheduled for 2/5/2021 at 7:15am

After I received the vaccine went home rested temp went up one time 99.0. The next day woke up heart was pounding check my BP 150/80 laid back down. I woke up around 5pm my BP had elevated to 160 (don't remember diastolic reading) pulse rate normal limits. I informed my spouse of what was happening called 911. At the hospital checked vitals, EKG, CT Scan, Chest X-ray, Blood work and Potassium was low took 2 Potassium pills. I went back home on 12/31 returned to work did fine that day. On New Years day everything started back again discomfort went back to ER. I felt like force in my chest the doctor collected my information and I was placed on a low dose BP medication until I return to my PCP, cardiologist(stress test). I followed up with PCP via Telehealth about my BP concerns, my dosage was increased to 25 mg and due to my symptoms I was placed on leave from work 2 wks. I also have a appointment scheduled with Neurologist.

Daughter call in for VAERS report to file for father whom committed suicide 1/16/2021 in the AM after reportable ae of COVID 19 vaccine administered 1/14/2021. Patient sought care twice at ER; first visit by ambulance around 5PM and Friday 1/15/2021 Medical Center: Emergency Room. 1st Discharge summary diagnosis: adverse reaction to COVID shot; 2nd Discharge summary diagnosis: adverse reaction to COVID shot, fever, Panic Disorder-- ER. Medical Center Discharge summary diagnosis: Adverse reaction to the vaccine, acute anxiety. Reportable patient symptoms at, 1st visit : fever, shaking stomach cramps, breathing issues. Medical Center -- No fever, confusion and dementia type, patient would not stay in patient bed; patient would get up and sit down again repeatedly, agitated and anxious. Attempted to urinated hospital bed. Patient committed suicide in home.

Anaphylaxis (urticaria, tongue swelling, subjective difficulty breathing) starting approx. 24hrs first moderna dose. No prior episodes of anaphylaxis/allergic rxn. Treated with Benadryl 100mg PO (prior to arrival, pt administered), famotidine 20mg IV, Epinepherine 0.3mg IM. Monitored in ED, complete resolution of symptoms, discharged home.

Weakness, Low O2, death. Positive for COVID on 1/12/21, dies on 1/16/21

Patient presented to ED with complaint of chest pain, radiating down left arm, not relieved with Tums. Symptoms started at 0530 1/12/2020. Patient presented to ED b/c of strong family history of CAD, with father having MI in his 50s.

On 1/17/2021 at 4:35 am resident found apneic and pulseless, at 4:40am death confirmed

I was vaccinated at 3:30pm . At 5:27pm while driving home i felt a cold sensation in the back of my neck and back of my throat which began spreading to the back of my head . My heart felt as if I was startled by something. I looked at my smart watch and my heart rate was 145. I began trembling and having abdominal cramping . The back of my head felt like I had swelling or collection of fluid. I opened my windows and began taking slow deep breaths to bring down my heart rate . It took quite a while to get it below 100. I felt as if I was going to pass out. After deep breathing for what felt like atleasr 15 to 20

minutes , my pulse came down and I closed my windows . As soon as my body warmed back up in the car , the symptoms returned and my heart rate went back up to 130s , 140s . I had to keep my windows down and deep breathe the entire way home which took an hour . My body was trembling. When I got home I felt as if I was too week to get out of the car . I still felt that startled feeling in my heart and was afraid of what could happen next . My lips and face were swollen. My lips were also slightly itchy. I called 911 for help . By the time they arrived my vital signs had stabilized but I still had swelling in my face and lips . My EKG , vital signs and oxygen levels checked out normal so I did not go to the ER. That night I took benadryl and Tylenol. Day 2 post vaccine the collection of fluid or swelling in the back of my head had now spread to the top . That night I had the feeling that my throat was swelling do I took benadryl and Tylenol and my face and lips were still slightly swollen . Day 3 post vaccine I woke up with slightly blurry vision. The swelling in my head now feels like it has encompassed my entire head and have a slight headache. I went to the urgent care requesting an MRI of the head and an epi pen . I was given Medrol dose pack , an RX for epi pen for emergencies and advised to continue benadryl and Tylenol. Day 4 post vaccine, slight headache continues. Slightly blurry vision

12/29/2020 Vaccination. Within minutes blurry vision, dizzy, tx to stretcher. EXTREME HA, coughing, sensitivity to light. EPI pen in ER. I fell asleep. Woke up, don't remember much. Admitted to hospital. Chest pains started within 2 hours, SOB, HA. Admitted for 2 nights, 3 days. Discharged home. Still having SOB and referred to Pulmonologist. Waiting on appt. *did NOT have problems before this vaccine. I was fine. Now i am completely different person, I have to monitor my walking, etc.

"80YO male who htn, cva, epilepsy, ckd, cerebral avm s/p repair, cad s/p cab, cva (left sided hemiplegia) , hx of prostate cancer recent admission for pna on abx presents to ED on 1/11 with dizziness, hypoxia. CT with Bilateral PE ""Large bilateral pulmonary artery emboli in the right and left main pulmonary artery extending into the right and left main pulmonary artery branches bilaterally. Findings are associated with right-sided heart strain."" ""Patchy alveolar airspace disease within the lungs highly suspicious for COVID pneumonia"" Covid negative. Patients wife recovered from Covid-19 infection within last month. Patent thus far has tested negative. Doppler lower extremity revealed Acute occlusive vein thrombosis of the entire course of the gastrocnemius vein and soleal vein. Patient received covid vaccine on 1/4/21. Patient has several risk factors for clot - age, previous CVA, hx of prostate cancer. Also had positive covid exposure though tested negative"

Resident was seen by MD on 1/11/2021 due to increasing in edema and shortness of breath. Lasix 40 mg STAT given. New orders to get a STAT CBC, CMP, and BNP. Resident has been dependent on Oxygen since his diagnosis of COVID-19 on 11/23/2020. Labs were abnormal. Continued on the lasix 40 mgs. Resident remained short of breath with exertion and on oxygen. He was assisted to the toilet on 1/15/2021 in the morning where he subsequently passed away.

hives on her face; This is a spontaneous report from a contactable healthcare professional (physician assistant). A 42-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot number: EK5730), via an unspecified route of administration, on 24Dec2020 as a single dose (reported as 0.3) for COVID-19 immunization. The patient had no medical history or concomitant medications. The patient experienced hives on her face in Dec2020, which was reported as

medically significant. It was reported that within 24 hours of vaccination, the patient had hives for 48 hours. The event was reported as a moderate systemic reaction. The clinical outcome of hives on her face was recovered in Dec2020.; Sender's Comments: Based on the compatible time association, the event hives on her face is possibly related to suspect BNT162B2 administration. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

"a low grade fever; cough; doesn't feel very well; feeling yucky; soreness in the arm where vaccine was given; This is a spontaneous report from a contactable Nurse (reporting for herself). A 29-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE solution for injection, bacth/lot no: EK9231 while expiry date was unknown), intramuscular on left deltoid on 07Jan2021 16:45 at a single dose for covid-19 immunization. There were no medical history and concomitant medications reported. Patient has no prior vaccination within 4 weeks.The patient got her first dose of the COVID 19 vaccine yesterday (07Jan2021) from her employer. She started ""feeling yucky"" today (08Jan2021) around noon with a low grade fever,and developed a cough that was not persistent. Patient has soreness in the arm where vaccine was given. She was asking what should she do about it? Outcome of the events low grade fever, cough, feeling unwell, feeling abnormal were not recovered while vaccination site pain was unknown. The events low grade fever, cough, feeling unwell were considered serious medically significant and related to vaccine.; Sender's Comments: Based on the time association, the events fever, cough and malaise are possibly related to suspect BNT162B2 administration. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate."

generalized weakness; flushing; my BP is high; dose 1 start date 19Dec2020; dose 2 start date 8Jan2021; This is a spontaneous report from a contactable pharmacist. A 34-year-old female patient received the second dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number EL3246), intramuscular in left arm on 08Jan2021 at a single dose for COVID-19 immunization. Medical history included chronic HTN and allergies to baclofen and statins. The patient's concomitant medications were unspecified medications taken for hypertension. The patient previously received the first dose of bnt162b2 on 19Dec2020 via intramuscular in left arm, lot EL0140. On 08Jan2021, the patient was brought into ER as code MET. Patient was receiving her second vaccine for COVID-19 when she experienced generalized weakness and flushing. She stated that she knew her BP was high. Endorses hx chronic HTN, reports she took all three medications this AM. The patient denied any headache, new visual change, CP, SOB, or focal weakness. The events recovered on an unknown date in Jan2021. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. No treatment was received for the events.; Sender's Comments: Based on the time association, the events asthenia, flushing and hypertension are possibly related to suspect BNT162B2 administration. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer

procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Profuse watery vaginal bleeding 12 hrs after injection. Bleeding lasted approximately six hours. After first injection and vaginal bleeding, gynecology exam completed for abnormalities; This is a spontaneous report from a contactable physician (patient). A 55-year-old female patient received the first dose of BNT162B2 (Pfizer-BIONTECH Covid-19 Vaccine), intramuscular in the left arm on 22Dec2020 at 16:00 at a single dose; and the second dose via intramuscular in the left arm on 08Jan2021 at 08:00 at a single dose as COVID-19 vaccine. Medical history included a known latex allergy and previous spontaneous cerebral artery dissection x 3 (nonspecific connective tissue disease). The patient was not pregnant at the time of vaccination and did not receive any other vaccine within 4 weeks prior to the COVID vaccine. The patient was not diagnosed with COVID-19 prior to the vaccination and was not tested for COVID-19 post vaccination. Concomitant medications (reported as other medications within two weeks of vaccination) included estrogens conjugated (PREMARIN), micronized progesterone, colecalciferol (Vitamin D), folic acid (FOLATE), and diphenhydramine hydrochloride (BENADRYL). On 23Dec2020, the patient experienced profuse watery vaginal bleeding 12 hours after the injection. The bleeding lasted approximately six hours. After the first injection and vaginal bleeding, a gynecology exam was completed for abnormalities. Previously diagnosed uterine fibroids present and some free fluid in the pelvis by ultrasound. Bleeding resolved by the end of post-vaccine day 1. After the second vaccine, heavy vaginal bleeding started 10 hours after a injection. It was reported that the adverse event result in a doctor or other healthcare professional office/clinic visit. Treatment for the event involved removal of the IUD. Outcome of the event was recovering. The case was reported as non-serious (did not result in death, was not life-threatening, did not cause/prolong hospitalization, was not disabling/incapacitating, and did not result to any congenital anomaly/birth defect). Information about the lot/batch number has been requested.; Sender's Comments: There is reasonable possibility that the event vaginal hemorrhage is related to suspect drug BNT162B2 based on a compatible temporal relation between vaccination and the onset of events. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

few enlarged and abnormal lymph nodes believed to be reactive in nature; patient was pregnant at the time of vaccination; large mass appeared in right axilla; mass was painful to touch; large mass appeared in right axilla; mass was painful to touch; This is a spontaneous report from a contactable healthcare professional (patient). A 36-year-old female patient received the first dose of bnt162b2 (COVID 19, brand: Pfizer) lot no: EJ1685, via an unspecified route of administration in right arm on 23Dec2020 07:15 at a single dose for COVID-19 immunization in a hospital. The patient had no relevant medical history and no known allergies. The patient was pregnant at the time of vaccination, last menstrual date was on 05Oct2020, delivery date will be on 12Jun2021, gestation period: 11. Concomitant medication includes daily multivitamin. The patient did not receive other vaccines within 4 weeks prior to the COVID vaccine.

The patient was not diagnosed with COVID-19 prior to vaccination and was not tested for COVID-19 since the vaccination. On 30Dec2020 04:00 am, 7 days after vaccine (as reported), a large mass appeared in right axilla. The mass was painful to touch. Overnight mass more than doubled in size on 31Dec2020 the mass took up her entire arm pit, went to immediate care and was given antibiotics. The mass decreased in size but has not gone away. She followed up with primary care. She had bloodwork and ultrasound of axilla and right breast. Blood work was normal. Ultrasound showed a few enlarged and abnormal lymph nodes believed to be reactive in nature. Largest lymph node as of 08Dec2020 2.5 x 0.9 x 2.2 cm. The events were reported as non-serious. The events resulted in doctor or other healthcare professional office/clinic visit and emergency room/department or urgent care. Outcome of the events was unknown.; Sender's Comments: A causal association between BNT162B2 and the reported events cannot be excluded based on a compatible temporal relation between vaccination and onset of events. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

Syncopal event; Nausea; Vomiting; This is a spontaneous report from a contactable nurse. A 29-year-old female received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number:EL1284), via an unspecified route of administration on the right arm on 08Jan2021 12:15 at single dose for COVID-19 immunisation. The patient medical history was not reported. Concomitant medication included influenza vaccine (INFLUENZA VACCINE) on 13Dec2020. The patient previously took first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899) on 18Dec2021 12:15. The patient experienced syncopal event, nausea and vomiting on 09Jan2021 05:00. The patient received no treatment. The outcome of the events was recovering. No follow-up attempts are possible. No further information is expected.; Sender's Comments: Based on the compatible time association, the event syncope is possibly related to suspect drug BNT162B2 administration. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

allergic reaction; large red itchy rash on her neck / chest area; trembling; This is a spontaneous report from a contactable pharmacist. A 33-year-old female patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via unspecified route of administration (lot number: EL1283) in the arm right on 07Jan2021 09:00; at single doses for COVID-19 immunization. Medical history included known allergies: latex. Concomitant medications included magnesium oxide (MAG OXIDE) at 200 mg, daily (every day) and cetirizine hydrochloride (ZYRTEC) at 10 mg, daily (every day); and toprolol at 25 mg, every day (pending clarification for the drug). The patient previously received first dose of BNT162B2 on 17Dec2020 (lot number: EK5730) for COVID-19 immunization. Patient was not diagnosed with COVID-19 prior to vaccination; and has not been tested for COVID-19 since vaccination. Within the 15-minute observation period on 07Jan2021, the patient developed a large red itchy rash on her neck and chest area; she stated she felt fine but was observed trembling. She was transported to ED

(emergency department, 5 min transport). She was treated with diphenhydramine hydrochloride (BENADRYL) at 25mg IV X1 (intravenous), and methylprednisolone (SOLUMEDROL) at 60mg IV X1 and famotidine 20mg IV X 1. Patient diagnosis was allergic reaction on 07Jan2021. Patient improved after treatment and was discharged (after being in Emergency room/department or urgent care) as she was observed from 09:11 until 10:33. Final outcome of the events was all recovered on unspecified date.; Sender's Comments: Based on the time association, the allergic reaction, rash erythematous and trembling are possibly related to suspect BNT62B2 administration.The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

couldn't differentiate the tingling in hands and feet from shot or from that; sharp pain jolt behind eyes/eyes hurt; icreamed; Her hand eye coordination was off as well and she wasn't able to be accurate on keyboard and her cursive was off; Whole body still weak; sharp pain jolt behind eyes, left one in particular so bad she screamed and the nerves went all the way to finger tips; Twitching of face when do certain movements; brain zaps and brain buzzing began; numbness to right side of face to neck/made its way to left side; Horrible headache; fatigue; felt pressure behind her right eye; felt in a fog; forgetful mid conversation; This is a spontaneous report from a contactable other health professional (patient). A 42-year-old female patient (not pregnant at the time of vaccination) received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, EL0140), intramuscular on 23Dec2020 08:00 at single dose at right arm for COVID-19 immunization; prednisone via an unspecified route of administration from an unspecified date to an unspecified date (for 4 days) at 50 mg for an unspecified indication. Medical history included Known allergis: latex, contrast dye. Concomitant medication included the first dose of influenza vaccine (FLU) on 30Nov2020 at single dose at right arm for immunization. Facility where the most recent COVID-19 vaccine was administered at Hospital. The patient received other vaccines within 4 weeks prior to the COVID vaccine. It was reported that Day 1: on 23Dec2020 08:15, the patient felt pressure behind her right eye after shot, felt in a fog, forgetful mid conversation. Day 2. (24Dec2020) Horrible headache started, fatigue. Day 3 (25Dec2020) brain zaps and brain buzzing began, headache, fatigue, numbness to right side of face to neck. By day 5 (27Dec2020) made its way to left side. Twitching of face when do certain movements. Her Dr gave her Prednisone and she took 50 mg for 4 days and stopped because she couldn't differentiate the tingling in hands and feet from shot or from that. Still brain zaps, newest issue sharp pain jolt behind eyes, left one in particular so bad she screamed and the nerves went all the way to finger tips. Her hand eye coordination was off as well and she wasn't able to be accurate on keyboard and her cursive was off. Whole body still weak, eyes hurt. Head a lot better than a day ago but still having buzzing and twitching. Today was day 18. She was awaiting an MRI with contrast on Friday hoping it got moved sooner as she was scared to what was going on. The adverse events result in Doctor or other healthcare professional office/clinic visit and Emergency room/department or urgent care. Treatment received for the adverse events included CT/MRI/Optic Nerve Scan/Pain Shot/Meds for Zaps. The events were non-serious per the reporter. Prior to vaccination, the patient wasn't diagnosed with COVID-19. Since the vaccination, the patient had been tested for COVID-19. The patient underwent lab tests and procedures which

included Nasal Swab: negative on 28Dec2020. The action taken in response to the events for prednisone was permanently withdrawn on an unspecified date. The outcome of the events reported as not recovered.; Sender's Comments: A possible causal association between administration of BNT162B2 and the onset of all these reported serious events might not be fully excluded, considering the plausible temporal relationship. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

"Heart fluttering; chest pressure; This is a spontaneous report from a contactable nurse (patient). A 55-year-old female patient received first dose BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Solution for injection; lot number: EK5730; expiration date: not known), via an unspecified route of administration in the left arm at hospital on 31Dec2020 10:00 at at single dose for COVID-19 immunization. Medical history included known allergies with sulfa. The patient is not pregnant. The patient's concomitant medications were not reported. The patient previously took clarithromycin (BIAXIN), metronidazole benzoate (FLAGYL), and sulfamethoxazole, trimethoprim (BACTRIM), and all but experienced allergies (reported as ""known allergies: Biaxin, Flagyl, sulfa, Bactrim""). No COVID prior to vaccination and no COVID tested post vaccination. The patient experienced heart fluttering and chest pressure on 04Jan2021. There was no treatment received for the reported events. The outcome of the events was not recovered.; Sender's Comments: A causal relationship between the reported heart fluttering and the use of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) cannot be completely excluded due to temporal relationship. The case will be reassessed should additional information become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate."

Tachycardia up to 150 resting; Nausea; Vomiting; Diarrhea; Headache; Migraine; Body aches; Chills; Fever up to 102; This is a spontaneous report from a contactable nurse (patient). This 26-year-old female patient (pregnant: no) received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, lot number: EL3248), intramuscular on 08Jan2021 at 07:45 AM at single dose on right arm for COVID-19 immunisation. Medical history included anxiety and depression. No known allergies. Concomitant medication included fluoxetine hydrochloride (PROZAC), bupropion hydrochloride (WELLBUTRIN), diphenhydramine hydrochloride (ZZZQUIL). No other-vaccine-in-four weeks. The patient previously received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, lot number: EK5730), intramuscular on 22Dec2020 at 08:00 PM on right arm for COVID-19 immunisation. The patient experienced tachycardia up to 150 resting, nausea, vomiting, diarrhea, headache, migraine, body aches, chills and fever up to 102. Symptom onset around 7PM on 08Jan2021 and stopped around 12PM 09Jan2021 except for headache which was still persisting as of 9PM 09Jan2021. No treatment was received for the events. The outcome of headache was not recovered. The outcome of other events was

recovered on 09Jan2021 at 12PM. The patient did not have COVID-prior-vaccination. The patient did not have COVID tested post vaccination.; Sender's Comments: The reported tachycardia was probably related to the use of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE) due to temporal relationship. The case will be reassessed should additional information become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Bell's palsy onset within 48 hours of second vaccine, R side of face; First dose of vaccine on 20Dec2020 and second dose received on 06Jan2021; First dose of vaccine on 20Dec2020 and second dose received on 06Jan2021; This is a spontaneous report from a contactable healthcare professional reporting for himself from a Pfizer sponsored program. A 24-year-old male patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection; lot number EJ1686) via an unspecified route of administration, on 06Jan2021 at 11:30am on left arm, single dose for COVID-19 immunization. Relevant medical history and concomitant medications were reported as none. The patient had no known allergies. The patient had no other vaccine in four weeks and no other medications in two weeks. The patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number EL0140) at right arm on 20Dec2020 10:30am for COVID-19 immunization. On 08Jan2021 at 12:00pm, the patient experienced facial droop 2 days after taking the 2nd dose of the vaccine. The patient went to the hospital for doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care and were advised to take Valtrex and Prednisone and told its Bell's palsy. Bell's palsy onset within 48 hours of second vaccine, R side of face. Wanted to confirm if there will be a problem once they take these drugs since the paient have just received the vaccine recently or wanted to know if the new medications prescribed will affect the vaccine's effectivity. The patient was not diagnosed with COVID prior vaccination and was not tested for COVID post vaccination. Outcome of the event Bell's palsy was not recovered.; Sender's Comments: Facial droop/ Bell's palsy occurred 2 days after taking the 2nd dose of the BNT162B2 vaccine, a possible causal association between administration of BNT162B2 and the event onset thus might not be fully excluded, considering the plausible temporal relationship. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

7 days later diagnosed with pneumonia; 3 days after developed hives on my stomach and arm; felt tired; confused; unwell; This is a spontaneous report from a contactable healthcare professional (patient). A 37-year-old female patient received her first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: Ek5730), via an unspecified route of administration on the left arm on 28Dec2020 12:00PM at a single dose for COVID-19 immunization at hospital facility. Medical history included Hashimotos disease. The patient had no known allergies and has not had COVID prior to vaccination. The patient's concomitant medications were not reported. The patient reported that she felt tired and confused and unwell on day of injection, 28Dec2020. After three days (31Dec2020), she developed hives on her

stomach and arm and seven days later (04Jan2021), she was diagnosed with pneumonia and continued to have hives all over her legs and arms to this day. The patient was treated with antibiotics for pneumonia. She underwent Covid test/ Nasal swab post vaccination on 09Jan2021, pending result. The outcome of the events was not recovered.; Sender's Comments: The reported pneumonia was more likely an intercurrent disease, and unlikely causally related to the use of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE). The case will be reassessed should additional information become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

difficult breathing; Pain on the chest; Not being able to move my upper neither lower body; itchiness all over my body; unconscious; Headaches; major anxiety; depression; very light-headed; weak; almost faint; This is a spontaneous report from a contactable Other HCP (patient). A 28-years-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 08Jan2021 12:00 at single dose on Left arm for COVID-19 immunisation. Facility type vaccine was Hospital. Medical history was none. The patient's concomitant medications were not reported. No other vaccine in four weeks. The patient experienced Not being able to move my upper neither lower body, Headaches, major anxiety, and depression, unconscious, very light-headed, weak, almost faint, Pain on the chest, difficult breathing, itchiness all over my body on 08Jan2021. AEs resulted in Emergency room/department or urgent care, Hospitalization. Received injected fluids as treatment. The outcome was Not Recovered. No COVID prior vaccination. No COVID tested post vaccination. Information on the lot/ batch number has been requested.; Sender's Comments: Based on a close temporal association, a causal relationship between reported events and BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

I had a very early miscarriage at five weeks; I had a very early miscarriage at five weeks; I had a very early miscarriage at five weeks; This is a spontaneous report from a contactable Physician (patient). A 31-year-old female patient received BNT162B2 first dose of (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EJI685) intramuscular at arm right on 19Dec2020 06:30 at single dose for covid-19 immunization. Facility type vaccine was hospital. Medical history was none. The patient had no known allergies or other medical history. There were no concomitant medications. No other vaccine in four weeks and no other medications in two weeks. The patient experienced a very early miscarriage at five weeks on 01Jan2021. The event result in doctor or other healthcare professional office/clinic visit. No treatment received. The outcome of the event miscarriage was recovered in Jan2021. No covid prior vaccination and no covid tested post vaccination.; Sender's Comments: All pregnancies have a risk of birth defect, loss, or other adverse outcomes. The data on BNT162B2 administered to pregnant women is insufficient to make a meaningful medical assessment hence, the events are conservatively assessed as related to the suspect drug BNT162B2 until further information becomes available. The impact of this

report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

almost pass out; Chills; nausea; diarrhea; abdominal pain; clammy; elevated heart rate; dizzy; This is a spontaneous report from a contactable consumer (patient's parent). A 24-year-old female patient (pregnant: No) received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK9231) via an unspecified route of administration on left arm on an unspecified date in Dec2020 at single dose for COVID-19 immunization. The relevant medical history included asthma, migraines and anxiety all from an unspecified date. Concomitant medications included ethinylestradiol, etonogestrel (NUVARING), topiramate (TOPAMAX), verapamil and sertraline hydrochloride (ZOLOFT). The patient experienced chills, nausea, diarrhea, abdominal pain, clammy, elevated heart rate, almost pass out, dizzy, all on 05Jan2021. The patient had no treatment for the events. No covid prior vaccination. The patient underwent lab test included heart rate showed elevated on 05Jan2021, Nasal Swab showed negative on 06Jan2021. The outcome of the events was not recovered.

Rash on lower legs similar to that seen with Thrombocytopenia.; Rash on lower legs similar to that seen with Thrombocytopenia.; This is a spontaneous report from a contactable Other HCP (patient). A 21-year-old female patient (not pregnant) received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, Lot number= EJ1686), via an unspecified route of administration at Left arm on 05Jan2021 10:00 AM at single dose for covid-19 immunization. The COVID-19 vaccine was administered at Hospital. The patient's medical history and concomitant medications were unknown. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient experienced rash on lower legs similar to that seen with thrombocytopenia on 09Jan2021 at time of 12:00 PM. No treatment received for the events. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, the patient was not been tested for COVID-19. The outcome of the events was not recovered.; Sender's Comments: A possible contributory effect of suspect drug on reported thrombocytopenia cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

Fatigued; Sore in her throat; Lost her voice (hoarse); Reddish nose; Intermittent coughs; she went to work to a COVID unit which she usually didn't do; described her symptoms as a chest cold; Feeling strange like coming down; swelling and soreness in the injection site for a day or two; swelling and soreness in the injection site for a day or two; This is a spontaneous report from a contactable nurse reported for self. This 41-year-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number unknown) via unspecified route of administration on 07Jan2021 13:30 PM at single dose for COVID-19 immunization. The patient medical history and concomitant medications were not provided. The patient previously received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number unknown) for COVID-19 immunization on an

unspecified date. On 07Jan2021 after second dose vaccination, the patient started experiencing swelling and soreness in the injection site for a day or two. On 08Jan2021 the next day, she went to work to a COVID unit which she usually didn't do. On 08Jan2021 the next day after her shift at 15:00 PM, she started feeling strange like coming down. On 09Jan2021, she felt totally fatigued. The symptom that bothered her the most is the sore in her throat which has gone 10Jan2021, she said she lost her voice (hoarse). She was also experiencing a reddish nose and intermittent coughs. She described her symptoms as a chest cold. The patient also stated she didn't have fever or chills. She's afraid she might be sick. The outcome of event the sore in her throat was resolved on 10Jan2021. The outcome of other events was unknown. Information about lot/batch number has been requested.; Sender's Comments: A possible contributory effect of suspect BNT162B2 on reported chest cold cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

"tingling sensation in right eye and mid cheek area,Unable to wink, or scrunch right eye; muscles on the right side of my face were noticeably weaker; This is a spontaneous report from a contactable nurse (patient). This 48-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot # EH9899), via an unspecified route of administration, on 23Dec2020 at 04:00 PM at single dose for COVID-19 immunisation. Vaccine location was right arm. The patient was vaccinated at Public Health Clinic/Veterans Administration facility, age at vaccination was 48-years-old. No other vaccine was received in four weeks. Medical history included gastrooesophageal reflux disease (GERD). Known allergies included levofloxacin (LEVOFLOXACIN), pethidine hydrochloride (DEMEROL), phenobarbital, cefalexin monohydrate (KEFLEX), charithromycin (BIAXIN). Concomitant medications included dexlansoprazole (DEXILANT), estradiol, phentermine, ergocalciferol (VIT D), calcium. The patient was not tested for covid prior or post vaccination. On 23Dec2020 at 04:45 PM, after leaving the clinic, the patient felt tingling sensation in right eye and mid cheek area. Within 1.5 hours, muscles on the right side of her face were noticeably weaker. Unable to wink, or scrunch right eye. The events resulted in doctor or other healthcare professional office/clinic visit, and emergency room/department or urgent care. The patient was treated with prednisone. Outcome was recovering.; Sender's Comments: Based on a close temporal relationship causality between events ""tingling sensation in right eye and mid cheek area"" and ""muscles on the right side of her face were noticeably weaker"" and BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate."

She is still freezing to death; Sick as a dog; Fever; Chills; cannot eat and have no appetite; nauseous; This is a spontaneous report from a contactable nurse (patient). A 79-year-old female patient received first dose of bnt162b2 (also reported as Pfizer Covid vaccine, lot number: EK4176), intramuscular into left arm on 05Jan2021 16:00 at single dose indicated as presentation because she is a nurse/Covid-19

immunization. Medical history included Type 2 Diabetes, about 2 years ago in 2019 in which she takes metformin 1,000mg twice daily. Concomitant medication included metformin on unspecified date at 1,000mg twice daily for Type 2 Diabetes. There was no history of all previous immunization with the Pfizer vaccine nor there were additional vaccines administered on same date of the Pfizer Covid vaccine. The patient received the Pfizer COVID vaccine last Tuesday and since 06Jan2021 at 06:00, she has been sick as a dog. She is running a fever, has chills, can't eat and has no appetite because she is nauseous; all on 06Jan2021 at 06:00. This is the third day of it. She would like to know what she can she do. She said that it all started Wednesday morning when she got up. It just gets worse every day. It looks like it would get better by now, but it hasn't. She never runs a temperature, but she has now (unspecified date). She is still freezing to death on unspecified date. She usually has a good appetite. Even the thought of food makes her sick. She further reported that she has had nothing but chills, fever, and nausea and states it will not go away. She is treating it with ibuprofen. She confirms she already talked to a nurse in this department to report this and she was transferred to see what she could do and states they never answered. This is her first dose and she does not know if she should get the second dose. The patient can't calm down since she has been sick since last Wednesday. She stated that she needed some help because she is so sick. She was suggested to call again calling Pfizer medical information department. She stated that she had called back three times, but there is no such number. The events sick as a dog, fever, chills, can't eat and has no appetite, and nauseous were considered serious (Other medically important condition). The outcome of the events sick as a dog, fever, chills, can't eat and has no appetite, and nauseous was not recovered, and the outcome of the remaining event was unknown.; Sender's Comments: A causal association between BNT162B2 and the reported events cannot be completed based on known safety profile and a compatible temporal relation between vaccination and onset of events. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

palms of my hands were bright red; very warm flush feeling; nausea; swelling of the throat; rash on my arms and abdomen; This is a spontaneous report from a contactable nurse (patient). A 49-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899 and expiration date not provided), intramuscular in the left arm on 06Jan2021 16:00 (at the age of 49 years old) at a single dose for COVID-19 immunization. Medical history included psoriasis, microscopic colitis, allergies to shellfish, and coconut. The patient's concomitant medications were not reported. The patient previously took estrogen patch, etanercept (ENBREL) and sulfamethoxazole, trimethoprim (BACTRIM) and experienced allergies to all. The patient was not pregnant at the time of vaccination. The patient did not receive any other vaccine within 4 weeks prior to the COVID vaccine and did not take any other medications with 2 weeks of vaccination. Prior to the vaccination, the patient was not diagnosed with COVID-19. On 06Jan2021 16:15, the patient experienced a very warm flush feeling, nausea started and by 15 minutes, she had swelling of the throat and rash on her arms and abdomen and the palms of her hands were bright red. The events resulted in Emergency room/department or urgent care visit. The patient was treated with diphenhydramine hcl (BENADRYL), steroids (unspecified), famotidine (PEPCID) and ondansetron (ZOFRAN) in response to the events. The patient assessed the events as non-serious.

The outcome of the events was recovered with sequel on an unspecified date in Jan2021. The patient has not been tested for COVID-19 since the vaccination.; Sender's Comments: A possible contributory effect of suspect BNT162B2 on reported events cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

glaucoma; This is spontaneous report from a contactable consumer (patient). A female patient of an unspecified age received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number and expiry date unknown) via unspecified route of administration on unspecified date at single dose for Covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient received the first shot and was scheduled to receive the second dose on 27Jan2021 however, she has an eye surgery for glaucoma scheduled on 22Jan2021 and 25Jan2021. The patient wanted to know if she re-schedule the eye surgery. The outcome of the event glaucoma was unknown. Follow-up activities are possible, information on the batch number has been requested.

"Stevens Johnson Syndrome; rash was starting to peel; developed a rash all over her neck/ the rash has spread to face eyes, cheek; developed a rash all over her neck, ""looks like its peeling and taut""; developed a rash all over her neck, ""looks like its peeling and taut""; This is a spontaneous report from a contactable nurse (patient). A female patient of an unspecified age (Age: 48, Unit unknown) received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 10Jan2021 at single dose for covid-19 immunization. Medical history included she had an allergic reaction to sulfa and developed Stevens Johnson syndrome from an unknown date and unknown if ongoing. The patient's concomitant medications were not reported. The patient experienced Stevens Johnson Syndrome, developed a rash all over her neck/ the rash has spread to face eyes, cheek; ""looks like its peeling and taut""; and the rash was starting to peel, all in Jan2021. The patient received 1st dose of vaccine on 10Jan2021, developed a rash all over her neck, ""looks like its peeling and taut"". She had an allergic reaction to sulfa and developed Stevens Johnson syndrome, this looks similar to that (Experience of Stevens Johnson Syndrome). The patient was asking if she did take the steroid dose pack from her dermatologist for the skin rash will it prohibit her from taking the second dose of the vaccine. She called yesterday and reported a rash after receiving the first dose of the COVID-19 vaccine. She stated that she went to her Dermatologist this morning because the rash has spread to face eyes, cheek and the rash was starting to peel. She stated that the dermatologist wanted to know if it was safe to treat her with a prednisone dose pack after receiving the vaccine. Her rash was worsening so she went to her dermatologist for treatment. She was asking if she should get the second dose. The outcome of events for developed a rash all over her neck/ the rash has spread to face eyes, cheek was not resolved, for other events was unknown. Information about lot/batch number has been requested.; Sender's Comments: A possible causal association between administration of BNT162B2 and the onset of suspect Stevens Johnson Syndrome presented as skin reactions cannot be excluded, considering the plausible temporal relationship. Severe allergic reaction is the known risk for the vaccine. The underlying

predisposing condition of an allergic reaction to sulfa developed Stevens Johnson syndrome may put the patient at high risk of the similar occurrence. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate"

following day around 7pm lip swelling; tongue tingling; body hives; chills; After first dose of Covid vaccine face flushing; increased HR about 45 mins. went away on its own; hours later left eye swollen; This is a spontaneous report from a contactable Nurse (patient). A 31-years-old female patient received first dose of bnt162b2 (BNT162B2, Lot number: EK9231), via an unspecified route of administration on 06Jan2021 15:00 at single dose on Left arm for covid-19 immunisation. Medical history included Known allergies: Shellfish, IV contrast dye, Penicillin. There were no concomitant medications. No other vaccine in four weeks. No other medications in two weeks. The patient experienced after first dose of covid vaccine face flushing; increased hr about 45 mins. went away on its own since 06Jan2021 16:00; hours later left eye swollen on 06Jan2021; following day around 7pm lip swelling, tongue tingling, body hives, chills on 07Jan2021 19:00. The patient underwent lab tests and procedures which included heart rate: increased on Jan2021. Ae resulted in: Doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care. Ae treatment: Steroids, IV fluids, Benadryl. No COVID prior vaccination. No COVID tested post vaccinate. This report was reported non-serious. The event outcome of increased hr about 45 mins. went away on its own was recovered on 06Jan2021 16:45, outcome of other events were not recovered.; Sender's Comments: Based on the compatible time association, the serious events are possibly related to suspect BNT162B2 administration. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

kidneys weren't acting/kidney issues; not having the feeling to urinate; Light-headed; This is a spontaneous report from a contactable consumer (reported for herself). A 91-year-old female patient received first dose BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Solution for injection; lot number: EL3248; expiration date: not known), via an unspecified route of administration in the left arm on 07Jan2021 at single dose for COVID-19 immunization. Medical history included high blood pressure and blood thinner. Concomitant medication included apixaban (ELIQUIS) for blood thinner. The patient is asking if there were any reports of adverse events with kidneys and the vaccine. She received the 1st shot last Thursday (07Jan2021) and told that yesterday (10Jan2021), she had an episode where kidneys weren't acting. She also mentioned that she is on a blood thinner, ELIQUIS. She is due to receive the 2nd shot on 28Jan2021. She said that she wouldn't want to receive the 2nd dose if this was related to her adverse reaction. The issue with the kidney started after on 10Jan2021, yesterday she was really having problems, she went to church then came home by that time she would have to go to the bathroom, but she did not go, she ended up cooking dinner which was 3 hours later, she was noticing that she was not urinating. She drank some Gatorade and that made it little better, she is wondering if it's a side effect.

On 10Jan2021, when she noticed the kidney issues, she did not know for certain if it started before that, she didn't pay attention. Also, yesterday (10Jan2021), she got sick in which she had to grab the counter, she felt bad, she wasn't dizzy, but felt light-headed. The symptom of not having the feeling to urinate had improved a little today but she is concerned and wanted to know if this was a side effect. Her being light-headed only occurred on 10Jan2021, it was a onetime occurrence yesterday. However, she was also just sitting around, laying around, after that yesterday. The outcome of the event 'light-headed' was unknown; while outcome of other events was recovering.

difficulty thinking; Extreme fatigue; dizziness; This is a spontaneous report from a contactable nurse (patient). A 42-year-old female patient received her second dose of BNT162B2(PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 10Jan2021 11:15 at single dose at Arm Right for COVID-19 immunisation. Medical history included hypothyroidism, thyroid cancer, hypertension from an unknown date and ongoing, Known allergies: Latex, aluminium, nickel.The patient was not pregnant. Concomitant medication included gabapentin, propranolol, levothyroxine sodium (SYNTHROID), and pantoprazole. The patient has previously received her first dose of BNT162B2 on 20Dec2020 08:45 PM for COVID-19 immunisation at Arm left. There was no any other vaccines within 4 weeks prior to the COVID vaccine.The patient experienced difficulty thinking, extreme fatigue and dizziness resulted in Doctor or other healthcare professional office/clinic visit. All the events occurred on 11Jan2021 09:00 with outcome of recovering. No treatment was received. Prior to vaccination the patient was not diagnosed with COVID-19 and since the vaccination, the patient has not been tested for COVID-19.The events were considered as non-serious. Information about lot/batch number has been requested.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the mental impairment and other reported events due to temporal relationship. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

concern for injection to the subcutaneous tissue/concerned about improper administration/patient has a mark where you can see the vaccine and it's higher up where you expect it to be; induration at the injection site; felt induration was moving down his/her arm/can feel it migrated down her arm, 7 inches below injection site; This is a spontaneous report from a contactable pharmacist. A patient of unspecified age and gender received the second dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number: EK4176), subcutaneous (reported as injection to the subcutaneous tissue to deltoid) on 09Jan2021 at 0.3 mL, single to prevent from getting COVID. The patient's medical history and concomitant medications were not reported. The patient previously took the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) on Dec2020 for COVID-19 immunization. On 09Jan2021, within a couple hours after, the patient experienced induration at the

injection site. The patient felt induration was moving down his/her arm with concern for injection to the subcutaneous tissue. The patient can feel it migrated down his/her arm, 7 inches below injection site. The reporter assessed that the causality was yes for the suspect drug and the patient was concerned about improper administration. The reporter was unsure if it is administration or vaccine, the patient has a mark where you can see the vaccine and it's higher up where you expect it to be. Outcome of the vaccination site induration and induration was not recovered. The events were considered medically significant by the reporter.; Sender's Comments: Based on the available information a causal relationship between reported events induration at the injection site / induration and incorrect route (subcutaneous) of BNT162B2 vaccine administration cannot be excluded. The case will be reevaluated should additional information become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Slight left sided facial weakness/droop 4 days post vaccination; Slight left sided facial weakness/droop 4 days post vaccination; Tingling in injected arm and facial tingling in cheeks/lips same day of vaccination/Tingling to lower extremities; Tingling in injected arm and facial tingling in cheeks/lips same day of vaccination; Tingling in injected arm and facial tingling in cheeks/lips same day of vaccination; This is a spontaneous report from a contactable consumer (patient herself). A 36-year-old female patient received her first dose of bnt162b2 (BNT162B2 also reported as COVID 19 brand Pfizer, lot EK9231), via an unspecified route of administration in the left arm on 04Jan2021 13:00 at single dose, for Covid-19 immunisation. The vaccine was given in a Nursing Home/Senior Living Facility. Medical history was none. No known drug allergies. No other vaccine in four weeks. No Covid-19 prior vaccination. Concomitant medication included naproxen sodium (ALEVE). The patient experienced tingling in injected arm and facial tingling in cheeks/lips same day of vaccination (04Jan2021). Tingling to lower extremities the day after vaccination (still continuing). Slight left sided facial weakness/droop 4 days post vaccination (04Jan2021). Tingling to left arm continuing on and off. No treatment reported. On 04Jan2021, she was negative to PCR covid test post vaccination. She went to the Emergency room/department or urgent care. The outcome of events was not recovered.

"slurring speech; rash around his neck and upper chest; his earlobes were bright red, as was his nose; mouth was dry; nose was dry; dry throat; almost ""drunk""; Only abnormal finding was BP 159/94; This is a spontaneous report from contactable pharmacist. A 36-year-old male patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number=EL1283 and Expiration Date unknown) via Intramuscular on 08Jan2021 11:25 at single dose for COVID-19 immunisation. The patient's medical history was reported toradol made him feel lightheaded and foggy (similar to his first Pfizer BioNTech covid vaccine), Attention deficit hyperactivity disorder (ADHD). History vaccine included first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number =EK5730 and Expiration Date unknown) via Intramuscular on 18Dec2020 at single dose for COVID-19 immunisation. Patient did report that on first vaccine it made him feel a little sluggish, tired and foggy minded. The concomitant medications were reported as amfetamine aspartate, amfetamine sulfate, dexamfetamine saccharate,

dexamfetamine sulfate (Adderall XR) at 25mg twice a day (BID) and escitalopram oxalate (LEXAPRO) oral (PO) at 10mg every day. No other vaccine in four weeks. Patient was vaccinated at 11:25. Patient was observed for 30 minutes. Pharmacist checked on patient at 17 minutes after vaccination - he was fine able to communicate and showed no signs of distress. Pharmacist came back and checked on patient at 25 minutes after vaccination (11:50) and patient was slurring speech, had developed rash around his neck and upper chest, his earlobes were bright red, as was his nose - mouth was dry, reported dry throat - no visible swelling of the lips or tongue. Patient was transported to ED (2 min) Home meds: Adderall XR 25mg BID [Twice a day], Lexapro 10mg Q [every]PM. Only abnormal finding was BP 159/94 - after initial workup patient was noted to be almost ""drunk"" as reported by Emergency Room (ER Doc). Patient was offered diphenhydramine declined several times but eventually agreed. Approx 30 min after diphenhydramine patient fully recovered and stated ""I'm back"". The second dose reaction was much more exaggerated and lasted much longer. No COVID prior vaccination and no COVID tested post vaccination. The adverse event result in Emergency room/department or urgent care. The outcome of events was recovered in Jan2021 after treatment was given.; Sender's Comments: Based on the time association, all events are possibly related to suspect BNT162B2 administration. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate."

SOB; leukocytosis; acute onset of fever (101.2); CXR = bilateral vascular congestion; This is a spontaneous report from a contactable consumer. An elderly NH resident patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on an unspecified date, at single dose, for COVID-19 immunization. Medical history and concomitant medications were not reported. On an unspecified date the patient experienced shortness of breath (SOB), leukocytosis (17,800), acute onset of fever (101.2), bilateral vascular congestion. The patient was admitted with acute onset of fever (101.2), leukocytosis (17,800, no eosinophilia) and SOB, all beginning 3-4 hours after BNT162B2 administration. CXR showed bilateral vascular congestion. No facial or SQ edema. No evidence of myocardial damage or CHF based on BNP and troponin, respectively. The patient was treated with brief (3 days) pulse of methylprednisolone sodium succinate (SOLUMEDROL) with improvement. Chalking it up to acute capillary leak syndrome 2^2 vaccine. The final events outcome was unknown. Information on lot/batch number has been requested.

Blood in stool; Fever; Night sweats; Chills; Ache; This is a spontaneous report from a contactable physician reporting for herself. An adult (reported as 30-something year old) female patient received the 1st dose of bnt162b2 (BNT162B2), via an unspecified route of administration, on 30Dec2020, at single dose, for COVID-19 immunisation. The patient's medical history was none. Concomitant medications were not reported. The patient experienced blood in stool in Jan2021 with outcome of unknown, chills on 31Dec2020 with outcome of unknown, ache on 31Dec2020 with outcome of unknown, fever in Jan2021 with outcome of unknown, night sweats in Jan2021 with outcome of unknown. The patient reported that 24 hours after vaccination she experienced chills and aches, and after the 24 hours experienced some significant fevers that wouldn't break and chills. Then, after about 2 hours, the fever

would break and come back and it was like a cycle. Also had night sweats and blood in her stools after that. The information on the lot/batch number has been requested.; Sender's Comments: The female patient received the 1st dose of bnt162b2 (BNT162B2) on 30Dec2020, and experienced blood in stool in Jan2021 with outcome of unknown. The information available is limited, and case will be reassessed should additional information become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Patient presented to our Emergency Department via EMS in full code status; asystole. Patient expired. Per nursing, husband stated patient awoke this AM and reported pain in back between shoulders and in bilateral shoulders. Patient then went unresponsive and husband called EMS.

1/11/21 at 8:57 Resident with fever and at 11 am saturation down to 83 O2 to 10 liters. Resident continued to decline until CTB on 1/14/2021 at 1325

I was diagnosed with COVID-19 on 12/7/2020. My course of symptoms lasted 16 days, meaning I started feeling healthy again on 12/23/20. I am a pharmacist with a healthcare system and they have been offering the Pfizer/Biontech COVID-19 vaccine for essential associates. I received by first dose of vaccine on 12/31/20. On 1/1/20 I woke up with very noticeable muscle aches and fairly profound lethargy, which last 18-20 hours. I was not able to do much on 1/1/21 because of the way I was feeling. I'm not sure if this reaction is normal for patients who receive their COVID-19 vaccine close to their illness/infection with COVID-19, which is why I'm reporting this to the FDA.

Heart rate slowed significantly down to 32bpm Tightness in chest, trouble breathing Elevated blood pressure

injection site became red & swollen, the size of a softball. Employee started having seizure like symptoms on 1/14/21 and was admitted to hospital. DC from hospital on 1/16/21 and on 1/17/21 started having seizures again and readmitted back to hospital. Employee has no history of seizures.

I received the Pfizer vaccine on 12/21/20 without adverse events other than soreness in deltoid. On 12/31/20 I began to notice pain, redness and swelling in second toe on R foot from base of toe to base of nail. I initially thought it was gout and self medicated with ibuprofen 400 mg BID x 1 day on 01/01/21 with some improvement. I did not take anything on 01/02/21 and woke up on 01/03/21 with return of swelling, redness and pain. I took another 400 mg of ibuprofen and it felt better but after examining the toe, I questioned whether I had developed pernio (COVID toe).

patient began with vomiting and diarrhea the day after administration, leading to bowel and urine incontinence. patient was hospitalized on 01/16/20 with sepsis. no origin discovered yet. still waiting on blood/urine/stool cultures.

Patient was living in a nursing home with positive cases when administered. His age and chronic condition was such that he did not have time after the vaccination to avoid exposure or develop immunity.

Resident had seizure like activity that was about 30 minutes in duration where her upper/lower extremities were shaking uncontrollably. Resident had to be admitted into hospital for observation.

blistering rash - bullous pemphigoid, steroids, admitted to hospital pending further evaluation.

1day after vaccine,developed severe headache & later blister in head officially Shingle . Then decreased platelet count fatally to 29(ITP).now hospitalized getting treatment.

Was feeling anxious right after vaccine given. Laid in cot for a short time, then stated her throat felt like it was closing.

Severe rash. Platelets drop to almost needing transfusion

1252 Resident rang with complaints of chest pain and shortness of breath. BP 126/70, Temp 97.5, pulse 72, resp. 20, O2 sats on room air 90%. While awaiting transport complained of increasing shortness of breath. Resident transported to Community Hospital via Ambulance with 3L O2 . Resident placed on ventilator and transported to Medical Center

severe body aches; severe chills; night sweats; Fatigue; This is a spontaneous report from a contactable Physician (patient). A 55-year-old male patient received the second dose bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 06Jan2021 at 12:00 at single dose in left arm for covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient previously received the first dose bnt162b2 in Dec2020 three weeks ago at 12:00 noon in the left arm for covid-19 immunization and experienced mild pain at the injection site which lasted two days and then was gone. The patient experienced severe body aches, severe chills, night sweats, and fatigue on 07Jan2021. Event details: The patient reported that he received the first dose of the Pfizer COVID 19 vaccine three weeks ago at 12:00 noon in the left arm. He did not know the exact date. After the first dose there was mild pain at the injection site which lasted two days and then was gone. He received the second dose of the Pfizer COVID 19 vaccine on 06Jan2021 at 12:00 noon in the left arm. He noticed 12 hours later severe body aches, severe chills, and night sweats. He also felt fatigue. Everything had mostly resolved except for the night sweats and they were still pretty severe. All events were reported as serious by reporter per medically significant. The outcome of event night sweats was not resolved, outcome of other events was resolved on 10Jan2021. Information about lot/batch number has been requested.; Sender's Comments: The Company cannot completely exclude the possible causality between the reported severe body aches, severe chills, fatigue and night sweats, and the administration of the COVID 19 vaccine, bnt162b2, based on the reasonable temporal association. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RA, IEC, as appropriate.

eosinophil count is 12.2%; Congestion; rhinitis; Cough; This is a spontaneous report from a contactable consumer. A 68-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot/batch number unknown), via an unspecified route of administration on 21Dec2020 at a single dose for Covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient who is an MD received the COVID vaccine on 21Dec2020. She quickly developed rhinitis, cough, and congestion which have persisted. Her eosinophil count is 12.2%. She received a Medrol pack, but it did not relieve her symptoms. She has delayed her second injection for now. The outcome of the events was unknown. Information about lot/batch number has been requested.

resident expired; This is a spontaneous report from a contactable healthcare professional. An 82-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot number: EL0140), intramuscular in the left arm on 05Jan2021 15:00 at a single dose for COVID-19 immunization. Medical history included metabolic encephalopathy from, failure to thrive (FTT), diabetes mellitus (DM) 2 , chronic obstructive pulmonary disease (COPD), arthritis, weakness, hyperlipidemia, chronic kidney disease (CKD), dementia. Known allergies was none. The patient took unspecified concomitant medication. On 11Jan2021, the resident expired. The patient underwent lab tests and procedures which included nasal swab: negative on 09Jan2021. There was no treatment given for the event. The patient died on 11Jan2021. An autopsy was not performed.; Sender's Comments: Lacking information on the cause of patient's demise, the Company cannot completely exclude a causal relationship between COVID 19 vaccine, BNT162B2, and patient's death of unknown cause, as a cautionary measure and for reporting purposes. The patient's pre-existing medical condition of metabolic encephalopathy from, failure to thrive (FTT), diabetes mellitus (DM) 2 , chronic obstructive pulmonary disease (COPD), arthritis, weakness, hyperlipidemia, chronic kidney disease (CKD), dementia may have provided the contribution to the event in this 82-year-old male patient. The impacts of this report on the benefit/risk profile of the product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.; Reported Cause(s) of Death: resident expired

Facial paralysis; This is a spontaneous report from a contactable consumer (patient herself). A 36-year-old female patient received bnt162b2 (COVID-19 Vaccine by Pfizer, lot EK9231, expiry date was not reported), via an unspecified route of administration on 08Jan2021 at SINGLE DOSE for Covid-19 immunisation (to prevent the COVID). Medical history was none. There were no concomitant medications. The patient experienced facial paralysis on the left side of her face upon waking up on 09Jan2021. The outcome of event was not recovered.

"Congestion in my lungs; I am coughing up junk; This is a spontaneous report from a contactable consumer (patient). A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number and expiry date was not reported) via an unspecified route of administration on an unspecified date at single dose for covid-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient experienced congestion in lungs and was reportedly coughing up ""junk"" on an unspecified date. It was also reported that the patient

woke up this morning with a pretty bad side effect. Outcome of events was unknown. Information on the lot/batch number has been requested."

"Started to have symptoms and fainted; Hit her nose and has a scar now; She blacked out; hit her nose, got the scar in the nose, àshe was bleeding from that scar; hit her nose, got the scar in the nose, àshe was bleeding from that scar; She started to feel unwell; Chills; Nausea; Rash in her arm; She had little red in her bumps; This is a spontaneous report from a contactable physician. A 29-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE Solution for injection, batch/lot no. and expiry date: unknown), via an unspecified route of administration on arm on unspecified date at a single dose (2nd dose) for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. Physician stated, ""she had no medical conditions, she was in very good you know very like standing with herself."" Patient had her 1st dose of Covid vaccine on unspecified date for COVID-19 immunization. Physician (reporter) stated, ""I am the parent of someone who got the COVID dose, the second dose yesterday. I am very concerned because my daughter yesterday (08Jan2021) started to have symptoms and fainted at 4:00 in the morning and hit her nose and has a scar now. She had her second dose yesterday (pending clarification), after the second dose last night she started to feel unwell, getting chills, nausea and when she got up to go to the bathroom, she fainted, she blacked out. She lives alone, she is an adult, she hit her nose, got the scar in the nose, and the bleeding wouldn't stop, she was bleeding from that scar. She told me it took two hours for bleeding to stop from that scar."" When asked when the events started, Physician stated, ""Last night (08Jan2021), at 4:00 am she took the shot during the day while she was at work. She said, she started to getting chills and then she was nauseated."" When asked if patient was still experiencing the event, the parent reported no as patient was just resting. Also stated, ""She didn't take any treatment but she said she took Tylenol."" Physician further added, ""I am concerned, we are going to be taking her to the urgent care now but I am concerned about what is going on with platelets and all of that because of what had happened, last night the bleeding wouldn't stop for two hours and she was alone at the night and weekends. She said, she had to lay down and then her dad is there now because he is closer, he is going to be taking care of the urgent care but I want Pfizer to know what my daughter has gone through last night after she took this second dose."" Physician further added, ""she is having a rash in her arm, she had little red in her bumps as well. I want her to go get checked up as soon as possible in urgent care."" Patient was taking some Ibuprofen (later clarified that patient took Tylenol as treatment). She was not taking any other medication. Outcome of the events was unknown. Information Requested on Lot/ Batch number.; Sender's Comments: The reported faint was most likely due to an accident, and less likely causally related to the use of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE). The case will be reassessed should additional information become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate."

1) Skin rash over 80% of my body including, face and lips; started to change my voice sound and started to compromise my airways. 2) Uncontrollable shakes, but not sure if this was related to Covid-19 itself.

Was given steroids via injection into my blood stream, within minutes the shakes stopped and within 2 hours the rash was gone.

12/22 Vaccine 12/23 ER. Admitted to hospital for 7 days. Dr stated was due to fluid. Radiology stated no fluid present. Couldn't breath. Pulmonologist put on 2nd inhaler. Coughing a lot. Not able to walk more then 6 steps without stopping to catch breath. *Has had 2nd vaccination on 1/13/2020

1/12 vaccination 1/13 swelling and pain at injection site. Admitted for 4 days.

patient suddenly developed pneumonia 7 days after vaccination and died the evening of developing pneumonia

Couple hours after the vaccine, experienced elevated temperature, difficulty taking full deep breathes (attributed to fatigue). Temperature improved but fatigue and shortness of breathe continued until 1/16/21. a bilater arm rash occurred and employee went to the Emergency Department for an assessment. At this time, she was having chest tightness, shortness of breathe. Lab - troponins elevated. Other labs - within normal limits. Admitted to hospital for observation and discharged next day. Today, during cardiac follow-up appt, was having decreased oxygen saturation levels, increased pulse rate. Admitted again today for obsevation with cncern of acute endocarditis.

Death

1 hour post injection patient returned with redness and borderline hives in her left arm, chest, neck and face. She complained of feeling very hot and with mental confusion. We administered 50 mg of diphenhydramine, and 15 minutes later sent her to the ED. At the ED they diagnosed her with a minor anaphylaxis reaction, gave her methylprednisolone and epinephrine.

"Individual felt fine except a sore arm until 1/5/2021 legs became weak and dizziness and light headed and did t"" feel well"" and passed out. had general muscle weakness and went to ER. She was given fluid for possible dehydration and went home and weakness increase and went back to ER and was admitted to hospital for testing."

Individual had no side effect except sore arm for 5 days then on 1/5/2021 became weak and dizzy and passed out. had not felt well in am. she had continued weakness and extreme leg weakness and taken to ER for evaluation. She states got IV fluids and sent home but weakness increase and went back to ER on 1/5/2021 and admitted to hospital.

patient started to decline 1/10/2021, patient seen at facility by medical professional - patient deceased 1/13/2021

REPORTING ONLY AS RESIDENT EXPIRED ON 1/17/2021 3 DAYS AFTER. S/S HYPOXIA/CONGESTED LUNG SOUNDS

ventricular fibrillation cardiac arrest. Witnessed collapse. Bystander CPR performed. Paramedics performed ACLS with defibrillation x 6 before ROSC

PVCs with compensatory pauses, postural orthostatic hypotension associated with chest tightness, shortness of breath, dizziness and blurry vision

The day following the vaccine, the patient complained of throat issues and anxiety. This was not new... however . That evening he reported difficulty breathing and was placed on oxygen; a COVID test was performed and was negative. On 12/30/2020, patient complained of sternal pressure and was transferred to the hospital. The patient died 12/31/2020 and records obtained from the hospital indicated the patient died from a massive myocardial infarction.

Seizure

WITHIN 30 SECONDS OF RECEIVING VACCINE PATIENT STATED THAT SHE DID NOT FEEL WELL. HER FACE BECAME FLUSHED. HER LIPS BECAME NUMB AND HER TONGUE AND THROAT STARTED SWELLING. AN EPIPEN WAS ADMINISTERED AND 911 CALLED. AFTER THE EPIPEN SYMPTOMS BEGAN TO RESOLVE. EMS CHECKED HER OUT AND SHE REFUSED TRANSPORT.

8 hours after vaccine severe injection site pain/swelling, severe body aches, 101.0 temp. 16 hours after vaccine woke up from sleeping with flushed skin, facial swelling, and throat swelling. I immediately took 100mg of Benadryl and went to hospital emergency room. Approximately 30-40 minutes later symptoms started to lessen. Once at the ER, at the same time symptoms began to resolve, I was given PO Solumedrol and Pepcid. I was monitored and then discharged with RX for prednisone, and EPIPEN (to use if needed). No other issues with allergic reaction. Mild injection site soreness, mild body aches, 99.3 temp persist at 36 hours post injection.

Received Moderna COVID vaccine 12/31/20, 3 days later noticed generalized joint pain all over. Day 4 noticed both knees were red and tender and could palpate pockets of fluid. Had bilateral ankle and foot pain, right ankle swollen. Overnight 1/5-1/6/21 was in severe pain and unable to sleep, very difficult to walk on ankles and feet, stairs were very painful. Motrin relieved symptoms to where able to walk more comfortably but generalized achiness and tenderness to ankles and knees remain.

Anaphylaxis after Covid 19 vaccine #1. Pfizer Lot # EH9899

71 year old woman at rehabilitation center for physical therapy with history of cirrhosis of the liver, asthma, and heart condition was tested for COVID-19 on 01/07/21, received 1st dose of Pfizer COVID-19 vaccine on 01/08/21, positive test result for COVID-19 received on 01/09/21. She was sent to the hospital and admitted on 01/12/21 after O2 was 70% and was in a confused state. Patient passed away on 01/17/21.

Received shot Wednesday night, developed arm soreness and mild flu like symptoms on left side of my body and facial paresthesias on the left side of my face. Twelve hours later, after waking up those same symptoms were only on the right side of my body. Friday morning, mostly normal physically just with some overall fatigue. Friday afternoon I started to get hives on my chest and overnight into Saturday they were on my lower back, sides, and legs. I took 50 mg of Benadryl every 6-12 hours until Monday mid-day when Benadryl was not helping reduce the hives and so I had full body hives. I did try an

drugstore cortisone cream which did not help. Sought treatment at an urgent care as I was feeling anxious and could not control the itching. I and was diagnosed with likely allergic reaction to the covid-19 vaccine.

She woke up soaking wet. She had sweats kind of.; Tested positive for COVID; Tested positive for COVID; This is a spontaneous report from a Pfizer-sponsored program Pfizer First Connect. A contactable nurse (patient herself) reported that a 64-year-old female patient received her first dose of bnt162b2 (BNT162B2 also reported as PFIZER-BIONTECH COVID-19 VACCINE, lot EK5730, expiry date not reported), via an unspecified route of administration in the upper left arm on 21Dec2020 17:00 at SINGLE DOSE for Covid-19 immunisation. Medical history included ongoing hypertension (blood pressure high). She was a former smoker, a teenage smoker. She has not smoked since the age of 19 years old. Concomitant medication included amlodipine for high blood pressure. The patient informed that she was vaccinated on 21Dec2020. On 05Jan2021, she had a positive COVID Test and she was wondering when she should have the second dose of the COVID Vaccine. She thought initially she just had a cold. She took the COVID test as a precaution. It started out with a stuffy nose. She had a congested cough, upper airway cough, nothing deep in the lungs. She had a low grade fever. It was like 99.9. It was possible it was higher, but she had taken Ibuprofen at night. She woke up soaking wet. She had sweats kind of. Her temperature however never registered a true fever if a fever was considered 100.4. She was not really having body aches any more unusual than one would have for a 64 year old. She has a very mild sore throat. Her stuffy nose had improved, it's still there slightly, but not like it was the first few days. The outcome of events was unknown.; Sender's Comments: Test positive for covid19 found 14 day following the first dose of COVID-19 vaccination, bnt162b2, no adequate effect of the suspect vaccine thus could be reasonably achieved to protect from the targeted infection/disease due to the very short time lag.

"received the first dose of vaccine in a hospital on 18Dec2020/tested positive for COVID on 01Jan2021; received the first dose of vaccine in a hospital on 18Dec2020/tested positive for COVID on 01Jan2021; This is a spontaneous report from a contactable nurse (patient) via Pfizer-sponsored program, Pfizer First Connect. A 43-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Solution for injection, Lot number: EK5730, expiration 31Mar2021) , via an unspecified route of administration in left arm, on 18Dec2020 at 15:00, at 0.3 mL, single, for COVID-19 immunization. Medical history and concomitant medications were reported as none. The patient received the first dose of vaccine in a hospital on 18Dec2020 at 15:00 as she works in emergency room and tested positive for COVID on 01Jan2021. The patient stated that the second dose is scheduled this afternoon (08Jan2021) and wants to know if she should proceed with the vaccine. The patient is looking for guidance on whether or not to get the second dose or wait. The patient has been directed to receive second COVID vaccine. No additional vaccines administered on the same date. The event required a visit to urgent care. The patient did not have prior vaccinations within 4 weeks. No events prior to vaccination. The patient underwent lab tests and procedures which included COVID 19: positive on 01Jan2021. Outcome of the events was unknown. The event was assessed as serious (medically significant). The event ""Tested positive for COVID"" was assessed as unrelated to COVID vaccine as her husband was COVID positive before her.; Sender's Comments: The information currently provided is too

limited to make a meaningful medical assessment hence, the events are conservatively assessed as related to the suspect drug BNT162B2 until further information becomes available."

She reported being exposed to her husband, who tested positive for COVID, and that she tested positive following her first vaccine dose; She reported being exposed to her husband, who tested positive for COVID, and that she tested positive following her first vaccine dose; She reported being exposed to her husband, who tested positive for COVID, and that she tested positive following her first vaccine dose; This is a spontaneous report from a contactable female nurse (patient). A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE Solution for injection, batch/lot no. and expiry date unspecified) via an unspecified route of administration on 23Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient was asking if it is safe to get the second dose of the vaccine after being exposed to or having COVID? She reported being exposed to her husband (on an unspecified date), who tested positive for COVID, and that she tested positive following her first vaccine dose. She got her Covid-19 vaccine on the 23Dec2020 and tested positive for Covid-19 on the 28Dec2020. She was scheduled to get the next dose on Wednesday and wants to know if she should still get it. Outcome of the events drug ineffective, COVID-19 and Exposure to COVID-19 was unknown. Information on the lot/batch number has been requested.; Sender's Comments: The patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE) on 23Dec2020, and COVID-19 test positive on 28Dec2020. No effect of the suspect vaccine could be reasonably achieved to protect from the targeted infection/disease due to the very short time lag. Instead, the positive COVID test was likely associated with being exposed to her husband, who had COVID-19. Further information is needed for full medical assessment.

She had sniffles and post nasal drip; Got first dose then went to (Entertainment complex name) and contracted COVID/tested positive after getting the 1st dose; Tested positive after getting the 1st dose; She returned home with sniffles, fatigue, and no taste/She had sniffles and post nasal drip; This is a spontaneous report from a contactable nurse (patient) via Pfizer-sponsored program: IBCC (Inbound Call Center for HCPs). A 53-year-old female patient received first single dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK5730, exp date not reported), via an unspecified route of administration on 19Dec2020 for given since patient works with COVID patients (COVID-19 immunisation). The patient had no relevant medical history. There were no concomitant medications. Nurse called asking if she can get the 2nd dose of the vaccine 6 days after the 21st day. She tested positive on 05Jan2021 after getting the 1st dose and was still in quarantine. The nurse works at a hospital. She received her first dose of the COVID-19 Vaccine on 19Dec2020, and afterwards donated blood on the same day. She got the vaccine through her place of work. She said when she donated blood on 19Dec2020, her blood was tested for the COVID-19 Virus antibodies, and her blood was negative for the virus antibodies. She lives about 30 mins from work, so she thought she would get both done in the same day. She gave blood right before she got the vaccine. She gave the blood then went and got the Vaccine. She said on 26Dec2020 she went to Entertainment complex as it was her vacation. Her and her family went for 4 days. On 30Dec2020 she returned home with sniffles, fatigue, and no taste. She said she tested positive for the COVID-19 Virus on 05Jan2021. On 30Dec2020 they got back,

and on 02Jan2021 she had sniffles and post nasal drip. On 03Jan2021 she did not wanna get out of bed. She was profoundly fatigued. She also lost her smell. She had to go back to work on 07Jan2021, but did not want to go back in unless she was sure she was okay because she works with babies. She had no other symptoms after 03Jan2021, except no smell and no taste. She got tested for COVID and was positive on 05Jan2021 (also reported as 06Jan2021 [pending clarification]). Her and her husband were both positive, but her kids were not. The weird thing was she also on 06Jan2021 got her results back from giving blood and she was negative for COVID on 19Dec2020 prior to getting the vaccine. Caller clarifies that her COVID test was a nasal swab. Patient thought her age may have contributed to her feelings of fatigue. She had indicated she worked in either a hospital NICU or nursery, and that is why she had to quarantine for 14 days. She probably would not have even gotten tested for COVID if she was not a nurse and did not know that losing taste and smell were a sign. She feels fine. She said she was scheduled for her second dose of the COVID-19 Vaccine on 12Jan2021. She said she was now in quarantine for 14 days due to testing positive for the COVID-19 Virus, and her quarantine period ends on 14Jan2021. Since now she is in quarantine, she will miss her second dose which was supposed to be on 12Jan2021. She said she rescheduled her second dose of the COVID-19 Vaccine to 18Jan2021, which was 6 days later than when she was supposed to receive the 2nd COVID-19 Vaccine dose. She asked if getting the dose 6 days late was okay. The events were considered as non-serious by the reporter. The outcome of the events was unknown.; Sender's Comments: The information currently provided is too limited to make a meaningful medical assessment hence, the events are conservatively assessed as related to the suspect drug BNT162B2 until further information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

tested positive for COVID; tested positive for COVID; achiness; Chills; not feeling well; This is a spontaneous report from a Pfizer-sponsored program Pfizer First Connect. A contactable consumer (patient's wife) reported similar events for four patients. This is the first of four reports. A 48-year-old male patient received his first dose of bnt162b2 (BNT162B2 also reported as Pfizer-Biontech Covid-19 Vaccine, lot/batch number and expiry date were not reported), via an unspecified route of administration on 17Dec2020 at single dose, for Covid-19 immunisation. Medical history was none. There were no concomitant medications. The patient received the vaccine last 17Dec2020. The following day, 18Dec2020, he was not feeling well. Clarified those side effects as achiness and chills. He had been working so hard and thought initially were getting side effects from the COVID Vaccine. He was tested positive for COVID on 22Dec2020. He was in bed basically until 31Dec2020. His wife wants to know if he should get the second dose. The outcome of events was recovered. Information on the Lot/Batch number has been requested.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021019513 same drug, similar events, different patient;US-PFIZER INC-2021019535 same drug, similar events, different patient;US-PFIZER INC-2021019534 same drug, similar events, different patient

"tested positive for SARS-COV-2; tested positive for SARS-COV-2; This is a spontaneous report from a Pfizer-sponsored program Pfizer First Connect, received from a contactable nurse (patient). A 31-year-

old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot/batch number and expiry date were not reported), via an unspecified route of administration on 18Dec2020 at a single dose for an unspecified indication. The patient's medical history and concomitant medications were not reported. The patient received first dose of vaccine on 18Dec2020 and tested positive for SARS-COV-2 20Dec2020. She reported ""las major symptom"" on 27Dec2020 and asked if it was okay to take the second dose. Outcome of the events was unknown. Information about lot/batch number has been requested.; Sender's Comments: Positive SARS-COV-2 came back 2 days following the vaccine use is compatible with COVID 19 infection. No adequate effect of the suspect vaccine could be reasonably achieved to protect from the targeted infection/disease due to the very short time lag."

Fevers; Chills; he is suspecting that he got infected with the Covid-19 though he already received the 1st dose; he is suspecting that he got infected with the Covid-19 though he already received the 1st dose; Body aches; Patient suspected that he has gotten infected also from his spouse; This is a spontaneous report from a contactable physician (patient). A 48-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 05Jan2021 (Tuesday) at single dose for covid-19 immunization. The patient medical history and concomitant medications were not reported. Patient reported body aches developing the evening of receiving the vaccine, and it has persisted for three days. Patient started to get the chills on Wednesday (06Jan2021). Patient said his wife has been tested positive after he took the 1st dose and he is suspecting that he got infected with the Covid-19 though he already received the 1st dose. Patient thought that he may have been infected by his spouse. He got the vaccine on Tuesday and on Wednesday had fever and chills and still has them. Stated that his spouse lost her sense of smell and taste and tested positive for Covid on Wednesday. Patient stated that this was the day after he received his vaccine. Patient suspected that he has gotten infected also from his spouse and was not aware when he got the vaccine. Stated that now that he is having expected side effects of fever and chills. The outcome events was not recovered. This case was reported as non-serious. Information on the lot/batch number has been requested.; Sender's Comments: The subject received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE) on 05Jan2021, and suspected got COVID-19 infection via exposure to COVID-19 living with his wife, who lost her sense of smell and taste and tested positive for COVID on 06Jan2021. No effect of the suspect vaccine could be reasonably achieved to protect from the targeted infection/disease due to the very short time lag. Further information is needed for full medical assessment.

exposed to her 6 month old grand daughter who was positive; tested and received a positive test result, without symptoms.; tested and received a positive test result, without symptoms.; This is a spontaneous report from a contactable consumer. A 59-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EJ1685), via an unspecified route of administration at the right arm on 30Dec2020 at a single dose for COVID-19 immunization. Medical history included high blood pressure from 2001 and ongoing. There were no concomitant medications. Patient had the flu, shingles and pneumonia vaccines and a booster for MMR in the past 6 months. Patient was exposed to COVID-19 on 01Jan2021. Patient was tested on 07Jan2021 and received a positive test result on

08Jan2021. Patient does not have any symptoms. She was exposed to her 6 month old grand daughter who was positive. The doctor said he thinks it was a false positive. Outcome of the events was unknown.

Tested positive for the Covid virus; Tested positive for the Covid virus; This is a spontaneous report from a contactable nurse. A male patient of an unspecified age received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 29Dec2020 at single dose for COVID-19 immunisation. The patient medical history and concomitant medications were not reported. The patient received the first dose of the vaccine on 29Dec2020 and four days ago, he tested positive for the Covid virus (02Jan2021). The outcome of the event was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Test positive for the Covid virus found 4 day following the vaccination, no adequate effect of the suspect vaccine thus could be reasonably achieved to protect from the targeted infection/disease due to the very short time lag.

"the symptoms as ""having Covid all over again""; the symptoms as ""having Covid all over again""; headache; nausea; severe joint and body pain; body pain; coughing; fever; This is a spontaneous report from a contactable other healthcare professional (HCP) reporting for herself. A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for covid-19 immunization. Medical history included covid-19 from an unknown date. The patient's concomitant medications were not reported. The patient just got the Covid vaccine and was experiencing side effects. She described the symptoms as ""having Covid all over again"", mentioned headache, nausea, severe joint and body pain, coughing and fever on an unknown date. Want to see how long these side effects last. The outcome of the events was unknown. Information regarding lot/batch number has been requested.; Sender's Comments: Based on the information currently available, a lack of efficacy with the suspected vaccine BNT162B2 in this patient cannot be completely excluded. Further information like confirmative virus genome /nucleic acid detection is needed for meaningful medical assessment."

caller was rushed to the emergency room and was tested positive for COVID-19; caller was rushed to the emergency room and was tested positive for COVID-19; caller became symptomatic and experienced headaches; This is a spontaneous report from a contactable physician. A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 18Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. It was reported that the patient received the first dose on 18Dec2020 and is scheduled for the second dose today, 09Jan2021. However, on 24Dec2020, she became symptomatic and experienced headaches. On Saturday, she was rushed to the emergency room and was tested positive for COVID-19. Her physician told her that she could get the COVID-19 vaccine if she has no symptoms anymore. She wanted to know the guidance per Pfizer. The patient underwent lab tests and procedures which included SARS-COV-2 test: positive on 09Jan2021. The outcome of the events was unknown. Information about lot/batch number has been requested.; Sender's Comments: Based on the information currently available, a lack of efficacy with BNT162B2 in this patient cannot be completely excluded.

got a positive test on 31Dec2020. Her 2nd dose is due on Wed and she is currently symptomatic.; got a positive test on 31Dec2020. Her 2nd dose is due on Wed and she is currently symptomatic.; This is a spontaneous report from a contactable consumer via Pfizer-sponsored program . A female patient of an unspecified age received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, batch/lot and expiration date unknown), via an unspecified route of administration on an unspecified date at a single dose for covid-19 immunization. The patient's medical history and concomitant medications were not reported. On 31Dec2020, the patient got a positive test. Her 2nd dose was due on wed and she was currently symptomatic. Patent would to know if she should get second dose on her scheduled date even though she still was feeling unwell. The outcome of the events was unknown. Information about batch/lot number has been requested.

COVID test result as positive; COVID test result as positive; Chills; Body aches; Headache; Weakness; This is a spontaneous report from a contactable nurse (patient). A 46-year-old female patient received first dose BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Solution for injection, Lot number: 49899, unknown expiration), intramuscular in right arm, in Dec2020 at 09:00 AM, at single dose, for COVID-19 immunization. Medical history included asthma, hypothyroid, and interstitial cystitis. The patient has no known allergies. Concomitant medication included influenza vaccine in right arm (lot number: US47SAA) on 08Dec2020 for immunization. Patient also received other unspecified medication within two weeks of vaccination. COVID-19 vaccine was administered in a hospital. On 23Dec2020 at 01:30 AM, the patient woke up with chills, body aches, headache and weakness. On 31Dec2020, the patient had nasal swab for COVID with COVID test result as positive post vaccination. Patient is not pregnant at the time of vaccination. The patient did not have COVID prior to vaccination. The patient received ibuprofen for the events chills, body aches, headache and weakness. The patient recovered from the events chills, body aches, headache and weakness on unspecified date; while unknown outcome for the remaining events.; Sender's Comments: The patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE) on 23Dec2020, and nasal swab for COVID-19 test positive on 31Dec2020. No effect of the suspect vaccine could be reasonably achieved to protect from the targeted infection/disease due to the very short time lag. Instead, the positive COVID likely represents the pre-existing infection prior to vaccine use. Further information is needed for full medical assessment.

maybe she could have COVID too; maybe she could have COVID too; a rash on her leg; some shortness of breath; This is a spontaneous report from a contactable consumer. A 72-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number and expiry date were not reported), via an unspecified route of administration on 06Jan2021 at a single dose for Covid-19 immunization. The patient's medical history and concomitant medications were not reported. It was reported that the patient received her first dose of COVID-19 vaccine on Wednesday, 06Jan2021 and today, on 09Jan2021, the patient started having a rash on her leg, some shortness of breath. She used an asthma inhaler. She experienced some of the symptoms before Wednesday. The reporter was concerned that maybe the patient could have COVID, too. The reporter heard that with COVID, sometimes rashes and/or shortness of breath can come, too. The outcome of the events was unknown. Information on the lot/batch number has been requested.

severe headache behind the eyes; Initially extreme fatigue; started to have shortness of breath; muscle aches; cough; second dose on 05Jan2021 08:30; This is a spontaneous report from a contactable physician (patient). A 39-year-old female patient received second dose of BNT162B2 (Lot number: EL3246), intramuscularly on 05Jan2021 08:30 in left arm at single dose for COVID-19 immunization. Medical history included known allergies: latex and asthma. Patient did not have COVID prior vaccination. Concomitant medications included sertraline hydrochloride (ZOLOFT), drospirenone/ethinylestradiol (YASMIN), melatonin, and ibuprofen (MOTRIN). Patient previously took montelukast sodium (SINGULAIR) and experienced allergy. Patient received first dose of BNT162B2 (Lot number: EK5730), intramuscularly on 18Dec2020 09:00 in left arm at single dose for COVID-19 immunization. Patient experienced initially extreme fatigue, then muscle ached all within 12-24 hours, severe headache behind the eyes. Then when thought was getting better, she started to have shortness of breath, worsening fatigue, and cough; all on 05Jan2021 12:00. These events were resulted in emergency room/department or urgent care. COVID was tested post vaccination. COVID test type post vaccination was nasal swab. COVID test name post vaccination was COVID 19 nasopharyngeal swan. COVID test date was on 08Jan2021. Test result was pending. Treatment received included nebulizer treatment, and steroid course. Patient was not recovered from these events.; Sender's Comments: Based on a compatible temporal relationship and known product safety profile, causality between events severe headache and extreme fatigue and BNT162B2 vaccine cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Hospitalized for stroke on 31Dec two days after vaccine.; sudden loss of hearing to right ear; dizzy and lightheaded/severe dizziness/felt like fainting; difficulty breathing; vomiting; This is a spontaneous report from a contactable nurse (patient). This 43-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), (Lot number: EL1285) via intramuscular route on 29Dec2020 14:30 at single dose on the left arm for COVID-19 immunization. Medical history included anxiety. No known allergies. Concomitant medications were not reported. Patient was not pregnant. Facility type vaccine was Nursing Home/Senior Living Facility. No other vaccine received in four weeks. Patient hospitalized for stroke on 31Dec2020 two days after vaccine (Days of hospitalization: 4). Day of vaccine-6 hours after patient had dizzy and lightheaded for about 45 min then went away. On 31Dec2020 at 19:15 had sudden loss of hearing to right ear and severe dizziness, difficulty breathing, vomiting, and felt like fainting. Paramedics were called-sent to ER, had CTA which showed partial blockage and received TPA. Treatment included TPA, fluids, medications, hospital stay, outpatient follow ups, physical therapy. Patient was not diagnosed with COVID prior to vaccination. Patient has been tested for COVID post vaccination. The patient underwent lab tests and procedures which included Nasal Swab: Negative and Pixel: Negative on 08Jan2021. Outcome of the events was recovering.; Sender's Comments: The Company cannot completely exclude the possible causality between the reported events including stroke, dizzy/lightheaded/felt like fainting, difficulty breathing, vomiting, and sudden loss of hearing to right, and the administration of the COVID-19 vaccine, BNT162B2. More

information regarding the patient's underlying medical conditions, relevant lab tests would be helpful for the Company to make a more meaningful causality assessment.

fever 102 F; headache; chills; body aches; This is a spontaneous report from a contactable Nurse reported for herself. A 63-years-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) at single dose on 22Dec2020 14:30 and the second dose single dose (lot number=EK9231) on 09Jan2021 19:15 for COVID-19 immunization. Vaccine location=Left arm, dose number 1 and dose number 2. Facility-type-vaccine: Hospital. Medical history included asthma. The patient's concomitant medications were not reported. On 10Jan2021 at 14:00 the patient experienced headache with outcome of not recovered, fever 102 ¦F with outcome of not recovered, chills with outcome of not recovered and body aches with outcome of not recovered. The action taken was not applicable. Tylenol was received as therapeutic measures for fever.; Sender's Comments: Based on a compatible temporal association and known product safety profile, a causal relationship between reported events and BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Developed chest tightness around right side of chest into back and SOB 50.5 hours after vaccination. Went to local ER and found to have a right lower lobe pulmonary embolism. Treated with Xarelto and sent home with outpatient follow up.

Temperature spike to 104.6; received first dose of bnt162b2 on 20Dec2020 and second dose on 08Jan2021 13:15; This is a spontaneous report from a contactable consumer. A 38-year-old male patient received the second dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiry date were not reported), via an unspecified route of administration, on the left arm on 08Jan2021 13:15 at a single dose for COVID-19 immunization. Medical history included prediabetic kidney disease. Concomitant medications included salmo salar oil (OMEGA-3 [SALMO SALAR OIL]), lisinopril, furosemide, escitalopram, and rosuvastatin calcium (CRESTOR). The patient is reported to have received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) on 20Dec2020 15:45, on the left arm, for COVID-19 immunization. The patient had no prior Covid vaccination. The patient was not tested for Covid post vaccination. The patient had no known allergies. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. It was reported that the patient received first dose of bnt162b2 on 20Dec2020 and second dose on 08Jan2021 13:15. On 09Jan2021 at 04:30, the patient experienced temperature spike to 104.6, brought down with TYLENOL to hover around 101.0 to 102.0 for 24 hours, normal after that. The patient called a nurse who instructed to go the emergency room/physician office visit. Outcome of the event Temperature spike to 104.6 was recovered on unspecified date in Jan2021. Information about lot/batch number has been requested.

tested positive for COVID; tested positive for COVID; This is a spontaneous report from a non-contactable consumer. A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH

COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunisation. The patient medical history and concomitant medications were not reported. The patient who is a nurse visited last weekend in the reporter's home for a few hours was advised that she tested positive for COVID today (unspecified date) and her family as well. She was vaccinated recently with the Pfizer vaccine. The outcome of the events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

I tested positive for COVID 8 days after my first dose.; I tested positive for COVID 8 days after my first dose.; This is a spontaneous report from a contactable consumer (patient). A 55-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number and expiration date were not reported), via an unspecified route of administration on an unspecified date in Dec2020 at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient got his first dose of Pfizer COVID 19 vaccine 21 days ago in Dec2020. He mentioned that he tested positive for COVID 8 days after his first dose in Dec2020. He stated that he got the second dose yesterday (unspecified date) and queried if should he not have gotten it. The outcome of the events was unknown. Information about Lot/batch number has been requested.

9th: cold (?fever?), restless, body aches (especially headache, neck pain, bilateral knee pain), nausea, vomiting 10th: profound fatigue, hives, intermittent vertigo 11-17th: vertigo, mild headache and neck pain, nausea, vomiting 18th-current: vertigo, nausea, vomiting *Hospitalized from 17-18th, diagnosed with vestibular neuritis secondary to the vaccine

positive COVID-19 test with symptoms; positive COVID-19 test with symptoms; This is a spontaneous report from a Pfizer-sponsored program, Pfizer First Connect. A contactable 39-year-old male healthcare professional reported to have received the first single dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 02Jan2021, for COVID-19 immunization. Medical history and concomitant medications were not reported. On an unspecified date in Jan2021, after the first dose of vaccine, the patient felt sick at some point, so he took a rapid test which came back positive. He stated that the test if testing the antigens (as reported). Antibody testing was not currently recommended to assess for immunity to COVID-19 following Pfizer-BioNTech COVID-19 vaccination. Events outcome was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Based on the information currently available, a lack of efficacy with BNT162B2 in this patient cannot be completely excluded.

13 people, who were applied the vaccine previously, were corona positive after a week; 13 people, who were applied the vaccine previously, were corona positive after a week; This is a spontaneous report from a non-contactable consumer. This consumer reported similar events for 13 patients. This is first of 13 reports. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Solution for injection; lot number and expiration date: not known), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. It was reported that 13 people, who were applied the vaccine previously, were corona positive after a week on an unspecified date. The outcome of the events was unknown. No follow-up attempts are possible; information about lot/batch number

cannot be obtained.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021018408 same reporter, similar suspect drug and event; different patient;US-PFIZER INC-2021018409 same reporter, similar suspect drug and event; different patient;US-PFIZER INC-2021018410 same reporter, similar suspect drug and event; different patient;US-PFIZER INC-2021018411 same reporter, similar suspect drug and event; different patient;US-PFIZER INC-2021018412 same reporter, similar suspect drug and event; different patient;US-PFIZER INC-2021018413 same reporter, similar suspect drug and event; different patient;US-PFIZER INC-2021018414 same reporter, similar suspect drug and event; different patient;US-PFIZER INC-2021018415 same reporter, similar suspect drug and event; different patient;US-PFIZER INC-2021018416 same reporter, similar suspect drug and event; different patient;US-PFIZER INC-2021018417 same reporter, similar suspect drug and event; different patient;US-PFIZER INC-2021018418 same reporter, similar suspect drug and event; different patient;US-PFIZER INC-2021018419 same reporter, similar suspect drug and event; different patient;US-PFIZER INC-2021018410 same reporter, similar suspect drug and event; different patient.;US-PFIZER INC-2021018412 same reporter, similar suspect drug and event; different patient.

After getting the first shot and the patient test positive for Corona virus; After getting the first shot and the patient test positive/perhaps positive; This is a spontaneous report from a Pfizer-sponsored program IBCC (Inbound Call Center for HCPs). A contactable pharmacist reported that a patient of unspecified age and gender started to receive BNT162B2 (PFIZER BIONTECH COVID-19 VACCINE), via an unspecified route of administration, first dose on an unspecified date at single dose for COVID-19 vaccination. The patient's medical history and concomitant medications were not reported. A pharmacist in a hospital wanted to know if after getting the first shot and the patient test positive for Corona virus, how long do they have to wait to get the second? A colleague is perhaps positive. He doesn't know if they got tested. Outcome of the events was unknown. Information on the lot/ batch number has been requested.; Sender's Comments: A causal association between reported event and BNT162B2 cannot be excluded.

Tested positive for COVID; Tested positive for COVID; Phlegm in throat; Cough; Runny nose; cold; Sneezing; Body aches; Nausea; Chills; Headache; This is a spontaneous report from a contactable consumer (patient). A 51-year-old female patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 29Dec2020 14:50 at single dose at right arm for covid-19 immunization. No additional vaccines administered on the same date. Patient didn't receive any other vaccines within 4 weeks prior to the COVID vaccine. Medical history included ongoing migraine. Concomitant medication included acetylsalicylic acid, caffeine, paracetamol (EXCEDRIN EXTRA STRENGTH) for migraine, patient had been alternating this with paracetamol (TYLENOL) while she has been recovering. She clarified the symptoms she experienced as the same day she got the vaccine that evening she had a headache on 29Dec2020. It eventually became a migraine and she left work early. On 30Dec2020 she had body aches, little nausea, and chills. On 31Dec2020, she had more chills, a runny nose, she felt like she was coming down with a cold. She was sneezing, had more chills, more body aches. On 01Jan2021 she felt like she noticed she had phlegm in her throat, but she did not have any pain. The phlegm was causing her to cough more. She had a runny nose the next morning as well. She did the rapid test for COVID on 02Jan2021 evening, and it was positive. She had a headache almost every day. The body aches had pretty much worn off. Runny nose and sneezing

resolved in Jan2021. Phlegm in throat confirmed with no pain. This also resolved, as well as coughing. Outcome of event tested positive for COVID was unknown, outcome of event headache was not recovered. outcome of event nausea was recovered on 07Jan2021, event chills was recovered on 08Jan2021, outcome of other events was recovered on unspecified date in Jan2021. The adverse events resulted in neither doctor or other healthcare professional office/clinic visit, nor emergency room/department or urgent care. Information of lot/batch number has been requested.

Positive COVID test; Positive COVID test; This is a spontaneous report from a contactable consumer (patient's wife). This consumer reported similar events for 2 patients. This is the 2nd of 2 reports. A male patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date not reported), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient was an Odontist and received COVID vaccine on Monday. He was scheduled to have a cath done on Thursday, but that was not happening now. The patient has positive COVID test. The outcome of the events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021013678 same reporter/drug, similar event, different patient

Her stomach is still weirded out/sour stomach; feeling sick; arm pain; She was sick to her stomach; kidneys were hurting; body aches; tested positive; tested positive; The arm wasn't swollen it was just burning.; This is a spontaneous report from a contactable consumer (patient). A 51-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number EL1284) via an unspecified route of administration on 29Dec2020 at single dose for COVID-19 immunization. Medical history was none. The patient's concomitant medications were not reported. At first, she thought she was having a reaction, but then she started feeling sick so she got tested. She was positive so she wasn't having a reaction. She was scared from the pain of COVID. She experienced sickness. Her stomach was still weirded out. She did experience arm pain from the vaccine. Her doctor told her it was fine that it needed to air out. She left the bandage on too long. She didn't have a prescribing doctor. She received the vaccine on the 29Dec2020. She tested positive 02Jan2020. The arm wasn't swollen it was just burning. She was sick to her stomach when she got the stomach. The sick to the stomach lasted maybe two days, but then she got COVID. The burning was around the arm. It wasn't that bad. It lasted for a day. It started the day she got the shot (on the 29Dec2020). On 07Jan2021, she went to the hospital because her kidneys were hurting. The doctor said her kidneys were good. They did labs which were good. She was still going through body aches. She was told she was currently in the worst part of the virus. She still had a sour stomach going on from the virus as well. The outcome of the body aches and sour stomach was not recovered, for other events was unknown.

tested positive after receiving the vaccine; tested positive after receiving the vaccine; she did not think symptoms were related to COVID like leg pain. She noticed that it was a lot worst; she did not think symptoms were related to COVID like leg pain. She noticed that it was a lot worst; This is a spontaneous report from a contactable consumer (patient herself). A 27-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE Solution for injection, batch/lot no. EH9899 and expiry date Mar2021), via an unspecified route of administration on 05Jan2021 on her left arm at a single dose

for covid-19 immunization. Medical history included leg pain. There was no reported concomitant medications. On an unspecified date, patient received COVID vaccine. She stated that she was symptomatic during the vaccine and somewhere after confirmed that she was COVID-positive. She wanted to know if there are any health concerns with getting the vaccine while COVID positive. She added that this was her first dose. she did not think symptoms were related to COVID like leg pain. She noticed that it was a lot worst but did not think that it was a symptom. She stated that she does not recall the first time ever that she had leg pain but stated that the leg pain was really bad the night before the vaccine. She added that she was isolated until 14Jan2021. Outcome of the events drug ineffective, COVID-19 virus test positive and leg pain were unknown.; Sender's Comments: Leg pain is considered intercurrent and unrelated to suspect BNT162B2.

COVID-19 or flu-like symptoms following COVID-19 vaccination/COVID-19 results were to be positive; COVID-19 or flu-like symptoms following COVID-19 vaccination/COVID-19 results were to be positive; COVID-19 or flu-like symptoms following COVID-19 vaccination; This is a spontaneous report from a contactable Other-HCP. A 61-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via unspecified route of administration on unspecified date at single dose for COVID-19 immunization. Patient medical history and concomitant medications were not reported. On unspecified date, COVID-19 or flu-like symptoms following COVID-19 vaccination was reported for the patient. COVID-19 results were to be positive on unspecified date. Changing diet to vegan was reported. Outcome of the events was unknown. Information on the lot/batch number has been requested.

contracted COVID two days after receiving vaccine; contracted COVID two days after receiving vaccine; This is a spontaneous report from a non-contactable nurse. A patient of unspecified age and gender received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number and expiry date were not reported), via an unspecified route of administration on an unspecified date at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. It was reported that the patient got their first dose of the COVID vaccination. The patient contracted COVID on an unspecified date two days after receiving the vaccine. The outcome of the events was unknown. No follow-up attempts are possible. Information about lot/batch could not be obtained. No further information is expected.; Sender's Comments: A causal association between reported event and suspect BNT162B2 cannot be excluded.

tested positive for covid; tested positive for covid; This is a spontaneous report from a contactable consumer (patient) via a Pfizer sponsored program Pfizer Connect. A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number and expiry date not reported), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient works for a hospital. Said had 1st dose of vaccine. Had tested positive for covid on an unspecified date and is under quarantine. The patient would like to know when she should get 2nd dose. The patient underwent lab tests and procedures which included sars-cov-2 test: positive on an unspecified date. The outcome of the events was unknown. Information on the lot/Batch number has been requested.

got sick and tested positive with COVID; got sick and tested positive with COVID; This is a spontaneous report from a contactable consumer via Pfizer Sponsored Pfizer First Connect. A contactable consumer reported similar events for four patients. This is second of four reports. A patient of unspecified age and gender received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, batch/lot and expiration date unknown), via an unspecified route of administration on an unspecified date at a single dose for covid-19 immunisation. The patient's medical history and concomitant medications were not reported. It was reported that the patient got sick and tested positive with covid on an unspecified date. It was further reported that patient who received the COVID vaccine, tested positive for COVID, and experienced side effects afterwards. The outcome of the events was unknown. Information about batch/lot number has been requested.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021013589 same drug, similar events, different patient

got sick and tested positive with COVID; got sick and tested positive with COVID; This is a spontaneous report from a contactable consumer via Pfizer Sponsored Pfizer First Connect. A contactable consumer reported similar events for four patients. This is fourth of four reports. A patient of unspecified age and gender received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, batch/lot and expiration date unknown), via an unspecified route of administration on an unspecified date at a single dose for covid-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient got sick and tested positive with covid on an unspecified date and experienced side effects afterwards. The outcome of the events was unknown. Information about batch/lot number has been requested.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021013589 same drug, similar events, different patient

got sick and tested positive with COVID after getting the first dose of the COVID vaccine; got sick and tested positive with COVID after getting the first dose of the COVID vaccine; This is a spontaneous report from a contactable consumer received from Pfizer-sponsored program Pfizer First Connect. This consumer reported similar events for four patients. This is 3rd of four reports. A patient of unspecified age and gender received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiry date were not reported), via an unspecified route of administration on an unspecified date at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient got sick and tested positive with COVID after getting the first dose of the COVID vaccine. The outcome of the events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021013589 same reporter, same product, similar events, different patient.

caller tested positive on covid a week after taking the 1st dose of vaccine; caller tested positive on covid a week after taking the 1st dose of vaccine; This is a spontaneous report from a contactable consumer (patient) via Pfizer-sponsored program Pfizer First Connect. A female patient of an unspecified age received the 1st dose of bnt162b2 (BNT162B2) at single dose on an unspecified date for Covid-19 immunisation. The patient medical history was and concomitant medications were not reported. The patient was tested positive for Covid a week after taking the 1st dose of vaccine on an unspecified date. The outcome of events was unknown. Patient wanted to know if she can get the second dose. Information on the lot/batch number has been requested.

"COVID-19 virus test positive; COVID-19 virus test positive; This is a spontaneous report from a Pfizer-sponsored program ""Pfizer First Connect"" from a contactable consumer reporting for himself. A male patient of an unspecified age received the 1st dose of bnt162b2 (BNT162B2), via an unspecified route of administration, on 22Dec2020, at single dose, for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient experienced COVID-19 virus test positive on an unspecified date with outcome of unknown. It was reported that the patient was scheduled to get his second dose on 12Jan2021, however between 22Dec2020 and 12Jan2021 the patient experienced the adverse event. The information on the lot/batch number has been requested."

Got the first dose and was contracted with COVID; Got the first dose and was contracted with COVID; This is a spontaneous report from a contactable consumer (patient) from a Pfizer-sponsored program IBCC (Inbound Call Center for HCPs). A female patient of an unspecified age received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 20Dec2020 at single dose for COVID-19 immunisation. The patient medical history and concomitant medications were not reported. The patient was contracted with covid on an unspecified date in Dec2020 (27Dec2020 or 28Dec2020) with outcome of unknown. Information about lot/batch number has been requested.

throat swelling; headache; Pain; little bit of chills; GI upset; This is a spontaneous report from a contactable nurse. A 48-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot: EK9231, expiry: 30Apr2021), via an unspecified route of administration on an unspecified date at 0.3 mL, single dose for covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient received her first dose of bnt162b2 on an unknown date for covid-19 immunization and experienced pain at the injection site. On an unspecified date, the patient experienced head ache, throat swelling, gastrointestinal (GI) upset, pain, and little bit of chills (don't believe to have had fever). It was clarified that the event took place after use of product. The outcome of the events was unknown.; Sender's Comments: The information in this report is limited, and does not allow a full medically meaningful assessment of the case. Considering temporal relationship, a causal relationship between the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) and the reported events including throat swelling cannot be excluded. The case will be reassessed should additional information become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

five employees in a nursing home have gotten the first dose of the vaccine, and then tested positive for COVID; five employees in a nursing home have gotten the first dose of the vaccine, and then tested positive for COVID; This is a spontaneous report from a contactable nurse. This nurse reported similar events for five patients. This is the first of five reports. A patient of unspecified age and gender received first dose BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection; lot number and expiry date not reported) via an unspecified route of administration, on an unspecified date, single dose for COVID-19 immunization. Relevant medical history and concomitant medications were not reported.

It was reported that five employees in a nursing home have gotten the first dose of the vaccine, and then tested positive for COVID on an unspecified date. They would like to know if they still get the second dose. Outcome of the events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the reported events of Covid-19 virus test positive and suspected LOE due to temporal relationship. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.,Linked Report(s) : US-PFIZER INC-2021021909 Same reporter/ drug/ event for different patients.;US-PFIZER INC-2021021910 Same reporter/ drug/ event for different patients.;US-PFIZER INC-2021021911 Same reporter/ drug/ event for different patients.;US-PFIZER INC-2021021912 Same reporter/ drug/ event for different patients.

five employees in a nursing home have gotten the first dose of the vaccine, and then tested positive for COVID; five employees in a nursing home have gotten the first dose of the vaccine, and then tested positive for COVID; This is a spontaneous report from contactable nurse. This nurse reported similar events for 5 patients. This is the second of five reports. A patient of unspecified age and gender received first dose BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection; lot number and expiry date not reported) via an unspecified route of administration, on an unspecified date, single dose for COVID-19 immunization. Relevant medical history and concomitant medications were not reported. It was reported that five employees in a nursing home have gotten the first dose of the vaccine, and then tested positive for COVID on an unspecified date. They would like to know if they still get the second dose. Outcome of the events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: The information currently provided is too limited to make a meaningful medical assessment hence, the events are conservatively assessed as related to the suspect drug BNT162B2 until further information becomes available.,Linked Report(s) : US-PFIZER INC-2021021881 Same reporter/ drug/ event for different patients

five employees in a nursing home have gotten the first dose of the vaccine, and then tested positive for COVID; five employees in a nursing home have gotten the first dose of the vaccine, and then tested positive for COVID; This is a spontaneous report from a contactable nurse. This nurse reported similar events for five patients. This is the third of five reports. A patient of unspecified age and gender received first dose BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection; lot number and expiry date: not reported), via an unspecified route of administration, on an unspecified date at single dose for COVID-19 immunisation. Relevant medical history and concomitant medications were not reported. It was reported that five employees in a nursing home have gotten the first dose of the vaccine, and then tested positive for COVID on an unspecified date. They would like to know if they still get the second dose. Outcome of the events was unknown. Information on the Lot/Batch number has

been requested.; Sender's Comments: The information currently provided is too limited to make a meaningful medical assessment hence, the events are conservatively assessed as related to the suspect drug BNT162B2 until further information becomes available.,Linked Report(s) : US-PFIZER INC-2021021881 Same reporter/ drug/ event for different patients.

five employees in a nursing home have gotten the first dose of the vaccine, and then tested positive for COVID; five employees in a nursing home have gotten the first dose of the vaccine, and then tested positive for COVID; This is a spontaneous report from a contactable nurse. This nurse reported similar events for five patients. This is the fourth of five reports. A patient of unspecified age and gender received first dose BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection; lot number and expiry date not reported) via an unspecified route of administration, on an unspecified date, single dose for COVID-19 immunization. Relevant medical history and concomitant medications were not reported. It was reported that five employees in a nursing home have gotten the first dose of the vaccine, and then tested positive for COVID on an unspecified date. They would like to know if they still get the second dose. Outcome of the events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: The information currently provided is too limited to make a meaningful medical assessment hence, the events are conservatively assessed as related to the suspect drug BNT162B2 until further information becomes available.,Linked Report(s) : US-PFIZER INC-2021021881 Same reporter/ drug/ event for different patients

five employees in a nursing home have gotten the first dose of the vaccine, and then tested positive for COVID; five employees in a nursing home have gotten the first dose of the vaccine, and then tested positive for COVID; she had felt weird; This is a spontaneous report from a contactable nurse. This nurse reported similar events for five patients. This is the fifth of five reports. A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; batch/lot number and expiration date unknown), via an unspecified route of administration on an unspecified date at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The nurse reported on behalf of her sister (patient). It was reported that the patient called right before Christmas and she had gotten the Pfizer COVID Vaccine. She reported that she had felt weird and had side effects to the vaccine. The patient works in a nursing home type thing, and she said she has had people who have gotten the first dose of the vaccine, and then tested positive for COVID. The patient called to ask the reporter if they should still get the second dose. The only other details that her sister (patient) provided her was that this has happened with several people; 5 employees and several or 9 patients. She is unsure if she said several patients or 9 patients, but there were 5 employees. The outcome of the events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: The information currently provided is too limited to make a meaningful medical assessment hence, the events are conservatively assessed as related to the suspect drug BNT162B2 until further information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics

Committees, and Investigators, as appropriate.,Linked Report(s) : US-PFIZER INC-2021021881 Same reporter/ drug/ event for different patients.

Diarrhea; nausea and vomiting; nausea and vomiting; rash on her right arm, like a hive or whelp; Fever; Headache; really sore right arm; right arm felt numb; This is a spontaneous report from a contactable nurse (patient). A 44-year-old female patient received the first dose of BNT162B2 (Pfizer COVD 19 vaccine), lot number: EL0142, via an unspecified route of administration on 07Jan2021 17:00 at single dose in right arm for COVID-19 immunisation. Medical history included blood pressure abnormal, had a cough from having COVID 19 on 16Dec2020, cough was ongoing and unknown for COVID-19. Concomitant medication included amlodipine from an unspecified date (taking for 2 years) and ongoing at 10mg once daily by mouth for blood pressure abnormal. No other vaccines were administered on same date and no prior vaccinations (within 4 weeks). Registered nurse (patient) was calling regarding Pfizer COVID 19 vaccine. Reported she received the first dose last Wednesday 07Jan2021 17:00 in the right arm. Reported she noticed the next day (08Jan2021) fever and a headache. On 08Jan2021, Friday she had a really sore right arm and her right arm felt numb. On 09Jan2021, Saturday, she experienced nausea and vomiting and also noticed a rash on her right arm, like a hive or whelp. On 10Jan2021 Sunday, again with the fever, nausea, vomiting and she had diarrhea. Today she stated she woke up a new woman. She feels felt with no fever and her arm was better. She still had a cough from having COVID 19 on 16Dec2020. Stated she was used to coughing. Added she treated the fever with Tylenol 1000mg. Stated she didn't remember exactly but she took a little everyday starting on Thursday the day after the vaccine. Stated she was unsure if she would have the next dose. The events didn't require a visit to physician office or emergency room. The outcome of fever was recovered on 10Jan2021, of Headache, sore arm, rash on right arm, nausea and vomiting was recovered on 11Jan2021, of arm numb was recovered on 09Jan2021, of diarrhea was recovering. Serious criteria for fever was reported as yes, medical significant, for Headache, sore arm, arm numb and Diarrhea was non-serious, for rash on right arm, nausea and vomiting was unspecified.; Sender's Comments: Based on the compatible time association, the event fever is possibly related to suspect BNT162B2 administration. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

COVID-19 confirmed by positive COVID-19 test; COVID-19 confirmed by positive COVID-19 test; This is a spontaneous report from a contactable consumer (patient). A patient of unspecified age and gender received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration in Dec2020 at single dose for COVID-19 immunisation. The patient medical history and concomitant medications were not reported. The patient develop Covid-19 diagnosed by PCR about may be six or seven days after received the vaccine. The patient recovered from the event. Information on the lot/batch number has been requested.

after the patient got vaccinated his relative tested positive; after the patient got vaccinated his relative tested positive; This is a spontaneous report from a Pfizer-sponsored program . A contactable nurse (relative of the patient) reported for a patient of unspecified age and gender received the first dose of

bnt162b2 (also reported as Pfizer Covid-19 Vaccine, lot no. and expiry date was not reported), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The nurse called in because his relative got the 1st dose of vaccine but after the patient got vaccinated his relative tested positive on unspecified date. The nurse called in if the patient can take the 2nd dose of vaccine. The outcome of the event was unknown. Information on the Lot/Batch number has been requested.; Sender's Comments: The patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE) but after the patient got vaccinated his relative tested positive on unspecified date. The case will be reassessed should additional information become available.

Tested positive for COVID; Tested positive for COVID; This is a spontaneous report from a contactable nurse (patient). A male patient of an unspecified age received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date not provided), via an unspecified route of administration on 22Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and patient's concomitant medications were not reported. The patient received his first dose on 22Dec2020 then, nine days later, on 31Dec2020, he tested positive for COVID. He is scheduled for his second dose on 12Jan2021. However, he is still out of work. He called to see if he could get his second dose a couple of days later or does it have to be exactly 3 weeks from the first shot and if it is okay to go a little longer. During the call, he stated he just wanted his question answered about the second shot, if can he wait a little longer. The outcome of the events was unknown. Follow-up attempts are completed. The following information on the batch number has been requested.; Sender's Comments: A causal association between reported event and suspect BNT162B2 cannot be excluded.

Got my Covid vaccine on the 20th and then I came back positive for Covid last week; Got my Covid vaccine on the 20th and then I came back positive for Covid last week; This is a spontaneous report from a contactable consumer. A patient of unspecified age and gender started to receive BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number/expiration date unknown), via an unspecified route of administration on 20Dec2020 at a single dose for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. It was reported that the patient got the COVID vaccine on the 20th (20Dec2020) and then came back positive for COVID on an unspecified in Jan2021 (reported as last week), then tested negative on 08Jan2021 and was due for vaccine on 09Jan2021. It was asked if the patient will be able to get the vaccine. The outcome of the events was recovered on 08Jan2021. Information on the lot/batch number has been requested.

"diagnosed with Covid; diagnosed with Covid; This is a spontaneous report from contactable other healthcare professional via a Pfizer sales representative. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number and expiry date was not reported) via an unspecified route of administration on 04Jan2021 at single dose for covid-19 immunisation. The patient's medical history and concomitant medications were not reported. It was reported that the patient received the vaccine on 04Jan2021 and was diagnosed with COVID on 07Jan2021. Outcome of the event was unknown. Information about Lot/Batch number has been requested.; Sender's Comments: Although, BNT162B2 vaccine immunogenicity is not in full effect after short time (3 days in this case) from the first dose administration, a causal relationship between event

""diagnosed with COVID"" (coded to Drug ineffective / COVID-19) and BNT162B2 vaccine cannot be completely excluded."

Patient received 1st dose on 28Dec and presented symptoms on 05Jan; Patient received 1st dose on 28Dec and presented symptoms on 05Jan; This is a spontaneous report from a contactable pharmacist reporting for self via Pfizer field representative (Field Medical Director). A patient of unspecified age and gender received the first single dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (lot number and expiry date not reported) on 28Dec2020 via an unspecified route of administration for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient presented COVID-19 symptoms on 05Jan2021. No lab tests reported. The outcome of the event was unknown. Information about lot/batch number has been requested.; Sender's Comments: The patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE) on 28Dec2020, and patient presented COVID-19 symptoms on 05Jan2021. No effect of the suspect vaccine could be reasonably achieved to protect from the targeted infection/disease due to the very short time lag. Instead, patient's COVID-19 symptoms on 05Jan2021 likely represents a pre-existing infection prior to vaccine use. Further information is needed for full medical assessment.

This morning he is diabetic. His sugar it was elevated, it was up to 300 which is he said much higher than normal; This is a spontaneous report from a contactable consumer (patient) from a Pfizer-sponsored program Pfizer First Connect. A male patient of unspecified age received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 09Jan2021 at single dose for COVID-19 immunisation. Medical history and concomitant medications were not reported. He has his first dose of the COVID Vaccine yesterday and this morning he is diabetic. When he woke up this morning to test his sugar it was elevated, it was up to 300 which is he said much higher than normal and wants to know if that would be a symptom. Outcome of event was unknown. Information on the lot/batch number has been requested.

1/16/21, Covid vaccine injection at 12:09 PM Minute 1: dizzy and light headed (like drinking a beer on an empty stomach) Minute 10: Nausea Minutes 23-25: Neck tightness (like doing unsupported crunches and holding my head up) Minute 27: Inability to swallow and inability to speak EMS on site administered EpiPen auto-injection to left thigh, immediate improvement in symptoms Transport to hospital via ambulance Hospital monitored me for several hours and discharged same day

itching, hives, short of breath, numbness and tingling to lips with hives to bottom. headache.

On 1/13/2021, resident had sudden emesis. Immediately following emesis he was noted without a pulse and pronounced deceased. No acute symptoms noted prior to this episode. Resident does have a significant cardiac history.

Started with severe chills, body aches and feverish. The. Slight leg pain which worsened with time , swelling on the right leg calf, warm to touch and difficulty breathing. Got hospitalized on 1/16 21 with multiple clots in my right leg and clot in the lung. Still in the hospital now.

She had the first dose of Pfizer vaccine at the Campus on Friday 1/15 at 4:30 pm. After the vaccine, she had no new symptoms or signs of vaccine reaction and MD friend reports that he checked her pulse which was not elevated from baseline. On 1/16, she awakened and continued to feel at her recent baseline. However, in the early afternoon, she complained of headache, nausea/epigastric pain, and chest heaviness. These apparently were not unusual symptoms for her to feel intermittently. Per her niece, who has a home O2 sat device, her 02 sat that morning was 97 with a HR of 87 irregularly irregular. She was afebrile. (continue on page 2)

Aphasia, ,right-sided weakness and garbled speech

"Had severe body aches m, fever, headache, progressed into dizziness and ""foggy memory"", started to have some chest pain. Felt as if I was intoxicated, lasted the whole day. Woke up the next morning and still felt ""out of it"" and weak but thought it would get better, went to work (im a nurse). Started having continous vomiting, shortness of breath and chest pain at work. As well as severe tremors. I was taken to the hospital, given fluids and my QT was prolonged with my heart which i have never had before . Was given iv magnesium and waited for my heart rhythm to improve. Was told not to take anymore of my prescribed medications or nausea medications and follow up with my pcp the next day. Im still feeling horrible, nausea, body aches, low grade fever and I am 72 hours out. Now I have huge hospital bill to pay, can't work currently because I still feel bad and my heart has a weird rhythm. Hoping this helps as if this was what I was expecting I would have never got it."

Pt complained at ED of Headache, Nausea, SOB, felt like had been running. Pt in AFIB started on cardizem admitted to hospital 1/15 discharged 1/17

Patient tested positive for COVID 19 on Jan 5th 2021 Patient was admitted to the hospital January 9th for pneumonia due to COVID

Acute liver injury requiring transplant evaluation and acute kidney injury

Anaphylaxis after Covid 19 vaccine #1. Pfizer Lot # EH9899

Two days after her shot, she was sitting down working on her computer paying bills. She became nauseas and dizzy and then fainted. She hit the tile floor.

Lot number for the first dose was EK5730. After receiving the 2nd dose on the 01/11/2021 went to lunch and in the evening started feeling nausea and was throwing and abdominal pain. Went to work sick Tuesday and Wednesday low grade fever, nausea and abdominal pain, wasn't eating was to sick to eat. Thursday early morning hours the pain was unbearable so she went to the ER and the cat scan. It was determined that she had appendicitis and they removed my appendix same day. Feels so much better now.

"After receiving Moderna vaccine, pt became increasingly tired, withdrawn, and confused, refusing to walk at home. He has begun to have mild memory changes after suspected COVID illness (covid testing negative) in November, but daughter of patient, with whom he lives, states that his memory and orientation now significantly changed- he seems to have forgotten the last ""3 years"" of memory.

Presented to ER 1/16/21 as she checked his O2 and found him to be hypoxic in 60s. He is being treated for possible CAP with underlying perviously undiagnosed ILD vs post-covid lung changes (per pulmonology), and his energy and ability to walk have returned but memory is significantly impaired, confabulating and oriented only to self despite good oxygenation on 5L O2 by NC."

About 22 hours after the shot, I had a mini stroke that required going to the emergency room by ambulance. I was transported that evening to the stroke division that same evening for further evaluation, tests and care. I have never had a mini stroke before this.The doctors said it may have been from the vaccination, or it may not have been precipitated by it. They said they don't have enough information on the Moderna vaccine to make that call.

Patient was vaccinated in right arm. Within 5 to 10 seconds after vaccination, patient started clinching his hands tightly and became unresponsive. Patient was lowered to the floor and did not exhibit a pulse. CPR was initiated and 911 was called. An AED was used and healthcare professionals onsite continued compressions until the paramedics arrived.

Death

Received vaccination on 12/30/2020, had positive Covid test result on 1/6/2021, was hospitalized with respiratory issues on 1/11/2021, and discharged home from the hospital on 1/18/2021

12:52 PM resident rang her call bell with complaints of chest pain and shortnes of breath. BP 126/70, Temp 97.5, Pulse 72, Resp. 20, O@ stats on room air 90%. resident requesting transport to ER. EMS called at their arrival resident had increasing SOB o2 on at 3L Nasal Canula. Transported to hospital. Resident placed on ventilator and tranported to different hospital.

"Felt tachycardia immediately, thought she was anxious. After 35-45 minutes she felt like she was having a hard time swallowing which progressed to tongue swelling, all taste buds popped up and sore, hives on face & neck, reddened face. Itchy neck and face. Took double dose of Atarax and went to bed. Felt extremely fatigued unsure if double dose of Atarax. Woke with swelling all over body. Woke up feeling heaviness as if she had ""sumo wrestler"" on her body. 24 hours post vaccine heaviness started to lift but felt as if she had a vise on her lungs. Continuing to take Atarax every 6 hours per MD order."

Resident received vaccination on January 15, 2021. She was found unresponsive with shallow respirations on the morning of January 16, 2021 and was sent to ER via ambulance. The resident was admitted to medical center ICU where she passed away later that day.

resident had a pressure ulcer to RT hip, was getting treatment on. Was scheduled to have wound debrided and wound vac applied on 1-19-2021. Appetite was poor, not wanting to get out of bed, and decline in alertness. Passed away on 1-16-2021

patient received vaccine 12/29. Unexpected death 1/5.

Patient had received second Pfizer vaccination after no reported issues with the first dose. Patient was observed post vaccination without incident and released. Patient developed wheezing and attempted to

treat with her albuterol inhaler but did not improve. patient presented to the ED approximately 2 hours after vaccination and was admitted for respiratory failure and placed on BiPAP for a brief period of time. patient has known history of Asthma Exacerbation requiring hospitalization and intubations. D/C diagnosis Asthma Exacerbation

Systemic: Anaphylaxis-Severe; symptoms lasted 1 day

Systemic: Anaphylaxis-Severe, Systemic: Seizure-Severe

Temp of 104.5, hospitalization

COVID 19 Vaccination administered by pharmacy staff. No adverse effect at the present time. Staff will continue to observe adverse reaction. Will continue to monitor. Patient at start of shift awake in the bed. Pt at 3am was on the commode leaned to the side. Patient body still warm to touch no pulse. Called for assistance Asap. Cpr started promptly. Cpr given patient on floor 911 arrived at the scene at 3:10am Cpr rotated Between Nursing and EMT on Scene. Cpr was given to patient for over 45 minutes. Patient was pronounced at the scene at 3:50am. Call placed to Pt family by supervisor on shift. MD to be notified. AT 3:00am, I was notified by the nurse that resident is unresponsive. Upon entering room, resident was sitting on the commode unresponsive with absent respiration and pulse. Resident lowered down on the floor with 4 person assist. CPR initiated, AED pads placed on chest with no shock indicated. 911 called and EMT and paramedics arrived around 3:10am. ACLS performed until code stopped and pronounced death at 3:48am. I called and notified family member of his demise and awaiting for family to call us back for funeral arrangements.

One week after the shot (1-14-2021) Patient (19 y.o.)reported side pain and appeared constipated, Laxatives given along with Tylenol, on further assessment Patient was noted to have left leg redness and abdominal fullness. Dr. was updated and we had orders for close monitoring, the next day when she got up, her leg appeared better, and she had passed a small BM, but by lunch she had developed significant pain and edema in her left leg, and the color of her leg was reddened again. She was sent to the emergency room with her symptoms. She was admitted back to our facility yesterday, her diagnoses included Acute provoked left external illiac, femoral, popliteal, and peroneal DVT. Elevated Factor II levels, Elevated APC resistant, May-Thurner Syndrome, history of developmental disabilities, fecal impaction and urinary retention - suspected related to her fecal impaction. Vascular surgery was consulted, and pt. was started on a heparin drip, and mechanical thrombectomy was needed for both legs due to multiple clots. She was started on Eliquis and Plavix, and thigh high compression stockings were ordered, ace wraps being used until these are supplied. Her Fecal impaction was addressed also and the urinary retention resolved.

Death

Hx Covid infection Had Covid vaccine #1 - no problems Within 1 hr after Covid vaccine #2 progressed to SOB, pruritis throat tickle TxT-ed self with Benadrl but symptoms persisted Went to ED txt with Bendryl, prednisone, zyrtec.

"right sided weakness with numbness from her face down her entire body; right sided weakness with numbness from her face down her entire body; right sided weakness with numbness from her face down her entire body; bad headache; pain at the injection site; This is a spontaneous report from a contactable consumer (patient). A female patient of an unspecified age (reported as 41 unknown unit) received the first dose of bnt162b2 (BNT162B2) via an unspecified route of administration on an unspecified date at a single dose for covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient wanted to know how long side effects last after receiving the first dose of the Covid vaccine. The patient received first dose of Covid vaccine on Thursday (unspecified date) and reported side effects. She reported side effects of right sided weakness with numbness from her face down her entire body. She describes the feeling as if she's been ""shot up with novocaine on the right side of her body."" She was also experiencing a really bad headache and pain at the injection site. She reported that the side effects do not seem to be wearing off. She wanted to know if this has been reported as a common side effect. Outcome of the events was unknown. Information on the lot/batch number has been requested."

Severe headache from 12-36h post administration impairing ability to perform ADLs with inability to turn head from side to side or to change positions without lancing temporal pain and a/w photophobia; Severe headache from 12-36h post administration impairing ability to perform ADLs with inability to turn head from side to side or to change positions without lancing temporal pain and a/w photophobia; Severe malaise; Severe headache from 12-36h post administration impairing ability to perform ADLs with inability to turn head from side to side or to change positions without lancing temporal pain and a/w photophobia; loss of appetite; Transient dysgeusia; Mild nausea; Pleuritic chest pain; This is a spontaneous report from a non-contactable physician. This 27-year-old female physician (patient) reported that she received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number=E15249), via unspecified route at left arm on 08Jan2021 07:30 AM at single dose for COVID-19 immunization. Medical history was none. Concomitant medication was not reported. The historical vaccine included the first dose of BNT162B2 for COVID-19 immunization. Facility type of vaccine was hospital. No other vaccine in four weeks. No Covid prior vaccination. No covid tested post vaccination. On 08Jan2021 06:00 PM, patient experienced severe headache from 12-36h post administration (as reported), impairing ability to perform ADLs with inability to turn head from side to side or to change positions without lancing temporal pain and a/w photophobia (nearly meningeal signs); mild nausea; pleuritic chest pain; severe malaise; transient dysgeusia; loss of appetite. Treatment for events included initially NSAIDs until had difficulty tolerating was received. Outcome of events was recovering. No follow-up attempts are possible. No further information is expected.; Sender's Comments: Based on the time association, the possible contribution of suspect BNT162B2 to the events cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

tachycardia; shortness of breath; elevated blood pressure 165/90; tired; stomach upset; felt unwell; This is a spontaneous report from a contactable other health professional (patient). A 25-year-old female

patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 31Dec2020 at single dose for COVID-19 immunization. The patient medical history and concomitant medications were not reported. The patient experienced on 04Jan2021 felt unwell, tired, stomach upset (it continued all week) and on 07Jan2021 tachycardia and shortness of breath. Clinical course: she was feeling very like short of breath and her heart racing, had elevated blood pressure 165/90, usually it was normal. The patient was sent to the emergency room (ER) and got worked up, she had a complete blood panel, everything came back normal; she had a chest X-Ray and 2 bags of fluid, then the patient was discharged. The patient outcome of the events was recovered. The information on the batch number has been requested.; Sender's Comments: A causal association between BNT162B2 and the reported events cannot be excluded based on a compatible temporal relation between vaccination and onset of events. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

started having a lot of left eye pain/he diagnosed her with Scleritis; This is a spontaneous report from a contactable other healthcare professional (HCP) a Nurse Practitioner, who reported for herself. A 35-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Batch/lot number: EJ1685 also reported as ES1685), intramuscular in left deltoid on 24Dec2020 at single dose for COVID-19 immunization. Medical history included ongoing anxiety diagnosed years ago, maybe when she was 23. Concomitant medication included ongoing celecoxib (CELEXA) for anxiety started about a year, or year and a half ago. She did not take other vaccines on the same day as the COVID vaccine. She had no recent labs. On 02Jan2021 the patient experienced scleritis. Event was described as follows: patient got her first COVID vaccine on 24Dec2020 and on 02Jan2021 she started having a lot of left eye pain. She went to her Ophthalmologist and he diagnosed her with Scleritis. She had no history of anything with her eyes or any vascular or autoimmune issues; no eye disorder history or rheumatology history. Patient is due to get her second dose of the vaccine on 14Jan2021, and she spoke with her primary care doctor and her ophthalmologist, and neither of them have any answer on if she should get the second dose or not, they did not have much guidance for her as this was such a new product. Patient reported that scleritis was persisting, but it has improved and she was on Prednisone eye drops. Event scleritis was considered serious as Medically significant because of what it is and what it can do, but this was not a severe case (as reported). Final outcome of scleritis was recovering.; Sender's Comments: The reported scleritis was more likely an intercurrent disease, and less likely causally related to the use of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE). The case will be reassessed should additional information become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics committees and Investigators, as appropriate.

Appendicitis; Vomiting; Nausea; Chills; This is a spontaneous report from a contactable consumer. A consumer reported that her 65-year-old mother received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot number Unknown), into the arm at single dose on 31Dec2020 for COVID-19 immunization. The patient did not have any medical history and did not receive any concomitant products. On 31Dec2020 the same evening of vaccination, the patient experienced vomiting, nausea and chills that were considered flu like. On 03Jan2021 or 04Jan2021 her appendix ruptured. She entered emergency room on 07Jan2021 and was diagnosed with appendicitis. She was admitted to hospital on 07Jan2021. She has been given hospital care for past four days. She will have surgery in 6 weeks to repair and right now they are cleaning ruptured area. Her care team is wondering if she should get second dosage. The patient is currently hospitalized. The patient recovered from the event vomiting on 31Dec2020, recovered from the events Nausea and Chills on 07Jan2021 and was Recovering from the appendicitis. Information on the lot/batch number has been requested.

"Bell's Palsy; This is a spontaneous report from a contactable consumer. A 63-years-old female patient received the first dose of BNT162B2 Pfizer-BioNTech COVID-19 Vaccine, Batch/lot number: ELD14D, via an unspecified route of administration, in left side of arm, on 04Jan2021 at single dose for COVID-19 immunization. Medical history included early breast cancer from 2017 and ongoing. Concomitant medication included tamoxifen citrate 20 mg tablet by mouth once daily from 2017 and ongoing for breast cancer (cancer pill, she has to be on it for 5 years). The patient received the vaccine as she is ""with fire department, thought she needed to take it, she had early breast cancer, is around lots of people"". On 09Jan2021 the patient was diagnosed with Bell's palsy, assessed as medically significant and in Jan2021 she experienced earache (she thought it was an earache, but it was more than that, but it made her ear hurt, and she has no infection), her mouth was drawled a little, further detailed as numbness and ""the eye, it is messing with it, when she is trying to see out of it, she can see, but it's blurry like"" and, ""where the ear thing is"", on the back of the lymph node was real sore and her face was kind of puffy, which is the reason she went to the doctor. The patient had to go to her doctor, he told her she had a reaction to the shot, he called it Bell's Palsy, and said to let Pfizer know. Her doctor gave her something to take for mouth drawled/numbness, which is supposed to help, and she has to go back in a week. The event Bell's palsy outcome was unknown at the time of the report."

Doesn't feel like eating; Fever; Chills/ Chilled; Nausea; Severe Headache/Dull headache/Frontal headache; Fatigue; Body aches; This is a spontaneous report from a contactable Nurse (patient). This 61-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number EJ1686), via intramuscular, on 06Jan2021 (at 14:30) at single dose at left deltoid for COVID-19 immunisation, administered at hospital. Age at vaccination is 61-year-old. Historical vaccine included Diphtheria and Tetanus vaccine (intramuscular, at single dose) on 15Dec2020 for immunization; and Shingles vaccine (intramuscular, at single dose) on 15Dec2020 for varicella immunization. Relevant medical history included usual tenderness. No relevant concomitant medications were provided. On 07Jan2021, she woke up at 2:00 in the morning, she had a high temperature, she was chilled, she had a severe headache, nausea, fatigue, and body aches. She got up and took ibuprofen (ADVIL). She was basically in bed, she had to cancel all her appointments in the morning, she just laid in bed and the following afternoon her fever broke at about 4:30 in the afternoon then she just had a low grade

temperature and a dull headache, nausea through the next day, Friday the 08Jan2021. She still has a very dull headache and just not right, kind of like a flu bug. She had no fever; she had not had any fever after Friday afternoon or Saturday. Fever started at 2 in the morning 07Jan2021 and she experienced the chills until after fever broke. Fever went above 102 degrees. She still had a little of the nausea, she just didn't feel like eating. She still had the dull headache. The nausea and headache have improved when compared to how it was on the 07Jan2021. She was back to work now she just has a dull frontal headache. The reporting nurse assessed all the events, except of 'Doesn't feel like eating', serious for disability. She stated she may have had usual tenderness but nothing like this. The patient had recovered from the event fever on 08Jan2021 and from the event 'chills/chilled' on 07Jan2021; the patient was recovering from 'nausea' and 'severe Headache/Dull headache/Frontal headache', while the outcome of the remaining events was unknown.; Sender's Comments: A possible contribution role of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) to the onset of the reported events cannot be excluded due to temporal relationship. It is worth noting that patient had other vaccines not far ago, including Diphtheria and Tetanus vaccine and Shingles vaccine on 15Dec2020 for immunization. The case will be reassessed should additional information become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics committees and Investigators, as appropriate.

throat and tongue started to feel weird and tight/throat got to the point of so swollen and itchy I couldn't swallow; throat and tongue started to feel weird and tight/throat got to the point of so swollen and itchy I couldn't swallow; throat and tongue started to feel weird and tight/throat got to the point of so swollen and itchy I couldn't swallow; throat and tongue started to feel weird and tight/throat got to the point of so swollen and itchy I couldn't swallow; This is a spontaneous report from a non-contactable consumer (patient) via a Pfizer-sponsored program Corporate (Pfizer) Social Media Platforms. This patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration at single dose on an unspecified date for covid-19 immunisation. The patient medical history and concomitant medications were not reported. On an unspecified date, the patient experienced throat and tongue started to feel weird and tight/throat got to the point of so swollen and itchy I couldn't swallow. The patient condition was life threatening. The patient described the events as follows: 40 min after injection my throat and tongue started to feel weird and tight. Pharmacy at my work hospital gave me 25 mg Benadryl and 650mg Tylenol. At about 1 hr 45 min after injection my throat got to the point of so swollen and itchy I couldn't swallow. I went to nearest emergency room hospital they administered Decadron orally, Pepcid P.O. (orally), and Toradol via IM (Intramuscular). The outcome of the events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

"Have a cut in my leg which is very unusual; Saw a big cut in my feet; I was bleeding from somewhere; It was quite a lot of blood drawing out of my body; This is a spontaneous report from a contactable consumer (patient). A 62-year-old male patient started to receive single dose of BNT162B2 (Solution for injection, batch/lot number and exp date not reported), via an unspecified route of administration on

23Dec2020 09:00 for COVID-19 immunization; and adalimumab (HUMIRA), via an unspecified route of administration from an unspecified date at unspecified dose (injection every other month) for arthritis. Medical history included arthritis, blood pressure (abnormal), and blood cholesterol (abnormal). Concomitant medication included rosuvastatin for blood cholesterol, olmesartan medoxomil, metoprolol succinate (TOPROL XL), and vitamins: ascorbic acid, ergocalciferol, nicotinamide, retinol, riboflavin, thiamine hydrochloride. Patient stated, ""The reason I am calling, I have just a concern that something happened to me. I did not pay much attention but now I have read the news one doctor died after getting this COVID Vaccine (Further details were not available over the call) I have a small incident happened to me the day after I received my first dose of the COVID Vaccine. I just wanted to get some information. You know what happened the next day night, in the evening I was taking a shower and all of sudden I was bleeding from somewhere. Lot of blood was coming out while I was toweling my body out. I couldn't find out where the blood is coming from. I checked, it's not from my urine, not from my rectum but it was quite a lot of blood drawing out of my body. Immediately, I called my wife into bathroom, then I squeezed my body then the bleeding stops. It was on 24Dec2020. You know my kids were at home. I don't want them to find it. The bleeding stopped and everything went away. Then I thought maybe it is something related to my GI. I went to my GI doctor yesterday to have a checkup, they don't know anything either but I am due for my second dose for next week Wednesday. Now I had this news about thrombocytopenia on this doctor died (Clarification unknown). So I am just afraid if there is anything related this. Do you have any explanation on how I bleed and where it bleed? It was lot of bleeding even my towel was full of blood."" Patient wanted to see if anybody else had similar experience or if he get the second dose and he get the complication again. Patient was a medical technologist. He was doing ultrasounds. He was working in a pediatric hospital. Patient was not prescribed/recommended vaccination. ""Nobody recommended it. During my hospital. I am healthcare professional. So everybody in my hospital. I just went there and get it. I didn't ask my doctor."" Patient added, ""You know everything I read about this case and then you know, I have a cut in my leg which is very unusual. I have never seen that. I don't know how it happened. You know all of sudden oneday I wake up and I saw a big cut in my feet also. So, I am just afraid (onset date not reported)."" The action taken in response to the events for adalimumab was unknown. The outcome of the events was unknown. Information about Lot/Batch number is requested."

Possible Bells Palsy; Arm/neck soreness; Arm/neck soreness/ neck are painful; travel up neck to side of face/around temple/ Side of head/face/cheeks/jaw; travel up neck to side of face/around temple/ Side of head/face/cheeks/jaw; travel up neck to side of face/around temple/ Side of head/face/cheeks/jaw; Feel numb; Sore-all on same side as injection; This is a spontaneous report from a contactable consumer (patient). A 52-year-old female patient received first dose of bnt162b2 (Pfizer COVID 19 vaccine, lot number: EL3246) , via an unspecified route of administration on 13Jan2021 17:00 at single dose on left arm for covid-19 immunisation . The patient medical history was not reported. Concomitant medication included fluticasone propionate (FLONASE), pantoprazole. The patient experienced arm/neck soreness, travel up neck to side of face/around temple; side of head/face/cheeks/jaw, neck are painful, feel numb, and sore-all on same side as injection; and possible Bells Palsy on 14Jan2021 02:00. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19.

No allergies to medications, food, or other products. No treatment was received for the events. The outcome of the events was not recovered.

his platelet levels dropped and he had a hemorrhagic stroke; his platelet levels dropped and he had a hemorrhagic stroke; This is a spontaneous report from a contactable consumer. A male patient of unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The relevant medical history and concomitant medications were not reported. The patient died 2 weeks after his COVID shot because his platelet levels dropped and he had a hemorrhagic stroke. No further information provided. The autopsy was unknown. The outcome of the events was fatal. Information on the lot/ batch number has been requested.; Reported Cause(s) of Death: his platelet levels dropped and he had a hemorrhagic stroke; his platelet levels dropped and he had a hemorrhagic stroke

expired before receiving the second dose; This is a spontaneous report from a contactable nurse. This nurse reported similar death events for 8 patients. This report is for 5th of 8 patients. A patient of unspecified age and gender received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 22Dec2020 at single dose for COVID-19 immunisation. The patient medical history and concomitant medications were not reported. The patient expired before receiving the second dose on an unspecified date. The patient died on an unspecified date. It was unknown if an autopsy was performed. Information on the lot/batch number has been requested.; Sender's Comments: The limited information provided in this report does not allow a full assessment of the case. The event death with unknown cause is assessed as related to the suspect drug per company guidance. This case will be reassessed when additional information, particularly the clinical course before death, complete medical history and concomitant medication and autopsy report, becomes available.,Linked Report(s) : US-PFIZER INC-2021034595 same drug, reporter and event but different patient; Reported Cause(s) of Death: expired before receiving the second dose

passed unexpectedly; This is a spontaneous report from a contactable nurse communicated to a Pfizer colleague. This nurse reported similar death events for 8 patients. This report is for 8th of 8 patients. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 22Dec2020 at single dose for COVID-19 immunisation. The patient medical history and concomitant medications were not reported. The patient passed unexpectedly on an unspecified date. The patient died on an unspecified date. It was unknown if an autopsy was performed. Information on the lot/batch number has been requested.; Sender's Comments: The limited information provided in this report does not allow a full assessment of the case. The event death with unknown cause is assessed as related to the suspect drug per company guidance. This case will be reassessed when additional information, particularly the clinical course before death, complete medical history and concomitant medication and autopsy report, becomes available. The case will be reassessed if additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.,Linked Report(s) : US-PFIZER INC-

2021034595 same drug, reporter and event but different patient; Reported Cause(s) of Death: passed unexpectedly

allergy; Short of breath; Tachycardia/my heartrate was like 140 - 150; Blood pressure was like 165 over 114/my blood pressure just like skyrocketed; Upset stomach; Tired; Started to feel not very good/not feeling like wonderful/overall sickness; Muscle ache; This is a spontaneous report from a contactable consumer (patient). A 25-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), lot number: EL014 (can't really tell), via an unspecified route of administration on 31Dec2020 at single dose for COVID-19 immunization. Medical history included allergy and heartburn. Concomitant medication included omeprazole for heartburn, cetirizine hydrochloride (off-brand for Zyrtec) as allergy medicine and a birth control medicine. Consumer stated, she just was calling this number because she didn't necessarily know if she had an adverse reaction or a symptom. She just wanted to report it and see if maybe you had any insight if this has happened to anybody else. Consumer further stated, she had an adverse reaction where she had to go to the emergency room. So, she didn't know if it was from the Vaccine or not because her reaction was very delayed. She got her vaccine on 31Dec2020, New Year's Eve and then starting on Monday after the vaccine on 04Jan2021. She started to feel not very good, it was mostly just like overall sickness, just as muscle aches, tired, having upset stomach so that was after 4 days. Patient had allergy from an unspecified date. And then on 07Jan2021, a week after she got the vaccine, she had signs of tachycardia and her blood pressure just like skyrocketed, her blood pressure was like 165 over a 114 and her heartrate was like 140 - 150. And she worked in healthcare, which was why she was one of the first ones to get the vaccine and she went to the ER and got worked up and they couldn't find, nothing was abnormal with her labs or blood work. She even had a chest X-ray and they couldn't find anything and they just gave her fluids and sent her home. And she was home now and still not feeling like wonderful, she felt better though but she just wanted to report that and see if there was any correlation. She didn't really know because it was so delayed, a week later. So she just wanted to report it. Consumer further stated, she forget to tell one thing, she was also short of breath on 07Jan2021. So that was why they had sent her to ER because of Tachycardia, shortness of breath and her blood pressure was really high. They didn't give her any medicine they just gave two big bags of fluid and then they discharged her. Consumer stated, she was scheduled to have her second one, she thought it was 14Jan2021. She wanted to know if she should get the second one. Consumer stated, when she went into the ER she had a lot of lab work. She didn't even know what all they did but a lot like, blood panels, she checked everything was there, that was on Thursday, last week, 07Jan2021. Consumer stated no treatment was received for the events. Outcome of the events was unknown.; Sender's Comments: A causal association between BNT162B2 and the reported events cannot be excluded based on a compatible temporal relation between vaccination and onset of events. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

Approximately 3 days after my injection I began experience severe tremors Ib bilateral arms, bilateral legs, head, and vocal cord tremors as well as blurry vision and memory impairment. Unfortunately, the symptoms don't seem to be improving. My MD prescribed metoprolol, which I will begin today.

a couple hours after the vaccine, I experienced a bit of rapid heart rate, which resolved after a few minutes. The following day around 3 pm I began to have chills and felt like I had the raid heart rate again. By 5 pm I was beginning to feel really bad, I was freezing, chills and my heart rate was now extremely fast, I was having trouble speaking complete sentences, my husband drove me to the emergency department. I had a very high heart rate and high fever, I was admitted and in the hospital until Sunday afternoon. The diagnosis was pneumonia, I don't really believe this, as I felt fine and had no symptoms prior to the onset of the fever.

Patient died 1 week after vaccination. According to family was having very rapid decline in status in recent weeks and they did not think related to vaccination.

Anaphylaxis less than two hours after vaccination. I had no symptoms immediately after vaccine however did develop symptoms within one minute of completing a run. Developed b/l hand swelling and tingling, diffuse hives and itching, tachycardia, elevated blood pressure, lips tingling and swelling which required emergency room visit and EpiPen, IV fluids, Benadryl and IV steroids. This is similar to previous reactions I have had to running previously. Symptoms resolved within one hour after treatment in ED.

Severe headaches, vomiting, dehydration, shortness of breath ... led to trip to Emergency Room at Hospital on 1/16/21 at 10:45 am; diagnosis for treatment was Diabetic Ketoacidosis (DKA); patient was admitted to ICU to address critical fluid and electrolyte imbalances , headaches, body aches, dehydration, nausea, shortness of breath. DKA is medical emergency.

Pt brought to the ER with SVT. He was given 2 doses of adenosine by EMT's. Pt was found to have hypomagnesemia and hypophosphatemia in the ER. He was admitted for observation and evaluated by Cardiology. He remained stable with NSR during admission. Pt has a follow up appt with Cardiology EP clinic on 2/18/21.

Fatigue, wheezing, soreness, palpitations

38 year old female - healthy with no significant past medical history. Morning of 1/15/21, pt woke up with difficulty speaking (would be talking and then unable to articulate words which were replaced by grunting sounds) and tingling to her face. No changes to breathing, no numbness/tingling to extremities, equal facial symmetry. Slow onset of symptoms. Pt went to the ED, where she received a CT, MRI (inconclusive reading), lab work reported as normal per pt, EKG and chest x-ray. Symptoms self resolved while in the ED, however MD staff wanted to admit patient for 24 hours of observation and to complete an echocardiogram. Pt left AMA the evening of 1/15/21 due to resolution of symptoms and wanting to follow up with her cardiologist for the echocardiogram. Pt told by MD staff symptoms were likely caused by either TIA, possible reaction to vaccine or migraine presentation (no report of headaches/auras). Plan

was to have patient on blood thinners x 30 days then baby Aspirin thereafter. Pt still needing to follow up with PCP and cardiologist for further work up.

Received vaccine on 1/16/21, on 1/17/21 started with coughing, white phlegm, SOB and on 1/18/21 developed fever to 101 and increased need for oxygen. Home requirement increased from 3L O2 to 6L O2. On 1/18/21 presented to hospital. Quickly defervesced with steroids and cefepime. Possible post-obstructive pneumonia vs immune response to vaccination.

Patient could not open and close hand after the first day of vaccination. On the third day his arm turned purple and could not be moved and was numb. A week and a half after vaccine, arm hurt and was numb. Patient was hospitalized.

Systemic: Pt monitored by nursing for 30min after inj,pt was stable/no reaction.At ~1hr post inj pt was unresponsive.Pt was a hospice/dnr per director

9 to 36 hours. Lymphnode swelling , pain left axilla. Fever, chills ,muscle aches, brain fog. 1 week post Facial paralysis, fatigue, vocal cord weakness, feeling of unwell.

12/28/2020: generalized weakness and fell twice at home, cough, nausea,1/04/2021: cough, nausea, fever and chronic pain when she fell from being weak. admitted to hospital with Covid pneumonia, shortness of breath, covid postive, 1/09/2021: pt on bipap, 1/15/2021: pt was intubated, on TPN, pt DNR, 1/18/2021: was extubated and put on comfort measures and passed away

Patient was vaccinated for SARS-CoV-2 on 6-Jan-21 at his site of employment, a Nursing Home. Patient presented to Urgent Care on 15-Jan-21 complaining of left sided chest pain that started the evening before with an associated slight cough. Pt was afebrile with a heart rate of 88 and an O2 sat on room air of 98% in triage. His EKG showed a sinus tachycardia of 114 with a slightly prolonged QTc of 463 ms. Physical exam was significant for bibasilar crackles and X-ray showed bibasilar infiltrates consistent with COVID pneumonia but bacterial pneumonia could not be excluded. The patients BP was documented as 97/64. He was treated with Zofran for nausea and tylenol. He was prescribed a five day course of Azithromycin, an Albuterol inhaler, guaifenessin with codeine cough syrup, and Zofran. Labs were drawn and he was discharged. His lab results were reported after his departure and were significant for a white blood cell count of 1.33, platelet count of 73, 2% myelocytes, 1% metamyelocytes, an absolute neutrophil count of 0.75 K/ul, a creatinine of 1.83, total bilirubin of 1.3, with direct bilirubin of 0.8, alkaline phosphatase of 294 and AST of 112 with ALT noted to be within normal limit. His COVID nasopharyngeal swab from the visit was reported as negative and a swab performed at his employment on 13-Jan-21 was also reported to be negative. Patient could not be reached by phone after discharge from Urgent Care about these labs. On the evening of 16-Jan-21, Police Department received a 911 call about an adult at the patient's address who was found unresponsive. Upon arrival on scene, the patient was found to be deceased and a decision was made not to attempt to resuscitate. The death was deemed to be non-suspicious and the patient's body was transported to a funeral home. On 19-Jan-21, I contacted the State Medical Examiner's Office. They have decided to perform an autopsy and have recovered the CBC and chemistry specimens obtained for further testing.

27-year-old female with past medical history of anxiety, allergic to shellfish, presented for COVID-19 vaccination, developed shortness of breath after COVID-19 Moderna injection, felt lightheadedness and noted with cyanosis as per nursing, received epinephrine injection and transferred to ED. In ED she received solumedrol, benadryl and pepcid. Vitals in the ER Revealed tachycardia HR 95-105 , Sat 96% on room air not in distress. Patient was admitted for further observation

1. Shaking 2. Whole body tingling 3. Left arm tense (injection was provided in right arm) 4. Felt clammy Walked over to hospital attached to the facility and was discharged the same day. All symptoms resolved.

"Patient called this nurse stating she had an allergic reaction to COVID vaccination given on Friday 1/15/21. States she felt fine for the 15 minutes post immunization, was on her way home and started feeling dizzy, short of breath, chest heavy, throat felt full ""like a ball in it"". She came back to clinic which was closed but sat in the parking lot for a while. While in parking lot trying to figure out what to do, her symptoms lessened. She got home safely but started to feel jittery/shaky and her BP was very high (couldnt remember exact number). She then went to urgent care where they told her she was having an allergic reaction and given a pill of something and steroid for 6 days. Went home from urgent care and BP still high but got better at bedtime. Saturday she had a ""really bad headache and just layed around all day. I was not able to function at all."" Sunday she still had a headache and added muscle aches. Monday she started feeling ""a lot better"" until 8 PM when she was walking around doing her nightly routine and started to feel a wave of dizziness, throat felt funny so she sat down and took her BP with result of 207/131. Says this reaction felt worse than Friday's reaction so she went to ER where she was again told she was having an allergic reaction and the steroid given to her at Urgent Care was not helping and to stop taking them. Given Benadryl in the waiting room, had labs and EKG which came back ""normal"", and given a different med Vistaril to take with any future symptoms. Was also told to NOT take the second dose of COVID vaccination. Says she has not had to take the Vistaril yet and has not had any sign of reaction today so far. Said she did report the initial headache on the V-safe app."

Anaphylactic

At approximately 4pm on Jan 11, 2021, I began to have hard chills and fever that reached 104.9. I was admitted to ICU at the Hospital. My blood pressure dropped to dangerous levels. I was diagnosed with sepsis and the doctors determined it was caused by the vaccine.

Pulmonary Edema, fever, nausea, vomiting

Moderna COVID- 19 Vaccine. Vaccine recipient reported on 1/19/2021 that they received the Moderna Vaccine on 1/8/2021. The following week on 1/15/2021, they reported while driving, their area around their right eye became numb and they began to have blurry vision. The numbness spread to around their face/mouth. They pulled over and their spouse drove him to the hospital. Roughly 20 minutes after the initial symptoms, they developed chest pain and patient reported that the ED noted an abnormality on their EKG. The patient had to be admitted overnight for observation. The patient reported that on 1/18/2021, they still had mild chest pain and facial numbness remains around the right eye, left mouth/cheek area, and tongue. They did develop fever and a headache. The patient reported that on

1/19/2021, they are waiting on results, additional testing, and further follow-up appointment with their provider.

Visited Provider appx 500 pm 1.14.2021 DVT - left calf - 2 clots via ultrasound on Eliquis now

Lacunar infarct (CVA) of right thalamus

Patient developed symptoms of Guillain-Barre syndrome on January 15, 2021 and was admitted the Hospital. She was diagnosed and eventually required ICU level care and has been treated with plasmapheresis. She is currently still in the ICU but is stable.

Family was told that Patient expired in his sleep during the early morning hours of 1/15. I spoke with him the evening before (on 1/14), which was a day after he had received the Covid vaccine. He was not having any symptoms of allergy or reaction then. He did say that he felt tired, but he often complained of feeling tired over time.

Hypoglycemia(40mg/dL) and required ICU admission.

Resident was noted unresponsive, no respiration, no blood pressure, no pulse, code blue called according to facility protocol, resident is full code, CPR started, 911 called, arrived and took over from staff. Resident was pronounced dead at 1:16pm 1/18/21

"""Patient states that he received the Covid vaccine today on left arm. Immediately after receiving it, felt his left arm went numb, then felt his lips on the left side going numb. Sensation progressed to his whole face, and down his neck, and back down to the whole left arm. He states that he even felt his truncal area, kidney, and part of his right foot going numb. States that he went to the ER for further evaluation, and while waiting there for about an hour, the sensation resolved. He denies any tingling or painful sensation. Does not think he was weak at the time."""

Resident was found deceased in his bed at 7:15 am.

Tachycardia, Shortness of breath, headache, dizzyness, weakness, chills, nausea, fever

Dizziness, Headache, Myalgia, Tachypnea, CoughWheeze, NauseaVomiting, Palpitations & Tachycardia & Narrative: Patient stated that after receiving injection on 01/06/2021, tasted metal in her mouth. No reaction noted in clinic after vaccine administered. Patient states that after returning home, she began to have chills, headache, and muscle aches. Could not sleep. On 01/07/2021. Patient continued to experience above symptoms. Approx. 13:50 on 01/07/2021. Patient presented with respiratory difficult, tachypnea stridor, and stated she felt as if her airway was closing. Patient was vomiting and was tachycardic. Epi-pen administered via left lateral thigh. Patient administered 50mg of PO Benadryl, and 2 puffs of albuterol inhaler. Continuous V/S initiated. Patient began to experience relief of symptoms. HR and blood pressure remained elevated, but this was expected side effect of epi. SpO2 stabilized around 99% on room air. Patient was monitored for 60 minutes. Transportation home was arranged and family was present to observe overnight.

mi Narrative: patient with asymptomatic covid 19, covid positive 12/10/2020.

dose given 1/13/21, patient hospitalized with high blood sugar, hyperkalemia, hypernatremia on 1/15/21 after being lethargic with shallow breathing. Patient still hospitalized as of 1/19/21 and diagnosed with Diabetes

Severe dissociative event (psychotic break) beginning <72hr after administration of vaccine, and continuing another 48 hours before resolution. Patient has no prior adverse psychiatric history. Transported to local ER on Monday 11th upon worsening of condition. Administered Haldol in the ER as a sedative after becoming combative during dissociative state. Patient woke up Tuesday the 12th with recurrent, but significantly diminished, dissociation, which had largely resolved by late Tuesday. Patient transported to Mental Health on a 5150. Released Friday the 15th around noon. No recurrent symptoms since.

Resident reported she didn't feel well. She started running a fever of 103. Resident complained her stomach and genitals were burning and pain in her legs. Resident has been vomiting today and diarrhea. EMS was called and resident transported to Hospital today 1/19/21

COVID 19 vaccine, unknown which company Chronically ill in a skilled nursing facility found diaphoretic, hypotensive, hypoxia to 85% arrived to Emergency dept in cardiac arrest Died within 65 minutes of nursing finding patient in distress Wife felt it may have been related to vaccine date of vaccination 1/6/20 hx covid 19 PNA in April 2020

hypoxia, secretions,cough, dyspnea Narrative: ALS patient on hospice with ongoing history of aspiration pna, receiving tube feeds. Developed incr in secretions, hypoxeia, temp and with recently noted clogged feeding tube.

pneumonia Narrative: On 11/9/20, Patient had a presumptive positive COVID (COBAS) screen as part of routine CLC screening and then on 11/13/20, he had a repeat COVID (CEPHID) that was negative. Then on 12/22/20, he received his first COVID vaccine. On 12/26/20, he began to have c/o hurting all over. Noted history of aspiration and COPD. On 12/29/20, he began to have coughing, increased shortness of breath and runny nose with course breath sounds in his bilateral lower lobes. A chest xray was done and he was initiated on oral azithromycin and cefepime for a bilateral pneumonia. On 1/3/21, he continued to decline with increasing shortness of breath and was subsequently transferred to acute care medicine. All COVID tests have been negative since the presumptive positive on 11/9/20. He did have a CTA that ruled out PE but did show bilateral pneumonia. His antibiotics have been changed to meropenem, vancomycin and IV azithromycin. He remains on acute care at time and has not required ICU care.

COVID positive Narrative: Patient is a resident and received his first COVID vaccine on 12/28/20. On 1/4/21, he had a COVID routine screen done that returned positive on 1/6/21. Per notes, he was asymptomatic at the time; however for isolation purposes, he was transferred to acute care medicine services. On 1/7/21, he was noted to have a slight increase in BUN/creatinine ratio thought to be due to volume depletion and has been ordered IV fluids. He still remains free of any respiratory symptoms at this time.

The patient had severe shortness of breath resulting in cardiac arrest on the 5th day after the vaccine. Shortness of breath started 12 hours after injection. On the 5th day, the patient was discovered to also have a rash throughout his body, but it is unknown when this rash started.

Diarrhea & NauseaVomiting Narrative:

Pt is 39 y/o female. Pt is casual RN for ED. Pt received COVID-19 vaccination here on the 23rd of December. Pt began feeling weak on the 17th of January. On the 18, Pt began experiencing numbness and tingling in hands and feet. Pt has been seen at facility and her PCP prior to coming to ED. Pt PCP called me and told me she is concerned that the Pt might have Guillain Barre syndrome and referred her here. Pt now c/o numbness and tingling from feet to mid abdomen and numbness/tingling up entire arm. IV was established and labs drawn, CT Head normal. Pt to IR for LP for definitive Dx of Guillain Berre. Pt admitted to room 202. Director of ED notified.

COVID-19 Vaccine

Sudden death without warning symptoms 4 days after vaccine. Many medical problems which most likely explain the outcome but spouse feels it is related and it is a new vaccine. Monitor for pattern?

Excruciating abdominal pain, left arm pain, chest pain. Gangrenous appendicitis requiring emergency surgery and followed by admission for complicated acute abdomen.

"Resident experienced chest pain the evening he received the vaccine and requested to go to the hospital as he stated his ""chest is pounding""."

Resident received 1st on 1/11/21 at 12:10am (1/12/21) resident was found unresponsive. Code Blue, 911 called at 12:11am. FD and EMS arrived, resident pronounced at 12:51am.

24 hours after the vaccine administration, patient began experiencing respiratory (asthma) symptoms. She was treated with nubulizer treatment and albuterol HFA inhaler.

Hypotension, Prolonged seizure with bowel incontinence, cough, weakness and delirium, resulting in 911 transport and admission to hospital for intubation and mechanical ventilation for acute respiratory hypoxia.

Appendicitis

received first dose of COVID vaccine on 18Dec2020 and tested positive on 30Dec2020; received first dose of COVID vaccine on 18Dec2020 and tested positive on 30Dec2020; she had a 5 day migraine after the first dose; This is a spontaneous report from a contactable other healthcare professional (patient). A female patient of an unspecified age started to receive BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) Solution for injection (lot number and expiry date were unknown), via an unspecified route of administration on 18Dec2020 at first single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient received first dose of COVID vaccine on 18Dec2020 and tested positive on 30Dec2020. The patient stated her isolation will be over

the day that she was to receive her second dose. The patient stated that she had a 5-day migraine after the first dose. Outcome of the events was unknown. Information on the lot/batch number has been requested. Follow-up (06Jan2021): New information received in response to query via mail includes confirmation of the primary reporter's last name. Information on the lot/batch number has been requested.; Sender's Comments: Based on the information currently available, a lack of efficacy with the suspected vaccine BNT162B2 in this patient cannot be completely excluded. Further information like confirmative virus genome /nucleic acid detection needed for meaningful medical assessment.

Pregnant at the time of vaccination; Pregnant at the time of vaccination; Miscarriage (symptoms started 08Jan2021, confirmed 10Jan2021); This is a spontaneous report from a contactable physician (patient herself). A 37-year-old female patient received her first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiry date were unknown), via an unspecified route of administration on the right arm on 06Jan2021 12:30 at a single dose for COVID-19 immunization at the hospital facility. The patient had no relevant medical history and no known allergies. Concomitant medication included azelastine;fluticasone nasal sprays, prenatal. The patient did not have any other vaccine in four weeks. She did not have COVID prior to vaccination. The patient was 6 weeks pregnant at the onset of the event. Last menstrual date was on 11Nov2020 and Gestational period was 7. The patient was due to deliver on 26Aug2021. The patient reported miscarriage (symptoms started 08Jan2021 06:00 PM, confirmed 10Jan2021). The event resulted in doctor or other healthcare professional office/clinic visit, Congenital anomaly or birth defect. Treatment and event outcome were unknown. The patient had not been COVID tested post vaccination. Information on the lot/batch number has been requested.; Sender's Comments: Based on a close compatible temporal association, contributory role of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) to patient's miscarriage cannot be completely excluded. The case will be reevaluated should additional information become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

tested positive after 1st dose; tested positive after 1st dose; This is a spontaneous report from a contactable nurse reporting for herself. This nurse reported similar events for 2 patients: this is the first of two reports. This 39-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 28Dec2020 for COVID-19 immunization. Medical history and concomitant medications were not reported. On an unknown date, the patient tested positive after first dose. Outcome was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Based on the information currently available, a lack of efficacy with the suspected vaccine BNT162B2 cannot be completely excluded. However, it is unlikely that the patient would have fully developed immunity due to the very short time lag between the first vaccine dose and the event onset.,Linked Report(s) : US-PFIZER INC-2021021888 same reporter/drug/AE, different patient.

"Between then and now I tested positive; Between then and now I tested positive; This is a spontaneous report from a contactable consumer (patient). A male patient of an unspecified age received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot/batch number unknown), via an

unspecified route of administration on 28Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient stated, ""I have taken the vaccine (1st dose) on 28Dec2020 at the hospital. Between then and now I tested positive on the 04Jan2021, the hospital sent me home for 2 weeks. The 2nd part of the vaccine is coming up, it isn't until the 18Jan2021."" The outcome of the events was unknown. Information about lot/batch number has been requested."

"Hypertensive Emergency (BP 219/114) with no previous blood pressure issues; Radiating chest pain, left arm pain; jaw pain; This is a spontaneous report from a contactable other Health Professional (patient). A 40-year-old non-pregnant female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EX5170), via an unspecified route of administration on 16Dec2020 15:00 at single dose in left arm for covid-19 immunization. Medical history included symptomatic PVC's (Premature ventricular contractions), tachycardia, bradycardia, CVA (cerebrovascular accident) from 2018 to an unknown date, asthma and rhythm. Concomitant medication included flecainide, spironolactone, metoprolol for rhythm. The patient had known allergies included hydrocodone bitartrate, paracetamol (VICODIN), eletriptan and adhesive. Prior vaccination, the patient had no covid. On 22Dec2020 18:00, the patient experienced hypertensive Emergency (BP 219/114) with no previous blood pressure issues. Radiating chest pain, left arm pain, and jaw pain. Admitted to the hospital where an echocardiogram and angiogram was performed showing clear coronary arteries and no hypertensive remodeling of the heart. Issue has been ongoing since, despite interventions. The events result in emergency room/department or urgent care and hospitalization from an unspecified date for 1 day. The patient received the treatment for the events included frequent nitroglycerin, hydralazine and metoprolol. The patient underwent curative-SARS-Cov-2 Assay RT-PCR on 01Jan2021 with negative result. The outcome of the events was not recovered.; Sender's Comments: Based on the information available, contributory role of BNT162B2 ((PFIZER-BIONTECH COVID-19 VACCINE,) to event ""hypertensive emergency (BP 219/114) with no previous blood pressure issues"" cannot be excluded. The events chest pain and pain in jaw are attributed to underlying medical conditions and assessed unrelated. BNT162B2 ((PFIZER-BIONTECH COVID-19 VACCINE,). The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate."

having symptoms, tested covid+(positive); having symptoms, tested covid+(positive); This is a spontaneous report from a contactable consumer (patient). This 57-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unknown route, on 17Dec2020 at single dose for COVID-19 immunization. No relevant medical history and concomitant medications were provided. The patient started having symptoms on 23Dec2020 and she was tested for COVID 19 on 27Dec2020 and resulted positive. The outcome of the event was unknown. Information on the batch/lot number has been requested.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021015240 Same patient/reporter, 2nd dose of drug, different AE

tested + 9 days after dose #1; tested + 9 days after dose #1; exposed to Covid-19 four days after vaccination; This is a spontaneous report from a contactable patient. A patient of unknown age and gender received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, on 26Dec2020 at single dose for COVID-19 immunisation. Medical history and concomitant medications were unknown. The patient was exposed to Covid-19 four days after vaccination and tested positive (+) nine days after dose 1 on 04Jan2021. The patient would like the advice for receiving the second dose. Outcome was unknown. Information about batch/lot number has been requested.

"I still have uncomfortable feeling in my arm/I was finally able to raise it above my head, my left arm, after two days but it was not comfortable to do it, it was painful; I have severe pain in my arm/it started hurting and then it continued to get worse and worse and it was severe; It was the worst pain I have ever had and I could not move my arm; It continued to get worse and that night I went to bed and I cannot sleep, it hurts so bad/I could not sleep on the right side or on a left side; This is a spontaneous report from a contactable consumer (patient). An 82-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date was not provided), via an unspecified route of administration (left arm) first dose on 30Dec2020 10:30 at single dose for covid-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient stated that I had the vaccine back a week and half ago on 30Dec2020 and was due to get the booster this month and wanted to report severe pain arm for two days. The patient stated that he had many vaccine (Unspecified Vaccine) over the years and have never had anything that hurts so bad after about six hours. The patient just wanted to know that was that normal. Consumer further stated, ""I took the vaccine about 10:30 in the morning and about four hours later, it started getting sore but that thing was normal you know some vaccines (Unspecified Vaccine) do that but along with that it started hurting about four hours after the vaccine and it continued to get worse and that night I went to bed and I cannot sleep, it hurts so bad. The patient even have thoughts about getting up and go in to the emergency room. It was the worst pain I have ever had and I could not move my arm. I could not sleep on the right side or on a left side and all I did was take Tylenol as prescribed and that helped a little bit but not much but I did not go to the emergency room, I am not going to do that but I felt like it because it hurts so bad but I made it through the night and next day it continued to hurt really bad. I just keep taking Tylenol every four hours and that continued for two days and then finally I was able to raise my arm up above my head without little pain, it was discomfort, but it was not hurting so bad."" The patient stated that the event started about two hours later it started, it started hurting and then it continued to get worse and worse and it was severe, that is the reason why I am calling that it was severe. I wanted a shot or morphine to relieve myself that how bad it was."" (no clarified further). The patient stated that the vaccine was given in my left arm only about one inch below the top of my shoulder which I think that might have been the problem, I don't know if you can answer that or not but I have never received the vaccine or shot anywhere near that area, it is always three or four inches down in my muscle, on my arm either on left or right, this was given in my left arm but this was given almost in my joint I am wondering if that would cause pain."" The patient stated it was given only one inch below the tip above shoulder may be that is causing so much pain."" The patient just wanted to report the severe pain, that was for two whole days and then it was subsided and it lasted for four days and I still have

uncomfortable feeling in my arm. I was finally able to raise it above my head, my left arm, after two days but it was not comfortable to do it, it was painful."" The outcome of the events was unknown. Information on the lot/batch number has been requested."

"Spot on arm where I got the vaccine probably 4 days ago is continuing to increase in size and is red, swollen and hard; it's huge and it's purple and red and it feels like bee sting, it feels like an allergic reaction; purple and red; continuing to increase in size and it is red and swollen and hard now; Made me really, really sick like bedridden for 2 days; Spot on arm where I got the vaccine probably 4 days ago is continuing to increase in size and is red, swollen and hard; This is a spontaneous report from a contactable Other HCP (patient). An unknown age and gender patient received BNT162B2 (lot# unknown) on Jan2021 at single dose for COVID-19 immunization. Medical history and concomitant drug were not reported. Patient stated, ""I just have a question, my Pfizer COVID Vaccine made me really, really sick like bedridden for 2 days which I am finding out is probably normal. But the spot on my arm where I got the vaccine, it was probably 4 days ago that I got it and it's continuing to increase in size and it is red and swollen and hard now. Like I am a Nurse Practitioner, this is not like a normal injection site reaction, it's huge and it's purple and red and it feels like bee sting, it feels like an allergic reaction, should I be concerned, do I need to go to the hospital?"" Outcome of the event was unknown. Information on the lot/ batch number has been requested.; Sender's Comments: A causal association between BNT162B2 and the reported events cannot be excluded based on a compatible temporal relation between vaccination and onset of events. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate."

"Tested positive for Covid/had the (Covid) infection; Tested positive for Covid/had the (Covid) infection; Swollen lymph nodes under my right arm; This is a spontaneous report from a contactable nurse. This 42-year-old female nurse (patient) reported for herself that she received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot#: nurse stated she thought she had a lot# it looked like EK5703), via unspecified route at right deltoid on 21Dec2020 at single dose for COVID-19 immunization. Medical history included blood pressure (patient had taken blood pressure medicine but hadn't taking currently because her blood pressure was being controlled). Concomitant medications included unspecified vitamins. Patient was tested positive for Covid on the 29Dec2020. She stated she didn't know about causality, she was saying no but she did have swollen lymph nodes under the right arm before getting sick (Dec2020), now she thought that might get from her vaccination but in her understanding she could get it from Covid so, she couldn't answer that, she tested positive, she didn't think it's from vaccination but her concern was because she had got the vaccination the first one then had the (Covid) infection and right now she should get the second one or not. Regarding treatment, patient stated she was taking methylprednisolone sodium succinate (SOLU-MEDROL) and salbutamol (ALBUTEROL) inhaler, taking over the counter Vitamin D3, Zinc and Vitamin C and acetylsalicylic acid (ASPIRIN). Patient reported she did go to the physician office/ emergency room. Outcome of events was unknown.; Sender's Comments: Based on the mechanism of action of BNT162B2 vaccine, it is unlikely

the patient would have fully developed immunity for the vaccine to be effective, due to the number of days passed since the vaccine was given (8 days in this case). However, a causal relationship between events ""Tested positive for Covid/had the (Covid) infection"" (coded to Drug ineffective / COVID-19) and swollen lymph nodes and BNT162B2 vaccine cannot be completely excluded.The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate."

I am a registered nurse at hospital. On 12/25, seven days after receiving the shot I started to get right lower leg pain and I kept complaining about it till New Years Day. I had no symptoms of a DVT. I triaged on 1/1/21 and the doctors ordered labs/imaging and the results were as followed: D-Dimer biomarker (+) , Ultrasound of the Rt lower leg (-) , CTA showed a PE (segmental right upper lobe pulmonary artery consistent with pulmonary embolus). I was discharged on Xarelto and advised to follow up with a hematologist. On 1/5/2021, I went to hematology and they did a whole bunch of labs. I was sent to get a ultrasound of the leg because the pain persist and they found a clot hidden by my soleus. The plan is to continue on the Xarelto for 6 months. Come back in 3 weeks to scan my leg again and get my lab results. On 1/12/2021, I received the 2nd shot of the Pfizer vaccination.

"Client was administer 2nd dose of Moderna COVID-19 vaccine at 1:32pm. Client reported has ""sore arm from first dose"", but denied any other issues from 1st dose. At 1:44pm, client reported was feeling flushed and slightly dizzy/light headed. Client appeared flushed, clammy and was slightly confused. Client was sitting in chair and was assisted to the floor and clinical assist code was called. VS were: BP: 149/84 and pulse ox was 97% on RA. Initially, HR was in the low 30's, but after lying down, came up to 86 and stayed in the 80-90's during assist. Client began to report chest tightness and feeling foggy and remained slightly confused and at times speech was garbled. Client denies sensation of throat closing and denied shortness of breath. Client was assisted to a cot and transported by ER staff and MD to the ER for evaluation."

Presented to Urgent Care for weakness and confusion, transferred to ED, patient had a cardiac arrest and was unable to be resuscitated

"""I received the Pfizer Covid vaccine Wed afternoon around 4pm. Thursday morning around 9:30 I started with severe pain in my left leg. The pain worsened through the day and my leg began swelling. No other symptoms at all. This morning my leg was twice the size of my right leg so I went to the ER. I live in so I'm at ED. I have a massive blood clot running the the length of my leg - from my thigh to my ankle. I'm very lucky I got here so fast! I?m a very healthy 49 year old with no history of DVT or blood clots so they dug further to find out why. A cat scan showed I have a congenital condition called May Thurner Syndrome. I?m so relieved to have an answer and it?s fixable! The vascular doctors are not 100% convinced that?s not all that was going on as I was born with the syndrome and I?ve gone this long without a clot. So they are doing lots of labs to see if anything else shows up. This is where we are at. I?m being admitted to take care of the clot."""

Pt woke up with tongue swelling morning following her vaccine. Was admitted for angioedema.

Rapid heart Rate that began about 12 hours after the injection. Heart rate of 123 all night and went to ER next morning after calling Nurse on Call system. I was admitted and the Dr ordered bag after bag of fluids to and kept me in the unit overnight for observation. Did may hear tests (EKG, ECHO STRESS,CTA chest) and results all came back good. I was released on 1/19/21 at 2pm and my hear rate is back to normal (82 bpm).

Extreme fatigue since getting shot - effecting ability to work

Started with cough, mild shortness of breath and feeling terrible in evening of 1/19.

Death 3 days after receiving 2nd dose of COVID vaccine, unknown if related to vaccine administration.

Approximately after 20 minutes after vaccine administration, my throat felt numb and i could not swallow my saliva, no acute breathing difficulty , I could not swallow water , I was very anxious and went back to facility I got vaccine , The attending doctor administered Benadryl I 50 mg IM , and then EPI 0.3 mg . EMT was called , and ED at Hospital i was attended , and Solumedrol 1.25 mg was administered IV and Pepsid for GERD , i also had, I was observed for a few HRs and skript for Prednisone and Benadryl was issued. I was then feeling better,

My arm was a little sore after the vaccination but no other symptoms. And on 12/30 I woke up with a sever fever, vomiting and diarreah. Went to the ER and was diagnosed with CHF because my feet were so swollen and was given lasix and released. I continued to feel bad so on that Sunday 1/3 I went back to the hospital and was admitted and tested positive for COVID-19. I spent from Sun-Wed in the hospital

Patient has end stage renal disease and rapidly worsening dementia, family could no longer care for him at home, and he was admitted for 14-day quarantine prior to admission to inpatient hospice. Received vaccine on 1/12 without apparent adverse reactions. Patient started refusing oral intake on 1/16, and CMP on 1/17 showed hypernatremia 165 (new issue). His BUN 138 CREAT 6.93 K 5.2 were his baseline. He was found to be deceased on 1/18 at 11:18 pm.

Pt found unresponsive at home, respiratory distress. Had reported nausea and vointing for two days prior to admit which started 1/15. Acute metabolic encephalopathy and acute renal failure Currently at time of this report still in critical care

Myalgia Narrative:

Shaking and then became unresponsive

Headache and stoke

Stroke-like symptoms approximately 2-3 hours after receiving shot (aphasia), BP bottomed out, was transported by EMS and is currently on a ventilator in hospital. CT scan clear; MRI pending.

The next morning I felt chills, really cold, my arm never hurt at all. I was freezing. I had no energy. Very lethargic, with a blanket around me. Never had a fever. All of a sudden, around 2:30PM all dissipated, it was all gone and I was fine. A week later I called my PCP because the symptoms came back - the lethargy. He suggested me to go to the ER. I went and could barely write my name on the sign in sheet at the hospital. They did 5 COVID tests and 4 of them were negative. I was at the ER for 3 days and finally was admitted and stayed for 11 days. I was sent home with oxygen and my levels are finally getting back to 92/93. I can't walk at this time. I lost 17 lbs and if I try to walk my lungs shut down. (I went to the ER n 01/07 and was discharged on the 17th - I was also at the ER the week before when they tested me and it kept coming back negative) My pulmonary MD

death by suicide Narrative: death by suicide; 12/26/20, self inflicted gun shot wound; found deceased by family member

Started with HA/fever/fatigue and body aches on date of vaccine on 1/5/21. Also had shakes,and had numbness loss of feeling to leg leg. Was admitted to Hospital for 5days. Had intermittnet seizure type episodes. Has had labs and imaging tests that have been neg Under the care of the A Neuro Group. MRI scheduled for 1/20/21. As of 1/20/21 feeling better but still weak.

Fainting, dizziness and weakness, trembling, BP 168/129. HR 145

Patient received Vaccine and during observation period began starring forward and not responding to staff. Patient was taken to the emergency room and evaluated and noted to have a flat affect and general weakness. Patient did not loos consciousness or have any signs of distress. Was admitted to the hospital and noted that she had been in out of country for a week (possibly had cosmetic surgery)

Around 10pm on Tuesday I started to have severe neck pain, headache, fatigue. I ended up going to the emergency room after my shift but due to the physicians recommendations I deferred the lumbar puncture while there. Later Thursday night, the neck pain continued, and I started having fevers with a max of 102.1 so I returned to the ER the following day for the lumbar puncture. I was admitted to the hospital for aseptic meningitis.

severe temporary paralysis from the neck down.

Resident was noted to have increase weakness on 1/15/2021. Resident was warm to touch with low grade fever of 99.3 F. Resident was up propelling self in w/c on 1/16/2021 he was pleasant, accepted medications and ate lunch. He was found slumped over in his w/c not responding and vital signs absent.

Pt was 18 weeks pregnant at the time of the vaccine. Second pregnancy. Pt is a physician. Pregnancy was entirely normal up to that time. On 1/18/2021, she began to have heavy vaginal bleeding probably due to a placental abruption and subsequently delivered at 18 weeks. Baby was stillborn. Ultrasound done 1/15/2021 normal. Lethal event for the fetus. The patient did well.

sinus arrhythmia; Night sweats; Heart rate low; Dyskinesia; This is a spontaneous report from a contactable nurse (patient). This 36-year-old female patient the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), intramuscular at single dose in the left arm on 07Jan2021 10:00 for

covid-19 immunisation. Medical history included hypotension, rheumatoid arthritis, asthma. Concomitant medication included clonazepam, methylprednisolone. On 07Jan2021 21:00, the patient experienced sinus arrhythmia, night sweats, heart rate low, dyskinesia, all with outcome of recovered with sequelae. Therapeutic measures were taken as a result of the events included Inderal 10mg. The events were assessed as congenital anomaly. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient was not diagnosed with COVID-19 prior to vaccination. The patient had not been tested for COVID-19 since the vaccination. The patient was not pregnant at the time of vaccination. Information on the lot/batch number has been requested.; Sender's Comments: A possible contributory effect of suspect BNT162B2 on reported events cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

postural dizziness; dyspnea; paresthesia; This is a spontaneous report from a contactable Physician. This Physician reported for a 28-year-old male patient received 2nd dose of BNT162B2 Intramuscular on 10Jan2021 07:30 on Left arm for covid-19 immunization. Medical history and concomitant drug were not reported. No other-vaccine-in-four weeks. No other-medications-in-two weeks. Historical Vaccine was first dose of BNT162B2 on an unspecific date. Patient experienced Moderate reaction: postural dizziness, dyspnea, and paresthesia on 10Jan2021 09:00 AM that resolved with H1 and H2 antagonists and IV hydration. AE-resulted-in Emergency room/department or urgent care. Outcome of the event was recovered. No covid-prior-vaccination. No covid-tested-post-vaccination. Information on the lot/batch number has been requested.; Sender's Comments: A causal association between BNT162B2 and the reported events cannot be excluded based on a compatible temporal relation between vaccination and onset of events. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

passed out; dizzy; hit the ground; nausea; pain at injection site; fever; chills; tired; severe headache; vomiting x 2; cold; experienced orthostatic hypotension; This is a spontaneous report from a contactable other HCP. A 65-years-old female patient started to receive bnt162b2 (BNT162B2; Lot # EK9231) vaccine , intramuscular in the left arm on 07Jan2021 11:00 at single dose for Covid-19 immunisation . Medical history included rubber sensitivity (Latex). The patient's concomitant medications were not reported. On 09Jan2021 12:00 the patient experienced orthostatic hypotension , passed out with outcome of recovered , dizzy with outcome of recovered , hit the ground with outcome of recovered. These events were considered serious because medically significant. On 09Jan2021 12:00 the patient also experienced the following non serious events: nausea with outcome of recovered , pain at injection site with outcome of recovered , fever with outcome of recovered , chills with outcome of recovered , tired with outcome of recovered , severe headache on with outcome of recovered , vomiting twice with outcome of recovered , cold with outcome of recovered. The reporter stated the patient attempted to get out of

bed and she passed and hit the floor. Caller states she think she may have experienced orthostatic hypotension. Caller stated if she had stayed in bed she probably would not have fallen. Her husband found her laying in vomit The patient underwent lab tests and procedures which included body temperature: 99.6 fahrenheit on unknown date.; Sender's Comments: Based on a chronological temporal association a causal relationship between events orthostatic hypotension , passed out dizzy and falling down and BNT162B2 vaccine cannot be completely excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Several back operations of stimulator in the back and in pain management; This is a spontaneous report from a contactable Consumer. This adult female Consumer(patient) reported that: An adult female patient received bnt162b2 (BNT162B2) at single dose on an unspecified date for Covid-19 immunisation. Medical history was none. No known allergies. The patient's concomitant medications were not reported. Patient was not pregnant a time of vaccination. The patient had not received any other vaccines within 4 weeks prior to the BNT162B2 vaccine. The patient had not experienced Covid-19 prior to vaccination. The patient experienced several back operations of stimulator in the back and in pain management on an unspecified date, resulted in disability or permanent damage. Post the vaccination, the patient has not been tested for COVID-19. The outcome of events was unknown. Information on the lot/batch number has been requested.

"I began to pass out and yelled for my husband, he said when he came in I was sitting on the toilet with my head back, eyes rolling back not responsive.; I had my 2nd vaccine at work early Sat the 9th and felt increasingly worse all day; I woke up at midnight and felt extreme malaise; I was covered in sweat; vomited; I checked my temp and it was 99.7¦F; sore; I think I had either a seizure or a vasovagal response.; This is a spontaneous report from a contactable nurse (patient). This 58-year-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (Lot EJ1685 or FJ1685), intramuscular at single dose in the left arm on 09Jan2021 06:00 for Covid-19 immunisation. Medical history included atrial fibrillation on unknown date (1 episode), allergic to Keflex. There were no concomitant medications. The patient previously received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (Lot EJ1685 or FJ1685), intramuscular in the left arm on 22Dec2020 for Covid-19 immunisation. On 10Jan2021 01:00 AM, the patient experienced: I began to pass out and yelled for my husband, he said when he came in i was sitting on the toilet with my head back, eyes rolling back not responsive (loss of consciousness) (medically significant), I had my 2nd vaccine at work early sat the 9th and felt increasingly worse all day (feeling abnormal), Iwoke up at midnight and felt extreme malaise (malaise), I was covered in sweat (hyperhidrosis), vomited (vomiting), I checked my temp and it was 99.7¦F (pyrexia), sore (pain), I think I had either a seizure or a vasovagal response (seizure). No treatment required. The outcome of the events was recovered. The events were described as follows: I am healthy RN with no active medical problems. I had my 2nd vaccine at work early Sat the 9th and felt increasingly worse all day, I expected this so was not alarmed and went to bed around 10pm. I woke up at midnight and felt extreme malaise and went to the bathroom in case I might vomit, etc. and I tried to

have a BM. I began to pass out and yelled for my husband, he said when he came in I was sitting on the toilet with my head back, eyes rolling back not responsive. He yelled at me for about 10 seconds and I came to, I was covered in sweat. I asked him to walk me back to the bedroom where I again passed out, fell to the floor and hit the bed, then was unresponsive again for about 10 seconds then came to again and vomited. After this I felt completely relieved of my malaise. I checked my temp and it was 99.7¦F. After this I was sore but otherwise completely okay, the next day I had a temp of 99.5¦F. Today I am back to normal. I think I had either a seizure or a vasovagal response. The vaccine was administered at Hospital Facility. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient was not diagnosed with COVID-19 prior to vaccination. The patient had not been tested for COVID-19 since the vaccination. The patient was not pregnant at the time of vaccination.; Sender's Comments: Based on the close temporal relationship, the association between the event ""began to pass out"" with BNT162b2 can not be fully excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate."

"suddenly lost mobility of left arm; Continue paresthesia and proprioreceptive deficits of left arm; Continue paresthesia and proprioreceptive deficits of left arm; This is a spontaneous report from a contactable nurse (patient). This 46-year-old female patient received the first single dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot EK5730) intramuscular, in right arm, on 16Dec2020 at 14:00, for COVID-19 immunization. No other vaccine was given in 4 weeks. Medical history included hypothyroidism, migraine headaches, IBS and COVID-19 (on an unspecified date prior to vaccination). Past drug history included allergy to morphine. Concomitant medication included levothyroxine sodium (SYNTHROID). On 23Dec2020 at 09:30 the patient experienced suddenly lost mobility of left arm, continue paresthesia and proprioreceptive deficits of left arm. She was transported to the ER and was admitted to hospital for 2 days. CT of brain X3, MRI of brain X2, MRI of C-spine and Brachioplexus were performed with unknown results. The patient was not tested for COVID19 after vaccination. The events resulted in: Doctor or other healthcare professional office/clinic visit, emergency room/department or urgent care, hospitalization, disability or permanent damage. No treatment was administered. The events had not yet resolved.; Sender's Comments: Based on the temporal relationship, the association between the events "" lost mobility of left arm, continue paresthesia and proprioceptive deficits of left arm"" with BNT162b2 can not be fully excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate."

thrombocytopenia; This is a spontaneous report from a contactable other health professional (patient). A 59-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration in arm left on 04Jan2021 13:30 at single dose for COVID-19 immunization. Medical history was none. The patient's concomitant medications were not reported. The

patient did not have COVID tested post vaccination and did not have COVID prior vaccination. The patient experienced thrombocytopenia on an unspecified date with outcome of unknown. It was reported he had thrombocytopenia but did not experience any side effects. Information about lot/batch number has been requested.; Sender's Comments: A possible contributory effect of suspect BNT162B2 on reported thrombocytopenia cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

on 1/12 started body aches and chills, took Tylenol and felt better, Wednesday felt short beat and irregular and heart beat not regular. checked pulse and it was irregular, that night 9-9:30 I went to ER close to house and pulse and heart rate abnormal after 2 hours went home and advised to contact cardiologist, he said to come in Thursday and the irregular beats were off and on atrial flutter, on Friday I came home and went back to hospital and got the shot cardio version or ablation to revert the rhythm and because the rhythm was back and forth I was observed until released on 1/19/21. Surgery was in 2017 and never had problems and they stated heart was compromised and maybe this is your reaction to the vaccine.

The patient was seen in my office on 1/19/21 with complaint of heavy vaginal bleeding. A CBC was obtained which revealed an H/H of 12.2/36.1 and a platelet count of 1 (not 1K, but 1 platelet!) and this was confirmed on smear review. She was immediately sent to the Hospital ED and repeat CBC confirmed the critically low platelet count. She is currently hospitalized and she has received platelet transfusions but her platelet count is still critically low. She is also receiving steroids and immunoglobulin and is under the care of MD (Heme/Onc)

Resident became lethargic, general weakness outside baseline, unable to walk, bumbled speech. Elevated HR and Temp of 105.2F

Death on 1/15/2020

Patient developed right facial numbness and facial droop on 1/7/21. She came to the TMH ED and was admitted. She was afebrile; neurologic exam was consistent with a peripheral facial palsy on the right.

Sudden Death within 24 hours of vaccine

Hemorrhagic Stroke, Right Basal Ganglion

12:00 noon my arm was super sore and swollen and I could barely raise it. By the evening on the 24th I was super tired. Christmas , the 25th,I was really fatigued. 26th, I was very fatigued and no energy - like I almost had the flu. 27th - the same - couldn't get out of bed. 28th - started getting a dry, hacky cough and then it went away. 29th - tried to go to work and I didn't feel good at all and I just wasn't feeling myself. Had brain fog. Went to work - things that I know that Know wasn't there because of brain fog. Felt really like flu symptoms that night. 30th - body aches; headache and eyes felt like pressure behind

them. Sent me to COVID and it was positive - was out 2 weeks from work. Went to back to work last week - but I still had shortness of breath, brain fog and fatigue and cough on Moday the11th; super tired still and I kept pushing myself to try to work and by Friday, 15th, I was just done. Exhausted. 16th - still having fatigue and 17th I thought I felt better when I woke up but still had my shortness of breath, cough and brain fog. At 2:00 pm I started feeling dizzy and faint like. I ate and within 20-30 min after food started throwing up, pounding headache. Every time I started trying to drink I would throw up. Monday, 18th, I went to work and I noticed whenever I moved around I was dizzy and short of breath and I couldn't eat or I would throw up. So slept the rest of the day. About 4:pm on Monday I thought I was going to pass out. 02 level at 86. Heartrate - Palpitations at 130. It was bouncing. Hving chest pressure, dizzy, pounding heart - 02 86 and Heartrate145. ER at 5:00 pm at Medical Ctr. Nausea medicine: Phenergan and Zofran. Did IV to hydrate me as I was dehydrated. Gave me Pepsid. I was a direct admit. They kept giving me hydration and nausea med and med for headaches and cardio workup - cardio came back normal. Severe lung inflammation. Was in the hospital until evening of 19th.

Patient woke apx 0200 complaining of nausea to group home staff. Vitals were checked at that time and WNL. Patient went back to bed. When staff went to wake patient apx 0530, he was unresponsive and had no pulse. Chest compressions were started and EMS called.

Patient got her 2nd dose of Pfizer covid vaccine on 1/8. On 1/11 she had intermittent chest pain that lasted a few days and started to notice small purpura rash on left breast. She didn't think much of it but noticed the same type of rash on her pant line and then right thigh. On 1/15 she called Occupational Health who advised her to go straight to the ED.

On 1/9/2021 observed with elevated respirations of 38-42 per minute, BP manually 72/50. pulse is jumping rapidly between 110-16 bpm. oxygen sat 76% RA, resident refusing oxygen at first attempt, allowed oxygen to be placed, is now 84% on 4L. resident shaking head yes that he is hurting, and yes that he would take medication for pain. Dr. notified, branch block. Received order for morphine 2mg per hr as needed for elevated respirations and pain. Dr. also gave orders to D/C Tamsulosin and finasteride. Resident continue with decreased O2 sats and elevated respirations. Absence of vital signs on 1/10/21 at 826PM.

Jan 4, 2021 received shot at work in morning around 11:00 am- felt fine at work all day. Around 7:00 that night began to have back pain, fever reached up to 102 around 2:00 am and took Tylenol. Felt very weak, headache, difficulty walking and decreased balance. On Jan 5, 2021 still had back ache and headache. On Jan 6, 2021 I felt better and began to have abdominal pain after eating dinner. I assumed it may be because of eating more then I had in past few days and did not attribute to much but the pain gradually increased to a strange burning/pressure across my upper abdomen that night. Very nauseous and ran low grade fever (99.45). Next morning I had less diffuse pain and could localize it to right lower quadrant.

Tinnitus started in right ear within hour after receiving first vaccination but resolved within a couple of day. Within 24 hours of receiving second vaccination had muffled hearing, Jan 3, 2021. Symptoms were ignored thinking they would resolve. When symptoms persisted and evaluated patient was noted to

have a severe right sided low frequency hearing loss with poor word recognition score. Patient was started on high dose steroids with partial recovery of symptoms.

Idiopathic intracranial HTN - IIH

Unknown as to any correlation with vaccine as this was a hospice patient that was already experiencing decline. Patient became Jaundice for approximately one week prior to expiring.

Unrelenting headache, chills, nausea, body aches, fever of 101.3F. Onset 14 hours after vaccine. Fever 20 hours after. Relieved with Tylenol and Motrin, ice packs.

Patient received COVID 19 vaccine 01/14/2021. Patient died in his sleep 01/16/2021.

Patient received COVID-19 vaccination on 1/14/2021. On 1/17/2021, patient was transferred to Hospital s/p multiple cardiac arrests. Patient was hyperkalemic and in acute renal failure at time of transfer. Hyperkalemia was treated, but the patient suffered PEA vs VFib. At the time of transfer, patient was on vasopressin, norepinephrine, and epinephrine. The patient had an EF of 40-45% and elevated troponins. Patient was made DNR and placed on comfort care. Patient passed away on 1/18/2021. Ultimately we suspect that the patients condition was a direct result of his underlying disease states, but wanted to make sure reporting was made available.

Thursday 1/6/21 body aches, fever, chills Fri, Sat, Sun- Vomiting and diarrhea. Low blood pressure (average 70/40 Went to ER Sunday for hydration and low BP Wednesday 1/20/21 diarrhea x 25 episodes while at work, Sent home at 3:30pm. Body aches, chills, sever abdominal pain.

Patient died 4 days after immunization. Probably unrelated to immunization, as patient has been in poor health and was receiving hospice services. I have no details related to his illness or symptoms. Daughter is the HIPAA/emergency contact and will have all the information needed.

Sudden Sensorineural Hearing Loss in left ear. Symptoms began Friday evening Jan. 8, 2021. Sounded like muffled sound in my ear, water running, ringing. Then on Saturday Jan.9, 2021 my left ear felt like it had to pop and I felt my hearing was impaired. By Sunday evening Jan. 10, 2021, I could barely hear out of my left ear. I called MD immediately Monday morning, Jan. 11, 2021 and was seen that afternoon. I was examined and had a hearing test. I was diagnosed with SSHL and started treatment of a series of steroid injections directly into my eardrum to save my hearing immediately. I have had 2 injections and hearing test since then. The doctors feel this was a side effect of the COVID vaccine due to my compromised immune system, but not an allergic reaction, but a side effect. I had the same condition about 15 years ago from a virus.

Pt passed away the day after the vaccine was given.

12 hours after vaccination began experiencing fever, chills, body aches, slight head ache - lasted around 12 hours Had slight pain above eye prior to getting vaccination Saw PCP on 01/08/2021 due to eye pain - had CT scan for possible aneurysm, found 2 spots on brain, thought patient had shingles On 01/10/2021 shingles rash appeared

I was having episodes of dyspnea and non productive cough starting from 1/1/2021. On 1/13/2021 I experienced severe dyspnea and had loss of consciousness for 5 seconds and was found down. I was rushed to the hospital and diagnosed with multiple pulmonary embolus (about 9) which was treated with direct TPA via catheterization. I then recovered in the ICU and transitioned to oral anticoagulation and discharged home on 1/15/2021.

Anaphylaxis Allergic reaction COVID-19 vaccine: dizziness, vomiting and shortness of breath. Received vaccine and about 5/10 minutes later developed symptoms of chest tightness shortness of breath wheezing. Arrived to ED at 1156 and discharged at 1507. Given epi IM Solu-Medrol, Pepcid, Benadryl, albuterol.

1/4/21- Patient stated she had tenderness on the back of her left lower leg with redness then 1/8/21 started to have shortness of breath and made a doctor's appointment for 1/13/21. Seen by provider on 1/13/21 and was sent to ED and admitted to the hospital [ICU] with NSTEMI, acute deep, occlusive venous thrombosis left femoral vein and saddle embolus of pulmonary artery. Transferred to another acute care hospital for removal of thrombosis. Patient started on Eliqus and no intervention for removal of the thrombosis.

Patient received her first dose of the Moderna COVID-19 Vaccination on Saturday January 16th 2021 at approximately 12pm. She completed all necessary screening forms and was deemed to be at low risk for serious allergic reactions. She tolerated the vaccination well, and no complications or immediate adverse events occurred. She was observed for a full 15 mins per CDPHE/CDC guidelines and left the Clinic in stable condition after her observation period was complete. On the morning of Tuesday, January 19th, 2021, the patient was found unconscious and unresponsive by her husband. She was transferred by Ambulance to Hospital shortly thereafter. She was diagnosed with a brain bleed that was determined to be inoperable. She was transferred to other Hospital for higher level care. She was seen by neurosurgery and diagnosed with a ruptured aneurysm. She was treated in the ICU for 24 hours, at which point her team determined that the severity of her brain bleed would not respond to treatment. Supportive cares were withdrawn on Wednesday Jan 20th, and she passed away shortly thereafter.

Resident has increase weakness and lethargy with abnormal labs. He was transferred to the ER. He was admitted to the hospital and treated for worsening AKI and hypotension.

Appendicitis, presenting as periumbilical tenderness at onset (26 hrs after vaccine admin) migrating to RLQ approx 20hrs later (46hrs after vaccine admin) accompanied by fever, chills, sweats, and nausea. Presented to ER that evening and CT confirmed appendicitis (52hrs after vaccine admin). Surgery following day laparoscopic appendectomy (69hrs after vaccine admin). Recovery and clinical improvement over next 8hrs (77hrs after vaccine admin). Discharged following day (96hrs after vaccine admin)

3 days post = tremors; 4 days post= pneumonia; 6 days post= hospitalized

Patient unresponsive post vaccine. Taken to hospital. Please contact facility for full Report.

Per Nursing Staff- patient died within 24 hours of receiving the vaccine. patient has hospice. Please contact director of nursing for more details.

Started itching within (left arm) 15 minutes. THey said I was fine and to go back to work. About an hour later, I started breaking out in hives and whole body itching. I went back in and they gave me to full strength Benadryl and it was not helping and my BP was 190/140 (stroke level) and they tried to bring that down. About 10:15 my face was starting to swell and I was short of breath and 10:30 they took me to ER - and gave me Cortisol shot. And IV fluids. And I was in ER for two hours. They wrote me a prescription for six days for 2 prednisone for every day for one week. The PA saw me at the ER and he prescribed. I went home but couldn't drive home because I couldn't see straight so got a ride home. They tested my O2 levels before they left me. Oxygen was 96. My blood pressure was down to 140/95 - so it was down but still elevated. I still had facial swelling for 3 days. But after three or four days it resolved the face swelling. Had a weakness from the shot and still itching but nothing like it was that day still after the four days. Dr. told me I couldn't get second dose. It was an anaphalactic reaction. Dr - prescribed me an EpiPen in case I have another bad reaction to anything.

per staff at facility patient died 24 hours post vaccination. Please contact Director of Nursing for further details.

Swelling all over her body, ear popping all the time, hands and feet are numb, torso swollen and numb, face swollen and red. Taking steroids for four days. Went to hospital. Then went to other facility.

short of breath Narrative: patient complained of shortness of breath prior to getting covid vaccine, patient and wife stating it was his norm. After vaccine he complained of increasing shortness of breath, and hypoxic with bluish nail beds, lips, and greyish in color. Applied O2 via mask, and nail beds, lips, and facial color returned, sent patient to local ER for treatment and evaluation.

"Narrative: Patient seen in ED 1-17-21 with c/c of ""bloated with epigastric pain"". Patient with complicated medical history including stage 1B pancreatic cancer (was currently on chemotherapy mFOLFIRINOX), and a leadless permanent pacemaker implantation on 1-11-21 for long episodes of SR with complete heart block following symptoms of syncope (other cardiac history: CAD s/p CABG 2009, PAF, and HTN). Regarding ER visit for epigastric pain, nothing notable was found on workup and patient was to discharge home to rest. There were available doses of COVID-19 Vaccine following a vaccine clinic that same day, and patient was offered and agreed to a dose of vaccine. Patient was monitored for 15 minutes post vaccine with no notable issues. The following day, Monday 1-18-21, patient's caregiver called facility at 22:30 to report he had a fever of 102.8 degrees and that he had been ""feeling kind of bad all day"". Patient was advise to seek urgent medical care and reported back to ED on 1-19-21 at 00:55. Patient wasd admitted for SIRS (tachycardia and febrile) -- patient also reported diffuse myalgia. WBC WNL, CXR unremarkable for infection, UA neg for bacteria, LFTs WNL, blood cultures negative. Procalcitonin elevated at 17.8 -- suggesting inflammatory response. Patient initially reported feeling better on the morning of 1-19-21, but around 13:00 began rapidly declining (confusion, unable to walk) and started experiencing EKG changes (9 beats of SVT). Patient then coded and resuscitation was

attempted for approximately 30 minutes. Patient did not survive the code. Coroner has been notified and family is considering autopsy at time of this report."

Vaccine was administered very high, presumably in the joint space, rather than the deltoid. Patient experienced intense pain in the entire shoulder area for 24 hours following administration. After initial 24 hours, pain remained more localized in the joint itself. Pain is intensified when moving out of the neutral position.

significant facial/lip angioedema first noted ~20 hours post vaccination, leading to intubation in ED due to concern for airway protection. extubated and discharged in 2 days

Admitted in Hospital for Anaphylaxis.

Noticed small area of burning sensation at right side of wrist and the vein there was very enlarged and sticking out.

Began itching and wheezing approximately 5 minutes after the injection. Gave first epi dose. Throat started tightening, and nausea presented. Gave second epi 5 min after the first. Gave third epi 5 min after the second. EMS arrived, gave 4th epi in ambulance. ER treated with breathing treatment, IV steroids, IV Benadryl, IV Pepcid and IV zofran. Was observed for 6.5 hours.

Patient came to ED at 1600 with right upper lip swelling and finger swelling after getting covid vaccine earlier. Angioedema of lips, initial encounter; History of allergic reaction; Lip swelling; Vaccination side effects, initial encounter. Pt has history of rheumatoid arthritis. Was treated & discharged home on 1/12/21

Slurred speech started morning of 1/8 and patient went to ED after dialysis appointment. Admitted for TIA (transient ischemic attack). Discharged home on 1/10 with follow up appts with Neurology.

Presented to ED 1/12 with primary complaint of Fatigue starting that AM. Being treated for Stage IV Sacral Decubitus Ulcer w/ possible osteomyelitis, Still admitted

Pt reported difficulty in swallowing and wife noticed left-sided facial droop morning of 1/10. Patient admitted for concerns of TIA. Symptoms resolved prior to hospitalization. Patient had MRI brain without contrast of the find evidence of acute infarct. Neurology recommended treatment patient has TIA and having dual anti-platelet therapy for 21 days followed by monotherapy of Plavix for stroke prevention. Patient was stable discharge to home 1/12/21

Patient was receiving dialysis and had low grade fevers on the morning on 1/15/2021. Patient was sent to the hospital's emergency room and was found to have a temperature of 103. The patient also had mental status changes. It is unsure what caused the mental status changes and fevers.

Pt presented to ED with Left facial numbness and concern for stroke. Observed over night. MRI brain negative for acute process. Stable at baseline neuro status 1/10/21, discharged home.

Pt Rec'd Covid vaccine and injection in Lt eye for macular degeneration. Monday 1/11 slurring speech/jumbled words since dinner, went to bed, wife states improved from last night but still difficult clearly communicating. Also reports difficulty writing. Came to ED and admitted for stroke evaluation. Stable for discharge home 1/13 with neurology follow up visits.

Pt presented to ED 1/12 complaining of shortness of breath and nonproductive cough which onset approximately 8 days ago. Tested positive for COVID. Remains admitted for management of COVID.

Stated since Xmas he has not feeling well after a family gathering. His wife in hospital for Covid-19 pneumonia. He reports for about 1 week, his SOB worsen, not eating well at all for the past 3 days. Which prompt him to visit the ED. Admitted to Hopital for Dehydration; Dyspnea; Pneumonia due to COVID-19 virus; COVID+ 1/10/21; still admitted

expired before receiving the second dose; This is a spontaneous report from a contactable nurse. This nurse reported similar death events for 8 patients. This report is for 1st of 8 patient. A patient of unspecified age and gender received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 22Dec2020 at single dose for covid-19 immunisation. The patient medical history was and concomitant medications were not reported. The patient expired before receiving the second dose on an unspecified date. It was not reported if an autopsy was performed. Information about Lot/Batch number is requested.; Sender's Comments: Current information is very limited for full assessment. The patient died following the vaccine use; further information such as patient demographics, complete medical history, concomitant medications, concurrent illness and event term details especially death cause and autopsy results are needed for meaningful evaluation. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.,Linked Report(s) : US-PFIZER INC-2021034597 same drug, reporter and event but different patient;US-PFIZER INC-2021034598 same drug, reporter and event but different patient;US-PFIZER INC-2021034599 same drug, reporter and event but different patient;US-PFIZER INC-2021034600 same drug, reporter and event but different patient;US-PFIZER INC-2021034601 same drug, reporter and event but different patient;US-PFIZER INC-2021034603 same drug, reporter and event but different patient;US-PFIZER INC-2021034596 same drug, reporter and event but different patient.; Reported Cause(s) of Death: expired before receiving the second dose

expired before receiving the second dose; This is a spontaneous report from a contactable nurse. This nurse reported similar events for 8 patients. This report is for 2nd of 8 patients. A patient of unspecified age and gender received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 22Dec2020 at single dose for covid-19 immunisation. The patient medical history and concomitant medications were not reported. The patient expired before receiving the second dose on an unspecified date. It was not reported if an autopsy was performed. Information about Lot/Batch number is requested.; Sender's Comments: Current information is very limited for full assessment. The patient died following the vaccine use; further information such as patient

demographics, complete medical history, concomitant medications, concurrent illness and event term details especially death cause and autopsy results are needed for meaningful evaluation. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.; Reported Cause(s) of Death: expired before receiving the second dose

expired before receiving the second dose; This is a spontaneous report from a contactable nurse. This nurse reported similar events for 8 patients. This report is for 3rd of 8 patients. A patient of unspecified age and gender received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 22Dec2020 at single dose for covid-19 immunisation. The patient medical history and concomitant medications were not reported. The patient expired before receiving the second dose on an unspecified date. It was not reported if an autopsy was performed. Information about Lot/Batch number is requested.; Sender's Comments: Based on the reasonable temporal association, the Company cannot completely exclude the possible causality between the reported death and the administration of COVID 19 vaccine, bnt162b2. However, more information on the patient's underlying medical condition, concomitant medications, patient's age group, clinical course and relevant lab tests would be helpful for the Company to make a more meaningful causality assessment. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RA, IEC, as appropriate.; Reported Cause(s) of Death: expired before receiving the second dose

expired before receiving the second dose; This is a spontaneous report from a contactable nurse. This nurse reported similar events for 8 patients. This report is for 4th of 8 patient. A patient of unspecified age and gender received the first dose bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 22Dec2020 at single dose for covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient expired before receiving the second dose on an unspecified date. The patient died on an unspecified date. It was not reported if an autopsy was performed. Information about Lot/Batch number has been requested.; Sender's Comments: Current information is very limited for full assessment. The patient died following the vaccine use; further information such as patient demographics, complete medical history, concomitant medications, concurrent illness and event term details especially death cause and autopsy results are needed for meaningful evaluation. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.,Linked Report(s) : US-PFIZER INC-2021034595 same drug, reporter and event but different patient; Reported Cause(s) of Death: expired before receiving the second dose

7 residents expired before receiving the second dose; This is a spontaneous report from a contactable nurse. This nurse reported similar events for 8 patients. This report is for 6th of 8 patients. A patient of unspecified age and gender received first dose bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at SINGLE DOSE for covid-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient expired before receiving the second dose on an unspecified date. It was not reported if an autopsy was performed. Information on the lot/batch number has been requested.; Sender's Comments: The event death is assessed as related to BNT162b2 vaccine and documented as such in the global safety database until sufficient information is available to allow an unrelated causality assessment. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.,Linked Report(s) : US-PFIZER INC-2021034595 same drug, reporter and event but different patient; Reported Cause(s) of Death: 7 residents expired before receiving the second dose

expired before receiving the second dose; This is a spontaneous report from a contactable nurse. This nurse reported similar death events for 8 patients. This report is for 7th of 8 patient. A patient of unspecified age and gender received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 22Dec2020 at single dose for covid-19 immunisation. The patient medical history was and concomitant medications were not reported. The patient expired before receiving the second dose on an unspecified date. It was not reported if an autopsy was performed. Information about Lot/Batch number is requested.; Sender's Comments: Current information is very limited for full assessment. The patient died following the vaccine use; further information such as patient demographics, complete medical history, concomitant medications, concurrent illness and event term details especially death cause and autopsy results are needed for meaningful evaluation. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.,Linked Report(s) : US-PFIZER INC-2021034595 same drug, reporter and event but different patient; Reported Cause(s) of Death: expired before receiving the second dose

platelets dropped so low/thrombocytopenia; Hemorrhagic stroke/brain hemorrhage; This is a spontaneous report from a contactable nurse. A 56-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 18Dec2020 at single dose for covid-19 immunisation. Medical history and concomitant medications were unknown. The reporter read about the doctor that died that developed thrombocytopenia after taking the vaccine, stated it was in the news yesterday. The patient received the Pfizer Covid vaccine on 18Dec2020, and he died 16 days later from a brain hemorrhage. Autopsy stated that said he had a hemorrhagic stroke on 03Jan2021. His platelets dropped so low that he had specialists that tried to get his platelet count back up again and they could not get his platelets back up again and he ended up having the hemorrhagic stroke. The

reporter already had thrombocytopenia and she was debating what she should do about getting vaccine. Outcome of the events was fatal. Information on the lot/batch number has been requested.; Sender's Comments: Very limited information is currently available. Lacking patient's underlying medical conditions, clinical course, relevant lab data, the Company cannot make a meaningful causality assessment. The reported hemorrhagic stroke following low platelet count are managed as related to the suspect, BNT162B2, for reporting purpose only. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RA, IEC, as appropriate.; Reported Cause(s) of Death: Hemorrhagic stroke/brain hemorrhage; platelets dropped so low/thrombocytopenia

"died; tested positive for COVID; tested positive for COVID; This is a spontaneous report from a contactable consumer from a Pfizer-sponsored program, Pfizer First Connect. A 97-year-old male patient received the first dose of the bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration on 30Dec2020 at 97-years-old at a single dose for COVID-19 immunization; administered by the nursing home. Medical history included glaucoma from an unknown date and unknown if ongoing. Concomitant medications included: ""used a sav for skin tears"", and ""eye drops for glaucoma"" from an unknown date to an unknown date. On 07Jan2021, the patient experienced: tested positive for COVID (medically significant). The patient died (death, medically significant) on 17Jan2021. The clinical course was reported as follows: The reporter stated that in regard to the patient's height and weight: ""was probably getting down to about five foot eight. Shrinking."" The reporter stated that If she remembered correctly, they were trying to maintain the patient's weight 135 to 136 pounds. The reporter stated that her father was in a nursing home. The patient received his first dose of the COVID vaccine on 30Dec2020. The patient died on 17Jan2021. The reporter stated that she ""wanted Pfizer to know that the little old people in the nursing might not be strong enough for the vaccine."" The reporter stated that she was ""not calling to complaining."" The reporter stated that there was nothing wrong with her dad. He was elderly with no health issues. ""He was literally on no medications. The only reason he was in the nursing home was because he was afraid to walk."" The reporter stated that she received a call about giving the patient the vaccine and she said yes because she wanted him to have the vaccine. One week after the vaccine, the patient tested positive for COVID ""like all the other people"" (no further details provided). The reporter stated that her dad had no symptoms of COVID. The director of nursing said the patient was doing so well. The patient ate his lunch, he laid down for nap, and at 14:30 he was gone. The patient ""went peacefully in his sleep."" The reporter then again stated that the patient literally had nothing wrong with him. ""They were shocked. They fed him and he took a nap. He was sleeping, but it was eternally."" The reporter stated that, ""it might not have been the Pfizer vaccine, maybe his heart wore out."" In regard to an autopsy: the reporter stated that they would get it done if needed. The patient underwent lab tests and procedures which included COVID-19 virus test: positive on 07Jan2021. History of all previous immunization with the Pfizer vaccine considered as suspect: none. It was unknown if there were additional vaccines administered on the same date of the Pfizer suspect, but the reporter doubted it. There were no prior vaccinations within 4 weeks. There were no adverse events following the prior vaccinations. The clinical

outcome of the event, died, was fatal. The clinical outcome of the event, tested positive for COVID, was unknown. The patient died on 17Jan2021 due to an unknown cause of death. An autopsy was not performed. The batch/lot numbers for the vaccine, PFIZER-BIONTECH COVID-19 MRNA VACCINE, were not provided and will be requested during follow up.; Reported Cause(s) of Death: died"

At approximately 930am I arrived at Memory Care. I met with the director of the facility and she directed me to where my team would be setting up. My team consisted of (technician), (nurse) and I. As we were setting up, the director asked how she can help. I explained to her that we would need a designated area for patients to be monitored after vaccination for 15 minutes and maybe even longer . I also explained that we would need one of her staff monitoring while we vaccinate. She agreed, and proceeded to designate her staff and the cafeteria area, facing the vaccination station,the monitoring station. Throughout the day, nurse and I were both vaccinating,while the staff of the facility would monitor the vaccinated patients. I would also stop occasionally to mix the vaccine and check the temperature of the aero safe. At approximately 12:50pm, the director rushed in and stated that a patient is not responding, and that she had been vaccinated. At that point, I grabbed epipens and a thermometer and I also instructed nurse to grab an Epipen and come with me. We followed the director to pt's room. Once we got to the room, the patient was in bed and there were 4 staff members standing bedside and one of them turned and stated the patient has passed. At that point I asked the staff how long ago did the patient get the vaccine, they stated about 30 minutes ago. They also stated that the patient was a hospice patient and that the patient had declined, and was rapidly detiorating and had not eaten or drank anything all day . They also stated that the patient had been monitored for 15 minutes post vaccination. I then left the room and grabbed the patients COVID Vaccine intake consent form. I looked at the answered questionaire and all the responses were circled NO. Patient had a temp of 96.5 at the time of vaccination.The vaccine administration information for Immunizer Section was filled out by Nurse. I then proceeded to ask the director once again if there were staff that was monitoring her for 15 minutes, the director stated they had staff monitoring her. She also stated the Hospice nurse has to announce her death, so they waited for the Hospice Nurse to come. I then called Corporate and explained the situation. After speaking to corporate, I also asked nurse, if she remembered the patient. She stated that she did and at the time of the vaccination the patient was not alert, there were two staff members with the patient. She was non oriented and she kept closing her eyes. At that point, Nurse stated that she asked the two staff members with her if this is how she usually is and if its ok to vaccinate her. Both Staff members stated that it its ok,this is how she is. The Nurse then proceeded to vaccinate. At approximately 3:10pm, as I was leaving I spoke to the director, and one of her Staff members. Staff that the patient has actually not eaten/ or drank anything for the past several days, including today(01/18/21). Staff also stated that on Friday, Jan 15th,2021, they had informed the family that the patient was rapidly detiorating. Staff also stated that the family knowingly gave the consent to vaccinate her. She also stated that the hospice Nurse believes that the death was primarily caused by her detiorating state. She also stated that the hospice Nurse informed that the death was not due to the Vaccine. Per Lead Pharmacist at the clinic.

Extreme Fatigue

Patient developed 104.4 temp approximately 48 hours after being given the vaccine. I treated him with antibiotics, IV fluids, cooling methods. CXR does show a new right perihilar infiltrate. However, his fever came down within the next 24-48 hours. Unfortunately, he suffered a cardiac arrest on 1/21/21 in the early morning and expired.

Resident returned to the memory support unit at 1500. Resident was than toileted and transferred in to bed per his request. At 1515 resident was observed face down beside bed, resident sustained a 1inX1in eccyhmotic/hematoma to the forehead. Neuro Checks with in normal limes Vital signs: 100/52, 100, 97.2, 28. Resident sent to ED for further medical evaluation via EMS.

possibly got it at clinic, possibly who administered shot. Pts. daughter said the pts boyfriend denied any symptoms the whole day but that in the middle of the night the pt passed away.

This is a 94-year-old male who is brought in by ambulance after being found on the floor with unknown downtime. He was in asystole upon EMS arrival. He remains in asystole. No advanced airway is in place. The patient is getting compressions from Lucas device upon arrival. It was reported that he was last talked to by family at 2 PM. The patient got his SARS-CoV-2 vaccination this morning. The patient is evaluated emergently. CPR was ongoing with 3 rounds of epinephrine given. The patient remains in asystole. He has rigor mortis. The patient's pupils are fixed and dilated. The patient has compressions paused and ultrasound is used to evaluate for cardiac activity. None is detected. The patient has no electrical activity on monitor. The patient's time of death is 2113.

approximately 3 hours prior to expiring the patient was experiencing forceful emesis. later was found to have expired, patient was comfort care only.

Theápatientáreceivedáhisávaccineáináthe.ámorningáofá1/20/2021,áwhileágettingáintoácarátoágoáseeáhisápulmonologist,áaboutá2áhoursáafter,ácollapsed,áunresponsiveáwitháasystolicácardiacáarrest.ááNoásymptomsáprioráotheráthanáchronicádyspnea.ááNoáallergicátypeásymptomsáreportedábyáfamily.ááAsystoleáwitháEMS,ánoáresponseátoáACLS,ápresentedátoáED,áDOA.

1/13/2021 12:00 PM: Patient received COVID-19 Vaccine. 1/14/2021 21:00: Nurse performed routine rounds and the patient appeared okay. 1/14/2021 22:00: CNA discovered patient unresponsive in bed, began CPR, and called 911. 1/14/2021 23:08: Pronounced deceased.

Narrative:

"Narrative: Was pt previously covid positive?- Yes. Initial- 10/27/2020, 11/29/2020, 12/22/2020 Are there any predisposing factors for patient experiencing adverse drug event?- Yes, patient had multiple co-morbidities including GI bleed, hepatitis congestion due to cardiac issues, treatment for PE, NSTEMI, or antibiotics for PNA, also on concurrent medications APAP, Atorvastatin, Mirtazapine and Duloxetine. Pt with 2 doses of covid-19 vaccine, second one on 01/08/2021, 2 days pre-death Any occurrence of an ADR at time of administration? Did not specify injection site issues, per RN admin note- Vaccine ""administered without complications."" Did patient recover from event? Not s/p dose on 01/08/2021. First dose given on 12/21/2021, LFTS increased ~01/01/2021, peaked on 01/03/2021 and were

decreasing on 01/07/2021 Was there an ADR between observation period and date of death? No Did patient recover from event? No (01/08/2021 event, died 01/10/2021) Was patient hospitalized prior to vaccination? Yes, in between inpatient and nursing home Was patient hospitalized prior to death--was hospitalization attributable to ADE? Yes re-admitted to inpatient on 12/31/2020. GI bleed Is there an alternative cause of death? Yes, as noted above. Quite a complicated case with many comorbidities/concurrent medications as noted above. Primary Diagnosis: Upper GI Bleed in the death note from 01/10/2021"

tired; legs felt heavy; stopped breathing; This is a spontaneous report from a Pfizer-sponsored program a non-contactable consumer. A 93-year-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 04Jan2021 11:00 at single dose for covid-19 immunisation. The patient medical history and concomitant medications were not reported. Patient received vaccine around 11:00 a.m. About two hours later, he said he was tired and couldn't continue with the physical therapy he was doing. He was taken back to his room, where he said his legs felt heavy. Soon after, he stopped breathing. A nurse declared a do-not-resuscitate order. The patient died on 04Jan2021. It was not reported if an autopsy was performed. Outcome of stopped breathing was fatal. Outcome of tired and legs felt heavy was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Reported Cause(s) of Death: stopped breathing

died; This is a spontaneous report from a Pfizer-sponsored program. A contactable consumer reported that an 83-year-old female patient (reporter mother) received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection), via an unspecified route of administration on an unspecified date at single dose for covid-19 immunization. Medical history included hospice care and dementia. The patient's concomitant medications were not reported. The patient died one day after getting vaccine. She was reportedly in good health the day before receiving vaccine. She was on hospice, frail, but in good condition and checked by a hospice nurse the day before which she reported her in good health considering. She was with dementia but stable in her health. The reporter read investigating 23 deaths of people receiving vaccine in similar conditions. The patient died on an unspecified date. It was not reported if an autopsy was performed.; Reported Cause(s) of Death: died

"Called to schedule second vaccine and daughter reports that he died on01/19/2021 with ""COVID"""

"Patient's wife called this morning stating that her husband has passed away last night. After receiving first dose of Pfizer COVID-19 vaccine at around 0830, patient remained in the Immunizations Department for the 15-minute monitoring period. Per wife, patient's only complaint was pain at the injection site. At 1300, wife states that patient complaint of dizziness which ""dissipated after a few minutes"" followed by a headache which ""dissipated after a few minutes"" as well. Then patient complained of nausea, no vomiting and ""couldn't relax."" Per wife, from around 1400/1500, patient stayed on his recliner while still having a conversation with her--""he didn't get up to eat."" Last conversation they had was around 2000/2100. Per wife, at around 2100/2200, patient was quiet and when she checked on him, ""he wasn't responding anymore."" Wife then called 911, ""but they couldn't revive him."""

Admitted to hospital after vaccination with Acute hypoxemic respiratory failure, Septic shock; Aneurysm of arteriovenous dialysis fistula; expired 1/16/2021

We do not believe that the patient's death was an adverse event from the vaccine. Patient received COVID vaccine from Pfizer Dose #1 12/19/2020 (lot # EK5730) and Dose #2 1/7/2021 (lot # EL1284). No side effects or adverse events noted; lived in 24/7 care facility and monitored twice daily for reaction. Patient died 1/10/2021 from chronic respiratory failure and congestive heart failure after recent aspiration pneumonia requiring hospitalization. Death was anticipated and not sudden. We were told to report his death to VAERS even though his death was anticipated and not related to his vaccination.

Patient deceased

Patient did not have any adverse reaction to the COVID vaccine, but we were asked by our health dept to submit a VAERS report since the patient died between his first and second dose. Received Pfizer Dose #1 12/17/2020. No side effects or adverse events noted; lived in 24/7 care facility and monitored twice daily for reaction. Date of death 12/23/2020 from aspiration pneumonia complicated by end-stage heart failure and ischemic cardiomyopathy. Death was anticipated and not sudden.

patient expired 1/15/2021; had been treated as outpatient for pneumonia, likely COVID-19 but no positive test result in December 2020. PMH diabetes

Admitted 1/14/21: Patient is an elderly 93-year-old female with multiple medical problems including chronic combined CHF, P 80, diabetes mellitus, HTN, hyperlipidemia, CKD stage 3, has been complaining of generalized weakness, fatigue, decreased appetite for the past few days. She had an outpatient COVID-19 vaccine earlier today. Within 2 hr of admitting the patient to the hospital, condition clinically deteriorated. Patient elected to be DNR/DNI while in the ED. Patient was pronounced dead at 10:30 p.m. earlier today. Preliminary cause of death: Hypoglycemia induced lactic acidosis.

Pt received second dose of COVID vaccine on 01/20/2021 at 1430. At 1600 Pt developed a wet productive cough with coarse crackles. Pt ate dinner at 5 pm cough persisted. At 18:30 the nurse went to Pt's room to give him his medications. Pt still had a cough, denied shortness of breath. Pt was in a good mood and joking with staff. Pt asked to be shaved. At 19:45 Pt was sitting in the lounge and a CNA noticed that Pt was pale/white in color and clammy. 02 Sat was 85%. Respirations were labored. Pt was placed on 4 L of 02. Increased to 5 L via face mask and 02 sat was 89-90%. Ambulance was called at unknown time. Pt arrived at Medical Center at 2120 and was pronounced dead at 2127.

On Saturday, 1/16/2021, Patient went to the grocery store. Upon her return, she indicated she was experiencing N/V and some throat swelling. Patient subsequently collapsed and expired before she could be brought to an emergency room. During investigation by Coroners Office, it has been reported that Patient may have gotten some takeout food while she was out. Labs are pending and the Coroners investigation is ongoing. Spouse believes that her death was caused by the vaccine.

No immediate reaction. Patient-reported deceased four days later on Jan. 19, 2021. As of this date cause of death is unknown to our clinic.

unknown. Event occurred after leaving vaccination site

presented to ED 1/9/21 with abdominal pain, progressive worsening weakness and fatigue and new onset A fib with RVR likely due to hypertensive urgency . Patient progressed clinically with severe hypoxia and transferred to ICU and started on BiPAP; progressive decline with decreased urinary output with uremia likely secondary to sepsis. Concern with patient worsening clinical decline, palliative care had been consulted on end of life care. Patient expired 1/17/21

Narrative:

Fever, Tachypnea, HYPERtension, Tachycardia & HYPERglycemia Narrative: Was inpatient overnight in a telemetry until. DC with diagnosis of DM and CHF

1/11 asymptomatic COVID Positive test Narrative:

Narrative: Symptoms: & Cardiac Arrest; Death Treatment: EPINEPHRINE

shaking, altered consciousness Narrative: One day after pt received his first covid vaccine, pt experienced upper extremity shaking leading to ED visit and subsequent hospitalization with concern for seizure. Examination and labs were not consistent with seizure. He had features of lewy body disease and parkinsonism. Labs were significant for leukocytosis, but pt had no other signs/symptoms of infection or findings to indicate a source of infection. Pt referred to Neurology.

Patient diagnosed with COVID on January 9, 2021 after being exposed to family member that was under quarantine in the same household. Admitted to the hospital and was discharged on January 14, 2021 with home hospice. Patient passed away on January 18, 2021

Patient passed away on 01/18/2021

Patient died unexpectedly 5 days after receiving vaccine (1/10/2021).

Patient deceased on 01/17/2021

Death; This is a spontaneous report from four non-contactable consumers via a Pfizer-sponsored program Corporate (Pfizer) Social Media Platforms. A 78-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration, on 28Dec2020 at a single dose for COVID-19 immunization. Ongoing medical history included Alzheimer's Disease, encephalopathy, hypertension, acute kidney failure, urinary retention and recent urinary tract infection (UTI), all from an unspecified date. Concomitant medication included acetaminophen (MANUFACTURER UNKNOWN), bisacodyl (MANUFACTURER UNKNOWN), bupropion (MANUFACTURER UNKNOWN), escitalopram (MANUFACTURER UNKNOWN), hydrocodone bitartrate, paracetamol (HYDROCODONE/ACETAMINOPHEN), loperamide (MANUFACTURER UNKNOWN), ondansetron (MANUFACTURER UNKNOWN), senna alexandrina (SENNA PLUS), vitamin d3 (MANUFACTURER UNKNOWN). The patient had no known drug allergies. The patient experienced death on 30Dec2020. The vaccine was given on 28Dec2020 with no adverse events and no issues on 29Dec2020. The patient

died on 30Dec2020, at approximately 2:00 AM. It was unknown if an autopsy was performed. It was unknown if the event was related to the suspect drug, the administrator marked as natural causes. No follow-up attempts are possible; information about batch/lot number cannot be obtained.; Reported Cause(s) of Death: Death

Pt died 4 days after vaccine, no known reaction to the vaccination

Death, which I believe is unrelated to vaccination

Narrative:

Death - Hospice patient with metastatic CA admitted to facility and received vaccine during stay. No adverse sequelae noted from vaccine administration, but reporting as required because pt died 7 days later. Narrative: Reporting this event because patient died 7 days after receiving vaccine in the facility where he was in hospice care for metastatic cancer. Vaccine was administered by protocol without complications. The patient had been asked and denied any prior severe reaction to this vaccine or its components and gave permission to receive it. No vaccine adverse sequelae were documented after the immunization as monitored for 15 minutes nor in facility notes for 7 days after the immunization. The patient's death was felt to be due to underlying terminal illness.

Pt on hospice in facility for severe cardiomyopathy unable to perform interventions received vaccine without adverse sequelae died 5 days later. Reporting as required. Narrative: Reporting as required patient death 5 days after immunization with Pfizer vaccine. However, no adverse sequelae were noted to the vaccine in the 15minute observation period, nor in the days following the immunization related to the vaccine. The patient denied any prior severe reaction to this vaccine or its components, and the patient gave verbal consent to receive the vaccine. Patient had been in the facility on hospice since 11/18/20 for severe decompensated HF and newly diagnosed cardiomyopathy, unable to perform interventions, also LE ischemic wounds with very poor potential to heal due to advanced PVD.

Narrative: Temporary restriction on driving until further evaluation due to symptoms of seizures.

loss of consciousness; respiratory distress Narrative: Patient tolerated his 1st dose of the COVID-19 vaccine well, on 12/16/2020, and received his 2nd dose on 1/6/2021. Patient had some mild clinical decline the past few days prior to 2nd vaccination, with a decreased appetite and some increased fatigue per nursing report, but no significant changes. He experienced nausea on the evening of 1/6/21, which was effectively managed, but by early morning he spiked a fever of 102.9 with a sat of 86.1%. He continued to deteriorate from that point on and died 1/7/21 @13:20. Clinically, the presentation was most consistent with an aspiration pneumonia.

Death on 1-5-21

Death 1-15-21

Note: Submitting a report to VAERS does not mean that healthcare personnel or the vaccine caused or contributed to the adverse event (possible side effect).